

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

INTERSECT ENT, INC.,

Petitioner,

v.

NEW AMSTERDAM, LLC

Patent Owner.

Case No. IPR2024-00713

U.S. Patent No. 6,916,483

**PETITION FOR *INTER PARTES* REVIEW OF
CLAIMS 1–20 OF U.S. PATENT NO. 6,916,483**

TABLE OF CONTENTS

	Page
I. INTRODUCTION	1
II. MANDATORY NOTICES UNDER 37 C.F.R. § 42.8.....	1
A. Real Party-in-Interest (37 C.F.R. § 42.8(b)(1)).....	1
B. Related Matters (37 C.F.R. § 42.8(b)(2))	1
C. Counsel (37 C.F.R. § 42.8(b)(3)) and Service Information (37 C.F.R. § 42.8(b)(4)).....	2
III. SERVICE OF THE PETITION ON PATENT OWNER.....	2
IV. CERTIFICATION OF GROUNDS FOR STANDING	3
V. OVERVIEW OF CHALLENGE AND RELIEF REQUESTED.....	3
A. Asserted Prior Art.....	4
B. Statutory Grounds for Challenges	5
VI. CLAIM LISTING.....	6
VII. THE '483 PATENT.....	10
VIII. THE ASSERTED PRIOR ART	14
A. <i>Watson</i>	14
B. <i>Schwartz</i>	20
IX. LEVEL OF ORDINARY SKILL IN THE ART	25
X. CLAIM CONSTRUCTION	25
XI. CLAIMS 1–20 OF THE '483 PATENT ARE UNPATENTABLE.....	26
A. Ground 1: Claims 1-20 Are Obvious Over <i>Watson</i> In View of the Knowledge of a PHOSITA.....	26

B.	Ground 2: Claims 5, 6, 18, and 19 Are Obvious Over <i>Watson</i> In View of <i>Glover</i> and the Knowledge of a PHOSITA.	56
C.	Ground 3: Claim 9 Is Obvious Over <i>Watson</i> In View of <i>Tormala</i> and the Knowledge of a PHOSITA.....	61
D.	Ground 4: Claims 1-4, 7-10, 13-15, 17, and 20 Are Obvious Over <i>Schwartz</i> In View of the Knowledge of a PHOSITA.....	62
E.	Ground 5: Claims 5, 6, 18, and 19 Are Obvious Over <i>Schwartz</i> In View of <i>Glover</i> and the Knowledge of a PHOSITA.....	84
F.	Ground 6: Claim 9 Is Obvious Over <i>Schwartz</i> In View of <i>Tormala</i> and the Knowledge of a PHOSITA.....	88
G.	Ground 7: Claims 11, 12, and 16 Are Obvious Over <i>Schwartz</i> In View of <i>Watson</i> and the Knowledge of a PHOSITA.....	89
XII.	SECONDARY CONSIDERATIONS	94
XIII.	DISCRETIONARY DENIAL IS NOT WARRANTED.....	94
A.	Discretionary Denial Under the <i>Fintiv</i> Factors Is Not Warranted.	94
B.	Discretionary Denial Under the <i>General Plastic</i> Factors Is Not Warranted.	96
C.	Discretionary Denial Under 35 U.S.C. § 325(d) Is Not Warranted.	96
XIV.	CONCLUSION.....	97

PETITIONER’S EXHIBIT LIST

Exhibit	Description
1001	U.S. Patent No. 6,916,483 (“’483 Patent”).
1002	Affidavit of Service in <i>New Amsterdam, LLC v. Medtronic, Inc.</i> , No. 1:23-cv-00460-RP (W.D. Tex. April 27, 2023).
1003	U.S. Patent No. 6,936,270 (“ <i>Watson</i> ”).
1004	U.S. Patent No. 5,769,899 (“ <i>Schwartz</i> ”).
1005	File History, Application No. 10/200,355
1006	Complaint in <i>New Amsterdam LLC v. Medtronic, Inc.</i> , No. 1:23-cv-00460-RP (W.D. Tex).
1007	Complaint in <i>New Amsterdam LLC v. Medtronic plc, et al.</i> , Case No. 2:23-cv-421-JRG-RSP (E.D. Tex.)
1008	Notice of Hearing: In-Person Scheduling/Case Management Conference Reset for March 25, 2024
1009	U.S. Pub. No. 2004/0013702A1 (“ <i>Glover</i> ”).
1010	U.S. Patent No. 5,916,584 (“ <i>O’Donoghue</i> ”).
1011	U.S. Patent No. 6,579,533 (“ <i>Tormala</i> ”).
1012	Waiver of Service for Intersect ENT, Inc. in <i>New Amsterdam LLC v. Medtronic plc, et al.</i> , Case No. 2:23-cv-421 (E.D. Tex.).

1013	Preliminary Infringement Contentions, <i>New Amsterdam LLC v. Medtronic plc, et al.</i> , Case No. 2:23-cv-421 (E.D. Tex. Mar. 11, 2024).
1014	Plaintiff's Preliminary Infringement Claim Chart, <i>New Amsterdam LLC v. Medtronic plc, et al.</i> , Case No. 2:23-cv-421 (E.D. Tex. Mar. 11, 2024).
1015	https://www.britannica.com/animal/mammal
1016	https://operonstrategist.com/orthopaedic-implants-manufacturing/
1017	Declaration of Bruce Beynnon, in Support of Intersect ENT, Inc.'s Petition for <i>Inter Partes</i> Review.
1018	<i>Curriculum Vitae</i> of Bruce Beynnon.

I. INTRODUCTION

Intersect ENT, Inc. (“Petitioner”) requests *inter partes* review of claims 1–20 (the “Challenged Claims”) of U.S. Patent No. 6,916,483 (“’483 Patent”), purportedly assigned to New Amsterdam, LLC (“Patent Owner”).

II. MANDATORY NOTICES UNDER 37 C.F.R. § 42.8

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

The real parties-in-interest are Petitioner, Medtronic, Inc., Medtronic plc, Medtronic USA, Inc., and Medtronic Xomed, Inc.

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

The ’483 Patent is presently the subject of a patent-infringement lawsuit brought by Patent Owner against Petitioner: *New Amsterdam LLC v. Medtronic, plc, et al.*, Case No. 2:23-cv-421-JRG-RSP (E.D. Tex.) (the “EDTX Litigation”). The ’483 Patent was also the subject of a patent-infringement lawsuit brought by Patent Owner against Medtronic, Inc. in the Western District of Texas, *New Amsterdam LLC v. Medtronic, Inc.*, Case No. 1:23-cv-460 (W.D. Tex.), that was dismissed on January 29, 2024.

C. Counsel (37 C.F.R. § 42.8(b)(3)) and Service Information (37 C.F.R. § 42.8(b)(4))

Petitioner designates John Wittenzellner (Reg. No. 61,662) as lead counsel, and Mark McCarthy (Reg. No. 69,575) and Michael J. Fagan, Jr. (Reg. No. 78,701) as back-up-counsel.

Postal and hand deliveries for lead and back-up counsel should be addressed to Williams Simons & Landis PLLC, 601 Congress Avenue, Austin, Texas 78701 (Telephone: (512) 543-1373; Fax: (512) 793-9575).

Pursuant to 37 C.F.R. § 42.8(b)(4), Petitioner consents to e-mail service at: johnw@wsltrial.com; mmccarthy@wsltrial.com; mfagan@wsltrial.com; and MedtronicWSLCounsel@wsltrial.com.

Pursuant to 37 C.F.R. § 42.10(b), a Power of Attorney is filed concurrently herewith.

III. SERVICE OF THE PETITION ON PATENT OWNER

A copy of this entire Petition, including all Exhibits and a power of attorney, is being served by FEDERAL EXPRESS, costs prepaid, to the address of the attorney or agent of record for New Amsterdam LLC in the EDTX Litigation regarding the '483 Patent:

Garteiser Honea, PLLC
119 W. Ferguson Street
Tyler, Texas 75702

Ni, Wang & Massand, PLLC
8140 Walnut Hill Ln., Ste. 615
Dallas, TX 75231

A copy of this entire Petition, including all Exhibits and a power of attorney, is being served by FEDERAL EXPRESS, costs prepaid, to the correspondence address listed for the '483 Patent:

Norris McLaughlin, P.A.
7 Times Square, 21st Floor
New York, NY 10036-6524

IV. CERTIFICATION OF GROUNDS FOR STANDING

Petitioner certifies pursuant to Rule 42.104(a) that the '483 Patent is eligible for *inter partes* review and that Petitioner is not barred or estopped from requesting an *inter partes* review challenging the patent claims on the grounds identified in this Petition. Ex. 1002; Ex. 1006; Ex. 1012.

V. OVERVIEW OF CHALLENGE AND RELIEF REQUESTED

Pursuant to Rules 42.22(a)(1) and 42.104(b)(1)–(2), Petitioner challenges claims 1–20 (“Challenged Claims”) of the '483 Patent.

A. Asserted Prior Art

The earliest-effective filing date of the '483 Patent is July 22, 2002. Ex. 1001; Ex. 1013 at 1 (“The priority date of each of the '483 Patent is July 22, 2002.”). The following prior-art references form the grounds of unpatentability:

1. U.S. Patent No. 6,936,270 (Ex. 1003, “*Watson*”) was filed on May 2, 2002, is a continuation-in-part of U.S. Application No. 09/985,319, which was filed on November 2, 2001, and claims priority to three provisional patent applications filed on May 18, 2001, December 14, 2000, and November 3, 2000. *Watson* issued on August 30, 2005. Accordingly, *Watson* is prior art under at least pre-AIA 35 U.S.C. § 102(e).¹

2. U.S. Patent No. 5,769,899 (Ex. 1004, “*Schwartz*”) was filed on August 15, 1996, as a continuation of U.S. Application No. 08/289,387, which was filed on August 12, 1994. *Schwartz* issued on June 23, 1998. Accordingly, *Schwartz* is prior art under at least pre-AIA 35 U.S.C. § 102(b).

3. U.S. Pub. No. 2004/0013702A1 (Ex. 1009, “*Glover*”) was filed on July 16, 2002, and published on January 22, 2004. Accordingly, *Glover* is prior art under at least pre-AIA 35 U.S.C. § 102(e).

¹ The '483 Patent issued from an application filed before the enactment of the America Invents Act (“AIA”), so the pre-AIA statutory framework applies.

4. U.S. Patent No. 6,579,533 (Ex. 1011, “*Tormala*”) was filed on November 30, 1999, and issued on June 17, 2003. Accordingly, *Tormala* is prior art under at least pre-AIA 35 U.S.C. § 102(e).

None of the prior-art references asserted in this Petition were considered during prosecution of the ’483 Patent. Ex. 1001; Ex. 1005.

B. Statutory Grounds for Challenges

This Petition requests cancellation of the Challenged Claims under the following Grounds under 35 U.S.C. § 103:

Ground 1: Claims 1-20 are obvious over *Watson* in view of the knowledge of a PHOSITA.

Ground 2: Claims 5, 6, 18, and 19 are obvious over *Watson* in view of *Glover* and the knowledge of a PHOSITA.

Ground 3: Claim 9 is obvious over *Watson* in view of *Tormala* and the knowledge of a PHOSITA.

Ground 4: Claims 1-4, 7-10, 13-15, 17, and 20 are obvious over *Schwartz* in view of the knowledge of a PHOSITA.

Ground 5: Claims 5, 6, 18, and 19 are obvious over *Schwartz* in view of *Glover* and the knowledge of a PHOSITA.

Ground 6: Claim 9 is obvious over *Schwartz* in view of *Tormala* and the knowledge of a PHOSITA.

Ground 7: Claims 11, 12, and 16 are obvious over *Schwartz* in view of *Watson*

and the knowledge of a PHOSITA.

VI. CLAIM LISTING

Claim 1

1[a]	An implantable prosthetic device having a surface contour,
1[b]	and comprising a solid modular implantable drug delivery device within a shaped recess within the outer surface of an implantable prosthesis,
1[c]	said device being operable for releasing a therapeutic agent into the body of an animal following implantation of the prosthesis within the body of the animal, the device comprising:
1[d]	(a) solid module comprising a biodegradable polymer dimensioned to fit snugly within the shaped recess in the prosthesis; and
1[e]	(b) a therapeutic agent that is released into the body of the animal during biodegradation of said biodegradable polymer over a predefined dosing period.

Claim 2

2	The device of claim 1 wherein when said solid module comprising a biodegradable polymer is received within the shaped recess of the implantable prosthesis, the contour of the outer surface of the prosthesis is not substantially altered.
----------	--

Claim 3

3	The device of claim 1 wherein said solid module comprising a biodegradable polymer is affixed to said prosthesis.
----------	---

Claim 4

4	The device of claim 2 wherein said solid module comprising a biodegradable polymer is affixed to said prosthesis.
----------	---

Claim 5

5	The device of claim 1 wherein said therapeutic agent is contained within a cavity in said solid module.
----------	---

Claim 6

6	The device of claim 2 wherein said therapeutic agent is contained within a cavity in said solid module.
----------	---

Claim 7

7	The device of claim 1 comprising a plurality of solid modules.
----------	--

Claim 8

8	The device of claim 7 wherein said plurality of solid modules are affixed to one another.
----------	---

Claim 9

9	The implantable prosthetic device of claim 1 comprising:
----------	--

	(a) a mesh container; and (b) at least one solid module comprising a biodegradable polymer and a therapeutic agent contained within, said mesh container.
--	--

Claim 10

10	The implantable prosthetic device of claim 1 wherein the prosthesis is a femoral pin.
-----------	---

Claim 11

11	The implantable prosthetic device of claim 1 wherein the prosthesis is a bone plate.
-----------	--

Claim 12

12	The implantable prosthetic device of claim 11, wherein the solid module is shaped like a rectangular tile, and the recess is a mating receptacle therefor.
-----------	--

Claim 13

13	The implantable prosthetic device of claim 1 wherein the recess is formed by drilling a hole in the prosthesis.
-----------	---

Claim 14

14	The implantable prosthetic device of claim 1, wherein the solid module is shaped like a rod, and is placed, within a cylindrical recess in the prosthesis.
-----------	--

Claim 15

15	The implantable prosthetic device of claim 7, wherein one of the solid modules is hollowed out to increase the surface area in contact with the body fluids, and increase the rate of release of a therapeutic agent therefrom.
-----------	---

Claim 16

16	The implantable prosthetic device of claim 1, wherein the solid module is shaped like a tapered conical plug.
-----------	---

Claim 17

17	The implantable prosthetic device of claim 1, wherein the solid module is shaped like a threaded cylindrical plug.
-----------	--

Claim 18

18	The implantable prosthetic device of claim 1, wherein the solid module is shaped like a threaded cylindrical plug.
-----------	--

Claim 19

19	The implantable prosthetic device of claim 1, wherein the solid module is shaped like a capped tub.
-----------	---

Claim 20

20[a]	A method for controlled phased release of a therapeutic agent into an orthopedic surgical site,
--------------	---

20[b]	comprising providing an implantable prosthesis,
20[c]	forming at least one shaped solid modular drug delivery device comprising a biodegradable polymer and a therapeutic agent,
20[d]	forming a recess in the surface of the prosthesis shaped to receive the shaped solid modular drug delivery device,
20[e]	placing at least one shaped solid modular drug delivery device in the recess,
20[f]	and implanting the prosthesis in the body of an animal.

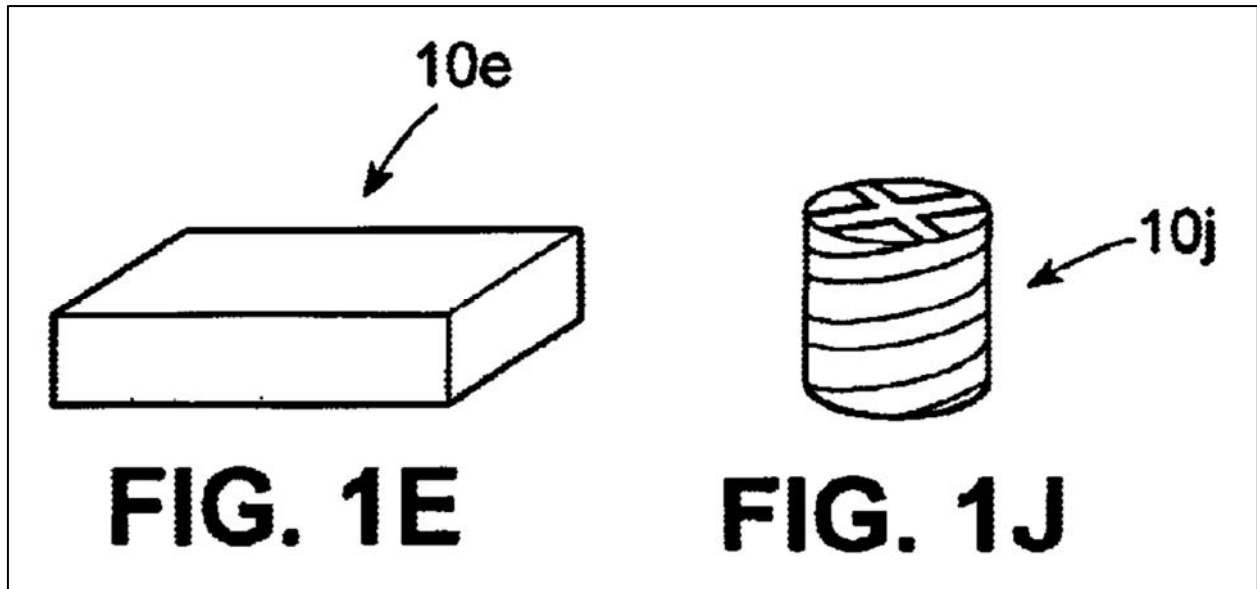
VII. THE '483 PATENT

The '483 Patent states that its invention “relates to methods and implantable devices for dispensing one or more therapeutic agents at a surgical site.” Ex. 1001, 1:7-9. In essence, the '483 Patent claims a biodegradable device or plug that is affixed to a prosthesis—the device or plug releases therapeutic agents as part of the biodegradation process:

... it is desirable to provide an implantable drug delivery device in the form of a shaped plug that may be affixed to a prosthesis, thereafter to biodegrade and deliver one or more therapeutic agents contained therein at a controllable rate to the surrounding tissue.

Id., 3:46-51; Ex. 1017, ¶¶46-50. The figures of the '483 Patent depict various biodegradable devices and plugs. For example, Figure 1E depicts a “tile embodiment” that is “designed to be received within, and adhered to, a mating

receptacle within the flat outer surface of a prosthesis such as a bone plate,” whereas Figure 1J depicts a “threaded cylindrical embodiment” that can be screwed into a prosthesis:



Id., Figs. 1E & 1J, 5:43-47, 5:65-67.

The “Prior Art” section of the ’483 Patent recognizes that “[b]iodegradable materials are used in medicine for a variety of purposes including drug delivery devices and as aids in tissue repair,” and it is well known in the art that the properties of those materials can be tailored to specific applications. *Id.*, 1:14-22. In fact, the ’483 Patent identifies many prior-art references that collectively show that the claims of the ’483 Patent are neither novel nor non-obvious. *Id.*, 1:14-3:51.

For example, the ’483 Patent concedes that U.S. Patent No. 5,697,976 discloses a surgical implant that “may also contain a therapeutic agent,” such as “an

antimicrobial agent, dye, growth factors and combinations thereof.” *Id.*, 1:53-67. In another example, the ’483 Patent concedes that U.S. Patent No. 5,700,476 discloses implantable materials that can be “incorporated separately into the matrix and/or substructure so as to achieve controlled or phasic release of the active agents into the wound.” *Id.*, 2:9-20. The ’483 Patent identifies only one supposed shortcoming of the prior art:

The porous bioabsorbable implants that have been suggested to date are generally isotropic materials.... This, in turn, means that the active agents are released uniformly into the wound site at a rate determined only by the rate at which the implant material biodegrades and the surface area of the implant.

Id., 2:50-58. By simply modifying the implantable device to be a shaped plug, the ’483 Patent purports to address that alleged shortcoming: “... it is desirable to provide an implantable drug delivery device in the form of a shaped plug that may be affixed to a prosthesis.” *Id.*, 3:46-51.

That simple change is consistent with the claim amendments that the patentee made during prosecution of the ’483 Patent. In response to a rejection, the patentee made three substantive amendments to the claims:

Listing of Claims:

1. (Currently Amended) An implantable prosthetic device having a surface contour, and comprising a solid modular implantable drug delivery device adapted to be received within a shaped recess within an the outer surface of an implantable prosthesis wherein the outer surface of the prosthesis has a surface contour, said device being operable for releasing a therapeutic agent into the body of an animal following implantation of the prosthesis within the body of the animal, the device comprising:

 (a) solid module comprising a biodegradable polymer dimensioned to fit snugly within the shaped recess in the prosthesis; and

 (b) a therapeutic agent that is released into the body of the animal during biodegradation of said biodegradable polymer over a predefined dosing period.

Ex. 1005, 46. The patentee narrowed the scope of the claims to only a “prosthetic device having a surface contour, and comprising a solid modular implantable drug delivery device” because the prior art cited by the Examiner used a flexible bladder to accomplish the same goals of the ’483 Patent. *Id.*, 52-54. The patentee also clarified that release of the therapeutic agent occurs as a result of biodegradation of the biodegradable polymer of a predefined dosing period. *Id.*, 53.

The patentee amended the claim language after conducting an interview with the Examiner wherein “suggestions were made to amend claim restrictions by incorporating the terms ‘solid modular,’ ‘prosthesis,’ and ‘controlled release of the therapeutic agent over a predefined dosing period’ to place the application in condition for allowance. *Id.*, 33-36.

VIII. THE ASSERTED PRIOR ART

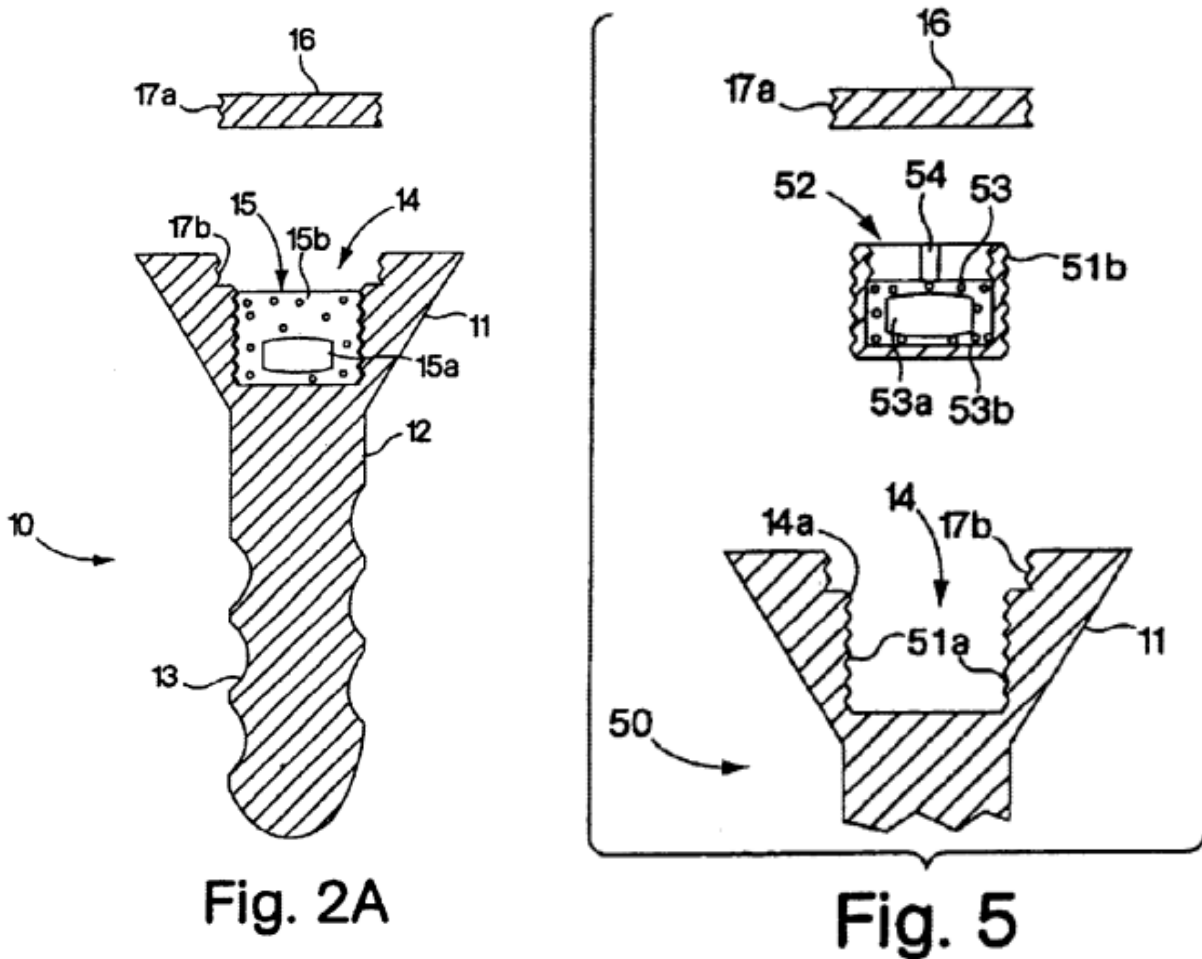
A. *Watson*

Watson discloses a “therapeutically effective compound [that] is locally administered by associating the compound with a piece of orthopedic hardware that is implanted at an appropriate site within a body.” Ex. 1003, 2:57-59. *Watson* further discloses that “[t]he compound is adapted, such as through a sustained release device, to administer an effective dosage continuously over an extended period of time.” *Id.*, 2:59-61.

