

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

W.L. GORE & ASSOCIATES, INC.)	
Plaintiff,)	
)	
v.)	Civil Action No. _____
)	
)	JURY TRIAL DEMANDED
MILLIPORE CORPORATION,)	
Defendant.)	

COMPLAINT FOR DECLARATORY JUDGMENT

Plaintiff W. L. Gore & Associates, Inc. (“Gore”) seeks a declaratory judgment that it does not infringe any valid claim of United States Patent No. 7,927,316, entitled “Disposable, Sterile Fluid Transfer Device” and with the first named inventor of Stephen Proulx (“the ‘316 Patent”). Gore also seeks a declaratory judgment that the claims of the ‘316 Patent are invalid. A copy of the ‘316 Patent can be found at the website for the U.S. Patent & Trademark Office, www.uspto.gov, and is attached to this complaint as Exhibit A.

PARTIES, JURISDICTION, AND VENUE

1. Plaintiff Gore is a Delaware corporation with its principal place of business at 555 Paper Mill Road, Newark, Delaware 19711.
2. On information and belief, Defendant Millipore Corporation (“Millipore”) is a Massachusetts corporation with a place of business at 290 Concord Road, Billerica, Massachusetts 01821.
3. Millipore is the assignee of the ‘316 Patent.

4. This action arises under the Federal Declaratory Judgment Act, 28 U.S.C. §§ 2201, 2202, and the patent laws of the United States, 35 U.S.C. §§ 101, *et. seq.*

5. This Court has subject matter jurisdiction under the provisions of 28 U.S.C. § 1338(a).

6. This Court has personal jurisdiction over Millipore because (1) Millipore has continuous and systematic contacts with Delaware through business dealings with Gore in Delaware and numerous other commercial activities in Delaware, (2) Millipore is present in Delaware through a registered agent in Delaware, and (3) Millipore has directed acts identified in this Complaint toward Gore in Delaware and has engaged in acts identified in the Complaint that have caused injury to Gore in Delaware.

7. Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400.

FACTUAL BACKGROUND

8. Gore sells products for use in pharmaceutical bioprocess applications, including (a) Gore's STA-PURE® Fluid Sampling System, a system used for fluid sampling applications, and (b) Gore's Single-Use Valve, a product used for maintaining positive fluid flow in bioprocess applications. This Complaint will refer to the STA-PURE® Fluid Sampling System and the Single-Use Valve as the "Threatened Gore Products."

9. Gore brings this declaratory judgment action because Millipore has engaged in a series of acts that constitute a clear threat that Millipore will sue Gore for infringement of the '316 Patent based on Gore's manufacture, sale, and use of the Threatened Gore Products. These affirmative acts by Millipore create a case or controversy between the parties. Gore need not risk a suit for infringement by continuing to engage in the manufacture, sale, and use of the Threatened Gore Products without seeking a declaration of its legal rights.

10. On July 31, 2006, Millipore's Chief Patent Counsel J. Dana Hubbard sent a letter to Robert Aulicino, Vice President of Amesil, Inc. (Gore acquired the assets of the bioprocess products business of Amesil early in 2007.) Mr. Hubbard wrote:

Dear Sir,

We have obtained a sample of Amesil's "HF Silicone Steam Valve" currently being offered for sale and/or sold.

This is to provide you with written notice under 35 U.S.C. § 154(d) of our two pending and published U.S. Patent Applications, U.S. 2005/0016620A1 and U.S. 2006/0142730A1, relating to our Lynx® connector [see attached copies of the applications and pending claims herewith].

You may wish to review these applications and ensure that any product you sell or offer for sale does not fall within the scope of the claims of either application.

11. One of the two published applications referenced by Mr. Hubbard in his July 31, 2006 letter—U.S. 2005/0016620A1—ultimately issued as the '316 Patent. The HF Silicone Steam Valve identified by Mr. Hubbard in the letter is now being sold by Gore as the Single-Use Valve. The statutory provision cited by Mr. Hubbard in his letter, 35 U.S.C. § 154(d), addresses the ability of a patent applicant, under certain circumstances, to make a claim for a pre-patent issuance reasonable royalty from a party who makes, uses, sells, or offers to sell the invention in the application.

12. In sending the July 31, 2006 letter, Millipore asserted rights under the '316 patent and its published application against Gore's Single-Use Valve. Millipore also asserted rights under the '316 Patent and its published application against "any product" Gore sells or offers that may fall within the scope of the '316 patent. Thus, with the issuance of the '316 Patent, Millipore's letter creates an actual case or controversy with Gore concerning the '316 Patent and Gore's past and current manufacture, sale, and use of the Gore Single-Use Valve. The letter also creates an actual case or controversy with respect to any other product that Millipore believes to fall within the scope of the '316 Patent. On information and belief, Millipore believes that

Gore's STA-PURE® Fluid Sampling System falls within the scope of the '316 Patent.

13. Millipore has also created a case or controversy by engaging in an aggressive patent litigation campaign against Gore over the last two years in the area of pharmaceutical bioprocess technology, asserting patent infringement against Gore in three different lawsuits, including one that involved Gore's STA-PURE® Fluid Sampling System.

14. On May 11, 2009, Millipore filed a Complaint in the District of Massachusetts in *Millipore Corp. v. W.L. Gore & Associates, Inc.*, Civil Action No. 1:09-10765 DPW (D. Mass.), alleging that Gore's STA-PURE® Fluid Sampling System infringed U.S. Patent No. 7,293,477 ("the '477 Patent"). On September 21, 2010, the Massachusetts Court dismissed Millipore's infringement claim by granting Gore's motion for summary judgment of noninfringement.

