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 EXHIBIT 2009

FILED ELECTRONICALLY

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Appl. No.	:	10/566,423	Confirmation No. 2985
Applicant	:	Thorsten Siess	
Filed	:	January 30. 2006	
Art Unit	:	3766	
Examiner	:	Dinga, Roland	
Title	:	AN INTRACARDIAC PUMPING DEVICE	
Client/Matter		IMPEL 72926	
Customer No.	:	68,919	April 24, 2012

Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

APPEAL BRIEF

Dear Sir:

This Appeal Brief is being filed pursuant to the Notice of Appeal that was filed on January 9, 2012 in response to the Final Office Action of August 9, 2011 and the Advisory Action of December 12, 2011. A Pre-Appeal Brief Request for Review was filed January 9, 2012 and a Notice of Panel Decision was issued on February 27, 2012 setting a deadline for filing an Appeal Brief of March 27, 2012. A request for a one month extension of time along with the requisite fees is being filed herewith.

INTRODUCTION

The present invention relates to an intracardiac pump, and more particularly, to a pump configuration that prevents pump suction from causing injury to heart tissue. The claimed pump configuration includes a spacer element that extends from the inlet portion of the pump to prevent the pump from becoming adhered to heart tissue by suction.

The present application, US Serial No. 10/566,423, was filed January 30, 2006 based on a PCT filing and claiming priority from DE 103 36 902.3 filed August 8, 2003

I. REAL PARTY IN INTEREST

The real party in interest in this appeal is ABIOMED EUROPE GMBH, Neuenhofer Weg 3, 52074, Aachen, Germany. This patent application was originally assigned by the inventor THORSTEN SIESS to IMPELLA CARDIOSYSTEMS GMBH, Neuenhofer Weg 3, 52074, Aachen 52074, Germany by Assignment executed January 4, 2006, which was recorded by the U.S. Patent Office on January 30, 2006, beginning at Reel 017530, Frame 0215. Ownership of the patent rights were subsequently transferred to ABIOMED EUROPE GMBH.

II. RELATED APPEALS AND INTERFERENCES

None.

III. STATUS OF CLAIMS

The present application was originally filed with claims 1-9. Claims 1-3 and 5-9 as amended, are currently pending, are under final rejection and are being appealed herewith.

A clean copy of the claims being appealed is appended as Exhibit 1.

IV. STATUS OF AMENDMENTS

A response to the Final Office Action of August 9, 2011 in which no claims were amended was filed on November 9, 2011. In the Advisory Action of December 12, 2011, it was indicated that the applicant's arguments were not found to be persuasive.

V. SUMMARY OF THE CLAIMED SUBJECT MATTER

Claims 1-3 and 5-9 are directed to an intracardiac pump.

Independent Claim 1:

Independent claim 1 is supported in the specification and in the drawings as follows:

1. An intracardiac pumping device (Fig. 1, #11-21) for percutaneous insertion, comprising a pump (Fig. 1, #11) connected at the proximal end (Fig. 1, #12) with a catheter (Fig. 1, #14) and at the suction-side distal end (Fig. 1, #13) with a canula (Fig. 1, #15) having inlet openings (Fig. 1, #17) remote from the pump (spec page 4, lines 18-20), characterized in that a flexible pigtail tip (Fig. 1, #20, 21) is provided at the canula distal of all of the inlet openings (spec page 2, lines 7-8), wherein said flexible pigtail tip forms a spacer for keeping said inlet openings spaced apart from adjacent heart walls (Fig. 1, #H; spec page 2, lines 8-10).

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Pursuant to the final Office Action mailed August 9, 2011, the claims were rejected as follows:

Claims 1-3 and 4-9 were rejected under 35 U.S.C. § 103(a) as obvious over Siess et al (WO 2002/043791 per the translation in US2004/0044266) in view of Sammler et al (USPN 6,544,216) and further in view of Garcia (USPN 5,037,403).

VII. ARGUMENT

The present invention provides an intracardiac pump, and more particularly, a pump configuration that prevents pump suction from causing injury to heart tissue. None of the three references being relied upon by the Examiner recognizes any potential for problems that may arise when the inlet portion of a high capacity pump is inserted into the heart and its inlet is sucked up against and becomes adhered to heart tissue during operation of the pump. Moreover, none of the references recognize that such problem is exacerbated by the substantial movement a pump in such an orientation relative to the heart is subjected to during each pumping cycle of the heart (the pump's suction tends to pull it into the heart during diastole while it is prone to ejection from the heart during systole) which can frustrate efforts to avoid contact between the heart wall and the pump inlet. Not surprisingly, none of the references suggest a solution to such problems, let alone the particular solution that is being claimed in the rejected claims.

