Stephen M. Orlofsky
New Jersey Resident Partner
David C. Kistler
BLANK ROME LLP
301 Carnegie Center
3rd Floor
Princeton, New Jersey 08540
Telephone (609) 750-7700
Facsimile (609) 750-7701
Orlofsky@BlankRome.com
Kistler@BlankRome.com
Counsel for Plaintiff

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

MEDICAL COMPONENTS, INC.,	
Plaintiff, v.)) Civil Action No.
· ·)
C.R. BARD, INC.,)
)
Defendant.	
)
)

COMPLAINT

Plaintiff Medical Components, Inc. ("MedComp"), by and through its undersigned attorneys, hereby complains of Defendant C.R. Bard, Inc. ("Bard") as follows:

NATURE OF ACTION

1. This is an action under 35 U.S.C. § 146 to review decisions of the Board of Patent Appeals and Interferences, now known as the Patent and Trial Appeal Board ("the Board"), of the United States Patent and Trademark Office ("PTO") in Interference No. 105,860 ("the '860 Interference").

THE PARTIES

- 2. MedComp is a corporation organized under the laws of the Commonwealth of Pennsylvania and has its principal place of business located at 1499 Delp Drive, Harleysville, Pennsylvania, 19438. MedComp makes, sells, offers for sale, and/or uses medical components, including implantable port products, throughout the United States, including within this District.
- 3. Upon information and belief, Defendant is a corporation organized and existing under the laws of the State of New Jersey with its principal place of business located at 730 Central Avenue, Murray Hill, New Jersey, 07974. Defendant makes, sells, offers for sale, and/or uses medical components, including implantable port products, throughout the United States, including within this District.

JURISDICTION, VENUE AND TIMELINESS

- 4. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338 and 35 U.S.C. § 146.
- 5. Bard is subject to personal jurisdiction in this Court because, *inter alia*, it systematically and continuously transacts business within the State of New Jersey and because this action arises out of and/or relates to Bard's business activities in New Jersey.
 - 6. Venue is proper in this Court under 28 U.S.C. § 1391 (b) and (d).
- 7. This action under 35 U.S.C. § 146 is timely as 37 C.F.R. § 1.304(a)(1) requires that the time for commencing a civil action shall expire two (2) months after action on a request for rehearing or reconsideration of a decision of the Board. On November 23, 2012, the Board issued a Decision on Rehearing, in response to a Request for Rehearing filed by Zinn. In

accordance with 37 C.F.R. § 41.127(d), Zinn's Request for Rehearing was timely filed October 11, 2012, within thirty (30) days of a Judgment on Merits, which was dated September 11, 2012. *See Paragraphs 27-30, below.*

PROCEDURAL BACKGROUND

- 8. This action arises from the '860 Interference, which was declared by the PTO on November 10, 2011. *See Paper No. 1*.
- 9. The '860 Interference concerned U.S. Patent Application Serial No. 11/725,287 ("the '287 Application"), of Kenneth M. Zinn, Raymond Bizup, Kevin Sanford, and Timothy M. Schweikert and U.S. Patent No. 7,785,302 ("the '302 Patent"), to Kelly B. Powers. *See Paper No. 1.* A copy of the '302 Patent is appended hereto as Exhibit A.
- 10. Raymond Bizup, Kevin Sanford, and Timothy M. Schweikert assigned their interest in the '287 Application to Medcomp, and the assignment is recorded at the PTO at Reel 023544 and Frame 0549.
- 11. Kenneth M. Zinn assigned his interest in the '287 Application to Innovative Medical Devices, LLC ("IMD"), a corporation organized under the laws of the State of Connecticut with a principal place of business located at 6 Mary Jane Lane, Westport, Connecticut, 06880, and the assignment is recorded at the PTO at Reel 021063 and Frame 0457.
- 12. IMD assigned its interest in the '287 Application to Medcomp on January 19,2013, and the assignment was filed at the PTO on January 20, 2013.
- 13. Kelly B. Powers assigned his interest in the '302 Patent to Bard and the assignment is recorded at the PTO at Reel 023568 and Frame 0601 and Reel 026435 and Frame 0292.