15. On July 9, 2009, Millipore issued a press release publicly signaling its intention to litigate "vigorously" against Gore, including a statement from the president Millipore's bioprocess division that the lawsuit "reflects our intention to vigorously defend our intellectual property."

16. On May 12, 2010, Millipore filed a motion for contempt against Gore in the District of New Jersey in *NovaSeptum AB et al. v. Amesil, Inc.*, Civil Action No. 2:05-05175 (DMC/MF) (D.N.J.), alleging that Gore's sale of certain crimp and cut tools used in pharmaceutical bioprocesses was in contempt of the Consent Judgment in that case. The New Jersey Court denied Millipore's contempt motion on December 29, 2010.

17. On March 15, 2011, Millipore filed a Complaint against Gore in the District of New Jersey in *Millipore Corp. et al v. W.L. Gore & Associates, Inc.*, Civil Action No. 2:11-01453 (DMC-JAD) (D.N.J.), alleging that Gore's sale of certain crimp and cut tools used in pharmaceutical bioprocesses was infringing two Millipore patents.

18. During the period in which Millipore publicly announced its “vigorous” patent enforcement strategy and brought several patent infringement actions against Gore, Millipore was also aggressively prosecuting the application that became the ‘316 Patent. While Gore believes that there are substantial differences between the device disclosed in the ‘316 Patent and the Threatened Gore Products, they are in the broadest sense “disposable, sterile fluid transfer devices.” In 2009, having had ample time to study Gore products in the market, Millipore began a concerted attempt to remove narrowing limitations that Millipore had included in its claims earlier in the prosecution. Millipore’s attempt to broaden the claims of the ‘316 Patent during prosecution indicates that Millipore was preparing the ‘316 Patent so that it could be asserted against the Threatened Gore Products.

19. Millipore’s threatened litigation relating to the ‘316 Patent and the Threatened Gore Products has caused real and concrete injury to Gore, and threatens immediate future injury to Gore, for at least the following reasons: (1) Millipore’s claim that it is entitled to a reasonable royalty for pre-issuance activity related to the invention disclosed in the application that ultimately gave rise to the ‘316 Patent; (2) business uncertainty caused by Millipore’s threats to assert infringement against Gore products, including the Threatened Gore Products; (3) harm to Gore’s current and prospective business relationships with distributors and end users of Gore’s pharmaceutical products, including the Threatened Gore Products; and (4) harm to Gore’s business reputation and good will in the market for Gore’s pharmaceutical bioprocess products.

20. For a number of reasons, Gore is entitled to make, use, sell, and offer to sell the Threatened Gore Products notwithstanding Millipore’s position with respect to the ‘316 Patent.

21. The Threatened Gore Products do not infringe any valid claim of the ‘316 patent at least because they lack the “cam” and “cam slot” limitations required by the claims.

22. The Threatened Gore Products cannot be found to infringe the claims of the '316 Patent because Millipore is barred from asserting infringement against the Threatened Gore Products under the doctrine of prosecution laches.

23. The claims of the '316 Patent are invalid under 35 U.S.C. §§ 102, 103, 112, and/or 256 at least based on (1) Millipore's own prior art Sanitary Sampling Valve and Opticap Disposable Capsule Filters, (2) prior art stainless steel sampling valves, (3) Millipore's failure to name all inventors, and (4) Millipore's failure to claim that which the inventors of the '316 Patent regarded as their invention and Millipore's decision to claim sterile transfer devices beyond those invented and possessed by the inventors of the '316 Patent.

COUNT ONE

Declaratory Judgment of Non-Infringement of the '316 Patent
28 U.S.C. § 2201

24. Gore repeats and realleges paragraphs 1 through 23 of this complaint, as though fully set forth.

25. For the reasons set out in this complaint, an actual case and controversy exists between Millipore and Gore based on Millipore's '316 Patent and the Threatened Gore Products.

26. Gore is entitled to make, use, sell, and offer to sell the Threatened Gore Products because Gore does not infringe any valid claim of the '316 Patent, at least because the Threatened Gore Products lack the "cam" or "cam slot" required by the claims.

27. Gore asks the Court to declare that Gore has not infringed any valid claim of the '316 Patent.

COUNT TWO

Declaratory Judgment of Invalidity of the '316 Patent
28 U.S.C. § 2201

28. Gore repeats and realleges paragraphs 1 through 26 of this complaint, as though fully set forth.

29. For the reasons set out in this complaint, an actual case and controversy exists between Millipore and Gore based on Millipore's '316 Patent and the Threatened Gore Products.

30. The claims of the '316 Patent are invalid under 35 U.S.C. §§ 102, 103, 112, and/or 256 at least based on (1) Millipore's own prior art Sanitary Sampling Valve and Opticap Disposable Capsule Filters, (2) prior art stainless steel sampling valves, (3) Millipore's failure to name all inventors, and (4) Millipore's failure to claim that which the inventors of the '316 Patent regarded as their invention and Millipore's decision to claim sterile transfer devices beyond those invented and possessed by the inventors of the '316 Patent.

31. Gore asks the Court to declare that the claims of the '316 Patent are invalid.

PRAYER FOR RELIEF

Wherefore, Gore prays for the following relief:

A. That the Court declare and enter judgment that Gore has not infringed and does not infringe any valid claim of the '316 Patent;

B. That the Court declare and enter judgment that the claims of the '316 Patent are invalid;

C. That Gore be awarded its reasonable costs and attorneys' fees pursuant to 35 U.S.C. § 285; and

D. That the Court award Gore such other relief as the Court deems just and proper.

DEMAND FOR JURY TRIAL

Gore demands a trial by jury of all issues triable of right by jury.

Respectfully submitted,

/s/ John W. Shaw

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