

**UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF OHIO  
WESTERN DIVISION**

<b>ARTHUR RAY BOWLING, ET AL.,</b>	:	
	:	<b>No. C-1-91-256</b>
<b>PLAINTIFF,</b>	:	
	:	
<b>v.</b>	:	<b>JUDGE HERMAN J. WEBER,</b>
	:	<b>SENIOR JUDGE</b>
<b>PFIZER, INC. ET AL.,</b>	:	
	:	
<b>DEFENDANT.</b>	:	

**NOTICE OF FILING OF THE TWENTY-NINTH REPORT OF THE  
SPECIAL MASTERS/TRUSTEES COVERING THE PERIOD  
FROM APRIL 2, 2008 TO OCTOBER 8, 2008**

NOTICE IS HEREBY GIVEN to all counsel of record that the TWENTY-NINTH REPORT OF THE SPECIAL MASTERS/TRUSTEES COVERING THE PERIOD FROM APRIL 2, 2008 TO OCTOBER 8, 2008 is hereby filed with the Court.

Respectfully submitted,

/s/ Nancy A. Lawson  
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*Attorney for  
Special Masters/Trustees*

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF OHIO  
WESTERN DIVISION

IN RE: : Case No. C-1-91-256  
: :  
BOWLING-PFIZER LITIGATION : Judge Herman J. Weber,  
: Senior Judge

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TWENTY-NINTH REPORT OF THE SPECIAL MASTERS/TRUSTEES  
COVERING THE PERIOD FROM APRIL 2, 2008 TO OCTOBER 8, 2008

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SPECIAL MASTERS/TRUSTEES

James A. Higgins, Esq.  
Peter J. Strauss, Esq.

**AGENDA**

**TWENTY-NINTH REPORT OF THE SPECIAL MASTERS/TRUSTEES**

In Re: Bowling-Pfizer Litigation

Case No. C-1-91-256

October 23, 2008

11:00 A.M.

Hon. Herman J. Weber, Senior Judge

1. Introductory remarks by Judge Weber.
2. Report of the Special Masters/Trustees.
3. Comments from Counsel:
  - Class Counsel.
  - Counsel for Defendants.
4. Questions and comments from those in attendance.
5. Request for date of next report of Trustees.
6. Closing remarks of Judge Weber.

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- A. Twenty-Ninth Report of the Special Masters/Trustees
- B. Appendices to Court Report
  - 1. Index of Intellectual Property
  - 2. Summary of Research
  - 3. "Hit Report" regarding the Supervisory Panel's Website.
  - 4. Unaudited balance sheet as of August 31, 2008 and an unaudited statement of income and funds balance for the eight months ended August 31, 2008.

**UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF OHIO  
WESTERN DIVISION**

**IN RE:** : **Case No. C-1-91-256**  
:   
**BOWLING-PFIZER LITIGATION** : **Judge Herman J. Weber,**  
: **Senior Judge**

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**TWENTY-NINTH REPORT OF THE SPECIAL MASTERS/TRUSTEES**

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To the Honorable Herman J. Weber, Senior Judge, United States District Court:

Your Special Masters/Trustees respectfully present their twenty-ninth periodic report, covering activities from April 2, 2008 to October 8, 2008. This report is submitted fifteen days prior to the status hearing before the Court scheduled for October 23, 2008.

**I. PATIENT BENEFIT FUND**

A. Supervisory Panel. The patient studies with the ACES device at The Ohio State University have been concluded and a final report was received in May, 2007. The imaging and acoustics committee was favorably impressed with the ACES work and made a recommendation to the full panel for continued studies. The panel considered the results of the ACES work and agreed that there was sufficient promise in the technology to pursue additional work. Therefore, a research project for ACES to study the BSCC heart valve sound recordings made on patients who participated in the imaging studies at Stanford and Beaumont was recommended by the panel and approved by the Court. That study is ongoing. The panel has recommended the approval of a short-term study by Dr. J. de Hart of Eindhoven University in The Netherlands entitled "Outlet strut vibratory response study of BSCC valves at disc-strut closure impact". The

purpose of the study is to conduct in vitro research on seven BSCC heart valves, including the valve which had been implanted in a sheep at BioSurg, but was misclassified.

With regard to BioQuantetics, the panel has been unsuccessful in obtaining a report on the clinical trials from Dr. Rambod. The trials were done without the sponsorship or funding of the Trustees. The Trustees have been advised by Dr. Rambod, however, that no device employing the technology funded by the Trust has been developed.

