

PATENT ASSIGNMENT

Electronic Version v1.1

Stylesheet Version v1.1

SUBMISSION TYPE:	NEW ASSIGNMENT
NATURE OF CONVEYANCE:	LICENSE
CONVEYING PARTY DATA	
Name	Execution Date
Department of Veterans Affairs	06/19/2006
RECEIVING PARTY DATA	
Name:	Gary Jarvis
Street Address:	4150 Clement Street
City:	San Francisco
State/Country:	CALIFORNIA
Postal Code:	94121
Name:	Constance John
Street Address:	4150 Clement Street
City:	San Francisco
State/Country:	CALIFORNIA
Postal Code:	94121
PROPERTY NUMBERS Total: 1	
Property Type	Number
Patent Number:	6770622
CORRESPONDENCE DATA	
Fax Number:	(303)447-7800
<i>Correspondence will be sent via US Mail when the fax attempt is unsuccessful.</i>	
Phone:	303-447-7802
Email:	lmurray@faegre.com
Correspondent Name:	Lea E. Murray
Address Line 1:	Faegre & Benson LLP
Address Line 2:	90 South Seventh Street, Suite 2200
Address Line 4:	Minneapolis, MINNESOTA 55402
ATTORNEY DOCKET NUMBER:	363953

OP \$40.00 6770622

PATENT

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REEL: 020773 FRAME: 0403

NAME OF SUBMITTER:

Lea E. Murray

Total Attachments: 11

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DEPARTMENT OF VETERANS AFFAIRS
Office of the General Counsel
Washington DC 20420

MAR 28 2008

In Reply Refer To: 024J

Constance M. John, R.Ph., Ph.D.
President
MandalMed, Inc.
605 3rd St., Suite 250
San Francisco, CA 94107

Re: N-Terminally Truncated Gatectin03 for Treatment of Breast Cancer,
VHA No. 05-047
Inventors: Gary Jarvis and Constance John

Dear Dr. John:

You have requested a copy of the signed Determination of Rights (DOR) letter that was mailed to you on June 19, 2006 in regard to the above-referenced invention. As one of my staff attorneys explained to you recently, it was our custom and practice in June of 2006 to send signed copies of the DOR to the inventors and only retain unsigned copies in our files. Accordingly, we are unable to comply with your specific request to provide you with a signed copy.

For purposes of working with the rights you retain in the invention, however, I hereby certify that the enclosed are true and correct copies of the documents in the possession of the Department of Veterans Affairs with respect to this invention:

- 1) DOR for VHA #05-047, including Exhibit A;
- 2) Follow-up for Government Use License signed by Constance John, dated 01/02/2008;
- 3) DOR receipt signed by Gary Jarvis, dated 7/20/06;
- 4) Confirmatory License signed by Constance John, signed and notarized August 9, 2005, and
- 5) VA letter to the Director of the USPTO, mailed October 26, 2005.

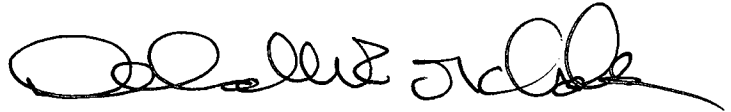
The above certification is made pursuant to authority delegated to the undersigned to certify copies of documents, records, or papers in Department of Veterans Affairs files (38 U.S.C. 302 and 38 C.F.R. 2.5).

2.

Constance M. John, R.Ph., Ph.D.

If we can be of any further assistance, please do not hesitate to contact us.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Deborah K. McCallum', with a stylized flourish at the end.

