**UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF MASSACHUSETTS**

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| Maquet Cardiovascular LLC,<br><br>Plaintiff,<br><br>vs.<br><br>Abiomed, Inc., Abiomed R&D, Inc., and Abiomed Europe GmbH,<br><br>Defendants. | C.A. NO. 1:17-CV-12311<br><br>JURY DEMAND |

**FIRST AMENDED COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiff Maquet Cardiovascular LLC, by and through its counsel, alleges and states as follows:

**THE PARTIES**

1. Maquet Cardiovascular LLC ("Maquet" or "Plaintiff") is a limited liability company formed and existing under the laws of Delaware and having its principal place of business at 45 Barbour Pond Dr., Wayne, New Jersey 07470. Maquet is a leader in the development of medical devices, both in the United States and worldwide. Maquet is the owner by assignment of numerous patents and patent applications, including the patents identified below, that relate to innovative intravascular blood pumps and other innovative and life-saving technologies. Maquet sells many of its innovative products to hospitals, heart clinics, and physicians throughout the United States and worldwide. Maquet's products have saved countless lives.

2. Upon information and belief, Abiomed, Inc. is a Delaware corporation having its principal place of business at 22 Cherry Hill Dr., Danvers, MA 01923. Abiomed, Inc. is in the

business of, among other activities, manufacturing, marketing, distributing, and selling medical products including intravascular blood pumps that it markets under the Impella product name.

3. Upon information and belief, Abiomed R&D, Inc. ("Abiomed R&D") is a Delaware corporation having its principal place of business at 22 Cherry Hill Dr., Danvers, MA 01923. Abiomed R&D is a subsidiary of Abiomed, Inc. and is involved in the design and development of Abiomed, Inc.'s medical products, including the Impella products, and is also involved in the marketing and distribution of these products.

4. Upon information and belief, Abiomed Europe GmbH ("Abiomed Europe") is a German company having its principal place of business at Neuenhofer Weg 3, Aachen, Nordrhein-Westfalen 52074, Germany. Abiomed Europe is a subsidiary of Abiomed, Inc. and is involved in manufacturing, developing, distributing, and/or importing into the United States Abiomed, Inc.'s medical products, and for preparing, distributing, and/or importing into the United States instructional materials relating to Abiomed, Inc.'s medical products. These acts include activities in the United States.

5. Abiomed, Inc., Abiomed R&D, and Abiomed Europe are referred to herein collectively as "Defendants."

6. Maquet has standing to bring this suit because Maquet is the owner by assignment of the patents asserted below.

**JURISDICTION AND VENUE**

7. This action arises under the Patent Act, Title 35 of the United States Code, as an action for patent infringement under § 271.

8. This Court has original jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

9. This Court has personal jurisdiction over the Defendants under this State's long-arm statute and consistent with the underlying due process principles of the U.S. Constitution. Personal jurisdiction is proper because (i) Abiomed, Inc. has purposefully directed the activities that form the basis for this action towards this judicial district, for example by filing a declaratory judgment suit against Maquet concerning patents related to the patents asserted below in this district (*Abiomed, Inc. v. Maquet Cardiovascular LLC*, No. 1:16-cv-10914-FDS (D. Mass. May 19, 2016)) and has thus submitted to the Court's personal jurisdiction, (ii) Abiomed, Inc. and Abiomed R&D have their principal places of business in this district, and (iii) upon information and belief, Defendants are collectively doing business in this district, have significant contacts in this district, have offered for sale and sold infringing products in this district, and have caused and continue to cause Maquet injury in this district including by committing, inducing, and contributing to acts of patent infringement in this district as alleged herein.

10. Venue is proper in this Court pursuant to 28 U.S.C. § 1400(b) because Defendants have committed acts of patent infringement in this district as alleged herein.

11. Specifically, upon information and belief, Defendants have purposefully directed, and continue to direct, sales and marketing activities concerning their infringing products towards residents of this district including hospitals, heart clinics, and physicians. Defendants derive benefit from their sales and marketing activities concerning their infringing products in this district.

