

Georgia, Clarke County

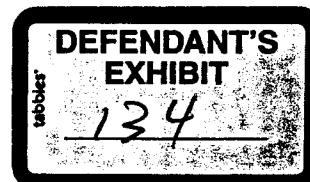
Invention Report
The University of Georgia
for
II-A. Sponsor-Supported Efforts and
II-B. University-Assigned Efforts Inventions

The following is a disclosure of inventions, discoveries, new designs, or novel plant varieties which reasonably appear to qualify for protection under the patent laws of the United States or other protective statutes, as exist now, upon enactment, or as subsequently amended, whether or not patentable or protected thereunder, hereinafter referred to as "invention," made by faculty, staff, or students employed by The University of Georgia or made by any person whether or not using facilities of The University of Georgia who is required to disclose inventions to The University of Georgia.

1. Title of invention is "Ophthalmic Cyclosporin preparation
_____."
_____."

2. List full name(s) of the true and original inventor or joint inventors, with title(s) or position(s), complete University or business mailing address(es), University or business phone number(s) including area code(s), complete residence mailing address(es), county(ies) of residence and citizenship(s) below. If the invention is a joint invention, all joint inventors must be listed below; also, all joint inventors must sign this invention disclosure form. A joint invention is an invention conceived with the means to reduce to practice by two or more persons acting jointly. A person who merely suggests an idea of a result rather than the means of accomplishing it is not a joint inventor. A person who merely

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carries out experiments planned wholly by another is not a joint inventor. A person who does not contribute to the inventive concepts is not a joint inventor.

Renee L. Kaswan, DVM
Clinical Resident Ophthalmology
Assistant Professor Ophthalmology as of 7/1/84
College of Veterinary Medicine
University of Georgia
Athens, GA 30602

(404-542-3221)

165 Snapfinger Drive
Athens, GA 30605
Clarke County 546-0162

3. For a joint invention the inventors' share of net income from each joint invention shall be divided equally among joint inventors unless some other division is indicated, either below or in a separate written statement signed by all the joint inventors filed with the University of Georgia Research Foundation, Inc. prior to the filing of a patent application or the execution of a license agreement whichever occurs first:

4. Name and address of facility at which invention was made:

College of Veterinary Medicine
University of Georgia

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5. Briefly describe in general terms the respective contributions to the invention of personnel, money, facilities, and materials provided by any public (public sponsors include all federal agencies--funds received on or after July 1, 1981 under the HATCH ACT, the McINTIRE-STENNIS COOPERATIVE FORESTRY ACT, the ANIMAL HEALTH AND DISEASE ACT, or the COLLEGES OF 1890 AND TUSKEGEE INSTITUTE ACT are deemed to be provided by USDA as a public sponsor) or private sponsor(s), The University of Georgia, and University of Georgia Research Foundation, Inc.; also, state public (governmental) sponsor's grant or contract number if applicable: Supported by awards from the UGACVM Memorial Research Fund, Hill's Pet Foods, NIH Biomedical Research Grant

→ RO3EY05720-01

6. Indicate the category under The University of Georgia Patent that you think applies to the invention: ~~NEW USE EXISTING PRODUCT~~ II-A .

7. Attach a photocopy of an unpublished draft paper or description, entitled "Modulation of Experimental lens induced uveitis with Cyclosporine"

disclosing the invention which is incorporated herein by reference.

8. Briefly describe possible commercial uses of the invention stating advantages over existing technology now available: Currently cyclosporine* (Sandimmune^(R)) has been administered systemically for treatment of uveitis in humans in a clinical experiment. Ophthalmic cyclosporine has been investigated for corneal transplantation in experimental animals. Use of an ophthalmic preparation for uveitis avoids severe adverse drug reactions which occur commonly after systemic administration.

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*Cyclosporine is the first licensed cyclosporin, a newly discovered group of immunosuppressive drugs characterized by a cyclic endecapeptide structure with a new and unique amino acid, the "N-methyl C-9" amino acid. Review Ref: "First International Congress on Cyclosporine", Transpl. Proc. Supp. Dec. 1983.

9. Briefly describe any technical problems known to you which may affect commercialization of the invention:

None

10. State why the invention is not obvious to a person of reasonable skill in your field and distinguish your invention from existing, closely related tech-

nology: Intraocular penetration of cyclosporine was first demonstrated in our laboratory. Total body immunosuppression was believed to be necessary for efficacy of cyclosporine. However we have found that local immunomodulation within the eye is also therapeutic, possibly even more effective than systemic dosage for ocular disease.

11. List any patents known to you by name of inventor, assignee, and patent

number, if known, which are related to the invention: Compound was patented by Sandoz Pharmaceuticals Inc. approximately 1972, Basle Switzerland at that time ophthalmic use was not contemplated.