Deborah K. McCallum
Assistant General Counsel

Enclosure

cc: 12(TT) (w/o enclosure)



DEPARTMENT OF VETERANS AFFAIRS
Office of the General Counsel
Washington DC 20420

In Reply Refer To: 024J
VHA #05-047

JUN 19 2006

Dr. Gary Jarvis and
Dr. Constance John
c/o Director (662/00)
VA Medical Center
4150 Clement Street
San Francisco, CA 94121

Re: N-Terminally Truncated Gatectin-3 for Treatment of Breast Cancer

Dear Dr. Jarvis and Dr. John:

This letter refers to your above-referenced invention which you disclosed pursuant to 38 C.F.R. §1.656. That regulation provides that it is the duty of the General Counsel to determine the respective ownership rights as between the VA and a VA employee in an employee invention; this letter constitutes such a determination and supersedes my previous letter determination issued on June 10, 2005.

Before issuing a determination I would like to explain generally what this decision does and does not do. The VA recognizes that an inventor may be a part-time VA employee and part-time employee of another organization, such as a university affiliate, and that an invention can be made while the inventor is acting as an employee of both. It is important to realize that this letter determines ownership rights only to the extent the invention was made in connection with the inventor's VA employment or with a substantial VA contribution. This letter does not address any ownership rights another organization may have through you. If another organization has a joint ownership interest, the VA will contact and work with the joint owner to expedite the development of the invention. It will also substantially share with the inventor and the facility any ensuing royalties. For more information see http://www.research.va.gov/programs/tech_transfer/default.cfm.

Turning to your particular disclosure, we note that you provided a descriptive summary of your invention. A copy of the summary is included at Exhibit A.

Dr. Jarvis, concerning the circumstances surrounding the development of your invention, you indicated that it was created while you were employed as an Associate Professor of Laboratory Medicine at UCSF and, as of the date of the invention, August 8, 2000, were serving at VA as a Without Compensation (WOC) Employee. The file reveals that you, Dr. Jarvis, have a duty to perform research for VA. Regarding such work, you certified that your invention was made during official

2.

Dr. Gary Jarvis and Dr. Constance John

working hours and with a VA contribution of facilities and equipment. You also indicated that the development of the invention bears a direct relation to your official research duties. Since you were conducting research prior to the implementation of the VA WOC Intellectual Property Agreement, however, VA has no authority to obtain any ownership rights in or to the invention through you. Consequently, I find that you are entitled to retain right, title, and interest in and to the invention subject to law (37 C.F.R. 501.6(a)(4)).

Dr. John, concerning the circumstances surrounding the development of your invention, you indicated that it was created while you were serving as a Research Chemist at the VA Medical Center in San Francisco, CA. You certified that at the time of the invention, that you, Dr. John, had a duty to perform research for VA. Regarding such work, you also certified that your invention was made during official working hours and with a VA contribution of facilities and equipment. Finally, you indicated that the development of the invention bears a direct relation to your official research duties and was made in consequence of those duties.

According to 37 C.F.R. § 501.6(a)(1), the Government is entitled to the entire right, title, and interest in and to any invention made by a Government employee (i) during working hours, or (ii) with a contribution of the Government of facilities and equipment, or (iii) which bears a direct relation to or is made in consequence of the official duties of the inventor. The regulations also provide that in any case where the contribution of the Government is insufficient equitably to justify a requirement of assignment to the Government of the entire right, title and interest, the Government shall leave title to the invention in the employee subject, however, to the reservation to the Government of a nonexclusive, irrevocable, royalty-free license in the invention with power to grant licenses for all governmental purposes. Such reservation is to appear, where practicable, in any patent, domestic or foreign, which may issue on such invention. 37 C.F.R. § 501.6(a)(2).

Officials of the Veterans Health Administration (VHA) have reviewed your disclosure, advised as to the VA's involvement in development of the invention, and have reviewed its usefulness to the VA medical care system. Based on their review, it has been recommended that VA leave title of this invention to you subject to the Government license referenced above.

We concur with VHA's recommendation in this matter. Pursuant to 37 C.F.R. §501.6(a)(2), I find that you, Dr. John, are entitled to the right, title, and interest in and to the invention, subject to a nonexclusive, irrevocable, royalty-free license in the invention with power to grant licenses for all governmental purposes.

3.

