

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

DEXCOM, INC.,
Petitioner,

v.

WAVEFORM TECHNOLOGIES, INC.,
Patent Owner.

Case IPR2016-01680
Patent 8,187,433 B2

Before ERICA A. FRANKLIN, JON B. TORNQUIST, and
ELIZABETH M. ROESEL, *Administrative Patent Judges*.¹

ROESEL, *Administrative Patent Judge*.

FINAL WRITTEN DECISION
35 U.S.C. § 318 and 37 C.F.R. § 42.73

¹ Administrative Patent Judge Erica A. Franklin replaces former panel member Brian P. Murphy, who is no longer with the Patent Trial and Appeal Board.

In this *inter partes* review, instituted pursuant to 35 U.S.C. § 314, Dexcom, Inc. (“Petitioner”) challenges patentability of claims 1–3, 5, 6, and 8–11 of U.S. Patent No. 8,187,433 B2 (Ex. 1001, “the ’433 patent”), owned by Waveform Technologies, Inc. (“Patent Owner”).

We have jurisdiction under 35 U.S.C. § 6. This final written decision is issued pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73.

For the reasons that follow, we determine that Petitioner has not shown by a preponderance of the evidence that claims 1–3, 5, 6, and 8–11 of the ’433 patent are unpatentable.

I. BACKGROUND

A. *Procedural History*

Petitioner filed a Petition seeking *inter partes* review of claims 1–3, 5, 6, 8–11, 14, and 15 of the ’433 patent. Paper 1 (“Pet.”). Patent Owner filed a Preliminary Response. Paper 7 (“Prelim. Resp.”). We instituted *inter partes* review of 1–3, 5, 6, and 8–11. Paper 10 (“Institution Decision” or “Dec.”).

Patent Owner filed a Response. Paper 29 (“PO Resp.”).² Petitioner filed a Reply. Paper 34 (“Pet. Reply”).

With the Petition, Petitioner filed a Declaration of David Vachon, Ph.D. Ex. 1004. Patent Owner cross-examined Dr. Vachon and filed a transcript of his deposition testimony as Exhibit 2029.

With the Preliminary Response, Patent Owner filed declarations of John L. Smith, Ph.D. (Ex. 2001) and Matthew J. Schurman, Ph.D. (Ex. 2004). With the Patent Owner Response, Patent Owner filed

² We rely on the public, redacted version of Patent Owner’s Response.

declarations of Dr. Schurman (Ex. 2030) and Ellen M. Anderson (Ex. 2031). Petitioner cross-examined Drs. Smith and Schurman and filed transcripts of their deposition testimony as follows: Dr. Smith (Ex. 1037) and Dr. Schurman (Ex. 1039).

Oral argument was held December 7, 2017, and a transcript was entered in the record. Paper 45 (“Tr.”).

As further discussed below, Patent Owner filed a motion to exclude Petitioner’s evidence.

B. Related Matters

The parties identify the following district court proceeding involving the ’433 patent: *WaveForm Technologies, Inc. v. Dexcom, Inc.*, No. 3:16-cv-00536-MO (D. Or.). Pet. 78; Paper 14, 2 (Patent Owner’s updated mandatory notices).

In addition, the parties identify the following *inter partes* review proceedings: *Dexcom, Inc. v. WaveForm Technologies, Inc.*, IPR2016-01679, involving U.S. Patent No. 7,146,202 B2 (“the ’202 patent”);³ and *Dexcom, Inc. v. WaveForm Technologies, Inc.*, IPR2017-01051, involving U.S. Patent No. 7,529,574. Paper 14, 2; Paper 39, 2 (Petitioner’s updated mandatory notices).

C. Instituted Grounds of Unpatentability

We instituted *inter partes* review on the following grounds of unpatentability asserted in the Petition:

³ The ’433 patent (Ex. 1001) was issued from U.S. Application No. 11/538,340, filed October 3, 2006, which is a division of U.S. Application No. 10/869,133, filed June 16, 2004, which issued as the ’202 patent (Ex. 2003).

References	Statutory Basis	Challenged Claims
Wilson ⁴ and Rosenblatt ⁵	§ 103(a)	1–3, 5, 6, and 9–11
Wilson, Rosenblatt, and Heller ⁶	§ 103(a)	8

C. The '433 Patent

The '433 patent, titled “Compound Material Analyte Sensor,” was issued May 29, 2012. Ex. 1001, at (54). The '433 patent relates to a sensing element adapted to be inserted, at least in part, into a mammalian body. *Id.* at Abstract, 1:46–47. The '433 patent discloses that the sensing element includes a core of a structurally robust material having a plated portion comprising an electrochemically active metal. *Id.* at Abstract, 1:48–50. The sensing element may be used in a method for continuous sensing of an analyte, such as glucose, within a mammalian body. *Id.* at Abstract, 1:51–56.

According to the '433 patent, the disclosed sensing element addresses problems with platinum wire sensors, including: (1) platinum is a weak metal that is susceptible to sensor fatigue and breakage when subjected to flexure caused by bodily movement; and (2) platinum is expensive and can strain the budget for sensor production. *Id.* at 1:16–42.

An embodiment of a sensing element is depicted in Figure 1, which is reproduced below:

⁴ G. S. Wilson et al., *Progress toward the Development of an Implantable Sensor for Glucose*, 38(9) Clin. Chem. 1613–17 (1992). Ex. 1006.

⁵ U.S. Patent No. 2,719,797, issued October 4, 1955. Ex. 1007.

⁶ U.S. Patent No. 5,593,852, issued January 14, 1997. Ex. 1008.

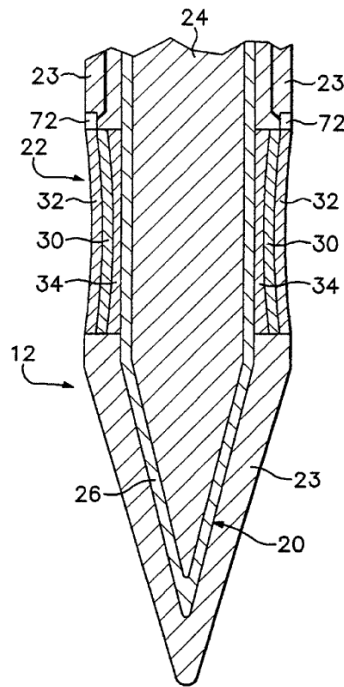


Figure 1, above, shows sensing element 12 including bimetallic wire 20, membrane system 22 coated on at least a portion of wire 20, and protective layer 23, e.g., polyimide, coated on portions of wire 20 not coated with membrane system 22. Ex. 1001, 2:13–25. Wire 20 includes core 24 and electrochemically active layer 26. *Id.* at 2:26–30. Membrane system 22, also referred to as sensing region 22, includes reactive layer 30 containing enzyme, permselective layer 32, and interferent reducing layer 34. *Id.* at 3:46–4:6.

