Trials@uspto.gov
Tel: 571-272-7822

Paper 128
Entered: June 7, 2021

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.

IPR2020-00126 (Patent 8,048,032), IPR2020-00127 (Patent 8,048,032),
IPR2020-00128 (Patent RE45,380), IPR2020-00129 (Patent RE45,380),
IPR2020-00130 (Patent RE45,380), IPR2020-00132 (Patent RE45,760),
IPR2020-00134 (Patent RE45,760), IPR2020-00135 (Patent RE45,760),
IPR2020-00136 (Patent RE45,760), IPR2020-00137 (Patent RE47,379),
IPR2020-00138 (Patent RE47,379)[1]

Before SHERIDAN K. SNEDDEN, JON B. TORNQUIST, and CHRISTOPHER G. PAULRAJ, *Administrative Patent Judges.*

PAULRAJ, *Administrative Patent Judge*.

---

[1] This Order addresses issues that are the same in all identified proceedings. We exercise our discretion to issue one Order to be filed in each proceeding. The parties, however, are not authorized to use this style heading in subsequent papers.

IPR2020-00126 (Patent 8,048,032), IPR2020-00127 (Patent 8,048,032), IPR2020-00128 (Patent RE45,380), IPR2020-00129 (Patent RE45,380), IPR2020-00130 (Patent RE45,380), IPR2020-00132 (Patent RE45,760), IPR2020-00134 (Patent RE45,760), IPR2020-00135 (Patent RE45,760), IPR2020-00136 (Patent RE45,760), IPR2020-00137 (Patent RE47,379), IPR2020-00138 (Patent RE47,379)

ORDER
Granting Patent Owner's Unopposed Motions to Seal
Granting Petitioner's Unopposed Motions to Seal
Requiring Parties to Submit Redacted Versions of Final Written Decisions
37 C.F.R. §§ 42.14, 42.54

Introduction

Patent Owner and Petitioner filed various unopposed Motions to Seal in the above-captioned proceedings. The Parties further submitted a stipulated Joint Protective Order to govern the treatment of the information and documents identified by the various Motions to Seal. Paper 10, Appendix A.[2]

Under 37 C.F.R. § 42.14, the default rule is that all papers filed in such proceedings are available to the public. Only "confidential information" is subject to protection against public disclosure. 35 U.S.C. § 326(a)(7); 37 C.F.R. § 42.55. The Board also observes a strong policy in favor of making all information filed in *inter partes* review proceedings open to the public. *See Argentum Pharms. LLC v. Alcon Research, Ltd.*, IPR2017-01053, Paper 27, 3–4 (PTAB Jan. 19, 2018) (informative). The moving parties bear the burden of showing the requested relief should be granted. 37 C.F.R. § 42.20(c). To establish "good cause" for the requested relief, the Parties must make a sufficient showing that:

> (1) the information sought to be sealed is truly confidential, (2) a concrete harm would result upon public disclosure, (3) there

[2] Unless otherwise noted, all citations are to IPR2020-00126 with the understanding that the other proceedings include papers having substantially the same substantive content.

> exists a genuine need to rely in the trial on the specific information sought to be sealed, and (4), on balance, an interest in maintaining confidentiality outweighs the strong public interest in having an open record.

Argentum, Paper 27 at 3–4; *see also Corning Optical Commc'ns RF, LLC, v. PPC Broadband, Inc.*, IPR2014-00440, Paper 46 at 2 (PTAB April 6, 2015) (requiring a showing that information has not been "excessively redacted"); *see also* 37 C.F.R. § 42.54(a).

We address the Parties' motions and showings of good cause below.

Patent Owner's Motions to Seal

On March 9, 2020; March 10, 2020; or April 8, 2020, Patent Owner filed unopposed Motions to Seal in IPR2020-00126, IPR2020-00128, IPR2020-00129, IPR2020-00132, IPR2020-00134, IPR2020-00135, IPR2020-00136, IPR2020-00137, IPR2020-00138. Paper 10. In the Motion, Patent Owner requested sealing: the redacted portions of Patent Owner's Preliminary Response (Paper 8), and the entirety of Exhibits 2001–2011–2038, 2040, 2041, 2043, 2045, 2058, and 2074. *Id.* at 2. On March 7, 2021, Patent Owner removed the request to seal Exhibits 2002, 2004–2011, 2013, 2014, 2016, 2019–2035, and 2040. Paper 123.

Patent Owner contends that the "portions of the under seal version of the Preliminary Response corresponding to the redacted portions of the public version of the Preliminary Response contain confidential research, development, and/or commercial information." Paper 10, 3. Patent Owner

contends that the remaining portions of the Preliminary Response discuss: (1) "business development information that Medtronic considers confidential" or (2) "revenue numbers for Patent Owner's GuideLiner products and market share estimates." *Id.* Patent Owner contends that the Exhibits include confidential research, development or commercial information. *See id.* at 4–9.

On April 7, 2020, Patent Owner filed unopposed Motions to seal in IPR2020-00127 and IPR2020-00130. IPR2020-00127, Paper 11; IPR2020-00130, Paper 11. In the Motion, Patent Owner requested sealing the redacted portions of Patent Owner's Preliminary Response (Paper 10) and Exhibits 2043 and 2058. *Id.* at 2.

Patent Owner contends that the "portions of the under seal version of the Preliminary Response corresponding to the redacted portions of the public version of the Preliminary Response contain confidential research, development, and/or commercial information." IPR2020-00127, Paper 11, 3. Patent Owner contends that the remaining portions of the Preliminary Response discuss: (1) "business development information that Medtronic considers confidential" or (2) "revenue numbers for Patent Owner's GuideLiner products and market share estimates." *Id.*

On October 1, 2020 or October 2, 2020, Patent Owner filed unopposed Motions to Seal in all of the above-captioned proceedings. Paper 42. In the Motion, Patent Owner requested sealing the redacted portions of Patent Owner's Response (Paper 43) and the entirety of Exhibits 2139, 2140, 2141, 2153, 2154, 2197, 2198, 2201, 2202. *Id.* at 2.

IPR2020-00126 (Patent 8,048,032), IPR2020-00127 (Patent 8,048,032), IPR2020-00128 (Patent RE45,380), IPR2020-00129 (Patent RE45,380), IPR2020-00130 (Patent RE45,380), IPR2020-00132 (Patent RE45,760), IPR2020-00134 (Patent RE45,760), IPR2020-00135 (Patent RE45,760), IPR2020-00136 (Patent RE45,760), IPR2020-00137 (Patent RE47,379), IPR2020-00138 (Patent RE47,379)

Patent Owner contends that the redacted portions of Patent Owner's response "on pages 45, 47, 50, and 53 contain confidential Patent Owner sales data regarding GuideLiner revenue and units sold, as well as reflect licensing strategy. The remaining redacted portions reflect information that Petitioner Medtronic has designated as confidential under" the protective order in the co-pending district court proceeding. *Id.* at 3. Patent Owner contends that the Exhibits include "confidential research, development, or commercial information." *Id.* at 4.

On November 24, 2020, Patent Owner filed unopposed Motions to Seal in all of the above-captioned proceedings. Paper 71. In the Motion, Patent Owner requested sealing Exhibit 2221. *Id.* at 2.

On February 1, 2021, Patent Owner filed unopposed Motions to Seal in all of the above-captioned proceedings. Paper 88. In the Motion, Patent Owner requested sealing portions of Patent Owner's Sur-Reply on Conception and Reduction to Practice ("CRTP") (Paper 103), the redacted portions of Exhibit 2242, and the entirety of Exhibit 2235. *Id.* at 2. Patent Owner contends that the Exhibit contains "confidential information concerning Patent Owner's business, pricing, and marketing strategy" and has been previously designated as confidential in the co-pending district court proceeding. *Id.* at 3.

On March 4, 2021, Patent Owner filed unopposed Motions to Seal in all of the above-captioned proceedings. Paper 119. In the Motion, Patent Owner requested sealing portions of Patent Owner's Demonstratives, namely slides 256, 262, 263, 274, and 276–278. *Id.* at 2. In the Motion,

IPR2020-00126 (Patent 8,048,032), IPR2020-00127 (Patent 8,048,032), IPR2020-00128 (Patent RE45,380), IPR2020-00129 (Patent RE45,380), IPR2020-00130 (Patent RE45,380), IPR2020-00132 (Patent RE45,760), IPR2020-00134 (Patent RE45,760), IPR2020-00135 (Patent RE45,760), IPR2020-00136 (Patent RE45,760), IPR2020-00137 (Patent RE47,379), IPR2020-00138 (Patent RE47,379)

Patent Owner contends that "redacted slides 256, 274, and 276–78 contain information that Petitioner has contended is confidential research, development, and testing information related to its products, regulatory communications, and marketing." *Id.* at 3. Patent Owner contends that "redacted slides 262–63 contain information that Patent Owner has contended contain confidential commercial information relating to revenue and units sold." *Id.*

Petitioner's Motions to Seal

On December 17, 2020, Petitioner filed unopposed Motions to Seal in IPR2020-00126, IPR2020-00128, IPR2020-00129, IPR2020-00132, IPR2020-00134, IPR2020-00135, and IPR2020-00137. Paper 80. In the Motion, Petitioner requested sealing portions of Petitioner's Reply addressing CRTP (Paper 78), portions of Exhibit 1755, and the entirety of Exhibits 1108, 1308, 1708, 1114, 1314, 1714, 1758, 1759, 1760, 1761, 1763, 1765, 1767, 1768, 1769, 1770, 1774, 1775, 1778, 1779, 1782, 1783, 1786, 1787, 1788, 1789, 1790, 1791, 1792, and 1793. *Id.* at 1.

In the Motion, Petitioner contends that the redacted portions of Paper 78 "discuss Patent Owner's confidential information, specifically, information related to Patent Owner's product development, product design, marketing, and related efforts and strategies." *Id.* at 2–3. Petitioner contends that Ex. 1755 also discusses Patent Owner's confidential information related to the similar material. Petitioner contends that the remaining referenced Exhibits "describe Patent Owner's product

development, product design, marketing, and related efforts and strategies." *Id.* at 4. Petitioner notes that the redacted portions of Petitioner's CRTP Reply and Ex. 1755, as well as the entirety of the remaining Exhibits, were produced and designated confidential under the protective order in the co-pending district court litigation. *Id.* at 2–4.

On December 22, 2020 or December 23, 2020, Petitioner filed unopposed Motions to Seal in IPR2020-00126, IPR2020-00127, IPR2020-00128, IPR2020-00129, IPR2020-00130, IPR2020-00132, IPR2020-00134, IPR2020-00136, IPR2020-00137, and IPR202-00138. Paper 84. In the Motion, Petitioner requested sealing portions of Petitioner's Reply to Patent Owner's Response (Paper 83), and portions of Exhibits 1806, 1807, and 1830, and the entirety of Exhibits 1114, 1115, and 1821–1823. *Id.* at 1.

In the Motion, Petitioner contends that the redacted portions of Paper 82 "discuss Patent Owner's confidential information, specifically, information related to Patent Owner's product development, product design, marketing, and related efforts and strategies." *Id.* at 2. Petitioner contends that the redacted portions of Exhibits 1806, 1807, and 1830 discuss "Patent Owner's confidential information, specifically, information related to Patent Owner's product development, product design, marketing, and related efforts and strategies, as well as deposition testimony regarding the same." *Id.* at 3. Petitioner contends that Exhibits 1114, 1115, and 1821–1823, "describe Patent Owner's product development, product design, marketing, and related efforts and strategies." *Id.* at 3–4. Petitioner notes that the redacted portions of Petitioner's Reply to Patent Owner's Response and

IPR2020-00126 (Patent 8,048,032), IPR2020-00127 (Patent 8,048,032), IPR2020-00128 (Patent RE45,380), IPR2020-00129 (Patent RE45,380), IPR2020-00130 (Patent RE45,380), IPR2020-00132 (Patent RE45,760), IPR2020-00134 (Patent RE45,760), IPR2020-00135 (Patent RE45,760), IPR2020-00136 (Patent RE45,760), IPR2020-00137 (Patent RE47,379), IPR2020-00138 (Patent RE47,379)

Exhibits 1806, 1807, and 1830, as well as the entirety of the remaining Exhibits, were produced and designated confidential under the protective order in the co-pending district court litigation. *Id.* at 2–4

On March 4, 2021, Petitioner filed unopposed Motions to Seal in all of the above-captioned proceedings. Paper 118. Petitioner requested sealing portions of Petitioner's Demonstratives, namely slides 259, 269, and 270. *Id.* at 1–2. In the Motion, Petitioner contends that redacted slides 259, 269, and 270 "discuss Patent Owner's confidential information, specifically, information related to Patent Owner's product development, product design, marketing, and related efforts and strategies." *Id.* at 2. Petitioner notes that this information was designated as confidential under a protective order in the co-pending district court proceeding. *Id.*

Analysis

Upon considering the Parties representations and arguments, the contents of the exhibits sought to be sealed in their entirety, and the contents of the information sought to be redacted, we conclude that the Parties have established good cause for sealing the requested documents.

On June 7, 2021, we issued our Final Written Decisions in these proceedings. Because these Decisions cite to one or more of the foregoing documents that have been sealed, we designated the Decisions as "Board and Parties Only." The parties are directed to review our Decisions to verify if any confidential information is mentioned, meet and confer in good faith, and submit joint proposed redacted versions of the Decisions within five

IPR2020-00126 (Patent 8,048,032), IPR2020-00127 (Patent 8,048,032), IPR2020-00128 (Patent RE45,380), IPR2020-00129 (Patent RE45,380), IPR2020-00130 (Patent RE45,380), IPR2020-00132 (Patent RE45,760), IPR2020-00134 (Patent RE45,760), IPR2020-00135 (Patent RE45,760), IPR2020-00136 (Patent RE45,760), IPR2020-00137 (Patent RE47,379), IPR2020-00138 (Patent RE47,379)

business days after entry of this Order. The proposed redacted versions shall be emailed to Trials@uspto.gov.

ORDER

In consideration of the foregoing, it is hereby:

ORDERED that the parties' joint motion to enter the Proposed Protective Order (Paper 10, Appendix A) is *granted*, and the Proposed Protective Order is, accordingly, entered;

FURTHER ORDERED that Patent Owner's requests to seal Exhibits 2001, 2003, 2015, 2017, 2018, 2036–2038, 2041, 2058, 2074, 2139–2141, 2153, 2154, 2197, 2198, 2201, 2202, 2221, and 2235, are *granted*;

FURTHER ORDERED that Patent Owner's requests to seal redacted portions of Patent Owner's Preliminary Response, Patent Owner's Response, Patent Owner's Sur-Reply on CRTP, Exhibits 2043, 2045, and 2242, and Patent Owner's Demonstratives are *granted*;

FURTHER ORDERED that Petitioner's requests to seal Exhibits 1108, 1114, 1115, 1308, 1314, 1708, 1714, 1758, 1759, 1760, 1761, 1763, 1765, 1767–1770, 1774, 1775, 1778, 1779, 1782, 1783, 1786, 1787–1793, and 181–1823 are *granted*;

FURTHER ORDERED that Petitioner's requests to seal redacted portions of Exhibits 1755, 1806, 1807, and 1830, Petitioner's Reply addressing CRTP, Petitioner's Reply to Patent Owner's Response, and Petitioner's Demonstratives are *granted*; and

IPR2020-00126 (Patent 8,048,032), IPR2020-00127 (Patent 8,048,032), IPR2020-00128 (Patent RE45,380), IPR2020-00129 (Patent RE45,380), IPR2020-00130 (Patent RE45,380), IPR2020-00132 (Patent RE45,760), IPR2020-00134 (Patent RE45,760), IPR2020-00135 (Patent RE45,760), IPR2020-00136 (Patent RE45,760), IPR2020-00137 (Patent RE47,379), IPR2020-00138 (Patent RE47,379)

FURTHER ORDERED that the parties shall meet and confer and propose joint redacted versions of our Final Written Decisions in these proceedings within five business days.

IPR2020-00126 (Patent 8,048,032), IPR2020-00127 (Patent 8,048,032), IPR2020-00128 (Patent RE45,380), IPR2020-00129 (Patent RE45,380), IPR2020-00130 (Patent RE45,380), IPR2020-00132 (Patent RE45,760), IPR2020-00134 (Patent RE45,760), IPR2020-00135 (Patent RE45,760), IPR2020-00136 (Patent RE45,760), IPR2020-00137 (Patent RE47,379), IPR2020-00138 (Patent RE47,379)

FOR PETITIONER:

Cyrus Morton
Sharon Roberg-Perez
Christopher Pinahs
William E. Manske
Emily J. Tremblay
ROBINS KAPLAN LLP
cmorton@robinskaplan.com
sroberg-perez@robinskaplan.com
cpinahs@robinskaplan.com
wmanske@robinskaplan.com
etremblay@robinskaplan.com

FOR PATENT OWNER:

Derek Vandenburgh
Dennis Bremer
CARLSON, CASPERS, VANDENBURGH & LINDQUIST, P.A.
dvandenburgh@carlsoncaspers.com
dbremer@carlsoncaspers.com

Trials@uspto.gov
571-272-7822

Paper 127
Date: June 7, 2021

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.

IPR2020-00126
Patent 8,048,032 B2

Before SHERIDAN K. SNEDDEN, JON B. TORNQUIST, and CHRISTOPHER G. PAULRAJ, *Administrative Patent Judges.*

PAULRAJ, *Administrative Patent Judge*.

JUDGMENT
Final Written Decision
Determining No Challenged Claims Unpatentable
Not Deciding Patent Owner's Contingent Motion to Amend
35 U.S.C. § 318(a)

ORDER
Denying Petitioner's Motion to Exclude (Paper 111)
37 C.F.R. § 42.64(c)

I. INTRODUCTION

A. Background and Summary

This is our Final Written Decision entered pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73. For the reasons explained in our analysis below, we determine that the primary reference relied upon by Petitioner for all its patentability challenges does not qualify as prior art because Patent Owner has antedated that reference. Thus, Petitioner has not demonstrated that any of the challenged claims are unpatentable in this proceeding.

On November 12, 2019, Medtronic, Inc. and Medtronic Vascular, Inc. (collectively, "Petitioner") filed a Petition requesting an *inter partes* review of claims 1–20 and 22 of U.S. Patent No. 8,048,032 B2 ("the '032 patent," Ex. 1001). Paper 1 ("Pet."). Teleflex Innovations S.À.R.L. ("Patent Owner")[1] filed a Preliminary Response. Papers 8 (confidential version), 9 (redacted version) ("Prelim. Resp."). In our Institution Decision, we determined that there was a reasonable likelihood that Petitioner would prevail with respect to at least one challenged claim and accordingly, instituted an *inter partes* review pursuant to 35 U.S.C. § 314 based on all challenges presented in the Petition. Paper 22 ("Institution Decision" or "Inst. Dec.").

Following institution, Patent Owner filed two post-institution responses: (1) a Consolidated Response Addressing Conception and

[1] Patent Owner represents that "Teleflex Innovations S.A.R.L. merged into Teleflex Medical Devices S.A.R.L," which subsequently "transferred ownership of [the '032 patent] to Teleflex Life Sciences Limited." Paper 7, 2.

Reduction to Practice (Paper 39 ("PO CRTP Response" or "PO CRTP Resp.")) and (2) a post-institution Response addressing Petitioner's anticipation and obviousness arguments (Papers 43 (confidential version), 44 (redacted version) ("PO Resp.")).

Petitioner filed a Reply to Patent Owner's Response Addressing Conception and Reduction to Practice (Papers 78 (confidential version), 79 (redacted version) ("Pet. CRTP Reply")) and a Reply to Patent Owner's Response (Papers 83 (confidential version), 82 (redacted version) ("Reply")). Patent Owner then filed its post-institution Sur-Reply Addressing Conception and Reduction to Practice (Paper 97 ("PO CRTP Sur-Reply")), and Petitioner filed its post-institution Sur-Reply Addressing Conception and Reduction to Practice (Paper 112 ("Pet. CRTP Sur-Sur-Reply")). Patent Owner also filed a post-institution Sur-Reply to Petitioner's Reply to Patent Owner's Response (Papers 103 (confidential version), 104 (redacted version) ("PO Sur-Reply")).

Patent Owner also filed a Contingent Motion to Amend. Paper 38 (original), Paper 96 (corrected) ("Motion").[2] The Motion requests that if any of claims 1, 11, or 16 is found unpatentable, they should be replaced by proposed substitute claims 23–25. Motion 1. Petitioner filed an Opposition to Motion to Amend. Paper 102. Patent Owner filed a Reply in Support of the Corrected Motion to Amend (Paper 106), and Petitioner filed a Sur-Reply (Paper 114).

[2] Pursuant to a stipulation by the parties, we authorized the filing of the corrected Motion to Amend in order to clarify certain antecedent bases and thereby simplify the issues.

An oral hearing was held on March 8, 2021, and a transcript of the hearing is included in the record. Papers 125 (redacted version) ("Tr."), 126 (confidential version).

B. Real Parties-in-Interest

Petitioner identifies Medtronic, Inc. and Medtronic Vascular, Inc., as the real parties-in-interest, and notes that "Medtronic plc is the ultimate parent of both entities." Pet. 5. Patent Owner identifies the real parties-in-interest for itself as Teleflex Medical Devices S.À.R.L., Vascular Solutions LLC, Arrow International, Inc., Teleflex LLC, and Teleflex Life Sciences Limited and notes that "Teleflex Incorporated is the ultimate parent of the entities listed above." Paper 4, 2; Paper 7, 2.

C. Related Matters

Patent Owner is asserting the '032 patent against Petitioner in the United States District Court for the District of Minnesota in *Vascular Solutions LLC, et al. v. Medtronic, Inc., et al.*, No. 19-cv-01760 (D. Minn., filed July 2, 2019). Pet. 5; Paper 4, 2. The '032 patent is also the subject of a declaratory judgement action filed by another party, *QXMedical, LLC v. Vascular Solutions, LLC*, No. 17-cv-01969 (D. Minn., filed June 8, 2017), which was stayed pending our Institution Decision. Paper 19; Paper 20. The '032 patent was also previously the subject of litigation in the District of Minnesota in *Vascular Solutions, Inc. v. Boston Scientific Corp.*, No. 13-cv-01172 (D. Minn., filed May 16, 2013), and the subject of previous *inter partes* reviews in IPR2014-00760 and IPR2014-00761 filed by Boston Scientific Corp., which terminated based on settlement. Pet. 5.

Petitioner has also filed another petition challenging the '032 patent based on different prior art. IPR2020-00127. We also instituted *inter partes* review in IPR2020-00127. IPR2020-00127, Paper 20. In addition, Petitioner has filed concurrent petitions challenging related reissue patents: RE45,380 (IPR2020-00128; IPR2020-00129; IPR2020-00130; IPR2020-00131), RE45,760 (IPR2020-00132; IPR2020-00133; IPR2020-00134), RE45,776 (IPR2020-00135; IPR2020-00136), and RE47,379 (IPR2020-00137; IPR2020-00138).

D. The '032 Patent (Ex. 1001)

The '032 patent, entitled "Coaxial Guide Catheter for Interventional Cardiology Procedures," issued on November 1, 2011, from a non-provisional application filed May 3, 2006. Ex. 1001, codes (45), (54), (22).

The '032 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 '032 patent, interventional cardiology procedures often include inserting guidewires or other instruments through catheters into coronary arteries that branch off from the aorta. *Id.* at 1:15–17. In coronary artery disease, the coronary arteries may be narrowed or occluded by atherosclerotic plaques or other lesions in a phenomenon known as stenosis. *Id.* at 1:20–26. In treating the stenosis, a guide catheter is inserted through the aorta and into the ostium of the coronary artery, sometimes with the aid of a guidewire, and is passed beyond the occlusion or stenosis. *Id.* at 1:30–36. However, crossing tough lesions can create enough backward force to dislodge the guide catheter from the ostium of the artery being treated, which can make it

difficult or impossible for the interventional cardiologist to treat certain forms of coronary artery disease. *Id.* at 1:36–40.

To solve this problem, the '032 patent describes a coaxial guide catheter that is deliverable through standard guidewires by utilizing a guidewire rail segment to permit delivery without blocking use of the guide catheter. *Id.* at 2:53–56. The '032 patent teaches that 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, and this feature allows removal of the tapered inner catheter after the coaxial guide catheter is in place. *Id.* at 2:57–61. Figures 1 and 2, reproduced below, show a coaxial guide catheter and a tapered inner catheter in accordance with the invention described in the '032 patent:

Fig. 1

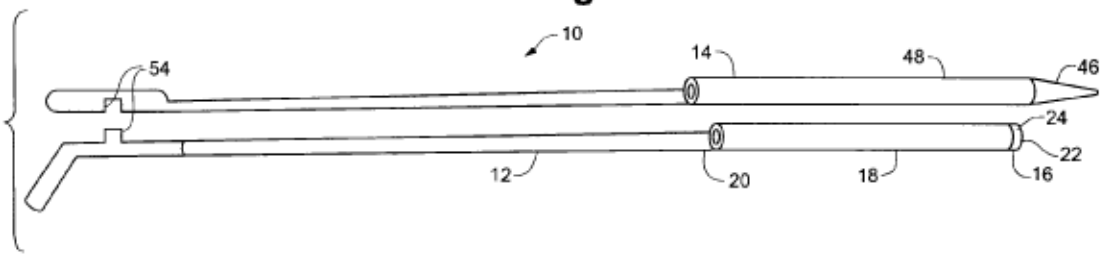


Fig. 2

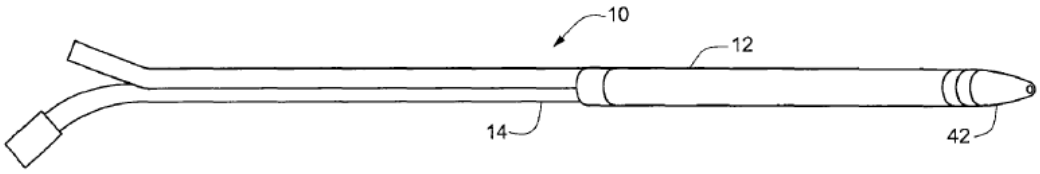


Figure 1 is a schematic depiction of the coaxial guide catheter and tapered inner catheter separately, and Figure 2 depicts those two elements assembled together. *Id.* at 5:15–21, Figs. 1, 2. As shown above, coaxial guide catheter assembly 10 includes coaxial guide catheter 12 and tapered inner catheter

14. *Id.* at 6:6–8. Coaxial guide catheter 12 includes tip portion 16, reinforced portion 18, and rigid portion 20. *Id.* at 6:9–10. Tip portion 16 generally includes bump tip 22 and marker band 24. *Id.* at 6:13–14. Bump tip 22 includes taper 26 and is relatively flexible. *Id.* at 6:14–15. Marker band 24 is formed of a radiopaque material such as platinum/iridium alloy. *Id.* at 6:19–20. Tapered inner catheter tip 42 includes tapered portion 46 at a distal end thereof, and straight portion 48. *Id.* at 6:59–60. Both tapered portion 46 and straight portion 48 are pierced by lumen 50 (not labeled in the figures above). *Id.* at 6:60–61. 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 6:64–67.

In operation, the tapered inner catheter is inserted inside and through the coaxial guide catheter. *Id.* at 4:12–13. The coaxial guide catheter/ tapered inner catheter combination may then be inserted into a blood vessel that communicates with the aorta, and advanced until the tapered inner catheter is passed into the ostium of a coronary artery over the guidewire. *Id.* at 4:15–23. The tapered inner catheter may be removed once the coaxial guide catheter/guide catheter combination has been inserted sufficiently into the ostium of the coronary artery to achieve deep seating. *Id.* at 4:23–26. Once 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.* at 4:30–33. The presence of the coaxial guide catheter provides additional backup support to make it less likely that the coaxial guide catheter/guide catheter combination will be dislodged from the ostium of the coronary artery while directing the coronary therapeutic device past a tough lesion. *Id.* at 4:33–39.

E. Illustrative Claim

Among the challenged claims, independent claim 1 is representative and reproduced below:

> 1. A device for use with 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 to the branch artery, the device comprising:
>
> a flexible tip portion 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 guide catheter, the tubular structure having a cross-sectional outer diameter sized to be insertable through the cross-sectional inner diameter of the continuous lumen of the guide catheter and defining a coaxial lumen having a cross-sectional inner diameter through which interventional cardiology devices are insertable; and
>
> a substantially rigid portion proximal of and operably connected to, and more rigid along a longitudinal axis than, the flexible tip portion and 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,
>
> such that when at least a distal portion of the flexible tip portion is extended distally of the distal end of the guide catheter, at least a portion of the proximal portion of the substantially rigid portion extends proximally through the hemostatic valve in common with interventional cardiology devices that are insertable into the guide catheter.

Ex. 1001, 10:21–54 (cl. 1).

F. Prior Art and Asserted Grounds

We instituted review of claims 1–20 and 22 of the '032 patent on the following grounds (Inst. Dec. 7–8, 31):

Claim(s) Challenged	35 U.S.C. §	Reference(s)/Basis
1–19, 22	102	Itou[3]
3, 13, 14	103(a)	Itou, Ressemann,[4] the knowledge of a person of ordinary skill in the art ("POSITA")
20	103(a)	Itou, Berg,[5] the knowledge of POSITA

In support of its arguments, Petitioner relies on declarations submitted by Dr. Stephen Jon David Brecker (Exs. 1005, 1806), Dr. Richard A. Hillstead (Ex. 1042), Mr. Michael Jones (Ex. 1807), and Dr. Paul Zalesky (Exs. 1755, 1830, 1919). Patent Owner relies on the declarations submitted by Ms. Deborah Schmalz (Ex. 2039), Ms. Amy Welch (Ex. 2044), Mr. Howard Root (Ex. 2118), Mr. Gregg Sutton (Ex. 2119), Mr. Mark Goemer (Ex. 2120), Ms. Amanda O'Neil (Ex. 2121), Mr. Steve Erb (Ex. 2122), Mr. Peter T. Keith (Exs. 2123, 2124, 2138, 2243), Dr. John J. Graham (Ex. 2145), Dr. Lorenzo Azzalini (Ex. 2151), Mr. Steve Jagodzinkski (Exs. 2152 (redacted), 2153 (confidential)), Ms. Heather S. Rosecrans (Ex. 2205), and Dr. Craig Thompson (Ex. 2215).

[3] Itou et al., US 7,736,355 B2, issued June 15, 2010 (Ex. 1007) ("Itou").
[4] Ressemann et al., US 7,604,612 B2, issued October 20, 2009 (Ex. 1008) ("Ressemann").
[5] Berg et al., US 5,911,715, issued June 15, 1999 (Ex. 1051) ("Berg").

II. ANALYSIS

A. Priority Date of the '032 Patent

Petitioner argues that "[t]he '032 patent is subject to the AIA's first-to-file provisions because it contains at least one claim that lacks a written description, and therefore, pre-AIA priority." Pet. 14. Petitioner advances this argument to preclude Patent Owner from swearing behind the Itou reference based on a showing of prior invention, which could otherwise be done for a pre-AIA "first-to-invent" application. *Id.* We are not persuaded by Petitioner's argument.

The AIA's first-to-file provisions apply to patent applications "that contain[] or contained at any time a claim to a claimed invention that has an effective filing date" on or after March 16, 2013. AIA § 3(n)(1). The effective filing date is "the actual filing date of the patent or the application for the patent containing a claim to the invention;" or "the filing date of the earliest application for which the patent or application is entitled." 35 U.S.C. § 100(i)(1). In the present case, the '032 patent issued from an application filed May 3, 2006, and does not claim the benefit of any other filing date. Ex. 1001, code (22). Thus, the only possible effective filing date of the '032 patent is May 3, 2006, which thus qualifies it as a pre-AIA patent.[6]

[6] Petitioner's priority date argument appears to be a back door attempt to have us address whether the '032 patent satisfies the written description requirement of 35 U.S.C. § 112. But this is a question we may not address in an IPR. *See* 35 U.S.C. § 311(b).

B. Level of Ordinary Skill in the Art

We consider the asserted grounds of unpatentability in view of the understanding of a person of ordinary skill in the art (POSITA). Petitioner provides two alternatives for a person having ordinary skill in the art. First, Petitioner asserts that "[i]f a person of ordinary skill in the art ('POSITA') was a medical doctor, s/he would have had (a) a medical degree; (b) completed a coronary intervention training program, and (c) experience working as an interventional cardiologist." Pet. 14. Alternatively, Petitioner asserts that "if a POSITA was an engineer s/he 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." *Id.* at 14–15. Additionally, Petitioner contends that "[e]xtensive experience and technical training might substitute for education, and advanced degrees might substitute for experience." *Id.* at 15.

Patent Owner does not dispute Petitioner's proposed definition of a POSITA. PO Resp. 8.

Upon review of the parties' arguments and supporting evidence, we adopt Petitioner's definitions for a POSITA, as they are undisputed and consistent with the evidence of record. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001) (the prior art itself can reflect the appropriate level of ordinary skill in the art).

C. Claim Construction

We interpret a claim "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)(2019). This standard requires that we construe claims "in accordance with the ordinary and customary meaning of such claim[s] as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent." *Id.*

Upon review of the parties' arguments and supporting evidence, we determine that it is not necessary to construe any claim terms to resolve the disputed issues for purposes of this Final Written Decision. *See Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999) (holding that "only those terms need to be construed that are in controversy, and only to the extent necessary to resolve the controversy"); *see also Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (applying *Vivid Techs.* in the context of an *inter partes* review).

D. Status of Itou as Prior Art - Conception and Reduction to Practice

The dispositive issue in this case is whether Itou, which is relied upon for all grounds in the Petition, qualifies as prior art.

Itou was filed on September 23, 2005, published on March 30, 2006, and issued on June 15, 2010. Ex. 1007, codes (22), (45), (65). Petitioner contends Itou is prior art under pre-AIA § 102(e). Pet. 19–20.[7] In the Conception and Reduction to Practice ("CRTP") briefing that we separately authorized for these proceedings, Patent Owner argues that Itou does not

[7] In addition to this Petition, Petitioner similarly asserts Itou in the petitions in IPR2020-00128, -00129, -00132, -00134, -00135, and -00137. Our analysis regarding the prior art status of Itou is similar for each of these proceedings.

qualify as prior art based on research and development related to the claimed invention that took place at Vascular Solutions, Inc. ("VSI"), Patent Owner's predecessor-in-interest, starting around early 2005 and continuing through the filing of the priority application for the challenged patent. *See generally* PO CRTP Response; PO CRTP Sur-Reply. Petitioner disputes these contentions. *See generally* Pet. CRTP Reply; Pet. CRTP Sur-Sur-Reply.

In its CRTP Response, Patent Owner identifies the evidence on which it relies to antedate Itou, including certain inventor testimony, non-inventor testimony, and other documentary evidence. PO CRTP Resp. 2. As to inventor testimony, Patent Owner relies on the respective declarations of co-inventors Howard Root (Ex. 2118) and Gregg Sutton (Ex. 2119). As to non-inventor testimony, Patent Owner relies on the declaration of its expert Peter T. Keith (Ex. 2123), the declarations of VSI employees Steven Erb (Ex. 2122) and Deborah Schmalz (Ex. 2039), and the declarations of employees of third-party vendors, Amanda O'Neil (Ex. 2121) and Mark Goemer (Ex. 2120). As to documentary evidence, Patent Owner relies on nearly 75 exhibits. These documents include inventor lab notebooks and handwritten notes (Exs. 2002, 2004); internal company memoranda, presentations, and other similar documents (Exs. 2003, 2005, 2017–2018, 2024, 2025, 2036–2038, 2040–2041, 2099–2100, 2105, 2109, 2127–2134); invoices, sales orders, and certificates of completion from technical equipment vendors (Exs. 2006–2011, 2013, 2016, 2020–2021, 2026–2035, 2089–2095, 2097, 2104, 2106–2108, 2110–2112); a photograph (Ex. 2014); deposition transcripts (Exs. 2015, 2116); communications with and documents from VSI's outside patent counsel (Exs. 2019, 2023, 2096, 2098, 2101–2103, 2117); and engineering drawings (Exs. 2022, 2113–2115).

We have considered this evidence and other rebuttal evidence offered by Petitioner. For the following reasons, we conclude that a preponderance of the evidence demonstrates that Patent Owner conceived the subject matter recited in the challenged claims before September 23, 2005, the date on which Itou is effective as prior art ("critical date") and either actually reduced the invention to practice prior to the critical date or diligently worked towards constructive reduction to practice until the priority application for the challenged patent was filed on May 3, 2006. Accordingly, we conclude that Itou does not qualify as prior art to the challenged patent.

For our analysis, we first set forth the relevant legal standards, followed by our fact findings and analysis on conception, actual reduction to practice, and diligence towards constructive reduction to practice.

1. Legal Standards

"To antedate (or establish priority) of an invention, a [patent owner] must show either an earlier reduction to practice, or an earlier conception followed by a diligent reduction to practice." *Purdue Pharma L.P. v. Boehringer Ingelheim GMBH*, 237 F.3d 1359, 1365 (Fed. Cir. 2001). "Conception is the formation, in the mind of the inventor, of a definite and permanent idea of the complete and operative invention, as it is thereafter to be applied in practice." *Cooper v. Goldfarb*, 154 F.3d 1321, 1327 (Fed. Cir. 1998). "A reduction to practice can be either a constructive reduction to practice, which occurs when a patent application is filed, or an actual reduction to practice." *Id.* "In order to establish an actual reduction to practice, the [patent owner] must prove that: (1) [the inventors] constructed

an embodiment or performed a process that met all the limitations of the [claimed invention]; and (2) [the inventors] determined that the invention would work for its intended purpose." *Id.*

If a patent owner has not shown actual reduction to practice prior to the "critical date" of a reference, the patent owner may nonetheless antedate the reference by establishing prior conception and reasonable diligence towards the constructive reduction to practice. *Purdue Pharma*, 237 F.3d at 1365. "Reasonable diligence must be shown throughout the entire critical period, which begins just prior to the competing reference's effective date and ends on the date of the invention's reduction to practice." *Arctic Cat Inc. v. GEP Power Prods., Inc.*, 919 F.3d 1320, 1331 (2019). However, the "diligence need not be perfectly continuous—only *reasonably* continuous." *Id.*

To be persuasive, an inventor's testimony of conception and reduction to practice must be corroborated by other independent evidence. "Conception must be proved by corroborating evidence which shows that the inventor disclosed to others his completed thought expressed in such clear terms as to enable those skilled in the art to make the invention." *REG Synthetic Fuels, LLC v. Neste Oil Oyj*, 841 F.3d 954, 962 (Fed. Cir. 2016) (citations and quotation marks omitted). "However, there is no final single formula that must be followed in proving corroboration." *Id.* (citations and quotation marks omitted); *see also Kolcraft Enters., Inc. v. Graco Children's Prods., Inc.*, 927 F.3d 1320, 1324 (Fed. Cir. 2019); *Medichem, S.A. v. Rolabo, S.L.*, 437 F.3d 1157, 1169–70 (Fed. Cir. 2006).

"In the final analysis, each corroboration case must be decided on its own facts with a view to deciding whether the evidence as a whole is

persuasive." *Berges v. Gottstein*, 618 F.2d 771, 776 (CCPA 1980). Corroborating evidence may consist of "testimony of a witness, other than the inventor," or "evidence of surrounding facts and circumstances independent of information received from the inventor." *Medichem*, 437 F.3d at 1171. "Even the most credible inventor testimony is *a fortiori* required to be corroborated by independent evidence, which may consist of documentary evidence as well as the testimony of non-inventors." *Id.* at 1171–72. We assess whether evidence corroborates conception and reduction to practice under a "rule of reason" analysis. *Cooper*, 154 F.3d at 1330.

In an *inter partes* review, 35 U.S.C. § 316(e) imposes the ultimate burden of persuasion to "prove unpatentability by a preponderance of the evidence" onto the petitioner. This burden never shifts to the patent owner. *Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015). However, when the patent owner attempts to antedate the prior art, "[a] second and distinct burden, the burden of production" can shift between the petitioner and the patentee. *Id.* at 1379; *see In re Magnum Oil Tools Int'l, Ltd.*, 829 F.3d 1364, 1375–76 (Fed. Cir. 2016). Specifically, the patent owner "bears the burden of establishing that its claimed invention is entitled to an earlier priority date than an asserted prior art reference." *Magnum Oil Tools*, 829 F.3d at 1375–76. Once the patent owner establishes it is entitled to an earlier priority date, the burden of production then shifts back to the petitioner "to convince the court that [the patent owner] is not entitled to the benefit" of the earlier priority date. *Dynamic Drinkware*, 800 F.3d at 1379 (citing *Tech. Licensing Corp. v. Videotek, Inc.*, 545 F.3d 1316, 1328 (Fed. Cir. 2008)).

2. Conception

To show prior conception, Patent Owner relies primarily upon Mr. Root's testimony submitted in support of its CRTP Response. Ex. 2118 (Root Declaration in support of CRTP).[8,9] Mr. Root was the founder and Chief Executive Officer of VSI from 1997 to 2017. *Id.* ¶¶ 1–2. Patent Owner also relies upon the testimony of co-inventor Mr. Sutton, who was Vice President, Research & Development at VSI from 2004 until mid-2006. Ex. 2119 (Sutton Declaration in support of CRTP). As additional documentary corroboration for this inventor testimony, Patent Owner relies upon certain pages from Mr. Sutton's laboratory notebook dated January 4, 2005 (Ex. 2002), a "market feasibility" memorandum from Mr. Root dated February 4, 2005 (Ex. 2003), and some additional handwritten notes and drawings from Mr. Root dated February 7, 2005 (Ex. 2004). We first set forth the relevant facts based on these declarants' testimony and

[8] Patent Owner previously submitted a declaration by Mr. Root with its Preliminary Response (Ex. 2001), but withdrew that declaration in favor of Ex. 2118. PO CRTP Resp. 2 n.1.

[9] The testimonial evidence that Patent Owner presents in support of conception is largely undisputed. Indeed, during a teleconference addressing Patent Owner's request to present live testimony from Mr. Root in these proceedings, Petitioner's counsel acknowledged that Mr. Root's testimony was not disputed in a manner that would require our credibility assessment. *See* Ex. 1920, 11:10–11 ("And I don't think we have, you know, directly said Mr. Root is lying on this topic."); *id.* at 17:17–18 ("We don't have any issue at play here that goes to credibility."). Accordingly, in view of our conclusion that "the credibility of Mr. Root is not in question," we denied Patent Owner's request to present live testimony from Mr. Root at the oral hearing. *See* Paper 110, 4–5 (distinguishing *K-40 Elecs., LLC v. Escort, Inc.*, IPR2013-00203, Paper 34 (PTAB May 21, 2014) (precedential)).

corroborating evidence, and then address any disputed issues of material fact and legal issues as needed in our analysis.

a) Fact Findings for Conception

In his declaration, Mr. Root attests that conception started around the time he attended the Transcatheter Cardiovascular Therapeutics ("TCT") conference from September 27 to October 1, 2004, by which time he had recognized the issue of "guide catheter backout" that physicians were experiencing when performing complex interventional coronary procedures. Ex. 2118 ¶ 5. Accordingly, Mr. Root asserts that he recognized a need for a solution "that provided better guide positioning, device delivery, and procedural conveniences" than what previously existed in the market. *Id.* To solve this problem, Mr. Root indicates that he came up with "the idea for a guide extension catheter that would provide improved back-up support with rapid exchange delivery, which would offer far more convenience than other options available at the time." *Id.* ¶ 6. And "[s]ometime after the TCT conference, but before 2005," Mr. Root met with his co-inventors, including Mr. Sutton, to discuss more particular ideas for how to make this device. *Id.*

The "guide extension catheter" device that the inventors thought of at this time included certain key features. It was to be used within a standard guide catheter that was one "French size" larger than the "guide extension catheter," and was parsed into two distinct portions—a substantially rigid proximal portion comprising a "rail" structure and a distal tubular portion with a lumen—which together were longer than a standard guide catheter. *Id.* ¶ 7. During a procedure, after the standard guide catheter was inserted into the vasculature so its distal end was in the ostium of a cardiac artery, the

guide extension catheter would be inserted into the lumen until the distal end of the tubular portion went past the distal end of the guide catheter and into the cardiac artery. *Id.* With both catheters in place, an interventional cardiology device could be thereafter inserted through the standard guide catheter (running along the rail of the guide extension catheter) until it reached the distal end of the distal tubular portion of the guide extension catheter, thereby entering the cardiac artery. *Id.*

The device they undertook to develop was initially called the "Guide-Liner" device, but the hyphen was later dropped and it became known as the "GuideLiner" device. *Id.* ¶ 9. Although the original idea for the GuideLiner was a "rapid exchange" ("RX") version of the guide extension catheter, "[s]ometime between February and June of 2005, a decision was made to concurrently pursue development of an over-the-wire ('OTW') version of GuideLiner." *Id.* ¶ 19. Mr. Root acknowledges, however, that "[t]he OTW GuideLiner was not part of the inventions of the [challenged] patents," but instead was more akin to the "mother-and-child" design that was known in the prior art and discussed in the background of the challenged patents. *Id.* (citing Ex. 1001, 2:17–44).[10]

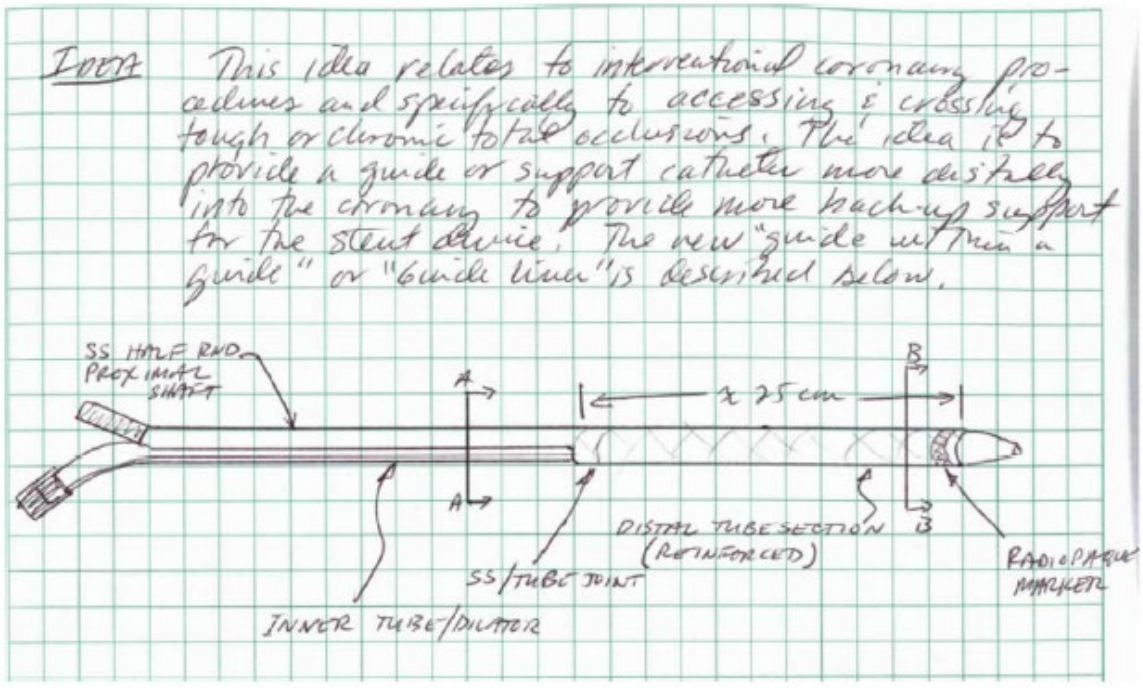
Mr. Sutton in his own declaration sets forth a story consistent with that set forth by Mr. Root. He attests that "[s]tarting in late-2004 until [he] left VSI, [he] performed research and development work on what became the GuideLiner guide extension catheter." Ex. 2119 ¶ 2. Although VSI did not retain all of its files from that time, Mr. Sutton recalls, based on his

[10] It is undisputed that only the work done in developing the RX GuideLiner is relevant for conception and reduction to practice. PO CRTP Resp. 13 n.3; Pet. CRTP Reply 1.

memory and documents he reviewed, that "we knew very early on that the GuideLiner rapid exchange device would work for its intended purpose," and that "[t]he research and development that followed our original conception of the GuideLiner rapid exchange was to optimize materials, dimensions, and design details that would allow us to manufacture and bring the product to market in a way that would be commercially viable." *Id.* ¶ 6.

The earliest documentary evidence that corroborates this testimony is Mr. Sutton's laboratory notebook pages relating to the concept for a "Guide-Liner" device. Ex. 2002. Mr. Sutton signed the relevant pages on January 4, 2005, and Jeffrey Welch, another co-inventor and engineer at VSI, witnessed those pages on March 2, 2005. Ex. 2002, 7–8; *see* Ex. 2119 ¶ 7.

A portion of one page from Mr. Sutton's notebook is reproduced below:



Ex. 2002, 7. As shown above, Mr. Sutton's notebook sets forth an "idea" that "relates to interventional coronary procedures and specifically to accessing & crossing tough or chronic total occlusions," which "is to provide a guide or support catheter more distally into the coronary to provide more back-up support for the stent device." *Id.*; Ex. 2118 ¶ 9. Mr. Sutton's lab notebook also includes drawings of the cross section of various portions of the guide extension catheter and a drawing of how the Guide-Liner would be used that are similar to figures included in the challenged patents. *Cf.* Ex. 1001, Figs. 1, 2, 5, 6 (depicting patent drawings of the guide extension catheter that are similar to Mr. Sutton's drawings). For example, the notebook includes a drawing of a "5F" (5-French) Guide-Liner in operation and notes that the Guide-Liner a) "is used where there is difficulty crossing lesions," b) "allows back-up support distally," c) "allows for Rapid X change," and d) "would fit in std. 6F Guides." *Id.* at 8. The notebook pages also describe the main features of the device, including 1) an inner tube/dilator that "fits snugly" within a stainless steel ("SS") half-tube; 2) a reinforced distal tube section with a braided "PTFE/SS/PEBAX" material that is "soft for coronaries"; and 3) a design that "allows for rapid exchange." Ex. 2002, 7. Additionally, the notebook identifies the "5F Design Specs," including an overall device length of between 105 cm and 115 cm. *Id.* Both Mr. Root and Mr. Sutton authenticate the contents of the notebook pages. Ex. 2118 ¶¶ 9–11; Ex. 2119 ¶¶ 7–14. Mr. Sutton attests that his notebook was "issued and maintained in the regular course of VSI's business." Ex. 2119 ¶ 7.

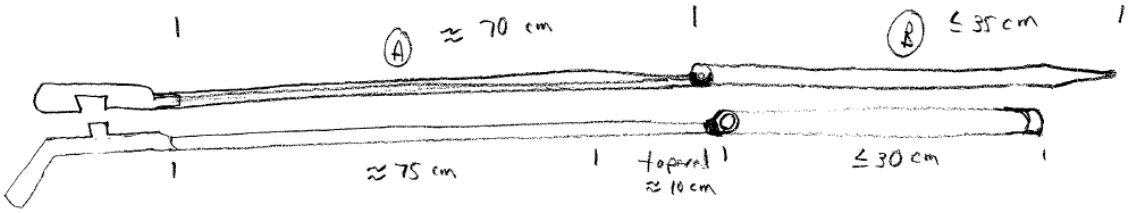
By early February 2005, Mr. Root realized this device would have "substantial market potential," so he wrote a "Market Feasibility"

memorandum ("memo") for GuideLiner catheters, dated February 4, 2005. Ex. 2118 ¶ 11; Ex. 2003 (confidential); Ex. 2127 (public). Mr. Root attests that he would only have drafted this kind of memo if he "had developed high confidence that a concept would work," so that non-inventors in the company (e.g., regulatory personnel and engineers) could join a project to bring the new product to market. Ex. 2118 ¶ 11. The memo itself recognizes the "substantial market potential" for the RX GuideLiner device based on an estimated 30,000 procedures a year. Ex. 2003, 1. The memo indicates that three versions were anticipated (i.e., a "5in6," a "6in7," and a "7in8" GuideLiner), and notes problems with the prior art OTW methods. *Id.* The memo also generally describes the RX GuideLiner in a manner consistent with the description in Mr. Sutton's notebook including, among other features, that it would be delivered within a standard guide catheter for interventional cardiology procedures; it had a short distal tube segment to allow for rapid exchange delivery; it was inserted through the existing hemostatic valve; and it was one French size smaller than the standard guide catheter. *Id.* at 2.

Mr. Root also references his own handwritten notes, dated February 7, 2005.[11] Ex. 2118 ¶¶ 12–14; Ex. 2004. These notes show certain features of

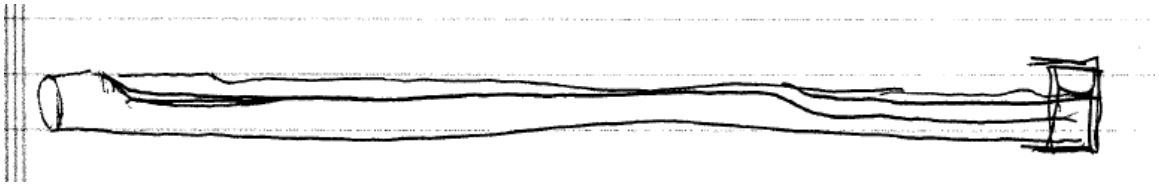
[11] Although only the first page of these notes is dated, Mr. Root attests he made the notes on the other two pages "contemporaneously with [his] notes on page 1." Ex. 2118 ¶ 14. Petitioner contends that the third page, in addition to being undated and unwitnessed, appears to come from "a different set of notes" because, unlike the first two pages, the paper is lined. Pet. CRTP Reply 7 n.4. Petitioner also points out that Mr. Sutton testified that he had not seen the third page until his deposition in the stayed district court litigation. *Id.* (citing Ex. 1108, 41:1–6, 46:7–47:3). Mr. Sutton, however, is not the author of these notes. Although we recognize that the

the RX GuideLiner device, including a "side opening" section that appears in the transition from a partial-round proximal portion to a full-round portion connected to a distal tube section. *Id.* The first drawing from Mr. Root's handwritten notes, reproduced below, is similar to Figure 1 of the '032 patent:



Ex. 2004, 1. As shown above, a "side opening" to allow for the RX capability is reflected through "crude shading" between the rail structure and tubular portion above the notation reading "tapered ≈ 10 cm," and was considered by Mr. Root to be "[a]n important feature of GuideLiner." Ex. 2118 ¶ 13. Mr. Root testifies that the side opening "facilitates entry of interventional cardiology devices into the proximal end of the tubular portion." *Id.*

The third page of Mr. Root's notes depicts another drawing, reproduced below, that also shows the side opening concept:



type of paper used to record the notes may have been different, we find that the content of page 3 seems to be otherwise consistent with the remainder of the notes and Patent Owner's other conception documents. We therefore find no basis to question Mr. Root's testimony that all his notes from Exhibit 2004 were made contemporaneously on or about February 7, 2005.

Ex. 2004, 3. According to Mr. Root, the sketch above "shows a side opening structure that is cut-away in several segments including, from left (distal) to right (proximal): a full round portion; a first angled transition portion; a first partial round portion; a second angled transition portion; and a second partial round portion." Ex. 2118 ¶ 14. The notes also list dimensions for the contemplated sizes of the GuideLiner. *Id.* ¶ 12; Ex. 2004, 1–3.

Beyond these "core" conception documents (Exs. 2002–2004), Patent Owner also relies on certain engineering drawings as further corroboration for the inventors' testimony. PO CRTP Sur-Reply 3–5 (citing Exs. 2022, 2113, 2114). Patent Owner annotates two of these drawings to highlight features of the depicted GuideLiner, namely the "Side Opening," "Rail Structure," "Machined End for Connecting to Tubular Portion," "Soft Tip," and "Reinforced Pebax Tubular Portion." *Id.* at 4 (citing Ex. 2114), 5 (citing Ex. 2022). The drawings are dated March 2005 (Ex. 2113, 1), June 28, 2005 (Ex. 2114), and August 1, 2005 (Ex. 2022, 1). We have taken these documents into account in determining whether the inventors conceived of the claimed invention prior to the September 23, 2005, critical date.

b) Analysis for Conception

We first consider whether Patent Owner's proffered evidence corroborates the inventors' testimony of conception. Patent Owner does not assert a specific date of conception. *See* Tr. 60:4–6 ("Our story from day one has been that the exact date of conception doesn't matter."). We agree that we need not determine the exact date on which conception took place. Nonetheless, before we can move on to the question of reduction to practice,

we must determine that conception—as legally defined to be the formation of "a definite and permanent idea of the complete and operative invention," *Cooper*, 154 F.3d at 1327—was finalized at some point prior to the critical date of Itou. From the evidence Patent Owner relies upon, we can distill Patent Owner's broad theory of conception as having occurred either by February 2005, as corroborated by the core conception documents (Exs. 2002–2004), or by August 2005 during the course of building and testing prototypes, as further corroborated by the engineering drawings (Exs. 2113, 2114, 2022).

Petitioner argues Patent Owner's core documentary evidence—Mr. Sutton's notebook pages, the market feasibility memo, and Mr. Root's handwritten notes—cannot be used to corroborate inventor testimony insofar as they all originated from the inventors themselves as opposed to some other independent source. Pet. CRTP Reply 4. Petitioner relies principally on three cases as support for this argument. *Id.* at 3–4.

First, Petitioner cites *Apator Miitors ApS v. Kamstrup A/S*, 887 F.3d 1293 (Fed. Cir. 2018), to argue the documents relied upon by Patent Owner are "inventor documents" that cannot be used to corroborate an inventor's testimony on conception. Pet. CRTP Reply 4. The problem for the patent owner in *Apator* was that it was "stuck in a catch-22 of corroboration" because the evidence that was proffered to corroborate the inventor's testimony could "only provide that corroboration with help from [the same inventor's] testimony." 887 F.3d at 1296. For instance, in the bodies of the emails that were relied upon, the inventor indicated that he attached certain files related to his invention, but nothing in any part of the emails indicated what files were attached or what such attachments disclosed. *Id.* The court

agreed with the Board's finding that the inventor's testimony was the only evidence proffered to establish the existence and substance of the attachments. *Id.* at 1296–97. And though the drawings set forth dates that were after the reference's critical date, the inventor's testimony about certain file naming conventions was the only evidence offered by the patent owner to demonstrate that the drawings were actually created on an earlier date. *Id.* at 1294–95, 1296–97. The court rejected the patent owner's argument that the emails and drawings should still have "some corroborative value," like unwitnessed laboratory notebooks. *Id.* at 1297. The court acknowledged that the rule of reason permits "'a notebook entry' or other writing '[that] has not been promptly witnessed,'" *id.* (citing *Singh v. Brake*, 222 F.3d 1362, 1369 (Fed. Cir. 2000)), "to aid in corroborating witness testimony alongside other, more persuasive, evidence." *Id.* (citing examples where the Federal Circuit and one of its predecessors, the Court of Customs and Patent Appeals, permitted unwitnessed documents to contribute to corroboration of conception). But the court clarified that "an unwitnessed laboratory notebook, alone, cannot corroborate an inventor's testimony of conception." *Id.* (citing *Brown v. Barbacid*, 276 F.3d 1327, 1335 (Fed. Cir. 2002) (concluding there was no error in denying corroboration by "an inventor's own unwitnessed documentation"); *Procter & Gamble Co. v. Teva Pharms. USA, Inc.*, 566 F.3d 989, 998–99 (Fed. Cir. 2009) (concluding a laboratory notebook that "was unwitnessed and was not corroborated by any other evidence" could not corroborate inventor testimony of conception)).

Second, Petitioner cites *Kolcraft Enterprises, Inc. v. Graco Children's Products, Inc.*, 927 F.3d 1320 (Fed. Cir. 2019), in support of its argument that the documents relied upon by Patent Owner lack corroborative value

because they all "'originated with the inventors.'" Pet. CRTP Reply 4. In *Kolcraft*, the Federal Circuit observed that the evidence at issue—which it characterized as "even weaker than the evidence presented in *Apator*"—comprised a redacted inventor declaration, the inventor's deposition testimony, and undated photos attached to the inventor declaration. 927 F.3d at 1325. Of this evidence, the court noted that "[o]nly the Inventor Declaration, i.e., inventor testimony, supports the purported dates showing [prior] conception," but this was deemed insufficient because "[i]nventor testimony alone cannot prove conception." *Id.*

Third, Petitioner cites a non-precedential Board decision, *Curt Manufacturing, LLC v. Horizon Global Americas Inc.*, IPR2019-00625, 2020 WL 4687044, at *7 (PTAB Aug. 11, 2020), for the proposition that "[o]ne inventor cannot corroborate another." Pet. CRTP Reply 4; *see also* Tr. 35:20–36:12 (Petitioner's counsel citing *Curt* for the same proposition). In *Curt*, the Board stated that "[o]ne consequence of the independence requirement is that *testimony* of one co-inventor cannot be used to help corroborate *the testimony* of another." *Curt*, 2020 WL 4687044, at *7 (citing *Lacks Indus., Inc. v. McKechnie Vehicle Components USA, Inc.*, 322 F.3d 1335, 1350 (Fed. Cir. 2003) (emphases added) (approving refusal to accept cross-corroboration of oral testimony by interested witnesses)).[12] The Board further noted that "an inventor's *unwitnessed* laboratory notebooks,

[12] The Federal Circuit, however, has not categorically prohibited "cross-corroboration" of testimony by interested witnesses at least in other contexts. *See Nobel Biocare Servs. AG v. Instradent USA, Inc.*, 903 F.3d 1365, 1378 (Fed. Cir. 2018) ("The testimony of one witness may corroborate the testimony of another witness.").

emails, and drawings, *without other independent evidence*, cannot corroborate an inventor's testimony." *Id.* (emphases added) (citing *Kolcraft*, 927 F.3d at 1325–26; *Apator*, 887 F.3d at 1297; *Brown*, 276 F.3d at 1335). In a footnote quoting *Brown*, the Board highlighted the importance of two issues: whether the documentary evidence was witnessed and whether there is other corroborating evidence in the record. *Id.* at *7, n.7 (reiterating that physical evidence from an inventor does not need corroboration to demonstrate its contents, but the inventor's *unwitnessed* documentation "may not *single-handedly* corroborate" the inventor's testimony (quoting *Brown*, 276 F.3d at 1335) (other emphases omitted)). Lastly, the Board concluded that, "[n]otwithstanding this clear guidance, the law also recognizes that . . . a notebook entry or other writing that has not been promptly witnessed does not necessarily disqualify it in serving as corroboration of conception under a rule of reason analysis." *Id.* at *7 (citing *Apator*, 887 F.3d at 1297 (referring to cases where unwitnessed documentary evidence was considered alongside other evidence to corroborate inventor testimony)).

Considering the evidence of record as a whole, we reject Petitioner's arguments that the inventors' testimony on conception is not adequately corroborated. We find the case law cited by Petitioner to be distinguishable.

We first note that Mr. Sutton's laboratory notebook was witnessed shortly after the date of entry of the relevant pages. Specifically, the notebook pages presented here were witnessed by another inventor, Jeffrey Welch. Ex. 2002. Because the notebook is dated and witnessed, we may properly consider it for its probative value in corroborating Mr. Root's and Mr. Sutton's testimony. *See Singh*, 222 F.3d at 1369–70 (holding that a

belatedly witnessed lab notebook may serve as corroboration of conception); *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1378 (Fed. Cir. 1986) (same). Indeed, as noted above, even an unwitnessed notebook page may have some corroborative value under the rule of reason when considered in combination with other more persuasive evidence. *Apator*, 887 F.3d at 1297. Moreover, we discern no *per se* rule from the case law to suggest that a laboratory notebook witnessed by a co-inventor cannot be used to corroborate another inventor's testimony about conception. In this regard, we find that the witnessed notebook pages avoid the "catch-22 of corroboration" noted in *Apator* because the notebook pages do not depend upon either Mr. Root's or Mr. Sutton's testimony for an explanation of their content. The notebook pages also avoid the issue that arose in *Kolcraft* and *Curt* because Patent Owner has not relied upon only the inventors' testimony to prove conception. We note that, aside from whether the notebook pages can legally qualify as corroborative evidence of the date of conception, Petitioner has not disputed the authenticity or veracity of the content shown on those pages. As such, we have considered the content of the notebook pages at face value in our analysis.

We have also taken into account the market feasibility memo and Mr. Root's handwritten notes in our corroboration assessment. Ex. 2003; Ex. 2004. We recognize that these documents appear to have been authored by Mr. Root, and no witness other than Mr. Root has provided testimony about their content. As such, if considered in isolation, these conception documents may be more analogous to the type of "catch-22" documents found insufficient for corroborating the date of conception under *Apator*. Nonetheless, applying the rule of reason, we do not categorically exclude

them from the corroboration analysis because they can still "aid in corroborating witness testimony alongside other, more persuasive, evidence." *Apator*, 887 F.3d at 1297. We further note that, like the notebook pages, Petitioner has not disputed the authenticity or veracity of the content of the market feasibility memo and Mr. Root's handwritten notes, and thus we have also considered the content of these documents at face value.

Because we conclude that the notebook pages, along with the market feasibility memo and Mr. Root's handwritten notes, may be properly considered in our corroboration analysis, we next address whether these documents are in fact sufficiently corroborative of the inventors' testimony to show conception of the claimed invention prior to the critical date. On this point, Mr. Root includes as appendices to his declaration claim charts showing how certain VSI prototypes developed at the time meet the limitations of the challenged claims. Ex. 2118, App'x A–E.[13] The primary argument raised by Petitioner is that Patent Owner's core conception documents do not disclose the "side opening" feature recited in numerous

[13] Petitioner contends that Mr. Root's claim charts amount to an improper incorporation by reference in violation of 37 C.F.R. § 42.6(a)(3) and a circumvention of our word limits. Pet. CRTP Reply 2. However, in view of the commonality of the CRTP issues across these related proceedings, we authorized the parties to submit consolidated briefing on the issue. Paper 26 (Consolidated Scheduling Order), 2–3. Moreover, Petitioner also submitted similar rebuttal claim charts by its expert Dr. Zalesky as appendices to his expert report. Ex. 1755, App'x A–E. Under the circumstances, we are not persuaded that the manner in which Patent Owner presented its claim-by-claim arguments were a violation of our rules.

challenged claims. Pet. CRTP Reply 5–7.[14] According to Petitioner, without this demonstration, Patent Owner fails to establish conception of "every feature or limitation of the claimed invention." *Id.* at 3 (quoting *REG Synthetic Fuels*, 841 F.3d at 962). We are persuaded that the evidence shows that the RX GuideLiner device that the inventors had conceived of and were developing at the time included all the features of the challenged claims, including a side opening feature to allow for rapid exchange.

[14] For instance, claim 3 of the '032 patent recites

> The device of claim 2 wherein the proximal portion of the tubular structure further comprises structure defining a *proximal side opening* extending for a distance along the longitudinal axis, and accessible from a longitudinal side defined transverse to the longitudinal axis, *to receive an interventional cardiology device into the coaxial lumen while the proximal portion remains within the lumen of the guide catheter*.

Ex. 1001,10:63–11:3, cl. 3 (emphasis added). Claim 13 of the '032 patent recites "the substantially rigid portion further includes a partially cylindrical portion defining an opening extending for a distance along a side thereof," which the parties agree also refers to the "side opening" feature. *Id.*, 12:12–14, cl. 13.

As Petitioner acknowledges, this argument only applies to certain claims. *See* Tr. 59:5–12. According to Petitioner's table in its CRTP Sur-Sur-Reply, the side-opening limitation appears in the following claims: claims 3 and 4 of the '032 patent; claims 3, 4, 36 of the '380 patent; claims 25, 52, and 53 of the '776 patent; and claims 25, 48, 51, and 53 of the '760 patent. Pet. CRTP Sur-Sur-Reply 14–15. In its Sur-Sur-Reply, Petitioner also contends that Patent Owner is missing evidence that the RX prototypes satisfy certain additional claim limitations. *Id.* We consider this in addressing the actual reduction to practice issue below.

As noted above, Mr. Root attests that the first and third pages of his handwritten notes each depict a drawing that includes a side opening. Ex. 2118 ¶¶ 12–14 (citing Ex. 2004, 1, 3). In particular, Mr. Root asserts that

> [a]n important feature of GuideLiner is a "side opening" at the transition between the proximal rail structure and the distal tubular portion that facilitates entry of interventional cardiology devices into the proximal end of the tubular portion. This feature is reflected in the crude shading between the rail structure and the tubular portion shown in the sketch above from my February 7, 2005 notes.

Id. ¶ 13. We credit this testimony and find that it is corroborated by the drawings themselves.

Petitioner contends that the lab notebook pages, as confirmed by Mr. Sutton's deposition testimony, only show an "end opening" rather than a side opening for the device. Pet. CRTP Reply 5 (citing Ex. 1108, 70:18–71:23, 79:14–80:24). To further dispute the disclosure of a side opening, Petitioner relies on the declaration of its expert Dr. Zalesky. *Id.* at 6 (citing Ex. 1755 ¶¶ 83–84). Dr. Zalesky contends that the "crude shading" on the drawing on the first page of Dr. Root's notes "does not appear to show an angled opening at the proximal end of the tubular portion" and that Mr. Root's notes on the page do not refer to a side opening. Ex. 1755 ¶ 83. Dr. Zalesky further contends that the drawing on the third page of Mr. Root's notes "does not appear to correspond to any of the figures in the Root patents"; is "quite crude," making it "difficult to tell what it represents, if anything"; and "does not appear to show a side opening." *Id.* ¶ 84.

Although we recognize that Mr. Sutton testified that Figure 1 does not depict an angled side opening, it does not appear that Mr. Sutton categorically stated that the inventors had not conceived of a device that

included the side opening feature or otherwise directly contradicted Mr. Root's testimony on this point. We further note that the first drawing in Mr. Root's notes appears to closely match Figure 1 of the challenged patent (which depicts an unassembled coaxial guide catheter and tapered inner catheter), while the first drawing in Mr. Sutton's notes appears to closely match Figure 2 of the challenged patent (which depicts the assembled device). *Compare* Ex. 2004, 1, *with* Ex. 1001, Fig. 1; *compare* Ex. 2002, 7, *with* Ex. 1001, Fig. 2. We agree with Dr. Zalesky that the sketches included in Mr. Root's handwritten notes are "crude" and not a model of clarity. Nonetheless, taking into account both the documentary evidence and inventor testimony as a whole, we find that a preponderance of the evidence supports the conclusion that the inventors conceived of a device that included the side opening and all other claimed features prior to the critical date.

To the extent that the earlier core conception documents alone do not support prior conception, we have also taken into account the evidence proffered by Patent Owner with respect to the prototypes that were built between February and August 2005. *See* PO CRTP Sur-Reply 3 (explaining that if the early 2005 documents "were disregarded," other pre-Itou evidence "undisputedly shows conception of the entire invention, *including the side opening*" (emphasis added)). To support its theory, Patent Owner cites Dr. Zalesky's testimony, where he confirms that the engineering drawings depict a side opening. Ex. 2237, 211:11–16 (agreeing that "a side opening can be found in the hypotubes that were cut down by Spectralytics, specifically Exhibit 2113 and 2114"), 250:9–13 (agreeing that "Exhibit 2022 sets forth the concept for the rapid exchange GuideLiner"). Petitioner

acknowledges the probative value of the August 2005 drawing in showing conception prior to the critical date: "[a]t best, [Patent Owner] shows conception in August 2005, a mere month before Itou and *after* VSI's purported prototype work in April and July." Pet. CRTP Sur-Sur-Reply 3. Much of this evidence is also relied upon by Patent Owner to demonstrate that there was actual reduction to practice prior to the critical date. Given the overlap, we also address this evidence as part of our actual reduction to practice analysis.

In sum, Patent Owner's core documentary evidence—Mr. Sutton's lab notebook, the market feasibility memo, and Mr. Root's handwritten notes—sufficiently corroborate the stories of conception set forth in Mr. Root's and Mr. Sutton's declarations. These corroborating documents add credibility to the inventors' conception timelines. And even if Petitioner were correct that not every feature was conceived on or about February 2005, we find that additional evidence of record with respect to the prototypes, as discussed below, demonstrates conception no later than August 2005.

3. Actual Reduction to Practice

Patent Owner contends that actual reduction to practice also took place before the critical date of Itou. In support of this contention, Mr. Root attests in his declaration that employees at VSI, led by co-inventors Mr. Sutton and Mr. Welch, built and tested RX GuideLiner prototypes between January and August 2005.[15] Ex. 2118 ¶ 15. Mr. Sutton, as well as two non-

[15] Mr. Root explains that Patent Owner does not have many development documents from 2005, and it obtained many of the documents relevant to

inventors employed by VSI at the time, Steve Erb and Deborah Schmalz, also testify about relevant details of the research and development done with regard to the GuideLiner prototypes. Ex. 2039 (Schmalz Declaration); Ex. 2119 (Sutton Declaration); Ex. 2122 (Erb Declaration). Patent Owner also presents the declarations of Mark Goemer and Amanda O'Neil, who were employed by outside vendors from whom VSI purchased components to build the prototypes. Ex. 2120 (Goemer Declaration); Ex. 2121 (O'Neil Declaration). Additionally, Patent Owner has submitted an expert declaration by Mr. Peter Keith in further support of this contention. Ex. 2123 (Keith Declaration in support of CRTP). Patent Owner relies upon purchase invoices, engineering schematics, and other documentary evidence from as early as January 2005 through the September 2005 critical date of Itou in order to corroborate the fact declarants' testimony regarding actual reduction to practice.[16] We once again set forth the relevant facts based on these declarants' testimony and corroborating evidence, and then address any disputed issues of material fact and legal issues as needed in our analysis for actual reduction to practice.

---

actual reduction to practice from VSI's vendors and patent prosecution firm. Ex. 2118 ¶ 20.

[16] Patent Owner includes some documentary evidence created after Itou's critical date. *See, e.g.*, Ex. 2106 (invoices dated April 2006); Exhibit 2115 (engineering drawing dated November 2005). We do not find this post-critical date evidence to support Patent Owner's contentions regarding actual reduction to practice. However, we have considered some of this evidence in our analysis of whether there was diligence towards constructive reduction to practice (*see* discussion, *infra*), as well as to address Petitioner's argument that the continuing work done at VSI with respect to the GuideLiner demonstrates a lack of actual reduction to practice before Itou.

a) Fact Findings for Actual Reduction to Practice

After the inventors came up with the initial idea for the device (as set forth in the conception discussion above), VSI proceeded with the development of both the OTW and RX versions of the GuideLiner concurrently. Ex. 2118 ¶ 19; Ex. 2119 ¶ 15. Although it was based on existing technology, VSI decided to pursue the OTW version based on the belief that it could be brought to market more quickly with fewer regulatory challenges than the RX version. Ex. 2118 ¶ 19; Ex. 2119 ¶ 15. Nonetheless, the RX version remained a priority for continued development at VSI. *Id.* Consistent with Mr. Root's testimony, Mr. Sutton testifies that the RX GuideLiner was reduced to practice before September 2005, although further work towards commercialization of the product continued until he left the company. Ex. 2119 ¶ 6. According to Mr. Sutton, work for the OTW prototype "paled in comparison" to work required for the RX prototype because the OTW prototype "required very little engineering and was relatively easy to build because it was based on existing technology." *Id.* ¶ 15. In their declarations, Mr. Root and Mr. Sutton focus on two distinct sets of prototypes of the RX version that were built and tested before Itou's critical date: the "April 2005" prototypes and the "July 2005" prototypes. Ex. 2118 ¶ 48; Ex. 2119 ¶¶ 21–22.[17] As noted above, Mr. Root includes claim charts identifying how the April and July 2005 prototypes satisfied the

[17] Although Mr. Root refers to the likelihood that other sets of prototypes were also built, the bulk of Patent Owner's evidence and arguments relate to the April and July 2005 prototypes. Ex. 2118 ¶ 48. As such, we focus on these prototypes in determining whether there was actual reduction to practice.

limitations of the challenged claims. Ex. 2118, App'x A–E; *see also* Ex. 2123 ¶ 28 (Mr. Keith opining that the April and July 2005 prototypes satisfy the claim limitations based on these claim charts).

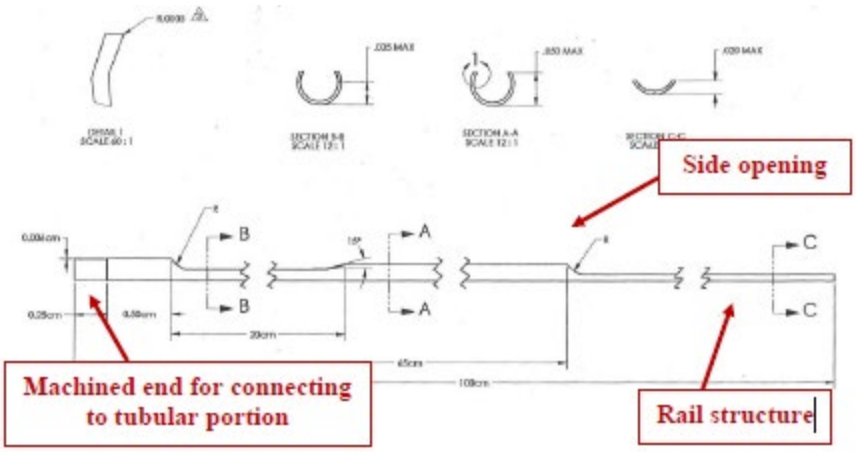
In developing these prototypes, a VSI technician and machinist, Mr. Erb, worked with the inventors to mechanically cut down stainless steel or nitinol "hypotubes" used for the proximal portion of an RX prototype. Ex. 2118 ¶ 16; Ex. 2119 ¶ 20; Ex. 2122 ¶¶ 8–10. The profile of some of these hypotubes started at full circumference at the distal end, then progressed to roughly half-round at the proximal end. Ex. 2118 ¶ 16. The hypotubes were combined with a polymer distal section to create the first RX GuideLiner prototypes. *Id.* At this time, the distal tubular portion was sometimes built by cutting a standard guide catheter to the appropriate length. *Id.* ¶ 24. The earliest prototypes, made in January or February 2005, largely comprised stock components modified through VSI's in-house machining capabilities. *Id.* ¶¶ 18, 20. However, by April 2005, the VSI engineers progressed to building more formal prototypes using custom-ordered materials from outside vendors for the proximal and distal portions of the device. Ex. 2122 ¶ 12. A spend report details at least some of the expenses that VSI incurred on purchases of the components used to build GuideLiner prototypes from February 11, 2005, to June 30, 2006. Ex. 2005; Ex. 2118 ¶¶ 21–22. According to Mr. Root, the fact that they had opened an account specific to the "Guideliner project" in May 2005, as reflected in this spend report, indicates that development had advanced to the point that they were confident with proceeding towards commercialization. Ex. 2118 ¶ 22.

With respect to the proximal portions, Patent Owner presents invoices and other documents reflecting VSI's purchases of laser-cut hypotubes from

three outside vendors: MicroGroup, Mountain Machine, Inc., and SPECTRAlytics. Ex. 2118 ¶¶ 23, 27, 29, 30, 32, 33, 40, 43 (citing Exs. 2006, 2007, 2009, 2010, 2013, 2020, 2091, 2094, 2095, 2110, 2111); Ex. 2119 ¶¶ 24–31 (discussing similar purchases); *see also* Ex. 2122 ¶ 7 (discussing purchases of stainless steel and nitinol hypotubes as reflected in Ex. 2110).[18] Because some of these invoices show purchases of the hypotubing by the foot, Mr. Root asserts that the materials were likely used for early evaluations of the RX GuideLiner concept. Ex. 2118 ¶ 23. Mr. Sutton similarly asserts that the hypotubing that was purchased at this time was used to make RX GuideLiner prototypes, as the OTW version never involved such hypotubing. Ex. 2119 ¶ 25. The ranges of the inner and outer diameters, wall thickness, and the overall length of the hypotubes that were ordered were consistent with what VSI would have needed at the time for prototyping the RX GuideLiner. *Id.* ¶¶ 24, 26.

