

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND**

_____)	
DAVID C. MACGREGOR, M.D.)	Civil Action No.
3971 Gulf Shore Boulevard North, #305)	
Naples, Florida 34103)	
Plaintiff)	
v.)	
_____)	
JOHNS HOPKINS HEALTH SYSTEM)	
600 North Wolfe Street)	
Baltimore, Maryland 21287-1900)	
Defendant)	
_____)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff, Dr. David C. MacGregor, complains of Defendant, Johns Hopkins Health System, as follows:

JURISDICTION AND VENUE

1. This is an action for patent infringement under Title 35 United States Code.
2. This Court has jurisdiction of this action under 28 U.S.C. §§ 1331, 1338(a).
3. Plaintiff, David C. MacGregor, M.D. B.Sc. (Med), F.R.C.S.(C), F.A.C.S., F.A.C.C., F.A.H.A. is an individual residing in the State of Florida and is the inventor and owner of United States Letters Patent Numbers 4,458,366 (the '366 patent) entitled Artificial Implantable Blood Pump and 4,374,669 entitled "Cardiovascular Prosthetic Devices and Implants with Porous Systems."
4. Defendant Johns Hopkins, upon information and belief, is a corporation existing under the laws of the state of Maryland. Defendant Johns Hopkins, uses, offers for sale and sells one or more of the infringing products, including those known as:

HeartMate Left Ventricular Assist System (LVAS);
Thoratec Ventricular Assist Device (VAD) System,
HeartMate Implantable Pneumatic (IP) LVAS and LVAD;
HeartMate Vented Electric (VE) LVAS and LVAD;
HeartMate XVE LVAS and LVAD;
HeartMate SNAP-VE LVAS and LVAD;
Heartmate I, II and III

in Maryland. Defendant is engaged in using, offering for sale and selling devices covered under the claims of the '366 and '669 patents in suit. Defendant has purchased product for use and sale in Maryland, and the accused products have been offered for sale, sold and used in the District of Maryland. Venue is proper in this District as to Defendant under 28 U.S.C. §1391(b) and §1400.

GENERAL ALLEGATIONS

5. Defendant operates a hospital facility which, upon information and belief, has used and uses and sells artificial implantable blood pumps and related services to patients, insurance companies and others. Specific implementations of products used by Defendant include one or more of the following:

HeartMate Left Ventricular Assist System (LVAS);
Thoratec Ventricular Assist Device (VAD) System,
HeartMate Implantable Pneumatic (IP) LVAS and LVAD;
HeartMate Vented Electric (VE) LVAS and LVAD;
HeartMate XVE LVAS and LVAD;
HeartMate SNAP-VE LVAS and LVAD;
Heartmate I, II and III

artificial implantable blood pumps which infringe the claims of the '366 and '669 patents.

6. Plaintiff on information and belief, alleges that Defendant has profited from its wrongful use of the intellectual property of Plaintiff. As a direct and proximate result of the

acts alleged above, Plaintiff has been damaged.

COUNT I
PATENT INFRINGEMENT OF U.S. 4,458,366

7. Plaintiff re-alleges each and every allegation set forth above and incorporate them herein by reference.

8. Plaintiff owns and have at all times owned and have had standing to sue for infringement of United States Letters Patent 4,458,366 which was duly and legally issued on July 10, 1984.

9. The '366 patent properly names Plaintiff David C. MacGregor as inventor, is entitled "Artificial Implantable Blood Pump" and includes independent Claims 1, 7 and 13 which read as follows:

1. A blood pump, comprising:
 - a rigid housing having an integral wall, said housing being constructed of a rigid material substantially inert to blood,
 - a resiliently flexible diaphragm located in said housing and defining a cavity with said internal wall, said diaphragm being constructed of resiliently flexible biocompatible polymeric material, said diaphragm being constructed to cyclically flex between contracted and expanded positions to vary the working volume of said cavity,
 - means for effecting cyclical flexing of said diaphragm between said contracted and expanded positions,
 - inlet means to said housing communication with said cavity and having first one-way valve means located therein permitting flow of blood into said cavity through said inlet means in response to an increase in the working volume of said cavity, and
 - outlet means from said housing communicating with said cavity and having second one-way valve means located therein permitting flow of blood out of said cavity through said outlet means in response to a decrease in the working volume of said cavity,
 - said internal wall of the rigid housing being composed of a single material of construction and consisting of a porous blood-engaging surface portion integral with a coherent substrate portion, said porous surface portion