The panel has been working with MedicAlert in an effort to develop a program in which MedicAlert expands its services to other countries. The Supervisory Panel has recently received a proposal from MedicAlert to provide emergency alert services to class members in Europe. The Panel will work with MedicAlert to determine if this is a feasible project.

At the hearing with the Court on April 30, 2008, the Court requested an analysis of the Bowling Pfizer contracts to determine if there is potential for any of the contracts to provide funds into the Trust for the benefit of the Class. Counsel for the Trustees has analyzed the contracts to determine whether there is any intellectual property which could be used to generate funds for the Class. Attached as Appendix 1 to this report is a chart listing the Trustees' inventory of intellectual property. Exhibit A to the chart lists the two research projects for which a patent application may be filed in the future. The first is BioQuantetics which will pay royalties to the trust if BioQuantetics derives income from commercialization of the technology resulting from the research funded by the Trust as the Trust licensed the technology to BioQuantetics. To date, no product has been commercialized and no income has been generated as a result of any product commercialization. The second research project for which a patent application may be filed is the ACES research. All rights are reserved to the Trust and it is not known at this time whether a device will be developed which could be commercialized and could

generate funds for the Trust. Exhibit B to Appendix 1 is a list of the research projects sponsored by the Trust for which patent applications will not be filed.

At the April 30, 2008 hearing with the Court, the Court also requested that the Trustees investigate the ramifications of indemnification by the Trust of the parties who are not otherwise protected by insurance in the event that the trust funds dwindle to the extent that indemnification is meaningless. The Trustees have analyzed this issue and determined that commercial insurance should be investigated. Therefore, the Trustees have submitted applications for such insurance from the Chubb Group of Insurance Companies and to Roy Kuhnell, an independent insurance broker at Dempsey & Siders Agency, Inc., in Cincinnati. No quotations for insurance have been received to date, but when they are, the Trustees will report to the Court. The insurance, if obtained would cover the members of the Supervisory Panel, the Trustees, the Administrator, and the three employees in the Bowling office.

B. Guidelines. Drs. Harrison, Ibrahim and Ivey regularly monitor the pertinent world-wide literature and review reported events occurring to class members to ensure that any issues which may impact the guidelines are detected and considered by the full panel.

C. Research. Our report on the status of the research program of the Supervisory Panel is set out in the attached Appendix 2.

D. Imaging. Since the imaging program at Penn State resumed again, effective April 26, 2005, there have been eleven imaging sessions for seven implantees who may qualify for valve replacement surgery. One implantee was imaged three times and two implantees were imaged two times during this period.

E. Repository. The Supervisory Panel maintains a repository of certain documents and information concerning the BSCC heart valve. The repository contains reports on the results of research sponsored by the Supervisory Panel, minutes of meetings of the Supervisory Panel, a

bibliography of published literature regarding the BSCC heart valves, certain unpublished reports prepared by Dr. Ron Brookmeyer of his statistical analysis, the Bowling Settlement Agreement, and other information. The repository is available electronically in a database. Some of the information, such as published articles are not available for review due to copyright and other intellectual property concerns. To access the on-line repository, an individual need only contact the Trustees' office for the website address and a password.

F. Website. The Supervisory Panel's website continues to be found at [www.bowling-pfizer.com](http://www.bowling-pfizer.com). It provides basic information on the parties involved (biographies, addresses, telephone numbers, email, etc.), certain orders of the Court including the Guidelines, the Settlement Agreement, Trustee Reports and a bibliography of relevant articles as well as other important information. The panel prepared a summary of key studies which is intended to provide a more user-friendly bibliography. This user-friendly bibliography is available on the website. A copy of the most recent "hit report" of the Supervisory Panel's website is attached to this Report as Appendix 3.

G. Valve Replacement Surgery Claims and Fracture Claims.

The Claims Administrator continues to receive and process claims for valve replacement surgery and outlet strut fracture. Some of the claimants have elected other courses of action rather than to receive the Settlement benefits.

From the beginning there have been 98 (74 foreign) qualified outlet strut fracture claims and 99 (39 foreign) qualified valve replacement surgery claims other than single leg fracture claims. In addition, there have been 39 (16 foreign) single leg fracture claims.

The office of the Claims Administrator continues to fulfill requests to calculate estimated annual fracture rates under the 2007 Guidelines and to respond to other inquiries from and on behalf of Class Members.

**III. FINANCIAL INFORMATION**

At August 31, 2008, the total balance of cash and cash equivalents was \$22,259,241.

