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

Paper 7
Entered: March 8, 2019

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

CARDIOVASCULAR SYSTEMS, INC.,
Petitioner,

v.

CARDIO FLOW, INC.,
Patent Owner.

Case IPR2018-01658
Patent 9,089,362 B2

Before BARRY L. GROSSMAN, JAMES A. TARTAL, and JAMES J. MAYBERRY, *Administrative Patent Judges*.

GROSSMAN, *Administrative Patent Judge*.

DECISION
Denying Institution of *Inter Partes* Review
35 U.S.C. § 314; 37 C.F.R. § 42.4(a)

I. INTRODUCTION

Cardiovascular Systems, Inc. ("Petitioner") filed a Petition, Paper 1 ("Petition" or "Pet."), to institute an *inter partes* review of claims 1–11 (the "challenged claims") of U.S. Patent No. 9,089,362 (the "'362 patent"). 35 U.S.C. § 311. Cardio Flow, Inc. ("Patent Owner") timely filed a Preliminary Response. Paper 6 ("Prelim. Resp.").

We have jurisdiction under 35 U.S.C. § 314, which authorizes the Director of the U.S. Patent and Trademark Office to decide whether to institute an *inter partes* review to reconsider the patentability of claims in existing patents. The Board determines whether to institute a trial on behalf of the Director. 37 C.F.R. § 42.4(a).

Under 35 U.S.C. § 314, an *inter partes* review may not be instituted "unless . . . there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." 35 U.S.C. § 314(a). Upon considering the Petition, Preliminary Response, and the evidence of record, we determine that the Petition has not shown a reasonable likelihood that it would prevail with respect to at least one of the challenged claims. Accordingly, we deny the Petition and do not institute an *inter partes* review.

A. Related Proceedings

The parties state that there are no related proceedings. Pet. 1; Paper 4.

We are aware that Petitioner filed a petition in IPR2018-01549 challenging the patentability of U.S. Patent No. 9,788,853, also owned by Patent Owner. *See Cardiovascular Systems, Inc. v. Cardio Flow, Inc.*, IPR2018-01549, Paper 11 (PTAB February 26, 2019) (denying institution of

an *inter partes* review) ("the '1549 IPR"). In the course of the proceedings in the '1549 IPR, Petitioner brought to our attention the pending case of *Cardiovascular Systems, Inc. v. Cardio Flow, Inc.*, Case No. 0:18-cv-1253-SRNKMM (D. Minn.), in which Petitioner "seeks a judgment declaring CSI [Petitioner in the proceeding before us] the owner and assignee of the 'Counterweight Patents.'" Ex. 3001 ¶ 34. The '362 patent is included in the defined "Counterweight Patents." *Id.* ¶ 20. Thus, Petitioner is seeking a declaration that it is the owner of the '362 patent.

At the time the Petition in the case before us was filed, however, it is clear that Petitioner was *not* the owner and assignee of record of the '362 patent. Ex. 3002. A person who is not the owner of a patent may file with the Office a petition to institute an *inter partes* review of the patent. 35 U.S.C. § 311(a); *see also First Data Corp. v. Inselberg*, 870 F.3d 1367, 1375 (Fed. Cir. 2017) (holding that a declaratory judgment plaintiff did not have standing where jurisdiction relied "on the 'contingent future event[ ]' of recovering title to the patents by having a court invalidate the assignment agreement"). In the case before us, Petitioner was eligible to file the Petition because its claim of ownership is merely contingent on future events that may never occur.

B. Asserted Grounds of Unpatentability

Petitioner challenges claims 1–11 under 35 U.S.C. § 103[1] on the following grounds:

[1] The Leahy-Smith America Invents Act ("AIA"), Pub. L. No. 112-29, 125 Stat. 284, 296–07 (2011), took effect on September 16, 2012. The changes to 35 U.S.C. §§ 102 and 103 in the AIA do not apply to any application filed

References	Claims
Carbo[2] in combination with Kallok[3] *or* Prudnikov[4]	1–4, 7–11
Carbo, Kallok *or* Prudnikov, and Rydell[5]	5
Carbo, Kallok *or* Prudnikov, and Maschke[6]	6
Shturman '458 in combination with Kallok *or* Prudnikov	1–4, 7–11
Shturman '458, Kallok *or* Prudnikov, and Rydell	5
Shturman '458, Kallok *or* Prudnikov, and Maschke	6

Pet. 5. Petitioner also relies on the Declaration testimony of Morten Olgaard Jensen, Ph.D., Dr. Med. *See* Ex. 1002 ¶ 9. Because each of the six grounds listed by Petitioner relies on either Kallok *or* Prudnikov as the basis of unpatentability, Petitioner asserts twelve separate and distinct grounds of unpatentability.