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12. To your knowledge, has any publication disclosed the invention? yes

If yes, list publication with complete citation and publication date:

Intraocular Penetration of Cyclosporine in Rabbits: R. L. Kaswan, R. L. Tackett, C. L. Martin, D. E. Bartell. Invest. Ophthalmol. Supp. Vol 25, March 1984, p. 36.

13. Person herein refers to any individual, corporation, partnership or other entity.

14. Give the earliest date in responding to subparagraphs a through k, below, and enter "NONE" when any event has not occurred:

a. Conception September 1983;

b. First Written Record October 1983;

c. Disclosure to persons other than inventor(s):

Oct 19, 1983 Ms. K. D. Roskaz
Date Name

Sandoz Inc., Route 10, East Hanover NJ, 07936
Address

Was this disclosure confidential or non-confidential?

3/29/84 Alcon Laboratories
Date Name

Fort Worth, Texas
Address

Was this disclosure confidential or non-confidential?

4/1/84 Society for Prevention of Blindness
Date Name

Address

Was this disclosure confidential or non-confidential?

Feb. 1984 Henry J. Kaplan
Date Name

Emory University School of Medicine, Atlanta, GA 30302
Address

Was this disclosure confidential or non-confidential?

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12/83 Randall Tackett
Date Name

College of Pharmacy, University of Georgia, Athens, GA 30602
Address

Was this disclosure confidential or non-confidential

12/83 Charles L. Martin
Date Name

College of Veterinary Medicine, University of Georgia, Athens, GA 3060
Address

Was this disclosure confidential or non-confidential?

d. First construction of model of the invention or written plan of experiments directly related to the invention when model inapplicable _____
September 1983 _____;

e. First test of model of the invention or first written experimental results proving or establishing invention when test of model is inapplicable _____
October 1983 _____;

f. First general experimental use such as further testing and/or developmental work December 1983 _____;

g. First public use March 1983 _____;

h. First commercial use none yet _____;

i. First offer to sell product of invention made by inventor which was subsequently accepted none _____;

j. First offer to purchase product of invention received by inventor which was subsequently accepted none _____;

k. First written publication, which even includes library cataloging a thesis, see #12 _____;

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15. Give the current location of laboratory records of the invention:

Room 366, College of Veterinary Medicine, University of Georgia

16. List any person you have contacted regarding developing and commercializing the invention; also state any commitments made to such person and whether you believe such a commitment, if any, to be legally binding:

Alcon Laboratories, Fort Worth, Texas. Discussed R & D of product, agreed to share initial data in confidence, retained right of use of information. (See confidentiality agreement attached).

17. List any person you think would be interested in licensing or otherwise commercializing the invention:

Sandoz Pharmaceuticals, Inc.
Alcon Pharmaceuticals, Inc.

18. When do you plan on publishing the results of your work which disclose the invention reported herein? Immediately

19. If you publish, will an abstract be published prior to a formal publication yes ? If yes, then when will the abstract be published?

March 1984

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20. If the invention has not already been described in a publication, please draft a non-confidential description of your invention below. This non-confidential description should not disclose any inventive elements, that is, someone skilled in your art should not be able to practice the invention by reading the non-confidential description.

SPECIAL INSTRUCTIONS TO INVENTOR OR JOINT INVENTORS: PLEASE REVIEW THIS FORM BEFORE SIGNING. PARAGRAPH 6 MUST BE COMPLETED FOR REVIEW BY THE PATENT COMMITTEE CHAIRMAN AND PATENT OFFICER.

I, OR WE, THE UNDERSIGNED true and original inventor or joint inventors, have read and understand this invention disclosure. I, or we, certify that the facts contained herein to the best of my, or our, knowledge are true and accurate. I, or we, request the Chairman of The University of Georgia's Patent Committee and The University of Georgia's Patent Officer to agree with the category in paragraph 6, above, under The University of Georgia Patent Policy and to authorize processing of the invention disclosure as a routine case under The University of Georgia Patent Policy. I, or we, authorize the University of Georgia Research Foundation, Inc. to review the invention, to evaluate its commercial potential, to submit non-confidential disclosures of the invention to third parties, to enter into confidentiality disclosure agreements with third parties providing for disclosure of the invention, to file patent applications, divisionals, continuations, continuations-in-part, and the like on the invention and to license or otherwise commercialize the invention, all at

