

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MEDTRONIC, INC., AND MEDTRONIC VASCULAR, INC.,
Petitioner,

v.

TELEFLEX INNOVATIONS S.À.R.L.,
Patent Owner.

IPR2020-01341
Patent 8,142,413 B2

Before SHERIDAN K. SNEDDEN, JAMES A. TARTAL, and
CHRISTOPHER G. PAULRAJ, *Administrative Patent Judges*.

TARTAL, *Administrative Patent Judge*.

JUDGMENT
Final Written Decision
Determining No Challenged Claims Unpatentable
Dismissing Petitioner's Motion to Exclude
35 U.S.C. § 318(a)

We have jurisdiction to conduct this *inter partes* review under 35 U.S.C. § 6. This Final Written Decision is issued pursuant to 35 U.S.C. § 318(a) (2018) and 37 C.F.R. § 42.73 (2019). For the reasons discussed below, we determine Medtronic, Inc. and Medtronic Vascular, Inc. (“Petitioner”)¹ has not shown by a preponderance of the evidence that any of claims 1, 2, 4, 5, and 7–14 (“the Challenged Claims”) of U.S. Patent No. 8,142,413 B2 (Ex. 1001, “the ’413 patent”) are unpatentable.

I. INTRODUCTION

A. Summary of Procedural History

Petitioner filed a Petition pursuant to 35 U.S.C. §§ 311–319 requesting an *inter partes* review of the Challenged Claims. Paper 1 (“Pet.”). We instituted an *inter partes* review of the Challenged Claims on all grounds of unpatentability asserted in the Petition. Paper 11 (“Inst. Dec.”). Teleflex Innovations S.À.R.L. (“Patent Owner”)² filed a Patent Owner Response.³ Paper 23 (“PO Resp.”) (under seal), 24 (redacted, publicly accessible). Petitioner filed a Reply to the Patent Owner Response. Paper 51 (“Pet. Reply”) (under seal), 52 (redacted, publicly accessible).

¹ Petitioner identifies as real parties-in-interest Medtronic, Inc. and Medtronic Vascular, Inc., and states, “Medtronic plc is the ultimate parent of both entities.” Pet. 4.

² Patent Owner identifies as real parties-in-interest Teleflex Medical Devices S.À.R.L.; Vascular Solutions LLC; Arrow International, Inc.; and Teleflex LLC. Paper 7, 2. Patent Owner also states, “Teleflex Incorporated is the ultimate parent of the entities listed above.” *Id.*

³ Prior to institution, Patent Owner filed a Preliminary Response to the Petition directed primarily to whether discretionary denial of the Petition was warranted, not to the merits of Petitioner’s unpatentability contentions. *See* Paper 8. Patent Owner also filed a Contingent Motion to Amend (Paper 26), which Patent Owner subsequently withdrew (Paper 56).

Patent Owner filed a Sur-reply in support of the Patent Owner Response. Paper 67 (“PO Sur-reply”).

Following oral argument, we entered a transcript of the hearing in the record. Paper 92 (“Tr.”). Petitioner bears the burden of proving unpatentability of each claim it has challenged by a preponderance of the evidence, and the burden of persuasion never shifts to Patent Owner. *See* 35 U.S.C. § 316(e); 37 C.F.R. § 42.1(d); *Dynamic Drinkware, LLC v. Nat’l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015).

B. Related Proceedings

Petitioner also challenges claims 1, 2, 4, 5, and 7–14 of the ’413 patent under separate grounds in IPR2020-01342. Pet. 5–6; Paper 7, 3. The ’413 patent also was the subject of a previous *inter partes* review in *Boston Scientific Corp. and Boston Scientific Scimed, Inc., v. Vascular Solutions, Inc.*, IPR2014-00759, which was terminated based on settlement and no final written decision was issued. IPR2014-00759, Paper 10, 2–3 (PTAB August 11, 2014).

The parties state the ’413 patent is a subject of *Vascular Solutions LLC, et al. v. Medtronic, Inc., et al.* No. 19-cv-01760 (D. Minn. filed July 2, 2019) and *QXMedical, LLC v. Vascular Solutions, LLC*, No. 17-cv-01969 (D. Minn. filed June 8, 2017). Pet. 4–5; Paper 7, 2. Patent Owner indicates that both of these district court proceedings currently are stayed. Paper 7, 2.

Additionally, Petitioner filed petitions challenging patents related to the ’413 patent in the following proceedings: IPR2020-00126 and IPR2020-00127 (Patent 8,048,032 B2); IPR2020-00128, IPR2020-00129, IPR2020-00130, and IPR2020-00131 (Patent RE45,380 E); IPR2020-00132, IPR2020-00133, and IPR2020-00134 (Patent RE45,760 E); IPR2020-00135

and IPR2020-00136 (Patent RE45,776 E); IPR2020-00137 and IPR2020-00138 (Patent RE47,379 E); and IPR2021-01343 and IPR2021-01344 (Patent RE46,116 E). Institution of *inter partes* review was denied in IPR2020-00131 and IPR2020-00133. Final written decisions are pending in IPR2021-01343 and IPR2021-01344. In the remaining listed proceedings, final written decisions were entered determining that a preponderance of the evidence did not show any claim challenged was unpatentable.

C. The '413 Patent

The '413 patent, titled “Coaxial Guide Catheter for Interventional Cardiology Procedures,” issued on March 27, 2012, from a non-provisional application filed June 28, 2010. Ex. 1001, codes (45), (54), (22). The '413 patent relates generally to a coaxial guide catheter for use with interventional cardiology devices that are insertable into a branch artery that branches off from a main artery. Ex. 1001, Abstract.

According to the '413 patent, interventional cardiology procedures often include inserting guidewires or other instruments through catheters into coronary arteries that branch off from the aorta. *Id.* at 1:21–23. In coronary artery disease, atherosclerotic plaques or other lesions may narrow or occlude the coronary arteries. *Id.* at 1:26–30. The '413 patent states that “[n]arrowing is referred to as stenosis.” *Id.* at 1:30–31. “In treating a stenosis, a guide catheter is typically inserted through the aorta and into the ostium of the coronary artery,” sometimes with the aid of a guidewire. *Id.* at 1:35–37. The '413 patent further states as follows:

A guide catheter is typically seated into the opening or ostium of the artery to be treated and a guidewire or other instrument is passed through the lumen of the guide catheter and inserted into the artery beyond the occlusion or stenosis. Crossing tough lesions can create enough backward force to dislodge the guide

catheter from the ostium of the artery being treated. This can make it difficult or impossible for the interventional cardiologist to treat certain forms of coronary artery disease.

Id. at 1:37–45. The ’413 patent discusses “four categories” of “[p]rior attempts to provide support to the guiding catheter to prevent backward dislodgement from the coronary ostium (referred to as ‘backup support’),” consisting of: (1) “guiding catheters that, through a combination of shape and stiffness, are configured to draw backup support from engaging the wall of the aortic arch;” (2) “guiding catheters that include a retractable appendage;” (3) guide catheters that have apporation that seeks to expand laterally;” and, (4) “placement of a smaller guide catheter within a larger guide catheter in order to provide add support.” *Id.* at 1:46–2:39. The ’413 patent identifies various deficiencies with these prior attempts, including an increased risk of damage to the aortic wall and mechanical complexity. *See id.* Specifically, with regard to the fourth category of prior attempts, the ’413 patent states as follows:

This technique is used in order to provide a method of deep seating the guide catheter within the ostium of the coronary artery. Deep seating refers to inserting the catheter more deeply into the ostium of the coronary artery than typically has been done before. Unfortunately, deep seating by this technique with a commonly available guide catheter creates the risk that the relatively stiff, fixed curve, guide catheter will damage the coronary artery. This damage may lead to dissection of the coronary artery when the catheter is advanced past the ostium.

Several other problems arise when using a standard guide catheter in this catheter-in-a-catheter fashion. First, the inner catheters must be substantially longer than the one hundred centimeter guide catheter. Second, a new hemostasis valve must be placed on the inner guide catheter which prevents the larger guide catheter from being used for contrast injections or pressure measurements. Third, the smaller guide catheter still must be inserted into the coronary vessel with great care since the smaller

guide catheter has no tapered transition or dilator at its tip and does not run over a standard 0.014 inch guidewire.

Id. at 2:30–50. The '413 patent states “a system that would be deliverable through standard guide catheters for providing backup support by providing the ability to effectively create deep seating in the ostium of the coronary artery” would be beneficial to “the interventional cardiology art.” *Id.* at 2:51–55.

The '413 patent describes “a coaxial guide catheter that is deliverable through standard catheters by utilizing a guidewire rail segment to permit delivery without blocking use of the guide catheter.” *Id.* at 2:59–62. “The coaxial guide catheter preferably includes a tapered inner catheter that runs over a standard 0.014 inch coronary guidewire to allow atraumatic placement within the coronary artery,” allowing “removal of the tapered inner catheter after the coaxial guide catheter is in place.” *Id.* at 2:62–67. Figures 1 and 2, reproduced below, show a coaxial guide catheter and a tapered inner catheter as described in the '413 patent:

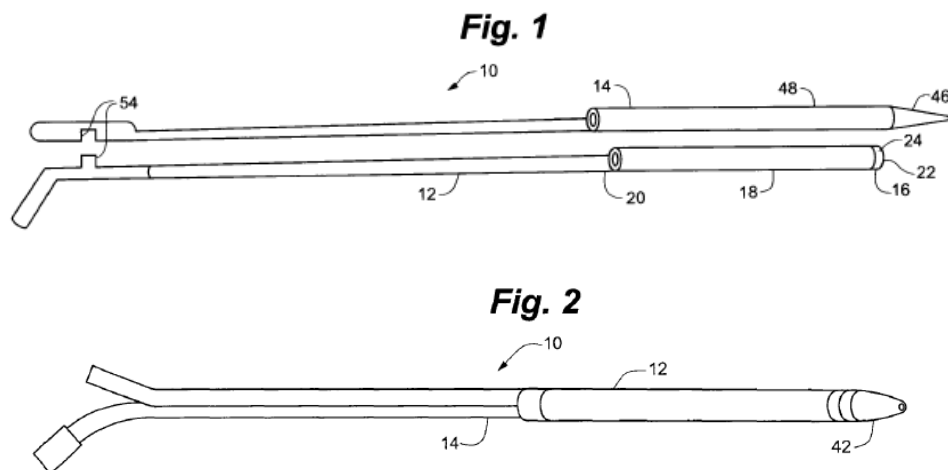
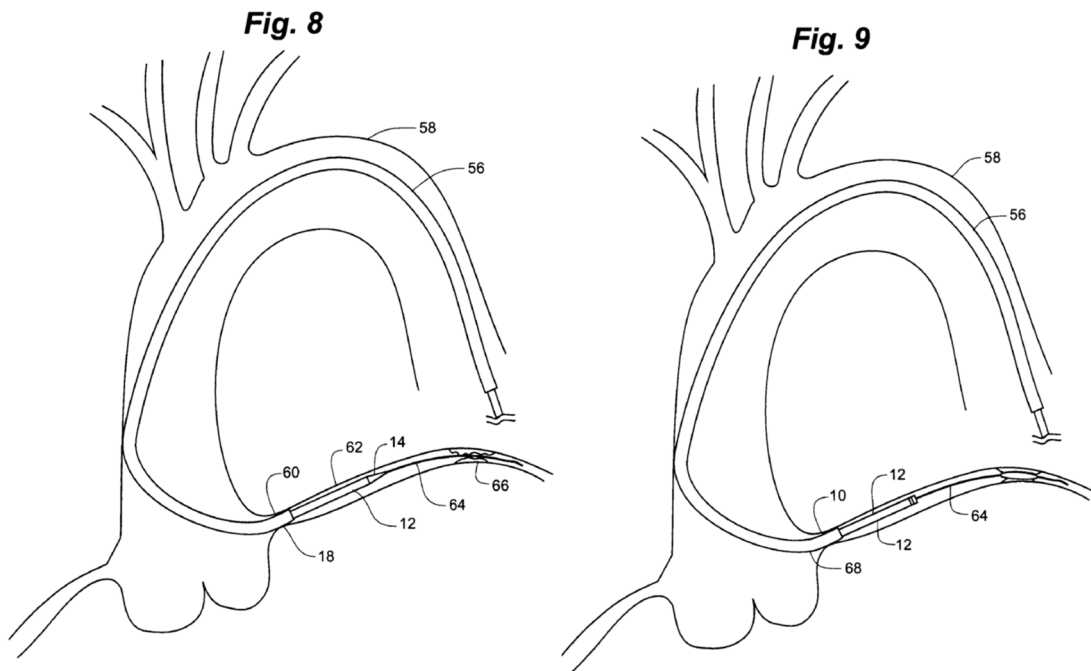


Figure 1 depicts tapered inner catheter 14 separate and above coaxial guide catheter 12, and Figure 2 depicts coaxial guide catheter 12 and tapered inner catheter 14 assembled as coaxial guide catheter assembly 10. *Id.* at 5:22–27,

6:12–14; Figs. 1 and 2. Coaxial guide catheter 12 includes tip portion 16, reinforced portion 18, and rigid portion 20. *Id.* at 6:15–16. Tip portion 16 generally includes bump tip 22 and marker band 24. *Id.* at 6:20–21. Bump tip 22 includes taper 26 and is relatively flexible. *Id.* at 6:21. Marker band 24 is formed of a radiopaque material such as platinum/iridium alloy. *Id.* at 6:25–26. Tapered inner catheter tip 42 includes tapered portion 46 at a distal end thereof, and straight portion 48. *Id.* at 6:65–66. Both tapered portion 46 and straight portion 48 are pierced by lumen 50 (not labeled in figures above). *Id.* at 6:65–67. Tapered inner catheter 14 may also include clip 54 at a proximal end thereof to releasably join tapered inner catheter 14 to coaxial guide catheter 12. *Id.* at 7:3–5.