Mr. Root and Mr. Sutton also reference the following annotated engineering schematics of the proximal portion of the RX GuideLiner that were drawn by a VSI engineer, Jim Kauphusman, on February 4, 2005:

[18] Although both stainless steel and nitinol hypotubes were ordered, Mr. Sutton asserts that nitinol was significantly more expensive and required additional post-processing steps as compared to stainless steel, and these factors ultimately weighed against using nitinol for the proximal portion of the RX GuideLiner. Ex. 2119 ¶ 28.



Ex. 2113; Ex. 2118 ¶ 34; Ex. 2119 ¶ 30. The drawings above show a design of the proximal portion with multiple angled transition regions bookending non-inclined regions, and Patent Owner's annotations to the drawings—which were added for this proceeding, *see* PO CRTP Sur-Reply 13—identify a "machined end for connecting to tubular portion," a "side opening," and a "rail structure." *Id.* These drawings were submitted as "prints" to SPECTRAlytics in order to specify the parameters for the hypotubes that were custom ordered, and include a drawing number "SS HYPO X04" that correlates to a purchase completed on April 4, 2005. Ex. 2118 ¶ 34; Ex. 2120 ¶ 9; Ex. 2095. Additional engineering drawings for the proximal portions were submitted to SPECTRAlytics around June 2005. Ex. 2118 ¶ 41; Ex. 2120 ¶ 11; Ex. 2114. Some of the engineering drawings are similar to figures included in the challenged patent. *Cf.* Ex. 1001, Figs. 12–16.[19] Mr. Goemer verifies and authenticates some of the purchase documents and the engineering drawings retrieved from SPECTRAlytics's files. Ex. 2120 ¶¶ 6–12.

[19] Mr. Sutton faxed these drawings to VSI's outside patent counsel on March 21, 2006. Ex. 2118 ¶ 42; Ex. 2019.

Additionally, Mr. Root and Mr. Sutton refer to purchases of distal tubular portions and the distal forming tips from vendors Medical Engineering & Design Inc. ("MED") and Farlow's Scientific Glassblowing Inc. between February and July 2005. Ex. 2118 ¶¶ 28, 31, 44, 45 (citing Exs. 2011, 2021, 2090, 2092); Ex. 2119 ¶¶ 32–34, 36 (additionally citing Exs. 2032, 2033, 2034, 2035, 2089, 2097, 2112). Ms. O'Neil, who is employed by MED's successor TE Connectivity ("TE"), verifies and authenticates some of these purchase documents, and notes that the documents were retrieved from the files of TE, but originated with MED in 2005. Ex. 2121 ¶¶ 5–6.

One of the documents from MED also includes engineering schematics for the distal portion that were drawn on February 10, 2005, by Mr. Kauphusman, as shown below:

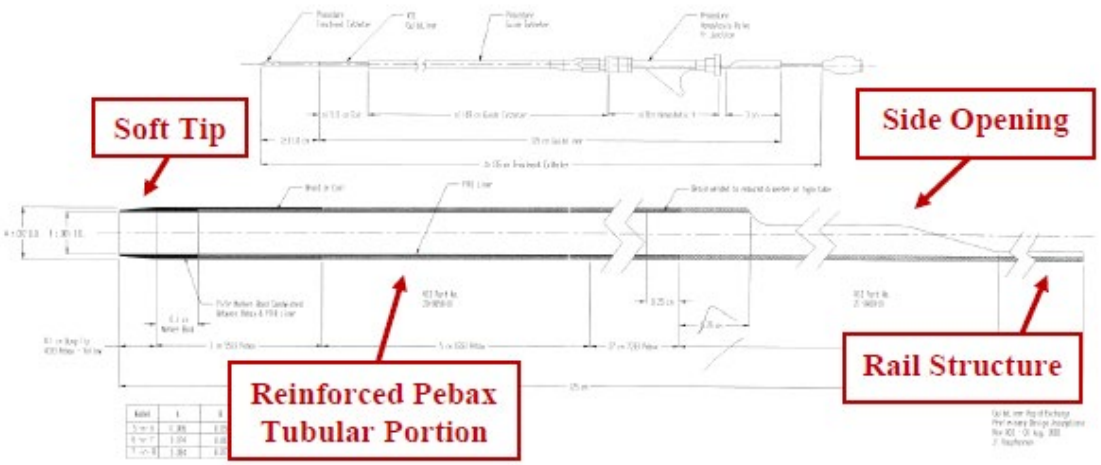
Ex. 2089, 8; Ex. 2118 ¶ 25; Ex. 2119 ¶ 32. The drawing above shows the distal portion with Patent Owner's annotations, *see* PO CRTP Resp. 9, identifying a "soft tip," "three reinforced Pebax portions," the "distal end," and the "proximal end." *Id.* Although Exhibit 2089 does not specify that the tubing was for the RX version of the GuideLiner, Mr. Root and Mr.

Sutton assert that the drawings and specifications were in fact specific to an RX device based on the notation that the proximal end should be "counter bored" (a requirement to facilitate attachment to the cut-down hypotube) as well as the overall length of 11.8 inches (because if this part were for an OTW device, it would have been significantly longer). *Id.* The order for distal portions as shown in Exhibit 2089 was placed on February 17, 2005, and the parts were shipped from MED and delivered to VSI on or about April 5, 2005. Ex. 2118 ¶ 25; Ex. 2119 ¶ 33. An update to the drawing shown in Exhibit 2089 was made on April 6, 2005, as shown in Exhibit 2092, with only minor changes, namely slightly reduced inner and outer diameters to fit a guide catheter and a slightly shortened tip. Ex. 2092, 8; Ex. 2118 ¶ 44. An order for distal tubular portions based on the updated design was placed on April 12, 2005 and those parts were delivered to VSI on or about June 16, 2005. *Id.*

The proximal and distal portions that were custom ordered and purchased from the outside vendors were thereafter combined in-house at VSI to form the prototypes of the complete RX GuideLiner. Ex. 2118 ¶ 24 ("From the earliest stages of the project, the plan was to combine the substantially rigid proximal portion of the rapid exchange GuideLiner with a distal polymer tubular portion that would be at least partially reinforced with coil or braid."); Ex. 2119 ¶ 34 ("[W]e combined these distal sections from MED with the proximal stainless steel sections discussed above to form prototypes of the GuideLiner rapid exchange in April and July 2005."). For example, the first set of formal prototypes (the April prototypes) appear to have been made by combining the laser-cut hypotubes from SPECTRAlytics with the distal tubular sections from MED that were shipped around April 5,

2005. Ex. 2118 ¶ 35 (citing Exs. 2011, 2089). Additional prototypes (the July prototypes) appear to have been built using the hypotubes from MicroGroup shipped around April 20, 2005, and/or the hypotubes from SPECTRAlytics shipped around July 18, 2005, in combination with the updated distal portions from MED shipped around June 16, 2005. *Id.* ¶¶ 39, 40, 46 (citing Exs. 2114, 2020, 2021, 2092, 2094). In making these prototypes, VSI "used an in-house thermal process to fuse the distal tubing sections from MED to the cut-down hypotubes." Ex. 2119 ¶ 35. VSI had the materials and equipment available to assemble the device at their facilities. *Id.*

As further evidence of an assembled device, inventors Mr. Root and Mr. Sutton reference the following engineering CAD schematics from August 1, 2005:



Ex. 2118 ¶ 49; Ex. 2119 ¶ 39; Ex. 2022. The drawings above show a version of the complete RX GuideLiner, as well as a cross-sectional view of the device with Patent Owner's annotations, *see* PO CRTP Resp. 16, identifying the "soft tip," the "reinforced Pebax tubular portion," the "side

opening," and the "rail structure." Ex. 2118 ¶ 49. The schematics are labeled "GuideLiner Rapid Exchange/Preliminary Design Assumptions/Rev X03," which according to Mr. Root, was an indication that VSI had moved past prototyping and into commercialization. *Id.* Mr. Sutton attests that the "X03" indicates that this was the third version of the CAD drawings, and that they had built and tested prototypes of the RX GuideLiner device shown in these drawings. Ex. 2119 ¶ 39. The document also references the same part number (20-0658) as those identified in certain purchase documents for distal tubular portions from MED. Ex. 2118 ¶ 51 (citing Ex. 2021, Ex. 2089, Ex. 2092). These drawings are nearly identical to Figures 3 and 4 of the patent. *Cf.* Ex. 1001, Figs. 3–4 (depicting patent drawings that resemble the CAD drawings).

The prototypes were tested using bench-top coronary models, including two-dimensional ("2D") acrylic heart models and three-dimensional ("3D") glass heart models, to simulate the native anatomy and environment. Ex. 2118 ¶¶ 17, 38, 47; Ex. 2119 ¶¶ 37–38, 41. These types of models were commonly used by VSI and other medical device companies to test interventional cardiology devices. Ex. 2118 ¶ 17; Ex. 2123 ¶ 21 (Mr. Keith noting that he had used similar models to test catheter designs during his time at Scimed and Boston Scientific Corporation). A sales presentation from July 2005 shows an example of a 2D coronary model. Ex. 2018, 12; Ex. 2129 (redacted version of the same presentation). While this particular presentation depicts testing of the OTW version of the GuideLiner concurrently under development, Mr. Root asserts that a similar model was used to test the RX version. Ex. 2118 ¶¶ 18, 38. The testing done using this model included performing pull tests as well as simulations comprising the

following steps: a) inserting a standard guide catheter into the coronary model; b) advancing the prototype into the guide catheter until the prototype's distal end extended beyond the guide catheter's distal end; and c) delivering a stent or balloon catheter into and through both devices. *Id.* ¶ 18. Although "more qualitative than quantitative," these tests enabled the inventors to observe the prototype's durability and the forces exerted on the prototype. Ex. 2118 ¶¶ 18, 47; Ex. 2119 ¶¶ 23, 41. Both Mr. Root and Mr. Sutton attest that this testing was sufficient to confirm that the RX GuideLiner would work for its intended purpose, namely facilitating delivery of interventional cardiology devices into challenging coronary anatomy by providing increased backup support as compared to a guide catheter alone. *Id.*

Patent Owner also presents other documentary evidence as corroboration of the testimony of inventors Mr. Root and Mr. Sutton. We have taken these documents into account, but find them somewhat less probative in showing actual reduction to practice.

For instance, a June 23, 2005, market feasibility memo (Ex. 2017), similar to the earlier memo from February 4, 2005 (Ex. 2003), confirms that the RX GuideLiner prototype was continuing to be developed, although the OTW version had been added to the development project at that point. Ex. 2118 ¶ 37; *see* Ex. 2017, 1 (noting that "it is possible to make the GuideLiner in an Over-the-Wire version, a Rapid Exchange Version, or both").

A "Product Requirements" document, dated August 24, 2005, sets forth the safety and performance requirements for both the OTW and RX

guide catheter support systems. Ex. 2118 ¶ 54; Ex. 2119 ¶ 44; Ex. 2024.[20] The document notes that "[t]hese safety and performance features are the minimal requirements for the device to be acceptable for its intended clinical use," and that the "[a]pplicable clinical use is for increase[d] guide catheter back-up support." Ex. 2024, 1. Mr. Root asserts that this document marked the start of the formal quality process for the RX and OTW GuideLiner catheters. Ex. 2118 ¶ 54. Both Mr. Root and Mr. Sutton, as well as Ms. Schmalz (VSI's Vice President of Regulatory and Clinical Affairs at the time), testify that that this document would have been created only after the product was tested, demonstrated to work, and ready to proceed with regulatory approval and commercialization. Ex. 2118 ¶ 54; Ex. 2119 ¶ 44; Ex. 2039 ¶ 7. Ms. Schmalz specifically recalls that a working prototype of the RX version was created prior to the creation of this document. Ex. 2039 ¶ 7. Although this document sets forth several user requirements for the device, it does not identify the product specifications and test methods correlating to those requirements. Ex. 2024, 2–4. The revision history of the document also indicates it is "pre-release," thereby suggesting that it may not have been finalized at the time. *Id.* at 4.

Mr. Root, Mr. Sutton, and Ms. Schmalz each also discuss two other documents both dated August 26, 2005—a Clinical Technical Report (Ex. 2025) and a staff meeting memo (Ex. 2040)—as further evidence that work

[20] Exhibit 2024 is the subject of Petitioner's motion to exclude. Paper 111. For the reasons we state below in addressing the motion to exclude (*see* discussion, *infra*), we decline to exclude Exhibit 2024 but have considered Petitioner's arguments in determining the weight to be given to this piece of evidence.

continued on the RX GuideLiner and that VSI was ready to seek regulatory approval for the device from the Food and Drug Administration ("FDA"). Ex. 2039 ¶¶ 9–10; Ex 2118 ¶¶ 55– 57; Ex. 2119 ¶¶ 45–46. The Clinical Technical Report states that VSI "has developed, and is currently manufacturing four types of catheters . . . [including] the GuideLiner Catheter Support System used to provide physicians with additional guide catheter support allowing access to more difficult anatomy," and goes on to describe both the RX and OTW versions of GuideLiner. Ex. 2025, 2–3, 5–6. We note, however, that the text discussing GuideLiner devices appears to be "redline" edits and does not include any signatures for "document approvals," thus suggesting that the document submitted as Exhibit 2025 may have only been a draft. *See id.* The staff memo refers to clinical literature reviews for the GuideLiner devices (both RX and OTW), which Mr. Root asserts was part of VSI's regulatory strategy for a "510(k)" submission to the FDA.[21] Ex. 2118 ¶ 57.

b) Analysis for Actual Reduction to Practice

To establish actual reduction to practice, Patent Owner must demonstrate two things: (1) that it constructed an embodiment that met all the limitations of the invention claimed in the patent at issue; and (2) that it determined that the invention would work for its intended purpose. *Cooper*, 154 F.3d at 1327. Having considered the evidence and arguments of record,

[21] A 510(k) submission is a premarket notification "to demonstrate that the device to be marketed is as safe and effective, that is, substantially equivalent, to a legally marketed device." *See* FDA, Premarket Notification 510(k), (accessed June 1, 2021), https://www.fda.gov/medical-devices/premarket-submissions/premarket-notification-510k.

including the testimonial and documentary evidence summarized above, we find that Patent Owner has met this burden with respect to the challenged claims based on the prototypes of the RX GuideLiner that were built and tested at VSI prior to September 2005. We address Petitioner's arguments to the contrary.

The first issue raised by Petitioner is whether there is sufficient corroborating documentary evidence to support the inventors' testimony on reduction to practice. As with conception, "a party seeking to prove an actual reduction to practice must proffer evidence corroborating [an inventor's] testimony." *Raytheon Co. v. Sony Corp.*, 727 F. App'x 662, 668 (Fed. Cir. 2018) (citing *Medichem*, 437 F.3d at 1169–71). The sufficiency of this corroboration is once again determined using a "rule of reason" analysis. *Id.*

Petitioner contends that "[n]o document shows that VSI built, much less tested, RX prototypes." Pet. CRTP Reply 8. Petitioner points to the lack of photographs, assembly instructions, subassembly drawings, and notebook pages (other than Mr. Sutton's initial conception pages) to corroborate the work done on the RX prototype in 2005. *Id.* By contrast, Petitioner asserts that VSI kept more documents, including notes from Mr. Kauphusman (the VSI engineer who led the GuideLiner project), relating to the OTW prototypes from that time. *Id.* at 9–10 (citing Ex. 1760, 86–87). Petitioner also contends that Patent Owner cannot justify VSI's failure to retain these reduction-to-practice documents because it "runs contrary to federal law and industry practice." *Id.* at 11 (citing Ex. 1755 ¶¶ 66–74, 143–145). Among the documentary evidence presented, Petitioner contends that at most four documents relate to particular prototypes, and the rest are

irrelevant insofar as they concern purchases of generic component parts untethered to particular projects or prototypes. *Id.* at 11–14. Petitioner further contends the documents do not show that VSI actually assembled the RX prototypes. *Id.* at 16–17.

We are not persuaded that the record lacks sufficient corroborating evidence of actual reduction to practice. "In order to corroborate a reduction to practice, it is not necessary to produce an actual over-the-shoulder observer. Rather, sufficient circumstantial evidence of an independent nature can satisfy the corroboration requirement." *Cooper*, 154 F.3d at 1330 (citing *Knorr v. Pearson*, 671 F.2d 1368, 1373 (CCPA 1982)). "Furthermore, an actual reduction to practice does not require corroboration for every factual issue contested by the parties." *Id.* (citing *Ethicon, Inc. v. U.S. Surgical Corp.*, 135 F.3d 1456, 1464 (Fed. Cir. 1998); *Mann v. Werner*, 347 F.2d 636, 640 (CCPA 1965) ("This court has rejected the notion that each individual act in the reduction to practice of a count must be proved in detail by an unbroken chain of corroboration.")). Put another way, the law "does not require that evidence have a source independent of the inventors on every aspect of conception and reduction to practice; such a standard is the antithesis of the rule of reason." *E.I. du Pont De Nemours & Co. v. Unifrax I LLC*, 921 F.3d 1060, 1077 (Fed. Cir. 2019) (internal quotation omitted).

As discussed above, Mr. Root and Mr. Sutton each provide detailed and consistent testimony explaining the work done at VSI towards building and testing the April and July 2005 prototypes of the RX GuideLiner. Critical aspects of this testimony are corroborated by other (non-inventor) testimony from Ms. Schmalz (recounting the regulatory and quality process

at VSI), Mr. Erb (recounting how they built early prototypes), Mr. Goemer (verifying purchases from SPECTRAlytics), and Ms. O'Neil (verifying purchases from MED). This testimony is further corroborated by a significant amount of documentary evidence, including purchase documents and engineering drawings, as set forth above. To the extent that there may have been other more detailed evidence with regard to the OTW GuideLiner, we do not find that such evidence detracts from or otherwise contradicts the evidence presented for the RX GuideLiner. Nor do we require Patent Owner to establish actual reduction to practice by retaining and then proffering the same type of documents that the FDA would have required Patent Owner to submit to gain approval of a medical device. *See* Ex. 2237, 63:20–64:9 (Dr. Zalesky acknowledging that "[t]he testing requirement for regulatory submission such as a 510(k) is quite extensive," and "a very significantly different level than that required to demonstrate reduction to practice.").

Petitioner contends that the purchased parts reflected in Patent Owner's documentary evidence could have been used for other VSI projects under development in 2005. Pet. CRTP Reply 12–16. We do not find that the evidence supports Petitioner's conjecture in this regard. For example, Petitioner cites the testimony of Dr. Zalesky to assert that the purchased hypotubing (and other parts) could have been used for VSI's Twin-Pass, Skyway, and Pronto V3 products, in addition to the OTW GuideLiner. *Id.* (citing Ex. 1755 ¶¶ 121–132, 153, 161, 203). But Dr. Zalesky does not point to any supporting evidence showing that these other VSI products used the same type of hypotubing as what would have been required for the RX GuideLiner. *See* Ex. 2237, 156:3–158:10, 173:10–174:12 (Dr. Zalesky admitting that he did not have any evidence that hypotubes were used in

other products, but stating his opinion was based on "informed speculation" or "reasonable speculation"). Rather than Dr. Zalesky's speculation, we credit the testimony of Mr. Root, Mr. Sutton, and Mr. Erb, each of whom had first-hand involvement in the project and independently attest that at least some of the purchased hypotubes were specific for the RX GuideLiner. Ex. 2118 ¶ 23; Ex. 2119 ¶ 23; Ex. 2122 ¶ 7.

The corroborating documents confirm that the purchases were for the RX GuideLiner, not a general ledger expense suggesting that the parts could be used for other unrelated products. *See, e.g.*, Ex. 2005 (spend report for accounts related to "new modalities" and "Guideliner project"). The sole document Petitioner cites to posit that the purchased hypotubes could have been used for OTW devices is an engineering schematic that bears November 2005 and January 2006 dates, which were later than the April and July 2005 prototypes. Ex. 1763, 6. Furthermore, the hypotube shown in the OTW drawing differs in materials and dimensions from the hypotubes purchased for the RX prototypes. The hypotube in the OTW drawing is nitinol and roughly 19 cm, quite different than the 100 cm stainless steel hypotubes used for the GuideLiner prototypes. *Id.* The 43-inch distal section in the OTW drawing also differs dramatically from the 11.8-inch distal section for the RX prototype. Ex. 2237, 164:24–167:19 (Dr. Zalesky agreeing that the distal portion shown in Exhibit 2089 is not the same as the distal portion of Exhibit 1763); *compare* Ex. 1763, 6, *with* Exs. 2089, and 2092.

With regard to whether the purchased components were actually assembled into an RX prototype, we find that the engineering schematic from August 2005 is strongly corroborative of an assembled device. Ex.

2022. Dr. Zalesky acknowledges that it "doesn't make a lot of sense" for VSI not to have assembled the purchased parts together. Ex. 2237, 208:10–25. A preponderance of the evidence supports the conclusion that the assembled RX prototypes met each of the limitations of the challenged claims, as set forth in the Appendices to Mr. Root's declaration. Ex. 2118, App'x A–E. In its Sur-Sur-Reply, Petitioner identifies certain claim limitations that were allegedly not met by the prototypes, but Petitioner does not point to any evidence to contradict Mr. Root's testimony on this point. Pet. CRTP Sur-Sur-Reply 14–15. We likewise find the charts included as Appendices to Dr. Zalesky's declaration to be insufficient in this regard. Ex. 1755, App'x A–E. Rather than identifying any specific technical reason why the prototype components reflected in the purchase documents could not have met the claim limitations, Dr. Zalesky's rebuttal claim charts appears to focus on whether there was sufficient corroborating evidence (which we have already discussed above). *Id.* As such, we find the evidence presented in this case to be more detailed than that found insufficient in *Valencell, Inc. v. Fitbit, Inc.*, 784 F. App'x 1005, 1009 (Fed. Cir. 2019), cited by Petitioner. Pet. CRTP Reply 16. There, no evidence—testimonial or documentary—addressed key claim limitations, which stands in contrast to the detailed testimony and corroborating documents cited in Mr. Root's and Mr. Sutton's declarations.

Having found that Patent Owner constructed embodiments that met all limitations of the challenged claims, we move on to the second issue: whether Patent Owner demonstrated that those embodiments worked for the intended purpose of the invention.

We begin this inquiry by identifying the "intended purpose" of the invention. Patent Owner puts forth a broad intended purpose. Initially, Patent Owner asserted testing was done to show that the prototypes "could serve their intended purpose of being placed in a standard guide catheter and deliver interventional cardiology devices alongside the rail segment, into the side opening and distal tubular portion, and then out the distal end of the distal tubular portion and into challenging coronary anatomy." PO CRTP Resp. 25 (citing Ex. 2118 ¶¶ 17–18, 38, 47; Ex. 2119 ¶ 41; Ex. 2123 ¶¶ 20–24). In its Sur-Reply, Patent Owner clarifies that the intended purpose was "to increase backup support for delivery of interventional cardiology devices, including procedures involving tough or chronic total occlusions." PO CRTP Sur-Reply 9 (citing Exs. 2002, 2003, 2024). By contrast, Petitioner argues for a narrower intended purpose, asserting that the intended purpose was "providing backup support necessary for accessing and crossing tough or chronic occlusions." Pet. CRTP Reply 17 (citing Ex. 2002; Ex. 2118 ¶ 18; Ex. 2119 ¶ 9; Ex. 1762, 47:11–52:17). Citing Patent Owner's Sur-Reply, Petitioner contends that the parties ostensibly "agree" that the intended purpose was "to increase backup support for accessing and crossing tough occlusions." Pet. CRTP Sur-Sur-Reply 7 (citing PO CRTP Sur-Reply 9); *see also* Tr. 49:3–12 ("Teleflex agrees the intended purpose was to increase back-up support for accessing and crossing tough or chronic total occlusions.").

We agree with Patent Owner's position on what constitutes the intended purpose of the invention. Petitioner is certainly correct that several of the documents we have considered refer to crossing "tough" or "chronic" occlusions when discussing the idea behind the invention. *See, e.g.*, Ex.

2002. But when considering all of the pertinent evidence, we find that the inventors were concerned with a broader primary purpose, namely generally providing improved backup support for a guide catheter, with crossing tough or total occlusions being one specific benefit or application of the device. In other words, we do not find that the RX GuideLiner had applicability only when there were tough or chronic occlusions in the artery that needed to be crossed. Indeed, the challenged patent itself recognizes this broader purpose when discussing the field and background of the invention. *See* Ex. 1001, 1:8–11 ("More particularly the present invention relates to methods and apparatus for increasing backup support for catheters inserted into the coronary arteries from the aorta."); *id.* at 2:45–49 ("Thus, the interventional cardiology art would benefit from the availability of 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.").

The documentary evidence we have considered and discussed above further supports this broader intended purpose. For example, while Mr. Sutton's lab notebook expresses the idea for the GuideLiner device as "relat[ing] to interventional coronary procedures and specifically to accessing & crossing tough or chronic total occlusions," it also more broadly notes that "[t]he idea is to provide a guide or support catheter more distally into the coronary to provide more back-up support for the stent device." Ex. 2002, 7. Mr. Sutton's lab notebook also contains two additional notes related to the invention: "Guide-Liner is used when there is difficulty crossing lesions"; and "Guide-Liner allows back-up support distally." *Id.* at 8. Similarly, in the February 4, 2005, Market Feasibility memo, Mr. Root

describes the purpose of the RX GuideLiner as "provid[ing] the ability to create a deep seating of the guide for added support in the interventional procedure." Ex. 2003, 1. Mr. Root explains that "[b]y safely deep seating the guide catheter, the physician can then have the added support for pushing a wire through a chronic total occlusion or advancing a balloon or stent through a tight stenosis." *Id.* The August 24, 2005, Products Requirement document indicates the "[a]pplicable clinical use" for both the RX and OTW GuideLiners to be "increas[ing] guide catheter back-up support." Ex. 2024, 1.

Additionally, Patent Owner's expert's testimony supports this conclusion. Patent Owner's expert, Mr. Keith, declares that testing the RX GuideLiner prototypes would be sufficient for reduction to practice if the testing showed the prototype "(a) could be delivered through a guide catheter so that the distal end of the tubular portion extended beyond the distal end of the guide catheter while being tracked over a winding path; and (b) allowed a stent delivery catheter or balloon catheter to pass into the tubular portion and out the far end of the tubular portion while located within the guide catheter." Ex. 2123 ¶ 22.

The testimony of inventors Mr. Root and Mr. Sutton cited by the parties also supports this conclusion. Mr. Root declares that the intended purpose of the RX GuideLiner was to "deliver interventional cardiology devices, such as a stent or balloon catheter, alongside the rail segment, into the side opening and distal tubular portion, and then out the distal end of the distal tubular portion and into challenging coronary anatomy." Ex. 2118 ¶ 18; *see also id.* ¶ 47 (describing the intended purpose as "facilitat[ing] the delivery of balloon catheters and stents deep into coronary arteries while

providing increased backup support"). During Mr. Root's deposition, counsel for Petitioner inquired about Mr. Root's understanding of the intended purpose. Ex. 1762, 47:11–52:17. Mr. Root repeatedly stated that accessing and crossing tough or chronic occlusions was not the sole intended purpose. *Id.* at 47:11–20 (identifying that Petitioner's asserted intended purpose was "one of them" but "not all of them"), 50:10–12 ("The important thing is this is not just a chronic total occlusion device. This can apply to much broader coronary interventions."). Mr. Sutton's declaration quotes the purpose identified in his notes in his lab notebook, discussed above. Ex. 2119 ¶ 9 (quoting Ex. 2002, 7, 8). Mr. Sutton also declares that he and his team tested the prototypes qualitatively "to determine that [they] provided backup support," "to ensure that [stents and balloon catheters] could safely be delivered and would not snag or get caught on the device," and "to deliver interventional cardiology devices and provide additional backup support compared to the guide catheter alone." *Id.* ¶ 41.

In sum, the pertinent evidence demonstrates that the intended purpose of the claimed invention, as embodied in the RX GuideLiner, was to increase backup support for delivery of interventional cardiology devices. Although crossing tough or total occlusions is one noted benefit of the invention, we do not find it to be the only or primary purpose of the invention.

We next consider whether the testing conducted at VSI was sufficient to determine that the RX GuideLiner prototypes would work for the intended purpose of increasing backup support for delivery of interventional cardiology devices. "Depending on the character of the invention and the problem it solves, determining that the invention will work for its intended

purpose may require testing." *Cooper*, 154 F.3d at 1327 (citing *Mahurkar v. C.R. Bard Inc.*, 79 F.3d 1572, 1578 (Fed. Cir. 1996)). "When testing is necessary, the embodiment relied upon as evidence of priority must actually work for its intended purpose." *Id.* (citing *Scott v. Finney*, 34 F.3d 1058, 1061 (Fed. Cir. 1994)). "[T]he testing requirement depends on the particular facts of each case, with the court guided by a common sense approach in weighing the sufficiency of the testing." *Scott*, 34 F.3d at 1061 (citations omitted). "This common sense approach prescribes more scrupulous testing under circumstances approaching actual use conditions when the problem includes many uncertainties," but "permits little or no testing to show the soundness of the principles of operation of the invention" "when the problem to be solved does not present myriad variables." *Id.* at 1063. "In tests showing the invention's solution of a problem, the courts have not required commercial perfection nor absolute replication of the circumstances of the invention's ultimate use." *Id.* "[T]ests performed outside the intended environment can be sufficient to show reduction to practice if the testing conditions are sufficiently similar to those of the intended environment." *DSL Dynamic Scis. Ltd. v. Union Switch & Signal, Inc.*, 928 F.2d 1122, 1125 (Fed. Cir. 1991) (citing *Tomecek v. Stimpson*, 513 F.2d 614, 618 (CCPA 1975)). For medical device inventions, a showing of actual reduction to practice does not require human testing in actual use conditions. *Scott*, 34 F.3d at 1063 ("Testing for the full safety and effectiveness of a prosthetic device is more properly left to the Food and Drug Administration (FDA). Title 35 does not demand that such human testing occur within the confines of Patent and Trademark Office (PTO) proceedings.").

Patent Owner relies on inventor and expert testimony, as well as documentary evidence, to establish that VSI's use of benchtop models was sufficient to test that the products were suitable for the intended purpose described above.[22] PO CRTP Resp. 11–12, 24–25. Mr. Root asserts that benchtop coronary models, as depicted in the July 2005 sales presentation, were commonly used at VSI and other medical device companies to test interventional cardiology catheters. Ex. 2118 ¶ 17 (citing Exs. 2018, 2129). Citing its expert's declaration, Patent Owner asserts that "[c]atheter inventions are routinely determined to work using benchtop models, and without human testing." PO CRTP Resp. 25 (citing Ex. 2123 ¶¶ 20–24; Ex. 1010). Applied to this invention, Patent Owner asserts its benchtop model emulated the cardiac anatomy, and was used to show that the RX GuideLiner could be "placed in a standard guide catheter and deliver interventional cardiology devices alongside the rail segment, into the side opening and distal tubular portion, and then out the distal end of the distal tubular portion and into challenging coronary anatomy." *Id.* (citing Ex. 2118 ¶¶ 17–18, 38, 47; Ex. 2119 ¶ 41; Ex. 2123 ¶¶ 20–24).

Petitioner's argument against Patent Owner's testing evidence depends on its narrower intended purpose, i.e., "using simulated tough lesions." Pet. CRTP Reply 18; *see also* Pet. CRTP Sur-Sur-Reply 7–9. In

[22] Referring to Petitioner's expert's testimony regarding a person of ordinary skill in the art's knowledge pertaining Itou, Patent Owner also contends that no testing would have been required to know the RX GuideLiner would have worked for its intended purpose. *See* PO CRTP Sur-Reply 9 (citing Ex. 2116, 110:20–113:24; Ex. 2238, 87:18–89:5). Because we determine that the evidence demonstrates that testing in benchtop models was sufficient, we do not address this theory.

light of our rejection of the narrower intended purpose identified by Petitioner, we likewise reject Petitioner's argument that the testing evidence presented by Patent Owner is insufficient. Moreover, Petitioner acknowledges that benchtop models could have been used to test a device like the RX GuideLiner. Pet. CRTP Reply 17–18. The testimony of Mr. Root, Mr. Sutton, Mr. Erb, and Mr. Keith, corroborated by the photograph of the model in the sales presentation, confirm that VSI utilized benchtop coronary models that were considered the standard for testing interventional cardiology devices such as catheters. *See* Ex. 2018; Ex. 2118 ¶¶ 17, 38, 47; Ex. 2119 ¶¶ 23, 37–38, 41; Ex. 2122 ¶ 11; Ex. 2123 ¶¶ 21–24. We consider this benchtop testing to be similar to the "countertop" testing that was found sufficient to show actual reduction to practice in *Mahurkar*. *See Mahurkar*, 79 F.3d at 1578 (determining for claims related to a double lumen catheter that flow and pressure drop tests conducted in the inventor's kitchen, using glycerine to simulate blood, was sufficient for actual reduction to practice because they "showed, to the limit of their design, the utility of the claimed invention"). As noted by Petitioner, Mr. Root indicated during his deposition that to reduce to practice, VSI needed to "(1) navigate RX through a guide catheter and out its distal end in a benchtop model, (2) deliver an interventional cardiology device, and (3) retrieve RX in one piece." Pet. CRTP Reply 18 (citing Ex. 1762, 100:1–102:3). We find that the "pull tests" done using the benchtop models demonstrated that the RX GuideLiner was capable of accomplishing at least this much, even if the tests were not conducted in an *in vivo* or *in vitro* environment that simulated tough lesions. Ex. 2118 ¶¶ 17, 38, 47. This is not a situation where there were significant variables or uncertainties that needed to be assessed in order

to determine whether the RX device would work properly, and thus the "qualitative" testing done by VSI using the benchtop models was sufficient. Ex. 2119 ¶ 41; Ex. 2123 ¶¶ 21–22. Accordingly, a preponderance of the evidence supports the conclusion that the testing done at VSI demonstrated that the RX GuideLiner would work for its intended purpose.

In our assessment of whether there was actual reduction to practice prior to the critical date, we have considered Petitioner's argument that the GuideLiner project was still in "early-stage concept development" in mid-to-late 2005, and that VSI was still experimenting in 2006 and did not have a working prototype even by 2008. Pet. CRTP Reply 22–27.

In support of this argument, Petitioner points to continuing changes to the RX design as evidence that the design was not completed before the critical date. *Id.* For example, a July 2005 Research & Development ("R&D") Update notes that "[t]he initial design is an over-the-wire configuration, with a rapid exchange version to follow." Ex. 2130, 3.[23] In contrast to the incomplete August 2005 Product Requirements document relied upon by Patent Owner (Ex. 2024), Petitioner contends that the official, completed version of the Product Requirements document for the GuideLiner project was not created until April 2009. Ex. 1767. A "2006

[23] We recognize that this document appears to contradict Mr. Root's recollection that the original idea was for the RX GuideLiner, and that the decision was later made to concurrently pursue development of the OTW version. Ex. 2118 ¶ 19. We do not find the issue of whether the initial idea was for the RX version or the OTW version to be material to our analysis on reduction to practice. Nonetheless, we note Mr. Sutton's original notebook pages suggest that the original idea was indeed for the RX version rather than the OTW version. Ex. 2002.

Strategic Objectives" document, dated December 1, 2005, indicates that the "rapid exchange version requires additional engineering and is not included in our 2006 forecasts." Ex. 2131, 10. Likewise, Petitioner points to a GuideLiner team meeting memo from May 2, 2006, that includes as agenda items "1) Review Initial Design and Intended Use," and "2) Determine what can be completed/started prior to design lock." Ex. 2109. According to another document, a "design freeze" for the GuideLiner device was expected to only take place May 30, 2007. Ex. 1769, 1. Indeed, an R&D update from July 2008 notes with respect to the GuideLiner device:

> Throughout this project, timelines have been pushed out due to drastic design changes and resource constraints. To date we have prototyped and tested a new design. This new design is more robust and cost effective. We are planning on an August 2008 design freeze with a 510k submission in November 2008.

Ex. 2132, 7.

We have taken the foregoing evidence into account, but do not find that it detracts from Patent Owner's evidence concerning reduction to practice based on building and testing the April and July 2005 prototypes discussed above. To be sure, the post-critical date documents highlighted by Petitioner make it clear that significant design revisions for the RX GuideLiner continued well into 2008, and these additional design changes may well have been required for FDA regulatory approval and/or commercialization of the device. Indeed, Patent Owner's declarants attest that additional engineering work was conducted to refine the product for regulatory purposes and commercialization. *See* Ex. 2118 ¶ 59 (Mr. Root attesting that "[f]rom September of 2005 forward, I and others at VSI continued to act diligently to bring the rapid exchange GuideLiner to

market."); Ex. 2119 ¶ 44 (Mr. Sutton attesting that, after the August 24, 2005, Product Requirements document, "we continued to refine prototypes of the GuideLiner [R]apid [E]xchange for purposes of manufacturability and commercialization"); Ex. 2122 ¶ 13 (Mr. Erb attesting that work continued on "develop[ing] manufacturing processes that were reproducible and a refined design that was able to be commercialized"). But we see no basis to conclude that these additional engineering and design changes were an indication that the April and July 2005 prototypes failed to demonstrate that the RX GuideLiner was capable of achieving increased backup support.

Ultimately, the RX GuideLiner was not commercialized until 2009, which we recognize is far later than the initial projected timeframe of late 2005/early 2006 and the date of actual reduction to practice. Ex. 2118 ¶ 89. Mr. Root asserts that one reason for this delay was due to turnover in R&D personnel. *Id.* Under the circumstances, we do not find that the additional engineering and design work done with respect to the RX GuideLiner to achieve regulatory approval and commercialization indicates a lack of actual reduction to practice prior to the critical date. *See Loral Fairchild Corp. v. Matsushita Elec.*, 266 F.3d 1358, 1362–63 (Fed. Cir. 2001) ("Once the invention has been shown to work for its intended purpose, reduction to practice is complete. Further efforts to commercialize the invention are simply not relevant to determining whether a reference qualifies as prior art against the patented invention.").

In sum, we find that Patent Owner has demonstrated actual reduction to practice prior to Itou's critical date by a preponderance of the evidence based on the work done at VSI in building and testing the April and July 2005 prototypes of the RX GuideLiner. Nonetheless, to the extent that this

evidence is not sufficient for actual reduction to practice, we find that it demonstrates at least conception of the claimed invention prior to the critical date.

4. Constructive Reduction to Practice

In addition to asserting actual reduction to practice, Patent Owner alternatively relies upon a theory of constructive reduction to practice. Antedating based on this theory would require Patent Owner to demonstrate diligence from just before the date Itou was filed until the date Patent Owner filed its priority application for the GuideLiner patents,[24] i.e., from September 23, 2005, to May 3, 2006. *See Perfect Surgical Techniques, Inc. v. Olympus Am., Inc.*, 841 F.3d 1004, 1007 (Fed. Cir. 2016) (requiring diligence for the "entire critical period, which begins just prior to the competing reference's effective date and ends on the date of the invention's reduction to practice").

To demonstrate diligence, Patent Owner again relies on testimony from its inventor and non-inventor declarants, as well as correspondences with VSI's outside patent counsel at the Patterson Law Firm and documents reflecting further engineering and development work done during this period. PO CRTP Resp. 18–19; PO CRTP Sur-Reply 12.

According to Mr. Root, following the initial conception and the building of the April and July 2005 prototypes, he and others at VSI

[24] We use term "GuideLiner patents," in the same manner as the parties' declarants, to refer to the patents challenged in IPR2020-00126, -00128, -00129, -00132, -00134, -00135, and -00137. *See, e.g.*, Ex. 2118 ¶ 1; Ex. 2119 ¶¶ 1, 3; Ex. 2123 ¶ 1.

continued working, from September 2005 onward, to bring the RX GuideLiner to market. Ex. 2118 ¶ 59. This project was one of VSI's primary development initiatives at the time, and they worked on it continuously until they brought it to market in 2009. *Id.*; *see id.* ¶ 89. Thus, they worked continuously at least until the May 3, 2006, application date. *Id.* ¶ 76. Ms. Schmalz likewise testifies that "[a]t no time between the start of the regulatory process for GuideLiner in August of 2005 and the filing of the patent application in May 2006 was the rapid exchange GuideLiner project abandoned or paused." Ex. 2039 ¶ 12.

Mr. Sutton sent a fax to the Patterson Law Firm on March 21, 2006, which includes drawings that are similar to the proximal portion of the RX GuideLiner depicted in Exhibit 2114. Ex. 2118 ¶ 42 (citing Ex. 2019). The firm also possessed the August 1, 2005, CAD drawing of a complete RX GuideLiner prototype. *Id.* ¶¶ 49–50 (citing Ex. 2022).

Upon Mr. Root's request, the firm opened a matter to conduct a patentability search for the GuideLiner on August 11, 2005. *Id.* ¶ 52 (citing Ex. 2023). Mr. Root provided the firm with the full prototype drawing in Exhibit 2022 to conduct the search. *Id.* Mr. Root testifies that he would not engage in freedom-to-operate searching until after he had made a full prototype that was shown to work for its intended purpose and ready to move forward to commercialization. *Id.* An invoice from the firm demonstrates work performed for a "patent search for guide liner" in August 2005. *Id.* ¶ 53 (citing Ex. 2096).

In his declaration, Mr. Root then sets forth the timeline of events with documentary and circumstantial evidence during the critical period for diligence, i.e. from September 23, 2005, to May 3, 2006.

For September 2005, Mr. Root refers to invoices dated September 7, 2005, and a check for forming tips that would have been used for the distal tip of the GuideLiner prototype. *Id.* ¶ 60 (citing Ex. 2097). He refers to these documents to demonstrate that VSI was continuing to refine the prototypes during this period. Mr. Root also refers to a copy of the Patterson Law Firm's privilege log showing that a partner of the firm sent Mr. Root a confidential letter dated September 14, 2005, pertaining to prior art related to the GuideLiner. *Id.* ¶ 61 (citing Ex. 2098).

For October 2005, Mr. Root refers to a business update presented to VSI's Board of Directors during its October 2005 meeting. *Id.* ¶ 62 (citing Exs. 2041 (confidential), 2133 (public)). Mr. Root declares this update included extremely favorable reviews of the RX GuideLiner from VSI's physician advisors. *Id.* Mr. Root further declares the update included projected timelines for regulatory filings, with intentions to file in the end of 2005 for OTW and early 2006 for RX. *Id.* Mr. Root also refers to the matter the Patterson Law Firm opened this month for work leading towards the initial GuideLiner patent application. *Id.* (citing Ex. 2023).

For November 2005, Mr. Root declares that VSI continued refining the proximal portion of the RX GuideLiner. *Id.* ¶ 63. Mr. Root refers to engineering drawings obtained from SPECTRAlytics, including one dated November 2005, which closely resembles Figure 10 of the GuideLiner patents. *Id.* (citing Ex. 2115). Mr. Root also refers to a VSI R&D planning document for 2006, which was drafted by Mr. Sutton on November 22, 2005. *Id.* ¶ 64 (citing Ex. 2099). The planning document demonstrates VSI's intent, as of late November 2005, to continue with the regulatory approval process for the RX GuideLiner in 2006. *Id.*

For December 2005, Mr. Root refers to a VSI Strategic Objectives document for 2006, which was drafted on December 1, 2005. *Id.* ¶ 65 (citing Ex. 2100). The document indicates that the RX GuideLiner required additional work for commercialization, which would continue through the end of 2006. *Id.* Mr. Root also refers to an invoice from the Patterson Law Firm, which shows the time invested in preparing the GuideLiner patent application during December 2005. *Id.* ¶ 66 (citing Ex. 2117).

For January 2006, Mr. Root refers to another invoice from the Patterson Law Firm, which shows time invested in preparing the GuideLiner patent application during January 2006. *Id.* (citing Ex. 2101). Mr. Root also refers to a fax sent from Mr. Sutton to the law firm on January 23, 2006. *Id.* ¶ 67 (citing Ex. 2102). The fax contains three figures that illustrate examples of the problem to be solved by the RX GuideLiner, and which are nearly identical to Figures 7, 8, and 9 of the GuideLiner patents. *Id.*

For March 2006, Mr. Root refers to a Patterson Law Firm invoice showing time invested in preparing the GuideLiner patent application during March 2006. *Id.* ¶ 68 (citing Ex. 2103). Mr. Root also refers to purchase records for stainless steel tubing from Vita Needle Company on March 24, 2006. *Id.* ¶ 69 (citing Ex. 2104). Mr. Root declares that VSI used this tubing to refine the RX GuideLiner for commercialization. *Id.* Mr. Root also refers to a March 30, 2006, engineering drawing from SPECTRAlytics's files. *Id.* ¶ 70 (citing Ex. 2115). The drawing, which is similar to the photographs of RX GuideLiner prototypes depicted in Exhibit 2014, shows VSI's attempt to reduce manufacturing costs by cutting two proximal portions from a single hypotube. *Id.*

For April 2006, Mr. Root refers to a Budget to Actual Variances report provided to the VSI Board of Directors for its April 2006 meeting. *Id.* ¶ 71 (citing Ex. 2105). The report shows GuideLiner R&D expenses by that time had been more than double the amount that was budgeted. *Id.* Mr. Root refers to purchase records for laser-cut and electropolished GuideLiner hypotubes from LSA, with an invoice dated April 7, 2006. *Id.* ¶ 72 (citing Ex. 2106). These hypotubes were used to refine the RX GuideLiner during commercialization. *Id.* Mr. Root refers to purchase records for twenty hypotubes from MicroGroup, with an invoice dated April 18, 2006. *Id.* ¶ 73 (citing Ex. 2107). These hypotubes were used to refine the RX GuideLiner during commercialization. *Id.* Mr. Root refers to other purchase records, including an April 19, 2006, invoice for cut GuideLiner hypotubes from LSA, which were used to commercialize the RX GuideLiner. *Id.* ¶ 74 (citing Ex. 2108).

For May 2006, other than the filing of the application on May 3, 2006, Mr. Root refers to notes from a GuideLiner team meeting held May 2, 2006, which confirm they were still working towards commercializing the RX GuideLiner. *Id.* ¶ 75 (citing Ex. 2109).

Mr. Sutton's diligence timeline, including the documents he refers to, largely matches Mr. Root's. For essentially the same reasons as Mr. Root, Mr. Sutton refers to: the drawing of the fully-assembled RX GuideLiner, Ex. 2119 ¶ 39 (citing Ex. 2022); his fax sent March 21, 2006, to the Patterson Law Firm, including the drawings similar to Figures 12 through 16 of the patents, *id.* ¶ 40 (citing Ex. 2019); his fax sent on January 23, 2006, to the Patterson Law Firm, which contains three figures that illustrate examples of the GuideLiner situated in the aorta, which are nearly identical to Figures

7, 8, and 9 of the GuideLiner patents, *id.* ¶ 42 (citing Ex. 2102); the VSI R&D planning document for 2006, dated November 22, 2005, *id.* ¶ 48 (citing Ex. 2099); the VSI marketing document dated December 1, 2005, *id.* ¶ 49 (citing Ex. 2100); the Vita Needle purchase records for stainless steel hypotubes shipped on March 24, 2006, which were used for the RX GuideLiners, *id.* ¶ 51 (citing Ex. 2104); and the April 2006 VSI budget report, indicating expenses on commercializing the RX GuideLiner more than doubled the amount VSI budgeted, *id.* ¶ 52 (citing Ex. 2105). Mr. Sutton also refers to the January 2006 R&D Update that he prepared for the VSI Board of Directors, *id.* ¶ 50 (citing Ex. 2134). In that update, Mr. Sutton reported to VSI's Board that both GuideLiner projects were still planned, with OTW regulatory filings next up at the time. *Id.*

In addition to testimony from inventors Mr. Root and Mr. Sutton, Patent Owner also points to testimony from Ms. Schmalz, Mr. Erb, and Mr. Keith. Ms. Schmalz declares that, from "the start of the regulatory process for GuideLiner in August of 2005 and the filing of the patent application in May 2006," the RX GuideLiner "was always a high priority project during [her] time at VSI" and was never "abandoned or paused." Ex. 2039 ¶ 12. Mr. Erb declares that VSI was "continually working to optimize the design" of the RX GuideLiner for commercialization. Ex. 2122 ¶ 13. As an example, he recalls the weighing of advantages and disadvantages between stainless steel and nitinol for the proximal portion during the commercialization stage. *Id.* ¶ 14. Mr. Keith explains his understanding that further commercialization work was performed after August 2005. Ex. 2123 ¶¶ 25–27.

Patent Owner contends that the evidence it relies on to prove conception and reduction to practice shows that "VSI worked steadily on the GuideLiner invention from conception through the date the patent was filed." PO CRTP Resp. 28 (citing *id.* at 3–19). Patent Owner acknowledges that it took more time and resources than anticipated, but that this delay should have "no bearing whatsoever on the [diligence] analysis." *Id.* at 28–29.

Petitioner argues Patent Owner's response "does not contain any detail showing diligence." Pet. CRTP Reply 28. Petitioner deems the "handful" of events identified by Patent Owner during the critical period—opening a patent application file, working on the patent application, exchanging emails, and buying parts—to be insufficient evidence of diligence. *Id.* at 28–29. It appears from Petitioner's visual timeline of Patent Owner's events that two periods in particular allegedly represent a lack of diligence: from September 23, 2005, to the end of November 2005, during which there was only a component design change; and the month of February 2006, during which there were no diligence-related events. *Id.* at 28 (citing Ex. 2115). Petitioner also faults Patent Owner's delay in regulatory submissions for the RX GuideLiner, which were initially planned for late 2005 and 2006 but were postponed until 2008. *Id.* (citing Ex. 1762, 131:3–133:3; Ex. 2132, 7).

When evaluating diligence, we are mindful of recent Federal Circuit admonitions clarifying that we must not apply a standard that is "too exacting" or "too rigid." *Perfect Surgical*, 841 F.3d at 1008; *Arctic Cat*, 919 F.3d at 1331. Though "periods of inactivity within the critical period do not automatically vanquish a patent owner's claim of reasonable diligence,"

Arctic Cat, 919 F.3d at 1331, "[m]erely asserting diligence is not enough" and a party must "account for the entire period during which diligence is required." *In re Meyer Mfg. Corp.*, 411 F. App'x 316, 319 (Fed. Cir. 2010). "[D]iligence need not be perfectly continuous—only *reasonably* continuous." *Arctic Cat*, 919 F.3d at 1331. The key question for diligence is whether, "in light of the evidence as a whole, the invention was not abandoned or unreasonably delayed." *Id.* (internal quotations omitted). Applying this standard, we conclude that Patent Owner sufficiently demonstrates reasonably continuous diligence throughout the critical period.

The evidence demonstrates that Patent Owner did not unreasonably delay the RX GuideLiner project. As both parties acknowledge, there were indeed delays in the project. Petitioner asserts "VSI prioritized *other projects* in late 2005 and 2006 and postponed RX regulatory submissions through 2008." Pet. CRTP Reply 29 (citing Ex. 1762, 131:3–133:3; Ex. 2132, 7) (emphasis in original). But the cited portion of Mr. Root's deposition testimony sufficiently explains why the delay was reasonable under the circumstances. As noted by Mr. Root, OTW GuideLiner regulatory submissions came first "[b]ecause it was much easier to get regulatory approval and do the testing." Ex. 1762, 131:3–8. "[T]ransition in personnel" also complicated the project. *Id.* at 131:12–17. And as for the RX, Mr. Root explained that commercialization took longer due to "vendor optimization," *id.*, 132:25–133:9, which tracks the greater difficulty associated with bringing the RX GuideLiner to market. Ms. Schmalz further corroborates this explanation with her declaration that RX GuideLiner "was always a high priority project during [her] time at VSI." Ex. 2039 ¶ 12.

Nor does it appear that Patent Owner abandoned the RX GuideLiner invention. For one thing, Patent Owner engaged counsel to prepare its GuideLiner patent application, which was ultimately filed on May 3, 2006. The Patterson Law Firm opened a patent search on August 11, 2005 (Ex. 2023, 5) then reported the results to VSI on September 14, 2005 (Ex. 2098, 2). On October 10, 2005, the firm opened a patent prosecution matter for the GuideLiner. Ex. 2023, 5. There is evidence in the record of the firm working on preparing the application in December 2005 (Ex. 2117, 20), January 2006 (Ex. 2101, 7), and March 2006 (Ex. 2103, 6). There is also evidence of communications between the firm and VSI, namely Mr. Root and Mr. Sutton, in January 2006 and March 2006. Ex. 2102; Ex. 2098, 4; Ex. 2019. To be sure, there is not an abundance of documents in the record related to preparing the application, including drafts of the specification and claims, but Patent Owner clarified at oral argument that it lacks many documents due to the passage of time, not the refusal to waive attorney-client privilege. Tr. 64:8–21. A lack of documents due to the passage of time does not foreclose sufficient corroboration. *See, e.g.*, *NFC Tech., LLC v. Matal*, 871 F.3d 1367, 1374 (Fed. Cir. 2017) (concluding there was sufficient corroboration of conception based on circumstantial evidence, "particularly considering the amount of time that ha[d] passed").

Moreover, the other documents Patent Owner proffers provide additional circumstantial evidence that VSI was working on and did not abandon the RX GuideLiner project throughout this time. Petitioner again faults Patent Owner for not providing direct evidence. Pet. CRTP Reply 28 (pointing out lack of events "related to actual work on an RX device"); *id.* at 29 (arguing Patent Owner "cannot tie the component parts purchases to

RX"). But, as we noted above, direct evidence is not required for adequate corroboration. Internal VSI documents, such as updates for VSI's Board and budget documents, show that work on the RX project continued from October 2005 through April 2006. Ex. 2133, 4, 7; Ex. 2099; Ex. 2100, 8–9; Ex. 2105, 4–5. Additionally, there are invoices related to supplies that support the testimony of inventors Mr. Root and Mr. Sutton regarding continued work on the RX GuideLiner in March 2006 and April 2006. Ex. 2104; Ex. 2005, 5; Ex. 2115; Ex. 2106, 3; Ex. 2107; Ex. 2108, 4–5. All of this evidence corroborates Mr. Root's and Mr. Sutton's testimony that VSI worked diligently and continuously on the RX GuideLiner project without abandoning the project.

Finally, we are not convinced that the periods from September 23, 2005, to the end of November 2005 or in February 2006 demonstrate lack of diligence. Petitioner's argument for these periods is conclusory, and contradicted by the reasonable commercialization delays that we addressed above.

Considering all of the pertinent evidence, we find that Patent Owner did not abandon or unreasonably delay the RX GuideLiner project during the critical period. Petitioner's arguments implying the need for direct evidence and scouring the timeline for periods of inactivity are unpersuasive. We therefore conclude that Patent Owner demonstrates, by a preponderance of the evidence, that VSI was reasonably continuous in its diligence during the critical period. Because we have also found that Patent Owner demonstrated conception prior to Itou's critical date, Patent Owner has met its burden to successfully demonstrate that Itou is not prior art to the challenged claims of the '032 patent.

III. MOTION TO EXCLUDE

Petitioner has moved to exclude Exhibit 2024, which is the August 24, 2005, Product Requirements document. Paper 111. Petitioner contends that Exhibit 2024 is unreliable on its face and that none of Patent Owner's witnesses can authenticate the document. *Id.* at 2–9. Patent Owner responds that Exhibit 2024 is authenticated under Federal Rule of Evidence 901 based on the declaration and/or deposition testimony of Mr. Peterson (Ex. 1926 ¶ 18), Ms. Schmalz (Ex. 2039 ¶¶ 6–7), Mr. Root (Ex. 2118 ¶ 54), and Mr. Sutton (Ex. 2119 ¶ 44). Paper 115.

Documents are authenticated by evidence "sufficient to support a finding that the item is what the proponent claims it is." Fed. R. Evid. 901(a); *see Fox Factory v. SRAM, LLC*, IPR2016-01876, Paper 59 at 63 (PTAB Apr. 2, 2018) (quoting same). "Authenticity is, therefore, not an especially high hurdle for a party to overcome." *Fox Factory*, Paper 59 at 63 (citing *United States v. Patterson*, 277 F.3d 709, 713 (4th Cir. 2002)

We determine that Exhibit 2024 has been authenticated under Federal Rule of Evidence 901. In addition, Petitioner's arguments go to the weight of the evidence and not its admissibility. Accordingly, we deny Petitioner's Motion to Exclude.

IV. MOTION TO AMEND

In its Corrected Contingent Motion to Amend, Patent Owner requests that if any of claims 1, 11, and 16 is found unpatentable, they should be replaced by proposed substitute claims 23–25. Motion 1. Because we do not find any of the challenged claims unpatentable in this proceeding, we do not reach the Motion to Amend.

V. CONSTITUTIONAL CHALLENGE

Patent Owner argues that the Petition should be denied because "the manner in which administrative law judges are appointed is unconstitutional." PO Resp. 64 (citing *Arthrex, Inc. v. Smith & Nephew, Inc.*, 941 F.3d 1320, 1325 (Fed. Cir. 2019)). Patent Owner further argues that the purported remedy imposed by the *Arthrex* decision "is insufficient to remedy the constitutional defect." *Id.* (citing *Arthrex*, 941 F.3d at 1338–39). We decline to consider Patent Owner's constitutional argument because the Federal Circuit addressed this issue in *Arthrex*. *Arthrex*, 941 F.3d at 1328.

VI. CONCLUSION

After reviewing the arguments and evidence of record, we determine that Patent Owner has antedated the Itou reference based on a showing of prior conception coupled with either actual reduction or diligence towards constructive reduction to practice. Because Itou is relied upon for all the challenges in the Petition, Petitioner has not demonstrated by a preponderance of the evidence that claims 1–20 and 22 of the '032 patent are unpatentable.

In summary:

Claims	35 U.S.C. §	Reference(s)/Basis	Claims Shown Unpatentable	Claims Not Shown Unpatentable
1–19, 22	102	Itou		1–19, 22
3, 13, 14	103(a)	Itou, Ressemann, the knowledge of POSITA		3, 13, 14
20	103(a)	Itou, Berg, the knowledge of POSITA		20
Outcome				1–20, 22

The table below summarizes our conclusions as to Patent Owner's Revised Motion to Amend the claims.

Motion to Amend Outcome	**Claim(s)**
Original Claims Cancelled by Amendment	
Substitute Claims Proposed in the Amendment	23–25
Substitute Claims: Motion to Amend Granted	
Substitute Claims: Motion to Amend Denied	
Substitute Claims: Not Reached	23–25

VII. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that Petitioner has not demonstrated by a preponderance of the evidence that claims 1–20 and 22 of the '032 patent are unpatentable;

ORDERED that Petitioner's Motion to Exclude is *denied*;

ORDERED that we do not reach Patent Owner's Contingent Motion to Amend; and

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

FOR PETITIONER:

Cyrus Morton
Sharon Roberg-Perez
Christopher Pinahs
William E. Manske
Emily J. Tremblay
ROBINS KAPLAN LLP
cmorton@robinskaplan.com
sroberg-perez@robinskaplan.com
cpinahs@robinskaplan.com
wmanske@robinskaplan.com
etremblay@robinskaplan.com

FOR PATENT OWNER:

Derek Vandenburgh
Dennis Bremer
CARLSON, CASPERS, VANDENBURGH & LINDQUIST, P.A.
dvandenburgh@carlsoncaspers.com
dbremer@carlsoncaspers.com

Trials@uspto.gov
571-272-7822

Paper 127
Date: June 7, 2021

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.

IPR2020-00128
Patent RE45,380

Before SHERIDAN K. SNEDDEN, JON B. TORNQUIST, and CHRISTOPHER G. PAULRAJ, *Administrative Patent Judges*.

TORNQUIST, *Administrative Patent Judge*.

JUDGMENT
Final Written Decision
Determining No Challenged Claims Unpatentable
Not Deciding Patent Owner's Contingent Motion to Amend
35 U.S.C. § 318(a)

ORDERS
Denying Petitioner's Motion to Exclude (Paper 111)
37 C.F.R. § 42.64(c)

I. INTRODUCTION

Medtronic, Inc. and Medtronic Vascular, Inc. (collectively "Petitioner") filed a Petition (Paper 1, "Pet.") requesting an *inter partes* review of claims 1–4, 6–10, 12–21, and 23 of U.S. Reissue Patent RE45,380E (Ex. 1001, "the '380 patent"). Teleflex Innovations S.À.R.L. ("Patent Owner") [1] filed a Preliminary Response to the Petition (Paper 8). Upon review of the Petition and Preliminary Response, we instituted an *inter partes* review of all claims on all grounds asserted in the Petition (Paper 22, "Inst. Dec." or "Institution Decision").

Patent Owner subsequently filed a Patent Owner Response (Paper 43, "PO Resp.") (redacted version available at Paper 44), Petitioner filed a Reply (Paper 83, "Pet. Reply") (redacted version available at Paper 82), and Patent Owner filed a Sur-Reply (Paper 103, "Sur-Reply") (redacted version available at Paper 104).

With prior authorization of the Board, Patent Owner filed a Consolidated Response Addressing Conception and Reduction to Practice (Paper 39, "PO CRTP Resp."), to which Petitioner filed Reply (Paper 78, "Pet. CRTP Reply") (redacted version available at Paper 79), Patent Owner filed a Sur-Reply (Paper 97, "PO CRTP Sur-Reply"), and Petitioner filed a Sur-Sur-Reply (Paper 112, "Pet. CRTP Sur-Sur-Reply").

Patent Owner also filed a Contingent Motion to Amend (Paper 38). The Motion requests that if claims 1 or 12 of the '380 patent are determined

[1] Patent Owner represents that "Teleflex Innovations S.A.R.L. merged into Teleflex Medical Devices S.A.R.L," which subsequently "transferred ownership of [the '380 patent] to Teleflex Life Sciences Limited." Paper 7, 2.

to be unpatentable, that the Board replace the unpatentable claim(s) with proposed substitute claims 43 and 44. Motion 1. Petitioner filed an Opposition to the Motion to Amend (Paper 85), to which Patent Owner filed a reply (Paper 106), and Petitioner filed a sur-reply (Paper 114).

An oral hearing was held on March 8, 2021, and a transcript of the hearing is included in the record. Paper 126 ("Tr.") (redacted version available at Paper 125).

A. Real Parties in Interest

Petitioner identifies Medtronic, Inc. and Medtronic Vascular, Inc., as the real parties-in-interest, and notes that "Medtronic plc is the ultimate parent of both entities." Pet. 5.

Patent Owner identifies the real parties-in-interest for itself as Teleflex Medical Devices S.À.R.L., Vascular Solutions LLC, Arrow International, Inc., and Teleflex LLC, and notes that "Teleflex Incorporated is the ultimate parent of the entities listed above." Paper 4, 2.

B. Related Matters

The parties indicate that the '380 patent is the subject of litigation in *Vascular Solutions LLC, et al. v. Medtronic, Inc., et al.*, No. 19-cv-01760 (D. Minn.) and *QXMedical, LLC v. Vascular Solutions, LLC*, No. 17-cv-01969 (D. Minn). Pet. 5–6; Paper 4, 2. The '380 patent is also at issue in IPR2020-00129, IPR2020-00130, and IPR2020-00131 (institution denied). Paper 4, 3; Pet. 6.

The following proceedings before the Board also involve the same parties and related patents: IPR2020-00126 (U.S. Patent No. 8,048,032 B2), IPR2020-00127 (U.S. Patent No. 8,048,032 B2), IPR2020-00132 (U.S. Patent No. RE45,760 E1), IPR2020-00134 (U.S. Patent No. RE45,760 E1),

IPR2020-00135 (U.S. Patent No. RE45,776 E1), IPR2020-00136 (U.S. Patent No. RE45,776 E1), IPR2020-00137 (U.S. Patent No. RE47379 E1), IPR2020-00138 (U.S. Patent No. RE47379 E1).

C. The '380 Patent

The '380 Patent is a reissue of U.S. Patent 8,292,850, and claims priority as a division of application No. 11/416,629, filed on May 3, 2006, now U.S. Patent 8,048,032. Ex. 1001, codes (62), (64). The '380 patent relates to catheters used in interventional cardiology procedures and, in particular, to "methods and apparatus for increasing backup support for catheters inserted into the coronary arteries from the aorta." *Id.* at 1:31–35.

"In coronary artery disease the coronary arteries may be narrowed or occluded by atherosclerotic plaques or other lesions." *Id.* at 1:44–46. This narrowing is referred to as stenosis. *Id.* at 1:48–49. To treat a stenosis, "it is commonly necessary to pass a guidewire or other instruments through and beyond the occlusion or stenosis of the coronary artery." *Id.* at 1:49–52. In this method, a guide catheter is inserted through the aorta and into the ostium of the coronary artery where it is typically seated into the opening or ostium of the artery to be treated. *Id*. at 1:53–57. A guidewire or other instrument is then passed through the lumen of the guide catheter and inserted into the artery beyond the stenosis. *Id*. at 1:39–41, 1:57–59. Crossing the tough lesions, however, may create enough backwards force to dislodge the guide catheter from the ostium of the artery being treated, making it difficult or impossible to treat certain forms of coronary artery disease. *Id*. at 1:59–63.

Figures 1 and 2 of the '380 patent are reproduced below:

Fig. 1

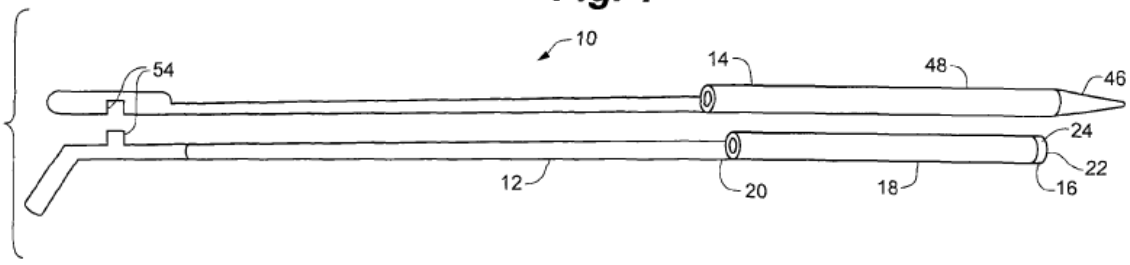


Fig. 2

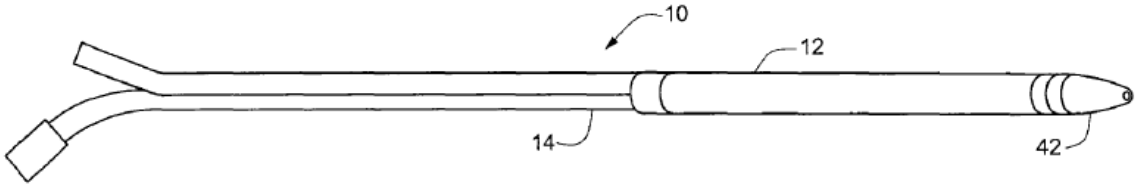


Figure 1 is a schematic depiction of a coaxial guide catheter and a tapered inner catheter and Figure 2 is a schematic depiction of these two elements assembled together. *Id.* at 5:40–45. As shown in Figure 1, coaxial guide catheter 12 includes tip portion 16, reinforced portion 18, and rigid portion 20. *Id.* at 6:34–35. Tapered inner catheter 14 includes tapered portion 46 at a distal end thereof and straight portion 48. *Id.* at 7:16–17. Clip 54 releasably joins tapered inner catheter 14 to coaxial guide catheter 12. *Id.* at 7:21–23.

Figure 8 of the ’380 patent is reproduced below:

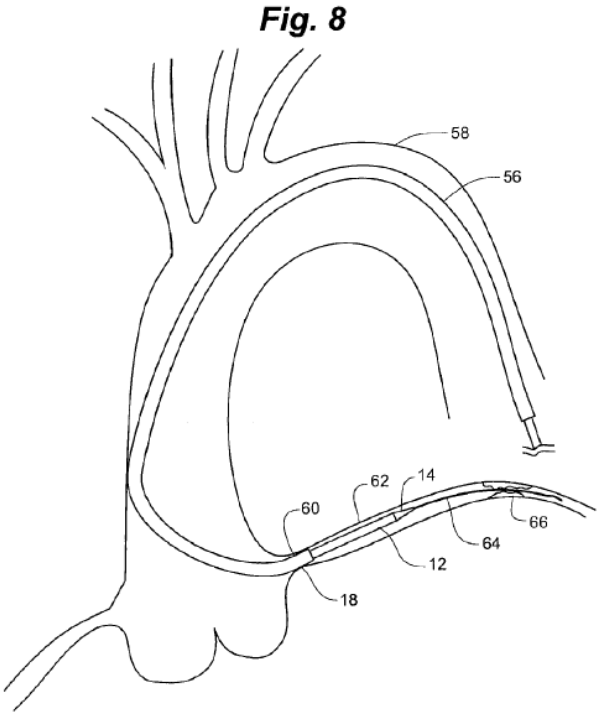


Figure 8 is a schematic view of a guide catheter, a guidewire, a coaxial guide catheter, and a tapered inner catheter located in the aortic arch and coronary artery. *Id.* at 5:61–64. In Figure 8, “coaxial guide catheter 12 with tapered inner catheter 14 is passed through guide catheter 56 and over guidewire 64 into coronary artery 62 after the guide catheter 56 has been placed in the ostium 60 of coronary artery 62.” *Id.* at 8:6–10. The ’380 patent explains that “[c]oaxial guide catheter 12, with tapered inner catheter 14, provides an inner support member for proper translation over guidewire 64.” *Id*. at 8:10–14. “Once coaxial guide catheter 12 is in place, tapered inner catheter 14 is removed from the inside of coaxial guide catheter 12.” *Id*. at 8:14–17. At this point, coaxial guide catheter 12 is ready to accept a treatment catheter such as a stent or balloon catheter. *Id*. at 8:18–19. The ’380 patent explains that coaxial guide catheter 12 provides additional backup support to

resist dislodging of guide catheter 56 from ostium 60 when force is applied to guidewire 64 to pass through stenotic lesion 66. *Id*. at 8:23–30.

D. Illustrative Claim

Independent claim 1 is illustrative of the challenged claims and is reproduced below.

> 1. A system for use with interventional cardiology devices adapted to be insertable into a branch artery, the system comprising:
>
> a 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 the 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 continuous lumen of the guide catheter; and
>
> a device adapted for use with the guide catheter, including:
>
> a flexible tip portion defining a tubular structure and having a circular cross-section and a length that is shorter than the predefined length of the continuous lumen of the guide catheter, the tubular structure having a cross-sectional outer diameter sized to be insertable through the cross-sectional inner diameter of the continuous lumen of the guide catheter and defining a coaxial lumen having a cross-sectional inner diameter through which interventional cardiology devices are insertable; and
>
> a substantially rigid portion proximal of and operably connected to, and more rigid along a longitudinal axis than the flexible tip portion and defining a rail structure without a lumen 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, such that when at least a distal portion of the flexible tip portion is extended distally of the distal end of the guide catheter, at least a portion of the proximal portion of the substantially rigid portion extends proximally through the hemostatic valve in common with interventional cardiology devices that are insertable into the guide catheter;
>
> *wherein the tubular structure includes a flexible cylindrical distal tip portion and a flexible cylindrical reinforced portion proximal to the flexible cylindrical distal tip portion and wherein the flexible cylindrical distal tip portion is more flexible than the flexible cylindrical reinforced portion.*

Ex. 1001, 10:47–11:24 (limitations added by reissue in italics).

E. Prior Art and Asserted Grounds

We instituted review of claims 1–4, 6–10, 12–21, and 23 of the '380 patent on the following grounds (Inst. Dec. 7, 30):

Claim(s) Challenged	35 U.S.C. §	Reference(s)/Basis
1–4, 6–10, 12–20, 23	102	Itou[2]
3, 14, 15	103	Itou, Ressemann[3]
21	103	Itou, Berg[4]

In support of its arguments, Petitioner relies on the expert declarations of Dr. Stephen Jon David Brecker (Exs. 1005, 1806, 1902), Dr. Richard A. Hillstead (Exs. 1042, 1905, 1907), Mr. Michael Jones (Ex. 1807), and Dr. Paul Zalesky (Exs. 1755, 1830, 1919). Patent Owner relies on the declarations of Ms. Amy Welch (Ex. 2044) (redacted), Ms. Deborah Schmalz (Ex. 2039), Mr. Howard Root (Ex. 2118), Mr. Gregg Sutton (Ex.

[2] Itou, US 7,736,355 B2, issued June 15, 2010 (Ex. 1007) ("Itou").
[3] Ressemann, US 7,604,612 B2, issued October 20, 2009 (Ex. 1008) ("Ressemann").
[4] Berg, US 5,911,715, issued June 15, 1999 (Ex. 1051) ("Berg").

2119), Mr. Mark Goemer (Ex. 2120), Ms. Amanda O'Neil (Ex. 2121), Mr. Steve Erb (Ex. 2122), Mr. Peter T. Keith (Ex. 2123, 2124, 2138, 2243), Dr. John J. Graham (Ex. 2145), Dr. Lorenzo Azzalini (Ex. 2151), Mr. Steve Jagodzinkski (Ex. 2152 (redacted), 2153 (confidential)), Ms. Heather S. Rosecrans (Ex. 2205), and Dr. Craig Thompson (Ex. 2215).

II. ANALYSIS

A. Priority Date of the '380 Patent

The AIA's first-to-file provisions apply to patent applications "that contain[] or contained at any time a claim to a claimed invention that has an effective filing date" on or after March 16, 2013. AIA § 3(n)(1). The application for reissue for the '380 patent was filed November 1, 2013 and sought reissue of US Patent No. 8,292,850, which issued October 23, 2012 from an application filed January 26, 2012. Ex. 1001, codes (22), (64). Petitioner contends that because there is no written description support for the subject matter of at least claim 27 of the '380 patent, the '380 patent has an effective filing date after March 16, 2013. Pet. 14. Thus, according to Petitioner, the '380 patent is subject to the AIA's first-to-file provisions, which precludes Patent Owner's from attempting to swear behind Itou's filing date. *Id.*

"The effective filing date for a claimed invention in an application for reissue or reissued patent shall be determined by deeming the claim to the invention to have been contained in the patent for which reissue was sought." 35 U.S.C. § 100(i)(2) (2018). As the "patent for which reissue was sought" in this case was issued October 23, 2012, we are not persuaded that AIA's first-to-file provisions apply to the '380 patent. Indeed, Petitioner

provides no legal support for the proposition that claims in a reissue patent are not entitled to a filing date as if they appeared in the original patent for which reissue was sought.[5]

B. Level of Ordinary Skill in the Art

We consider the asserted grounds of unpatentability in view of the understanding of a person of ordinary skill in the art ("POSITA"). Petitioner provides two alternative definitions of a person of ordinary skill in the art. First, Petitioner asserts that if a person of ordinary skill in the art "was a medical doctor, s/he would have had (a) a medical degree; (b) completed a coronary intervention training program, and (c) experience working as an interventional cardiologist." Pet. 15. Alternatively, Petitioner asserts that if a person of ordinary skill in the art was "an engineer, s/he 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." *Id.* Additionally, Petitioner contends that "[e]xtensive experience and technical training might substitute for education, and advanced degrees might substitute for experience." *Id.*

Patent Owner "does not dispute Petitioner's proposed definition of a POSITA." PO Resp. 9.

Upon review of the parties' arguments and supporting evidence, we adopt Petitioner's definitions for a person of ordinary skill in the art,

[5] To the extent the original patent for which reissue was sought does not contain written description support for a reissue claim, that claim may be invalid. But this is a question we may not address in an IPR. 35 U.S.C. § 311(b).

allowing experience as a medical doctor or as an engineer, as they are undisputed and consistent with the level of skill reflected in the prior art and the written description of the '380 patent. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001) (the prior art itself can reflect the appropriate level of ordinary skill in the art).

C. Claim Construction

We interpret a claim "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)(2019). This standard requires that we construe a 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.*

Upon review of the parties' arguments and supporting evidence, we determine that it is not necessary to construe any claim terms to resolve the disputed issues for purposes of this Final Written Decision. *See Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 295, 803 (Fed. Cir. 1999) (holding that "only those terms need to be construed that are in controversy, and only to the extent necessary to resolve the controversy").

D. Status of Itou as Prior Art - Conception and Reduction to Practice

Before reaching the merits of the grounds in the Petition, we address whether Petitioner's primary reference, Itou, which is relied upon for all grounds in the Petition, qualifies as prior art.

Itou was filed on September 23, 2005, published on March 30, 2006, and issued on June 15, 2010. Ex. 1007, codes (22), (45), (65). Petitioner

contends that Itou is prior art under pre-AIA § 102(e). Pet. 19–20.[6] In the Conception and Reduction to Practice (CRTP) briefing that we separately authorized for these proceedings, Patent Owner argues that Itou does not qualify as prior art based on research and development related to the claimed invention that took place at Vascular Solutions, Inc. ("VSI"), Patent Owner's predecessor-in-interest, starting around early 2005 and continuing through the May 3, 2006, filing of the original priority application for the '380 patent. *See generally* PO CRTP Resp.; PO CRTP Sur-Reply. Petitioner disputes these contentions. *See generally* Pet. CRTP Reply; Pet. CRTP Sur-Sur-Reply.

In its CRTP Response, Patent Owner identifies the evidence on which it relies to antedate Itou, including certain inventor testimony, non-inventor testimony, and other documentary evidence. PO CRTP Resp. 2. As to inventor testimony, Patent Owner relies on the respective declarations of co-inventors Howard Root (Ex. 2118) and Gregg Sutton (Ex. 2119). As to non-inventor testimony, Patent Owner relies on the declaration of its expert Peter T. Keith (Ex. 2123), the declarations of VSI employees Steven Erb (Ex. 2122) and Deborah Schmalz (Ex. 2039), and the declarations of employees of third-party vendors, Amanda O'Neil (Ex. 2121) and Mark Goemer (Ex. 2120). As to documentary evidence, Patent Owner relies on nearly seventy-five exhibits. These documents include inventor lab notebooks and handwritten notes (Exs. 2002, 2004); internal company memoranda,

[6] In addition to this Petition, Petitioner similarly asserts Itou in the petitions in IPR2020-00126, -00129, -00132, -00134, -00135, and -00137. Our analysis regarding the prior art status of Itou is similar for each of these proceedings.

presentations, and other similar documents (Exs. 2003, 2005, 2017–2018, 2024, 2025, 2036–2038, 2040–2041, 2099–2100, 2105, 2109, 2127–2134); invoices, sales orders, and certificates of completion from technical equipment vendors (Exs. 2006–2011, 2013, 2016, 2020–2021, 2026–2035, 2089–2095, 2097, 2104, 2106–2108, 2110–2112); a photograph (Ex. 2014); deposition transcripts (Exs. 2015, 2116); communications with and documents from VSI's outside patent counsel (Exs. 2019, 2023, 2096, 2098, 2101–2103, 2117); and engineering drawings (Exs. 2022, 2113–2115).

We have considered this evidence and other rebuttal evidence offered by Petitioner. For the following reasons, we conclude that a preponderance of the evidence demonstrates that Patent Owner conceived the subject matter recited in the challenged claims before the date on which Itou is effective as prior art (i.e., September 23, 2005) and either actually reduced the invention to practice prior to the critical date or diligently worked towards constructive reduction to practice until the first priority application for the '380 patent was filed on May 3, 2006. Accordingly, we conclude that Itou does not qualify as prior art to the '380 patent.

For our analysis, we first set forth the relevant legal standards, followed by our fact findings and analysis on conception, actual reduction to practice, and diligence towards constructive reduction to practice.