The '433 patent discloses that wire core 24 may be made of any structurally robust material, such as tantalum, stainless steel, nitinol (an alloy of nickel and titanium), polymeric material, or glass fiber. *Id.* at 2:35–43. Electrochemically active layer 26 may be made of a noble metal, such as platinum, palladium, gold, or a combination of one of these with iridium. *Id.* at 2:43–47. The '433 patent discloses various methods for making plated

wire 20, including electroplating, foil cladding, plasma vapor deposition, and sputtering. *Id.* at 2:48–3:45.

In operation, a voltage is placed on wire 20 relative to a reference electrode. Glucose and oxygen (or glucose only) reacts with the enzyme in layer 30 producing hydrogen peroxide, which permeates layer 34 and causes an electric current to be produced in wire 20. The current flow is indicative of the concentration of glucose in body fluid. *Id.* at 2:13–18, 3:46–4:6.

According to the '433 patent, sensing element 12 may be inserted into the body for a number of days, or it may be used as a single use sensing element indwelling for less than three minutes. *Id.* at 4:30–44.

D. Illustrative Claim

The '433 patent includes 16 claims, of which claims 1, 12, 14, and 16 are independent. We instituted *inter partes* review of claims 1–3, 5, 6, and 8–11—a subset of the claims challenged in the Petition. Claim 1 is illustrative of the challenged claims and is reproduced below with paragraph breaks and parenthetical letters added to correspond to Petitioner's contentions:

1. (a) An analyte sensing element, comprising:
 - (b) a structurally flexible core having an outer surface;and
 - (c) a continuous layer of electrochemically active metal surrounding, covering, and in contact with said outer surface of said core,
 - (d) wherein the electrochemically active metal prevents body fluid from contacting said core
 - (e) and has at least one sensing surface,
 - (f) wherein said layer of electrochemically active metal is at least partially surrounded by a membrane system comprising an enzyme.

Ex. 1001, 4:54–62.

II. ANALYSIS

A. Claim Construction

In an *inter partes* review, claim terms in an unexpired patent are given their broadest reasonable interpretation in light of the specification of the patent in which they appear. 37 C.F.R. § 42.100(b); *Cuozzo Speed Tech., LLC v. Lee*, 136 S. Ct. 2131, 2142 (2016). Under that standard, we give claim terms their ordinary and customary meaning, as understood by a person of ordinary skill in the art in the context of the entire patent disclosure. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007). The Board, however, may not “construe claims during IPR so broadly that its constructions are *unreasonable* under general claim construction principles. . . . ‘[T]he protocol of giving claims their broadest reasonable interpretation . . . does not include giving claims a legally incorrect interpretation.’” *Microsoft Corp. v. Proxyconn, Inc.*, 789 F.3d 1292, 1298 (Fed. Cir. 2015) (citation omitted). “Even under the broadest reasonable interpretation, the Board’s construction ‘cannot be divorced from the specification and the record evidence,’” and “[t]he PTO should also consult the patent’s prosecution history in proceedings in which the patent has been brought back to the agency for a second review.” *Id.* (citations omitted).

We address certain claim terms below. No other claim term requires express construction for purposes of resolving the patentability disputes on this record. *Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999) (“only those terms need be construed that are in controversy, and only to the extent necessary to resolve the controversy”).

1. “*structurally flexible*”

Claim 1 of the ’433 patent recites: “[a]n analyte sensing element, comprising: a structurally flexible core.” Ex. 1001, 4:54–55. In the Institution Decision, we preliminarily construed “a structurally flexible core” to mean “a core that is robust and able to be flexed or bent repeatedly.” Dec. 11.

The “robust” portion of our construction was based on descriptions in the Specification of ’433 patent, including the disclosure that “wire core 24 may be of any structurally robust material” and statements that the sensor core is made of a “structurally robust” material. *Id.* at 8–9 (quoting Ex. 1001 at Abstract, 1:48, 1:56–57, 1:65, 2:27, 2:35–41, 3:16, 3:22–23). We also relied upon the Specification’s disclosure that fatigue, weakness, and breakage are undesirable characteristics of an indwelling wire sensor. *Id.* at 9 (citing Ex. 1001, 1:16–32).

The portion of our construction that requires that the core is “able to be flexed or bent repeatedly” was based, in part, on a dictionary definition. The McGraw Hill Dictionary of Scientific and Technical Terms defines “flexibility” as “the quality or state of being able to be flexed or bent repeatedly.” *Id.* at 10 (citing Ex. 3001, 620). As stated in our Institution Decision, this definition is consistent with the description of a “structurally flexible” core in the ’433 patent. *Id.*

Our Institution Decision invited the parties to indicate whether they agree or disagree with our preliminary construction and to present arguments and evidence in support of, or in opposition to, our preliminary construction, and/or to propose a modification thereof. *Id.* at 11.

In its Response, Patent Owner states it “does not object to the Board’s proposed construction,” asserting that it “reflects the key point that a ‘structurally flexible core’ must be one that is sufficiently robust to withstand repeated bending and flexing.” PO Resp. 4. According to Patent Owner, the Specification of the ’433 patent demonstrates that “[f]lexibility alone is not enough; the structurally flexible core material must also be robust.” *Id.* (citing Ex. 1001, 1:25–26).

Petitioner argues that the Board’s preliminary construction improperly reads a “robustness” requirement into “structurally flexible” that the prosecution history prohibits. Pet. Reply 3. More particularly, Petitioner argues that a “robustness” requirement is impermissible because applicant struck “robust” from the claims during prosecution. *Id.* at 4.

After reviewing the portion of the prosecution history cited by Petitioner, we are persuaded that our preliminary construction was incorrect to the extent it imposed a requirement for robustness apart from flexibility. As noted above, the ’433 patent (Ex. 1001) was issued on a divisional of an application that issued as the ’202 patent (Ex. 2003). Claim 1 of the ’202 patent was prosecuted as claim 35. Ex. 1020, 22. When first presented, claim 35 recited: “a sensor having . . . a core of structurally robust material.” *Id.* at 77–78. The Examiner rejected that claim over Sohrab⁷ and Smart,⁸ asserting that Sohrab taught a sensor having a core wire made of structurally robust material. *Id.* at 70. In response to that rejection, Applicants amended the claim to recite, “a sensor having a structurally flexible core,” instead of “a sensor having a core of structurally robust

⁷ U.S. Patent No. 6,501,976, issued December 31, 2002.