Watson recognizes that “[s]teroid injections are a common treatment for a variety of conditions.” *Id.*, 1:59-61. But a shortcoming is that they “provide an initial level of steroid that is greater than therapeutically required and which rapidly declines beneath therapeutic levels.” *Id.*, 2:38-40. *Watson* addresses that shortcoming with an implantable device that provides a sustained release of the drug (i.e., the claimed “predefined dosing period”): “Broadly, there exists a need for an

improved implantable sustained release drug delivery device and method and apparatus for implantation of said device.” *Id.*, 2:47-53.

Figures 2A and 5 of *Watson* disclose a prosthesis with a chamber 14 for holding a sustained release device 15, 53. *Id.*, Figs. 2A & 5. Figure 5 is similar to Figure 2A, “except that an inner surface 14*a* of chamber 14 has threads 51*a*, and a second chamber 52 is removably attachable inside chamber 14. Second chamber 52 carries a sustained release device 53 ... functionally similar to sustained release device 15 described in detail above. Second chamber 52 has threads 51*b* that threading engage threads 51*a* in the inner wall of chamber 14.” *Id.*, 12:26-36.



Id., Figs. 2A & 5. *Watson* defines “sustained release device” as “capable of releasing one or more drugs and/or compounds over an extended period of time in a controlled fashion” (i.e., the claimed “predefined dosing period”). *Id.*, 4:46-48.

In sum, Figure 2A of *Watson* depicts sustained release device 15 that is received within chamber 14 of system 10. *Id.*, Fig. 2A. Figure 1E of the '483 Patent similarly depicts tile embodiment 10e that is “designed to be received within, and adhered to, a mating receptacle within the flat outer surface of a prosthesis such as a bone plate.” Ex. 1001, 5:45-47.

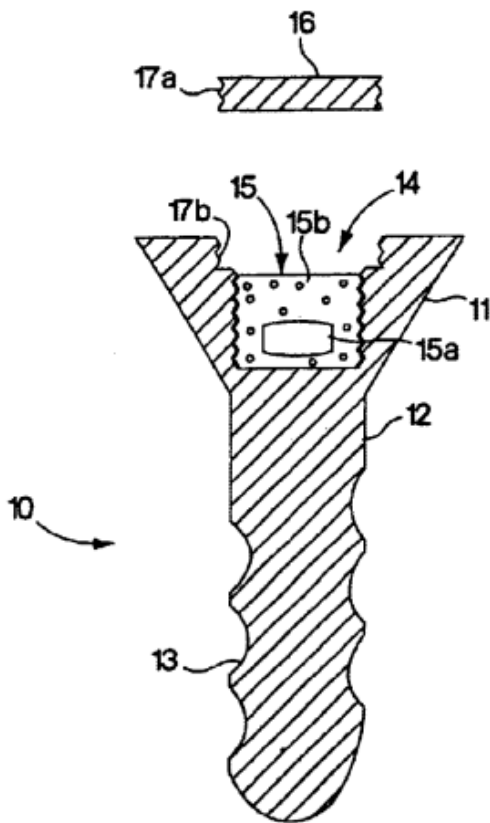


Fig. 2A

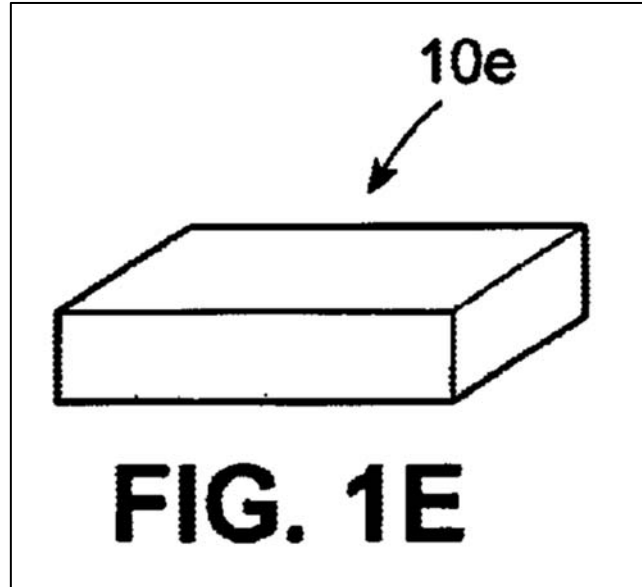


FIG. 1E

Compare Ex. 1003, Fig. 2A (depicting system 10, chamber 14, and sustained release device 15), *with* Ex. 1001, Fig. 1E (depicting tile embodiment 10e).

Figure 5 of *Watson* depicts sustained release device 53 that is received within chamber 14 of system 50 via threads 51b that engage threads 51a in the inner wall of chamber 14. Ex. 1003, Fig. 5. Figure 1J of the '483 Patent similarly depicts a threaded cylindrical embodiment that can be screwed into a prosthesis. Ex. 1001, Fig. 1J.

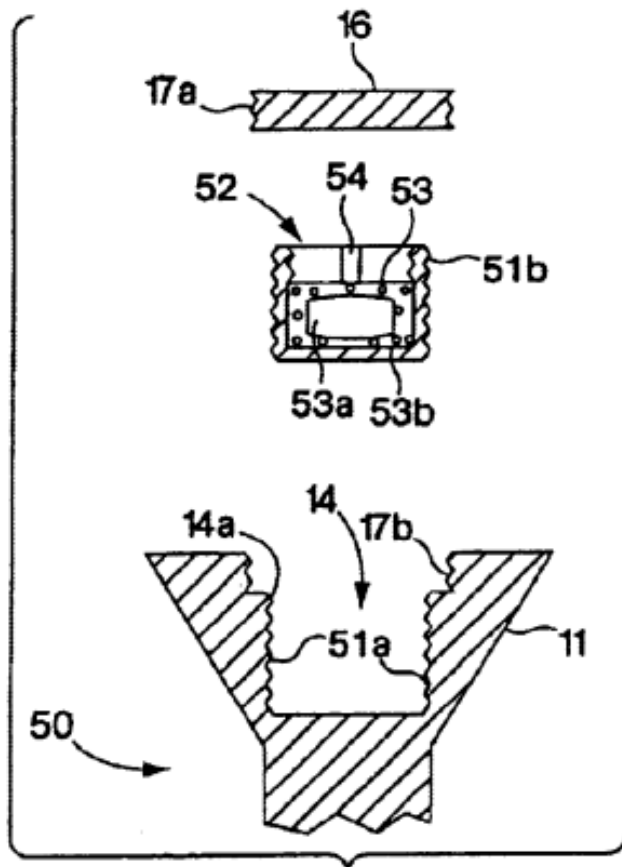


Fig. 5

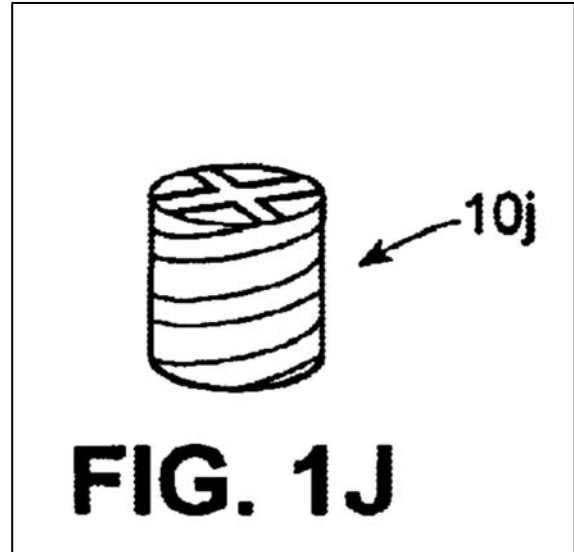
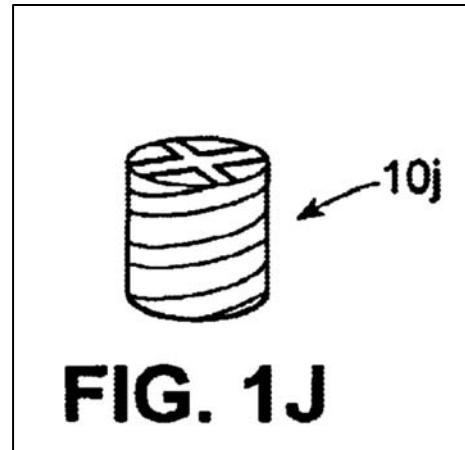
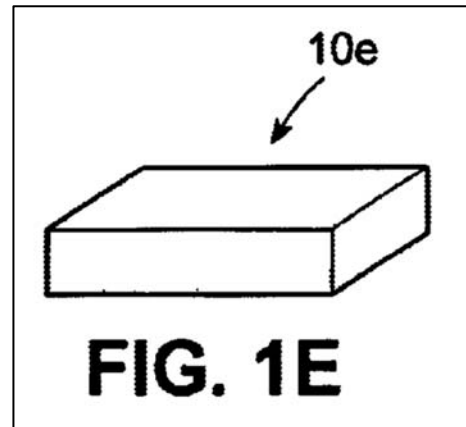
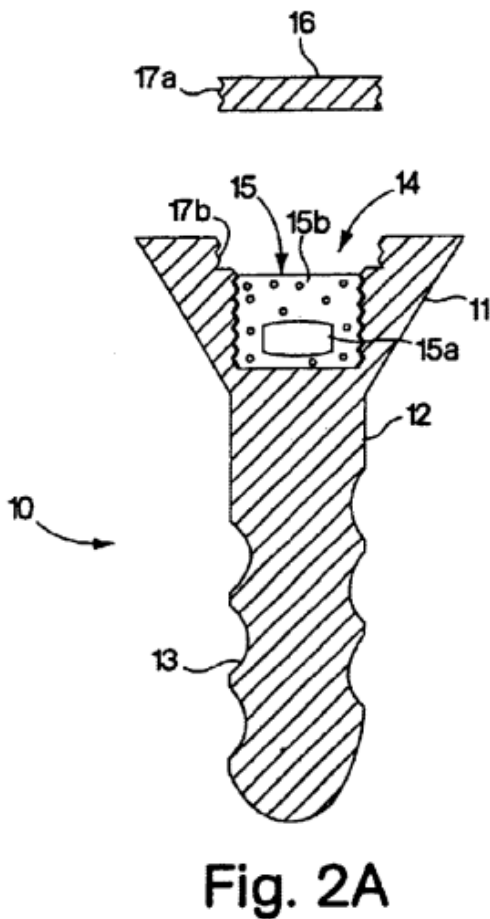


FIG. 1J

Compare Ex. 1003, Fig. 5 (depicting system 50, chamber 14, sustained release device 53, and threads 51a and 51b), *with* Ex. 1001, Fig. 1J (depicting cylindrical embodiment 10j).

Like claim 1 of the '483 Patent, *Watson* discloses an implantable prosthetic device (system 10 in FIG. 2A) with a shaped recess (chamber 14) that receives a solid modular implantable drug delivery device (sustained release device 15). Ex. 1003, Fig. 2.



Compare Ex. 1003, Fig. 2A (depicting system 10, chamber 14, and sustained release device 15), *with* Ex. 1001, Fig. 1E (depicting tile embodiment 10e), and Ex. 1001, Fig. 1J (depicting cylindrical embodiment 10j).

Claim 1 of the '483 Patent further recites “said device being operable for releasing a therapeutic agent ... the device comprising: (a) solid module comprising a biodegradable polymer dimensioned to fit snugly within the shaped recess in the prosthesis; and (b) a therapeutic agent that is released into the body of the animal

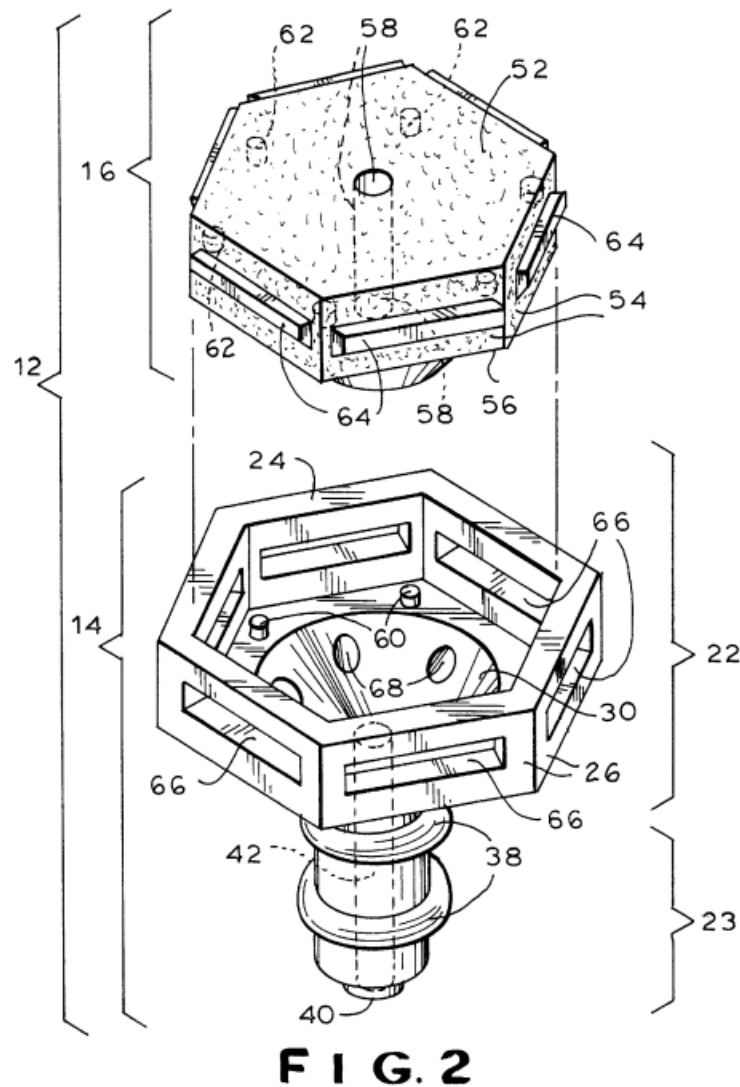
during biodegradation of said biodegradable polymer over a predefined dosing period.”

Ex. 1001, 9:1-10. *Watson* discloses that sustained release device 15 “is capable of releasing one or more drugs and/or compounds over an extended period of time in a controlled fashion” and that “the sustained release device 15 may be formed from a bioerodible material bearing a drug or a plurality of drugs. Ex. 1003, 4:47-48, 11:60-62.

B. *Schwartz*

Schwartz discloses a “bio-absorbable cartilage repair system for regenerating damaged or destroyed articular cartilage on the surface of a bone” Ex. 1004, 2:34-36. *Schwartz* further discloses that the bio-absorbable cartilage repair system comprises “a bio-absorbable delivery unit ... and a porous bio-absorbable insert The insert preferably includes a repair factor (e.g., a growth factor, an attachment factor, or both) releasably disposed in the insert to assist in establishing the chondrogenic growth-supporting matrix.” *Id.*, 2:41-47, 8:45-50.

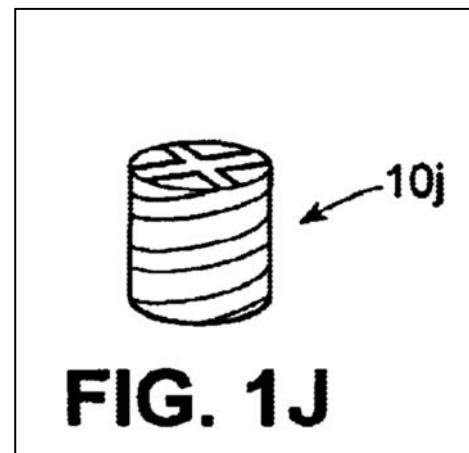
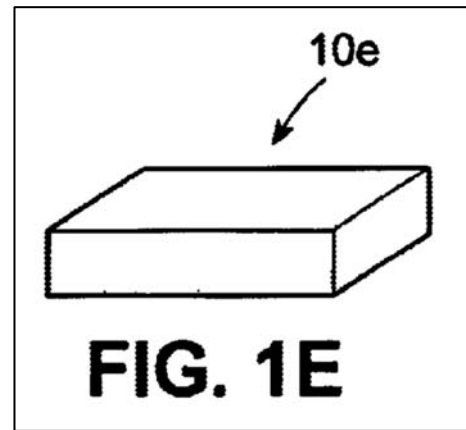
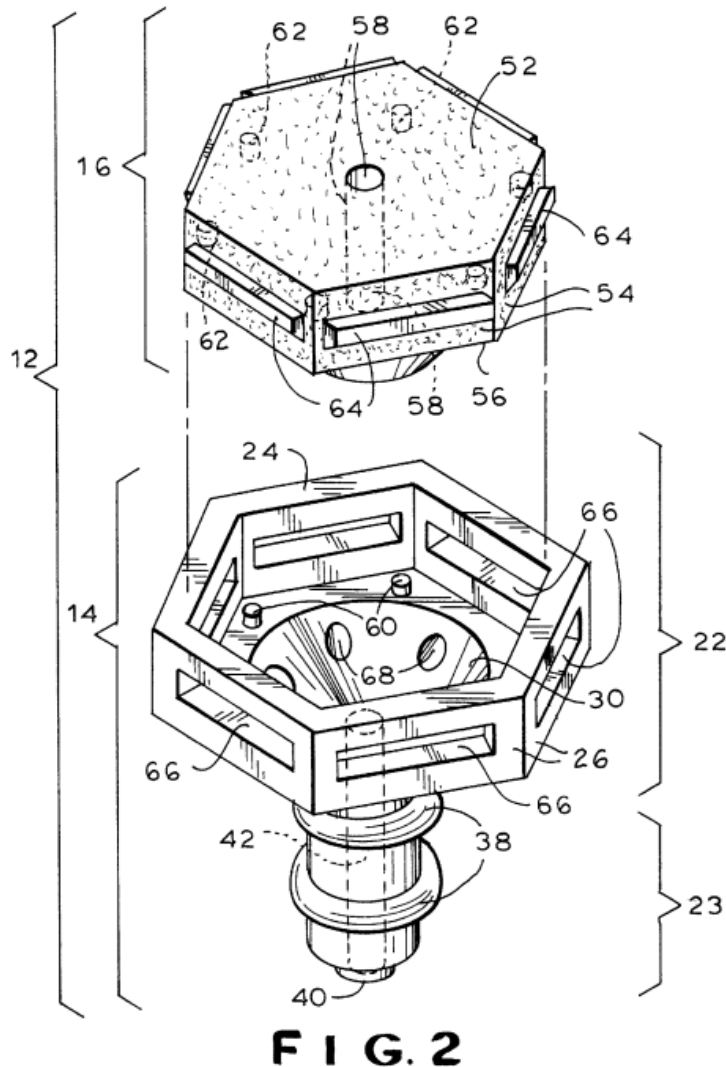
Figure 2 of *Schwartz* discloses a prosthesis comprising delivery unit 14 that receives insert 16:



Id., Fig. 2. *Schwartz* explains that “the support frame 22 of the delivery unit 14 receives the insert 16 therein, with the side walls 26 of the support frame 22 receiving therewithin the side walls 54 of the insert 50 [16]. The bottom surface 56 of the insert 16 and the bottom portion 30 of the support frame 22 are correspondingly shaped, preferably with the bottom surface of the insert 16 defining a protrusion and the upper surface of the bottom portion 30 defining a protrusion-receiving cavity.”

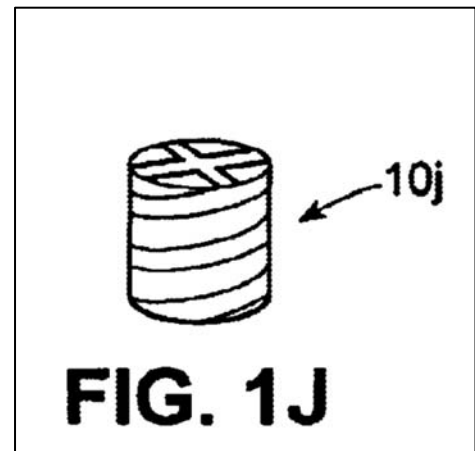
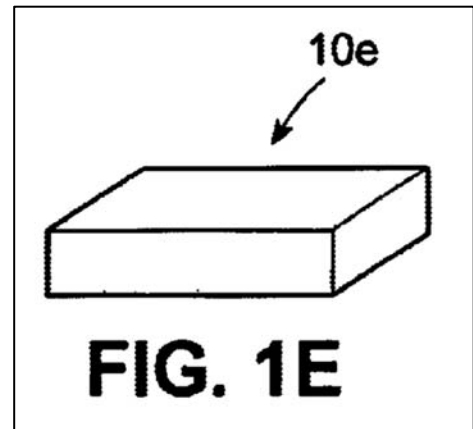
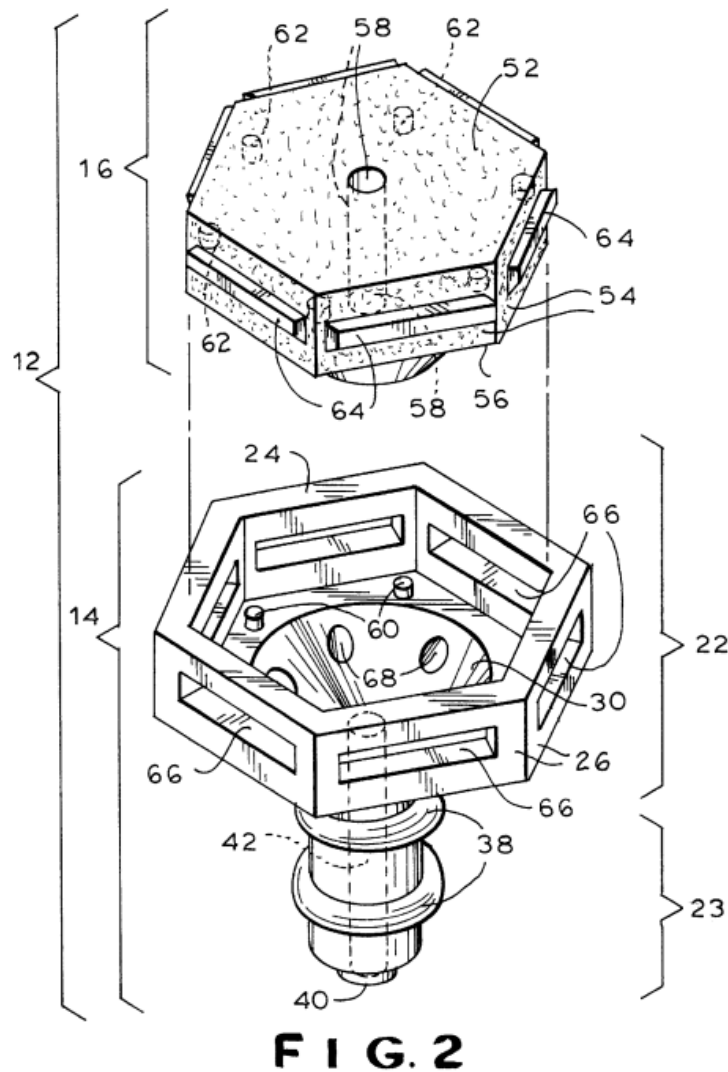
Id., 5:18-25. “As the basic bio-absorbable composition of the insert 16 degrades or hydrolyzes over time, any repair factors contained therein are progressively released into the site, thus further promoting cellular regeneration.” *Id.*, 8:34-38.