The primary reference that is being relied upon by the Examiner comprises one of the present inventor's own patents. It is directed to an **intravascular** pump devoid of any spacing elements adjacent its proximal port nor distal port, either of which could serve as inlet in view of the disclosure that flow can be pumped through the device in either direction. It is to be noted that the reference lacks any discussion or even a recognition of the potential danger for irritating or injuring heart tissue that could result should the inlet ports become sucked up against heart tissue during the operation of the pump in the event the pump is for some reason used as an **intracardiac** device and its inlet is inserted into a heart chamber.

Accordingly, motivation is clearly lacking in this reference for taking any steps or making any modification in an effort to mitigate a problem that is not recognized thereby.

The Examiner then attempts to rely on the teachings of the secondary Sammler et al reference in an effort to overcome the above-described fundamental shortcoming of the primary reference by pointing to the guiding element (Figs. 4-6, # 35a, 46, 48) that extends from the distal end of the intracardiac pumping device. While the Examiner focuses on the fact that the guiding element extends from the distal end of the device, he ignores the fact that such guiding element is in fact shown and described as extending from the **outlet** end of the device and indeed must extend from the outlet end. The present invention on the other hand absolutely requires and the claims unequivocally call for the spacer element to be positioned so as to keep the **inlet** openings spaced apart from adjacent tissue. The guiding element of the Sammler reference is incapable of maintaining the inlet openings 13 spaced apart from tissue in view of the fact that the inlet openings are positioned on the opposite end of the device. Moreover, it is absolutely imperative for the guiding element to be positioned adjacent the outlet end of the device in order for Sammler's guide element to perform its stated function, i.e. to guide by being "entrained by the natural blood flow" and thereby be "washed via the natural blood path first into the right ventricle 24 and then into the pulmonary artery 26" (col 4, lines 1-4). Since the inlet of a pumping device is necessarily upstream relative to the natural blood flow, a repositioning of Sammler's "guiding element" adjacent to the inlet would not be expected to be able to guide the downstream end of the device. Sammler therefore unequivocally teaches the positioning of the guiding element adjacent to outlet end of the pumping device.

In the "clarification" attached to the Panel Decision from Pre-Appeal Brief Review, the Examiner further offers that the Sammler reference was added the primary reference to show that a flexible catheter with the balloon could be added at the distal end of the cannula as shown in Figures 4-6 in order to act as a guiding element for the catheter. As is set forth above, in order for the described guiding element to be able to guide the device shown in Figures 4-6, it would be necessary for the distal end to serve as the outlet, not the inlet for blood flow. In distinction thereto, the rejected claims unequivocally call for the pump to be configured such that its distal end comprises its suction side, i.e. inlet end, and that the spacer element is to be positioned so as to keep the inlet spaced apart from adjacent tissue.

Finally, the Examiner relies on the Garcia reference to substitute the pigtail described therein for the catheter and balloon guiding element taught by Sammler. In view of the fact that Sammler absolutely requires the guiding element to be attached to the outlet end of the pumping device as was established above, substitution of Garcia's pigtail therefor (which incidentally is also shown as being attached to the **outlet** end of a device) would not somehow result in a shifting of its point of attachment from the outlet side to the inlet side of the pumping device as is required in the rejected claims.

At the very best, combining the three references would result in a structure in which a pigtail tip is attached to the outlet end of a pumping device. There is absolutely no motivation to attach the pigtail to the inlet of a pumping device as it would not be capable of guiding by entrainment in the natural blood flow as per Sammler nor preventing recoil during high pressure injection as per Garcia. None of the three references recognize any need for keeping the inlet end of a pumping device spaced apart from tissue. No motivation, other than the present patent

application, is identified for rearranging the elements of the three references to arrive at the structure as claimed.