having a network of interconnected pores therein, a pore size of less than 200 microns, a porosity of about 10 to about 50% by volume and a thickness of up to about 500 microns,

said surface portion being constituted by a plurality of particles which are integrally joined to each other at their points of contact with each other by the material of construction of said internal wall to define said network of interconnected pores and which are integrally joined to said coherent substrate portion by the material of construction of said internal wall.

7. A blood pump, comprising
a rigid housing having a generally circularly cross-sectioned cavity, said housing being constructed of rigid material substantially inert to blood,
inlet means coaxial with said housing and communicating with said cavity permitting flow of blood into said cavity through said inlet means,
outlet means tangential to said housing and communicating with said cavity permitting flow of blood out of said cavity through said outlet means, and
impeller means mounted in said cavity for rotation about an axis coaxial with said inlet means for impelling blood within said cavity from said inlet means to said outlet means,

the internal wall of said cavity being composed of a single material of construction and consisting of a porous blood-engaging surface portion integral with a coherent substrate portion, said porous network portion having a network of interconnected pores therein, a pore size of less than 200 microns, a porosity of about 10 to about 50% by volume and a thickness of up to about 500 microns,

said surface portion being constituted by a plurality of particles which are integrally joined to each other at their points of contact with each other by the material of construction of said internal wall to define said network of interconnected pores and which are integrally joined to said coherent substrate portion by the material of construction of said internal wall.

13. A blood pump diaphragm constructed of resiliently-flexible biocompatible polymeric material and comprising a planar sheet having at least sufficient strength to withstand pulsatile arterial blood pressure of greater than about 300 mm Hg in its physiological environment for at least 1 year, said sheet comprising a resiliently-flexible coherent polymeric substrate layer and a resiliently-flexible porous coating layer adhered to the substrate layer and adapted to engage blood and having a network of interconnected pores distributed therethrough, said porous coating layer consisting of particles of material joined together by the material of construction thereof, said porous coating having a pore size of less than about 200 microns, a porosity of about 10 to about 70% by volume and a thickness of less than about 500 microns.

10. Upon information and belief, Johns Hopkins has marketed, offered for sale, used and sold artificial implantable blood pumps.

11. Upon information and belief, Johns Hopkins has infringed the claims of the '366 patent by its marketing, offering for sale, using and selling blood pumps.

12. Upon information and belief, Johns Hopkins has contributed to infringement by third parties by its marketing, offering for sale, using and selling blood pumps.

13. Upon information and belief, Johns Hopkins has actively induced third parties to infringe the claims of the '366 patent by its marketing, offering for sale, using and selling blood pumps. Johns Hopkins knew, or should have known, that its actions would induce others to use artificial implantable blood pumps in a manner which infringes the claims of the '366 patent. The acts of inducement includes implanting infringing blood pumps and providing written materials and other teaching materials teaching how to use the blood pumps in a manner that infringes.

14. Plaintiff is entitled to recover from the Defendant the damages sustained as a result of Defendant's infringing acts.

COUNT II

PATENT INFRINGEMENT OF U.S. 4,374,669

15. Plaintiff re-alleges each and every allegation set forth above and incorporate them herein by reference.

16. Plaintiff owns and has at all times owned and had standing to sue for infringement of United States Letters Patent 4,374,669 which was duly and legally issued on

February 22, 1983.

17. The '669 patent properly names Plaintiff David C. MacGregor as inventor, is entitled "Cardiovascular Prosthetic Devices and Implants with Porous Systems" and includes independent Claim 1 which reads as follows:

1. A method of formation of a composite structure in cardiovascular devices or implants constructed of rigid metal inert to blood to inhibit the incidence of thromboembolism and consisting of a rigid coherent metal substrate and a porous coating formed on and adhered to blood-engaging surfaces of said substrate consisting of a plurality of small discrete particles bonded together at their points of contact with each other in at least two layers to define a plurality of connected interstitial pores uniformly distributed throughout the coating, said method comprising:
roughening the coherent metal substrate surfaces desired to be coated,
forming a viscous self-supporting coating of a plurality of layers of at least one metal or at least one thermally-decomposable metal compound particles adhesively bound together and to the substrate,
drying said adhesive to provide a preform on said substrate; and
sintering said preform to cause interconnection of metal particles to each other and to said substrate.