In sum, Figure 2 of *Schwartz* depicts insert 16 that is received within delivery unit 14 of assembly 12, much like the tile and “threaded cylindrical” embodiments depicted in Figures 1E and 1J of the ’483 Patent, respectively:



Compare Ex. 1004, Fig. 2 (depicting assembly 12, delivery unit 14, and insert 16), *with* Ex. 1001, Fig. 1E (depicting tile embodiment 10e), and Ex. 1001 at Fig. 1J (depicting cylindrical embodiment 10j).

Like claim 1 of the '483 Patent, *Schwartz* discloses an implantable prosthetic device (assembly 12 in FIG. 2) containing a shaped recess (bottom portion 30 of delivery unit 14) that receives a solid modular implantable drug delivery device (insert 16). Ex. 1004, Fig. 2.



Compare Ex. 1004, Fig. 2 (depicting assembly 12, delivery unit 14, insert 16, and bottom portion 30), *with* Ex. 1001, Fig. 1E (depicting tile embodiment 10e), and Ex. 1001, Fig. 1J (depicting cylindrical embodiment 10j).

Claim 1 of the '483 Patent further recites “said device being operable for releasing a therapeutic agent into the body of an animal ... the device comprising:
(a) solid module comprising a biodegradable polymer dimensioned to fit snugly

within the shaped recess in the prosthesis; and (b) a therapeutic agent that is released into the body of the animal during biodegradation of said biodegradable polymer over a predefined dosing period.” Ex. 1001, 9:1-10. *Schwartz* discloses that “the insert [16] consists substantially of a bio-absorbable material” and that “[a]s the basic bio-absorbable composition of the insert 16 degrades or hydrolyzes over time, any repair factors contained therein are progressively released into the site” Ex. 1004, 3:1-2, 8:34-36. *Schwartz* further discloses that “[t]he absorption rate is formula controlled and can range from 6-12 weeks to one year depending on its site-specific application.” *Id.*, 8:31-33.

IX. LEVEL OF ORDINARY SKILL IN THE ART

A person having ordinary skill in the art (“PHOSITA”) would have had at least (i) a medical degree and experience working in a field involving medical implants and prostheses or (ii) a Bachelor’s degree in bioengineering or mechanical engineering (or a related field) and at least three years designing medical devices, including medical implants and prostheses. Ex. 1017, ¶¶25-28. Additional graduate education could substitute for professional experience, or vice versa. *Id.*

X. CLAIM CONSTRUCTION

No court has construed any terms of the ’483 Patent claims. Petitioner has applied its understanding of Patent Owner’s interpretation of the claims. Ex. 1007; Ex. 1014. Petitioner contends that the claims are unpatentable under any reasonable

construction, and that for purposes of this proceeding, the terms should be given their plain meaning. Petitioner reserves the right to construe any terms in this proceeding or any district-court proceeding.

Claims 1-4, 9, and 20 recite the term “biodegradable.” The ’483 Patent defines the term “biodegradable” to mean “that the composition will degrade over time by enzymatic action, by hydrolytic action and/or by other similar mechanisms in the human body.” Ex. 1001, 5:9-12. As a result, the term “biodegradable” should be construed according to the meaning in the ’483 Patent. *See ParkerVision, Inc. v. Vidal*, 88 F.4th 969 (Fed. Cir. 2023).

XI. CLAIMS 1–20 OF THE ’483 PATENT ARE UNPATENTABLE.

A. Ground 1: Claims 1-20 Are Obvious Over *Watson* In View of the Knowledge of a PHOSITA.

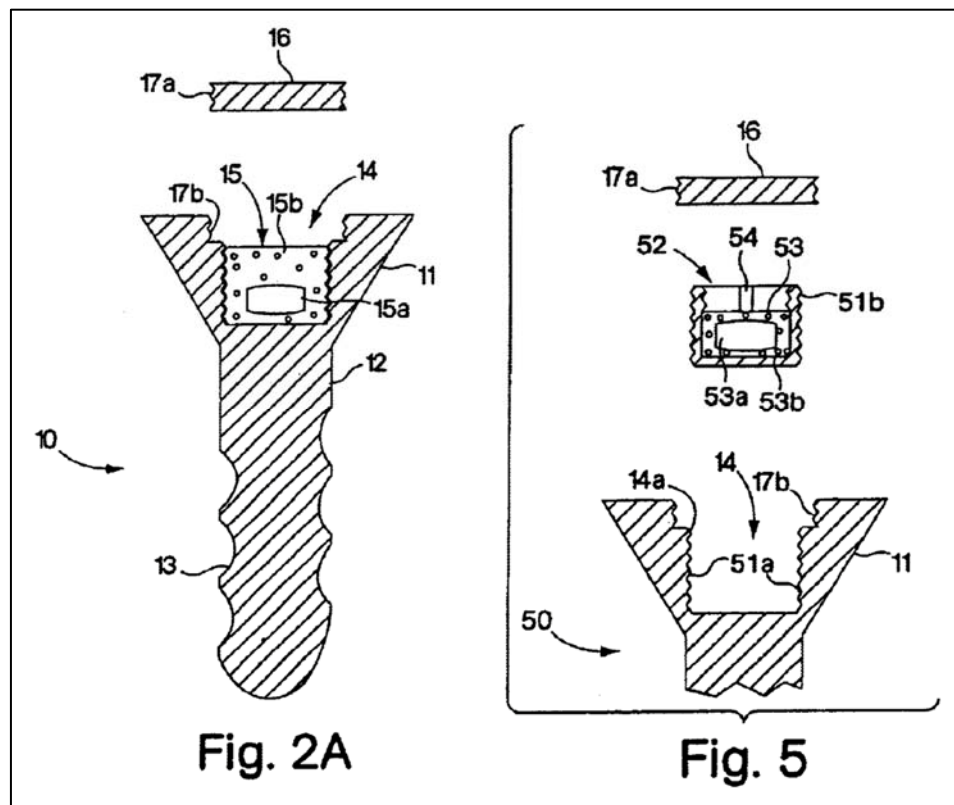
1. Claim 1.

1[a] An implantable prosthetic device ...

Watson teaches this limitation; any alleged differences would have been obvious in view of the knowledge of a PHOSITA. Ex. 1017, ¶¶63-65. *Watson* teaches that “[a] therapeutically effective compound is locally administered by associating the compound with a piece of orthopedic hardware that is implanted at an appropriate site within a body.” Ex. 1003, Abstract. *Watson* covers “[a] wide range of orthopedic hardware, such as bone screws and staples” and notes that although several embodiments of *Watson* are described in terms of a bone screw,

“the general principle of configuring orthopedic hardware as a platform for a drug delivery system may be readily adapted, with little experimentation, to a large number of orthopedic hardware components” that are meant for “long-term insertion in the body.” *Id.*, Abstract, 11:39-47, 21:1-6.

Figures 2A and 5 of Watson depict a bone screw(10), which is an example of an implantable prosthetic device:

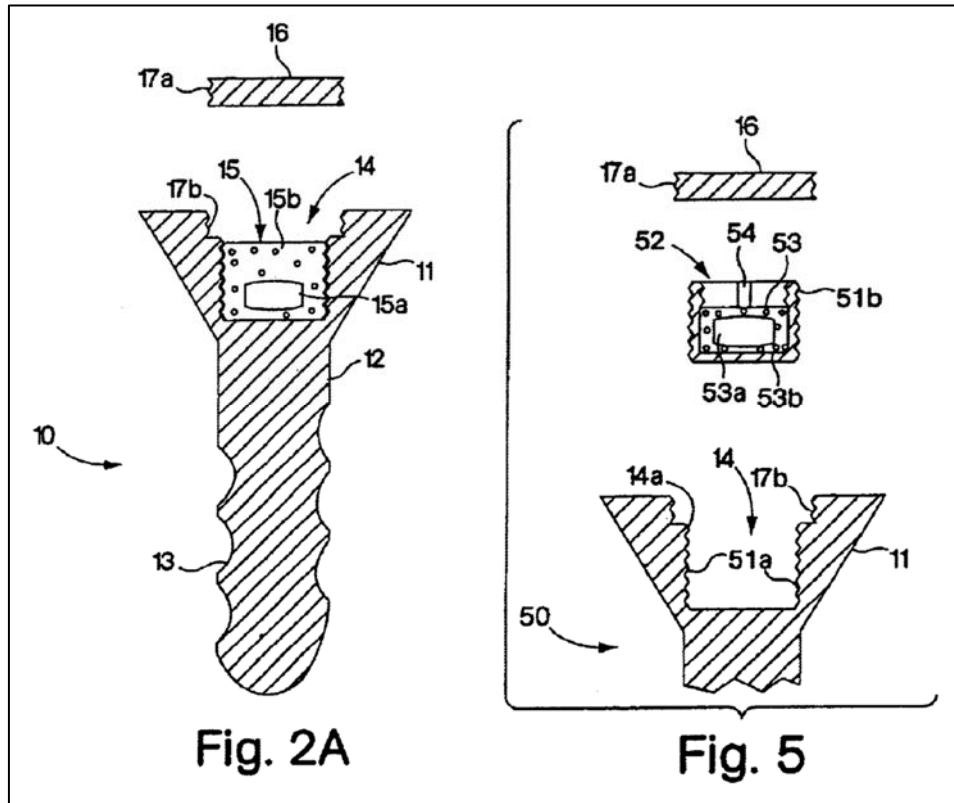


Ex. 1003, Figs. 2A & 5. That device includes a surface profile, for example, the portions of head 11 adjacent to where the “sustained release device” (15) threads into bone screw (10). *Id.*, 11:39-47, Figs. 2A & 5; Ex. 1017, ¶64.

As the '483 Patent notes, a prosthesis is a device used to replace bone or hard tissue. Ex. 1001, 1:30-33. The '483 Patent identifies femoral pins and bone plates as examples of an implantable prosthetic device. *Id.*, 4:16-17, 9:34-10:2. The bone screw (10) or staples of *Watson* are implantable prosthetic devices because they serve the same purpose as femoral pins and bone plates: replacing bone or hard tissue. Ex. 1017, ¶65. To the extent that the bone screw of *Watson* is not an implantable prosthetic device, it would have been obvious to a PHOSITA to apply the teachings of *Watson* to an implantable prosthetic device because *Watson* states that its disclosure is for use with implantable hardware and also states that “the general principle of configuring orthopedic hardware as a platform for a drug delivery system may be readily adapted, with little experimentation, to a large number of orthopedic hardware components.” Ex. 1003, 21:1-6; Ex. 1017, ¶65.

1[b] and comprising a solid modular implantable drug delivery device ...

Watson teaches this limitation; any alleged differences would have been obvious in view of the knowledge of a PHOSITA. Ex. 1017, ¶¶66-68. *Watson* teaches a “sustained release device” (15) that is received within the threading of device 10:



Ex. 1003, 11:39-47, 12:24-37, Figs. 2A & 5. The “shaped recess within the outer surface of an implantable prosthesis” is the portion of the device into which the “sustained release device” (15) is inserted, including the threading (51a). Ex. 1017, ¶67.

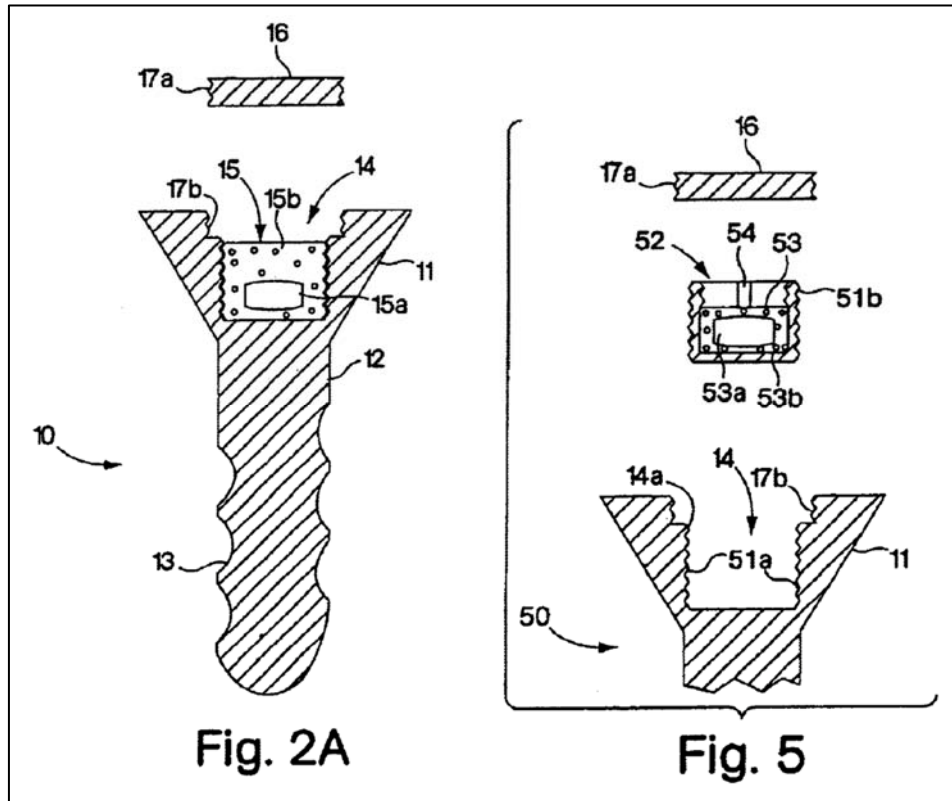
Watson’s “sustained release device” (15) is a “solid modular implantable drug delivery device.” *Watson’s* device is made of solid materials, such as bioerodible or bioresorbable polymeric materials, including “linear aliphatic polyesters (polyglycolide, lactide, caprolactone, hydroxybutyrate) and their copolymers (poly[glycolide-lactide], [glycolide-caprolactone], [glycolide-trimethylene carbonate], [lactic acid-lysine], [lactide-urethane], [ester-amide]), polyanhydrides,

poly(orthoesters), polyphosphazenes, orthoesters, and poly(orthoester)/poly(ethylene glycol) block copolymers, to name a few.” Ex. 1003, 12:1-8. The ’483 Patent identifies many of the same materials as suitable for its device:

It will be understood by the artisan that the bioabsorbable drug delivery devices discussed hereinbelow may be formed out of polymer blends of glycolide and/or lactide homopolymer, copolymer and/or glycolide/lactide copolymer and polycaprolactone copolymers, and/or copolymers of glycolide, lactide, poly (L-lactide-co-DL-lactide), caprolactone, polyorthoesters, polydioxanone, trimethylene carbonate and/or polyethylene oxide or any other bioabsorbable material.

Ex. 1001, 4:62-5:3.

Watson’s “sustained release device” (15) is modular because, as in the ’483 Patent, it is a separate physical device that can be inserted into the shaped recess of device (10). Ex. 1001, 4:23-29 (“Embodiments of a drug delivery device in accordance with the present invention include modular plugs ... that may be screwed into a hole drilled within a bone or the rigid body of a prosthesis....”). By providing the device in modular form, the therapeutic agent can be tailored to a specific patient without having to modify the prosthesis. Ex. 1017, ¶68. Like the ’483 Patent, *Watson* discloses tapered conical plugs and threaded cylindrical plugs:



Ex. 1003, 11:39-47, 12:24-37, Figs. 2A & 5.

1[c] said device being operable ...

Watson teaches this limitation; any alleged differences would have been obvious in view of the knowledge of a PHOSITA. Ex. 1017, ¶¶69-70. *Watson* describes its “sustained release device” (15) as “capable of releasing one or more drugs and/or compounds over an extended period of time in a controlled fashion.” Ex. 1003, 4:45-48. That release would occur after implantation into the body because it occurs as a result of biodegradation of the polymer. Ex. 1003, 11:60-62, 12:8-11, 18:47-51; Ex. 1017, ¶69. The therapeutic agents identified in *Watson* include “a steroid, an anti-inflammatory drug, an antibiotic, an anti-viral agent, a

cancer-fighting drug, including antiproliferative, antimyotic, and antimetabolite compounds, or a pain reliving [sic] drug.” Ex. 1003, 4:48-53 (emphasis added). The ’483 Patent also identifies antibiotics and pain-relieving drugs (i.e., analgesics) as suitable therapeutic agents. Ex. 1001, 5:3-8.

The device of *Watson* is designed for implantation into humans, and humans are animals. Ex. 1003, 12:65-13:1; Ex. 1017, ¶70.

1[d] (a) solid module ...

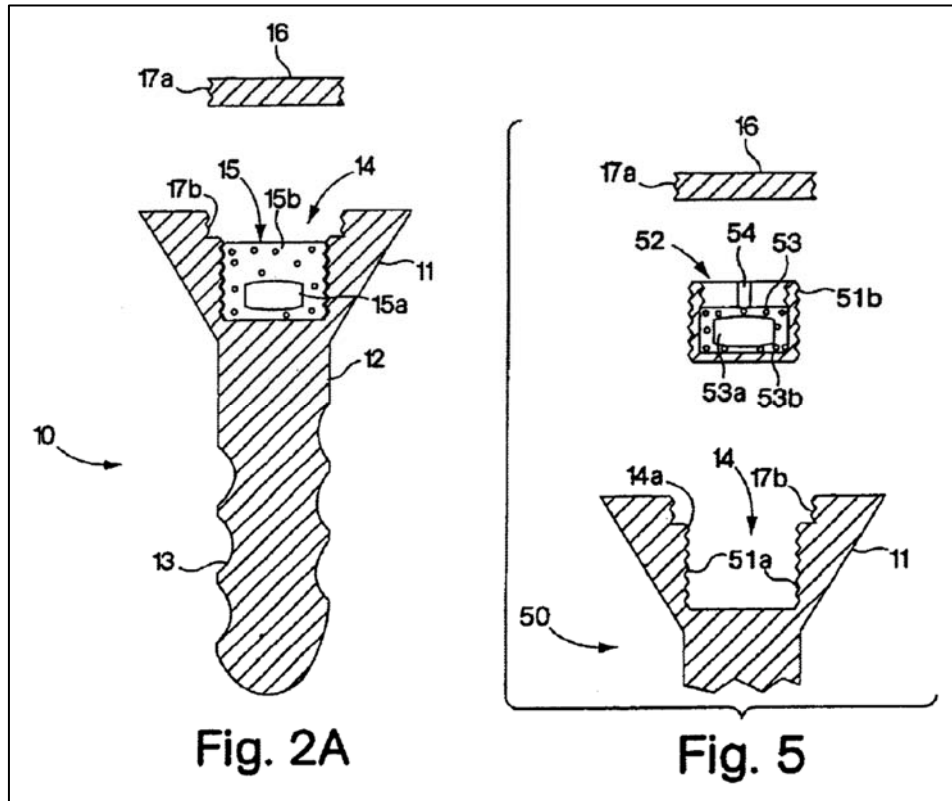
Watson teaches this limitation; any alleged differences would have been obvious in view of the knowledge of a PHOSITA. Ex. 1017, ¶¶71-73. *Watson*’s device is made of solid materials, such as “bioerodible,” “bioresorbable,” or “bioabsorbable polymeric” materials, including “linear aliphatic polyesters (polyglycolide, lactide, caprolactone, hydroxybutyrate) and their copolymers (poly[glycolide-lactide], [glycolide-caprolactone], [glycolide-trimethylene carbonate], [lactic acid-lysine], [lactide-urethane], [ester-amide]), polyanhydrides, poly(orthoesters), polyphosphazenes, orthoesters, and poly(orthoester)/poly(ethylene glycol) block copolymers, to name a few.” Ex. 1003, 11:60-12:8; Ex. 1017, ¶71. Those materials are solid for the additional reason that they are used to provide the “sustained release device” that physically interacts with threads. The ’483 Patent identifies many of the same materials as suitable for its device:

It will be understood by the artisan that the bioabsorbable drug delivery devices discussed hereinbelow may be formed out of polymer blends of glycolide and/or lactide homopolymer, copolymer and/or glycolide/lactide copolymer and polycaprolactone copolymers, and/or copolymers of glycolide, lactide, poly (L-lactide-co-DL-lactide), caprolactone, polyorthoesters, polydioxanone, trimethylene carbonate and/or polyethylene oxide or any other bioabsorbable material.

Ex. 1001, 4:62-5:3.

The '483 Patent states that the “term ‘bioabsorbable,’ means that the composition will be biodegraded and that the products of biodegradation will either be absorbed by tissue within the body or excreted.” *Id.*, 5:13:16. Thus, “bioabsorbable” materials are a type of “biodegradeable” material. *Id.*; Ex. 1017, ¶72. *Watson* identifies its “polymeric materials” as “bioerodible (and/or resorable),” therefore, they are biodegradable polymers. Ex. 1003, 11:64-12:1; Ex. 1017, ¶72. Such materials degrade over time by enzymatic action, by hydrolytic action and/or by other similar mechanisms in the human body. Ex. 1003, 11:64-12:1; Ex. 1017, ¶72.

The solid modular implantable drug delivery device (sustained release device 15) fits snugly within the shaped recess in the prosthesis (cavity/chamber 14):



Id., 11:39-47, 12:24-37, Figs. 2A & 5. For example, “sustained release device” (15) fits snugly within the shaped recess because it engages threading (51a). *Id.*; Ex. 1017, ¶73.