In response to the applicant's position that there is an utter lack of motivation for combining the references in the manner set forth in the Examiner's rejection, the Examiner points out that there is no requirement that a motivation to make a modification need be expressly articulated. The applicant agrees but points out that not only is an express articulation lacking, but even the mere implication, insinuation or inference of a motivation for doing so is lacking. None of the three references alone or in combination even recognize, let alone address the problem of preventing injury to heart tissue due to the suction of the pump. The primary reference lacks altogether any element attached to the inlet end of the pump while both of the secondary references merely teach the attachment of various elements to the outlet end of devices that can necessarily only perform their intended functions at the outlet or downstream end of the respective devices. As such, the combination of disclosures taken as a whole do not suggest any modification of the inlet end of an intracardiac pump. It is respectfully submitted that the combination of the references as proposed by the Examiner merely amounts to an arbitrary rearrangement of parts and that only the present patent application provides **any** motivation for even modifying the inlet end of an intracardiac pump, let alone in the particular configuration that is being claimed.

The Examiner had also previously argued that the modification of Sammler to have a pigtail tip would achieve the predictable result of minimizing trauma. Again, the Examiner is ignoring the fact that the modification of Sammler to have a pigtail tip would result in the pigtail tip being attached to the outlet end of the pumping device. As such, the pigtail tip would be incapable of minimizing trauma that would be caused by the inlet being sucked up against heart tissue. It is

respectfully submitted that combining the teachings of the references that are being relied upon by the Examiner would only predictably result in the positioning of a pigtail on an intracardiac pump where there is no danger of a suction-related injury. In contrast thereto, the unexpected result that is provided by the present invention is that the attachment of a pigtail to the inlet end of an intracardiac pump serves to protect heart tissue from injury that the cited references do not even recognize as being at risk.

In sum, the present invention provides a simple and elegant solution to a problem that is not recognized by the cited art. Moreover, the combination of elements that appear in the cited art in the manner taught by the cited art would not result in the structure as it is being claimed. Attachment of a pigtail to the inlet end of an intracardiac pump is simply not taught or suggested nor justified by a fair reading of the cited art.

Finally, it must also be noted that the Examiner has not identified any teachings in the cited art relating to certain elements that are specifically claimed in the dependent claims. More particularly, claim 5 calls for the inlet openings to be provided in an expansible suction basket including an inflow funnel. Such claimed structure was ignored in the rejections. Claim 8 calls for a guide wire to be provided that leads through the pump and into the pigtail. Again, this structure was not addressed in the rejections. Finally, claim 9 calls for the pigtail to have lateral auxiliary openings. No teaching was relied upon to reject this claim.

VIII. CLAIM APPENDIX

See Exhibit 1.

IX. EVIDENCE APPENDIX

None.

X. RELATED PROCEEDINGS APPENDIX

None.

XI. CONCLUSION

As argued above, it is respectfully submitted that the present invention as claimed is not obvious in view of the cited reference. Reversal of the rejection of claims 1-3 and 5-9 is therefore respectfully requested.

Respectfully submitted,

FULWIDER PATTON LLP

/Gunther O. Hanke/
Gunther O. Hanke, Reg. No. 32,989

LIST OF EXHIBITS

EXHIBIT	DESCRIPTION
1	Appealed Claims

EXHIBIT 1

Claims on Appeal:

1. An intracardiac pumping device for percutaneous insertion, comprising a pump connected at the proximal end with a catheter and at the suction-side distal end with a canula having inlet openings remote from the pump, characterized in that a flexible pigtail tip is provided at the canula distal of all of the inlet openings, wherein said flexible pigtail tip forms a spacer for keeping said inlet openings spaced apart from adjacent heart walls.

2. The pumping device of claim 1, wherein the pigtail tip comprises a non-sucking projection.

3. The pumping device of claim 1 wherein the pigtail tip comprises a hollow hose whose lumen is in communication with that of the canula.

5. The pumping device of claim 1, wherein the inlet openings are provided in an expansible suction basket including an inflow funnel.

6. The pumping device of claim 1, wherein the pigtail tip has an outer diameter that is smaller than that of the canula.

7. The pumping device claim 1, the canula has a preformed bend.

8. The pumping device of claim 1, wherein a guide wire is provided that leads through the pump and is adapted to be advanced from the canula into the pigtail tip.

9. The pumping device of claim 1, wherein the pigtail tip has lateral auxiliary openings.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/566,423	01/30/2006	Thorsten Siess	IMPEL.72926	2985

24201 7590 09/25/2012

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EXAMINER	
DINGA, ROLAND	
ART UNIT	**PAPER NUMBER**
3766	

NOTIFICATION DATE	DELIVERY MODE
09/25/2012	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/566,423
Filing Date: January 30, 2006
Appellant(s): SIESS, THORSTEN

Gunther O. Hanker
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 04/24/2012 appealing from the Office action mailed 08/09/2012.