⁸ U.S. Patent Publication No. 20020137998, published September 26, 2002.

material.” *Id.* at 57. In other words, Applicants removed the word “robust” and replaced it with the word “flexible.” *Id.* The claim was allowed without the word “robust” (*id.* at 20, 28), as were the claims of the ’433 patent (Ex. 1002, 5, 11–13).

We agree with Petitioner that, in view of this prosecution history, it is inappropriate for us to construe the term, “structurally flexible core,” as requiring that the core be “robust.” Although the ordinary meaning of “flexible” may imply some degree of robustness (*see* Ex. 3001, 620), the prosecution history does not support reading the term “robust” back into the claim after it was removed by Applicants during prosecution. *Laryngeal Mask Co. v. Ambu A/S*, 618 F.3d 1367, 1373 (Fed. Cir. 2010) (“it would be improper to read a . . . limitation back into” the claim after it was deleted from the claim during prosecution).

Patent Owner argues that Applicants’ claim amendment was made to distinguish “rigid piercing elements” as disclosed in Sohrab and Smart. Tr. 31:8–21; *see also* Ex. 1020, 63 (Applicants’ remarks: “Neither Sohrab nor Smart provide any teaching of a flexible core, but rather teach the use of rigid piercing elements.”).

Patent Owner’s argument does not persuade us to read a requirement for robustness back into the claim after it was removed by Applicants during prosecution. The impropriety of reading such limitations back into the claim applies “[r]egardless of why [applicant] amended its claims” to remove the limitation. *Laryngeal*, 618 F.3d at 1373. Patent Owner’s argument does not convince us that there is a requirement for robustness beyond what is implicit in the ordinary meaning of “flexible.” Applicants’ claim amendment (Ex. 1020, 57) demonstrates that there is no requirement for

robustness separate from a requirement that the core be “flexible,” i.e., that it can be flexed or bent repeatedly.

Alternatively, Patent Owner argues that the claim construction should specify that the core is able to be bent or flexed repeatedly “without breaking.” Tr. 34:8–12; *see also* Ex. 2030 ¶¶ 24, 31. After considering Patent Owner’s proposal, we determine that it is unnecessary to add the words, “without breaking,” to the construction. Although these words are not expressly stated, they are implied by our construction, which provides, “able to be flexed or bent repeatedly.” Logic dictates that a metal core that breaks when flexed or bent cannot be flexed or bent “repeatedly.”

In view of the foregoing, we revise the claim construction provided in the Institution Decision to remove the requirement that the core be “robust.” We construe the term, “structurally flexible,” to mean “able to be flexed or bent repeatedly.”

Our construction is consistent with the Specification of the ’433 patent, which does not define the term, “structurally flexible,” but indicates that the use of tantalum or nitinol for the sensor core is “desireable because they are both naturally flexible.” Ex. 1001, 2:39–40. The Specification indicates that such flexibility “is of particular importance if [the sensor] is to be inserted in a patient and worn for a period of days.” *Id.* at 2:40–41. By implication, a sensor that is implanted in a patient for a period of days would need to be able to be flexed or bent repeatedly. *See id.* at 1:18 (discussing “flexure caused by bodily movement”). Our construction is also supported by the dictionary definition for “flexibility”: “able to be flexed or bent repeatedly.” Ex. 3001, 620.

2. “in contact with”

Claim 1 recites “a continuous layer of electrochemically active metal *surrounding, covering, and in contact with* said outer surface of said core.” Ex. 1001, 4:56–58 (emphasis added). In the Institution Decision, we directed the parties to provide and justify an express construction for the term, “in contact with,” as recited in claim 1. Dec. 12. We further directed the parties that, in providing an express construction, they should address the ’433 patent specification, as well as any relevant prosecution history, including whether and to what extent any relevant subject matter was disclaimed or disavowed. *Id.*

The parties agree that the term “in contact with” should be construed to mean “touching.” PO Resp. 5; Pet. Reply 5. As support for this construction, Patent Owner relies on a dictionary definition for “contact” (Ex. 2038), the prosecution history and disclosed embodiments of the ’433 patent, and claims 7 and 16 of the ’433 patent. PO Resp. 4–16 (citing Exs. 1001, 1002, 2026–2028, 2038). Petitioner, however, asserts that Patent Owner’s construction for “in contact with” does not preclude an intervening layer. Pet. Reply 6. We address the parties’ arguments and evidence below.

Patent Owner argues that the prosecution history of the parent ’202 patent shows “a clear and unambiguous disavowal of a configuration in which a structural layer is interposed between the core and the electrochemically active metal, such that they do not touch.” PO Resp. 7–8. As support for a prosecution history disavowal, Patent Owner directs us to Applicants’ claim amendment adding the words, “in contact with,” and to

remarks distinguishing Macur.⁹ *Id.* at 6 (citing Ex. 2026, 3, 9). There, Applicants argued:

Macur provides an electrochemically active layer 32/33 that is not in contact with the core. Macur uses an intervening insulating layer 14 that separates the core from the electrochemically active layer. Thus, the active layer is not in contact with the outer surface of the core, as provided in claim 35.

Ex. 2026, 9. Thereafter, the Examiner allowed the claims. Ex. 2028. Applicants' claim amendment and remarks persuade us that Applicants disavowed a claim construction for "in contact with" that is broad enough to encompass an intervening layer between the electrochemically active metal and the outer surface of the core.

Patent Owner relies on claim 16 of the '433 patent, arguing that the term, "in contact with," is used in that claim consistent with its ordinary meaning, "touching." PO Resp. 8–9 (citing Ex. 1001, 6:19–27 and Ex. 2038). Patent Owner additionally argues that claim 16 is directed to a three-layer embodiment that is not encompassed by claim 1 of the '433 patent. *Id.* at 10, 12. We are persuaded by both of these arguments. Claim 16 describes three metal layers: a stainless steel core, a layer of gold "in contact with" the outer surface of the core, and a layer of platinum "in contact with" the layer of gold. Ex. 1001, 6:19–27. In each instance, claim 16 uses the term, "in contact with," consistent with its ordinary meaning, "touching." Whereas claim 16 expressly recites an intervening layer of gold between the outer surface of the core and the layer of platinum (an electrochemically active metal), no such intervening layer is permitted by

⁹ U.S. Patent No. 3,957,613, issued May 18, 1976. Ex. 2027.

the language of claim 1, which recites that the electrochemically active metal is “in contact with” the outer surface of the core.