II. THE '362 PATENT

The '362 patent discloses a rotational atherectomy, or angioplasty, device and a method of using the device. Ex. 1001, Abstract, 1:25–28. These devices rotate an abrasive element to remove blockages within a

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before March 16, 2013. Because the application for the patent at issue in this proceeding has a claimed effective filing date of April 6, 2010, we refer to the pre-AIA version of the statute.

[2] U.S. Patent No. 5,250,060, issued October 5, 1993 ("Carbo") (Ex. 1004).

[3] U.S. Patent No. 8,177,801, filed March 17, 2009 ("Kallok") (Ex. 1003).

[4] U.S. Patent No. 8,348,965, filed October 23, 2007 ("Prudnikov") (Ex. 1009).

[5] U.S. Patent No. 4,784,636, issued November 15, 1988 ("Rydell") (Ex. 1005).

[6] U.S. Publ. No. 2007/0066888, March 22, 2007 ("Maschke") (Ex. 1006).

blood vessel, such as a coronary artery. *Id.* at 1:35–36. The general structure and function of rotational atherectomy devices are well-known, as acknowledged and summarized in the '362 patent. *Id.* at 1:36–2:56.

Figure 2 from the '362 patent is reproduced below.

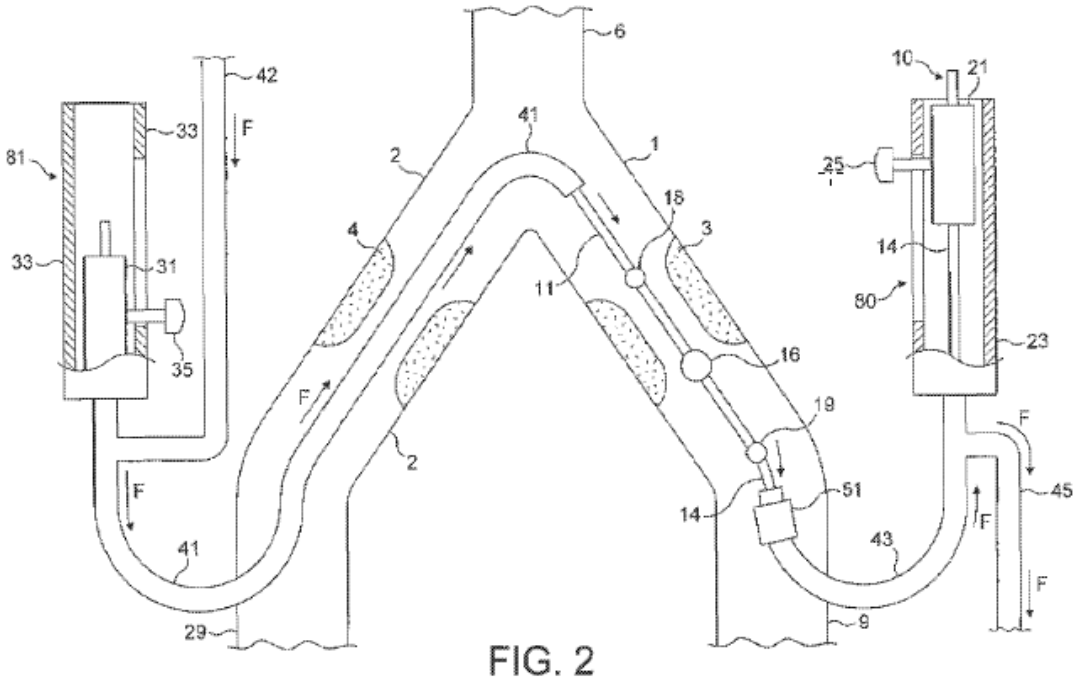


FIG. 2

Figure 2 is a side sectional view of the disclosed rotational atherectomy device inserted into iliac arteries. Ex. 1001, 6:43–63.

As shown in Figures 1 and 2, and as described in the Specification (*see id.* at 7:55–8:1), blockage, or stenotic lesion, 3 to be treated is shown in the right iliac artery. Drive shaft 10 of an atherectomy device extends through the iliac arteries. Eccentric abrasive element 16 is mounted to drive shaft 10 between, and spaced away from, counterweights 18, 19. *Id.* at 7:58–62. Counterweights 18, 19 are mounted to elongated portions 11, 14 of the drive shaft. *Id.* Motor, or prime mover, 21 rotates drive shaft 10. *Id.* at 8:37–38. The rotational atherectomy device is inserted through the

iliac arteries until abrasive element 16 is adjacent the blockage to be removed. As the drive shaft rotates, centrifugal forces allow abrasive element 16 to move outwardly and open the blocked artery to a diameter substantially larger than the maximum diameter of the abrasive element. *Id.* at 1:66–2:3.