Dr. Gary Jarvis and Dr. Constance John

With the granting of title to this invention subject to a government use license, Dr. John, you have acquired two additional responsibilities:

1. Complete the attached Follow-Up for Government Use License form and return it to the Technology Transfer office at the address indicated on the form.
2. Consistent with guidance from the United States Government Accountability Office (GAO), if you have not yet applied for or are in the process of applying for a patent, instruct your attorney in connection with applying for patent protection on this invention to include the following language in the Government Rights section of the application:

"This work was supported by the U.S. Department of Veterans Affairs and the Federal Government has certain rights in this invention."

When you file a patent application, or if you have already applied for or been granted a patent, we will contact you further to obtain a copy of a license agreement, signed by you, to be filed by the VA with the U.S. Patent & Trademark Office, consistent with 37 C.F.R. §501.6(a)(2). The information you provide to us will assist in protecting VA's license rights.

In addition, please note that we request that you give the VA credit for the invention in any commercial publication.

Should you disagree with this determination you have the right to appeal it to

Under Secretary for Technology
c/o Office of Federal Technology
Room 4837
United States Department of Commerce
Washington, D.C. 20230

Pursuant to 37 C.F.R. § 501.8, two copies of any appeal must be filed within 30 days of receipt of this notice. The Secretary of Commerce may, for good cause shown in writing, determine a longer appeal period. As required by 37 C.F.R. §501.10, a copy of 37 C.F.R. Part 501 and 38 C.F.R. §§1.650—1.663 are available for you by accessing http://www.research.va.gov/programs/tech_transfer/policies/outline-of-rights.cfm and clicking on the following links: "the official sources for the content on this page are 37 C.F.R. and 38 C.F.R."

4.

Dr. Gary Jarvis and Dr. Constance John

I am enclosing a copy of this determination along with a Follow-up for Government License form which I request you, Dr. John, to sign to acknowledge receipt and return to the address indicated below for VHA's Technology Transfer Program.

Sincerely yours,

Deborah K. McCallum
Assistant General Counsel

Enclosures

cc: 12(TT)
University of California

d. **Non-Technical Description.** Describe on one page or less (double spaced) the invention in terms understandable to non-scientists.

Recent scientific evidence suggests that a cell-surface protein termed galectin-3 which binds to sugars on adjacent cells plays a role in breast cancer metastasis. The goal of this research was to evaluate a potential therapeutic agent based on a shortened version of galectin-3 called galectin-3C. The overall purpose of the research was to determine the effectiveness of galectin-3C in a nude mouse model of metastatic breast cancer based on implantation of breast tumor tissue. To this end, recombinant human galectin-3 was produced in *Escherichia coli* from which galectin-3C was derived by enzyme digestion. The maximum tolerated dose of galectin-3C in nude mice at 5 days was determined to be a minimum of 125 mg/kg without adverse effects. At 8 hours after injection of galectin-3C, levels in the blood were highest in those mice injected in the muscle compared to those injected either beneath the skin or in a vein. Organ studies revealed that galectin-3C localized to the liver, kidneys, and spleen but not to the heart or lungs. An analysis over time of the intramuscular administration of galectin-3C indicated that 50% of the galectin-3C associated with blood cells was eliminated by 5.02 hours and that 50% of the galectin-3C in the noncellular portion of the blood was eliminated by 4.56 hours. Mice bearing orthotopically implanted tumors derived from breast cancer cell line MDA-MB435 were treated intramuscularly twice daily for 90 days with galectin-3C or a vehicle control. We found that the mean tumor volumes and weights were statistically significantly less in mice treated with galectin-3C compared with control mice, and that fewer numbers of mice exhibited lymph node metastases in the treated group compared with the control group. We concluded that galectin-3C is not overtly toxic and is efficacious in reducing metastases and tumor volumes and weights in primary tumors.