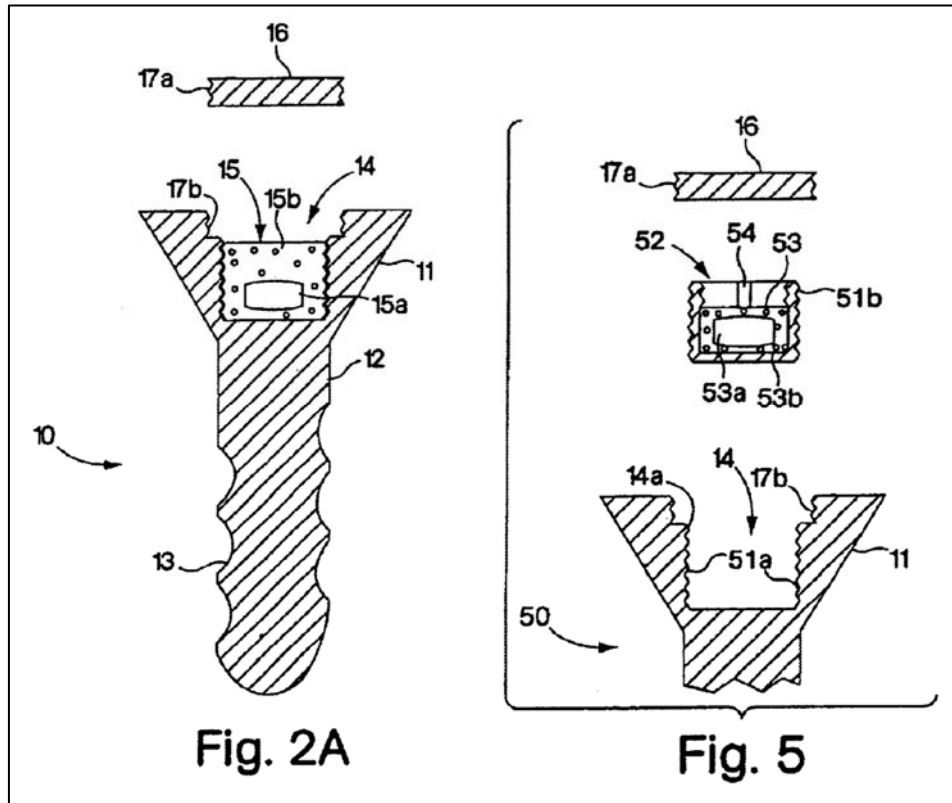
1[e] (b) a therapeutic agent ...

Watson teaches this limitation; any alleged differences would have been obvious in view of the knowledge of a PHOSITA. Ex. 1017, ¶74. As discussed for limitation 1[c], *Watson* teaches a therapeutic agent that is released into the body of an animal. *Watson* describes its “sustained release device” as “a device that is capable of releasing one or more drugs and/or compounds over an extended period of time in a controlled fashion,” akin to the claimed “predefined dosing period.” *Id.*,

4:46-48; Ex. 1017, ¶74. *Watson* further discloses that the biodegradable polymer can be selected to provide a specific predefined dosing period. *Id.*, 12:8-11 (“The bioerodible material may comprise combinations of materials or layers to achieve a desired result of bioeroding or bioabsorbing at a known, controlled rate.”), 18:47-51 (“Once implanted, the drug payload 300 is released at a controlled rate over an extended period of time”); Ex. 1017, ¶74. The dosing period (i.e., the period of time during which the therapeutic agent is released) is predefined by the controlled rate for the bioerodible material and the amount of that material. Ex. 1003, 12:8-11, 18:47-51; Ex. 1017, ¶74. The therapeutic agent is released during biodegradation of the biodegradable polymer. Ex. 1003, 11:60-62, 12:8-11, 18:47-51 (“Once implanted, the drug payload 300 is released at a controlled rate over an extended period of time, in accord with the intended therapeutic result, into the area of the patient’s body surrounding the insertion site as represented in FIG. 14D.”); Ex. 1017, ¶74.

2. Claim 2.

Watson teaches this claim; any alleged differences would have been obvious in view of the knowledge of a PHOSITA. Ex. 1017, ¶75. Sustained release device (15) is received within the shaped recess (chamber 14) of the implantable prosthesis (system 10):

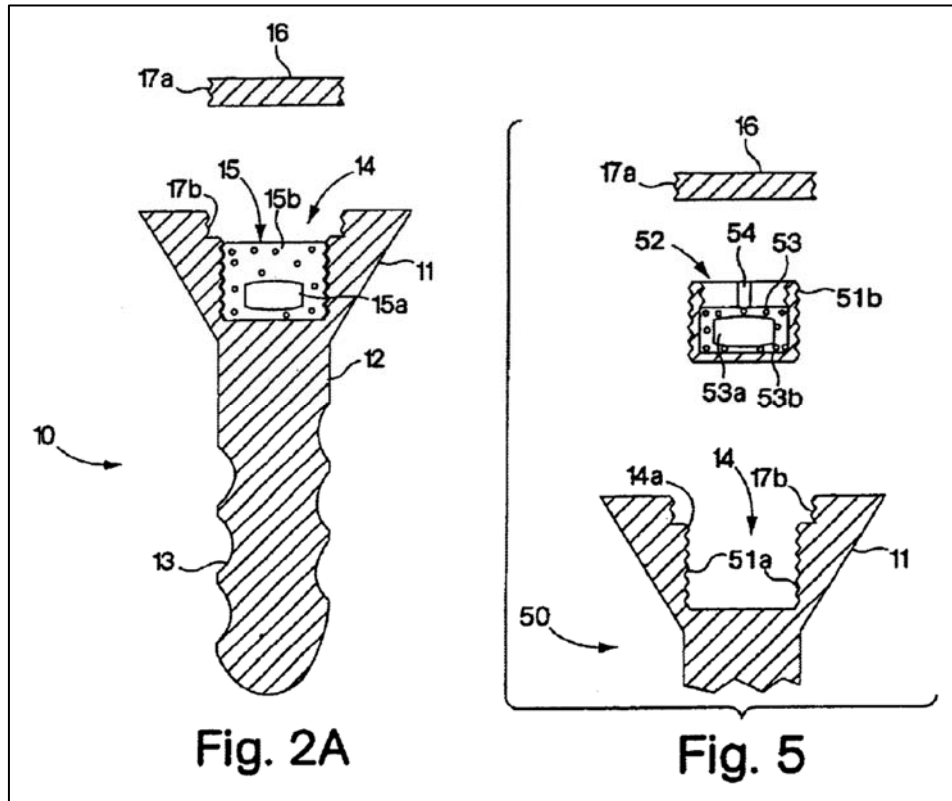


Ex. 1003, 11:39-47, 12:24-37, Figs. 2A & 5. When received within the implantable prosthesis (system 10), sustained release device (15) can be recessed, with an attachable retainer (16) flush to the surface of the prosthesis, or sustained release device (15) can be flush to the surface of the prosthesis. *Id.*, 12:12-15; Figs. 2A & 5; Ex. 1017, ¶75. Figs. 2A & 5 of *Watson* depict an implantable prosthesis (system 10) with an outer surface that is not substantially altered because the “sustained release device” is flush with the surface of the prosthesis. It would have been obvious to not substantially alter the outer surface of the prosthesis because a prosthesis with a flat surface provides the best geometry for articulation against an opposing joint surface or soft/hard tissue structure. *Id.* The outer surface of the

prosthesis is preferably flush to the surface of the surrounding/abutting soft and hard tissues so that the prosthesis is able to mechanically function without fraying or inducing stress to the surrounding/abutting soft and hard tissues. *Id.* Moreover, the contour of the outer surface of the prosthesis is designed specifically to meet requirements for strength and for directing healing in the area proximate to the prosthesis. *Id.* Accordingly, it would have been obvious to not substantially alter the contour of that surface. *Id.*

3. Claim 3.

Watson teaches this claim; any alleged differences would have been obvious in view of the knowledge of a PHOSITA. Ex. 1017, ¶76. *Watson* teaches that the sustained release device can be affixed to the prosthesis by threads, as depicted in Figure 5:



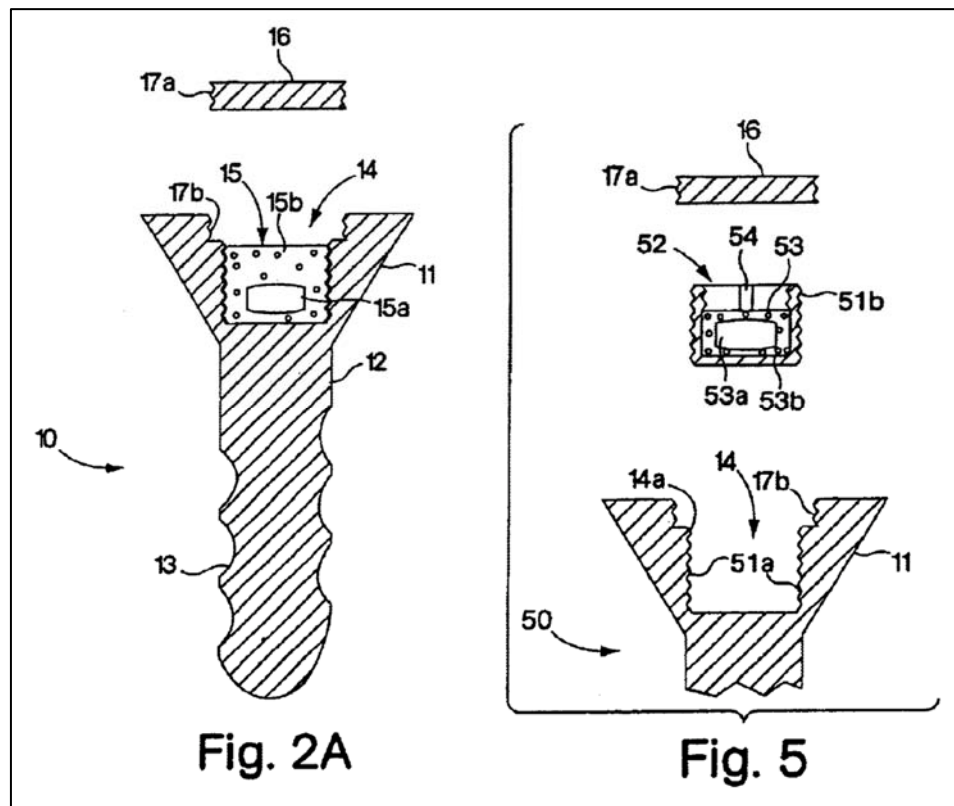
Ex. 1003, 12:12-38, Figs. 2A & 5. *Watson* also teaches that the sustained release device can be affixed to the prosthesis using an adhesive. Ex. 1003, 18:9-13 (“An adhesive 305 is provided along one or more inner surfaces of the sustained release holding device 250 prior to insertion of the drug payload 300. Upon insertion of the drug payload 300, the adhesive 305 sets and retains the drug payload in place.”).

4. Claim 4.

Watson teaches or renders obvious this claim for the same reasons as claim 3, as discussed above. Ex. 1017, ¶77.

5. Claim 5.

Watson teaches this claim; any alleged differences would have been obvious in view of the knowledge of a PHOSITA. Ex. 1017, ¶78. *Watson* teaches that the therapeutic agent may be contained in an inner core (15 *a* and 53 *a*) of the sustained release device (15 and 53), as depicted in Figures 2 and 5:



Id., Figs. 2A & 5, 13:3-7 (“The sustained release device 15 or second chamber 35, 52 containing the sustained release device can be easily replaced as necessary when the drug of the inner core 15 *a*, 36 *a*, 53 *a* has been completely released without removing the entire system from the body.”) (emphasis added). Claim 11 of *Watson*, which depends from Claim 9, further teaches that “the sustained

release device includes an inner core containing the compound,” and the compound in Claim 9 is described as “having a therapeutic effect over an extended period of time wherein the compound is a low-solubility compound.” *Id.*, 23:23-25, 30-31. The therapeutic agent disclosed in the ’483 Patent is not limited by solubility. Ex. 1001, 7:46-53 (“The release of the biologically-active agent from the matrix of the composition may be varied, for example, by the solubility of the biologically-active agent in aqueous tissue fluids ...”) (emphasis added).

6. Claim 6.

Watson teaches or renders obvious this claim for the same reasons as claim 5, as discussed above. Ex. 1017, ¶79.

7. Claim 7.

Watson teaches this claim; any alleged differences would have been obvious in view of the knowledge of a PHOSITA. Ex. 1017, ¶¶80-82. *Watson* teaches a solid module for the reasons given with respect to claim 1. *Watson* further teaches embodiments that provide for “the sustained release of two or more drugs simultaneously” (i.e., the claimed “therapeutic agents”). Ex. 1003, 5:19-27. It would have been obvious to a PHOSITA to provide two or more therapeutic agents because those agents can provide different benefits to the patient. Ex. 1017, ¶80. For example, the therapeutic agents identified in *Watson* include “a steroid, an anti-inflammatory drug, an antibiotic, an anti-viral agent, a cancer-fighting drug,

including antiproliferative, antimyotic, and antimetabolite compounds, or a pain relieving [*sic*] drug.” Ex. 1003, 4:48-53. An orthopedic patient can benefit from both antibiotics and pain-relieving drugs to aid in recovery from implantation of a prosthesis, so it would have been obvious to provide both. Ex. 1017, ¶80. In addition, a PHOSITA would understand that different therapeutic agents would have differing compatibility and solubility (which affects potential dosing) in different polymers, so it would have been obvious to provide a plurality of solid modules to provide more than one therapeutic agent, along with the best-suited polymer for each agent. *Id.*, ¶81.

The therapeutic agents in *Watson* are released during biodegradation of the module, as discussed above with respect to claim limitation 1[e]. *Watson* teaches that its “bioerodible material may comprise combinations of materials or layers to achieve a desired result of bioeroding or bioabsorbing at a known, controlled rate.” Ex. 1003, 12:8-11 (emphasis added). By providing multiple materials or layers, each layer would be a different solid module. *Id.*; Ex. 1017, ¶82. It would have been obvious to a PHOSITA to use a plurality of solid modules to provide two or more therapeutic agents because the biodegradable polymer associated with each therapeutic agent can be tailored to provide the correct delivery rate for each therapeutic agent. Ex. 1003, 11:60-12:11 (“The bioerodible material may comprise

combinations of materials or layers to achieve a desired result of bioeroding or bioabsorbing at a known, controlled rate.”); Ex. 1017, ¶82.

8. Claim 8.

Watson teaches this claim; any alleged differences would have been obvious in view of the knowledge of a PHOSITA. Ex. 1017, ¶83. As discussed for claim 7, *Watson* teaches that its “bioerodible material may comprise combinations of materials or layers to achieve a desired result of bioeroding or bioabsorbing at a known, controlled rate,” so each layer would be a different solid module. Ex. 1003, 12:8-11. It would have been obvious to a PHOSITA that those materials or layers are affixed to one another because they are part of the same sustained release device. Ex. 1017, ¶83. It also would have been obvious to affix the solid modules to one another to reduce the complexity of installing the sustained release device within the prosthesis. *Id.*

9. Claim 9.

Watson teaches this claim; any alleged differences would have been obvious in view of the knowledge of a PHOSITA. Ex. 1017, ¶¶84-87. As discussed for claim 7, *Watson* teaches that its “bioerodible material may comprise combinations of materials or layers to achieve a desired result of bioeroding or bioabsorbing at a known, controlled rate,” so each layer would be a different solid module. Ex. 1003, 12:8-11. By providing multiple materials or layers, each layer would be a different

solid module. *Id.*; Ex. 1017, ¶84. It would have been obvious to a PHOSITA to use a plurality of solid modules to provide two or more therapeutic agents because the biodegradable polymer associated with each therapeutic agent can be tailored to provide the correct delivery rate for each therapeutic agent. Ex. 1003, 11:60-12:11 (“The bioerodible material may comprise combinations of materials or layers to achieve a desired result of bioeroding or bioabsorbing at a known, controlled rate.”); Ex. 1017, ¶84.

It would have been obvious to a PHOSITA to use a mesh container in conjunction with an implantable prosthetic device to include a greater volume of therapeutic agent, resulting in a longer degradation period of the therapeutic agent. Ex. 1017, ¶85. *Watson* teaches that drug delivery systems “may be readily adapted, with little experimentation, to a large number of orthopedic hardware components.” Ex. 1003, 21:1-6. *Watson* further teaches that “[a] wide range of suitable orthopedic hardware is known in the art, and is described for example in several well-established orthopedic texts” *Id.*, 21:18-20.

It also would have been obvious to a PHOSITA to use a mesh container in conjunction with an implantable prosthetic device to induce varying degradation rates with two or more therapeutic agents. For example, it would have been obvious to a PHOSITA to use a first therapeutic agent in a first solid module in the mesh container because that therapeutic agent would degrade faster (and thus act quicker)

than the second therapeutic agent in the second solid module in the implantable prosthesis due to the greater porous surface area of the mesh container. Ex. 1017, ¶86. In another example, a PHOSITA would recognize that it would have been obvious to use a mesh container because it would allow for flexibility in the placement of the solid module within different types of tissue, such as soft tissue. *Id.*, ¶87. In addition, in instances where the size and/or mechanical requirements of the prosthesis limit the size of the solid module, the mesh container could allow for the implantation of more biodegradable polymer and therapeutic agent. *Id.*

10. Claim 10.

Watson teaches this claim; any alleged differences would have been obvious in view of the knowledge of a PHOSITA. Ex. 1017, ¶88. Claim 18 of *Watson* states that the “orthopedic hardware component” can be “a staple, a tack, a dart, a bolt, a washer, a plate, a prosthetic joint, a component of a prosthetic joint, an anchor, a pin, a wire, or a button.” Ex. 1003, 24:16-20 (emphasis added). Similarly, the specification states that “orthopedic hardware components include ... pins such as those driven into or through bones, buttons, staples, and wires.” *Id.*, 21:7-11. And *Watson* states that “it will be appreciated that the general principle of configuring orthopedic hardware as a platform for a drug delivery system may be readily adapted, with little experimentation, to a large number of orthopedic hardware

components,” so it would have been obvious to a PHOSITA that the prosthesis can be a femoral pin. *Id.*, 21:1-6; Ex. 1017, ¶88.

11. Claim 11.

Watson teaches this claim; any alleged differences would have been obvious in view of the knowledge of a PHOSITA. Ex. 1017, ¶89. Claim 18 of *Watson* states that the “orthopedic hardware component” can be “a staple, a tack, a dart, a bolt, a washer, a plate, a prosthetic joint, a component of a prosthetic joint, an anchor, a pin, a wire, or a button.” Ex. 1003, 24:16-20 (emphasis added). And *Watson* states that “it will be appreciated that the general principle of configuring orthopedic hardware as a platform for a drug delivery system may be readily adapted, with little experimentation, to a large number of orthopedic hardware components,” so it would have been obvious to a PHOSITA that the prosthesis can be a bone plate. *Id.*, 21:1-6; Ex. 1017, ¶89.

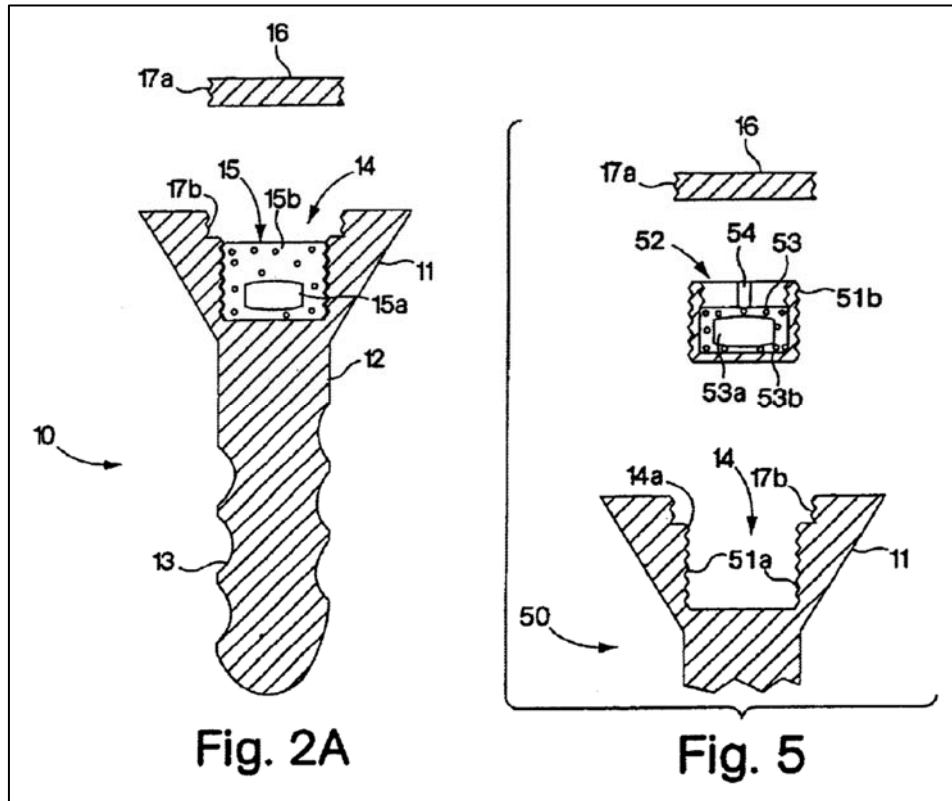
12. Claim 12.

Watson teaches this claim; any alleged differences would have been obvious in view of the knowledge of a PHOSITA. Ex. 1017, ¶90. As discussed for claim 11, it would have been obvious to a PHOSITA that the prosthesis can be a bone plate. Bone plates are often rectangular in shape. *Id.* And *Watson* discloses that its device can be shaped like a tablet, which is often rectangular in shape. Ex. 1003, 21:59-22:7 (“the device may simply comprise a tablet embedded within, or affixed

to the surface of, the orthopedic hardware component”). Accordingly, it would have been obvious to shape the solid module as a rectangular tile so as to avoid substantially altering the surface of the prosthesis. Ex. 1017, ¶90. The recess is a mating receptacle for the “solid module” because *Watson* discloses that the “tablet” can be “embedded within, or affixed to the surface of, the orthopedic hardware component.” To that end, *Watson* discloses that the recess can provide an “interference fit” with the solid module such that the module and prosthesis are “frictionally engaged to another.” Ex. 1003, 21:45-47.

13. Claim 13.

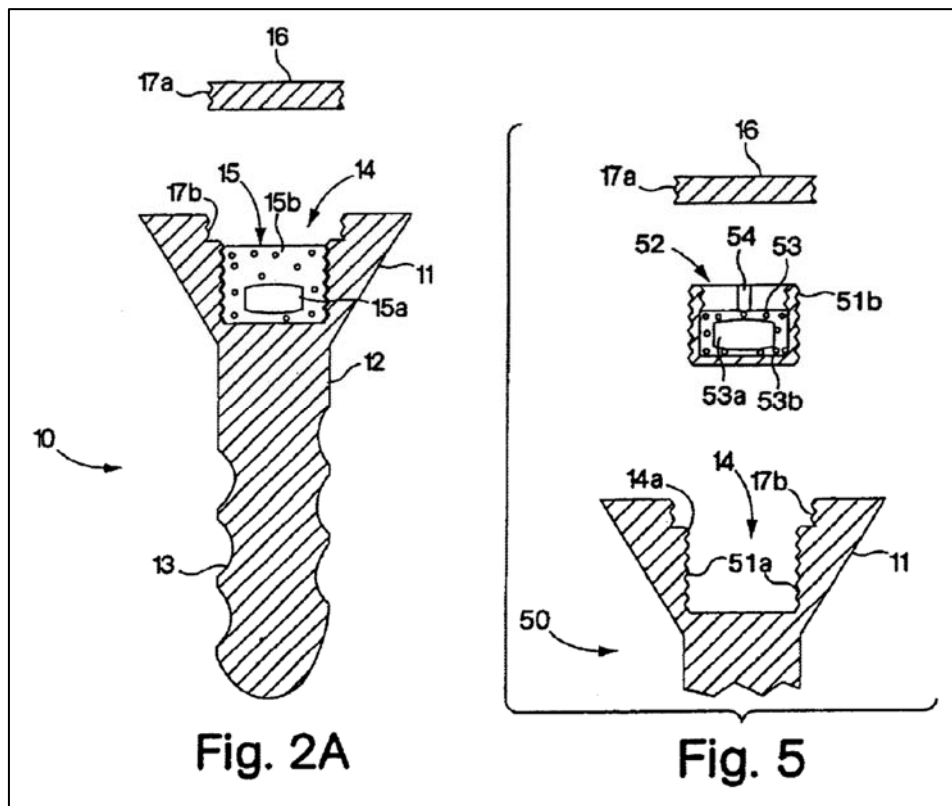
Watson teaches this claim; any alleged differences would have been obvious in view of the knowledge of a PHOSITA. Ex. 1017, ¶91. The “shaped recess within the outer surface of an implantable prosthesis” is the portion of the device into which the “sustained release device” (15) is inserted, including the threading (51a):



Id., 11:39-47, 12:24-37, Figs. 2A & 5. As depicted, the recess can be a cylindrical hole in the prosthesis. *Id.*, 11:39-43 (“The recess (chamber 14) may be cylindrical shaped ...”). A PHOSITA would understand that forming a recess by drilling a hole in the prosthesis is one of a limited number of options for forming a recess, the other being casting/molding the prosthesis where the recess is formed a part of the same process. Ex. 1017, ¶91; Ex. 1016. In addition, the presence of threads in *Watson* indicates to a PHOSITA that the recess was formed by drilling and tapping the prosthesis because it would provide strength to the threads. Ex. 1017, ¶91.