Figures 8 and 9 of the '413 patent are reproduced below.



Figures 8 and 9 are schematic illustrations of guide catheter 56 with coaxial guide catheter 12 inserted into ostium 60 of coronary artery 62. *Id.* at 5:43–49, 7:53–55, 7:67–8:4. The catheter assembly of Figure 8 includes optional tapered inner catheter 14, whereas the apparatus of Figure 9 does not. *Id.*

The '413 patent states “the presence of coaxial guide catheter 12 within guide catheter 56” provides “improved distal anchoring of guide catheter 56 and coaxial guide catheter 56” and “stiffer back up support than guide catheter 56 alone.” *Id.* at 7:67–8:6. The '413 patent describes in detail a method of use, as follows:

In operation, a guide catheter 56 is inserted into a major blood vessel in the body such as aortic arch 58 over guidewire 64 and the distal end 68 of guide catheter 56 is brought into proximity of ostium 60 of a smaller branch blood vessel, such as coronary artery 62, that it is desired to enter. Coaxial guide catheter 12, with tapered inner catheter 14, is inserted through guide catheter 56 and over guidewire 64. Guide catheter 56, guidewire 64, coaxial guide catheter 12, and tapered inner catheter 14 are manipulated to insert tapered inner catheter tip 42 into the ostium 60 of the blood vessel that branches off from the major blood vessel. The bump tip 22 of coaxial guide catheter 12 is inserted with tapered inner catheter tip 42 well into ostium 60 of coronary artery 62 or other blood vessel until bump tip 22 of coaxial guide catheter 12 achieves a deep seated position. Tapered inner catheter 14 is then withdrawn from the lumen of coaxial guide catheter 12. An interventional cardiology treatment device such as a catheter bearing a stent or a balloon (not shown) is then inserted through the lumen of coaxial guide catheter 12 which remains inside guide catheter 56.

When the interventional cardiology device reaches a stenosis or blockage in coronary artery 62 or another branch blood vessel, force may be applied to the interventional cardiology device catheter while reinforced portion 18 and rigid portion 20 of coaxial guide catheter 12 provide back up support. The back force that would tend to dislodge bump tip 22 from a deep seated position in the ostium in the branch blood vessel is transferred through reinforced portion 18 to rigid portion 20 of coaxial guide catheter 12. A physician may apply a force to the proximal end of the coaxial guide catheter 12 to resist dislodging of bump tip 22 from the ostium of the branch artery.

Id. at 9:51–10:15; *see also id.* at 1:23–26 (stating that “the term ‘interventional cardiology devices’ is to be understood to include but not be limited to guidewires, balloon catheters, stents and stent catheters”). Patent Owner summarizes the method described in the ’413 patent and notes the use of the tapered inner catheter is optional. *See* PO Resp. 3 (stating that “[o]ptionally, a tapered inner catheter may be inserted with the coaxial guide catheter and advanced to the second vessel, and removed before an [interventional cardiology device] is inserted into the coaxial guide catheter” (citing Ex. 1001, 9:55–66)).

D. Illustrative Claim of the ’413 Patent

Petitioner challenges claims 1, 2, 4, 5, and 7–14 of the ’413 patent. Pet. 1. Claim 1, reproduced below, is the only independent claim of the ’413 patent and is illustrative of the claimed subject matter.

1. A method of providing backup support for an interventional cardiology device for use in the coronary vasculature, the interventional cardiology device being adapted to be passed through a standard guide catheter, the standard guide catheter having a continuous lumen extending for a predefined length from a proximal end at a hemostatic valve to a distal end adapted to be placed in a branch artery, the continuous lumen of the guide catheter having a circular cross-sectional inner diameter sized such that interventional cardiology devices are insertable into and through the lumen, the method comprising:

[1.a] inserting the standard guide catheter into a first artery over a guidewire, the standard guide catheter having a distal end;

[1.b] positioning the distal end of the standard guide catheter in a branch artery that branches off from the first artery;

[1.c] inserting a flexible tip portion of a coaxial guide catheter defining a tubular structure having a circular cross-section and a length that is shorter than the predefined length of the continuous lumen of the standard guide catheter, into the continuous lumen of the standard guide catheter, and,

[1.d] further inserting a substantially rigid portion that is proximal of, operably connected to, and more rigid along a longitudinal axis than the flexible tip portion, into the continuous lumen of the standard guide catheter, the substantially rigid portion defining a rail structure without a lumen and having a maximal cross-sectional dimension at a proximal portion that is smaller than the cross-sectional outer diameter of the flexible tip portion and having a length that, when combined with the length of the flexible distal tip portion, defines a total length of the device along the longitudinal axis that is longer than the length of the continuous lumen of the guide catheter;

[1.e] advancing a distal portion of the flexible tip portion distally beyond the distal end of the standard guide catheter and into the second artery such that the distal portion extends into the second artery and such that at least a portion of the proximal portion of the substantially rigid portion extends proximally through the hemostatic valve; and

[1.f] inserting the interventional cardiology device into and through the continuous lumen of the standard guide catheter alongside of the substantially rigid portion and advancing the interventional cardiology device through and beyond a lumen of the flexible tip portion into contact with or past a lesion in the second artery.

Ex. 1001, 10:28–11:6 (bracketed labeling added).

E. References and Testimony

Petitioner's contentions rely, in part, on testimony from Dr. Brecker, Dr. Hillstead, and Mr. Jones. Dr. Brecker states that he has been an interventional cardiologist for over 24 years, that he has been Chief of Cardiology at St. Georges University Hospitals London since 2015, and that he is a Professor of Cardiology and Chief of Cardiology Clinical Academic Group at St. George's University. Ex. 1005 ¶¶ 4, 5, 7. Dr. Hillstead states that he is CEO of a medical device development and entrepreneurship consulting firm, the Chairman of a wound healing device company, a named

inventor on numerous patents and pending applications related to catheter design, and that he has been involved in the design and development of medical devices for more than thirty years. Ex. 1042 ¶¶ 5, 10, 12. Mr. Jones states that he has worked in contract mechanical engineering since 1997 on projects including “prototype designs for minimally invasive, surgical, and implantable devices, development and fabrication for surgical devices, test fixture design and fabrication, and process validation,” that he previously worked as an engineer on medical device design, development and manufacturing, including on catheters, and that he is a named inventor on over 100 patents. Ex. 1807 ¶¶ 8–10.

Patent Owner’s arguments rely, in part, on testimony from Mr. Keith and Dr. Graham. Mr. Keith states that his work between 1987 and 1996 as an engineer at a medical device company focused in the field of interventional cardiology and catheter design, that since 1997 he has served as an independent consultant for early stage medical device companies in product design and intellectual property development, that he co-founded a medical device company “focused on catheter-based treatments for chronic sinusitis,” and that he is a named inventor on over 140 patents. Ex. 2138 ¶¶ 3–6. Dr. Graham states that he is an interventional cardiologist at St. Michael’s Hospital, an Assistant Professor in the Division of Cardiology at the University of Toronto, and that he has over twenty years of experience in interventional cardiology. Ex. 2145 ¶ 1.

Below we provide a table identifying the references asserted by Petitioner, as well as the exhibits corresponding to the declarations and

deposition testimony in the record for Dr. Brecker, Dr. Hillstead, Mr. Jones, Mr. Keith, and Dr. Graham.⁴

References and Witness Testimony	Date	Ex. No.
U.S. Patent No. 7,736,355 B2 (“Itou”)	June 15, 2010	1007
U.S. Patent No. 7,604,612 B2 (“Ressemann”)	October 20, 2009	1008
Declaration of Stephen Jon David Brecker, MD, FRCP, FESC, FACC	July 30, 2020	1005
Supplemental Declaration of Stephen Jon David Brecker, MD, FRCP, FESC, FACC	August 6, 2021	1806
Deposition Transcript of Stephen Brecker, M.D.	April 20, 2021	2245
Deposition Transcript of Stephen Brecker, M.D.	September 14, 2021	2260
Declaration of Dr. Richard A. Hillstead, Ph.D.	July 30, 2020	1042
Deposition Transcript of Richard Hillstead, Ph.D.	April 13, 2021	2244
Declaration of Michael Jones Submitted in Support of Petitioner’s Replies and Petitioner’s Opposition to Patent Owner’s Motion to Amend	August 6, 2021	1807
Deposition Transcript of Michael Jones	September 9, 2021	2259
Declaration of Peter T. Keith	May 14, 2021	2138
Deposition Transcript of Peter T. Keith	July 8, 2021	1797
Declaration of Dr. John J. Graham, MB, ChB, MRCP (UK)	May 13, 2021	2145
Deposition Transcript of Dr. John J. Graham, MB, ChB, MRCP (UK)	June 10, 2021	1846

⁴ The table provided identifies only a select number of documents. A complete identification of the papers and exhibits that form the record of this case is available in the docket of this proceeding. *See also* Paper 68 (Patent Owner’s Exhibit List); Paper 74 (Petitioner’s Exhibit List).

F. Asserted Grounds of Unpatentability

Petitioner alleges unpatentability of the Challenged Claims on the following grounds:

Claims Challenged	35 U.S.C. §⁵	Reference(s)/Basis
1, 2, 4, 7–14	103(a)	Itou
1, 2, 4, 5, 7–14	103(a)	Itou
1, 2, 4, 5, 7–14	103(a)	Itou, Ressemann

Pet. 7.

II. MOTION TO EXCLUDE

The party moving to exclude evidence bears the burden of proving that it is entitled to the relief requested—namely, that the material sought to be excluded is inadmissible under the Federal Rules of Evidence (“FRE”). *See* 37 C.F.R. §§ 42.20(c), 42.62(a) (2019). In an *inter partes* review in which we both decide admissibility and serve as the fact-finder, we are well-positioned to determine and assign appropriate weight to evidence presented, and we recognize that a complete record of the evidence is preferable to facilitate public access as well as appellate review. *See, e.g., Sony Computer Entm’t Am. LLC v. Game Controller Tech. LLC*, IPR2013-00634, Paper 32 at 31 (PTAB Apr. 14, 2015); *see also Gnosis S.p.A. v. S. Alabama Med. Sci. Found.*, IPR2013-00118, Paper 64 at 43 (PTAB June 20, 2014) (citing *Donnelly Garment Co. v. NLRB*, 123 F.2d 215, 224 (8th Cir. 1941))

⁵ The Leahy-Smith America Invents Act (“AIA”) included revisions to 35 U.S.C. §§ 102, 103 that became effective on March 16, 2013. Pub. L. No. 112-29, §§ 3(b)–3(c), 3(n)(1), 125 Stat. 284, 285–87, 293 (2011). There is no dispute that the Challenged Claims have an effective filing date before March 16, 2013, and we apply the pre-AIA versions of these statutes.

(“If the record on review contains not only all evidence which was clearly admissible, but also all evidence of doubtful admissibility, the court which is called upon to review the case can usually make an end of it, whereas if evidence was excluded which that court regards as having been admissible, a new trial or rehearing cannot be avoided.”)).

Petitioner moves to exclude Exhibit 2024, a document titled “Product Requirements: Guideliner Catheter System,” as well as certain portions of the deposition testimony of Steven Erb (specifically, Ex. 1799, 37:2–7, 37:20–38:6, 39:17–40:20). Paper 73 (the “Motion”); *see also* Paper 82 (Petitioner’s reply in support of its motion to exclude). Patent Owner opposes the Motion. Paper 77.

Petitioner argues Patent Owner failed to authenticate Exhibit 2024, citing FRE 901. Paper 73, 3–10. Petitioner also argues that the portions of the testimony of Mr. Erb it seeks to exclude are prejudicial, citing FRE 403. *Id.* at 10–15. For purposes of this Decision, we do not rely on either Exhibit 2024 or the portions of Mr. Erb’s testimony Petitioner seeks to exclude. Accordingly, we dismiss the Motion as moot.

III. ANALYSIS OF PATENTABILITY

In our analysis of Petitioner’s unpatentability contentions with respect to the Challenged Claims, we next address the applicable principles of law; the level of ordinary skill in the art; the proposed construction of claim terms; the scope and content of the asserted prior art; and then further analyze Petitioner’s contentions with respect to each alleged ground of unpatentability for purposes of determining whether Petitioner shows by a preponderance of the evidence the unpatentability of the Challenged Claims.

A. Principles of Law

Petitioner contends under one ground that claims of the '413 patent are unpatentable based on anticipation. Pet. 21–70. A claim is anticipated if a single prior art reference either expressly or inherently discloses every limitation of the claim. *Orion IP, LLC v. Hyundai Motor Am.*, 605 F.3d 967, 975 (Fed. Cir. 2010). “A single prior art reference may anticipate without disclosing a feature of the claimed invention if such feature is necessarily present, or inherent, in that reference.” *Allergan, Inc. v. Apotex Inc.*, 754 F.3d 952, 958 (Fed. Cir. 2014) (citing *Schering Corp. v. Geneva Pharm.*, 339 F.3d 1373, 1377 (Fed. Cir. 2003)).