As shown in Figure 2, sheaths 41 and 43 surround elongated portions 11 and 14, respectively, of drive shaft 10. *Id.* at 8:21–27. Sheaths 41 and 43 are spaced apart and do not surround abrasive element 16 or counterweights 18 and 19. *Id.* at 8:25–33. In use, positioning abrasive element 16 adjacent blockage 3 in Figure 2, for example, allows abrasive element 16 to engage blockage 3, and allows abrasive element 16 to be moved back and forth along the blockage. *Id.* at 8:29–33, 3:28–24; *but see, id*, 3:19–22 (acknowledging that an abrasive element which is moved back and forth across a blockage by alternately pulling and pushing on the elongated drive shaft is well-known in prior art devices).

A. Illustrative Claim

Claim 1 is the sole independent claim. It is reproduced below.[7]

> [1a]. A method of treating an iliac artery of a patient, comprising:
>
> positioning an elongate catheter of a system for performing rotational atherectomy in a blood vessel of a patient, the elongate catheter defining a first lumen and a second lumen,

[7] In the Petition, Petitioner added letters to identify clauses in claim 1. *See, e.g.*, Pet. 19 (labelling a portion of claim 1 as clause "[1a]"). For ease of discussion and analysis of the Petition, we also have added to claim 1 the same lettering scheme for clauses used by Petitioner.

[1b] the elongate catheter including an inflatable balloon member attached to and surrounding an outer diameter of an end portion of the elongate catheter, the balloon member in fluid communication with the first lumen,

[1c] the balloon member configured to contact a blood vessel wall when the balloon member is in an inflated configuration;

[1d] rotating a rotational atherectomy device of the system while the rotational atherectomy device is at least partially disposed within the second lumen of the elongate catheter,

[1e] the rotational atherectomy device comprising an elongate flexible drive shaft defining a central lumen and a longitudinal axis, the drive shaft configured for rotation about the longitudinal axis,

[1f] an eccentric abrasive element that is mounted to the drive shaft such that a center of mass of the abrasive element is offset from the longitudinal axis of the drive shaft, and

[1g] a pair of stability elements including a first stability element that is fixed to the drive shaft at a location proximal to the abrasive element, and a second stability element that is fixed to the drive shaft at a location distal to the abrasive element,

[1h] wherein a distal portion of the drive shaft extends distally of a distal end of the second stability element,

[1i] wherein said rotating the rotational atherectomy device is caused by a prime mover for rotating the drive shaft; and

[1j] repeatedly moving the rotating drive shaft and its abrasive element back and forth across a stenotic lesion to remove stenotic lesion material from the blood vessel, wherein the abrasive element abrades the stenotic lesion material from the blood vessel.

Ex. 1001, 10:48–11:16.

B. Claim Construction

The Petition was filed on September 5, 2018. Paper 3. This was before the Patent and Trademark Office implemented a new rule on claim construction adopting the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. 282(b). *See* Changes to the Claim Construction Standard for Interpreting Claims in Trial Proceedings Before the Patent Trial and Appeal Board, 83 Fed. Reg. 51,340 (Nov. 13, 2018) (to be codified at 37 C.F.R. pt. 42). This rule was effective on November 13, 2018, and applies to all petitions filed on or after the effective date. *Id.* This claim construction standard is generally referred to as the *Phillips* standard. *See Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (en banc). Because the Petition before us was filed before the effective date of the new rule, our old rule, using a "broadest reasonable" claim construction, applies to this case. Both parties agree. Pet. 9; Prelim. Resp. 12–13.

Petitioner proposes specific constructions for the terms "abrasive elements," "stability element, "elongate catheter," and "prime mover." Pet. 10–11. Patent Owner asserts that "there is no need to provide a formal construction of these terms at this time." Prelim. Resp. 13. We agree with Patent Owner.

"[W]e need only construe terms 'that are in controversy, and only to the extent necessary to resolve the controversy.'" *Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co. Ltd.*, 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)).

We determine that an explicit construction of the claims is not necessary for the purposes of determining whether there is a reasonable likelihood that the Petitioner would prevail with respect to at least one of the claims challenged in the Petition.

C. Level of Ordinary Skill

The level of skill in the art is "a prism or lens" through which we view the prior art and the claimed invention. *Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001) ("the level of skill in the art is a prism or lens through which a judge, jury, or the Board views the prior art and the claimed invention").