Attached as Appendix 4 are the following: an unaudited balance sheet as of August 31, 2008 and an unaudited statement of income and funds balance for the eight months ended August 31, 2008 (which includes the budgeted amounts for expenses for the administrative office for the period January 1, 2008 through December 31, 2008).

**IV. COMMUNICATIONS**

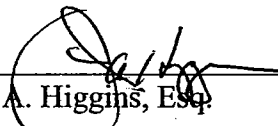
Communications remain open, whether with physicians, Class Members, other BSCC heart valve implantees, Class Counsel, Special Counsel, Defendant's Counsel, or Counsel for Public Citizen.


**V. APPROVALS**

Your honor, the Special Masters/Trustees request that the Court:

- Approve this Report, and
- Approve, or provide guidance with respect to, each of the Appendices to this Report, and
- Provide guidance with respect to any duty of the Special Masters/Trustees, and
- Fix the date for the next Report.

Respectfully submitted,

  
\_\_\_\_\_  
James A. Higgins, Esq.

  
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Peter J. Strauss, Esq.

**CERTIFICATE OF SERVICE**

The undersigned hereby certifies that a copy of this Twenty-Ninth Report of the Special Master/Trustee Covering Period from April 3, 2008 to October 8, 2008, has been electronically sent to the following this 8<sup>th</sup> day of October, 2008.

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Nancy A. Lawson

# APPENDIX

1

**EXHIBIT A**  
**CURRENT AND PROSPECTIVE TECHNOLOGY AND**  
**INTELLECTUAL PROPERTY RIGHTS OF CLASS FOR WHICH**  
**PATENT APPLICATIONS MAY BE FILED.**

	<b>Institution</b>	<b>Date</b>	<b>Description of Project</b>	<b>Ownership</b>
1.	BioQuantetics, Inc.	May, 2000 through September, 2006	Development of ultrasound related techniques and devices for the detection of single leg separation in BSSC heart valves.	Licensed to BioQuantetics. Royalties to be paid by BioQuantetics if BioQuantetics derives income from commercialization of the technology resulting from research funded by the Trust. To date, no product has been commercialized and no income has been generated as a result of any product commercialization.
2.	ACES	January, 2006 - present	Passive acoustic detection of implanted BSSC heart valves in sheep and patients.	All rights retained.

**EXHIBIT B  
RESEARCH PROJECTS SPONSORED BY THE  
BOWLING-PFIZER TRUSTEES FOR WHICH PATENT  
APPLICATIONS WILL NOT BE FILED**

	<b>Institution</b>	<b>Date</b>	<b>Description of Project</b>	<b>Ownership</b>
1.	Stichting BSCC-Hartkleppen Onderzoek Nederland and University of Utrecht, Julius Center for Patient Oriented Research	March, 1995 through December, 2005	Continuation of Dutch Follow-up Study. This project was originally sponsored by Shiley Incorporated and was assumed by the Trustees. Purpose is to provide more precise information regarding the hazards of strut fracture over a long period of time and better define subgroups of BSCC patients who are at higher risk of outlet strut fracture	No IP provision in Agreement
2A.	BioSurg, Inc.	June, 1995 through December, 1996	Maintenance of flock of sheep originally maintained for Shiley Incorporated.	
2B.	BioSurg, Inc.	October 2005 to September 2006	Implantation of BSCC heart valve in living sheep; support of in vivo testing of sheep by the other panel sponsored researchers, maintenance and euthanasia of sheep.	
3.	Royal Post Graduate Medical School and RPMS Technology Limited and in December 2001 I.C. Consultants Limited, Acting on behalf of Imperial College School of Science, Technology and Medicine	July, 1995 through December, 2003	UK cohort study. Continued monitoring of the BSCC heart valve population in the UK.	Rights retained to new IP. Trustees agreed no interest in background IP.
4.	The Board of Trustees of the Leland Stanford Junior University and Stephen N. Oesterle, M.D.	November, 1995 through December, 1996	Continuance of imaging program originally sponsored by Shiley Incorporated.	Stanford retained IP rights. Trustees retained exclusive license to use technology.

