

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Abiomed, Inc., Abiomed R&D, Inc., and Abiomed Europe GmbH
Petitioners

v.

Maquet Cardiovascular, LLC
Patent Owner

Case IPR2017-02151
U.S. Patent No. 9,327,068

PATENT OWNER'S PRELIMINARY RESPONSE

TABLE OF CONTENTS

	<u>Page</u>
TABLE OF AUTHORITIES	iv
LIST OF EXHIBITS	vi
I. INTRODUCTION	1
A. The <i>General Plastic</i> Factors Demonstrate That The Board Should Deny Institution	4
1. Factor 1: whether the same petitioner previously filed a petition directed to the same claims of the same patent	5
2. Factor 2: whether at the time of filing the first petition petitioner knew or should have known of the prior art asserted in the second petition	5
3. Factor 3: whether at the time of filing the second petition petitioner had the patent owner’s preliminary response to the first petition or the Board’s institution decision on the first petition	7
4. Factor 4: the length of time elapsed between when petitioner learned of the prior art asserted in the second petition and the filing of the second petition	9
5. Factor 5: whether petitioner provides adequate explanation for the time elapsed between the filings of multiple petitions directed to the same claims of the same patent	9
6. Factor 6: the finite resources of the Board	12
7. Factor 7: the requirement for a final determination within 1 year of institution	14
B. The Board Should Exercise Its Discretion under 35 U.S.C. § 325(d)	14

II.	THE BOARD SHOULD NOT INSTITUTE	16
A.	Petitioners Fail to Carry Their Burden.....	17
1.	Aboul-Hosn in view of Sammler Fails to Render Obvious Claims 10 and 13-15 (Ground 1)	18
a.	Aboul-Hosn fails to teach or suggest the claimed “intravascular blood pump system”	18
i.	The Petition Improperly Relies on the Extravascular Reverse Flow Pump of Aboul-Hosn	22
ii.	The Figures Confirm That the Reverse Flow Pump Remains Outside the Vasculature	23
iii.	Figure 12 Illustrates the Reverse Flow Pump Assembly is Positioned Within the Conduit	29
iv.	Reverse Flow Pumps Are Not Suited for Intravascular Use.....	32
v.	The Petition Mischaracterizes the Stabilization System—a Separately Disclosed Embodiment	36
vi.	The Petition Improperly Relies on the Rotor Design of the Reverse Flow Pump of Aboul- Hosn to Teach the Claimed “Rotor”	36
vii.	The Petition Improperly Relies on Figure 23 of Aboul-Hosn to Teach an “Intravascular Blood Pump Coupled to a Catheter on a Proximal End and a Cannula on a Distal End”	39
b.	Aboul-Hosn fails to teach or suggest the claimed “a first set and a second set of apertures”	43
c.	Aboul-Hosn Does Not Disclose the Guide Mechanism of the Challenged Claims.....	47

i.	The Aboul-Hosn intravascular pump does not include the guide mechanism as claimed.....	47
ii.	The central passage disclosed in Aboul-Hosn is distinct from the claimed guide mechanism.....	51
d.	Aboul-Hosn and Sammler Fail to Disclose a “Blood Pressure Detection Mechanism”	52
i.	A POSITA Would Not Be Motivated to Combine Aboul-Hosn and Sammler	53
ii.	Neither Aboul-Hosn nor Sammler Measures Blood Pressure “Proximate the Intravascular Blood Pump”	55
e.	Petitioners’ Ground 1 Fails to Disclose the Claimed Method	60
f.	Ground 1 Fails to Invalidate Dependent Claims 13-15	62
2.	Aboul-Hosn Fails to Anticipate Claim 20 (Ground 2)	62
III.	PERSON OF ORDINARY SKILL	63
IV.	CONCLUSION.....	65
V.	CERTIFICATE OF WORD COUNT	66
VI.	CERTIFICATE OF SERVICE	67

TABLE OF AUTHORITIES

	Page(s)
CASES	
<i>Alarm.com Inc. v. Vivint, Inc.</i> , IPR2016-01091 (PTAB Nov. 23, 2016).....	12
<i>Apotex Inc. v. Wyeth LLC</i> , IPR2015-00873 (PTAB Sept. 16, 2015).....	7
<i>Apple Inc. v. Immersion Corp.</i> , IPR2017-01371 (PTAB Nov. 21, 2017).....	6
<i>Conopco, Inc. dba Unilever v. The Procter & Gamble Co.</i> , IPR2014-00506 (PTAB Dec. 10, 2014)	15
<i>Gen. Plastic Indus. Co., Ltd. v. Canon Kabushiki Kaisha</i> , IPR2016-01357 (PTAB Sept. 6, 2017).....	<i>passim</i>
<i>Hengdian Grp. DMEGC Magnetics Co., Ltd. v. Hitachi Metals, Ltd.</i> , IPR2017-01313 (PTAB Nov. 6, 2017).....	18
<i>Hockerson-Halberstadt, Inc. v. Avia Grp. Int’l</i> , 222 F.3d 951 (Fed. Cir. 2000)	30
<i>Integrated Global Concepts, Inc. v. Advanced Messaging Techs., Inc.</i> , IPR2014-01027 (PTAB Dec. 22, 2014)	16
<i>Personal Web Techs., LLC v. Apple, Inc.</i> , 848 F.3d 987 (Fed. Cir. 2017)	35, 55
<i>Prism Pharma Co., Ltd v. Choongwae Pharma Corp.</i> , IPR2014-00315 (PTAB Jul. 8, 2014)	16
<i>R.J. Reynolds Vapor Co. v. Fontem Holdings I B.V.</i> , IPR2017-01319 (PTAB Nov. 8, 2017).....	6
<i>Samsung Elecs. Co. Ltd. v. Rembrandt Wireless Techs., LP</i> , IPR2015-00555 (PTAB June 19, 2015)	7, 14
<i>Standard Oil Co. v. Am. Cyanamid Co.</i> , 774 F.2d 448 (Fed. Cir. 1985)	63

<i>Travelocity.com LP v. Cronos Techs., LLC</i> , CBM2015-00047 (PTAB June 15, 2015)	5, 15
-----------------------------------------------------------------------------------------------	-------

<i>Verdegaal Bros. v. Union Oil Co. of Cal.</i> , 814 F.2d 628 (Fed. Cir. 1987)	62
------------------------------------------------------------------------------------------	----

STATUTES

35 U.S.C. § 102(b)	17
--------------------------	----

35 U.S.C. § 103(a)	17
--------------------------	----

35 U.S.C. § 314(a)	<i>passim</i>
--------------------------	---------------

35 U.S.C. § 325(d)	4, 7, 15, 16
--------------------------	--------------

RULES

37 C.F.R. § 1.68	18
------------------------	----

37 C.F.R. § 42.1(b)	14
---------------------------	----

37 C.F.R. § 42.108(a)	4
-----------------------------	---

37 C.F.R. § 42.108(c)	17, 65
-----------------------------	--------

OTHER AUTHORITIES

MPEP § 608.02	23
---------------------	----

LIST OF EXHIBITS

Exhibit No.	Description
2001	Letter from Ajey Atre, Managing Dir., Maquet Cardiovascular LLC, to Michael R. Minogue, CEO, President and Chairman, Abiomed, Inc. (Dec. 15, 2015)
2002	J. Chlupac et al., <i>Blood Vessel Replacement: 50 years of Development and Tissue Engineering Paradigms in Vascular Surgery</i> , 58 <u>Physiol. Res.</u> (Suppl. 2) S119 (2009) (“Chlupac”)
2003	Kenneth Shann, CCP, and Serguei Melnitchouk, MD, <i>Advances in Perfusion Techniques: Minimally Invasive Procedures</i> , 18 <u>Seminars in Cardiothoracic and Vascular Anesthesia</u> 146 (2014) (“Shann”)
2004	Shahna L. Bronson, CCP, et al., <i>Prescriptive Patient Extracorporeal Circuit and Oxygenator Sizing Reduces Hemodilution and Allogeneic Blood Product Transfusion during Adult Cardiac Surgery</i> , 45 <u>The J of ExtraCorporeal Tech.</u> 167 (2013) (“Bronson”)
2005	Mahesh Ramchandani, MD, et al., <i>Cannulation Strategies and Pitfalls in Minimally Invasive Cardiac Surgery</i> , XII(1) <u>Houston Methodist DeBakey Cardiovascular J</u> 10 (2016) (“Ramchandani”)
2006	Thorsten Siess et al., <i>Hemodynamic System Analysis of Intraarterial Microaxial Pumps In Vitro and In Vivo</i> , 20(6) <u>Artificial Organs</u> 650 (1996) (“Siess 1996”)

Exhibit No.	Description
2007	Alan Keith Berger, MD, Hemodynamic Principles: The Fundamentals, University of Minnesota Divs. of Cardiology and Epidemiology Presentation (Sept. 10, 2003) (“Berger”)
2008	Bart Meyns, MD, PhD, et al., <i>Mechanical Support with Microaxial Blood Pumps for Postcardiotomy Left Ventricular Failure: Can Outcome be Predicted?</i> , 120 <u>The J of Thoracic and Cardiovascular Surgery</u> 393 (1999) (“Meyns”)
2009	Excerpts from the file history for U.S. Patent Application No. 10/566,423
2010	Abiomed’s Opening Claim Construction Brief, <i>Abiomed Inc. v. Maquet Cardiovascular LLC</i> , No. 1:16-cv-10914-FDS (D. Mass. Dec. 15, 2017)
2011	Order on Discovery Motions, <i>Abiomed Inc. v. Maquet Cardiovascular LLC</i> , No. 1:16-cv-10914-FDS (D. Mass. Oct. 6, 2017)
2012	Motion Hearing Transcript, <i>Abiomed Inc. v. Maquet Cardiovascular LLC</i> , No. 1:16-cv-10914-FDS (D. Mass. Oct. 10, 2017)

I. INTRODUCTION

IPR2017-02151 is precisely the sort of duplicative, prejudicial, and resource-squandering serial petition that the Board criticized in its recent decision in *General Plastic Industries Co., Ltd. v. Canon Kabushiki Kaisha*, IPR2016-01357, Paper 19 (PTAB Sept. 6, 2017) (Precedential). Petitioners file this Petition having filed a total of twenty Petitions, five motions for joinder, five reply motions in support of joinder, fourteen rehearing requests, and thousands of pages of exhibits. Worse than the pure cost alone is the fact that before the Petitioners filed the current Petition, they took advantage of roughly three months to review and consider Patent Owner's Preliminary Response in IPR2017-01029 and waited for the decision denying institution of IPR2017-01029. Petitioners therefore had full benefit of the roadmap provided by Patent Owner's responses and the Board's findings when filing this Petition.

Petitioners have been unsuccessful at every turn and cannot be allowed to continue to burden both the Patent Owner and the Board. *Id.* at 17. Worse still, Petitioners admit that they were aware of the *General Plastic* decision,¹ but they nevertheless filed this improper petition and ignored the factors espoused by the Board. Indeed, Petitioners admit important facts relevant to the factors that the

¹ *General Plastic* was cited on pages 88-90 of the Petition.

expanded panel in *General Plastic* indicates weigh heavily in favor of denying institution:

- Petitioners admit in their motion for joinder that: “this . . . ***Petition relies only on the previously-identified prior art references.***” (Paper 3 [Motion for Joinder], 4 (emphasis added)).
- Petitioners further admit: “[the] ***Petition relies on substantially overlapping prior art.***” (*Id.* (emphasis added)).
- Petitioners admit that they had Patent Owner’s Preliminary Responses and the Board’s Institution Decisions. (Petition, 89).

These admissions made clear that this Petition should never have been filed. The only logical conclusion that can be discerned as to why Petitioners filed the present follow-on Petition is that Petitioners are hoping to test multiple invalidity theories in the hopes that the Board will validate one of them, Patent Owner will make statements on the record that Petitioners will want to use against it in district court, or, at the very least, that Patent Owner will disclose its litigation strategy. Decision at 17, *Gen. Plastic*, Paper 19. The fundamental unfairness of this improper Petition is that Petitioners will have succeeded in their goal of increasing cost and expanding prosecution history no matter the outcome. Allowing such abusive filings by Petitioners, Petitioners who knowingly file Petitions that are doomed from the start, is a threat to the *inter partes* review system at its core.

Petitioners' improper conduct is not limited to these proceedings. In the co-pending infringement action, the Court has already found that Petitioners improperly withheld technical documents by imposing an arbitrary cut-off date. (Ex. 2011, 10). The District Court also denied Petitioners' attempt to add Patent Owner's foreign parent company as a party (Ex. 2012, 19:10-14) and rejected Petitioners' request to depose the parent company's general counsel. (*See* Ex. 2011, 6). Recently in the district court action, Petitioners proposed construing a great many terms in the claims, while in contrast expressly construing only two terms in the Petition. (Petition, 23-25). The district court later restricted Petitioners to eighteen terms, seven of which relate to the claims at issue here. It is noteworthy that Petitioners never assert explicit constructions for any of these seven terms here.² Different claim construction standards aside, Petitioners generally rely on

² For example, Petitioners argued in the district court that the claimed "blade extending radially outward from the rotor hub" is "an extension of a radius of the rotor hub (*i.e. a straight line*)."