## NATURE OF THE ACTION

12. Maquet, a worldwide leader in the development of medical devices, owns a number of patents relating to intravascular blood pumps, including the patents asserted below. Specifically, the asserted patents concern medical devices that can be introduced into a patient's

vascular system. These devices can be used to supplement and even fully support the circulation of blood in a patient.

13. Since at least 2008 and continuing to the present, Defendants have manufactured, marketed, sold, and/or imported into the United States intravascular blood pumps, including at least the Impella Recover LP 2.5 device ("Impella 2.5"), the Impella 5.0, and the Impella CP products, all of which embody claims of Maquet's asserted patents, without authority from Maquet. Defendants have therefore infringed Maquet's rights in the asserted patents by the foregoing activities.

14. As a result of Defendants' improper conduct, Maquet requests injunctive and monetary relief for patent infringement in violation of the Patent Act (35 U.S.C. § 271).

**CLAIM I – INFRINGEMENT OF U.S. PATENT NO. 9,789,238**

15. Maquet repeats, realleges, and incorporates by reference Paragraphs 1 through 14 above as if set forth in full herein.

16. On October 17, 2017, the United States Patent Office duly and lawfully issued United States Patent No. 9,789,238 entitled "Guidable Intravascular Blood Pump and Related Methods" ("the '238 Patent"). Maquet is the lawful owner of the '238 Patent, including the right to sue and recover for past infringement thereof. A true and correct copy of the '238 Patent is attached hereto as Exhibit A.

17. Defendants have had knowledge of U.S. Patent Application 14/966,669, which is the application that led to the '238 Patent, since at least about August 24, 2016. On that date, Maquet's counsel sent Defendants' counsel a letter identifying the Application Serial No. 14/966,669 and notifying Defendants that the pending claims "read directly on Abiomed's products" including Defendants' Impella pumps. Upon information and belief, this information

was communicated to Defendants by their counsel. Maquet's August 24, 2016 letter, without enclosures, is attached hereto as Exhibit B.

18. On August 7, 2017, the United States Patent and Trademark Office issued a Notice of Allowance for Application Serial No. 14/966,669. On August 24, 2017, Counsel for Maquet notified Defendants' counsel in connection with *inter partes* review ("IPR") proceedings concerning patents related to the '238 Patent that the Notice of Allowance had issued. Additionally, on August 25, 2017, Maquet updated its mandatory notices in those same IPR proceedings to include a listing of the same Notice of Allowance. These mandatory notices were served on Defendants' counsel. The claims of the '238 Patent are identical to the claims pending in Application Serial No. 14/966,669 as of the date of the August 7, 2017 Notice of Allowance.

19. During prosecution of U.S. Patent Application 14/966,669, which is the application that led to the '238 Patent, Maquet disclosed to the examiner the briefs and documents filed in connection with the IPR proceedings initiated by Defendants concerning patents related to the '238 Patent, including the prior art references introduced in those IPR proceedings. The examiner considered those documents and references, including the IPR arguments raised by Defendants, in allowing the claims of the '238 Patent and issued a separate Notice of Allowance on September 5, 2017. *See, e.g.*, U.S. Pat. Appl. No. 14/966,669, Information Disclosure Statements dated July 7, 2017, July 10, 2017, July 27, 2017, and August 26, 2017; Notice of Allowance dated September 5, 2017.

20. Abiomed, Inc. has directly infringed, and continues to directly infringe, the claims of the '238 Patent, including at least Claims 1, 13, and/or 19, in violation of 35 U.S.C. § 271(a). Upon information and belief, during the term of the '238 Patent, Abiomed, Inc.'s employees have served as technical consultants present in the operating room during surgeries involving the

Impella 2.5, the Impella 5.0, and the Impella CP products at hospitals and heart clinics within the State and District of Massachusetts. Upon information and belief, these Abiomed, Inc. employees instruct and direct the actions of end users, including physicians, as to the function, placement, and use of the Impella 2.5, the Impella 5.0, and the Impella CP products.