- 14. The '287 Application was filed on March 19, 2007, and claims priority to U.S. Provisional Patent Application Serial No. 60/852,591 ("the '591 Provisional"), filed on October 18, 2006.
- 15. The '302 Patent issued from U.S. Patent Application Serial No. 11/368,954 (the '954 Application"), which was filed on March 6, 2006. The '954 Application claims priority to U.S. Provisional Patent Application Serial No. 60/658,518 ("the Powers '518 Provisional"), filed on March 4, 2005.
- 16. During the '860 Interference, MedComp was designated as the Junior Party [Zinn] and Bard was designated as the Senior Party [Powers]. *See Paper No. 1*.
- 17. The '860 Interference had one Count: Claim 22 of the '287 Application or Claim 5 of the '302 Patent. *See Paper No. 1*.
- 18. The '287 Application contains ten claims, Claims 18-27, and all of the ten claims of the '287 Application were designated in the '860 Interference as corresponding to the Count ("Zinn's involved claims"). *See Paper No. 1*.
- 19. The '302 Patent contains ten claims, Claims 1-10, and all of the ten claims of the '302 Patent were designated in the '860 Interference as corresponding to the Count ("Powers' involved claims"). *See Paper No. 1*.
- 20. On December 28, 2011, Junior Party Zinn filed its list of proposed motions. Zinn requested authorization to file the following motions: (1) a motion to deny Powers the benefit of the March 4, 2005, filing date of the Powers '518 Provisional and the March 6, 2006, filing date of the '954 Application because neither application provides sufficient written description; (2) a motion for judgment that Powers' involved claims were invalid under 35 U.S.C. § 112, first paragraph, for failure to satisfy the written description requirement; (3) a motion for judgment on

priority awarding Count 1 to Zinn; (4) a motion the Powers' involved claims were invalid under 35 U.S.C. § 102 and/or 35 U.S.C. § 103; (5) a miscellaneous motion requesting that Figures 52A and 52B and the corresponding text be removed from the '302 Patent and all applications and patents claiming priority to the underlying '954 Application; (6) a miscellaneous motion to add U.S. Patent No. 7,947,022 to Amin *et al.* ("the '022 Patent") to the interference; (7) a miscellaneous motion to add U.S. Patent No. 8,029,482 to Maniar *et al.* ("the '482 Patent") to the interference; and (8) a miscellaneous motion seeking suspension of prosecution in U.S. Patent Application Serial No. 13/159,230 ("the '230 Application"), which claims the benefit of the '518 Provisional. A copy of the '022 Patent and the '482 Patent are appended hereto as Exhibits B and C, respectively.

21. On December 28, 2011, Senior Party Powers filed its list of proposed motions. Powers requested authorization to file the following motions: (1) for priority of invention/derivation; (2) a motion for judgment that all of Zinn's involved claims are unpatentable under 35 U.S.C. § 102(e) as anticipated by U.S. Patent Publication No. 2006/0247584 ("the '584 Publication"), *i.e.*, the published version of the '954 Application, or under 35 U.S.C. § 103 as obvious due to the '584 Publication in view of U.S. Patent No. 6,287,293 to Jones; (3) a motion for judgment that all of Zinn's involved claims are unpatentable under 35 U.S.C. § 102(e) as anticipated by U.S. Patent Publication No. 2006/0264898 ("the '898 Publication") or under 35 U.S.C. § 103 as obvious due to the '898 Publication in view of U.S. Patent No. 6,287,293 to Jones; (4) a motion to substitute the Count "which reflects that Powers' earliest actual reduction to practice includes an alphanumeric message which arguably fails to 'indicat[e] that the assembly is power injectable' as recited in Powers half of the count (claim 5)."