(Ex. 2010, 36 (emphasis added)). In this Petition, however, Petitioners cite to Figure 7C of Aboul-Hosn as allegedly showing that "the rotor 70 has blades 72 each extending radially outward from the central hub 74." (Petition, 40 (citing Ex. 1004, 17:1-2)). Petitioners' position in the instant Petition is in stark contrast to that of Petitioners' claim construction, as the blades

overly broad constructions in their IPR petitions while simultaneously urging drastically different, overly narrow claim constructions in district court, apparently to support non-infringement arguments.

Petitioners have unfairly relied on previous proceedings as a roadmap, take opposing claim construction positions in different forums in an attempt to force Patent Owner to expend resources in a war of attrition, and fail to demonstrate a reasonable likelihood of success. This Petition is a clear abuse of the system, an abuse that the expanded panel in *General Plastic* identified as inequitable and one that endangers the *inter partes* review system. It is appropriate that the Board apply its precedential seven factor test from *General Plastic* and exercise its discretion pursuant to § 314(a) and § 325(d), and stop this proceeding.

A. The *General Plastic* Factors Demonstrate That The Board Should Deny Institution

The Board may exercise discretion in declining to institute follow-on petitions based on an evaluation of equities pursuant to 35 U.S.C. § 314(a) and 37 C.F.R. § 42.108(a). Decision at 15, *Gen. Plastic*, Paper 19. In exercising such discretion, the Board considers the following seven factors that each weigh in favor of denying institution.

in Figure 7C of Aboul-Hosn are not straight but instead have some angling or curvature.

1. Factor 1: whether the same petitioner previously filed a petition directed to the same claims of the same patent

The claims asserted in IPR2017-01029 were Claims 10-22 of the '068 patent, and the present petition challenges Claims 10, 13-15, and 20. Petitioners admit they challenge the same claims that were previously challenged as they assert “specific and targeted *additional* arguments focusing on a subset of the claims.” (Petition, 88 (emphasis added)). Thus, Factor 1 weighs heavily in favor of denying institution. *See* Decision at 10, *Gen. Plastic*, Paper 19.

2. Factor 2: whether at the time of filing the first petition petitioner knew or should have known of the prior art asserted in the second petition

Petitioners never address this factor and never assert that any reference was identified after the filing of the first petition. *See* Decision at 20, *Gen. Plastic*, Paper 19. Instead, in their motions for joinder, Petitioners admitted the opposite, asserting that the “Petition relies on substantially overlapping prior art” and “relies only on the previously-identified prior art references.” (Paper 3 [Motion for Joinder], 4). *See* Decision at 10, *Travelocity.com LP v. Cronos Techs., LLC*, CBM2015-00047 (PTAB June 15, 2015), Paper 7 (“Petitioner acknowledges that the *same* references are applied in the earlier and the present Petitions. On that basis alone, we may exercise our discretion and decline to institute covered business method patent review.”) (emphasis in original) (citations omitted).

Each of the references that are relied on in this Petition were known by or should have been known by Petitioners. For instance, Aboul-Hosn was the primary reference used in all of the first-round petitions. (IPR2017-01029, Ex. 1004 (“Aboul-Hosn”)). This is sufficient to show that Factor 2 weighs against institution. Decision at 13-14, *Apple Inc. v. Immersion Corp.*, IPR2017-01371 (PTAB Nov. 21, 2017), Paper 7.

In fact, the only prior art reference that Petitioners assert as allegedly “new” is not new at all. (*See* Petition, 88). First, the Sammler reference asserted is the German priority application that is identical to and in the chain of priority of U.S. Sammler cited as Exhibit 1018 in their prior petition. (*Compare* IPR2017-01029, Ex. 1018; IPR2017-02151, Ex. 1045). Sammler is also cited on the face of the ’068 Patent. (Ex. 1001, 2). *See* Decision at 7-9, *R.J. Reynolds Vapor Co. v. Fontem Holdings 1 B.V.*, IPR2017-01319 (PTAB Nov. 8, 2017), Paper 7 (finding that Factor 2 weighed against institution because “Petitioner knew, or should have known” about prior art references that are listed on the face of the challenged patent).

To the extent that Petitioners are to deny knowledge of Sammler or any other cited reference, this factor explicitly considers whether Petitioners ***should have known*** about the references. Petitioners admit that they themselves should have known of each reference because they admit that a POSITA reviewing

Sammler “would have naturally looked to Siess because . . . Siess is also named as a co-inventor of Sammler.” (IPR2017-02150, Paper 2, 82). By Petitioners’ own admission, someone reviewing Siess, asserted as a secondary reference in *all fourteen* of the first round of petitions, would also look to Sammler. (*See, e.g.*, IPR2017-01025, Paper 2 (Grounds 1-2)). As Petitioners themselves note, a thorough and diligent review of a reference featured in *every* Ground of their first round of petitions would have likewise yielded Sammler. *See* Decision at 7-8, *Samsung Elecs. Co. Ltd. v. Rembrandt Wireless Techs., LP*, IPR2015-00555 (PTAB June 19, 2015), Paper 20 (quoting 35 U.S.C. § 325(d)); Decision at 6, *Apotex Inc. v. Wyeth LLC*, IPR2015-00873 (PTAB Sept. 16, 2015), Paper 8.

Petitioners have made no cogent arguments to rebut any of the above (or even to address the issue in the first instance), and thus Factor 2 weighs heavily in favor of the Board exercising its discretion under § 314(a) to deny the present petition.

3. Factor 3: whether at the time of filing the second petition petitioner had the patent owner’s preliminary response to the first petition or the Board’s institution decision on the first petition

At the time of the filing of the follow-on petitions, Petitioners had Patent Owner’s preliminary responses in all *fourteen* of the original proceedings, the first of which came as early as June 27, 2017. Petitioners had the benefit of evaluating and considering Patent Owner’s responsive arguments for months before filing the

follow-on petitions. *See* Decision at 17, *Gen. Plastic*, Paper 19 (“The absence of any restrictions on follow-on petitions would allow petitioners the opportunity to strategically stage their prior art and arguments in multiple petitions, using our decisions as a roadmap, until a ground is found that results in the grant of review.”).

Not disputing having Patent Owner’s response for roughly three months, Petitioners’ sole defense is that they did not have the Board’s decision ***long enough***. Specifically, Petitioners now claim that the present follow-on petitions “as a practical matter could not have, been prepared using the Board’s decision as a roadmap.” (Petition, 89, n.23). However, the Board issued an eleven page decision confirming Patent Owner’s argument that Aboul-Hosn had numerous shortcomings and confirming that the “Petitioner also fails to provide a sufficient rationale to combine the teachings of Aboul-Hosn’s different embodiments.” (IPR2017-01029, Paper 9, 10; *see also*, Petition, 12-19, 30-38). Petitioners had plenty of time to bolster their new petitions and in fact did so, knowing where the Board found shortcomings.

Much the same as the Petitioner in *General Plastic*, Petitioners here have “modified its challenges in the follow-on petitions in an attempt to cure the deficiencies that the Board identified in its first-filed petitions” which “was a shift in Petitioner’s positions and arguments from the first-filed petitions based on the

analysis articulated in our Decisions Denying Institution of those petitions.”

Decision at 11, *Gen. Plastic*, Paper 19. Factor 3 therefore weighs heavily in favor of denying this Petition.

4. Factor 4: the length of time elapsed between when petitioner learned of the prior art asserted in the second petition and the filing of the second petition

As outlined in connection with Factor 2, Petitioners knew or should have known of the prior art asserted in this Petition at the time of filing the first round of petitions—mid-March of 2017. Indeed, Petitioners themselves do not dispute this, remarking that the follow-on petitions “rel[y] only on the previously-identified prior art references.” (Paper 3 [Motion for Joinder], 4). This means that Petitioners had knowledge of these prior art references for over six months before deciding to file the follow-on petitions after the Board issued its decisions in the first round of proceedings. Factor 4 therefore weighs heavily in favor of denying this Petition.

5. Factor 5: whether petitioner provides adequate explanation for the time elapsed between the filings of multiple petitions directed to the same claims of the same patent

Petitioners include a cursory discussion of so-called “mitigating factors” that attempt to explain their delay in filing this serial Petition. None of these cursory reasons overcomes the bad facts in this case (*i.e.*, having the preliminary response and the Board’s decision as a roadmap, reliance on previously known and redundant art, etc.), and none of these purported reasons qualify as the required

“adequate explanation” that would result in this factor favoring institution.

Decision at 16, *Gen. Plastic*, Paper 19.

Petitioners cite to the *General Plastic* decision on pages 88-90 of the Petition only to ignore the factors it required Petitioners to address. Petitioners instead argue that because the one-year bar had yet to expire, the Petition is timely. (Petition, 89). Petitioners further assert that a Petition on a limited number of challenged claims is justifiably fair. (Petition, 88).

Had Petitioners studied *General Plastic* and its related cases, Petitioners would have realized that their arguments had long since been explicitly rejected by the PTAB. Specifically, Petitioners’ arguments ignore that the *General Plastic* decision addresses the one-year bar and issues of fundamental fairness by stating (1) that the Board must put in place more restrictions than just the one-year bar to curb the potential for abuse by Petitioners, and (2) that the *General Plastic* factors themselves provide for the efficiency and “fundamental fairness of the process for all parties.” Decision at 18, *Gen. Plastic*, Paper 19. The precedential *General Plastic* factors already take Petitioners’ arguments into account and dismiss them in an effort to limit the “abuse of the review process by repeated attacks on patents.” *Id.* at 17.

Petitioners next assert that the follow-on petitions were filed without delay, without consideration of the Board’s decisions, and based on a limited set of the

same claims. These assertions have been addressed above and fail to support Petitioners' positions. Indeed, Petitioners' assertions are without merit as there is no dispute that Petitioners had Patent Owner's preliminary response, Petitioners had the Board's decision, and that Petitioners are challenging claims that they previously challenged with art they previously had.

Finally, Petitioners wrongly rely on ongoing prosecution, so-called misrepresentations, and infringement contentions to justify this Petition. First, Petitioners do not cite to any on-going prosecution within the Petition nor argue why such prosecution has any influence on the interpretation of the claims or the prior art. Second, Petitioners' so-called misrepresentations were not misrepresentations at all, as the Board independently analyzed Aboul-Hosn and came to the same conclusion as that asserted by Patent Owner.³ Finally, Petitioners were well aware of Patent Owner's positions, as it sent claim charts largely mirroring the infringement contentions as early as December of 2015. *See* Ex. 2001. The notion that Petitioners "needed sufficient time to review, digest and

³ Petitioners admit that Aboul-Hosn's "FIGS. 1 and 2 show an extracorporeal blood pump system" (Petition, 13, n.7). The Board noted the same, stating that "Aboul-Hosn's Figure 1, reproduced below, illustrates a reverse flow pump located external to the vasculature." (IPR2017-01029, Paper 9, 8).

formulate its views with respect to those positions” is gamesmanship at its finest. (Petition, 89).

Petitioners had the opportunity to present their case and lost. Petitioners asked to be reheard, and lost again. Such losses preclude further follow-on petitions in these circumstances. Weighing the equities and the burden on both the Board and the Patent Owner, further actions before the Patent Office are prejudicial and unjustified. Decision at 17, *Gen. Plastic*, Paper 19 (“Our intent in formulating the factors was to take undue inequities and prejudices to Patent Owner into account.”). Therefore, Factor 5 weighs in favor of the Board exercising its discretion under § 314(a) to deny this Petition.

6. Factor 6: the finite resources of the Board

Multiple, staggered petition filings, such as those here, are an inefficient use of the *inter partes* review process and the Board’s resources. “The Board’s resources would be more fairly expended on initial petitions, rather than on follow-on petitions, such as the Petition in this case. This is especially apparent when, as here, we are confronted with the third challenge to a patent” Decision at 13-14, *Alarm.com Inc. v. Vivint, Inc.*, IPR2016-01091 (PTAB Nov. 23, 2016), Paper 11.