1. Legal Standards

"To antedate (or establish priority) of an invention, a [patent owner] must show either an earlier reduction to practice, or an earlier conception followed by a diligent reduction to practice." *Purdue Pharma L.P. v. Boehringer Ingelheim GmbH*, 237 F.3d 1359, 1365 (Fed. Cir. 2001). "Conception is the formation, in the mind of the inventor, of a definite and

permanent idea of the complete and operative invention, as it is thereafter to be applied in practice." *Cooper v. Goldfarb*, 154 F.3d 1321, 1327 (Fed. Cir. 1998). "A reduction to practice can be either a constructive reduction to practice, which occurs when a patent application is filed, or an actual reduction to practice." *Id.* "In order to establish an actual reduction to practice, the [patent owner] must prove that: (1) [the inventors] constructed an embodiment or performed a process that met all the limitations of the [claimed invention]; and (2) [the inventors] determined that the invention would work for its intended purpose." *Id.*

If a patent owner has not shown actual reduction to practice prior to the "critical date" of a reference, the patent owner may nonetheless antedate the reference by establishing prior conception and reasonable diligence towards a constructive reduction to practice. *Purdue Pharma*, 237 F.3d at 1365. "Reasonable diligence must be shown throughout the entire critical period, which begins just prior to the competing reference's effective date and ends on the date of the invention's reduction to practice." *Arctic Cat Inc. v. GEP Power Prods., Inc.*, 919 F.3d 1320, 1331 (2019). However, the "diligence need not be perfectly continuous—only *reasonably* continuous." *Id.*

To be persuasive, an inventor's testimony of conception and reduction to practice must be corroborated by other independent evidence. "Conception must be proved by corroborating evidence which shows that the inventor disclosed to others his completed thought expressed in such clear terms as to enable those skilled in the art to make the invention." *REG Synthetic Fuels, LLC v. Neste Oil Oyj*, 841 F.3d 954, 962 (Fed. Cir. 2016) (internal quotation marks omitted). "However, there is no final single

formula that must be followed in proving corroboration." *Id.* (quotation marks omitted); *see also Kolcraft Enters., Inc. v. Graco Children's Prods., Inc.*, 927 F.3d 1320, 1324 (Fed. Cir. 2019); *Medichem, S.A. v. Rolabo, S.L.*, 437 F.3d 1157, 1169–70 (Fed. Cir. 2006).

"In the final analysis, each corroboration case must be decided on its own facts with a view to deciding whether the evidence as a whole is persuasive." *Berges v. Gottstein*, 618 F.2d 771, 776 (CCPA 1980). Corroborating evidence may consist of "testimony of a witness, other than the inventor," or "evidence of surrounding facts and circumstances independent of information received from the inventor." *Medichem*, 437 F.3d at 1171. "Even the most credible inventor testimony is *a fortiori* required to be corroborated by independent evidence, which may consist of documentary evidence as well as the testimony of non-inventors." *Id.* at 1171–72. We assess whether evidence corroborates conception and reduction to practice under a "rule of reason" analysis. *Cooper*, 154 F.3d at 1330.

In an *inter partes* review, 35 U.S.C. § 316(e) imposes the ultimate burden persuasion to "prove unpatentability by a preponderance of the evidence" onto the petitioner. This burden never shifts to the patent owner. *Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015). However, when the patent owner attempts to antedate the prior art, "[a] second and distinct burden, the burden of production" can shift between the petitioner and the patentee. *Id.* at 1379; *see In re Magnum Oil Tools Int'l, Ltd.*, 829 F.3d 1364, 1375–76 (Fed. Cir. 2016). Specifically, the patent owner "bears the burden of establishing that its claimed invention is entitled to an earlier priority date than an asserted prior art reference."

Magnum Oil Tools, 829 F.3d at 1375–76. Once the patent owner establishes it is entitled to an earlier priority date, the burden of production then shifts back to the petitioner "to convince the court that [the patent owner] is not entitled to the benefit" of the earlier priority date. *Dynamic Drinkware*, 800 F.3d at 1379 (citing *Tech. Licensing Corp. v. Videotek, Inc.*, 545 F.3d 1316, 1328 (Fed. Cir. 2008)).

2. Conception

To show prior conception, Patent Owner relies primarily upon Mr. Root's testimony submitted in support of its CRTP Response. Ex. 2118 (Root Declaration in support of CRTP).[7,8] Mr. Root was the founder and Chief Executive Officer of VSI from 1997 to 2017. *Id.* ¶¶ 1–2. Patent Owner also relies upon the testimony of co-inventor Mr. Sutton, who was Vice President, Research & Development at VSI from 2004 until mid-2006. Ex. 2119 (Sutton Declaration in support of CRTP). As additional documentary corroboration for this inventor testimony, Patent Owner relies

[7] Patent Owner previously submitted a declaration by Mr. Root with its Preliminary Response (Ex. 2001), but withdrew that declaration in favor of Ex. 2118. PO CRTP Resp. 2 n.1.

[8] The testimonial evidence that Patent Owner presents in support of conception is largely undisputed. Indeed, during a teleconference addressing Patent Owner's request to present live testimony from Mr. Root in these proceedings, Petitioner's counsel acknowledged that Mr. Root's testimony was not disputed in a manner that would require our credibility assessment. *See* Ex. 1920, 11:10–11 ("And I don't think we have, you know, directly said Mr. Root is lying on this topic."); *id.* at 17:17–18 ("We don't have any issue at play here that goes to credibility."). Accordingly, in view of our conclusion that "the credibility of Mr. Root is not in question," we denied Patent Owner's request to present live testimony from Mr. Root at the oral hearing. *See* Paper 110, 4–5 (distinguishing *K-40 Elecs., LLC v. Escort, Inc.*, IPR2013-00203, Paper 34 (PTAB May 21, 2014) (precedential)).

upon certain pages from Mr. Sutton's laboratory notebook dated January 4, 2005 (Ex. 2002), a "market feasibility" memorandum from Mr. Root dated February 4, 2005 (Ex. 2003), and some additional handwritten notes and drawings from Mr. Root dated February 7, 2005 (Ex. 2004). We first set forth the relevant facts based on these declarants' testimony and corroborating evidence, and then address any disputed issues of material fact and legal issues as needed in our analysis.

a) Fact Findings for Conception

In his declaration, Mr. Root attests that conception started around the time he attended the Transcatheter Cardiovascular Therapeutics (TCT) conference from September 27 to October 1, 2004, by which time he had recognized the issue of "guide catheter backout" that physicians were experiencing when performing complex interventional coronary procedures. Ex. 2118 ¶ 5. Accordingly, Mr. Root asserts that he recognized a need for a solution "that provided better guide positioning, device delivery, and procedural conveniences" than what previously existed in the market. *Id.* To solve this problem, Mr. Root indicates that he came up with "the idea for a guide extension catheter that would provide improved back-up support with rapid exchange delivery, which would offer far more convenience than other options available at the time." *Id.* ¶ 6. And "[s]ometime after the TCT conference, but before 2005," Mr. Root met with his co-inventors, including Mr. Sutton, to discuss more particular ideas for how to make this device. *Id.*

The "guide extension catheter" device that the inventors had thought of at this time included certain key features. It was to be used within a standard guide catheter that was one "French size" larger than the "guide

extension catheter," and was parsed into two distinct portions—a substantially rigid proximal portion comprising a "rail" structure and a distal tubular portion with a lumen—which together were longer than a standard guide catheter. *Id.* ¶ 7. During an operation, after the standard guide catheter was inserted into the vasculature so its distal end was in the ostium of a cardiac artery, the guide extension catheter would be inserted into the lumen until the distal end of the tubular portion went past the distal end of the guide catheter and into the cardiac artery. *Id.* With both catheters in place, an interventional cardiology device could be thereafter inserted through the standard guide catheter (running along the rail of the guide extension catheter) until it reached the distal end of the distal tubular portion of the guide extension catheter, thereby entering the cardiac artery. *Id.*

The device they undertook to develop was initially called the "Guide-Liner" device, but the hyphen was later dropped and it became known as the "GuideLiner" device. *Id.* ¶ 9. Although the original idea for the GuideLiner was a "rapid exchange" ("RX") version of the guide extension catheter, "[s]ometime between February and June of 2005, a decision was made to concurrently pursue development of an over-the-wire ('OTW') version of GuideLiner." *Id.* ¶ 19. Mr. Root acknowledges, however, that "[t]he OTW GuideLiner was not part of the inventions of the [challenged] patents," but instead was more akin to the "mother-in-child" design that was known in the prior art and discussed in the background of the challenged patents. *Id.* (citing Ex. 1001, 2:17–44).[9]

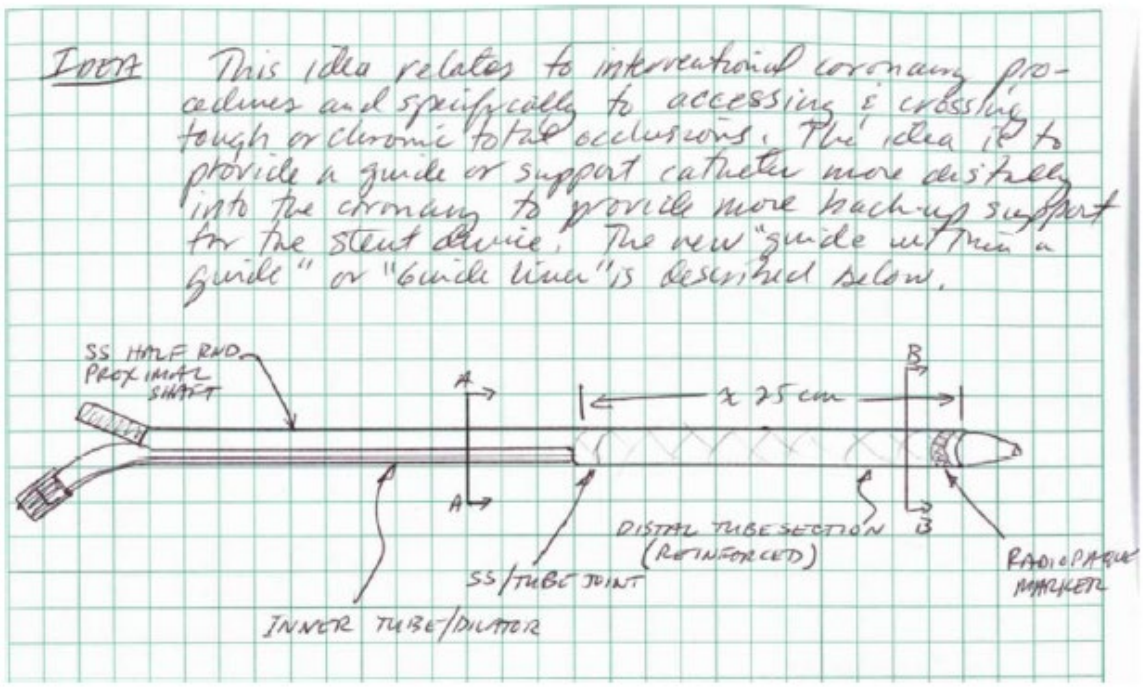
[9] It is undisputed that the work done in developing the RX GuideLiner, not the OTW GuideLiner, must provide the basis for conception and reduction

Mr. Sutton in his own declaration sets forth a story consistent with that set forth by Mr. Root. He attests that "[s]tarting in late-2004 until [he] left VSI, [he] performed research and development work on what became the GuideLiner guide extension catheter." Ex. 2119 ¶ 2. Although VSI did not retain all of its files from that time, Mr. Sutton recalls, based on his memory and documents he reviewed, that "we knew very early on that the GuideLiner rapid exchange device would work for its intended purpose," and that "[t]he research and development that followed our original conception of the GuideLiner rapid exchange was to optimize materials, dimensions, and design details that would allow us to manufacture and bring the product to market in a way that would be commercially viable." *Id.* ¶ 6.

The earliest documentary evidence that corroborates this testimony is Mr. Sutton's laboratory notebook pages relating to the concept for a "Guide-Liner" device. Ex. 2002. Mr. Sutton signed the relevant pages on January 4, 2005, and Jeffrey Welch, another co-inventor and engineer at VSI, witnessed those pages on March 2, 2005. *Id.* at 7–8; *see* Ex. 2119 ¶ 7.

A portion of one page from Mr. Sutton's notebook is reproduced below:

to practice of the claimed invention. PO CRTP Resp. 13 n. 3; Pet. CRTP Reply 1.



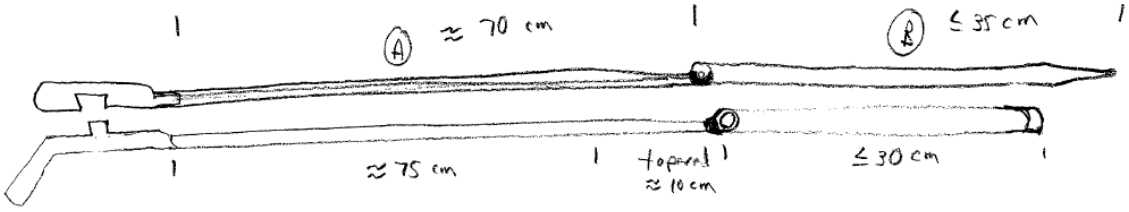
Ex. 2002, 7. As shown above, Mr. Sutton's notebook sets forth an "idea" that "relates to interventional coronary procedures and specifically to accessing & crossing tough or chronic occlusions," which "is to provide a guide or support catheter more distally into the coronary to provide more back-up support for the stent device." *Id.*; Ex. 2118 ¶ 9. Mr. Sutton's lab notebook also includes drawings of the cross section of various portions of the guide extension catheter and a drawing of how the Guide-Liner would be used that are similar to figures included in the challenged patents. *Cf.* Ex. 1001, Figs. 1, 2, 5, 6 (depicting patent drawings of the guide extension catheter that are similar to Mr. Sutton's drawings). For example, his notebook includes a drawing of a "5F" (5-French) Guide-Liner in operation and notes that the Guide-Liner a) "is used where there is difficulty crossing lesions," b) "allows back-up support distally," c) "allows for Rapid X change," and d) "would fit std. 6F Guides." Ex. 2002, 8. The notebook

pages also describe the main features of the device, including: 1) an inner tube/dilator that "fits snugly" within a stainless steel ("SS") half-tube; 2) a reinforced distal tube section with a braided "PTFE/SS/PEBAX" material that is "soft for coronaries"; and 3) a design that "allows for rapid exchange." *Id.* at 7. Additionally, the notebook identifies the "5F Design Specs," including an overall device length of between 105 cm and 115 cm. *Id.* Both Mr. Root and Mr. Sutton authenticate the contents of the notebook pages and Mr. Sutton attests that his notebook was "issued and maintained in the regular course of VSI's business." Ex. 2118 ¶¶ 9–11; Ex. 2119 ¶¶ 7–14.

By early February 2005, Mr. Root realized this device would have "substantial market potential," so he wrote a "Market Feasibility" memorandum (memo) for GuideLiner catheters, dated February 4, 2005. Ex. 2118 ¶ 11; Ex. 2003 (confidential); Ex. 2127 (public). Mr. Root attests that he would only have drafted this kind of memo if he "had developed high confidence that a concept would work," so that non-inventors in the company (e.g., regulatory personnel and engineers) could join a project to bring the new product to market. Ex. 2118 ¶ 11. The memo itself recognizes the "substantial market potential" for the RX GuideLiner device based on an estimated 30,000 procedures a year. Ex. 2003, 1. The memo indicates that three versions were anticipated (i.e., a "5in6," a "6in7," and a "7in8" GuideLiner), and notes problems with the prior art OTW methods. *Id.* The memo also generally describes the RX GuideLiner in a manner consistent with the description in Mr. Sutton's notebook including, among other features, that: it would be delivered within a standard guide catheter for interventional cardiology procedures; it had a short distal tube segment to allow for rapid exchange delivery; it was inserted through the existing

hemostatic valve; and it was one French size smaller than the standard guide catheter. *Id.* at 2.

Mr. Root also references his own handwritten notes, dated February 7, 2005.[10] Ex. 2118 ¶¶ 12–14; Ex. 2004. These notes show certain features of the RX GuideLiner device, including a "side opening" section that appears in the transition from a partial-round proximal portion to a full round portion connected to a distal tube section. Ex. 2004. The first drawing from Mr. Root's handwritten notes, reproduced below, is similar to Figure 1 of the '380 patent:

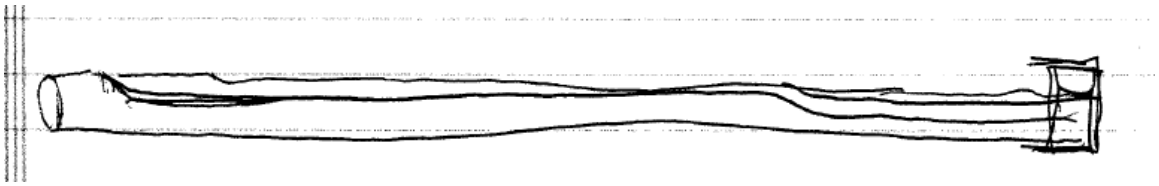


Ex. 2004, 1. As shown above, a "side opening" to allow for the RX capability is reflected through "crude shading" between the rail structure and tubular portion above the notation reading "tapered ≈ 10 cm," and was

[10] Although only the first page of these notes is dated, Mr. Root attests he made the notes on the other two pages "contemporaneously with [his] notes on page 1." Ex. 2118 ¶ 14. Petitioner contends that the third page, in addition to being undated and unwitnessed, appears to come from "a different set of notes" because, unlike the first two pages, the paper is lined. Pet. CRTP Reply 7 n.4. Petitioner also points out that Mr. Sutton testified that he had not seen the third page until his deposition in the stayed district court litigation. *Id.* (citing Ex. 1108, 41:1–6, 46:7–47:3). Mr. Sutton, however, is not the author of these notes. Although we recognize that the type of paper used to record the notes may have been different, we find that the content of page 3 seem to be otherwise consistent with the remainder of the notes and Patent Owner's other conception documents. We therefore find no basis to question Mr. Root's testimony that all his notes from Exhibit 2004 were made contemporaneously on or about February 7, 2005.

considered by Mr. Root to be "an important feature of GuideLiner." Ex. 2118 ¶ 13. Mr. Root testifies that the side opening "facilitates entry of interventional cardiology devices into the proximal end of the tubular portion." *Id.*

The third page of Mr. Root's notes depicts another drawing, reproduced below, that also shows the side opening concept:



Ex. 2004, 3. According to Mr. Root, the sketch above "shows a side opening structure that is cut-away in several segments including, from left (distal) to right (proximal): a full round portion; a first angled transition portion; a first partial round portion; a second angled transition portion; and a second partial round portion." Ex. 2118 ¶ 14. The notes also list dimensions for the contemplated sizes of the GuideLiner. *Id.* ¶ 12; Ex. 2004, 1–3.

Beyond these "core" conception documents (Exs. 2002–2004), Patent Owner also relies on certain engineering drawings as further corroboration for the inventors' testimony. PO CRTP Sur-Reply 3–5 (citing Exs. 2022, 2113, 2114). Patent Owner annotates two of these drawings to highlight features of the depicted GuideLiner, namely the "Side Opening," "Rail Structure," "Machined End for Connecting to Tubular Portion," "Soft Tip," and "Reinforced Pebax Tubular Portion." *Id.* at 4 (citing Ex. 2114), 5 (citing Ex. 2022). The drawings are dated March 2005 (Ex. 2113, 1), June 28, 2005 (Ex. 2114), and August 1, 2005 (Ex. 2022, 1). We have taken these

documents into account in determining whether the inventors conceived of the claimed invention prior to the September 23, 2005 critical date.

b) Analysis for Conception

We first consider whether Patent Owner's proffered evidence corroborates the inventors' testimony of conception. Patent Owner does not assert a specific date of conception. *See* Tr. 60:4–6 ("Our story from day one has been that the exact date of conception doesn't matter."). We agree that we need not determine the exact date on which conception took place. Nonetheless, before we can move on to the question of reduction to practice, we must determine that conception—as legally defined to be the formation of "a definite and permanent idea of the complete and operative invention," *Cooper*, 154 F.3d at 1321—was finalized at some point prior to the critical date of Itou. From the evidence Patent Owner relies upon, we can distill Patent Owner's broad theory of conception as having occurred either by February 2005, as corroborated by the core conception documents (Exs. 2002–2004), or by August 2005 during the course of building and testing prototypes, as further corroborated by the engineering drawings (Exs. 2113, 2114, 2022).

Petitioner argues that Patent Owner's core documentary evidence—Mr. Sutton's notebook pages, the market feasibility memo, and Mr. Root's handwritten notes—cannot be used to corroborate inventor testimony insofar as they all originated from the inventors themselves as opposed to some other independent source. Pet. CRTP Reply 4. Petitioner relies principally on three cases as support for this argument. *Id.* at 3–4.

First, Petitioner cites *Apator Miitors ApS v. Kamstrup A/S*, 887 F.3d 1293 (Fed. Cir. 2018), to argue the documents relied upon by Patent Owner are "inventor documents" that cannot be used to corroborate an inventor's testimony on conception. *Id.* at 4. The problem for the patent owner in *Apator* was that it was "stuck in a catch-22 of corroboration" because the evidence that was proffered to corroborate the inventor's testimony could "only provide that corroboration with help from [the same inventor's] testimony." 887 F.3d at 1296. For instance, in the bodies of the emails that were relied upon, the inventor indicated that he attached certain files related to his invention, but nothing in any part of the emails indicated what files were attached or what such attachments disclosed. *Id.* The court agreed with the Board's finding that the inventor's testimony was the only evidence proffered to establish the existence and substance of the attachments. *Id.* at 1296–97. And though the drawings set forth dates that were after the reference's critical date, the inventor's testimony about certain file naming conventions was the only evidence offered by the patent owner to demonstrate that the drawings were actually created on an earlier date. *Id.* at 1294–95, 1296–97. The court rejected the patent owner's argument that the emails and drawings should still have "some corroborative value," like unwitnessed laboratory notebooks. *Id.* at 1297. The court acknowledged that the rule of reason permits "'a notebook entry' or other writing '[that] has not been promptly witnessed,'" *id.* (citing *Singh v. Brake*, 222 F.3d 1362, 1370 (Fed. Cir. 2000)), "to aid in corroborating witness testimony alongside other, more persuasive, evidence." *Id.* (citing examples where the Federal Circuit and one of its predecessors, the Court of Customs and Patent Appeals, permitted unwitnessed documents to contribute to corroboration of

conception). But the court clarified that "an unwitnessed laboratory notebook, alone, cannot corroborate an inventor's testimony of conception." *Id.* (citing *Brown v. Barbacid*, 276 F.3d 1327, 1335 (Fed. Cir. 2002) (concluding there was no error in denying corroboration by "an inventor's own unwitnessed documentation"); *Procter & Gamble Co. v. Teva Pharms. USA, Inc.*, 566 F.3d 989, 998–99 (Fed. Cir. 2009) (concluding a laboratory notebook that "was unwitnessed and was not corroborated by any other evidence" could not corroborate inventor testimony of conception)).

Second, Petitioner cites *Kolcraft*, 927 F.3d at 1320, in support of its argument that the documents relied upon by Patent Owner lack corroborative value because they all "'originated with the inventors.'" Pet. CRTP Reply 4. In *Kolcraft*, the Federal Circuit observed that the evidence at issue—which it characterized as "even weaker than the evidence presented in *Apator*"—comprised a redacted inventor declaration, the inventor's deposition testimony, and undated photos attached to the inventor declaration. 927 F.3d at 1325. Of this evidence, the court noted that "[o]nly the Inventor Declaration, i.e., inventor testimony, supports the purported dates showing [prior] conception," but this was deemed insufficient because "[i]nventor testimony alone cannot prove conception." *Id.*

Third, Petitioner cites a non-precedential Board decision, *Curt Manufacturing, LLC v. Horizon Global Americas Inc.*, IPR2019-00625, 2020 WL 4687044, at *7 (PTAB Aug. 11, 2020), for the proposition that "[o]ne inventor cannot corroborate another." Pet. CRTP Reply 4; *see also* Tr. 38:20–39:13 (Petitioner's counsel citing *Curt* for the same proposition). In *Curt*, the Board stated that "[o]ne consequence of the independence requirement is that *testimony* of one co-inventor cannot be used to help

corroborate *the testimony* of another." Pet. CRTP Reply 4 (citing *Lacks Indus., Inc. v. McKechnie Vehicle Components USA, Inc.*, 322 F.3d 1335, 1350 (Fed. Cir. 2003) (emphases added) (approving refusal to accept cross-corroboration of oral testimony by interested witnesses)).[11] The Board further noted that "an inventor's *unwitnessed* laboratory notebooks, emails, and drawings, *without other independent evidence*, cannot corroborate an inventor's testimony." *Curt*, 2020 WL 4687044, at * 7 (emphases added) (citing *Kolcraft*, 927 F.3d at 1325–26; *Apator*, 887 F.3d at 1297; *Brown*, 276 F.3d at 1335). In a footnote quoting *Brown*, the Board highlighted the importance of two issues: whether the documentary evidence was witnessed and whether there is other corroborating evidence in the record. *Id.* at *7 n.7 (reiterating that physical evidence from an inventor does not need corroboration to demonstrate its contents, but the inventor's *unwitnessed* documentation "may not *single-handedly* corroborate" the inventor's testimony) (quoting *Brown*, 276 F.3d at 1335) (other emphases omitted). Lastly, the Board concluded that, "[n]otwithstanding this clear guidance, the law also recognizes that . . . a notebook entry or other writing that has not been promptly witnessed does not necessarily disqualify it in serving as corroboration of conception under a rule of reason analysis." *Id.* at *7 (citing *Apator*, 887 F.3d at 1297 (referring to cases where unwitnessed

[11] The Federal Circuit, however, has not categorically prohibited "cross-corroboration" of testimony by interested witnesses at least in other contexts. *See Nobel Biocare Servs. AG v. Instradent USA, Inc.*, 903 F.3d 1365, 1378 (Fed. Cir. 2018) ("The testimony of one witness may corroborate the testimony of another witness.").

documentary evidence was considered alongside other evidence to corroborate inventor testimony)).

Considering the evidence of record as a whole, we reject Petitioner's arguments that the inventors' testimony on conception is not adequately corroborated. We find the case law cited by Petitioner to be distinguishable.

We first note that Mr. Sutton's laboratory notebook was witnessed shortly after the date of entry of the relevant pages. Specifically, the notebook pages presented here were witnessed by another inventor, Jeffery Welch, Ex. 2002. Because the notebook is dated and witnessed, we may properly consider it for its probative value in corroborating Mr. Root's and Mr. Sutton's testimony. *See Singh*, 222 F.3d at 1369–70 (holding that a belatedly witnessed lab notebook may serve as corroboration of conception); *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1378 (Fed. Cir. 1986) (same). Indeed, as noted above, even an unwitnessed notebook page may have some corroborative value under the rule of reason when considered in combination with other more persuasive evidence. *Apator*, 887 F.3d at 1297. Moreover, we discern no *per se* rule from the case law to suggest that a laboratory notebook witnessed by a co-inventor cannot be used to corroborate another inventor's testimony about conception. In this regard, we find that the witnessed notebook pages avoid the "catch-22 of corroboration" noted in *Apator* because the notebook pages do not depend upon either Mr. Root's or Mr. Sutton's testimony for an explanation of their content. The notebook pages also avoid the issue that arose in *Kolcraft* and *Curt* because Patent Owner has not relied upon only the inventors' testimony to prove conception. We note that, aside from whether the notebook pages can legally qualify as corroborative evidence of the date of conception,

Petitioner has not disputed the authenticity or veracity of the content shown on those pages. As such, we have considered the content of the notebook pages at face value in our analysis.

We have also taken into account the market feasibility memo and Mr. Root's handwritten notes in our corroboration assessment. Ex. 2003; Ex. 2004. We recognize that these documents appear to have been authored by Mr. Root, and no witness other than Mr. Root has provided testimony about their content. As such, if considered in isolation, these conception documents may be more analogous to the type of "catch-22" documents found insufficient for corroborating the date of conception under *Apator*. Nonetheless, applying the rule of reason, we do not categorically exclude them from the corroboration analysis because they can still "aid in corroborating witness testimony alongside other, more persuasive, evidence."[12] *Apator*, 887 F.3d at 1297.

Because we conclude that the notebook pages, along with the market feasibility memo and Mr. Root's handwritten notes, may be properly considered in our corroboration analysis, we next address whether these documents are in fact sufficiently corroborative of the inventors' testimony to show conception of the claimed invention prior to the critical date. On this point, Mr. Root includes as appendices to his declaration claim charts showing how certain VSI prototypes developed at the time meet the

[12] Like the notebook pages, Petitioner has not disputed the authenticity or veracity of the content of the market feasibility memo and Mr. Root's handwritten notes, and thus we have also considered the content of these documents at face value.

limitations of the challenged claims. Ex. 2118, App'x A–E.[13] The primary argument raised by Petitioner is that Patent Owner's core conception documents do not disclose the "side opening" feature recited in numerous challenged claims.[14] Pet. CRTP Reply 5–7. According to Petitioner, without this demonstration, Patent Owner fails to establish conception of "every feature or limitation of the claimed invention."[15] *Id.* at 3 (quoting

---

[13] Petitioner contends that Mr. Root's claim charts amount to an improper incorporation by reference in violation of 37 C.F.R. § 42.6(a)(3) and a circumvention of our word limits. Pet. CRTP Reply 2. However, in view of the commonality of the CRTP issues across these related proceedings, we authorized the parties to submit consolidated briefing on the issue. Paper 26 (Consolidated Scheduling Order), 2–3. Moreover, Petitioner also submitted similar rebuttal claim charts by its expert Dr. Zalesky as appendices to his expert report. Ex. 1755, App'x A–E. Under the circumstances, we are not persuaded that the manner in which Patent Owner presented its claim-by-claim arguments were a violation of our rules.

[14] For instance, claim 3 of the '380 patent recites

> The device of claim 2, wherein the proximal portion of the tubular structure further comprises structure defining a proximal side opening extending for a distance along the longitudinal axis, and accessible from a longitudinal side defined transverse to the longitudinal axis, to receive the interventional cardiology devices into the coaxial lumen while the proximal portion remains within the lumen of the guide catheter.

Ex. 1001, 11:33–40. Claim 14 of the '380 patent also recites "the substantially rigid portion further includes a partially cylindrical portion defining an opening extending for a distance along a side thereof," which the parties agree also refers to the "side opening" feature. *Id.* at 12:57–65.

[15] According to Petitioner's table in its CRTP Sur-Sur-Reply, the side-opening limitation appears in the following claims: claims 3 and 4 of the '032 patent; claims 3, 4, 36 of the '380 patent; claims 25, 52, and 53 of the '776 patent; and claims 25, 48, 51, and 53 of the '760 patent. Pet. CRTP Sur-Sur-Reply 14–15.

REG Synthetic Fuels, 841 F.3d at 962). We are not persuaded that the evidence fails to show that the RX GuideLiner device that the inventors had conceived of and were developing at the time included all the features of the challenged claims, including a side opening feature to allow for rapid exchange.[16]

As noted above, Mr. Root attests that the first and third pages of his handwritten notes each depict a drawing that includes a side opening. Ex. 2118 ¶¶ 12–14 (citing Ex. 2004, 1, 3). In particular, Mr. Root asserts that

> [a]n important feature of GuideLiner is a "side opening" at the transition between the proximal rail structure and the distal tubular portion that facilitates entry of interventional cardiology devices into the proximal end of the tubular portion. This feature is reflected in the crude shading between the rail structure and the tubular portion shown in the sketch above from my February 7, 2005 notes.

Id. ¶ 13. We credit this testimony and find that it is corroborated by the drawings themselves.

Petitioner contends that the lab notebook pages, as confirmed by Mr. Sutton's deposition testimony, only show an "end opening," rather than a side opening for the device. Pet. CRTP Reply 5 (citing Ex. 1108, 70:18–71:23, 79:14–80:24). To further dispute the disclosure of a side opening, Petitioner relies on the declaration of its expert Dr. Zalesky. *Id.* at 6 (citing Ex. 1755 ¶¶ 83–84). Dr. Zalesky contends that the "crude shading" on the

[16] In its Sur-Sur-Reply, Petitioner also contends that Patent Owner is missing evidence that the RX prototypes satisfy certain additional claim limitations. Pet. CRTP Sur-Sur-Reply 14–15. We consider this in addressing the actual reduction to practice issue below.

drawing on the first page of Dr. Root's notes "does not appear to show an angled opening at the proximal end of the tubular portion" and that Mr. Root's notes on the page do not refer to a side opening. Ex. 1755 ¶ 83. Dr. Zalesky further contends that the drawing on the third page of Mr. Root's notes "does not appear to correspond to any of the figures in the Root patents," is "quite crude," making it "difficult to tell what it represents, if anything," and "does not appear to show a side opening." *Id.* ¶ 84.

Although we recognize that Mr. Sutton testified that Figure 1 of the '380 patent does not depict an angled side opening, it does not appear that Mr. Sutton categorically stated that the inventors had not conceived of a device that included the side opening feature or otherwise directly contradicted Mr. Root's testimony on this point. We further note that the first drawing in Mr. Root's notes appears to closely match Figure 1 of the challenged patent (which depicts an unassembled coaxial guide catheter and tapered inner catheter), while the first drawing in Mr. Sutton's notes appears to closely match Figure 2 of the challenged patent (which depicts the assembled device). *Compare* Ex. 2004, 1, *with* Ex. 1001, Fig. 1; *compare* Ex. 2002, 7, *with* Ex. 1001, Fig. 2. We agree with Dr. Zalesky that the sketches included in Mr. Root's handwritten notes are "crude" and not a model of clarity. Nonetheless, taking into account both the documentary evidence and inventor testimony as a whole, we find that a preponderance of the evidence supports the conclusion that the inventors conceived of a device that included the side opening and all other claimed features prior to the critical date.

To the extent that the earlier core conception documents alone do not support prior conception, we have also taken into account the evidence

proffered by Patent Owner with respect to the prototypes that were built between February and August 2005. *See* PO CRTP Sur-Reply 3 (explaining that if the early 2005 documents "were disregarded," other pre-Itou evidence "undisputedly show[s] conception of the entire invention, *including the side opening*" (emphasis added)). To support its theory, Patent Owner cites Dr. Zalesky's testimony, where he confirms that the engineering drawings depict a side opening. Ex. 2237, 211:11–16 (agreeing that "a side opening can be found in the hypotubes that were cut down by Spectralytics, specifically Exhibit 2113 and 2114"), 250:9–13 (agreeing that "Exhibit 2022 sets forth the concept for the rapid exchange GuideLiner"). Petitioner acknowledges the probative value of the August 2005 drawing in showing conception prior to the critical date: "[a]t best, [Patent Owner] shows conception in August 2005, a mere month before Itou and *after* VSI's purported prototype work in April and July." Pet. CRTP Sur-Reply 2. Much of this evidence is also relied upon by Patent Owner to demonstrate that there was actual reduction to practice prior to the critical date. Given the overlap, we also address this evidence as part of our actual reduction to practice analysis.

In sum, Patent Owner's core documentary evidence—Mr. Sutton's lab notebook, the market feasibility memo, and Mr. Root's handwritten notes—sufficiently corroborate the stories of conception set forth in Mr. Root's and Mr. Sutton's declarations. These corroborating documents add credibility to the inventors' conception timelines. And even if Petitioner were correct that not every feature was conceived on or about February 2005, we find that additional evidence of record with respect to the prototypes, as discussed below, demonstrates conception no later than August 2005.

3. Actual Reduction to Practice

Patent Owner contends that actual reduction to practice also took place before the critical date of Itou. In support of this contention, Mr. Root attests in his declaration that employees at VSI, led by co-inventors Mr. Sutton and Mr. Welch, built and tested RX GuideLiner prototypes between January and August 2005.[17] Ex. 2118 ¶ 15. Mr. Sutton, as well as two non-inventors employed by VSI at the time, Steve Erb and Deborah Schmalz, also testify about relevant details of the research and development done with regard to the GuideLiner prototypes. Ex. 2039 (Schmalz Declaration); Ex. 2119 (Sutton Declaration); Ex. 2122 (Erb Declaration). Patent Owner also presents the declarations of Mark Goemer and Amanda O'Neil, who were employed by outside vendors from whom VSI purchased components to build the prototypes. Ex. 2120 (Goemer Declaration); Ex. 2121 (O'Neil Declaration). Additionally, Patent Owner has submitted an expert declaration by Mr. Peter Keith in further support of this contention. Ex. 2123 (Keith Declaration in support of CRTP). Patent Owner relies upon purchase invoices, engineering schematics, and other documentary evidence from as early as January 2005 through the September 2005 critical date of Itou in order to corroborate the fact declarants' testimony regarding actual reduction to practice.[18] We once again set forth

[17] Mr. Root explains that Patent Owner does not have many development documents from 2005, and it obtained many of the documents relevant to actual reduction to practice from VSI's vendors and patent prosecution firm. Ex. 2118 ¶ 20.

[18] Patent Owner includes some documentary evidence created after Itou's critical date. *See, e.g.*, Ex. 2106 (invoices dated April 2006); Exhibit 2115 (engineering drawing dated Nov. 1, 2005). We do not find this post-critical

the relevant facts based on these declarants' testimony and corroborating evidence, and then address any disputed issues of material fact and legal issues as needed in our analysis for actual reduction to practice.

a) Fact Findings for Actual Reduction to Practice

After the inventors came up with the initial idea for the device (as set forth in the conception discussion above), VSI proceeded with the development of both the OTW and RX versions of the GuideLiner concurrently. Ex. 2118 ¶ 19; Ex. 2119 ¶ 15. Although it was based on existing technology, VSI decided to pursue the OTW version based on the belief that it could be brought to market more quickly with fewer regulatory challenges than the RX version. Ex. 2118 ¶ 19; Ex. 2119 ¶ 15. Nonetheless, the RX version remained a priority for continued development at VSI. Ex. 2118 ¶ 19; Ex. 2119 ¶ 15. Consistent with Mr. Root's testimony, Mr. Sutton testifies that the RX GuideLiner was reduced to practice before September 2005, although further work towards commercialization of the product continued until he left the company. Ex. 2119 ¶¶ 6, 15. According to Mr. Sutton, work for the OTW prototype "paled in comparison" to work required for the RX prototype because the OTW prototype "required very little engineering and was relatively easy to build because it was based on existing technology." *Id.* ¶ 15. In their declarations, Mr. Root and Mr. Sutton focus on two distinct sets of prototypes of the RX version that

---

date evidence to support Patent Owner's contentions regarding actual reduction to practice. However, we have considered some of this evidence in our analysis of whether there was diligence towards constructive reduction to practice (*see* discussion, *infra*), as well as to address Petitioner's argument that the continuing work done at VSI with respect to the GuideLiner demonstrates a lack of actual reduction to practice before Itou.

were built and tested before Itou's critical date: the "April 2005" prototypes and the "July 2005" prototypes. Ex. 2118 ¶ 48; Ex. 2119 ¶¶ 21–22.[19] As noted above, Mr. Root includes claim charts identifying how the April and July 2005 prototypes satisfied the limitations of the challenged claims. Ex. 2118, App'x A–E; *see also* Ex. 2123 ¶ 28 (Mr. Keith opining that the April and July 2005 prototypes satisfy the claim limitations based on these claim charts).

In developing these prototypes, a VSI technician and machinist Mr. Erb worked with the inventors to mechanically cut down stainless steel or nitinol "hypotubes" used for the proximal portion of an RX prototype. Ex. 2118 ¶ 16; Ex. 2119 ¶ 20; Ex. 2122 ¶¶ 8–10. The profile of some of these hypotubes started at full circumference at the distal end, then progressed to roughly half-round at the proximal end. Ex. 2118 ¶ 16. The hypotubes were combined with a polymer distal section to create the first RX GuideLiner prototypes. *Id.* At this time, the distal tubular portion was sometimes built by cutting a standard guide catheter to the appropriate length. *Id.* ¶ 24. The earliest prototypes, made in January or February 2005, largely comprised stock components modified through VSI's in-house machining capabilities. *Id.* ¶¶ 18, 20. However, by April 2005, the VSI engineers progressed to building more formal prototypes using custom-ordered materials from outside vendors for the proximal and distal portions

[19] Although Mr. Root refers to the likelihood that other sets of prototypes were also built, the bulk of Patent Owner's evidence and arguments relate to the April and July 2005 prototypes. Ex. 2118 ¶ 48. As such, we focus on these prototypes in determining whether there was actual reduction to practice.

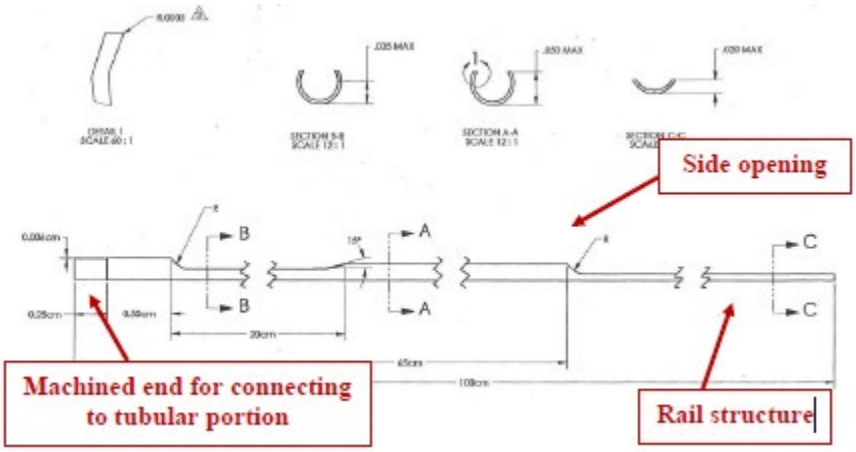
of the device. Ex. 2122 ¶ 12. A spend report details at least some of the expenses that VSI incurred on purchases of the components used to build GuideLiner prototypes from February 11, 2005, to June 30, 2006. Ex. 2005; Ex. 2118 ¶¶ 21–22. According to Mr. Root, the fact that they had opened an account specific to the "Guideliner project" in May 2005, as reflected in this spend report, indicates that development had advanced to the point that they were confident with proceeding towards commercialization. Ex. 2118 ¶ 22.

With respect to the proximal portions, Patent Owner presents invoices and other documents reflecting VSI's purchases of laser-cut hypotubes from three outside vendors MicroGroup, Mountain Machine, Inc., and SPECTRAlytics. Ex. 2118 ¶¶ 23, 27, 29, 30, 32, 33, 40, 43 (citing Exs. 2006, 2007, 2009, 2010, 2013, 2020, 2091, 2094, 2095, 2110, 2111); Ex. 2119 ¶¶ 24–31 (discussing similar purchases); *see also* Ex. 2122 ¶ 7 (discussing purchases of stainless steel and nitinol hypotubes as reflected in Ex. 2110).[20] Because some of these invoices show purchases of the hypotubing by the foot, Mr. Root asserts that the materials were likely used for early evaluations of the RX GuideLiner concept. Ex. 2118 ¶ 23. Mr. Sutton similarly asserts that the hypotubing that was purchased at this time was used to make RX GuideLiner prototypes, as the OTW version never involved such hypotubing. Ex. 2119 ¶¶ 23, 25. The ranges of the inner and outer diameters, wall thickness, and the overall length of the

[20] Although both stainless steel and nitinol hypotubes were ordered, Mr. Sutton asserts that nitinol was significantly more expensive and required additional post-processing steps as compared to stainless steel, and these factors ultimately weighed against using nitinol for the proximal portion of the RX GuideLiner. Ex. 2119 ¶ 28.

hypotubes that were ordered were consistent with what VSI would have needed at the time for prototyping the RX GuideLiner. *Id.* ¶¶ 24, 26.

Mr. Root and Mr. Sutton also reference the following annotated engineering schematics of the proximal portion of the RX GuideLiner that were drawn by a VSI engineer Jim Kauphusman on February 4, 2005:



Ex. 2113; Ex. 2118 ¶ 34; Ex. 2119 ¶ 30. The drawings above show a design of the proximal portion with multiple angled transition regions bookending non-inclined regions, and Patent Owner's annotations to the drawings—which were added for this proceeding, *see* PO CRTP Sur-Reply 13—identify a "machined end for connecting to tubular portion," a "side opening," and a "rail structure." *Id.* These drawings were submitted as "prints" to SPECTRAlytics in order to specify the parameters for the hypotubes that were custom ordered, and include a drawing number "SS HYPO X04" that correlates to a purchase completed on April 4, 2005. Ex. 2118 ¶ 34; Ex. 2120 ¶ 9; Ex. 2095. Additional engineering drawings for the proximal portions were submitted to SPECTRAlytics around June 2005. Ex. 2118 ¶ 41; Ex. 2120 ¶ 11; Ex. 2114. Some of the engineering drawings are similar to figures included in the challenged patent. *Cf.* Ex. 1001, Figs. 12–

16.[21] Mr. Goemer verifies and authenticates some of the purchase documents and the engineering drawings retrieved from SPECTRAlytics's files. Ex. 2120 ¶¶ 6–12.

Additionally, Mr. Root and Mr. Sutton refer to purchases of distal tubular portions and the distal forming tips from vendors Medical Engineering & Design Inc. ("MED") and Farlow's Scientific Glassblowing Inc. between February and July 2005. Ex. 2118 ¶¶ 28, 31, 44, 45 (citing Exs. 2011, 2021, 2090, 2092); Ex. 2119 ¶¶ 32–34, 36 (additionally citing Exs. 2032, 2033, 2034, 2035, 2089, 2097, 2112). Ms. O'Neil, who is employed by MED's successor TE Connectivity ("TE"), verifies and authenticates some of these purchase documents, and notes that the documents were retrieved from the files of TE, but originated with MED in 2005. Ex. 2121 ¶¶ 5–6.

One of the documents from MED also includes engineering schematics for the distal portion that were drawn on February 10, 2005, by Mr. Kauphusman, as shown below:

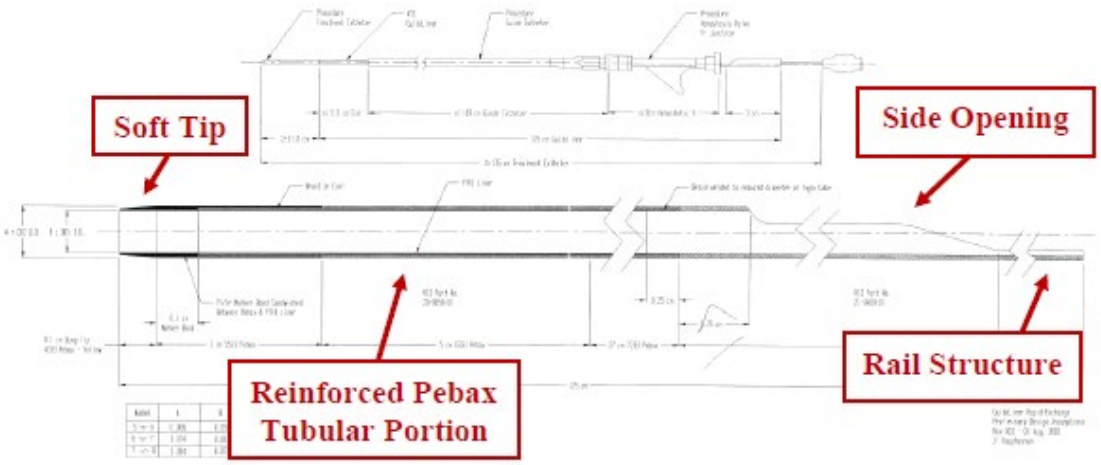
[21] Mr. Sutton faxed these drawings to VSI's outside patent counsel on March 21, 2006. Ex. 2118 ¶ 42; Ex. 2019.

Ex. 2089, 8; Ex. 2118 ¶ 25; Ex. 2119 ¶ 32. The drawing above shows the distal portion with Patent Owner's annotations, *see* PO CRTP Resp. 9, identifying a "soft tip," "three reinforced Pebax portions," the "distal end," and the "proximal end." *Id.* Although Exhibit 2089 does not specify that the tubing was for the RX version of the GuideLiner, Mr. Root and Mr. Sutton assert that the drawings and specifications were in fact specific to an RX device based on the notation that the proximal end should be "counter bored" (a requirement to facilitate attachment to the cut-down hypotube) as well as the overall length of 11.8 inches (because if this part were for an OTW device, it would have been significantly longer). Ex. 2118 ¶ 25; Ex. 2119 ¶ 32. The order for distal portions as shown in Exhibit 2089 was placed on February 17, 2005, and the parts were shipped from MED and delivered to VSI on or about April 5, 2005. Ex. 2118 ¶ 25; Ex. 2119 ¶ 33. An update to the drawing shown in Exhibit 2089 was made on April 6, 2005, as shown in Exhibit 2092, with only minor changes, namely slightly reduced inner and outer diameters to fit a guide catheter and a slightly shortened tip. Ex. 2092, 8; Ex. 2118 ¶ 44. An order for distal tubular portions based on the

updated design was placed on April 12, 2005 and those parts were delivered to VSI on or about June 16, 2005. *Id.*

The proximal and distal portions that were custom ordered and purchased from the outside vendors were thereafter combined in-house at VSI to form the prototypes of the complete RX GuideLiner. Ex. 2118 ¶ 24 ("From the earliest stages of the project, the plan was to combine the substantially rigid proximal portion of the rapid exchange GuideLiner with a distal polymer tubular portion that would be at least partially reinforced with coil or braid."); Ex. 2119 ¶ 34 ("[W]e combined these distal sections from MED with the proximal stainless steel sections discussed above to form prototypes of the GuideLiner rapid exchange in April and July 2005."). For example, the first set of formal prototypes (the April prototypes) appear to have been made by combining the laser-cut hypotubes from SPECTRAlytics with the distal tubular sections from MED that were shipped around April 5, 2005. Ex. 2118 ¶ 35 (citing Exs. 2011,2089). Additional prototypes (the July prototypes) appear to have been built using the hypotubes from MicroGroup shipped around April 20, 2005, and/or the hypotubes from SPECTRAlytics shipped around July 18, 2005, in combination with the updated distal portions from MED shipped around June 16, 2005. *Id.* ¶¶ 39, 40, 46 (citing Exs. 2114, 2020, 2021, 2092, 2094). In making these prototypes, VSI "used an in-house thermal process to fuse the distal tubing sections from MED to the cut-down hypotubes." Ex. 2119 ¶ 35. VSI had the materials and equipment available to assemble the device at their facilities. *Id.*

As further evidence of an assembled device, inventors Mr. Root and Mr. Sutton reference the following engineering CAD schematics from August 1, 2005:



Ex. 2118 ¶ 49; Ex. 2119 ¶ 39; Ex. 2022. The drawings above show a version of the complete RX GuideLiner, as well as a cross-sectional view of the device with Patent Owner's annotations, *see* PO CRTP Resp. 16, identifying the "soft tip," the "reinforced Pebax tubular portion," the "side opening," and the "rail structure." Ex. 2118 ¶ 50. The schematics are labeled "GuideLiner Rapid Exchange/Preliminary Design Assumptions/Rev X03," which according to Mr. Root was an indication that VSI had moved past prototyping and into commercialization. *Id.* Mr. Sutton attests that the "X03" indicates that this was the third version of the CAD drawings, and that they had built and tested prototypes of the RX GuideLiner device shown in these drawings. Ex. 2119 ¶ 39. The document also references the same part number (20-0658) as those identified in certain purchase documents for distal tubular portions from MED. Ex. 2118 ¶ 51 (citing Ex. 2021, Ex. 2089, Ex. 2092). These drawings are nearly identical to Figures 3 and 4 of the

patent. *Cf.* Ex. 1001, Figs. 3–4 (depicting patent drawings that resemble the CAD drawings).

The prototypes were tested using bench-top coronary models, including two-dimensional ("2D") acrylic heart models and three-dimensional ("3D") glass heart models, to simulate the native anatomy and environment. Ex. 2118 ¶¶ 17, 38, 47; Ex. 2119 ¶¶ 37–38, 41. These types of models were commonly used by VSI and other medical device companies to test interventional cardiology devices. Ex. 2118 ¶ 17; Ex. 2123 ¶ 21 (Mr. Keith noting that he had used similar models to test catheter designs during his time at Scimed and Boston Scientific Corporation). A sales presentation from July 2005 shows an example of a 2D coronary model. Ex. 2018, 12; Ex. 2129 (redacted version of same presentation). While this particular presentation depicts testing of the OTW version of the GuideLiner concurrently under development, Mr. Root asserts that a similar model was used to test the RX version. Ex. 2118 ¶¶ 18, 38. The testing done using this model included performing pull tests as well as simulations comprising the following steps: a) inserting a standard guide catheter into the coronary model; b) advancing the prototype into the guide catheter until the prototype's distal end extended beyond the guide catheter's distal end; and c) delivering a stent or balloon catheter into and through both devices. *Id.* ¶ 18. Although "more qualitative than quantitative," these tests enabled the inventors to observe the prototype's durability and the forces exerted on the prototype. Ex. 2118 ¶¶ 18, 47; Ex. 2119 ¶¶ 23, 41. Both Mr. Root and Mr. Sutton attest that this testing was sufficient to confirm that the RX GuideLiner would work for its intended purpose, namely facilitating delivery of interventional cardiology devices into challenging coronary

anatomy by providing increased backup support as compared to a guide catheter alone. Ex. 2118 ¶¶ 18, 47; Ex. 2119 ¶¶ 23, 41.

Patent Owner also presents other documentary evidence as corroboration of the testimony of inventors Mr. Root and Mr. Sutton. We have taken these documents into account, but find them somewhat less probative in showing actual reduction to practice.

For instance, a June 23, 2005, market feasibility memo (Ex. 2017), similar to the earlier memo from February 4, 2005 (Ex. 2003), confirms that the RX GuideLiner prototype was continuing to be developed, although the OTW version had been added to the development project at that point. Ex. 2118 ¶ 37; *see* Ex. 2017, 1 (noting that "it is possible to make the GuideLiner in an Over-the-Wire version, a Rapid Exchange version, or both").

A "Product Requirements" document, dated August 24, 2005, sets forth the safety and performance requirements for both the OTW and RX guide catheter support systems. Ex. 2118 ¶ 54; Ex. 2119 ¶ 44; Ex. 2024.[22] The document notes that "[t]hese safety and performance features are the minimal requirements for the device to be acceptable for its intended clinical use," and that the "[a]pplicable clinical use is for increase[d] guide catheter back-up support." Ex. 2024, 1. Mr. Root asserts that this document marked the start of the formal quality process for the RX and OTW GuideLiner

[22] Exhibit 2024 is the subject of Petitioner's motion to exclude. Paper 111. For the reasons we state below in addressing the motion to exclude (*see* discussion, *infra*), we decline to exclude Exhibit 2024 but have considered Petitioner's arguments in determining the weight to be given to this piece of evidence.

catheters. Ex. 2118 ¶ 54. Both Mr. Root and Mr. Sutton, as well as Ms. Schmalz (VSI's Vice President of Regulatory and Clinical Affairs at the time), testify that that this document would have been created only after the product was tested, demonstrated to work, and ready to proceed with regulatory approval and commercialization. Ex. 2118 ¶ 54; Ex. 2119 ¶ 44; Ex. 2039 ¶ 7. Ms. Schmalz specifically recalls that a working prototype of the RX version was created prior to the creation of this document. Ex. 2039 ¶ 7. Although this document sets forth several user requirements for the device, it does not identify the product specifications and test methods correlating to those requirements. Ex. 2024, 2–4. The revision history of the document also indicates it is "pre-release," thereby suggesting that it may not have been finalized at the time. *Id.* at 4.

Mr. Root, Mr. Sutton, and Ms. Schmalz each also discuss two other documents both dated August 26, 2005—a Clinical Technical Report (Ex. 2025) and a staff meeting memo (Ex. 2040)—as further evidence that work continued on the RX GuideLiner and that VSI was ready to seek regulatory approval for the device from the Food and Drug Administration ("FDA"). Ex. 2039 ¶¶ 9–10; Ex. 2118 ¶¶ 55– 57; Ex. 2119 ¶¶ 45–46. The Clinical Technical Report states that VSI "has developed, and is currently manufacturing four types of catheters . . . [including] the GuideLiner Catheter Support System used to provide physicians with additional guide catheter support allowing access to more difficult anatomy," and goes on to describe both the RX and OTW versions of GuideLiner. Ex. 2025, 2–3, 5–6. We note, however, that the text discussing GuideLiner devices appears to be "redline" edits and does not include any signatures for "document approvals," thus suggesting that the document submitted as Exhibit 2025

may have only been a draft. *See id.* The staff memo refers to clinical literature reviews for the GuideLiner devices (both RX and OTW), which Mr. Root asserts was part of VSI's regulatory strategy for a "510(k)" submission to the FDA.[23] Ex. 2118 ¶ 57.

b) Analysis for Actual Reduction to Practice

To establish actual reduction to practice, Patent Owner must demonstrate two things: (1) that it constructed an embodiment that met all the limitations of the invention claimed in the patents at issue; and (2) that it determined that the invention would work for its intended purpose. *Cooper*, 154 F.3d at 1327. Having considered the evidence and arguments of record, including the testimonial and documentary evidence summarized above, we find that Patent Owner has met this burden with respect to the challenged claims based on the prototypes of the RX GuideLiner that were built and tested at VSI prior to September 2005. We address Petitioner's arguments to the contrary.

The first issue raised by Petitioner is whether there is sufficient corroborating documentary evidence to support the inventors' testimony on reduction to practice. As with conception, "a party seeking to prove an actual reduction to practice must proffer evidence corroborating [an inventor's] testimony." *Raytheon Co. v. Sony Corp.*, 727 F. App'x 662, 668 (Fed. Cir. 2018) (citing *Medichem*, 437 F.3d at 1169–71). The sufficiency

[23] A 510(k) submission is a premarket notification to demonstrate that the device to be marketed is as safe and effective, that is, substantially equivalent, to a legally marketed device. *See* FDA, Premarket Notification 510(k), (accessed June 1, 2021), https://www.fda.gov/medical-devices/premarket-submissions/premarket-notification-510k.

of this corroboration is once again determined using a "rule of reason" analysis. *Id.*

Petitioner contends that "[n]o document shows that VSI built, much less tested, RX prototypes." Pet. CRTP Reply 8. Petitioner points to the lack of photographs, assembly instructions, subassembly drawings, and notebook pages (other than Mr. Sutton's initial conception pages) to corroborate the work done on the RX prototype in 2005. *Id.* By contrast, Petitioner asserts that VSI kept more documents, including notes from Mr. Kauphusman (the VSI engineer who led the GuideLiner project), relating to the OTW prototypes from that time. *Id.* at 9–10 (citing Ex. 1760, 86–87). Petitioner also contends that Patent Owner cannot justify VSI's failure to retain these reduction-to-practice documents because it "runs contrary to federal law and industry practice." *Id.* at 11 (citing Ex. 1755 ¶¶ 66–74, 143–145). Among the documentary evidence presented, Petitioner contends that at most four documents relate to particular prototypes, and the rest are irrelevant insofar as they concern purchases of generic component parts untethered to particular projects or prototypes. *Id.* at 11–14. Petitioner further contends the documents do not show that VSI actually assembled the RX prototypes. *Id.* at 16–17.

We are not persuaded that the record lacks sufficient corroborating evidence of actual reduction to practice. "In order to corroborate a reduction to practice, it is not necessary to produce an actual over-the-shoulder observer. Rather, sufficient circumstantial evidence of an independent nature can satisfy the corroboration requirement." *Cooper*, 154 F.3d at 1330 (citing *Knorr v. Pearson*, 671 F.2d 1368, 1373 (CCPA 1982)). "Furthermore, an actual reduction to practice does not require corroboration

for every factual issue contested by the parties." *Id.* (citing *Ethicon, Inc. v. U.S. Surgical Corp.*, 135 F.3d 1456, 1464 (Fed. Cir. 1998); *Mann v. Werner*, 347 F.2d 636, 640 (CCPA 1965) ("This court has rejected the notion that each individual act in the reduction to practice of a count must be proved in detail by an unbroken chain of corroboration.")). Put another way, the law "does not require that evidence have a source independent of the inventors on every aspect of conception and reduction to practice; such a standard is the antithesis of the rule of reason." *E.I. du Pont De Nemours & Co. v. Unifrax I LLC*, 921 F.3d 1060, 1077 (Fed. Cir. 2019) (internal quotations omitted).

As discussed above, Mr. Root and Mr. Sutton each provide detailed and consistent testimony explaining the work done at VSI towards building and testing the April and July 2005 prototypes of the RX GuideLiner. Critical aspects of this testimony are corroborated by other (non-inventor) testimony from Ms. Schmalz (recounting the regulatory and quality process at VSI), Mr. Erb (recounting how they built early prototypes), Mr. Goemer (verifying purchases from SPECTRAlytics), and Ms. O'Neil (verifying purchases from MED). This testimony is further corroborated by a significant amount of documentary evidence, including purchase documents and engineering drawings, as set forth above. To the extent that there may have been other more detailed evidence with regard to the OTW GuideLiner, we do not find that such evidence detracts from or otherwise contradicts the evidence presented for the RX GuideLiner. Nor do we require Patent Owner to establish actual reduction to practice by retaining and then proffering the same type of documents that the FDA would have required Patent Owner to submit to gain approval of a medical device. *See* Ex. 2237, 63:20–64:9

(Dr. Zalesky acknowledging that "[t]he testing requirement for regulatory submission such as a 510(k) is quite extensive," and "a very significantly different level than that required to demonstrate reduction to practice.");

Petitioner contends that the purchased parts reflected in Patent Owner's documentary evidence could have been used for other VSI projects under development in 2005. Pet. CRTP Reply 12–16. We do not find that the evidence supports Petitioner's conjecture in this regard. For example, Petitioner cites the testimony of Dr. Zalesky to assert that the purchased hypotubing (and other parts) could have been used for VSI's Twin-Pass, Skyway, and Pronto V3 products, in addition to the OTW GuideLiner. *Id.* (citing Ex. 1755 ¶¶ 121–132, 153, 166, 203). But Dr. Zalesky does not point to any supporting evidence showing that these other VSI products used the same type of hypotubing as what would have been required for the RX GuideLiner. *See* Ex. 2237, 156:3–158:10, 173:10–174:12 (Dr. Zalesky admitting that he did not have any evidence that hypotubes were used in other products, but stating his opinion was based on "informed speculation" or "reasonable speculation"). Rather than Dr. Zalesky's speculation, we credit the testimony of Mr. Root, Mr. Sutton, and Mr. Erb, each of whom had first-hand involvement in the project and independently attest that at least some of the purchased hypotubes were specific for the RX GuideLiner. Ex. 2118 ¶ 23; Ex. 2119 ¶ 23; Ex. 2122 ¶ 7.

The corroborating documents confirm that the purchases were for the RX GuideLiner, not a general ledger expense that would suggest the parts could be used for other products. *See, e.g.*, Ex. 2005 (spend report for accounts related to "new modalities" and "Guideliner project"). The sole document Petitioner cites to posit that the purchased hypotubes could have

been used for OTW devices is an engineering schematic that bears November 2005 and January 2006 dates, which were later than the April and July 2005 prototypes. Ex. 1763, 6. Furthermore, the hypotube shown in the OTW drawing differs in materials and dimensions from the hypotubes purchased for the RX prototypes. The hypotube in the OTW drawing is nitinol and roughly 19 cm, quite different than the 100 cm stainless steel hypotubes used for the GuideLiner prototypes. *Id.* The 43-inch distal section in the OTW drawing also differs dramatically from the 11.8-inch distal section for the RX prototype. Ex. 2237, 164:24–167:19 (Dr. Zalesky agreeing that the distal portion shown in Exhibit 2089 is not the same as the distal portion of Exhibit 1763); *compare* Ex. 1763, 6 *with* Exs. 2089 and 2092.

With regard to whether the purchased components were actually assembled into an RX prototype, we find that the engineering schematic from August 2005 is strongly corroborative of an assembled device. Ex. 2022. Dr. Zalesky acknowledges that it "doesn't make a lot of sense" for VSI not to have assembled the purchased parts together. Ex. 2237, 208:10–25. A preponderance of the evidence supports the conclusion that the assembled RX prototypes met each of the limitations of the challenged claims, as set forth in the Appendices to Mr. Root's declaration. Ex. 2118, App'x A–E. In its Sur-Sur-Reply, Petitioner identifies certain claim limitations that were allegedly not met by the prototypes, but Petitioner does not point to any evidence to contradict Mr. Root's testimony on this point. Pet. CRTP Sur-Sur-Reply 14–15. We likewise find the charts included as Appendices to Dr. Zalesky's declaration to be insufficient in this regard. Ex. 1755, App'x A–E. Rather than identifying any specific technical reason

why the prototype components reflected in the purchase documents could not have met the claim limitations, Dr. Zalesky's rebuttal claim charts appears to focus on whether there was sufficient corroborating evidence (which we have already discussed above). *Id.* As such, we find the evidence presented in this case to be more detailed than that found insufficient in *Valencell, Inc. v. Fitbit, Inc.*, 784 F. App'x 1005, 1009 (Fed. Cir. 2019), cited by Petitioner. Pet. CRTP Reply 16. There, no evidence—testimonial or documentary—addressed key claims limitations, which stands in contrast to the detailed testimony and corroborating documents cited in Mr. Root's and Mr. Sutton's declarations.

Having found that Patent Owner constructed embodiments that met all limitations of the challenged claims, we move on to the second issue: whether Patent Owner demonstrated that those embodiments worked for the intended purpose of the invention.

We begin this inquiry by identifying the "intended purpose" of the invention. Patent Owner puts forth a broad intended purpose. Initially, Patent Owner asserted testing was done to show that the prototypes "could serve their intended purpose of being placed in a standard guide catheter and deliver interventional cardiology devices alongside the rail segment, into the side opening and distal tubular portion, and then out the distal end of the distal tubular portion and into challenging coronary anatomy." PO CRTP Resp. 25 (citing Ex. 2118 ¶¶ 17–18, 38, 47; Ex. 2119 ¶ 41; Ex. 2123 ¶¶ 20–24). In its Sur-Reply, Patent Owner clarifies that the intended purpose was "to increase backup support for delivery of interventional cardiology devices, including procedures involving tough or chronic total occlusions." PO CRTP Sur-Reply 9 (citing Exs. 2002, 2003, 2024). By contrast,

Petitioner argues for a narrower intended purpose, asserting that the intended purpose was "providing backup support necessary for accessing and crossing tough or chronic occlusions." Pet. CRTP Reply 17 (citing Ex. 2002; Ex. 2118 ¶ 18; Ex. 2119 ¶ 9; Ex. 1762, 47:11–52:17 (Root Deposition)). Citing Patent Owner's Sur-Reply, Petitioner contends that the parties ostensibly "agree" that the intended purpose was "to increase backup support for accessing and crossing tough occlusions." Pet. CRTP Sur-Sur-Reply 7 (citing PO CRTP Sur-Reply 9); *see also* Tr. 49:3–12 ("Teleflex agrees the intended purpose was to increase back-up support for accessing and crossing tough or chronic total occlusions.").

We agree with Patent Owner's position on what constitutes the intended purpose of the invention. Petitioner is certainly correct that several of the documents we have considered refer to crossing "tough" or "chronic" occlusions when discussing the idea behind the invention. *See, e.g.*, Ex. 2002. But when considering all of the pertinent evidence, we find that inventors were concerned with a broader primary purpose, namely generally providing improved backup support for a guide catheter, with crossing tough or total occlusions being one specific benefit or application of the device. In other words, we do not find that the RX GuideLiner had applicability only when there were tough or chronic occlusions in the artery that needed to be crossed. Indeed, the challenged patent itself recognizes this broader purpose when discussing the field and background of the invention. *See* Ex. 1001, 1:32–35 ("More particularly the present invention relates to methods and apparatus for increasing backup support for catheters inserted into coronary arteries from the aorta."); *id.* at 3:1–5 ("Thus, the interventional cardiology art would benefit from the availability of 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.")

The documentary evidence we have considered and discussed above further supports this broader intended purpose. For example, while Mr. Sutton's lab notebook expresses the idea for the GuideLiner device as "relat[ing] to interventional coronary procedures and specifically to accessing & crossing tough or chronic total occlusions," it also more broadly notes that "[t]he idea is to provide a guide or support catheter more distally into the coronary to provide more back-up support for the stent device." Ex. 2002, 7. Mr. Sutton's lab notebook also contains two additional notes related to the invention: "Guide-Liner is used when there is difficulty crossing lesions"; and "Guide-Liner allows back-up support distally." *Id.* at 8. Similarly, in the February 4, 2005 Market Feasibility memo, Mr. Root describes the purpose of the RX GuideLiner as "provid[ing] the ability to create a deep seating of the guide for added support in the interventional procedure." Ex. 2003, 1. Mr. Root explains that "[b]y safely deep seating the guide catheter, the physician can then have the added support for pushing a wire through a chronic total occlusion or advancing a balloon or stent through a tight stenosis." *Id.* The August 24, 2005 Products Requirement document indicates the "[a]pplicable clinical use" for both the RX and OTW GuideLiners to be "increas[ing] guide catheter back-up support." Ex. 2024, 1.

Additionally, Patent Owner's expert's testimony supports this conclusion. Patent Owner's expert, Mr. Keith, declares that testing the RX GuideLiner prototypes would be sufficient for reduction to practice if the

testing showed the prototype "(a) could be delivered through a guide catheter so that the distal end of the tubular portion extended beyond the distal end of the guide catheter while being tracked over a winding path;" and "(b) allowed a stent delivery catheter or balloon catheter to pass into the tubular portion and out the far end of the tubular portion while located within the guide catheter." Ex. 2123 ¶ 22.

The testimony of inventors Mr. Root and Mr. Sutton cited by the parties also supports this conclusion. Mr. Root declares that the intended purpose of the RX GuideLiner was to "deliver interventional cardiology devices, such as a stent or balloon catheter, alongside the rail segment, into the side opening and distal tubular portion, and then out the distal end of the distal tubular portion and into challenging coronary anatomy." Ex. 2118 ¶ 18; *see also id.* ¶ 47 (describing the intended purpose as "facilitat[ing] the delivery of balloon catheters and stents deep into coronary arteries while providing increased backup support"). During Mr. Root's deposition, counsel for Petitioner inquired about Mr. Root's understanding of the intended purpose. Ex. 1762, 47:11–52:17. Mr. Root repeatedly stated that accessing and crossing tough or chronic occlusions was not the sole intended purpose. *Id.* at 47:11–20 (identifying that Petitioner's asserted intended purpose was "one of them" but "not all of them"), 50:10–12 ("The important thing is this is not just a chronic total occlusion device. This can apply to much broader coronary interventions."). Mr. Sutton's declaration quotes the purpose identified in his notes in his lab notebook, discussed above. Ex. 2119 ¶ 9 (quoting Ex. 2002, 7, 8). Mr. Sutton also declares that he and his team tested the prototypes qualitatively "to determine that [they] provided backup support," "to ensure that [stents and balloon catheters] could safely

be delivered and would not snag or get caught on the device," and "to deliver interventional cardiology devices and provide additional backup support compared to the guide catheter alone." *Id.* ¶ 41.

In sum, the pertinent evidence demonstrates that the intended purpose of the claimed invention, as embodied in the RX GuideLiner, was to increase backup support for delivery of interventional cardiology devices. Although crossing tough or total occlusions is one noted benefit of the invention, we do not find it to be the only or primary purpose of the invention.

We next consider whether the testing conducted at VSI was sufficient to determine that the RX GuideLiner prototypes would work for the intended purpose of increasing backup support for delivery of interventional cardiology devices. "Depending on the character of the invention and the problem it solves, determining that the invention will work for its intended purpose may require testing." *Cooper*, 154 F.3d at 1327 (citing *Mahurkar v. C.R. Bard Inc.*, 79 F.3d 1572, 1578 (Fed. Cir. 1996)). "When testing is necessary, the embodiment relied upon as evidence of priority must actually work for its intended purpose." *Id.* (citing *Scott v. Finney*, 34 F.3d 1058, 1061 (Fed. Cir. 1994)). "[T]he testing requirement depends on the particular facts of each case, with the court guided by a common sense approach in weighing the sufficiency of the testing." *Scott*, 34 F.3d at 1061. "This common sense approach prescribes more scrupulous testing under circumstances approaching actual use conditions when the problem includes many uncertainties," but "permits little or no testing to show the soundness of the principles of operation of the invention" "when the problem to be solved does not present myriad variables." *Id.* at 1063. "In tests showing

the invention's solution of a problem, the courts have not required commercial perfection nor absolute replication of the circumstances of the invention's ultimate use." *Id*. "[T]ests performed outside the intended environment can be sufficient to show reduction to practice if the testing conditions are sufficiently similar to those of the intended environment." *DSL Dynamic Scis. Ltd. v. Union Switch & Signal, Inc.*, 928 F.2d 1122, 1125 (Fed. Cir. 1991) (citing *Tomecek v. Stimpson*, 513 F.2d 614, 618 (CCPA 1975)). For medical device inventions, a showing of actual reduction to practice does not require human testing in actual use conditions. *Scott*, 34 F.3d at 1063 ("Testing for the full safety and effectiveness of a prosthetic device is more properly left to the Food and Drug Administration (FDA). Title 35 does not demand that such human testing occur within the confines of Patent and Trademark Office (PTO) proceedings.").

Patent Owner relies on inventor and expert testimony, as well as documentary evidence, to establish that use of benchtop models was sufficient to test that the products were suitable for the intended purpose described above.[24] PO CRTP Resp. 11–12, 24–25. Mr. Root asserts that benchtop coronary models, as depicted in the July 2005 sales presentation, were commonly used at VSI and other medical device companies to test interventional cardiology catheters. Ex. 2118 ¶ 17 (citing Exs. 2018, 2129).

[24] Referring to Petitioner's expert's testimony regarding a person of ordinary skill in the art's knowledge pertaining to Itou, Patent Owner also contends that no testing would have been required to know the RX GuideLiner would have worked for its intended purpose. *See* PO CRTP Sur-Reply 9 (citing Ex. 2116, 110:20–113:24; Ex. 2238, 87:18–89:5). Because we determine that the evidence demonstrates that testing in benchtop models was sufficient, we do not address this theory.

Citing its expert's declaration, Patent Owner asserts that "[c]atheter inventions are routinely determined to work using benchtop models, and without human testing." PO CRTP Resp. 25 (citing Ex. 2123 ¶¶ 20–24; Ex. 1010). Applied to this invention, Patent Owner asserts that its benchtop model emulated the cardiac anatomy, and was used to show that the RX GuideLiner could be "placed in a standard guide catheter and deliver interventional cardiology devices alongside the rail segment, into the side opening and distal tubular portion, and then out the distal end of the distal tubular portion and into challenging coronary anatomy." *Id.* (citing Ex. 2118 ¶¶ 17–18, 38, 47; Ex. 2119 ¶ 41; Ex. 2123 ¶¶ 20–24).

Petitioner's argument against Patent Owner's testing evidence depends on its narrower intended purpose, i.e., "using simulated tough lesions." Pet. CRTP Reply 18; *see also* Pet. CRTP Sur-Sur-Reply 7–9. In light of our rejection of the narrower intended purpose identified by Petitioner, we likewise reject Petitioner's argument that the testing evidence presented by Patent Owner is insufficient. Moreover, Petitioner acknowledges that benchtop models could have been used to test a device like the RX GuideLiner. Pet. CRTP Reply 17–18. The testimony of Mr. Root, Mr. Sutton, Mr. Erb, and Mr. Keith, corroborated by the photograph of the model in the sales presentation, confirm that VSI utilized benchtop coronary models that were considered the standard for testing interventional cardiology device such as catheters. *See* Ex. 2018; Ex. 2118 ¶¶ 17, 38, 47; Ex. 2119 ¶¶ 23, 37–38, 41; Ex. 2122 ¶ 11; Ex. 2123 ¶¶ 21–24. We consider this benchtop testing to be similar to the "countertop" testing that was found sufficient to show actual reduction to practice in *Mahurkar*. *See Mahurkar*, 79 F.3d at 1578 (determining for claims related to a double

lumen catheter that flow and pressure drop tests conducted in the inventor's kitchen, using glycerine to simulate blood, was sufficient for actual reduction to practice because they "showed, to the limit of their design, the utility of his claimed invention"). As noted by Petitioner, Mr. Root indicated during his deposition that to reduce to practice, VSI needed to "(1) navigate RX through a guide catheter and out its distal end in a benchtop model, (2) deliver an interventional cardiology device, and (3) retrieve RX in one piece." Pet. CRTP Reply 18 (citing Ex. 1762, 100:1–102:3). We find that the "pull tests" done using the benchtop models demonstrated that the RX GuideLiner was capable of accomplishing at least this much, even if the tests were not conducted in an *in vivo* or *in vitro* environment that simulated tough lesions. Ex. 2118 ¶¶ 17, 38, 47. This is not a situation where there were significant variables or uncertainties that needed to be assessed in order to determine whether the RX device would work properly, and thus the "qualitative" testing done by VSI using the benchtop models was sufficient. Ex. 2119 ¶ 41; Ex. 2123 ¶¶ 21–22. Accordingly, a preponderance of the evidence supports the conclusion that the testing done at VSI demonstrated that the RX GuideLiner would work for its intended purpose.

In our assessment of whether there was actual reduction to practice prior to the critical date, we have considered Petitioner's argument that the GuideLiner project was still in "early-stage concept development" in mid-to-late 2005, and that VSI was still experimenting in 2006 and did not have a working prototype even by 2008. Pet. CRTP Reply 22–27.

In support of this argument, Petitioner points to continuing changes to the RX design as evidence that the design was not completed before the critical date. *Id.* For example, a July 2005 Research & Development (R&D)

Update notes that "[t]he initial design is an over-the-wire configuration, with a rapid exchange version to follow." Ex. 2130, 3.[25] In contrast to the incomplete August 2005 Product Requirements document relied upon by Patent Owner (Ex. 2024), Petitioner contends that the official, completed version of the Product Requirements document for the GuideLiner project was not created until April 2009. Ex. 1767. A "2006 Strategic Objectives" document, dated December 1, 2005, indicates that the "rapid exchange version requires additional engineering and is not included in our 2006 forecasts." Ex. 2131, 10. Likewise, Petitioner points to a GuideLiner team meeting memo from May 2, 2006 that includes as agenda items "1) Review Initial Design and Intended Use," and "2) Determine what can be completed/started prior to design lock." Ex. 2109. According to another document, a "design freeze" for the GuideLiner device was expected to only take place May 30, 2007. Ex. 1769, 1. Indeed, an R&D update from July 2008 notes with respect to the GuideLiner device:

> Throughout this project, timelines have been pushed out due to drastic design changes and resource constraints. To date we have prototyped and tested a new design. This new design is more robust and cost effective. We are planning on an August 2008 design freeze with a 510k submission in November 2008.

Ex. 2132, 7.

---

[25] We recognize that this document appears to contradict Mr. Root's recollection that the original idea was for the RX GuideLiner, and that the decision was later made to concurrently pursue development of the OTW version. Ex. 2118 ¶ 19. We do not find the issue of whether the initial idea was for the RX version or the OTW version to be material to our analysis on reduction to practice. Nonetheless, we note Mr. Sutton's original notebook pages suggest that the original idea was indeed for the RX version rather than the OTW version. Ex. 2002.

We have taken the foregoing evidence into account, but do not find that it detracts from Patent Owner's evidence concerning reduction to practice based on building and testing the April and July 2005 prototypes discussed above. To be sure, the post-critical date documents highlighted by Petitioner make it clear that significant design revisions for the RX GuideLiner continued well into 2008, and these additional design changes may well have been required for FDA regulatory approval and/or commercialization of the device. Indeed, Patent Owners' declarants attest that additional engineering work was conducted to refine the product for regulatory purposes and commercialization. *See* Ex. 2118 ¶ 59 (Mr. Root attesting that "[f]rom September of 2005 forward, I and others at VSI continued to act diligently to bring the rapid exchange GuideLiner to market."); Ex. 2119 ¶ 44 (Mr. Sutton attesting that, after the August 24, 2005, Product Requirements document, "we continued to refine prototypes of the GuideLiner Rapid Exchange for purposes of manufacturability and commercialization"); Ex. 2122 ¶ 13 (Mr. Erb attesting that work continued on "develop[ing] manufacturing processes that were reproducible and a refined design that was able to be commercialized"). But we see no basis to conclude that these additional engineering and design changes were an indication that the April and July 2005 prototypes failed to demonstrate that the RX GuideLiner was capable of achieving increased backup support.

