

WASHINGTON UNIVERSITY



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ASSOCIATE VICE CHANCELLOR
FOR RESEARCH

September 30, 1985

DIRECTOR, RESEARCH CONTRACT AND
LICENSING ADMINISTRATION

Norman Latker
OPTI
Room 4837
Department of Commerce
14th and Constitution, N.W.
Washington, D.C. 20230

*File w/
Cooperative
Agreements*

Dear Norman:

Enclosed is a copy of the Washington University-Monsanto Biomedical Agreement which you requested.

Please note that we wish to restrict distribution of this Agreement and request that you inform us and receive permission from the University prior to further dissemination of the Agreement by your organization.

Please do not hesitate to contact me to discuss the Agreement in detail.

Very truly yours,

H. S. Leahy
Director
Industrial Contracts & Licensing

Enclosure



Signed Original

MONSANTO-WASHINGTON UNIVERSITY
BIOMEDICAL RESEARCH AGREEMENT

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Exhibit A - Agreement of Program Participants

AGREEMENT

This Agreement, effective as of July 1, 1982, is by and between the parties:

WASHINGTON UNIVERSITY, a corporation organized under the laws of Missouri and having its principal offices at Lindell and Skinker Boulevards, St. Louis, Missouri 63130 (hereinafter "University")

AND

MONSANTO COMPANY, a corporation organized under the laws of Delaware and having its principal offices at 800 North Lindbergh Boulevard, St. Louis, Missouri 63167 (hereinafter "Monsanto");

WITNESSETH THAT;

WHEREAS, the University has sought and continues to seek the advancement of knowledge through education and research;

WHEREAS, the University desires that the useful results of its research be made available to society through established avenues of trade and commerce;

WHEREAS, Monsanto has personnel and facilities for the conduct of research, for the development of new products and processes based on scientific research, and for efficient large scale manufacture and distribution;

WHEREAS, Monsanto seeks to utilize the fruits of scientific research as a source for the development, manufacture and distribution of new products, especially products for meeting human needs;

WHEREAS, the University and Monsanto recognize that each can benefit from a relationship in biomedical research extending over a span of years that will provide present and potential financial support for the University, potential benefit to health care consumers and potential commercial benefit for Monsanto, while enhancing the understanding and work of their respective scientists by close interaction among them;

WHEREAS, the University and Monsanto believe that industrial support of biomedical research can lead to enhancement of their respective capabilities and render important long range benefits to the University, to Monsanto and to society;

WHEREAS, the University and Monsanto believe that biomedical inventions are likely to be brought into public use for public benefit through the incentive of the protection of the Patent System utilized by the parties to make available

through Monsanto, new commercial products and processes, while concurrently providing royalty income to the University to support its educational and charitable activities;

WHEREAS, the University and Monsanto recognize that the concept of academic freedom must be preserved by this Agreement and shall be a guiding principle in its administration;

WHEREAS, the University and Monsanto recognize that the 1964 Statement on Preventing Conflicts of Interest in Government Sponsored Research at Universities, issued by the American Association of University Professors and the American Council on Education expresses principles applicable to corporate and university relationships;

WHEREAS, the University and Monsanto are prepared to undertake a collaborative effort in the field of biomedicine with a focus on proteins and peptides which modulate cellular function, where the University currently has substantial personnel and facilities for the conduct of research and a field where Monsanto has in-house research underway and wherein Monsanto expects to increase its in-house research emphasis; and

WHEREAS, Monsanto proposes to provide significant financial support to the University in furtherance of this collaborative effort according to the terms set forth in this Agreement.

NOW, THEREFORE, the parties hereto agree as follows:

ARTICLE I

PURPOSE AND SCOPE OF THIS AGREEMENT

The purpose of the present Agreement is to provide a contractual framework to govern conduct of this collaborative effort under which multiple research Projects (as hereinafter defined) can be undertaken. This Agreement is designed to recite the contractual provisions which would apply to all Projects authorized by the Advisory Committee under the Program (as hereinafter defined).

ARTICLE II - DEFINITIONS

2.1 "Program" means all research activities performed by or for the University under this Agreement which are authorized and funded by the Advisory Committee (as hereinafter defined) and Program Director from financial support provided by Monsanto.

2.2 "Project" means a specific research activity which has been authorized and funded by the Advisory Committee from financial support provided by Monsanto under the Program.

Projects shall be of three types:

- a) "Exploratory Projects": Those directed to fundamental research on basic scientific questions with a focus on proteins and peptides which modulate cellular function.

- b) "Specialty Projects": Those directed to applied research with a focus on proteins and peptides which modulate cellular function and in which Monsanto sees more immediate commercial utility either in terms of technologies or products or both.

- c) "Construction and Renovation Projects": Those construction and renovation activities directed to physical facilities required to accommodate and enhance the Program.