18. Upon information and belief, Johns Hopkins has marketed, offered for sale, used and sold cardiovascular prosthetic devices and implants with porous systems.

19. Upon information and belief, Johns Hopkins has infringed the claims of the '669 patent by its marketing, offering for sale, using and selling cardiovascular prosthetic devices.

20. Upon information and belief, Johns Hopkins has contributed to infringement by third parties by its marketing, offering for sale, using and selling cardiovascular prosthetic devices.

21. Upon information and belief, Johns Hopkins has actively induced third parties to infringe the claims of the '669 patent by its implanting, marketing, offering for sale, using and selling blood pumps. Johns Hopkins knew, or should have known, that its actions would

induce others to use cardiovascular prosthetic devices and implants with porous systems in a manner which infringe the claims of the '669 patent. The acts of inducement includes implanting and selling infringing cardiovascular prosthetic devices and implants with porous systems blood pumps and providing written materials and other teaching materials teaching how to use the blood pumps in a manner that infringes.

22. Plaintiff is entitled to recover from the Defendant the damages sustained as a result of Defendant's infringing acts.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment against Defendant as follows:

23. That Defendant be held to have infringed the '366 and/or '669 patents.
24. An award of damages as provided for in 35 U.S.C. 284.
25. That judgment be entered for Plaintiff against Defendant, for Plaintiff's actual damages according to proof, and for any additional profits attributable to infringements of Plaintiff's patent rights, in accordance with proof.
26. That judgment be entered for Plaintiff against Defendant, for reasonable royalties and/or other statutory damages based upon Defendant's acts of patent infringement and for its other violations of law.
27. That Defendant be required to account for all gains, profits, and advantages derived from its acts of infringement and for its other violations of law.
28. That judgment be entered for Plaintiff and against Defendant, for trebling of the damages awarded for patent infringement.

29. That Plaintiff have judgment against the Defendant for its costs and attorney's fees.

30. That the Court grant such other, further, and different relief as the Court deems proper under the circumstances.

DEMAND FOR TRIAL BY JURY

Plaintiff demands a trial by jury on all issues so triable.

Respectfully submitted,

/s/

Joseph J. Zito, 05640
ZITO *tlp*
26005 Ridge Road, Suite 203
Damascus, Maryland 20872
(301) 601-5010 Fax (301) 482-0779
joe@zitotlp.com
Attorneys for Plaintiff

United States District Court

DISTRICT OF Maryland

DAVID C. MACGREGOR, MD

SUMMONS IN A CIVIL CASE

V.

CASE NUMBER:

JOHN HOPKINS HEALTH SYSTEM

TO: (Name and address of defendant)

JOHNS HOPKINS HEALTH SYSTEM
600 North Wolfe Street
Baltimore, Maryland 21287-1900

YOU ARE HEREBY SUMMONED and required to serve upon PLAINTIFF'S ATTORNEY (name and address)

Joseph J. Zito
ZITO tlp
26005 Ridge Road
Suite 203
Damascus, Maryland 20872
(301) 601-5010
fax 482-0779

an answer to the complaint which is herewith served upon you, within 20 days after service of this summons upon you, exclusive of the day of service. If you fail to do so, judgment by default will be taken against you for the relief demanded in the complaint. You must also file your answer with the Clerk of this Court within a reasonable period of time after service.

CLERK

DATE

(BY) DEPUTY CLERK

JS 44MD (Rev. 3/99)

CIVIL COVER SHEET

The JS-44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON THE REVERSE OF THE FORM.)