To date, Petitioners have filed twenty petitions totaling over 1,800 pages (fourteen of which have been denied institution by this Board), twenty expert

declarations comprising nearly 4,500 pages, 991 exhibits, fourteen twenty-page requests for rehearing, five motions for joinder, and five reply briefs in support.⁴ In response to this onslaught, Patent Owner has been forced to respond in kind with fourteen preliminary responses and five oppositions to motions for joinder, and is currently employed in preparing preliminary responses to the six new follow-on petitions. In total, the Board will thus have been subjected to review and rule upon twenty individual petitions and preliminary responses, along with briefing on fourteen requests for rehearing and five motions for joinder, notwithstanding Petitioners' attempts to file replies in response to Patent Owner's preliminary responses. "Permitting second chances in cases like this one ties up the

⁴ Wastefully, Petitioners filed motions for joinder fully knowing there was simply nothing to join, and even admitted as such when they acknowledged that joinder was moot in the event that rehearing was denied. (Paper 8 [Reply in Support of Motion for Joinder], 5 (stating that the joinder "would become moot if the Board does not institute proceeding in IPR2017-01029")). Now that Petitioners' spurious rehearing requests have been denied by the Board, it is even more clear that Petitioners' doomed joinder strategy was merely an exercise in draining even more of Patent Owner's, and the Board's, time and resources. (IPR2017-01029, Paper 11).

Board's limited resources; [the Board] must be mindful not only of this proceeding, but of 'every proceeding.'" Decision at 8, *Samsung Elecs. Co., Ltd. v. Rembrandt Wireless Techs., LP*, IPR2015-00555 (PTAB June 19, 2015), Paper 20 (quoting 37 C.F.R. § 42.1(b)). Factor 6 therefore weighs in favor of the Board exercising its discretion pursuant to § 314(a).

7. Factor 7: the requirement for a final determination within 1 year of institution

Although the Board denied institution in IPR2017-01029, Petitioners should not get a pass on *General Plastic* Factor 7. The Board should still consider and weigh Petitioners' improper strategy of filing repeated and serial petitions. When the sheer volume of resources Petitioners have demanded for themselves is considered, it is highly likely that the Board will struggle to ensure the issuance of a final determination not later than one year after the date on which the Director notices institution of review. Therefore, Patent Owner respectfully submits that Factor 7 also weighs in favor of the Board exercising its discretion pursuant to § 314(a).

B. The Board Should Exercise Its Discretion under 35 U.S.C. § 325(d)

This Petition can also be denied under 35 U.S.C. § 325(d). As alluded to above, the present Petition presents nothing more than a recycled narrative using recycled prior art references.

Petitioners assert that the Board does not have the authority to deny the present follow-on petition pursuant to § 325(d) because Sammler represents a new ground of rejection. (Petition, 88). This in and of itself is no bar to application of § 325(d). *See* Decision at 5, *Conopco, Inc. dba Unilever v. The Procter & Gamble Co.*, IPR2014-00506 (PTAB Dec. 10, 2014), Paper 25 (Successive petitions by a single petitioner are often denied under § 325(d), even if there are differences in the art and argument). Moreover, Sammler is not a “new” Ground. The Sammler reference that is cited herein is identical to and in the chain of priority of the U.S. Sammler reference cited in the previously denied IPR. (*Compare* IPR2017-01029, Ex. 1018; IPR2017-02151, Ex. 1045). The inclusion of Sammler is just another example of Petitioners’ continued recycling of redundant references to raise the same trope of invalidity arguments before the Board. Indeed, even in Petitioners’ own words, the petitions raise only “substantially overlapping prior art” comprised “only on the previously-identified prior art references.” (Paper 3 [Motion for Joinder], 4; *see also Travelocity.com LP v. Cronos Techs., LLC*, CBM2015-00047 (PTAB June 15, 2015) (Paper 7)).

Putting aside the fact that the present Petition rehashes the first round of petitions and repeats prior arguments and art references, these references Petitioners now seek to rely on were before the Office during prosecution. Aboul-Hosn and Sammler (both US and DE versions relied upon in the petitions) were

before the Examiner during prosecution, along with many similar and redundant references. (Ex. 1003, 83, 117, 144; *see also* 35 U.S.C. § 325(d); Decision at 12-13, *Prism Pharma Co., Ltd v. Choongwae Pharma Corp.*, IPR2014-00315 (PTAB Jul. 8, 2014), Paper 14; Decision at 7-8, *Integrated Global Concepts, Inc. v. Advanced Messaging Techs., Inc.*, IPR2014-01027 (PTAB Dec. 22, 2014), Paper 16).

The present instance is exactly the situation that was contemplated by affording the Board discretion pursuant to § 325(d) to deny institution. Respectfully, Patent Owner submits that the Board exercise such discretion here.

II. THE BOARD SHOULD NOT INSTITUTE

Petitioners fare no better in their substantive arguments in this petition. U.S. Patent No. 9,327,068 (“’068 Patent”) relates to an intravascular blood pump system and method having a unique combination of features tailored to address the deficiencies associated with prior blood pump designs. The claimed system further includes a guide mechanism with an elongate lumen to safely and reliably position the intravascular blood pump in a predetermined location within the circulatory system—typically the heart.

Petitioners continue to overlook the complexities presented by blood pump design, combining multiple references and multiple embodiments within the references to piece together a position. In so doing, Petitioners continue to rely on

the same piecemeal arguments they presented in their first round of denied petitions. Specifically, Petitioners again make the fundamental error of relying on the reverse flow blood pump in Aboul-Hosn (e.g., Figures 3 and 12) as a purported basis for invalidity of the intravascular pump system claimed in the '068 Patent. Aboul-Hosn's reverse flow pump, which forms the basis for the sole ground of rejection alleged in the petition, is designed to be located outside the circulatory system, *i.e.*, it is an **extravascular** pump. Accordingly, Petitioners have failed to meet their burden under 37 C.F.R. § 42.108(c) of establishing a reasonable likelihood of success that any of Claims 10, 13-15, and 20 would be unpatentable, and the Board should decline to institute *inter partes* review.

A. Petitioners Fail to Carry Their Burden.

Petitioners assert that Claims 10 and 13-15 are invalid under 35 U.S.C. § 103(a) based on Aboul-Hosn in view of Sammler. (Petition, 4). Moreover, Petitioners assert that Claim 20 is invalid under 35 U.S.C. § 102(b) as being anticipated by Aboul-Hosn. (Petition, 4). Under 35 U.S.C. § 314(a), in order for an IPR to be instituted, Petitioners must establish that there is a reasonable likelihood that at least one of the challenged claims is unpatentable. Petitioners fail to meet this burden with respect to Claims 10 and 20 and the claims that depend therefrom (by virtue of their dependency).

1. Aboul-Hosn in view of Sammler⁵ Fails to Render Obvious Claims 10 and 13-15 (Ground 1)

a. Aboul-Hosn fails to teach or suggest the claimed “intravascular blood pump system”

Claim 10 is a method claim that includes recites an intravascular blood pump system that comprises a plurality of specifically claimed structures (*e.g.*, an intravascular blood pump, cannula, and catheter). Petitioners cannot demonstrate that Aboul-Hosn teaches or suggests such structures. Indeed, in attempting to do so, Petitioners are required to modify an extravascular pump located outside the blood vessel, without support, so as to use it in an unrelated embodiment related to a stabilization system. This argument fails.

⁵ Ex. 1045 of the Petition fails as it demonstrates that Petitioners did not go through the required steps to properly certify the reference’s translation from German as the “certification” affixed to the beginning of Ex. 1045 falls far short of the requirements of 37 C.F.R. § 1.68. 37 C.F.R. § 1.68. The Board therefore has reason to deny institution with respect to any ground related to Sammler. *See* Decision at n.2, *Hengdian Grp. DMEGC Magnetis Co., Ltd. v. Hitachi Metals, Ltd.*, IPR2017-01313 (PTAB Nov. 6, 2017), Paper 7.

Petitioners' sleight of hand can be seen in the very first sentence of the Petition's Ground 1, where Petitioners describe Aboul-Hosn's "intravascular blood pump system" and cite to 31:6-9, which is describing Figures 23 & 24. (Petition, 29; Ex. 1004, 31:6-9). Immediately thereafter, without addressing why a POSITA would switch between embodiments,⁶ Petitioners proceed into their arguments wherein they point to Figures 1 & 2 (to allegedly show the claimed pump, rotor, and cannula limitations), Figures 2 & 4 (to allegedly show the claimed aperture limitation), Figure 3 (to allegedly show the claimed pump, cannula, guide mechanism, blood pressure detection mechanism, and guide wire limitations), Figure 7A-C (to allegedly show the claimed rotor limitation), Figures 7C (to allegedly show the claimed blood pressure detection mechanism and elongate lumen limitations), Figure 10 (to allegedly show the claimed blood pressure detection mechanism limitation), and Figure 12 (to allegedly show the claimed

⁶ The Board recognized the distinct nature of Figures 23 & 24 in its denial of Petitioners' Requests for Rehearing, remarking that Aboul-Hosn "specifically references Figures 23 and 24 as *two* different embodiments, meaning that Figures 23 and 24 are *each* different embodiments, not only with respect to one another, but also with respect to the other embodiments disclosed." (IPR2017-01029, Paper 11, 5 (emphasis in original)).

catheter limitation and, along with Figure 11, to allegedly show the claimed guide mechanism limitation and support the positioning and miniaturizing aspect of their arguments). (Petition, 12-19, 29-72). Petitioners then take the multilumen catheter from Figures 21 & 23 and port it over to their modified extravascular reverse flow pump. (Petition, 37, n.15). Finally, Petitioners point to Figures 14-19, 21 & 23 to supposedly demonstrate that their modified extravascular reverse flow pump would be positioned inside the vasculature, with a modified cannula design, all without justifying why a POSITA would selectively redesign an extravascular blood pump, taking individual parts from each the distinct embodiments of Aboul-Hosn. (Petition, 34-38).

Once again, Petitioners simply assert that the POSITA would ignore explicit teachings with respect to each of the distinct embodiments of Aboul-Hosn and instead find them to be interchangeable with one another. (Petition, 30-38). Rather than providing arguments as to how a POSITA would be capable of using their modified device intravascularly, Petitioners simply claim that a POSITA would do so and then misleadingly mischaracterize and/or cite to distinct embodiments of Aboul-Hosn as purported proof. This course change by Petitioners is directly in response to Patent Owner's arguments and the Board's findings that Petitioners "failed to establish sufficiently that the features of those different embodiments are interchangeable." (IPR2017-01029, Paper 9, 8).

Aboul-Hosn discloses several distinct fluid transportation systems. (*See* IPR2017-01029, Paper 9, 9 (noting “Aboul-Hosn’s different embodiments”)). One is the reverse-flow pump system⁷ shown in Figures 1-13. In the Aboul-Hosn system, a reverse-flow pump, located outside the circulatory system, communicates with blood within a blood vessel via a cannula that enters the blood vessel. (Ex. 1004, 10:25–25:5). Indeed, the Board recognized as much in its prior decision denying institution. (IPR2017-01029, Paper 9, 8 (“Aboul-Hosn’s Figure 1 . . . illustrates a reverse flow pump located external to the vasculature.”)). Moreover, the Examiner in a related case⁸ stated that “[t]he remaining embodiments [(i.e., all embodiments other than the embodiments of Figures 21, 23, and 24 of Aboul-Hosn)] rely on a protruding or bulky pump that remains outside vasculature, and conveys blood through a loop.” (Ex. 1054, 8). Separately, Figures

⁷ Petitioners continuously refer to Aboul-Hosn as an “intravascular blood pump system.” This terminology is misleading as it is not the blood pump itself of Aboul-Hosn that is designed to be placed in the vasculature of the patient, it is the cannula. That is, while the cannula is placed into the vasculature, the pump, which according to the claims must itself be intravascular, is never inserted into the vasculature.

⁸ This Examiner was the same as the Examiner for the ’068 Patent.

21 and 23-24 in Aboul-Hosn illustrate a “stabilization system,” which stabilizes the heart during surgery. (Ex. 1004, 28:21–31:9). This, too, was noted by the Board: “Petitioner’s challenge treats the various features of Aboul-Hosn’s different embodiments as if they are interchangeable with one another.” (IPR2017-01029, Paper 9, 9). When the separate embodiments disclosed in Aboul-Hosn are appropriately considered, it becomes clear that this reference is directed to a fundamentally different design than the claimed invention. As a result, Petitioners’ arguments fail.

i. The Petition Improperly Relies on the Extravascular Reverse Flow Pump of Aboul-Hosn

Aboul-Hosn discloses that the same reverse flow pump assembly is depicted in each of Figures 1-13. Furthermore, Petitioners, and their expert, admit that the Aboul-Hosn pump is located outside of the blood vessel. Specifically, on page 13 of the Petition, Petitioners admit that “FIGS. 1 and 2 show an extracorporeal blood pump system . . .” (Petition, 13, n.7). However, without reason, Petitioners then assert that Figures 3 and 12, for example, are miniaturized blood pumps that include the same components as the extracorporeal pumps, but are somehow able to be inserted into the vasculature. (Petition, 30-33).

Petitioners are wrong. Figure 3 is simply another view of the *same reverse flow pump assembly* that is shown in Figures 1 and 2. (Ex. 1004, 8:20-25).