2.3 "Advisory Committee" means those representatives of the University and Monsanto charged with administering the Program. The Advisory Committee comprises a Program Director who shall be Chairman and appointed by the University, three (3) additional members appointed by the University, and four (4) members appointed by Monsanto. All members including the Program Director, shall have voting power.

2.4 "Project Investigator" means the scientist in charge of a Project and responsible for its conduct in accordance with the terms of the Project award and the accepted operating policies and procedures of the University. A Project Investigator shall be a faculty member qualified to be a principal investigator on research projects sponsored by government and nationally reputable agencies.

2.5 "Technical Developments" means any and all inventions, discoveries, advances, know-how, processes, devices, machines, materials, software and other information arising from the Program, whether or not the same are patentable, copyrightable or otherwise protectable by law.

2.6 "Patent" means any patent, certificate of invention, inventors certificate, utility model or similar form of protection, or plant patent or other form of protection of plant material, granted anywhere in the world covering an invention which is a Technical Development, and owned by the University or in which the University has licensing rights.

2.7 "Licensed Product" means any product covered by a claim or made by or used in a process covered by a claim of an unexpired Patent at the time and in the country wherein the product is manufactured, used or sold, which claim has not been adjudicated invalid in a final adjudication from which there can no longer be an appeal, and which Patent is licensed to Monsanto

as provided for in this Agreement.

2.8 "Agreement of Program Participants" means the specimen agreement set forth in Exhibit A attached hereto.

ARTICLE III - TERM OF AGREEMENT

3.1. This Agreement shall be for a period of five (5) years commencing July 1, 1982 and terminating June 30, 1987, unless earlier terminated under the provisions of Paragraphs 4.3, 12.2 or 12.3.

3.2 On or about February 1, 1985, the parties shall enter into discussions as to whether both parties desire to continue the Program beyond the normal termination date of June 30, 1987. If continuation is mutually desirable the parties shall proceed with negotiations to arrive at mutually acceptable terms and conditions for such continuation. If continuation is not desired by either or both parties, this fact shall be confirmed in writing before the end of the third year of the initial term of this Agreement.

3.3 If, in accordance with Paragraph 3.2 the parties decide not to continue the Program beyond June 30, 1987, then Monsanto shall have the option of electing to continue its support, on a Project by Project basis, for any Project started but not completed during the normal term. Monsanto shall make

such elections and the parties shall negotiate in good faith mutually acceptable financial terms and time extensions, not to exceed two (2) years in duration, prior to the expiration of this Agreement. All other relevant terms of this Agreement shall apply to such terminal Project continuations.

ARTICLE IV - PROGRAM ADMINISTRATION

4.1 The Program shall be under the direction of the Advisory Committee chaired by the Program Director, Dr. David M. Kipnis, who shall be assisted by seven (7) other Committee members including three (3) members, namely, Dr. Luis Glaser, Dr. Paul Lacy, and Dr. Joseph Davie, appointed by the University and four (4) members, namely, Dr. Howard A. Schneiderman, Dr. G. Edward Paget, Dr. Louis Fernandez and Dr. David C. Tiemeier, appointed by Monsanto. The University and Monsanto representatives on the Advisory Committee, other than the Program Director, may be changed at appropriate intervals by either of the parties with timely notice to the other party.

4.2 All actions to approve, defer or disapprove Program activities and to fund new Projects, to provide supplemental or continuation support to previously approved Projects or activities, and to discontinue previously approved Projects or activities shall be taken in convened meetings of the Advisory Committee. Any such action shall require approval of a majority of the members of the Advisory Committee, i.e., at least five (5)

of the eight (8) members.

4.3 Should the Program Director or any member of the Advisory Committee be unable to continue service, a replacement shall be promptly appointed by the appropriate party. Program Director replacements shall be mutually acceptable to Monsanto and the University; provided, however, that acceptance by Monsanto shall not be unreasonably withheld. If the University cannot nominate an acceptable replacement for the Program Director within one (1) month following the inability of the Program Director to continue service, Monsanto may suspend its financial support for the Program until an acceptable Program Director is appointed. If such suspension continues beyond six (6) months, Monsanto may summarily treat this Agreement as breached under provisions of Paragraph 12.2 and the ninety (90) day notice provision of Paragraph 12.2 is not applicable.

4.4 The Program Director shall convene a meeting of the Advisory Committee at least once each calendar quarter and otherwise as frequently as necessary to act on Program matters and pending proposals, to review the financial status and progress of active Projects, to deal with unanticipated problem areas, and to consider other matters concerned with the effectiveness of the Program. Except in an emergency, notice of a scheduled meeting and an agenda therefor shall be issued not less than two (2) weeks prior to any such meeting. Any Advisory Committee member may request convening of special meetings and

may have any matter related to the conduct of the Program placed on the Advisory Committee agenda for the next or forthcoming meeting by making such a request in writing to the Program Director sufficiently in advance of the meeting to allow adequate preparation for a productive discussion of the matter.

4.5 The Program Director shall, after each meeting of the Advisory Committee, distribute to all Committee members, whether present at the meeting or not, a written summary of matters considered and actions taken.