I. (a) PLAINTIFFS

DAVID C. MACGREGOR, M.D.
3971 Gulf Shore Boulevard North, #305
Naples, Florida 34103

(b) County of Residence of First Listed Plaintiff _____
(EXCEPT IN U.S. PLAINTIFF CASES)

DEFENDANTS

JOHNS HOPKINS HEALTH SYSTEM
600 North Wolfe Street
Baltimore, Maryland 21287-1900

County of Residence of First Listed Defendant _____
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE LAND INVOLVED.

(c) Attorney's (Firm Name, Address, and Telephone Number)

Joseph J. Zito, Esq.
26005 Ridge Road, Suite 203
Damascus, Maryland 20872 (301) 601-5010 Phone

Attorneys (If Known)

Richard P. Kidwell
Managing Atty
Johns Hopkins
410-955-7949

II. BASIS OF JURISDICTION (Place an "X" in One Box Only)

- 1 U.S. Government Plaintiff
- 3 Federal Question (U.S. Government Not a Party)
- 2 U.S. Government Defendant
- 4 Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff and One Box for Defendant)

- | | | | | | |
|---|----------------------------|----------------------------|---|----------------------------|----------------------------|
| | PTF | DEF | | PTF | DEF |
| Citizen of This State | <input type="checkbox"/> 1 | <input type="checkbox"/> 1 | Incorporated or Principal Place of Business In This State | <input type="checkbox"/> 4 | <input type="checkbox"/> 4 |
| Citizen of Another State | <input type="checkbox"/> 2 | <input type="checkbox"/> 2 | Incorporated and Principal Place of Business In Another State | <input type="checkbox"/> 5 | <input type="checkbox"/> 5 |
| Citizen or Subject of a Foreign Country | <input type="checkbox"/> 3 | <input type="checkbox"/> 3 | Foreign Nation | <input type="checkbox"/> 6 | <input type="checkbox"/> 6 |