Petitioners' reclassification of Figure 3 as an intravascular blood pump is in direct conflict with Aboul-Hosn—Aboul-Hosn specifically discloses that Figure 3 is “an exploded perspective view of a *reverse flow pump assembly*.” (Ex. 1004, 8:26 (emphasis added)). Exploded views are well known in the patent field and are used by illustrators to show the relationship or order of assembly of various parts. (MPEP § 608.02). Petitioners' faulty reclassification runs counter to their own arguments; as noted above, Petitioners are quick to note that Figure 3 “comprises the same pump components” as Figures 1 & 2, yet in the next instance claim that Figure 3 is an entirely different pump, now intravascular rather than extravascular. (Petition, 14-15).

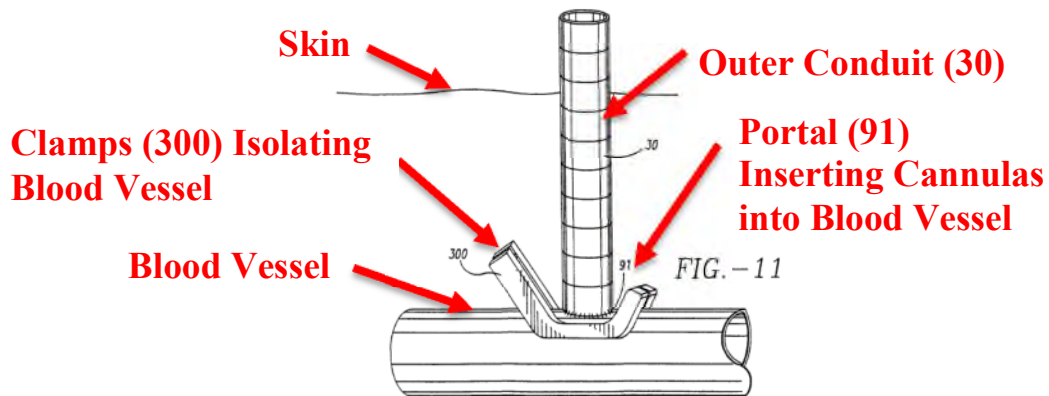
Moreover, Figure 4 is described as “an assembled *reverse flow pump* similarly shown in Fig. 3.” (Ex. 1004, 8:26-29 (emphasis added)). Finally, Figure 12 “is a simplified sectional perspective view of a *reverse flow pump assembly* positioned within the conduit shown in Fig. 11.” (Ex. 1004, 9:12-13 (emphasis added)). Contrary to Petitioners' unsupported claims, Aboul-Hosn discloses an extravascular reverse flow pump in each of Figures 1-13.

ii. The Figures Confirm That the Reverse Flow Pump Remains Outside the Vasculature

Aboul-Hosn consistently instructs the POSITA to locate the reverse flow pump assembly of Figures 1-13 *outside* of a patient's vasculature. On page 21, Aboul-Hosn discusses that portal (91) is created in the blood vessel, and the outer

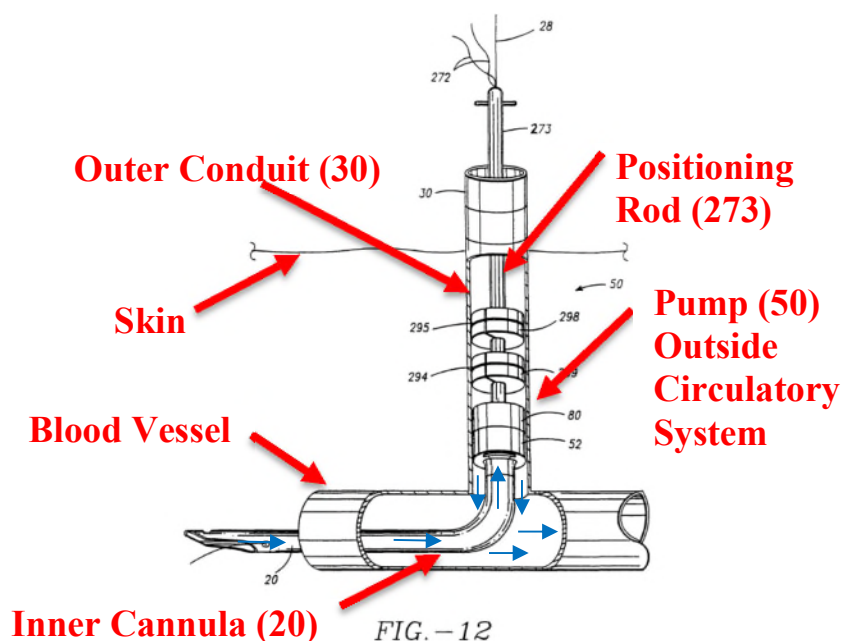
conduit (30) is then placed next to the portal and sutured such that this conduit extends perpendicular to the blood vessel. (Ex. 1004, 21:19-22).

Ex. 1004 at Figure 11 (Annotations in Red).



Aboul-Hosn then discloses that the pump assembly should be inserted within the outer conduit (30) and is not advanced beyond it. (Ex. 1004, 21:22-27; 22:10-21; 24:7-14). This is illustrated by Figure 12:

Ex. 1004 at Figure 12 (Annotations in Red and Blue (Showing Blood Flow)).



As Figure 12 shows, reverse flow pump (50) is located outside a patient's circulatory system and **only** inner cannula (20) actually extends inside the blood vessel. Aboul-Hosn discloses that this pump is not advanced past outer conduit 30 (or a similar graft) but instead is "advanced **to** the clamped section of a vessel." (Ex. 1004, 24:12-14 (emphasis added)). There is no disclosure of the pump advancing past that point. Indeed, Petitioners admit that the pump remains in the outer conduit 30. (Petition, 34 (stating "even if the intravascular blood pump were to remain within the conduit 30 as shown in FIG. 12"))).

The text of Aboul-Hosn further confirms that the reverse flow pump of Figure 12 does not go into the patient's vasculature, stating that the conduit must have sufficient length to contain the pump and the positioning rod: "[t]he outer

conduit or graft 30 may also be of sufficient length to accommodate the pump 50 from the distal end of the cannula 20 to the proximal end of the positioning rod 273.” (Ex. 1004, 21:24-26). Furthermore, Aboul-Hosn teaches a POSITA to secure the pump to the conduit—“[t]he pump 50 may then be secured to the proximal ends of the inner cannula and the outer conduit 30.” (Ex. 1004, 22:27-28). If the pump and the conduit were not secured in a fluid-tight manner, leaks from the pump past the outer conduit and outside the body would develop and the system would fail to deliver the blood back to the circulatory system of the patient.

Furthermore, the presence of not one but two silicone plugs 298 and 299 are consistent with the position of the pump 50 within the outer conduit 30 and not in the vessel. As shown above, silicone plugs 298 and 299 further seal the pump against the outer conduit and prevent any flow of blood past the pump. (Ex. 1004, Figure 12, 15:10-12). Positioning of this pump and both silicone plugs 298 and 299 inside the blood vessel would preclude any flow of blood past the pump and the plugs and, therefore, would preclude any perfusion of tissues located distally to the point of insertion in the femoral artery.

Placing the pump within the conduit does not make the pump intravascular. Petitioners argue that, once attached, “the conduit 30 forms an extension of the patient's vascular system akin to a branching blood vessel.” (Petition, 34). However, artificial conduits are historically used for either a) replacing a diseased

section of a blood vessel, or b) as an access point to the circulatory system. In cases of replacing a section of a blood vessel, an artificial graft is inserted in place of an excised portion of an actual blood vessel and has an outlet for blood flow, in addition to an inlet, and an identifiable tissue or organ perfused by blood flow coming from the outlet of that blood vessel replacement. (Ex. 2002, S122-123). In cases of an access point, there is typically no flow of blood through that artificial conduit, which is used as part of a cannulation procedure. (Ex. 2003, 149). In analyzing Figure 12, one cannot identify an outlet of the outer conduit 30, or any tissue or organ being perfused by that outlet, and therefore, outlet conduit 30 can be only characterized as an access point.⁹ (Petition, 33 (“As shown in FIG. 12, the conduit 30 acts as an “introducer” through which the intravascular blood pump is advanced....”))).

For at least these reasons, a POSITA would not consider a Dacron graft that extends from the vasculature (*i.e.*, an access point) as part of the circulatory system. It instead is being used as a distinct access point structure similar to a

⁹ Aboul-Hosn confirms that the graft is being used as an introducer or access point. (Ex. 1004, 12:7-9 (“***an introducer***, or a vascular graft, such as a DacronTM graft . . .”) (emphasis added)).

conventional cannula to provide fluid communication between the pump and the circulatory system.¹⁰

Petitioners ignore all of this and wrongly assert that the presence of the pump within the graft allows the pump to be considered “intravascular.” (Petition, 34-35).¹¹ In fact, if Petitioners’ argument that the conduit 30 becomes part of the vasculature is to be believed, then other medical devices in which a tube or conduit extends from the blood vessel, even to a device multiple feet away from the patient, would likewise be considered “intravascular.” As an example, all heart-lung bypass machines would thus constitute Petitioners’ notion of “intravascular.” Such a result would be nonsensical and contrary to the understanding of a POSITA.

¹⁰ It is desirable to place the pump closer to the body to reduce the amount of saline priming volume required and therefore reduce blood damage. (See Ex. 2003, 148; Ex. 2004, 167-168).

¹¹ Petitioners misleadingly point to Aboul-Hosn’s use of the term endovascular as evidence that the reverse flow pump is intravascular. (Petition, 18, 29). Petitioners mischaracterize Aboul-Hosn as Aboul-Hosn is referring to the **system** (*i.e.*, the inflow cannula) not the **pump** when it states that its “reverse flow blood pump **system**” is endovascular. (Ex. 1004, 6:24-7:5).

At bottom, all the discussion concerning reverse flow pump (50) instructs the POSITA to locate this device either in a conduit that extends from, and therefore is not part of, the circulatory system or is completely outside of the body altogether. As such, reverse flow pump (50) is not designed to and has not been disclosed to be an intravascular blood pump as claimed.

iii. Figure 12 Illustrates the Reverse Flow Pump Assembly is Positioned Within the Conduit

Petitioners also argue, without support, that Figure 12 depicts the pump system “in the process of being advanced.” (Petition, 34). Nothing in Aboul-Hosn indicates this, and rather the description of Figure 12 says “Fig. 12 is a simplified sectional perspective view of a reverse flow pump assembly *positioned within* the conduit shown in Fig. 11.” (Ex. 1004, 9:12-13 (emphasis added)).

Petitioners conclude that Figure 12 is “in the process of being advanced” simply because “the distal opening of the cannula and the outflow windows of the intravascular blood pump are not separated by a structure such as a heart valve” and that this necessarily means that “[t]he blood pump would need to be advanced further.” (Petition, 34). For one, Petitioners’ remarks as to what a POSITA would have found “preferable” is in contrast to Aboul-Hosn’s disclosure. (Petition, 37-38).

Moreover, the device shown in Fig. 12 simply **would not and could not** be progressed further than its illustrated position.¹² The positioning rod 273, which is connected to the pump and yet also extends out of the conduit, is a long rigid object that couldn't make the turn (*i.e.*, the turn at the intersection between the conduit and the vessel) into the vasculature. (Ex. 1004, 14:20-21 (“[t]he positioning rod 273 is preferably made from a metal or relatively stiff polymer”); *see also* Ex. 1004, 14:28-31). This rigidity is entirely consistent with the positioning rod 273's stated purpose of pushing the pump down into the conduit, but not past the conduit, but is entirely inconsistent with the notion that the pump assembly and attached positioning rod turn into the blood vessel and are advanced through the vasculature as argued by Petitioners. (Petition 33-37). Furthermore, in order for the rigid positioning rod 273 to serve its purpose of allowing the operator to push the pump into the conduit, it needs to be long enough to run from the skin

¹² Petitioners also assert that due to the relative sizes of the graft and pump shown in Figure 12, the pump could be advanced in the vasculature. But, Petitioners admit that “Aboul-Hosn does not indicate that Fig. 12 is drawn to scale.” (Petition, 36). The figures of Aboul-Hosn must be to scale for Petitioners to rely on any proportions based on the figures. *See Hockerson-Halberstadt, Inc. v. Avia Grp. Int'l*, 222 F.3d 951, 956 (Fed. Cir. 2000).

to the vasculature, plus some portion of the rod that remains outside the body.

Thus, the rigid positioning rod couldn't navigate through the vasculature system to the aorta.