Exhibit A

FOLLOW-UP FOR GOVERNMENT USE LICENSE

Re: N-Terminally Truncated Gatectin-3 for Treatment of Breast Cancer, VHA 05-047

Dr. John, you must answer the following questions and send your completed Government Use License Follow-Up form to the following address:

Department of Veterans Affairs
Program Manager, Technology Transfer Program (12/TT)
103 South Gay Street (5th Floor)
Baltimore, MD 21202

1. Has a patent been granted for this invention?

YES X

If yes, please provide: _____
Patent number

Issue Date

NO _____

2. If a patent has not been granted, have you filed a patent application?

YES _____

If yes, please provide: _____
Application Number

Filing Date

NO _____

3. If you have not filed a patent application, do you plan to file for one?

YES _____

When? _____

NO _____

If you do decide to file for a patent, please promptly inform the Technology Transfer Office at the above address.

I hereby certify that I have received a copy of the VA letter executed by Deborah K. McCallum retaining a Government Use license in and to the invention identified as VHA #05-047.

Acknowledgment of Receipt:

Constance John
Constance John, Ph.D.

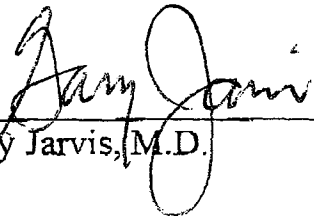
Date: 01/02/2008

Please return to the following address:

Department of Veterans Affairs
Program Manager, Technology Transfer Program (12TT)
103 South Gay Street (5th Floor)
Baltimore, MD 21202

I hereby certify that I have received a copy of the VA letter executed by Deborah K. McCallum asserting that I am entitled to retain right, title and interest in and to the invention VHA #05-047.

Acknowledgement of Receipt:



Gary Jarvis, M.D.



Date:

CONFIRMATORY LICENSE

Title: N-Terminally Truncated Galectin-3 for Treatment of Breast Cancer

Inventor: Constance John, Ph.D.

Patent Number or Application Number: 6,770.622

Issue Date: 8-3-04

VHA Number: 05-047

WHEREAS, the Inventor has been granted the right to retain title to the subject invention identified above;

WHEREAS, the nature of the services and contribution by the Department of Veterans Affairs are such to justify and lawfully entitle the Government of the United States to have the hereinafter recited rights and license;

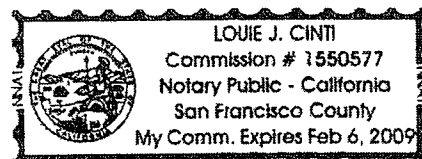
NOW THEREFORE, this document grants a nonexclusive, nontransferable, irrevocable, paid-up license to practice or to have practiced for or on behalf of the United States, this subject invention, patent application and any resulting patent, as well as any continuation, divisional, reissue, supplemental or continuation-in-part thereof, throughout the world, said license to extend through-out the world and to be effective for the full term for which any patent, domestic or foreign, or any reissue or extension thereof, is or may be granted on the invention or any part thereof.

Constance John
Constance John, Ph.D.

Subscribed and sworn to before me by CONSTANCE JOHN, PH.D., this
9th day of AUGUST, 2006, at 4:52 PM, in
the County of SAN FRANCISCO, and the State of CALIFORNIA.

Louie J. Cinti
Signature of Notary Public

My Commission expires: FEB 6, 2009





DEPARTMENT OF VETERANS AFFAIRS
Office of the General Counsel
Washington DC 20420

In Reply Refer To: 024M
VHA 05-047

Mail Stop Assignment Recordation Services
Director of the USPTO
P.O. Box 1450
Alexandria, VA 22313-1450

RE: Executive Order 9424, Confirmatory License for
John, VHA 05-047

Dear Director:

Enclosed please find the subject Confirmatory License submitted under
Recordation Form Cover Sheet, Form PTO-1595. I hereby certify that said
enclosure is a true copy of the original subject Confirmatory License. Pursuant
to 38 C.F.R. § 1.653, the undersigned is authorized to act for the Secretary of
Veterans Affairs in matters concerning patents and inventions.

Sincerely yours,

Deborah K. McCallum
Assistant General Counsel

Enclosure

cc: 12 (TT)