Federal Communications Commission
Washington, D.C. 20554

October 11, 2006

Mr. David A. Larson
P.O. Box 773
Ridgecrest, CA 93556

FOIA Control No. 2006-524

Dear Mr. Larson:

This is in reply to your letter dated August 23, 2006, in which you invoke the Freedom of Information Act (FOIA) (5 U.S.C. 552), seeking all documents, email communications, correspondence, facsimile transmissions, meeting minutes, and hand written notes that refer to, mention, pertain to, or reference in any way the following:

> 1. The Alfred E. Mann Foundation, or its principals, Alfred E. Mann, Joseph Schulman, or Robert Greenberg;
> 2. court or legal proceedings that transpired between the FCC and Mann Foundation Attorneys ("inc. their argument for rights/usage of spectrum"); and
> 3. a written complaint to the FCC from you pertaining to Alfred E. Mann Foundation and Joseph H. Schulman ("inc. what was done, how complaint was handled").

First, please be advised that we have no record of a complaint submitted by you. You can resend your complaint and we will address it upon receipt.

The Commission has located the following documents responsive to your request.

1. Application materials for an Experimental license for a "BION" transponder.
2. Personal meeting notes dated September 4, 2004.
3. Personal meeting notes dated April 14, 2005.

With respect to the experimental application materials, The Alfred Mann Foundation for Scientific Research (Mann) submitted a request to the Commission for confidential treatment for certain documents associated with its application. Mann submitted a redacted version of the original submission, disclosing only the information in the subject document which it considers to be suitable to disclosure. Mann, in its original request for confidentiality of the subject documents, asserted that the subject information is exempt

from disclosure pursuant to Exemption 4 of the FOIA, 5 U.S.C. § 552(b)(4), and Section 0.457(d) of the Commission's rules, 47 CFR 0.457(d). In response to an earlier FOIA request, Mann reiterated that the subject document contains highly sensitive information, including technical specifications, as well as detailed descriptions of the configuration and experimental operation of the Mann medical equipment. A copy of the redacted version, previously released, is enclosed pursuant to your request.

With respect to the handwritten meeting notes, Exemption 4 of the FOIA, 5 U.S.C. Section 552(b)(4), and Section 0.457(d) of the Commission's Rules, 47 CFR 0.457(d), permit nondisclosure of "trade secrets and commercial or financial information obtained from any person and privileged or confidential." 18 U.S.C. Section 1905 makes the disclosure of confidential information by a federal employee punishable criminally as a misdemeanor in addition to the sanction of removal from employment. FOIA Exemption 4 is intended to protect both the interests of commercial entities that submit proprietary information to the government and the interests of the government in receiving continued access to such data. In this instance, the exemption is being applied to information of a privileged and confidential nature that is of commercial interest to the submitter, and these handwritten notes are being withheld.

You may seek review of this disposition of your request by the Commission by filing an application for review with the Office of General Counsel within 30 days of the date of this letter. See 47 C.F.R. § 0.461(j).

Sincerely,

Julius P. Knapp
Acting Chief,
Office of Engineering & Technology

Enclosure (1)

EXHIBIT 1

Request for Confidential Treatment

Pursuant to Sections 0.457 and 0.459 of the Commission's rules,[1] the Alfred Mann Foundation for Scientific Research ("AMF") requests the Commission to withhold from public inspection and accord confidential treatment to Exhibit 2 of the accompanying application for experimental authorization (the "Application"). Exhibit 2 contains highly sensitive commercial and technical information, which customarily would be guarded from competitors. The disclosure of this information likely would cause substantial competitive and financial harm to AMF, and is therefore exempted from mandatory disclosure under Exemption 4 of the Freedom of Information Act ("FOIA Exemption 4")[2] and Section 0.457(d) of the Commission's rules.[3]

In support of this request for confidential treatment and pursuant to the requirements under Section 0.459(b) of the Commission's rules, AMF provides the following information:

(1) Identification of information for which confidential treatment is sought:

Exhibit 2 to the Application.

(2) Identification of the circumstances giving rise to the submission:

The information for which confidential treatment is sought is being submitted in response to Question 7 of FCC Form 442, which requires a narrative statement describing the complete program of research and experimentation proposed under the Application.

(3) Explanation of the degree to which the information is commercial or financial, or contains trade secrets or is privileged:

Exhibit 2 contains highly sensitive information, including technical specifications, concerning the testing and development of innovative and proprietary medical equipment.