14. Claim 14.

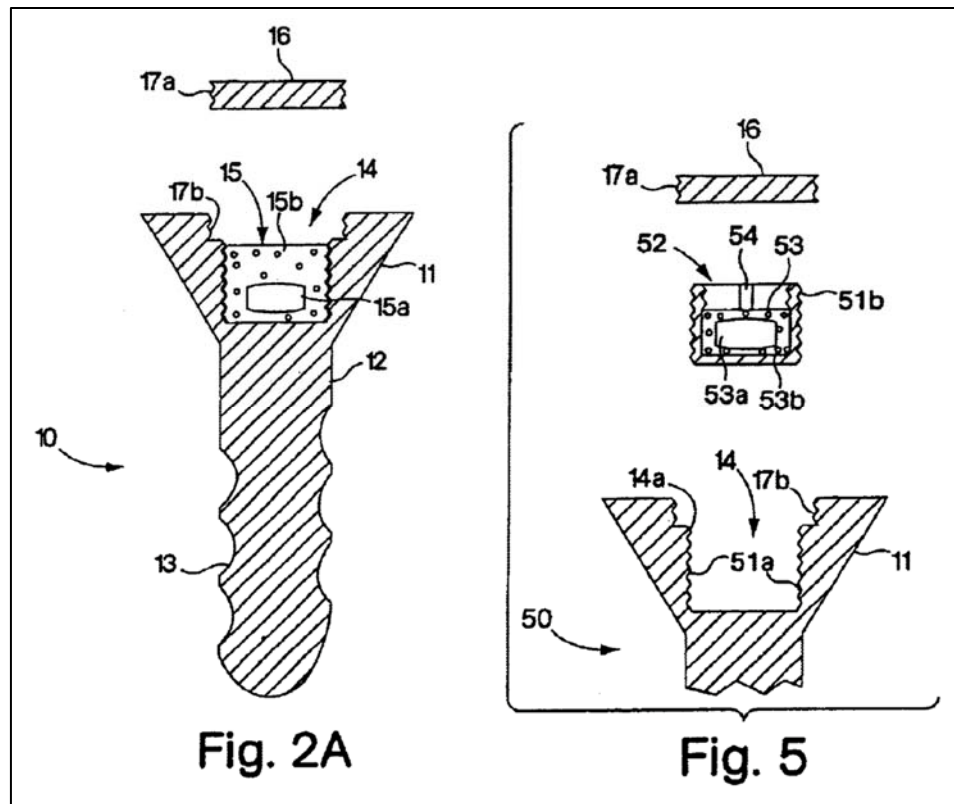
Watson teaches this claim; any alleged differences would have been obvious in view of the knowledge of a PHOSITA. Ex. 1017, ¶92. The sustained release device of *Watson* is shaped like a rod, and is placed, within a cylindrical recess in the prosthesis:



Id., 11:39-47, 12:24-37, Figs. 2A & 5. *Watson* further describes the recess as cylindrical and the sustained release device is shaped like a rod to fit snugly within the cylindrical recess. *Id.*, 11:39-43 (“The recess (chamber 14) may be cylindrical shaped ...”); Ex. 1017, ¶92.

15. Claim 15.

Watson teaches this claim; any alleged differences would have been obvious in view of the knowledge of a PHOSITA. Ex. 1017, ¶93. As discussed for limitation 1[e], the therapeutic agent is released as a result of biodegradation of the biodegradable polymer. *Watson* teaches that “[t]he release rate may be controlled, for example, by ... geometry.” *Id.*, 18:47-63. As depicted, the surface area of the sustained release device corresponds to its surface at the top of the prosthesis:

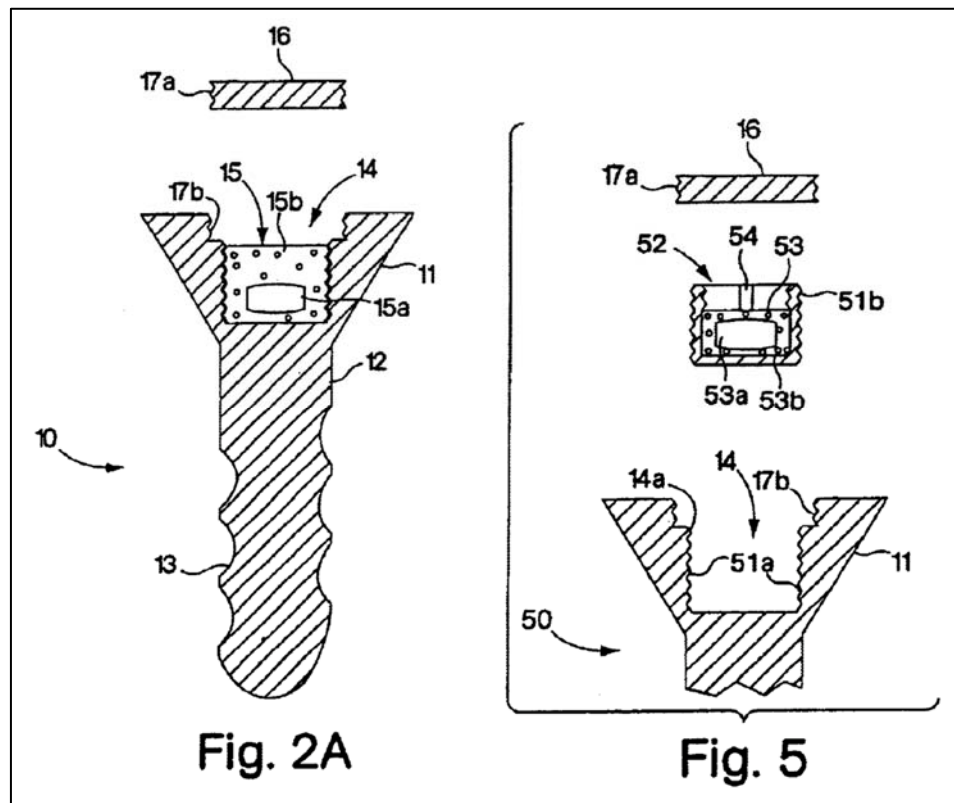


Id., 11:39-47, 12:24-37, Figs. 2A & 5. Because the other surfaces of the sustained release device are enclosed by the prosthesis (and thus not in contact with bodily fluids), it would have been obvious to hollow the surface of the sustained release

device (i.e., alter its geometry) to increase the surface area in contact with the body fluids, and increase the rate of release of a therapeutic agent therefrom. *Id.*; Ex. 1017, ¶¶93.

16. Claim 16.

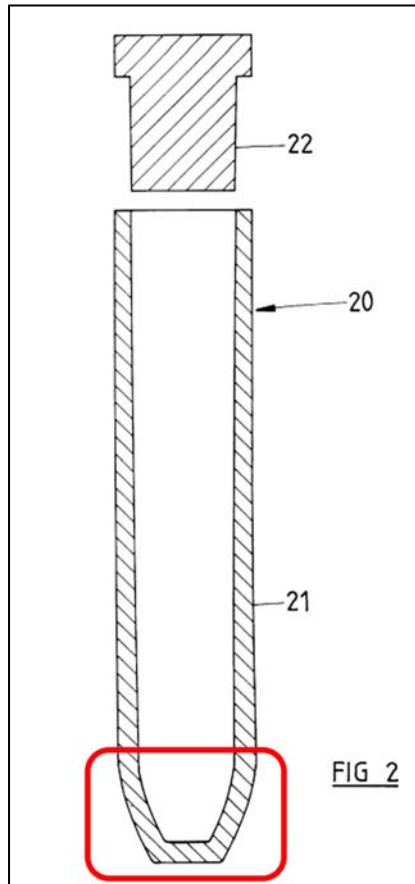
Watson teaches this claim; any alleged differences would have been obvious in view of the knowledge of a PHOSITA. Ex. 1017, ¶¶94-95. As depicted, the sustained release device of *Watson* is cylindrical, and is placed, within a cylindrical recess in the prosthesis:



Ex. 1003, 11:39-47, 12:24-37, Figs. 2A & 5. *Watson* further describes the recess as cylindrical. *Id.*, 11:39-43 (“The recess (chamber 14) may be cylindrical shaped ...”).

The sustained release device can be held in place via an “interference fit” in which “one piece is frictionally engaged to another.” *Id.*, 21:45-47. In such a configuration, a wedge or pin can be “driven into the sustained device to expand the device so that it engages the walls of a suitably fashioned cavity in the orthopedic hardware component.” *Id.*, 21:48-51. A PHOSITA would understand that a pin (i.e., cylindrical shape) would be suitable for a sustained release device that is cylindrical, whereas a wedge would be suitable for a sustained release device that is a tapered cone. Ex. 1017, ¶94. Specifically, the tapered conical plug is narrower at its bottom than its top. A wedge, that is also narrower at its bottom than its top, indicates to a PHOSITA that the corresponding sustained release device would be a tapered conical plug so as to expand the plug to engage the walls of the prosthesis. *Id.* The use of tapered plugs was well-known and used in the field as shown, for example, in *O’Donoghue*. *Id.*, ¶95. It would have been obvious to use a tapered conical plug because the taper at the bottom of the plug reduces the potential for voiding (i.e., unfilled space) at the bottom of the recess. *Id.*, ¶94.

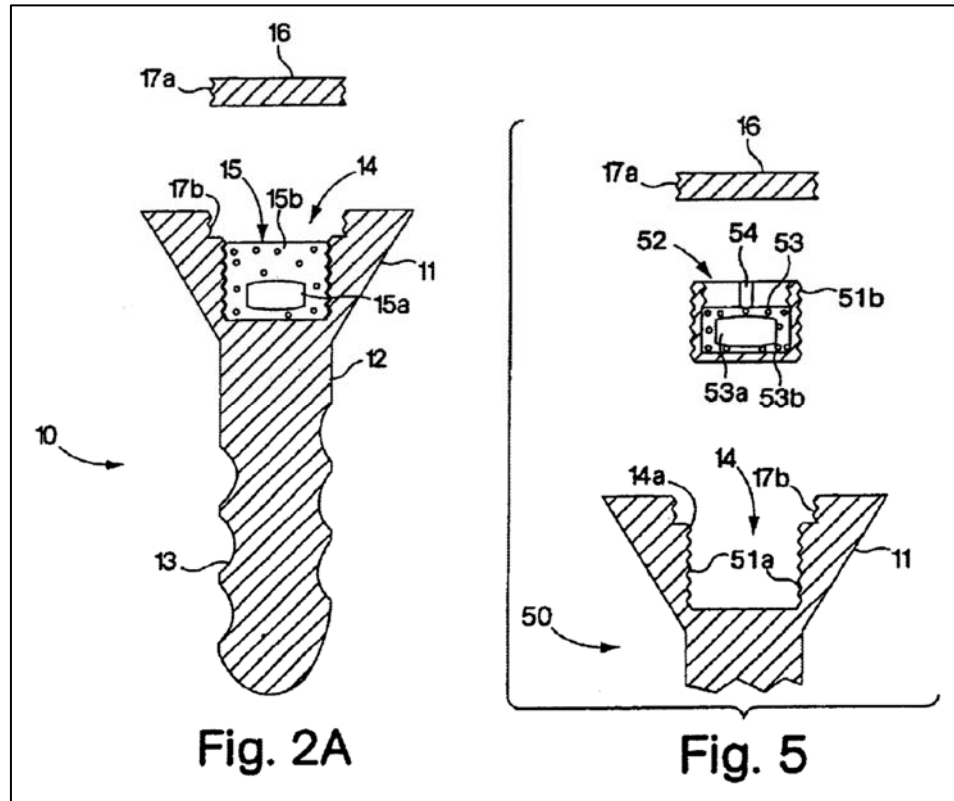
O’Donoghue teaches a biodegradable container 20 with a “tubular implant body 21 to house a core containing active ingredient and a cap 22 which seals the implant body 21. Once again, either or both of the implant body 21 or the cap 22 may be formed from biodegradable polymeric material.” Ex, 1010, 14:65-15:2.



Id., Fig. 2 (emphasis added highlighting tapered bottom). Figure 2 of *O'Donoghue* depicts a cylindrical tube module that includes a tip with a surface profile that is contoured as a tapered plug. *Id.*; Ex. 1017, ¶95. Specifically, the bottom of the module is tapered so, as a result, the plug would also be tapered. Ex. 1010, Fig. 2; Ex. 1017, ¶95. Claims 12 and 13 of *O'Donoghue* further teach that the container has “a shape selected from a group consisting of elongate, and generally cylindrical” and that the container “is formed as an implant device, or as part of an implant device.” Ex. 1004, 22:1-6. Accordingly, it would have been obvious to use a solid module shaped like a tapered conical plug.

17. Claim 17.

Watson teaches this claim; any alleged differences would have been obvious in view of the knowledge of a PHOSITA. Ex. 1017, ¶96. *Watson* teaches a “sustained release device” (15) that is received within the threading of device 10:



Ex. 1003, 11:39-47, 12:24-37, Figs. 2A & 5. As depicted and described in *Watson*, the sustained release device is a threaded cylindrical plug. *Id.* *Watson* describes “a number of threaded techniques,” including “a number of rotatably attachable and detachable sustained release device configuration that thread ... into the component.” *Id.*, 21:33-36.

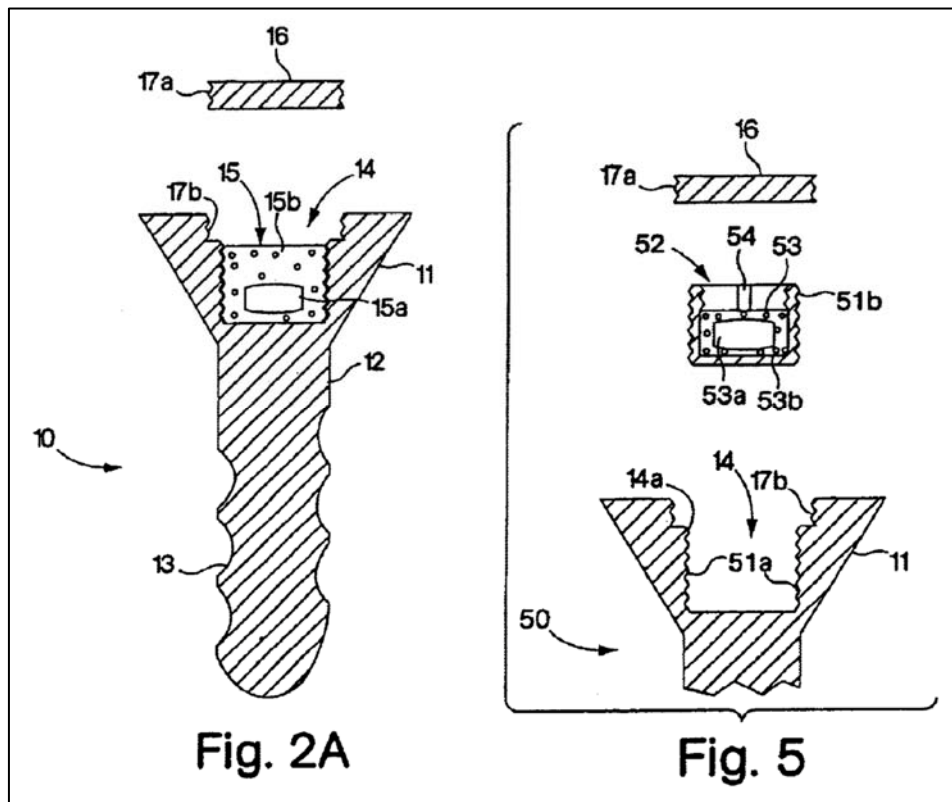
18. Claim 18.

Watson teaches this claim; any alleged differences would have been obvious in view of the knowledge of a PHOSITA. Ex. 1017, ¶¶97-98. As discussed for claim 7, *Watson* teaches that its “bioerodible material may comprise combinations of materials or layers to achieve a desired result of bioeroding or bioabsorbing at a known, controlled rate,” so each layer would be a different solid module. Ex. 1003, 12:8-11. By providing multiple materials or layers, each layer would be a different solid module. *Id.*; Ex. 1017, ¶98. It would have been obvious to a PHOSITA to use a plurality of solid modules to provide two or more therapeutic agents because the biodegradable polymer associated with each therapeutic agent can be tailored to provide the correct delivery rate for each therapeutic agent. Ex. 1003, 11:60-12:11 (“The bioerodible material may comprise combinations of materials or layers to achieve a desired result of bioeroding or bioabsorbing at a known, controlled rate.”); Ex. 1017, ¶98.

It also would have been obvious for the plurality of solid modules to be stacked and shaped like disks because *Watson* teaches that drug delivery systems “may be readily adapted, with little experimentation, to a large number of orthopedic hardware components.” Ex. 1003, 21:1-6. *Watson* further teaches that “[a] wide range of suitable orthopedic hardware is known in the art, and is described for example in several well-established orthopedic texts” *Id.*, 21:18-20.

19. Claim 19.

Watson teaches this claim; any alleged differences would have been obvious in view of the knowledge of a PHOSITA. Ex. 1017, ¶99. As discussed above for claim 17, *Watson* teaches that the sustained release device can be shaped like a cylindrical plug. And as discussed above for claim 15, it would have been obvious to hollow out the sustained release device to increase the surface area in contact with the body fluids. Hollowing out a cylindrical plug creates a tub or tube shaped sustained release device. *Watson* teaches that the sustained release device is shaped like a tub or tube:



Ex. 1003, 11:39-47, 12:24-37, Figs. 2A & 5. *Watson* further teaches that retainer 16 can be used to cap the sustained release device within the prosthesis. *Id.*, 21:30-40.

20. Claim 20.

20[a] A method for ...

See claim 1[a] & 1[c], *supra*; *see also* Ex. 1003, 3:60-5:67.

20[b] comprising providing an implantable prosthesis,

See claim 1[a], *supra*.

20[c] forming at least one ...

See claims 1[b]-[e], *supra*.

20[d] forming a recess ...

See claim 1[b], *supra*.

20[e] placing ...

See claim 1[b], *supra*.

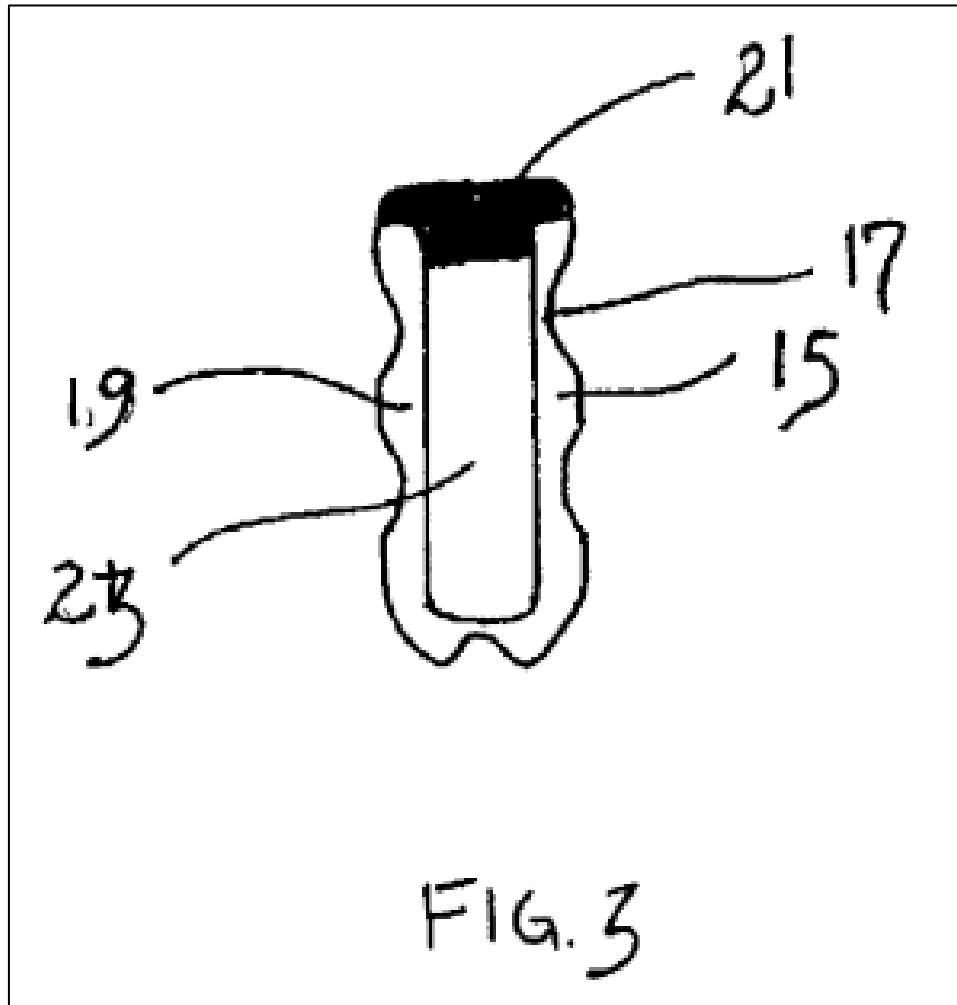
20[f] and implanting ...

See claim 1[c], *supra*; *see also* Ex. 1003, 6:1-11:18.

B. Ground 2: Claims 5, 6, 18, and 19 Are Obvious Over *Watson* In View of *Glover* and the Knowledge of a PHOSITA.

1. Claim 5.

In addition to *Watson*, *Glover* also teaches this claim. Ex. 1017, ¶106. *Glover* teaches a therapeutic agent 23 contained within a cavity of a capsule, as depicted in Figure 3:



Ex. 1009, Fig. 3, [0035] (“FIG. 3 depicts the cross-section of one embodiment of a capsule formed entirely of a biodegradable material. The wall 15 of the capsule varies in thickness such that there are thinner portions 17 and thicker portions 19. The capsule is sealed with a biodegradable plug 21 and is filled with a therapeutic agent 23.”). It would have been obvious to combine *Watson* and *Glover* to provide “combinations of materials or layers to achieve a desired result of bioeroding or bioabsorbing at a known, controlled rate,” as disclosed in *Watson* to provide increased options for varying the delivery rate, duration, schedule, and dosing of the

therapeutic agent. Ex. 1003, 12:8-11; Ex. 1017, ¶106. For example, providing the therapeutic agent within a cavity of the solid module would allow delayed release of the therapeutic agent (i.e., delivery of the therapeutic agent would not begin until the walls of the cavity degrade). *Id.* Alternatively, the therapeutic agent within the cavity would allow for one delivery rate as the sidewall degrades, followed by a different delivery rate (or different therapeutic agent) when the contents of the cavity are exposed to the body. *Id.* *Glover* is compatible with *Watson* because it is a “capsule formed entirely of a biodegradable material” just like the “sustained release device” of *Watson*. *Id.*; Ex. 1009, [0035]. Doing so would tailor the device to provide the correct delivery rate for each therapeutic agent. Ex. 1017, ¶106.