(1) Real Party in Interest

The examiner has no comment on the statement, or lack of statement, identifying by name the real party in interest in the brief.

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The following is a list of claims that are rejected and pending in the application:

Claims 1-3 and 5-9.

(4) Status of Amendments After Final

The examiner has no comment on the appellant's statement of the status of amendments after final rejection contained in the brief.

(**5) Summary of Claimed Subject Matter**

The examiner has no comment on the summary of claimed subject matter contained in the brief.

(6) Grounds of Rejection to be Reviewed on Appeal

The examiner has no comment on the appellant's statement of the grounds of rejection to be reviewed on appeal. Every ground of rejection set forth in the Office

action from which the appeal is taken (as modified by any advisory actions) is being maintained by the examiner except for the grounds of rejection (if any) listed under the subheading "WITHDRAWN REJECTIONS." New grounds of rejection (if any) are provided under the subheading "NEW GROUNDS OF REJECTION."

(7) Claims Appendix

The examiner has no comment on the copy of the appealed claims contained in the Appendix to the appellant's brief.

(8) Evidence Relied Upon

5,037,403	Garcia		08-1991
6,544,216	Sammler et al		04-2003
20040044266	Siess et al		03-2004
WO2002/043791	Siess et al	06-2002	06-2002

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1-3 and 5-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Siess et al (WO 2002/043791,herein Siess), relying on the translation provided by the US national stage application (US2004/0044266) of that international application pending any request by appellant for a machine translation (in view of Sammler et al (US6544216) previously cited) and further in view of Garcia (US 5,037,403).

3. Regarding claims 1-3,6-8, Siess discloses a pumping device (10) percutaneous insertion[see figures 12; abstract;[0026]]. Catheter (13) connect the pump 10 at it proximal end and at the suction side distal end with a cannula (18) having inlet 24 openings remote from the pump (10)[FIG.1-2;[0026](in the case opening (17) is considered “outlet" and (24) “inlet")]. Siess discloses an opening for passage of guidewire (34)[fig.1-2,9-15;[0036,0038] and in claim 6]. Siess failed to disclose a flexible projection provided at the cannula distal of all of the inlet openings, wherein the flexible projection forms a spacer for keeping the inlet openings spaced apart from adjacent heart walls. However, Sammler discloses a flexible projection (see elements 46,48)[FIG.4-6] at the distal end of cannula (14a,14b) [FIG.4-6] , the flexible projection (46,48) is capable of forming a spacer for keeping the distal end of the cannula spaced apart from adjacent heart walls[FIG.4-6]. The projection has an opening (49)[FIG.6] and projection (46,48) has an outer diameter that is smaller than that of the cannula(14a,14b) and projection is a hollow hose whose lumen (49,50) is in communication with that of the cannula (14a,14b)[FIG.4-6]. Thus, it would have been obvious to one with ordinary skills in the art by the time the invention was made to modify Siess with the flexible projection of Sammler in order to achieve the predictable

results of prevent the distal end of the cannula from touching the heart walls and blocking the inlet. Neither Siess nor Sammler discloses a pigtail tip. Garcia discloses that the distal end of catheter (10) defines a "pigtail" (18) that is to stay a spiral section as shown [see figure.1; col.3, lines 39-40; col.2, lines 53-68]. Thus it would have been obvious to one with ordinary skills in the art by the time the invention was made to modify Sammler to have a pigtail tip in view of Garcia since to substitute one apparatus for the other to achieve the predictable result of minimizing trauma [Col.2, lines 61-62].

4. Regarding claim 5, Siess discloses an inlet opening (24) in an inflow funnel shape capable of expanding[see figures.1-2]

5. Regarding claim 9, Siess discloses substantially the invention as claimed but failed to disclose the pigtailed tip has lateral auxiliary openings. However, Garcia discloses a pigtail tip that has lateral auxiliary openings [see fig.1; element (16)]. Thus, it would have been obvious to one with ordinary skills in the art by the time the invention was made to modify Siess to have a pigtail tip that has lateral auxiliary openings in order to provide additional support in case the other openings fails.

