

UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS

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TYCO HEALTHCARE GROUP, LP,		)	
		)	
	Plaintiff,	)	
		)	
	v.	)	CASE NO. 05-12327 NG
		)	
ARGON MEDICAL DEVICES, INC.,		)	
ARGON MEDICAL DEVICES		)	
HOLDINGS, INC., ACI MEDICAL		)	
DEVICES, INC., and CLINICAL		)	
INNOVATIONS, LLC.		)	
	Defendants.	)	
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**FIRST AMENDED COMPLAINT FOR DECLARATORY JUDGMENT**

Plaintiff Tyco Healthcare Group LP (“Tyco Healthcare”), through its counsel, hereby brings this declaratory judgment cause of action for a declaration of patent invalidity, unenforceability and noninfringement against defendants, Argon Medical Devices, Inc. (“AMD”), Argon Medical Devices Holdings, Inc. (“AMD Holdings”), ACI Medical Devices, Inc. (“ACI”) and Clinical Innovations, LLC. (“CI LLC”) (the defendants are collectively referred to as “Defendants”).

**PARTIES**

1. Plaintiff Tyco Healthcare is a Delaware corporation, having a principal place of business at 15 Hampshire Street, Mansfield, Massachusetts 02048 and 2 Ludlow Park Chicopee, Massachusetts 01022.

2. Defendant AMD is a Delaware corporation doing business in the state of Massachusetts, and having a principal place of business at 272 E. Deerpath Road, Suite 316, Lake Forest, Illinois 60045-5326.

3. Defendant AMD Holdings is an unincorporated entity having a principal place of business at 272 E. Deerpath Road, Suite 316, Lake Forest, Illinois 60045-5326.

4. Defendant ACI is an unincorporated entity having a principal place of business at 272 E. Deerpath Road, Suite 316, Lake Forest, Illinois 60045-5326.

5. Defendant CI LLC is a Delaware limited liability company having a principal place of business at 747 West 4170 South, Murray, Utah 84123.

### **JURISDICTION AND VENUE**

6. This is a civil action arising under the Patent laws of the United States and under the Federal Declaratory Judgment Act. This court has jurisdiction over this action by virtue of 28 U.S.C. §§ 1338(a), 2201 and 2202.

7. Upon information and belief, Defendants are doing business in this district and therefore are residents of this district. Accordingly, venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391(b) and (c).

8. An actual controversy exists between Tyco Healthcare, on the one hand, and AMD, AMD Holdings, ACI and/or CI LLC, on the other hand, as to the alleged infringement by Tyco Healthcare of the '524 Patent, and as to the validity and enforceability of the '524 Patent.

### **FACTUAL BACKGROUND**

9. United States Patent No. 6,231,524 ("the '524 Patent") issued on May 15, 2001 and is entitled "Pressure Catheter Device With Enhanced Fluid Monitoring Features." (Exhibit A). The '524 Patent on its face lists William Dean Wallace, Christopher A. Cutler and Steven R. Smith as inventors and Clinical Innovations Associates, Inc. ("Clinical Innovations") as assignee at the time the patent issued.

10. AMD acquired all right, title and interest in the '524 Patent by assignment from Clinical Innovations on April 29, 2005.

11. On information and belief, at or about the same time, AMD Holdings and ACI acquired some right, title and interest in the '524 patent in addition to AMD.

12. On July 28, 2005, Clinical Innovations filed a complaint against plaintiff Tyco Healthcare, Tyco International (US), Inc. and Tyco International Ltd., alleging that Tyco Healthcare's Accu-Trace™ intrauterine pressure catheter infringes the '524 Patent ("Clinical Innovations Suit"). Tyco Healthcare has offered for sale and sold, and continues to offer for sale and sells its Accu-Trace™ intrauterine pressure catheter.

13. On October 3, 2005, Tyco Healthcare filed its answer and affirmative defenses in the Clinical Innovations Suit, in which it alleged, among other things, that Clinical Innovations lacked standing because it did not own the '524 Patent.

14. On November 16, 2005 Clinical Innovations acknowledged in writing that Clinical Innovations was erroneously identified in the Clinical Innovations Suit as the owner of the '524 Patent, and that the true owner is AMD.

15. Tyco Healthcare became concerned that AMD, AMD Holdings and/or ACI would pursue an action for infringement of the '524 Patent against Tyco Healthcare.

16. On November 21, 2005, Tyco Healthcare filed a complaint against AMD, AMD Holdings and ACI, in this court, seeking a declaration that the '524 Patent is invalid, unenforceable or not infringed.

17. On January 4, 2006, Tyco Healthcare's concerns that it would be sued by the true owner of the '524 Patent were borne out, when a new entity, CI LLC, filed a complaint against Tyco Healthcare and Tyco International (US), Inc. in Utah District Court. In its complaint, CI

LLC specifically alleged that it had acquired title to the '524 Patent from AMD on December 30, 2005.