21. Defendants have indirectly infringed, and continue to indirectly infringe, the claims of the ’238 Patent, including at least Claims 1, 13, and/or 19, in violation of 35 U.S.C. § 271(b) and (c). Upon information and belief, during the term of the ’238 Patent, Defendants’ customers and end users have infringed the patent by at least making, using, offering for sale, selling, or importing into the United States intravascular blood pumps including at least the Impella 2.5, the Impella 5.0, and the Impella CP products, and continue to do so, all without authority from Maquet. Defendants have recommended, encouraged, and promoted infringement of the ’238 Patent by, among other things, providing and making available documentation that instructs use of the Impella 2.5, the Impella 5.0, and the Impella CP products in an infringing manner.

22. Upon information and belief, Defendants know their customers’ and end users’ conduct infringes the claims of the ’238 Patent, and/or Defendants are willfully and deliberately ignoring that their customers’ and end users’ conduct infringes the claims of the ’238 Patent.

23. Despite their knowledge, Defendants have encouraged, aided and abetted, and continue to encourage, aid and abet, their customers and end users to infringe the claims of the ’238 Patent.

24. Despite their knowledge, Defendants have sold, and continue to sell, to their customers Defendants’ intravascular blood pumps and/or blood pump parts of their Impella line including the Impella 2.5, the Impella 5.0, and the Impella CP products. These Impella blood pumps and/or pump parts are a material part of the invention claimed in the ’238 Patent, and the

Impella blood pumps are not a stable article or commodity of commerce suitable for substantial noninfringing uses.

25. Defendants' customers and end users, including physicians, directly infringe the claims of the '238 Patent, including at least Claims 1, 13, and/or 19. These customers and end users directly infringe, at least, by practicing: A method for providing left-heart support using an intravascular blood pump system, the intravascular blood pump system comprising: an intravascular blood pump adapted to be guided to a predetermined location within the circulatory system of a patient by a guide wire and configured to provide left-heart support, the intravascular blood pump comprising a rotor having a rotor hub tapering in the distal direction and a rotor shroud at least partially disposed about the rotor hub, at least one blade extending radially outward from the rotor hub, a distal end of the hub extending distally beyond a most distal portion of the at least one blade; a catheter coupled to a proximal end of the intravascular blood pump, a purge lumen extending through the catheter; a cannula coupled to a distal end of the intravascular blood pump, a portion of the rotor shroud having an outer diameter matching an inner diameter of a proximal portion of the cannula, the proximal portion of the cannula disposed about a distal end of the rotor shroud, one or more first ports and one or more second ports establishing fluid communication between a cannula lumen and an exterior region of the cannula, wherein at least one first port is located in proximity to the rotor and at least one second port is spaced apart from and located distal to the at least one first port; an elongate lumen associated with the cannula and sized to slidably receive the guide wire and dimensioned such that the guide wire passes slidably and coaxially through the elongate lumen, the elongate lumen is sized smaller cross sectionally than the cannula lumen, both the elongate lumen and the cannula lumen not extending through the rotor hub, the elongate lumen adapted to guide the guide wire through a distal end of the intravascular blood

pump system, the elongate lumen shorter in length than the cannula lumen, the entire elongate lumen distal to the rotor; a housing connected to a proximal end of the catheter; and first and second conduits each connected to the housing, at least one of the first conduit and second conduit in fluid communication with the purge lumen, the housing remains outside the patient while providing left-heart support; the method comprising: passing the guide wire through the patient's femoral artery such that a distal end of the guide wire is positioned in the left ventricle of the patient's heart; placing the guide wire through both the cannula and the elongate lumen such that the guide wire extends proximally away from the intravascular blood pump, the guide wire not passing through the rotor hub or the catheter, and the guide wire extends out of the intravascular blood pump system in a distal direction through the elongate lumen; advancing the cannula into the patient using the guide wire and positioning the cannula across an aortic valve of the patient such that a distal end of the cannula and the at least one second port are positioned in the left ventricle and a proximal end of the cannula and the at least one first port are positioned in the aorta, and the elongate lumen lies wholly within the left ventricle during left-heart support; passing purge fluid through one of the first and second conduits, through the housing and purge lumen toward the intravascular blood pump; measuring pressure adjacent the intravascular blood pump; and spinning the rotor so as to pump blood from the patient's heart into the at least one second port through the cannula lumen and out the at least one first port to provide left-heart support.