Ultimately, the RX GuideLiner was not commercialized until 2009, which we recognize is far later than the initial projected timeframe of late 2005/early 2006 and the date of actual reduction to practice. Ex. 2118 ¶ 89. Mr. Root asserts that one reason for this delay was due to turnover in R&D personnel. *Id.* Under the circumstances, we do not find that the additional

engineering and design work done with respect to the RX GuideLiner to achieve regulatory approval and commercialization indicates a lack of actual reduction to practice prior to the critical date. *See Loral Fairchild Corp. v. Matsushita Elec.*, 266 F.3d 1358, 1362–63 (Fed. Cir. 2001) ("Once the invention has been shown to work for its intended purpose, reduction to practice is complete. Further efforts to commercialize the invention are simply not relevant to determining whether a reference qualifies as prior art against the patented invention.").

In sum, we find that Patent Owner has demonstrated actual reduction to practice prior to Itou's critical date by a preponderance of the evidence based on the work done at VSI in building and testing the April and July 2005 prototypes of the RX GuideLiner. Nonetheless, to the extent that this evidence is not sufficient for actual reduction to practice, we find that it demonstrates at least conception of the claimed invention prior to the critical date.

4. Constructive Reduction to Practice

In addition to asserting actual reduction to practice, Patent Owner alternatively relies upon a theory of constructive reduction to practice. Antedating based on this theory would require Patent Owner to demonstrate diligence from just before the date Itou was filed until the date Patent Owner filed its priority application for the GuideLiner patents,[26] i.e., from September 23, 2005 to May 3, 2006. *See Perfect Surgical Techniques, Inc.*

[26] We use term "GuideLiner patents," in the same manner as the parties' declarants, to refer to the patents challenged in IPR2020-00126, -00128, -00129, -00132, -00134, -00135, and -00137. *See, e.g.*, Ex. 2118 ¶ 1; Ex. 2119 ¶¶ 1, 3; Ex. 2123 ¶ 1.

v. Olympus America, Inc., 841 F.3d 1004, 1007 (Fed. Cir. 2016) (requiring diligence for the "entire critical period, which begins just prior to the competing reference's effective date and ends on the date of the invention's reduction to practice").

To demonstrate diligence, Patent Owner again relies on testimony from its inventor and non-inventor declarants, as well as correspondences with VSI's outside patent counsel at the Patterson Law Firm and documents reflecting further engineering and development work done during this period. PO CRTP Resp. 18–19; PO CRTP Sur-Reply 12.

According to Mr. Root, following the initial conception and the building of the April and July 2005 prototypes, he and others at VSI continued from September 2005 onward to bring the RX GuideLiner to market. Ex. 2118 ¶ 59. This project was one of VSI's primary development initiatives at the time, and they worked on it continuously until they brought it to market in 2009. *Id.*; *see id.* ¶ 89. Thus, they worked continuously at least until the May 3, 2006 application date. *Id.* ¶ 76. Ms. Schmalz likewise testifies that "[a]t no time between the start of the regulatory process for GuideLiner in August of 2005 and the filing of the patent application in May 2006 was the rapid exchange GuideLiner project abandoned or paused." Ex. 2039 ¶ 12.

Mr. Sutton sent a fax to the Patterson Law Firm on March 21, 2006, which includes drawings that are similar to the proximal portion of the RX GuideLiner depicted in Exhibit. 2114. Ex. 2118 ¶ 42 (citing Ex. 2019). The firm also possessed the August 1, 2005, CAD drawing of a complete RX GuideLiner prototype. *Id.* ¶¶ 49–50 (citing Ex. 2022).

Upon Mr. Root's request, the firm opened a matter to conduct a patentability search for the GuideLiner on August 11, 2005. *Id.* ¶ 52 (citing Ex. 2023). Mr. Root provided the firm with the full prototype drawing in Ex. 2022 to conduct the search. *Id.* Mr. Root testifies that he would not engage in freedom-to-operate searching until after he had made a full prototype that was shown to work for its intended purpose and ready to move forward to commercialization. *Id.* An invoice from the firm demonstrates work performed for a "patent search for guide liner" in August 2005. *Id.* ¶ 53 (citing Ex. 2096).

In his declaration, Mr. Root then sets forth the timeline of events with documentary and circumstantial evidence during the critical period for diligence, i.e., from September 23, 2005, to May 3, 2006.

For September 2005, Mr. Root refers to invoices dated September 7, 2005, and a check for forming tips that would have been used for the distal tip of the GuideLiner prototype. *Id.* ¶ 60 (citing Ex. 2097). He refers to these documents to demonstrate that VSI was continuing to refine the prototypes during this period. Mr. Root also refers to a copy of the Patterson Law Firm's privilege log showing that a partner of the firm sent Mr. Root a confidential letter dated September 14, 2005, pertaining to prior art related to the GuideLiner. *Id.* ¶ 61 (citing Ex. 2098).

For October 2005, Mr. Root refers to a business update presented to VSI's Board of Directors during its October 2005 meeting. *Id.* ¶ 62 (citing Exs. 2041 (confidential), 2133 (public)). Mr. Root declares this update included extremely favorable reviews of the RX GuideLiner from VSI's physician advisors. *Id.* Mr. Root further declares the update included projected timelines for regulatory filings, with intentions to file in the end of

2005 for OTW and early 2006 for RX. *Id.* Mr. Root also refers to the matter the Patterson Law Firm opened this month for work leading towards the initial GuideLiner patent application. *Id.* (citing Ex. 2023).

For November 2005, Mr. Root declares that they continued refining the proximal portion of the RX GuideLiner. *Id.* ¶ 63. Mr. Root refers to engineering drawings obtained from SPECTRAlytics, including one dated November 2005, which closely resembles Figure 10 of the GuideLiner patents. *Id.* (citing Ex. 2115). Mr. Root also refers to a VSI R&D planning document for 2006, which was drafted by Mr. Sutton on November 22, 2005. *Id.* ¶ 64 (citing Ex. 2099). The planning document demonstrates VSI's intent, as of late November 2005, to continue with the regulatory approval process for the RX GuideLiner in 2006. *Id.*

For December 2005, Mr. Root refers to a VSI Strategic Objectives document for 2006, which was drafted on December 1, 2005. *Id.* ¶ 65 (citing Ex. 2100). The document indicates that the RX GuideLiner required additional work for commercialization, which would continue through the end of 2006. *Id.* Mr. Root also refers to an invoice from the Patterson Law Firm, which shows the time invested in preparing the GuideLiner patent application during December 2005. *Id.* ¶ 66 (citing Ex. 2117).

For January 2006, Mr. Root refers to another invoice from the Patterson Law Firm, which shows time invested in preparing the GuideLiner patent application during January 2006. *Id.* (citing Ex. 2101). Mr. Root also refers to a fax sent from Mr. Sutton to the law firm on January 23, 2006. *Id.* ¶ 67 (citing Ex. 2102). The fax contains three figures that illustrate examples of the problem to be solved by the RX GuideLiner, and which are nearly identical to Figures 7, 8, and 9 of the GuideLiner patents. *Id.*

For March 2006, Mr. Root refers to a Patterson Law Firm invoice showing time invested in preparing the GuideLiner patent application during March 2006. *Id.* ¶ 68 (citing Ex. 2103). Mr. Root also refers to purchase records for stainless steel tubing from Vita Needle Company on March 24, 2006. *Id.* ¶ 69 (citing Ex. 2104). Mr. Root declares that VSI used this tubing to refine the RX GuideLiner for commercialization. *Id.* Mr. Root also refers to a March 30, 2006, engineering drawing from SPECTRAlytics's files. *Id.* ¶ 70 (citing Ex. 2115). The drawing, which is similar to the photographs of RX GuideLiner prototypes depicted in Exhibit 2014, shows VSI's attempt to reduce manufacturing costs by cutting two proximal portions from a single hypotube. *Id.*

For April 2006, Mr. Root refers to a Budget to Actual Variances report provided to the VSI Board of Directors for its April 2006 meeting. *Id.* ¶ 71 (citing Ex. 2105). The report shows GuideLiner R&D expenses by that time had been more than double the amount that was budgeted. *Id.*
Mr. Root refers to purchase records for laser-cut and electropolished GuideLiner hypotubes from LSA, with an invoice dated April 7, 2006. *Id.* ¶ 72 (citing Ex. 2106). These hypotubes were used to refine the RX GuideLiner during commercialization. *Id.* Mr. Root refers to purchase records for twenty hypotubes from MicroGroup, with an invoice dated April 18, 2006. *Id.* ¶ 73 (citing Ex. 2107). These hypotubes were used to refine the RX GuideLiner during commercialization. *Id.* Mr. Root refers to other purchase records, including an April 19, 2006, invoice for cut GuideLiner hypotubes from LSA, which were used to commercialize the RX GuideLiner. *Id.* ¶ 74 (citing Ex. 2108).

For May 2006, other than the filing of the application on May 3, 2006, Mr. Root refers to notes from a GuideLiner team meeting held May 2, 2006, which confirm they were still working towards commercializing the RX GuideLiner. *Id.* ¶ 75 (citing Ex. 2109).

Mr. Sutton's diligence timeline, including the documents he refers to, largely matches Mr. Root's. For essentially the same reasons as Mr. Root, Mr. Sutton refers to: the drawing of the fully-assembled RX GuideLiner, Ex. 2119 ¶ 39 (citing Ex. 2022); his fax sent March 21, 2006, to the Patterson Law Firm, including the drawings similar to Figures 12 through 16 of the patents, *id.* ¶ 40 (citing Ex. 2019); his fax sent on January 23, 2006, to the Patterson Law Firm, which contains three figures that illustrate examples of the GuideLiner situated in the aorta, which are nearly identical to Figures 7, 8, and 9 of the GuideLiner patents, *id.* ¶ 42 (citing Ex. 2102); the VSI R&D planning document for 2006, dated November 22, 2005, *id.* ¶ 48 (citing Ex. 2099); the VSI marketing document dated December 1, 2005, *id.* ¶ 49 (citing Ex. 2100); the Vita Needle purchase records for stainless steel hypotubes shipped on March 24, 2006, which were used for the RX GuideLiners, *id.* ¶ 51 (citing Ex. 2104); and the April 2006 VSI budget report, indicating expenses on commercializing the RX GuideLiner more than doubled the amount VSI budgeted, *id.* ¶ 52 (citing Ex. 2105). Mr. Sutton also refers to the January 2006 R&D Update that he prepared for the VSI Board of Directors, *id.* ¶ 50 (citing Ex. 2134). In that update, Mr. Sutton reported to VSI's Board that both GuideLiner projects were still planned, with OTW regulatory filings next up at the time. *Id.*

In addition to testimony from inventors Mr. Root and Mr. Sutton, Patent Owner also points to testimony from Ms. Schmalz, Mr. Erb, and

Mr. Keith. Ms. Schmalz declares that, from "the start of the regulatory process for GuideLiner in August of 2005 and the filing of the patent application in May 2006," the RX GuideLiner "was always a high priority project during [her] time at VSI" and was never "abandoned or paused." Ex. 2039 ¶ 12. Mr. Erb declares that VSI was "continually working to optimize the design of the RX GuideLiner for commercialization. Ex. 2122 ¶ 13. As an example, he recalls the weighing of advantages and disadvantages between stainless steel and nitinol for the proximal portion during the commercialization stage. *Id.* ¶ 14. Mr. Keith explains his understanding that further commercialization work was performed after August 2005. Ex. 2123 ¶¶ 25–27.

Patent Owner contends that the evidence it relies on to prove conception and reduction to practice shows that "VSI worked steadily on the GuideLiner invention from conception through the date the patent was filed." PO CRTP Resp. 28 (citing *id.* at 3–19). Patent Owner acknowledges that it took more time and resources than anticipated, but that this delay should have "no bearing whatsoever on the [diligence] analysis." *Id.* at 28–29.

Petitioner argues Patent Owner's response "does not contain any detail showing diligence." Pet. CRTP Reply 28. Petitioner deems the "handful" of events identified by Patent Owner during the critical period—opening a patent application file, working on the patent application, exchanging emails, and buying parts—to be insufficient evidence of diligence. *Id.* at 28–29. It appears from Petitioner's visual timeline of Patent Owner's events that two periods in particular allegedly represent a lack of diligence: from September 23, 2005, to the end of November 2005,

during which there was only a component design change; and the month of February 2006, during which there were no diligence-related events. *Id.* at 29 (citing Ex. 2115). Petitioner also faults Patent Owner's delay in regulatory submissions for the RX GuideLiner, which were initially planned for late 2005 and 2006 but were postponed until 2008. *Id.* (citing Ex. 1762, 131:3–133:3; Ex. 2132, 7).

When evaluating diligence, we are mindful of recent Federal Circuit admonitions clarifying that we must not apply a standard that is "too exacting" or "too rigid." *Perfect Surgical*, 841 F.3d at 1008; *Arctic Cat*, 919 F.3d at 1331. Though "[p]eriods of inactivity within the critical period do not automatically vanquish a patent owner's claim of reasonable diligence," *Arctic Cat*, 919 F.3d at 1331, "[m]erely asserting diligence is not enough" and a party must "account for the entire period during which diligence is required." *In re Meyer Mfg. Corp.*, 411 F. App'x 316, 320 (Fed. Cir. 2010). "[D]iligence need not be perfectly continuous—only *reasonably* continuous." *Arctic Cat*, 919 F.3d at 1331. The key question for diligence is whether, "in light of the evidence as a whole, the invention was not abandoned or unreasonably delayed." *Id.* (internal quotations omitted). Applying this standard, we conclude that Patent Owner sufficiently demonstrates reasonably continuous diligence throughout the critical period.

The evidence demonstrates that Patent Owner did not unreasonably delay the RX GuideLiner project. As both parties acknowledge, there were indeed delays in the project. Petitioner asserts "VSI prioritized *other projects* in late 2005 and 2006 and postponed RX regulatory submissions through 2008." Pet. CRTP Reply 29 (citing Ex. 1762, 131:3–133:3; Ex. 2132, 7). But the cited portion of Mr. Root's deposition testimony

sufficiently explains why the delay was reasonable. As noted by Mr. Root, OTW GuideLiner regulatory submissions came first "[b]ecause it was much easier to get regulatory approval and do the testing." Ex. 1762, 131:3–8. "[T]ransition in personnel" also complicated the project. *Id.* at 131:12–17. And as for the RX version, Mr. Root explained that commercialization took longer due to "vendor optimization," *id.* at 132:25–133:9, which tracks the greater difficulty associated with bringing the RX GuideLiner to market. Ms. Schmalz further corroborates this explanation with her declaration that RX GuideLiner "was always a high priority project during [her] time at VSI." Ex. 2039 ¶ 12.

Nor does it appear that Patent Owner abandoned the RX GuideLiner invention. For one thing, Patent Owner engaged counsel to prepare its GuideLiner patent application, which was ultimately filed on May 3, 2006. The Patterson Law Firm opened a patent search on August 11, 2005 (Ex. 2023, 5) then reported the results to VSI on September 14, 2005 (Ex. 2098, 2). On October 10, 2005, the firm opened a patent prosecution matter for the GuideLiner. Ex. 2023, 5. There is evidence in the record of the firm working on preparing the application in December 2005 (Ex. 2117, 20), January 2006 (Ex. 2102, 1), and March 2006 (Ex. 2103, 6). There is also evidence of communications between the firm and VSI, namely Mr. Root and Mr. Sutton, in January 2006 and March 2006. Ex. 2102; Ex. 2098, 4; Ex. 2019. To be sure, there is not an abundance of documents in the record related to preparing the application, including drafts of the specification and claims, but Patent Owner clarified at oral argument that it lacks many documents due to the passage of time, not the refusal to waive attorney-client privilege. Tr. 64:8–21. A lack of documents due to the passage of

time does not foreclose sufficient corroboration. *See, e.g.*, *NFC Tech., LLC v. Matal*, 871 F.3d 1367, 1374 (Fed. Cir. 2017) (concluding there was sufficient corroboration of conception based on circumstantial evidence, "particularly considering the amount of time that ha[d] passed").

Moreover, the other documents Patent Owner proffers provide additional circumstantial evidence that VSI was working on and did not abandon the RX GuideLiner project throughout this time. Petitioner again faults Patent Owner for not providing direct evidence. Pet. CRTP Reply 28 (pointing out lack of events "related to actual work on an RX device"); *id.* at 29 (arguing Patent Owner "cannot tie the component parts purchases to RX"). But, as we noted above, direct evidence is not required for adequate corroboration. Internal VSI documents, such as updates for VSI's Board and budget documents, show that work on the RX project continued from October 2005 through April 2006. Ex. 2133, 4, 7; Ex. 2099; Ex. 2100, 8–9; Ex. 2105, 4–5. Additionally, there are engineering drawings and invoices related to supplies that support the testimony of inventors Mr. Root and Mr. Sutton regarding continued work on the RX GuideLiner in March 2006 and April 2006. Ex. 2104; Ex. 2005, 5; Ex. 2115; Ex. 2106, 3; Ex. 2107; Ex. 2108, 4–5. All of this evidence corroborates Mr. Root's and Mr. Sutton's testimony that VSI worked diligently and continuously on the RX GuideLiner project without abandoning the project.

Finally, we are not convinced that the periods from September 23, 2005, to the end of November 2005 or in February 2006 demonstrate lack of diligence. Petitioner's argument for these periods is conclusory, and contradicted by the reasonable commercialization delays that we addressed above.

Considering all of the pertinent evidence, we find that Patent Owner did not abandon or unreasonably delay the RX GuideLiner project during the critical period. Petitioner's arguments implying the need for direct evidence and scouring the timeline for periods of inactivity are unpersuasive. We therefore conclude that Patent Owner demonstrates, by a preponderance of the evidence, that VSI was reasonably continuous in its diligence during the critical period. Because we have also found that Patent Owner demonstrated conception prior to Itou's critical date, Patent Owner has met its burden to successfully demonstrate that Itou is not prior art to the challenged claims of the '380 patent.

E. Challenges Based on Itou

Petitioner contends that claims 1–4, 6–10, 12–20, 23 are anticipated by Itou (Pet. 19–65), claims 3, 14, 15 would have been obvious over Itou and Ressemann (*id.* at 65–76), and claim 21 would have been obvious over Itou and Berg (*id.* at 76–80). Because Itou is not prior art to the '380 patent, Petitioner's challenges based on Itou are not persuasive. Accordingly, Petitioner has not demonstrated by preponderance of the evidence that claims 1–4, 6–10, 12–21, and 23 are unpatentable over the Itou-based grounds asserted in the Petition.

III. CONTINGENT MOTION TO AMEND

Patent Owner's Motion to Amend requests that if either of claims 1 or 12 of the '380 patent is determined to be unpatentable, that the Board substitute those claims with proposed substitute claims 43 and 44, respectively. Motion 1. Because we do not find any of the challenged claims unpatentable in this proceeding, we do not reach the merits of the Motion to Amend.

IV. CONSTITUTIONAL CHALLENGE

Patent Owner argues that the Petition should be denied because "the manner in which administrative law judges are appointed is unconstitutional." PO Resp. 63 (citing *Arthrex, Inc. v. Smith & Nephew, Inc.*, 941 F.3d 1320, 1325 (Fed. Cir. 2019)). Patent Owner further argues that the remedy in the *Arthrex* decision "severing certain removal protections, is insufficient to cure the constitutional defect, because, e.g., it still does not give a properly appointed principle office the power to review administrative law judge decisions." *Id.* (citing *Lucia v. SEC*, 138 S. Ct. 2044, 2055 (2018)). We decline to consider Patent Owner's constitutional argument because the Federal Circuit addressed this issue in *Arthrex*. *Arthrex*, 941 F.3d at 1328.

V. MOTION TO EXCLUDE

Petitioner has moved to exclude Exhibit 2024, which is the August 24, 2005 Product Requirements document. Paper 111. Petitioner contends that Exhibit 2024 is unreliable on its face and that none of Patent Owner's witnesses can authenticate the document. *Id.* at 2–9. Patent Owner responds that Exhibit 2024 is authenticated under Federal Rule of Evidence 901 based on the declaration and/or deposition testimony of Mr. Peters (Ex. 1926 ¶ 18), Ms. Schmalz (Ex. 2039 ¶¶ 6–7), Mr. Root (Ex. 2118 ¶ 54), and Mr. Sutton (Ex. 2119 ¶ 44). Paper 115.

Documents are authenticated by evidence "sufficient to support a finding that the item is what the proponent claims it is." Fed. R. Evid. 901(a); *see Fox Factory v. SRAM, LLC*, IPR2016-01876, Paper 59 at 63 (PTAB Apr. 2, 2018) (quoting same). "Authenticity is, therefore, not an

especially high hurdle for a party to overcome." *Fox Factory*, Paper 59 at 63 (citing *United States v. Patterson*, 277 F.3d 709, 713 (4th Cir. 2002)).

We determine that Exhibit 2024 has been authenticated under Federal Rule of Evidence 901. In addition, Petitioner's arguments go to the weight of the evidence and not its admissibility. Accordingly, we deny Petitioner's Motion to Exclude. We note, however, that even if we were to exclude Exhibit 2024, it would not change the outcome or our general analysis of this case.

VI. CONCLUSION

After reviewing the arguments and evidence of record, we determine that Petitioner has not demonstrated by a preponderance of the evidence that claims 1–4, 6–10, 12–21, and 23 of the '380 patent are unpatentable on the grounds asserted in the Petition.

In summary:

Claims	35 U.S.C. §	Reference(s)/Basis	Claims Shown Unpatentable	Claims Not Shown Unpatentable
1–4, 6–10, 12–20, 23	102	Itou		1–4, 6–10, 12–20, 23
3, 14, 15	103	Itou, Ressemann		3, 14, 15
21	103	Itou, Berg		21
Outcome				1–4, 6–10, 12–21, 23

The table below summarizes our conclusions as to Patent Owner's Revised Motion to Amend the claims.

Motion to Amend Outcome	**Claim(s)**
Original Claims Cancelled by Amendment	
Substitute Claims Proposed in the Amendment	43, 44
Substitute Claims: Motion to Amend Granted	
Substitute Claims: Motion to Amend Denied	
Substitute Claims: Not Reached	43, 44

VII. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that claims 1–4, 6–10, 12–21, and 23 have not been shown to be unpatentable;

FURTHER ORDERED that we do not reach Patent Owner's Contingent Motion to Amend;

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

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

IPR2020-00128
Patent RE45,380E

FOR PETITIONER:
Cyrus Morton
Sharon Roberg-Perez
Christopher Pinahs
William E. Manske
Emily J. Tremblay
ROBINS KAPLAN LLP
cmorton@robinskaplan.com
sroberg-perez@robinskaplan.com
cpinahs@robinskaplan.com
wmanske@robinskaplan.com
etremblay@robinskaplan.com

FOR PATENT OWNER:
Derek Vandenburgh
Dennis Bremer
CARLSON, CASPERS, VANDENBURGH & LINDQUIST, P.A.
dvandenburgh@carlsoncaspers.com
dbremer@carlsoncaspers.com

Trials@uspto.gov
571-272-7822

Paper 125
Date: June 7, 2021

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.

IPR2020-00132
Patent RE45,760 E

Before SHERIDAN K. SNEDDEN, JON B. TORNQUIST, and CHRISTOPHER G. PAULRAJ, *Administrative Patent Judges.*

SNEDDEN, *Administrative Patent Judge*.

JUDGMENT
Final Written Decision
Determining No Challenged Claims Unpatentable
Not Deciding Patent Owner's Contingent Motion to Amend
35 U.S.C. § 318(a)

ORDERS
Denying Petitioner's Motion to Exclude (Paper 109)
37 C.F.R. § 42.64(c)

I. INTRODUCTION

Medtronic, Inc. and Medtronic Vascular, Inc. ("Petitioner") filed a Petition for *inter partes* review of claims 25–42, 44, and 47 of U.S. Patent No. RE45,760 E ("the '760 patent," Ex. 1001). Paper 1 ("Pet."). Teleflex Medical Devices S.À.R.L. ("Patent Owner")[1] filed a Preliminary Response. Papers 8 (confidential version), 9 (redacted version) ("Prelim. Resp."). Upon review of the Petition and Preliminary Response, we instituted an *inter partes* review of all claims on all grounds asserted in the Petition (Paper 22, "Inst. Dec." or "Institution Decision").

Patent Owner subsequently filed a Patent Owner Response (Paper 43, "PO Resp.") (redacted version available at Paper 44), Petitioner filed a Reply (Paper 83, "Pet. Reply") (redacted version available at Paper 82), and Patent Owner filed a Sur-Reply (Paper 101, "Sur-Reply") (redacted version available at Paper 102).

With prior authorization of the Board, Patent Owner filed a Consolidated Response Addressing Conception and Reduction to Practice (Paper 39, "PO CRTP Resp." or "PO CRTP Response"), to which Petitioner filed a Reply (Paper 78, "Pet. CRTP Reply") (redacted version available at Paper 79), Patent Owner filed a Sur-Reply (Paper 96, "PO CRTP Sur-Reply"), and Petitioner filed a Sur-Sur-Reply (Paper 110, "Pet. CRTP Sur-Sur-Reply").

Patent Owner also filed a Contingent Motion to Amend. Paper 38. The Motion requests that if any of issued claims 37, 38, 39, 48, or 51 of the

[1] Patent Owner represents that "Teleflex Innovations S.A.R.L. merged into Teleflex Medical Devices S.A.R.L," which subsequently "transferred ownership of U.S. Patent No. RE45,760E to Teleflex Life Sciences Limited." Paper 7, 2.

'760 patent are determined to be unpatentable, they should be replaced by proposed substitute claims 54–58. *Id.* at 1. Petitioner filed an Opposition to the Motion to Amend (Paper 85), to which Patent Owner filed a reply (Paper 104), and Petitioner filed a sur-reply (Paper 112).

An oral hearing was held on March 8, 2021, and a transcript of the hearing is included in the record. Paper 124 ("Tr.") (redacted version available at Paper 123).

A. Real Parties in Interest

Petitioner identifies its real parties-in-interest as Medtronic, Inc. and Medtronic Vascular, Inc., and notes that "Medtronic plc is the ultimate parent of both entities." Pet. 5.

Patent Owner identifies its real parties-in-interest as Teleflex Medical Devices S.A.R.L.; Vascular Solutions LLC; Arrow International, Inc.; and Teleflex LLC. Paper 4, 2. Patent Owner also notes that "Teleflex Incorporated is the ultimate parent of the entities listed above." Paper 7, 2.

B. Related Matters

The '760 patent is at issue in *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) ("*QXM*"). Pet. 5–6; Paper 4, 2. The '760 patent is a reissue of U.S. Pat. No. 8,292,850 ("the '850 patent).

The '850 patent was the subject of two previous *inter partes* reviews: IPR2014-00762, filed May 16, 2014 and terminated August 11, 2014 by way of joint motion to terminate, and IPR2014-00763, filed May 16, 2014 and terminated August 11, 2014 by way of joint motion to terminate. Pet. 6; Paper 4, 2–3. The '850 patent was also at issue in the U.S. District Court for

the District of Minnesota in *Vascular Solutions, Inc. v. Boston Scientific Corp.*, No. 13-cv-01172 (D. Minn., filed May 16, 2013). *Id.*

Petitioner has filed two additional Petitions for *inter partes* review of the '760 patent as IPR2020-00133 and IPR2020-00134.

C. The '760 Patent

1. Specification

The subject matter claimed in the '760 patent is directed to a device for use with a standard guide catheter. Ex. 1001, 13:36–17:13. Figures 1 and 5 of the '760 patent, reproduced below, depict a coaxial guide catheter and a tapered inner catheter.

Fig. 1

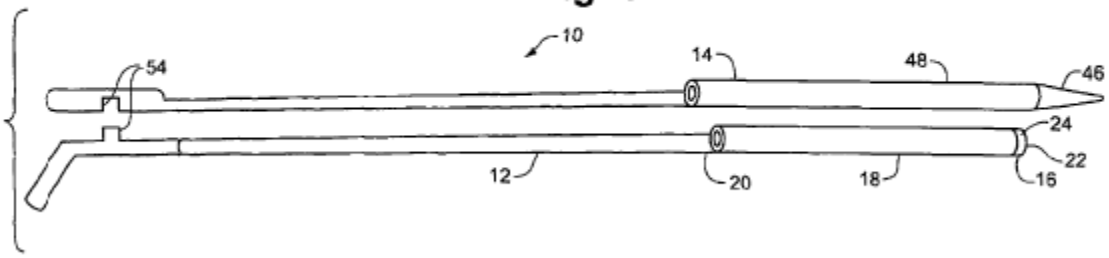


Figure 1 of the '760 patent

Fig. 5

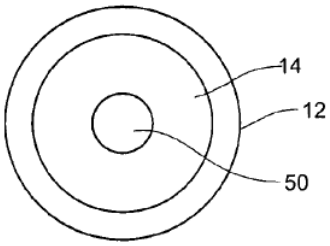


Figure 5 of the '760 patent

As shown in Figures 1 and 5, above, coaxial guide catheter assembly 10 includes coaxial guide catheter 12 and tapered inner catheter 14. *Id.* at 6:37–39. Coaxial guide catheter 12 generally includes tip portion 16,

reinforced portion 18, and rigid portion 20. *Id.* at 6:40–41. Tip portion 16 generally includes bump tip 22 and marker band 24. *Id.* at 6:44–45. Bump tip 22 includes taper 26 and is relatively flexible. *Id.* at 6:45–46. Marker band 24 is formed of a radiopaque material such as platinum/iridium alloy. *Id.* at 6:49–50. Tapered inner catheter tip 42 includes tapered portion 46 at a distal end thereof, and straight portion 48. *Id.* at 7:22–23. Both tapered portion 46 and straight portion 48 are pierced by lumen 50. *Id.* at 7:23–24. 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 7:27–29. Thus, tapered inner catheter 14 is keyed to coaxial guide catheter 12. *Id.* at 7:29–30.

2. Illustrative Claim

Independent claim 25, reproduced below, is illustrative of the challenged claims.

25. A system, comprising:

> a guide catheter configured to be advanceable through a main blood vessel to a position adjacent an ostium of a coronary artery, the guide catheter having a lumen extending from a hemostatic valve at a proximal end of the guide catheter to a distal end of the guide catheter that is adapted to be positioned adjacent the ostium of the coronary artery; and
>
> a guide extension catheter configured to be partially advanceable through the guide catheter and into the coronary artery, the guide extension catheter having a length such that a distal end of the guide extension catheter is extendable through the lumen and beyond the distal end of the guide catheter, and a proximal end of the guide extension catheter is extendable through the hemostatic valve at the proximal end of the guide catheter,
>
> the guide extension catheter including, in a proximal to distal direction, a substantially rigid segment, a segment defining

a side opening, and a tubular structure defining a lumen coaxial and in fluid communication with the lumen of the guide catheter, the lumen of the tubular structure having a length that is shorter than the length of the lumen of the guide catheter and having a uniform cross-sectional inner diameter that is not more than one French size smaller than the cross-sectional inner diameter of the lumen of the guide catheter, the side opening extending for a distance along a longitudinal axis of the segment defining the side opening and accessible from a longitudinal side defined transverse to the longitudinal axis, and the side opening and the lumen of the tubular structure configured to receive one or more stents or balloon catheters when the segment defining the side opening and a proximal end portion of the tubular structure are positioned within the lumen of the guide catheter and the distal end of the guide extension catheter extends beyond the distal end of the guide catheter;

wherein a material forming the segment defining the side opening is more rigid than the tubular structure.

Ex. 1001, 13:36–14:7.

D. Evidence

Petitioner relies upon the following prior art references.

Ex. 1007, T. Itou et al., U.S. Patent No. 7,736,355 B2 (issued June 15, 2010) ("Itou").

Ex. 1008, T. V. Ressemann et al., U.S. Patent No. 7,604,612 B2 (issued Oct. 20, 2009) ("Ressemann").

Ex. 1025, Y. Kataishi et al., U.S. Patent Application Publication No. 2005/0015073 A1 (published Jan. 20, 2005) ("Kataishi").

Ex. 1050, C. D. Enger et al., U.S. Patent No. 5,980,486 (issued Nov. 9, 1999) ("Enger").

In support of its arguments, Petitioner relies on the expert declarations of Dr. Stephen Jon David Brecker (Exs. 1005, 1806, 1902), Dr. Richard A. Hillstead (Exs. 1042, 1905, 1907), Mr. Michael Jones (Ex. 1807), and Dr. Paul Zalesky (Exs. 1755, 1830, 1919).

Patent Owner relies on the declarations of Ms. Amy Welch (Ex. 2044) (redacted), Ms. Deborah Schmalz (Ex. 2039), Mr. Howard Root (Ex. 2118), Mr. Gregg Sutton (Ex. 2119), Mr. Mark Goemer (Ex. 2120), Ms. Amanda O'Neil (Ex. 2121), Mr. Steve Erb (Ex. 2122), Mr. Peter T. Keith (Ex. 2042, 2123, 2124, 2138, 2243), Dr. John J. Graham (Ex. 2145), Dr. Lorenzo Azzalini (Ex. 2151), Mr. Steve Jagodzinkski (Ex. 2152 (redacted), 2153 (confidential)), Ms. Heather S. Rosecrans (Ex. 2205), and Dr. Craig Thompson (Ex. 2215).

E. Asserted Grounds of Unpatentability

Petitioner asserts that claims 25–42, 44, and 47 would have been unpatentable on the following grounds.

Claim(s) Challenged	35 U.S.C. §[2]	Reference(s)/Basis
25–31, 33–38, 41, 42, 44, 47	102(e)	Itou
25, 30, 32, 39, 40	103(a)	Itou, Ressemann
32	103(a)	Itou, Kataishi
32	103(a)	Itou, Enger

[2] The Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011) ("AIA"), amended 35 U.S.C. §§ 102 and 103. Because the challenged claims of the '760 patent have an effective filing date before the effective date of the applicable AIA amendments, we refer to the pre-AIA versions of 35 U.S.C. § 103 throughout this Decision.

II. ANALYSIS

A. Priority Date of the '760 Patent

The AIA's first-to-file provisions apply to patent applications "that contain[] or contained at any time a claim to a claimed invention that has an effective filing date" on or after March 16, 2013. AIA § 3(n)(1). The application for reissue for the '760 patent was filed March 3, 2014 and sought reissue of US Patent No. 8,292,850, which issued October 23, 2012 from an application filed January 26, 2012. Ex. 1001, codes (22), (64). Petitioner contends,

> The '760 patent is subject to the AIA first-to-file provisions because (1) it contains claims that lack written description, and therefore pre-AIA priority, and (2) it claims priority to RE 45,380 ("the '380 patent"), which is subject to the AIA first-to-file provisions. Thus, Patent Owner cannot swear behind Itou in this proceeding.

Pet. 14. Petitioner contends that because there is no written description support for the subject matter of at least claim 32 of the '760 patent, the '760 patent has an effective filing date after March 16, 2013. *Id.* at 14. Thus, according to Petitioner, the '760 patent is subject to the AIA's first-to-file provisions, which precludes Patent Owner's from attempting to swear behind Itou's filing date. *Id.*

"The effective filing date for a claimed invention in an application for reissue or reissued patent shall be determined by deeming the claim to the invention to have been contained in the patent for which reissue was sought." 35 U.S.C. § 100(i)(2) (2018). As the "patent for which reissue was sought" in this case was issued October 23, 2012, we are not persuaded that the AIA's first-to-file provisions apply to the '760 patent. Indeed, Petitioner provides no legal support for the proposition that claims in a reissue patent

are not entitled to an effective filing date as if they appeared in the original patent for which reissue was sought.[3]

B. Level of Ordinary Skill in the Art

We consider the asserted grounds of unpatentability in view of the understanding of a person of ordinary skill in the art ("POSITA"). Petitioner provides two alternative definitions of a person of ordinary skill in the art. First, Petitioner asserts that if a person of ordinary skill in the art "was a medical doctor, s/he would have had (a) a medical degree; (b) completed a coronary intervention training program, and (c) experience working as an interventional cardiologist." Pet. 15. Alternatively, Petitioner asserts that if a person of ordinary skill in the art was "an engineer s/he 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." *Id.* Additionally, Petitioner contends that "[e]xtensive experience and technical training might substitute for education, and advanced degrees might substitute for experience." *Id.*

Patent Owner "does not dispute [Petitioner]'s proposed definition of a POSITA." PO Resp. 9.

Upon review of the parties' arguments and supporting evidence, we adopt Petitioner's definitions for a person of ordinary skill in the art, which allow the ordinarily skilled artisan to be either a medical doctor or an engineer, as they are undisputed and consistent with the level of skill

[3] To the extent the original patent for which reissue was sought does not contain written description support for a reissue claim, that claim may be invalid. But this is a question we may not address in an IPR. 35 U.S.C. § 311(b).

reflected in the prior art and the written description of the '032 patent. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001) (the prior art itself can reflect the appropriate level of ordinary skill in the art).

C. Claim Construction

We interpret a claim "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) (2019). This standard requires that we construe a 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.*

Upon review of the parties' arguments and supporting evidence, we determine that it is not necessary to construe any claim terms to resolve the disputed issues for purposes of this Final Written Decision. *See Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 295, 803 (Fed. Cir. 1999) (holding that "only those terms need to be construed that are in controversy, and only to the extent necessary to resolve the controversy").

D. Status of Itou as Prior Art - Conception and Reduction to Practice

The dispositive issue in this case is whether Itou, which is relied upon for all grounds in the Petition, qualifies as prior art.

Itou was filed on September 23, 2005, published on March 30, 2006, and issued on June 15, 2010. Ex. 1007, codes (22), (45), (65). Petitioner contends that Itou is prior art under pre-AIA § 102(e). Pet. 19–20.[4] In the

[4] In addition to this Petition, Petitioner similarly asserts Itou in the petitions in IPR2020-00126, -00128, -00129, -00134, -00135, and -00137. Our analysis regarding the prior art status of Itou is similar for each of these proceedings.

Conception and Reduction to Practice ("CRTP") briefing that we separately authorized for these proceedings, Patent Owner argues that Itou does not qualify as prior art based on research and development related to the claimed invention that took place at Vascular Solutions, Inc. ("VSI"), Patent Owner's predecessor-in-interest, starting around early 2005 and continuing through the May 3, 2006, filing of the original priority application for the '760 patent. *See generally* PO CRTP Resp.; PO CRTP Sur-Reply. Petitioner disputes these contentions. *See generally* Pet. CRTP Reply; Pet. CRTP Sur-Sur-Reply.

In its CRTP Response, Patent Owner identifies the evidence on which it relies to antedate Itou, including certain inventor testimony, non-inventor testimony, and other documentary evidence. PO CRTP Resp. 2. As to inventor testimony, Patent Owner relies on the respective declarations of co-inventors Howard Root (Ex. 2118) and Gregg Sutton (Ex. 2119). As to non-inventor testimony, Patent Owner relies on the declaration of its expert Peter T. Keith (Ex. 2123), the declarations of VSI employees Steven Erb (Ex. 2122) and Deborah Schmalz (Ex. 2039), and the declarations of employees of third-party vendors, Amanda O'Neil (Ex. 2121) and Mark Goemer (Ex. 2120). As to documentary evidence, Patent Owner relies on nearly seventy-five exhibits. These documents include inventor lab notebooks and handwritten notes (Exs. 2002, 2004); internal company memoranda, presentations, and other similar documents (Exs. 2003, 2005, 2017–2018, 2024, 2025, 2036–2038, 2040–2041, 2099–2100, 2105, 2109, 2127–2134); invoices, sales orders, and certificates of completion from technical equipment vendors (Exs. 2006–2011, 2013, 2016, 2020–2021, 2026–2035, 2089–2095, 2097, 2104, 2106–2108, 2110–2112); a photograph (Ex. 2014); deposition transcripts (Exs. 2015, 2116); communications with and

documents from VSI's outside patent counsel (Exs. 2019, 2023, 2096, 2098, 2101–2103, 2117); and engineering drawings (Exs. 2022, 2113–2115).

We have considered this evidence and other rebuttal evidence offered by Petitioner. For the following reasons, we conclude that a preponderance of the evidence demonstrates that Patent Owner conceived the subject matter recited in the challenged claims before September 23, 2005, the date on which Itou is effective as prior art ("critical date") and either actually reduced the invention to practice prior to the critical date or diligently worked towards constructive reduction to practice until the priority application for the challenged patent was filed on May 3, 2006. Accordingly, we conclude that Itou does not qualify as prior art to the '760 patent.

For our analysis, we first set forth the relevant legal standards, followed by our fact findings and analysis on conception, actual reduction to practice, and diligence towards constructive reduction to practice.

1. Legal Standards

"To antedate (or establish priority) of an invention, a [patent owner] must show either an earlier reduction to practice, or an earlier conception followed by a diligent reduction to practice." *Purdue Pharma L.P. v. Boehringer Ingelheim GmbH*, 237 F.3d 1359, 1365 (Fed. Cir. 2001)). "Conception is the formation, in the mind of the inventor, of a definite and permanent idea of the complete and operative invention, as it is thereafter to be applied in practice." *Cooper v. Goldfarb*, 154 F.3d 1321, 1327 (Fed. Cir. 1998)). "A reduction to practice can be either a constructive reduction to practice, which occurs when a patent application is filed, or an actual reduction to practice." *Id.* "In order to establish an actual reduction to

practice, the inventor must prove that: (1) he constructed an embodiment or performed a process that met all the limitations of the [claimed invention]; and (2) he determined that the invention would work for its intended purpose." *Id.*

If a patent owner has not shown actual reduction to practice prior to the "critical date" of a reference, the patent owner may nonetheless antedate the reference by establishing prior conception and reasonable diligence towards a constructive reduction to practice. *Purdue Pharma*, 237 F.3d at 1365. "Reasonable diligence must be shown throughout the entire critical period, which begins just prior to the competing reference's effective date and ends on the date of the invention's reduction to practice." *Arctic Cat Inc. v. GEP Power Prods., Inc.*, 919 F.3d 1320, 1331 (2019). However, the "diligence need not be perfectly continuous—only *reasonably* continuous." *Id.*

To be persuasive, an inventor's testimony of conception and reduction to practice must be corroborated by other independent evidence. "Conception must be proved by corroborating evidence which shows that the inventor disclosed to others his completed thought expressed in such clear terms as to enable those skilled in the art to make the invention." *REG Synthetic Fuels, LLC v. Neste Oil Oyj*, 841 F.3d 954, 962 (Fed. Cir. 2016) (internal quotation marks omitted). "However, there is no final single formula that must be followed in proving corroboration." *Id.* (quotation marks omitted); *see also Kolcraft Enters., Inc. v. Graco Children's Prods., Inc.*, 927 F.3d 1320, 1324 (Fed. Cir. 2019); *Medichem, S.A. v. Rolabo, S.L.*, 437 F.3d 1157, 1169–70 (Fed. Cir. 2006).

"In the final analysis, each corroboration case must be decided on its own facts with a view to deciding whether the evidence as a whole is

persuasive." *Berges v. Gottstein*, 618 F.2d 771, 776 (CCPA 1980). Corroborating evidence may consist of "testimony of a witness, other than the inventor," or "evidence of surrounding facts and circumstances independent of information received from the inventor." *Medichem*, 437 F.3d at 1171. "Even the most credible inventor testimony is *a fortiori* required to be corroborated by independent evidence, which may consist of documentary evidence as well as the testimony of non-inventors." *Id.* at 1171–72. We assess whether evidence corroborates conception and reduction to practice under a "rule of reason" analysis. *Cooper*, 154 F.3d at 1330.

In an *inter partes* review, 35 U.S.C. § 316(e) imposes the ultimate burden of persuassian to "prove unpatentability by a preponderance of the evidence" onto the petitioner. This burden never shifts to the patent owner. *Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015). However, when the patent owner attempts to antedate the prior art, "[a] second and distinct burden, the burden of production" can shift between the petitioner and the patentee. *Id.* at 1379; *see In re Magnum Oil Tools Int'l, Ltd.*, 829 F.3d 1364, 1375–76 (Fed. Cir. 2016). Specifically, the patent owner "bears the burden of establishing that its claimed invention is entitled to an earlier priority date than an asserted prior art reference." *Magnum Oil Tools*, 829 F.3d at 1375–76. Once the patent owner establishes it is entitled to an earlier priority date, the burden of production then shifts back to the petitioner "to convince the court that [the patent owner] is not entitled to the benefit" of the earlier priority date. *Dynamic Drinkware*, 800 F.3d at 1379 (citing *Tech. Licensing Corp. v. Videotek, Inc.*, 545 F.3d 1316, 1328 (Fed. Cir. 2008)).

2. Conception

To show prior conception, Patent Owner relies primarily upon Mr. Root's testimony submitted in support of its CRTP Response. Ex. 2118 (Root Declaration in support of CRTP).[5,6] Mr. Root was the founder and Chief Executive Officer of VSI from 1997 to 2017. *Id.* ¶¶ 1–2. Patent Owner also relies upon the testimony of co-inventor Mr. Sutton, who was Vice President, Research & Development at VSI from 2004 until mid-2006. Ex. 2119 (Sutton Declaration in support of CRTP). As additional documentary corroboration for this inventor testimony, Patent Owner relies upon certain pages from Mr. Sutton's laboratory notebook dated January 4, 2005 (Ex. 2002), a "market feasibility" memorandum from Mr. Root dated February 4, 2005 (Ex. 2003), and some additional handwritten notes and drawings from Mr. Root dated February 7, 2005 (Ex. 2004). We first set forth the relevant facts based on these declarants' testimony and

[5] Patent Owner previously submitted a declaration by Mr. Root with its Preliminary Response (Ex. 2001), but withdrew that declaration in favor of Ex. 2118. PO CRTP Resp. 2 n.1.

[6] The testimonial evidence that Patent Owner presents in support of conception is largely undisputed. Indeed, during a teleconference addressing Patent Owner's request to present live testimony from Mr. Root in these proceedings, Petitioner's counsel acknowledged that Mr. Root's testimony was not disputed in a manner that would require our credibility assessment. *See* Ex. 1920, 11:10–11 ("And I don't think we have, you know, directly said Mr. Root is lying on this topic."); *id.* at 17:17–18 ("We don't have any issue at play here that goes to credibility."). Accordingly, in view of our conclusion that "the credibility of Mr. Root is not in question," we denied Patent Owner's request to present live testimony from Mr. Root at the oral hearing. *See* Paper 108, 4–5 (distinguishing *K-40 Elecs., LLC v. Escort, Inc.*, IPR2013-00203, Paper 34 (PTAB May 21, 2014) (precedential)).

corroborating evidence, and then address any disputed issues of material fact and legal issues as needed in our analysis.

a) Fact Findings for Conception

In his declaration, Mr. Root attests that conception started around the time he attended the Transcatheter Cardiovascular Therapeutics ("TCT") conference from September 27 to October 1, 2004, by which time he had recognized the issue of "guide catheter backout" that physicians were experiencing when performing complex interventional coronary procedures. Ex. 2118 ¶ 5. Accordingly, Mr. Root asserts that he recognized a need for a solution "that provided better guide positioning, device delivery, and procedural conveniences" than what previously existed in the market. *Id.* To solve this problem, Mr. Root indicates that he came up with "the idea for a guide extension catheter that would provide improved back-up support with rapid exchange delivery, which would offer far more convenience than other options available at the time." *Id.* ¶ 6. And "[s]ometime after the TCT conference, but before 2005," Mr. Root met with his co-inventors, including Mr. Sutton, to discuss more particular ideas for how to make this device. *Id.*

The "guide extension catheter" device that the inventors thought of at this time included certain key features. It was to be used within a standard guide catheter that was one "French size" larger than the "guide extension catheter," and was parsed into two distinct portions—a substantially rigid proximal portion comprising a "rail" structure and a distal tubular portion with a lumen—which together were longer than a standard guide catheter. *Id.* ¶ 7. During an operation, after the standard guide catheter was inserted into the vasculature so its distal end was in the ostium of a cardiac artery, the guide extension catheter would be inserted into the lumen until the distal end

of the tubular portion went past the distal end of the guide catheter and into the cardiac artery. *Id.* With both catheters in place, an interventional cardiology device could be thereafter inserted through the standard guide catheter (running along the rail of the guide extension catheter) until it reached the distal end of the distal tubular portion of the guide extension catheter, thereby entering the cardiac artery. *Id.*

The device they undertook to develop was initially called the "Guide-Liner" device, but the hyphen was later dropped and it became known as the "GuideLiner" device. *Id.* ¶ 9. Although the original idea for the GuideLiner was a "rapid exchange" ("RX") version of the guide extension catheter, "[s]ometime between February and June of 2005, a decision was made to concurrently pursue development of an over-the-wire ('OTW') version of GuideLiner." *Id.* ¶ 19. Mr. Root acknowledges, however, that "[t]he OTW GuideLiner was not part of the inventions of the [challenged] patents," but instead was more akin to the "mother-in-child" design that was known in the prior art and discussed in the background of the challenged patents. *Id.* (citing Ex. 1001, 2:17–44).[7]

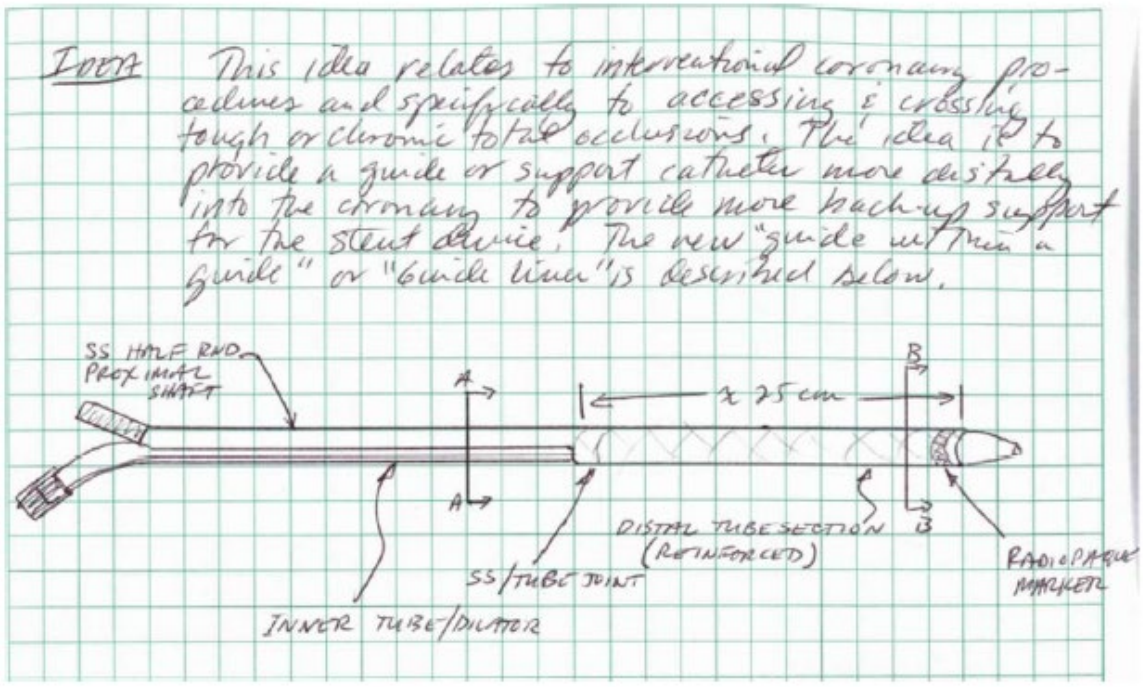
Mr. Sutton in his own declaration sets forth a story consistent with that set forth by Mr. Root. He attests that "[s]tarting in late-2004 until [he] left VSI, [he] performed research and development work on what became the GuideLiner guide extension catheter." Ex. 2119 ¶ 2. Although VSI did not retain all of its files from that time, Mr. Sutton recalls, based on his memory and documents he reviewed, that "we knew very early on that the

[7] It is undisputed that the work done in developing the RX GuideLiner, not the OTW GuideLiner, must provide the basis for conception and reduction to practice of the claimed invention. PO CRTP Resp. 13 n.3; Pet. CRTP Reply 1.

GuideLiner rapid exchange device would work for its intended purpose," and that "[t]he research and development that followed our original conception of the GuideLiner rapid exchange was to optimize materials, dimensions, and design details that would allow us to manufacture and bring the product to market in a way that would be commercially viable." *Id.* ¶ 6.

The earliest documentary evidence that corroborates this testimony is Mr. Sutton's laboratory notebook pages relating to the concept for a "Guide-Liner" device. Ex. 2002. Mr. Sutton signed the relevant pages on January 4, 2005, and Jeffrey Welch, another co-inventor and engineer at VSI, witnessed those pages on March 2, 2005. *Id.* at 7–8; *see* Ex. 2119 ¶ 7.

A portion of one page from Mr. Sutton's notebook is reproduced below:



Ex. 2002, 7. As shown above, Mr. Sutton's notebook sets forth an "idea" that "relates to interventional coronary procedures and specifically to accessing & crossing tough or chronic occlusions," which "is to provide a

guide or support catheter more distally into the coronary to provide more back-up support for the stent device." *Id.*; Ex. 2118 ¶ 9. Mr. Sutton's lab notebook also includes drawings of the cross section of various portions of the guide extension catheter and a drawing of how the Guide-Liner would be used that are similar to figures included in the challenged patents. *Cf.* Ex. 1001, Figs. 1, 2, 5, 6 (depicting patent drawings of the guide extension catheter that are similar to Mr. Sutton's drawings). For example, his notebook includes a drawing of a "5F" (5-French) Guide-Liner in operation and notes that the Guide-Liner a) "is used where there is difficulty crossing lesions," b) "allows back-up support distally," c) "allows for Rapid X change," and d) "would fit std. 6F Guides." Ex. 2002, 8. The notebook pages also describe the main features of the device, including: 1) an inner tube/dilator that "fits snugly" within a stainless steel ("SS") half-tube; 2) a reinforced distal tube section with a braided "PTFE/SS/PEBAX" material that is "soft for coronaries"; and 3) a design that "allows for rapid exchange." *Id.* at 7. Additionally, the notebook identifies the "5F Design Specs," including an overall device length of between 105 cm and 115 cm. *Id.* Both Mr. Root and Mr. Sutton authenticate the contents of the notebook pages and Mr. Sutton attests that his notebook was "issued and maintained in the regular course of VSI's business." Ex. 2118 ¶¶ 9–11; Ex. 2119 ¶¶ 7–14.

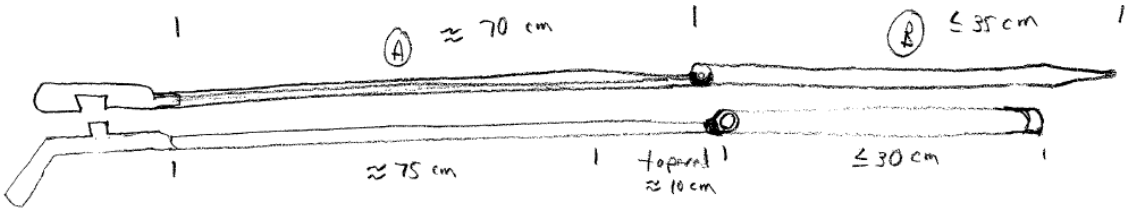
By early February 2005, Mr. Root realized this device would have "substantial market potential," so he wrote a "Market Feasibility" memorandum ("memo") for GuideLiner catheters, dated February 4, 2005. Ex. 2118 ¶ 11; Ex. 2003 (confidential); Ex. 2127 (public). Mr. Root attests that he would only have drafted this kind of memo if he "had developed high confidence that a concept would work," so that non-inventors in the company (e.g., regulatory personnel and engineers) could join a project to

bring the new product to market. Ex. 2118 ¶ 11. The memo itself recognizes the "substantial market potential" for the RX GuideLiner device based on an estimated 30,000 procedures a year. Ex. 2003, 1. The memo indicates that three versions were anticipated (i.e., a "5in6," a "6in7," and a "7in8" GuideLiner), and notes problems with the prior art OTW methods. *Id.* The memo also generally describes the RX GuideLiner in a manner consistent with the description in Mr. Sutton's notebook including, among other features, that it would be delivered within a standard guide catheter for interventional cardiology procedures; it had a short distal tube segment to allow for rapid exchange delivery; it was inserted through the existing hemostatic valve; and it was one French size smaller than the standard guide catheter. *Id.* at 2.

Mr. Root also references his own handwritten notes, dated February 7, 2005.[8] Ex. 2118 ¶¶ 12–14; Ex. 2004. These notes show certain features of the RX GuideLiner device, including a "side opening" section that appears in the transition from a partial-round proximal portion to a full-round portion

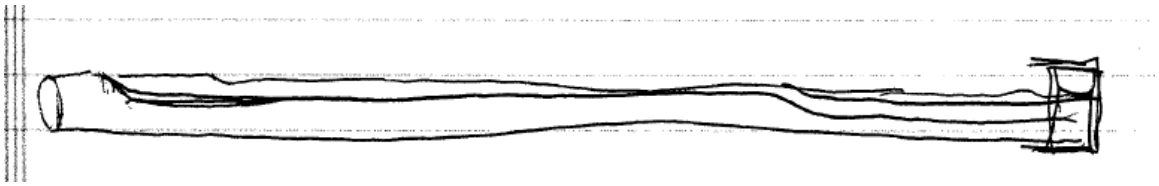
[8] Although only the first page of these notes is dated, Mr. Root attests he made the notes on the other two pages "contemporaneously with [his] notes on page 1." Ex. 2118 ¶ 14. Petitioner contends that the third page, in addition to being undated and unwitnessed, appears to come from "a different set of notes" because, unlike the first two pages, the paper is lined. Pet. CRTP Reply 7 n.4. Petitioner also points out that Mr. Sutton testified that he had not seen the third page until his deposition in the stayed district court litigation. *Id.* (citing Ex. 1108, 41:1–6, 46:7–47:3). Mr. Sutton, however, is not the author of these notes. Although we recognize that the type of paper used to record the notes may have been different, we find that the content of page 3 seems to be otherwise consistent with the remainder of the notes and Patent Owner's other conception documents. We therefore find no basis to question Mr. Root's testimony that all his notes from Exhibit 2004 were made contemporaneously on or about February 7, 2005.

connected to a distal tube section. *Id.* The first drawing from Mr. Root's handwritten notes, reproduced below, is similar to Figure 1 of the '770 patent:



Ex. 2004, 1. As shown above, a "side opening" to allow for the RX capability is reflected through "crude shading" between the rail structure and tubular portion above the notation reading "tapered ≈ 10 cm," and was considered by Mr. Root to be "an important feature of GuideLiner." Ex. 2118 ¶ 13. Mr. Root testifies that the side opening "facilitates entry of interventional cardiology devices into the proximal end of the tubular portion." *Id.*

The third page of Mr. Root's notes depicts another drawing, reproduced below, that also shows the side opening concept:



Ex. 2004, 3. According to Mr. Root, the sketch above "shows a side opening structure that is cut-away in several segments including, from left (distal) to right (proximal): a full round portion; a first angled transition portion; a first partial round portion; a second angled transition portion; and a second partial round portion." Ex. 2118 ¶ 14. The notes also list dimensions for the contemplated sizes of the GuideLiner. *Id.* ¶ 12; Ex. 2004, 1–3.

Beyond these "core" conception documents (Exs. 2002–2004), Patent Owner also relies on certain engineering drawings as further corroboration for the inventors' testimony. PO CRTP Sur-Reply 3–5 (citing Exs. 2022, 2113, 2114). Patent Owner annotates two of these drawings to highlight features of the depicted GuideLiner, namely the "Side Opening," "Rail Structure," "Machined End for Connecting to Tubular Portion," "Soft Tip," and "Reinforced Pebax Tubular Portion." *Id.* at 4 (citing Ex. 2114), 5 (citing Ex. 2022). The drawings are dated March 2005 (Ex. 2113, 1), June 28, 2005 (Ex. 2114), and August 1, 2005 (Ex. 2022, 1). We have taken these documents into account in determining whether the inventors conceived of the claimed invention prior to the September 23, 2005, critical date.

b) Analysis for Conception

We first consider whether Patent Owner's proffered evidence corroborates the inventors' testimony of conception. Patent Owner does not assert a specific date of conception. *See* Tr. 60:4–6 ("Our story from day one has been that the exact date of conception doesn't matter."). We agree that we need not determine the exact date on which conception took place. Nonetheless, before we can move on to the question of reduction to practice, we must determine that conception—as legally defined to be the formation of "a definite and permanent idea of the complete and operative invention," *Cooper*, 154 F.3d at 1321—was finalized at some point prior to the critical date of Itou. From the evidence Patent Owner relies upon, we can distill Patent Owner's broad theory of conception as having occurred either by February 2005, as corroborated by the core conception documents (Exs. 2002–2004), or by August 2005 during the course of building and testing

prototypes, as further corroborated by the engineering drawings (Exs. 2113, 2114, 2022).

Petitioner argues Patent Owner's core documentary evidence—Mr. Sutton's notebook pages, the market feasibility memo, and Mr. Root's handwritten notes—cannot be used to corroborate inventor testimony insofar as they all originated from the inventors themselves as opposed to some other independent source. Pet. CRTP Reply 4. Petitioner relies principally on three cases as support for this argument. *Id.* at 3–4.

First, Petitioner cites *Apator Miitors ApS v. Kamstrup A/S*, 887 F.3d 1293 (Fed. Cir. 2018), to argue the documents relied upon by Patent Owner are "inventor documents" that cannot be used to corroborate an inventor's testimony on conception. Pet. CRTP Reply 4. The problem for the patent owner in *Apator* was that it was "stuck in a catch-22 of corroboration" because the evidence that was proffered to corroborate the inventor's testimony could "only provide that corroboration with help from [the same inventor's] testimony." 887 F.3d at 1296. For instance, in the bodies of the emails that were relied upon, the inventor indicated that he attached certain files related to his invention, but nothing in any part of the emails indicated what files were attached or what such attachments disclosed. *Id.* The court agreed with the Board's finding that the inventor's testimony was the only evidence proffered to establish the existence and substance of the attachments. *Id.* at 1296–97. And though the drawings set forth dates that were after the reference's critical date, the inventor's testimony about certain file naming conventions was the only evidence offered by the patent owner to demonstrate that the drawings were actually created on an earlier date. *Id.* at 1294–95, 1296–97. The court rejected the patent owner's argument that the emails and drawings should still have "some corroborative value," like

unwitnessed laboratory notebooks. *Id.* at 1297. The court acknowledged that the rule of reason permits "'a notebook entry' or other writing '[that] has not been promptly witnessed,'" *id.* (citing *Singh v. Brake*, 222 F.3d 1362, 1369 (Fed. Cir. 2000)), "to aid in corroborating witness testimony alongside other, more persuasive, evidence." *Id.* (citing examples where the Federal Circuit and one of its predecessors, the Court of Customs and Patent Appeals, permitted unwitnessed documents to contribute to corroboration of conception). But the court clarified that "an unwitnessed laboratory notebook, alone, cannot corroborate an inventor's testimony of conception." *Id.* (citing *Brown v. Barbacid*, 276 F.3d 1327, 1335 (Fed. Cir. 2002) (concluding there was no error in denying corroboration by "an inventor's own unwitnessed documentation"); *Procter & Gamble Co. v. Teva Pharms. USA, Inc.*, 566 F.3d 989, 998–99 (Fed. Cir. 2009) (concluding a laboratory notebook that "was unwitnessed and was not corroborated by any other evidence" could not corroborate inventor testimony of conception)).

Second, Petitioner cites *Kolcraft Enterprises, Inc. v. Graco Children's Products, Inc.*, 927 F.3d 1320 (Fed. Cir. 2019), in support of its argument that the documents relied upon by Patent Owner lack corroborative value because they all "'originated with the inventors.'" Pet. CRTP Reply 4. In *Kolcraft*, the Federal Circuit observed that the evidence at issue—which it characterized as "even weaker than the evidence presented in *Apator*"—comprised a redacted inventor declaration, the inventor's deposition testimony, and undated photos attached to the inventor declaration. 927 F.3d at 1325. Of this evidence, the court noted that "[o]nly the Inventor Declaration, i.e., inventor testimony, supports the purported dates showing [prior] conception," but this was deemed insufficient because "[i]nventor testimony alone cannot prove conception." *Id.*

Third, Petitioner cites a non-precedential Board decision, *Curt Manufacturing, LLC v. Horizon Global Americas Inc.*, IPR2019-00625, 2020 WL 4687044, at *7 (PTAB Aug. 11, 2020), for the proposition that "[o]ne inventor cannot corroborate another." Pet. CRTP Reply 4; *see also* Tr. 35:20–36:12 (Petitioner's counsel citing *Curt* for the same proposition). In *Curt*, the Board stated that "[o]ne consequence of the independence requirement is that *testimony* of one co-inventor cannot be used to help corroborate *the testimony* of another." *Id.* (citing *Lacks Indus., Inc. v. McKechnie Vehicle Components USA, Inc.*, 322 F.3d 1335, 1350 (Fed. Cir. 2003) (emphases added) (approving refusal to accept cross-corroboration of oral testimony by interested witnesses)).[9] The Board further noted that "an inventor's *unwitnessed* laboratory notebooks, emails, and drawings, *without other independent evidence*, cannot corroborate an inventor's testimony." *Id.* (emphases added) (citing *Kolcraft*, 927 F.3d at 1325–26; *Apator*, 887 F.3d at 1297; *Brown*, 276 F.3d at 1335). In a footnote quoting *Brown*, the Board highlighted the importance of two issues: whether the documentary evidence was witnessed and whether there is other corroborating evidence in the record. *Id.* at *7, n.7 (reiterating that physical evidence from an inventor does not need corroboration to demonstrate its contents, but the inventor's *unwitnessed* documentation "may not *single-handedly* corroborate" the inventor's testimony (quoting *Brown*, 276 F.3d at 1335) (other emphases omitted)). Lastly, the Board concluded that, "[n]otwithstanding this clear

[9] The Federal Circuit, however, has not categorically prohibited "cross-corroboration" of testimony by interested witnesses at least in other contexts. *See Nobel Biocare Servs. AG v. Instradent USA, Inc.*, 903 F.3d 1365, 1378 (Fed. Cir. 2018) ("The testimony of one witness may corroborate the testimony of another witness.").

guidance, the law also recognizes that . . . a notebook entry or other writing that has not been promptly witnessed does not necessarily disqualify it in serving as corroboration of conception under a rule of reason analysis." *Id.* at *7 (citing *Apator*, 887 F.3d at 1297 (referring to cases where unwitnessed documentary evidence was considered alongside other evidence to corroborate inventor testimony)).

Considering the evidence of record as a whole, we reject Petitioner's arguments that the inventors' testimony on conception is not adequately corroborated. We find the case law cited by Petitioner to be distinguishable.

We first note that Mr. Sutton's laboratory notebook was witnessed shortly after the date of entry of the relevant pages. Specifically, the notebook pages presented here were witnessed by another inventor, Jeffrey Welch. Ex. 2002. Because the notebook is dated and witnessed, we may properly consider it for its probative value in corroborating Mr. Root's and Mr. Sutton's testimony. *See Singh*, 222 F.3d at 1369–70 (holding that a belatedly witnessed lab notebook may serve as corroboration of conception); *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1378 (Fed. Cir. 1986) (same). Indeed, as noted above, even an unwitnessed notebook page may have some corroborative value under the rule of reason when considered in combination with other more persuasive evidence. *Apator*, 887 F.3d at 1297. Moreover, we discern no *per se* rule from the case law to suggest that a laboratory notebook witnessed by a co-inventor cannot be used to corroborate another inventor's testimony about conception. In this regard, we find that the witnessed notebook pages avoid the "catch-22 of corroboration" noted in *Apator* because the notebook pages do not depend upon either Mr. Root's or Mr. Sutton's testimony for an explanation of their content. The notebook pages also avoid the issue that arose in *Kolcraft* and

Curt because Patent Owner has not relied upon only the inventors' testimony to prove conception. We note that, aside from whether the notebook pages can legally qualify as corroborative evidence of the date of conception, Petitioner has not disputed the authenticity or veracity of the content shown on those pages. As such, we have considered the content of the notebook pages at face value in our analysis.

We have also taken into account the market feasibility memo and Mr. Root's handwritten notes in our corroboration assessment. Ex. 2003; Ex. 2004. We recognize that these documents appear to have been authored by Mr. Root, and no witness other than Mr. Root has provided testimony about their content. As such, if considered in isolation, these conception documents may be more analogous to the type of "catch-22" documents found insufficient for corroborating the date of conception under *Apator*. Nonetheless, applying the rule of reason, we do not categorically exclude them from the corroboration analysis because they can still "aid in corroborating witness testimony alongside other, more persuasive, evidence." *Apator*, 887 F.3d at 1297. We further note that, like the notebook pages, Petitioner has not disputed the authenticity or veracity of the content of the market feasibility memo and Mr. Root's handwritten notes, and thus we have also considered the content of these documents at face value.

Because we conclude that the notebook pages, along with the market feasibility memo and Mr. Root's handwritten notes, may be properly considered in our corroboration analysis, we next address whether these documents are in fact sufficiently corroborative of the inventors' testimony to show conception of the claimed invention prior to the critical date. On this point, Mr. Root includes as appendices to his declaration claim charts

showing how certain VSI prototypes developed at the time meet the limitations of the challenged claims. Ex. 2118, App'x A–E.[10] The primary argument raised by Petitioner is that Patent Owner's core conception documents do not disclose the "side opening" feature recited in numerous challenged claims. Pet. CRTP Reply 5–7.[11] According to Petitioner, without this demonstration, Patent Owner fails to establish conception of "every feature or limitation of the claimed invention." *Id.* at 3 (quoting *REG Synthetic Fuels*, 841 F.3d at 962). We are persuaded that the evidence shows that the RX GuideLiner device that the inventors had conceived of

[10] Petitioner contends that Mr. Root's claim charts amount to an improper incorporation by reference in violation of 37 C.F.R. § 42.6(a)(3) and a circumvention of our word limits. Pet. CRTP Reply 2. However, in view of the commonality of the CRTP issues across these related proceedings, we authorized the parties to submit consolidated briefing on the issue. Paper 26 (Consolidated Scheduling Order), 2–3. Moreover, Petitioner also submitted similar rebuttal claim charts by its expert Dr. Zalesky as appendices to his expert report. Ex. 1755, App'x A–E. Under the circumstances, we are not persuaded that the manner in which Patent Owner presented its claim-by-claim arguments were a violation of our rules.

[11] As Petitioner acknowledges, this argument only applies to certain claims. *See* Tr. 59:5–12. Petitioner does not identify specifically which limitation of the '760 patent claims constitute the "side opening" limitation, but we note that claim 25 of the '760 patent requires a "side opening extending for a distance along a longitudinal axis of the segment defining the side opening and accessible from a longitudinal side defined transverse to the longitudinal axis." Ex. 1001, 13:62–66. According to Petitioner's table in its CRTP Sur-Sur-Reply, the side-opening limitation appears in the following claims: claims 3 and 4 of the '032 patent; claims 3, 4, 36 of the '380 patent; claims 25, 52, and 53 of the '776 patent; and claims 25, 48, 51, and 53 of the '760 patent. Pet. CRTP Sur-Sur-Reply 14–15. In its Sur-Sur-Reply, Petitioner also contends that Patent Owner is missing evidence that the RX prototypes satisfy certain additional claim limitations. *Id.* We consider this in addressing the actual reduction to practice issue below.

and were developing at the time included all the features of the challenged claims, including a side opening feature to allow for rapid exchange.

As noted above, Mr. Root attests that the first and third pages of his handwritten notes each depict a drawing that includes a side opening. Ex. 2118 ¶¶ 12–14 (citing Ex. 2004, 1, 3). In particular, Mr. Root asserts that

> [a]n important feature of GuideLiner is a "side opening" at the transition between the proximal rail structure and the distal tubular portion that facilitates entry of interventional cardiology devices into the proximal end of the tubular portion. This feature is reflected in the crude shading between the rail structure and the tubular portion shown in the sketch above from my February 7, 2005 notes.

Id. ¶ 13. We credit this testimony and find that it is corroborated by the drawings themselves.

Petitioner contends that the lab notebook pages, as confirmed by Mr. Sutton's deposition testimony, only show an "end opening" rather than a side opening for the device. Pet. CRTP Reply 5 (citing Ex. 1108, 70:18–71:23, 79:14–80:24). To further dispute the disclosure of a side opening, Petitioner relies on the declaration of its expert Dr. Zalesky. *Id.* at 6 (citing Ex. 1755 ¶¶ 83–84). Dr. Zalesky contends that the "crude shading" on the drawing on the first page of Dr. Root's notes "does not appear to show an angled opening at the proximal end of the tubular portion" and that Mr. Root's notes on the page do not refer to a side opening. Ex. 1755 ¶ 83. Dr. Zalesky further contends that the drawing on the third page of Mr. Root's notes "does not appear to correspond to any of the figures in the Root patents"; is "quite crude," making it "difficult to tell what it represents, if anything"; and "does not appear to show a side opening." *Id.* ¶ 84.

Although we recognize that Mr. Sutton testified that Figure 1 does not depict an angled side opening, it does not appear that Mr. Sutton

categorically stated that the inventors had not conceived of a device that included the side opening feature or otherwise directly contradicted Mr. Root's testimony on this point. We further note that the first drawing in Mr. Root's notes appears to closely match Figure 1 of the challenged patent (which depicts an unassembled coaxial guide catheter and tapered inner catheter), while the first drawing in Mr. Sutton's notes appears to closely match Figure 2 of the challenged patent (which depicts the assembled device). *Compare* Ex. 2004, 1, *with* Ex. 1001, Fig. 1; *compare* Ex. 2002, 1, *with* Ex. 1001, Fig. 2. We agree with Dr. Zalesky that the sketches included in Mr. Root's handwritten notes are "crude" and not a model of clarity. Nonetheless, taking into account both the documentary evidence and inventor testimony as a whole, we find that a preponderance of the evidence supports the conclusion that the inventors conceived of a device that included the side opening and all other claimed features prior to the critical date.

To the extent that the earlier core conception documents alone do not support prior conception, we have also taken into account the evidence proffered by Patent Owner with respect to the prototypes that were built between February and August 2005. *See* PO CRTP Sur-Reply 3 (explaining that if the early 2005 documents "were disregarded," other pre-Itou evidence "undisputedly shows conception of the entire invention, *including the side opening*" (emphasis added)). To support its theory, Patent Owner cites Dr. Zalesky's testimony, where he confirms that the engineering drawings depict a side opening. Ex. 2237, 211:11–16 (agreeing that "a side opening can be found in the hypotubes that were cut down by Spectralytics, specifically Exhibit 2113 and 2114"), 250:9–13 (agreeing that "Exhibit 2022 sets forth the concept for the rapid exchange GuideLiner"). Petitioner

acknowledges the probative value of the August 2005 drawing in showing conception prior to the critical date: "[a]t best, [Patent Owner] shows conception in August 2005, a mere month before Itou and *after* VSI's purported prototype work in April and July." *Id.* Much of this evidence is also relied upon by Patent Owner to demonstrate that there was actual reduction to practice prior to the critical date. Given the overlap, we also address this evidence as part of our actual reduction to practice analysis.

In sum, Patent Owner's core documentary evidence—Mr. Sutton's lab notebook, the market feasibility memo, and Mr. Root's handwritten notes—sufficiently corroborate the stories of conception set forth in Mr. Root's and Mr. Sutton's declarations. These corroborating documents add credibility to the inventors' conception timelines. And even if Petitioner were correct that not every feature was conceived on or about February 2005, we find that additional evidence of record with respect to the prototypes, as discussed below, demonstrates conception no later than August 2005.

3. Actual Reduction to Practice

Patent Owner contends that actual reduction to practice also took place before the critical date of Itou. In support of this contention, Mr. Root attests in his declaration that employees at VSI, led by co-inventors Mr. Sutton and Mr. Welch, built and tested RX GuideLiner prototypes between January and August 2005.[12] Ex. 2118 ¶ 15. Mr. Sutton, as well as two non-inventors employed by VSI at the time, Steve Erb and Deborah Schmalz, also testify about relevant details of the research and development done with

[12] Mr. Root explains that Patent Owner does not have many development documents from 2005, and it obtained many of the documents relevant to actual reduction to practice from VSI's vendors and patent prosecution firm. Ex. 2118 ¶ 20.

regard to the GuideLiner prototypes. Ex. 2039 (Schmalz Declaration); Ex. 2119 (Sutton Declaration); Ex. 2122 (Erb Declaration). Patent Owner also presents the declarations of Mark Goemer and Amanda O'Neil, who were employed by outside vendors from whom VSI purchased components to build the prototypes. Ex. 2120 (Goemer Declaration); Ex. 2121 (O'Neil Declaration). Additionally, Patent Owner has submitted an expert declaration by Mr. Peter Keith in further support of this contention. Ex. 2123 (Keith Declaration in support of CRTP). Patent Owner relies upon purchase invoices, engineering schematics, and other documentary evidence from as early as January 2005 through the September 2005 critical date of Itou in order to corroborate the fact declarants' testimony regarding actual reduction to practice.[13] We once again set forth the relevant facts based on these declarants' testimony and corroborating evidence, and then address any disputed issues of material fact and legal issues as needed in our analysis for actual reduction to practice.

a) Fact Findings for Actual Reduction to Practice

After the inventors came up with the initial idea for the device (as set forth in the conception discussion above), VSI proceeded with the development of both the OTW and RX versions of the GuideLiner

[13] Patent Owner includes some documentary evidence created after Itou's critical date. *See, e.g.*, Ex. 2106 (invoices dated April 2006); Exhibit 2115 (engineering drawing dated Nov. 1, 2005). We do not find this post-critical date evidence to support Patent Owner's contentions regarding actual reduction to practice. However, we have considered some of this evidence in our analysis of whether there was diligence towards constructive reduction to practice (*see* discussion, *infra*), as well as to address Petitioner's argument that the continuing work done at VSI with respect to the GuideLiner demonstrates a lack of actual reduction to practice before Itou.

concurrently. Ex. 2118 ¶ 19; Ex. 2119 ¶ 15. Although it was based on existing technology, VSI decided to pursue the OTW version based on the belief that it could be brought to market more quickly with fewer regulatory challenges than the RX version. Ex. 2118 ¶ 19; Ex. 2119 ¶ 15. Nonetheless, the RX version remained a priority for continued development at VSI. *Id.* Consistent with Mr. Root's testimony, Mr. Sutton testifies that the RX GuideLiner was reduced to practice before September 2005, although further work towards commercialization of the product continued until he left the company. Ex. 2119 ¶ 6. According to Mr. Sutton, work for the OTW prototype "paled in comparison" to work required for the RX prototype because the OTW prototype "required very little engineering and was relatively easy to build because it was based on existing technology." *Id.* ¶ 15. In their declarations, Mr. Root and Mr. Sutton focus on two distinct sets of prototypes of the RX version that were built and tested before Itou's critical date: the "April 2005" prototypes and the "July 2005" prototypes. Ex. 2118 ¶ 48; Ex. 2119 ¶¶ 21–22.[14] As noted above, Mr. Root includes claim charts identifying how the April and July 2005 prototypes satisfied the limitations of the challenged claims. Ex. 2118, App'x A–E; *see also* Ex. 2123 ¶ 28 (Mr. Keith opining that the April and July 2005 prototypes satisfy the claim limitations based on these claim charts).