5.	West Glasgow Hospitals University NHS Trust	November, 1995 through December 31, 1996	Continuance of imaging program originally sponsored by Shiley Incorporated.	All rights retained.
6.	William Beaumont Hospital	November, 1995 through December 31, 1996	Continuance of imaging program originally sponsored by Shiley Incorporated.	All rights retained.
7.	Structural Acoustics, Inc.	November, 1995 through February, 1996	Verify and test SAI algorithm to classify BSCC valves as intact or SLS from acoustic signatures.	SAI retained IP rights. Trustees retained exclusive license with right to sub-license.
8.	Cinema Research Corporation	November, 1995 through December 31, 1996	Reproduction of cine film.	No IP provision in Agreement.
9.	Tracor Applied Sciences, Inc.	November, 1995 through December 31, 1996	Data quality assurance testing on acoustic data obtained at Stanford, Aachen, and Glasgow imaging sites. Maintenance and acoustic support for phonocardiographic data acquisition systems at Stanford, Aachen, and Glasgow imagine sites.	All rights retained.
10.	Medical Data Research Center of the Providence Health System	January, 1996 through April, 1996	Literature analysis of reoperative risk focusing on 90 day and one year morbidity and mortality outcome. Analysis of Shiley Heart Valve Research Center database to determine projected occurrence of actual OSF over time.	All rights retained.
11.	The Pennsylvania State University and The Milton S. Hershey Medical Center	May, 1996 through May, 1997	To determine the feasibility of detecting single leg separation in BSCC heart valves by radiographic imaging through use of static water bath and a working phantom.	All rights retained.
12.	The United States Department of Energy (Lawrence Livermore National Laboratory)	July, 1996 through November, 1996	Process blinded BSCC heart valve acoustic recordings. Design, assemble and operate instrumentation to acquire and analyze anechoic acoustic data from a matrix of BSCC heart valves.	Retained right to elect to retain rights. Trustees granted U.S. Government a non-exclusive license to practice process worldwide.

13.	William Beaumont Hospital	July, 1998 through July, 2000	Epidemiologic follow-up study of patients who previously participated in imaging study at William Beaumont Hospital.	No IP provision in Agreement.
14.	West Glasgow Hospitals University NHS Trust	August, 1998 through August, 2000	Epidemiologic follow-up study of patients who previously participated in imaging study at Western Infirmary Glasgow	No IP provision in Agreement.
15.	Health Data Research, Inc.	November, 1998 through April, 2000	Assessment of the risks and outcomes of patients undergoing heart valve re-placement. To determine the morality and morbidity outcomes of patients requiring re-operation due to heart valve complications. To test (validate) the accuracy of the Piehler model on a data set	All rights retained.
16.	The Board of Trustees of the Leland Stanford Junior University and Stephen N. Oesterle, M.D.	December, 1998 through December, 2000	Epidemiologic follow-up study of patients who previously participated in imaging study at Stanford University Hospital.	No IP provision in Agreement.
17.	The Board of Trustees of the Leland Stanford Junior University and Stephen N. Oesterle, M.D.	December, 1998 through December, 1999	X-Ray imaging study of BSCC patients.	Stanford retained IP rights. Trustees retained exclusive license with right to sub-license.

18.	California Institute of Technology	May, 1999 through November, 1999	To apply state-of-the-art, high frame rate, parallel processing digital color Doppler ultrasound system measurements in-vitro, to differentiate the actively excited resonance frequencies by the single-leg-separation valve from that of an intact outlet strut valve.	CIT retained IP rights. Trustees retained exclusive license with right to sub-license.
19.	Edison Welding Institute	May, 1999 through February, 2000	To study welding process variables to identify the variables that have the most significant effect on joint integrity; conduct a failure analysis of the welded joints of the BSCC heart valve; use computer modeling of residual stress to determine the stress state in the as-welded condition prior to implantation and during operation; and, evaluate the aspects of the weld design that may contribute to failures in BSCC heart valves.	All rights retained.
20.	University of Cincinnati on Behalf of Institute for Health Policy and Health Services Research	June, 1999 through June, 2000	To evaluate the quality and comprehensiveness of the research conducted regarding the failure of the BSCC heart valve and to develop recommendations regarding the use of such research and areas for future research which may be beneficial to class members.	UC retained IP rights. Trustees retained exclusive license with right to sub-license.
21.	Battelle Memorial Institute, Commercial Business Operations	July, 1999 through December, 1999	Review of research projects previously completed by Shiley, Pfizer or the Trustees and make recommendations about future research projects.	Battelle retained IP rights. Trustees retained exclusive license with right to sub-license.
22.	University of Utrecht, Julius Center for Patient Oriented Research	July, 1999 through July, 2001	MRI brain scan used as indicator of valve failure and whether paramagnetic defects are associated with cognitive disturbances.	All rights retained.

