IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW HAMPSHIRE

UNITED STATES OF AMERICA,	)	
	)	
Plaintiff,	)	
	)	
v.	)	**Civil Action No. _____**
	)	
ATRIUM MEDICAL CORP.,	)	
MAQUET HOLDING B.V. & CO. KG,	)	
MAQUET CARDIOVASCULAR, LLC,	)	
MAQUET CARDIOPULMONARY AG,	)	**COMPLAINT FOR**
corporations,	)	**PERMANENT INJUNCTION**
	)	
and	)	
	)	
HEINZ JACQUI,	)	
GAIL CHRISTIE,	)	
individuals,	)	
	)	
Defendants.	)	
	)	

The United States of America, Plaintiff, by and through its undersigned counsel, and on behalf of the United States Food and Drug Administration ("FDA"), respectfully represents as follows:

1. This statutory injunction proceeding is brought under the Federal Food, Drug, and Cosmetic Act (the "Act"), 21 U.S.C. § 332(a), to permanently enjoin the defendants, Atrium Medical Corporation ("Atrium"), Maquet Holdings B.V. and Co. KG ("Maquet"), Maquet Cardiovascular, LLC ("Maquet CV"), and Maquet Cardiopulmonary AG ("Maquet CV"), corporations ("Corporate Defendants") and Heinz Jacqui and Gail Christie, individuals (collectively, "Defendants") from:

(a) violating 21 U.S.C. § 331(a) by introducing and causing to be introduced, and delivering and causing to be delivered for introduction, into interstate commerce articles of device, as defined by 21 U.S.C. § 321(h), that are (1) adulterated within the meaning of 21 U.S.C. § 351(h), in that the methods used in, and the facilities and controls used for, their manufacture, packing, storage, and installation are not in conformity with the current good manufacturing practice ("CGMP") requirements for devices, *see* 21 U.S.C. § 360j(f) and 21 C.F.R. Part 820 (the Quality System ("QS") regulation); and (2) misbranded within the meaning of 21 U.S.C. § 352(t)(2), in that Defendants fail to furnish information or material respecting their devices, as set forth in 21 U.S.C. § 360i and the medical device reporting ("MDR") and correction and removals ("CR") regulations, 21 C.F.R. Parts 803 and 806;

(b) violating 21 U.S.C. § 331(k) by doing acts that result in devices, as defined in 21 U.S.C. § 321(h), becoming adulterated within the meaning of 21 U.S.C. § 351(h) and/or misbranded within the meaning of 21 U.S.C. § 352(t)(2), while such devices are held for sale after the shipment of one or more of their components in interstate commerce; and

(c) violating 21 U.S.C. § 331(e) by failing to maintain and/or submit reports respecting their devices, as required by 21 U.S.C. § 360i.

JURISDICTION AND VENUE

2. This Court has jurisdiction over the subject matter and all parties to this action under 28 U.S.C. §§ 1331, 1337, and 1345 and 21 U.S.C. § 332(a).

3. Venue in this district is proper under 28 U.S.C. § 1391(b) & (c).

DEFENDANTS AND THEIR BUSINESSES

4. Maquet, a German business entity, manages quality operations for Defendants Atrium, Maquet CV, and Maquet CP. Maquet's headquarters are located at Kehler Strasse 31, Rastatt, Germany 76437.

5. Atrium is incorporated under the laws of Delaware. Atrium's manufacturing and support facilities are located in two locations in Hudson, NH, including its manufacturing facility located at 5 Wentworth Drive, Hudson, NH 03051. Atrium manufactures medical devices for cardiovascular-related uses, including chest drains, surgical meshes, vascular grafts, and stent systems.

6. Maquet CV is organized under the laws of New Jersey. Maquet CV's manufacturing facility is located at 45 Barbour Pond Drive, Wayne, NJ 07470.

7. Maquet CP is a German business entity. Maquet CP has manufacturing facilities located at Neue Rottenburger Strasse 37, Hechingen, Germany 72379, and Kehler Strasse 31, Rastatt, Germany 76437.

8. Heinz Jacqui, an individual, has been Maquet's Chief Executive Officer and Managing Director since April 1, 2012. He is responsible for and oversees all aspects of Corporate Defendants' businesses, including, but not limited to, device manufacturing and quality operations. Mr. Jacqui performs his duties at Kehler Strasse 31, Rastatt, Germany 76437.