As purported support for their argument that the “the blood pump would need to be advanced further” or is capable of being advanced further into the vasculature, Petitioners point to Figs. 14-19 of Aboul-Hosn to demonstrate that “the distal end of the cannula is positioned, for example, across a heart valve.” (Petition, 34). However, none of those figures include a pump within the vasculature as Petitioners purport to suggest. (*See* Ex. 1004, Figures 14-19, 9:16-10:3). Indeed, the figures themselves illustrate distinct embodiments for right heart support (Figure 14), attachment of the outer conduit to the aorta itself (Figure 15), the use of multiple blood pumps (Figures 16-18), and the use of balloons on the outside diameter of the cannula (Figure 19). Each of these figures relies on an internal cannula and the same reverse flow pump that is to remain outside of the vasculature. Quite simply, nothing in Aboul-Hosn itself actually supports Petitioners' claims that the pump of Figure 3 and as shown in Figure 12 would be progressed any further than that shown in the figures.

Petitioners then claim that due to “frictional head loses [sic] associated with a long cannula” and the supposed necessity of “a larger pump to offset those losses,” “it would have been preferable to use intravascular blood pumps that can

be inserted further distally into the vasculature, closer to the heart.” (Petition, 36-37). This statement is never found in the reference and is contrary to Aboul-Hosn’s teaching of using a long cannula. Like Aboul-Hosn, many devices have made use of long cannulas to reach inside the patient’s vasculature so as to allow for the use of pumps that remain outside the vasculature. (Ex. 1004, 7:14-18; Ex. 2003, Figure 1; Ex. 2005).

Quite simply, Figure 12 is not a system in the process of being advanced into a conduit—let alone being advanced into the aorta; rather, Figure 12 illustrates the final position of the pump. In fact, Figure 11 makes clear that the pump is secured to the conduit so that it cannot advance any further. Specifically, Aboul-Hosn discloses that “[a] suture or a laparoscopic clamping device may be employed to hold the apparatus in position or the outside diameter of the housing body 52 may also be secured to the outer conduit or graft 30 using similar techniques to secure the distal plug.” (Ex. 1004, 22:21-24). At bottom, Aboul-Hosn solely teaches that the reverse flow blood pump of Figure 1-13 is to be positioned outside of the vasculature.

iv. Reverse Flow Pumps Are Not Suited for Intravascular Use

A POSITA would not use a reverse flow pump as an intravascular blood pump because it pumps in the wrong direction (*i.e.*, back to the heart instead of to the extremities). Moreover, a POSITA would not use a reverse flow pump (50) in

an intravascular application for multiple reasons, including the limited size constraints of the vasculature. (See Ex. 1002, ¶ 47 (“To operate within the patient’s vasculature and heart, the pumps must have a sufficiently small diameter (e.g., 7 to 9 mm or smaller).”)). A POSITA would understand that small size is critical so a doctor can guide the device through the tortuous path of a patient’s vasculature. At the same time, the pump’s inlet and outlet must be large enough to support a sufficient amount of blood flow without damaging the blood. This contradictory relationship is precisely the reason why reverse flow pumps are not used intravascularly.

Aboul-Hosn understood this contradictory relationship when identifying the specific disadvantages of devices that could be percutaneously positioned within the circulatory system: “[o]ther available devices that permit percutaneous access to the heart similarly have disadvantages such as their limited circulatory capabilities due to the strict size constraints for their positioning even within major blood vessels.” (Ex. 1004, 3:31-4:4). Understanding these disadvantages, Aboul-Hosn specifically counseled against miniaturization as miniaturized pumps for percutaneous access to the heart have “a high likelihood of mechanical failure” and that “the flow capacity of these devices are significantly diminished.” (Ex. 1004, 4:3-4:8). Furthermore, Petitioners’ comparison between Figures 12 and 13 is of no

consequence, as both are reverse flow pumps and neither are designed to go into the vasculature. (Petition, 33; *see also* Ex. 1004, 21:19-26, 24:15-19).

Reverse flow pumps have inlet and outlet passageways that overlies each other. The area of the inlet opening must be similar to that of the outlet opening to avoid causing blood damage. If placed in a vessel, arranging the inlet and outlet in this fashion cuts in half the area available for either the inlet or the outlet. Indeed, Figure 2 of Aboul-Hosn confirms this, as it discloses the inlet and the outlet occupying the same space and resulting in smaller sizes for both despite a larger overall diameter for the pump as a whole. (Ex. 1004, Fig. 2). Therefore, in order to be sized small enough to operate where Petitioners assert Aboul-Hosn's reverse flow pump does, the cross-sectional limitations of the inlet and outlet passageways dictate that the flow of such a device would be too low to function in any meaningful way. On the other hand, if the reverse flow pump of Aboul-Hosn is able to generate sufficient flow within the passageways, it simply would not fit inside the vasculature. At bottom, Aboul-Hosn designed his device to remain outside of the circulatory system to provide sufficient flow.

This contradictory relationship is exacerbated when one considers that Petitioners claim that components of the stabilization system embodiment shown in Figures 21 & 23 are used in conjunction with this reverse flow pump. (Petition, 37-38). Given that the stabilization system embodiment concerns a full-bypass

device operating when the heart is stopped, such a reverse flow pump system would need to be able to support up to 5 L/min of blood flow (*see* Ex. 1002, ¶ 45), necessitating a cross-section of the pump that would not fit inside the vasculature.

Petitioners simply assert that “the intravascular blood pump system can comprise the same components which are properly sized in order to fit into an introducer for positioning within the vascular system of the patient.” (Petition, 13, n.7). Notably, this key sentence has absolutely no support, and completely overlooks the myriad of technical difficulties that POSITAs understand exist when trying to miniaturize and develop pump components for intravascular use—none of which are addressed or even attempted to be reconciled by Petitioners.

Petitioners also fail to include any commentary or evidence that a POSITA would expect success in making the proposed miniaturization, which is particularly critical in the present instance due to the complexity of the claimed invention. Without evidence directed to the expectation of success, there is no way for the Board to determine whether “a person of ordinary skill in the art would have...had a reasonable expectation of success” in combining the embodiments in the matter claimed. *Personal Web Techs., LLC v. Apple, Inc.*, 848 F.3d 987, 991 (Fed. Cir. 2017). As such, there is simply insufficient evidence to support an obviousness determination. Accordingly, Aboul-Hosn does not teach or suggest the claimed “intravascular pump system” and/or “intravascular pump.” ***The Petition does not***

cite to Sammler to make up for these shortcomings. Accordingly, the Petition should be denied.

v. The Petition Mischaracterizes the Stabilization System—a Separately Disclosed Embodiment

Petitioners also once again rely on figures that, as the Board noted in its decision denying institution of the IPR2017-01029 Petition, “illustrate different embodiments of the present invention.” (IPR2017-01029, Paper 9, 9 (citing Ex. 1004, 30:20-21)). Petitioners point to Figures 21 & 23 as alleged support for the notion that *the reverse flow pump of Figure 3* that they’ve relied upon in their arguments would be inserted inside the patient’s vasculature, and as with the original petitions, this simply is not supported by Aboul-Hosn. (*See* Petition, 37-38). Indeed, Aboul-Hosn clarifies that if the reverse flow pump (50) of Figure 1-13 is to be used, it should be used with the configuration shown in Figure 24 (an extravascular pump configuration), not the configuration shown in Figure 23 (an internal, or intravascular, pump configuration). (Ex. 1004, 30:29-31:4).

vi. The Petition Improperly Relies on the Rotor Design of the Reverse Flow Pump of Aboul-Hosn to Teach the Claimed “Rotor”

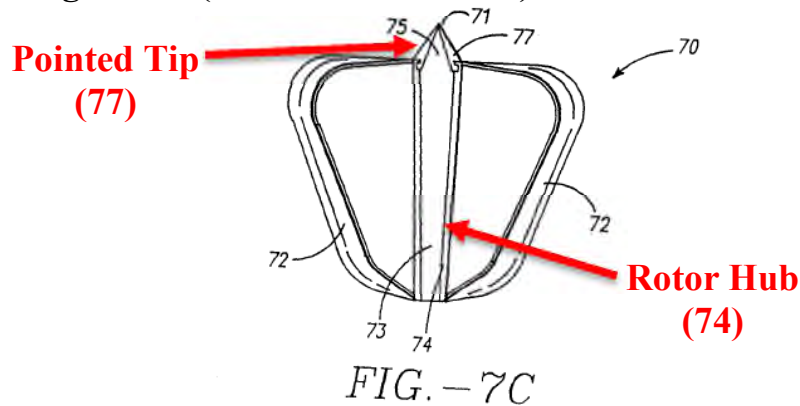
To allegedly render claim 10 obvious, specifically “an intravascular blood pump comprising a rotor having a rotor hub tapering in the distal direction and at least one blade extending radially outward from the rotor hub,” the Petition relies solely on Figure 7C and the related disclosure of Aboul-Hosn. (Petition, 39-40).

Petitioners mislead the reader by reciting: “[t]he *intravascular blood pump* of Aboul-Hosn has a rotor having a rotor hub.” (Petition, 39 (emphasis added)). But Figure 7C is directed to “a rotor for a *reverse flow pump* having a hub and blade portions.” (Ex. 1004, 9:2-3 (emphasis added)). Indeed, as previously discussed herein, the reverse flow pump of Aboul-Hosn cannot be used intravascularly. (*supra* §§ II(A)(1)(a)(i)-(v)).

Petitioners continue by quoting Aboul-Hosn: “FIGS. 7A-C ‘illustrate various configurations of a rotor 70 that may be used in a reverse flow pump or any other type of fluid transport apparatus.’” (Petition, 39 (quoting Ex. 1004, 16:30-31)). Petitioners, however, never explain why the POSITA would use this rotor design in conjunction with the intravascular pump they rely upon in Figures 21 and 23. Indeed, Petitioners do not even mention the intravascular pump of Figures 21 and 23 in conjunction with the rotor of Figure 7C. Without more, Petitioners’ arguments fail.

Irrespective of this error, the rotor design in Figure 7C is not the claimed rotor design.

Ex. 1004 at Figure 7C (Annotations in Red)



The claims require that the rotor have a “rotor hub tapering in the distal direction.” (Ex. 1001, 19:41). Aboul-Hosn’s hub illustrated in Figure 7C above as reference numeral 74, while having a pointed tip (77), has a rotor hub that tapers in the opposite direction, *i.e.*, it tapers in the proximal direction. Put another way, the rotor hub of Aboul-Hosn’s Figure 7C tapers almost entirely in the proximal direction—not the distal direction as required by Claim 10. For this additional reason, Aboul-Hosn fails to teach or suggest the claim elements.

The Petition does not cite to Sammler to make up for these shortcomings.

Accordingly, the Petition should be denied.

vii. The Petition Improperly Relies on Figure 23 of Aboul-Hosn to Teach an “Intravascular Blood Pump Coupled to a Catheter on a Proximal End and a Cannula on a Distal End”

Claim 10 recites: “the intravascular blood pump coupled to a catheter on a proximal end and a cannula on a distal end.”¹³ (Ex. 1001, 19:43-44). As is common throughout the Petition, Petitioners again rely on a nonsensical combination of Figures 1-12 and Figures 21 and 23 to meet this limitation. (Petition, 40-44). Moreover, Petitioners provide no reason that the POSITA would do so.

First, Petitioners rely on Figures 1 and 2 to assert that “the cannula 20 is connected to, and extends from, the inlet neck 62 of the housing cap 60 (green) that is coupled to the inlet tube 55 (green) within the housing body 52 that forms the shroud of the intravascular blood pump . . . [i]n such a formation, there is a direct connection between the cannula 20 and the shroud of the intravascular blood pump.” (Petition, 41). However, Petitioners have already admitted Figures 1 and 2

¹³ In the instant Petition, Petitioners feign ignorance as to what is meant by “the intravascular blood pump coupled to a catheter on a proximal end.” (Petition, 40). In the IPR2017-01029 Petition, which also challenged Claim 10, however, Petitioners failed to raise any issues pertaining to interpretation of this claim language. (IPR2017-01029, Paper 2, 36-40). As such, Petitioners’ “confusion” only arose after their arguments failed in IPR2017-01029.

disclose an extracorporeal pump. Specifically, on page 13 of the Petition, Petitioners state that “FIGS. 1 and 2 show an extracorporeal blood pump system” (Petition, 13, n.7). Accordingly, Petitioners’ challenge should be denied.

Second, with respect to “the intravascular blood pump coupled to a catheter on a proximal end,” Petitioners argue that the positioning rod 273 that is evidenced in Figures 1-13 “corresponds to a catheter.” (Petition, 42-43). Petitioners argue, with specific reference to Figure 12, that Aboul-Hosn discloses “that the positioning rod 273 includes a central passageway 275 ‘for passing wires, tubes or similar accessories needed by the drive unit 80’ when the blood pump is positioned within the vasculature.” (Petition, 42). However, the blood pump of Figure 12 is never inserted into the vasculature as demonstrated above (*supra* §§ II(A)(1)(a)(i)-(iii)), and the positioning rod 273 does not “correspond to a catheter.”