Factors pertinent to a determination of the level of ordinary skill in the art include: (1) educational level of the inventor; (2) type of problems encountered in the art: (3) prior art solutions to those problems; (4) rapidity with which innovations are made; (5) sophistication of the technology, and (6) educational level of workers active in the field. *Environmental Designs, Ltd. v. Union Oil Co.*, 713 F.2d 693, 696–697 (Fed. Cir. 1983) (citing *Orthopedic Equip. Co. v. All Orthopedic Appliances, Inc.*, 707 F.2d 1376, 1381–82 (Fed. Cir. 1983)). Not all such factors may be present in every case, and one or more of these or other factors may predominate in a particular case. *Id.* Moreover, these factors are not exhaustive but are merely a guide to determining the level of ordinary skill in the art. *Daiichi Sankyo Co. Ltd, Inc. v. Apotex, Inc*., 501 F.3d 1254, 1256 (Fed. Cir. 2007).

In determining a level of ordinary skill, we also may look to the prior art, which may reflect an appropriate skill level. *Okajima*, 261 F.3d at 1355.

Additionally, the Supreme Court informs us that "[a] person of ordinary skill is also a person of ordinary creativity, not an automaton." *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398, 421 (2007).

Petitioner asserts that a person of ordinary skill in the art at the relevant time

> would have had a range of knowledge roughly equivalent to the knowledge and/or training of a person holding the degree of Bachelor of Science in Mechanical Engineering, Biomedical Engineering or equivalent, and at least two years of practical experience (or comparable and/or equivalent education or training), including familiarity with rotational atherectomy.

Pet. 9 (citing Ex. 1002, ¶¶ 19–23).[8]

Patent Owner refers repeatedly in its Preliminary Response to a person of "ordinary skill in the art" (e.g., Prelim. Resp. 12–13) but does not provide any argument or evidence defining its position on what is the relevant skill level.

We determine that the Petitioner's proposed level is reasonable and supported by a credible analysis by Dr. Jensen. *See* Ex. 1002 ¶¶ 16–19. Accordingly, we adopt Petitioner's proposed level of ordinary skill in this Decision.

[8] Petitioner's citation to the Declaration testimony of Dr. Jensen (Ex. 1002) cites to the incorrect paragraphs of the Declaration. Dr. Jensen's testimony concerning the level of ordinary skill is at paragraphs 16–19, which we have considered.

III. ASSERTED UNPATENTABILITY

A. Legal Principles

Section 103(a) forbids issuance of a patent when "the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." *KSR*, 550 U.S. at 406. The question of obviousness is resolved on the basis of underlying factual determinations, including: (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of ordinary skill in the art; and (4) when available, evidence such as commercial success, long felt but unsolved needs, and failure of others. *Graham v. John Deere Co*., 383 U.S. 1, 17–18 (1966); *see KSR*, 550 U.S. at 407 ("While the sequence of these questions might be reordered in any particular case, the [Graham] factors continue to define the inquiry that controls."). The Court in *Graham* explained that these factual inquiries promote "uniformity and definiteness," for "[w]hat is obvious is not a question upon which there is likely to be uniformity of thought in every given factual context." 383 U.S. at 18.

The Supreme Court made clear that we apply "an expansive and flexible approach" to the question of obviousness. *KSR*, 550 U.S. at 415. Whether a patent claiming the combination of prior art elements would have been obvious is determined by whether the improvement is more than the predictable use of prior art elements according to their established functions. *Id*. at 417. To reach this conclusion, however, it is not enough to show merely that the prior art includes separate references covering each separate

limitation in a challenged claim. *Unigene Labs., Inc. v. Apotex, Inc.*, 655 F.3d 1352, 1360 (Fed. Cir. 2011). Rather, obviousness additionally requires that a person of ordinary skill at the time of the invention "would have selected and combined those prior art elements in the normal course of research and development to yield the claimed invention." *Id.*; *see also Orexo AB v. Actavis Elizabeth LLC*, 903 F.3d 1265, 1273 (Fed. Cir. 2018) ("The question is not whether the various references separately taught components of the '330 Patent formulation, but whether the prior art suggested the selection and combination achieved by the '330 inventors.").

In determining whether there would have been a motivation to combine prior art references to arrive at the claimed invention, it is insufficient to simply conclude the combination would have been obvious without identifying any reason *why* a person of skill in the art would have made the combination. *Metalcraft of Mayville, Inc. v. The Toro Co.*, 848 F.3d 1358, 1366 (Fed. Cir. 2017).

"A reference must be considered for everything it teaches by way of technology and is not limited to the particular invention it is describing and attempting to protect." *EWP Corp. v. Reliance Universal Inc.*, 755 F.2d 898, 907 (Fed. Cir. 1985).