26. Despite their knowledge, Defendants' infringement has been and continues to be willful and deliberate because Defendants know, or are willfully and deliberately ignoring that each of their actions constitutes infringement of the '238 Patent, and/or are willfully and deliberately ignoring an objectively high risk that each of their actions constitutes infringement of the '238 Patent.

## CLAIM II – INFRINGEMENT OF U.S. PATENT NO. 10,238,783

27. Maquet repeats, realleges, and incorporates by reference Paragraphs 1 through 26 above as if set forth in full herein.

28. On March 26, 2019, the United States Patent Office duly and lawfully issued United States Patent No. 10,238,783 entitled "Guidable Intravascular Blood Pump and Related Methods" ("the '783 Patent"). Maquet is the lawful owner of the '783 Patent, including the right to sue and recover for past infringement thereof. A true and correct copy of the '783 Patent is attached hereto as Exhibit C.

29. Defendants have had knowledge of U.S. Patent Application 16/138,788, which is the application that led to the '783 Patent, since at least about January 31, 2019. On that date, Maquet's counsel sent Abiomed, Inc. and Defendants' counsel a letter identifying Application Serial No. 16/138,788, enclosing U.S. Patent Application Publication No. US 2019/0030231 A1, which published on that date and corresponds to the foregoing application, and notifying Defendants that "Abiomed's acts, including the making, using, offering for sale, selling in the United States and/or importing into the United States, of the invention as claimed in the published patent application, concerning some or all of the Impella products identified by Maquet in its pleadings in *Abiomed, Inc. v. Maquet Cardiovascular LLC*, United States District Court, District of Massachusetts, Case # 116CV10914FDS and *Maquet Cardiovascular LLC v. Abiomed, Inc., et al.*, United States District Court, District of Massachusetts, Case # 117CV12311FDS, will give rise to provisional rights under 35 U.S.C. § 154(d), if the invention as claimed in the patent as issued is substantially identical to the invention as claimed in the published patent application." Upon information and belief, this information was communicated to all Defendants by their counsel. Maquet's January 31, 2019 letter, without enclosure, is attached hereto as Exhibit D. The

claims of the issued ’783 Patent are identical to those of U.S. Patent Application Publication No. US 2019/0030231 A1. Upon information and belief, during the period beginning on January 31, 2019, the date of publication of U.S. Patent Application Publication No. US 2019/0030231 A1, and including up to March 26, 2019, the date the ’783 Patent issued, Defendants made, used, offered for sale, and/or sold in the United States the invention as claimed in at least then-pending claims 2, 9, 18, and/or 25 of the foregoing publication (corresponding to Claims 1, 8, 17, and/or 24 of the ’783 Patent), or imported such an invention into the United States, in violation of 35 U.S.C. § 154(d).

30. Abiomed, Inc. has directly infringed, and continues to directly infringe, claims of the ’783 Patent, including at least Claims 1, 8, 17, and/or 24, in violation of 35 U.S.C. § 271(a). During the term of the ’783 Patent, Abiomed, Inc. has made, used, offered to sell, sold, and/or imported into the United States intravascular blood pumps including at least the Impella 2.5, the Impella 5.0, and the Impella CP products, and continue to do so, all without authority from Maquet.