Both parties rely on claim 7 of the ’433 patent as relevant to the meaning of “in contact with” in claim 1. PO Resp. 14–16; Pet. Reply 5. Claim 7 depends from claim 1 of the ’433 patent. Ex. 1001, 5:7. Claim 7 recites: “wherein said outer surface of said core comprises a passivated oxide surface.” *Id.* at 5:7–9. Patent Owner argues, “[b]ecause the outer surface of the core comprises the oxide, the electrochemically active metal is ‘in contact with’ the core’s outer surface when it touches the oxidized surface.” PO Resp. 14. Petitioner, on the other hand, argues that claim 7 shows that “[t]he core can comprise an intervening layer, such as a passivated oxide layer.” Pet. Reply 5.

We determine that claim 7 of the ’433 patent is consistent with the ordinary meaning of “contact” and Applicants’ disavowal of an intervening layer between the electrochemically active metal layer and the outer surface of the core. According to claim 7, the “passivated oxide surface” is ***part of*** the outer surface of the core (Ex. 1001, 5:7–9), not an “intervening layer,” as disclaimed during prosecution (Ex. 2026, 9).

Accordingly, we construe the term “in contact with” to mean “touching,” as proposed by Patent Owner.

B. Principles of Law

Petitioner bears the burden of proving unpatentability of the challenged claims, and the burden of persuasion never shifts to Patent Owner. *Dynamic Drinkware, LLC v. Nat’l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015). To prevail,

Petitioner must establish the facts supporting its challenge by a preponderance of the evidence. 35 U.S.C. § 316(e); 37 C.F.R. § 42.1(d).

A patent claim is unpatentable as obvious under 35 U.S.C. § 103(a) if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious to a person of ordinary skill in the art at the time the invention was made. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). Obviousness is resolved based on underlying factual determinations, including: (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of ordinary skill in the art; and (4) objective evidence of nonobviousness, i.e., secondary considerations. *See Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966).

C. Level of Ordinary Skill in the Art

For purposes of our Institution Decision, we accepted the definition of a person of ordinary skill in the art (“POSA”) provided by Petitioner’s declarant, Dr. Vachon. Dec. 13 (citing Ex. 1004 ¶ 22). That definition is: a bachelor’s degree or equivalent training or experience in mechanical engineering, bioengineering, or a related field and at least three years of experience relating to biosensor research and development. *Id.* Dr. Schurman accepts and applies this definition of a POSA for purposes of his

opinions. Ex. 2030 ¶ 18 (Dr. Schurman). Neither of the parties' declarants indicates that any proffered opinion would change depending on the level of ordinary skill in the art.

Therefore, we adopt Dr. Vachon's definition of a POSA. Ex. 1004 ¶ 22. We also rely on the cited prior art references as reflecting the level of ordinary skill in the art at the time of the invention. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001).

After reviewing the qualifications of Dr. Vachon and Dr. Schurman, as set forth in their respective declarations and curriculum vitae, we find that each of these declarants is qualified to testify from the perspective of a POSA. Regarding Dr. Vachon, we rely in particular on his experience as director of glucose sensor research and development at MiniMed from 1998 to 2001, where he worked on an implantable electrochemical glucose sensor. Ex. 1004 ¶ 8, App. A. Regarding Dr. Schurman, we rely in particular on his experience as a consultant in the field of glucose monitoring and insulin delivery and as chief technology officer of GlucoLight Corporation from 2002 to 2009, where he worked on development of a non-invasive glucose monitor. Ex. 2030 ¶¶ 5, 7, App. A. There is no contention that either of these declarants is not qualified to testify as an expert in this case.

D. Prior Art References

For purposes of this Decision, it is not necessary to consider the disclosure of Heller in detail. We therefore confine our discussion of the prior art references to Wilson and Rosenblatt.

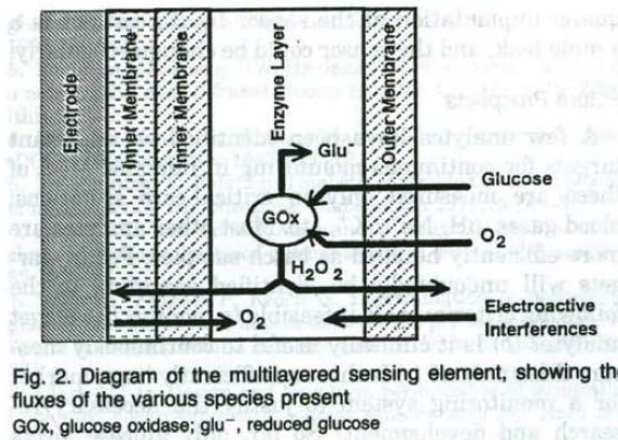
1. Wilson (Ex. 1006)

Wilson is an article published in 1992 entitled, "Progress toward the Development of an Implantable Sensor for Glucose." Ex. 1006. There is no

dispute that Wilson is prior art to the '433 patent under 35 U.S.C. § 102(b). Pet. 6; Ex. 1011 (declaration of librarian, Morris M. Jackson, attesting to facts relating to public accessibility of Wilson as of September 1992).

Wilson discusses the development of a needle-shaped glucose sensor that is flexible and implanted subcutaneously using a catheter. Ex. 1006, 1613(1).¹⁰ According to Wilson, the device had been used to monitor glucose concentrations for as long as ten days in rats. *Id.*

Wilson's glucose sensor is schematically illustrated in Figure 2, which is reproduced below:

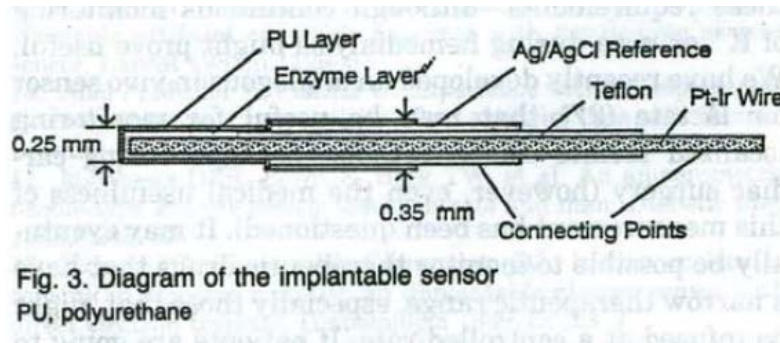


Wilson Figure 2 is a schematic diagram of a multilayered sensing element, including an electrode, a pair of inner membranes, an enzyme layer, and an outer membrane. Ex. 1006, 1615, Fig. 2. In Figure 2, glucose and oxygen are shown flowing through the outer membrane to the enzyme layer, where they react to form hydrogen peroxide and reduced glucose (gluconic acid). *Id.*; see also *id.* at 1614(1) (reaction of glucose with oxygen to form gluconic acid and hydrogen peroxide). Hydrogen peroxide is shown

¹⁰ We use parenthetical numbers following the internal page numbers to indicate the first and second columns on each page.

migrating through the inner membranes to the electrode, where it is oxidized to form oxygen. *Id.* at 1615, Fig. 2.