As a factfinder, we also must be aware "of the distortion caused by hindsight bias and must be cautious of arguments reliant upon *ex post* reasoning." *KSR*, 550 U.S. at 421. This does not deny us, however, "recourse to common sense" or to that which the prior art teaches. *Id.*

"In an [*inter partes* review], the petitioner has the burden from the onset to show with particularity why the patent it challenges is unpatentable." *Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1363 (Fed.

Cir. 2016). The burden of persuasion never shifts to Patent Owner. *Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015).

Against this general background, we consider the references, other evidence, and arguments on which the parties rely.

B. Claims 1–4, 7–11 Based on Carbo in combination with Kallok or Prudnikov

Petitioner asserts that claims 1–4 and 7–11 would have been obvious under 35 U.S.C. § 103 based on Carbo in combination with Kallok or Prudnikov. *E.g.*, Pet. 19.

Patent Owner argues that the references fail to disclose "certain required structures[9] recited in claim 1," and also fails to provide "articulated reasons" as to why a person of ordinary skill would have been motivated to combine the references as proposed by Petitioner. Prelim. Resp. 13–14 (citing Ex. 2001 ¶ 18[10]). We address these arguments below.

Patent Owner also argues that the Board should exercise its discretion under 35 U.S.C. § 314(a) to deny the Petition because "the petition is rooted in harassment" (*id.* 5 (heading III)) because "[t]here is no case or controversy here" (*id.*). There is no "case or controversy" requirement for filing a petition for an *inter partes* review. Any "person who is not the owner of a patent may file with the Office a petition to institute an inter

[9] The challenged claims each recite a method. The issues raised by Petitioner and Patent Owner, however, relate to structural limitations in the method claims.

[10] Exhibit 2001 is the Declaration testimony of Kristina Rouw, Ph.D. Dr. Rouw has been retained as an expert witness on behalf of Patent Owner. Ex. 2001 ¶ 1.

partes review of the patent." 35 U.S.C. § 311(a). Patent Owner speculates about Petitioner's motives, but cites no persuasive evidence to support Patent Owner's speculation. The fact that Petitioner did not accept Patent Owner's offer of a covenant not to sue (*see* Prelim. Resp. 5 (citing Exs. 2003, 2004)) is not persuasive of the asserted harassment. Thus, we decline the invitation to exercise our discretion under § 314(a).

Additionally, Patent Owner argues that the Petition fails to identify "with particularity" the asserted grounds. *Id.* 7–12. We address this issue below.

1. Independent Claim 1

Petitioner provides a clause-by-clause analysis of the sole independent claim, claim 1. Pet. 19–26. We identify Petitioner's argument and evidence on several of the clauses [a]–[j] and provide our analysis of claim 1. We follow this format because Petitioner has argued whether the elements and limitations of the various clauses would have been obvious (e.g., Pet. 26 ("the *elements* of claim 1 are obvious over Carbo in view of Kallok, or alternatively Prudnikov") (emphasis added)), but does not address the ultimate determination of whether the claimed invention as a whole would have been obvious.

a) Clause [1a]

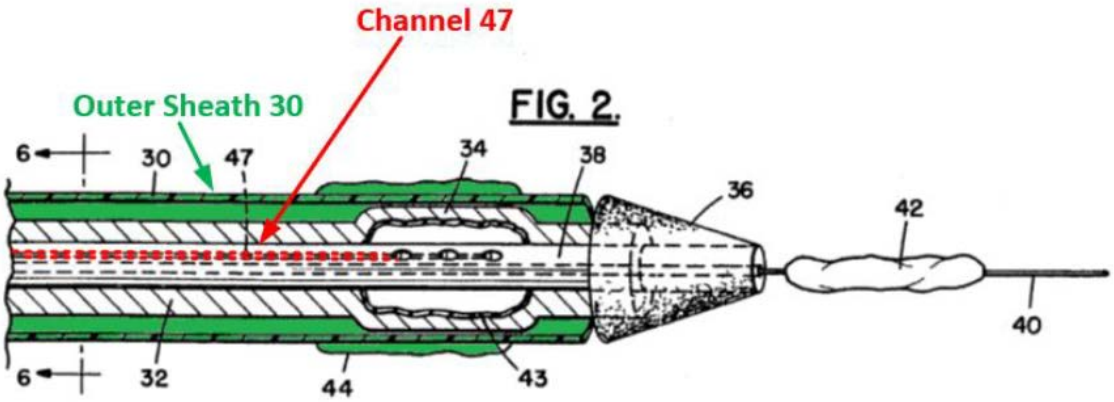
Clause [1a] recites that the claimed invention is a "method of treating an iliac artery of a patient" comprising an "elongate catheter defining a first lumen and a second lumen." Ex. 1001, 10:48–53. Petitioner relies solely on Carbo for disclosing the limitations in clause [1a]. Pet. 19.