9. Gail Christie, an individual, has been Maquet's Corporate Chief Quality Assurance/Regulatory Affairs and Compliance Officer since October 1, 2013. She is responsible for Corporate Defendants' compliance with the QS regulation at their manufacturing facilities. Ms. Christie performs her duties at Kehler Strasse 31, Rastatt, Germany 76437.

10. Defendants have been, and are now, manufacturing and distributing in interstate commerce various articles of devices, as defined in 21 U.S.C. § 321(h), including the Express Chest Drain distributed from Atrium. Defendants have been, and are now, receiving in interstate commerce one or more components used to manufacture their devices.

FDA'S REGULATION OF DEVICES

11. A device must be manufactured, packed, stored, and installed in conformity with good manufacturing practice to ensure its safety and effectiveness. 21 U.S.C. § 360j(f). The statutory good manufacturing practice requirement is set out in the QS regulation for devices, 21 C.F.R. Part 820. A device that has been manufactured, packed, stored, or installed in violation of the QS requirement is deemed to be adulterated. 21 U.S.C. § 351(h).

12. The introduction or delivery for introduction into interstate commerce of an adulterated or misbranded device is a violation of the Act, 21 U.S.C. § 331(a).

13. Doing an act that causes the adulteration or misbranding of a device while it is held for sale after shipment of one or more of its component parts in interstate commerce is a violation of the Act, 21 U.S.C. § 331(k).

14. The failure to establish or maintain certain records, or make certain reports, with respect to medical devices, is a violation of the Act, 21 U.S.C. § 331(e).

ATRIUM

October 2013 Inspection

15. FDA inspected Atrium's manufacturing facility on July 9 – October 1, 2013 ("Atrium 2013 Inspection"). During this inspection, the FDA investigators documented numerous violations of the QS regulation, 21 C.F.R. Part 820, and the MDR regulation, 21 C.F.R. Part 803, including:

a. failure to use established procedures to adequately validate a process whose results could not be fully verified by subsequent inspection and test, in violation of 21 C.F.R. § 820.75(a);

b. failure to establish and maintain adequate procedures for monitoring and control of process parameters for a validated process, in violation of 21 C.F.R. § 820.75(b);

c. failure to establish and maintain adequate procedures for finished device acceptance, in violation of 21 C.F.R. § 820.80(d);

d. failure to establish and maintain procedures for implementing corrective and preventive action, in violation of 21 C.F.R. § 820.100(a); and

e. failure to submit an MDR report within 30 days of receiving or otherwise becoming aware of information that reasonably suggested that a marketed device may have caused or contributed to a death or serious injury, in violation of 21 C.F.R. § 803.50(a)(1).

16. Atrium made promises to correct its violations in a written response to the Atrium 2013 Inspection, dated October 22, 2013, and in several follow-up responses, which detailed how and when the corrections promised in the October 22, 2013 letter had been made. Atrium's responses were inadequate because they did not address and/or include adequate corrective actions for all of the violations.

Prior Inspections

17. FDA previously inspected Atrium's facility in September 2012, March 2010, and March 2009. At each of these inspections, FDA observed and documented violations of the QS regulation similar to those cited during the Atrium 2013 Inspection, including but not limited to, violations involving: process validation (21 C.F.R. § 820.75), corrective and preventive action (21 C.F.R. § 820.100), and device acceptance activities (21 C.F.R. § 820.80).

Prior Notice of Violations

18. At the conclusion of each inspection of Atrium's facility described in paragraphs 15 and 17 above, the FDA investigators issued to Atrium a Form FDA-483 detailing its numerous violations of the Act, and discussed the documented observations with Atrium representatives. Atrium representatives promised corrections at the conclusion of each inspection.

19. FDA issued a Warning Letter dated October 11, 2012 to Atrium. The letter referenced, among other things, the QS violations observed during the September 2012 inspection at the Atrium facility including violations relating to process validation (21 C.F.R. § 820.75), corrective and preventive actions (21 C.F.R. § 820.100), and complaint handling (21 C.F.R. § 820.198). The letter also warned Atrium that further enforcement actions, including an injunction, could occur if it did not correct the violations.