31. Abiomed, Inc. has also directly infringed, and continues to directly infringe, the claims of the ’783 Patent, including at least Claims 1, 8, 17, and/or 24, in violation of 35 U.S.C. § 271(f). During the term of the ’783 Patent, Abiomed, Inc. has, without authority: supplied or caused to be supplied in or from the United States all or a substantial portion of the components of the Impella 2.5, the Impella 5.0, and/or the Impella CP products, or at least one component of the Impella 2.5, the Impella 5.0, and/or the Impella CP products that is especially made or especially adapted for use in those products and not a staple article or commodity of commerce suitable for substantial noninfringing use; where such component(s) is/are uncombined in whole or in part; and in such manner as to actively induce the combination of such component(s) outside of the United States in a manner that would infringe the ’783 Patent if such combination occurred

within the United States, or knowing that such component(s) is/are so made or adapted and intending that such component(s) will be combined outside of the United States in a manner that would infringe the '783 Patent if such combination occurred within the United States. For example, upon information and belief, Abiomed, Inc. has, without authority, supplied or caused to be supplied in or from the United States, one or more components that are especially made or especially adapted for use in the Impella 2.5, the Impella 5.0, and the Impella CP products—and that are not staple articles or commodities of commerce suitable for substantial noninfringing uses—which are assembled into final Impella 2.5, Impella 5.0, and Impella CP products in Aachen, Germany that are sold outside the United States.

32. Upon information and belief, Abiomed R&D has developed and used intravascular blood pumps including at least the Impella 2.5, the Impella 5.0, and the Impella CP products. Abiomed R&D also works with Abiomed, Inc. to market and distribute these intravascular blood pumps. Thus, Abiomed R&D has made, used, offered to sell, sold, and/or imported into the United States intravascular blood pumps including at least the Impella 2.5, the Impella 5.0, and the Impella CP products, and continues to do so, all without authority from Maquet.

33. Upon information and belief, Abiomed Europe manufactures and distributes intravascular blood pumps including at least the Impella 2.5, the Impella 5.0, and the Impella CP products. Thus, Abiomed Europe has made, used, offered to sell, sold, and/or imported into the United States intravascular blood pumps including at least the Impella 2.5, the Impella 5.0, and the Impella CP products, and continues to do so, all without authority from Maquet.

34. These intravascular blood pumps including at least the Impella 2.5, the Impella 5.0, and the Impella CP products include: an intravascular blood pump system, comprising: an intravascular blood pump comprising: a rotor having a rotor hub tapering in a distal direction, at

least one blade extending outward from the rotor hub, the rotor hub has a distal end extending distally beyond the most distal portion of the at least one blade and a shroud within which the rotor is rotatably disposed; a cannula extending from the shroud and comprising an outer cannula surface, the outer cannula surface having a substantially circular cross-section along a portion of its length; a guide mechanism comprising a lumen having a proximal end and a distal end, the guide mechanism adapted to guide a distal portion of said intravascular blood pump system to a predetermined location within a circulatory system of a patient; wherein an axis coaxial with and extending through a portion of said guide mechanism extends through a region delimited by the outer cannula surface, and wherein the guide mechanism is configured to allow for a guide wire to slideably advance therealong.

35. Defendants have also indirectly infringed, and continue to indirectly infringe, the claims of the ’783 Patent, including at least Claims 1, 8, 17, and/or 24, in violation of 35 U.S.C. § 271(b) and (c). During the term of the ’783 Patent, Defendants’ customers and end users have infringed the patent by at least making, using, offering for sale, selling, or importing into the United States intravascular blood pumps including at least the Impella 2.5, the Impella 5.0, and the Impella CP products, and continue to do so, all without authority from Maquet. Upon information and belief, Defendants know their customers’ and end users’ conduct infringes the claims of the ’783 Patent, and/or Defendants are willfully and deliberately ignoring that their customers’ and end users’ conduct infringes the claims of the ’783 Patent.

36. Despite their knowledge, Defendants have encouraged, aided and abetted, and continue to encourage, aid and abet, their customers and end users to infringe the claims of the ’783 Patent.