In developing these prototypes, a VSI technician and machinist, Mr. Erb, worked with the inventors to mechanically cut down stainless steel or

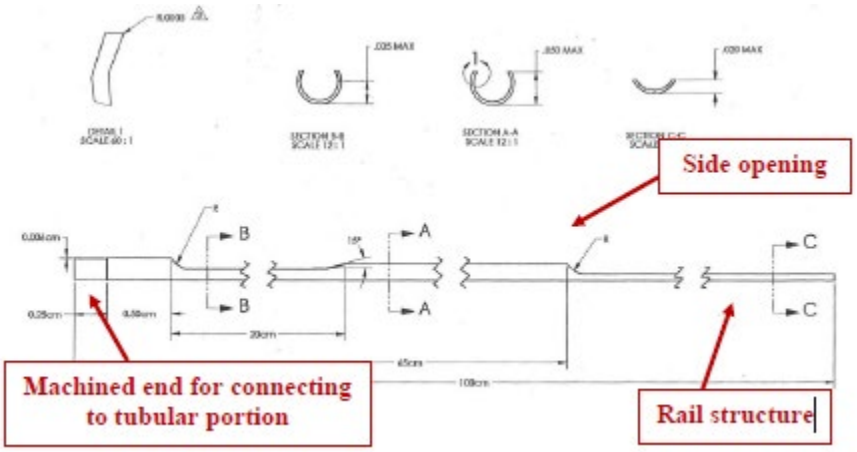
[14] Although Mr. Root refers to the likelihood that other sets of prototypes were also built, the bulk of Patent Owner's evidence and arguments relate to the April and July 2005 prototypes. Ex. 2118 ¶ 48. As such, we focus on these prototypes in determining whether there was actual reduction to practice.

nitinol "hypotubes" used for the proximal portion of an RX prototype. Ex. 2118 ¶ 16; Ex. 2119 ¶ 20; Ex. 2122 ¶¶ 8–10. The profile of some of these hypotubes started at full circumference at the distal end, then progressed to roughly half-round at the proximal end. Ex. 2118 ¶ 16. The hypotubes were combined with a polymer distal section to create the first RX GuideLiner prototypes. *Id.* At this time, the distal tubular portion was sometimes built by cutting a standard guide catheter to the appropriate length. *Id.* ¶ 24. The earliest prototypes, made in January or February 2005, largely comprised stock components modified through VSI's in-house machining capabilities. *Id.* ¶¶ 18, 20. However, by April 2005, the VSI engineers progressed to building more formal prototypes using custom-ordered materials from outside vendors for the proximal and distal portions of the device. Ex. 2122 ¶ 12. A spend report details at least some of the expenses that VSI incurred on purchases of the components used to build GuideLiner prototypes from February 11, 2005, to June 30, 2006. Ex. 2005; Ex. 2118 ¶¶ 21–22. According to Mr. Root, the fact that they had opened an account specific to the "Guideliner project" in May 2005, as reflected in this spend report, indicates that development had advanced to the point that they were confident with proceeding towards commercialization. Ex. 2118 ¶ 22.

With respect to the proximal portions, Patent Owner presents invoices and other documents reflecting VSI's purchases of laser-cut hypotubes from three outside vendors: MicroGroup, Mountain Machine, Inc., and SPECTRAlytics. Ex. 2118 ¶¶ 23, 27, 29, 30, 32, 33, 40, 43 (citing Exs. 2006, 2007, 2009, 2010, 2013, 2020, 2091, 2094, 2095, 2110, 2111); Ex. 2119 ¶¶ 24–31 (discussing similar purchases); *see also* Ex. 2122 ¶ 7 (discussing purchases of stainless steel and nitinol hypotubes as reflected in

Ex. 2110).[15] Because some of these invoices show purchases of the hypotubing by the foot, Mr. Root asserts that the materials were likely used for early evaluations of the RX GuideLiner concept. Ex. 2118 ¶ 23. Mr. Sutton similarly asserts that the hypotubing that was purchased at this time was used to make RX GuideLiner prototypes, as the OTW version never involved such hypotubing. Ex. 2119 ¶ 23. The ranges of the inner and outer diameters, wall thickness, and the overall length of the hypotubes that were ordered were consistent with what VSI would have needed at the time for prototyping the RX GuideLiner. *Id.* ¶¶ 24, 26.

Mr. Root and Mr. Sutton also reference the following annotated engineering schematics of the proximal portion of the RX GuideLiner that were drawn by a VSI engineer, Jim Kauphusman, on February 4, 2005:



Ex. 2113; Ex. 2118 ¶ 34; Ex. 2119 ¶ 30. The drawings above show a design of the proximal portion with multiple angled transition regions bookending non-inclined regions, and Patent Owner's annotations to the drawings—

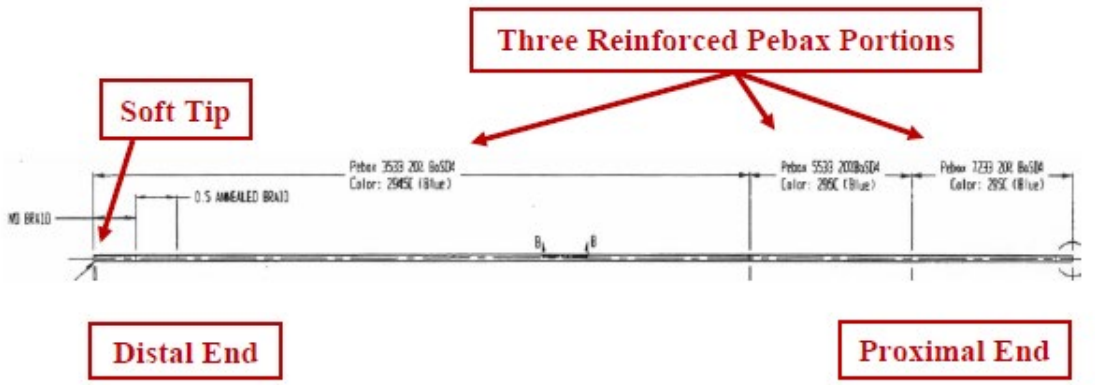
[15] Although both stainless steel and nitinol hypotubes were ordered, Mr. Sutton asserts that nitinol was significantly more expensive and required additional post-processing steps as compared to stainless steel, and these factors ultimately weighed against using nitinol for the proximal portion of the RX GuideLiner. Ex. 2119 ¶ 28.

which were added for this proceeding, *see* PO CRTP Sur-Reply 13—identify a "machined end for connecting to tubular portion," a "side opening," and a "rail structure." *Id.* These drawings were submitted as "prints" to SPECTRAlytics in order to specify the parameters for the hypotubes that were custom ordered, and include a drawing number "SS HYPO X04" that correlates to a purchase completed on April 4, 2005. Ex. 2118 ¶ 34; Ex. 2120 ¶ 9; Ex. 2095. Additional engineering drawings for the proximal portions were submitted to SPECTRAlytics around June 2005. Ex. 2118 ¶ 41; Ex. 2120 ¶ 11; Ex. 2114. Some of the engineering drawings are similar to figures included in the challenged patent. *Cf.* Ex. 1001, Figs. 12–16.[16] Mr. Goemer verifies and authenticates some of the purchase documents and the engineering drawings retrieved from SPECTRAlytics's files. Ex. 2120 ¶¶ 6–12.

Additionally, Mr. Root and Mr. Sutton refer to purchases of distal tubular portions and the distal forming tips from vendors Medical Engineering & Design Inc. ("MED") and Farlow's Scientific Glassblowing Inc. between February and July 2005. Ex. 2118 ¶¶ 28, 31, 44, 45 (citing Exs. 2011, 2021, 2090, 2092); Ex. 2119 ¶¶ 32–34, 36 (additionally citing Exs. 2032, 2033, 2034, 2035, 2089, 2097, 2112). Ms. O'Neil, who is employed by MED's successor TE Connectivity ("TE"), verifies and authenticates some of these purchase documents, and notes that the documents were retrieved from the files of TE, but originated with MED in 2005. Ex. 2121 ¶¶ 5–6.

[16] Mr. Sutton faxed these drawings to VSI's outside patent counsel on March 21, 2006. Ex. 2118 ¶ 42; Ex. 2019.

One of the documents from MED also includes engineering schematics for the distal portion that were drawn on February 10, 2005, by Mr. Kauphusman, as shown below:

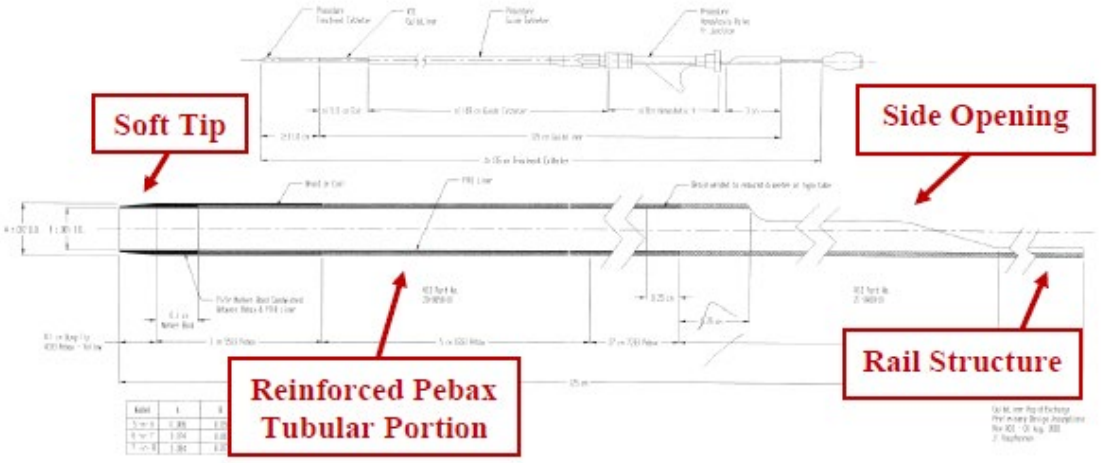


Ex. 2089, 8; Ex. 2118 ¶ 25; Ex. 2119 ¶ 32. The drawing above shows the distal portion with Patent Owner's annotations, *see* PO CRTP Resp. 9, identifying a "soft tip," "three reinforced Pebax portions," the "distal end," and the "proximal end." *Id.* Although Exhibit 2089 does not specify that the tubing was for the RX version of the GuideLiner, Mr. Root and Mr. Sutton assert that the drawings and specifications were in fact specific to an RX device based on the notation that the proximal end should be "counter bored" (a requirement to facilitate attachment to the cut-down hypotube) as well as the overall length of 11.8 inches (because if this part were for an OTW device, it would have been significantly longer). *Id.* The order for distal portions as shown in Exhibit 2089 was placed on February 17, 2005, and the parts were shipped from MED and delivered to VSI on or about April 5, 2005. Ex. 2118 ¶ 25; Ex. 2119 ¶ 33. An update to the drawing shown in Exhibit 2089 was made on April 6, 2005, as shown in Exhibit 2092, with only minor changes, namely slightly reduced inner and outer

diameters to fit a guide catheter and a slightly shortened tip. Ex. 2092, 8; Ex. 2118 ¶ 44. An order for distal tubular portions based on the updated design was placed on April 12, 2005 and those parts were delivered to VSI on or about June 16, 2005. *Id.*

The proximal and distal portions that were custom ordered and purchased from the outside vendors were thereafter combined in-house at VSI to form the prototypes of the complete RX GuideLiner. Ex. 2118 ¶ 24 ("From the earliest stages of the project, the plan was to combine the substantially rigid proximal portion of the rapid exchange GuideLiner with a distal polymer tubular portion that would be at least partially reinforced with coil or braid."); Ex. 2119 ¶ 24 ("[W]e combined these distal sections from MED with the proximal stainless steel sections discussed above to form prototypes of the GuideLiner rapid exchange in April and July 2005."). For example, the first set of formal prototypes (the April prototypes) appear to have been made by combining the laser-cut hypotubes from SPECTRAlytics with the distal tubular sections from MED that were shipped around April 5, 2005. Ex. 2118 ¶ 35 (citing Exs. 2011, 2089). Additional prototypes (the July prototypes) appear to have been built using the hypotubes from MicroGroup shipped around April 20, 2005, and/or the hypotubes from SPECTRAlytics shipped around July 18, 2005, in combination with the updated distal portions from MED shipped around June 16, 2005. *Id.* ¶¶ 39, 40, 46 (citing Exs. 2114, 2020, 2021, 2092, 2094). In making these prototypes, VSI "used an in-house thermal process to fuse the distal tubing sections from MED to the cut-down hypotubes." Ex. 2119 ¶ 35. VSI had the materials and equipment available to assemble the device at their facilities. *Id.*

As further evidence of an assembled device, inventors Mr. Root and Mr. Sutton reference the following engineering CAD schematics from August 1, 2005:



Ex. 2118 ¶ 49; Ex. 2119 ¶ 39; Ex. 2022. The drawings above show a version of the complete RX GuideLiner, as well as a cross-sectional view of the device with Patent Owner's annotations, *see* PO CRTP Resp. 16, identifying the "soft tip," the "reinforced Pebax tubular portion," the "side opening," and the "rail structure." Ex. 2118 ¶ 49. The schematics are labeled "GuideLiner Rapid Exchange/Preliminary Design Assumptions/Rev X03," which according to Mr. Root, was an indication that VSI had moved past prototyping and into commercialization. *Id.* Mr. Sutton attests that the "X03" indicates that this was the third version of the CAD drawings, and that they had built and tested prototypes of the RX GuideLiner device shown in these drawings. Ex. 2119 ¶ 39. The document also references the same part number (20-0658) as those identified in certain purchase documents for distal tubular portions from MED. Ex. 2118 ¶ 51 (citing Ex. 2021, Ex. 2089, Ex. 2092). These drawings are nearly identical to Figures 3 and 4 of the

patent. *Cf.* Ex. 1001, Figs. 3–4 (depicting patent drawings that resemble the CAD drawings).

The prototypes were tested using bench-top coronary models, including two-dimensional ("2D") acrylic heart models and three-dimensional ("3D") glass heart models, to simulate the native anatomy and environment. Ex. 2118 ¶¶ 17, 38, 47; Ex. 2119 ¶¶ 37–38, 41. These types of models were commonly used by VSI and other medical device companies to test interventional cardiology devices. Ex. 2118 ¶ 17; Ex. 2123 ¶ 21 (Mr. Keith noting that he had used similar models to test catheter designs during his time at Scimed and Boston Scientific Corporation). A sales presentation from July 2005 shows an example of a 2D coronary model. Ex. 2018, 12; Ex. 2129 (redacted version of same presentation). While this particular presentation depicts testing of the OTW version of the GuideLiner concurrently under development, Mr. Root asserts that a similar model was used to test the RX version. Ex. 2118 ¶¶ 18, 38. The testing done using this model included performing pull tests as well as simulations comprising the following steps: a) inserting a standard guide catheter into the coronary model; b) advancing the prototype into the guide catheter until the prototype's distal end extended beyond the guide catheter's distal end; and c) delivering a stent or balloon catheter into and through both devices. *Id.* ¶ 18. Although "more qualitative than quantitative," these tests enabled the inventors to observe the prototype's durability and the forces exerted on the prototype. Ex. 2118 ¶¶ 18, 47; Ex. 2119 ¶¶ 23, 41. Both Mr. Root and Mr. Sutton attest that this testing was sufficient to confirm that the RX GuideLiner would work for its intended purpose, namely facilitating delivery of interventional cardiology devices into challenging coronary

anatomy by providing increased backup support as compared to a guide catheter alone. *Id.*

Patent Owner also presents other documentary evidence as corroboration of the testimony of inventors Mr. Root and Mr. Sutton. We have taken these documents into account, but find them somewhat less probative in showing actual reduction to practice.

For instance, a June 23, 2005, market feasibility memo (Ex. 2017), similar to the earlier memo from February 4, 2005 (Ex. 2003), confirms that the RX GuideLiner prototype was continuing to be developed, although the OTW version had been added to the development project at that point. Ex. 2118 ¶ 37; *see* Ex. 2017, 1 (noting that "it is possible to make the GuideLiner in an Over-the-Wire version, a Rapid Exchange version, or both").

A "Product Requirements" document, dated August 24, 2005, sets forth the safety and performance requirements for both the OTW and RX guide catheter support systems. Ex. 2118 ¶ 54; Ex. 2119 ¶ 44; Ex. 2024.[17] The document notes that "[t]hese safety and performance features are the minimal requirements for the device to be acceptable for its intended clinical use," and that the "[a]pplicable clinical use is for increase[d] guide catheter back-up support." Ex. 2024. Mr. Root asserts that this document marked the start of the formal quality process for the RX and OTW GuideLiner catheters. Ex. 2118 ¶ 54. Both Mr. Root and Mr. Sutton, as well as Ms.

[17] Exhibit 2024 is the subject of Petitioner's motion to exclude. Paper 111. For the reasons we state below in addressing the motion to exclude (*see* discussion, *infra*), we decline to exclude Exhibit 2024 but have considered Petitioner's arguments in determining the weight to be given to this piece of evidence.

Schmalz (VSI's Vice President of Regulatory and Clinical Affairs at the time), testify that that this document would have been created only after the product was tested, demonstrated to work, and ready to proceed with regulatory approval and commercialization. Ex. 2118 ¶ 54; Ex. 2119 ¶ 44; Ex. 2039 ¶ 7. Ms. Schmalz specifically recalls that a working prototype of the RX version was created prior to the creation of this document. Ex. 2039 ¶ 7. Although this document sets forth several user requirements for the device, it does not identify the product specifications and test methods correlating to those requirements. Ex. 2024, 2–4. The revision history of the document also indicates it is "pre-release," thereby suggesting that it may not have been finalized at the time. *Id.* at 4.

Mr. Root, Mr. Sutton, and Ms. Schmalz each also discuss two other documents both dated August 26, 2005—a Clinical Technical Report (Ex. 2025) and a staff meeting memo (Ex. 2040)—as further evidence that work continued on the RX GuideLiner and that VSI was ready to seek regulatory approval for the device from the Food and Drug Administration ("FDA"). Ex. 2039 ¶¶ 9–10; Ex 2118 ¶¶ 55– 57; Ex. 2119 ¶¶ 45–46. The Clinical Technical Report states that VSI "has developed, and is currently manufacturing four types of catheters . . . [including] the GuideLiner Catheter Support System used to provide physicians with additional guide catheter support allowing access to more difficult anatomy," and goes on to describe both the RX and OTW versions of GuideLiner. Ex. 2025, 2–3, 5–6. We note, however, that the text discussing GuideLiner devices appears to be "redline" edits and does not include any signatures for "document approvals," thus suggesting that the document submitted as Exhibit 2025 may have only been a draft. *See id.* The staff memo refers to clinical literature reviews for the GuideLiner devices (both RX and OTW), which

Mr. Root asserts was part of VSI's regulatory strategy for a "510(k)" submission to the FDA.[18] Ex. 2118 ¶ 57.

b) Analysis for Actual Reduction to Practice

To establish actual reduction to practice, Patent Owner must demonstrate two things: (1) that it constructed an embodiment that met all the limitations of the invention claimed in the patent at issue; and (2) that it determined that the invention would work for its intended purpose. *Cooper*, 154 F.3d at 1327. Having considered the evidence and arguments of record, including the testimonial and documentary evidence summarized above, we find that Patent Owner has met this burden with respect to the challenged claims based on the prototypes of the RX GuideLiner that were built and tested at VSI prior to September 2005. We address Petitioner's arguments to the contrary.

The first issue raised by Petitioner is whether there is sufficient corroborating documentary evidence to support the inventors' testimony on reduction to practice. As with conception, "a party seeking to prove an actual reduction to practice must proffer evidence corroborating [an inventor's] testimony." *Raytheon Co. v. Sony Corp.*, 727 F. App'x 662, 668 (Fed. Cir. 2018) (citing *Medichem*, 437 F.3d at 1169–71). The sufficiency of this corroboration is once again determined using a "rule of reason" analysis. *Id.*

[18] A 510(k) submission is a premarket notification "to demonstrate that the device to be marketed is as safe and effective, that is, substantially equivalent, to a legally marketed device." *See* FDA, Premarket Notification 510(k), (accessed June 1, 2021), https://www.fda.gov/medical-devices/premarket-submissions/premarket-notification-510k.

Petitioner contends that "[n]o document shows that VSI built, much less tested, RX prototypes." Pet. CRTP Reply 8. Petitioner points to the lack of photographs, assembly instructions, subassembly drawings, and notebook pages (other than Mr. Sutton's initial conception pages) to corroborate the work done on the RX prototype in 2005. *Id.* By contrast, Petitioner asserts that VSI kept more documents, including notes from Mr. Kauphusman (the VSI engineer who led the GuideLiner project), relating to the OTW prototypes from that time. *Id.* at 9–10 (citing Ex. 1760, 86–87). Petitioner also contends that Patent Owner cannot justify VSI's failure to retain these reduction-to-practice documents because it "runs contrary to federal law and industry practice." *Id.* at 11 (citing Ex. 1755 ¶¶ 66–74, 143–145). Among the documentary evidence presented, Petitioner contends that at most four documents relate to particular prototypes, and the rest are irrelevant insofar as they concern purchases of generic component parts untethered to particular projects or prototypes. *Id.* at 11–14. Petitioner further contends the documents do not show that VSI actually assembled the RX prototypes. *Id.* at 16–17.

We are not persuaded that the record lacks sufficient corroborating evidence of actual reduction to practice. "In order to corroborate a reduction to practice, it is not necessary to produce an actual over-the-shoulder observer. Rather, sufficient circumstantial evidence of an independent nature can satisfy the corroboration requirement." *Cooper*, 154 F.3d at 1330 (citing *Knorr v. Pearson*, 671 F.2d 1368, 1373 (CCPA 1982)). "Furthermore, an actual reduction to practice does not require corroboration for every factual issue contested by the parties." *Id.* (citing *Ethicon, Inc. v. U.S. Surgical Corp.*, 135 F.3d 1456, 1464 (Fed. Cir. 1998); *Mann v. Werner*, 347 F.2d 636, 640 (CCPA 1965) ("This court has rejected the notion that

each individual act in the reduction to practice of a count must be proved in detail by an unbroken chain of corroboration.")). Put another way, the law "does not require that evidence have a source independent of the inventors on every aspect of conception and reduction to practice; such a standard is the antithesis of the rule of reason." *E.I. du Pont De Nemours & Co. v. Unifrax I LLC*, 921 F.3d 1060, 1077 (Fed. Cir. 2019) (internal quotation omitted).

As discussed above, Mr. Root and Mr. Sutton each provide detailed and consistent testimony explaining the work done at VSI towards building and testing the April and July 2005 prototypes of the RX GuideLiner. Critical aspects of this testimony are corroborated by other (non-inventor) testimony from Ms. Schmalz (recounting the regulatory and quality process at VSI), Mr. Erb (recounting how they built early prototypes), Mr. Goemer (verifying purchases from SPECTRAlytics), and Ms. O'Neil (verifying purchases from MED). This testimony is further corroborated by a significant amount of documentary evidence, including purchase documents and engineering drawings, as set forth above. To the extent that there may have been other more detailed evidence with regard to the OTW GuideLiner, we do not find that such evidence detracts from or otherwise contradicts the evidence presented for the RX GuideLiner. Nor do we require Patent Owner to establish actual reduction to practice by retaining and then proffering the same type of documents that the FDA would have required Patent Owner to submit to gain approval of a medical device. *See* Ex. 1755, 63:20–64:9 (Dr. Zalesky acknowledging that "[t]he testing requirement for regulatory submission such as a 510(k) is quite extensive," and "a very significantly different level than that required to demonstrate reduction to practice.").

Petitioner contends that the purchased parts reflected in Patent Owner's documentary evidence could have been used for other VSI projects under development in 2005. Pet. CRTP Reply 12–16. We do not find that the evidence supports Petitioner's conjecture in this regard. For example, Petitioner cites the testimony of Dr. Zalesky to assert that the purchased hypotubing (and other parts) could have been used for VSI's Twin-Pass, Skyway, and Pronto V3 products, in addition to the OTW GuideLiner. *Id.* (citing Ex. 1755 ¶¶ 121–132, 153, 166, 203). But Dr. Zalesky does not point to any supporting evidence showing that these other VSI products used the same type of hypotubing as what would have been required for the RX GuideLiner. *See* Ex. 2237, 156:3–158:10, 173:10–174:12 (Dr. Zalesky admitting that he did not have any evidence that hypotubes were used in other products, but stating his opinion was based on "informed speculation" or "reasonable speculation"). Rather than Dr. Zalesky's speculation, we credit the testimony of Mr. Root, Mr. Sutton, and Mr. Erb, each of whom had first-hand involvement in the project and independently attest that at least some of the purchased hypotubes were specific for the RX GuideLiner. Ex. 2118 ¶ 23; Ex. 2119 ¶ 23; Ex. 2122 ¶ 7.

The corroborating documents confirm that the purchases were for the RX GuideLiner, not a general ledger expense suggesting that the parts could be used for other unrelated products. *See, e.g.*, Ex. 2005 (spend report for accounts related to "new modalities" and "Guideliner project"). The sole document Petitioner cites to posit that the purchased hypotubes could have been used for OTW devices is an engineering schematic that bears November 2005 and January 2006 dates, which were later than the April and July 2005 prototypes. Ex. 1763, 6. Furthermore, the hypotube shown in the OTW drawing differs in materials and dimensions from the hypotubes

purchased for the RX prototypes. The hypotube in the OTW drawing is nitinol and roughly 19 cm, quite different than the 100 cm stainless steel hypotubes used for the GuideLiner prototypes. *Id.* The 43-inch distal section in the OTW drawing also differs dramatically from the 11.8-inch distal section for the RX prototype. Ex. 2237, 164:24-167:19 (Dr. Zalesky agreeing that the distal portion shown in Exhibit 2089 is not the same as the distal portion of Exhibit 1763); *compare* Ex. 1763, 6, *with* Exs. 2089, and 2092.

With regard to whether the purchased components were actually assembled into an RX prototype, we find that the engineering schematic from August 2005 is strongly corroborative of an assembled device. Ex. 2022. Dr. Zalesky acknowledges that it "doesn't make a lot of sense" for VSI not to have assembled the purchased parts together. Ex. 2237, 208:10–25. A preponderance of the evidence supports the conclusion that the assembled RX prototypes met each of the limitations of the challenged claims, as set forth in the Appendices to Mr. Root's declaration. Ex. 2118, App'x A–E. In its Sur-Sur-Reply, Petitioner identifies certain claim limitations that were allegedly not met by the prototypes, but Petitioner does not point to any evidence to contradict Mr. Root's testimony on this point. Pet. CRTP Sur-Sur-Reply 14–15. We likewise find the charts included as Appendices to Dr. Zalesky's declaration to be insufficient in this regard. Ex. 1755, App'x A–E. Rather than identifying any specific technical reason why the prototype components reflected in the purchase documents could not have met the claim limitations, Dr. Zalesky's rebuttal claim charts appears to focus on whether there was sufficient corroborating evidence (which we have already discussed above). *Id.* As such, we find the evidence presented in this case to be more detailed than that found

insufficient in *Valencell, Inc. v. Fitbit, Inc.*, 784 F. App'x 1005, 1009 (Fed. Cir. 2019), cited by Petitioner. Reply 16. There, no evidence—testimonial or documentary—addressed key claims limitations, which stands in contrast to the detailed testimony and corroborating documents cited in Mr. Root's and Mr. Sutton's declarations.

Having found that Patent Owner constructed embodiments that met all limitations of the challenged claims, we move on to the second issue: whether Patent Owner demonstrated that those embodiments worked for the intended purpose of the invention.

We begin this inquiry by identifying the "intended purpose" of the invention. Patent Owner puts forth a broad intended purpose. Initially, Patent Owner asserted testing was done to show that the prototypes "could serve their intended purpose of being placed in a standard guide catheter and deliver interventional cardiology devices alongside the rail segment, into the side opening and distal tubular portion, and then out the distal end of the distal tubular portion and into challenging coronary anatomy." PO CRTP Resp. 25 (citing Ex. 2118 ¶¶ 17–18, 38, 47; Ex. 2119 ¶ 41; Ex. 2123 ¶¶ 20–24). In its Sur-Reply, Patent Owner clarifies that the intended purpose was "to increase backup support for delivery of interventional cardiology devices, including procedures involving tough or chronic total occlusions." PO CRTP Sur-Reply 9 (citing Exs. 2002, 2003, 2024). By contrast, Petitioner argues for a narrower intended purpose, asserting that the intended purpose was "providing backup support necessary for accessing and crossing tough or chronic occlusions." Pet. CRTP Reply 17 (citing Ex. 2002; Ex. 2118 ¶ 18; Ex. 2119 ¶ 9; Ex. 1762, 47:11–52:17). Citing Patent Owner's Sur-Reply, Petitioner contends that the parties ostensibly "agree" that the intended purpose was "to increase backup support for accessing and crossing

tough occlusions." Pet. CRTP Sur-Sur-Reply 7 (citing PO CRTP Sur-Reply 9); *see also* Tr. 49:3–12 ("Teleflex agrees the intended purpose was to increase back-up support for accessing and crossing tough or chronic total occlusions.").

We agree with Patent Owner's position on what constitutes the intended purpose of the invention. Petitioner is certainly correct that several of the documents we have considered refer to crossing "tough" or "chronic" occlusions when discussing the idea behind the invention. *See, e.g.*, Ex. 2002. But when considering all of the pertinent evidence, we find that the inventors were concerned with a broader primary purpose, namely generally providing improved backup support for a guide catheter, with crossing tough or total occlusions being one specific benefit or application of the device. In other words, we do not find that the RX GuideLiner had applicability only when there were tough or chronic occlusions in the artery that needed to be crossed. Indeed, the challenged patent itself recognizes this broader purpose when discussing the field and background of the invention. *See* Ex. 1001, 1:10–11 ("More particularly the present invention relates to methods and apparatus for increasing backup support for catheters inserted into the coronary arteries from the aorta."); *id.* at 2:45–49 ("Thus, the interventional cardiology art would benefit from the availability of a system that would be deliverable through standard guide catheters for providing backup support by providing the ability to effectively create deep seating of the coronary artery.").

The documentary evidence we have considered and discussed above further supports this broader intended purpose. For example, while Mr. Sutton's lab notebook expresses the idea for the GuideLiner device as "relat[ing] to interventional coronary procedures and specifically to

accessing & crossing tough or chronic total occlusions," it also more broadly notes that "[t]he idea is to provide a guide or support catheter more distally into the coronary to provide more back-up support for the stent device." Ex. 2002, 7. Mr. Sutton's lab notebook also contains two additional notes related to the invention: "Guide-Liner is used when there is difficulty crossing lesions"; and "Guide-Liner allows back-up support distally." *Id.* at 8. Similarly, in the February 4, 2005, Market Feasibility memo, Mr. Root describes the purpose of the RX GuideLiner as "provid[ing] the ability to create a deep seating of the guide for added support in the interventional procedure." Ex. 2003, 1. Mr. Root explains that "[b]y safely deep seating the guide catheter, the physician can then have the added support for pushing a wire through a chronic total occlusion or advancing a balloon or stent through a tight stenosis." *Id.* The August 24, 2005, Products Requirement document indicates the "[a]pplicable clinical use" for both the RX and OTW GuideLiners to be "increas[ing] guide catheter back-up support." Ex. 2024, 1.

Additionally, Patent Owner's expert's testimony supports this conclusion. Patent Owner's expert, Mr. Keith, declares that testing the RX GuideLiner prototypes would be sufficient for reduction to practice if the testing showed the prototype "(a) could be delivered through a guide catheter so that the distal end of the tubular portion extended beyond the distal end of the guide catheter while being tracked over a winding path; and (b) allowed a stent delivery catheter or balloon catheter to pass into the tubular portion and out the far end of the tubular portion while located within the guide catheter." Ex. 2123 ¶ 22.

The testimony of inventors Mr. Root and Mr. Sutton cited by the parties also supports this conclusion. Mr. Root declares that the intended

purpose of the RX GuideLiner was to "deliver interventional cardiology devices, such as a stent or balloon catheter, alongside the rail segment, into the side opening and distal tubular portion, and then out the distal end of the distal tubular portion and into challenging coronary anatomy." Ex. 2118 ¶ 18; *see also id.* ¶ 47 (describing the intended purpose as "facilitat[ing] the delivery of balloon catheters and stents deep into coronary arteries while providing increased backup support"). During Mr. Root's deposition, counsel for Petitioner inquired about Mr. Root's understanding of the intended purpose. Ex. 1762, 47:11–52:17. Mr. Root repeatedly stated that accessing and crossing tough or chronic occlusions was not the sole intended purpose. *Id.* at 47:11–20 (identifying that Petitioner's asserted intended purpose was "one of them" but "not all of them"), 50:10–12 ("The important thing is this is not just a chronic total occlusion device. This can apply to much broader coronary interventions."). Mr. Sutton's declaration quotes the purpose identified in his notes in his lab notebook, discussed above. Ex. 2119 ¶ 9 (quoting Ex. 2002, 7, 8). Mr. Sutton also declares that he and his team tested the prototypes qualitatively "to determine that [they] provided backup support," "to ensure that [stents and balloon catheters] could safely be delivered and would not snag or get caught on the device," and "to deliver interventional cardiology devices and provide additional backup support compared to the guide catheter alone." *Id.* ¶ 41.

In sum, the pertinent evidence demonstrates that the intended purpose of the claimed invention, as embodied in the RX GuideLiner, was to increase backup support for delivery of interventional cardiology devices. Although crossing tough or total occlusions is one noted benefit of the invention, we do not find it to be the only or primary purpose of the invention.

We next consider whether the testing conducted at VSI was sufficient to determine that the RX GuideLiner prototypes would work for the intended purpose of increasing backup support for delivery of interventional cardiology devices. "Depending on the character of the invention and the problem it solves, determining that the invention will work for its intended purpose may require testing." *Cooper*, 154 F.3d at 1327 (citing *Mahurkar v. C.R. Bard Inc.*, 79 F.3d 1572, 1578 (Fed. Cir. 1996)). "When testing is necessary, the embodiment relied upon as evidence of priority must actually work for its intended purpose." *Id.* (citing *Scott v. Finney*, 34 F.3d 1058, 1061 (Fed. Cir. 1994)). "The testing requirement depends on the particular facts of each case, with the court guided by a common sense approach in weighing the sufficiency of the testing." *Scott*, 34 F.3d at 1061 (citations omitted). "This common sense approach prescribes more scrupulous testing under circumstances approaching actual use conditions when the problem includes many uncertainties," but "permits little or no testing to show the soundness of the principles of operation of the invention" "when the problem to be solved does not present myriad variables." *Id.* at 1063. "In tests showing the invention's solution of a problem, the courts have not required commercial perfection nor absolute replication of the circumstances of the invention's ultimate use." *Id.* "[T]ests performed outside the intended environment can be sufficient to show reduction to practice if the testing conditions are sufficiently similar to those of the intended environment." *DSL Dynamic Scis. Ltd. v. Union Switch & Signal, Inc.*, 928 F.2d 1122, 1125 (Fed. Cir. 1991) (citing *Tomecek v. Stimpson*, 513 F.2d 614, 618 (CCPA 1975)). For medical device inventions, a showing of actual reduction to practice does not require human testing in actual use conditions. *Scott*, 34 F.3d at 1063 ("Testing for the full safety and effectiveness of a

prosthetic device is more properly left to the Food and Drug Administration (FDA). Title 35 does not demand that such human testing occur within the confines of Patent and Trademark Office (PTO) proceedings.").

Patent Owner relies on inventor and expert testimony, as well as documentary evidence, to establish that VSI's use of benchtop models was sufficient to test that the products were suitable for the intended purpose described above.[19] PO CRTP Resp. 11–12, 24–25. Mr. Root asserts that benchtop coronary models, as depicted in the July 2005 sales presentation, were commonly used at VSI and other medical device companies to test interventional cardiology catheters. Ex. 2118 ¶ 17 (citing Exs. 2018, 2129). Citing its expert's declaration, Patent Owner asserts that "[c]atheter inventions are routinely determined to work using benchtop models, and without human testing." PO CRTP Resp. 25 (citing Ex. 2123 ¶¶ 20–24; Ex. 1010). Applied to this invention, Patent Owner asserts its benchtop model emulated the cardiac anatomy, and was used to show that the RX GuideLiner could be "placed in a standard guide catheter and deliver interventional cardiology devices alongside the rail segment, into the side opening and distal tubular portion, and then out the distal end of the distal tubular portion and into challenging coronary anatomy." *Id.* (citing Ex. 2118 ¶¶ 17–18, 38, 47; Ex. 2119 ¶ 41; Ex. 2123 ¶¶ 20–24).

[19] Referring to Petitioner's expert's testimony regarding a person of ordinary skill in the art's knowledge pertaining Itou, Patent Owner also contends that no testing would have been required to know the RX GuideLiner would have worked for its intended purpose. *See* PO CRTP Sur-Reply 9 (citing Ex. 2116, 110:20–113:24; Ex. 2238, 87:18–89:5). Because we determine that the evidence demonstrates that testing in benchtop models was sufficient, we do not address this theory.

Petitioner's argument against Patent Owner's testing evidence depends on its narrower intended purpose, i.e., "using simulated tough lesions." Pet. CRTP Reply 18; *see also* Pet. CRTP Sur-Sur-Reply 7–9. In light of our rejection of the narrower intended purpose identified by Petitioner, we likewise reject Petitioner's argument that the testing evidence presented by Patent Owner is insufficient. Moreover, Petitioner acknowledges that benchtop models could have been used to test a device like the RX GuideLiner. Pet. CRTP Reply 17–18. The testimony of Mr. Root, Mr. Sutton, Mr. Erb, and Mr. Keith, corroborated by the photograph of the model in the sales presentation, confirm that VSI utilized benchtop coronary models that were considered the standard for testing interventional cardiology devices such as catheters. *See* Ex. 2018; Ex. 2118 ¶¶ 17, 38, 47; Ex. 2119 ¶¶ 23, 37–38, 41; Ex. 2122 ¶ 11; Ex. 2123 ¶¶ 21–24. We consider this benchtop testing to be similar to the "countertop" testing that was found sufficient to show actual reduction to practice in *Mahurkar*. *See Mahurkar*, 79 F.3d at 1578 (determining for claims related to a double lumen catheter that flow and pressure drop tests conducted in the inventor's kitchen, using glycerine to simulate blood, was sufficient for actual reduction to practice because they "showed, to the limit of their design, the utility of the claimed invention"). As noted by Petitioner, Mr. Root indicated during his deposition that to reduce to practice, VSI needed to "(1) navigate RX through a guide catheter and out its distal end in a benchtop model, (2) deliver an interventional cardiology device, and (3) retrieve RX in one piece." Pet. CRTP Reply 18 (citing Ex. 1762, 100:1–102:3). We find that the "pull tests" done using the benchtop models demonstrated that the RX GuideLiner was capable of accomplishing at least this much, even if the tests were not conducted in an *in vivo* or *in vitro* environment that simulated

tough lesions. Ex. 2118 ¶¶ 17, 38, 47. This is not a situation where there were significant variables or uncertainties that needed to be assessed in order to determine whether the RX device would work properly, and thus the "qualitative" testing done by VSI using the benchtop models was sufficient. Ex. 2119 ¶ 41; Ex. 2123 ¶¶ 21–22. Accordingly, a preponderance of the evidence supports the conclusion that the testing done at VSI demonstrated that the RX GuideLiner would work for its intended purpose.

In our assessment of whether there was actual reduction to practice prior to the critical date, we have considered Petitioner's argument that the GuideLiner project was still in "early-stage concept development" in mid-to-late 2005, and that VSI was still experimenting in 2006 and did not have a working prototype even by 2008. Pet. CRTP Reply 22–27.

In support of this argument, Petitioner points to continuing changes to the RX design as evidence that the design was not completed before the critical date. *Id.* For example, a July 2005 Research & Development ("R&D") Update notes that "[t]he initial design is an over-the-wire configuration, with a rapid exchange version to follow." Ex. 2130, 3.[20] In contrast to the incomplete August 2005 Product Requirements document relied upon by Patent Owner (Ex. 2024), Petitioner contends that the official, completed version of the Product Requirements document for the

[20] We recognize that this document appears to contradict Mr. Root's recollection that the original idea was for the RX GuideLiner, and that the decision was later made to concurrently pursue development of the OTW version. Ex. 2118 ¶ 19. We do not find the issue of whether the initial idea was for the RX version or the OTW version to be material to our analysis on reduction to practice. Nonetheless, we note Mr. Sutton's original notebook pages suggest that the original idea was indeed for the RX version rather than the OTW version. Ex. 2002.

GuideLiner project was not created until April 2009. Ex. 1767. A "2006 Strategic Objectives" document, dated December 1, 2005, indicates that the "rapid exchange requires additional engineering and is not included in our 2006 forecasts." Ex. 2131, 10. Likewise, Petitioner points to a GuideLiner team meeting memo from May 2, 2006, that includes as agenda items "1) Review Initial Design and Intended Use," and "2) Determine what can be completed/started prior to design lock." Ex. 2109. According to another document, a "design freeze" for the GuideLiner device was expected to only take place May 30, 2007. Ex. 1769, 1. Indeed, an R&D update from July 2008 notes with respect to the GuideLiner device:

> Throughout this project, timelines have been pushed out due to drastic design changes and resource constraints. To date we have prototyped and tested a new design. This new design is more robust and cost effective. We are planning on an August 2008 design freeze with a 510k submission in November 2008.

Ex. 2132, 7.

We have taken the foregoing evidence into account, but do not find that it detracts from Patent Owner's evidence concerning reduction to practice based on building and testing the April and July 2005 prototypes discussed above. To be sure, the post-critical date documents highlighted by Petitioner make it is clear that significant design revisions for the RX GuideLiner continued well into 2008, and these additional design changes may well have been required for FDA regulatory approval and/or commercialization of the device. Indeed, Patent Owner's declarants attest that additional engineering work was conducted to refine the product for regulatory purposes and commercialization. *See* Ex. 2118 ¶ 59 (Mr. Root attesting that "[f]rom September of 2005 forward, I and others at VSI continued to act diligently to bring the rapid exchange GuideLiner to

market."); Ex. 2119 ¶ 44 (Mr. Sutton attesting that, after the August 24, 2005, Product Requirements document, "we continued to refine prototypes of the GuideLiner Rapid Exchange for purposes of manufacturability and commercialization"); Ex. 2122 ¶ 13 (Mr. Erb attesting that work continued on "develop[ing] manufacturing processes that were reproducible and a refined design that was able to be commercialized"). But we see no basis to conclude that these additional engineering and design changes were an indication that the April and July 2005 prototypes failed to demonstrate that the RX GuideLiner was capable of achieving increased backup support.

Ultimately, the RX GuideLiner was not commercialized until 2009, which we recognize is far later than the initial projected timeframe of late 2005/early 2006 and the date of actual reduction to practice. Ex. 2118 ¶ 89. Mr. Root asserts that one reason for this delay was due to turnover in R&D personnel. *Id.* Under the circumstances, we do not find that the additional engineering and design work done with respect to the RX GuideLiner to achieve regulatory approval and commercialization indicates a lack of actual reduction to practice prior to the critical date. *See Loral Fairchild Corp. v. Matsushita Elec.*, 266 F.3d 1358, 1362–63 (Fed. Cir. 2001) ("Once the invention has been shown to work for its intended purpose, reduction to practice is complete. Further efforts to commercialize the invention are simply not relevant to determining whether a reference qualifies as prior art against the patented invention.").

In sum, we find that Patent Owner has demonstrated actual reduction to practice prior to Itou's critical date by a preponderance of the evidence based on the work done at VSI in building and testing the April and July 2005 prototypes of the RX GuideLiner. Nonetheless, to the extent that this evidence is not sufficient for actual reduction to practice, we find that it

demonstrates at least conception of the claimed invention prior to the critical date.

4. Constructive Reduction to Practice

In addition to asserting actual reduction to practice, Patent Owner alternatively relies upon a theory of constructive reduction to practice. Antedating based on this theory would require Patent Owner to demonstrate diligence from just before the date Itou was filed until the date Patent Owner filed its priority application for the GuideLiner patents,[21] i.e., from September 23, 2005, to May 3, 2006. *See Perfect Surgical Techniques, Inc. v. Olympus Am., Inc.*, 841 F.3d 1004, 1007 (Fed. Cir. 2016) (requiring diligence for the "entire critical period, which begins just prior to the competing reference's effective date and ends on the date of the invention's reduction to practice").

To demonstrate diligence, Patent Owner again relies on testimony from its inventor and non-inventor declarants, as well as correspondences with VSI's outside patent counsel at the Patterson Law Firm and documents reflecting further engineering and development work done during this period. PO CRTP Resp. 18–19; PO CRTP Sur-Reply 12.

According to Mr. Root, following the initial conception and the building of the April and July 2005 prototypes, he and others at VSI continued working, from September 2005 onward, to bring the RX GuideLiner to market. Ex. 2118 ¶ 59. This project was one of VSI's primary development initiatives at the time, and they worked on it

[21] We use term "GuideLiner patents," in the same manner as the parties' declarants, to refer to the patents challenged in IPR2020-00126, -00128, -00129, -00132, -00134, -00135, and -00137. *See, e.g.*, Ex. 2118 ¶ 1; Ex. 2119 ¶¶ 1, 3; Ex. 2123 ¶ 1.

continuously until they brought it to market in 2009. *Id.*; *see id.* ¶ 89. Thus, they worked continuously at least until the May 3, 2006, application date. *Id.* ¶ 76. Ms. Schmalz likewise testifies that "[a]t no time between the start of the regulatory process for GuideLiner in August of 2005 and the filing of the patent application in May 2006 was the rapid exchange GuideLiner project abandoned or paused." Ex. 2039 ¶ 12.

Mr. Sutton sent a fax to the Patterson Law Firm on March 21, 2006, which includes drawings that are similar to the proximal portion of the RX GuideLiner depicted in Exhibit 2114. Ex. 2118 ¶ 42 (citing Ex. 2019). The firm also possessed the August 1, 2005, CAD drawing of a complete RX GuideLiner prototype. *Id.* ¶¶ 49–50 (citing Ex. 2022).

Upon Mr. Root's request, the firm opened a matter to conduct a patentability search for the GuideLiner on August 11, 2005. *Id.* ¶ 52 (citing Ex. 2023). Mr. Root provided the firm with the full prototype drawing in Exhibit 2022 to conduct the search. *Id.* Mr. Root testifies that he would not engage in freedom-to-operate searching until after he had made a full prototype that was shown to work for its intended purpose and ready to move forward to commercialization. *Id.* An invoice from the firm demonstrates work performed for a "patent search for guide liner" in August 2005. *Id.* ¶ 53 (citing Ex. 2096).

In his declaration, Mr. Root then sets forth the timeline of events with documentary and circumstantial evidence during the critical period for diligence, i.e. from September 23, 2005, to May 3, 2006.

For September 2005, Mr. Root refers to invoices dated September 7, 2005, and a check for forming tips that would have been used for the distal tip of the GuideLiner prototype. *Id.* ¶ 60 (citing Ex. 2097). He refers to these documents to demonstrate that VSI was continuing to refine the

prototypes during this period. Mr. Root also refers to a copy of the Patterson Law Firm's privilege log showing that a partner of the firm sent Mr. Root a confidential letter dated September 14, 2005, pertaining to prior art related to the GuideLiner. *Id.* ¶ 61 (citing Ex. 2098).

For October 2005, Mr. Root refers to a business update presented to VSI's Board of Directors during its October 2005 meeting. *Id.* ¶ 62 (citing Exs. 2041 (confidential), 2133 (public)). Mr. Root declares this update included extremely favorable reviews of the RX GuideLiner from VSI's physician advisors. *Id.* Mr. Root further declares the update included projected timelines for regulatory filings, with intentions to file in the end of 2005 for OTW and early 2006 for RX. *Id.* Mr. Root also refers to the matter the Patterson Law Firm opened this month for work leading towards the initial GuideLiner patent application. *Id.* (citing Ex. 2023).

For November 2005, Mr. Root declares that VSI continued refining the proximal portion of the RX GuideLiner. *Id.* ¶ 63. Mr. Root refers to engineering drawings obtained from SPECTRAlytics, including one dated November 2005, which closely resembles Figure 10 of the GuideLiner patents. *Id.* (citing Ex. 2115). Mr. Root also refers to a VSI R&D planning document for 2006, which was drafted by Mr. Sutton on November 22, 2005. *Id.* ¶ 64 (citing Ex. 2099). The planning document demonstrates VSI's intent, as of late November 2005, to continue with the regulatory approval process for the RX GuideLiner in 2006. *Id.*

For December 2005, Mr. Root refers to a VSI Strategic Objectives document for 2006, which was drafted on December 1, 2005. *Id.* ¶ 65 (citing Ex. 2100). The document indicates that the RX GuideLiner required additional work for commercialization, which would continue through the end of 2006. *Id.* Mr. Root also refers to an invoice from the Patterson Law

Firm, which shows the time invested in preparing the GuideLiner patent application during December 2005. *Id.* ¶ 66 (citing Ex. 2117).

For January 2006, Mr. Root refers to another invoice from the Patterson Law Firm, which shows time invested in preparing the GuideLiner patent application during January 2006. *Id.* (citing Ex. 2101). Mr. Root also refers to a fax sent from Mr. Sutton to the law firm on January 23, 2006. *Id.* ¶ 67 (citing Ex. 2102). The fax contains three figures that illustrate examples of the problem to be solved by the RX GuideLiner, and which are nearly identical to Figures 7, 8, and 9 of the GuideLiner patents. *Id.*

For March 2006, Mr. Root refers to a Patterson Law Firm invoice showing time invested in preparing the GuideLiner patent application during March 2006. *Id.* ¶ 68 (citing Ex. 2103). Mr. Root also refers to purchase records for stainless steel tubing from Vita Needle Company on March 24, 2006. *Id.* ¶ 69 (citing Ex. 2104). Mr. Root declares that VSI used this tubing to refine the RX GuideLiner for commercialization. *Id.* Mr. Root also refers to a March 30, 2006, engineering drawing from SPECTRAlytics's files. *Id.* ¶ 70 (citing Ex. 2115). The drawing, which is similar to the photographs of RX GuideLiner prototypes depicted in Exhibit 2014, shows VSI's attempt to reduce manufacturing costs by cutting two proximal portions from a single hypotube. *Id.*

For April 2006, Mr. Root refers to a Budget to Actual Variances report provided to the VSI Board of Directors for its April 2006 meeting. *Id.* ¶ 71 (citing Ex. 2105). The report shows GuideLiner R&D expenses by that time had been more than double the amount that was budgeted. *Id.*
Mr. Root refers to purchase records for laser-cut and electropolished GuideLiner hypotubes from LSA, with an invoice dated April 7, 2006. *Id.* ¶ 72 (citing Ex. 2106). These hypotubes were used to refine the RX

GuideLiner during commercialization. *Id.* Mr. Root refers to purchase records for twenty hypotubes from MicroGroup, with an invoice dated April 18, 2006. *Id.* ¶ 73 (citing Ex. 2107). These hypotubes were used to refine the RX GuideLiner during commercialization. *Id.* Mr. Root refers to other purchase records, including an April 19, 2006, invoice for cut GuideLiner hypotubes from LSA, which were used to commercialize the RX GuideLiner. *Id.* ¶ 74 (citing Ex. 2108).

For May 2006, other than the filing of the application on May 3, 2006, Mr. Root refers to notes from a GuideLiner team meeting held May 2, 2006, which confirm they were still working towards commercializing the RX GuideLiner. *Id.* ¶ 75 (citing Ex. 2109).

Mr. Sutton's diligence timeline, including the documents he refers to, largely matches Mr. Root's. For essentially the same reasons as Mr. Root, Mr. Sutton refers to: the drawing of the fully-assembled RX GuideLiner, Ex. 2119 ¶ 39 (citing Ex. 2022); his fax sent March 21, 2006, to the Patterson Law Firm, including the drawings similar to Figures 12 through 16 of the patents, *id.* ¶ 40 (citing Ex. 2019); his fax sent on January 23, 2006, to the Patterson Law Firm, which contains three figures that illustrate examples of the GuideLiner situated in the aorta, which are nearly identical to Figures 7, 8, and 9 of the GuideLiner patents, *id.* ¶ 42 (citing Ex. 2102); the VSI R&D planning document for 2006, dated November 22, 2005, *id.* ¶ 48 (citing Ex. 2099); the VSI marketing document dated December 1, 2005, *id.* ¶ 49 (citing Ex. 2100); the Vita Needle purchase records for stainless steel hypotubes shipped on March 24, 2006, which were used for the RX GuideLiners, *id.* ¶ 51 (citing Ex. 2104); and the April 2006 VSI budget report, indicating expenses on commercializing the RX GuideLiner more than doubled the amount VSI budgeted, *id.* ¶ 52 (citing Ex. 2105). Mr.

Sutton also refers to the January 2006 R&D Update that he prepared for the VSI Board of Directors, *id.* ¶ 50 (citing Ex. 2134). In that update, Mr. Sutton reported to VSI's Board that both GuideLiner projects were still planned, with OTW regulatory filings next up at the time. *Id.*

In addition to testimony from inventors Mr. Root and Mr. Sutton, Patent Owner also points to testimony from Ms. Schmalz, Mr. Erb, and Mr. Keith. Ms. Schmalz declares that, from "the start of the regulatory process for GuideLiner in August of 2005 and the filing of the patent application in May 2006," the RX GuideLiner "was always a high priority project during [her] time at VSI" and was never "abandoned or paused." Ex. 2039 ¶ 12. Mr. Erb declares that VSI was "continually working to optimize the design" of the RX GuideLiner for commercialization. Ex. 2122 ¶ 13. As an example, he recalls the weighing of advantages and disadvantages between stainless steel and nitinol for the proximal portion during the commercialization stage. *Id.* ¶ 14. Mr. Keith explains his understanding that further commercialization work was performed after August 2005. Ex. 2123 ¶¶ 25–27.

Patent Owner contends that the evidence it relies on to prove conception and reduction to practice shows that "VSI worked steadily on the GuideLiner invention from conception through the date the patent was filed." PO CRTP Resp. 28 (citing *id.* at 3–19). Patent Owner acknowledges that it took more time and resources than anticipated, but that this delay should have "no bearing whatsoever on the [diligence] analysis." *Id.* at 28–29.

Petitioner argues Patent Owner's response "does not contain any detail showing diligence." Pet. CRTP Reply 28. Petitioner deems the "handful" of events identified by Patent Owner during the critical period—

opening a patent application file, working on the patent application, exchanging emails, and buying parts—to be insufficient evidence of diligence. *Id.* at 28–29. It appears from Petitioner's visual timeline of Patent Owner's events that two periods in particular allegedly represent a lack of diligence: from September 23, 2005, to the end of November 2005, during which there was only a component design change; and the month of February 2006, during which there were no diligence-related events. *Id.* at 28 (citing Ex. 2115). Petitioner also faults Patent Owner's delay in regulatory submissions for the RX GuideLiner, which were initially planned for late 2005 and 2006 but were postponed until 2008. *Id.* (citing Ex. 1762, 131:3–133:3; Ex. 2132, 7).

When evaluating diligence, we are mindful of recent Federal Circuit admonitions clarifying that we must not apply a standard that is "too exacting" or "too rigid." *Perfect Surgical*, 841 F.3d at 1008; *Arctic Cat*, 919 F.3d at 1331. Though "periods of inactivity within the critical period do not automatically vanquish a patent owner's claim of reasonable diligence," *Arctic Cat*, 919 F.3d at 1331, "[m]erely asserting diligence is not enough" and a party must "account for the entire period during which diligence is required." *In re Meyer Mfg. Corp.*, 411 F. App'x 316, 320 (Fed. Cir. 2010). "[D]iligence need not be perfectly continuous—only *reasonably* continuous." *Arctic Cat*, 919 F.3d at 1331. The key question for diligence is whether, "in light of the evidence as a whole, the invention was not abandoned or unreasonably delayed." *Id.* (internal quotations omitted). Applying this standard, we conclude that Patent Owner sufficiently demonstrates reasonably continuous diligence throughout the critical period.

The evidence demonstrates that Patent Owner did not unreasonably delay the RX GuideLiner project. As both parties acknowledge, there were

indeed delays in the project. Petitioner asserts "VSI prioritized *other projects* in late 2005 and 2006 and postponed RX regulatory submissions through 2008." Pet. CRTP Reply 29 (citing Ex. 1762, 131:3–133:3; Ex. 2132, 7) (emphasis in original). But the cited portion of Mr. Root's deposition testimony sufficiently explains why the delay was reasonable under the circumstances. As noted by Mr. Root, OTW GuideLiner regulatory submissions came first "[b]ecause it was much easier to get regulatory approval and do the testing." Ex. 1762, 131:3–8. "[T]ransition in personnel" also complicated the project. *Id.* at 131:12–17. And as for the RX, Mr. Root explained that commercialization took longer due to "vendor optimization," *id.*, 132:25–133:9, which tracks the greater difficulty associated with bringing the RX GuideLiner to market. Ms. Schmalz further corroborates this explanation with her declaration that RX GuideLiner "was always a high priority project during [her] time at VSI." Ex. 2039 ¶ 12.

Nor does it appear that Patent Owner abandoned the RX GuideLiner invention. For one thing, Patent Owner engaged counsel to prepare its GuideLiner patent application, which was ultimately filed on May 3, 2006. The Patterson Law Firm opened a patent search on August 11, 2005 (Ex. 2023, 5) then reported the results to VSI on September 14, 2005 (Ex. 2098, 2). On October 10, 2005, the firm opened a patent prosecution matter for the GuideLiner. Ex. 2023, 5. There is evidence in the record of the firm working on preparing the application in December 2005 (Ex. 2117, 20), January 2006 (Ex. 2102, 7), and March 2006 (Ex. 2103, 6). There is also evidence of communications between the firm and VSI, namely Mr. Root and Mr. Sutton, in January 2006 and March 2006. Ex. 2102; Ex. 2098, 4; Ex. 2019. To be sure, there is not an abundance of documents in the record related to preparing the application, including drafts of the specification and

claims, but Patent Owner clarified at oral argument that it lacks many documents due to the passage of time, not the refusal to waive attorney-client privilege. Tr. 64:8–21. A lack of documents due to the passage of time does not foreclose sufficient corroboration. *See, e.g.*, *NFC Tech., LLC v. Matal*, 871 F.3d 1367, 1374 (Fed. Cir. 2017) (concluding there was sufficient corroboration of conception based on circumstantial evidence, "particularly considering the amount of time that ha[d] passed").

Moreover, the other documents Patent Owner proffers provide additional circumstantial evidence that VSI was working on and did not abandon the RX GuideLiner project throughout this time. Petitioner again faults Patent Owner for not providing direct evidence. Pet. CRTP Reply 28 (pointing out lack of events "related to actual work on an RX device"); *id.* at 29 (arguing Patent Owner "cannot tie the component parts purchases to RX"). But, as we noted above, direct evidence is not required for adequate corroboration. Internal VSI documents, such as updates for VSI's Board and budget documents, show that work on the RX project continued from October 2005 through April 2006. Ex. 2133, 4, 7; Ex. 2099; Ex. 2100, 8–9; Ex. 2105, 4–5. Additionally, there are invoices related to supplies that support the testimony of inventors Mr. Root and Mr. Sutton regarding continued work on the RX GuideLiner in March 2006 and April 2006. Ex. 2104; Ex. 2005, 5; Ex. 2115; Ex. 2106, 3; Ex. 2107; Ex. 2108, 4–5. All of this evidence corroborates Mr. Root's and Mr. Sutton's testimony that VSI worked diligently and continuously on the RX GuideLiner project without abandoning the project.

Finally, we are not convinced that the periods from September 23, 2005, to the end of November 2005 or in February 2006 demonstrate lack of diligence. Petitioner's argument for these periods is conclusory, and

contradicted by the reasonable commercialization delays that we addressed above.

Considering all of the pertinent evidence, we find that Patent Owner did not abandon or unreasonably delay the RX GuideLiner project during the critical period. Petitioner's arguments implying the need for direct evidence and scouring the timeline for periods of inactivity are unpersuasive. We therefore conclude that Patent Owner demonstrates, by a preponderance of the evidence, that VSI was reasonably continuous in its diligence during the critical period. Because we have also found that Patent Owner demonstrated conception prior to Itou's critical date, Patent Owner has met its burden to successfully demonstrate that Itou is not prior art to the challenged claims of the '760 patent.

E. Challenges Based on Itou

Petitioner contends: i) claims 25–31, 33–38, 41, 42, 44, and 47 are anticipated by Itou (Pet. 19–56); ii) claims 25, 30, 32, 39, and 40 would have been obvious over Itou and Ressemann (*id.* at 56–73); iii) claim 32 would have been obvious over Itou and Kataishi (*id.* at 73–79); and iv) claim 32 would have been obvious over Itou and Enger (*id.* at 79–83). Because Itou is not prior art to the '760 patent, Petitioner's challenges based on Itou are not persuasive. Accordingly, Petitioner has not demonstrated by preponderance of the evidence that claims 25–42, 44, and 47 are unpatentable over the Itou-based grounds asserted in the Petition.

III. CONTINGENT MOTION TO AMEND

Patent Owner's Motion to Amend requests that if any of issued claims 37, 38, 39, 48, or 51 of the '760 patent are determined to be unpatentable, that the Board substitute those claims with proposed substitute claims 54–

58. Paper 38, 1. Claims 48 and 51 are not challenged in this proceeding. 35 U.S.C. § 316(d) does not permit a patent owner to cancel or propose substitute claims for unchallenged claims. 35 U.S.C. § 316(d)(1)(B) (motion to amend may "[f]or each challenged claim, propose a reasonable number of substitute claims"). Thus, we do not consider proposed substitute claims 57 and 58 that correspond to unchallenged claims 48 and 51, respectively.[22]

Because we do not find any of the challenged claims 37, 38, and 39 unpatentable in this proceeding, we do not reach the merits of the Motion to Amend with regard to proposed substitute claims 54, 55, and 56 that correspond to challenged claims 37, 38, and 39, respectively.

IV. CONSTITUTIONAL CHALLENGE

Patent Owner argues that the Petition should be denied because "the manner in which administrative law judges are appointed is unconstitutional." PO Resp. 68 (citing *Arthrex, Inc. v. Smith & Nephew, Inc*., 941 F.3d 1320, 1325 (Fed. Cir. 2019)). Patent Owner further argues that the remedy in the *Arthrex* decision "severing certain removal protections, is insufficient to cure the constitutional defect, because, e.g., it still does not give a properly appointed principle office the power to review administrative law judge decisions." *Id.* (citing *Lucia v. SEC*, 138 S. Ct. 2044, 2055 (2018)). We decline to consider Patent Owner's constitutional argument because the Federal Circuit addressed this issue in *Arthrex*. *Arthrex*, 941 F.3d at 1328.

[22] Patent Owner's Motion to Amend with respect to claims 48 and 51 is addressed in IPR2020-00134, a proceeding in which Petitioner challenges claims 48 and 51.

V. MOTION TO EXCLUDE

Petitioner has moved to exclude Exhibit 2024, which is the August 24, 2005 Product Requirements document. Paper 109. Petitioner contends that Exhibit 2024 is unreliable on its face and that none of Patent Owner's witnesses can authenticate the document. *Id.* at 2–9. Patent Owner responds that Exhibit 2024 is authenticated under Federal Rule of Evidence 901 based on the declaration and/or deposition testimony of Mr. Peters (Ex. 1926 ¶ 18), Ms. Schmalz (Ex. 2039 ¶¶ 6–7), Mr. Root (Ex. 2118 ¶ 54), and Mr. Sutton (Ex. 2119 ¶ 44). Paper 115.

Documents are authenticated by evidence "sufficient to support a finding that the item is what the proponent claims it is." Fed. R. Evid. 901(a); *see Fox Factory v. SRAM, LLC*, IPR2016-01876, Paper 59 at 63 (PTAB Apr. 2, 2018) (quoting same). "Authenticity is, therefore, not an especially high hurdle for a party to overcome." *Fox Factory*, Paper 59 at 63 (citing *United States v. Patterson*, 277 F.3d 709, 713 (4th Cir. 2002)

We determine that Exhibit 2024 has been authenticated under the low bar required under Federal Rule of Evidence 901. In addition, Petitioner's arguments go to the weight of the evidence and not its admissibility. Accordingly, we deny Petitioner's Motion to Exclude. We note, however, that even if we were to exclude Exhibit 2024, it would not change the outcome or our general analysis of this case.

VI. CONCLUSION

After reviewing the arguments and evidence of record, we determine that Petitioner has not demonstrated by a preponderance of the evidence that claims 25–42, 44, and 47 of the '760 patent are unpatentable.

In summary:

Claims	35 U.S.C. §	Reference(s)/Basis	Claims Shown Unpatentable	Claims Not Shown Unpatentable
25–31, 33–38, 41, 42, 44, 47	102	Itou		25–31, 33–38, 41, 42, 44, 47
25, 30, 32, 39, 40	103	Itou, Ressemann		25, 30, 32, 39, 40
32	103	Itou, Kataishi		32
32	103	Itou, Enger		32
Overall Outcome				25–42, 44, 47

The table below summarizes our conclusions as to Patent Owner's Revised Motion to Amend the claims.

Motion to Amend Outcome	Claim(s)
Original Claims Cancelled by Amendment	
Substitute Claims Proposed in the Amendment	54–58
Substitute Claims: Motion to Amend Granted	
Substitute Claims: Motion to Amend Denied	
Substitute Claims: Not Reached	54–58

VII. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that claims 25–42, 44, and 47 have not been shown to be unpatentable;

FURTHER ORDERED that we do not reach Patent Owner's Contingent Motion to Amend;

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

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

FOR PETITIONER:

Cyrus Morton
Sharon Roberg-Perez
Christopher Pinahs
William E. Manske
Emily J. Tremblay
ROBINS KAPLAN LLP
cmorton@robinskaplan.com
sroberg-perez@robinskaplan.com
cpinahs@robinskaplan.com
wmanske@robinskaplan.com
etremblay@robinskaplan.com

FOR PATENT OWNER:

Derek Vandenburgh
Dennis Bremer
CARLSON, CASPERS, VANDENBURGH & LINDQUIST, P.A.
dvandenburgh@carlsoncaspers.com
dbremer@carlsoncaspers.com

Trials@uspto.gov
571-272-7822

Paper 126
Date: June 7, 2021

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.

IPR2020-00135
Patent RE45,776 E

Before SHERIDAN K. SNEDDEN, JON B. TORNQUIST, and CHRISTOPHER G. PAULRAJ, *Administrative Patent Judges.*

PAULRAJ, *Administrative Patent Judge*.

JUDGMENT
Final Written Decision
Determining No Challenged Claims Unpatentable
No Deciding Patent Owner's Contingent Motion to Amend
35 U.S.C. § 318(a)

ORDER
Denying Petitioner's Motion to Exclude (Paper 110)
37 C.F.R. § 42.64(c)

I. INTRODUCTION

A. Background and Summary

This is our Final Written Decision entered pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73. For the reasons explained in our analysis below, we determine that the primary reference relied upon by Petitioner for all its patentability challenges does not qualify as prior art because Patent Owner has antedated that reference. Thus, Petitioner has not demonstrated that any of the challenged claims are unpatentable in this proceeding.

On November 14, 2019, Medtronic, Inc. and Medtronic Vascular, Inc. (collectively, "Petitioner") filed a Petition requesting an *inter partes* review of claims 25–27, 29–33, 35–39, 41–49, and 52–56 of U.S. Patent No. RE45,776 E ("the '776 patent," Ex. 1001). Paper 1 ("Pet."). Teleflex Innovations S.À.R.L. ("Patent Owner")[1] filed a Preliminary Response. Papers 8 (confidential version), 9 (redacted version). In our Institution Decision, we determined that there was a reasonable likelihood that Petitioner would prevail with respect to at least one challenged claim and accordingly, instituted an *inter partes* review pursuant to 35 U.S.C. § 314 based on all challenges presented in the Petition. Paper 22 ("Institution Decision" or "Inst. Dec.").

Following institution, Patent Owner filed two post-institution responses: (1) a Consolidated Response Addressing Conception and Reduction to Practice (Paper 39 ("PO CRTP Response" or "PO CRTP

[1] Patent Owner represents that "Teleflex Innovations S.A.R.L. merged into Teleflex Medical Devices S.A.R.L," which subsequently "transferred ownership of [the '776 patent] to Teleflex Life Sciences Limited." Paper 7, 2.

Resp.")) and (2) a post-institution Response addressing Petitioner's anticipation and obviousness arguments (Papers 43 (confidential version), 44 (redacted version) ("PO Resp.")).

Petitioner filed a Reply to Patent Owner's Response Addressing Conception and Reduction to Practice (Papers 78 (confidential version), 79 (redacted version) ("Pet. CRTP Reply")) and a Reply to Patent Owner's Response (Papers 82 (confidential version), 83 (redacted version) ("Reply")). Patent Owner then filed its post-institution Sur-Reply Addressing Conception and Reduction to Practice (Paper 96, "PO CRTP Sur-Reply"), and Petitioner filed its post-institution Sur-Reply Addressing Conception and Reduction to Practice (Paper 111 ("Pet. CRTP Sur-Sur-Reply")). Patent Owner also filed a post-institution Sur-Reply to Petitioner's Reply to Patent Owner's Response (Papers 102 (confidential version), 103 (redacted version) ("PO Sur-Reply")).

Patent Owner also filed a Contingent Motion to Amend. Papers 38 (original), 95 (corrected) ("Motion").[2] The Motion requests that if any of claims 27, 33, 37, 42, 43, 45, 47, or 56 is found unpatentable, they should be replaced by proposed substitute claims 58–65. Motion 1. Petitioner filed an Opposition to the Motion to Amend. Paper 101. Patent Owner filed a Reply in Support of the Corrected Motion to Amend (Paper 105), and Petitioner filed a Sur-Reply (Paper 113).

[2] Pursuant to a stipulation by the parties, we authorized the filing of the corrected Motion to Amend in order to clarify certain antecedent bases and thereby simplify the issues.

An oral hearing was held on March 8, 2021, and a transcript of the hearing is included in the record. Papers 124 (redacted version) ("Tr."), 125 (confidential version).

B. Real Parties-in-Interest

Petitioner identifies Medtronic, Inc. and Medtronic Vascular, Inc. as the real parties-in-interest, and notes that "Medtronic plc is the ultimate parent of both entities." Pet. 5. Patent Owner identifies the real parties-in-interest for itself as Teleflex Medical Devices S.À.R.L., Vascular Solutions LLC, Arrow International, Inc., Teleflex LLC, and Teleflex Life Sciences Limited and notes that "Teleflex Incorporated is the ultimate parent of the entities listed above." Paper 4, 2; Paper 7, 2.

C. Related Matters

Patent Owner is asserting the '776 patent against Petitioner in the United States District Court for the District of Minnesota in *Vascular Solutions LLC, et al. v. Medtronic, Inc., et al.*, No. 19-cv-01760 ((D. Minn., filed July 2, 2019). Pet. 5; Paper 4, 2. The '776 patent is also the subject of a declaratory judgement action filed by another party, *QXMedical, LLC v. Vascular Solutions, LLC*, No. 17-cv-01969 (D. Minn., filed June 8, 2017), which was stayed pending our Institution Decision. Paper 19; Paper 20. Petitioner further notes that the '776 patent is a reissue of U.S. Patent No. 8,292,850 ("'850 patent"), which was the subject of a prior district court action and *inter partes* reviews in IPR2014-00762 and IPR2014-00763 filed by a different petitioner. Pet. 5.

Petitioner filed another petition challenging the '776 patent based on different prior art, and we instituted *inter partes* review on that petition on June 26, 2020. *See* IPR2020-00136, Paper 20. We issue our final written decision in IPR2020-00136 concurrently with this Decision. In addition, Petitioner has filed concurrent petitions challenging other related patents: U.S. Patent No. 8,048,032 (IPR2020-00126; IPR2020-00127), RE45,380 (IPR2020-00128; IPR2020-00129; IPR2020-00130; IPR2020-00131), RE 45,760 (IPR2020-00132; IPR2020-00133; IPR2020-00134), and RE47,379 (IPR2020-00137; IPR2020-00138).

D. The '776 Patent

The '776 patent, entitled "Coaxial Guide Catheter for Interventional Cardiology Procedures," issued on October 27, 2015, as a reissue of the '850 patent, which itself issued from a non-provisional application filed January 26, 2012. Ex. 1001, codes (45), (64). It claims priority as a divisional of Application No. 11/416,629, filed on May 3, 2006, which issued as U.S. Patent No. 8,048,032. *Id.* at code (60).

The '776 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 '776 patent, interventional cardiology procedures often include inserting guidewires or other instruments through catheters into coronary arteries that branch off from the aorta. *Id.* at 1:45–47. In coronary artery disease, the coronary arteries may be narrowed or occluded by atherosclerotic plaques or other lesions in a phenomenon known as stenosis. *Id.* at 1:50–55. In treating the stenosis, a guide catheter is inserted through the aorta and into

the ostium of the coronary artery, sometimes with the aid of a guidewire, and is passed beyond the occlusion or stenosis. *Id.* at 1:59–65. However, crossing tough lesions can create enough backward force to dislodge the guide catheter from the ostium of the artery being treated, which can make it difficult or impossible for the interventional cardiologist to treat certain forms of coronary artery disease. *Id.* at 1:65–67.

To solve this problem, the '776 patent describes a coaxial guide catheter that is deliverable through standard guidewires by utilizing a guidewire rail segment to permit delivery without blocking use of the guide catheter. *Id.* at 3:15–18. The '776 patent teaches that 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, and this feature allows removal of the tapered inner catheter after the coaxial guide catheter is in place. *Id.* at 3:24–27. Figures 1 and 2, reproduced below, show a coaxial guide catheter and a tapered inner catheter in accordance with the invention described in the '776 patent:

Fig. 1

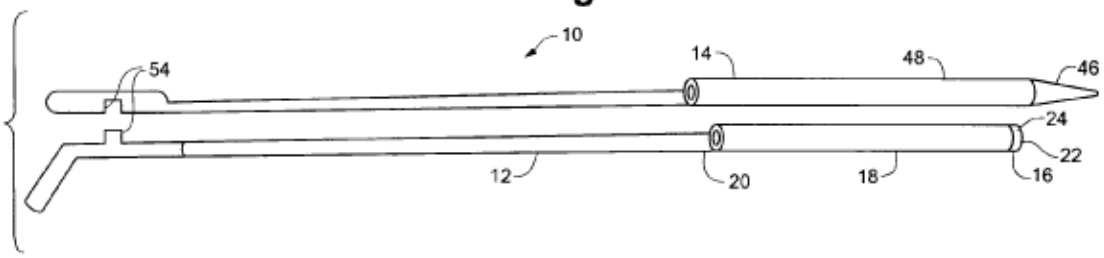


Fig. 2

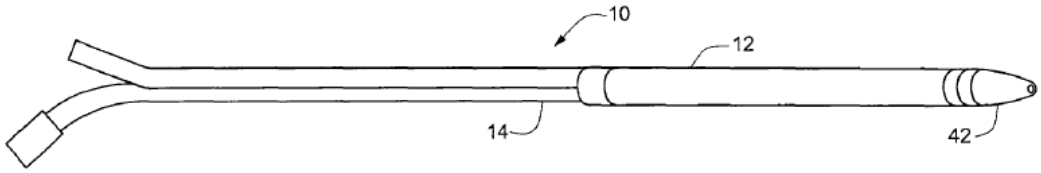


Figure 1 is a schematic depiction of the coaxial guide catheter and tapered inner catheter separately, and Figure 2 depicts those two elements assembled together. *Id.* at 5:47–52, Figs. 1, 2. As shown above, coaxial guide catheter assembly 10 includes coaxial guide catheter 12 and tapered inner catheter 14. *Id.* at 6:37–39. Coaxial guide catheter 12 includes tip portion 16, reinforced portion 18, and rigid portion 20. *Id.* at 6:40–41. Tip portion 16 generally includes bump tip 22 and marker band 24. *Id.* at 6:44–45. Bump tip 22 includes taper 26 and is relatively flexible. *Id.* at 6:45–46. Marker band 24 is formed of a radiopaque material such as platinum/iridium alloy. *Id.* at 6:49–50. Tapered inner catheter tip 42 includes tapered portion 46 at a distal end thereof, and straight portion 48. *Id.* at 7:22–23. Both tapered portion 46 and straight portion 48 are pierced by lumen 50 (not labeled in the figures above). *Id.* at 7:23–24. 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 7:27–29.

In operation, the tapered inner catheter is inserted inside and through the coaxial guide catheter. *Id.* at 4:43–44. The coaxial guide catheter/ tapered inner catheter combination may then be inserted into a blood vessel that communicates with the aorta, and advanced until the tapered inner catheter is passed into the ostium of a coronary artery over the guidewire. *Id.* at 4:47–54. The tapered inner catheter may be removed once the coaxial guide catheter/guide catheter combination has been inserted sufficiently into the ostium of the coronary artery to achieve deep seating. *Id.* at 4:54–57. Once 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.* at 4:61–

64. The presence of the coaxial guide catheter provides additional backup support to make it less likely that the coaxial guide catheter/guide catheter combination will be dislodged from the ostium of the coronary artery while directing the coronary therapeutic device past a tough lesion. *Id.* at 4:64–5:3.

E. Illustrative Claims

Among the challenged claims, independent claim 25 is representative and reproduced below:

> 25. A guide extension catheter for use with a guide catheter, comprising:
>
> a substantially rigid segment;
>
> a tubular structure defining a lumen and positioned distal to the substantially rigid segment; and
>
> a segment defining a partially cylindrical opening positioned between a distal end of the substantially rigid segment and a proximal end of the tubular structure, the segment defining the partially cylindrical opening having an angled proximal end, formed from a material more rigid than a material or material combination forming the tubular structure, and configured to receive one or more interventional cardiology devices therethrough when positioned within the guide catheter,
>
> wherein a cross-section of the guide extension catheter at the proximal end of the tubular structure defines a single lumen.

Ex. 1001, 13:36–52 (cl. 25).

F. Prior Art and Asserted Grounds

We instituted review of claims 25–27, 29–33, 35–39, 41–49, and 52–56 of the '776 patent on the following grounds (Inst. Dec. 7, 39):

Claims Challenged	35 U.S.C. §	Reference(s)/Basis
25–27, 29–33, 35–37, 41–45, 47–49	102	Itou[3]
39, 46	103(a)	Itou, the knowledge of a person of ordinary skill in the art ("POSITA")
36, 37, 52–56	103(a)	Itou, Kataishi,[4] the knowledge of POSITA
32, 36–38, 46, 52–56	103(a)	Itou, Ressemann,[5] the knowledge of POSITA
52–56	103(a)	Itou, Enger,[6] the knowledge of POSITA

In support of its arguments, Petitioner relies on the expert declarations of Dr. Stephen Jon David Brecker (Exs. 1005, 1806, 1904), Dr. Richard A. Hillstead (Exs. 1042, 1905), Mr. Michael Jones (Ex. 1807), and Dr. Paul Zalesky (Exs. 1755, 1830, 1919). Patent Owner relies on the declarations of Ms. Deborah Schmalz (Ex. 2039), Ms. Amy Welch (Ex. 2044), Mr. Howard Root (Ex. 2118), Mr. Gregg Sutton (Ex. 2119), Mr. Mark Goemer (Ex. 2120), Ms. Amanda O'Neil (Ex. 2121), Mr. Steve Erb (Ex. 2122), Mr. Peter T. Keith (Exs. 2042, 2123, 2124, 2138, 2243), Dr. John J. Graham (Ex. 2145), Dr. Lorenzo Azzalini (Ex. 2151), Ms. Heather S. Rosecrans (Ex. 2205), and Dr. Craig Thompson (Ex. 2215).