MAQUET CV

October 2013 Inspection

20. FDA inspected Maquet CV's manufacturing facility on July 1 – October 16, 2013 ("Maquet CV 2013 Inspection"). During this inspection, the FDA investigators documented numerous violations of the QS regulation, 21 C.F.R. Part 820, the MDR regulation, 21 C.F.R. Part 803, and the CR regulation, 21 C.F.R. 806, including:

a. failure to establish and maintain procedures for implementing corrective and preventive action, in violation of 21 C.F.R. § 820.100(a);

b. failure to establish and maintain adequate procedures for design change, in violation of 21 C.F.R. § 820.30(i);

c. failure to include required information in the investigation records of MDR reportable complaints, in violation of 21 C.F.R. § 820.198(e);

d. failure to submit an MDR report within 30 days of receiving or otherwise becoming aware of information that reasonably suggested that a marketed device may have caused or contributed to a death or serious injury, in violation of 21 C.F.R. § 803.50(a)(1); and

e. failure to report in writing to FDA a correction or removal of a device conducted to reduce a risk to health posed by the device, in violation of 21 C.F.R. § 806.10(a)(1).

21. Maquet CV made promises to correct its violations in a written response to the October 2013 Inspection, dated November 6, 2013, and several follow-up responses, which detailed how and when the corrections promised in the November 6, 2013 letter had been made. Maquet CV's responses were inadequate because they did not address and/or include adequate corrective actions for all of the violations.

Prior Inspections

22. FDA inspected Maquet CV's facility previously in June 2012, April 2011, and May 2010. At each of these inspections, FDA observed and documented violations of the QS, MDR, and CR regulations, similar to those cited during the Maquet CV 2013 Inspection, including but not limited to, violations involving: corrective and preventive action (21 C.F.R. § 820.100), submission of MDRs (21 C.F.R. § 803.50); and correction and removal reporting (21 C.F.R. § 806.10).

Prior Notice of Violations

23. At the conclusion of each inspection of Maquet CV's facility described in paragraphs 20 and 22 above, the FDA investigators issued to Maquet CV a Form FDA-483 detailing its numerous violations of the Act, and discussed the documented observations with

Maquet CV representatives. Maquet CV representatives promised corrections at the conclusion of each inspection.

24. FDA issued a Warning Letter dated August 11, 2010, to Maquet CV ("2010 Warning Letter"). The letter referenced, among other things, the violations observed during the May 2010 inspection of the Maquet CV facility, including QS violations relating to process validation (21 C.F.R. § 820.75) and CR violations relating to correction and removal reporting (21 C.F.R. § 806.10). The letter also warned Maquet CV that further enforcement actions, including an injunction, could occur if it did not correct the violations.

MAQUET CP

2013 Inspections

25. FDA inspected Maquet CP's manufacturing facility in Hechingen, Germany, on September 17 – 23, 2013 ("Hechingen 2013 Inspection"). During this inspection, the FDA investigators documented numerous violations of the QS regulation, 21 C.F.R. Part 820, and the MDR regulation, 21 C.F.R. Part 803, including:

a. failure to use established procedures to adequately validate a process whose results could not be fully verified by subsequent inspection and test, in violation of 21 C.F.R. § 820.75(a);

b. failure to establish and maintain procedures for implementing corrective and preventive action, in violation of 21 C.F.R. § 820.100(a); and

c. failure to submit an MDR report within 30 days of receiving or otherwise becoming aware of information that reasonably suggested that a marketed device malfunctioned and this device or a similar marketed device would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur, in violation of 21 C.F.R. § 803.50(a)(2).

26. FDA also inspected Maquet CP's manufacturing facility in Rastatt, Germany, on September 24 – 26, 2013 ("Rastatt 2013 Inspection"). During this inspection, the FDA investigators documented numerous violations of the QS regulation, 21 C.F.R. Part 820, including:

a. failure to establish and maintain procedures for implementing corrective and preventive action, in violation of 21 C.F.R. § 820.100(a);

b. failure to establish and maintain adequate procedures for receiving, reviewing, and evaluating complaints, in violation of 21 C.F.R. § 820.198(a); and

c. failure to establish and maintain adequate procedures for verifying device design, in violation of 21 C.F.R. § 820.30(f).