(10) Response to Argument

Appellant's main argument is that none of the references relied upon by the examiner recognizes any potential for problems that may arise when the inlet portion of a high capacity pump is inserted into the heart and its inlet is sucked up against and becomes adhered to heart tissue during operation of the pump. None of the references suggest a solution to such problem.

In response to appellant's argument that the references fail to show certain features of appellant's invention, it is noted that the features upon which appellant relies (i.e., the potential for problems that may arise when the inlet portion of a high capacity pump is inserted into the heart and its inlet is sucked up against and becomes adhered to heart tissue during operation of the pump) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Appellant argued that the examiner attempts to rely on the teachings of secondary reference of Sammler in an effort to overcome the shortcomings of Siess by pointing to the guiding element 35a,46,48 in figure 4-6, and that the examiner has ignored the fact that such guiding element is in fact shown and described as extending from the outlet end of the device, while the present invention on the other hand absolutely requires and the claims unequivocally call for the spacer element to be positioned so as to keep the inlet openings spaced apart from adjacent tissue.

In response to that, the examiner added Sammler reference to Siess just to show that a flexible catheter with the balloon could added at the distal end of the cannula as shown in figures.4-6 in order to act as a guiding element for the catheter[col.4,lines 44-col.5,lines 1-8]. Sammler wasn't use to modify Siess open (24)[figures.1-2], which was already considered by examiner as an inlet. Thus, the flexible catheter of Sammler is going to be used in a distal end that has an inlet.

Appellant continue the same argument on Garcia as Sammler. In response to that, Garcia and Sammler wasn't use to modify Siess open (24)[figures.1-2], which was already considered by examiner as an inlet. The reference of Garcia was added to Siess et al and Sammler to show that the distal end of the catheter of Seiss et al/Sammler could have a pigtail shape as in Garcia figure.1 for permitting easier maneuvering of the catheter through the ventricle and also for helping to minimize trauma [col.2,lines 53-65]. The examiner has taken the position that, by having the distal end in a pigtail shape, the catheter would perform the same function of appellant's spacer for keeping heart wall apart from the catheter openings.

In response to appellant's argument against the references individually, one cannot show nonobviousness by attacking reference individually where the rejections are based on combinations of references. see *In re Keller*, 642 F.2d413, 208 USPQ 871 (CCPA 1981).

Appellant also, argued that no motivation, other than the present patent application is identified for rearranging the elements of the three references to arrive at the structure as claimed.

In response to appellant's argument that there is no motivation to combine the reference, the examiner recognizes that obviousness may be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion or motivation to do so found either in the references themselves or in the knowledge general available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed.Cir.1988).

Finally, appellant argued that the examiner has not identified any teachings in the cited art relating to certain elements that are specifically claimed in the dependent claims 5, 8, and 9.

In response to that, the limitations of these claims are addressed as seem in paragraph 3-5 as set forth above.

In conclusion, all rejections are maintained and appellant's arguments are not found persuasive.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/ROLAND DINGA/

Examiner, Art Unit 3766

Conferees:

/CARL H LAYNO/

Supervisory Patent Examiner, Art Unit 3766

/Niketa I. Patel/

Supervisory Patent Examiner, Art Unit 3762

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Appl. No.	:	10/566,423	Confirmation No. 2985
Applicant	:	Thorsten Siess	
Filed	:	January 30, 2006	
Art Unit	:	3766	
Examiner	:	Roland Dinga	
Title	:	AN INTRACARDIAC PUMPING DEVICE	
Docket No.:	:	IMPEL 72926	
Customer No.	:	24210	November 19, 2012

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Alexandria, VA 22313-1450

REPLY BRIEF

This Reply Brief is responsive to the Examiner's Answer mailed September 25, 2012 relating to the above-referenced appeal. This reply is in compliance with 37 C.F.R. § 41.41 and is being filed within the two month time period set forth therein.

ARGUMENT

In the 'Response to Argument', the Examiner insists that the "features" that the applicant is relying on for patentability are not recited in the rejected claims and that therefore, applicant's argument for patentability fails. In fact, the Examiner is improperly characterizing part of applicant's argument for patentability, i.e. the identification of problems that are solved by the invention as it is claimed that are not solved by devices described in the cited art nor even recognized in such references, as an unclaimed element of the invention and asserts that since such "features" are not recited in the rejected claims, the applicant's position fails. Applicant respectfully submits that the Examiner is confusing structure with a problem that is solved by the claimed structure and that therefore, it is the Examiner's position that is flawed.