[3] Itou, US 7,736,355 B2, issued June 15, 2010 (Ex. 1007) ("Itou").
[4] Kataishi, US 2005/0015073 A1, published January 20, 2005 (Ex. 1025) ("Kataishi").
[5] Ressemann, US 7,604,612 B2, issued October 20, 2009 (Ex. 1008) ("Ressemann").
[6] Enger, US 5,980,486, issued November 9, 1999 (Ex. 1050) ("Enger").

II. ANALYSIS

A. Priority Date for the '776 Patent

Petitioner argues that "[t]he '776 patent is subject to the AIA's first-to-file provisions because (1) it contains claims that lack written description, and therefore pre-AIA priority, and (2) it claims priority to RE45,380 ('the '380 patent'), which is subject to the AIA first-to-file provisions." Pet. 12 (footnote omitted). Petitioner advances this argument to preclude Patent Owner from swearing behind the Itou reference based on a showing of prior invention, which could otherwise be done for a pre-AIA "first-to-invent" application. *Id.* We are not persuaded by Petitioner's argument.

"The effective filing date for a claimed invention in an application for reissue or reissued patent shall be determined by deeming the claim to the invention to have been contained in the patent for which reissue was sought." 35 U.S.C. § 100(i)(2). As the '850 patent, the "patent for which reissue was sought" in this case, was issued October 23, 2012, and that patent claims priority to an application filed May 3, 2006, we are not persuaded that the AIA's first-to-file provisions apply to the '776 patent. Indeed, Petitioner provides no legal support for the proposition that claims in a reissue patent are not entitled to an effective filing date as if they appeared in the original patent for which reissue was sought.[7]

[7] Petitioner's priority date argument appears to be a back door attempt to have us address whether the '776 patent satisfies the written description requirement of 35 U.S.C. § 112. But this is a question we may not address in an IPR. *See* 35 U.S.C. § 311(b).

B. Level of Ordinary Skill in the Art

We consider the asserted grounds of unpatentability in view of the understanding of a person of ordinary skill in the art (POSITA). Petitioner provides two alternatives for a person having ordinary skill in the art. First, Petitioner asserts that "[i]f a person of ordinary skill in the art ('POSITA') was a medical doctor, s/he would have had (a) a medical degree; (b) completed a coronary intervention training program, and (c) experience working as an interventional cardiologist." Pet. 13. Alternatively, Petitioner asserts that "if a POSITA was an engineer s/he 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." *Id.* Additionally, Petitioner contends that "[e]xtensive experience and technical training might substitute for education, and advanced degrees might substitute for experience." *Id.*

Patent Owner does not dispute Petitioner's proposed definition of a POSITA. PO Resp. 6.

Upon review of the parties' arguments and supporting evidence, we adopt Petitioner's definitions for a POSITA, as they are undisputed and consistent with the evidence of the record. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001) (the prior art itself can reflect the appropriate level of ordinary skill in the art).

C. Claim Construction

We interpret a claim "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) (2019). This standard requires that we construe claims "in accordance with the ordinary and customary meaning of such claim[s] as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent." *Id.*

Petitioner proposes constructions for the claim terms a "concave track" and "flexural modulus." Pet. 15–16. Patent Owner proposes constructions for "one or more interventional cardiology devices" (all claims) and "the segment defining the angled proximal end of the partially cylindrical opening includes at least one inclined region that tapers into a non-inclined region." PO Resp. 7–11.

Upon review of the parties' arguments and supporting evidence, we determine that no express construction of any claim term is necessary to decide the patentability of the claims. *See Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999) (holding that "only those terms need to be construed that are in controversy, and only to the extent necessary to resolve the controversy"); *see also Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (applying *Vivid Techs.* in the context of an *inter partes* review).

D. Status of Itou as Prior Art - Conception and Reduction to Practice

The dispositive issue in this case is whether Itou, which is relied upon for all grounds in the Petition, qualifies as prior art.

Itou was filed on September 23, 2005, published on March 30, 2006, and issued on June 15, 2010. Ex. 1007, codes (22), (45), (65). Petitioner

contends Itou is prior art under pre-AIA § 102(e). Pet. 16–18.[8] In the Conception and Reduction to Practice ("CRTP") briefing that we separately authorized for these proceedings, Patent Owner argues that Itou does not qualify as prior art based on research and development related to the claimed invention that took place at Vascular Solutions, Inc. ("VSI"), Patent Owner's predecessor-in-interest, starting around early 2005 and continuing through the filing of the priority application for the challenged patent. *See generally* PO CRTP Response; PO CRTP Sur-Reply. Petitioner disputes these contentions. *See generally* Pet. CRTP Reply; Pet. CRTP Sur-Sur-Reply.

In its CRTP Response, Patent Owner identifies the evidence on which it relies to antedate Itou, including certain inventor testimony, non-inventor testimony, and other documentary evidence. PO CRTP Resp. 2. As to inventor testimony, Patent Owner relies on the respective declarations of co-inventors Howard Root (Ex. 2118) and Gregg Sutton (Ex. 2119). As to non-inventor testimony, Patent Owner relies on the declaration of its expert Peter T. Keith (Ex. 2123), the declarations of VSI employees Steven Erb (Ex. 2122) and Deborah Schmalz (Ex. 2039), and the declarations of employees of third-party vendors, Amanda O'Neil (Ex. 2121) and Mark Goemer (Ex. 2120). As to documentary evidence, Patent Owner relies on nearly 75 exhibits. These documents include inventor lab notebooks and handwritten notes (Exs. 2002, 2004); internal company memoranda, presentations, and other similar documents (Exs. 2003, 2005, 2017–2018, 2024, 2025, 2036–

[8] In addition to this Petition, Petitioner similarly asserts Itou in the petitions in IPR2020-00126, -00128, -00129, -00132, -00134, -00135, and -00137. Our analysis regarding the prior art status of Itou is similar for each of these proceedings.

2038, 2040–2041, 2099–2100, 2105, 2109, 2127–2134); invoices, sales orders, and certificates of completion from technical equipment vendors (Exs. 2006–2011, 2013, 2016, 2020–2021, 2026–2035, 2089–2095, 2097, 2104, 2106–2108, 2110–2112); a photograph (Ex. 2014); deposition transcripts (Exs. 2015, 2116); communications with and documents from VSI's outside patent counsel (Exs. 2019, 2023, 2096, 2098, 2101–2103, 2117); and engineering drawings (Exs. 2022, 2113–2115).

We have considered this evidence and other rebuttal evidence offered by Petitioner. For the following reasons, we conclude that a preponderance of the evidence demonstrates that Patent Owner conceived the subject matter recited in the challenged claims before September 23, 2005, the date on which Itou is effective as prior art ("critical date") and either actually reduced the invention to practice prior to the critical date or diligently worked towards constructive reduction to practice until the priority application for the challenged patent was filed on May 3, 2006. Accordingly, we conclude that Itou does not qualify as prior art to the challenged patent.

For our analysis, we first set forth the relevant legal standards, followed by our fact findings and analysis on conception, actual reduction to practice, and diligence towards constructive reduction to practice.

1. Legal Standards

"To antedate (or establish priority) of an invention, a [patent owner] must show either an earlier reduction to practice, or an earlier conception followed by a diligent reduction to practice." *Purdue Pharma L.P. v. Boehringer Ingelheim GMBH*, 237 F.3d 1359, 1365 (Fed. Cir. 2001).

"Conception is the formation, in the mind of the inventor, of a definite and permanent idea of the complete and operative invention, as it is thereafter to be applied in practice." *Cooper v. Goldfarb*, 154 F.3d 1321, 1327 (Fed. Cir. 1998). "A reduction to practice can be either a constructive reduction to practice, which occurs when a patent application is filed, or an actual reduction to practice." *Id.* "In order to establish an actual reduction to practice, the [patent owner] must prove that: (1) [the inventors] constructed an embodiment or performed a process that met all the limitations of the [claimed invention]; and (2) [the inventors] determined that the invention would work for its intended purpose." *Id.*

If a patent owner has not shown actual reduction to practice prior to the "critical date" of a reference, the patent owner may nonetheless antedate the reference by establishing prior conception and reasonable diligence towards the constructive reduction to practice. *Purdue Pharma*, 237 F.3d at 1365. "Reasonable diligence must be shown throughout the entire critical period, which begins just prior to the competing reference's effective date and ends on the date of the invention's reduction to practice." *Arctic Cat Inc. v. GEP Power Prods., Inc.*, 919 F.3d 1320, 1331 (2019). However, the "diligence need not be perfectly continuous—only *reasonably* continuous." *Id.*

To be persuasive, an inventor's testimony of conception and reduction to practice must be corroborated by other independent evidence. "Conception must be proved by corroborating evidence which shows that the inventor disclosed to others his completed thought expressed in such clear terms as to enable those skilled in the art to make the invention." *REG Synthetic Fuels, LLC v. Neste Oil Oyj*, 841 F.3d 954, 962 (Fed. Cir. 2016)

(citations and quotation marks omitted). "However, there is no final single formula that must be followed in proving corroboration." *Id.* (citations and quotation marks omitted); *see also Kolcraft Enters., Inc. v. Graco Children's Prods., Inc.*, 927 F.3d 1320, 1324 (Fed. Cir. 2019); *Medichem, S.A. v. Rolabo, S.L.*, 437 F.3d 1157, 1169–70 (Fed. Cir. 2006).

"In the final analysis, each corroboration case must be decided on its own facts with a view to deciding whether the evidence as a whole is persuasive." *Berges v. Gottstein*, 618 F.2d 771, 776 (CCPA 1980). Corroborating evidence may consist of "testimony of a witness, other than the inventor," or "evidence of surrounding facts and circumstances independent of information received from the inventor." *Medichem*, 437 F.3d at 1171. "Even the most credible inventor testimony is *a fortiori* required to be corroborated by independent evidence, which may consist of documentary evidence as well as the testimony of non-inventors." *Id.* at 1171–72. We assess whether evidence corroborates conception and reduction to practice under a "rule of reason" analysis. *Cooper*, 154 F.3d at 1330.

In an *inter partes* review, 35 U.S.C. § 316(e) imposes the ultimate burden of persuasion to "prove unpatentability by a preponderance of the evidence" onto the petitioner. This burden never shifts to the patent owner. *Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015). However, when the patent owner attempts to antedate the prior art, "[a] second and distinct burden, the burden of production" can shift between the petitioner and the patentee. *Id.* at 1379; *see In re Magnum Oil Tools Int'l, Ltd.*, 829 F.3d 1364, 1375–76 (Fed. Cir. 2016). Specifically, the patent owner "bears the burden of establishing that its claimed invention is

entitled to an earlier priority date than an asserted prior art reference." *Magnum Oil Tools*, 829 F.3d at 1375–76. Once the patent owner establishes it is entitled to an earlier priority date, the burden of production then shifts back to the petitioner "to convince the court that [the patent owner] is not entitled to the benefit" of the earlier priority date. *Dynamic Drinkware*, 800 F.3d at 1379 (citing *Tech. Licensing Corp. v. Videotek, Inc.*, 545 F.3d 1316, 1328 (Fed. Cir. 2008)).

2. Conception

To show prior conception, Patent Owner relies primarily upon Mr. Root's testimony submitted in support of its CRTP Response. Ex. 2118 (Root Declaration in support of CRTP).[9,10] Mr. Root was the founder and Chief Executive Officer of VSI from 1997 to 2017. *Id.* ¶¶ 1–2. Patent Owner also relies upon the testimony of co-inventor Mr. Sutton, who was Vice President, Research & Development at VSI from 2004 until mid-2006.

---

[9] Patent Owner previously submitted a declaration by Mr. Root with its Preliminary Response (Ex. 2001), but withdrew that declaration in favor of Ex. 2118. PO CRTP Resp. 2 n.1.

[10] The testimonial evidence that Patent Owner presents in support of conception is largely undisputed. Indeed, during a teleconference addressing Patent Owner's request to present live testimony from Mr. Root in these proceedings, Petitioner's counsel acknowledged that Mr. Root's testimony was not disputed in a manner that would require our credibility assessment. *See* Ex. 1920, 11:10–11 ("And I don't think we have, you know, directly said Mr. Root is lying on this topic."); *id.* at 17:17–18 ("We don't have any issue at play here that goes to credibility."). Accordingly, in view of our conclusion that "the credibility of Mr. Root is not in question," we denied Patent Owner's request to present live testimony from Mr. Root at the oral hearing. *See* Paper 109, 4–5 (distinguishing *K-40 Elecs., LLC v. Escort, Inc.*, IPR2013-00203, Paper 34 (PTAB May 21, 2014) (precedential)).

Ex. 2119 (Sutton Declaration in support of CRTP). As additional documentary corroboration for this inventor testimony, Patent Owner relies upon certain pages from Mr. Sutton's laboratory notebook dated January 4, 2005 (Ex. 2002), a "market feasibility" memorandum from Mr. Root dated February 4, 2005 (Ex. 2003), and some additional handwritten notes and drawings from Mr. Root dated February 7, 2005 (Ex. 2004). We first set forth the relevant facts based on these declarants' testimony and corroborating evidence, and then address any disputed issues of material fact and legal issues as needed in our analysis.

a) Fact Findings for Conception

In his declaration, Mr. Root attests that conception started around the time he attended the Transcatheter Cardiovascular Therapeutics ("TCT") conference from September 27 to October 1, 2004, by which time he had recognized the issue of "guide catheter backout" that physicians were experiencing when performing complex interventional coronary procedures. Ex. 2118 ¶ 5. Accordingly, Mr. Root asserts that he recognized a need for a solution "that provided better guide positioning, device delivery, and procedural conveniences" than what previously existed in the market. *Id.* To solve this problem, Mr. Root indicates that he came up with "the idea for a guide extension catheter that would provide improved back-up support with rapid exchange delivery, which would offer far more convenience than other options available at the time." *Id.* ¶ 6. And "[s]ometime after the TCT conference, but before 2005," Mr. Root met with his co-inventors, including Mr. Sutton, to discuss more particular ideas for how to make this device. *Id.*

The "guide extension catheter" device that the inventors thought of at this time included certain key features. It was to be used within a standard guide catheter that was one "French size" larger than the "guide extension catheter," and was parsed into two distinct portions—a substantially rigid proximal portion comprising a "rail" structure and a distal tubular portion with a lumen—which together were longer than a standard guide catheter. *Id.* ¶ 7. During a procedure, after the standard guide catheter was inserted into the vasculature so its distal end was in the ostium of a cardiac artery, the guide extension catheter would be inserted into the lumen until the distal end of the tubular portion went past the distal end of the guide catheter and into the cardiac artery. *Id.* With both catheters in place, an interventional cardiology device could be thereafter inserted through the standard guide catheter (running along the rail of the guide extension catheter) until it reached the distal end of the distal tubular portion of the guide extension catheter, thereby entering the cardiac artery. *Id.*

The device they undertook to develop was initially called the "Guide-Liner" device, but the hyphen was later dropped and it became known as the "GuideLiner" device. *Id.* ¶ 9. Although the original idea for the GuideLiner was a "rapid exchange" ("RX") version of the guide extension catheter, "[s]ometime between February and June of 2005, a decision was made to concurrently pursue development of an over-the-wire ('OTW') version of GuideLiner." *Id.* ¶ 19. Mr. Root acknowledges, however, that "[t]he OTW GuideLiner was not part of the inventions of the [challenged] patents," but instead was more akin to the "mother-and-child" design that was known in

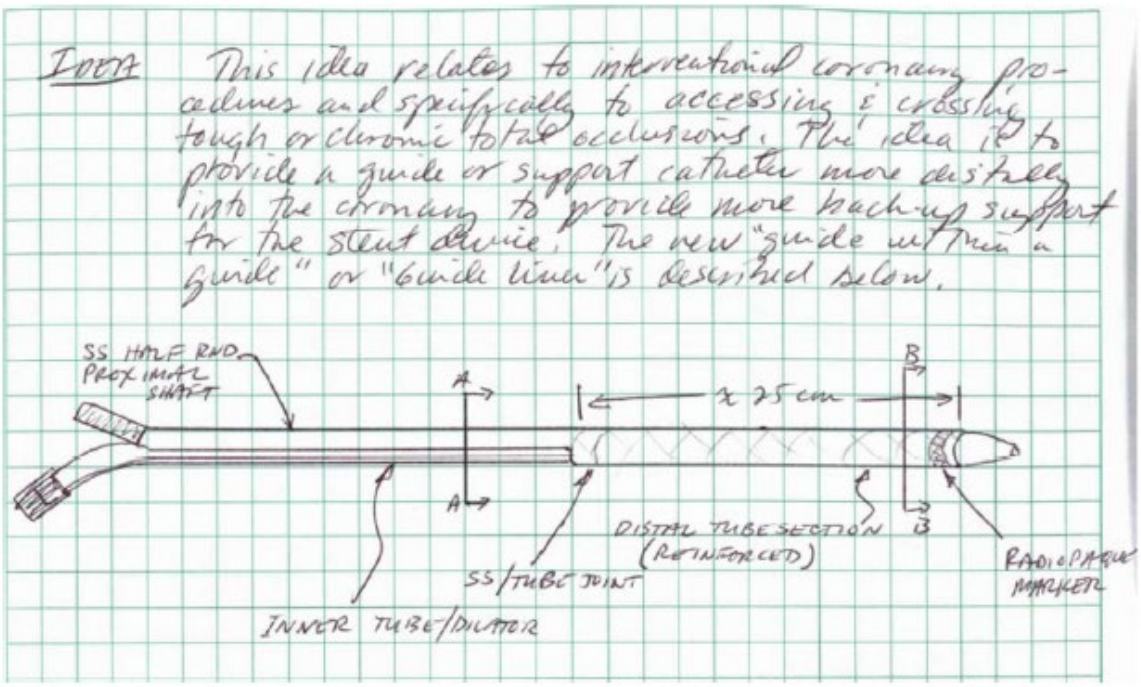
the prior art and discussed in the background of the challenged patents. *Id.* (citing U.S. Patent No. 8,048,032 B2, 2:17–44).[11]

Mr. Sutton in his own declaration sets forth a story consistent with that set forth by Mr. Root. He attests that "[s]tarting in late-2004 until [he] left VSI, [he] performed research and development work on what became the GuideLiner guide extension catheter." Ex. 2119 ¶ 2. Although VSI did not retain all of its files from that time, Mr. Sutton recalls, based on his memory and documents he reviewed, that "we knew very early on that the GuideLiner rapid exchange device would work for its intended purpose," and that "[t]he research and development that followed our original conception of the GuideLiner rapid exchange was to optimize materials, dimensions, and design details that would allow us to manufacture and bring the product to market in a way that would be commercially viable." *Id.* ¶ 6.

The earliest documentary evidence that corroborates this testimony is Mr. Sutton's laboratory notebook pages relating to the concept for a "Guide-Liner" device. Ex. 2002. Mr. Sutton signed the relevant pages on January 4, 2005, and Jeffrey Welch, another co-inventor and engineer at VSI, witnessed those pages on March 2, 2005. Ex. 2002, 7–8; *see* Ex. 2119 ¶ 7.

A portion of one page from Mr. Sutton's notebook is reproduced below:

[11] It is undisputed that only the work done in developing the RX GuideLiner is relevant for conception and reduction to practice. PO CRTP Resp. 13 n.3; Pet. CRTP Reply 1.



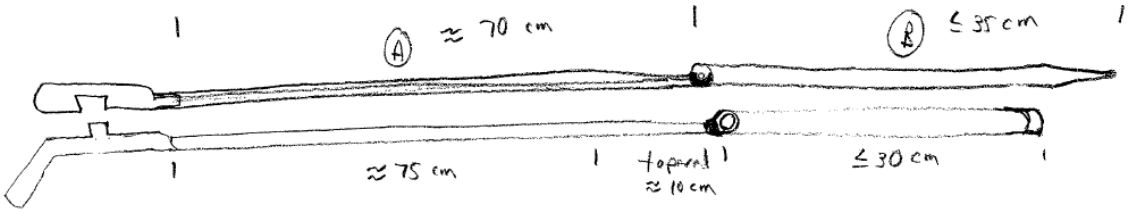
Ex. 2002, 7. As shown above, Mr. Sutton's notebook sets forth an "idea" that "relates to interventional coronary procedures and specifically to accessing & crossing tough or chronic total occlusions," which "is to provide a guide or support catheter more distally into the coronary to provide more back-up support for the stent device." *Id.*; Ex. 2118 ¶ 9. Mr. Sutton's lab notebook also includes drawings of the cross section of various portions of the guide extension catheter and a drawing of how the Guide-Liner would be used that are similar to figures included in the challenged patents. *Cf.* Ex. 1001, Figs. 1, 2, 5, 6 (depicting patent drawings of the guide extension catheter that are similar to Mr. Sutton's drawings). For example, the notebook includes a drawing of a "5F" (5-French) Guide-Liner in operation and notes that the Guide-Liner a) "is used where there is difficulty crossing lesions," b) "allows back-up support distally," c) "allows for Rapid X change," and d) "would fit in std. 6F Guides." *Id.* at 8. The notebook

pages also describe the main features of the device, including 1) an inner tube/dilator that "fits snugly" within a stainless steel ("SS") half-tube; 2) a reinforced distal tube section with a braided "PTFE/SS/PEBAX" material that is "soft for coronaries"; and 3) a design that "allows for rapid exchange." Ex. 2002, 7. Additionally, the notebook identifies the "5F Design Specs," including an overall device length of between 105 cm and 115 cm. *Id.* Both Mr. Root and Mr. Sutton authenticate the contents of the notebook pages. Ex. 2118 ¶¶ 9–11; Ex. 2119 ¶¶ 7–14. Mr. Sutton attests that his notebook was "issued and maintained in the regular course of VSI's business." Ex. 2119 ¶ 7.

By early February 2005, Mr. Root realized this device would have "substantial market potential," so he wrote a "Market Feasibility" memorandum ("memo") for GuideLiner catheters, dated February 4, 2005. Ex. 2118 ¶ 11; Ex. 2003 (confidential); Ex. 2127 (public). Mr. Root attests that he would only have drafted this kind of memo if he "had developed high confidence that a concept would work," so that non-inventors in the company (e.g., regulatory personnel and engineers) could join a project to bring the new product to market. Ex. 2118 ¶ 11. The memo itself recognizes the "substantial market potential" for the RX GuideLiner device based on an estimated 30,000 procedures a year. Ex. 2003, 1. The memo indicates that three versions were anticipated (i.e., a "5in6," a "6in7," and a "7in8" GuideLiner), and notes problems with the prior art OTW methods. *Id.* The memo also generally describes the RX GuideLiner in a manner consistent with the description in Mr. Sutton's notebook including, among other features, that it would be delivered within a standard guide catheter for interventional cardiology procedures; it had a short distal tube segment to

allow for rapid exchange delivery; it was inserted through the existing hemostatic valve; and it was one French size smaller than the standard guide catheter. *Id.* at 2.

Mr. Root also references his own handwritten notes, dated February 7, 2005.[12] Ex. 2118 ¶¶ 12–14; Ex. 2004. These notes show certain features of the RX GuideLiner device, including a "side opening" section that appears in the transition from a partial-round proximal portion to a full-round portion connected to a distal tube section. *Id.* The first drawing from Mr. Root's handwritten notes, reproduced below, is similar to Figure 1 of the '776 patent:

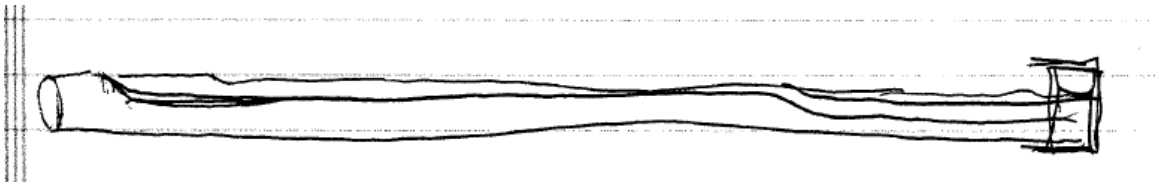


Ex. 2004, 1. As shown above, a "side opening" to allow for the RX capability is reflected through "crude shading" between the rail structure and

[12] Although only the first page of these notes is dated, Mr. Root attests he made the notes on the other two pages "contemporaneously with [his] notes on page 1." Ex. 2118 ¶ 14. Petitioner contends that the third page, in addition to being undated and unwitnessed, appears to come from "a different set of notes" because, unlike the first two pages, the paper is lined. Pet. CRTP Reply 7 n.4. Petitioner also points out that Mr. Sutton testified that he had not seen the third page until his deposition in the stayed district court litigation. *Id.* (citing Ex. 1108, 41:1–6, 46:7–47:3). Mr. Sutton, however, is not the author of these notes. Although we recognize that the type of paper used to record the notes may have been different, we find that the content of page 3 seems to be otherwise consistent with the remainder of the notes and Patent Owner's other conception documents. We therefore find no basis to question Mr. Root's testimony that all his notes from Exhibit 2004 were made contemporaneously on or about February 7, 2005.

tubular portion above the notation reading "tapered ≈ 10 cm," and was considered by Mr. Root to be "[a]n important feature of GuideLiner." Ex. 2118 ¶ 13. Mr. Root testifies that the side opening "facilitates entry of interventional cardiology devices into the proximal end of the tubular portion." *Id.*

The third page of Mr. Root's notes depicts another drawing, reproduced below, that also shows the side opening concept:



Ex. 2004, 3. According to Mr. Root, the sketch above "shows a side opening structure that is cut-away in several segments including, from left (distal) to right (proximal): a full round portion; a first angled transition portion; a first partial round portion; a second angled transition portion; and a second partial round portion." Ex. 2118 ¶ 14. The notes also list dimensions for the contemplated sizes of the GuideLiner. *Id.* ¶ 12; Ex. 2004, 1–3.

Beyond these "core" conception documents (Exs. 2002–2004), Patent Owner also relies on certain engineering drawings as further corroboration for the inventors' testimony. PO CRTP Sur-Reply 3–5 (citing Exs. 2022, 2113, 2114). Patent Owner annotates two of these drawings to highlight features of the depicted GuideLiner, namely the "Side Opening," "Rail Structure," "Machined End for Connecting to Tubular Portion," "Soft Tip," and "Reinforced Pebax Tubular Portion." *Id.* at 4 (citing Ex. 2114), 5 (citing Ex. 2022). The drawings are dated March 2005 (Ex. 2113, 1), June 28, 2005 (Ex. 2114), and August 1, 2005 (Ex. 2022, 1). We have taken these

documents into account in determining whether the inventors conceived of the claimed invention prior to the September 23, 2005, critical date.

b) Analysis for Conception

We first consider whether Patent Owner's proffered evidence corroborates the inventors' testimony of conception. Patent Owner does not assert a specific date of conception. *See* Tr. 60:4–6 ("Our story from day one has been that the exact date of conception doesn't matter."). We agree that we need not determine the exact date on which conception took place. Nonetheless, before we can move on to the question of reduction to practice, we must determine that conception—as legally defined to be the formation of "a definite and permanent idea of the complete and operative invention," *Cooper*, 154 F.3d at 1327—was finalized at some point prior to the critical date of Itou. From the evidence Patent Owner relies upon, we can distill Patent Owner's broad theory of conception as having occurred either by February 2005, as corroborated by the core conception documents (Exs. 2002–2004), or by August 2005 during the course of building and testing prototypes, as further corroborated by the engineering drawings (Exs. 2113, 2114, 2022).

Petitioner argues Patent Owner's core documentary evidence—Mr. Sutton's notebook pages, the market feasibility memo, and Mr. Root's handwritten notes—cannot be used to corroborate inventor testimony insofar as they all originated from the inventors themselves as opposed to some other independent source. Pet. CRTP Reply 4. Petitioner relies principally on three cases as support for this argument. *Id.* at 3–4.

First, Petitioner cites *Apator Miitors ApS v. Kamstrup A/S*, 887 F.3d 1293 (Fed. Cir. 2018), to argue the documents relied upon by Patent Owner are "inventor documents" that cannot be used to corroborate an inventor's testimony on conception. Pet. CRTP Reply 4. The problem for the patent owner in *Apator* was that it was "stuck in a catch-22 of corroboration" because the evidence that was proffered to corroborate the inventor's testimony could "only provide that corroboration with help from [the same inventor's] testimony." 887 F.3d at 1296. For instance, in the bodies of the emails that were relied upon, the inventor indicated that he attached certain files related to his invention, but nothing in any part of the emails indicated what files were attached or what such attachments disclosed. *Id.* The court agreed with the Board's finding that the inventor's testimony was the only evidence proffered to establish the existence and substance of the attachments. *Id.* at 1296–97. And though the drawings set forth dates that were after the reference's critical date, the inventor's testimony about certain file naming conventions was the only evidence offered by the patent owner to demonstrate that the drawings were actually created on an earlier date. *Id.* at 1294–95, 1296–97. The court rejected the patent owner's argument that the emails and drawings should still have "some corroborative value," like unwitnessed laboratory notebooks. *Id.* at 1297. The court acknowledged that the rule of reason permits "'a notebook entry' or other writing '[that] has not been promptly witnessed,'" *id.* (citing *Singh v. Brake*, 222 F.3d 1362, 1369 (Fed. Cir. 2000)), "to aid in corroborating witness testimony alongside other, more persuasive, evidence." *Id.* (citing examples where the Federal Circuit and one of its predecessors, the Court of Customs and Patent Appeals, permitted unwitnessed documents to contribute to corroboration of

conception). But the court clarified that "an unwitnessed laboratory notebook, alone, cannot corroborate an inventor's testimony of conception." *Id.* (citing *Brown v. Barbacid*, 276 F.3d 1327, 1335 (Fed. Cir. 2002) (concluding there was no error in denying corroboration by "an inventor's own unwitnessed documentation"); *Procter & Gamble Co. v. Teva Pharms. USA, Inc.*, 566 F.3d 989, 998–99 (Fed. Cir. 2009) (concluding a laboratory notebook that "was unwitnessed and was not corroborated by any other evidence" could not corroborate inventor testimony of conception)).

Second, Petitioner cites *Kolcraft Enterprises, Inc. v. Graco Children's Products, Inc.*, 927 F.3d 1320 (Fed. Cir. 2019), in support of its argument that the documents relied upon by Patent Owner lack corroborative value because they all "'originated with the inventors.'" Pet. CRTP Reply 4. In *Kolcraft*, the Federal Circuit observed that the evidence at issue—which it characterized as "even weaker than the evidence presented in *Apator*"—comprised a redacted inventor declaration, the inventor's deposition testimony, and undated photos attached to the inventor declaration. 927 F.3d at 1325. Of this evidence, the court noted that "[o]nly the Inventor Declaration, i.e., inventor testimony, supports the purported dates showing [prior] conception," but this was deemed insufficient because "[i]nventor testimony alone cannot prove conception." *Id.*

Third, Petitioner cites a non-precedential Board decision, *Curt Manufacturing, LLC v. Horizon Global Americas Inc.*, IPR2019-00625, 2020 WL 4687044, at *7 (PTAB Aug. 11, 2020), for the proposition that "[o]ne inventor cannot corroborate another." Pet. CRTP Reply 4; *see also* Tr. 35:20–36:12 (Petitioner's counsel citing *Curt* for the same proposition). In *Curt*, the Board stated that "[o]ne consequence of the independence

requirement is that *testimony* of one co-inventor cannot be used to help corroborate *the testimony* of another." *Curt*, 2020 WL 4687044, at *7 (citing *Lacks Indus., Inc. v. McKechnie Vehicle Components USA, Inc.*, 322 F.3d 1335, 1350 (Fed. Cir. 2003) (emphases added) (approving refusal to accept cross-corroboration of oral testimony by interested witnesses)).[13] The Board further noted that "an inventor's *unwitnessed* laboratory notebooks, emails, and drawings, *without other independent evidence*, cannot corroborate an inventor's testimony." *Id.* (emphases added) (citing *Kolcraft*, 927 F.3d at 1325–26; *Apator*, 887 F.3d at 1297; *Brown*, 276 F.3d at 1335). In a footnote quoting *Brown*, the Board highlighted the importance of two issues: whether the documentary evidence was witnessed and whether there is other corroborating evidence in the record. *Id.* at *7, n.7 (reiterating that physical evidence from an inventor does not need corroboration to demonstrate its contents, but the inventor's *unwitnessed* documentation "may not *single-handedly* corroborate" the inventor's testimony (quoting *Brown*, 276 F.3d at 1335) (other emphases omitted)). Lastly, the Board concluded that, "[n]otwithstanding this clear guidance, the law also recognizes that . . . a notebook entry or other writing that has not been promptly witnessed does not necessarily disqualify it in serving as corroboration of conception under a rule of reason analysis." *Id.* at *7 (citing *Apator*, 887 F.3d at 1297 (referring to cases where unwitnessed

[13] The Federal Circuit, however, has not categorically prohibited "cross-corroboration" of testimony by interested witnesses at least in other contexts. *See Nobel Biocare Servs. AG v. Instradent USA, Inc.*, 903 F.3d 1365, 1378 (Fed. Cir. 2018) ("The testimony of one witness may corroborate the testimony of another witness.").

documentary evidence was considered alongside other evidence to corroborate inventor testimony)).

Considering the evidence of record as a whole, we reject Petitioner's arguments that the inventors' testimony on conception is not adequately corroborated. We find the case law cited by Petitioner to be distinguishable.

We first note that Mr. Sutton's laboratory notebook was witnessed shortly after the date of entry of the relevant pages. Specifically, the notebook pages presented here were witnessed by another inventor, Jeffrey Welch. Ex. 2002. Because the notebook is dated and witnessed, we may properly consider it for its probative value in corroborating Mr. Root's and Mr. Sutton's testimony. *See Singh*, 222 F.3d at 1369–70 (holding that a belatedly witnessed lab notebook may serve as corroboration of conception); *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1378 (Fed. Cir. 1986) (same). Indeed, as noted above, even an unwitnessed notebook page may have some corroborative value under the rule of reason when considered in combination with other more persuasive evidence. *Apator*, 887 F.3d at 1297. Moreover, we discern no *per se* rule from the case law to suggest that a laboratory notebook witnessed by a co-inventor cannot be used to corroborate another inventor's testimony about conception. In this regard, we find that the witnessed notebook pages avoid the "catch-22 of corroboration" noted in *Apator* because the notebook pages do not depend upon either Mr. Root's or Mr. Sutton's testimony for an explanation of their content. The notebook pages also avoid the issue that arose in *Kolcraft* and *Curt* because Patent Owner has not relied upon only the inventors' testimony to prove conception. We note that, aside from whether the notebook pages can legally qualify as corroborative evidence of the date of conception,

Petitioner has not disputed the authenticity or veracity of the content shown on those pages. As such, we have considered the content of the notebook pages at face value in our analysis.

We have also taken into account the market feasibility memo and Mr. Root's handwritten notes in our corroboration assessment. Ex. 2003; Ex. 2004. We recognize that these documents appear to have been authored by Mr. Root, and no witness other than Mr. Root has provided testimony about their content. As such, if considered in isolation, these conception documents may be more analogous to the type of "catch-22" documents found insufficient for corroborating the date of conception under *Apator*. Nonetheless, applying the rule of reason, we do not categorically exclude them from the corroboration analysis because they can still "aid in corroborating witness testimony alongside other, more persuasive, evidence." *Apator*, 887 F.3d at 1297. We further note that, like the notebook pages, Petitioner has not disputed the authenticity or veracity of the content of the market feasibility memo and Mr. Root's handwritten notes, and thus we have also considered the content of these documents at face value.

Because we conclude that the notebook pages, along with the market feasibility memo and Mr. Root's handwritten notes, may be properly considered in our corroboration analysis, we next address whether these documents are in fact sufficiently corroborative of the inventors' testimony to show conception of the claimed invention prior to the critical date. On this point, Mr. Root includes as appendices to his declaration claim charts showing how certain VSI prototypes developed at the time meet the

limitations of the challenged claims. Ex. 2118, App'x A–E.[14] The primary argument raised by Petitioner is that Patent Owner's core conception documents do not disclose the "side opening" feature recited in numerous challenged claims. Pet. CRTP Reply 5–7.[15] According to Petitioner, without this demonstration, Patent Owner fails to establish conception of "every feature or limitation of the claimed invention." *Id.* at 3 (quoting *REG Synthetic Fuels*, 841 F.3d at 962). We are persuaded that the evidence shows that the RX GuideLiner device that the inventors had conceived of

[14] Petitioner contends that Mr. Root's claim charts amount to an improper incorporation by reference in violation of 37 C.F.R. § 42.6(a)(3) and a circumvention of our word limits. Pet. CRTP Reply 2. However, in view of the commonality of the CRTP issues across these related proceedings, we authorized the parties to submit consolidated briefing on the issue. Paper 26 (Consolidated Scheduling Order), 2–3. Moreover, Petitioner also submitted similar rebuttal claim charts by its expert Dr. Zalesky as appendices to his expert report. Ex. 1755, App'x A–E. Under the circumstances, we are not persuaded that the manner in which Patent Owner presented its claim-by-claim arguments were a violation of our rules.

[15] As Petitioner acknowledges, this argument only applies to certain claims. *See* Tr. 59:5–12. Petitioner does not identify specifically which limitation of the '776 patent claims constitute the "side opening" limitation, but we note that claim 25 recites "a segment defining a partially cylindrical opening positioned between a distal end of the substantially rigid segment and a proximal end of the tubular structure." Ex. 1001, 13:40–43, cl. 25. According to Petitioner's table in its CRTP Sur-Sur-Reply, the side-opening limitation appears in the following claims: claims 3 and 4 of the '032 patent; claims 3, 4, 36 of the '380 patent; claims 25, 52, and 53 of the '776 patent; and claims 25, 48, 51, and 53 of the '760 patent. Pet. CRTP Sur-Sur-Reply 14–15. In its Sur-Sur-Reply, Petitioner also contends that Patent Owner is missing evidence that the RX prototypes satisfy certain additional claim limitations. *Id.* We consider this in addressing the actual reduction to practice issue below.

and were developing at the time included all the features of the challenged claims, including a side opening feature to allow for rapid exchange.

As noted above, Mr. Root attests that the first and third pages of his handwritten notes each depict a drawing that includes a side opening. Ex. 2118 ¶¶ 12–14 (citing Ex. 2004, 1, 3). In particular, Mr. Root asserts that

> [a]n important feature of GuideLiner is a "side opening" at the transition between the proximal rail structure and the distal tubular portion that facilitates entry of interventional cardiology devices into the proximal end of the tubular portion. This feature is reflected in the crude shading between the rail structure and the tubular portion shown in the sketch above from my February 7, 2005 notes.

Id. ¶ 13. We credit this testimony and find that it is corroborated by the drawings themselves.

Petitioner contends that the lab notebook pages, as confirmed by Mr. Sutton's deposition testimony, only show an "end opening" rather than a side opening for the device. Pet. CRTP Reply 5 (citing Ex. 1108, 70:18–71:23, 79:14–80:24). To further dispute the disclosure of a side opening, Petitioner relies on the declaration of its expert Dr. Zalesky. *Id.* at 6 (citing Ex. 1755 ¶¶ 83–84). Dr. Zalesky contends that the "crude shading" on the drawing on the first page of Dr. Root's notes "does not appear to show an angled opening at the proximal end of the tubular portion" and that Mr. Root's notes on the page do not refer to a side opening. Ex. 1755 ¶ 83. Dr. Zalesky further contends that the drawing on the third page of Mr. Root's notes "does not appear to correspond to any of the figures in the Root patents"; is "quite crude," making it "difficult to tell what it represents, if anything"; and "does not appear to show a side opening." *Id.* ¶ 84.

Although we recognize that Mr. Sutton testified that Figure 1 does not depict an angled side opening, it does not appear that Mr. Sutton categorically stated that the inventors had not conceived of a device that included the side opening feature or otherwise directly contradicted Mr. Root's testimony on this point. We further note that the first drawing in Mr. Root's notes appears to closely match Figure 1 of the challenged patent (which depicts an unassembled coaxial guide catheter and tapered inner catheter), while the first drawing in Mr. Sutton's notes appears to closely match Figure 2 of the challenged patent (which depicts the assembled device). *Compare* Ex. 2004, 1, *with* Ex. 1001, Fig. 1; *compare* Ex. 2002, 7, *with* Ex. 1001, Fig. 2. We agree with Dr. Zalesky that the sketches included in Mr. Root's handwritten notes are "crude" and not a model of clarity. Nonetheless, taking into account both the documentary evidence and inventor testimony as a whole, we find that a preponderance of the evidence supports the conclusion that the inventors conceived of a device that included the side opening and all other claimed features prior to the critical date.

To the extent that the earlier core conception documents alone do not support prior conception, we have also taken into account the evidence proffered by Patent Owner with respect to the prototypes that were built between February and August 2005. *See* PO CRTP Sur-Reply 3 (explaining that if the early 2005 documents "were disregarded," other pre-Itou evidence "undisputedly shows conception of the entire invention, *including the side opening*" (emphasis added)). To support its theory, Patent Owner cites Dr. Zalesky's testimony, where he confirms that the engineering drawings depict a side opening. Ex. 2237, 211:11–16 (agreeing that "a side opening

can be found in the hypotubes that were cut down by Spectralytics, specifically Exhibit 2113 and 2114"), 250:9–13 (agreeing that "Exhibit 2022 sets forth the concept for the rapid exchange GuideLiner"). Petitioner acknowledges the probative value of the August 2005 drawing in showing conception prior to the critical date: "[a]t best, [Patent Owner] shows conception in August 2005, a mere month before Itou and *after* VSI's purported prototype work in April and July." Pet. CRTP Sur-Sur-Reply 3. Much of this evidence is also relied upon by Patent Owner to demonstrate that there was actual reduction to practice prior to the critical date. Given the overlap, we also address this evidence as part of our actual reduction to practice analysis.

In sum, Patent Owner's core documentary evidence—Mr. Sutton's lab notebook, the market feasibility memo, and Mr. Root's handwritten notes—sufficiently corroborate the stories of conception set forth in Mr. Root's and Mr. Sutton's declarations. These corroborating documents add credibility to the inventors' conception timelines. And even if Petitioner were correct that not every feature was conceived on or about February 2005, we find that additional evidence of record with respect to the prototypes, as discussed below, demonstrates conception no later than August 2005.

3. Actual Reduction to Practice

Patent Owner contends that actual reduction to practice also took place before the critical date of Itou. In support of this contention, Mr. Root attests in his declaration that employees at VSI, led by co-inventors Mr. Sutton and Mr. Welch, built and tested RX GuideLiner prototypes between

January and August 2005.[16] Ex. 2118 ¶ 15. Mr. Sutton, as well as two non-inventors employed by VSI at the time, Steve Erb and Deborah Schmalz, also testify about relevant details of the research and development done with regard to the GuideLiner prototypes. Ex. 2039 (Schmalz Declaration); Ex. 2119 (Sutton Declaration); Ex. 2122 (Erb Declaration). Patent Owner also presents the declarations of Mark Goemer and Amanda O'Neil, who were employed by outside vendors from whom VSI purchased components to build the prototypes. Ex. 2120 (Goemer Declaration); Ex. 2121 (O'Neil Declaration). Additionally, Patent Owner has submitted an expert declaration by Dr. Peter Keith in further support of this contention. Ex. 2123 (Keith Declaration in support of CRTP). Patent Owner relies upon purchase invoices, engineering schematics, and other documentary evidence from as early as January 2005 through the September 2005 critical date of Itou in order to corroborate the fact declarants' testimony regarding actual reduction to practice.[17] We once again set forth the relevant facts based on these declarants' testimony and corroborating evidence, and then address

[16] Mr. Root explains that Patent Owner does not have many development documents from 2005, and it obtained many of the documents relevant to actual reduction to practice from VSI's vendors and patent prosecution firm. Ex. 2118 ¶ 20.

[17] Patent Owner includes some documentary evidence created after Itou's critical date. *See, e.g.*, Ex. 2106 (invoices dated April 2006); Exhibit 2115 (engineering drawing dated November, 2005). We do not find this post-critical date evidence to support Patent Owner's contentions regarding actual reduction to practice. However, we have considered some of this evidence in our analysis of whether there was diligence towards constructive reduction to practice (*see* discussion, *infra*), as well as to address Petitioner's argument that the continuing work done at VSI with respect to the GuideLiner demonstrates a lack of actual reduction to practice before Itou.

any disputed issues of material fact and legal issues as needed in our analysis for actual reduction to practice.

a) Fact Findings for Actual Reduction to Practice

After the inventors came up with the initial idea for the device (as set forth in the conception discussion above), VSI proceeded with the development of both the OTW and RX versions of the GuideLiner concurrently. Ex. 2118 ¶ 19; Ex. 2119 ¶ 15. Although it was based on existing technology, VSI decided to pursue the OTW version based on the belief that it could be brought to market more quickly with fewer regulatory challenges than the RX version. Ex. 2118 ¶ 19; Ex. 2119 ¶ 15. Nonetheless, the RX version remained a priority for continued development at VSI. *Id.* Consistent with Mr. Root's testimony, Mr. Sutton testifies that the RX GuideLiner was reduced to practice before September 2005, although further work towards commercialization of the product continued until he left the company. Ex. 2119 ¶ 6. According to Mr. Sutton, work for the OTW prototype "paled in comparison" to work required for the RX prototype because the OTW prototype "required very little engineering and was relatively easy to build because it was based on existing technology." *Id.* ¶ 15. In their declarations, Mr. Root and Mr. Sutton focus on two distinct sets of prototypes of the RX version that were built and tested before Itou's critical date: the "April 2005" prototypes and the "July 2005" prototypes. Ex. 2118 ¶ 48; Ex. 2119 ¶¶ 21–22.[18] As noted above, Mr. Root includes

[18] Although Mr. Root refers to the likelihood that other sets of prototypes were also built, the bulk of Patent Owner's evidence and arguments relate to the April and July 2005 prototypes. Ex. 2118 ¶ 48. As such, we focus on

claim charts identifying how the April and July 2005 prototypes satisfied the limitations of the challenged claims. Ex. 2118, App'x A–E; *see also* Ex. 2123 ¶ 28 (Mr. Keith opining that the April and July 2005 prototypes satisfy the claim limitations based on these claim charts).

In developing these prototypes, a VSI technician and machinist, Mr. Erb, worked with the inventors to mechanically cut down stainless steel or nitinol "hypotubes" used for the proximal portion of an RX prototype. Ex. 2118 ¶ 16; Ex. 2119 ¶ 20; Ex. 2122 ¶¶ 8–10. The profile of some of these hypotubes started at full circumference at the distal end, then progressed to roughly half-round at the proximal end. Ex. 2118 ¶ 16. The hypotubes were combined with a polymer distal section to create the first RX GuideLiner prototypes. *Id.* At this time, the distal tubular portion was sometimes built by cutting a standard guide catheter to the appropriate length. *Id.* ¶ 24. The earliest prototypes, made in January or February 2005, largely comprised stock components modified through VSI's in-house machining capabilities. *Id.* ¶¶ 18, 20. However, by April 2005, the VSI engineers progressed to building more formal prototypes using custom-ordered materials from outside vendors for the proximal and distal portions of the device. Ex. 2122 ¶ 12. A spend report details at least some of the expenses that VSI incurred on purchases of the components used to build GuideLiner prototypes from February 11, 2005, to June 30, 2006. Ex. 2005; Ex. 2118 ¶¶ 21–22. According to Mr. Root, the fact that they had opened an account specific to the "Guideliner project" in May 2005, as reflected in this spend report,

---

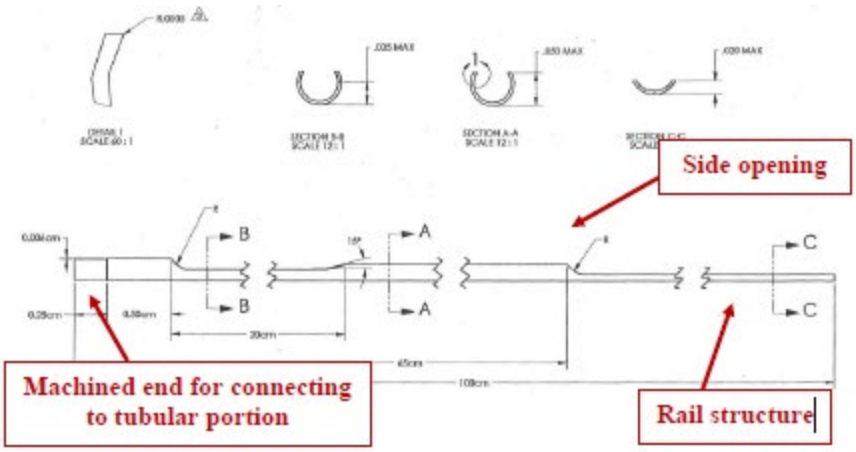
these prototypes in determining whether there was actual reduction to practice.

indicates that development had advanced to the point that they were confident with proceeding towards commercialization. Ex. 2118 ¶ 22.

With respect to the proximal portions, Patent Owner presents invoices and other documents reflecting VSI's purchases of laser-cut hypotubes from three outside vendors: MicroGroup, Mountain Machine, Inc., and SPECTRAlytics. Ex. 2118 ¶¶ 23, 27, 29, 30, 32, 33, 40, 43 (citing Exs. 2006, 2007, 2009, 2010, 2013, 2020, 2091, 2094, 2095, 2110, 2111); Ex. 2119 ¶¶ 24–31 (discussing similar purchases); *see also* Ex. 2122 ¶ 7 (discussing purchases of stainless steel and nitinol hypotubes as reflected in Ex. 2110).[19] Because some of these invoices show purchases of the hypotubing by the foot, Mr. Root asserts that the materials were likely used for early evaluations of the RX GuideLiner concept. Ex. 2118 ¶ 23. Mr. Sutton similarly asserts that the hypotubing that was purchased at this time was used to make RX GuideLiner prototypes, as the OTW version never involved such hypotubing. Ex. 2119 ¶ 25. The ranges of the inner and outer diameters, wall thickness, and the overall length of the hypotubes that were ordered were consistent with what VSI would have needed at the time for prototyping the RX GuideLiner. *Id.* ¶¶ 24, 26.

Mr. Root and Mr. Sutton also reference the following annotated engineering schematics of the proximal portion of the RX GuideLiner that were drawn by a VSI engineer, Jim Kauphusman, on February 4, 2005:

[19] Although both stainless steel and nitinol hypotubes were ordered, Mr. Sutton asserts that nitinol was significantly more expensive and required additional post-processing steps as compared to stainless steel, and these factors ultimately weighed against using nitinol for the proximal portion of the RX GuideLiner. Ex. 2119 ¶ 28.



Ex. 2113; Ex. 2118 ¶ 34; Ex. 2119 ¶ 30. The drawings above show a design of the proximal portion with multiple angled transition regions bookending non-inclined regions, and Patent Owner's annotations to the drawings—which were added for this proceeding, *see* PO CRTP Sur-Reply 13—identify a "machined end for connecting to tubular portion," a "side opening," and a "rail structure." *Id.* These drawings were submitted as "prints" to SPECTRAlytics in order to specify the parameters for the hypotubes that were custom ordered, and include a drawing number "SS HYPO X04" that correlates to a purchase completed on April 4, 2005. Ex. 2118 ¶ 34; Ex. 2120 ¶ 9; Ex. 2095. Additional engineering drawings for the proximal portions were submitted to SPECTRAlytics around June 2005. Ex. 2118 ¶ 41; Ex. 2120 ¶ 11; Ex. 2114. Some of the engineering drawings are similar to figures included in the challenged patent. *Cf.* Ex. 1001, Figs. 12–16.[20] Mr. Goemer verifies and authenticates some of the purchase documents and the engineering drawings retrieved from SPECTRAlytics's files. Ex. 2120 ¶¶ 6–12.

[20] Mr. Sutton faxed these drawings to VSI's outside patent counsel on March 21, 2006. Ex. 2118 ¶ 42; Ex. 2019.

Additionally, Mr. Root and Mr. Sutton refer to purchases of distal tubular portions and the distal forming tips from vendors Medical Engineering & Design Inc. ("MED") and Farlow's Scientific Glassblowing Inc. between February and July 2005. Ex. 2118 ¶¶ 28, 31, 44, 45 (citing Exs. 2011, 2021, 2090, 2092); Ex. 2119 ¶¶ 32–34, 36 (additionally citing Exs. 2032, 2033, 2034, 2035, 2089, 2097, 2112). Ms. O'Neil, who is employed by MED's successor TE Connectivity ("TE"), verifies and authenticates some of these purchase documents, and notes that the documents were retrieved from the files of TE, but originated with MED in 2005. Ex. 2121 ¶¶ 5–6.

One of the documents from MED also includes engineering schematics for the distal portion that were drawn on February 10, 2005, by Mr. Kauphusman, as shown below:

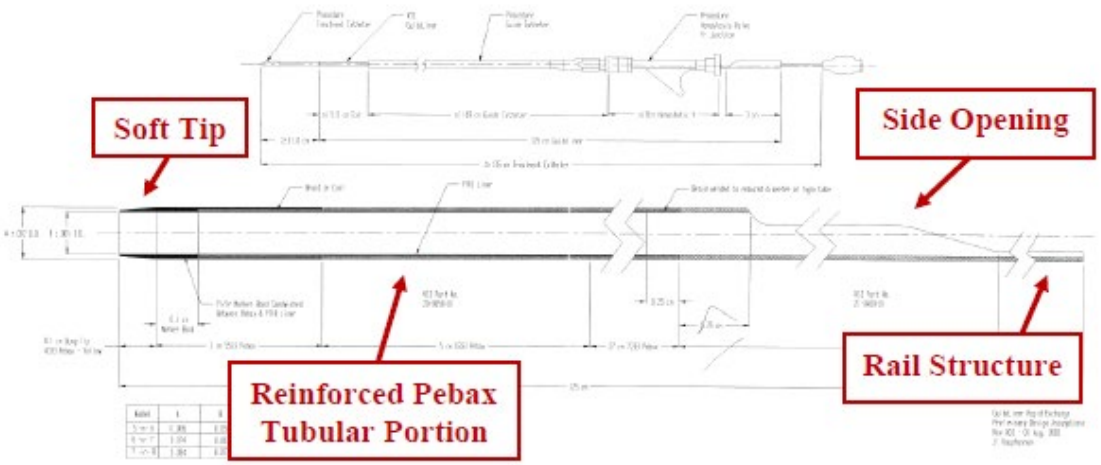
Ex. 2089, 8; Ex. 2118 ¶ 25; Ex. 2119 ¶ 32. The drawing above shows the distal portion with Patent Owner's annotations, *see* PO CRTP Resp. 9, identifying a "soft tip," "three reinforced Pebax portions," the "distal end," and the "proximal end." *Id.* Although Exhibit 2089 does not specify that the tubing was for the RX version of the GuideLiner, Mr. Root and Mr.

Sutton assert that the drawings and specifications were in fact specific to an RX device based on the notation that the proximal end should be "counter bored" (a requirement to facilitate attachment to the cut-down hypotube) as well as the overall length of 11.8 inches (because if this part were for an OTW device, it would have been significantly longer). *Id.* The order for distal portions as shown in Exhibit 2089 was placed on February 17, 2005, and the parts were shipped from MED and delivered to VSI on or about April 5, 2005. Ex. 2118 ¶ 25; Ex. 2119 ¶ 33. An update to the drawing shown in Exhibit 2089 was made on April 6, 2005, as shown in Exhibit 2092, with only minor changes, namely slightly reduced inner and outer diameters to fit a guide catheter and a slightly shortened tip. Ex. 2092, 8; Ex. 2118 ¶ 44. An order for distal tubular portions based on the updated design was placed on April 12, 2005 and those parts were delivered to VSI on or about June 16, 2005. *Id.*

The proximal and distal portions that were custom ordered and purchased from the outside vendors were thereafter combined in-house at VSI to form the prototypes of the complete RX GuideLiner. Ex. 2118 ¶ 24 ("From the earliest stages of the project, the plan was to combine the substantially rigid proximal portion of the rapid exchange GuideLiner with a distal polymer tubular portion that would be at least partially reinforced with coil or braid."); Ex. 2119 ¶ 34 ("[W]e combined these distal sections from MED with the proximal stainless steel sections discussed above to form prototypes of the GuideLiner rapid exchange in April and July 2005."). For example, the first set of formal prototypes (the April prototypes) appear to have been made by combining the laser-cut hypotubes from SPECTRAlytics with the distal tubular sections from MED that were shipped around April 5,

2005. Ex. 2118 ¶ 35 (citing Exs. 2011, 2089). Additional prototypes (the July prototypes) appear to have been built using the hypotubes from MicroGroup shipped around April 20, 2005, and/or the hypotubes from SPECTRAlytics shipped around July 18, 2005, in combination with the updated distal portions from MED shipped around June 16, 2005. *Id.* ¶¶ 39, 40, 46 (citing Exs. 2114, 2020, 2021, 2092, 2094). In making these prototypes, VSI "used an in-house thermal process to fuse the distal tubing sections from MED to the cut-down hypotubes." Ex. 2119 ¶ 35. VSI had the materials and equipment available to assemble the device at their facilities. *Id.*

As further evidence of an assembled device, inventors Mr. Root and Mr. Sutton reference the following engineering CAD schematics from August 1, 2005:



Ex. 2118 ¶ 49; Ex. 2119 ¶ 39; Ex. 2022. The drawings above show a version of the complete RX GuideLiner, as well as a cross-sectional view of the device with Patent Owner's annotations, *see* PO CRTP Resp. 16, identifying the "soft tip," the "reinforced Pebax tubular portion," the "side

opening," and the "rail structure." Ex. 2118 ¶ 49. The schematics are labeled "GuideLiner Rapid Exchange/Preliminary Design Assumptions/Rev X03," which according to Mr. Root, was an indication that VSI had moved past prototyping and into commercialization. *Id.* Mr. Sutton attests that the "X03" indicates that this was the third version of the CAD drawings, and that they had built and tested prototypes of the RX GuideLiner device shown in these drawings. Ex. 2119 ¶ 39. The document also references the same part number (20-0658) as those identified in certain purchase documents for distal tubular portions from MED. Ex. 2118 ¶ 51 (citing Ex. 2021, Ex. 2089, Ex. 2092). These drawings are nearly identical to Figures 3 and 4 of the patent. *Cf.* Ex. 1001, Figs. 3–4 (depicting patent drawings that resemble the CAD drawings).

The prototypes were tested using bench-top coronary models, including two-dimensional ("2D") acrylic heart models and three-dimensional ("3D") glass heart models, to simulate the native anatomy and environment. Ex. 2118 ¶¶ 17, 38, 47; Ex. 2119 ¶¶ 37–38, 41. These types of models were commonly used by VSI and other medical device companies to test interventional cardiology devices. Ex. 2118 ¶ 17; Ex. 2123 ¶ 21 (Mr. Keith noting that he had used similar models to test catheter designs during his time at Scimed and Boston Scientific Corporation). A sales presentation from July 2005 shows an example of a 2D coronary model. Ex. 2018, 12; Ex. 2129 (redacted version of the same presentation). While this particular presentation depicts testing of the OTW version of the GuideLiner concurrently under development, Mr. Root asserts that a similar model was used to test the RX version. Ex. 2118 ¶¶ 18, 38. The testing done using this model included performing pull tests as well as simulations comprising the

following steps: a) inserting a standard guide catheter into the coronary model; b) advancing the prototype into the guide catheter until the prototype's distal end extended beyond the guide catheter's distal end; and c) delivering a stent or balloon catheter into and through both devices. *Id.* ¶ 18. Although "more qualitative than quantitative," these tests enabled the inventors to observe the prototype's durability and the forces exerted on the prototype. Ex. 2118 ¶¶ 18, 47; Ex. 2119 ¶¶ 23, 41. Both Mr. Root and Mr. Sutton attest that this testing was sufficient to confirm that the RX GuideLiner would work for its intended purpose, namely facilitating delivery of interventional cardiology devices into challenging coronary anatomy by providing increased backup support as compared to a guide catheter alone. *Id.*

Patent Owner also presents other documentary evidence as corroboration of the testimony of inventors Mr. Root and Mr. Sutton. We have taken these documents into account, but find them somewhat less probative in showing actual reduction to practice.

For instance, a June 23, 2005, market feasibility memo (Ex. 2017), similar to the earlier memo from February 4, 2005 (Ex. 2003), confirms that the RX GuideLiner prototype was continuing to be developed, although the OTW version had been added to the development project at that point. Ex. 2118 ¶ 37; *see* Ex. 2017, 1 (noting that "it is possible to make the GuideLiner in an Over-the-Wire version, a Rapid Exchange Version, or both").

A "Product Requirements" document, dated August 24, 2005, sets forth the safety and performance requirements for both the OTW and RX

guide catheter support systems. Ex. 2118 ¶ 54; Ex. 2119 ¶ 44; Ex. 2024.[21] The document notes that "[t]hese safety and performance features are the minimal requirements for the device to be acceptable for its intended clinical use," and that the "[a]pplicable clinical use is for increase[d] guide catheter back-up support." Ex. 2024. Mr. Root asserts that this document marked the start of the formal quality process for the RX and OTW GuideLiner catheters. Ex. 2118 ¶ 54. Both Mr. Root and Mr. Sutton, as well as Ms. Schmalz (VSI's Vice President of Regulatory and Clinical Affairs at the time), testify that that this document would have been created only after the product was tested, demonstrated to work, and ready to proceed with regulatory approval and commercialization. Ex. 2118 ¶ 54; Ex. 2119 ¶ 44; Ex. 2039 ¶ 7. Ms. Schmalz specifically recalls that a working prototype of the RX version was created prior to the creation of this document. Ex. 2039 ¶ 7. Although this document sets forth several user requirements for the device, it does not identify the product specifications and test methods correlating to those requirements. Ex. 2024, 2–4. The revision history of the document also indicates it is "pre-release," thereby suggesting that it may not have been finalized at the time. *Id.* at 4.

Mr. Root, Mr. Sutton, and Ms. Schmalz each also discuss two other documents both dated August 26, 2005—a Clinical Technical Report (Ex. 2025) and a staff meeting memo (Ex. 2040)—as further evidence that work

[21] Exhibit 2024 is the subject of Petitioner's motion to exclude. Paper 110. For the reasons we state below in addressing the motion to exclude (*see* discussion, *infra*), we decline to exclude Exhibit 2024 but have considered Petitioner's arguments in determining the weight to be given to this piece of evidence.

continued on the RX GuideLiner and that VSI was ready to seek regulatory approval for the device from the Food and Drug Administration ("FDA"). Ex. 2039 ¶¶ 9–10; Ex 2118 ¶¶ 55– 57; Ex. 2119 ¶¶ 45–46. The Clinical Technical Report states that VSI "has developed, and is currently manufacturing four types of catheters . . . [including] the GuideLiner Catheter Support System used to provide physicians with additional guide catheter support allowing access to more difficult anatomy," and goes on to describe both the RX and OTW versions of GuideLiner. Ex. 2025, 2–3, 5–6. We note, however, that the text discussing GuideLiner devices appears to be "redline" edits and does not include any signatures for "document approvals," thus suggesting that the document submitted as Exhibit 2025 may have only been a draft. *See id.* The staff memo refers to clinical literature reviews for the GuideLiner devices (both RX and OTW), which Mr. Root asserts was part of VSI's regulatory strategy for a "510(k)" submission to the FDA.[22] Ex. 2118 ¶ 57.

b) Analysis for Actual Reduction to Practice

To establish actual reduction to practice, Patent Owner must demonstrate two things: (1) that it constructed an embodiment that met all the limitations of the invention claimed in the patent at issue; and (2) that it determined that the invention would work for its intended purpose. *Cooper*, 154 F.3d at 1327. Having considered the evidence and arguments of record,

[22] A 510(k) submission is a premarket notification "to demonstrate that the device to be marketed is as safe and effective, that is, substantially equivalent, to a legally marketed device." *See* FDA, Premarket Notification 510(k), (accessed June 1, 2021), https://www.fda.gov/medical-devices/premarket-submissions/premarket-notification-510k.

including the testimonial and documentary evidence summarized above, we find that Patent Owner has met this burden with respect to the challenged claims based on the prototypes of the RX GuideLiner that were built and tested at VSI prior to September 2005. We address Petitioner's arguments to the contrary.

The first issue raised by Petitioner is whether there is sufficient corroborating documentary evidence to support the inventors' testimony on reduction to practice. As with conception, "a party seeking to prove an actual reduction to practice must proffer evidence corroborating [an inventor's] testimony." *Raytheon Co. v. Sony Corp.*, 727 F. App'x 662, 668 (Fed. Cir. 2018) (citing *Medichem*, 437 F.3d at 1169–71). The sufficiency of this corroboration is once again determined using a "rule of reason" analysis. *Id.*

Petitioner contends that "[n]o document shows that VSI built, much less tested, RX prototypes." Pet. CRTP Reply 8. Petitioner points to the lack of photographs, assembly instructions, subassembly drawings, and notebook pages (other than Mr. Sutton's initial conception pages) to corroborate the work done on the RX prototype in 2005. *Id.* By contrast, Petitioner asserts that VSI kept more documents, including notes from Mr. Kauphusman (the VSI engineer who led the GuideLiner project), relating to the OTW prototypes from that time. *Id.* at 9–10 (citing Ex. 1760, 86–87). Petitioner also contends that Patent Owner cannot justify VSI's failure to retain these reduction-to-practice documents because it "runs contrary to federal law and industry practice." *Id.* at 11 (citing Ex. 1755 ¶¶ 66–74, 143–145). Among the documentary evidence presented, Petitioner contends that at most four documents relate to particular prototypes, and the rest are

irrelevant insofar as they concern purchases of generic component parts untethered to particular projects or prototypes. *Id.* at 11–14. Petitioner further contends the documents do not show that VSI actually assembled the RX prototypes. *Id.* at 16–17.

We are not persuaded that the record lacks sufficient corroborating evidence of actual reduction to practice. "In order to corroborate a reduction to practice, it is not necessary to produce an actual over-the-shoulder observer. Rather, sufficient circumstantial evidence of an independent nature can satisfy the corroboration requirement." *Cooper*, 154 F.3d at 1330 (citing *Knorr v. Pearson*, 671 F.2d 1368, 1373 (CCPA 1982)). "Furthermore, an actual reduction to practice does not require corroboration for every factual issue contested by the parties." *Id.* (citing *Ethicon, Inc. v. U.S. Surgical Corp.*, 135 F.3d 1456, 1464 (Fed. Cir. 1998); *Mann v. Werner*, 347 F.2d 636, 640 (CCPA 1965) ("This court has rejected the notion that each individual act in the reduction to practice of a count must be proved in detail by an unbroken chain of corroboration.")). Put another way, the law "does not require that evidence have a source independent of the inventors on every aspect of conception and reduction to practice; such a standard is the antithesis of the rule of reason." *E.I. du Pont De Nemours & Co. v. Unifrax I LLC*, 921 F.3d 1060, 1077 (Fed. Cir. 2019) (internal quotation omitted).

As discussed above, Mr. Root and Mr. Sutton each provide detailed and consistent testimony explaining the work done at VSI towards building and testing the April and July 2005 prototypes of the RX GuideLiner. Critical aspects of this testimony are corroborated by other (non-inventor) testimony from Ms. Schmalz (recounting the regulatory and quality process

at VSI), Mr. Erb (recounting how they built early prototypes), Mr. Goemer (verifying purchases from SPECTRAlytics), and Ms. O'Neil (verifying purchases from MED). This testimony is further corroborated by a significant amount of documentary evidence, including purchase documents and engineering drawings, as set forth above. To the extent that there may have been other more detailed evidence with regard to the OTW GuideLiner, we do not find that such evidence detracts from or otherwise contradicts the evidence presented for the RX GuideLiner. Nor do we require Patent Owner to establish actual reduction to practice by retaining and then proffering the same type of documents that the FDA would have required Patent Owner to submit to gain approval of a medical device. *See* Ex. 2237, 63:20–64:9 (Dr. Zalesky acknowledging that "[t]he testing requirement for regulatory submission such as a 510(k) is quite extensive," and "a very significantly different level than that required to demonstrate reduction to practice.").

Petitioner contends that the purchased parts reflected in Patent Owner's documentary evidence could have been used for other VSI projects under development in 2005. Pet. CRTP Reply 12–16. We do not find that the evidence supports Petitioner's conjecture in this regard. For example, Petitioner cites the testimony of Dr. Zalesky to assert that the purchased hypotubing (and other parts) could have been used for VSI's Twin-Pass, Skyway, and Pronto V3 products, in addition to the OTW GuideLiner. *Id.* (citing Ex. 1755 ¶¶ 121–132, 153, 161, 203). But Dr. Zalesky does not point to any supporting evidence showing that these other VSI products used the same type of hypotubing as what would have been required for the RX GuideLiner. *See* Ex. 2237, 156:3–158:10, 173:10–174:12 (Dr. Zalesky admitting that he did not have any evidence that hypotubes were used in

other products, but stating his opinion was based on "informed speculation" or "reasonable speculation"). Rather than Dr. Zalesky's speculation, we credit the testimony of Mr. Root, Mr. Sutton, and Mr. Erb, each of whom had first-hand involvement in the project and independently attest that at least some of the purchased hypotubes were specific for the RX GuideLiner. Ex. 2118 ¶ 23; Ex. 2119 ¶ 23; Ex. 2122 ¶ 7.

The corroborating documents confirm that the purchases were for the RX GuideLiner, not a general ledger expense suggesting that the parts could be used for other unrelated products. *See, e.g.*, Ex. 2005 (spend report for accounts related to "new modalities" and "Guideliner project"). The sole document Petitioner cites to posit that the purchased hypotubes could have been used for OTW devices is an engineering schematic that bears November 2005 and January 2006 dates, which were later than the April and July 2005 prototypes. Ex. 1763, 6. Furthermore, the hypotube shown in the OTW drawing differs in materials and dimensions from the hypotubes purchased for the RX prototypes. The hypotube in the OTW drawing is nitinol and roughly 19 cm, quite different than the 100 cm stainless steel hypotubes used for the GuideLiner prototypes. *Id.* The 43-inch distal section in the OTW drawing also differs dramatically from the 11.8-inch distal section for the RX prototype. Ex. 2237, 164:24–167:19 (Dr. Zalesky agreeing that the distal portion shown in Exhibit 2089 is not the same as the distal portion of Exhibit 1763); *compare* Ex. 1763, 6, *with* Exs. 2089, and 2092.

With regard to whether the purchased components were actually assembled into an RX prototype, we find that the engineering schematic from August 2005 is strongly corroborative of an assembled device. Ex.

2022. Dr. Zalesky acknowledges that it "doesn't make a lot of sense" for VSI not to have assembled the purchased parts together. Ex. 2237, 208:10–25. A preponderance of the evidence supports the conclusion that the assembled RX prototypes met each of the limitations of the challenged claims, as set forth in the Appendices to Mr. Root's declaration. Ex. 2118, App'x A–E. In its Sur-Sur-Reply, Petitioner identifies certain claim limitations that were allegedly not met by the prototypes, but Petitioner does not point to any evidence to contradict Mr. Root's testimony on this point. Pet. CRTP Sur-Sur-Reply 14–15. We likewise find the charts included as Appendices to Dr. Zalesky's declaration to be insufficient in this regard. Ex. 1755, App'x A–E. Rather than identifying any specific technical reason why the prototype components reflected in the purchase documents could not have met the claim limitations, Dr. Zalesky's rebuttal claim charts appears to focus on whether there was sufficient corroborating evidence (which we have already discussed above). *Id.* As such, we find the evidence presented in this case to be more detailed than that found insufficient in *Valencell, Inc. v. Fitbit, Inc.*, 784 F. App'x 1005, 1009 (Fed. Cir. 2019), cited by Petitioner. Pet. CRTP Reply 16. There, no evidence—testimonial or documentary—addressed key claims limitations, which stands in contrast to the detailed testimony and corroborating documents cited in Mr. Root's and Mr. Sutton's declarations.

Having found that Patent Owner constructed embodiments that met all limitations of the challenged claims, we move on to the second issue: whether Patent Owner demonstrated that those embodiments worked for the intended purpose of the invention.

We begin this inquiry by identifying the "intended purpose" of the invention. Patent Owner puts forth a broad intended purpose. Initially, Patent Owner asserted testing was done to show that the prototypes "could serve their intended purpose of being placed in a standard guide catheter and deliver interventional cardiology devices alongside the rail segment, into the side opening and distal tubular portion, and then out the distal end of the distal tubular portion and into challenging coronary anatomy." PO CRTP Resp. 25 (citing Ex. 2118 ¶¶ 17–18, 38, 47; Ex. 2119 ¶ 41; Ex. 2123 ¶¶ 20–24). In its Sur-Reply, Patent Owner clarifies that the intended purpose was "to increase backup support for delivery of interventional cardiology devices, including procedures involving tough or chronic total occlusions." PO CRTP Sur-Reply 9 (citing Exs. 2002, 2003, 2024). By contrast, Petitioner argues for a narrower intended purpose, asserting that the intended purpose was "providing backup support necessary for accessing and crossing tough or chronic occlusions." Pet. CRTP Reply 17 (citing Ex. 2002; Ex. 2118 ¶ 18; Ex. 2119 ¶ 9; Ex. 1762, 47:11–52:17). Citing Patent Owner's Sur-Reply, Petitioner contends that the parties ostensibly "agree" that the intended purpose was "to increase backup support for accessing and crossing tough occlusions." Pet. CRTP Sur-Sur-Reply 7 (citing PO CRTP Sur-Reply 9); *see also* Tr. 49:3–12 ("Teleflex agrees the intended purpose was to increase back-up support for accessing and crossing tough or chronic total occlusions.").

We agree with Patent Owner's position on what constitutes the intended purpose of the invention. Petitioner is certainly correct that several of the documents we have considered refer to crossing "tough" or "chronic" occlusions when discussing the idea behind the invention. *See, e.g.*, Ex.

2002. But when considering all of the pertinent evidence, we find that the inventors were concerned with a broader primary purpose, namely generally providing improved backup support for a guide catheter, with crossing tough or total occlusions being one specific benefit or application of the device. In other words, we do not find that the RX GuideLiner had applicability only when there were tough or chronic occlusions in the artery that needed to be crossed. Indeed, the challenged patent itself recognizes this broader purpose when discussing the field and background of the invention. *See* Ex. 1001, 1:38–41 ("More particularly the present invention relates to methods and apparatus for increasing backup support for catheters inserted into the coronary arteries from the aorta."); *id.* at 3:7–11 ("Thus, the interventional cardiology art would benefit from the availability of 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.").

The documentary evidence we have considered and discussed above further supports this broader intended purpose. For example, while Mr. Sutton's lab notebook expresses the idea for the GuideLiner device as "relat[ing] to interventional coronary procedures and specifically to accessing & crossing tough or chronic total occlusions," it also more broadly notes that "[t]he idea is to provide a guide or support catheter more distally into the coronary to provide more back-up support for the stent device." Ex. 2002, 7. Mr. Sutton's lab notebook also contains two additional notes related to the invention: "Guide-Liner is used when there is difficulty crossing lesions"; and "Guide-Liner allows back-up support distally." *Id.* at 8. Similarly, in the February 4, 2005, Market Feasibility memo, Mr. Root

describes the purpose of the RX GuideLiner as "provid[ing] the ability to create a deep seating of the guide for added support in the interventional procedure." Ex. 2003, 1. Mr. Root explains that "[b]y safely deep seating the guide catheter, the physician can then have the added support for pushing a wire through a chronic total occlusion or advancing a balloon or stent through a tight stenosis." *Id.* The August 24, 2005, Products Requirement document indicates the "[a]pplicable clinical use" for both the RX and OTW GuideLiners to be "increas[ing] guide catheter back-up support." Ex. 2024, 1.

Additionally, Patent Owner's expert's testimony supports this conclusion. Patent Owner's expert, Mr. Keith, declares that testing the RX GuideLiner prototypes would be sufficient for reduction to practice if the testing showed the prototype "(a) could be delivered through a guide catheter so that the distal end of the tubular portion extended beyond the distal end of the guide catheter while being tracked over a winding path; and (b) allowed a stent delivery catheter or balloon catheter to pass into the tubular portion and out the far end of the tubular portion while located within the guide catheter." Ex. 2123 ¶ 22.

The testimony of inventors Mr. Root and Mr. Sutton cited by the parties also supports this conclusion. Mr. Root declares that the intended purpose of the RX GuideLiner was to "deliver interventional cardiology devices, such as a stent or balloon catheter, alongside the rail segment, into the side opening and distal tubular portion, and then out the distal end of the distal tubular portion and into challenging coronary anatomy." Ex. 2118 ¶ 18; *see also id.* ¶ 47 (describing the intended purpose as "facilitat[ing] the delivery of balloon catheters and stents deep into coronary arteries while

providing increased backup support"). During Mr. Root's deposition, counsel for Petitioner inquired about Mr. Root's understanding of the intended purpose. Ex. 1762, 47:11–52:17. Mr. Root repeatedly stated that accessing and crossing tough or chronic occlusions was not the sole intended purpose. *Id.* at 47:11–20 (identifying that Petitioner's asserted intended purpose was "one of them" but "not all of them"), 50:10–12 ("The important thing is this is not just a chronic total occlusion device. This can apply to much broader coronary interventions."). Mr. Sutton's declaration quotes the purpose identified in his notes in his lab notebook, discussed above. Ex. 2119 ¶ 9 (quoting Ex. 2002, 7, 8). Mr. Sutton also declares that he and his team tested the prototypes qualitatively "to determine that [they] provided backup support," "to ensure that [stents and balloon catheters] could safely be delivered and would not snag or get caught on the device," and "to deliver interventional cardiology devices and provide additional backup support compared to the guide catheter alone." *Id.* ¶ 41.

In sum, the pertinent evidence demonstrates that the intended purpose of the claimed invention, as embodied in the RX GuideLiner, was to increase backup support for delivery of interventional cardiology devices. Although crossing tough or total occlusions is one noted benefit of the invention, we do not find it to be the only or primary purpose of the invention.

We next consider whether the testing conducted at VSI was sufficient to determine that the RX GuideLiner prototypes would work for the intended purpose of increasing backup support for delivery of interventional cardiology devices. "Depending on the character of the invention and the problem it solves, determining that the invention will work for its intended

purpose may require testing." *Cooper*, 154 F.3d at 1327 (citing *Mahurkar v. C.R. Bard Inc.*, 79 F.3d 1572, 1578 (Fed. Cir. 1996)). "When testing is necessary, the embodiment relied upon as evidence of priority must actually work for its intended purpose." *Id.* (citing *Scott v. Finney*, 34 F.3d 1058, 1061 (Fed. Cir. 1994)). "[T]he testing requirement depends on the particular facts of each case, with the court guided by a common sense approach in weighing the sufficiency of the testing." *Scott*, 34 F.3d at 1061 (citations omitted). "This common sense approach prescribes more scrupulous testing under circumstances approaching actual use conditions when the problem includes many uncertainties," but "permits little or no testing to show the soundness of the principles of operation of the invention" "when the problem to be solved does not present myriad variables." *Id.* at 1063. "In tests showing the invention's solution of a problem, the courts have not required commercial perfection nor absolute replication of the circumstances of the invention's ultimate use." *Id.* "[T]ests performed outside the intended environment can be sufficient to show reduction to practice if the testing conditions are sufficiently similar to those of the intended environment." *DSL Dynamic Scis. Ltd. v. Union Switch & Signal, Inc.*, 928 F.2d 1122, 1125 (Fed. Cir. 1991) (citing *Tomecek v. Stimpson*, 513 F.2d 614, 618 (CCPA 1975)). For medical device inventions, a showing of actual reduction to practice does not require human testing in actual use conditions. *Scott*, 34 F.3d at 1063 ("Testing for the full safety and effectiveness of a prosthetic device is more properly left to the Food and Drug Administration (FDA). Title 35 does not demand that such human testing occur within the confines of Patent and Trademark Office (PTO) proceedings.").