Petitioner contends under two grounds that claims of the '413 patent are unpatentable based on obviousness. Pet. 70–95. As set forth in 35 U.S.C. § 103(a),

[a] patent may not be obtained . . . 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 at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

The question of obviousness is resolved on the basis of 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) when in evidence, objective evidence of nonobviousness. *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

An obviousness analysis “need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ.” *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007); accord *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1259 (Fed. Cir. 2007).

However, Petitioner cannot satisfy its burden of proving obviousness by employing “mere conclusory statements.” *In re Magnum Oil Tools Int’l, Ltd.*, 829 F.3d 1364, 1380 (Fed. Cir. 2016). Instead, Petitioner must articulate a reason why a person of ordinary skill in the art would have combined the prior art references. *In re NuVasive*, 842 F.3d 1376, 1382 (Fed. Cir. 2016).

B. Level of Ordinary Skill in the Art

In determining whether an invention would have been obvious at the time it was made, 35 U.S.C. § 103 requires us to resolve the level of ordinary skill in the pertinent art at the time of the invention. *Graham*, 383 U.S. at 17. The person of ordinary skill in the art is a hypothetical person who is presumed to have known the relevant art at the time of the invention. *In re GPAC, Inc.*, 57 F.3d 1573, 1579 (Fed. Cir. 1995). In determining the level of ordinary skill in the art, various factors may be considered, including the “type of problems encountered in the art; prior art solutions to those problems; rapidity with which innovations are made; sophistication of the technology; and educational level of active workers in the field.” *Id.* (citation omitted).

Petitioner contends that a person of ordinary skill in the art at the time of the invention would have been either: (1) a medical doctor who would have had “(a) a medical degree; (b) completed a coronary intervention training program, and (c) experience working as an interventional cardiologist;” or (2) an engineer who would have had (a) an undergraduate degree in engineering, such as mechanical or biomedical engineering; and (b) at least three years of experience designing medical devices, including catheters or catheter-deployable devices.” Pet. 11–12. Additionally, Petitioner contends “[e]xtensive experience and technical

training might substitute for education, and advanced degrees might substitute for experience.” *Id.* at 12. Further, according to Petitioner, a person of ordinary skill in the art “with a medical degree” and a person of ordinary skill in the art “with an engineering degree” may have had access to each other. *Id.* (citing Ex. 1005 ¶ 31; Ex. 1042 ¶¶ 18–19).

Patent Owner does not dispute Petitioner’s proposed level of ordinary skill. PO Resp. 6. We adopt Petitioner’s proposed level of ordinary skill in the art as it is undisputed and consistent with the level of skill reflected in the prior art and the specification of the ’413 patent. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001) (explaining that specific findings regarding ordinary skill level are not required “where the prior art itself reflects an appropriate level and a need for testimony is not shown”) (quoting *Litton Indus. Prods., Inc. v. Solid State Sys. Corp.*, 755 F.2d 158, 163 (Fed. Cir. 1985)).

As their qualifications are undisputed, we also determine that the parties’ experts are qualified to opine on the issues in this proceeding from the perspective of a person of ordinary skill in the art. Ex. 1042 ¶¶ 5, 10, 12 (Dr. Hillstead’s qualifications); Ex. 1807 ¶¶ 8–10 (Mr. Jones’s qualifications); Ex. 2138 ¶¶ 3–6 (Mr. Keith’s qualifications); Ex. 2145 ¶ 1 (Dr. Graham’s qualifications); *see Kyocera Senco Indus. Tools Inc. v. Int’l Trade Comm’n*, 22 F.4th 1369 (Fed. Cir. 2022) (“To offer expert testimony from the perspective of a skilled artisan in a patent case . . . a witness must at least have ordinary skill in the art.”).

C. Claim Construction

“In an *inter partes* review proceeding, a claim of a patent . . . shall be construed using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. 282(b).” 37 C.F.R.

§ 42.100(b). That standard “includ[es] construing the claim in accordance with the ordinary and customary meaning of such claim as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent.” *Id.*; *see also Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (en banc).

1. Whether the Steps of Claim 1 Must be Performed in the Order Written

Claim 1 of the ’413 patent recites a method comprised of six steps. Ex. 1001, 10:28–11:6; *see also, supra*, Section I.D. (reproducing claim 1 and labeling six steps [1.a] to [1.f]). Whether the steps recited in a method claim must be performed in a particular order is properly a part of claim construction. *See, e.g., Altiris, Inc. v. Symantec Corp.*, 318 F.3d 1363, 1371–72 (Fed. Cir. 2003). Steps in a method claim need not necessarily be performed in the order they are written, but if grammar, logic, the specification, or the prosecution history require the steps to be performed sequentially, then the claims are so limited. *Id.* at 1369; *see also Loral Fairchild Corp. v. Sony Corp.*, 181 F.3d 1313, 1322 (Fed. Cir. 1999) (“Although not every process claim is limited to the performance of its steps in the order written, the language of the claim, the specification and the prosecution history support a limiting construction in this case.”). “*Interactive Gift* recites a two-part test for determining if the steps of a method claim that do not otherwise recite an order, must nonetheless be performed in the order in which they are written.” *Altiris*, 318 F.3d 1369 (citing *Interactive Gift Express, Inc. v. CompuServe Inc.*, 256 F.3d 1323, 1342–43 (Fed. Cir. 2001)). “First, we look to the claim language to determine if, as a matter of logic or grammar, they must be performed in the order written.” *Id.* “If not, we next look to the rest of the specification to

determine whether *it* directly or implicitly requires such a narrow construction.” *Id.* at 1370 (citation omitted).

Petitioner argues that certain steps of claim 1 need not be performed in the order recited in the claim. Pet. 49 n.12. In abbreviated summary, claim 1 recites the following six steps:

- [1.a] “inserting the standard guide catheter . . . into a first artery;”
- [1.b] “positioning . . . the standard guide catheter in a branch artery;”
- [1.c] “inserting a flexible tip portion of a coaxial guide catheter;”
- [1.d] “further inserting a substantially rigid portion . . . connected to the flexible tip portion;”
- [1.e] “advancing . . . the flexible tip portion” beyond the “end of the standard guide catheter and into the second artery;” and
- [1.f] “inserting the interventional cardiology device . . . alongside of the substantially rigid portion and advancing the interventional cardiology device through and beyond a lumen of the flexible tip portion.”

Ex. 1001, 10:28–11:6. Petitioner specifically contends that step 1.f “does not recite two separate, sequential insertion steps with respect to the interventional cardiology device and coaxial guide catheter.” Pet. 49 n.12. According to Petitioner, “[t]here is nothing in the language” of step 1.f “that requires the coaxial guide catheter to be inserted first, followed (separately) by the interventional cardiology device,” and “[t]he devices are inserted ‘alongside’ one another.” *Id.* (citing *Interactive Gift Express*, 256 F.3d at 1342; *Altiris*, 318 F.3d at 1370–71). Petitioner further suggests that, under its interpretation that claim 1 (or at least step 1.f of claim 1) requires no specific sequence, “‘alongside’ of” means “at the same time as.” Pet. 71. Petitioner identifies no support for the notion that “alongside” can be

interpreted to mean “at the same time as.” *See id.* Petitioner also does not address in the Petition whether steps 1.a to 1.e must be performed sequentially, and, if so, how that comports with its argument that step 1.f need not be performed in the sequence recited. Petitioner, in the Petition, also does not direct us to anything additional in the Specification of the ’413 patent to support its proposed construction. *See generally* Pet.

In determining whether steps of a method must be performed in order, we must first look to the claim language to determine whether, “as a matter of logic or grammar,” the method steps must be performed in the order written. *See Altiris*, 318 F.3d at 1369. Patent Owner argues, and we agree, that the method of claim 1 “only makes sense if the steps take place in order.” PO Resp. 10. As Patent Owner explains, step 1.b (positioning the standard guide catheter) “cannot logically occur until after step 1.a (inserting the standard guide catheter), “steps 1.c–1.e (inserting various parts of the coaxial guide catheter) must occur in sequence,” and step 1.e (advancing the coaxial guide catheter beyond the standard guide catheter) necessarily requires performing steps 1.a and 1.b prior to steps 1.c to 1.e. *Id.* at 10 (citing Ex. 1001, 10:39–67; Ex. 2138 ¶102; Ex. 2145 ¶¶ 102–106; Ex. 2244, 61:24–62:3; Ex. 2245, 87:24–88:14, 89:21–90:3, 90:13–23).

Patent Owner further explains, and we agree, “as a matter of logic and grammar, claim 1 requires that step 1.f (insertion and advancement of the interventional cardiology device) occur after steps 1.c–1.e. (insertion of the coaxial guide catheter in the guide catheter).” *Id.* at 10–12 (citing, e.g., Ex. 2138 ¶ 105). Specifically, Patent Owner shows that “inserting an [interventional cardiology device] ‘alongside of the substantially rigid portion’ means that the substantially rigid portion is already in place inside the guide catheter, and when the [interventional cardiology device] is

inserted into the guide catheter it moves ‘alongside’ the already positioned substantially rigid portion.” *Id.* at 11 (citing Ex. 2138, ¶103; Ex. 2145 ¶ 103). As Patent Owner notes, “Petitioner’s own expert, Dr. Hillstead, agrees that ‘alongside’ in this context means that the substantially rigid portion is already in place in the guide catheter when the [interventional cardiology device] is inserted ‘alongside’ of it.” *Id.* (citing Ex. 2244, 63:6–64:1).

We further find that Patent Owner persuasively shows that the claim language of step 1.f requires “advancing” the interventional cardiology device “through and beyond a lumen of the flexible tip portion” of the coaxial guide catheter, which “strongly suggests that the coaxial guide catheter’s flexible tip is already in the anatomy.” *Id.* at 11 (citing Ex. 1001, 10:39–11:6; Ex. 2138 ¶ 103; Ex. 2145, ¶ 103). Patent Owner also shows that “Petitioner’s expert Dr. Hillstead agreed that step 1.f’s language requires that insertion of the interventional cardiology device ‘take place after the prior steps that are recited in the claim.’” *Id.* (citing Ex. 2244, 62:18–24, 63:13–64:1).

Having determined that, as a matter of logic or grammar, the steps of claim 1 must be performed in the order written, we need not look to the Specification “to determine whether *it* directly or implicitly requires” the same. *See Altiris*, 318 F.3d at 1370. Nevertheless, we note that our determination that claim 1 requires the steps to be performed in the order written is consistent with the Specification. Patent Owner explains, and we agree, that the Specification expressly details the necessary order of steps as follows:

“a guide catheter 56 is inserted into a major blood vessel . . .
[c]oaxial guide catheter 12 . . . is inserted through guide

catheter 56 . . . coaxial guide catheter 12 achieves a deep seated position . . . [a]n interventional cardiology treatment device such as a catheter bearing a stent or balloon (not shown) *is then inserted* through the lumen of coaxial guide catheter 12, which *remains inside* guide catheter 56.”

PO Resp. 13 (quoting Ex. 1001, 9:51–10:3 (emphasis added)).

Petitioner’s arguments in reply in support of its proposed construction are not persuasive. Pet. Reply 4–7. Petitioner concedes that claim 1 requires “some steps” to be performed in the order written, including steps 1.a to 1.e, but maintains that “the plain claim language permits an [interventional cardiology device] to be advanced *either* simultaneously with the coaxial guide catheter *or* sequentially.” Pet. Reply 5 (citing Ex. 1005 ¶¶ 221–25, 250–59, 320–24; Ex. 1806 ¶¶ 17–23; Pet. 49–51). Petitioner’s conclusory assertion is unsupported by any rationale based on logic or grammar. Petitioner further argues that “[t]he [S]pecification’s disclosure of an embodiment in which insertion is sequential does not limit the claims.” *Id.* at 5 (citing *Altiris*, 318 F.3d at 1369–1371). We agree the single embodiment disclosed does not limit the claims, and do not rely on the disclosed embodiment in such a manner; however, the single disclosed embodiment and the Specification as a whole consistently require the steps recited as claim 1 to be performed in the order written, which is consistent with the construction we adopt based on both logic and grammar. We have considered Petitioner’s remaining arguments and find they have no merit. *See* Pet. Reply 5–7. In sum, Petitioner seeks to show that “[t]his is not a case in which sequential insertion is required to perform the claimed method.” *Id.* at 5. The issue of claim construction presented is not whether the claimed method *could* be performed out of the written sequence, in the abstract, but whether “as a matter of logic or grammar,” the steps of claim 1

must be performed in the order written. For the reasons discussed above, Patent Owner has shown that logic and grammar require that the steps of claim 1 must be performed in the order written.

Lastly, Petitioner argues generally that the '413 patent does not require every step to be performed in the order recited based on arguments Petitioner raises concerning steps required by dependent claims 10 and 11. Pet. Reply 7 n.2. Claims 10 and 11 recite additional requirements relevant to the insertion of the interventional cardiology device and further limit step 1.f in independent claim 1. Ex. 1001, 12:14–25. We find that whether logic and grammar require additional steps in dependent claims 10 or 11 to be performed in the order written is of little or no relevance to whether the steps of the method of claim 1 must be performed in the order written, because the dependent claim limitations do not alter the logic and grammar of claim 1. For all of the reasons discussed above, we determine that claim 1 recites a method comprised of a series of steps that must be performed in the order written in the claim.