- 22. On December 29, 2011, the Board issued an Order that, *inter alia*, authorized both Zinn and Powers to each file a Supplemental List of Proposed Motions. *See Paper No. 17*. On January 3, 2012, Junior Party Zinn filed its Substitute List of Motions. Zinn requested authorization to file: (9) a motion to deny Powers the benefit of the March 4, 2005, filing date of the Powers '518 Provisional because the Powers '518 Provisional does not describe an embodiment within the scope of Count 1; (10) a motion for judgment that Powers' involved claims are unpatentable under 35 U.S.C. § 112, first paragraph, for failure to satisfy the written description requirement; (11) a motion for judgment awarding priority to Zinn; (12) a motion for judgment that Powers' involved claims are unpatentable under at least 35 U.S.C. § 103 in view of at least one or more of the following references, taken alone or in combination:
 - (a) BioEnterics® LAP-BAND® "Adjustable Gastric Banding System" by Inamed Health (Product Brochure 12/2003);
 - (b) Jones (U.S. Patent No. 6,287,293);
 - (c) Tallarida (U.S. Patent No. 6,527,754);
 - (d) Jordan (U.S. Patent No. 5,423,334);
 - (e) Watson (International Patent Publication WO 97/11726);
 - (f) JP 2500388 (Japanese Patent Publication No. 2-55963);
 - (g) Imran (U.S. Patent No. 7,076,305);
 - (h) Carter (U.S. Patent No. 4,863,470);
 - (i) Parks (U.S. Patent No. 4,479,798);
 - (i) Jagmin (U.S. Patent No. 5,044,955);
 - (k) Tanaka (U.S. Patent No. 4,928,298);
 - (1) Lee (U.S. Patent No. 5,203,777);
 - (m) Soffiati (U.S. Patent Publication No. 2004/0157952).

Zinn specifically alleged that Powers' involved claims were unpatentable under 35 U.S.C. § 103 over at least:

```
BioEnterics® LAP-BAND® in view of Watson (WO 97/11726);
BioEnterics® LAP-BAND® in view of Watson (WO 97/11726) and further in
view of JP 2500388 (JP Pub. No. 2-55963);
BioEnterics® LAP-BAND® in view of JP 2500388 (JP Pub. No. 2-55963);
BioEnterics® LAP-BAND® in view of Imran (US 7,076,305);
```

BioEnterics® LAP-BAND® in view of Parks (US 4,479,798); BioEnterics® LAP-BAND® in view of Parks (US 4,479,798) and further in view of Watson (WO 97/11726); and

BioEnterics® LAP-BAND® in view of Parks (US 4,479,798) and further in view of JP 2500388 (JP Pub. No. 2-55963);

and (13) a miscellaneous motion to add the '022 Patent, which claims the benefit of the Powers '518 Provisional, to the interference, arguing that all claims of the '022 Patent should be designated as corresponding to the Count because they are within the scope of the Count and are more narrow than at least Claim 5 of the '302 Patent and are similar to all of the claims of the '302 Patent. Zinn elaborated and stated that for example, Claim 1 recites a "body," which corresponds to the "housing" of the Count, "a fluid cavity," which corresponds to the "reservoir" of the Count, and "at least one radiopaque identification feature" and "one or more alphanumeric characters," which correspond to the "radiopaque alphanumeric message" of the Count. Thus, the features of Claim 1 of the '022 Patent are very similar to the features of Count 1.

Count 1	Claim 1 of the '022 Patent Corresponding to the Count
A venous access port assembly for implantation into a patient, comprising:	1. An access port for providing subcutaneous access to a patient, comprising:
a housing having an outlet, and a needle-penetrable septum, the needle- penetrable septum and the housing together defining a reservoir,	a body defining a fluid cavity accessible by inserting a needle through a septum;

wherein:
the assembly includes a
radiopaque alphanumeric
message observable through
interaction with X-rays
subsequent to subcutaneous
implantation of the assembly
and the alphanumeric
message indicating that the
assembly is power injectable.

and at least one radiopaque identification feature of the access port observable via imaging technology subsequent to subcutaneous implantation of the access port, the at least one radiopaque identification feature including one or more alphanumeric characters identifying the access port as a power-injectable port.