(4) Explanation of the degree to which the information concerns a service that is subject to competition:

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[1] 47 C.F.R. §§ 0.457, 0.459.

[2] 5 U.S.C. § 552(b)(4). *See Public Citizen Health Research Group v. FDA*, 704 F.2d 1280, 1290-91 (D.C. Cir. 1983).

[3] 47 C.F.R. § 0.457(d).

Exhibit 2 contains highly sensitive information concerning the testing and operation of medical devices, the development and manufacturing of which are subject to competition from a number of medical equipment manufacturers.

(5) *Explanation of how disclosure of the information could result in substantial competitive harm:*

Disclosure of the information in Exhibit 2 could provide AMF's competitors with direct and material information as to its medical research activities and development of innovative medical devices. This information has not been publicly disclosed. Knowledge of the unique technical specifications of AMF's experimental program could allow competitors to benefit from its efforts and develop or improve upon similar equipment, while avoiding research and development expenses.

(6) *Identification of any measures taken by the submitting party to prevent unauthorized disclosure:*

AMF has instituted an internal policy prohibiting employees from divulging any proprietary or confidential information, which would include the subject matter of the Application.

(7) *Identification of whether the information is available to the public and the extent of any previous disclosure of the information to third parties:*

Information contained in Exhibit 2 is not generally available to the public. Consistent with and except as provided under appropriate nondisclosure agreements or requirements, there has been no disclosure of this information to any third parties.

(8) *Justification of the period during which the submitting party asserts that material should not be available for public disclosure:*

AMF requests confidential treatment of Exhibit 2 for an indefinite period. During the operational lifetime of the medical devices under development, equipment manufacturers and other competitors could use the otherwise confidential information to their competitive advantage and to AMF's detriment.

(9) *Any other information that the party believes useful in assessing the confidentiality request:*

The information contained in Exhibit 2 qualifies for confidential treatment under FOIA Exemption 4, which sets forth a two-prong standard for protecting information that both: (1) constitutes trade secrets and commercial or financial information, and is (2) privileged or confidential.[4] The term "commercial" in the

[4] *See* 5 U.S.C. § 552(b)(4).

first prong of the standard includes not only information regarding basic commercial operations, but also "information about work performed for the purpose of conducting a business's commercial operations."[5] Information provided voluntarily satisfies the standard's second prong as being "confidential" if "'it is of a kind that the provider would not customarily release to the public.'"[6]

As for the first prong of the FOIA Exemption 4 standard, Exhibit 1 contains technical details and elements of AMF's medical research with respect to the development of innovative medical equipment. As such, the information involves work performed for the purpose of conducting commercial operations.

As for the second prong of the FOIA Exemption 4 standard, the information in Exhibit 2 is not of the type customarily released to the public precisely because such information could be used to AMF's competitive disadvantage. Where disclosure could result in competitive harm to the information provider, the Commission generally finds that the information is confidential.[7] Disclosure of the information in Exhibit 2 would provide AMF's competitors with insight into its medical research and development of new equipment. The courts have held that information is confidential under FOIA Exemption 4 for voluntarily submitted information if it is of the kind that the provider itself would not customarily release to the public. As stated above, AMF's customary practice, as evidenced by its internal non-disclosure policies, is to prohibit public release of this type of highly sensitive information.[8]

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[5] *See Southern Company*, 14 FCC Rcd 1851, 1860 ¶ 17 (WTB 1998) (*citing Public Citizens Research Group v. FDA*, 704 F. 2d 1280, 1290 (D.C. Cir. 1983)); *see also Examination of Current Policy Concerning the Treatment of Confidential Information Submitted to the Commission*, 13 FCC Rcd 24816, 24818 ¶ 3 (1998).

[6] *Southern Company*, 14 FCC Rcd at 1860 ¶ 17.

[7] *See, e.g., id.* (upholding confidentiality for applicant's list of sites and construction information because "other businesses could use this comprehensive data to [the applicant's] competitive disadvantage"); *Jeffrey A Krause On Request for Inspection*, 11 FCC Rcd 10819, 10820 ¶ 4 (1996) (recognizing confidential status of technical aspects and design of equipment used in provision of interactive video and data service because release of such information would likely cause substantial competitive harm in that it would "lessen the value of their technologically innovative product by enabling others to utilize the information to develop similar products"); *Ward & Mendelsohn, P.C*, 88 FCC2d 1049, 1052 ¶ 10 (1981) (upholding confidentiality of sales contracts for satellite transponders because "competition exist[ed] among the sellers to secure advantages in negotiating the terms and conditions of transponder sales").