Applicant's argument for non-obvious is not an element of an apparatus claim. Moreover, such argument would not be expected to carry any patentable weight as it is not structural in nature. However, the argument does serve to underscore why it is that the structural difference that does exist between the present invention as claimed and the devices that are shown in the cited references is not obvious, i.e. why it would not be obvious to modify the prior art devices or recombine various elements thereof so as to arrive at the present invention as claimed. The critical structural feature inherent in the device as claimed is the presence of a spacer element that extends **from the inlet side** of the pumping device. NONE of the cited references suggest such an arrangement - neither the primary reference to Siess, which is completely devoid of a spacer element, nor the secondary reference to Sammler, which shows a guide element extending from the **outlet end** of the pumping device, nor the secondary reference to Garcia which not only shows a pigtail extending from the **outlet end** of an injection catheter but is

additionally wholly devoid of an inlet to a pumping device. Moreover, none of the cited references even recognize the potential for problems that may arise when the inlet portion of a high capacity pump is inserted into the heart and its inlet is sucked up against and becomes adhered to heart tissue during operation of the pump and as a consequence fail to address such problem, let alone attempt to offer a solution. Yet the Examiner insists that it would be obvious to recombine selected elements of the cited references so as to arrive at the structure being claimed – wherein such recombination would be arbitrary but for the teaching provided by the present invention. The applicant maintains that it would not be obvious to do so as the only motivation to do so would be to prevent problems that are not even recognized by any of the references.

In responding further to appellant's argument, the Examiner goes on to argue that Sammler was added to Siess "just to show" that a flexible catheter with the balloon of Sammler could be added at the distal end of Siess which Examiner considers an inlet in order to act as a guiding element. It is respectfully submitted that such assertion demonstrates a fundamental misunderstanding of how the balloon guiding element of Sammler functions. As is described in Sammler's description, the balloon guiding element MUST extend from the outlet of the catheter as it is the flow of fluid that serves to push the balloon which in turn pulls the catheter and therefore guides the catheter along its path. Attaching the balloon guiding element to the inlet of a pumping device would simply cause the balloon to be sucked up against the inlet and therefore incapable of guiding the catheter. Attaching the balloon guiding element of Sammler to the distally positioned inlet of Siess would not only defeat the guiding capability of the guiding element as taught by Sammler but would compromise the ability of the pumping device of

Siess to draw in fluid. Accordingly, the only reason to do so would be to mimic the structure being claimed in the rejected claims of the present invention.

The Examiner also asserts that the pigtail of the Garcia reference was added to Siess and Sammler to show that the distal end could have a pigtail shape and that the catheter would then perform the same function of appellant's spacer for keeping the heart wall apart from the catheter openings. While such capability would admittedly then be achieved, it is respectfully submitted that the only motivation for doing so is to again to mimic the structure of the rejected claim as the function of the pigtail as described in the Garcia reference would cease being capable of performing the expressed function – namely, to prevent recoil or kickback during the high pressure injection of contrast fluid out of the outlet end.

The appellant continues to agree with the Examiner that obviousness may be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is **some** teaching, suggestion or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill the art. However, the Examiner has failed to point to a **single instance** of such a teaching, suggestion or motivation and the appellant maintains that the **only** motivation for attaching a pigtail spacer element to the inlet end of a pumping device is provided by the present invention.

Finally, in response to the appellant's assertion that the limitations present in dependent claim 5 had not been addressed by the Examiner, the Examiner now baldly states that Siess discloses an inlet opening in an inflow funnel shape capable of expanding. Appellant respectfully submits that no such teaching is present as the reference is absolutely silent as to expandability, let alone expanding into a funnel shape.

With regard to the missing teaching of a guide wire extending through the pump, the cannula and into the pig tail tip as is specifically claimed in claim 8, the Examiner again simply ignores such limitation. No such structure is found, suggested or taught in any of the references.

With regard to the missing teaching of auxiliary openings in the pigtail tip as is claimed in claim 9, the Examiner now asserts that elements 16 comprises such auxiliary openings when in fact the described openings are nowhere near the pigtail 18. The openings 16 that are shown are clearly formed in the tubing portion 10 of the device well proximal of the curled distal section (18).

CONCLUSION

For the foregoing reasons, it is maintained that the Examiner's rejections of claims 1-3 and 5-9 were therefore in error. Accordingly, appellant respectfully requests reversal of all rejections.