Aboul-Hosn never discloses that the positioning rod 273 includes any more than a passageway and never indicates that a catheter would be placed within the passageway. Aboul-Hosn does not provide such a disclosure because a catheter is unnecessary given that the Aboul-Hosn pump remains outside of the circulatory system. That is, a catheter may be a flexible tube that can be inserted into the body, and because the pump never extends into the body, no catheter is needed in Aboul-Hosn. (*See* Ex. 1002, ¶¶ 49, 53, 80, 86 (identifying various flexible catheters that

are inserted in the body); IPR2017-01029, Paper 2, 24-25 (describing a flexible catheter serving multiple functions, including guiding a pump to a predetermined location in the body)).

Further, positioning rod 273 is “made from metal or relatively stiff polymer” in order to be sufficiently rigid to transmit such torque and to push the pump into the conduit. (Ex. 1004, 14:18-15:3). Such rigidity is not desirable in a catheter because it would not allow anything inserted through the catheter to make the necessary turns through tortuous vessels. Conversely, if positioning rod 273 was sufficiently flexible to function as a catheter, it would be inoperable as a positioning rod. Accordingly, contrary to Petitioners’ assertions,¹⁴ positioning rod 273 does not “correspond to a catheter.”

Nevertheless, understanding their feeble argument with regard to the positioning rod, Petitioners predictably then cite to the stabilization systems of Figures 21 and 23. (Petition, 43). The Petition recites: “for placement in the heart, the multilumen catheter 428 is necessarily used in place of the positioning rod 273” and that “the multilumen catheter 428 and positioning rod 273 are interchangeable, and the catheter 428 can be configured to perform the same functions as the

¹⁴ Petitioners cite to the Collins declaration at paragraph 168. However, paragraph 168 provides nothing more than what is already presented in the Petition.

positioning rod 273.” (Petition, 43-44). However, there is no support for Petitioners’ assertion. Aboul-Hosn describes its catheter used with the stabilization system (*i.e.* catheter 428) as having “an elongated ***flexible*** shaft portion.” (Ex. 1004, 8:11-12). Catheter 428 is used to position an intravascular pump in the body and, as such, must be flexible to navigate the intravascular pump through the tortuous vessels leading to the heart. (Ex. 1004, 29:17-19). However, this flexibility would prevent catheter 428 from performing the same functions as the stiff positioning rod 273, namely positioning reverse flow blood pump 50 in the outer conduit 30. The stiffness of positioning rod 273 is necessary with regard to the specific extravascular pump of Aboul-Hosn to exert sufficient force on reverse flow blood pump 50 to position it in outer conduit 30 because outer conduit 30 has an inner diameter equal to the outer diameter of reverse flow blood pump 50, resulting in a hemostatic seal between the outside of the pump and the inside of the outer conduit. (Ex. 1004, 12:23-26). Accordingly, positioning rod 273 and catheter 428 are ***not*** interchangeable and ***cannot*** be configured to perform the same functions. Moreover, as described above, Petitioners provide no credible evidence that the reverse flow blood pump, having a specific rotor design, is the pump that is connected to multilumen catheter 428.

Irrespective of the theory, Petitioners are unable to make their case. The Petition either relies on the embodiment of Figures 1-13 that is designed to be

external to the circulatory system (or even the body) and is *missing a catheter* or on an *incompatible combination* of Figures 1-13 and Figures 21 and 23.

b. Aboul-Hosn fails to teach or suggest the claimed “a first set and a second set of apertures”

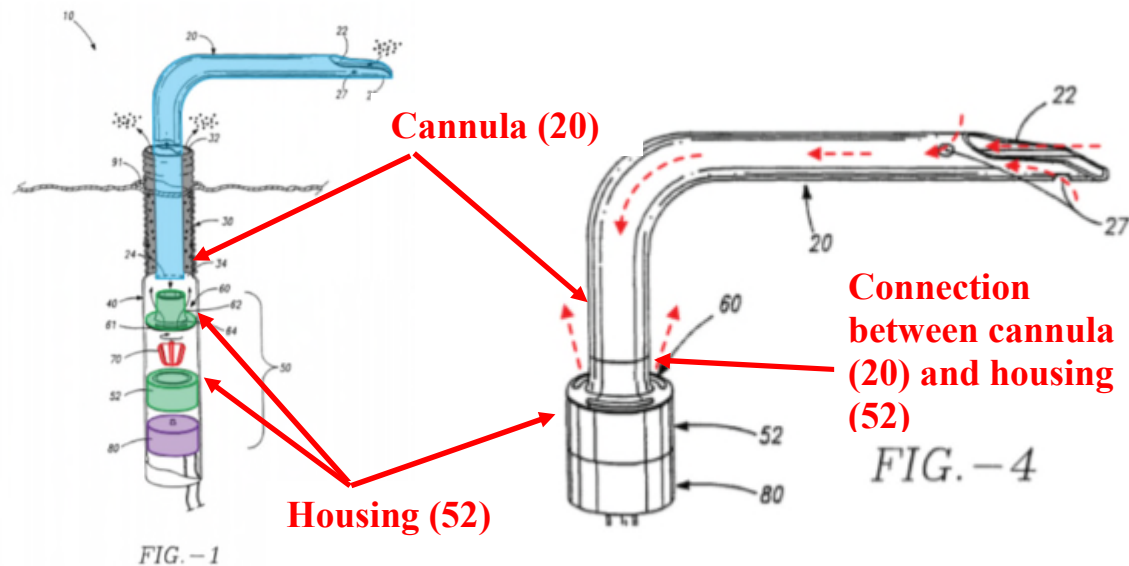
The Petition fails to demonstrate that Aboul-Hosn teaches, suggests, or discloses the claimed “a first set and a second set of apertures.” (Ex. 1001, 19:44-45). In particular, Aboul-Hosn does not disclose “a first set and a second set of apertures establishing fluid communication between an interior of the cannula and an exterior region of the cannula” or “the second set of apertures is spaced apart from and located distal to the first set of apertures,” as required by Claim 10. (Ex. 1001, 19:44-49). To allegedly meet this recitation, Petitioners assert that in Aboul-Hosn “the cut-outs 57 and/or the outflow windows 64” are the “first set of apertures” (Petition, 45), and the distal openings 27 of Aboul-Hosn are the “second set of apertures.”¹⁵ (Petition, 46). Such an interpretation of Aboul-Hosn is incorrect.

¹⁵ Petitioners improperly rely on the same structures in Aboul-Hosn for “a first set of apertures and a second set of apertures” recited in independent Claim 10 and “a plurality of egress flow ports...and a plurality of ingress flow ports” recited in Claim 13. (*Compare* Petition, 44-46 *with* Petition, 72-76).

Aboul-Hosn fails to teach that cut-outs 57 or outflow windows 64 lead directly out of the cannula so as to “establish[] fluid communication between an interior of the cannula and an exterior region of the cannula,” as recited in Claim 10. (Ex. 1001, 19:45-47). Instead, the cut-outs 57 are formed along inlet tube 55 to direct blood out of inlet tube 55 and into passageway 59 formed between inlet tube 55 and housing body 52. (Ex. 1004, 13:15-20). The outflow windows 64 are formed on base member 61 of housing cap 60 attached to the distal opening of housing body 52 and direct blood from passageway 59 out into outer conduit 30. (Ex. 1004, 13:4-7, 20-31).

Throughout the analysis, Petitioners are clear that the cut-outs 57 or outflow windows 64 are part of the housing of the pump and **not** part of the cannula. That is, until this recitation cut-outs 57 or outflow windows 64 are part of the housing body 52 (green) and not part of the inner cannula 20 (blue). (Petition, 44). This comparison is shown by Petitioners’ own annotations to Figure 1 compared to Figure 4.

Figures 1 (Petition, 31) and 4 (Petition, 46) (Annotations in Red).

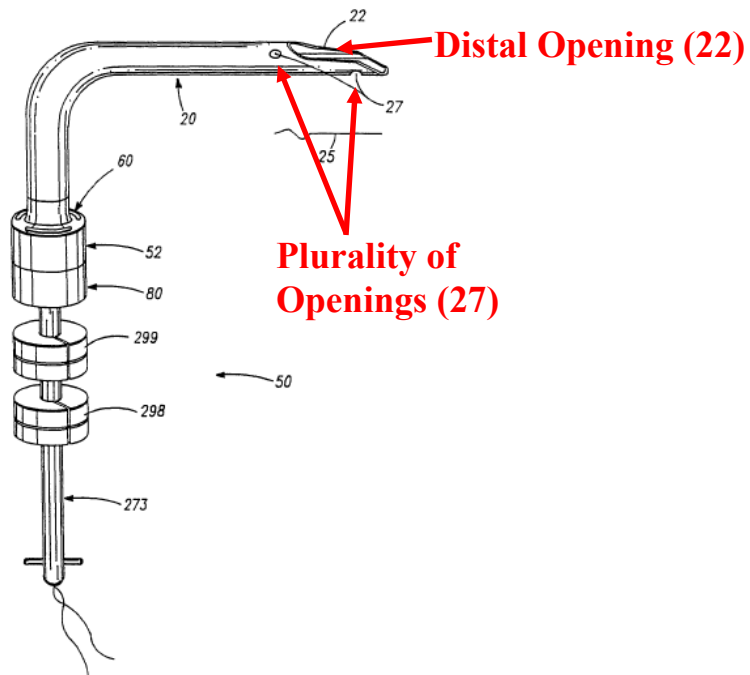


As such, while the cut-outs 57 and outflow windows 64 work together to allow blood to flow from inside the pump into the conduit, cut-outs 57 and outflow windows 64 do *not* “establish[] fluid communication *between an interior of the cannula and an exterior region of the cannula,*” as required by Claim 10. (Ex. 1001, 19:45-47 (emphasis added). In this regard, neither cut-outs 57 nor outflow windows 64 can be the claimed “first set of apertures.”

Indeed, an independent patent examiner confirmed such a reading of Aboul-Hosn. Specifically, in a Notice of Allowance for a related application having a common Examiner with the '068 Patent, the Examiner identified the distal opening 22 and plurality of openings 27 as being the only openings in the Aboul-Hosn cannula (Ex. 1054, 8 (“[N]one of the embodiments of Aboul-Hosn are compatible

with the claimed cannula having first and second ports....The cannula has **only** a distal opening and additional side openings (...distal opening 22 and plurality of openings 27).”) (emphasis added)). The distal opening 22 and plurality of openings 27 are shown in Figure 4 below:

Ex. 1004 at Figure 4 (Annotations in Red).



Moreover, the distal opening 22 and plurality of openings 27 overlap and thus it would be improper to classify them as being the two distinct openings. The Examiner confirmed. Specifically, the Examiner further indicated that, as shown in Figure 2 above, “distal opening 22 and plurality of openings 27 overlap, and therefore do not provide a second port spaced from the first port.” (Ex. 1054, 8).

As such, Aboul-Hosn fails to disclose the claimed apertures. *The Petition does not cite to Sammler to make up for these shortcomings.* Accordingly, Petitioners' arguments fail.

c. Aboul-Hosn Does Not Disclose the Guide Mechanism of the Challenged Claims.

The Petition fails to demonstrate that Aboul-Hosn teaches, suggests, or discloses: “a guide mechanism configured as an elongate lumen and adapted to guide said intravascular blood pump, cannula, and catheter to a predetermined location within the circulatory system of a patient.” (Ex. 1001, 19:50-53).

i. The Aboul-Hosn intravascular pump does not include the guide mechanism as claimed

The Petition asserts that Figures 3 and 12 of Aboul-Hosn render the claimed “guide mechanism” obvious. (Petition, 46-53). The Petition recites: “the guide wire 28 passes through a central passage (i.e. a lumen) that runs through the motor 80, the rotor 70, the housing cap 60, and the inner cannula 20, and then exits out of the distal opening 22 of the cannula.” (Petition, 46-47). Petitioners further cite to Figure 12 to “illustrate[] the introduction and positioning of Aboul-Hosn's intravascular blood pump system in the patient's circulatory system.” (Petition, 50). Again, Figures 3 and 12 relate to an embodiment where only the cannula is guided into the circulatory system. That is, the reverse flow pump is not configured to and, due to its size, cannot be guided into the circulatory system.

(*supra* §§ II(A)(1)(a)(i)-(iv)). Moreover, Figures 3 and 12 do not include the claimed catheter, but instead require a positioning rod. Accordingly, Figures 1-12 of Aboul-Hosn cannot teach or suggest the claimed guide mechanism.