[8] *See Critical Mass Energy Project v. NRC*, 975 F.2d 871, 879 (D.C. Cir. 1992) (holding that the test for determining confidentiality under FOIA Exemption 4 is an objective one, under which "the agency invoking Exemption 4 must meet the burden of proving the provider's custom"); *Mobile Relay Associates*, 14 FCC Rcd 18919, 18922-23 ¶ 8 (WTB 1999) (upholding confidentiality of applicant's customer lists, in part, because applicant showed "the care it takes to

To provide adequate protection from public disclosure, the Commission should strictly limit distribution of copies of Exhibit 2 within the Commission on a "need to know" basis. In the event that any person or entity outside the Commission requests disclosure of Exhibit 2, AMF requests that it be so notified immediately so that it can oppose such request or take other action to safeguard its interests as it deems necessary.

protect this information, including policies that prohibit the information from normally leaving its business premises or being made available to third parties").

EXHIBIT 2

PROGRAM OF RESEARCH AND EXPERIMENTATION, AND GOVERNMENT CONTRACT REQUIREMENTS

The Alfred Mann Foundation for Scientific Research ("AMF"), a nonprofit research corporation devoted to development of advanced medical products, submits this application (the "Application") for experimental authorization under Part 5 of the Federal Communications Commission's ("FCC" or the "Commission") rules to test and develop a unique medical system operating on radiofrequencies ("RF") in the 216-225 MHz and 380-470 MHz frequency bands to restore mobility and other functions to paralyzed limbs and organs.

Pursuant to Section 5.71 of the FCC's rules,[1] AMF requests an experimental authorization for a period of five years. [REDACTED]

[REDACTED]

I. Purpose

The requested experimental authorization will permit AMF to test, develop, and demonstrate the feasibility of using small, battery-powered, implantable devices that provide stimulating, sensing, and high-speed communication capabilities to enable patients suffering from spinal cord injury ("SCI"), stroke, and other neurological disorders to regain mobility and other functions. AMF seeks to conduct studies to determine, among other things, the effect of the operation of its proposed equipment on other co-channel or adjacent-channel systems, and vice versa.

Each year there are approximately 11,000 new cases of spinal cord injury ("SCI") in the United States. This estimate could increase as injured U.S. soldiers return from the war in Iraq and other military operations abroad. Additionally, strokes occur in approximately 700,000 patients in the United States each year. SCI and its associated lower limb paralysis lead to neuromusculoskeletal disorders such as osteoporosis, disuse atrophy, spasticity, muscle and joint contractures, cardiopulmonary dysfunction, and loss of muscle endurance and metabolic function. Currently, functional electric stimulation ("FES"), which is the application of electrical stimulation to improve a person's ability to

[1] 47 C.F.R. § 5.71.

perform daily functions, is the only uniform therapeutic strategy that can obviate these conditions.

AMF seeks to test and develop the BION® medical system, which is designed to perform FES to restore mobility and other functions to paralyzed limbs and organs. Although FES has been used successfully in devices such as the cardiac pacemaker and cochlear implant to pace the heart and restore hearing, it has not been widely adopted as a means of reanimating paralyzed limbs and organs resulting from SCI and stroke. The potential of FES to produce health benefits in these areas has been largely unfulfilled because of the limitations of the available equipment. Currently, FES devices designed to restore function to paralyzed limbs and organs utilize one of three types of technology: (1) transcutaneous stimulation with electrodes placed on the surface of the skin; (2) percutaneous stimulation with electrodes crossing through the skin, and (3) fully implantable systems where electrodes are connected to a single, implantable, multi-channel stimulator, which is powered by a battery or transformer coupled by an externally generated magnetic field.

All three approaches suffer from significant limitations that confine their widespread use. The transcutaneous approach requires extensive time commitment and personal assistance to don and doff the electrodes. Moreover, the repeatability of electrode placement is poor, and the painful sensation elicited by stimulation electrodes are undesirable. The percutaneous approach also requires time commitment in maintaining the site where the electrodes exit the skin. Additionally, the site is prone to infection and generally unacceptable to many patients on principle. Although the fully implantable approach presented great promise, the technology available to date failed to deliver because of its high level of invasiveness requiring hours of surgery, risk of infection from having many long wires in the body all connected to a common point, and lack of flexibility in application.