2. Claim 6.

This claim is obvious for the same reasons as claim 5, as discussed above. Ex. 1017, ¶107.

3. Claim 18.

In addition to *Watson*, *Glover* also teaches this claim. Ex. 1017, ¶108. *Glover* teaches that a plurality of capsules containing therapeutic agents may be linked together “to release the same or different agents and to release their contents at approximately the same time or at different times. For example, an implant might consist of five linked capsules.... The links between capsules can be formed of the same material as the capsules themselves or the [*sic*] can be formed of a different

material.” Ex. 1009, [0019]. A PHOSITA would have been motivated to combine *Watson* and *Glover* because, as discussed for claim 7, it would have been obvious to provide multiple therapeutic agents. Ex. 1017, ¶108. Providing stacked discs would improve the efficiency of assembling the multiple therapeutic agents during preparation of the prosthesis, as well as surgery. Ex. 1017, ¶108.

4. Claim 19.

In addition to *Watson*, *Glover* also teaches this claim. Ex. 1017, ¶109. *Glover* teaches a therapeutic agent 23 contained within a cavity of a capsule, as depicted in Figure 3:

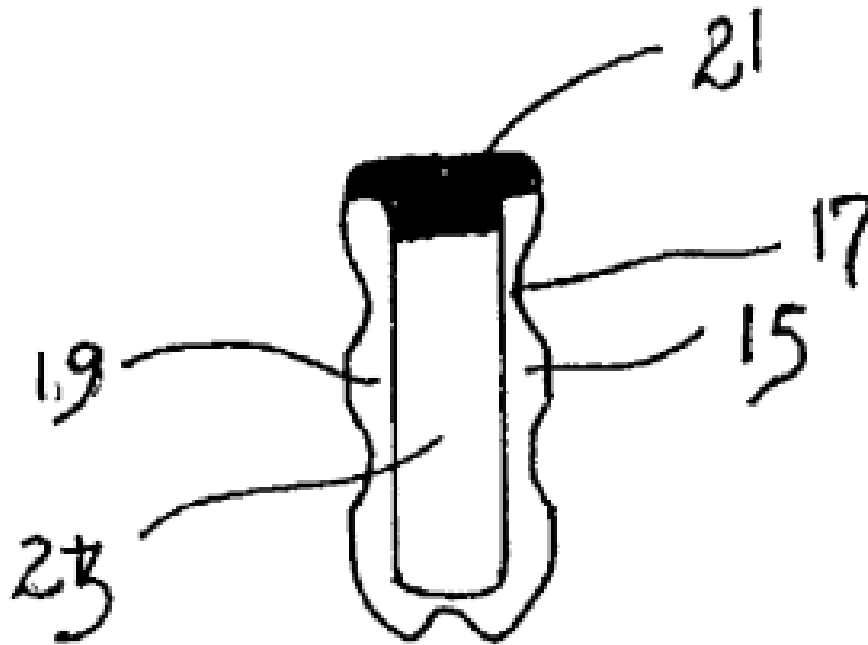


FIG. 3

Ex. 1009, Fig. 3, [0035] (“FIG. 3 depicts the cross-section of one embodiment of a capsule formed entirely of a biodegradable material. The wall 15 of the capsule varies in thickness such that there are thinner portions 17 and thicker portions 19. The capsule is sealed with a biodegradable plug 21 and is filled with a therapeutic agent 23.”) (emphasis added). It would have been obvious to combine *Watson* and *Glover* because, as *Watson* teaches, “[t]he release rate may be controlled, for example, by appropriate variance of coating layer or rate-limiting barrier 315 properties and geometry.” Ex. 1001, 18:47-63 (emphasis added). Because the other

surfaces of the sustained release device are enclosed by the prosthesis (and thus not in contact with bodily fluids), the capped tub or tube would increase the surface area in contact with the body fluids, and increase the rate of release of a therapeutic agent therefrom. Ex. 1017, ¶109. *Glover* is compatible with *Watson* because it is a “capsule formed entirely of a biodegradable material” just like the “sustained release device” of *Watson*. *Id.*; Ex. 1009, [0035].

C. Ground 3: Claim 9 Is Obvious Over *Watson* In View of *Tormala* and the Knowledge of a PHOSITA.

In addition to *Watson*, *Tormala* also teaches this claim. Ex. 1017, ¶110. *Tormala* teaches that numerous materials can be used for drug delivery and implants, including meshes. Ex. 1011 6:29-38 (“The drug delivery materials and implants of the present invention can be in any appropriate form into which the polymer matrix, including antibiotic(s) and ceramic particle and/or fiber phase, can be formed with polymer technological processing methods. Typical forms are ... fiber constructions, like threads, cords, fabrics, meshes, non-woven felts, laminates or membranes and polymeric films.”) (emphasis added). *Tormala* further teaches that “drug delivery materials of the invention may also be formed into fixation devices and guided tissue regeneration devices, like pins, rods, screws, plates, membranes, meshes, tacks, bolts, intramedullary nails, clamps, arrows, or other devices which are used in bone-to-bone or soft tissue-to-bone fixation and whose geometries are

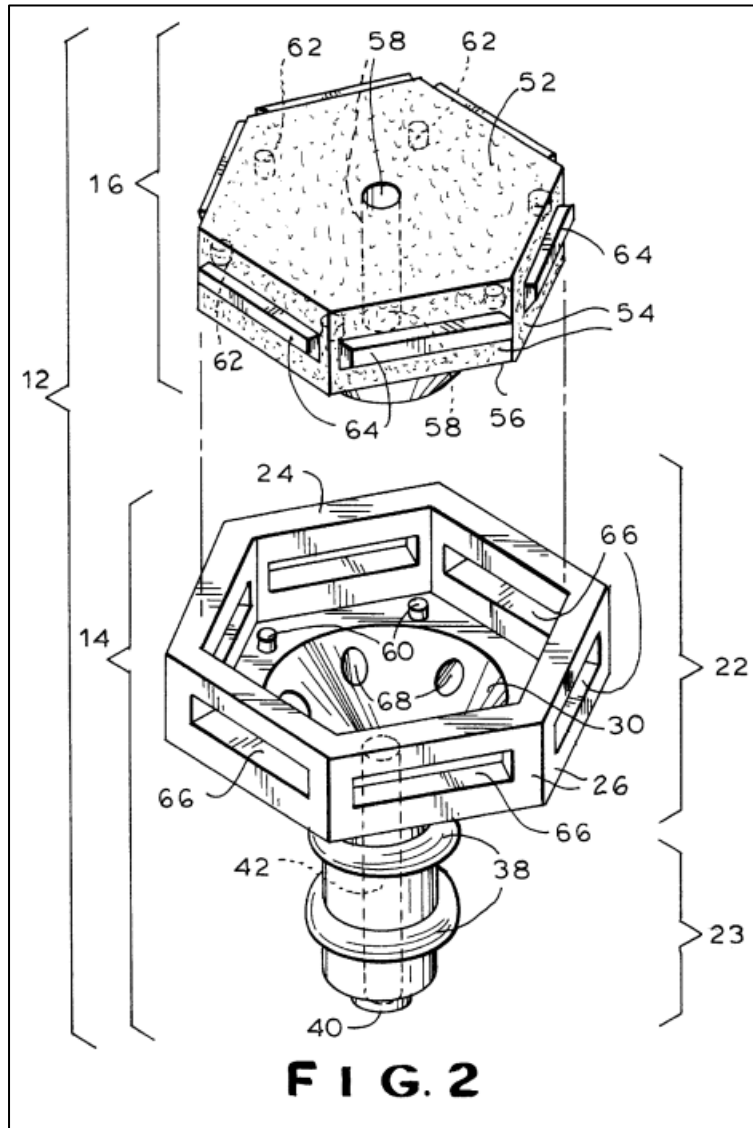
described extensively in the literature” *Id.*, 6:47-54 (emphasis added). In doing so, *Tormala* also identifies the orthopedic hardware (e.g., rods, screws, plates) in *Watson* as alternative forms for its disclosure. *Id.* That teaching is consistent with the disclosure in *Watson*, and understanding of a PHOSITA, that “the general principle of configuring orthopedic hardware as a platform for a drug delivery system may be readily adapted, with little experimentation, to a large number of orthopedic hardware components.” Ex. 1001, Abstract, 21:1-6; Ex. 1017, ¶110. Accordingly, it would have been obvious to a PHOSITA to combine *Watson* with *Tormala* to use a mesh container containing a solid module in conjunction with an implantable prosthetic device for the same reasons set forth above for claim 9 in Ground 1. *Id.*

D. Ground 4: Claims 1-4, 7-10, 13-15, 17, and 20 Are Obvious Over *Schwartz* In View of the Knowledge of a PHOSITA.

1. Claim 1.

1[a] An implantable prosthetic device ...

Schwartz teaches this limitation; any alleged differences would have been obvious in view of the knowledge of a PHOSITA. Ex. 1017, ¶111. *Schwartz* teaches a “cartilage repair system which does employ cement or non-bio-absorbable prosthetic devices.” Ex. 1004, 2:27-29 (emphasis added). Figure 2 of *Schwartz* discloses a prosthesis comprising a delivery unit 14 that receives an insert 16:

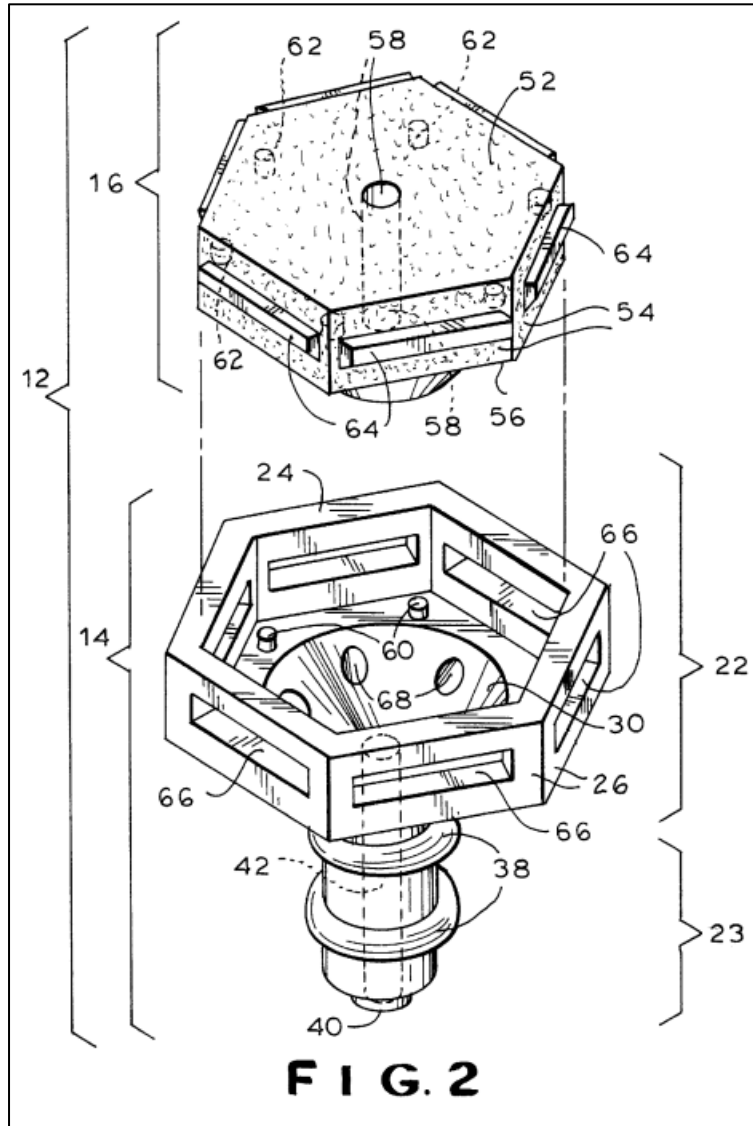


Id., Fig. 2. That device includes a surface contour, for example, upper rim (24) and side walls (26).

1[b] and comprising a solid modular implantable drug delivery device ...

Schwartz teaches this limitation; any alleged differences would have been obvious in view of the knowledge of a PHOSITA. Ex. 1017, ¶¶112-113. Figure 2

of *Schwartz* discloses a prosthesis comprising a delivery unit 14 that receives an insert 16:



Id., Fig. 2. The “shaped recess within the outer surface of an implantable prosthesis” is the portion of delivery unit 14 that receives an insert 16, including support frame (22). *Id.*, 5:18-31 (“The support frame 22 of the delivery unit 14 receives the insert 16 therein, with the side walls 26 of the support frame 22 receiving therewithin the

side walls 54 of the insert 50 [16]. The bottom surface 56 of the insert 16 and the bottom portion 30 of the support frame 22 are correspondingly shaped, preferably with the bottom surface of the insert 16 defining a protrusion and the upper surface of the bottom portion 30 defining a protrusion-receiving cavity....”).

Schwartz’s insert 16 is a “solid modular implantable drug delivery device.” Insert 16 is made of solid materials, such as “bio-absorbable” polymers, including “hyaluronic acid, polyglycolic acid, collagen, polylactic acid, fibrin clot, periosteal cells, polydioxane, polyester, alginate and combinations thereof.” *Id.*, 3:1-11. The ’483 Patent identifies many of the same materials as suitable for its device:

It will be understood by the artisan that the bioabsorbable drug delivery devices discussed hereinbelow may be formed out of polymer blends of glycolide and/or lactide homopolymer, copolymer and/or glycolide/lactide copolymer and polycaprolactone copolymers, and/or copolymers of glycolide, lactide, poly (L-lactide-co-DL-lactide), caprolactone, polyorthoesters, polydioxanone, trimethylene carbonate and/or polyethylene oxide or any other bioabsorbable material.

Ex. 1001, 4:62-5:3. *Schwartz*’s insert 16 is modular because, as in the ’483 Patent, it is a separate physical device. Moreover, because it is modular, it can be “selected from a supply of different inserts 16 at the time of surgery so as to meet the particular needs of the patient at the time with regard to both the basic composition of the insert 16 and any repair factor composition therein.” Ex. 1004, 4:49-53. Insert 16 is a

“drug delivery device” because “the basic bio-absorbable composition of the insert 16 degrades or hydrolyzes over time, any repair factors contained therein are progressively released into the site, thus further promoting cellular regeneration. Cellular regeneration occurs throughout the insert.” *Id.*, 8:34-38.

1[c] said device being operable ...

Schwartz teaches this limitation; any alleged differences would have been obvious in view of the knowledge of a PHOSITA. Ex. 1017, ¶¶114-115. *Schwartz* states that as “the basic bio-absorbable composition of the insert 16 degrades or hydrolyzes over time, any repair factors contained therein are progressively released into the site, thus further promoting cellular regeneration. Cellular regeneration occurs throughout the insert.” Ex. 1004, 8:34-38. The therapeutic agents identified in *Schwartz* include repair factors that “may be a growth factor, preferably one selected from the group consisting of fibroblast growth factor, transforming growth factor beta, insulin, insulin-like growth factor, platelet derived growth factor and combinations thereof. Alternatively, the repair factor may be an attachment factor, preferably one selected from the group consisting of fibronectin, RGD polypeptide and combinations thereof.” *Id.*, 2:51-57. Those repair/growth factors promote healing of the cartilage, bone, and surrounding tissue. *Id.*, 1:7-13; Ex. 1017, ¶114. The ’483 Patent also identifies “compositions effective for reducing infection and/or

promoting healing of a wound formed at a surgical site” as suitable therapeutic agents. Ex. 1001, 5:7-9 (emphasis added).

Insert 16 is designed for implantation into humans. Ex. 1004, 6:19-22 (“However, it must be kept in mind that in the present invention, over time, the bio-absorbable elements—that is, the delivery unit 14 and the insert 16—will be disappearing as the human body hydrolyzes the material from which they are made.”). Humans are animals. Ex. 1017, ¶115.

1[d] (a) solid module ...

Schwartz teaches this limitation; any alleged differences would have been obvious in view of the knowledge of a PHOSITA. Ex. 1017, ¶¶116-118. *Schwartz*’s insert 16 is made of solid materials, such as “bio-absorbable” polymers, including “hyaluronic acid, polyglycolic acid, collagen, polylactic acid, fibrin clot, periosteal cells, polydioxane, polyester, alginate and combinations thereof.” Ex. 1004, 3:1-11; Ex. 1017, ¶117. Those materials are solid for the additional reason that they are used to provide the “sustained release device” that physically interacts with threads. The ’483 Patent identifies many of the same materials as suitable for its device:

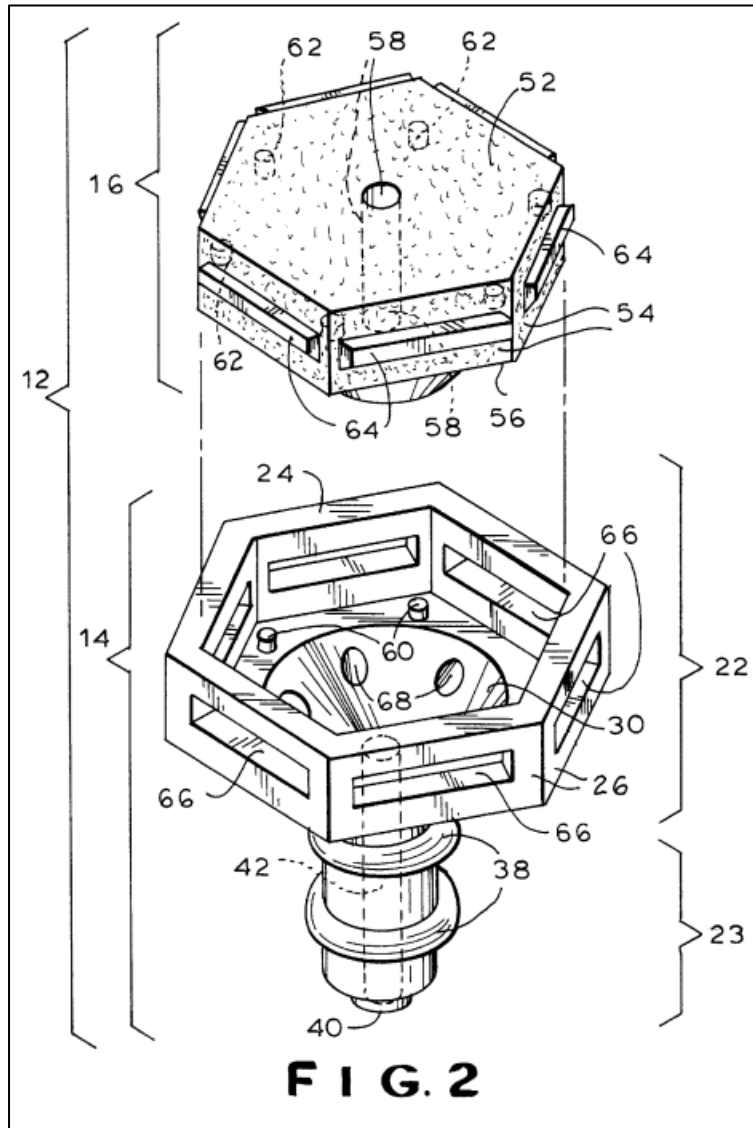
It will be understood by the artisan that the bioabsorbable drug delivery devices discussed hereinbelow may be formed out of polymer blends of glycolide and/or lactide homopolymer, copolymer and/or glycolide/lactide copolymer and polycaprolactone copolymers, and/or copolymers of glycolide, lactide, poly (L-lactide-co-DL-lactide),

caprolactone, polyorthoesters, polydioxanone, trimethylene carbonate and/or polyethylene oxide or any other bioabsorbable material.

Ex. 1001, 4:62-5:3.

The '483 Patent states that the “term ‘bioabsorbable,’ means that the composition will be biodegraded and that the products of biodegradation will either be absorbed by tissue within the body or excreted.” *Id.*, 5:13:16. Thus, “bioabsorbable” materials are a type of “biodegradeable” material. *Id.*; Ex. 1017, ¶117. *Schwartz* identifies its materials as “bio-absorbable” therefore, they are biodegradable polymers.

The solid modular implantable drug delivery device (insert 16) fits snugly within the shaped recess in the prosthesis (i.e., the portion of delivery unit 14 that receives an insert 16, including support frame (22)):



Ex. 1004., Fig. 2, 5:18-31 (“The support frame 22 of the delivery unit 14 receives the insert 16 therein, with the side walls 26 of the support frame 22 receiving therewithin the side walls 54 of the insert 50. The bottom surface 56 of the insert 16 and the bottom portion 30 of the support frame 22 are correspondingly shaped, preferably with the bottom surface of the insert 16 defining a protrusion and the upper surface of the bottom portion 30 defining a protrusion-receiving cavity....”).

For example, insert 16 fits snugly within the shaped recess because it includes flanges (64) that “are preferably resiliently flexible.” *Id.*, 6:5-6. Those insert includes “windows 66 therethrough configured and dimensioned to snugly receive the flanges 64 therein or therethrough.” *Id.*, 5:63-65 (emphasis added); Ex. 1017, ¶118. Similarly, “[t]he number of bosses 60 and recesses 62 as well as the shape, size and placement thereof, are selected so that, when the insert 16 is within the delivery unit 14, the bosses 60 are snugly received in the recesses 62, such that the insert 16 and delivery unit 14 are precluded from relative rotation as long as the insert 16 is within the support frame 22.” Ex. 1004, 5:53-59 (emphasis added).

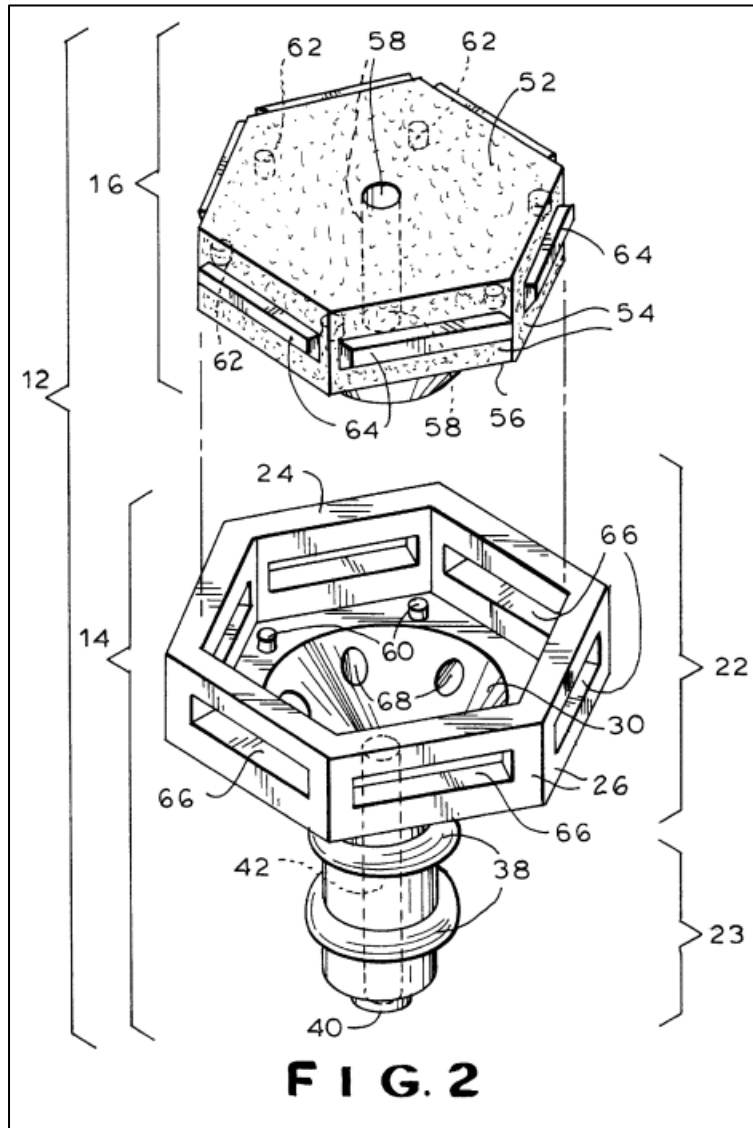
1[e] (b) a therapeutic agent ...