IV. NATURE OF SUIT (Place an "X" in One Box Only)

CONTRACT	TORTS	FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES
<input type="checkbox"/> 110 Insurance <input type="checkbox"/> 120 Marine <input type="checkbox"/> 130 Miller Act <input type="checkbox"/> 140 Negotiable Instrument <input type="checkbox"/> 150 Recovery of Overpayment & Enforcement of Judgment <input type="checkbox"/> 151 Medicare Act <input type="checkbox"/> 152 Recovery of Defaulted Student Loans (Excl. Veterans) <input type="checkbox"/> 153 Recovery of Overpayment of Veteran's Benefits <input type="checkbox"/> 160 Stockholders' Suits <input type="checkbox"/> 190 Other Contract <input type="checkbox"/> 195 Contract Product Liability	PERSONAL INJURY <input type="checkbox"/> 310 Airplane <input type="checkbox"/> 315 Airplane Product Liability <input type="checkbox"/> 320 Assault, Libel & Slander <input type="checkbox"/> 330 Federal Employers' Liability <input type="checkbox"/> 340 Marine <input type="checkbox"/> 345 Marine Product Liability <input type="checkbox"/> 350 Motor Vehicle <input type="checkbox"/> 355 Motor Vehicle Product Liability <input type="checkbox"/> 360 Other Personal Injury	PERSONAL INJURY <input type="checkbox"/> 362 Personal Injury—Med. Malpractice <input type="checkbox"/> 365 Personal Injury—Product Liability <input type="checkbox"/> 368 Asbestos Personal Injury Product Liability PERSONAL PROPERTY <input type="checkbox"/> 370 Other Fraud <input type="checkbox"/> 371 Truth in Lending <input type="checkbox"/> 380 Other Personal Property Damage <input type="checkbox"/> 385 Property Damage Product Liability <input type="checkbox"/> 555 Prison Condition	<input type="checkbox"/> 422 Appeal 28 USC 158 <input type="checkbox"/> 423 Withdrawal 28 USC 157 PROPERTY RIGHTS <input type="checkbox"/> 820 Copyrights <input checked="" type="checkbox"/> 830 Patent <input type="checkbox"/> 840 Trademark SOCIAL SECURITY <input type="checkbox"/> 861 HIA (1395f) <input type="checkbox"/> 862 Black Lung (923) <input type="checkbox"/> 863 DIWC/DIWW (405(g)) <input type="checkbox"/> 864 SSID Title XVI <input type="checkbox"/> 865 RSI (405(g)) FEDERAL TAX SUITS <input type="checkbox"/> 870 Taxes (U.S. Plaintiff or Defendant) <input type="checkbox"/> 871 IRS—Third Party 26 USC 7609	<input type="checkbox"/> 400 State Reapportionment <input type="checkbox"/> 410 Antitrust <input type="checkbox"/> 430 Banks and Banking <input type="checkbox"/> 450 Commerce/ICC Rates/etc. <input type="checkbox"/> 460 Deportation <input type="checkbox"/> 470 Racketeer Influenced and Corrupt Organizations <input type="checkbox"/> 810 Selective Service <input type="checkbox"/> 850 Securities/Commodities/Exchange <input type="checkbox"/> 875 Customer Challenge 12 USC 3410 <input type="checkbox"/> 891 Agricultural Acts <input type="checkbox"/> 892 Economic Stabilization Act <input type="checkbox"/> 893 Environmental Matters <input type="checkbox"/> 894 Energy Allocation Act <input type="checkbox"/> 895 Freedom of Information Act <input type="checkbox"/> 900 Appeal of Fee Determination Under Equal Access to Justice <input type="checkbox"/> 950 Constitutionality of State Statutes <input type="checkbox"/> 890 Other Statutory Actions
REAL PROPERTY <input type="checkbox"/> 210 Land Condemnation <input type="checkbox"/> 220 Foreclosure <input type="checkbox"/> 230 Rent Lease & Ejectment <input type="checkbox"/> 240 Torts to Land <input type="checkbox"/> 245 Tort Product Liability <input type="checkbox"/> 290 All Other Real Property	CIVIL RIGHTS <input type="checkbox"/> 441 Voting <input type="checkbox"/> 442 Employment <input type="checkbox"/> 443 Housing/Accommodations <input type="checkbox"/> 444 Welfare <input type="checkbox"/> 440 Other Civil Rights	PRISONER PETITIONS <input type="checkbox"/> 510 Motions to Vacate Sentence Habeas Corpus: <input type="checkbox"/> 530 General <input type="checkbox"/> 535 Death Penalty <input type="checkbox"/> 540 Mandamus & Other <input type="checkbox"/> 550 Civil Rights <input type="checkbox"/> 555 Prison Condition	<input type="checkbox"/> 610 Agriculture <input type="checkbox"/> 620 Other Food & Drug <input type="checkbox"/> 625 Drug Related Seizure of Property 21 USC 881 <input type="checkbox"/> 630 Liquor Laws <input type="checkbox"/> 640 R.R. & Truck <input type="checkbox"/> 650 Airline Regs. <input type="checkbox"/> 660 Occupational Safety/Health <input type="checkbox"/> 690 Other LABOR <input type="checkbox"/> 710 Fair Labor Standards Act <input type="checkbox"/> 720 Labor/Mgmt. Relations <input type="checkbox"/> 730 Labor/Mgmt. Reporting & Disclosure Act <input type="checkbox"/> 740 Railway Labor Act <input type="checkbox"/> 790 Other Labor Litigation <input type="checkbox"/> 791 Empl. Ret. Inc. Security Act	

V. ORIGIN

(PLACE AN "X" IN ONE BOX ONLY)

- 1 Original Proceeding
- 2 Removed from State Court
- 3 Remanded from Appellate Court
- 4 Reinstated or Reopened
- 5 Transferred from another district (specify)
- 6 Multidistrict Litigation
- 7 Appeal to District Judge from Magistrate Judgment

VI. CAUSE OF ACTION

(Cite the U.S. Civil Statute under which you are filing and write brief statement of cause. Do not cite jurisdictional statutes unless diversity.)

Title 35 United States Code - Patent Infringement

VII. REQUESTED IN COMPLAINT:

CHECK IF THIS IS A CLASS ACTION UNDER F.R.C.P. 23

DEMAND \$

CHECK YES only if demanded in complaint:

JURY DEMAND: Yes No

VIII. RELATED CASE(S) IF ANY (See instructions):

JUDGE Andre M. Davis DOCKET NUMBER AMD 03-1233

DATE 10-27-03 SIGNATURE OF ATTORNEY OF RECORD

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____