[REDACTED]

Thus, the proposed experimental operation will contribute to the radio art by providing for the testing and development of innovative wireless technology that promises to deliver invaluable health benefits to patients suffering from spinal cord injury ("SCI"), stroke, and other neurological disorders. Accordingly, the proposed operation qualifies for an experimental authorization as an "[e]xperimentation[] in scientific or

technical radio research" and as "development of radio technique, equipment or engineering data not related to an existing or proposed service."[2]

II. Overview of Experimental Operations

[REDACTED]

[2] *Id.* § 5.3(a), (h).

[REDACTED]

PUBLIC INSPECTION COPY

AMENDMENT TO EXHIBIT 2

PROGRAM OF RESEARCH AND EXPERIMENTATION, AND GOVERNMENT CONTRACT REQUIREMENTS

The Alfred Mann Foundation for Scientific Research ("AMF") submits this amendment to Exhibit 2 of its application (FCC File No. 0255-EX-PL-2004) (the "Application") for experimental authorization to test and develop a unique medical system (the "BION® system") operating on radiofrequencies ("RF") in the 216-225 MHz and 380-470 MHz frequency bands that can restore mobility and other functions to paralyzed limbs and organs. This amendment provides a more detailed description of the configuration and proposed experimental operation of the BION® system.

[REDACTED]

As the studies proceed over the course of the five-year period, expanding the scope of the studies to include an increasing number of subjects will yield more accurate and reliable data to demonstrate the feasibility and effectiveness of the devices. The

expanded scope also will allow researchers to assess the operation of the devices, as they are used in a number of different applications to address neuromusculoskeletal disorders and injuries affecting various parts of the body.

DAVID A. LARSON
P.O. Box 773 Ridgecrest Ca 93556-0773
Phone: 760 793-8653

December 30, 2006

Federal Communications Commission
Julius P. Knapp
445 12th Street SW
Washington DC 20554

Re: FOIA Appeal and request for review; FOIA Control No. 2006-524

Please accept this letter as written notification and request for review regarding my recent request for materials, made under Freedom of Information (FOIA) provisions (5 U.S.C. 552). The materials provided in response to the original request, which sought information regarding activities of the Alfred E. Mann Foundation, FOIA Control #2006-524, were incomplete with several pages redacted, and other materials such as hand written notes were also withheld. I am requesting access to or copies of the redacted material under FOIA regulation and procedure.

Specifically, the materials requested are:

1. Personal meeting notes dated September 4, 2004.
2. Personal meeting notes dated April 14, 2005
3. Copy of the Application materials for an experimental license for a "BION" Transponder in it's entirety, unredacted, as per the original submission.

With respect to any claims of "commercial" or "trade secrets" by the Alfred Mann Foundation, please consider the following:

1. I have no commercial interests in the materials requested. I have no interest, shares, or involvement in any competing ventures or business and I do not own any Intellectual Property or patents. My career path has included journalism, photography and advertising.
2. This request is being made in good faith, based on necessity, and is of significant public interest.
3. The materials being requested, and which were previously redacted, serve to explain research efforts that will affect society and that circumvent normal licensing requirements and restrictions.
4. Previous Mann Foundation research efforts conducted without this special application have been conducted in a manner which constitutes felony criminal misconduct and has resulted in criminal investigations by law enforcement and regulatory personnel. This is detailed in a letter sent December 28th 2006 to Chairman Martin.
5. There is significant supporting evidence that indicates experimental research efforts by the Mann Foundation that will be performed under the FCC experimental license consists primarily of Defense and Intelligence applications, and is being falsely presented as medical technology due to the controversial nature of Mann's governmental contract work.

In closing, the materials submitted to the FCC by the Mann Foundation request to conduct experimental research efforts, which circumvent normal licensing and regulation requirements, circumvent the accountability and oversight that would normally be present with licensed/regulated use of spectrum, and from what has been publicly presented, fails to disclose the intended application for the research. The Mann Foundation request for confidentiality and non-disclosure is being made to allow them to avoid licensing requirements that led to criminal investigations in the past and to permit encryption of data not normally permitted to Technician class license holders.

Continued...

The FCC has a responsibility to public safety that should be considered first and foremost and should take precedence over the desire of a Defense contractor to conceal research activities performed in an unethical manner. Thank you for considering this very important matter. I look forward to your reply.

Sincerely,

David A. Larson
P.O. Box 773
Ridgecrest CA 93556-0773
760 793-8653

cc: Office of General Counsel
Chairman Kevin J. Martin