Schwartz teaches this limitation; any alleged differences would have been obvious in view of the knowledge of a PHOSITA. Ex. 1017, ¶119. As discussed for limitation 1[c], *Schwartz* teaches a therapeutic agent that is released into the body of an animal. *Schwartz* teaches that “[a]s the basic bio-absorbable composition of the insert 16 degrades or hydrolyzes over time, any repair factors contained therein are progressively released into the site, thus further promoting cellular regeneration. Cellular regeneration occurs throughout the insert.” *Id.*, 8:34-38 (emphasis added). *Schwartz* further discloses that the biodegradable polymer can be selected to provide a specific predefined dosing period. *Id.*, 8:18-33 (“The cartilage repair system of the invention is bio-absorbed over time and therefore need not be surgically removed

during or after cartilage regeneration. The absorption rate is formula controlled and can range from 6-12 weeks to one year depending on its site-specific application.”). The dosing period (i.e., the period of time during which the therapeutic agent is released) is predefined by the controlled rate for the bioerodible and the amount of that material. *Id.*, 8:18-38; Ex. 1017, ¶119. The therapeutic agent is released during biodegradation of the biodegradable polymer. Ex. 1004, 8:34-38; Ex. 1017, ¶119.

2. Claim 2.

Schwartz teaches this claim; any alleged differences would have been obvious in view of the knowledge of a PHOSITA. Ex. 1017, ¶120. Insert 16 is received within the shaped recess in the prosthesis (i.e., the portion of delivery unit 14 that receives an insert 16, including support frame (22)):

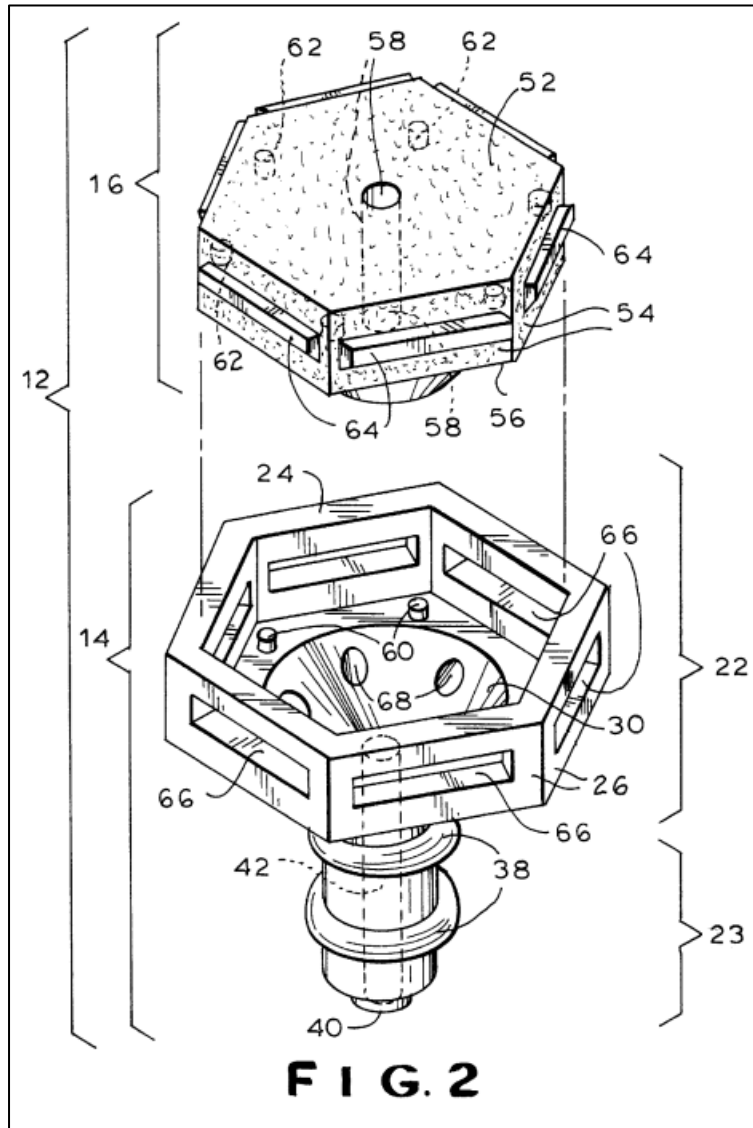


Ex. 1004., Fig. 2, 5:18-31. It would have been obvious to not substantially alter the outer surface of the prosthesis because Fig. 2 of *Schwartz* depicts an implantable prosthesis (assembly 12) with an outer surface that is not substantially altered because insert 16 becomes seated flush with the surface of the prosthesis. Further, it would have been obvious to not substantially alter the outer surface of the prosthesis because a prosthesis with a flat surface provides the best geometry for

articulation against an opposing joint surface or soft/hard tissue structure. Ex. 1017, ¶120. The outer surface of the prosthesis is preferably flush to the surface of the surrounding/abutting soft and hard tissues so that the prosthesis is able to mechanically function without fraying or inducing stress to the surrounding/abutting soft and hard tissues. *Id.* Moreover, the contour of the outer surface of the prosthesis is designed specifically to meet requirements for strength and for directing healing in the area proximate to the prosthesis. *Id.* Accordingly, it would have been obvious to not substantially alter the contour of that surface. *Id.*

3. Claim 3.

Schwartz teaches this claim; any alleged differences would have been obvious in view of the knowledge of a PHOSITA. Ex. 1017, ¶121. *Schwartz* teaches that insert 16 can be affixed to the prosthesis by bosses 60 and extending flanges 64:



Id., Fig. 2, 5:32-6:8.

4. Claim 4.

Schwartz teaches or renders obvious this claim for the same reasons as claim 3, as discussed above. Ex. 1017, ¶122.

5. Claim 7.

Schwartz teaches this claim; any alleged differences would have been obvious in view of the knowledge of a PHOSITA. Ex. 1017, ¶123. *Schwartz* teaches a solid module for the reasons given with respect to claim 1. *Schwartz* also teaches that the solid module can include more than one therapeutic agent. Ex. 1004, 2:48-59. An orthopedic patient can benefit from multiple therapeutic agents (e.g., both growth and attachment factors), so it would have been obvious to provide both. *Id.*, 2:48-59; Ex. 1017, ¶123. It would have been obvious to a PHOSITA to use a plurality of solid modules to provide two or more therapeutic agents because the biodegradable polymer associated with each therapeutic agent can be tailored to provide the correct delivery rate for each therapeutic agent. *Id.* That is consistent with the disclosure in *Schwartz* that “[t]he cartilage repair system typically includes a plurality of the aforementioned assemblies....” Ex. 1004, 2:60-67. It is also consistent with the disclosure that insert 16 can “be selected from a supply of different inserts 16 at the time of surgery so as to meet the particular needs of the patient at the time with regard to both the basic composition of the insert 16 and any repair factor composition therein.” *Id.*, 4:49-53.

6. Claim 8.

Schwartz teaches this claim; any alleged differences would have been obvious in view of the knowledge of a PHOSITA. As discussed for claim 7, *Schwartz* teaches

the use of more than one insert and more than one therapeutic agent. It would have been obvious to affix the inserts to one another to reduce the complexity of installing them within the prosthesis, or to provide more than one therapeutic agent in instances where only a single prosthesis is implanted. Ex. 1017, ¶124.

7. Claim 9.

Schwartz teaches this claim; any alleged differences would have been obvious in view of the knowledge of a PHOSITA. Ex. 1017, ¶¶125-128. As discussed in claim 7, *Schwartz* teaches that the solid module can include more than one therapeutic agent. Ex. 1004, 2:48-59. An orthopedic patient can benefit from multiple therapeutic agents (e.g., both growth and attachment factors), so it would have been obvious to provide both. *Id.*, 2:48-59; Ex. 1017, ¶125. It would have been obvious to a PHOSITA to use a plurality of solid modules to provide two or more therapeutic agents because the biodegradable polymer associated with each therapeutic agent can be tailored to provide the correct delivery rate for each therapeutic agent. Ex. 1017, ¶125.

It would have been obvious to a PHOSITA to use a mesh container in conjunction with an implantable prosthetic device to include a greater volume of therapeutic agent, resulting in a longer degradation period of the therapeutic agent. Ex. 1017, ¶¶126-128. *Schwartz* teaches that insert 16 can be “made substantially of porous material in the form of a matrix or sponge, preferably defining at least 95%

voids by volume, so that it can serve as a biological scaffold for an invasion of cells to regenerate the articular cartilage. It typically has the felt-like feel of a non-woven fabric.” Ex. 1004, 7:4-9. A PHOSITA would understand that a mesh container is also porous, like the matrix or sponge disclosed in *Schwartz* Ex. 1017, ¶¶126-128. As a result, a PHOSITA would consider a mesh container as an alternative to the matrix or sponge disclosed in *Schwartz*. *Id.*

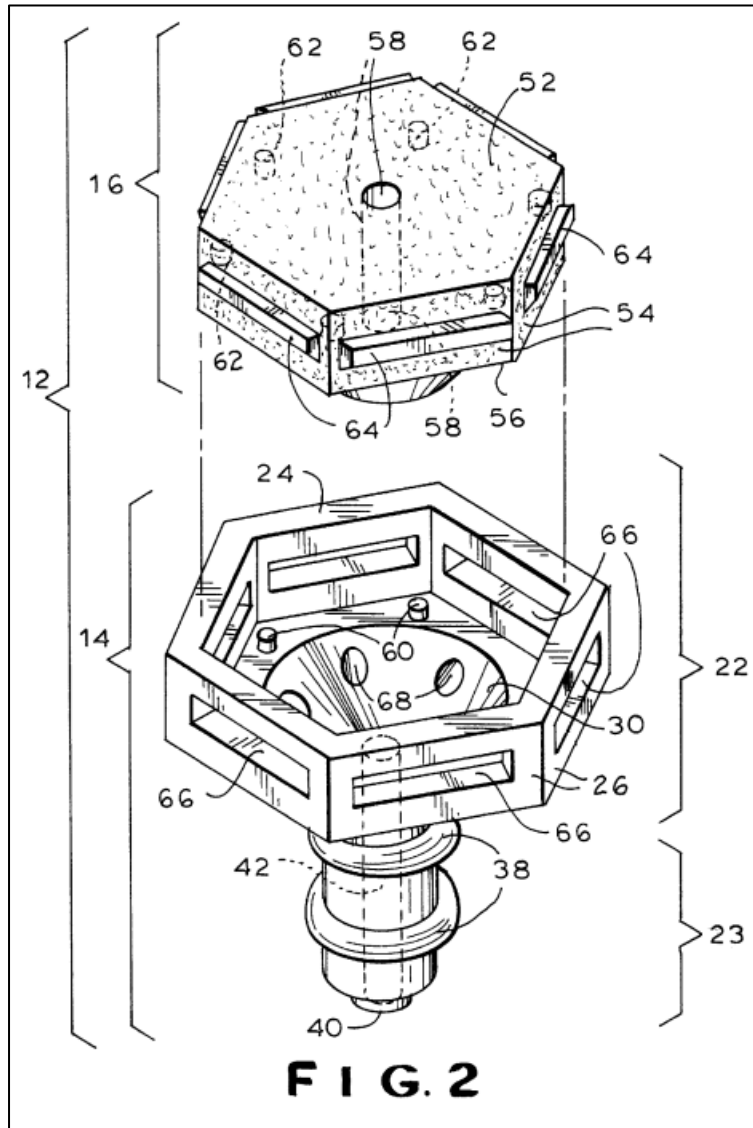
It also would have been obvious to a PHOSITA to use a mesh container in conjunction with an implantable prosthetic device to induce varying degradation rates with two or more therapeutic agents. For example, it would have been obvious to a PHOSITA to use a first therapeutic agent in a first solid module in the mesh container because that therapeutic agent would degrade faster (and thus act quicker) than the second therapeutic agent in the second solid module in the implantable prosthesis due to the greater porous surface area of the mesh container. *Id.* In another example, a PHOSITA would recognize that it would have been obvious to use a mesh container because it would allow for flexibility in the placement of the solid module within different types of tissue, such as soft tissue. *Id.* In addition, in instances where the size and/or mechanical requirements of the prosthesis limit the size of the solid module, the mesh container could allow for the implantation of more biodegradable polymer and therapeutic agent. *Id.*

8. Claim 10.

Schwartz teaches this claim; any alleged differences would have been obvious in view of the knowledge of a PHOSITA. Ex. 1017, ¶129. A PHOSITA would recognize that a femoral pin is an alternative to a screw that is affixed to the femur. *Id.* In fact, *Schwartz* recognizes that articular cartilage repair devices can take the form of screws (like that depicted in Figure 2 of *Schwartz*) or pins. Ex. 1004, 2:5-7 (“The articular cartilage repair piece is attached to the bone, for example, by bio-absorbable screws or pins or like temporary fixation techniques.”).

9. Claim 13.

Schwartz teaches this claim; any alleged differences would have been obvious in view of the knowledge of a PHOSITA. Ex. 1017, ¶130. *Schwartz* discloses that “where only a single assembly 12 will be used, other configurations, such as a circular configuration, may be preferred.” Ex. 1004, 4:34-36. In such a configuration, the insert would also be circular, consistent with the hexagonal configuration depicted in Figure 2, in which both insert 16 and delivery unit 14 are the same shape:



Id., Fig. 2, 4:34-36 (“where only a single assembly 12 will be used, other configurations, such as a circular configuration, may be preferred.”). A PHOSITA would understand that forming a recess by drilling a hole in the prosthesis is one of a limited number of options for forming a recess, the other being casting/molding the prosthesis where the recess is formed a part of the same process. Ex. 1017, ¶130. In addition, the presence of threads in *Watson’s* indicates to a PHOSITA that the

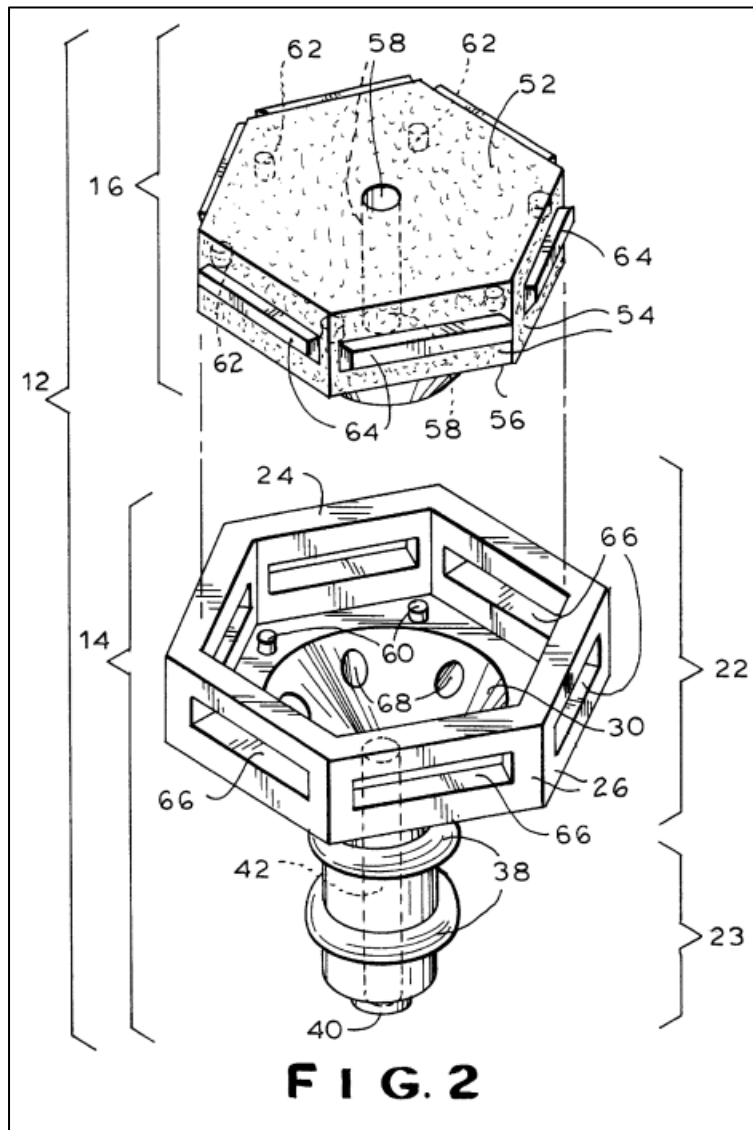
recess was formed by drilling and tapping the prosthesis because it would provide strength to the threads. *Id.*

10. Claim 14.

Schwartz teaches this claim; any alleged differences would have been obvious in view of the knowledge of a PHOSITA. Ex. 1017, ¶131. As shown for claim 13, it would have been obvious that insert 16 would be circular. Ex. 1004, 4:34-36 (“where only a single assembly 12 will be used, other configurations, such as a circular configuration, may be preferred.”). Because insert 16 is circular, and insert 16 is a three-dimensional object, it would be a cylindrical rod to fit snugly within the recess. Ex. 1017, ¶131.

11. Claim 15.

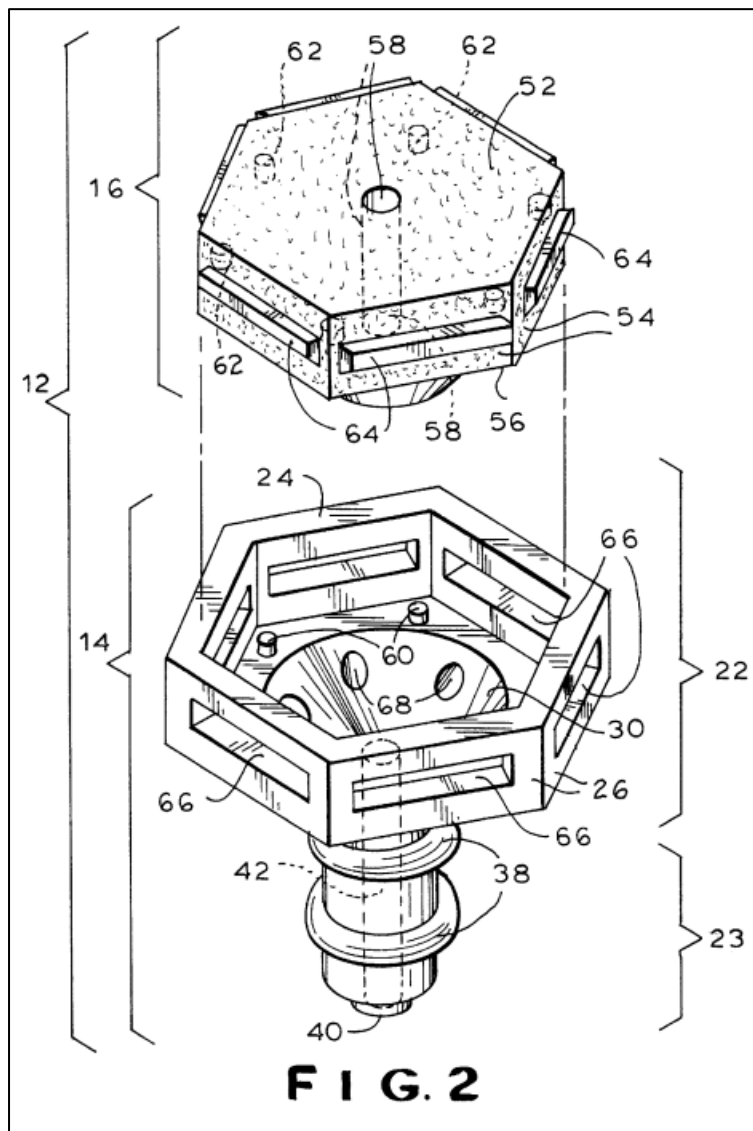
Schwartz teaches this claim; any alleged differences would have been obvious in view of the knowledge of a PHOSITA. Ex. 1017, ¶132. As discussed for limitation 1[e], the therapeutic agent is released as a result of biodegradation of the biodegradable polymer. *Schwartz* discloses that insert 16 is hollowed out to include bore (58):



Id., Fig. 2. The purpose of bore 58 is to increase access to the therapeutic agent through the increased surface area of bore 58. *Id.*, 6:31-35 (“In order to enable the insert 16 to function as a chondrogenic growth-supporting matrix, it must have access to vascular invasion and cellular migration to regenerate the articular cartilage defect. Such access is provided on the internal periphery of the insert 16 by the bore 58.”).

12. Claim 17.

Schwartz teaches this claim; any alleged differences would have been obvious in view of the knowledge of a PHOSITA. Ex. 1017, ¶133. As depicted in Figure 2, delivery unit 14 and insert 16 have the same shape (a hexagonal solid according to the embodiments depicted in Figure 2), including threads:



Ex. 1004., Fig. 2. *Schwartz* also discloses that “where only a single assembly 12 will be used, other configurations, such as a circular configuration, may be preferred.” *Id.*, 4:34-36. Accordingly, it would have been obvious to a PHOSITA that the solid module would be shaped like a threaded cylindrical plug in embodiments with a circular configuration. Ex. 1017, ¶133.

13. Claim 20.

20[a] A method for ...

See claim 1[a] & 1[c], supra.

20[b] comprising providing an implantable prosthesis,

See claim 1[a], supra.

20[c] forming at least one ...

See claims 1[b]-[e], supra.

20[d] forming a recess ...

See claim 1[b], supra.

20[e] placing ...

See claim 1[b], supra.

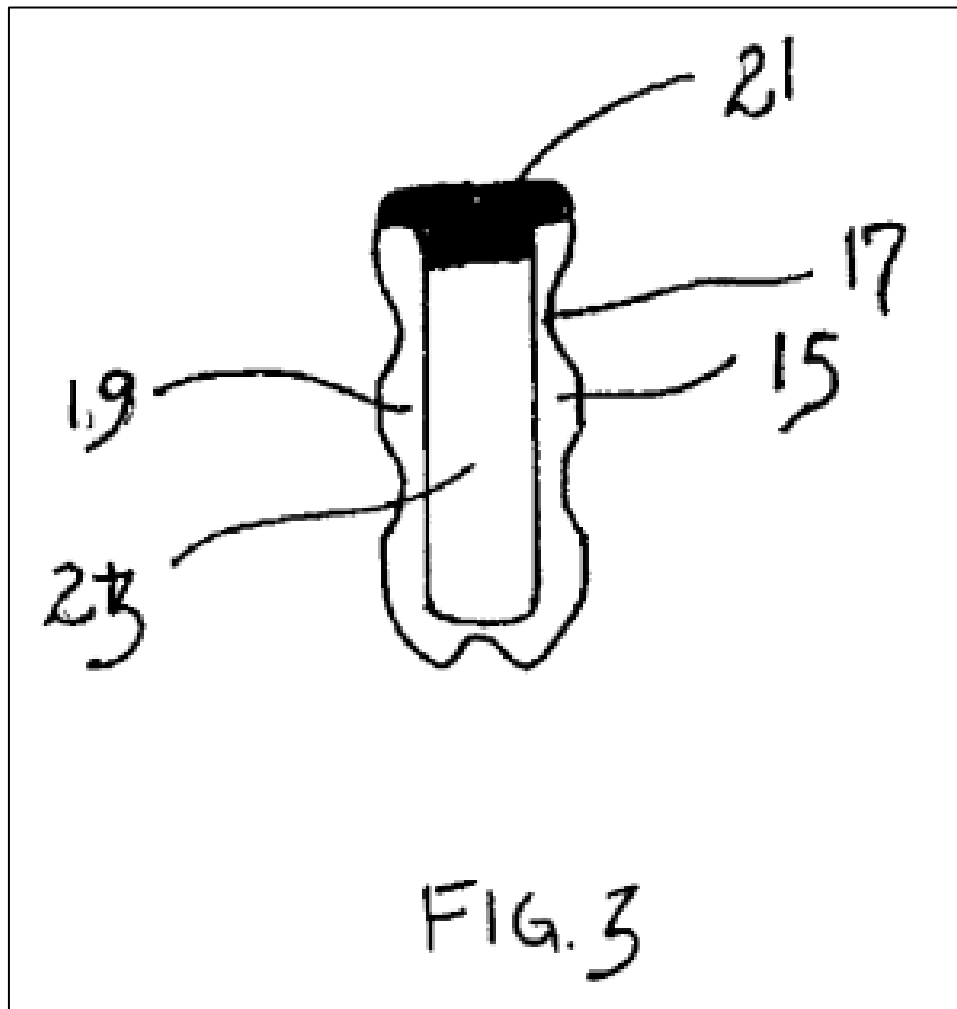
20[f] and implanting ...