2. “*interventional cardiology device(s)*”

Claim 1 of the '413 patent recites a method, including inserting an “*interventional cardiology device* into and through the continuous lumen of the standard guide catheter.” Ex. 1001, 10:31–11:6 (emphasis added). The preamble of claim 1 also recites the following:

A method of providing backup support for an *interventional cardiology device* for use in the coronary vasculature, the *interventional cardiology device* being adapted to be passed through a standard guide catheter, the standard guide catheter having a continuous lumen extending for a predefined length from a proximal end at a hemostatic valve to a distal end adapted to be placed in a branch artery, the continuous lumen of the guide catheter having a circular cross-sectional inner

diameter sized such that *interventional cardiology devices* are insertable into and through the lumen.”

Id. (emphases added). The ’413 patent expressly states that “the term ‘interventional cardiology devices’ is to be understood to include but not be limited to guidewires, balloon catheters, stents and stent catheters.” *Id.* at 1:23–26.

Petitioner explains that in a prior Board *inter partes* review institution decision addressing a patent sharing a common specification with the ’413 patent, the Board stated that “the term ‘interventional cardiology devices’ refers to at least two types of devices selected from the group that includes, but is not limited to, guidewires, balloon catheters, stents, and stent catheters.” Pet. 13 (quoting Ex. 1113, 20). Petitioner states that it “applies this construction” for purposes of this proceeding, and further states that “‘interventional cardiology device,’ which is singular, will require only one of the enumerated devices.” *Id.* at 14 (citing Ex. 1005 ¶¶ 139–40).

Patent Owner argues “interventional cardiology device” includes “in addition to the four standard [interventional cardiology devices] enumerated by the express definition in the specification, *any other device delivered beyond the end of the device for use with a standard guide catheter to a location in the vasculature requiring treatment, to provide treatment to that location*”. PO Resp. 14 (citing Ex. 2138 ¶¶ 107–112; Ex. 2145 ¶¶ 92–101). Patent Owner asserts that in the ’413 patent “interventional cardiology device” is used “interchangeably with ‘cardiac treatment device’ and ‘interventional cardiology treatment device,’” showing that “interventional cardiology device” is intended “to refer specifically to devices providing treatment.” *Id.* at 14–15 (citing Ex. 1001, 1:23–25, 4:35–36, 9:66–10:1). Patent Owner further argues that the ’413 patent distinguishes certain

devices from “interventional cardiology devices,” including “a protective catheter” or “tapered inner catheter.” *Id.* at 15. Specifically, Patent Owner notes that the ’413 patent expressly states “[o]nce the tapered inner catheter is removed a cardiac treatment device, such as a guidewire, balloon or stent, may be passed through the coaxial guide catheter within the guide catheter and into the coronary artery.” *Id.* (quoting Ex. 1001, 4:35–38 (emphases omitted)). Patent Owner concedes its proposed definition is “narrower than the broadest sense of ‘interventional cardiology devices,’” and argues it is “consistent with the understanding of a [person of ordinary skill in the art] at the time of the invention.” *Id.* at 16 (citing Ex. 2138 ¶ 112; Ex. 2145 ¶ 100). According to Patent Owner, “[interventional cardiology devices] were understood to be devices deployed through a delivery catheter, out the end of the catheter and to a treatment site, and then used to deliver treatment to that site.” *Id.* at 16 (citing Ex. 2145 ¶ 100).

Petitioner argues that different terms in the ’413 patent have different meanings, such that “‘interventional cardiology device(s)’ refers to a genus, of which ‘interventional cardiology treatment device’ is a species,” and “the two are not synonymous.” Pet. Reply 3 (citing Ex. 1806 ¶¶ 11–13). Petitioner further argues that if “interventional cardiology device” meant a device to “provide treatment to that location,” it would exclude a guidewire, which is expressly identified in the ’413 patent as an example of an “interventional cardiology device,” but which does not “provide treatment to that location.” *Id.* at 4 (citations omitted).

Patent Owner argues in reply that a “guidewire alone can provide treatment.” PO Sur-reply 20–21 (citing Ex. 1846, 21:14–22:18; Ex. 1806, ¶ 15; Ex. 2260, 31:9–13, 33:8–14). Patent Owner suggests that the dispute between the parties is not over whether an interventional cardiology device

“must provide treatment,” but whether distal end protective catheter 5 (hereinafter, “protective catheter 5”) of Itou corresponds to the recited “interventional cardiology device,” as Petitioner contends. *Id.* Patent Owner, however, proceeds to argue that Itou’s “protective catheter” is not an “interventional cardiology device,” because a protective catheter purportedly cannot “restore[] blood flow” like a guidewire can, implying again that under Patent Owner’s construction an “interventional cardiology device” must provide treatment, for example, by restoring blood flow like a guidewire *Id.* at 21–22.

We find an express construction of “interventional cardiology device” is not required for purposes of this Decision because, even if we assume Petitioner shows that the asserted art discloses an “interventional cardiology device,” Petitioner has not shown by a preponderance of the evidence the unpatentability of any of the Challenged Claims for the reasons detailed below. *See Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017); *Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999) (“[O]nly those terms need be construed that are in controversy, and only to the extent necessary to resolve the controversy”).

3. Other Claim Terms

We find no other claim term requires an express construction for purposes of this Decision.

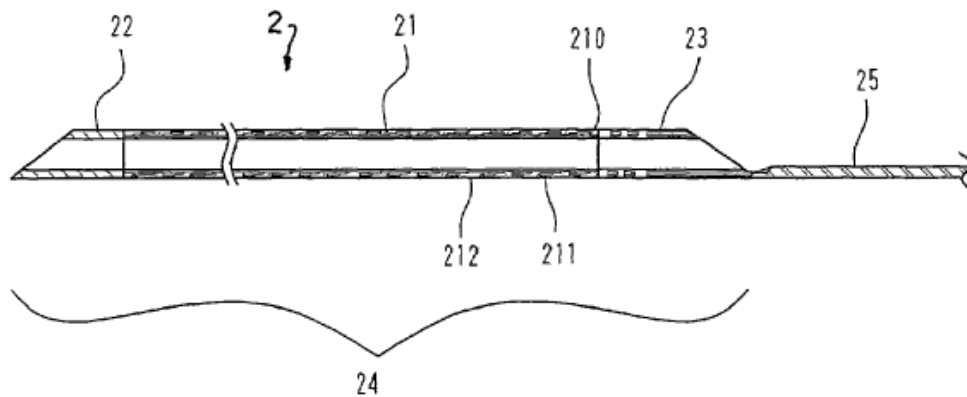
D. Scope and Content of the Asserted References

Petitioner relies on Itou and Ressemann to show the unpatentability of the Challenged Claims. Each of these references is summarized in relevant part below.

1. *Summary of Itou*

Itou, titled “Intravascular Foreign Matter Suction Assembly,” issued on June 15, 201, from a non-provisional application filed September 23, 2005.⁶ Ex. 1007, codes (22), (45), (54). Itou discloses “an intravascular foreign matter suction assembly” designed to suck, sample, and remove “foreign matter such as a thrombus or an embolus” from a blood vessel. *Id.* at 1:6–9, 1:47–49. This assembly includes a guiding catheter and a suction catheter configured to be inserted into the lumen of the guiding catheter. *Id.* at 1:49–65.

Figure 3 of Itou is reproduced below:



⁶ Petitioner contends Itou is prior art under pre-AIA § 102(e). Pet. 17; Pet. Reply 7–26. Patent Owner argues that Itou is not prior, because the method claimed in the ’413 patent purportedly was conceived and reduced to practice prior to the filing date of the application that issued as Itou. PO Resp. 17–37; PO Sur-reply 1–20. In several prior proceedings concerning related patents directed to an apparatus, the Board found Itou was not prior art based on Patent Owner’s showing of an earlier conception and reduction to practice. *See, e.g.*, IPR2020-00126, Paper 129, 12–71. For purposes of this Decision, however, we do not resolve the issue of whether Itou is prior art to the Challenged Claims. For the reasons that follow, we determine that even assuming for the sake of argument that Itou qualifies as prior art to the Challenged Claims, Petitioner has not shown by a preponderance of the evidence the unpatentability of any of the Challenged Claims.

Figure 3 is a cross section of a distal end portion of suction catheter 2. *Id.* at 2:61–62. Suction catheter 2 includes distal side tubular portion 24 and proximal side wire-like portion 25, formed from a solid metal wire and an outer layer such as a polymer coating. *Id.* at 3:46–50. Tubular portion 24 has reinforced tubular portion 21 and flexible distal tip 22. *Id.* at 2:15–51, 3:50–58. Tubular portion 24 has an outer diameter that allows it to be inserted into the lumen of a guide catheter and wire-like portion 25 has a sectional area smaller than the sectional area of the tube wall of tubular portion 24. *Id.* at 3:59–63.

Figure 5 of Itou is reproduced below:

FIG.5

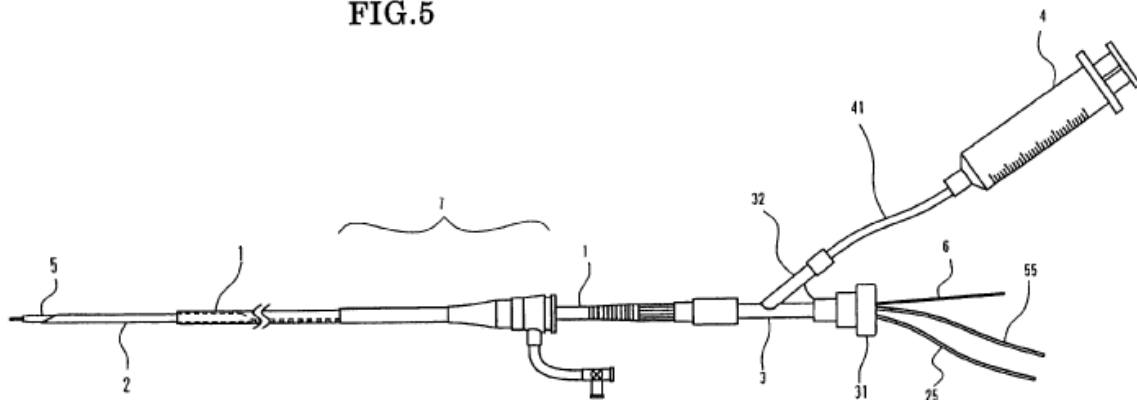


Figure 5 shows the suction assembly “in an assembled state.” *Id.* at 2:66–67. In this state, suction catheter 2 is disposed in the lumen of guiding catheter 1. *Id.* at 5:12–14. The distal end of protective catheter 5 is inserted into the lumen of suction catheter 2 and guide wire 6 is inserted into the lumen of protective catheter 5. *Id.* at 5:14–17. The proximal ends of suction catheter 2, protective catheter 5, and guide wire 6 are “introduced to the outside through main connector portion 31 of Y-shaped connector 3.” *Id.* at 5:17–20. A valve is built into main connector 31 and “can selectively clamp and fix” guide wire 6 and wire-like portions 25 or 55 “to prevent

leakage of the blood.” *Id.* at 5:20–23. In one embodiment, the inner diameter of the guiding catheter is 1.8 mm and the inner diameter of the suction catheter is 1.5 mm. *Id.* at 7:55–67 (Table 1).

A portion of Figure 6 of Itou is reproduced below:

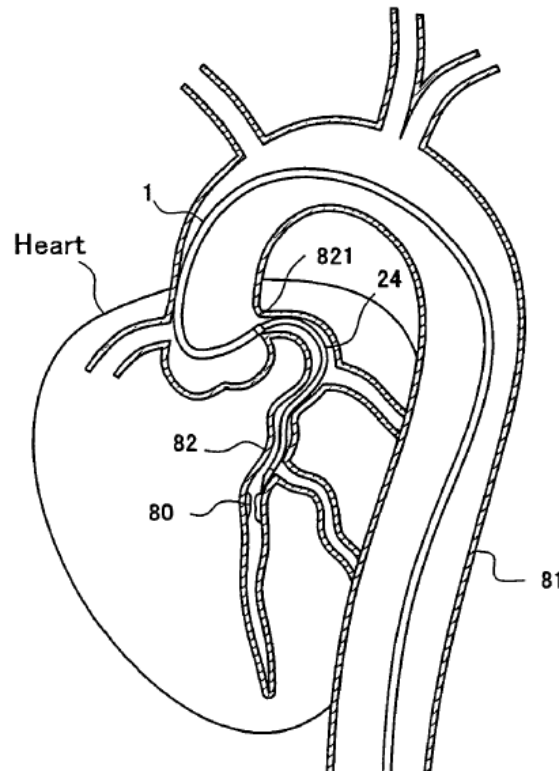


Figure 6 illustrates the disclosed apparatus disposed in a coronary artery of the heart. *Id.* at 3:1–3. In Figure 6, guiding catheter 1 is disposed in aorta 81 and its distal end “is secured in such a form that it is hooked at an ostium 821 of a coronary artery 82.” *Id.* at 5:29–34. Tubular portion 24 of suction catheter 2 is inserted into coronary artery 82 and is introduced along guide wire 6 to target location 80. *Id.* at 5:35–38. According to Itou, tubular portion 24 of suction catheter 2 has a “sufficient axial length so that the proximal end of the tubular portion 24 in an open state may not leap out from the distal end of the guiding catheter 1.” *Id.* at 5:38–41.