The Petition then turns to Figures 21 and 23. (Petition, 54-60). As in the first round of petitions, Petitioners assert that Aboul-Hosn expressly teaches combining the embodiments of Figures 1-13 and Figures 21 and 23, however Petitioners' interpretation reads Fig. 24 out of the quote below:

Notably, with respect to FIGS. 21 and 23, Aboul-Hosn discloses that “Fig. 21 is a stabilization system provided *in accordance with the present invention* that is introduced through a femoral artery,” and “[t]he stabilization systems shown in *Figs. 23 and 24* illustrate only some of the various types of commercially available intravascular and extracorporeal pumps that *are* compatible or *provided for by the present invention.*”

(Petition, 55 (quoting Ex. 1004, 10:6-7, 31:6-9) (emphasis in Petition)). Consistent with this statement, Aboul-Hosn teaches that Figure 24 discloses “[a]n access conduit 433 such as a DacronTM graft may be formed to receive an extracorporeal pump 421, or a reverse flow pump such as those described above” (Ex. 1004, 30:30-31:1). That is, even if Petitioners' assertion about the present invention is correct, Aboul-Hosn explains that the reverse flow pump described in Figures 1-13 is one of the various types of available *extracorporeal* pumps that can be used with respect to Figure 24 (not Figure 23).

Petitioners further assert that because Aboul-Hosn also states that “the present invention provides a reverse flow pump system,” and because the reverse flow pump system includes the intravascular blood pump system of Figures 3, 4, and 12 for reasons presented elsewhere in the Petition, the stabilization system of Figures 21 and 23 uses the pump of Figures 3, 4, and 12. (Petition, 55 (quoting Ex. 1004, 6:6-8)). However, the “present invention” in the passage refers to stabilization system (410), not reverse flow pump (50). The surrounding text confirms (Ex. 1004, 30:20-31:9), and the Board has agreed. (IPR2017-1209, Paper 8, 12, n.1 (“The citation to Aboul-Hosn at page 31, lines 6 through 9, fails to provide adequate support for the specific modifications proposed by Petitioner and Dr. Collins.”)). Petitioners’ misguided reading of the quote does not provide them the requisite motivation to combine the distinct embodiments of Aboul-Hosn.

Irrespective, Figures 21 and 23 do not disclose the claimed guide mechanism at all. Petitioners assert that “Aboul-Hosn expressly discloses that intravascular blood pumps can be introduced percutaneously through the femoral artery, *as shown in FIG. 21.*” (Petition, 59 (citing Ex. 1004, 29:17-19) (emphasis added)). Petitioners also admit that a “POSITA would have readily understood that the *extracorporeal blood pump system would not have been used as an intravascular blood pump system shown in FIGS 21 and 23*” but double down on their argument that Figures 3, 4, and 12 show an intravascular blood pump. (Petition,

56-57 (emphasis added)). However, as previously discussed herein, all of Figures 1-13 illustrate an extravascular reverse flow pump that is not inserted into the body. (*supra* §§ II(A)(1)(a)(i)-(iv)). As such, Petitioners' arguments regarding Figure 21 fail ***based on their own admissions***.

Moreover, Petitioners imply that the embodiments of both Figures 21 and 23 disclose percutaneous insertion of a blood pump, which is not the case. (Petition, 59). Tellingly, Petitioners only cite to language in Aboul-Hosn regarding percutaneous insertion of the stabilization system and pump of Figure 21. (Petition, 59). Indeed, the embodiment of Figure 23 is not designed to be inserted percutaneously into the femoral artery and navigated through the circulatory system by way of a guide wire as is the claimed system. Instead, the embodiment of Figure 23 is designed for direct aortic insertion, ***not*** percutaneous insertion. (Petition, 54 (citing Ex. 1004, 30:21-24)). Figure 23 does not illustrate a guide wire and there is no need to include one, given that the stabilization system is designed to be introduced into the vasculature near the heart. This distinction is important as direct aortic insertion requires an invasive cutdown procedure in the aorta. (Ex. 2008, 394). This procedure opens up a major blood artery in order to provide a surgeon direct access to a patient's heart to facilitate device location. (*Id.*). In contrast, percutaneous insertion only involves inserting the device via a needle in the femoral artery. (*Id.*).

Expert Collins concurs that direct aortic insertion does not require a guide wire. Specifically, Collins states that *either* a catheter was used to position the pump *or* a surgical method was used, such as direct aortic insertion, to position the pump: “[i]ntravascular blood pump systems were delivered either percutaneously by catheter...or by a surgical approach that introduces the device directly into the vasculature near the heart.” (Ex. 1002, ¶ 59). That is, when the surgical method is used, no catheter or guide wire is used or needed. Because the text of Aboul-Hosn confirms that the embodiment of Figure 23 relates to a surgical approach that introduces the device directly into the vasculature near the heart, there is no need for a catheter or guide wire.

As such, neither the embodiment of Figures 1-13 nor the embodiment of Figures 21 and 23 relies on “a guide mechanism configured as an elongate lumen and adapted *to guide said intravascular blood pump, cannula, and catheter to a predetermined location within the circulatory system of a patient.*” (Ex. 1001, 19:50-53 (emphasis added)). Accordingly, the embodiments of Aboul-Hosn do not teach or suggest the elements of Claim 10.

ii. The central passage disclosed in Aboul-Hosn is distinct from the claimed guide mechanism

Petitioners assert that central passage of Aboul-Hosn corresponds to the claimed elongate lumen. (Petition, 46). However, the claims specifically require that the elongate lumen “is arranged *in series longitudinally* with the cannula.”

(Ex. 1001, 19:56-61 (emphasis added)). Notably, Petitioners admit that the alleged lumen of Aboul-Hosn is not designed in the same manner as they admit that the elongate lumen is continuous through the cannula. The Petition recites: “[c]orrespondingly, Aboul-Hosn discloses that the positioning rod 273 or catheter 428..., drive unit 80, rotor 70, and inner cannula 20 have respective lumens or central passages that are co-aligned to *create a single continuous lumen* through those components—consistent with the ‘over the wire’ guide mechanism of the ’068 Patent.” (Petition, 49 (emphasis added)). Because Aboul-Hosn teaches a single continuous lumen through the reverse flow pump of Figures 1-13, the lumen cannot be in series longitudinally with the cannula. Accordingly, for at least this additional reason, Petitioners fail to carry their burden.

d. Aboul-Hosn and Sammler Fail to Disclose a “Blood Pressure Detection Mechanism”

Petitioners first assert that the ’068 Patent does not explain what it means to “detect the pressure of the blood proximate the intravascular blood pump” or what constitutes the “fluid column” but proceeds to define these claim terms collectively to mean “a fluid column for transmitting blood pressure near the blood pump.” (Petition, 60). Petitioners then assert that Aboul-Hosn in view of Sammler discloses the claimed “blood pressure detection mechanism.” (Petition, 60). However, for the reasons discussed below, Aboul-Hosn and Sammler fail to disclose “a blood pressure detection mechanism comprising a fluid column

configured to detect the pressure of the blood proximate the intravascular blood pump,” as recited in Claim 10. (Ex. 1001, 19:54-56).

i. A POSITA Would Not Be Motivated to Combine Aboul-Hosn and Sammler

A POSITA would not be motivated to combine Sammler and Aboul-Hosn because Aboul-Hosn and Sammler are directed to significantly different devices.

Petitioners never explain why a POSITA would look to devices that were designed for different sides of the heart. Sammler is a right heart assist device as it is designed to be placed through the right atrium and the right ventricle. In contrast, the embodiment relied upon by Petitioners in Aboul-Hosn is for left heart replacement.

Insertion principles on the left side are very different than insertion principles on the right side in three primary ways. First, on the left side of the heart, a guidance mechanism is required that allows the pump to advance against the flow, whereas, on the right side, once the device reaches the right atrium, the device will move with the blood flow. Another notable distinction is that on the left side of the heart, the extent of curvatures are less severe than the right side, which has two sharp turns. The final primary difference is that on the left side the device is inserted against the valve, whereas on the right side, both valves are aligned with both the flow and insertion directions. Because of the alignment of the direction of insertion path with the direction of flow, once in the right atrium, floating balloons

are commonly used as the first member to be positioned in the vasculature, followed by possible insertion of guide wires and the rest of the system. On the left side, however, the direction of insertion is opposite to the direction of blood flow. Therefore, a stiffer guide wire is commonly used first to overcome the incoming blood flow and cross the aortic valve. As a result, the guidance mechanism of right-sided devices is very different than left-sided devices of any kind, including intravascular blood pumps.

Foregoing the requirements for demonstrating obviousness, Petitioners fail to meet their burden. Indeed, Petitioners make no attempt to reconcile these differences between Sammler and Aboul-Hosn but instead merely assert that a “POSITA would have been motivated to configure Aboul-Hosn’s intravascular blood pump system to detect blood pressure in the manner taught by Sammler.” (Petition, 64). Petitioners provide little support for this assertion by solely identifying that both Sammler and Aboul-Hosn contemplate measuring blood pressure and equipping Aboul-Hosn with the blood pressure mechanism of Sammler would “provide[] a more efficient way of measuring blood pressure within the inner cannula using the preexisting structure of Aboul-Hosn’s intravascular blood pump system without the need to significantly reconfigure the system or its components.” (Petition, 65). This conclusory analysis fails to consider the clear distinctions between Aboul-Hosn and Sammler discussed above that

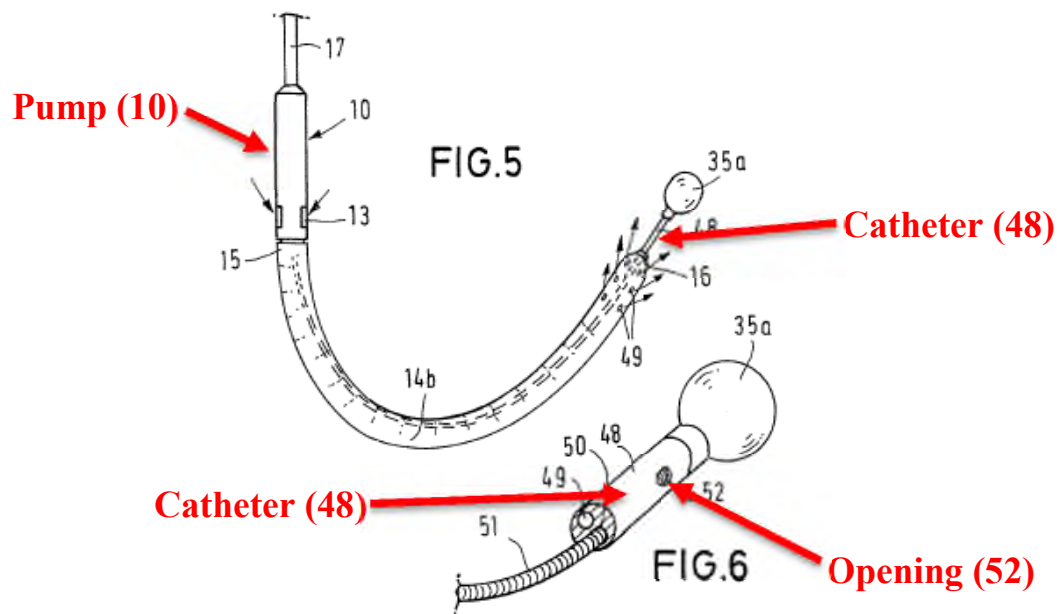
would render the combination inoperable. Accordingly, Petitioners’ cursory analysis is insufficient to meet Petitioners’ burden and fails as a matter of law. *Personal Web Techs., LLC v. Apple, Inc.*, 848 F.3d 987, 993-94 (Fed. Cir. 2017) (rejecting “reasoning [that] seems to say no more than that a skilled artisan, once presented with the two references, would have understood that they *could be* combined”) (emphasis in original). In fact, Petitioners cannot assert anything to the contrary, as in previous papers, they have previously argued before this Board that the guide mechanism of Sammler is incompatible with an intravascular blood pump configured for left heart support. (Ex. 2009, 4-6, 26-27).

ii. Neither Aboul-Hosn nor Sammler Measures Blood Pressure “Proximate the Intravascular Blood Pump”

Petitioners assert that “Aboul-Hosn’s intravascular blood pump system can be configured to detect the blood pressure proximate the intravascular blood pump, at the distal end of the rotor 70, using a fluid-filled lumen extending through the pump system’s components and connected to a blood pressure measuring instrument as taught by Sammler.” (Petition, 64). However, neither Aboul-Hosn nor Sammler measures pressure in the claimed location, *i.e. proximate the intravascular blood pump*.

Petitioners rely on Sammler to meet this recitation. Specifically, Petitioners propose modifying Aboul-Hosn to measure pressure at the location taught by

Sammler (*i.e.* opening 52). (Petition, 61-63). As shown in Figures 5 and 6 below, opening 52 of Sammler is positioned at the end of its device and is not proximate the intravascular blood pump. Petitioners confirm: “[t]he lumen 50 is ‘connected to a blood pressure measuring instrument’ to measure the blood pressure ***adjacent the opening 52.***” (Petition, 62 (citing Ex. 1002, ¶ 214; Ex. 1045, 6:10-12) (emphasis added)).