The commissioner is authorized to charge any deficiencies in fees or credit any overpayments to our Deposit Account No. 06-2425.

Respectfully submitted,

FULWIDER PATTON LLP

/Gunther O. Hanke/
Gunther O. Hanke, Esq.
Registration No. 32,898

GOH/lm

Electronic Acknowledgement Receipt

EFS ID:	14266885
Application Number:	10566423
International Application Number:	
Confirmation Number:	2985
Title of Invention:	Intracardiac Pumping Device
First Named Inventor/Applicant Name:	Thorsten Siess
Customer Number:	24201
Filer:	Gunther O. Hanke/Laura Martinez
Filer Authorized By:	Gunther O. Hanke
Attorney Docket Number:	IMPEL.72926
Receipt Date:	19-NOV-2012
Filing Date:	30-JAN-2006
Time Stamp:	16:37:51
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Reply Brief Filed	Reply_Brief.pdf	32470 8b94eafbe10d85a676cf75bcd44adb12558853ae	no	5

Warnings:	
Information:	

Total Files Size (in bytes):	32470

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National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/566,423	01/30/2006	Thorsten Siess	IMPEL.72926	2985

24201 7590 12/05/2012

FULWIDER PATTON LLP
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6060 CENTER DRIVE, TENTH FLOOR
LOS ANGELES, CA 90045

EXAMINER	
DINGA, ROLAND	
ART UNIT	**PAPER NUMBER**
3766	

NOTIFICATION DATE	DELIVERY MODE
12/05/2012	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docketla@fulpat.com
eOfficeAction@fulpat.com

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FULWIDER PATTON LLP
HOWARD HUGHES CENTER
6060 CENTER DRIVE, TENTH FLOOR
LOS ANGELES, CA 90045

Appeal No: 2013-001967
Application: 10/566,423
Appellant: Thorsten Siess

Patent Trial and Appeal Board Docketing Notice

Application 10/566,423 was received from the Technology Center at the Board on November 26, 2012 and has been assigned Appeal No: 2013-001967.

In all future communications regarding this appeal, please include both the application number and the appeal number.

The mailing address for the Board is:

PATENT TRIAL and APPEAL BOARD
UNITED STATES PATENT AND TRADEMARK OFFICE
P.O. BOX 1450
ALEXANDRIA, VIRGINIA 22313-1450

The facsimile number of the Board is 571-273-0052. Because of the heightened security in the Washington D.C. area, facsimile communications are recommended. Telephone inquiries can be made by calling 571-272-9797 and referencing the appeal number listed above.

By order of the Patent Trial and Appeal Board.

ELECTRONIC TRANSMISSION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No.	:	10/566,423	Confirmation No. :	2985
Applicant	:	Thorsten Siess		
Filed	:	January 30, 2006		
Title	:	INTRACARDIAC PUMPING DEVICE		
Art Unit	:	3766		
Examiner	:	Roland Dinga		
Docket No.	:	ABIOM-72926		
Customer No.	:	24201		
Date	:	October 9, 2014		

STATUS INQUIRY

Dear Sir:

Applicant hereby inquires into the status of the above-referenced application. The Appeal Brief was filed April 24, 2012, the Examiner's Answer was mailed by the Patent Office on September 25, 2012, the Reply Brief was filed November 19, 2012 and the Docketing Notice was mailed by the Office on December 5, 2012, to date we have received nothing further. Please advise as to the status of this application.

No fees are due with this communication. The Commissioner is authorized to charge any fees which may be required under 37 CFR § 1.16 and § 1.17 to Deposit Account No. 06 2425.

Respectfully submitted,

FULWIDER PATTON LLP

By: /thomas h. majcher/
Thomas H. Majcher
Registration No. 31,119

THM:jeb
781039.1

Electronic Acknowledgement Receipt

EFS ID:	20378922
Application Number:	10566423
International Application Number:	
Confirmation Number:	2985
Title of Invention:	Intracardiac Pumping Device
First Named Inventor/Applicant Name:	Thorsten Siess
Customer Number:	24201
Filer:	Thomas H. Majcher/Jane Barnett
Filer Authorized By:	Thomas H. Majcher
Attorney Docket Number:	IMPEL.72926
Receipt Date:	09-OCT-2014
Filing Date:	30-JAN-2006
Time Stamp:	17:28:41
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Request for status of Application	STATUS_INQUIRY_ABIOM-72926.pdf	11593 80ffd3316ee5b7ab9822db29d3f7f3cf3016f5d8	no	1
Warnings:					
Information:					

Total Files Size (in bytes):	11593

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte THORSTEN SIESS

Appeal 2013-001967
Application 10/566,423
Technology Center 3700

Before: CHARLES N. GREENHUT, MICHAEL L. HOELTER, and MICHAEL L. WOODS, *Administrative Patent Judges*.