**FIRST CAUSE OF ACTION**  
**(Declaratory Judgment of Non-infringement  
and/or Invalidity of the '524 Patent)**

18. Tyco Healthcare hereby incorporates Paragraphs 1-17 of this Complaint.

19. Tyco Healthcare does not infringe, induce the infringement nor contribute to the infringement, literally or under the doctrine of equivalents, of any valid claim of the '524 Patent.

20. The '524 Patent is invalid, in whole or in part, as not satisfying one or more of the conditions of patentability set forth in Part II of Title 35 of the United States Code, *inter alia*, Sections 101-103 and 112.

21. Thus Tyco Healthcare seeks a declaratory judgment in its favor that Tyco Healthcare has not infringed and is not infringing the '524 Patent and that the '524 Patent is invalid.

**SECOND CAUSE OF ACTION**  
**(Declaratory Judgment of Unenforceability of the '524 Patent)**

22. Tyco Healthcare hereby incorporates Paragraphs 1-21 of this Complaint.

23. Each claim of the '524 Patent is unenforceable because the inventors, each attorney or agent who prepared or prosecuted the application that ripened into the '524 Patent, and every other individual who was substantively involved in the preparation or prosecution of the application (hereafter referred to as "Applicants"), at the time of prosecution of the '524 Patent, deliberately and knowingly failed to disclose, and affirmatively misrepresented, material information to the examiner with the intent to deceive the PTO.

24. The '524 Patent issued from Application No. 09/309,332 filed May 11, 1999, which is a continuation of Application No. 08/878,054, filed June 18, 1997, which is a continuation-in-part of Application No. 08/706,837, filed September 3, 1996.

25. Statements made by the examiner during the prosecution of the '524 Patent demonstrate that the question of whether there were in the prior art intrauterine pressure catheter devices whose features included either a light transmissive medial portion or an entirely clear catheter was material to the patentability of the '524 Patent.

26. The Graphic Control Life Trace Fluid-Filled IUP monitoring kit ("Life Trace"), included an entirely clear catheter for intrauterine pressure monitoring and amnio infusion, and has been on sale and available in the market since 1995, *i.e.*, well before the earliest filing of any of the applications related to the '524 Patent.

27. Applicants knew about the Life Trace, knew that the Life Trace included an entirely clear catheter, and therefore knew that the Life Trace included a light transmissive medial portion, as evidenced by the fact that Applicants submitted a Life Trace product brochure to the examiner. This product brochure is cited on the face of the '524 Patent.

28. However, the Life Trace product brochure does not disclose on its face the clear structure of the prior art catheter.

29. Applicants failed to disclose the clear structure of the Life Trace to the examiner at the time of the prosecution of the application that matured into the '524 Patent.

30. The Quest ISOFLO Intrauterine Pressure (IUP) Monitoring Kit ("ISOFLO") has an entirely clear catheter, and, on information and belief, has been on sale and available in the market place since the early 1990's, *i.e.*, well before the earliest filing of any of the applications related to the '524 patent.

31. On information and belief, Applicants knew about ISOFL0, the ISOFL0's clear structure, and that ISOFL0 therefore included a light transmissive medial portion as evidenced by published studies identified on Plaintiff's website that reference ISOFL0.

32. Applicants failed to disclose ISOFL0 and its clear structure to the examiner at the time of prosecution of the application that matured into the '524 Patent.

33. Failing to disclose the clear structure of the Life Trace and ISOFL0 enabled Applicants to obtain issuance of the '524 Patent.

34. Moreover, during the prosecution, the examiner expressly stated that the feature of fabricating an entire wall of the outer tube from light-transmissive material was an obvious design choice since, according to the examiner, this feature is well known in the medical art. In response, Applicants affirmatively denied that this feature was known in the art, and affirmatively denied that this feature is an obvious design choice.

35. In addition, during prosecution, Applicants amended the claims to specifically recite that a "medial portion" of the claimed catheter was light transmissive.

36. Applicants affirmatively argued that the recited "medial portion" was not shown in the prior art.

37. Applicants deliberately misrepresented the state of the prior art and did so with the intent to deceive the examiner.

38. Applicants' misrepresentation of the material facts enabled them to improperly secure the issuance of the '524 Patent.

39. Applicants' failure to disclose material facts, as well as their affirmative misrepresentation of material facts, was coupled with an intent to deceive the examiner, such that inequitable conduct has occurred that renders all claims of the '524 Patent unenforceable.

**PRAYER FOR RELIEF**

Wherefore, plaintiff Tyco Healthcare respectfully requests a final judgment against defendants:

1. Declaring that the '524 Patent is invalid and unenforceable;
2. Declaring that Tyco Healthcare has neither infringed, literally or under the doctrine of equivalents, nor actively induced nor contributed to any infringement of any valid claim of the '524 Patent;
3. Awarding Tyco Healthcare its reasonable costs of suit and attorneys' fees incurred in the prosecution of this action; and
4. Granting to Tyco Healthcare such other and further relief as this Court deems just and proper.

**DEMAND FOR JURY TRIAL**

Plaintiff Tyco Healthcare hereby demands a jury trial on all appropriate factual and legal issues.

Respectfully submitted,

TYCO HEALTHCARE GROUP, LP  
By Its Attorneys,

*/s/ Jeffrey W. Moss*

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