A cross-section of Wilson's glucose sensor is illustrated in Figure 3, which is reproduced below:



Wilson Figure 3 is a sectional diagram depicting an implantable sensor, including a platinum-iridium (Pt-Ir) wire, a Teflon layer, an enzyme layer, a polyurethane (PU) layer, and a silver-silver chloride (Ag/AgCl) reference electrode. Ex. 1006, 1615, Fig. 3. Wilson discloses that “[b]ecause the sensor is extremely flexible, we can implant it by using a short (3 cm) stainless steel catheter (21 gauge), which is removed after the sensor is in place.” *Id.* at 1615 (1–2).

2. *Rosenblatt* (Ex. 1007)

Rosenblatt is a U.S. patent issued in 1955 entitled, “Platinizing Tantalum.” Ex. 1007. There is no dispute that Rosenblatt is prior art to the ’433 patent under 35 U.S.C. § 102(b). Pet. 6; Ex. 1007.

Rosenblatt discloses a process for producing platinum-coated tantalum for use as non-corroding anodes in electrochemical processes, such as the electrolysis of chlorides and the production of chlorine, chlorates, and per-compounds. Ex. 1007, 1:15–25, 6:3–9. According to Rosenblatt, platinum group metals are the “universal choice” for anodic material due to

their corrosion resistance, but the high cost of these precious metals has prompted a search for substitutes, such as tantalum. *Id.* at 1:29–40, 1:57–64. Rosenblatt explains that tantalum cannot be used as an anode because it forms an oxide film and that prior attempts to coat tantalum with platinum were unsatisfactory due to insufficient adherence between the metals. *Id.* at 1:64–2:21. Rosenblatt’s process aims to provide a thin, firmly adherent, practically inseparable coat of platinum on a tantalum base. *Id.* at 2:22–25.

In Rosenblatt’s process, a thin deposit of platinum metal is applied on the surface of a tantalum body, either by chemical deposition or electroplating. Ex. 1007, 2:40–43, 2:45–50; *see also id.* at 2:67–3:37 (chemical deposition); 3:38–3:60 (electroplating). Thereafter, the platinum metal deposit is bonded to the tantalum body by heating the whole to a high temperature under inert conditions. *Id.* at 2:43–45, 2:50–53; *see also id.* at 3:61–4:13 (bonding).

Rosenblatt discloses that the bonding treatment causes the platinum and tantalum metals to interdiffuse and become alloyed, forming a thin layer of platinum-tantalum alloy between the tantalum base and an outer layer of unalloyed platinum. *Id.* at 4:22–25, 4:46–51; *see also* 6:26–30 (claim 1). According to Rosenblatt, the resulting platinized tantalum is not attacked by hot aqua regia and behaves like a pure platinum electrode, without flaking off of the platinum film, even after extended use as an anode in a chlorine or chlorate production cell. *Id.* at 4:14–25, 4:51–56, 5:20–29.

E. Obviousness Based On Wilson and Rosenblatt

Petitioner contends that claims 1–3, 5, 6, and 9–11 of the ’433 patent are unpatentable as obvious in view of Wilson and Rosenblatt. Pet. 32–52.

Patent Owner opposes. PO Resp. 16–43. We address the parties’ arguments below.

1. Claim 1

Petitioner contends that it would have been obvious to substitute platinum-coated tantalum, as described by Rosenblatt, for the platinum-iridium wire disclosed in Wilson Figure 3, and that the resulting sensor would meet the limitations of claim 1. Pet. 35–46. Petitioner contends that Wilson in view of Rosenblatt discloses “a continuous layer of electrochemically active metal surrounding, covering, and in contact with said outer surface of said core,” as recited in claim 1. *Id.* at 37 (quoting Ex. 1001, 4:56–58). As support for that contention, Petitioner directs us to Rosenblatt’s disclosure of depositing platinum metal on a tantalum body and heating the whole to bond the platinum metal to the tantalum body. *Id.* (quoting Ex. 1007, 2:40–45). Petitioner also directs us to Rosenblatt’s disclosure of electroplating as one way to deposit platinum on tantalum. *Id.* (citing Ex. 1007, 2:44–50).

Patent Owner argues that the combination of Wilson and Rosenblatt fails to teach or suggest an electrochemically active metal “in contact with” the core. PO Resp. 26. According to Patent Owner, Rosenblatt teaches that creation of an intervening alloy layer is essential and prevents the “contact” required by claim 1 of the ’433 patent. *Id.* at 26, 35–37.

After considering the parties’ arguments and evidence, we determine that Petitioner has not shown by a preponderance of the evidence that the combination of Wilson and Rosenblatt teaches or suggests the “in contact with” limitation of claim 1 of the ’433 patent.

As explained below, Rosenblatt teaches that an intervening alloy layer is essential to achieving sufficient adherence between a platinum coating and a tantalum base. Ex. 1007, 1:71–2:25, 2:40–53, 4:14–25, 4:46–56. Neither the Petition nor the Vachon Declaration (Ex. 1004) addresses Rosenblatt’s intervening alloy layer, nor how the “in contact with” limitation of claim 1 is taught or suggested by the combination of Wilson and Rosenblatt, notwithstanding the intervening alloy layer. Petitioner’s reply arguments do not overcome this deficiency in Petitioner’s evidence. Pet. Reply 6–10.