Zinn also indicated that the Examiner's reason for allowance of the '022 Patent claims are substantially identical to the reasons proffered in the '302 Patent prosecution history, and a terminal disclaimer was filed during prosecution of the '022 Patent to overcome, or to avoid, a double patenting rejection in view of the '302 Patent.

- 23. On January 3, 2012, Senior Party Powers filed its Substitute List of Proposed Motions. Powers requested authorization to file the following motions: (1) for priority of invention/derivation; (2) a motion for judgment that all of Zinn's involved claims are unpatentable under 35 U.S.C. § 102(e) as anticipated by the '584 Publication or under 35 U.S.C. § 103 as obvious due to the '584 Publication in view of U.S. Patent No. 6,287,293 to Jones; and (3) a motion for judgment that all of Zinn's involved claims are unpatentable under 35 U.S.C. § 102(e) as anticipated by the '898 Publication or under 35 U.S.C. § 103 as obvious due to the '898 Publication in view of U.S. Patent No. 6,287,293 to Jones.
- 24. On January 5, 2012, the Board issued an Order that authorized Zinn to file its motion to deny Powers the benefit of the March 4, 2005, filing date of the Powers '518 Provisional because the Powers '518 Provisional does not describe an embodiment within the scope of Count 1. The Order authorized, contingent upon the grant of Zinn's benefit motion,

Zinn's motion for judgment that Powers' involved claims are unpatentable under 35 U.S.C. § 112, first paragraph, for failure to satisfy the written description requirement and Zinn's motion for judgment that Powers' involved claims are unpatentable under at least 35 U.S.C. § 103 (limited to one anticipation and one obviousness attack per claim). *See Paper No. 20*. The Order authorized, contingent upon the grant of Zinn's benefit motion, Powers' unpatentability motion due to prior art (limited to one anticipation and one obviousness attack per claim) and Powers' motion for priority of invention. *Id*.

- 25. On February 16, 2012, Zinn filed Zinn Motion 2, requesting that Powers be denied the benefit of the Powers '518 Provisional.
 - 26. On March 19, 2012, Powers filed Powers Opposition 2 to Zinn's Motion 2.
- 27. On April 12, 2012, Zinn filed Zinn Reply 2 regarding its request that Powers be denied the benefit of the Powers '518 Provisional.
- 28. On September 11, 2012, the Board issued its Decision on Motions ("the Decision"). *See Paper No. 50.* The Board concluded that "Zinn has not set forth a prima facie case of entitlement for relief" and denied Zinn Motion 2. *Id.* A copy of the Decision is appended hereto as Exhibit D.
- 29. On September 11, 2012, the Board issued its Judgment on Merits ("the Judgment") and ordered that judgment with respect to Count 1 be entered against Junior Party Zinn and ordered that Claims 18-27 of the '287 Application be finally refused. *See Paper No.* 51. A copy of the Judgment is appended hereto as Exhibit E.
- 30. On October 11, 2012, Zinn filed Zinn Miscellaneous Motion 3, requesting that the Board reconsider and reverse its Decision denying Zinn Motion 2 and entering Judgment against Zinn.

31. On November 23, 2012, the Board issued its Decision on Rehearing ("the Rehearing Decision"). *See Paper No. 53*. The Rehearing Decision granted the rehearing to the extent the Board reconsidered its decision on Zinn Motion 2 but otherwise denied the rehearing and did not change the decision on Zinn Motion 2. *Id.* A copy of the Rehearing Decision is appended hereto as Exhibit F.