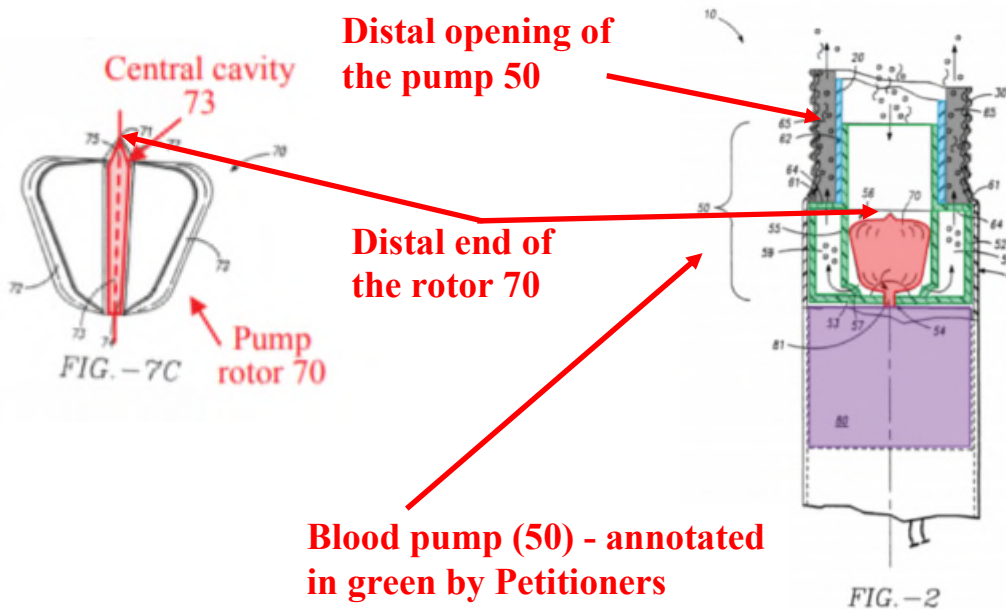
lumen to *detect the blood pressure at an opening* that is exposed by the removal of the guide wire as taught by Sammler.” (Petition, 63 (emphasis added)). Again, the opening is at the distal tip of the cannula and not proximate the pump. Petitioners’ arguments fail because there are no teachings in either reference to support measurement proximate the blood pump.

Petitioners then argue that pressure would be measured internal to the pump at the distal opening of the central passageway 73 of the pump rotor 70. (Petition, 65). This argument fails because the references cited allegedly teach the measurement of blood pressure only at the distal tip of the cannula, and Petitioners provide no support as to why the POSITA would relocate the measurement position. Moreover, measuring blood pressure at the distal opening of the central passageway 73 is internal, but not proximate, to the pump.

The Petition is clear that the blood pressure measurement is taken at the distal end of the rotor. (Petition, 64 (“Thus, Aboul-Hosn’s intravascular blood pump system can be configured to detect the blood pressure proximate the intravascular blood pump, *at the distal end of the rotor 70*....”) (emphasis added); *see also* Petition, 65). There is no dispute between the parties that the distal end of the rotor 70 is within the intravascular pump itself. (See *e.g.*, Petition 14, 30 (“The blood pump includes the rotor 70 (red) disposed within an inlet tube 55 of the housing body 52 (green), and connected to the drive unit 80 (purple)....”). As is

shown in Figures 7C and 2 below, the pump spans the distal opening of the housing cap 62 and terminates at the proximal edge of the housing body 52. The distal tip rotor is 70 is illustrated in Figure 2 as being within pump 50.

Figures 7C (Petition, 63) and 2 (Petition, 45) (Patent Owner's Annotations in Red Bold).



Measuring pressure inside the intravascular blood pump cannot be *proximate* the intravascular blood pump. As confirmed by Petitioners, “to detect the pressure of the blood proximate the intravascular blood pump” means “at the opening of the blood pump or the cannula.” (Ex. 2010, 55). Given that the area where Petitioners assert blood pressure is measured is inside the pump and not “at the opening of the blood pump or the cannula,” Petitioners fail to demonstrate that the combination of references teaches or suggests “detect the pressure of the blood *proximate* the intravascular blood pump.”

Moreover, measuring pressure inside the intravascular blood pump, a location proposed by Petitioners and distinct from the claimed invention, simply would not work. A POSITA would understand that the primary purpose of measuring blood pressure proximate to a blood pump is location sensing and monitoring blood flow. (Ex. 2006, 650-659). That is, the pressure measurement confirms that the pump is placed properly in the ventricle and that the blood flow is sufficient. To achieve this measurement, the blood pressure detection mechanism must measure pressure in the vasculature proximate the pump. It is inapposite to measure pressure within the pump because such an internal measurement would not be an accurate indicator that the pump is positioned and operating properly.

Under Petitioners' theories, the alleged fluid column of Aboul-Hosn would be required to support blood pressure measurement during the operation of the device. However, to use a fluid column based pressure sensing mechanism as asserted by Petitioners, the fluid column should be disturbed as little as possible to ensure accurate measurement. (Ex. 2007, Slide 25). Similarly, the fluid column should be protected from distortion to avoid the introduction of artifacts into the pressure waveform. (Ex. 2007, Slide 27). The presence of the rotating impeller of Aboul-Hosn, however, would impart significant disturbances to any signal transmitted through such a fluid column. (Ex. 2007, Slide 27; Ex. 2003, 146). Indeed, any blood in a lumen within the pump would suffer from extreme agitation

as a result of the vibrations of the rotor as it is spinning at 30,000 rotations per minute, and such a disturbance would have adverse effects on the fluid column. As such, measuring pressure via a fluid column that runs through the rotating impeller of Aboul-Hosn, as asserted by Petitioners, would be impractical and even impossible.

Further, even if Petitioners' arguments are to be interpreted as internal to the device, but not internal to the pump (*i.e.* a measure of the fluid filled column directly before said column enters the pump), this argument would likewise fail. Again, Aboul-Hosn discloses a reverse flow pump, which when in operation, would cause an extreme negative pressure (*i.e.* vacuum) at the distal tip of the pump due to routine pump operation. (Ex. 2003, 146). Such pressure again negatively effects the pressure reading, rendering Petitioners' asserted "blood pressure detection mechanism" inoperable or, at the very least, inaccurate.

Accordingly, Petitioners fail to demonstrate that the asserted combination of Aboul-Hosn and Sammler discloses "a blood pressure detection mechanism comprising a fluid column to detect the pressure of the blood proximate the intravascular blood pump." (Ex. 1001, 19:54-56).

e. Petitioners' Ground 1 Fails to Disclose the Claimed Method

To allegedly teach the claimed method steps, Petitioners again rely on their arguments with regard to Aboul-Hosn's Figure 12 and improperly combining the

embodiment of Figures 1-12 with the embodiment of Figures 21 and 23. (Petition, 70-72). For at least the reasons discussed *supra* at §§ II(A)(1)(a)(i)-(v), Petitioners' arguments fail.

For example, as discussed *supra* at § II(A)(1)(a)(iii), Petitioners rely heavily upon certain Figures of Aboul-Hosn to meet several limitations of Claim 10, in particular, Figure 12, and in doing so contort the actual disclosure of Aboul-Hosn to claim that the pump is "in the process" of being positioned. (Petition, 34). As discussed above, this is flatly controverted by Aboul-Hosn itself. Moreover, it also demonstrates that Petitioners have not met their burden in demonstrating that Claim 10's "advancing the blood pump system along the guide wire to the predetermined location" limitation. (Ex. 1001, 19:64-65).

Claim 10 makes clear that the predetermined location is "in the circulatory system," and that the pump system is "an intravascular blood pump system." (Ex. 1001, 19:38-65). The fact that the blood pump is intravascular requires that when the system is advanced to the predetermined location, the pump itself must be within the circulatory system. The reverse flow pump of Aboul-Hosn is not intravascular, and the pump is not in the circulatory system when Aboul-Hosn's pump system is advanced. ***The Petition does not cite to Sammler to make up for these shortcomings.*** As such, Petitioners have failed to disclose the claimed method limitations.

f. Ground 1 Fails to Invalidate Dependent Claims 13-15

Ground 1 also fails to invalidate any dependent claims in the '068 Patent. As previously discussed herein, no combination of Aboul-Hosn and Sammler teaches or suggests the intravascular blood pump system of Claim 10. Because dependent Claims 13-15 depend either directly or indirectly from Claim 10, Petitioners arguments likewise fail with regard to Claims 13-15 (*supra* §§ II(A)(1)(a)-(e)).

2. Aboul-Hosn Fails to Anticipate Claim 20 (Ground 2)

Relying on many of their previous arguments alone, Petitioners assert in Ground 2 that Aboul-Hosn anticipates Claim 20. (Petition, 80). “A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. v. Union Oil Co. of Cal.*, 814 F.2d 628, 631 (Fed. Cir. 1987). However, as previously discussed herein, Petitioners have failed to demonstrate that Aboul-Hosn ***renders obvious*** at least the claimed intravascular blood pump (*supra* § II(A)(1)(a)), the claimed elongate lumen “arranged in series longitudinally with the cannula” (*supra* § II(A)(1)(c)(ii)), and the claimed method steps. (*supra* § II(A)(1)(e)). Because Aboul-Hosn fails to render obvious these claim limitations of Claim 10, which are similarly recited in Claim 20, Aboul-Hosn likewise fails to anticipate Claim 20.

III. PERSON OF ORDINARY SKILL

The POSITA is not an extraordinarily innovative person, nor a researcher of inexhaustible patience, but is a person who thinks conventionally in matters affecting the art in which he or she is skilled. *Standard Oil Co. v. Am. Cyanamid Co.*, 774 F.2d 448, 454 (Fed. Cir. 1985). As discussed above, the present invention involves complex technology and numerous design considerations that must be balanced. Many of these are not readily apparent; thus, a POSITA would need practical design experience in the relevant field. A POSITA for the present invention would have to have either: (1) an undergraduate degree in mechanical engineering or bioengineering or similar subject matter and at least 10 years of experience designing intravascular heart assist devices; or (2) have an advanced degree in mechanical engineering or bioengineering (either a masters, Ph.D., or equivalent course work) and at least five years of experience designing intravascular heart assist devices.

In response to Patent Owner's arguments in the first set of preliminary responses pointing out that Dr. Collins is not a POSITA, Petitioners have bolstered Dr. Collins' "experience" in defense of his role as a POSITA. However, this enhanced section still does not demonstrate that he is a POSITA. For instance, while Petitioners stress that Collins has experience in designing devices, there is simply no evidence of that. (Petition, 27). Specifically, Petitioners state: "Dr.

Collins was not ‘merely familiar with devices’ but was involved in the design of a variety of medical devices, including intravascular heart assist devices, as detailed in his Declaration and accompanying CV.” (Petition, 27). To support this statement, Petitioners rely on Dr. Collins statements at paragraph 37 of his declaration. However, even after pointing out the shortcomings in its original Petition, *Petitioners never mention that Dr. Collins specifically has experience with “intravascular blood pumps.”*

Tellingly, Petitioners never quote Dr. Collins’ declaration. If they had, it would be readily apparent that Dr. Collins never identifies any work with an intravascular blood pump but instead to unrelated “vascular and intravascular medical devices.” (Ex. 1002, ¶ 37). Dr. Collins never identifies any of the medical devices as intravascular blood pumps nor attempts to explain why any of these products provide him with the necessary knowledge to be a POSITA. As such, Dr. Collins is not a POSITA, and the Board should disregard Dr. Collins’ Declaration.

IV. CONCLUSION

For at least the foregoing reasons, Petitioners have failed to meet their burden under 37 C.F.R. § 42.108(c), and Institution must be denied.

Dated: January 4, 2018

Respectfully submitted,

/Christopher TL Douglas/

Michael S. Connor (Reg. No. 34,141)

S. Benjamin Pleune (Reg. No. 52,421)

Christopher TL Douglas (Reg. No. 56,950)

Lauren E. Burrow (Reg. No. 70,447)

Attorneys for Patent Owner

Maquet Cardiovascular LLC

V. CERTIFICATE OF WORD COUNT

Pursuant to 37 C.F.R. § 42.24, the undersigned attorney for the Patent Owner, Patent Owner declares that this Patent Owner's Preliminary Response (Sections I-IV) has a total of 13,950 words, according to the word count tool in Microsoft Word™.

Dated: January 4, 2018

Respectfully submitted,

/Christopher TL Douglas/

Michael S. Connor (Reg. No. 34,141)
S. Benjamin Pleune (Reg. No. 52,421)
Christopher TL Douglas (Reg. No. 56,950)
Lauren E. Burrow (Reg. No. 70,447)

*Attorneys for Patent Owner
Maquet Cardiovascular LLC*

VI. CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. §42.6(e), the undersigned hereby certifies that, on January 4, 2018, a true copy of the foregoing “PATENT OWNER’S PRELIMINARY RESPONSE” and its cited exhibits for this *inter partes* review was served upon the following via email:

David M. Tennant (Reg. No. 48,362)
E-mail: WCABiomedIPR@whitecase.com

/Christopher TL Douglas/
Christopher TL Douglas
Reg. No. 56,950