See claim 1[c], supra.

E. Ground 5: Claims 5, 6, 18, and 19 Are Obvious Over *Schwartz* In View of *Glover* and the Knowledge of a PHOSITA.

1. Claim 5.

Glover teaches this claim. Ex. 1017, ¶140. *Glover* teaches a therapeutic agent 23 contained within a cavity of a capsule, as depicted in Figure 3:



Ex. 1009, Fig. 3, [0035] (“FIG. 3 depicts the cross-section of one embodiment of a capsule formed entirely of a biodegradable material. The wall 15 of the capsule varies in thickness such that there are thinner portions 17 and thicker portions 19.

The capsule is sealed with a biodegradable plug 21 and is filled with a therapeutic agent 23.”). It would have been obvious to modify insert 16 so that the therapeutic agent is provided in a cavity to provide increased options for varying the delivery rate, duration, schedule, and dosing of the therapeutic agent. Ex. 1017, ¶140. For example, providing the therapeutic agent within a cavity of the solid module would allow delayed release of the therapeutic agent (i.e., delivery of the therapeutic agent would not begin until the walls of the cavity degrade). *Id.* Alternatively, the therapeutic agent within the cavity would allow for one delivery rate as the sidewall degrades, followed by a different delivery rate (or different therapeutic agent) when the contents of the cavity are exposed to the body. *Id.* *Glover* is compatible with *Schwartz* because it is a “capsule formed entirely of a biodegradable material” just like the insert 16 of *Schwartz*. Ex. 1009, [0035]. And *Schwartz* also discloses that “where only a single assembly 12 will be used, other configurations, such as a circular configuration, may be preferred,” as depicted in *Glover*. Ex. 1004, 4:34-36.

2. Claim 6.

This claim is obvious for the same reasons as claim 5, as discussed above. Ex. 1017, ¶141.

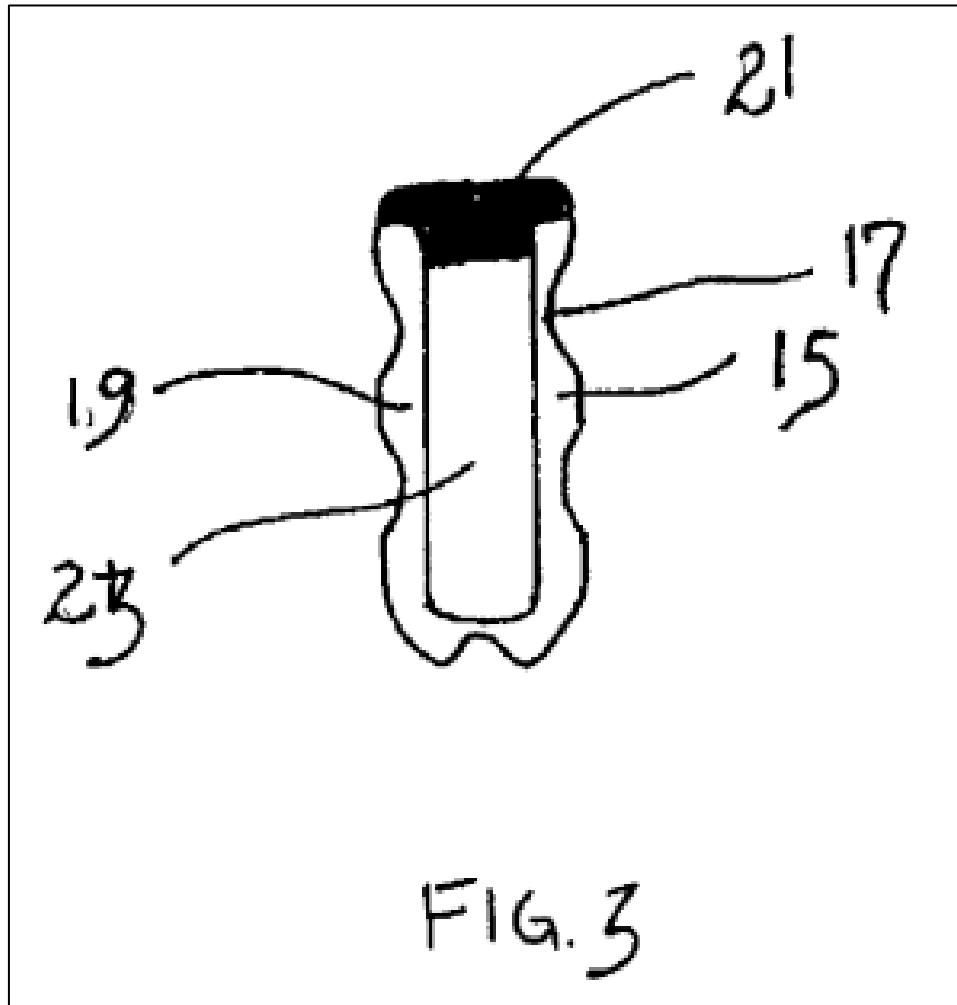
3. Claim 18.

Glover teaches that a plurality of capsules containing therapeutic agents may be linked together “to release the same or different agents and to release their

contents at approximately the same time or at different times. For example, an implant might consist of five linked capsules.... The links between capsules can be formed of the same material as the capsules themselves or the [sic] can be formed of a different material.” Ex. 1009, [0019]. It would have been obvious to combine *Schwartz* and *Glover* because, as discussed for claim 7, it would have been obvious to provide multiple therapeutic agents. Ex. 1017, ¶142. Providing stacked discs would improve the efficiency of assembling the multiple therapeutic agents during preparation of the prosthesis, as well as surgery. *Id.*; Ex. 1004, 4:34-36 (“where only a single assembly 12 will be used, other configurations, such as a circular configuration, may be preferred.”). *Glover* is compatible with *Schwartz* because it is a “capsule formed entirely of a biodegradable material” just like the insert 16 of *Schwartz*. Ex. 1009, [0035].

4. Claim 19.

Glover teaches a therapeutic agent 23 contained within a cavity of a capsule, as depicted in Figure 3:



Ex. 1009, Fig. 3, [0035] (“FIG. 3 depicts the cross-section of one embodiment of a capsule formed entirely of a biodegradable material. The wall 15 of the capsule varies in thickness such that there are thinner portions 17 and thicker portions 19. The capsule is sealed with a biodegradable plug 21 and is filled with a therapeutic agent 23.”). It would have been obvious to combine *Schwartz* and *Glover* to control the rate of release. Ex. 1017, ¶143. Because the other surfaces of the sustained release device are enclosed by the prosthesis (and thus not in contact with bodily fluids), the capped tub or tube would increase the surface area in contact with the

body fluids (specifically the inner surface of the tube as opposed to the lesser surface area without the exposed center of the tube, and increase the rate of release of a therapeutic agent therefrom. *Id.* *Glover* is compatible with *Schwartz* because it is a “capsule formed entirely of a biodegradable material” just like the insert 16 of *Schwartz*. *Id.*; Ex. 1009, [0035].

F. Ground 6: Claim 9 Is Obvious Over *Schwartz* In View of *Tormala* and the Knowledge of a PHOSITA.

In addition to *Schwartz*, *Tormala* also teaches this claim. Ex. 1017, ¶144. *Tormala* teaches that numerous materials can be used for drug delivery and implants, including meshes. Ex. 1011 6:29-38 (“The drug delivery materials and implants of the present invention can be in any appropriate form into which the polymer matrix, including antibiotic(s) and ceramic particle and/or fiber phase, can be formed with polymer technological processing methods. Typical forms are ... fiber constructions, like threads, cords, fabrics, meshes, non-woven felts, laminates or membranes and polymeric films.”) (emphasis added). *Tormala* further teaches that “drug delivery materials of the invention may also be formed into fixation devices and guided tissue regeneration devices, like pins, rods, screws, plates, membranes, meshes, tacks, bolts, intramedullary nails, clamps, arrows, or other devices which are used in bone-to-bone or soft tissue-to-bone fixation and whose geometries are described extensively in the literature” *Id.*, 6:47-54 (emphasis added). In doing so,

Tormala also identifies the orthopedic hardware (e.g., screws and pins) in *Schwartz* as alternative forms for its disclosure. *Id.* That teaching is consistent with the disclosure in *Watson*, and understanding of a PHOSITA, that “the general principle of configuring orthopedic hardware as a platform for a drug delivery system may be readily adapted, with little experimentation, to a large number of orthopedic hardware components.” Ex. 1001, Abstract, 21:1-6; Ex. 1017, ¶144. Accordingly, it would have been obvious to a PHOSITA to combine *Schwartz* with *Tormala* to use a mesh container containing a solid module in conjunction with an implantable prosthetic device for the same reasons set forth above for claim 9 in Ground 4. Ex. 1017, ¶144.

G. Ground 7: Claims 11, 12, and 16 Are Obvious Over *Schwartz* In View of *Watson* and the Knowledge of a PHOSITA.

1. Claim 11.

Watson teaches or renders this claim obvious for the reasons given above in Ground 1. Ex. 1017, ¶145. *Watson* states that “it will be appreciated that the general principle of configuring orthopedic hardware as a platform for a drug delivery system may be readily adapted, with little experimentation, to a large number of orthopedic hardware components.” Ex. 1003, 21:1-6. Similarly, *Schwartz* recognizes that its invention can be used in other prosthesis. Ex. 1004, 4:20-22 (“... those skilled in the medical arts will readily appreciate that the system 10 is equally

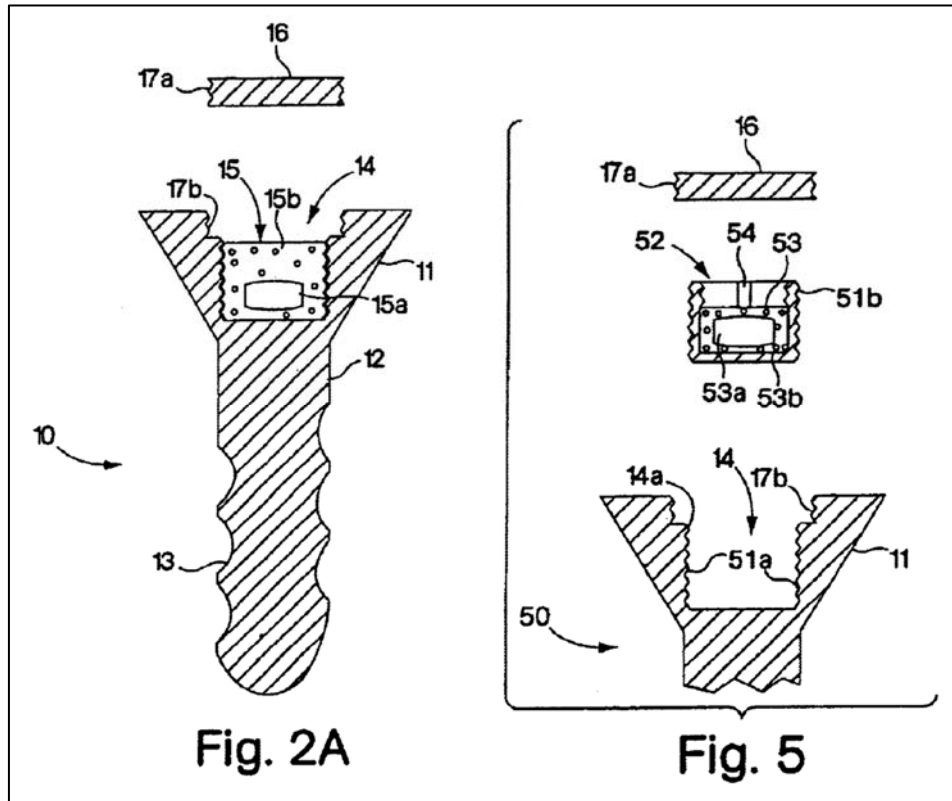
useful in other articular joints such as the shoulder, hip, and the like.”). Accordingly, it would have been obvious to a PHOSITA to combine *Schwartz* and *Watson* so to provide the implantable prosthetic device of claim 1 as a bone plate. Ex. 1017, ¶145.

2. Claim 12.

Schwartz teaches this claim; any alleged differences would have been obvious in view of the knowledge of a PHOSITA. Ex. 1017, ¶146. As discussed for claim 11, it would have been obvious to a PHOSITA that the prosthesis can be a bone plate. Bone plates are often rectangular (i.e., a type of polygon) in shape. *Id.* *Schwartz* discloses that its device can be shaped like a polygon, and a rectangle is a type of polygon. Ex. 1004, 2:65-67 (“Preferably the delivery units of the assemblies are polygonal in configuration and interfitting.”). Accordingly, it would have been obvious to shape the solid module as a rectangular tile so as to avoid substantially altering the surface of the prosthesis. Ex. 1017, ¶146. The recess is a mating receptacle for the “solid module” because *Schwartz* discloses that insert 16 can be snapped into supporting frame 22. Ex. 1004, 4:63-5:3.

3. Claim 16.

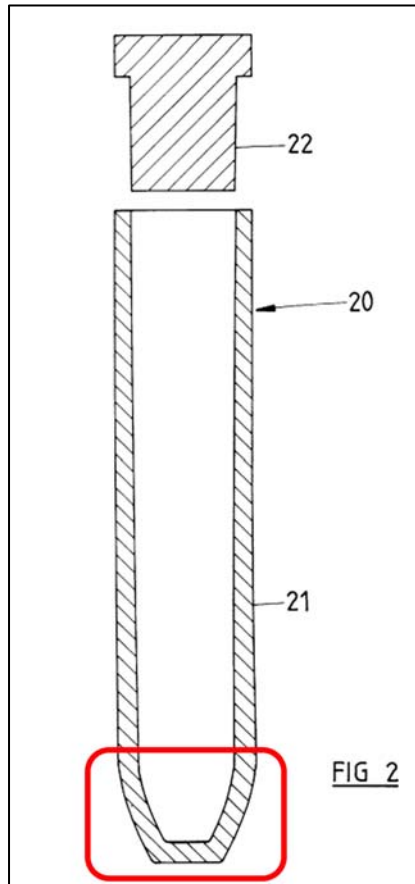
Schwartz teaches that “where only a single assembly 12 will be used, other configurations, such as a circular configuration, may be preferred.” Ex. 1004, 4:34-36. *Watson* teaches that its sustained release device is cylindrical, and is placed, within a cylindrical recess in the prosthesis:



Ex. 1003, 11:39-47, 12:24-37, Figs. 2A & 5. *Watson* further describes the recess as cylindrical. *Id.*, 11:39-43 (“The recess (chamber 14) may be cylindrical shaped ...”). The sustained release device can be held in place via an “interference fit” in which “one piece is frictionally engaged to another.” *Id.*, 21:45-47. In such a configuration, a wedge or pin can be “driven into the sustained device to expand the device so that it engages the walls of a suitably fashioned cavity in the orthopedic hardware component.” *Id.*, 21:48-51. A PHOSITA would understand that a pin (i.e., cylindrical shape) would be suitable for a sustained release device that is cylindrical, whereas a wedge would be suitable for a sustained release device that is a tapered cone. Ex. 1017, ¶147. Specifically, the tapered conical plug is narrower

at its bottom than its top. A wedge, that is also narrower at its bottom than its top, indicates to a PHOSITA that the corresponding sustained release device would be a tapered conical plug so as to expand the plug to engage the walls of the prosthesis. *Id.* It would have been obvious to a PHOSITA to combine *Schwartz* and *Watson* to taper the circular configuration of *Schwartz* to increase mechanical strength of the engagement between delivery unit 14 and insert 16. *Id.* The use of tapered plugs was well-known and used in the field as shown, for example, in *O'Donoghue*, to accomplish that result. *Id.* It would have been obvious to use a tapered conical plug because the taper at the bottom of the plug reduces the potential for voiding (i.e., unfilled space) at the bottom of the recess. *Id.*

O'Donoghue teaches a biodegradable container 20 with a “tubular implant body 21 to house a core containing active ingredient and a cap 22 which seals the implant body 21. Once again, either or both of the implant body 21 or the cap 22 may be formed from biodegradable polymeric material.” Ex, 1010, 14:65-15:2.



Id., Fig. 2 (emphasis added highlighting tapered bottom). Figure 2 of *O'Donoghue* depicts a cylindrical tube module that includes a tip with a surface profile that is contoured as a tapered plug. *Id.*; Ex. 1017, ¶148. Specifically, the bottom of the module is tapered so, as a result, the plug would also be tapered. Ex. 1010, Fig. 2; Ex. 1017, ¶148. Claims 12 and 13 of *O'Donoghue* further teach that the container has “a shape selected from a group consisting of elongate, and generally cylindrical” and that the container “is formed as an implant device, or as part of an implant device.” Ex. 1004, 22:1-6. Accordingly, it would have been obvious to use a solid module shaped like a tapered conical plug.

XII. SECONDARY CONSIDERATIONS

Petitioner is not aware of evidence of secondary considerations that would meaningfully rebut the showing of obviousness in this Petition. Patent Owner does not assert that any of its products embody the Challenged Claims. Ex. 1006; Ex. 1007; Ex. 1013. Accordingly, any secondary-considerations arguments presented by Patent Owner should be afforded no weight.

XIII. DISCRETIONARY DENIAL IS NOT WARRANTED.

A. Discretionary Denial Under the *Fintiv* Factors Is Not Warranted.

The Board evaluates six factors to determine whether to exercise its discretion under 35 U.S.C. § 314(a). *Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 11 at 5-6 (P.T.A.B. March 20, 2020) (precedential). Here, the factors weigh in favor of institution.

The first factor weighs in favor of institution because neither party has requested a stay in the district-court proceedings. Moreover, the Board does not speculate regarding whether a district court will grant a stay motion. *See, e.g., Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 15 at 12 (P.T.A.B. May 13, 2020) (informative).

The second factor weighs in favor of institution because, as of the time of this filing, the court has not set a trial date in the EDTX Litigation. Ex. 1008.

The third factor weighs in favor of institution because the parties and the district court have made little to no investments in the parallel proceedings. Ex. 1008. The fact that this Petition was being filed during the very preliminary stages of the case “has weighed against exercising the authority to deny institution under *NHK*.” *Apple, Inc. v. Seven Networks, LLC*, IPR2020-00156, Paper 10, p. 12 (P.T.A.B. June 15, 2020).

The fourth factor weights in favor of institution because there is no substantial overlap between issues raised in the Petition and the EDTX Litigation. As of this filing, Patent Owner asserts only claims 1-4 and 16 of the '483 Patent against Petitioner, whereas this Petition challenges the validity of claims 1-20 of the '483 Patent. Ex. 1013. Moreover, Petitioner stipulates that if the Board institutes *inter partes* review, the defendants in the EDTX Litigation will not pursue the same unpatentability grounds asserted in this proceeding. *See Sand Revolution II, LLC v. Cont'l Intermodal Group-Trucking LLC*, IPR2019-01393, Paper 24, p. 12 (PTAB June 16, 2020).

The fifth factor is neutral because Petitioner is one of the defendants in the EDTX Litigation, and Patent Owner is the plaintiff in the EDTX Litigation. Ex. 1007; *see also Cisco Sys., Inc. v. Ramot at Tel Aviv Univ. Ltd.*, IPR2020-00122, Paper 15, p. 10 (P.T.A.B. May 15, 2020) (APJ Crumbley, dissenting).

This sixth factor weighs in favor of institution because the EDTX Litigation is in the very preliminary stages, the petition presents compelling evidence the Challenged Claims are unpatentable, and the asserted prior art was not considered during examination of the '483 Patent.

B. Discretionary Denial Under the *General Plastic* Factors Is Not Warranted.

Discretionary denial under the *General Plastic* factors is not warranted because there are no previously filed petitions for *inter partes* review of the '483 Patent. *See General Plastic Indus. Co. v. Canon Kabushiki Kaisha*, IPR2016-01357, Paper 19 (P.T.A.B. Sept. 6, 2017).

C. Discretionary Denial Under 35 U.S.C. § 325(d) Is Not Warranted.

Discretionary denial under the framework in *Becton, Dickinson & Co. v. B. Braun Melsungen AG*, IPR2017-01586, Paper 8 (P.T.A.B. Dec. 15, 2017) and *Advanced Bionics LLC v. MED-EL Elektromedizinische Gerate GmbH*, IPR2019-01469, Paper 6 (P.T.A.B. Feb. 13, 2020) is not warranted because the Patent Office has not considered any of the prior art asserted in this petition. Neither the prior art, nor the arguments contained herein are substantially the same as the positions asserted by the examiner during prosecution of the '483 Patent. And the expert analysis of Dr. Bruce Beynnon submitted with this petition was not before the Patent Office during prosecution of the '483 Patent.

XIV. CONCLUSION

Petitioner respectfully requests that the Patent Office institute *inter partes* review of claims 1–20 of the '483 Patent, and cancel those claims as unpatentable.

Respectfully submitted,

March 25, 2024

/John Wittenzellner/
John Wittenzellner
Counsel for Petitioner
Registration No. 61,662

CERTIFICATE OF COMPLIANCE WITH TYPE-VOLUME LIMITS

This Petition includes 13,910 words, as counted by Microsoft Word, and is therefore in compliance with the 14,000 word limit established by 37 C.F.R. § 42.24(a)(1)(i). Accordingly, pursuant to 37 C.F.R. § 42.24(d) lead counsel for Petitioner hereby certifies that this Petition complies with the applicable type-volume limits.

Dated: March 25, 2024

Respectfully submitted,

/John Wittenzellner/
John Wittenzellner
Counsel for Petitioner
Registration No. 61,662

CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. §§ 42.6(e) and 42.105(b), I certify that I caused to be served a true and correct copy of the foregoing: Power of Attorney, Petition for *Inter Partes* Review of U.S. Patent No. 6,916,483 and the exhibits cited therein by FEDERAL EXPRESS, costs prepaid, on this day, March 25, 2024, to the address of the attorney or agent of record for New Amsterdam LLC in the district court proceedings regarding the '483 Patent:

Garteiser Honea, PLLC
119 W. Ferguson Street
Tyler, Texas 75702

Ni, Wang & Massand, PLLC
8140 Walnut Hill Ln., Ste. 615
Dallas, TX 75231

A copy of the Power of Attorney, Petition for *Inter Partes* Review of U.S. Patent No. 6,916,483 and the exhibits cited therein is being served by FEDERAL EXPRESS, costs prepaid, to the correspondence address listed for the '483 Patent:

Norris McLaughlin, P.A.
7 Times Square, 21st Floor
New York, NY 10036-6524

Dated: March 25, 2024

Respectfully submitted,

/John Wittenzellner/
John Wittenzellner
Counsel for Petitioner
Registration No. 61,662