The '362 patent refers to two lumens of the disclosed invention in its written description. It refers to a "drainage lumen" (Ex. 1001, 5:67) and a

"balloon inflation lumen" (*id.* at 6:4). The '362 patent does not refer to these two lumens in the detailed description of the disclosed invention.

Petitioner asserts that the Carbo catheter "defines a first lumen (47) and a second lumen into which a rotational atherectomy device (drive cable 32) is inserted." Pet. 19 (citing Ex. 1004, Figs. 1–9, 2:9–58, 3:60–5:7; Ex. 1002, ¶ 42–43). Petitioner identifies with particularity the structure that is the first lumen, or inside surface of a tubular structure, such as an artery, but does not identify with particularity what is the corresponding element in Carbo for the "second lumen."

An annotated Figure 2 from Carbo is reproduced below.



Annotated Figure 2 from Carbo is a cross section
of the leading end of the catheter with the balloons deflated.
Ex. 1004, 3:1–2 (annotation from Ex. 2001 ¶ 21)

Carbo discloses an elongated catheter mechanism adapted to be inserted into a blood vessel to the location of plaque deposit to be removed. Ex. 1004, 2:39–58. The catheter includes a plurality of concentric elongated members that provide channels for fluid pressures to be applied to inflatable elements located at the distant or leading end of the catheter. *Id.* One of these inflatable elements is distal balloon 42 located just beyond the vessel section to be cleared. *Id.* The channel or ports allowing distal balloon 42 to

be inflated and deflated are not shown in Carbo. *Id.* at 4:12–16. Another inflatable element is proximal balloon 44, located just before the blood vessel section containing the plaque, is inflated/deflated through channel 46, which permits fluid pressure to selectively expand and collapse proximal balloon 44. *Id.* at 4:17–21. Channel 47 provides fluid under pressure to milling balloon 43 that rotates to cut away or mill the plaque and which may be gradually expanded. *Id.* at 4:21–36. Infusion channel 50 is provided to withdraw the plaque particles out of the blood vessel as they are being cut or milled away. *Id.* at 4:37–40.

Petitioner fails to identify with specificity the structure in Carbo that corresponds to the claimed "second lumen" in claim 1 of the '362 patent.

b) Clause [1b]

Clause [1b] recites "the elongate catheter including an inflatable balloon member attached to and surrounding an outer diameter of an end portion of the elongate catheter, the balloon member in fluid communication with the first lumen." Ex. 1001, 10:53–57. Petitioner asserts that proximal balloon 44 in Carbo corresponds to the claimed balloon and that balloon 44 in Carbo is in fluid communication with first lumen 47 in Carbo. Pet. 19 (citing Ex. 1004, Figs. 2–3, 4:17–26; Ex. 1002 ¶ 44). Petitioner mischaracterizes the disclosure in Carbo.

Carbo discloses that proximal balloon 44 is inflated/deflated through channel 46, which permits fluid pressure to selectively expand and collapse proximal balloon 44. Ex. 1004, 4:17–21. Channel 47 of Carbo, on which Petitioner relies to meet the disclosure of clause [1b], provides fluid under pressure to milling balloon 43, not proximal balloon 44. *Id.* at 4:21–28.

Thus, the Petition fails to identify disclosure in Carbo that meets the limitations in clause [1b].

Petitioner relies solely on Carbo for the elements in clauses [1a] and [1b]. The failure to identify structure in the cited references that meet these limitations alone is sufficient to deny the Petition based on the six grounds that rely on Carbo. There is no reasonable likelihood that Petitioner will prevail on these grounds.

Petitioner also fails to discuss Prudnikov as an alternative reference to Kallok for the limitations in clause [1j]. *See* Pet. 26. Thus, Petitioner cannot reasonably likely prevail on the ground based on Prudnikov as an alternative reference.

2. Invention as a Whole

For all of the identified clauses, Petitioner identifies structure in the references that Petitioner asserts is disclosed in the references. Petitioner then concludes that "the *elements* of claim 1 *are obvious* over Carbo in view of Kallok, or alternatively Prudnikov." Pet. 26 (emphasis added). In determining the differences between the prior art and the claims, however, the question under 35 U.S.C. § 103 is not whether the differences themselves would have been obvious, but whether the claimed invention as a whole would have been obvious. *Litton Indus. Prods., Inc. v. Solid State Sys. Corp*., 755 F. 2d 158, 164 (Fed. Cir. 1985) ("It is elementary that the claimed invention must be considered as a whole in deciding the question of obviousness." (citation omitted)); *see also Stratoflex, Inc. v. Aeroquip Corp*., 713 F.2d 1530, 1537 (Fed. Cir. 1983) ("[T]he question under 35 U.S.C. § 103 is not whether the differences themselves would have been obvious. Consideration of differences, like each of the findings set forth in *Graham*,

is but an aid in reaching the ultimate determination of whether the claimed invention as a whole would have been obvious." (citation omitted)). Petitioner never addresses whether the invention as a whole would have been obvious.

A patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art. *KSR*, 550 U.S. at 418. "[I]nventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known." *Id.* at 418–419. Petitioner's argument shows that the cited references used for performing rotational atherectomy have elements that are the same as, or similar to, the claimed elements and limitations. Petitioner's analysis, however, fails to address the asserted obviousness of the invention as a whole.

3. Motivation to Combine

We also find that Petitioner fails to provide a persuasive motivation to combine the asserted references. Establishing that an invention would have been obvious also requires "a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does." *KSR*, 550 U.S. at 418. "[T]here must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *Id.*; *Unigene Labs*, 655 F.3d at 1360.

Throughout the assertion of obviousness based on the grounds relying on Carbo as a lead reference, Petitioner asserts that a "POSITA could modify" the references (Pet. 22); that modifications "are well within the knowledge and skill of the POSITA (*id.*); that a "POSITA would recognize

that extending the drive shaft distally from a distal end of the second (distal-most) stability element may be advantageous" (*id.* 25).

Petitioner's statements do not address the requirements of the statute. The applicable statute requires evidence that "the differences between the subject matter sought to be patented and the prior art are such that *the subject matter as a whole would have been obvious* at the time the invention was made to a person having ordinary skill" in the relevant technology." 35 U.S.C. § 103(a) (emphasis added). An understanding that something could be modified does not establish that it would have been obvious to do so at the time the '362 invention was made. *Belden Inc. v. Berk-Tek LLC*, 805 F.3d 1064, 1073 (Fed. Cir. 2015) ("obviousness concerns whether a skilled artisan not only *could have made* but *would have been motivated to make* the combinations or modifications of prior art to arrive at the claimed invention."). This is not an artificial distinction; it is a substantive difference. Petitioner fails to provide persuasive evidence that the challenged claims are unpatentable under the statutory grounds asserted. 37 C.F.R. § 42.104(b)(4).

Accordingly, we determine Petitioner has not provided a rationale based on persuasive evidence or argument for why a person of ordinary skill would have chosen certain features from the cited references, omitted other features, and combined the selected features to yield the invention in the challenged claims. *Metalcraft*, 848 F.3d at 1366; *ActiveVideo Networks, Inc. v. Verizon Commc'ns, Inc.*, 694 F.3d 1312, 1327–1328 (Fed. Cir. 2012).

4. Dependent claims 2–11

Petitioner's arguments and evidence presented against dependent claims 2–11, each of which depends directly or indirectly from claim 1, do not cure the deficiencies identified with the asserted grounds against claim 1.

C. Claims 1–4, 7–11 Based on Shturman '458 in combination with Kallok or Prudnikov

This group of grounds relies on Shturman '458 rather than Carbo as a lead reference. Patent Owner's arguments focus on clause [1d], which Patent Owner asserts is dispositive of all asserted grounds based on Shturman '458. Prelim. Resp. 47 ("Because this fatal flaw in the Petition's analysis of [1d] taints all permutations of Grounds 4-6, institution of these Grounds should be denied."). We agree with Patent Owner, as explained below.

Clause [1d] recites the step of "rotating a rotational atherectomy device of the system while the rotational atherectomy device is at least partially disposed within the second lumen of the elongate catheter." Ex. 1001, 10:60–63.

Petitioner asserts that Shturman '458 teaches rotating a rotational atherectomy device (drive shaft (5)) while the rotational atherectomy device (5) is at least partially disposed within the second lumen of the elongate catheter (12). Pet. 38 (citing Ex. 1010, Fig. 7, 53:5–31; Ex. 1002 ¶ 107. Dr. Jensen's testimony repeats Petitioner's argument without any facts, data, or additional analysis. Ex. 1002 ¶ 107. As such it is entitled to little probative weight. 37 C.F.R. § 65(a). The disclosure from Shturman '458 on which Petitioner relies relates to Figure 7.

Figure 7 from Shturman ’458, as annotated by Patent Owner, is reproduced below.