Patent Owner relies on inventor and expert testimony, as well as documentary evidence, to establish that VSI's use of benchtop models was sufficient to test that the products were suitable for the intended purpose described above.[23] PO CRTP Resp. 11–12, 24–25. Mr. Root asserts that benchtop coronary models, as depicted in the July 2005 sales presentation, were commonly used at VSI and other medical device companies to test interventional cardiology catheters. Ex. 2118 ¶ 17 (citing Exs. 2018, 2129). Citing its expert's declaration, Patent Owner asserts that "[c]atheter inventions are routinely determined to work using benchtop models, and without human testing." PO CRTP Resp. 25 (citing Ex. 2123 ¶¶ 20–24; Ex. 1010). Applied to this invention, Patent Owner asserts its benchtop model emulated the cardiac anatomy, and was used to show that the RX GuideLiner could be "placed in a standard guide catheter and deliver interventional cardiology devices alongside the rail segment, into the side opening and distal tubular portion, and then out the distal end of the distal tubular portion and into challenging coronary anatomy." *Id.* (citing Ex. 2118 ¶¶ 17–18, 38, 47; Ex. 2119 ¶ 41; Ex. 2123 ¶¶ 20–24).

Petitioner's argument against Patent Owner's testing evidence depends on its narrower intended purpose, i.e., "using simulated tough lesions." Pet. CRTP Reply 18; *see also* Pet. CRTP Sur-Sur-Reply 7–9. In

[23] Referring to Petitioner's expert's testimony regarding a person of ordinary skill in the art's knowledge pertaining Itou, Patent Owner also contends that no testing would have been required to know the RX GuideLiner would have worked for its intended purpose. *See* PO CRTP Sur-Reply 9 (citing Ex. 2116, 110:20–113:24; Ex. 2238, 87:18–89:5). Because we determine that the evidence demonstrates that testing in benchtop models was sufficient, we do not address this theory.

light of our rejection of the narrower intended purpose identified by Petitioner, we likewise reject Petitioner's argument that the testing evidence presented by Patent Owner is insufficient. Moreover, Petitioner acknowledges that benchtop models could have been used to test a device like the RX GuideLiner. Pet. CRTP Reply 17–18. The testimony of Mr. Root, Mr. Sutton, Mr. Erb, and Mr. Keith, corroborated by the photograph of the model in the sales presentation, confirm that VSI utilized benchtop coronary models that were considered the standard for testing interventional cardiology devices such as catheters. *See* Ex. 2018; Ex. 2118 ¶¶ 17, 38, 47; Ex. 2119 ¶¶ 23, 37–38, 41; Ex. 2122 ¶ 11; Ex. 2123 ¶¶ 21–24. We consider this benchtop testing to be similar to the "countertop" testing that was found sufficient to show actual reduction to practice in *Mahurkar*. *See Mahurkar*, 79 F.3d at 1578 (determining for claims related to a double lumen catheter that flow and pressure drop tests conducted in the inventor's kitchen, using glycerine to simulate blood, was sufficient for actual reduction to practice because they "showed, to the limit of their design, the utility of the claimed invention"). As noted by Petitioner, Mr. Root indicated during his deposition that to reduce to practice, VSI needed to "(1) navigate RX through a guide catheter and out its distal end in a benchtop model, (2) deliver an interventional cardiology device, and (3) retrieve RX in one piece." Pet. CRTP Reply 18 (citing Ex. 1762, 100:1–102:3). We find that the "pull tests" done using the benchtop models demonstrated that the RX GuideLiner was capable of accomplishing at least this much, even if the tests were not conducted in an *in vivo* or *in vitro* environment that simulated tough lesions. Ex. 2118 ¶¶ 17, 38, 47. This is not a situation where there were significant variables or uncertainties that needed to be assessed in order

to determine whether the RX device would work properly, and thus the "qualitative" testing done by VSI using the benchtop models was sufficient. Ex. 2119 ¶ 41; Ex. 2123 ¶¶ 21–22. Accordingly, a preponderance of the evidence supports the conclusion that the testing done at VSI demonstrated that the RX GuideLiner would work for its intended purpose.

In our assessment of whether there was actual reduction to practice prior to the critical date, we have considered Petitioner's argument that the GuideLiner project was still in "early-stage concept development" in mid-to-late 2005, and that VSI was still experimenting in 2006 and did not have a working prototype even by 2008. Pet. CRTP Reply 22–27.

In support of this argument, Petitioner points to continuing changes to the RX design as evidence that the design was not completed before the critical date. *Id.* For example, a July 2005 Research & Development ("R&D") Update notes that "[t]he initial design is an over-the-wire configuration, with a rapid exchange version to follow." Ex. 2130, 3.[24] In contrast to the incomplete August 2005 Product Requirements document relied upon by Patent Owner (Ex. 2024), Petitioner contends that the official, completed version of the Product Requirements document for the GuideLiner project was not created until April 2009. Ex. 1767. A "2006

[24] We recognize that this document appears to contradict Mr. Root's recollection that the original idea was for the RX GuideLiner, and that the decision was later made to concurrently pursue development of the OTW version. Ex. 2118 ¶ 19. We do not find the issue of whether the initial idea was for the RX version or the OTW version to be material to our analysis on reduction to practice. Nonetheless, we note Mr. Sutton's original notebook pages suggest that the original idea was indeed for the RX version rather than the OTW version. Ex. 2002.

Strategic Objectives" document, dated December 1, 2005, indicates that the "rapid exchange version requires additional engineering and is not included in our 2006 forecasts." Ex. 2131, 10. Likewise, Petitioner points to a GuideLiner team meeting memo from May 2, 2006, that includes as agenda items "1) Review Initial Design and Intended Use," and "2) Determine what can be completed/started prior to design lock." Ex. 2109. According to another document, a "design freeze" for the GuideLiner device was expected to only take place May 30, 2007. Ex. 1769, 1. Indeed, an R&D update from July 2008 notes with respect to the GuideLiner device:

> Throughout this project, timelines have been pushed out due to drastic design changes and resource constraints. To date we have prototyped and tested a new design. This new design is more robust and cost effective. We are planning on an August 2008 design freeze with a 510k submission in November 2008.

Ex. 2132, 7.

We have taken the foregoing evidence into account, but do not find that it detracts from Patent Owner's evidence concerning reduction to practice based on building and testing the April and July 2005 prototypes discussed above. To be sure, the post-critical date documents highlighted by Petitioner make it clear that significant design revisions for the RX GuideLiner continued well into 2008, and these additional design changes may well have been required for FDA regulatory approval and/or commercialization of the device. Indeed, Patent Owner's declarants attest that additional engineering work was conducted to refine the product for regulatory purposes and commercialization. *See* Ex. 2118 ¶ 59 (Mr. Root attesting that "[f]rom September of 2005 forward, I and others at VSI continued to act diligently to bring the rapid exchange GuideLiner to

market."); Ex. 2119 ¶ 44 (Mr. Sutton attesting that, after the August 24, 2005, Product Requirements document, "we continued to refine prototypes of the GuideLiner [R]apid [E]xchange for purposes of manufacturability and commercialization"); Ex. 2122 ¶ 13 (Mr. Erb attesting that work continued on "develop[ing] manufacturing processes that were reproducible and a refined design that was able to be commercialized"). But we see no basis to conclude that these additional engineering and design changes were an indication that the April and July 2005 prototypes failed to demonstrate that the RX GuideLiner was capable of achieving increased backup support.

Ultimately, the RX GuideLiner was not commercialized until 2009, which we recognize is far later than the initial projected timeframe of late 2005/early 2006 and the date of actual reduction to practice. Ex. 2118 ¶ 89. Mr. Root asserts that one reason for this delay was due to turnover in R&D personnel. *Id.* Under the circumstances, we do not find that the additional engineering and design work done with respect to the RX GuideLiner to achieve regulatory approval and commercialization indicates a lack of actual reduction to practice prior to the critical date. *See Loral Fairchild Corp. v. Matsushita Elec.*, 266 F.3d 1358, 1362–63 (Fed. Cir. 2001) ("Once the invention has been shown to work for its intended purpose, reduction to practice is complete. Further efforts to commercialize the invention are simply not relevant to determining whether a reference qualifies as prior art against the patented invention.").

In sum, we find that Patent Owner has demonstrated actual reduction to practice prior to Itou's critical date by a preponderance of the evidence based on the work done at VSI in building and testing the April and July 2005 prototypes of the RX GuideLiner. Nonetheless, to the extent that this

evidence is not sufficient for actual reduction to practice, we find that it demonstrates at least conception of the claimed invention prior to the critical date.

4. Constructive Reduction to Practice

In addition to asserting actual reduction to practice, Patent Owner alternatively relies upon a theory of constructive reduction to practice. Antedating based on this theory would require Patent Owner to demonstrate diligence from just before the date Itou was filed until the date Patent Owner filed its priority application for the GuideLiner patents,[25] i.e., from September 23, 2005, to May 3, 2006. *See Perfect Surgical Techniques, Inc. v. Olympus Am., Inc.*, 841 F.3d 1004, 1007 (Fed. Cir. 2016) (requiring diligence for the "entire critical period, which begins just prior to the competing reference's effective date and ends on the date of the invention's reduction to practice").

To demonstrate diligence, Patent Owner again relies on testimony from its inventor and non-inventor declarants, as well as correspondences with VSI's outside patent counsel at the Patterson Law Firm and documents reflecting further engineering and development work done during this period. PO CRTP Resp. 18–19; PO CRTP Sur-Reply 12.

According to Mr. Root, following the initial conception and the building of the April and July 2005 prototypes, he and others at VSI

[25] We use term "GuideLiner patents," in the same manner as the parties' declarants, to refer to the patents challenged in IPR2020-00126, -00128, -00129, -00132, -00134, -00135, and -00137. *See, e.g.*, Ex. 2118 ¶ 1; Ex. 2119 ¶¶ 1, 3; Ex. 2123 ¶ 1.

continued working, from September 2005 onward, to bring the RX GuideLiner to market. Ex. 2118 ¶ 59. This project was one of VSI's primary development initiatives at the time, and they worked on it continuously until they brought it to market in 2009. *Id.*; *see id.* ¶ 89. Thus, they worked continuously at least until the May 3, 2006, application date. *Id.* ¶ 76. Ms. Schmalz likewise testifies that "[a]t no time between the start of the regulatory process for GuideLiner in August of 2005 and the filing of the patent application in May 2006 was the rapid exchange GuideLiner project abandoned or paused." Ex. 2039 ¶ 12.

Mr. Sutton sent a fax to the Patterson Law Firm on March 21, 2006, which includes drawings that are similar to the proximal portion of the RX GuideLiner depicted in Exhibit 2114. Ex. 2118 ¶ 42 (citing Ex. 2019). The firm also possessed the August 1, 2005, CAD drawing of a complete RX GuideLiner prototype. *Id.* ¶¶ 49–50 (citing Ex. 2022).

Upon Mr. Root's request, the firm opened a matter to conduct a patentability search for the GuideLiner on August 11, 2005. *Id.* ¶ 52 (citing Ex. 2023). Mr. Root provided the firm with the full prototype drawing in Exhibit 2022 to conduct the search. *Id.* Mr. Root testifies that he would not engage in freedom-to-operate searching until after he had made a full prototype that was shown to work for its intended purpose and ready to move forward to commercialization. *Id.* An invoice from the firm demonstrates work performed for a "patent search for guide liner" in August 2005. *Id.* ¶ 53 (citing Ex. 2096).

In his declaration, Mr. Root then sets forth the timeline of events with documentary and circumstantial evidence during the critical period for diligence, i.e. from September 23, 2005, to May 3, 2006.

For September 2005, Mr. Root refers to invoices dated September 7, 2005, and a check for forming tips that would have been used for the distal tip of the GuideLiner prototype. *Id.* ¶ 60 (citing Ex. 2097). He refers to these documents to demonstrate that VSI was continuing to refine the prototypes during this period. Mr. Root also refers to a copy of the Patterson Law Firm's privilege log showing that a partner of the firm sent Mr. Root a confidential letter dated September 14, 2005, pertaining to prior art related to the GuideLiner. *Id.* ¶ 61 (citing Ex. 2098).

For October 2005, Mr. Root refers to a business update presented to VSI's Board of Directors during its October 2005 meeting. *Id.* ¶ 62 (citing Exs. 2041 (confidential), 2133 (public)). Mr. Root declares this update included extremely favorable reviews of the RX GuideLiner from VSI's physician advisors. *Id.* Mr. Root further declares the update included projected timelines for regulatory filings, with intentions to file in the end of 2005 for OTW and early 2006 for RX. *Id.* Mr. Root also refers to the matter the Patterson Law Firm opened this month for work leading towards the initial GuideLiner patent application. *Id.* (citing Ex. 2023).

For November 2005, Mr. Root declares that VSI continued refining the proximal portion of the RX GuideLiner. *Id.* ¶ 63. Mr. Root refers to engineering drawings obtained from SPECTRAlytics, including one dated November 2005, which closely resembles Figure 10 of the GuideLiner patents. *Id.* (citing Ex. 2115). Mr. Root also refers to a VSI R&D planning document for 2006, which was drafted by Mr. Sutton on November 22, 2005. *Id.* ¶ 64 (citing Ex. 2099). The planning document demonstrates VSI's intent, as of late November 2005, to continue with the regulatory approval process for the RX GuideLiner in 2006. *Id.*

For December 2005, Mr. Root refers to a VSI Strategic Objectives document for 2006, which was drafted on December 1, 2005. *Id.* ¶ 65 (citing Ex. 2100). The document indicates that the RX GuideLiner required additional work for commercialization, which would continue through the end of 2006. *Id.* Mr. Root also refers to an invoice from the Patterson Law Firm, which shows the time invested in preparing the GuideLiner patent application during December 2005. *Id.* ¶ 66 (citing Ex. 2117).

For January 2006, Mr. Root refers to another invoice from the Patterson Law Firm, which shows time invested in preparing the GuideLiner patent application during January 2006. *Id.* (citing Ex. 2101). Mr. Root also refers to a fax sent from Mr. Sutton to the law firm on January 23, 2006. *Id.* ¶ 67 (citing Ex. 2102). The fax contains three figures that illustrate examples of the problem to be solved by the RX GuideLiner, and which are nearly identical to Figures 7, 8, and 9 of the GuideLiner patents. *Id.*

For March 2006, Mr. Root refers to a Patterson Law Firm invoice showing time invested in preparing the GuideLiner patent application during March 2006. *Id.* ¶ 68 (citing Ex. 2103). Mr. Root also refers to purchase records for stainless steel tubing from Vita Needle Company on March 24, 2006. *Id.* ¶ 69 (citing Ex. 2104). Mr. Root declares that VSI used this tubing to refine the RX GuideLiner for commercialization. *Id.* Mr. Root also refers to a March 30, 2006, engineering drawing from SPECTRAlytics's files. *Id.* ¶ 70 (citing Ex. 2115). The drawing, which is similar to the photographs of RX GuideLiner prototypes depicted in Exhibit 2014, shows VSI's attempt to reduce manufacturing costs by cutting two proximal portions from a single hypotube. *Id.*

For April 2006, Mr. Root refers to a Budget to Actual Variances report provided to the VSI Board of Directors for its April 2006 meeting. *Id.* ¶ 71 (citing Ex. 2105). The report shows GuideLiner R&D expenses by that time had been more than double the amount that was budgeted. *Id.* Mr. Root refers to purchase records for laser-cut and electropolished GuideLiner hypotubes from LSA, with an invoice dated April 7, 2006. *Id.* ¶ 72 (citing Ex. 2106). These hypotubes were used to refine the RX GuideLiner during commercialization. *Id.* Mr. Root refers to purchase records for twenty hypotubes from MicroGroup, with an invoice dated April 18, 2006. *Id.* ¶ 73 (citing Ex. 2107). These hypotubes were used to refine the RX GuideLiner during commercialization. *Id.* Mr. Root refers to other purchase records, including an April 19, 2006, invoice for cut GuideLiner hypotubes from LSA, which were used to commercialize the RX GuideLiner. *Id.* ¶ 74 (citing Ex. 2108).

For May 2006, other than the filing of the application on May 3, 2006, Mr. Root refers to notes from a GuideLiner team meeting held May 2, 2006, which confirm they were still working towards commercializing the RX GuideLiner. *Id.* ¶ 75 (citing Ex. 2109).

Mr. Sutton's diligence timeline, including the documents he refers to, largely matches Mr. Root's. For essentially the same reasons as Mr. Root, Mr. Sutton refers to: the drawing of the fully-assembled RX GuideLiner, Ex. 2119 ¶ 39 (citing Ex. 2022); his fax sent March 21, 2006, to the Patterson Law Firm, including the drawings similar to Figures 12 through 16 of the patents, *id.* ¶ 40 (citing Ex. 2019); his fax sent on January 23, 2006, to the Patterson Law Firm, which contains three figures that illustrate examples of the GuideLiner situated in the aorta, which are nearly identical to Figures

7, 8, and 9 of the GuideLiner patents, *id.* ¶ 42 (citing Ex. 2102); the VSI R&D planning document for 2006, dated November 22, 2005, *id.* ¶ 48 (citing Ex. 2099); the VSI marketing document dated December 1, 2005, *id.* ¶ 49 (citing Ex. 2100); the Vita Needle purchase records for stainless steel hypotubes shipped on March 24, 2006, which were used for the RX GuideLiners, *id.* ¶ 51 (citing Ex. 2104); and the April 2006 VSI budget report, indicating expenses on commercializing the RX GuideLiner more than doubled the amount VSI budgeted, *id.* ¶ 52 (citing Ex. 2105). Mr. Sutton also refers to the January 2006 R&D Update that he prepared for the VSI Board of Directors, *id.* ¶ 50 (citing Ex. 2134). In that update, Mr. Sutton reported to VSI's Board that both GuideLiner projects were still planned, with OTW regulatory filings next up at the time. *Id.*

In addition to testimony from inventors Mr. Root and Mr. Sutton, Patent Owner also points to testimony from Ms. Schmalz, Mr. Erb, and Mr. Keith. Ms. Schmalz declares that, from "the start of the regulatory process for GuideLiner in August of 2005 and the filing of the patent application in May 2006," the RX GuideLiner "was always a high priority project during [her] time at VSI" and was never "abandoned or paused." Ex. 2039 ¶ 12. Mr. Erb declares that VSI was "continually working to optimize the design" of the RX GuideLiner for commercialization. Ex. 2122 ¶ 13. As an example, he recalls the weighing of advantages and disadvantages between stainless steel and nitinol for the proximal portion during the commercialization stage. *Id.* ¶ 14. Mr. Keith explains his understanding that further commercialization work was performed after August 2005. Ex. 2123 ¶¶ 25–27.

Patent Owner contends that the evidence it relies on to prove conception and reduction to practice shows that "VSI worked steadily on the GuideLiner invention from conception through the date the patent was filed." PO CRTP Resp. 28 (citing *id.* at 3–19). Patent Owner acknowledges that it took more time and resources than anticipated, but that this delay should have "no bearing whatsoever on the [diligence] analysis." *Id.* at 28–29.

Petitioner argues Patent Owner's response "does not contain any detail showing diligence." Pet. CRTP Reply 28. Petitioner deems the "handful" of events identified by Patent Owner during the critical period—opening a patent application file, working on the patent application, exchanging emails, and buying parts—to be insufficient evidence of diligence. *Id.* at 28–29. It appears from Petitioner's visual timeline of Patent Owner's events that two periods in particular allegedly represent a lack of diligence: from September 23, 2005, to the end of November 2005, during which there was only a component design change; and the month of February 2006, during which there were no diligence-related events. *Id.* at 28 (citing Ex. 2115). Petitioner also faults Patent Owner's delay in regulatory submissions for the RX GuideLiner, which were initially planned for late 2005 and 2006 but were postponed until 2008. *Id.* (citing Ex. 1762, 131:3–133:3; Ex. 2132, 7).

When evaluating diligence, we are mindful of recent Federal Circuit admonitions clarifying that we must not apply a standard that is "too exacting" or "too rigid." *Perfect Surgical*, 841 F.3d at 1008; *Arctic Cat*, 919 F.3d at 1331. Though "periods of inactivity within the critical period do not automatically vanquish a patent owner's claim of reasonable diligence,"

Arctic Cat, 919 F.3d at 1331, "[m]erely asserting diligence is not enough" and a party must "account for the entire period during which diligence is required." *In re Meyer Mfg. Corp.*, 411 F. App'x 316, 319 (Fed. Cir. 2010). "[D]iligence need not be perfectly continuous—only *reasonably* continuous." *Arctic Cat*, 919 F.3d at 1331. The key question for diligence is whether, "in light of the evidence as a whole, the invention was not abandoned or unreasonably delayed." *Id.* (internal quotations omitted). Applying this standard, we conclude that Patent Owner sufficiently demonstrates reasonably continuous diligence throughout the critical period.

The evidence demonstrates that Patent Owner did not unreasonably delay the RX GuideLiner project. As both parties acknowledge, there were indeed delays in the project. Petitioner asserts "VSI prioritized *other projects* in late 2005 and 2006 and postponed RX regulatory submissions through 2008." Pet. CRTP Reply 29 (citing Ex. 1762, 131:3–133:3; Ex. 2132, 7) (emphasis in original). But the cited portion of Mr. Root's deposition testimony sufficiently explains why the delay was reasonable under the circumstances. As noted by Mr. Root, OTW GuideLiner regulatory submissions came first "[b]ecause it was much easier to get regulatory approval and do the testing." Ex. 1762, 131:3–8. "[T]ransition in personnel" also complicated the project. *Id.* at 131:12–17. And as for the RX, Mr. Root explained that commercialization took longer due to "vendor optimization," *id.*, 132:25–133:9, which tracks the greater difficulty associated with bringing the RX GuideLiner to market. Ms. Schmalz further corroborates this explanation with her declaration that RX GuideLiner "was always a high priority project during [her] time at VSI." Ex. 2039 ¶ 12.

Nor does it appear that Patent Owner abandoned the RX GuideLiner invention. For one thing, Patent Owner engaged counsel to prepare its GuideLiner patent application, which was ultimately filed on May 3, 2006. The Patterson Law Firm opened a patent search on August 11, 2005 (Ex. 2023, 5) then reported the results to VSI on September 14, 2005 (Ex. 2098, 2). On October 10, 2005, the firm opened a patent prosecution matter for the GuideLiner. Ex. 2023, 5. There is evidence in the record of the firm working on preparing the application in December 2005 (Ex. 2117, 20), January 2006 (Ex. 2101, 7), and March 2006 (Ex. 2103, 6). There is also evidence of communications between the firm and VSI, namely Mr. Root and Mr. Sutton, in January 2006 and March 2006. Ex. 2102; Ex. 2098, 4; Ex. 2019. To be sure, there is not an abundance of documents in the record related to preparing the application, including drafts of the specification and claims, but Patent Owner clarified at oral argument that it lacks many documents due to the passage of time, not the refusal to waive attorney-client privilege. Tr. 64:8–21. A lack of documents due to the passage of time does not foreclose sufficient corroboration. *See, e.g.*, *NFC Tech., LLC v. Matal*, 871 F.3d 1367, 1374 (Fed. Cir. 2017) (concluding there was sufficient corroboration of conception based on circumstantial evidence, "particularly considering the amount of time that ha[d] passed").

Moreover, the other documents Patent Owner proffers provide additional circumstantial evidence that VSI was working on and did not abandon the RX GuideLiner project throughout this time. Petitioner again faults Patent Owner for not providing direct evidence. Pet. CRTP Reply 28 (pointing out lack of events "related to actual work on an RX device"); *id.* at 29 (arguing Patent Owner "cannot tie the component parts purchases to

RX"). But, as we noted above, direct evidence is not required for adequate corroboration. Internal VSI documents, such as updates for VSI's Board and budget documents, show that work on the RX project continued from October 2005 through April 2006. Ex. 2133, 4, 7; Ex. 2099; Ex. 2100, 8–9; Ex. 2105, 4–5. Additionally, there are invoices related to supplies that support the testimony of inventors Mr. Root and Mr. Sutton regarding continued work on the RX GuideLiner in March 2006 and April 2006. Ex. 2104; Ex. 2005, 5; Ex. 2115; Ex. 2106, 3; Ex. 2107; Ex. 2108, 4–5. All of this evidence corroborates Mr. Root's and Mr. Sutton's testimony that VSI worked diligently and continuously on the RX GuideLiner project without abandoning the project.

Finally, we are not convinced that the periods from September 23, 2005, to the end of November 2005 or in February 2006 demonstrate lack of diligence. Petitioner's argument for these periods is conclusory, and contradicted by the reasonable commercialization delays that we addressed above.

Considering all of the pertinent evidence, we find that Patent Owner did not abandon or unreasonably delay the RX GuideLiner project during the critical period. Petitioner's arguments implying the need for direct evidence and scouring the timeline for periods of inactivity are unpersuasive. We therefore conclude that Patent Owner demonstrates, by a preponderance of the evidence, that VSI was reasonably continuous in its diligence during the critical period. Because we have also found that Patent Owner demonstrated conception prior to Itou's critical date, Patent Owner has met its burden to successfully demonstrate that Itou is not prior art to the challenged claims of the '776 patent.

III. MOTION TO EXCLUDE

Petitioner has moved to exclude Exhibit 2024, which is the August 24, 2005, Product Requirements document. Paper 110. Petitioner contends that Exhibit 2024 is unreliable on its face and that none of Patent Owner's witnesses can authenticate the document. *Id.* at 2–9. Patent Owner responds that Exhibit 2024 is authenticated under Federal Rule of Evidence 901 based on the declaration and/or deposition testimony of Mr. Peterson (Ex. 1926 ¶ 18), Ms. Schmalz (Ex. 2039 ¶¶ 6–7), Mr. Root (Ex. 2118 ¶ 54), and Mr. Sutton (Ex. 2119 ¶ 44). Paper 114.

Documents are authenticated by evidence "sufficient to support a finding that the item is what the proponent claims it is." Fed. R. Evid. 901(a); *see Fox Factory v. SRAM, LLC*, IPR2016-01876, Paper 59 at 63 (PTAB Apr. 2, 2018) (quoting same). "Authenticity is, therefore, not an especially high hurdle for a party to overcome." *Fox Factory*, Paper 59 at 63 (citing *United States v. Patterson*, 277 F.3d 709, 713 (4th Cir. 2002)

We determine that Exhibit 2024 has been authenticated under Federal Rule of Evidence 901. In addition, Petitioner's arguments go to the weight of the evidence and not its admissibility. Accordingly, we deny Petitioner's Motion to Exclude.

IV. MOTION TO AMEND

In its Corrected Contingent Motion to Amend, Patent Owner requests that if any of claims 27, 33, 37, 42, 43, 45, 47, or 56 is found unpatentable, they should be replaced by proposed substitute claims 58–65. Motion 1. Because we do not find any of the challenged claims unpatentable in this proceeding, we do not reach the Motion to Amend.

V. CONSTITUTIONAL CHALLENGE

Patent Owner argues that the Petition should be denied because "the manner in which administrative law judges are appointed is unconstitutional." PO Resp. 66 (citing *Arthrex, Inc. v. Smith & Nephew, Inc.*, 941 F.3d 1320, 1325 (Fed. Cir. 2019)). Patent Owner further argues that the purported remedy imposed by the *Arthrex* decision "is insufficient to remedy the constitutional defect." *Id.* (citing *Arthrex*, 941 F.3d at 1338–39). We decline to consider Patent Owner's constitutional argument because the Federal Circuit addressed this issue in *Arthrex*. *Arthrex*, 941 F.3d at 1328.

VI. CONCLUSION

After reviewing the arguments and evidence of record, we determine that Patent Owner has antedated the Itou reference based on a showing of prior conception coupled with either actual reduction or diligence towards constructive reduction to practice. Because Itou is relied upon for all the challenges in the Petition, Petitioner has not demonstrated by a preponderance of the evidence that claims 25–27, 29–33, 35–39, 41–49, and 52–56 of the '776 patent are unpatentable.

In summary:

Claims	35 U.S.C. §	Reference(s)/Basis	Claims Shown Unpatentable	Claims Not Shown Unpatentable
25–27, 29–33, 35–37, 41–45, 47–49	102	Itou		25–27, 29–33, 35–37, 41–45, 47–49
39, 46	103(a)	Itou, the knowledge of POSITA		39, 46

36, 37, 52–56	103(a)	Itou, Kataishi, the knowledge of POSITA		36, 37, 52–56
32, 36–38, 46, 52–56	103(a)	Itou, Ressemann, the knowledge of POSITA		32, 36–38, 46, 52–56
52–56	103(a)	Itou, Enger, the knowledge of POSITA		52–56
Outcome				25–27, 29–33, 35–39, 41–49, 52–56

The table below summarizes our conclusions as to Patent Owner's Revised Motion to Amend the claims.

Motion to Amend Outcome	**Claim(s)**
Original Claims Cancelled by Amendment	
Substitute Claims Proposed in the Amendment	58–65
Substitute Claims: Motion to Amend Granted	
Substitute Claims: Motion to Amend Denied	
Substitute Claims: Not Reached	58–65

VII. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that Petitioner has not demonstrated by a preponderance of the evidence that claims 25–27, 29–33, 35–39, 41–49, and 52–56 of the '776 patent are unpatentable;

ORDERED that Petitioner's Motion to Exclude is *denied*;

ORDERED that we do not reach Patent Owner's Contingent Motion to Amend; and

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

FOR PETITIONER:

Cyrus Morton
Sharon Roberg-Perez
Christopher Pinahs
William E. Manske
Emily J. Tremblay
ROBINS KAPLAN LLP
cmorton@robinskaplan.com
sroberg-perez@robinskaplan.com
cpinahs@robinskaplan.com
wmanske@robinskaplan.com
etremblay@robinskaplan.com

FOR PATENT OWNER:

Derek Vandenburgh
Dennis Bremer
CARLSON, CASPERS, VANDENBURGH & LINDQUIST, P.A.
dvandenburgh@carlsoncaspers.com
dbremer@carlsoncaspers.com

Trials@uspto.gov
571-272-7822

Paper 128
Date: June 7, 2021

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.

IPR2020-00137
Patent RE47,379E

Before SHERIDAN K. SNEDDEN, JON B. TORNQUIST, and CHRISTOPHER G. PAULRAJ, *Administrative Patent Judges*.

TORNQUIST, *Administrative Patent Judge*.

JUDGMENT
Final Written Decision
Determining No Challenged Claims Unpatentable
Not Addressing Patent Owner's Motion to Amend
35 U.S.C. § 318(a)

ORDERS
Denying Petitioner's Motion to Exclude (Paper 112)
37 C.F.R. § 42.64(c)

I. INTRODUCTION

Medtronic, Inc. and Medtronic Vascular, Inc. (collectively "Petitioner") filed a Petition (Paper 1, "Pet.") requesting an *inter partes* review of claims 25, 26, 29–40, and 42–45 of U.S. Reissue Patent RE47,379E (Ex. 1001, "the '379 patent"). Teleflex Innovations S.À.R.L. ("Patent Owner")[1] filed a Preliminary Response to the Petition (Paper 8). Upon review of the Petition and Preliminary Response, we instituted an *inter partes* review of all claims on all grounds asserted in the Petition (Paper 22, "Inst. Dec." or "Institution Decision").

Patent Owner subsequently filed a Patent Owner Response (Paper 43, "PO Resp.") (redacted version available at Paper 44), Petitioner filed a Reply (Paper 82, "Pet. Reply") (redacted version available at Paper 83), and Patent Owner filed a Sur-Reply (Paper 104, "Sur-Reply") (redacted version available at Paper 105).

With prior authorization of the Board, Patent Owner filed a Consolidated Response Addressing Conception and Reduction to Practice (Paper 39, "PO CRTP Resp." or "PO CRTP Response"), to which Petitioner filed Reply (Paper 78, "Pet. CRTP Reply") (redacted version available at Paper 79), Patent Owner filed a Sur-Reply (Paper 98, "PO CRTP Sur-Reply"), and Petitioner filed a Sur-Sur-Reply (Paper 113, "Pet. CRTP Sur-Sur-Reply").

[1] Patent Owner represents that "Teleflex Innovations S.A.R.L. merged into Teleflex Medical Devices S.A.R.L," which subsequently "transferred ownership of [the '380 patent] to Teleflex Life Sciences Limited." Paper 7, 2.

Patent Owner also filed a contingent motion to amend (Paper 38) and a Corrected Contingent Motion to Amend (Paper 97, "Motion"). The Motion requests that if any of claims 25, 29, 30, 38, 43, or 45 of the '379 patent is determined to be unpatentable, that the Board substitute those claim(s) with proposed substitute claims 46–51.. Motion 1. Petitioner filed an opposition to the Corrected Contingent Motion to Amend (Paper 103), Patent Owner filed a reply (Paper 107), and Petitioner filed a sur-reply (Paper 115).[2]

An oral hearing was held on March 8, 2021, and a transcript of the hearing is included in the record. Paper 127 ("Tr.") (redacted version available at Paper 126).

A. Real Parties in Interest

Petitioner identifies Medtronic, Inc. and Medtronic Vascular, Inc., as the real parties-in-interest, and notes that "Medtronic plc is the ultimate parent of both entities." Pet. 5. Patent Owner identifies the real parties-in-interest for itself as Teleflex Medical Devices S.À.R.L., Vascular Solutions LLC, Arrow International, Inc., and Teleflex LLC, and notes that "Teleflex Incorporated is the ultimate parent of the entities listed above." Paper 4, 2.

B. Related Matters

The parties indicate that the '379 patent is the subject of litigation in *Vascular Solutions LLC, et al. v. Medtronic, Inc., et al.*, No. 19-cv-01760 (D. Minn.) and *QXMedical, LLC v. Vascular Solutions, LLC*, No. 17-cv-

[2] Patent Owner's filed an original, contingent motion to amend (Paper 38) to which Petitioner filed an Opposition (Paper 85). These documents were superseded by the corrected Motion to Amend and Patent Owner's Opposition to the Corrected Motion to Amend, identified above.

01969 (D. Minn). Pet. 5; Paper 4, 2. The '379 patent is also at issue in IPR2020-00138 (institution granted). IPR2020-00138, Paper 20.

The following proceedings before the Board also involve the same parties and related patents: IPR2020-00126 (U.S. Patent No. 8,048,032 B2), IPR2020-00127 (U.S. Patent No. 8,048,032 B2), IPR2020-00128 (U.S. Patent No. RE45,380 E1), IPR2020-00129 (U.S. Patent No. RE45,380 E1), IPR2020-00130 (U.S. Patent No. RE45,380 E1), IPR2020-00132 (U.S. Patent No. RE45,760 E1), IPR2020-00134 (U.S. Patent No. RE45,760 E1), IPR2020-00135 (U.S. Patent No. RE45,776 E1), IPR2020-00136 (U.S. Patent No. RE45,776 E1).

C. The '379 Patent

The '379 patent relates to catheters used in interventional cardiology procedures and, in particular, to "methods and apparatus for increasing backup support for catheters inserted into the coronary arteries from the aorta." Ex. 1001, 1:43–47. "In coronary artery disease the coronary arteries may be narrowed or occluded by atherosclerotic plaques or other lesions." *Id*. at 1:57–59. This narrowing is referred to as stenosis. *Id*. at 1:61. To diagnose or treat a stenosis, "it is commonly necessary to pass a guidewire or other instruments through and beyond the occlusion or stenosis of the coronary artery." *Id*. at 1:61–65. In this method, a guide catheter is inserted through the aorta and into the ostium of the coronary artery, where it is typically seated into the opening or ostium of the artery to be treated. *Id*. at 1:66–2:3. A guidewire or other instrument is then passed through the lumen of the guide catheter and inserted into the artery beyond the stenosis. *Id*. at 2:1–5. Crossing tough lesions, however, may create enough backwards force to dislodge the guide catheter from the ostium of the artery being

treated, making it difficult or impossible to treat certain forms of coronary artery disease. *Id*. at 2:6–10.

Figures 1 and 2 of the '379 patent are reproduced below:

Fig. 1

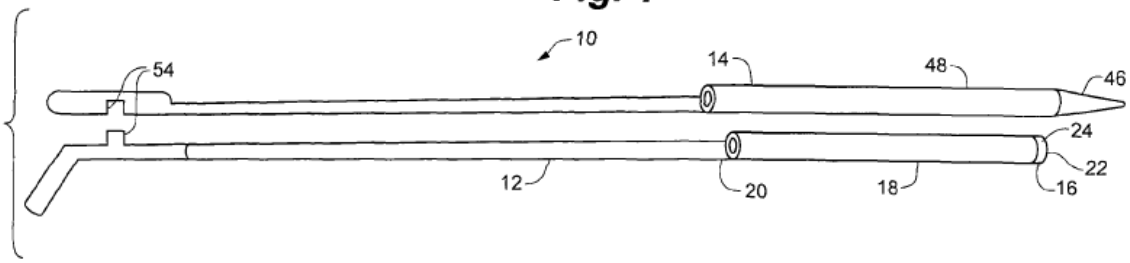


Fig. 2

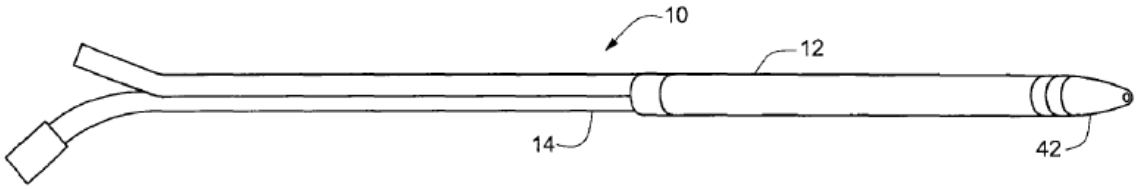
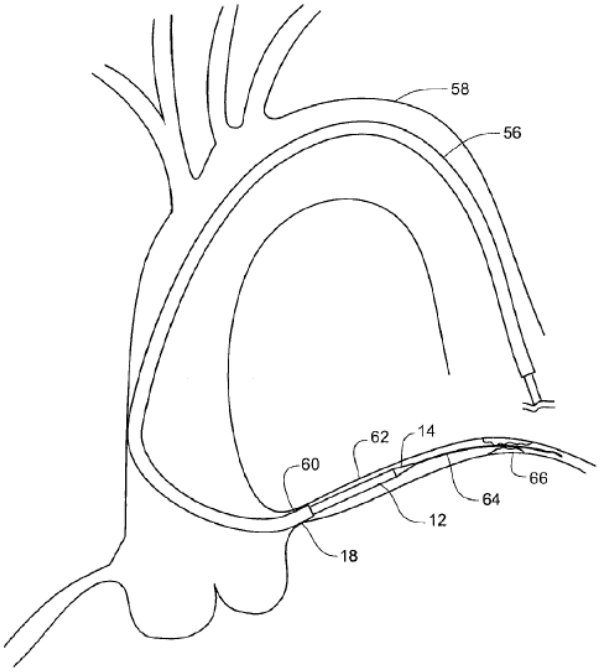


Figure 1 is a schematic depiction of a coaxial guide catheter and a tapered inner catheter and Figure 2 is a schematic depiction of these two elements assembled together. *Id.* at 5:57–62. As shown in Figure 1, coaxial guide catheter 12 includes tip portion 16, reinforced portion 18, and rigid portion 20. *Id.* at 6:50–51. Tapered inner catheter 14 includes tapered portion 46 at a distal end thereof and straight portion 48. *Id.* at 7:36–37. Clip 54 releasably joins tapered inner catheter 14 to coaxial guide catheter 12. *Id.* at 7:41–44.

Figure 8 of the '379 patent is reproduced below:

Fig. 8



"Figure 8 is a schematic view of a guide catheter, a guidewire, a coaxial guide catheter, catheter in accordance with the present invention and a tapered inner catheter located in the aortic arch and coronary artery." *Id.* at 6:11–14. In Figure 8, "coaxial guide catheter 12 with tapered inner catheter 14 is passed through guide catheter 56 and over guidewire 64 into coronary artery 62 after the guide catheter 56 has been placed in the ostium 60 of coronary artery 62." *Id.* at 8:26–32. "Coaxial guide catheter 12, with tapered inner catheter 14, provides an inner support member for proper translation over guidewire 64." *Id*. at 8:32–36. "Once coaxial guide catheter 12 is in place, tapered inner catheter 14 is removed from the inside of coaxial guide catheter 12." *Id*. at 8:36–38. At this point, coaxial guide catheter 12 is ready to accept a treatment catheter such as a stent or balloon catheter. *Id*. at 8:39–40. The '379 patent explains that the "combination of

improved distal anchoring and stiffening of the guide catheter 56/coaxial guide catheter 12 combination provides additional back up support to resist dislodging of guide catheter 56 from ostium 60 when force is applied to guidewire 64 to pass through stenotic lesion 66 or another lesion." *Id*. at 8:47–52.

D. Illustrative Claim

Independent claim 25 is illustrative of the challenged claims and is reproduced below.

25. A method of forming a device adapted for use with a standard guide catheter having a continuous lumen extending for a predefined length, the method comprising:

providing a flexible tip segment having a lumen therethrough;

providing a reinforced segment having a lumen therethrough, including one or more metallic elements covered with a polymer, and extending from a proximal end portion to a distal end portion;

providing a substantially rigid segment extending from a proximal end portion to a distal end portion, wherein the substantially rigid segment is more rigid along a longitudinal axis than the flexible tip segment;

defining a side opening portion, including forming, in a proximal to distal direction, an arcuate cross-sectional shape and a hemicylindrical cross-sectional shape;

eccentrically positioning the distal end portion of the substantially rigid segment relative to a longitudinal axis of the proximal end portion of the reinforced segment; and

coaxially aligning the distal end portion of the reinforced segment and a proximal end portion of the flexible tip segment,

wherein providing the substantially rigid segment, the reinforced segment, and the flexible tip segment includes forming a

> device length that is longer than the predefined length of the continuous lumen of the guide catheter such that when a distal end portion of the flexible tip segment is extended distally of a distal end of the guide catheter, the proximal end portion of the substantially rigid segment extends proximally of a proximal end of the guide catheter.

Ex. 1001, 13:61–14:25.

E. Prior Art and Asserted Grounds

We instituted review of claims 25, 26, 29–40, and 42–45 of the '379 patent on the following grounds (Inst. Dec. 7, 31):

Claim(s) Challenged	35 U.S.C. §	Reference(s)/Basis
25, 26, 29–31, 33–40, 42, 43, 45	102	Itou[3]
26, 38–40, 43–45	103	Itou, Ressemann[4]
32	103	Itou
44	103	Itou, Kataishi[5]
44	103	Itou, Enger[6]

In support of its arguments, Petitioner relies on the expert declarations of Dr. Stephen Jon David Brecker (Exs. 1005, 1806, 1901), Dr. Richard A. Hillstead (Exs. 1042, 1905), Mr. Michael Jones (Ex. 1807), Dr. Paul Zalesky (Exs. 1755, 1830, 1919). Patent Owner relies on the declarations of Ms. Deborah Schmalz (Ex. 2039), Mr. Howard Root (Ex. 2118), Mr. Gregg

[3] Itou, US 7,736,355 B2, issued June 15, 2010 (Ex. 1007) ("Itou").
[4] Ressemann, US 7,604,612 B2, issued October 20, 2009 (Ex. 1008) ("Ressemann").
[5] Kataishi, US 2005/0015073 A1, published January 20, 2005 (Ex. 1025) ("Kataishi").
[6] Enger, US 5,980,486, issued November 9, 1999 (Ex. 1050) ("Enger").

Sutton (Ex. 2119), Mr. Mark Goemer (Ex. 2120), Ms. Amanda O'Neil (Ex. 2121), Mr. Steve Erb (Ex. 2122), Mr. Peter T. Keith (Exs. 2123, 2124, 2138, 2243), Dr. John J. Graham (Ex. 2145), Dr. Lorenzo Azzalini (Ex. 2151), Ms. Heather S. Rosecrans (Ex. 2205), and Dr. Craig Thompson (Ex. 2215).

II. ANALYSIS

A. Priority Date of the '379 Patent

The AIA's first-to-file provisions apply to patent applications "that contain[] or contained at any time a claim to a claimed invention that has an effective filing date" on or after March 16, 2013. AIA § 3(n)(1). The application for reissue for the '379 patent was filed December 30, 2015 and sought reissue of US Patent No. 8,292,850, which issued October 23, 2012 from an application filed January 26, 2012. Ex. 1001, Codes (22), (64). Petitioner contends that because there is no written description support for the subject matter of at least claims 27 and 44 of the '379 patent in the applications to which the '379 patent claims priority, the '379 patent has an effective filing date after March 16, 2013. Pet. 15. Thus, according to Petitioner, the '379 patent is not supported by a pre-March 16, 2013 application making it subject to the AIA's first-to-file provisions. *Id.*

"The effective filing date for a claimed invention in an application for reissue or reissued patent shall be determined by deeming the claim to the invention to have been contained in the patent for which reissue was sought." 35 U.S.C. § 100(i)(2). As the '379 patent, the "patent for which reissue was sought" in this case, was issued October 23, 2012, we are not persuaded that the AIA's first-to-file provisions apply to the '379 patent. Indeed, Petitioner provides no legal support for the proposition that claims in

a reissue patent are not entitled to the filing date as if they appeared in the original patent for which reissue was sought.[7]

B. Level of Ordinary Skill in the Art

We consider the asserted grounds of unpatentability in view of the understanding of a person of ordinary skill in the art ("POSITA"). Petitioner provides two alternative definitions of a person of ordinary skill in the art. First, Petitioner asserts that if a person of ordinary skill in the art "was a medical doctor, s/he would have had (a) a medical degree; (b) completed a coronary intervention training program, and (c) experience working as an interventional cardiologist." Pet. 16. Alternatively, Petitioner asserts that if a person of ordinary skill in the art was "an engineer, s/he 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." *Id.* Additionally, Petitioner contends that "[e]xtensive experience and technical training might substitute for education, and advanced degrees might substitute for experience." *Id.*

Patent Owner "does not dispute Medtronic's proposed definition of a POSITA." PO Resp. 10.

Upon review of the parties' arguments and supporting evidence, we adopt both of Petitioner's definitions for a person of ordinary skill in the art, allowing either experience as a medical doctor or as an engineer, as they are

[7] To the extent the original patent for which reissue was sought does not contain written description support for a reissue claim, that claim may be invalid for lack of written description support. But this is a question we may not address in an IPR. *See* 35 U.S.C. § 311(b).

undisputed and consistent with the level of skill reflected in the prior art and the written description of the '379 patent. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001) (the prior art itself can reflect the appropriate level of ordinary skill in the art).

C. Claim Construction

In this proceeding, the claims of the '379 patent are 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). Under that standard, the words of a claim are generally given their "ordinary and customary meaning," which is the meaning the term would have had to a person of ordinary skill at the time of the invention, in the context of the entire patent including the specification. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–13 (Fed. Cir. 2005) (en banc).

Upon review of the parties arguments and supporting evidence, we determine that no claim terms of the '379 patent require express construction for purposes of this Decision. *See Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (quoting *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.")).

D. Status of Itou as Prior Art – Conception and Reduction to Practice

Before reaching the merits of the grounds in the Petition, we address whether Petitioner's primary reference, Itou, which is relied upon for all grounds in the Petition, qualifies as prior art.

Itou was filed on September 23, 2005, published on March 30, 2006, and issued on June 15, 2010. Ex. 1007, codes (22), (45), (65). Petitioner

contends Itou is prior art under pre-AIA § 102(e). Pet. 20–21.[8] In the Conception and Reduction to Practice ("CRTP") briefing that we separately authorized for these proceedings, Patent Owner argues that Itou does not qualify as prior art based on research and development related to the claimed invention that took place at Vascular Solutions, Inc. ("VSI"), Patent Owner's predecessor-in-interest, starting around early 2005 and continuing through the May 3, 2006, filing of the original priority application for the '379 patent. *See generally* PO CRTP Response; PO CRTP Sur-Reply. Petitioner disputes these contentions. *See generally* Pet. CRTP Reply; Pet. CRTP Sur-Sur-Reply.

In its CRTP Response, Patent Owner identifies the evidence on which it relies to antedate Itou, including certain inventor testimony, non-inventor testimony, and other documentary evidence. PO CRTP Resp. 2. As to inventor testimony, Patent Owner relies on the respective declarations of co-inventors Howard Root (Ex. 2118) and Gregg Sutton (Ex. 2119). As to non-inventor testimony, Patent Owner relies on the declaration of its expert Peter T. Keith (Ex. 2123), the declarations of VSI employees Steven Erb (Ex. 2122) and Deborah Schmalz (Ex. 2039), and the declarations of employees of third-party vendors, Amanda O'Neil (Ex. 2121) and Mark Goemer (Ex. 2120). As to documentary evidence, Patent Owner relies on nearly 75 exhibits. These documents include inventor lab notebooks and handwritten notes (Exs. 2002, 2004); internal company memoranda, presentations, and

[8] In addition to this Petition, Petitioner similarly asserts Itou in the petitions in IPR2020-00126, -00128, -00129, -00132, -00134, and -00135. Our analysis regarding the prior art status of Itou is similar for each of these proceedings.

other similar documents (Exs. 2003, 2005, 2017–2018, 2024, 2025, 2036–2038, 2040–2041, 2099–2100, 2105, 2109, 2127–2134); invoices, sales orders, and certificates of completion from technical equipment vendors (Ex. 2006–2011, 2013, 2016, 2020–2021, 2026–2035, 2089–2095, 2097, 2104, 2106–2108, 2110–2112); a photograph (Ex. 2014); deposition transcripts (Exs. 2015, 2116); communications with and documents from VSI's outside patent counsel (Exs. 2019, 2023, 2096, 2098, 2101–2103, 2117); and engineering drawings (Exs. 2022, 2113–2115).

We have considered this evidence and other rebuttal evidence offered by Petitioner. For the following reasons, we conclude that a preponderance of the evidence demonstrates that Patent Owner conceived the subject matter recited in the challenged claims before Itou's "critical date" (i.e., September 23, 2005) and either actually reduced the invention to practice prior to the critical date or diligently worked to constructively reduce to practice the invention on May 3, 2006, in the form of the first priority application for the '379 patent. Accordingly, we conclude that Itou does not qualify as prior art to the '379 patent.

For our analysis, we first set forth the relevant legal standards, followed by our fact findings and analysis on conception, actual reduction to practice, and diligence towards constructive reduction to practice.

1. Legal Standards

"To antedate (or establish priority) of an invention, a [patent owner] must show either an earlier reduction to practice, or an earlier conception followed by a diligent reduction to practice." *Purdue Pharma L.P. v. Boehringer Ingelheim GMBH*, 237 F.3d 1359, 1365 (Fed. Cir. 2001)). "Conception is the formation, in the mind of the inventor, of a definite and

permanent idea of the complete and operative invention, as it is thereafter to be applied in practice." *Cooper v. Goldfarb*, 154 F.3d 1321, 1327 (Fed. Cir. 1998)). "A reduction to practice can be either a constructive reduction to practice, which occurs when a patent application is filed, or an actual reduction to practice." *Id.* "In order to establish an actual reduction to practice, the [patent owner] must prove that: (1) [the inventors] constructed an embodiment or performed a process that met all the limitations of the [claimed invention]; and (2) [the inventors] determined that the invention would work for its intended purpose." *Id.*

If a patent owner has not shown actual reduction to practice prior to the "critical date" of a reference, the patent owner may nonetheless antedate the reference by establishing prior conception and reasonable diligence towards a constructive reduction to practice. *Purdue Pharma*, 237 F.3d at 1365. "Reasonable diligence must be shown throughout the entire critical period, which begins just prior to the competing reference's effective date and ends on the date of the invention's reduction to practice." *Arctic Cat Inc. v. GEP Power Prods., Inc.*, 919 F.3d 1320, 1331 (2019). However, the "diligence need not be perfectly continuous—only *reasonably* continuous." *Id.*

To be persuasive, an inventor's testimony of conception and reduction to practice must be corroborated by other independent evidence. "Conception must be proved by corroborating evidence which shows that the inventor disclosed to others his completed thought expressed in such clear terms as to enable those skilled in the art to make the invention." *REG Synthetic Fuels, LLC v. Neste Oil Oyj*, 841 F.3d 954, 962 (Fed. Cir. 2016) (citations and quotation marks omitted). "However, 'there is no final single

formula that must be followed in proving corroboration.'" *Id.* (citations and quotation marks omitted); *see also Kolcraft Enters, Inc. v. Graco Children's Prods., Inc.*, 927 F.3d 1320, 1324 (Fed. Cir. 2019); *Medichem, S.A. v. Rolabo, S.L.*, 437 F.3d 1157, 1169–70 (Fed. Cir. 2006).

"In the final analysis, each corroboration case must be decided on its own facts with a view to deciding whether the evidence as a whole is persuasive." *Berges v. Gottstein*, 618 F.2d 771, 776 (CCPA 1980). Corroborating evidence may consist of "testimony of a witness, other than the inventor," or "evidence of surrounding facts and circumstances independent of information received from the inventor." *Medichem*, 437 F.3d at 1171. "Even the most credible inventor testimony is *a fortiori* required to be corroborated by independent evidence, which may consist of documentary evidence as well as the testimony of non-inventors." *Id.* at 1171–72. We assess whether evidence corroborates conception and reduction to practice under a "rule of reason" analysis. *Cooper*, 154 F.3d at 1330.

In an *inter partes* review, 35 U.S.C. § 316(e) imposes the ultimate burden of persuasion to "prove unpatentability by a preponderance of the evidence" onto the petitioner. This burden never shifts to the patent owner. *Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015). However, when the patent owner attempts to antedate the prior art, , "[a] second and distinct burden, the burden of production" can shift between the petitioner and the patentee. *Id.* at 1379; *see In re Magnum Oil Tools Int'l, Ltd.*, 829 F.3d 1364, 1375–76 (Fed. Cir. 2016). Specifically, the patent owner the "bears the burden of establishing that its claimed invention is entitled to an earlier priority date than an asserted prior art

reference." *Magnum Oil Tools.*, 829 F.3d at 1375–76. Once the patent owner establishes it is entitled to an earlier priority date, the burden of production then shifts back to the petitioner "to convince the court that [the patent owner] is not entitled to the benefit" of the earlier priority date. *Dynamic Drinkware*, 800 F.3d at 1379 (citing *Tech. Licensing Corp. v. Videotek, Inc.*, 545 F.3d 1316, 1328 (Fed. Cir. 2008)).

2. Conception

To show prior conception, Patent Owner relies primarily upon Mr. Root's testimony submitted in support of its CRTP Response. Ex. 2118 (Root Declaration in support of CRTP).[9,10] Mr. Root was the founder and Chief Executive Officer of VSI from 1997 to 2017. *Id.* ¶¶ 1–2. Patent Owner also relies upon the testimony of co-inventor Mr. Sutton, who was Vice President, Research & Development at VSI from 2004 until mid-2006. Ex. 2119 (Sutton Declaration in support of CRTP). As additional documentary corroboration for this inventor testimony, Patent Owner relies

[9] Patent Owner previously submitted a declaration by Mr. Root with its Preliminary Response (Ex. 2001), but withdrew that declaration in favor of Ex. 2118. Paper 39, 2 n.1.

[10] The testimonial evidence that Patent Owner presents in support of conception is largely undisputed. Indeed, during a teleconference addressing Patent Owner's request to present live testimony from Mr. Root in these proceedings, Petitioner's counsel acknowledged that Mr. Root's testimony was not disputed in a manner that would require our credibility assessment. *See* Ex. 1920, 11:10–11 ("And I don't think we have, you know, directly said Mr. Root is lying on this topic."); *id.* at 17:17–18 ("We don't have any issue at play here that goes to credibility."). Accordingly, in view of our conclusion that "the credibility of Mr. Root is not in question," we denied Patent Owner's request to present live testimony from Mr. Root at the oral hearing. *See* Paper 111, 4–5 (distinguishing *K-40 Elecs., LLC v. Escort, Inc.*, IPR2013-00203, Paper 34 (PTAB May 21, 2014) (precedential)).

upon certain pages from Mr. Sutton's laboratory notebook dated January 4, 2005 (Ex. 2002), a "market feasibility" memorandum from Mr. Root dated February 4, 2005 (Ex. 2003), and some additional handwritten notes and drawings from Mr. Root dated February 7, 2005 (Ex. 2004). We first set forth the relevant facts based on these declarants' testimony and corroborating evidence, and then address any disputed issues of material fact and legal issues as needed in our analysis.

a) Fact Findings for Conception

In his declaration, Mr. Root attests that conception started around the time he attended the Transcatheter Cardiovascular Therapeutics (TCT) conference from September 27 to October 1, 2004, by which time he had recognized the issue of "guide catheter backout" that physicians were experiencing when performing complex interventional coronary procedures. Ex. 2118 ¶ 5. Accordingly, Mr. Root asserts that he recognized a need for a solution "that provided better guide positioning, device delivery, and procedural conveniences" than what previously existed in the market. *Id.* To solve this problem, Mr. Root indicates that he came up with "the idea for a guide extension catheter that would provide improved back-up support with rapid exchange delivery, which would offer far more convenience than other options available at the time." *Id.* ¶ 6. And "[s]ometime after the TCT conference, but before 2005," Mr. Root met with his co-inventors, including Mr. Sutton, to discuss more particular ideas for how to make this device. *Id.*

The "guide extension catheter" device that the inventors thought of at this time included certain key features. It was to be used within a standard guide catheter that was one "French size" larger than the "guide extension

catheter," and was parsed into two distinct portions—a substantially rigid proximal portion comprising a "rail" structure and a distal tubular portion with a lumen—which together were longer than a standard guide catheter. *Id.* ¶ 7. During an operation, after the standard guide catheter was inserted into the vasculature so its distal end was in the ostium of a cardiac artery, the guide extension catheter would be inserted into the lumen until the distal end of the tubular portion went past the distal end of the guide catheter and into the cardiac artery. *Id.* With both catheters in place, an interventional cardiology device could be thereafter inserted through the standard guide catheter (running along the rail of the guide extension catheter) until it reached the distal end of the distal tubular portion of the guide extension catheter, thereby entering the cardiac artery. *Id.*

The device they undertook to develop was initially called the "Guide-Liner" device, but the hyphen was later dropped and it became known as the "GuideLiner" device. *Id.* ¶ 9. Although the original idea for the GuideLiner was a "rapid exchange" ("RX") version of the guide extension catheter, "[s]ometime between February and June of 2005, a decision was made to concurrently pursue development of an over-the-wire ('OTW') version of GuideLiner." *Id.* ¶ 19. Mr. Root acknowledges, however, that "[t]he OTW GuideLiner was not part of the inventions of the [challenged] patents," but instead was more akin to the "mother-in-child" design that was known in the prior art and discussed in the background of the challenged patents. *Id.* (citing Ex. 1001, 2:17–44).[11]

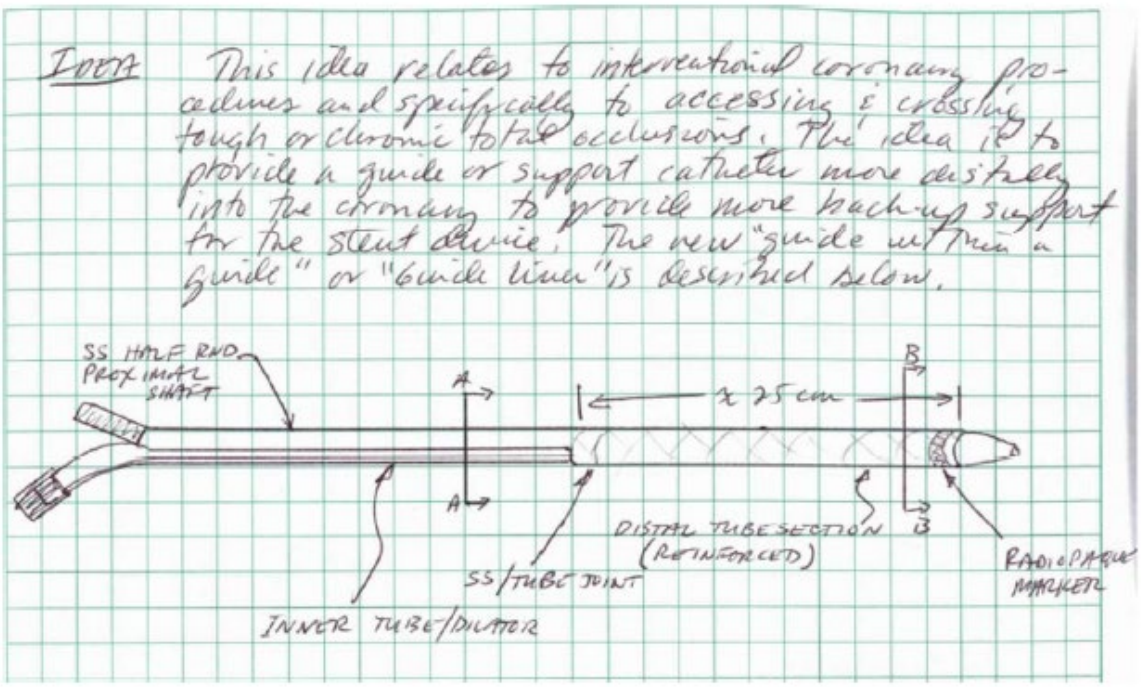
[11] It is undisputed that the work done in developing the RX GuideLiner, not the OTW GuideLiner, must provide the basis for conception and reduction

Mr. Sutton in his own declaration sets forth a story consistent with that set forth by Mr. Root. He attests that "[s]tarting in late-2004 until [he] left VSI, [he] performed research and development work on what became the GuideLiner guide extension catheter." Ex. 2119 ¶ 2. Although VSI did not retain all of its files from that time, Mr. Sutton recalls based on his memory and documents he reviewed that "we knew very early on that the GuideLiner rapid exchange device would work for its intended purpose," and that "[t]he research and development that followed our original conception of the GuideLiner rapid exchange was to optimize materials, dimensions, and design details that would allow us to manufacture and bring the product to market in a way that would be commercially viable." *Id.* ¶ 6.

The earliest documentary evidence that corroborates this testimony is Mr. Sutton's laboratory notebook pages relating to the concept for a "Guide-Liner" device. Ex. 2002. Mr. Sutton signed the relevant pages on January 4, 2005, and Jeffrey Welch, another co-inventor and engineer at VSI, witnessed those pages on March 2, 2005. Ex. 2002, 7–8; *see* Ex. 2119 ¶ 7.

A portion of one page from Mr. Sutton's notebook is reproduced below:

to practice of the claimed invention. PO CRTP Resp. 13 n. 3; Pet. CRTP Reply 1



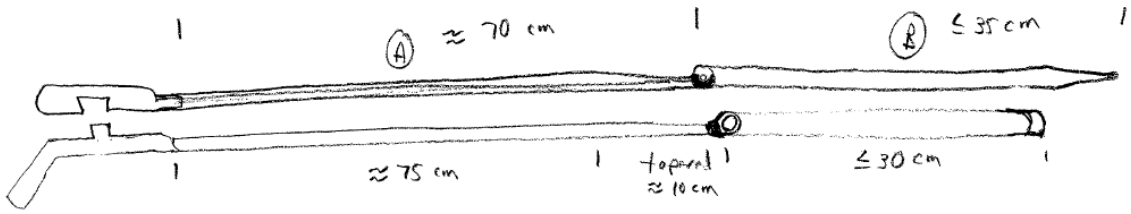
Ex. 2002, 7. As shown above, Mr. Sutton's notebook sets forth an "idea" that "relates to interventional coronary procedures and specifically to accessing & crossing tough or chronic occlusions," which "is to provide a guide or support catheter more distally into the coronary to provide more back-up support for the stent device." *Id.*; Ex. 2118 ¶ 9. Mr. Sutton's lab notebook also includes drawings of the cross section of various portions of the guide extension catheter and a drawing of how the Guide-Liner would be used that are similar to figures included in the challenged patents. *Cf.* Ex. 1001, Figs. 1, 2, 5, 6 (depicting patent drawings of the guide extension catheter that are similar to Mr. Sutton's drawings). For example, he notebook includes a drawing of a "5F" (5-French) Guide-Liner in operation and notes that the Guide-Liner a) "is used where there is difficulty crossing lesions," b) "allows back-up support distally," c) "allows for Rapid X change," and d) "would fit std. 6F Guides." Ex. 2002, 8. The notebook

pages also describe the main features of the device, including: 1) an inner tube/dilator that "fits snugly" within a stainless steel ("SS") half-tube; 2) a reinforced distal tube section with a braided "PTFE/SS/PEBAX" material that is "soft for coronaries"; and 3) a design that "allows for rapid exchange." Ex. 2002, 7. Additionally, the notebook identifies the "5F Design Specs," including an overall device length of between 105 cm and 115 cm. *Id.* Both Mr. Root and Mr. Sutton authenticate the contents of the notebook pages. Ex. 2118 ¶¶ 9–11; Ex. 2119 ¶¶ 7–14. Mr. Sutton attests that his notebook was "issued and maintained in the regular course of VSI's business." Ex. 2119 ¶ 7.

By early February 2005, Mr. Root realized this device would have "substantial market potential," so he wrote a "Market Feasibility" memorandum (memo) for GuideLiner catheters, dated February 4, 2005. Ex. 2118 ¶ 11; Ex. 2003 (confidential); Ex. 2127 (public). Mr. Root attests that he would only have drafted this kind of memo if he "had developed high confidence that a concept would work," so that non-inventors in the company (e.g., regulatory personnel and engineers) could join a project to bring the new product to market. Ex. 2118 ¶ 11. The memo itself recognizes the "substantial market potential" for the RX GuideLiner device based on an estimated 30,000 procedures a year. Ex. 2003, 1. The memo indicates that three versions were anticipated (i.e., a "5in6," a "6in7," and a "7in8" GuideLiner), and notes problems with the prior art OTW methods. *Id.* The memo also generally describes the RX GuideLiner in a manner consistent with the description in Mr. Sutton's notebook including, among other features, that: it would be delivered within a standard guide catheter for interventional cardiology procedures; it had a "short distal tube segment

to allow for rapid exchange delivery"; it was inserted through the existing hemostatic valve; and it was one French size smaller than the standard guide catheter. *Id.* at 2.

Mr. Root also references his own handwritten notes, dated February 7, 2005.[12] Ex. 2118 ¶¶ 12–14; Ex. 2004. These notes show certain features of the RX GuideLiner device, including a "side opening" section that appears in the transition from a partial-round proximal portion to a full round portion connected to a distal tube section. *Id.* The first drawing from Mr. Root's handwritten notes, reproduced below, is similar to Figure 1 of the '379 patent:

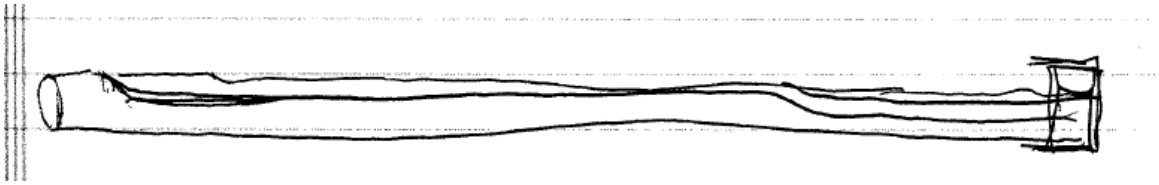


Ex. 2004, 1. As shown above, a "side opening" to allow for the RX capability is reflected through "crude shading" between the rail structure and

[12] Although only the first page of these notes is dated, Mr. Root attests he made the notes on the other two pages "contemporaneously with [his] notes on page 1." Ex. 2118 ¶ 14. Petitioner contends that the third page, in addition to being undated and unwitnessed, appears to come from "a different set of notes" because, unlike the first two pages, the paper is lined. Pet. CRTP Reply 7 n.4. Petitioner also points out that Mr. Sutton testified that he had not seen the third page until his deposition in the stayed district court litigation. *Id.* (citing Ex. 1108, 41:1–6, 46:7–47:3). Mr. Sutton, however, is not the author of these notes. Although we recognize that the type of paper used to record the notes may have been different, we find that the content of page 3 seems to be otherwise consistent with the remainder of the notes and Patent Owner's other conception documents. We therefore find no basis to question Mr. Root's testimony that all his notes from Exhibit 2004 were made contemporaneously on or about February 7, 2005.

tubular portion above the notation reading "tapered ≈ 10 cm," and was considered by Mr. Root to be "an important feature of GuideLiner." Ex. 2118 ¶ 13. Mr. Root testifies that the side opening "facilitates entry of interventional cardiology devices into the proximal end of the tubular portion." *Id.*

The third page of Mr. Root's notes depicts another drawing, reproduced below, that also shows the side opening concept:



Ex. 2004, 3. According to Mr. Root, the sketch above "shows a side opening structure that is cut-away in several segments including, from left (distal) to right (proximal): a full round portion; a first angled transition portion; a first partial round portion; a second angled transition portion; and a second partial round portion." Ex. 2118 ¶ 14. The notes also list dimensions for the contemplated sizes of the GuideLiner. *Id.* ¶ 12; Ex. 2004, 1–3.

Beyond these "core" conception documents (Exs. 2002–2004), Patent Owner also relies on certain engineering drawings as further corroboration for the inventors' testimony. PO CRTP Sur-Reply 3–5 (citing Exs. 2022, 2113, 2114). Patent Owner annotates two of these drawings to highlight features of the depicted GuideLiner, namely the "Side Opening," "Rail Structure," "Machined End for Connecting to Tubular Portion," "Soft Tip," and "Reinforced Pebax Tubular Portion[.]" *Id.* at 4 (citing Ex. 2114), 5 (citing Ex. 2022). The drawings are dated March 2005 (Ex. 2113, 1), June 28, 2005 (Ex. 2114), and August 1, 2005 (Ex. 2022, 1). We have taken

these documents into account in determining whether the inventors conceived of the claimed invention prior to the September 23, 2005 critical date.

b) Analysis for Conception

We first consider whether Patent Owner's proffered evidence corroborates the inventors' testimony of conception. Patent Owner does not assert a specific date of conception. *See* Tr. 60:4–6 ("Our story from day one has been that the exact date of conception doesn't matter."). We agree that we need not determine the exact date on which conception took place. Nonetheless, before we can move on to the question of reduction to practice, we must determine that conception—as legally defined to be the formation of "a definite and permanent idea of the complete and operative invention," *Cooper*, 154 F.3d at 1321—was finalized at some point prior to the critical date of Itou. From the evidence Patent Owner relies upon, we can distill Patent Owner's broad theory of conception as having occurred either by February 2005, as corroborated by the core conception documents (Exs. 2002–2004), or by August 2005 during the course of building and testing prototypes, as further corroborated by the engineering drawings (Exs. 2113, 2114, 2022).

Petitioner argues Patent Owner's core documentary evidence—Mr. Sutton's notebook pages, the market feasibility memo, and Mr. Root's handwritten notes—cannot be used to corroborate inventor testimony insofar as they all originated from the inventors themselves as opposed to some other independent source. Pet. CRTP Reply 4. Petitioner relies principally on three cases as support for this argument. *Id.* at 3–4.

First, Petitioner cites *Apator Miitors ApS v. Kamstrup A/S*, 887 F.3d 1293 (Fed. Cir. 2018), to argue the documents relied upon by Patent Owner are "inventor documents" that cannot be used to corroborate an inventor's testimony on conception. Pet. CRTP Reply 4. In *Apator*, the problem for the patent owner in that case was that it was "stuck in a catch-22 of corroboration" because the evidence that was proffered to corroborate the inventor's testimony could "only provide that corroboration with help from [the same inventor's] testimony." 887 F.3d at 1296. For instance, in the bodies of the emails that were relied upon, the inventor indicated that he attached certain files related to his invention, but nothing in any part of the emails indicated what files were attached or what such attachments disclosed. *Id.* The court agreed with the Board's finding that the inventor's testimony was the only evidence proffered to establish the existence and substance of the attachments. *Id.* at 1296–97. And though the drawings set forth dates that were after the reference's critical date, the inventor's testimony about certain file naming conventions was the only evidence offered by the patent owner to demonstrate that the drawings were actually created on an earlier date. *Id.* at 1294–95, 1296–97. The court rejected the patent owner's argument that the emails and drawings should still have "some corroborative value," like unwitnessed laboratory notebooks. *Id.* at 1297. The court acknowledged that the rule of reason permits "'a notebook entry' or other writing '[that] has not been promptly witnessed,'" *id.* (citing *Singh v. Brake*, 222 F.3d 1362, 1370 (Fed. Cir. 2000)), "to aid in corroborating witness testimony alongside other, more persuasive, evidence." *Id.* (citing examples where the Federal Circuit and one of its predecessors, the Court of Customs and Patent Appeals, permitted

unwitnessed documents to contribute to corroboration of conception). But the court clarified that "an unwitnessed laboratory notebook, alone, cannot corroborate an inventor's testimony of conception." *Id.* (citing *Brown v. Barbacid*, 276 F.3d 1327, 1335 (Fed. Cir. 2002) (concluding there was no error in denying corroboration by "an inventor's own unwitnessed documentation"); *Procter & Gamble Co. v. Teva Pharms. USA, Inc.*, 566 F.3d 989, 998–99 (Fed. Cir. 2009) (concluding a laboratory notebook that "was unwitnessed and was not corroborated by any other evidence" could not corroborate inventor testimony of conception)).

Second, Petitioner cites *Kolcraft Enterprises, Inc. v. Graco Children's Products, Inc.*, 927 F.3d 1320 (Fed. Cir. 2019), in support of its argument that the documents relied upon by Patent Owner lack corroborative value because they all "'originated with the inventors.'" Pet. CRTP Reply 4. In *Kolcraft*, the Federal Circuit observed that the evidence at issue—which it characterized as "even weaker than the evidence presented in *Apator*"—comprised a redacted inventor declaration, the inventor's deposition testimony, and undated photos attached to the inventor declaration. 927 F.3d at 1325. Of this evidence, the court noted that "[o]nly the Inventor Declaration, i.e., inventor testimony, supports the purported dates showing [prior] conception," but this was deemed insufficient because "[i]nventor testimony alone cannot prove conception." *Id.*

Third, Petitioner cites a non-precedential Board decision, *Curt Manufacturing, LLC v. Horizon Global Americas Inc.*, IPR2019-00625, Paper 31 (PTAB Aug. 11, 2020) (Final Written Decision), for the proposition that "[o]ne inventor cannot corroborate another." Pet. CRTP Reply 4; *see also* Tr. 38:20–39:13 (Petitioner's counsel citing *Curt* for the

same proposition). In *Curt*, the Board stated that "[o]ne consequence of the independence requirement is that *testimony* of one co-inventor cannot be used to help corroborate *the testimony* of another." *Curt., Paper 31* at 16 (citing *Lacks Indus., Inc. v. McKechnie Vehicle Components USA, Inc.*, 322 F.3d 1335, 1350 (Fed. Cir. 2003) (emphases added) (approving refusal to accept cross-corroboration of oral testimony by interested witnesses)[13] The Board further noted that "an inventor's *unwitnessed* laboratory notebooks, emails, and drawings, *without other independent evidence*, cannot corroborate an inventor's testimony." *Id.* (emphases added) (citing *Kolcraft*, 927 F.3d at 1325–26; *Apator*, 887 F.3d at 1297; *Brown*, 276 F.3d at 1335). In a footnote quoting *Brown*, the Board highlighted the importance of two issues: whether the documentary evidence was witnessed and whether there is other corroborating evidence in the record. *Id.* at 16–17 n.7 (reiterating that physical evidence from an inventor does not need corroboration to demonstrate its contents, but the inventor's *unwitnessed* documentation "may not *single-handedly* corroborate" the inventor's testimony (quoting *Brown*, 276 F.3d at 1335) other (emphases ommitted). Lastly, the Board concluded that, "[n]otwithstanding this clear guidance, the law also recognizes that . . . a notebook entry or other writing that has not been promptly witnessed does not necessarily disqualify it in serving as

[13] The Federal Circuit, however, has not categorically prohibited "cross-corroboration" of testimony by interested witnesses at least in other contexts. *See Nobel Biocare Servs. AG v. Instradent USA, Inc.*, 903 F.3d 1365 , 1378 (Fed. Cir. 2018) ("The testimony of one witness may corroborate the testimony of another witness.").

corroboration of conception under a rule of reason analysis." *Id.* (citing *Apator*, 887 F.3d at 1297 (referring to cases where unwitnessed documentary evidence was considered alongside other evidence to corroborate inventor testimony)).

Considering the evidence of record as a whole, we reject Petitioner's arguments that the inventors' testimony on conception is not adequately corroborated. We find the case law cited by Petitioner to be distinguishable.

We first note that Mr. Sutton's laboratory notebook was witnessed shortly after the date of entry of the relevant pages. Specifically, the notebook pages presented here were witnessed by another inventor, Jeffrey Welch. Ex. 2002. Because the notebook is dated and witnessed, we may properly consider it for its probative value in corroborating Mr. Root's and Mr. Sutton's testimony. *See Singh*, 222 F.3d at 1369–70 (holding that a belatedly witnessed lab notebook may serve as corroboration of conception); *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1378 (Fed. Cir. 1986) (same). Indeed, as noted above, even an unwitnessed notebook page may have some corroborative value under the rule of reason when considered in combination with other more persuasive evidence. *Apator*, 887 F.3d at 1297. To be sure, the notebook pages presented here were witnessed by another inventor, Jeffrey Welch, who has not provided any independent testimony in this proceeding. Ex. 2002. But we discern no *per se* rule from the case law to suggest that a laboratory notebook witnessed by a co-inventor cannot be used to corroborate another inventor's testimony about conception. In this regard, we find that the witnessed notebook pages avoid the "catch-22 of corroboration" noted in *Apator* because the notebook pages do not depend upon either Mr. Root's or Mr. Sutton's testimony for an

explanation of their content. The notebook pages also avoid the issue that arose in *Kolcraft* and *Curt* because Patent Owner has not relied upon only the inventors' testimony to prove conception. We note that, aside from whether the notebook pages can legally qualify as corroborative evidence of the date of conception, Petitioner has not disputed the authenticity or veracity of the content shown on those pages. As such, we have considered the content of the notebook pages at face value in our analysis.

We have also taken into account the market feasibility memo and Mr. Root's handwritten notes in our corroboration assessment. Ex. 2003; Ex. 2004. We recognize that these documents appear to have been authored by Mr. Root, and no witness other than Mr. Root has provided testimony about their content. As such, if considered in isolation, these conception documents may be more analogous to the type of "catch-22" documents found insufficient for corroborating the date of conception under *Apator*. Nonetheless, applying the rule of reason, we do not categorically exclude them from the corroboration analysis because they can still "aid in corroborating witness testimony alongside other, more persuasive, evidence."[14] *Apator*, 887 F.3d at 1297.

Because we conclude that the notebook pages, along with the market feasibility memo and Mr. Root's handwritten notes, may be properly considered in our corroboration analysis, we next address whether these documents are in fact sufficiently corroborative of the inventors' testimony

[14] Like the notebook pages, Petitioner has not disputed the authenticity or veracity of the content of the market feasibility memo and Mr. Root's handwritten notes, and thus we have also considered the content of these documents at face value.

to show conception of the claimed invention prior to the critical date. On this point, Mr. Root includes as appendices to his declaration claim charts showing how certain VSI prototypes developed at the time meet the limitations of the challenged claims. Ex. 2118, App'x A–E.[15] The primary argument raised by Petitioner is that Patent Owner's core conception documents do not disclose the "side opening" feature recited in numerous challenged claims. Pet. CRTP Reply 5–7.[16] According to Petitioner, without this demonstration, Patent Owner fails to establish conception of "every feature or limitation of the claimed invention."[17] *Id.* at 3 (quoting

[15] Petitioner contends that Mr. Root's claim charts amount to an improper incorporation by reference in violation of 37 C.F.R. § 42.6(a)(3) and a circumvention of our word limits. Pet. CRTP Reply 2. However, in view of the commonality of the CRTP issues across these related proceedings, we authorized the parties to submit consolidated briefing on the issue. Paper 26 (Consolidated Scheduling Order), 2–3. Moreover, Petitioner also submitted similar rebuttal claim charts by its expert Dr. Zalesky as appendices to his expert report. Ex. 1755, App'x A–E. Under the circumstances, we are not persuaded that the manner in which Patent Owner presented its claim-by-claim arguments were a violation of our rules.