2. Summary of Ressemann

Ressemann is directed to an apparatus “used to prevent the introduction of emboli into the bloodstream during and after surgery performed to reduce or remove blockage in blood vessels.” Ex. 1008, 1:13–16. Figures 1A and 1B of Ressemann are reproduced below:

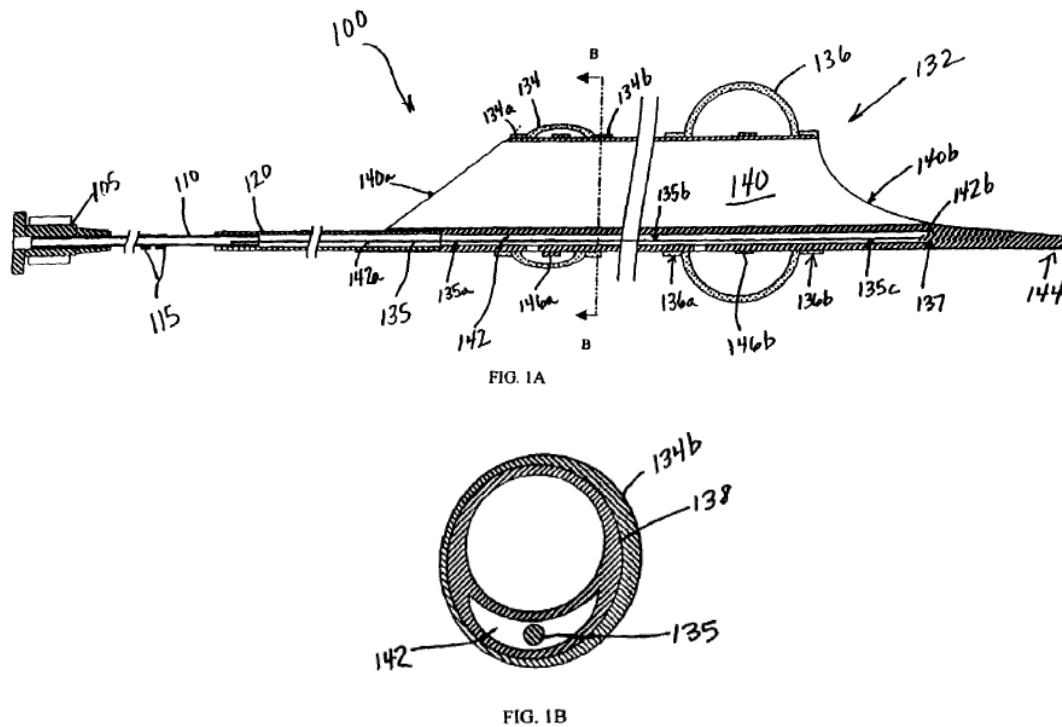


Figure 1A is a cross-sectional view of a partial length evacuation sheath. *Id.* at 3:16–18. Figure 1B is a cross-sectional view of the partial length evacuation sheath of Figure 1A, taken along line 1B-1B of Figure 1A. *Id.* at 3:19–20.

Figure 1A depicts evacuation sheath assembly 100, which “is sized to fit inside a guide catheter” and be advanced “into a blood vessel to treat a stenosis.” *Id.* at 6:18–24, Fig. 5A. Evacuation sheath assembly 100 includes a shaft having proximal shaft portion 110, intermediate shaft portion 120, and distal shaft portion 130 (not shown in Figure 1A). *Id.* at 10:30–35.

Evacuation head 132 includes multi-lumen tube 138 having evacuation lumen 140 and inflation lumen 142 and is preferably made of a relatively flexible polymer. *Id.* at 6:35–64. Evacuation lumen 140 is preferably larger than inflation lumen 142 and “is designed to allow for the passage of interventional devices such as, but not limited to, stent delivery systems and angioplasty catheters.” *Id.* at 6:44–47. Proximal and distal ends of evacuation lumen 140 are angled to allow for smoother passage of evacuation sheath assembly 100 through a guide catheter and to facilitate smoother passage of other therapeutic devices through evacuation lumen 140. *Id.* at 6:52–57. According to Ressemann, “[t]he larger area of the angled open ends also allows for larger deformable particulate matter to pass through the lumen more smoothly.” *Id.* at 6:58–60.

Stiffness transition member 135 is attached to the distal end of proximal shaft portion 110, “is located co-axially in the inflation lumen 142,” and extends to soft tip 144. *Id.* at 11:30–39. Inflation lumen 142, having open proximal end 142a and closed distal end 142b, is designed to provide fluid to inflate balloons on evacuation head 132. *Id.* at 6:61–64.

In use, a guiding catheter is directed to a blood vessel and then a coronary guide wire is advanced to a location just proximal to the distal tip of the guiding catheter. *Id.* at 12:9–14. Evacuation sheath assembly 100 is then advanced over the guide wire and positioned within the blood vessel. *Id.* at 12:19–21. In this process, evacuation head 132 is positioned with its distal end within the blood vessel while its proximal end remains in the guiding catheter. *Id.* at 12:37–39. Sealing balloons 136 and 134 are then inflated to provide a fluid seal between the sealing balloons and the blood vessel. *Id.* at 12:40–45.

Figure 6D of Ressemann is reproduced below:

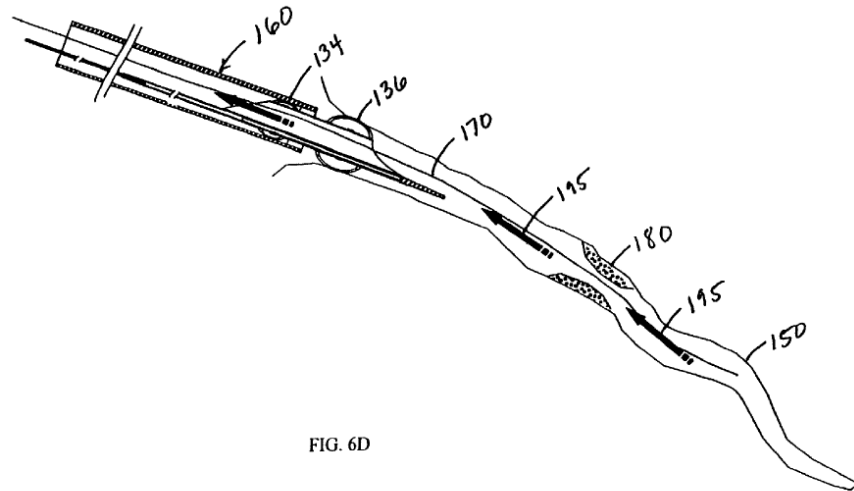


Figure 6D is a cross-sectional view of the partial length evacuation sheath of Figures 1A and 1B deployed within a blood vessel. *Id.* at 3:59–61. Guidewire 170 may be advanced beyond stenosis 180 in blood vessel 150. *Id.* at 13:3–16. A therapeutic device, such as a stent, may then be advanced over guide wire 170 and across stenosis 180. *Id.* at 13:57–60. As indicated by arrows 195, blood flow within the blood vessel is directed towards evacuation sheath 100. *Id.* at 13:35–41. According to Ressemann, “[t]his retrograde flow will carry any dislodged material out of the patient and into a collection chamber.” *Id.* at 13:43–44.

E. Alleged Anticipation by Itou

Petitioner asserts that claims 1, 2, 4, and 7–14 of the ’413 patent are anticipated by Itou. Pet. 7, 21–70; Pet. Reply 26–30. Patent Owner disputes Petitioner’s contentions. PO Resp. 37–42; PO Sur-reply 20–22.

1. Differences Between the Subject Matter of Independent Claim 1 and Itou

Claim 1 recites a method comprised of six steps. Ex. 1001, 10:28–11:6. To show anticipation by Itou, Petitioner relies only upon Itou’s teaching of a “preassembled” combination of protective catheter 5 and

suction catheter 2 being inserted together into guiding catheter 1 to show that the requirements of limitation 1.f are met. *See* Pet. 49. Petitioner’s argument that Itou anticipates claim 1, however, is premised on Petitioner’s proposed construction of claim 1 under which steps of claim 1 need not be performed in the order written. *See, e.g., Id.* at 49 n.12. For the reasons provided above, we reject Petitioner’s proposed construction and find that the steps of claim 1 must be performed in the order written. *See supra* Section II.C.1. Petitioner does not contend, much less show, that Itou discloses the steps of the method of claim 1, performed in the order written; therefore, we determine Petitioner has not shown by a preponderance of the evidence that claim 1 is anticipated by Itou.⁷

Additionally, claim 1 requires that the interventional cardiology device be advanced “into contact with or past a lesion in the second artery.” Ex. 1001, 10:28–11:6. Petitioner provides no persuasive explanation as to how Itou necessarily discloses this limitation, and instead merely asserts in the Petition that “Itou explains that ‘the distal end of the combination of the suction catheter 2 and the distal end protective catheter 5 is inserted *to the target location 80.*’” Pet. 50 (quoting Ex. 1007, 7:1–27 (emphasis added); *see also id.* at 7:20–23 (discussing positioning suction catheter 2 “to a location in front of a thrombus 80”). Petitioner does not expressly contend in the Petition that a “target location” is necessarily the site of a lesion.

⁷ Patent Owner argues that, contrary to Petitioner’s contentions, protective catheter 5 of Itou does not correspond to the recited “interventional cardiology device.” PO Resp. 37–40. For purposes of this Decision, we do not resolve this issue because, even assuming for the sake of argument that protective catheter 5 is an “interventional cardiology device,” Petitioner has not shown by a preponderance of the evidence the unpatentability of any of the Challenged Claims.

Petitioner cites the declaration of Dr. Becker in support, but his testimony mirrors the language in the Petition with no further explanation. Pet. 50 (citing Ex. 1005 ¶¶ 223, 225).

To that point, Patent Owner argues, and we agree, “[e]ven if Itou’s protective catheter is advanced to a ‘target location,’ this does not indicate it comes ‘into contact with’ a ‘lesion.’” PO Resp. 39 (citing Ex. 2138 ¶¶ 153–154; Ex. 2145 ¶ 125). Patent Owner further explains that Itou is directed to a suction catheter used to suction thrombus and employs a method whereby protective catheter 5 (what Petitioner contends corresponds to the recited “interventional cardiology device”) is removed, and then the suction catheter is positioned “in front of a thrombus.” *Id.* (quoting Ex. 1007, 1:1–27). Thus, we agree with Patent Owner that Petitioner identifies no disclosure in Itou of protective catheter 5 being advanced into contact with or past a lesion, as required by claim 1. Itou only discloses protective catheter 5 is “inserted to the target location 80.” Ex. 1007, 7:16–23 (further explaining that protective catheter 5 “is pulled out” and suction catheter 2 is “operated so as to be rotated, pushed or pulled until the distal end opening thereof is introduced to a location in front of a thrombus 80”). Mr. Keith explains in this regard that a person of ordinary skill in the art would have understood that “thrombus” refers to “a blood clot attached to the wall of a blood vessel,” whereas a “lesion” refers to “a buildup of plaque on the vessel wall.” Ex. 2138 ¶ 155.

In reply, Petitioner argues, “the ‘vast majority of the time,’ thrombi are associated with underlying lesions.” Pet. Reply 27 (citing, e.g., Ex. 1846, 100:7–10; Ex. 1806 ¶¶ 51–53). Petitioner’s argument effectively concedes that Itou does not anticipate claim 1, because even if “the vast majority of the time” thrombi “are associated” with a lesion, Petitioner

concedes thrombi are not necessarily “associated” with a lesion in all instances. *Id.* We credit the testimony of Dr. Graham, who explained, “[m]ost thrombus have a lesion underneath, but a small proportion are de novo in situ thrombus.” Ex. 1846, 100:5–21. In support of Petitioner, Dr. Brecker suggests a person of ordinary skill in the art would have understood merely from Figure 6 of Itou that “there was a lesion at target location 80.” Ex. 1806 ¶ 53. Figure 6 of Itou does not identify a lesion and even if Dr. Brecker’s suggestion that “the overwhelming majority of intercoronary thrombus form on a pre-existing atherosclerotic lesion” is correct, that, again, only suggests a possibility of the presence of a lesion in target area 80, as shown in Figure 6 of Itou. To the extent Petitioner is making an inherency argument in support of anticipation, its argument fails. “To establish inherency, the extrinsic evidence ‘must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill.’” *In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999) (citations omitted). “Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.”” *Id.*

Thus, merely showing a possibility that a lesion is located in the “target area” disclosed in Itou is insufficient to show that Itou teaches advancing the interventional cardiology device “into contact with or past a lesion in the second artery,” as required by claim 1. Indeed, even if we assume for the sake of argument that target area 80 of Itou includes a lesion, Petitioner has not shown that Itou discloses protective catheter 5 is, in fact, necessarily advanced “into contact with or past a lesion,” as required by claim 1. *See* Ex. 1007, 7:16–26 (stating only that protective catheter 5 is

“inserted to the target location 80,” after which the suction catheter is positioned and suction is used “to recover foreign matter in the blood vessel such as the thrombus”). Accordingly, Petitioner also has not shown by a preponderance of the evidence that Itou discloses step 1.f of claim 1 and, therefore, fails to show Itou anticipates claim 1.