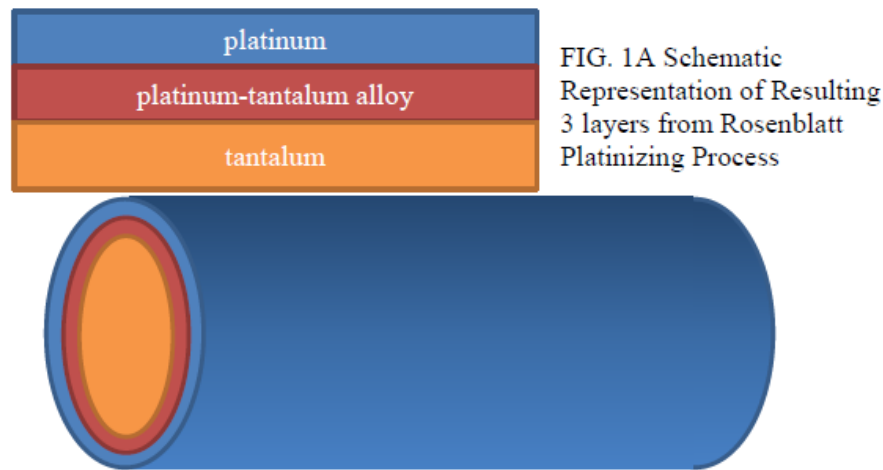
Petitioner relies on Rosenblatt, not Wilson, to teach the “in contact with” limitation of claim 1. Pet. 37–38. Rosenblatt discloses a process for coating tantalum with platinum to produce an anode. Ex. 1007, 1:15–23. According to Rosenblatt, known processes, such as electroplating, are “unsatisfactory” because they “do not produce a coat of platinum metal which adheres with sufficient tenacity to the tantalum base,” “result[] in a coating that may easily be stripped from the base,” and/or produce coats of platinum that “are not truly bonded to the tantalum.” *Id.* at 2:5–6, 2:9–10, 2:13, 2:17–18. To address these problems, Rosenblatt discloses a two-step process for providing a firmly adherent coat of platinum on a tantalum base. *Id.* at 2:22–25, 2:40–50. First, a thin deposit of platinum metal is applied on the surface of the tantalum body by electroplating or chemical decomposition. *Id.* at 2:40–43, 2:45–50; *see also id.* at 2:67–3:37 (chemical deposition); 3:38–3:60 (electroplating). Second, the platinum metal deposit is bonded to the tantalum body by heating the whole to a high temperature under inert conditions. *Id.* at 2:43–45; *see also id.* at 3:61–4:13 (bonding).

Rosenblatt teaches that the bonding process is essential to provide sufficient adherence between the platinum coating and the tantalum base and

to allow use of platinized tantalum as an anode. More specifically, Rosenblatt teaches that “the thin deposits [of platinum metal] . . . are not firm deposits until they have been subsequently bonded” in the manner taught by Rosenblatt. Ex. 1007, 2:50–53. Similarly, Rosenblatt teaches that “[a] platinum layer on a tantalum strip which has not been subjected to the bonding treatment . . . will upon being immersed in aqua[] regia become completely dissolved.” *Id.* at 4:14–17.

Rosenblatt discloses that the bonding process results in an intervening alloy layer between the platinum metal and the tantalum base. Rosenblatt discloses, in particular, that the bonding treatment “causes the platinum and tantalum metals to interdiffuse and become alloyed” thereby forming “a thin layer of platinum-tantalum alloy” between the tantalum base and an outer layer of unalloyed platinum. Ex. 1007, 4:22–25, 4:46–51. Claim 1 of Rosenblatt discloses that the platinum metal layer “is separated from the base by an interlayer of an alloy of the platinum with the base metal.” *Id.* at 6:26–30.

Both Petitioner and Patent Owner rely on the following schematic representation of the three layers that result from Rosenblatt’s platinizing process:



Prelim. Resp. 39–40; Pet. Reply 8. The above schematic representation shows a cylindrical shape having three layers: a tantalum core shown in orange, an intermediate platinum-tantalum alloy layer shown in red, and an outer platinum layer shown in blue.

In the structure taught by Rosenblatt, as illustrated by the above schematic representation, the platinum layer is not “in contact with” or touching the outer surface of the tantalum core. There is an intervening alloy layer that separates the platinum layer from the tantalum core. Ex. 1007, 4:22–25, 4:46–51, 6:26–30. As discussed above, this intervening alloy layer results from a bonding step, which Rosenblatt teaches is essential to achieving sufficient adherence between the platinum metal and the tantalum core. *Id.* at 2:43–45, 2:50–53, 3:61–4:13, 4:14–17.

Our findings regarding Rosenblatt are supported by the testimony of Dr. Schurman, who testifies:

Rosenblatt teaches that an alloy layer must be created between the pure platinum and pure tantalum layers, separating those layers and thus preventing them from being “*in contact with*” (or touching) one another, as required by the ’433 patent claims.

Ex. 2030 ¶ 131.

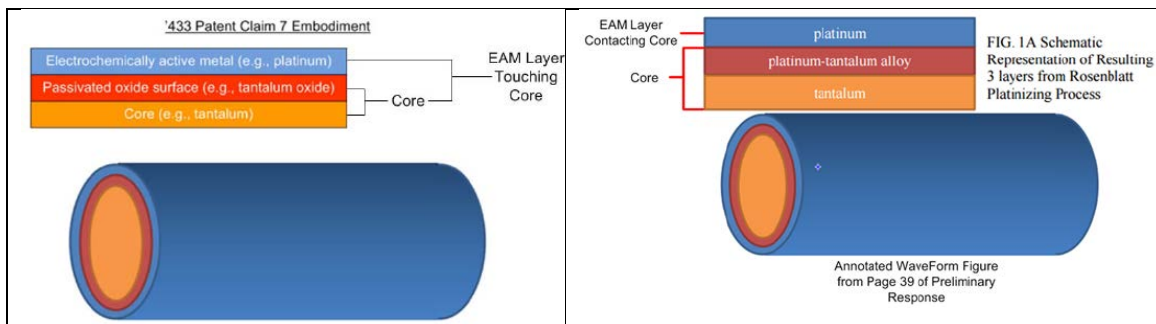
We have considered Petitioner’s reply arguments, but they do not persuade us that Petitioner has met its burden to show that the combination of Wilson and Rosenblatt teaches or suggest the “in contact with” limitation of claim 1.

First, Petitioner argues that “platinum and tantalum are touching” in Rosenblatt’s alloy layer. Pet. Reply 7. Petitioner’s assertion may be true as a technical matter, but it does not address the language of claim 1, which recites: “a continuous layer of electrochemically active metal surrounding, covering, and in contact with said outer surface of said core.” Ex. 1001, 4:56–58. Petitioner was required to prove that the prior art teaches or suggests a layer of electrochemically active metal, e.g., platinum, “in contact with” the outer surface of the core, e.g., tantalum. Petitioner does not explain how this claim limitation can be met by an alloy layer in which tantalum and platinum are intimately united. In addition, Petitioner does not present evidence that the tantalum/platinum alloy in the proposed combination of Wilson and Rosenblatt would be “electrochemically active.”