the absolute discretion of the University of Georgia Research Foundation, Inc. If the University of Georgia Research Foundation, Inc. in its absolute discretion decides to file patent applications, divisionals, continuations, continuations-in-part, and the like on the invention, I, or we, agree to execute all patent applications, divisionals, continuations, continuations-in-part, and the like to assign the invention including all patent applications, divisionals, continuations, continuations-in-part, and the like thereon to the University of Georgia Research Foundation, Inc., and to execute all other documents relating to patents, licensing, or otherwise commercializing the invention. I, or we, agree to advise the University of Georgia Research Foundation, Inc. in licensing or otherwise commercializing the invention. I, or we, agree to communicate directly with potential licensees and the like regarding technical aspects of the invention at the request of the University of Georgia Research Foundation, Inc. I, or we, also agree to cooperate with the University of Georgia Research Foundation, Inc. in any administrative or court proceedings involving the disclosed invention. My, or our, only compensation for the invention shall be pursuant to The University of Georgia Patent Policy, agreements between The University of Georgia and the University of Georgia Research Foundation, Inc., as exist now or as subsequently amended or revised, applicable governmental statutes and regulations, as exist now, upon enactment, or as subsequently amended, and institutional patent agreements. All of the above shall be binding upon my, or our, heirs. I, or we, agree to make no assignment of invention except as set out above. I, or we, warrant that only the true and original inventor or joint inventors are listed in paragraph 2, above, and that no joint inventor has been deleted from paragraph 2, above. The foregoing references to invention shall include new matter related to invention disclosed to the University of Georgia Research Foundation, Inc. after my, or our, execution

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below. Duly executed on the date(s) shown below by the true and original inventor or joint inventors as set out in paragraph 2, above.

5/8/84
Date of signature

Renee Kaswan
Signature of inventor or joint inventor
(with name typed below)

Date of signature

Signature of inventor or joint inventor
(with name typed below)

Date of signature

Signature of inventor or joint inventor
(with name typed below)

Date of signature

Signature of inventor or joint inventor
(with name typed below)

We, the undersigned witnesses, hereby declare that Renee Kaswan

(name(s) of inventor or joint inventors)

disclosed the contents of the foregoing disclosure form to us, that we have read and understood the invention, entitled "Ophthalmic cyclosporin
preparation(s)

_____, "
that we are not the joint inventors, and that we are unrelated to the inventor or joint inventors, and we hereby agree to keep the foregoing invention confidential until such time as it becomes part of the public domain or until released in writing by both the inventor or joint inventors and the

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University of Georgia Research Foundation, Inc.

Date of signature

Signature of witness
(with name typed below)

Date of signature

Signature of witness
(with name typed below)

The University of Georgia Patent Committee Chairman and The University of Georgia Patent Officer hereby acknowledges receipt of the foregoing disclosure from Renee Kaswan

(name(s) of inventor or joint inventor)

entitled "Ophthalmic Cyclosporin Preparation(s)"

agrees with The University of Georgia Patent Policy category in paragraph 6, above, and authorizes processing of this invention report as a routine case under The University of Georgia Patent Policy. The University of Georgia Research Foundation, Inc. is requested to review the invention, to evaluate its commercial potential, to submit confidential disclosures of the invention to third parties, to enter into confidentiality disclosure agreements with third parties providing for disclosure of the invention, to file patent applications, divisionals, continuations, continuations-in-part, and the like on the invention, and to license or otherwise commercialize the invention all at the absolute discretion of the University of Georgia Research Foundation,

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Inc. Duly executed by The University of Georgia this 21st day of
May, 19 84.

THE UNIVERSITY OF GEORGIA

By: William O. Burke
William O. Burke
Patent Committee Chairman,
Patent Officer, and
Assistant Vice President for Research

AS PATENT COMMITTEE CHAIRMAN,
PATENT OFFICER, AND
ASSISTANT VICE PRESIDENT FOR RESEARCH OF
THE UNIVERSITY OF GEORGIA

University of Georgia Research Foundation, Inc. hereby acknowledges
of the foregoing disclosure from Renee Kaswan

(name(s) of inventor or joint inventors)

for the invention, entitled "Ophthalmic cyclosporin preparation
,"

accepts the disclosure on the terms and conditions contained above, and agrees
to process said disclosure in accordance with The University of Georgia Patent
Policy, agreements between The University of Georgia and the University of
Georgia Research Foundation, Inc. and applicable governmental statutes, regu-
lations, and Institutional Patent Agreements. Duly executed by the University
of Georgia Research Foundation, Inc. this 21st day of May,
19 84.

UNIVERSITY OF GEORGIA
RESEARCH FOUNDATION, INC.

By: Nathan W. Dean
Nathan W. Dean
Executive Vice President

AS EXECUTIVE VICE PRESIDENT OF
UNIVERSITY OF GEORGIA
RESEARCH FOUNDATION, INC.

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IR/II-A and II-B/Master Form
06/06/83-03

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