2. Differences Between the Subject Matter of Dependent Claims 2, 4, and 7–14 and Itou

Each of dependent claims 2, 4, and 7–14 depend from claim 1. Ex. 1001, 11:7–13, 11:17–21, 11:34–12:38. Having failed to show by a preponderance of the evidence that claim 1 is anticipated by Itou, Petitioner necessarily fails to show that any of claims 2, 4, and 7–14 is anticipated by Itou for the same reasons provided above with regard to claim 1, from which they each depend.

3. Conclusion on Anticipation by Itou

For the reasons provided above, we determine that Petitioner has not shown that Itou discloses the steps of claim 1, performed in the order written, or that Itou discloses “advancing the interventional cardiology device through and beyond a lumen of the flexible tip portion into contact with or past a lesion,” as required by all of the Challenged Claims. Accordingly, Petitioner has not shown by a preponderance of the evidence that Itou anticipates any of the Challenged Claims.

F. Alleged Obviousness Over Itou

Petitioner asserts that claims 1, 2, 4, 5, and 7–14 of the ’413 patent would have been obvious over Itou. Pet. 7, 70–77; Pet. Reply 30–35. Patent Owner disputes Petitioner’s contentions. PO Resp. 37–42; PO Sur-reply 20–22.

1. Differences Between the Subject Matter of Independent Claim 1 and Itou

Petitioner argues that it would have been obvious to perform the steps of claim 1 in the order written based on the teachings of Itou and the knowledge of a person of ordinary skill in the art. Pet. 70–71 (citing Ex. 1005 ¶¶ 244–45). According to Petitioner, Itou teaches:

- a catheter assembly with guiding catheter 1 (corresponding to the recited “standard guide catheter”);
- suction catheter 2 (corresponding to the recited “coaxial guide catheter”) disposed in the lumen of guiding catheter 1;
- protective catheter 5 (corresponding to the recited “interventional cardiology device”) disposed in the lumen of suction catheter 2; and,
- guide wire 6 (corresponding to the recited “guidewire”) disposed in the lumen of protective catheter 5.

Pet. 17–19, 25, 31, 34, 49; Ex. 1007, 5:12–17, Fig. 5.

Petitioner concedes that, if the steps of claim 1 must be performed in the order written (as we found above), then Itou does not disclose inserting the interventional cardiology device (allegedly, protective catheter 5 of Itou) as required by step 1.f *after* advancing the coaxial guide catheter (allegedly, suction catheter 2 of Itou) beyond the standard guide catheter (allegedly, guiding catheter 1 of Itou), as required by step 1.e of claim 1. Pet. 70–72. Specifically, Petitioner argues as follows:

Itou discloses “an example of a method of use,” wherein at “the distal end protective catheter 5”—an interventional cardiology device—“is inserted into the guiding catheter 1 along the guide wire 6.” Ex-1007, 7:1–27. The protective catheter (5) is inserted into suction catheter (2) preassembled. *Id.*, 7:13–15; Ex-1005, ¶ 250–55. A POSITA would understand that suction

catheter (2) could, however, be inserted first (separately) followed by a different interventional cardiology device. Ex-1005, ¶ 256.

Pet. 73; *see also id.* at 49 (stating that “protective catheter (5) is inserted into catheter (2)—i.e. ‘preassembled’—before the combination of protective catheter (5) and catheter (2) (with its ‘substantially rigid portion’) are inserted into the [guide catheter] (1) together”) (citing Ex. 1007, 7:13–15; Ex. 1005 ¶ 221).

From the outset, Petitioner’s argument is unclear with regard to the modification it proposes. Petitioner states a “*different* interventional cardiology device” is used, suggesting that it is used *in place of* protective catheter 5, which Petitioner previously asserted corresponded to the “interventional cardiology device” of claim 1. Petitioner also reorders the operation of Itou, suggesting that instead of introducing protective catheter 5 prior to suction catheter 2, a person of ordinary skill in the art would have introduced “a different interventional cardiology device” after introducing suction catheter 2 “first (separately)”. *Id.* We note in this regard that Petitioner never characterized in the Petition the “different interventional cardiology device” as an “additional interventional cardiology device” or suggested it is “in addition” to protective catheter 5. Moreover, Petitioner’s argument that suction catheter 2 could be inserted “first (separately)” strongly suggests Petitioner proposes inserting suction catheter 2 alone, without protective catheter 5.

After Patent Owner addressed in detail why protective catheter 5 and suction catheter 2 are necessarily preassembled outside the body, and inserted together, Petitioner’s proposed modification appears to have shifted. *See* PO Resp. 44 (explaining that suction catheter 2 and protective catheter 5

must be preassembled outside the body for the protective catheter to serve its intended purpose of “protecting the distal bed of the suction catheter 2 when the suction catheter 2 is advanced,” by allowing the distal end of protective catheter 5 to be positioned beyond the distal end of suction catheter 2 before both are inserted in combination into the guide catheter) (citing Ex. 1007, 6:39–41, 7:13–18; Ex. 2138 ¶ 172; Ex. 2145 ¶ 129)). In Reply, Petitioner argues that “once [suction] catheter 2 is in place, [protective] catheter 5 is withdrawn (Ex.-1007, 7:16–19), which means that catheter 2 is in precisely the right location to deliver an [interventional cardiology device] other than catheter 5 (such as a balloon catheter or stent) into the coronary artery.” Pet. Reply 30–31 (citing Ex. 1001, 14:6–25; Ex. 1007, 5:35–42, Fig. 6, Table 1). Petitioner may not modify its contentions in its Reply in such a manner. *See Henny Penny Corporation v. Frymaster LLC*, 938 F.3d 1324, 1330–31 (Fed. Cir. 2019) (“[A]n IPR petitioner may not raise in reply ‘an entirely new rationale’ for why a claim would have been obvious.”); 37 C.F.R. § 42.23(b).

Nonetheless, even if we consider Petitioner’s proposal to modify the method of Itou to use suction catheter 2, after being placed, and after protective catheter 5 is removed, to insert some “different interventional cardiology device” into suction catheter 2, we find Petitioner’s identification in the prior art of the elements claimed insufficient. Petitioner does not suggest that Itou teaches the “different interventional cardiology device” that Petitioner relies upon to purportedly show obviousness of the method of claim 1 over Itou, alone. *See generally* Pet. Nor does Petitioner show what knowledge of a person of ordinary skill in the art, or the basis for that knowledge, Petitioner relies upon to fill the missing gap in Itou of what Petitioner calls “a different interventional cardiology device.” *See* Pet. 70–

75. Although Petitioner purports to rely on the testimony of Dr. Brecker, Dr. Brecker suggests that his opinion is premised on the '413 patent itself as providing “four exemplar ‘interventional cardiology devices.’” Ex. 1005

¶ 257. Dr. Brecker also identifies several examples of interventional cardiology devices that purportedly could have fit within Itou’s suction catheter. *Id.* Claim 1, however, is directed to a method and it remains undisputed that Itou does not teach or suggest inserting *any* “different interventional cardiology device” into the suction catheter of Itou and there is no evidence to suggest a person of ordinary skill in the art would have known to insert different interventional cardiology devices down suction catheter 2 of Itou. *See generally* Ex. 1007. In sum, Itou does not disclose step 1.f and that deficiency is not cured by pointing to a person of ordinary skill in the art’s mere knowledge of the size of Itou’s suction catheter and the size of various interventional cardiology devices that would fit within the suction catheter. Missing from Petitioner’s contentions is any disclosure in Itou or the knowledge of a person of ordinary skill in the art of the method required by step 1.f, performed in the order written. Accordingly, Petitioner fails to show by a preponderance of the evidence that each limitation of claim 1 is taught or suggested by Itou in light of the knowledge of a person of ordinary skill in the art.

2. Differences Between the Subject Matter of Dependent Claims 2, 4, 5, and 7–14 and Itou

Each of dependent claims 2, 4, 5, and 7–14 depend from claim 1. Ex. 1001, 11:7–13, 11:17–21, 11:34–12:38. Having failed to show by a preponderance of the evidence that each limitation of claim 1 is taught or suggested by Itou in light of the knowledge of a person of ordinary skill in the art, Petitioner necessarily fails to show how each limitation of claims 2,

4, 5, and 7–14 is taught or suggested by Itou in light of the knowledge of a person of ordinary skill in the art.

3. *Reasons for the Modification of Itou*

The entirety of Petitioner’s rationale for modifying the method of operation of Itou turns on Petitioner’s assertion that a person of ordinary skill in the art would have known that “a different interventional cardiology device” *could* be inserted into suction catheter 2 of Itou. Pet. 72. Petitioner cannot establish obviousness by merely showing what physically “could” be done, without articulating a persuasive reason why a person of ordinary skill in the art would have had reason to or been motivated to modify modified the method of Itou in the manner suggested to perform the method recited in claim 1. *See In re NuVasive*, 842 F.3d at 1382 (explaining that a showing of obviousness requires an articulated reason why a person of ordinary skill in the art would have combined the prior art references).

To begin, we note that according to Dr. Brecker, a person of ordinary skill in the art would understand performing the steps of claim 1 in the order written “to be obvious and to require no alteration of Itou’s assembly.” Ex. 1005 ¶ 245. As explained above, however, Petitioner relies on “a different interventional cardiology device” from what Petitioner identified in Itou as purportedly corresponding to the recited “interventional cardiology device.” Petitioner also proposes using Itou’s suction catheter 2 *not as a suction catheter*, but to instead convey a different interventional cardiology device into the vasculature. The suggestion that “no alteration” of Itou’s assembly is required fails to address the substantial alteration of Itou’s method and modification of Itou’s device to include new elements not taught by Itou. In this regard, Dr. Brecker confirmed that Itou does not describe any function

for the suction catheter other than suctioning thrombi in a distal to proximal direction. Ex. 2116, 94:1–11.

To the extent Petitioner’s argument is limited to proposing that Itou’s protective catheter 5 is replaced with a “different interventional cardiology device” to be inserted after suction catheter 2, we agree with Patent Owner’s arguments as follows:

Itou is a suction catheter, not an extension catheter. Ex-1007; Ex-2138, ¶¶113, 161, 184; Ex-2244, 68:18–24, 69:25–70:4; Ex-2245, 98:8–10, 99:4–13. Itou’s protective catheter’s purpose is protecting the blood vessel from the suction catheter’s sharp tip. Ex-2138, ¶184; Ex-1007, 2:9–11, 4:43–52, 6:35–40; Ex-2245, 101:1–17; Ex-2244, 74:23–75:6. There is no reason why a [person of ordinary skill in the art] would be motivated to insert the bare pointed suction catheter first and *alone*, and then try to insert the protective catheter after the tip of the suction catheter was already in the vasculature—this would negate the very purpose of the protective catheter. *Id.*

PO Resp. 49.

Even if Petitioner’s proposed modification includes placing Itou’s suction catheter 2 with the aid of protective catheter 5, then removing protective catheter 5 and introducing “a different interventional cardiology device, Petitioner fails to provide any persuasive rationale for such modification. Although Petitioner specifically offers three additional arguments, none of these arguments explains why a person of ordinary skill in the art would have had reason to modify Itou’s device and method of operation to perform the method recited in claim 1. *See* Pet. 72–75.

First, Petitioner asserts that “Itou’s assembly could be used such that an ‘interventional cardiology device’ is inserted into and through the continuous lumen of Itou’s suction catheter.” *Id.* at 72–73 (citing Ex. 1005 ¶ 257; Ex. 1007, 4:48–50, 5:15, Table 1, Fig. 5). This argument is

duplicative of the argument advanced by Petitioner addressed above. In short, even if portions of Itou's assembly *could* be used with a "different interventional cardiology device," taken from elsewhere, the mere possibility of what could be done is insufficient support to show that a person of ordinary skill in the art would have had reason to make such modifications, in the first place. As Patent Owner explains, "[e]ven assuming Itou's inner lumen was large enough to permit passage of [interventional cardiology devices], that is very different than it being obvious to use the lumen of a suction catheter to deliver [interventional cardiology devices]." PO Resp. 43–44 (citing Ex. 2138 ¶ 170; Ex. 2145 ¶¶ 130–31); *see also id.* at 46 (stating that "[n]o matter how big the lumen of the suction catheter [of Itou] is, there is no reason a [person of ordinary skill in the art] would look to use that device, meant for an entirely different purpose, and with a structure requiring insertion of its own protective catheter outside the body, to deliver [interventional cardiology devices] after the suction device is already positioned inside the guide catheter" (citing Ex. 2138 ¶ 177; Ex. 2145 ¶¶ 117, 122, 128–29)). Patent Owner argues that "the primary cardiology experts in this case, for both Petitioner and Patent Owner, have each confirmed that they have never actually used a suction catheter to deliver an [interventional cardiology device] like a stent or balloon." PO Resp. 49 (citing, e.g., Ex. 2116, 94:16–95:1, 98:12–17). While Dr. Brecker clarified that a "mother-and-child catheter" could be used both as a suction catheter and to deliver a balloon, and that other "prior art" describes using a suction catheter to insert a stent, he did not suggest he had personally ever used a suction catheter to deliver a stent or balloon, maintaining that the suction catheters he used were too small. Ex. 2116, 94:16–95:25, 98:12–17. Dr. Brecker states that he has practiced as an

interventional cardiologist for over 24 years, performing at his peak 300–350 coronary stenting procedures per year, and has “proctored over 1,000 coronary stenting procedures” in which he “assisted and taught other physicians how to perform coronary stenting. Ex. 1005 ¶¶ 7–8. Dr. Brecker was asked, “[i]f we go to a suction device like in Itou . . . are you aware of anybody putting a stent down a suction device of that type,” and answered, “I’m not, but it doesn’t mean that you couldn’t do it if you had a device like Itou.” Ex. 2116, 97:9–14. Patent Owner also argues that using a suction catheter to deliver an interventional cardiology device could be dangerous. PO Resp. 49 (citing Ex. 2138 ¶ 185; Ex. 2145 ¶¶ 132–34; Ex. 2240, 14:24–15:13). We credit the testimony of Dr. Graham in this regard, who explains as follows:

Advancing an interventional cardiology device through the lumen of Itou’s suction catheter after suctioning a thrombus creates this same risk of dislodging leftover thrombus. Therefore, for the same reasons described above, a physician would have to clean both Itou’s suction catheter and the guide catheter prior to inserting an interventional cardiology device into Itou’s suction catheter. To do this, the physician would have to completely remove the suction catheter from the body and flush it with saline to remove any residual thrombus retained along the walls of the suction catheter lumen. The physician would also have to disengage the guide catheter from the coronary ostium into the aorta and apply suction to remove any residue that remained in the guide catheter itself. Only after both devices were completely clean could the physician re-engage the guide catheter and reinsert the suction catheter using the process I discussed above. Supra at ¶ 119. This necessary flushing process completely eliminates any of the advantages Dr. Brecker identifies as being associated with using Itou to deliver interventional cardiology devices. E.g., IPR2020-01343, Ex. 1005 at ¶ 206 (“A POSITA would understand that, by using a suction catheter large enough to deliver a therapy catheter, a PCI procedure could be performed without needing to change out

the catheter between suction and stenting operations.”). It would also significantly increase procedure time, which is always undesirable from a patient safety standpoint.

Ex. 2145 ¶ 134. Dr. Brecker suggests that the risks addressed by Dr. Graham “must be balanced against the risks of prolonging the procedure,” and suggests “there is no reason that suction catheter (2) could not be used to sequentially deliver an embolic protection device, and then a stent, and then be used to suction emboli.” Ex. 1806 ¶¶ 75–80.

As explained above, even if you *could* use the device of Itou to insert interventional cardiology devices in place of suctioning a thrombus, or in combination with other procedures, that, alone, isn’t a sufficient reason why a person of ordinary skill in the art would have had reason or been motivated to do so.

Second, Petitioner argues “the inner surface of the tubular portion of suction catheter (2) is suitable for receiving interventional cardiology devices.” Pet. 73–74 (citing Ex. 1005 ¶ 258; Ex. 1007, 3:52–54; Ex. 1017, 5:19–21, 8:1–2; Ex. 1046, 2:32–39; Ex. 1034, 8:29–30; Ex. 1042 ¶¶ 66–67). Even if a surface of a feature of Itou is “suitable” for use in some other method not disclosed by Itou, that is insufficient to show a person of ordinary skill in the art would have had reason to modify the method of Itou to use that surface in conjunction with “a different interventional cardiology device,” in the first place.

Third, Petitioner argues that “PCI [(percutaneous coronary interventional)] is routinely performed in a step-wise fashion, where a catheter is inserted first followed by a different interventional cardiology device.” Pet. 74–75 (citing Ex. 1005 ¶ 259; Ex. 1008, 12:19–30, 13:60–14:10, Figs. 6B, 6E; Ex. 1009, 5:16–18, 7:45–52). According to Petitioner,

if the interventional cardiology device “is not pre-loaded in the lumen of the extension catheter,” “it is easier to manipulate the extension catheter” and “the extension catheter will have greater trackability.” *Id.* (citing Ex. 1005 ¶ 259). Petitioner’s argument is untethered to the method taught by Itou that Petitioner relies upon to purportedly show obviousness. *See* Ex. 2138 ¶ 183 (explaining that Petitioner’s argument of the benefits of not pre-loading is the opposite of what Itou teaches (citing Ex. 1007, 7:13–15)). As Patent Owner explains, “Itou teaches insertion of the protective catheter into the suction catheter outside the body, which combination is then inserted into the guide catheter—contrary to the step-wise procedure Petitioner claims was routine.” PO Resp. 48 (citing Pet. 72; Ex. 1001, 7:13–15; Ex. 2138 ¶ 183). The mere fact that a category of procedures Petitioner refers to as “PCI” includes procedures “routinely performed in a step-wise fashion” sheds no light on why a person of ordinary skill in the art would have had reason to substantially modify the method taught in Itou, including performing steps in a “step-wise” fashion not taught by Itou, to perform the steps of claim 1 of the ’413 patent in the order written. Petitioner’s arguments amount to no more than speculation of what *could* have been done with impermissible hindsight informed by the ’413 patent itself. “Without any explanation as to how or why the references would be combined to arrive at the claimed invention, we are left with only hindsight bias.” *Metalcraft of Mayville, Inc. v. The Toro Company*, 848 F.3d 1354, 1367 (Fed. Cir. 2017). “[W]e cannot allow hindsight bias to be the thread that stitches together prior art patches into something that is the claimed invention.” *Id.* *KSR* cautions a factfinder to be aware of the “distortion caused by hindsight bias” and to be “cautious of arguments reliant upon ex post reasoning. *KSR*, 550 U.S. at 421 (emphasis omitted). Petitioner’s

proposed combination of the cited references does not meet its burden of providing a sufficiently persuasive evidence-based reason why a person of ordinary skill would have selectively gleaned isolated elements from Itou, modified their operation, and then combined them with Ressemann to arrive at the method recited in claim 1.

We further agree with Patent Owner that the evidence of record supports that a person of ordinary skill in the art “would not advance a device into or through Itou *prior to* suction, because the presence of the device inside Itou’s suction catheter would interfere with suction.” PO Resp. 50 (citing Ex. 2138 ¶ 185; Ex. 2240, 16:8–17:22, 18:10-24); *see also id* (stating that a person of ordinary skill in the art “would not advance an interventional cardiology device through a suction catheter,” which is “why no expert in this case ever has done so.” (citing Ex. 2240, 12:12–17; Ex. 2249, 125:25–126:1)).

Lastly, Petitioner maintains, “[i]nserting Itou’s suction catheter (2) first (separately) followed by a different interventional cardiology device would have been nothing more than combining prior art elements according to known methods to yield predictable results.” *Id.* at 75 (citing Ex. 1005 ¶ 259; *KSR*, 550 U.S. at 417). Petitioner’s argument is merely a conclusory statement, which cannot satisfy its burden of proving obviousness. *In re Magnum Oil Tools Int’l, Ltd.*, 829 F.3d at 1380. Petitioner neglects the differences between the prior art and Itou, fails to explain precisely what “different” interventional cardiology device Petitioner proposes to insert, and offers no reason for the modification. Petitioner’s conclusory argument does not show by a preponderance of the evidence what prior art elements are being combined (and specifically, “a different interventional cardiology

device”), does not show what “known method” would have been used to combine those elements, or why the results would have been predictable.⁸

4. Objective Indicia of Nonobviousness

Patent Owner offers evidence directed to long-felt need, commercial success, industry praise, licensing, and copying as objective evidence of nonobviousness only with respect to dependent claims 4, 9, and 14. PO Resp. 55–76. Patent Owner does not identify objective indicia of nonobviousness with regard to claim 1. Because we find that Petitioner fails to show that claim 1 would have been obvious over Itou, and, therefore, has not shown that any claim depending from claim 1 would have been obvious, we do not reach the issue of whether Patent Owner’s evidence of indicia of nonobvious supports the nonobviousness of claims 4, 9, and 14.

5. Collective Consideration of the Graham Factors

Petitioner has not shown that Itou discloses every step of the method recited in claim 1, performed in the order written, and has not provided a sufficient reason in support of the modification of Itou’s method proposed by Petitioner. We do not reach the merits of Patent Owner’s evidence of

⁸ Petitioner, in its Reply, conflates its arguments directed to obviousness over Itou, alone, with its arguments directed to obviousness over Itou in combination with Ressemann. Pet. Reply 30–35; *see also* PO Sur-reply 26 (observing that because Petitioner’s Reply “consolidates” arguments with regard to obviousness over Itou, alone, and in combination with Ressemann, “[i]t is difficult to determine which arguments apply to which Grounds, but Petitioner’s arguments appear to all rely on Ressemann, indicating no reply in support of [obviousness over Itou, alone].”). We address Petitioner’s additional Reply arguments in our discussion of obviousness over Itou and Ressemann, as Petitioner frequently refers to Ressemann in its arguments, and find the arguments unpersuasive with respect to alleged obviousness over Itou, alone, for substantially the same reasons provided below with respect to Itou in combination with Ressemann.

indicia of nonobviousness, because we find, even without considering that evidence, Petitioner fails to show any of claims 1, 2, 4, 5, and 7–14 would have been obvious over Itou. On the whole, we find that the information provided by Petitioner and Patent Owner in consideration of the *Graham* factors collectively demonstrates that Petitioner has not shown by a preponderance of the evidence that the subject matter of claims 1, 2, 4, 5, and 7–14 of the '413 patent would have been obvious over Itou.

G. Alleged Obviousness Over Itou and Ressemann

Petitioner asserts that claims 1, 2, 4, 5, and 7–14 of the '413 patent would have been obvious over Itou in combination with Ressemann. Pet. 7, 77–95; Pet. Reply 30–35. Patent Owner disputes Petitioner's contentions. PO Resp. 51–55; PO Sur-reply 26–30.

1. Differences Between the Subject Matter of Independent Claim 1 and the Teachings of Itou and Ressemann

Petitioner argues if Itou “does not supply the teaching to actually pass [an interventional cardiology] device through Itou's [general catheter] or suction catheter,” or “do so” in the order written in claim 1, then it would have been obvious over Itou in view of Ressemann. Pet. 77. Petitioner asserts that a person of ordinary skill in the art would have understood “that Itou's assembly could be used such that an ‘interventional cardiology device’ is inserted into and through the continuous lumen of Itou's [guide catheter] (1) and suction catheter (2). *Id.* at 81. Petitioner further asserts that “the inner surface of the tubular portion of suction catheter (2) is suitable for receiving a stent or balloon catheter, such as that taught by Ressemann.” *Id.* Thus, it is our understanding that Petitioner relies on Ressemann as teaching the “other interventional cardiology device” missing

from Petitioner's assertion that claim 1 would have been obvious over Itou, alone.

Petitioner, however, provides no limitation-by-limitation analysis of claim 1 in the Petition to show how it contends the combination of Itou and Ressemann teaches or suggests each step of the method of claim 1, performed in the order written. *See* Pet. 77–83. As such, it is unclear precisely what features of the method of Itou are retained and what features of the method of Ressemann are applied to Itou according to Petitioner. *See* Pet. 77–81. Specifically, Petitioner does not directly address whether in its asserted combination protective catheter 5 of Itou continues to be used in conjunction with suction catheter 2. We note in this regard that Dr. Brecker provides only an incomplete claim chart discussing limitations 1.a and 1.f, but does not address the other steps of claim 1. Ex. 1005 ¶¶ 315–324.

Petitioner explains that Ressemann teaches inserting guide catheter 160 into an artery over guide wire 170, then advancing over guidewire 170 evacuation sheath assembly 100 with a proximal end opening “large enough to ‘allow the passage of most therapeutic devices such as angioplasty catheters, stent delivery catheters, [and] atherectomy catheters.’” Pet. 78–79 (citing Ex. 1008, 10:17–20, 12:3–4, 12:9–14, 12:19–30, 28:54–55, Figs. 6A, 6B). According to Petitioner, Ressemann expressly discloses inserting stent delivery catheter 193 (which Petitioner calls “a balloon catheter with a stent”) into evacuation sheath assembly 100 and advancing it until it is “positioned adjacent the stenosis 180.” *Id.* at 80–81 (citing Ex. 1005 ¶¶ 271–74; Ex. 1008, 6:25–34, 12:3–14, 12:19–40, 13:55–14:14, 29:56–59, Figs. 6A–F).

In this regard, according to Dr. Brecker, Itou teaches the “distal end of the combination of the suction catheter 2 and the distal end protective

catheter 5 is inserted to the target location 80.” *Id.* at ¶ 321 (quoting Ex. 1007, 5:43–45). Dr. Brecker then turns to Ressemann, as disclosing evacuation sheath assembly 100 should be positioned before a stent delivery system is advanced into guide catheter 160. *Id.* Thus, Dr. Brecker states “Ressemann teaches not to preassemble any telescoping structure prior to a device being inserted into the continuous lumen of the guide catheter.” *Id.* Dr. Brecker implies that protective catheter 5 of Itou would be left out of Petitioner’s proposed combination, noting that “in using the suction catheter (2) to deliver a balloon or stent, as taught by Ressemann, a [person of ordinary skill in the art] would be motivated to follow the non-preassembly insertion steps of Ressemann.” *Id.* at ¶ 322. Dr. Brecker, however, neglects to address any negative consequence to this approach.