Next, Petitioner relies on claim 7 of the ’433 patent, arguing that “platinum and tantalum are touching more so” in Rosenblatt’s alloy than in the claim 7 embodiment “where an oxide surface separates the central the core and electrochemically active layer.” Pet. Reply 7. Petitioner’s argument is not consistent with the language of the claims. Claim 1 of the ’433 patent requires that the electrochemically active metal layer be “in contact with” the “**outer surface**” of the core, **not** with a “**central portion**” of the core, as argued by Petitioner. Claim 7 recites: “wherein said outer surface of said core comprises a passivated oxide surface.” Ex. 2028, 5:7–9.

Claim 7 recites an oxide surface as **part of** the outer surface of the core, not an intervening layer **between** the electrochemically active metal layer and the outer surface of the core.

Next, Petitioner compares Rosenblatt's three-layer structure with the embodiment described in claim 7 of the '433 patent using the following illustrations:



Pet. Reply 7–8. Each of the above illustrations shows a cylindrical shape having three layers: a core shown in orange, an intermediate layer shown in red, and an outer layer shown in blue. Relying on the above illustrations, Petitioner contends that Rosenblatt's platinum-tantalum alloy layer (shown in red) is part of the core in the same way as the passivated oxide surface of the claim 7 embodiment (also shown in red) is part of the core. *Id.*

We agree with Petitioner that claim 7 of the '433 patent demonstrates that a "structurally flexible core" can be multilayered. Pet. Reply 7. Petitioner has not, however, provided evidence sufficient to show that Rosenblatt's platinum-tantalum alloy layer is part of a multilayered core. Although Petitioner contends that Rosenblatt's alloy layer is the outer surface of the core (Tr. 7:1–7), Petitioner's contention is contradicted by the testimony of its own expert. Dr. Vachon testified that, in Rosenblatt, the

outer surface of the core is the outer surface of the tantalum, not the outer surface of the alloy layer.

Q. So, Paragraph 79, you wrote that Rosenblatt discloses an electrode having a tantalum core; correct?

A. I did.

Q. So, the outer surface of the core in Rosenblatt, is the outer surface of the tantalum; correct?

A. Yes.

Ex. 2029, 90:17–23 (referencing paragraph 79 of Vachon Declaration in IPR2016-01679, which corresponds to paragraph 154 of Exhibit 1004).

As support for its argument that Rosenblatt's alloy layer is the outer surface of the core, Petitioner directs us to pages 123 to 124 of Dr. Vachon's deposition. Tr. 59:6–10. There, Dr. Vachon testified that he "might" and "probably would" define the core as "tantalum with the other layer over it." Ex. 2029, 124:2–4. But that testimony does not refer to Rosenblatt, and it is unclear whether "the other layer" referenced by Dr. Vachon corresponds to Rosenblatt's alloy layer. *Id.* In fact, Dr. Vachon disagrees that an alloy layer is even formed in Rosenblatt's process. *Id.* at 106:12–108:9. Furthermore, Dr. Vachon elaborated that his definition of a "core" is "something that I would start with before I put the platinum down onto it" or a "center portion that you are going to deposit something onto." *Id.* at 124:5–11. The record properly before us is insufficient to show that Rosenblatt's alloy layer fits Dr. Vachon's definition of a "core."¹¹

¹¹ For the first time at the oral hearing, Petitioner relied on an alternative embodiment disclosed in Rosenblatt. Tr. 12:13–14:7. The alternative embodiment is a three-step process whereby a thin primary coat of platinum is applied to a tantalum base, the primary coat is bonded to the tantalum base, and then a second coat of platinum is applied. Ex. 1007, 4:70–5:29. At the oral hearing, Petitioner argued that the primary coat, after bonding,

Accordingly, we are not persuaded that Dr. Vachon's testimony supports Petitioner's argument that Rosenblatt's alloy layer is the outer surface of the core.

Next, Petitioner argues that it relies not only on Rosenblatt's bonding technique, but also on Rosenblatt's electroplating technique. Pet. Reply 9. We are not persuaded, however, that Rosenblatt's disclosure of electroplating teaches the "in contact with" limitation of claim 1. Rosenblatt's only disclosure of electroplating is either in the context of an unsatisfactory prior art technique (Ex. 1007, 2:8–10) or as part of a platinizing process that includes a bonding step that results in the intervening alloy layer discussed above (*id.* at 2:40–50, 3:38–3:60, 4:22–25, 4:46–51, 4:74–5:13).

Accordingly, we determine that Petitioner has not shown by a preponderance of the evidence that the combination of Wilson and Rosenblatt teaches or suggests the "in contact with" limitation of claim 1. Thus, we conclude that Petitioner has not met its burden to prove that claim 1 of the '433 patent is unpatentable as obvious in view of Wilson and Rosenblatt.

2. *Claims 2, 3, 5, 6, and 9–11*

Claims 2, 3, 5, 6, and 9–11 of the '433 patent depend, directly or indirectly, from claim 1 and recite limitations relating to the metals that comprise the electrochemically active metal and the core (claims 2, 3, and

corresponds to the outer surface of the core. Tr. 14:8–20. That argument was not presented in the briefs and is therefore waived. Even if the argument were not waived, it is not supported by expert testimony and is contradicted by Dr. Vachon's testimony previously discussed. Ex. 2029, 90:17–23.

5), the shape of the core (claim 6), the analyte being measured (claim 9), adaptation for at least partial implantation (claim 10), and coverage of a first end of the core by electrochemically active metal (claim 11). Petitioner contends that the combination of Wilson and Rosenblatt teaches or suggests the limitations of dependent claims 2, 3, 5, 6, and 9–11. Pet. 22–28.

The deficiencies in Petitioner’s arguments and evidence regarding the “in contact with” limitation of independent claim 1, as discussed above, are not remedied by Petitioner’s arguments and evidence regarding dependent claims 2, 3, 5, 6, and 9–11. We therefore conclude that Petitioner has not met its burden to prove that claims 2, 3, 5, 6, and 9–11 of the ’433 patent are unpatentable as obvious in view of Wilson and Rosenblatt for the same reasons as discussed above with respect to claim 1.

F. Obviousness Based On Wilson, Rosenblatt, and Heller

Claim 8 depends from claim 1 and recites: wherein said layer of electrochemically active metal is at least partially surrounded by polyimide. Ex. 1001, 5:10–12.

Petitioner contends that claim 8 is unpatentable as obvious in view of Wilson and Rosenblatt in view of Heller (Ex. 1008). Pet. 52–55. Petitioner relies on Heller to teach the use of polyimide as an insulation material in an implantable glucose sensor. Pet. 52–53.

The deficiencies in Petitioner’s arguments and evidence regarding the “in contact with” limitation of independent claim 1, as discussed above, are not remedied by Petitioner’s arguments and evidence regarding Heller and dependent claim 8. We therefore conclude that Petitioner has not met its burden to prove that claim 8 of the ’433 patent is unpatentable as obvious in

view of Wilson, Rosenblatt, and Heller for the same reasons as discussed above with respect to claim 1.