PLAINTIFF'S DISSATISFACTION WITH THE BOARD'S DECISION

- 32. Plaintiff is dissatisfied with the Decision at least because the Decision misapprehended the Count and overlooked Zinn's expert-supported arguments showing why one of ordinary skill in the art would not have believed from the Powers Provisional that the inventors actually invented a venous access port assembly having a radiopaque alphanumeric message indicating that the assembly is power injectable. Contrary to the Decision's assertions, Plaintiff fully recognizes that *ipsis verbis* disclosure is not needed for benefit. But what *is* needed is "a described and enabled anticipation" of an embodiment within the scope of the Count. *37 C.F.R. § 41.201*. Contrary to the Decision's assertions, Zinn Motion 2 addressed all necessary issues. Zinn Motion 2 used the correct legal standard and set forth an expert-supported *prima facie* case that the Powers Provisional does not explicitly or inherently disclose "a described and enabled anticipation" because the last limitation of the Count is missing.
- 33. Plaintiff is further dissatisfied with the Decision at least because the manner in which the Decision arose precluded Plaintiff from establishing that Powers' involved claims are unpatentable under 35 U.S.C. § 112, first paragraph, for failure to satisfy the written description requirement.

- 34. Plaintiff is further dissatisfied with the Decision at least because the manner in which the Decision arose precluded Plaintiff from establishing that Powers' involved claims are unpatentable under at least 35 U.S.C. § 103.
- 35. Plaintiff is further dissatisfied with the Decision at least because the manner in which the Decision arose precluded Plaintiff from establishing that the '022 Patent should have been added to the interference and all claims thereof should have been designated as corresponding to the Count.
- 36. Plaintiff is further dissatisfied with the Decision at least because the manner in which the Decision arose precluded Plaintiff from establishing that the '482 Patent should have been added to the interference and all claims thereof should have been designated as corresponding to the Count.
- 37. Plaintiff has been harmed by the Decision, which is erroneous in both fact and law, and by the manner in which it arose.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays that the Court reverse the Decision and Judgment and decree the following:

- A. That the '022 Patent be added to the interference and all claims thereof designated as corresponding to the Count;
- B. That the '482 Patent be added to the interference and all claims thereof designated as corresponding to the Count;

C. Powers is not entitled to the benefit of the March 4, 2005, filing date of the Powers '518 Provisional because the Powers '518 Provisional does not describe an enabled

embodiment within the scope of the Count;

D. Powers' involved claims are unpatentable under 35 U.S.C. § 112, first paragraph,

for failure to satisfy the written description requirement;

E. Powers' involved claims are unpatentable under at least 35 U.S.C. § 103;

F. That priority of invention be awarded against Powers;

G. Reasonable costs and attorneys' fees in prosecuting this action; and

H. Award Plaintiff such other relief as the Court may deem just and proper.

Dated: January 22, 2013

s/Stephen M. Orlofsky
Stephen M. Orlofsky
New Jersey Resident Partner
David C. Kistler
BLANK ROME LLP
301 Carnegie Center
3rd Floor
Princeton, New Jersey 08540
Telephone (609) 750-7700
Facsimile (609) 750-7701
Orlofsky@BlankRome.com
Kistler@BlankRome.com
Counsel for Plaintiff

Alfred W. Zaher, Esq. (PHV to be filed)
Bruce D. George, Esq.
Peter K. Zacharias, Esq.
BLANK ROME LLP
One Logan Square
130 North 18th Street
Philadelphia, Pennsylvania 19103
Telephone (215) 569-5500
Facsimile (215) 832-5798
Zaher@BlankRome.com
George@BlankRome.com
Zacharias@BlankRome.com
Counsel for Plaintiff

Todd R. Walters, Esq. (PHV to be filed)
Erin M. Dunston, Esq. (PHV to be filed)
BUCHANAN INGERSOLL & ROONEY PC
1737 King Street, Suite 500
Alexandria, VA 22314-2727
Telephone (703) 836-6620
Facsimile (703) 836-2021
todd.walters@bipc.com
erin.dunston@bipc.com
Counsel for Plaintiff

LOCAL CIVIL RULE 11.2 CERTIFICATION

Medcomp hereby certifies that, to its knowledge, the matter in controversy in this action is not the subject of any other pending lawsuit, arbitration, or administrative proceeding.

<u>s/ Stephen M. Orlofsky</u> Stephen M. Orlofsky