37. In addition, despite this knowledge, Abiomed Europe and Abiomed R&D induce the infringement of Abiomed, Inc. Abiomed Europe has encouraged, aided and abetted, and continues to encourage, aid and abet, Abiomed, Inc. to infringe the claims of the '783 Patent, by among other things, manufacturing products that Abiomed, Inc. uses in its infringing activities and working in concert with Abiomed, Inc. to continue its infringing activities. In addition, Abiomed R&D has encouraged, aided and abetted, and continues to encourage, aid and abet, Abiomed, Inc. to infringe the claims of the '783 Patent, by among other things, developing products that Abiomed, Inc. uses in its infringing activities and working in concert with Abiomed, Inc. to continue its infringing activities.

38. Despite their knowledge, Defendants have sold, and continue to sell, to their customers Defendants' intravascular blood pumps and/or blood pump parts of their Impella line including the Impella 2.5, the Impella 5.0, and the Impella CP products, and continue to encourage their end users to use these products in an infringing manner. These Impella blood pumps and/or pump parts are a material part of the invention claimed in the '783 Patent, and the Impella blood pumps are not a stable article or commodity of commerce suitable for substantial noninfringing uses.

39. Despite their knowledge, Defendants' infringement has been and continues to be willful and deliberate because Defendants know, or are willfully and deliberately ignoring that each of their actions constituted infringement of the '783 Patent, and/or willfully and deliberately ignored an objectively high risk that each of their actions constituted infringement of the '783 Patent.

## RELIEF SOUGHT

Plaintiff Maquet respectfully seeks that the Court grant the following relief:

A. Enter judgment for Plaintiff and against Abiomed, Inc. for infringement of the ’238 and ’783 Patents;

B. Enter judgment for Plaintiff and against Defendants for induced infringement of the ’238 and ’783 Patents;

C. Enter judgment for Plaintiff and against Defendants for contributory infringement of the ’238 and ’783 Patents;

D. Enter judgment that Defendants’ infringement of the ’238 and ’783 Patents was and is willful;

E. In accordance with the principles of equity and applicable law, preliminarily and permanently enjoin Defendants, their officers, directors, principals, agents, sales representatives, servants, employees, successors, assigns, affiliates, subsidiaries, and all those acting in concert or participation with them, from directly or indirectly infringing, inducing infringement or contributing to the infringement of any claim of the ’238 and ’783 Patents;

F. Enter judgment in favor of Plaintiff and against Defendants in an amount that will adequately compensate Plaintiff for Defendants’ infringement, but under no circumstances an amount less than a reasonable royalty for Defendants’ use of Maquet’s patented inventions;

G. Enter judgment in favor of Plaintiff and against Defendants for three times the amount of damages awarded for each Defendant’s infringement of the ’238 and ’783 Patents pursuant to 35 U.S.C. § 284 because their infringement has been willful;

H. Enter judgment in favor of Plaintiff and against each Defendant pursuant to 35 U.S.C. § 154(d) for a reasonable royalty for Defendants’ making, using, selling, offering for sale,

or importing and/or Defendants' inducing or contributing to others making, using, selling, offering for sale, or importing of Maquet's patented inventions, after the publication of the applications that issued as the '238 and '783 Patents;

I. Enter judgment in favor of Plaintiff and against Defendants finding that this case is "exceptional" under 35 U.S.C. § 285;

J. Enter judgment in favor of Plaintiff and against Defendants for pre-judgment interest on all damages awarded;

K. Enter judgment in favor of Plaintiff and against Defendants for an award to Plaintiff of their reasonable attorneys' fees, expenses, and costs incurred in this action, to the extent not covered or allowed by the above; and

L. Enter such other and further relief as the Court may deem just and proper.

**DEMAND FOR JURY TRIAL**

Plaintiff requests a trial by jury on all claims so triable.

Dated: April 2, 2019

Respectfully submitted,

/s/ Wade G. Perrin

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**CERTIFICATE OF SERVICE**

I hereby certify that the above document was filed on the date appearing in the header of this page through the ECF system, which will send true copies of the document to the attorneys of record for each party.

*/s/* Wade G. Perrin
Wade G. Perrin (*pro hac vice*)