G. Patent Owner's Motion to Exclude

Patent Owner moves to exclude Petitioner's Exhibits 1016–1019, 1033, and 1041 and corresponding portions of the Reply (Pet. Reply 2, 13 n.2) on the grounds that Petitioner improperly relies upon these exhibits to assert new grounds of unpatentability in the Reply. Paper 37, 1–3, 5–7.

Petitioner relies on Exhibits 1016–1019, 1033, and 1041 to show prior art processes of applying platinum to tantalum and prior art use of platinum-clad tantalum as medical electrodes, as well as to show it was known in the art to substitute platinum-plated tantalum electrodes for pure platinum to reduce costs. Pet. Reply 2, 13 n.2.

We agree with Patent Owner that Petitioner's Exhibits 1016–1019, 1033, and 1041 should be excluded from evidence and that the corresponding portions of the Reply (Pet. Reply 2, 13 n.2) should not be considered. None of these exhibits was made of record at the institution stage. Although Carter (Ex. 1033), Haley (Ex. 1041), and Beer (Ex. 1016) were cited in the Vachon Declaration (Ex. 1004 ¶¶ 136–139, 180), these references were not cited in the Petition and were not filed as exhibits with the Petition. Although Bartig (Ex. 1017) was cited in the Petition (Pet. 27), it was likewise not made of record at the institution stage. In the co-pending related case, IPR2016-01679, these references were excluded from consideration in the Institution Decision. *Dexcom, Inc. v. Agamatrix, Inc.*, Case IPR2016-01679, Paper 10, 18 n.11 (PTAB Mar. 6, 2017) (citing 37 C.F.R. § 42.104(b)). Petitioner did not challenge the exclusion of these references in IPR2016-01679, for example, by requesting rehearing of the

Institution Decision. Nor did Petitioner seek authorization for a motion to submit supplemental information in either proceeding. 37 C.F.R. § 42.123(a).

Instead, Petitioner filed these exhibits for the first time with its Reply. We agree with Patent Owner that Petitioner's Reply relies on Exhibits 1016–1019, 1033, and 1041 to fill a gap in its *prima facie* case in view Patent Owner's argument that Rosenblatt fails to teach the “in contact with” limitation of claim 1. PO Resp. 26, 28; Pet. Reply 2. Specifically, Petitioner argues, “[t]o the extent there were any difficulties applying platinum to tantalum in 1950 (the time of Rosenblatt), . . . those complexities were solved in the 53 years prior to the '433 patent's earliest priority date.” Pet. Reply 2 (citing Exs. 1016–1019, 1033, and 1041). In other words, to the extent the Board is not persuaded by Rosenblatt, then Petitioner relies on Carter (Ex. 1033), Haley (Ex. 1041), Beer (Ex. 1016), Bartig (Ex. 1017), Williams (Ex. 1018), and Dahl (Ex. 1019) to show platinum-clad tantalum electrodes. *Id.*

Under our rules and trial practice guide, evidence necessary to make out a *prima facie* case of unpatentability may not be introduced for the first time in the reply brief. 37 C.F.R. § 42.23(b); Office Patent Trial Practice Guide, 77 Fed. Reg. 48,756, 48,767 (Aug. 14, 2012) (“Examples of indications that a new issue has been raised in a reply include new evidence necessary to make out a *prima facie* case for the . . . unpatentability of an original . . . claim, and new evidence that could have been presented in a prior filing.”). Federal Circuit case law indicates that a motion to exclude is a proper vehicle for enforcing our rule and trial practice guide regarding the scope of evidence that may be submitted with a reply brief. *Belden Inc. v.*

Berk-Tek LLC, 805 F.3d 1064, 1081 (Fed. Cir. 2015) (“a party may move to exclude evidence . . . as improper under the response-only regulation, under the Trial Practice Guide’s advice”); *see also Genzyme Therapeutic Prods. L.P. v. Biomarin Pharm. Inc.*, 825 F.3d 1360, 1368 (Fed. Cir. 2016) (“[i]f [patent owner] had wanted the Board to disregard those references, it could have filed a motion to exclude them,” citing 37 C.F.R. § 42.64(c) and *Belden, supra*); *Intelligent Bio-Systems, Inc. v. Illumina Cambridge, Ltd.*, 821 F.3d 1359 (Fed. Cir. 2016) (not error for the Board to exclude Petitioner’s new theory of invalidity supported by new evidence not relied upon in the Petition).

Under the circumstances of this case, it would violate the Administrative Procedures Act (“APA”)’s requirement for notice and opportunity to respond, if we were to rely upon Carter (Ex. 1033), Haley (Ex. 1041), Beer (Ex. 1016), Bartig (Ex. 1017), Williams (Ex. 1018), or Dahl (Ex. 1019) as evidence to show that the “in contact with” limitation of claim 1 was taught or suggested by the prior art, when that evidence was first submitted and relied upon in Petitioner’s Reply. Pet. Reply 2, 13 n.2. None of these references was submitted with the Petition, and none except Bartig (Ex. 1017) was even cited in the Petition. Patent Owner was entitled to rely upon the absence of these references from Petitioner’s case-in-chief, particularly since Petitioner took no action to have them made of record any earlier than the reply brief. *See EmeraChem Holdings LLC v. Volkswagen Group of Am., Inc.*, 859 F.3d 1341, 1348–52 (Fed. Cir. 2017) (APA’s notice and opportunity to respond requirements not satisfied where Institution Decision did not sufficiently notify patent owner that it would rely on reference for limitations of dependent claims).

III. CONCLUSION

Petitioner has not demonstrated by a preponderance of the evidence that that claims 1–3, 5, 6, and 9–11 of the '433 patent are unpatentable under 35 U.S.C. § 103(a) as obvious in view of Wilson and Rosenblatt. Petitioner has not demonstrated by a preponderance of the evidence that that claim 8 of the '433 patent is unpatentable under 35 U.S.C. § 103(a) as obvious in view of Wilson, Rosenblatt, and Heller.

IV. ORDER

Accordingly, in consideration of the foregoing, it is hereby:

ORDERED that Petitioner has not shown that claims 1–3, 5, 6, and 8–11 of the '433 patent are unpatentable;

FURTHER ORDERED that Patent Owner's motion to exclude Exhibits 1016–1019, 1033, and 1041 is *granted*;

FURTHER ORDERED that, because this is a Final Written Decision, the parties to the proceeding seeking judicial review of the decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

IPR2016-01680
Patent 8,187,433 B2

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