27. At the conclusion of both inspections of Maquet CP's facilities described in paragraphs 25 and 26 above, the FDA investigators issued Form FDA-483s detailing Maquet CP's numerous violations of the Act and discussed the documented observations with Maquet CP representatives. Maquet CP promised corrections at the conclusion of both inspections.

28. Maquet CP also made promises to correct its violations in written responses to the Hechingen 2013 Inspection and the Rastatt 2013 Inspection, dated October 10 and October 18, 2013, respectively ("2013 Response Letters"), and in several follow-up responses, detailing how and when the corrections promised in the 2013 Response Letters had been made. Maquet CP's responses were inadequate because they did not address and/or include adequate corrective actions for all of the violations.

29. FDA has repeatedly warned Corporate Defendants, both orally and in writing, about their violative conduct, and has emphasized the importance of Defendants' compliance with the Act.

30. Based on Corporate Defendants' conduct, Plaintiff believes that, unless restrained by order of this Court, Defendants will continue to violate 21 U.S.C. §§ 331(a), (e) and (k).

WHEREFORE, Plaintiff prays that the Court:

I. Permanently restrain and enjoin, under 21 U.S.C. § 332(a), Defendants and each of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them, from directly or indirectly doing or causing to be done any of the following acts:

a. violating 21 U.S.C. § 331(a), by introducing or delivering for introduction into interstate commerce, any article of device that is adulterated within the meaning of 21 U.S.C. § 351(h) and/or misbranded within the meaning of 21 U.S.C. § 352(t)(2);

b. violating 21 U.S.C. § 331(k), by causing any article of device to become adulterated within the meaning of 21 U.S.C. § 351(h) and/or misbranded within the meaning of 21 U.S.C. § 352(t)(2), while such device is held for sale after shipment of one or more of its components in interstate commerce; or

c. violating 21 U.S.C. § 331(e) by failing to maintain and/or submit reports respecting their devices, as required by 21 U.S.C. § 360i.

II. Permanently restrain and enjoin, under 21 U.S.C. § 332(a), Defendants and each of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them from manufacturing, processing, packing, labeling, holding, and distributing (domestically and internationally) devices, as defined in 21 U.S.C. §321(h), at or from Atrium's Hudson, NH manufacturing facility, unless and until Atrium's methods, facilities, and controls used to manufacture, process, pack, label, hold, and distribute devices are established, operated, and administered in

compliance with 21 U.S.C. § 360j(f)(1), the Quality System regulation prescribed in 21 C.F.R. Part 820, the Medical Device Reporting regulation prescribed in 21 C.F.R. Part 803, and the Correction and Removals regulation prescribed in 21 C.F.R. Part 806 in a manner that has been found acceptable to FDA:

III. Authorize FDA, pursuant to this injunction, to inspect Defendants' device manufacturing facilities to ensure continuing compliance with the terms of this injunction, with the costs of such inspections to be borne by Defendants at the rates prevailing at the time the inspections are performed.

IV. Order that Plaintiff be awarded costs and other such equitable relief as this Court deems just and proper.

DATED this 3rd day of February, 2015.

JOYCE R. BRANDA
Acting Assistant Attorney General
U.S. Department of Justice
Civil Division

JONATHAN F. OLIN
Deputy Assistant Attorney General
U.S. Department of Justice
Civil Division

MICHAEL S. BLUME
Director
U.S. Department of Justice
Consumer Protection Branch

OF COUNSEL:

WILLIAM B. SCHULTZ
General Counsel

ELIZABETH H. DICKINSON
Chief Counsel
Food and Drug Division

ANNAMARIE KEMPIC
Deputy Chief Counsel
for Litigation

SHANNON M. SINGLETON
Associate Chief Counsel
United States Department of
Health and Human Services
Office of the General Counsel
Food and Drug Administration
Building 32, Room 4312
10903 New Hampshire Avenue
Silver Spring, MD 20993
(301) 796-8717

/s/ Daniel M. Baeza
DANIEL M. BAEZA
Trial Attorney
Consumer Protection Branch
U.S. Department of Justice
P.O. Box 386
Washington, DC 20044