GREENHUT, *Administrative Patent Judge*.

DECISION ON APPEAL

STATEMENT OF CASE

Appellant appeals under 35 U.S.C. § 134 from a rejection of claims 1−3 and 5−9. We have jurisdiction under 35 U.S.C. § 6(b).

We reverse.

The claims are directed to an intracardiac pumping device. Claim 1, reproduced below, is illustrative of the claimed subject matter:

> 1. An intracardiac pumping device for percutaneous insertion, comprising a pump connected at the proximal end with a catheter and at the suction-side distal end with a canula having

> inlet openings remote from the pump, characterized in that a flexible pigtail tip is provided at the canula distal of all of the inlet openings, wherein said flexible pigtail tip forms a spacer for keeping said inlet openings spaced apart from adjacent heart walls.

REJECTION

Claims 1-3 and 5-9 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Siess (WO 2002/043791)[1], Sammler (US 6,544,216) and Garcia (US 5,037,403).

OPINION

In rejecting claim 1, the sole independent claim involved in this appeal, the Examiner first reasons that it would have been obvious to incorporate Sammler's distal end catheter 46/48 into Siess for the purpose of preventing Siess's distal end from touching the heart walls and thereby blocking Siess's inlet. Final Act. 3. Appellant correctly argues that there is no indication that Sammler's catheters 46/48 would be capable of performing this function. App. Br. 5. Further, the motivation stated by the Examiner appears to come directly from Appellant's own Specification. The Examiner does not provide any evidence or reasoning to demonstrate that even without any suggestion by Sammler that the catheters 46/48 could be used for this purpose, one skilled in the art would recognize them as capable of being put to this task. This suggests the use of impermissible hindsight in the Examiner's analysis.

In the Examiner's Answer, the Examiner provides alternate reasoning for making the proposed modification to Siess; to act as a guiding element for the catheter. Ans. 7. Appellant correctly points out that, to the extent

[1] relying on the translation provided by the US national stage application (US 2004/0044266)

catheters 46/48 act as guiding elements, they do so in conjunction with Sammler's balloon 35a. App. Br. 6. Sammler's balloon 35a acts as a guide by virtue of being washed or moved along by the natural blood flow. App. Br. 5 (citing Sammler col. 4, ll. 1−4). As Appellant correctly argues, it does not appear to make any sense to position such a balloon, and therefore catheters 46/48 at the suction side distal end of Siess as required to satisfy claim 1 because the balloon would be unable to serve its guiding purpose having to travel against blood flow. App. Br. 5−7. Thus, we agree with Appellant that the Examiner has not established that, without the benefit of Appellant's own disclosure, it would have been obvious to combine Siess and Sammler in the manner proposed so as to yield the claimed subject matter. Reply Br. 3.

To draw on hindsight knowledge of the patented invention, when the prior art does not contain or suggest that knowledge, is to use the invention as a template for its own reconstruction—an illogical and inappropriate process by which to determine patentability. *Sensonics Inc. v. Aerosonic Corp.*, 81 F.3d 1566, 1570 (Fed. Cir. 1996) (citing *W.L. Gore & Assoc. v. Garlock, Inc.,* 721 F.2d 1540, 1553 (Fed. Cir. 1983)). The invention must be viewed not after the blueprint has been drawn by the inventor, but as it would have been perceived in the state of the art that existed at the time the invention was made. *Id.* (citing *Interconnect Planning Corp. v. Feil,* 774 F.2d 1132, 1138 (Fed. Cir. 1985)).

We additionally note that the alleged benefits cited by the Examiner concerning Garcia's "pigtail" are attributed not to the "pigtail" itself, but to its reduced size. *See* Ans. 6 (citing Garcia Fig. 1; col. 3, ll 39–40; col. 2, ll. 53−68). Thus, the factual basis for the Examiner's rejection is, in this

regard, also not supported by a preponderance of the evidence of record.

Reply Br. 4.

DECISION

The Examiner's rejection is reversed.

REVERSED

pgc