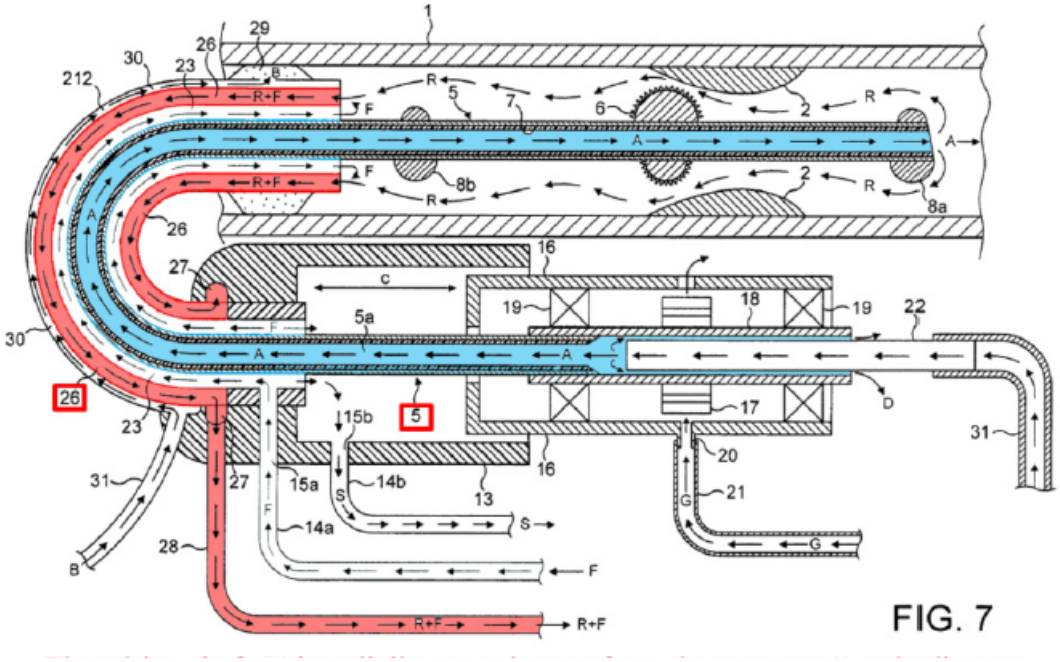


Fig. 7 is a side sectional view of Shturmna ’458, annotated by Patent Owner, of a rotational atherectomy device, inserted in a blood vessel, with an abrasive element mounted on the drive shaft and an inflatable element on the distal end of the drive shaft. *See* Prelim. Resp. 44.

Petitioner asserts the first lumen in Shturman ’458 is element 30 and the second lumen is element 26. Pet. 37. With respect to clause [1d], Petitioner asserts atherectomy device drive shaft 5 is at least partially disposed within second lumen 26. *Id.* 38.

Patent Owner asserts that drive shaft 5 is radially spaced away from, *not* disposed within, lumen 26.

Figure 7 in Shturman ’458 is identical to the embodiment described in Figures 6A and 6B except that the outer surface of sheath 212 is provided with inflatable element 29 such as a cuff or balloon situated close to its distal end. Ex. 1010, 53:6–8.

As disclosed in Shturman '458 and shown in Figure 7 of Shturman '458, sheath 212 is formed with at least one discrete lumen 26 extending through the sheath 212 which is separate from the annular channel 23 defined between drive shaft 5 and the wall of the sheath 212. Ex. 1010, 51:20–23, 53:5–8. As shown in Figure 7, lumen 26 is separate from channel 23. *See* Ex. 2001 ¶ 37. As shown in Figure 7, drive shaft 5 is not within the second lumen 26; it is outside of lumen 26.

Petitioner relies solely on Shturman '458 for the elements in clause [1d]. The failure to identify structure in the cited references that meet this limitation alone is sufficient to deny the Petition based on the six grounds that rely on Shturman '458. Petitioner has shown no reasonable likelihood of prevailing on these grounds.

1. Dependent Claims 2-11

Petitioner's arguments and evidence presented against dependent claims 2–11, each of which depends directly or indirectly from claim 1, do not cure the deficiencies identified with the asserted grounds against claim 1.

D. Conclusion

On this record, and based on the evidence and arguments of the parties, we determine that Petitioner has not met its burden to show a reasonable likelihood that it will prevail as to at least one challenged claim.

Accordingly, we do not institute an *inter partes* review.

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that, pursuant to 35 U.S.C. § 314, the Petition is denied and no *inter partes* review is instituted.

PETITIONER:

Anthony Son
ason@btlaw.com

Jeffrey Stone
jstone@btlaw.com

PATENT OWNER:

Michael Hawkins
hawkins@fr.com

Craig Deutsch
deutsch@fr.com

Grace Kim
gkim@fr.com

Mike Kane
kane@fr.com