Exhibit 2001

UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

Biomedical Device Consultants & Laboratories of Colorado, LLC,

Plaintiff,

v.

TA Instruments – Waters, LLC,

Defendants.

Civil File No. 0:17-cv-03403

DECLARATION OF MICHAEL GIRARD IN SUPPORT OF MOTION FOR PRELIMINARY INJUNCTION

I, Michael J. Girard, hereby declare and state as follows:

1. I have been retained by Plaintiff Biomedical Device Consultants & Laboratories of Colorado, LLC ("BDC") to offer technical analysis and opinions regarding various issues relevant to this action, including infringement and validity of the Patents-in-Suit, U.S. Patent Nos. 8,584,538 ("the '538 Patent"), 8,627,708 ("the '708 Patent"), 9,186,224 ("the '224 Patent"), 9,237,935 ("the '935 Patent") (collectively, the "Patents-in-Suit"). I have personal knowledge of the facts herein, and if called as a witness, I could and would testify competently thereto.

2. My education includes a Bachelor of Science in Civil (Structural) Engineering from the University of Illinois, and a Master of Business Administration from the University of St. Thomas.

3. I am currently the President of my own consulting firm, Girard Technical Services, Inc. My firm provides research and development, engineering, and technical management consulting services in the medical device industry.

4. I have thirty-seven years of experience in engineering, twenty-seven of which are in the medical device industry. I am a named inventor on 38 issued U.S. Patents with additional applications pending.

5. My experience includes work with many cardiovascular devices and specifically includes 19 years of heart valve experience. I've worked for several medical device companies in the role of development and testing of both surgical and transcatheter delivered prosthetic heart valves. Testing of heart valves usually includes durability testing at accelerated rates with equipment like the systems produced by BDC and TA Instruments. Therefore, I am very familiar with durability test equipment and the requirements of such testing. My curriculum vitae is attached hereto as Exhibit A.

A. Technology Overview

6. This case concerns equipment used for durability or high cycle fatigue testing of heart valves. Before any medical device, such as a heart valve, is marketed it must meet certain regulatory standards. International bodies, such as the International Organization for Standardization ("ISO"), set certain standards, such as those for testing the durability of medical devices, including heart valves. The specific standards for heart valves are defined in ISO 5840.

7. Prosthetic heart valves must be tested to ensure that they will function for the anticipated life of the patient by opening and closing the valve leaflets under flows and pressures that are present within the human vascular system. The normal human heart beats about 40 million times each year. The test requirements for evaluating prosthetic heart valves according to the standards require that the valves be able to

survive and function for hundreds of millions of cycles (e.g., at least 5 years or 200 million cycles). The valves must also be able operate over a specific range of opening and closing pressures that simulate physiological conditions, and therefore testing standards require that a specific pressure differential be generated across the valve when closed.

8. Testing systems use a test fluid to mimic blood and pressurize the fluid to mimic the blood pressure in the human body. Testing requires fluid flow through the valve and creating a pressure differential across the test valve when closed at a certain minimum pressure for a certain length of the cycle. A "drive mechanism" such as a pump drives the test fluid into the test chamber in order to create the fluid flow and desired pressure conditions. In order to complete hundreds of millions of cycles in a commercially viable timeframe, durability testing is done on an "accelerated" basis. In other words, the speed of the cycles is faster than a normal human heartbeat (a normal beat rate is 70 beats per minute - bpm). Using current technology at accelerated cycling of 800 bpm, testing takes approximately six months to simulate 200 million cycles.

B. Problems in Prior Art Technology

9. The Patents-in-Suit identify several problems with the prior art.

10. Driving mechanisms in the prior art had limited control over closing rates and would often produce "pressure spikes" when the systems maintain pressure above the testing threshold for the amount of time required by testing standards. These pressure spikes are undesirable because they wear out valves during testing faster than they would be worn out in the human body, causing false test failures.

11. According to the Patents-in-Suit, prior art valve testing devices also experienced operational problem. For example, one prior art device used a flexible metallic bellows to pressurize. '538 Patent col.1 ll.34-36. However, a higher load is required to drive the metallic bellows and can thus, impact the reliability of the test system and increase maintenance requirements which increases the already lengthy durability testing process.

C. Overview of the Patents-in-Suit

12. The Patents-in-Suit propose to solve these problems in the prior art.

13. For example, the '935 Patent covers a device for accelerated testing of valved prosthetics with several components including a test chamber and an "excess volume area" that is connected to a return chamber. The excess volume area and return chamber within the test chamber are shown below:

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