2. Dependent Claims 2, 4, 5, and 7–14

Each of dependent claims 2, 4, 5, and 7–14 depend from claim 1. Ex. 1001, 11:7–13, 11:17–21, 11:34–12:38. Petitioner argues that the combination of Itou and Ressemann teaches or suggests each of the additional limitation of these dependent claims. Pet. 83–95. We do not reach these additional arguments, because we find Petitioner fails to carry its burden of showing claim 1 would have been obvious over the combination of Itou and Ressemann for the reasons below, and, therefore, necessarily fails to show claims 2, 4, 5, and 7–14 would have been obvious over the combination of Itou and Ressemann.

3. Reasons for the Combination of Itou and Ressemann

Petitioner purports to show that the method of claim 1, performed in the order written, would have been obvious over Itou in view of Ressemann, because: (1) “Itou’s assembly could be used such that an ‘interventional cardiology device’ is inserted into and through” Itou’s guide catheter and

suction catheter; and, (2) the “inner surface” of Itou’s suction catheter is “suitable for receiving a stent or balloon catheter, such as that taught by Ressemann.” Pet. 81. Petitioner’s arguments mirror arguments made by Petitioner with respect to obviousness over Itou, alone, which we reject for substantially the same reasons provided above.

Even if Itou’s assembly “could” be used with an interventional cardiology device taught by Ressemann, and even if Itou’s inner surface would have been “suitable” for use with an interventional cardiology device taught by Ressemann, neither of these provide a sufficient reason why a person of ordinary skill in the art would have made the modification to Itou’s method proposed by Petitioner. As Patent Owner succinctly points out, Petitioner offers no persuasive reason why a person of ordinary skill in the art would have been “motivated to try to insert [interventional cardiology devices] through Itou’s suction catheter.” PO Resp. 51–54 (citing Ex. 2138 ¶¶ 191–202; Ex. 2145 ¶¶ 123–34).

As further support, Petitioner argues that both Itou and Ressemann “disclose devices that address the same problem in the same way—removing coronary vessel occlusions by using an aspiration catheter.” Pet. 81 (citing Ex. 1005 ¶¶ 271–87; Ex. 1007, Abstract, 1:13–16; 2:2–5, 2:29–38, 3:59–61, 5:32–34, 7:10, Figs. 1A, 1B, 5, 6; Ex. 1008, Abstract, 6:18–24, 12:9–12, 12:19–30, Figs. 6A–B). Petitioner also argues that, “[a]s Dr. Brecker explains, those working in the field knew that angioplasty or stent delivery ‘may break free fragments of friable plaque,’” and further asserts that “there was a motivation to combine stent delivery with the use of an embolic protection device” and a “reasonable expectation of success,” because “it was beneficial to be able to remove emboli from a coronary artery when

delivering a stent.” *Id.* at 81–82 (citing Ex. 1005 ¶ 277–288; Ex. 1015, 629–30, 1285; Ex. 1029, 174, 176).

Further, Petitioner argues as follows:

Additionally, using a suction catheter large enough to deliver a therapy catheter ensures that a PCI procedure can be completed without having to switch catheters between suction and stenting. Ex-1005, ¶ 289. Indeed, Ressemann identifies a potential “need for more therapeutic steps, e.g., further dilation of the stent with the balloon,” where “it is more convenient to have the balloon catheter already in position for any subsequent use.” Ex-1008, 14:29–34.

Itou’s prosecution history also demonstrates that it was appropriate to combine Itou and Ressemann. During prosecution of Itou, the Examiner rejected pending claims on a suction assembly based on a prior, angioplasty balloon catheter, because the latter was “capable of being an intravascular foreign matter suction assembly.” Ex-1021, 3. Claims were also rejected over the same art in combination with a prior aspiration catheter because—at the time of the invention—the references were analogous art, and it would have been obvious to combine angioplasty with removal of emboli. *Id.*, 4-5; Ex-1005, ¶¶ 290–314.

Pet. 82–83.

We have considered each of Petitioner’s arguments and determine that Petitioner neglects to address the differences between the Challenged Claims and the asserted combination of Itou and Ressemann, as required by *Graham*. See 383 U.S. at 17–18. As Patent Owner shows, contrary to Petitioner’s assertion, “Itou and Ressemann do not actually ‘address the same problem in the same way.’” PO Resp. 52. In particular, Ressemann discloses “embolic protection” devices and Itou is not an embolic protection device. *Id.* at 52–55. We find persuasive, and adopt as our own findings based on the cited evidence, Patent Owner’s following discussion:

Petitioner argues that a “POSITA would look to Ressemann when considering Itou because both references disclose devices that address the same problem in the same way—removing coronary vessel occlusions by using an aspiration catheter.” Petition, 81. Petitioner then contends that because PCI procedures such as angioplasty or stent delivery “may break free fragments of friable plaque,” there “was a motivation to combine stent delivery with the use of an embolic protection device.” Petition, 81-82. But contrary to these assertions, Itou and Ressemann do not actually “address the same problem in the same way.” Moreover, Itou is neither a stent delivery device nor an embolic protection device, and would not have been expected to be useful in mitigating pieces of friable plaque that may break free during treatment. Ex-2138, ¶¶191, 196; Ex-2145, ¶¶169–70.

Ressemann discloses “embolic protection” devices designed to occlude a vessel to stop blood flow and catch/remove the shower of particulates (“emboli”) released while treating a lesion. Ex-1008, 2:56–61, 6:18–19; Ex-2138, ¶¶119, 194–196; Ex-2145, ¶¶135–36, 171. Ressemann uses “sealing balloons” inflated against the blood vessel walls and the guide catheter to block blood flow while the treatment is performed to ensure particulates broken free during a procedure are not carried downstream. Ex-1008, Abstract, 1:13-16; Ex-2138, ¶¶119, 194–196; Ex-2145, ¶¶136, 171. Because blood flow is blocked during treatment, the distal tip of Ressemann’s device need not be advanced to the embolic particles to be aspirated, and Ressemann does not require a large suction force. Ex-2138, ¶¶119, 194–196; Ex-2145, ¶¶171–72. Thus, [interventional cardiology devices] inserted through the same suction lumen do not interfere with the capture of the dislodged debris. Ex-2138, ¶¶119, 194–196; Ex-2145, ¶172. Ressemann’s sealing balloons are a fundamental aspect of it being an “embolic protection device”; without the balloons, Ressemann provides no embolic protection.

Itou is not an embolic protection device. Ex-2138, ¶196; Ex-2145, ¶170. Petitioner’s experts agree. Ex-2244, 70:5–16; Ex-2245, 99:10–19. Instead, it is designed to target and remove pre-existing thrombus from a “target location.” Ex-1007, 1:64–65; *see also id.*, 1:47–53, 2:27–42, 7:1–27; Ex-2138, ¶¶118, 196–198; Ex-2145, ¶170. This does not require occluding blood flow,

and Itou has no features that would occlude a vessel. Ex-2138, ¶¶197, 199; Ex-2145, ¶¶170, 173; Ex-2245, 152:5–11. Because Ressemann functions so differently from Itou, a [person of ordinary skill in the art] would not be motivated by Ressemann to alter the process described by Itou. Ex-2138, ¶¶191–202; Ex-2145, ¶¶166–73.

Furthermore, there is no reason why a POSITA would want or need to insert a device through Itou, and Itou does not disclose doing so. Ex-2138, ¶¶113, 177, 191; Ex-2145, ¶173; Ex-2245, 99:4–9, 149:25–150:1; Ex-2244, 70:2–4. In fact, inserting an [interventional cardiology device] through Itou’s lumen would block Itou’s distal tip from properly interacting with and aspirating a thrombus or embolus. Ex-2138, ¶¶198, 201. Because Itou’s device does not stop blood flow, maximizing suction is particularly important, as Itou itself recognizes. Ex-1007, 4:4–15, 5:51–52; Ex-2138, ¶199.

Moreover, when a suction device is used to aspirate thrombotic material, residual debris invariably is left in the catheter. Ex-2145, ¶¶132–34; Ex-2244, 136:18–137:3. If the suction catheter were then used to introduce an [interventional cardiology device] (which it would not be), the presence of such residual debris creates a real risk of pushing out smaller, more mobile pieces of residual thrombotic material from the catheter and embolizing these further into the vascular system being treated. *Id.* Dr. Brecker, Petitioner’s own expert, admits that there is a risk of pushing residual thrombotic material downstream when a stent is advanced through a suction catheter, and that removing the suction catheter to flush it outside the body brings its own risks by prolonging the procedure. Ex-2240, 13:25–15:16.

Id. at 52–55.

In reply, Petitioner argues that Itou’s suction catheter (2) “is in precisely the right location to deliver an [interventional cardiology device] other than catheter 5 (such as a balloon catheter or stent) into the coronary artery.” Pet. Reply 31. Again, even if true, that is not a reason why a person of ordinary skill in the art would have had reason to deliver an interventional

cardiology device that Itou does not contemplate or disclose. Petitioner further argues that Itou and Ressemann are analogous art to the '413 patent; however, that is not in dispute. *Id.* at 31–32; *see generally* PO Resp. Lastly, Petitioner characterizes Patent Owner’s arguments as suggesting a person of ordinary skill in the art “would never use the same catheter to both suction and to deliver a stent,” and further asserts “[Mr.] Keith has a patent application that teaches using a catheter to suction thrombus, and then—while it *is still in position*—using it to place a stent.” Pet. Reply 32–33 (citing Ex. 1930 ¶¶ 84–85, Figs. 28, 29). Petitioner does not explain, however, how an unrelated patent application shows what a person of ordinary skill in the art would have understood at the time of the invention from Itou and Ressemann. For the same reason, even if Petitioner is correct that “GuideLiner has been used to *first* aspirate ‘thrombus-laden lesion[s]’”—and to *then* deliver stents—without requiring that it be removed from the vasculature between the two procedures,” that is not persuasive evidence of what would have been obvious to a person of ordinary skill in the art at the time of the invention from Itou and Ressemann. *Id.* at 33 (citing Ex. 1127, 250); *see also* PO Sur-reply 28 (arguing that Petitioner attempts to rely on a patent application and an article from 2014, “long after the GuideLiner patents 2006 filing”) (citing Reply 32–33; Ex. 1930; Ex. 1127).

Lastly, Petitioner argues, apparently for the first time, that “if embolic protection *was* desired (even though none of [the Challenged Claims] require it), Brecker explains that an interventional cardiologist would know that Itou’s catheter 2 could sequentially deploy a distal end protection device, deliver a stent, and then suction.” *Id.* (citing Ex. 1806 ¶ 80; Ex. 1811, Table 1). We agree with Patent Owner that Dr. Brecker “provides

no details on how or why this would be done with Itou,” and instead reflects no more than impermissible hindsight. PO Sur-reply 28–29 (citing Ex. 1806 ¶ 80). Petitioner’s arguments amount to no more than speculation of what *could* have been done with impermissible hindsight informed by the ’413 patent itself. “Without any explanation as to how or why the references would be combined to arrive at the claimed invention, we are left with only hindsight bias.” *Metalcraft*, 848 F.3d at 1367.

4. *Objective Indicia of Nonobviousness*

Patent Owner offers evidence directed to long-felt need, commercial success, industry praise, licensing, and copying as objective evidence of nonobviousness only with respect to dependent claims 4, 9, and 14. PO Resp. 55–76. Patent Owner does not identify objective indicia of nonobviousness with regard to claim 1. Because we find that Petitioner fails to show that claim 1 would have been obvious over Itou, and, therefore, has not shown that any claim depending from claim 1 would have been obvious, we do not reach the issue of whether Patent Owner’s evidence of indicia of nonobvious supports the nonobviousness of claims 4, 9, and 14.

5. *Collective Consideration of the Graham Factors*

Petitioner has not shown that the combination of Itou and Ressemann teaches or suggest each step of the method recited in claim 1, performed in the order written, and has not provided a sufficient reason in support of the modification of Itou’s method based on Ressemann proposed by Petitioner. We do not reach the merits of Patent Owner’s evidence of indicia of nonobviousness, because we find, even without considering that evidence, Petitioner fails to show any of claims 1, 2, 4, 5, and 7–14 would have been obvious over Itou. On the whole, we find that the information provided by Petitioner and Patent Owner in consideration of the *Graham* factors

collectively demonstrates that Petitioner has not shown by a preponderance of the evidence that the subject matter of claims 1, 2, 4, 5, and 7–14 of the '413 patent would have been obvious over Itou and Ressemann.

IV. CONCLUSION

The outcome for the Challenged Claims in this proceeding is set forth below in summary as follows:

Claim(s)	35 U.S.C. §	Reference(s)	Claim(s) Shown Unpatentable	Claims Not Shown Unpatentable
1, 2, 4, 7–14	102	Itou		1, 2, 4, 7–14
1, 2, 4, 5, 7–14	103(a)	Itou		1, 2, 4, 5, 7–14
1, 2, 4, 5, 7–14	103(a)	Itou, Ressemann		1, 2, 4, 5, 7–14
Overall Outcome				1, 2, 4, 5, 7–14

V. ORDER

Upon consideration of the record before us, it is:

ORDERED that claims 1, 2, 4, 5, and 7–14 of U.S. Patent No. 8,142,413 B2 have not been proven by a preponderance of the evidence to be unpatentable;

FURTHER ORDERED that Petitioner's Motion to Exclude is dismissed; and

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

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Patent 8,142,413 B2

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