[16] As Petitioner acknowledges, this argument only applies to certain claims. *See* Tr. 159:5–12. According to Petitioner's table in its CRTP Sur-Sur-Reply, the side-opening limitation appears in the following claims: claims 3 and 4 of the '032 patent; claims 3, 4, 36 of the '380 patent; claims 25, 52, and 53 of the '776 patent; and claims 25, 48, 51, and 53 of the '760 patent. Pet. CRTP Sur-Sur-Reply 14–15. We note, however, that claim 25 of the '379 patent also recites: "defining a side opening portion, including forming, in a proximal to distal direction, an arcuate cross-sectional shape and a hemicylindrical cross-sectional shape." Ex. 1001, cl. 25.

[17] In its Sur-Sur-Reply, Petitioner also contends that Patent Owner is missing evidence that the RX prototypes satisfy certain additional claim limitations. *Id.* We consider this in addressing the actual reduction to practice issue below.

REG Synthetic Fuels, 841 F.3d at 962). We are not persuaded that the evidence fails to show that the RX GuideLiner device that the inventors had conceived of and were developing at the time included all the features of the challenged claims, including a side opening feature to allow for rapid exchange.

As noted above, Mr. Root attests that the first and third pages of his handwritten notes each depict a drawing that includes a side opening. Ex. 2118 ¶¶ 12–14 (citing Ex. 2004, 1, 3). In particular, Mr. Root asserts that

> [a]n important feature of GuideLiner is a "side opening" at the transition between the proximal rail structure and the distal tubular portion that facilitates entry of interventional cardiology devices into the proximal end of the tubular portion. This feature is reflected in the crude shading between the rail structure and the tubular portion shown in the sketch above from my February 7, 2005 notes.

Id. ¶ 13. We credit this testimony and find that it is corroborated by the drawings themselves.

Petitioner contends that the lab notebook pages, as confirmed by Mr. Sutton's deposition testimony, only show an "end opening" rather than a side opening for the device. Pet. CRTP Reply 5 (citing Ex. 1108, 70:18–71:23, 79:14–80:24). To further dispute the disclosure of a side opening, Petitioner relies on the declaration of its expert, Dr. Zalesky. *Id.* at 6 (citing Ex. 1755 ¶¶ 83–84). Dr. Zalesky contends that the "crude shading" on the drawing on the first page of Dr. Root's notes "does not appear to show an angled opening at the proximal end of the tubular portion" and that Mr. Root's notes on the page do not refer to a side opening. Ex. 1755 ¶ 83. Dr. Zalesky further contends that the drawing on the third page of Root's notes "does not appear to correspond to any of the figures in the Root

patents" is "quite crude," making it "difficult to tell what it represents, if anything]" and "does not appear to show a side opening." *Id.* ¶ 84.

Although we recognize that Mr. Sutton testified that Figure 1 does not depict an angled side opening, it does not appear that Mr. Sutton categorically stated that the inventors had not conceived of a device that included the side opening feature or otherwise directly contradicted Mr. Root's testimony on this point. We further note that the first drawing in Mr. Root's notes appears to closely match Figure 1 of the challenged patent (which depicts an unassembled coaxial guide catheter and tapered inner catheter), while the first drawing in Mr. Sutton's notes appear to closely match Figure 2 of the challenged patent (which depicts the assembled device). *Compare* Ex. 2004, 1 *with* Ex. 1001, Fig. 1; *compare* Ex. 2002, 1 *with* Ex. 1001, Fig. 2. We agree with Dr. Zalesky that the sketches included in Mr. Root's handwritten notes are "crude" and not a model of clarity. Nonetheless, taking into account both the documentary evidence and inventor testimony as a whole, we find that a preponderance of the evidence supports the conclusion that the inventors conceived of a device that included the side opening and all other claimed features prior to the critical date.

To the extent that the earlier core conception documents alone do not support prior conception, we have also taken into account the evidence proffered by Patent Owner with respect to the prototypes that were built between February and August 2005. *See* PO CRTP Sur-Reply 3 (explaining that if the early 2005 documents "were disregarded," other pre-Itou evidence "undisputedly show[s] conception of the entire invention, *including the side opening*" (emphasis added)). To support its theory, Patent Owner cites

Dr. Zalesky's testimony, where he confirms that the engineering drawings depict a side opening. Ex. 2237, 211:11–16 (agreeing that "a side opening can be found in the hypotubes that were cut down by Spectralytics, specifically Exhibit 2113 and 2114"), 250:9–13 (agreeing that "Exhibit 2022 sets forth the concept for the rapid exchange GuideLiner"). Petitioner acknowledges the probative value of the August 2005 drawing in showing conception prior to the critical date: "[a]t best, [Patent Owner] shows conception in August 2005, a mere month before Itou and *after* VSI's purported prototype work in April and July." *Id.* Much of this evidence is also relied upon by Patent Owner to demonstrate that there was actual reduction to practice prior to the critical date. Given the overlap, we also address this evidence as part of our actual reduction to practice analysis.

In sum, Patent Owner's core documentary evidence—Mr. Sutton's lab notebook, the market feasibility memo, and Mr. Root's handwritten notes—sufficiently corroborate the stories of conception set forth in Mr. Root's and Mr. Sutton's declarations. These corroborating documents add credibility to the inventors' conception timelines. And even if Petitioner were correct that not every feature was conceived on or about February 2005, we find that additional evidence of record with respect to the prototypes, as discussed below, demonstrates conception no later than August 2005.

3. Actual Reduction to Practice

Patent Owner contends that actual reduction to practice also took place before the critical date of Itou. In support of this contention, Mr. Root attests in his declaration that employees at VSI, led by co-inventors Mr. Sutton and Mr. Welch, built and tested RX GuideLiner prototypes

between January and August 2005.[18] Ex. 2118 ¶ 15. Mr. Sutton, as well as two non-inventors employed by VSI at the time, Steve Erb and Deborah Schmalz, also testify about relevant details of the research and development done with regard to the GuideLiner prototypes. Ex. 2039 (Schmalz Declaration); Ex. 2119 (Sutton Declaration); Ex. 2122 (Erb Declaration). Patent Owner also presents the declarations of Mark Goemer and Amanda O'Neil, who were employed by outside vendors from whom VSI purchased components to build the prototypes. Ex. 2120 (Goemer Declaration); Ex. 2121 (O'Neil Declaration). Additionally, Patent Owner has submitted an expert declaration by Dr. Peter Keith in further support of this contention. Ex. 2123 (Keith Declaration in support of CRTP). Patent Owner relies upon purchase invoices, engineering schematics, and other documentary evidence from as early as January 2005 through the September 2005 critical date of Itou in order to corroborate the fact declarants' testimony regarding actual reduction to practice.[19] We once again set forth the relevant facts based on these declarants' testimony and corroborating evidence, and then address

[18] Mr. Root explains that Patent Owner does not have many development documents from 2005, and it obtained many of the documents relevant to actual reduction to practice from VSI's vendors and patent prosecution firm. Ex. 2118 ¶ 20.

[19] Patent Owner includes some documentary evidence created after Itou's critical date. *See, e.g.*, Ex. 2106 (invoices dated April 2006); Exhibit 2115 (engineering drawing dated Nov. 1, 2005). We do not find this post-critical date evidence to support Patent Owner's contentions regarding actual reduction to practice. However, we have considered some of this evidence in our analysis of whether there was diligence towards constructive reduction to practice (*see* discussion, *infra*), as well as to address Petitioner's argument that the continuing work done at VSI with respect to the GuideLiner demonstrates a lack of actual reduction to practice before Itou.

any disputed issues of material fact and legal issues as needed in our analysis for actual reduction to practice.

a) Fact Findings for Actual Reduction to Practice

After the inventors came up with the initial idea for the device (as set forth in the conception discussion above), VSI proceeded with the development of both the OTW and RX versions of the GuideLiner concurrently. Ex. 2118 ¶ 19; Ex. 2119 ¶ 15. Although it was based on existing technology, VSI decided to pursue the OTW version based on the belief that it could be brought to market more quickly with fewer regulatory challenges than the RX version. Ex. 2118 ¶ 19; Ex. 2119 ¶ 15. Nonetheless, the RX version remained a priority for continued development at VSI. *Id.* Consistent with Mr. Root's testimony, Mr. Sutton testifies that the RX GuideLiner was reduced to practice before September 2005, although further work towards commercialization of the product continued until he left the company. Ex. 2119 ¶ 15. According to Mr. Sutton, work for the OTW prototype "paled in comparison" to work required for the RX prototype because the OTW prototype "required very little engineering and was relatively easy to build because it was based on existing technology." *Id.* In their declarations, Mr. Root and Mr. Sutton focus on two distinct sets of prototypes of the RX version that were built and tested before Itou's critical date: the "April 2005" prototypes and the "July 2005" prototypes. Ex. 2118 ¶ 48; Ex. 2119 ¶¶ 21–22.[20] As noted above, Mr. Root includes claim charts

[20] Although Mr. Root refers to the likelihood that other sets of prototypes were also built, the bulk of Patent Owner's evidence and arguments relate to the April and July 2005 prototypes. Ex. 2118 ¶ 48. As such, we focus on

identifying how the April and July 2005 prototypes satisfied the limitations of the challenged claims. Ex. 2118, App'x A–E; *see also* Ex. 2123 ¶ 28 (Mr. Keith opining that the April and July 2005 prototypes satisfy the claim limitations based on these claim charts).

In developing these prototypes, a VSI technician and machinist Mr. Erb worked with the inventors to mechanically cut down stainless steel or nitinol "hypotubes" used for the proximal portion of an RX prototype. Ex. 2118 ¶ 16; Ex. 2119 ¶ 20; Ex. 2122 ¶¶ 8–10. The profile of some of these hypotubes started at full circumference at the distal end, then progressed to roughly half-round at the proximal end. Ex. 2118 ¶ 16. The hypotubes were combined with a polymer distal section to create the first RX GuideLiner prototypes. *Id.* At this time, the distal tubular portion was sometimes built by cutting a standard guide catheter to the appropriate length. *Id.* ¶ 24. The earliest prototypes, made in January or February 2005, largely comprised stock components modified through VSI's in-house machining capabilities. *Id.* ¶¶ 18, 20. However, by April 2005, the VSI engineers progressed to building more formal prototypes using custom-ordered materials from outside vendors for the proximal and distal portions of the device. Ex. 2122 ¶ 12. A spend report details at least some of the expenses that VSI incurred on purchases of the components used to build GuideLiner prototypes from February 11, 2005, to June 30, 2006. Ex. 2005; Ex. 2118 ¶¶ 21–22. According to Mr. Root, the fact that they had opened an account specific to the "Guideliner project" in May 2005, as reflected in this spend report,

---

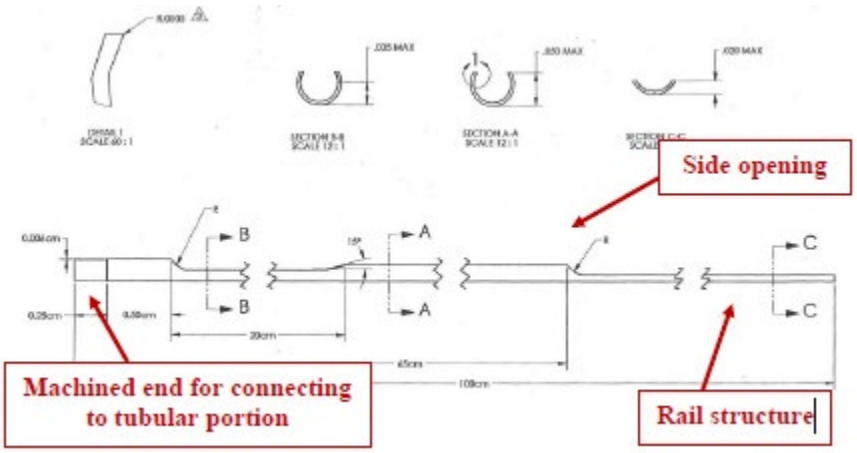
these prototypes in determining whether there was actual reduction to practice.

indicates that development had advanced to the point that they were confident with proceeding towards commercialization. Ex. 2118 ¶ 22.

With respect to the proximal portions, Patent Owner presents invoices and other documents reflecting VSI's purchases of laser-cut hypotubes from three outside vendors: MicroGroup, Mountain Machine, Inc., and SPECTRAlytics. Ex. 2118 ¶¶ 23, 27, 29, 30, 32, 33, 40, 43 (citing Exs. 2006, 2007, 2009, 2010, 2013, 2020, 2091, 2094, 2095, 2110, 2111); Ex. 2119 ¶¶ 24–31 (discussing similar purchases); *see also* Ex. 2122 ¶ 7 (discussing purchases of stainless steel and nitinol hypotubes as reflected in Ex. 2110).[21] Because some of these invoices show purchases of the hypotubing by the foot, Mr. Root asserts that the materials were likely used for early evaluations of the RX GuideLiner concept. Ex. 2118 ¶ 23. Mr. Sutton similarly asserts that the hypotubing that was purchased at this time was used to make RX GuideLiner prototypes, as the OTW version never involved such hypotubing. Ex. 2119 ¶ 23. The ranges of the inner and outer diameters, wall thickness, and the overall length of the hypotubes that were ordered were consistent with what VSI would have needed at the time for prototyping the RX GuideLiner. *Id.* ¶¶ 24, 26.

Mr. Root and Mr. Sutton also reference the following annotated engineering schematics of the proximal portion of the RX GuideLiner that were drawn by a VSI Engineer, Jim Kauphusman, on February 4, 2005:

[21] Although both stainless steel and nitinol hypotubes were ordered, Mr. Sutton asserts that nitinol was significantly more expensive and required additional post-processing steps as compared to stainless steel, and these factors ultimately weighed against using nitinol for the proximal portion of the RX GuideLiner. Ex. 2119 ¶ 28.

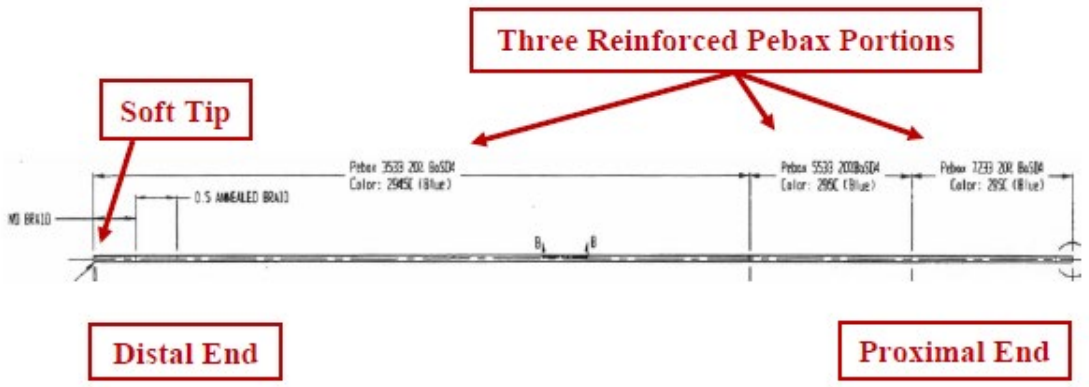


Ex. 2113; Ex. 2118 ¶ 34; Ex. 2119 ¶ 30. The drawings above show a design of the proximal portion with multiple angled transition regions bookending non-inclined regions, and Patent Owner's annotations to the drawings—which were added for this proceeding, *see* PO CRTP Sur-Reply 13—identify a "machined end for connecting to MED component," a "side opening," and a "rail structure." *Id.* These drawings were submitted as "prints" to SPECTRAlytics in order to specify the parameters for the hypotubes that were custom ordered, and include a drawing number "SS HYPO X04" that correlates to a purchase completed on April 4, 2005. Ex. 2118 ¶ 34; Ex. 2120 ¶ 9; Ex. 2095. Additional engineering drawings for the proximal portions were submitted to SPECTRAlytics around June 2005. Ex. 2118 ¶ 41; Ex. 2120 ¶ 11; Ex. 2114. Some of the engineering drawings are similar to figures included in the challenged patent. *Cf.* Ex. 1001, Figs. 12–16.[22] Mr. Goemer verifies and authenticates some of the purchase documents and the engineering drawings retrieved from SPECTRAlytics's files. Ex. 2120 ¶¶ 6–12.

[22] Mr. Sutton faxed these drawings to VSI's outside patent counsel on March 21, 2006. Ex. 2118 ¶ 42; Ex. 2019.

Additionally, Mr. Root and Mr. Sutton refer to purchases of distal tubular portions and the distal forming tips from vendors Medical Engineering & Design Inc. ("MED") and Farlow's Scientific Glassblowing Inc. between February and July 2005. Ex. 2118 ¶¶ 28, 31, 44, 45 (citing Exs. 2011, 2021, 2090, 2092); Ex. 2119 ¶¶ 32–34, 36 (additionally citing Exs. 2032, 2033, 2034, 2035, 2089, 2097, 2112). Ms. O'Neil, who is employed by MED's successor TE Connectivity ("TE"), verifies and authenticates some of these purchase documents, and notes that the documents were retrieved from the files of TE, but originated with MED in 2005. Ex. 2121 ¶¶ 5–6.

One of the documents from MED also includes engineering schematics for the distal portion that were drawn on February 10, 2005, by Mr. Kauphusman, as shown below:



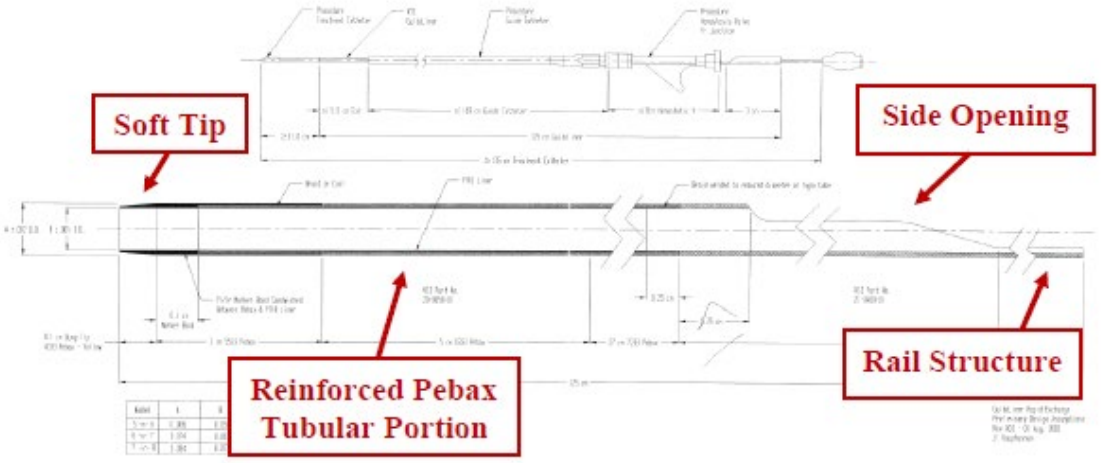
Ex. 2089, 8; Ex. 2118 ¶ 25; Ex. 2119 ¶ 32. The drawing above shows the distal portion with Patent Owner's annotations, *see* PO CRTP Resp. 9, identifying a "soft tip," "three reinforced Pebax portions," the "distal end," and the "proximal end." *Id.* Although Exhibit 2089 does not specify that

the tubing was for the RX version of the GuideLiner, Mr. Root and Mr. Sutton assert that the drawings and specifications were in fact specific to an RX device based on the notation that the proximal end should be "counter bored" (a requirement to facilitate attachment to the cut-down hypotube) as well as the overall length of 11.8 inches (because if this part were for an OTW device, it would have been significantly longer). *Id.* The order for distal portions as shown in Exhibit 2089 was placed on February 17, 2005, and the parts were shipped from MED and delivered to VSI on or about April 5, 2005. Ex. 2118 ¶ 25; Ex. 2119 ¶ 33. An update to the drawing shown in Exhibit 2089 was made on April 6, 2005, as shown in Exhibit 2092, with only minor changes, namely slightly reduced inner and outer diameters to fit a guide catheter and a slightly shortened tip. Ex. 2092, 8; Ex. 2118 ¶ 44. An order for distal tubular portions based on the updated design was placed on April 12, 2005 and those parts were delivered to VSI on or about June 16, 2005. *Id.*

The proximal and distal portions that were custom ordered and purchased from the outside vendors were thereafter combined in-house at VSI to form the prototypes of the complete RX GuideLiner. Ex. 2118 ¶ 24 ("From the earliest stages of the project, the plan was to combine the substantially rigid proximal portion of the rapid exchange GuideLiner with a distal polymer tubular portion that would be at least partially reinforced with coil or braid."); Ex. 2119 ¶ 34 ("[W]e combined these distal sections from MED with the proximal stainless steel sections discussed above to form prototypes of the GuideLiner rapid exchange in April and July 2005."). For example, the first set of formal prototypes (the April prototypes) appear to have been made by combining the laser-cut hypotubes from SPECTRAlytics

with the distal tubular sections from MED that were shipped around April 5, 2005. Ex. 2118 ¶ 35 (citing Exs. 2011 and 2089). Additional prototypes (the July prototypes) appear to have been built using the hypotubes from MicroGroup shipped around April 20, 2005, and/or the hypotubes from SPECTRAlytics shipped around July 18, 2005, in combination with the updated distal portions from MED shipped around June 16, 2005. *Id.* ¶¶ 39, 40, 46 (citing Exs. 2114, 2020, 2021, 2092, 2094). In making these prototypes, VSI "used an in-house thermal process to fuse the distal tubing sections from MED to the cut-down hypotubes." Ex. 2119 ¶ 35. VSI had the materials and equipment available to assemble the device at their facilities. *Id.*

As further evidence of an assembled device, inventors Mr. Root and Mr. Sutton reference the following engineering CAD schematics from August 1, 2005:



Ex. 2118 ¶ 49; Ex. 2119 ¶ 39; Ex. 2022. The drawings above show a version of the complete RX GuideLiner, as well as a cross-sectional view of the device with Patent Owner's annotations, *see* PO CRTP Resp. 16

identifying the "soft tip," the "reinforced Pebax tubular portion," the "side opening," and the "rail structure." Ex. 2118 ¶ 49. The schematics are labeled GuideLiner Rapid Exchange/ "Preliminary Design Assumptions/Rev X03," which according to Mr. Root was an indication that VSI had moved past prototyping and into commercialization. *Id.* Mr. Sutton attests that the "X03" indicates that this was the third version of the CAD drawings, and that they had built and tested prototypes of the RX GuideLiner device shown in these drawings. Ex. 2119 ¶ 39. The document also references the same part number (20-0658) as those identified in certain purchase documents for distal tubular portions from MED. Ex. 2118 ¶ 51 (citing Ex. 2021, Ex. 2089, Ex. 2092). These drawings are nearly identical to Figures 3 and 4 of the patent. *Cf.* Ex. 1001, Figs. 3–4 (depicting patent drawings that resemble the CAD drawings).

The prototypes were tested using bench-top coronary models, including two-dimensional ("2D") acrylic heart models and three-dimensional ("3D") glass heart models, to simulate the native anatomy and environment. Ex. 2118 ¶¶ 17, 38, 47; Ex. 2119 ¶¶ 37–38, 41. These types of models were commonly used by VSI and other medical device companies to test interventional cardiology devices. Ex. 2118 ¶ 17; Ex. 2123 ¶ 21 (Mr. Keith noting that he had used similar models to test catheter designs during his time at Scimed and Boston Scientific Corporation). A sales presentation from July 2005 shows an example of a 2D coronary model. Ex. 2018, 12; Ex. 2129 (redacted version of same presentation). While this particular presentation depicts testing of the OTW version of the GuideLiner concurrently under development, Mr. Root asserts that a similar model was used to test the RX version. Ex. 2118 ¶¶ 18, 38. The testing done using this

model included performing pull tests as well as simulations comprising the following steps: a) inserting a standard guide catheter into the coronary model; b) advancing the prototype into the guide catheter until the prototype's distal end extended beyond the guide catheter's distal end; and c) delivering a stent or balloon catheter into and through both devices. *Id.* ¶ 18. Although "more qualitative than quantitative," these tests enabled the inventors to observe the prototype's durability and the forces exerted on the prototype. Ex. 2118 ¶¶ 18, 47; Ex. 2119 ¶¶ 23, 41. Both Mr. Root and Mr. Sutton attest that this testing was sufficient to confirm that the RX GuideLiner would work for its intended purpose, namely facilitating delivery of interventional cardiology devices into challenging coronary anatomy by providing increased backup support as compared to a guide catheter alone. *Id.*

Patent Owner also presents other documentary evidence as corroboration of the testimony of inventors Mr. Root and Mr. Sutton. We have taken these documents into account, but find them somewhat probative in showing actual reduction to practice.

For instance, a June 23, 2005, market feasibility memo (Ex. 2017), similar to the earlier memo from February 4, 2005 (Ex. 2003), confirms that the RX GuideLiner prototype was continuing to be developed, although the OTW version had been added to the development project at that point. Ex. 2118 ¶ 37; *see* Ex. 2017, 1 (noting that "it is possible to make the GuideLiner in an Over-the-Wire version, a Rapid Exchange version, or both").

A "Product Requirements" document, dated August 24, 2005, sets forth the safety and performance requirements for both the OTW and RX

guide catheter support systems. Ex. 2118 ¶ 54; Ex. 2119 ¶ 44; Ex. 2024.[23] The document notes that "[t]hese safety and performance features are the minimal requirements for the device to be acceptable for its intended clinical use," and that the "[a]pplicable clinical use is for increase[d] guide catheter back-up support." Ex. 2024. Mr. Root asserts that this document marked the start of the formal quality process for the RX and OTW GuideLiner catheters. Ex. 2118 ¶ 54. Both Mr. Root and Mr. Sutton, as well as Ms. Schmalz (VSI's Vice President of Regulatory and Clinical Affairs at the time), testify that that this document would have been created only after the product was tested, demonstrated to work, and ready to proceed with regulatory approval and commercialization. Ex. 2118 ¶ 54; Ex. 2119 ¶ 44; Ex. 2039 ¶ 7. Ms. Schmalz specifically recalls that a working prototype of the RX version was created prior to the creation of this document. Ex. 2039 ¶ 7. Although this document sets forth several user requirements for the device, it does not identify the product specifications and test methods correlating to those requirements. Ex. 2024, 2–4. The revision history of the document also indicates it is "pre-release," thereby suggesting that it may not have been finalized at the time. *Id.* at 4.

Mr. Root, Mr. Sutton, and Ms. Schmalz each also discuss two other documents both dated August 26, 2005—a Clinical Technical Report (Ex. 2025) and a staff meeting memo (Ex. 2040)—as further evidence that work

[23] Exhibit 2024 is the subject of Petitioner's motion to exclude. Paper 111. For the reasons we state below in addressing the motion to exclude (*see* discussion, *infra*), we decline to exclude Exhibit 2024 but have considered Petitioner's arguments in determining the weight to be given to this piece of evidence.

continued on the RX GuideLiner and that VSI was ready to seek regulatory approval for the device from the Food and Drug Administration ("FDA"). Ex. 2039 ¶¶ 9–10; Ex 2118 ¶¶ 55– 57; Ex. 2119 ¶¶ 45–46. The Clinical Technical Report states that VSI "has developed, and is currently manufacturing four types of catheters: . . . [including] the GuideLiner Catheter Support System used to provide physicians with additional guide catheter support allowing access to more difficult anatomy," and goes on to describe both the RX and OTW versions of GuideLiner. Ex. 2025, 2–3, 5–6. We note, however, that the text discussing GuideLiner devices appear to be "redline" edits and does not include any signatures for "document approvals," thus suggesting that the document submitted as Exhibit 2025 may have only been a draft. The staff memo refers to clinical literature reviews for the GuideLiner devices (both RX and OTW), which Mr. Root asserts was part of VSI's regulatory strategy for a "510(k)" submission to the FDA.[24] Ex. 2118 ¶ 57.

b) Analysis for Actual Reduction to Practice

To establish actual reduction to practice, Patent Owner must demonstrate two things: (1) that it constructed an embodiment that met all the limitations of the invention claimed in the patents at issue; and (2) that it determined that the invention would work for its intended purpose. *Cooper*, 154 F.3d at 1327. Having considered the evidence and arguments of record,

[24] A 510(k) submission is a premarket notification to demonstrate that the device to be marketed is as safe and effective, that is, substantially equivalent, to a legally marketed device. *See* FDA, Premarket Notification 510(k), (accessed June 1, 2021), https://www.fda.gov/medical-devices/premarket-submissions/premarket-notification-510k.

including the testimonial and documentary evidence summarized above, we find that Patent Owner has met this burden with respect to the challenged claims based on the prototypes of the RX GuideLiner that were built and tested at VSI prior to September 2005. We address Petitioner's arguments to the contrary.

The first issue raised by Petitioner is whether there is sufficient corroborating documentary evidence to support the inventors' testimony on reduction to practice. As with conception, "a party seeking to prove an actual reduction to practice must proffer evidence corroborating [an inventor's] testimony." *Raytheon Co. v. Sony Corp.*, 727 F. App'x 662, 668 (Fed. Cir. 2018) (citing *Medichem*, 437 F.3d at 1169–71). The sufficiency of this corroboration is once again determined using a "rule of reason" analysis. *Id.*

Petitioner contends that "[n]o document shows that VSI built, much less tested, RX prototypes." Pet. CRTP Reply 8. Petitioner points to the lack of photographs, assembly instructions, subassembly drawings, and notebook pages (other than Mr. Sutton's initial conception pages) to corroborate the work done on the RX prototype in 2005. *Id.* By contrast, Petitioner asserts that VSI kept more documents, including notes from Mr. Kauphusman (the VSI engineer who led the GuideLiner project), relating to the OTW prototypes from that time. *Id.* at 9–10 (citing Ex. 1760, 86–87). Petitioner also contends that Patent Owner cannot justify VSI's failure to retain these reduction-to-practice documents because it "runs contrary to federal law and industry practice." *Id.* at 11 (citing Ex. 1755 ¶¶ 66–74, 143–145). Among the documentary evidence presented, Petitioner contends that at most four documents relate to particular prototypes, and the rest are

irrelevant insofar as they concern purchases of generic component parts untethered to particular projects or prototypes. *Id.* at 11–14. Petitioner further contends the documents do not show that VSI actually assembled the RX prototypes. *Id.* at 16–17.

We are not persuaded that the record lacks sufficient corroborating evidence of actual reduction to practice. "In order to corroborate a reduction to practice, it is not necessary to produce an actual over-the-shoulder observer. Rather, sufficient circumstantial evidence of an independent nature can satisfy the corroboration requirement." *Cooper*, 154 F.3d at 1330 (citing *Knorr v. Pearson*, 671 F.2d 1368, 1373 (CCPA 1982)). "Furthermore, an actual reduction to practice does not require corroboration for every factual issue contested by the parties." *Id.* (citing *Ethicon, Inc. v. U.S. Surgical Corp.*, 135 F.3d 1456, 1464 (Fed. Cir. 1998); *Mann v. Werner*, 347 F.2d 636, 640 (CCPA 1965) ("This court has rejected the notion that each individual act in the reduction to practice of a count must be proved in detail by an unbroken chain of corroboration.")). Put another way, the law "does not require that evidence have a source independent of the inventors on every aspect of conception and reduction to practice; such a standard is the antithesis of the rule of reason." *E.I. du Pont De Nemours & Co. v. Unifrax I LLC*, 921 F.3d 1060, 1077 (Fed. Cir. 2019) (internal quotation omitted).

As discussed above, Mr. Root and Mr. Sutton each provide detailed and consistent testimony explaining the work done at VSI towards building and testing the April and July 2005 prototypes of the RX GuideLiner. Critical aspects of this testimony are corroborated by other (non-inventor) testimony from Ms. Schmalz (recounting the regulatory and quality process at VSI), Mr. Erb (recounting how they built early prototypes), Mr. Goemer

(verifying purchases from SPECTRAlytics), and Ms. O'Neil (verifying purchases from MED). This testimony is further corroborated by a significant amount of documentary evidence, including purchase documents and engineering drawings, as set forth above. To the extent that there may have been other more detailed evidence with regard to the OTW GuideLiner, we do not find that such evidence detracts from or otherwise contradicts the evidence presented for the RX GuideLiner. Nor do we require Patent Owner to establish actual reduction to practice by retaining and then proffering the same type of documents that the FDA would have required Patent Owner to submit to gain approval of a medical device. *See* Ex. 1755, 63:20–64:9 (Dr. Zalesky acknowledging that "[t]he testing requirement for regulatory submission such as a 510(k) is quite extensive," and "a very significantly different level than that required to demonstrate reduction to practice.").

Petitioner contends that the purchased reflected in Patent Owner's documentary evidence could have been used for other VSI projects under development in 2005. Pet. CRTP Reply 12–16. We do not find that the evidence supports Petitioner's conjecture in this regard. For example, Petitioner cites the testimony of Dr. Zalesky to assert that the purchased hypotubing (and other parts) could have been used for VSI's Twin-Pass, Skyway, and Pronto V3 products, in addition to the OTW GuideLiner. *Id.* (citing Ex. 1755 ¶¶ 121–132, 153, 161, 203). But Dr. Zalesky does not point to any supporting evidence showing that these other VSI products used the same type of hypotubing as what would have been required for the RX GuideLiner. *See* Ex. 2237, 156:3–158:10, 173:10–174:12 (Dr. Zalesky admitting that he did not have any evidence that hypotubes were used in other products, but stating his opinion was based on "informed speculation"

or "reasonable speculation"). Rather than Dr. Zalesky's speculation, we credit the testimony of Mr. Root, Mr. Sutton, and Mr. Erb, each of whom had first-hand involvement in the project and independently attest that at least some of the purchased hypotubes were specific for the RX GuideLiner. Ex. 2118 ¶ 23; Ex. 2119 ¶ 23; Ex. 2122 ¶ 7.

The corroborating documents confirm that the purchases were for the RX GuideLiner, not a general ledger expense that would suggest the parts could be used for other products. *See, e.g.*, Ex. 2005 (spend report for accounts related to "new modalities" and "Guideliner project"). The sole document Petitioner cites to posit that the purchased hypotubes could have been used for OTW devices is an engineering schematic that bears November 2005 and January 2006 dates, which were later than the April and July 2005 prototypes. Ex. 1763, 6. Furthermore, the hypotube shown in the OTW drawing differs in materials and dimensions from the hypotubes purchased for the RX prototypes. The hypotube in the OTW drawing is nitinol and roughly 19 cm, quite different than the 100 cm stainless steel hypotubes used for the GuideLiner prototypes. *Id.* The 43-inch distal section in the OTW drawing also differs dramatically from the 11.8-inch distal section for the RX prototype. Ex. 2237, 164:24-167:19 (Dr. Zalesky agreeing that the distal portion shown in Exhibit 2089 is not the same as the distal portion of Exhibit 1763); *compare* Ex. 1763, 6 *with* Exs. 2089 and 2092.

With regard to whether the purchased components were actually assembled into an RX prototype, we find that the engineering schematic from August 2005 is strongly corroborative of an assembled device. Ex. 2022. Dr. Zalesky acknowledges that it "doesn't make a lot of sense" for

VSI not to have assembled the purchased parts together. Ex. 2237, 208:10–25. A preponderance of the evidence supports the conclusion that the assembled RX prototypes met each of the limitations of the challenged claims, as set forth in the Appendices to Mr. Root's declaration. Ex. 2118, App'x A–E. In its Sur-Sur-Reply, Petitioner identifies certain claim limitations that were allegedly not met by the prototypes, but Petitioner does not point to any evidence to contradict Mr. Root's testimony on this point. Pet. CRTP Sur-Sur-Reply 14–15. We likewise find the charts included as Appendices to Dr. Zalesky's declaration to be insufficient in this regard. Ex. 1755, App'x A–E. Rather than identifying any specific technical reason why the prototype components reflected in the purchase documents could not have met the claim limitations, Dr. Zalesky's rebuttal claim charts appears to focus on whether there was sufficient corroborating evidence (which we have already discussed above). *Id.* As such, we find the evidence presented in this case to be more detailed than that found insufficient in *Valencell, Inc. v. Fitbit, Inc.*, 784 F. App'x 1005, 1009 (Fed. Cir. 2019), cited by Petitioner. Reply 16. There, no evidence—testimonial or documentary—addressed key claims limitations, which stands in contrast to the detailed testimony and corroborating documents cited in Mr. Root's and Mr. Sutton's declarations.

Having found that Patent Owner constructed embodiments that met all limitations of the challenged claims, we move on to the second issue: whether Patent Owner demonstrated that those embodiments worked for the intended purpose of the invention.

We begin this inquiry by identifying the "intended purpose" of the invention. Patent Owner puts forth a broad intended purpose. Initially,

Patent Owner asserted testing was done to show that the prototypes "could serve their intended purpose of being placed in a standard guide catheter and deliver interventional cardiology devices alongside the rail segment, into the side opening and distal tubular portion, and then out the distal end of the distal tubular portion and into challenging coronary anatomy." PO CRTP Resp. 25 (citing Ex. 2118 ¶¶ 17–18, 38, 47; Ex. 2119 ¶ 41; Ex. 2123 ¶¶ 20–24). In its Sur-Reply, Patent Owner clarifies that the intended purpose was "to increase backup support for delivery of interventional cardiology devices, including procedures involving tough or chronic total occlusions." PO CRTP Sur-Reply 9 (citing Exs. 2002, 2003, 2024). By contrast, Petitioner argues for a narrower intended purpose, asserting that the intended purpose was "providing backup support necessary for accessing and crossing tough or chronic occlusions." Pet. CRTP Reply 17 (citing Ex. 2002; Ex. 2118 ¶ 18; Ex. 2119 ¶ 9; Ex. 1762, 47:11–52:17). Citing Patent Owner's Sur-Reply, Petitioner contends that the parties ostensibly "agree" that the intended purpose was "to increase backup support for accessing and crossing tough occlusions." Pet. CRTP Sur-Sur-Reply 7 (citing PO CRTP Sur-Reply 9); *see also* Tr. 49:3–12 ("Teleflex agrees the intended purpose was to increase back-up support for accessing and crossing tough or chronic total occlusions.").

We agree with Patent Owner's position on what constitutes the intended purpose of the invention. Petitioner is certainly correct that several of the documents we have considered refer to crossing "tough" or "chronic" occlusions when discussing the idea behind the invention. *See, e.g.*, Ex. 2002. But when considering all of the pertinent evidence, we find that the inventors were concerned with a broader primary purpose, namely generally

providing improved backup support for a guide catheter, with crossing tough or total occlusions being one specific benefit or application of the device. In other words, we do not find that the RX GuideLiner had applicability only when there were tough or chronic occlusions in the artery that needed to be crossed. Indeed, the challenged patent itself recognizes this broader purpose when discussing the field and background of the invention. *See* Ex. 1001, 1:44–47 ("More particularly the present invention relates to methods and apparatus for increasing backup support for catheters inserted into the coronary arteries from the aorta."); *id.* at 3:18–22 ("Thus, the interventional cardiology art would benefit from the availability of 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.")

The documentary evidence we have considered and discussed above further supports this broader intended purpose. For example, while Mr. Sutton's lab notebook expresses the idea for the GuideLiner device as "relat[ing] to interventional coronary procedures and specifically to accessing & crossing tough or chronic total occlusions," it also more broadly notes that "[t]he idea is to provide a guide or support catheter more distally into the coronary to provide more back-up support for the stent device." Ex. 2002, 7. Mr. Sutton's lab notebook also contains two additional notes related to the invention: "Guide-Liner is used when there is difficulty crossing lesions"; and "Guide-Liner allows back-up support distally." *Id.* at 8. Similarly, in the February 4, 2005 Market Feasibility memo, Mr. Root describes the purpose of the RX GuideLiner as "provid[ing] the ability to create a deep seating of the guide for added support in the interventional

procedure." Ex. 2003, 1. Mr. Root explains that "[b]y safely deep seating the guide catheter, the physician can then have the added support for pushing a wire through a chronic total occlusion or advancing a balloon or stent through a tight stenosis." *Id.* The August 24, 2005 Products Requirement document indicates the "[a]pplicable clinical use" for both the RX and OTW GuideLiners to be "increas[ing] guide catheter back-up support." Ex. 2024, 1.

Additionally, Patent Owner's expert's testimony supports this conclusion. Patent Owner's expert, Mr. Keith, declares that testing the RX GuideLiner prototypes would be sufficient for reduction to practice if the testing showed the prototype "(a) could be delivered through a guide catheter so that the distal end of the tubular portion extended beyond the distal end of the guide catheter while being tracked over a winding path; and (b) allowed a stent delivery catheter or balloon catheter to pass into the tubular portion and out the far end of the tubular portion while located within the guide catheter." Ex. 2123 ¶ 22.

The testimony of inventors Mr. Root and Mr. Sutton cited by the parties also supports this conclusion. Mr. Root declares that the intended purpose of the RX GuideLiner was to "deliver interventional cardiology devices, such as a stent or balloon catheter, alongside the rail segment, into the side opening and distal tubular portion, and then out the distal end of the distal tubular portion and into challenging coronary anatomy." Ex. 2118 ¶ 18; *see also id.* ¶ 47 (describing the intended purpose as "facilitat[ing] the delivery of balloon catheters and stents deep into coronary arteries while providing increased backup support"). During Mr. Root's deposition, counsel for Petitioner inquired about Mr. Root's understanding of the

intended purpose. Ex. 1762, 47:11–52:17. Mr. Root repeatedly stated that accessing and crossing tough or chronic occlusions was not the sole intended purpose. *Id.* at 47:11–20 (identifying that Petitioner's asserted intended purpose was "one of them" but "not all of them"), 50:10–12 ("The important thing is this is not just a chronic total occlusion device. This can apply to much broader coronary interventions."). Mr. Sutton's declaration quotes the purpose identified in his notes in his lab notebook, discussed above. Ex. 2119 ¶ 9 (quoting Ex. 2002, 7, 8). Mr. Sutton also declares that he and his team tested the prototypes qualitatively "to determine that [they] provided backup support," "to ensure that [stents and balloon catheters] could safely be delivered and would not snag or get caught on the device," and "to deliver interventional cardiology devices and provide additional backup support compared to the guide catheter alone." *Id.* ¶ 41.

In sum, the pertinent evidence demonstrates that the intended purpose of the claimed invention, as embodied in the RX GuideLiner, was to increase backup support for delivery of interventional cardiology devices. Although crossing tough or total occlusions is one noted benefit of the invention, we do not find it to be the only or primary purpose of the invention.

We next consider whether the testing conducted at VSI was sufficient to determine that the RX GuideLiner prototypes would work for the intended purpose of increasing backup support for delivery of interventional cardiology devices. "Depending on the character of the invention and the problem it solves, determining that the invention will work for its intended purpose may require testing." *Cooper*, 154 F.3d at 1327 (citing *Mahurkar v. C.R. Bard Inc.*, 79 F.3d 1572, 1578 (Fed. Cir. 1996)). "When testing is

necessary, the embodiment relied upon as evidence of priority must actually work for its intended purpose." *Id.* (citing *Scott v. Finney*, 34 F.3d 1058, 1061 (Fed. Cir. 1994)). "The testing requirement depends on the particular facts of each case, with the court guided by a common sense approach in weighing the sufficiency of the testing." *Scott*, 34 F.3d at 1061 (citations omitted). "This common sense approach prescribes more scrupulous testing under circumstances approaching actual use conditions when the problem includes many uncertainties," but "permits little or no testing to show the soundness of the principles of operation of the invention" "when the problem to be solved does not present myriad variables." *Id.* at 1063. "In tests showing the invention's solution of a problem, the courts have not required commercial perfection nor absolute replication of the circumstances of the invention's ultimate use." *Id.* "[T]ests performed outside the intended environment can be sufficient to show reduction to practice if the testing conditions are sufficiently similar to those of the intended environment." *DSL Dynamic Scis. Ltd. v. Union Switch & Signal, Inc.*, 928 F.2d 1122, 1125 (Fed. Cir. 1991) (citing *Tomecek v. Stimpson*, 513 F.2d 614, 618 (CCPA 1975)). For medical device inventions, a showing of actual reduction to practice does not require human testing in actual use conditions. *Scott*, 34 F.3d at 1063 ("Testing for the full safety and effectiveness of a prosthetic device is more properly left to the Food and Drug Administration (FDA). Title 35 does not demand that such human testing occur within the confines of Patent and Trademark Office (PTO) proceedings.").

Patent Owner relies on inventor and expert testimony, as well as documentary evidence, to establish that the use of benchtop models was sufficient to test that the products were suitable for the intended purpose

described above.[25] PO CRTP Resp. 11–12, 24–25. Mr. Root asserts that benchtop coronary models, as depicted in the July 2005 sales presentation, were commonly used at VSI and other medical device companies to test interventional cardiology catheters. Ex. 2118 ¶ 17 (citing Exs. 2018, 2129). Citing its expert's declaration, Patent Owner asserts that "[c]atheter inventions are routinely determined to work using benchtop models, and without human testing." PO CRTP Resp. 25 (citing Ex. 2123 ¶¶ 20–24; Ex. 1010). Applied to this invention, Patent Owner asserts its benchtop model emulated the cardiac anatomy, and was used to show that the RX GuideLiner could be "placed in a standard guide catheter and deliver interventional cardiology devices alongside the rail segment, into the side opening and distal tubular portion, and then out the distal end of the distal tubular portion and into challenging coronary anatomy." *Id.* (citing Ex. 2118 ¶¶ 17–18, 38, 47; Ex. 2119 ¶ 41; Ex. 2123 ¶¶ 20–24).

Petitioner's argument against Patent Owner's testing evidence depends on its narrower intended purpose, i.e., "using simulated tough lesions." Pet. CRTP Reply 18; *see also* Pet. CRTP Sur-Sur-Reply 7–9. In light of our rejection of the narrower intended purpose identified by Petitioner, we likewise reject Petitioner's argument that the testing evidence presented by Patent Owner is insufficient. Moreover, Petitioner

[25] Referring to Petitioner's expert's testimony regarding a person of ordinary skill in the art's knowledge pertaining Itou, Patent Owner also contends that no testing would have been required to know the RX GuideLiner would have worked for its intended purpose. *See* PO CRTP Sur-Reply 9 (citing Ex. 2116, 110:20–113:24; Ex. 2238, 87:18–89:5). Because we determine that the evidence demonstrates that testing in benchtop models was sufficient, we do not address this theory.

acknowledges that benchtop models could have been used to test a device like the RX GuideLiner. Pet. CRTP Reply 17–18. The testimony of Mr. Root, Mr. Sutton, Mr. Erb, and Mr. Keith, corroborated by the photograph of the model in the sales presentation, confirm that VSI utilized benchtop coronary models that were considered the standard for testing interventional cardiology device such as catheters. *See* Ex. 2018; Ex. 2118 ¶¶ 17, 38, 47; Ex. 2119 ¶¶ 23, 37–38, 41; Ex. 2122 ¶ 11; Ex. 2123 ¶¶ 21–24. We consider this benchtop testing to be similar to the "countertop" testing that was found sufficient to show actual reduction to practice in *Mahurkar*. *See Mahurkar*, 79 F.3d at 1578 (determining for claims related to a double lumen catheter that flow and pressure drop tests conducted in the inventor's kitchen, using glycerine to simulate blood, was sufficient for actual reduction to practice because they "showed, to the the limit of their design, the utility of his claimed invention"). As noted by Petitioner, Mr. Root indicated during his deposition that to reduce to practice, VSI needed to "(1) navigate RX through a guide catheter and out its distal end in a benchtop model, (2) deliver an interventional cardiology device, and (3) retrieve RX in one piece." Pet. CRTP Reply 18 (citing Ex. 1762, 100:1–102:3). We find that the "pull tests" done using the benchtop models demonstrated that the RX GuideLiner was capable of accomplishing at least this much, even if the tests were not conducted in an *in vivo* or *in vitro* environment that simulated tough lesions. Ex. 2118 ¶¶ 17, 38, 47. This is not a situation where there were significant variables or uncertainties that needed to be assessed in order to determine whether the RX device would work properly, and thus the "qualitative" testing done by VSI using the benchtop models was sufficient. Ex. 2119 ¶ 41; Ex. 2123 ¶¶ 21–22. Accordingly, a preponderance of the

evidence supports the conclusion that the testing done at VSI demonstrated that the RX GuideLiner would work for its intended purpose.

In our assessment of whether there was actual reduction to practice prior to the critical date, we have considered Petitioner's argument that the GuideLiner project was still in "early-stage concept development" in mid-to-late 2005, and that VSI was still experimenting in 2006 and did not have a working prototype even by 2008. Pet. CRTP Reply 22–27.

In support of this argument, Petitioner points to continuing changes to the RX design as evidence that the design was not completed before the critical date. *Id.* For example, a July 2005 Research & Development (R&D) Update notes that "[t]he initial design is an over-the-wire configuration, with a rapid exchange version to follow." Ex. 2130, 3.[26] In contrast to the incomplete August 2005 Product Requirements document relied upon by Patent Owner (Ex. 2024), Petitioner contends that the official, completed version of the Product Requirements document for the GuideLiner project was not created until April 2009. Ex. 1767. A "2006 Strategic Objectives" document, dated December 1, 2005, indicates that the "rapid exchange version requires additional engineering and is not included in our 2006 forecasts." Ex. 2131, 10. Likewise, Petitioner points to a GuideLiner team

[26] We recognize that this document appears to contradict Mr. Root's recollection that the original idea was for the RX GuideLiner, and that the decision was later made to concurrently pursue development of the OTW version. Ex. 2118 ¶ 19. We do not find the issue of whether the initial idea was for the RX version or the OTW version to be material to our analysis on reduction to practice. Nonetheless, we note Mr. Sutton's original notebook pages suggest that the original idea was indeed for the RX version rather than the OTW version. Ex. 2002.

meeting memo from May 2, 2006 that includes as agenda items "1) Review Initial Design and Intended Use," and "2) Determine what can be completed/started prior to design lock." Ex. 2109. According to another document, a "design freeze" for the GuideLiner device was expected to only take place May 30, 2007. Ex. 1769, 1. Indeed, an R&D update from July 2008 notes with respect to the GuideLiner device:

> Throughout this project, timelines have been pushed out due to drastic design changes and resource constraints. To date we have prototyped and tested a new design. This new design is more robust and cost effective. We are planning on an August 2008 design freeze with a 510k submission in November 2008.

Ex. 2132, 7.

We have taken the foregoing evidence into account, but do not find that it detracts from Patent Owner's evidence concerning reduction to practice based on building and testing the April and July 2005 prototypes discussed above. To be sure, the post-critical date documents highlighted by Petitioner make it is clear that significant design revisions for the RX GuideLiner continued well into 2008, and these additional design changes may well have been required for FDA regulatory approval and/or commercialization of the device. Indeed, Patent Owners' declarants attest that additional engineering work was conducted to refine the product for regulatory purposes and commercialization. *See* Ex. 2118 ¶ 59 (Mr. Root attesting that "[f]rom September of 2005 forward, I and others at VSI continued to act diligently to bring the rapid exchange GuideLiner to market."); Ex. 2119 ¶ 44 (Mr. Sutton attesting that, after the August 24, 2005 Product Requirements document, "we continued to refine prototypes of the GuideLiner Rapid Exchange for purposes of manufacturability and

commercialization"); Ex. 2122 ¶ 13 (Mr. Erb attesting that work continued on "develop[ing] manufacturing processes that were reproducible and a refined design that was able to be commercialized"). But we see no basis to conclude that these additional engineering and design changes were an indication that the April and July 2005 prototypes failed to demonstrate that the RX GuideLiner was capable of achieving increased backup support.

Ultimately, the RX GuideLiner was not commercialized until 2009, which we recognize is far later than the initial projected timeframe of late 2005/early 2006 and the date of actual reduction to practice. Ex. 2118 ¶ 89. Mr. Root asserts that one reason for this delay was due to turnover in R&D personnel. *Id.* Under the circumstances, we do not find that the additional engineering and design work done with respect to the RX GuideLiner to achieve regulatory approval and commercialization indicates a lack of actual reduction to practice prior to the critical date. *See Loral Fairchild Corp. v. Matsushita Elec.*, 266 F.3d 1358, 1362–63 (Fed. Cir. 2001) ("Once the invention has been shown to work for its intended purpose, reduction to practice is complete. Further efforts to commercialize the invention are simply not relevant to determining whether a reference qualifies as prior art against the patented invention.").

In sum, we find that Patent Owner has demonstrated actual reduction to practice prior to Itou's critical date by a preponderance of the evidence based on the work done at VSI in building and testing the April and July 2005 prototypes of the RX GuideLiner. Nonetheless, to the extent that this evidence is not sufficient for actual reduction to practice, we find that it demonstrates at least conception of the claimed invention prior to the critical date.

4. Constructive Reduction to Practice

In addition to asserting actual reduction to practice, Patent Owner alternatively relies upon a theory of constructive reduction to practice. Antedating based on this theory would require Patent Owner to demonstrate diligence from just before the date Itou was filed until the date Patent Owner filed its priority application for the GuideLiner patents,[27] i.e., from September 23, 2005 to May 3, 2006. *See Perfect Surgical Techniques, Inc. v. Olympus America, Inc.*, 841 F.3d 1004, 1007 (Fed. Cir. 2016) (requiring diligence for the "entire critical period, which begins just prior to the competing reference's effective date and ends on the date of the invention's reduction to practice").

To demonstrate diligence, Patent Owner again relies on testimony from its inventor and non-inventor declarants, as well as correspondences with VSI's outside patent counsel at the Patterson Law Firm and documents reflecting further engineering and development work done during this period. PO CRTP Resp. 18–19; PO CRTP Sur-Reply 12.

According to Mr. Root, following the initial conception and the building of the April and July 2005 prototypes, he and others at VSI continued working from September 2005 onward to bring the RX GuideLiner to market. Ex. 2118 ¶ 59. This project was one of VSI's primary development initiatives at the time, and they worked on it continuously until they brought it to market in 2009. *Id.* Thus, they worked

[27] We use term "GuideLiner patents," in the same manner as the parties' declarants, to refer to the patents challenged in IPR2020-00126, -00128, -00129, -00132, -00134, -00135, and -00137. *See, e.g.*, Ex. 2118 ¶ 1; Ex. 2119 ¶¶ 1, 3; Ex. 2123 ¶ 1.

continuously at least until the May 3, 2006 application date. *Id.* ¶ 76. Ms. Schmalz likewise testifies that "[a]t no time between the start of the regulatory process for GuideLiner in August of 2005 and the filing of the patent application in May 2006 was the rapid exchange GuideLiner project abandoned or paused." Ex. 2039 ¶ 12.

Mr. Sutton sent a fax to the Patterson Law Firm on March 21, 2006, which includes drawings that are similar to the proximal portion of the RX GuideLiner depicted in Ex. 2114. Ex. 2118 ¶ 42 (citing Ex. 2019). The firm also possessed the August 1, 2005, CAD drawing of a complete RX GuideLiner prototype. *Id.* ¶¶ 49–50 (citing Ex. 2022).

Upon Mr. Root's request, the firm opened a matter to conduct a patentability search for the GuideLiner on August 11, 2005. *Id.* ¶ 52 (citing Ex. 2023). Mr. Root provided the firm with the full prototype drawing in Ex. 2022 to conduct the search. *Id.* Mr. Root testifies that he would not engage in freedom-to-operate searching until after he had made a full prototype that was shown to work for its intended purpose and ready to move forward to commercialization. *Id.* An invoice from the firm demonstrates work performed for a "patent search for guide liner" in August 2005. *Id.* ¶ 53 (citing Ex. 2096).

In his declaration, Mr. Root then sets forth the timeline of events with documentary and circumstantial evidence during the critical period for diligence, i.e., from September 23, 2005, to May 3, 2006.

For September 2005, Mr. Root refers to invoices dated September 7, 2005, and a check for forming tips that would have been used for the distal tip of the GuideLiner prototype. *Id.* ¶ 60 (citing Ex. 2097). He refers to these documents to demonstrate that VSI was continuing to refine the

prototypes during this period. Mr. Root also refers to a copy of the Patterson Law Firm's privilege log showing that a partner of the firm sent Mr. Root a confidential letter dated September 14, 2005, pertaining to prior art related to the GuideLiner. *Id.* ¶ 61 (citing Ex. 2098).

For October 2005, Mr. Root refers to a business update presented to VSI's Board of Directors during its October 2005 meeting. *Id.* ¶ 62 (citing Exs. 2041 (confidential), 2133 (public)). Mr. Root declares this update included extremely favorable reviews of the RX GuideLiner from VSI's physician advisors. *Id.* Mr. Root further declares the update included projected timelines for regulatory filings, with intentions to file in the end of 2005 for OTW and early 2006 for RX. *Id.* Mr. Root also refers to the matter the Patterson Law Firm opened this month for work leading towards the initial GuideLiner patent application. *Id.* (citing Ex. 2023).

For November 2005, Mr. Root declares that they continued refining the proximal portion of the RX GuideLiner. *Id.* ¶ 63. Mr. Root refers to engineering drawings obtained from SPECTRAlytics, including one dated November 2005, which closely resembles Figure 10 of the GuideLiner patents. *Id.* (citing Ex. 2115). Mr. Root also refers to a VSI R&D planning document for 2006, which was drafted by Mr. Sutton on November 22, 2005. *Id.* ¶ 64 (citing Ex. 2099). The planning document demonstrates VSI's intent, as of late November 2005, to continue with the regulatory approval process for the RX GuideLiner in 2006. *Id.*

For December 2005, Mr. Root refers to a VSI Strategic Objectives document for 2006, which was drafted on December 1, 2005. *Id.* ¶ 65 (citing Ex. 2100). The document indicates that the RX GuideLiner required additional work for commercialization, which would continue through the

end of 2006. *Id.* Mr. Root also refers to an invoice from the Patterson Law Firm, which shows the time invested in preparing the GuideLiner patent application during December 2005. *Id.* ¶ 66 (citing Ex. 2117).

For January 2006, Mr. Root refers to another invoice from the Patterson Law Firm, which shows time invested in preparing the GuideLiner patent application during January 2006. *Id.* (citing Ex. 2101). Mr. Root also refers to a fax sent from Mr. Sutton to the law firm on January 23, 2006. *Id.* ¶ 67 (citing Ex. 2102). The fax contains three figures that illustrate examples of the problem to be solved by the RX GuideLiner, and which are nearly identical to Figures 7, 8, and 9 of the GuideLiner patents. *Id.*

For March 2006, Mr. Root refers to a Patterson Law Firm invoice showing time invested in preparing the GuideLiner patent application during March 2006. *Id.* ¶ 68 (citing Ex. 2103). Mr. Root also refers to purchase records for stainless steel tubing from Vita Needle Company on March 24, 2006. *Id.* ¶ 69 (citing Ex. 2104). Mr. Root declares that VSI used this tubing to refine the RX GuideLiner for commercialization. *Id.* Mr. Root also refers to a March 30, 2006, engineering drawing from SPECTRAlytics's files. *Id.* ¶ 70 (citing Ex. 2115). The drawing, which is similar to the photographs of RX GuideLiner prototypes depicted in Exhibit 2014, shows VSI's attempt to reduce manufacturing costs by cutting two proximal portions from a single hypotube. *Id.*

For April 2006, Mr. Root refers to a Budget to Actual Variances report provided to the VSI Board of Directors for its April 2006 meeting. *Id.* ¶ 71 (citing Ex. 2105). The report shows GuideLiner R&D expenses by that time had been more than double the amount that was budgeted. *Id.*
Mr. Root refers to purchase records for laser-cut and electropolished

GuideLiner hypotubes from LSA, with an invoice dated April 7, 2006. *Id.* ¶ 72 (citing Ex. 2106). These hypotubes were used to refine the RX GuideLiner during commercialization. *Id.* Mr. Root refers to purchase records for twenty hypotubes from MicroGroup, with an invoice dated April 18, 2006. *Id.* ¶ 73 (citing Ex. 2107). These hypotubes were used to refine the RX GuideLiner during commercialization. *Id.* Mr. Root refers to other purchase records, including an April 19, 2006, invoice for cut GuideLiner hypotubes from LSA, which were used to commercialize the RX GuideLiner. *Id.* ¶ 74 (citing Ex. 2108).

For May 2006, other than the filing of the application on May 3, 2006, Mr. Root refers to notes from a GuideLiner team meeting held May 2, 2006, which confirm they were still working towards commercializing the RX GuideLiner. *Id.* ¶ 75 (citing Ex. 2109).

Mr. Sutton's diligence timeline, including the documents he refers to, largely matches Mr. Root's. For essentially the same reasons as Mr. Root, Mr. Sutton refers to: the drawing of the fully-assembled RX GuideLiner, Ex. 2119 ¶ 39 (citing Ex. 2022); his fax sent March 21, 2006, to the Patterson Law Firm, including the drawings similar to Figures 12 through 16 of the patents, *id.* ¶ 40 (citing Ex. 2019); his fax sent on January 23, 2006, to the Patterson Law Firm, which contains three figures that illustrate examples of the GuideLiner situated in the aorta, which are nearly identical to Figures 7, 8, and 9 of the GuideLiner patents, *id.* ¶ 42 (citing Ex. 2102); the VSI R&D planning document for 2006, dated November 22, 2005, *id.* ¶ 48 (citing Ex. 2099); the VSI marketing document dated December 1, 2005, *id.* ¶ 49 (citing Ex. 2100); the Vita Needle purchase records for stainless steel hypotubes shipped on March 24, 2006, which were used for the RX GuideLiners, *id.*

¶ 51 (citing Ex. 2104); and the April 2006 VSI budget report, indicating expenses on commercializing the RX GuideLiner more than doubled the amount VSI budgeted, *id.* ¶ 52 (citing Ex. 2105). Mr. Sutton also refers to the January 2006 R&D Update that he prepared for the VSI Board of Directors, *id.* ¶ 50 (citing Ex. 2134). In that update, Mr. Sutton reported to VSI's Board that both GuideLiner projects were still planned, with OTW regulatory filings next up at the time. *Id.*

In addition to testimony from inventors Mr. Root and Mr. Sutton, Patent Owner also points to testimony from Ms. Schmalz, Mr. Erb, and Mr. Keith. Ms. Schmalz declares that, from "the start of the regulatory process for GuideLiner in August of 2005 and the filing of the patent application in May 2006," the RX GuideLiner "was always a high priority project during [her] time at VSI" and was never "abandoned or paused." Ex. 2039 ¶ 12. Mr. Erb declares that VSI was "continually working to optimize the design [of the RX GuideLiner] for commercialization. Ex. 2122 ¶ 13. As an example, he recalls the weighing of advantages and disadvantages between stainless steel and nitinol for the proximal portion during the commercialization stage. *Id.* ¶ 14. Mr. Keith explains his understanding that further commercialization work was performed after August 2005. Ex. 2123 ¶¶ 25–27.

Patent Owner contends that the evidence it relies on to prove conception and reduction to practice shows that "VSI worked steadily on the GuideLiner invention from conception through the date the patent was filed." PO CRTP Resp. 28 (citing *id.* at 3–19). Patent Owner acknowledges that it took more time and resources than anticipated, but that this delay

should have "no bearing whatsoever on the [diligence] analysis." *Id.* at 28–29.

Petitioner argues Patent Owner's response "does not contain any detail showing diligence." Pet. CRTP Reply 28. Petitioner deems the "handful" of events identified by Patent Owner during the critical period—opening a patent application file, working on the patent application, exchanging emails, and buying parts—to be insufficient evidence of diligence. *Id.* at 28–29. It appears from Petitioner's visual timeline of Patent Owner's events that two periods in particular allegedly represent a lack of diligence: from September 23, 2005, to the end of November 2005, during which there was only a component design change; and the month of February 2006, during which there were no diligence-related events. *Id.* at 29 (citing Ex. 2115). Petitioner also faults Patent Owner's delay in regulatory submissions for the RX GuideLiner, which were initially planned for late 2005 and 2006 but were postponed until 2008. *Id.* (citing Ex. 1762, 131:3–133:3; Ex. 2132, 7).

When evaluating diligence, we are mindful of recent Federal Circuit admonitions clarifying that we must not apply a standard that is "too exacting" or "too rigid." *Perfect Surgical*, 841 F.3d at 1008; *Arctic Cat*, 919 F.3d at 1331. Though "periods of inactivity within the critical period do not automatically vanquish a patent owner's claim of reasonable diligence," *Arctic Cat*, 919 F.3d at 1331, "[m]erely asserting diligence is not enough" and a party must "account for the entire period during which diligence is required." *In re Meyer Mfg. Corp.*, 411 F. App'x 316, 320 (Fed. Cir. 2010). "[D]iligence need not be perfectly continuous—only *reasonably* continuous." *Arctic Cat*, 919 F.3d at 1331. The key question for diligence

is whether, "in light of the evidence as a whole, the invention was not abandoned or unreasonably delayed." *Id.* (internal quotations omitted). Applying this standard, we conclude that Patent Owner sufficiently demonstrates reasonably continuous diligence throughout the critical period.

The evidence demonstrates that Patent Owner did not unreasonably delay the RX GuideLiner project. As both parties acknowledge, there were indeed delays in the project. Petitioner asserts "VSI prioritized *other projects* in late 2005 and 2006 and postponed RX regulatory submissions through 2008." Pet. CRTP Reply 29 (citing Ex. 1762, 131:3–133:3; Ex. 2132, 7) (emphasis in original). But the cited portion of Mr. Root's deposition testimony sufficiently explains why the delay was reasonable. As noted by Mr. Root, OTW GuideLiner regulatory submissions came first "[b]ecause it was much easier to get regulatory approval and do the testing." Ex. 1762, 131:3–8. "[T]ransition in personnel" also complicated the project. *Id.*, 131:12–17. And as for the RX, Mr. Root explained that commercialization took longer due to "vendor optimization," *id.*, 132:25–133:9, which tracks the greater difficulty associated with bringing the RX GuideLiner to market. Ms. Schmalz further corroborates this explanation with her declaration that RX GuideLiner "was always a high priority project during [her] time at VSI." Ex. 2039 ¶ 12.

Nor does it appear that Patent Owner abandoned the RX GuideLiner invention. For one thing, Patent Owner engaged counsel to prepare its GuideLiner patent application, which was ultimately filed on May 3, 2006. The Patterson Law Firm opened a patent search on August 11, 2005 (Ex. 2023, 5) then reported the results to VSI on September 14, 2005 (Ex. 2098, 2). On October 10, 2005, the firm opened a patent prosecution matter for the

GuideLiner. Ex. 2023, 5. There is evidence in the record of the firm working on preparing the application in December 2005 (Ex. 2117, 20), January 2006 (Ex. 2102, 7), and March 2006 (Ex. 2103, 6). There is also evidence of communications between the firm and VSI, namely Mr. Root and Mr. Sutton, in January 2006 and March 2006. Ex. 2102; Ex. 2098, 4; Ex. 2019. To be sure, there is not an abundance of documents in the record related to preparing the application, including drafts of the specification and claims, but Patent Owner clarified at oral argument that it lacks many documents due to the passage of time, not the refusal to waive attorney-client privilege. Tr. 64:8–21. A lack of documents due to the passage of time does not foreclose sufficient corroboration. *See, e.g.*, *NFC Tech., LLC v. Matal*, 871 F.3d 1367, 1374 (Fed. Cir. 2017) (concluding there was sufficient corroboration of conception based on circumstantial evidence, "particularly considering the amount of time that ha[d] passed").

Moreover, the other documents Patent Owner proffers provide additional circumstantial evidence that VSI was working on and did not abandon the RX GuideLiner project throughout this time. Petitioner again faults Patent Owner for not providing direct evidence. Pet. CRTP Reply 28 (pointing out lack of events "related to actual work on an RX device"); *id.* at 29 (arguing Patent Owner "cannot tie the component parts purchases to RX"). But, as we noted above, direct evidence is not required for adequate corroboration. Internal VSI documents, such as updates for VSI's Board and budget documents, show that work on the RX project continued from October 2005 through April 2006. Ex. 2133, 4, 7; Ex. 2099; Ex. 2100, 8–9; Ex. 2105, 4–5. Additionally, there are invoices related to supplies that support the testimony of inventors Mr. Root and Mr. Sutton regarding

continued work on the RX GuideLiner in March 2006 and April 2006. Ex. 2104; Ex. 2005, 5; Ex. 2115; Ex. 2106, 3; Ex. 2107; Ex. 2108, 4–5. All of this evidence corroborates theMr. Root's and Mr. Sutton's ' testimony that VSI worked diligently and continuously on the RX GuideLiner project without abandoning the project.

Finally, we are not convinced that the periods from September 23, 2005, to the end of November 2005 or in February 2006 demonstrate lack of diligence. Petitioner's argument for these periods is conclusory, and contradicted by the reasonable commercialization delays that we addressed above.

Considering all of the pertinent evidence, we find that Patent Owner did not abandon or unreasonably delay the RX GuideLiner project during the critical period. Petitioner's arguments implying the need for direct evidence and scouring the timeline for periods of inactivity are unpersuasive. We therefore conclude that Patent Owner demonstrates, by a preponderance of the evidence, that VSI was reasonably continuous in its diligence during the critical period. Because we have also found that Patent Owner demonstrated conception prior to Itou's critical date, Patent Owner has met its burden to successfully demonstrate that Itou is not prior art to the challenged claims of the '379 patent.

E. Challenges Based on Itou

Petitioner contends claims 25, 26, 29–31, 33–40, 42, 43, and 45 are anticipated by Itou (Pet. 20–60), claims 26, 38–40, and 43–45 would have been obvious over Itou and Ressemann (*id.* at 60–74), claim 32 would have been obvious over Itou (*id.* at 74–77), claim 44 would have been obvious over Itou and Kataishi (*id.* at 77–82), and claim 44 would have been obvious

over Itou and Enger (*id.* at 82–87). Because Itou is not prior art to the '379 patent, Petitioner's challenges relying on Itou, in whole or in part, are not persuasive. Accordingly, Petitioner has not demonstrated by a preponderance of the evidence that claims 25, 26, 29–40, and 42–45 are unpatentable over the Itou-based grounds asserted in the Petition.

III. CONTINGENT MOTION TO AMEND

Patent Owner's Motion to Amend requests that if claims 25, 29, 30, 38, 43, or 45 of the '379 patent are determined to be unpatentable, that the Board substitute those claims with proposed substitute claims 46–51. Motion 1. Because we do not find any of the challenged claims unpatentable in this proceeding, we do not reach the merits of the Motion to Amend.

IV. CONSTITUTIONAL CHALLENGE

Patent Owner argues that the Petition should be denied because "the manner in which administrative law judges are appointed is unconstitutional." PO Resp. 51 (citing *Arthrex, Inc. v. Smith & Nephew, Inc.*, 941 F.3d 1320, 1325 (Fed. Cir. 2019)). Patent Owner further argues that the remedy in the *Arthrex* decision "severing certain removal protections, is insufficient to cure the constitutional defect, because, e.g., it still does not give a properly appointed principle office the power to review administrative law judge decisions." *Id.* (citing *Lucia v. SEC*, 138 S. Ct. 2044, 2055 (2018)). We decline to consider Patent Owner's constitutional argument because the Federal Circuit addressed this issue in *Arthrex*. *Arthrex*, 941 F.3d at 1328.

V. MOTION TO EXCLUDE

Petitioner has moved to exclude Exhibit 2024, which is the August 24, 2005 Product Requirements document. Paper 112. Petitioner contends that Exhibit 2024 is unreliable on its face and that none of Patent Owner's witnesses can authenticate the document. *Id.* at 2–9. Patent Owner responds that Exhibit 2024 is authenticated under Federal Rule of Evidence 901 based on the declaration and/or deposition testimony of Mr. Peters (Ex. 1926 ¶ 18), Ms. Schmalz (Ex. 2039 ¶¶ 6–7), Mr. Root (Ex. 2118 ¶ 54), and Mr. Sutton (Ex. 2119 ¶ 44). Paper 116.

Documents are authenticated by evidence "sufficient to support a finding that the item is what the proponent claims it is." Fed. R. Evid. 901(a); *see Fox Factory v. SRAM, LLC*, IPR2016-01876, Paper 59 at 63 (PTAB Apr. 2, 2018) (quoting same). "Authenticity is, therefore, not an especially high hurdle for a party to overcome." *Fox Factory*, Paper 59 at 63 (citing *United States v. Patterson*, 277 F.3d 709, 713 (4th Cir. 2002). We determine that Exhibit 2024 has been authenticated under Federal Rule of Evidence 901. In addition, Petitioner's arguments go to the weight of the evidence and not its admissibility. Accordingly, we deny Petitioner's Motion to Exclude. We note, however, that even if we were to exclude Exhibit 2024, it would not change our general analysis or the outcome in this case.

VI. CONCLUSION

After reviewing the arguments and evidence of record, we determine that Petitioner has not demonstrated by a preponderance of the evidence that claims 25, 26, 29–40, and 42–45 are unpatentable.

In summary:

Claims	35 U.S.C. §	Reference(s)/ Basis	Claims Shown Unpatentable	Claims Not Shown Unpatentable
25, 26, 29–31, 33–40, 42, 43, 45	102	Itou		25, 26, 29–31, 33–40, 42, 43, 45
26, 38–40, 43–45	103	Itou, Ressemann		26, 38–40, 43–45
32	103	Itou		32
44	103	Itou, Kataishi		44
44	103	Itou, Enger		44
Outcome				25, 26, 29–40, 42–45

The table below summarizes our conclusions as to Patent Owner's Revised Motion to Amend the claims.

Motion to Amend Outcome	Claims
Original Claims Cancelled by Amendment	
Substitute Claims Proposed in the Amendment	25, 29, 30, 38, 43, 45
Substitute Claims: Motion to Amend Granted	
Substitute Claims: Motion to Amend Denied	
Substitute Claims: Not Reached	25, 29, 30, 38, 43, 45

VII. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that Petitioner has not demonstrated that challenged claims 25, 26, 29–40, and 42–45 are unpatentable;

FURTHER ORDERED that we do not address Patent Owner's Corrected Contingent Motion to Amend;

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

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

IPR2020-00137
Patent RE47,379E

FOR PETITIONER:
Cyrus Morton
Sharon Roberg-Perez
Christopher Pinahs
William E. Manske
Emily J. Tremblay
ROBINS KAPLAN LLP
cmorton@robinskaplan.com
sroberg-perez@robinskaplan.com
cpinahs@robinskaplan.com
wmanske@robinskaplan.com
etremblay@robinskaplan.com

FOR PATENT OWNER:
Derek Vandenburgh
Dennis Bremer
CARLSON, CASPERS, VANDENBURGH & LINDQUIST, P.A.
dvandenburgh@carlsoncaspers.com
dbremer@carlsoncaspers.com

Trials@uspto.gov
571.272.7822

Paper 132
Entered: August 27, 2021

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE OFFICE OF THE UNDERSECRETARY AND DIRECTOR OF THE UNITED STATES PATENT AND TRADEMARK OFFICE

MEDTRONIC, INC. and MEDTRONIC VASCULAR, INC.,
Petitioner,

v.

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

IPR2020-00126 (Patent 8,043,032 B2)
IPR2020-00128 (Patent RE45,380 E)
IPR2020-00132 (Patent RE45,760 E)
IPR2020-00134 (Patent RE45,760 E)
IPR2020-00135 (Patent RE45,776 E)
IPR2020-00137 (Patent RE47,379 E)

Before ANDREW HIRSHFELD, *Commissioner for Patents, Performing the Functions and Duties of the Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office.*

ORDER

IPR2020-00126 (Patent 8,043,032 B2)
IPR2020-00128 (Patent RE45,380 E)
IPR2020-00132 (Patent RE45,760 E)
IPR2020-00134 (Patent RE45,760 E)
IPR2020-00135 (Patent RE45,776 E)
IPR2020-00137 (Patent RE47,379 E)

The Office has received a request for Director review of the Final Written Decision in each of these cases. *See, e.g.*, IPR2020-00126, Ex. 3100. Each request was referred to Mr. Hirshfeld, Commissioner for Patents, Performing the Functions and Duties of the Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office.

It is ORDERED that the request for Director review in each case is denied; and

FURTHER ORDERED that the Patent Trial and Appeal Board's Final Written Decision in each case is the final decision of the agency.

IPR2020-00126 (Patent 8,043,032 B2)
IPR2020-00128 (Patent RE45,380 E)
IPR2020-00132 (Patent RE45,760 E)
IPR2020-00134 (Patent RE45,760 E)
IPR2020-00135 (Patent RE45,776 E)
IPR2020-00137 (Patent RE47,379 E)

For PETITIONER:

Cyrus Morton
Sharon Roberg-Perez
Christopher Pinahs
William E. Manske
Emily J. Tremblay
ROBINS KAPLAN LLP
cmorton@robinskaplan.com
sroberg-perez@robinskaplan.com
cpinahs@robinskaplan.com
wmanske@robinskaplan.com
etremblay@robinskaplan.com

For PATENT OWNER:

Derek Vandenburgh
Dennis Bremer
CARLSON, CASPERS, VANDENBURGH & LINDQUIST, P.A.
dvandenburgh@carlsoncaspers.com
dbremer@carlsoncaspers.com

Trials@uspto.gov
571.272.7822

Paper 133
Date: September 8, 2021

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.

IPR2020-00126 (Patent 8,043,032 B2)
IPR2020-00128 (Patent RE45,380 E)
IPR2020-00132 (Patent RE45,760 E)
IPR2020-00134 (Patent RE45,760 E)
IPR2020-00135 (Patent RE45,776 E)
IPR2020-00137 (Patent RE47,379 E)

Before ANDREW HIRSHFELD, *Commissioner for Patents, Performing the Functions and Duties of the Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office*, SCOTT R. BOALICK, *Chief Administrative Patent Judge*, and JACQUELINE WRIGHT BONILLA, *Deputy Chief Administrative Patent Judge.*

PER CURIAM.

IPR2020-00126 (Patent 8,043,032 B2)
IPR2020-00128 (Patent RE45,380 E)
IPR2020-00132 (Patent RE45,760 E)
IPR2020-00134 (Patent RE45,760 E)
IPR2020-00135 (Patent RE45,776 E)
IPR2020-00137 (Patent RE47,379 E)

ORDER

The Office has received a request for Precedential Opinion Panel (POP) review of an issue raised in each of these cases. *See, e.g.*, IPR2021-00126, Ex. 3100. The request was referred to the POP panel referenced above.

Upon consideration of the request, it is ORDERED that:

The request for POP review in each case is denied; and

FURTHER ORDERED that the original panel maintains authority over all matters, including considering the submitted rehearing request.

IPR2020-00126 (Patent 8,043,032 B2)
IPR2020-00128 (Patent RE45,380 E)
IPR2020-00132 (Patent RE45,760 E)
IPR2020-00134 (Patent RE45,760 E)
IPR2020-00135 (Patent RE45,776 E)
IPR2020-00137 (Patent RE47,379 E)

For PETITIONER:

Cyrus Morton
Sharon Roberg-Perez
Christopher Pinahs
William E. Manske
Emily J. Tremblay
ROBINS KAPLAN LLP
cmorton@robinskaplan.com
sroberg-perez@robinskaplan.com
cpinahs@robinskaplan.com
wmanske@robinskaplan.com
etremblay@robinskaplan.com

For PATENT OWNER:

Derek Vandenburgh
Dennis Bremer
CARLSON, CASPERS, VANDENBURGH & LINDQUIST, P.A.
dvandenburgh@carlsoncaspers.com
dbremer@carlsoncaspers.com