4.6 Should a member of the Advisory Committee not be able to attend a given meeting, an alternate representative may be designated by so notifying the Program Director on a meeting by meeting basis. If the Program Director is unable to attend a meeting of the Advisory Committee, he may designate another University member of the Advisory Committee to chair the meeting and perform the functions of the Program Director at that meeting. However, it is understood by the parties that the effectiveness of the Advisory Committee will be promoted by continuity of membership and regular attendance at meetings by members.

ARTICLE V - PROJECT SELECTION AND IMPLEMENTATION

5.1 The Advisory Committee shall decide on both the Exploratory and Specialty Projects which are to be supported

under the Program. The Advisory Committee shall strive to identify and fund Projects in which the University enjoys scientific leadership and in which Monsanto has a meaningful interest.

5.2 The Advisory Committee has ultimate responsibility for identification and selection of all Projects as well as for overall and ongoing direction of the Program. As a general guide, the parties to this Agreement intend for the Program to embrace two (2) types of Projects, namely, Exploratory Projects and Specialty Projects. Ultimately during the term of this Agreement, it is expected that approximately thirty percent (30%) of the research effort would be directed toward fundamental questions (Exploratory Projects) while seventy percent (70%) would be directed toward specific products (Specialty Projects). The parties hereto recognize that facility renovation and construction is to be funded as a Program activity within the limitation of the financial support specified in Article VIII hereof. -

5.3 Following the identification of a field of interest by the Advisory Committee the Program Director shall seek Project proposals from faculty members of the University.

5.4 Project proposals, continuations and supplements thereto shall be on forms provided by the Program Director. The Program Director shall provide copies of Project proposals to all

members of the Advisory Committee at least one (1) month prior to the Committee meeting at which such requests are to be considered.

5.5 Whenever the Advisory Committee has identified a field of research of mutual interest, and has received an acceptable Project proposal, a Project may be created by the authorization of the Advisory Committee in writing. The Project authorization shall identify the Project Investigator, define the research activities to be pursued, the level of effort to be devoted to the Project by the Project Investigator, include a budget covering all costs of such research, define the time duration and such other terms and conditions as may be agreed to and be approved by the Project Investigator consistent with the purposes and conditions of this Agreement.

5.6 With concurrence of the Advisory Committee, and in furtherance of productive interaction between scientists of Monsanto and those of the University, Monsanto representatives on the Committee shall designate a Monsanto Project Scientist who shall act as the primary contact with each Project Investigator during the conduct of a given Project.

5.7 The Program Director shall submit to Monsanto in writing summary reports of all important findings and results as soon as available and detailed annual Program reports on each anniversary of this Agreement. The annual reports shall include

summaries and conclusions for each active Project.

ARTICLE VI

INTERACTION BETWEEN MONSANTO AND THE UNIVERSITY

6.1 To optimize the mutual benefit and collaboration intended by this Program, the parties desire that there be mutually productive and continuing interchanges between University and Monsanto scientists. Accordingly, the University will ensure that all University scientists engaged in the Program are available to appropriate Monsanto scientists for consultation in the area of their respective Projects. Temporary office space at the University shall be made available to collaborating Monsanto scientists.

6.2 The University agrees to permit individual scientists and technicians from Monsanto, with the consent of the Program Director and Project Investigator and at Monsanto's expense, to spend appropriate periods of time in University laboratories where Project research is being conducted to learn techniques developed therein, to participate if mutually desirable, and to facilitate the transfer of Technical Developments to Monsanto. Monsanto agrees that its employees who are permitted to train and function in the laboratories of the University pursuant to this paragraph shall be required to observe the applicable policies of the University.

6.3 It is anticipated that interaction between the Project Investigators and Monsanto Project Scientists will identify facilities and capabilities of Monsanto which may be used by University scientists to enhance the progress of Projects. Moreover, it is appropriate that evaluation of the commercial potential of research leads and products be addressed through the interaction of the Project Investigators and the Monsanto Project Scientists.

ARTICLE VII - SCIENTIFIC REVIEW PANEL

7.1 To assess the scientific merit and cost effectiveness of Projects supported by the Program, the parties hereto recognize the need for periodic review by an independent panel of scientists.

7.2 During the third year of the initial term of this Agreement and every two (2) years thereafter, the Advisory Committee shall commission a scientific review panel comprising at least four (4) distinguished scientists, not employees of Monsanto or members of the University staff, to review all then-current Project work and to appraise the direction of the Program, both qualitatively and quantitatively. Composition of the review panel should be designed to include scientists having clinical and pharmaceutical orientation as well as academic orientation.

7.3 The review panel shall be required to issue a confidential report to the Advisory Committee and to the Chancellor of the University and the Chief Executive Officer of Monsanto stating its views, conclusions and recommendations regarding the scientific merit and cost effectiveness of the Program and Projects and the impact of the Program on the respective institutions involved.

7.4 Costs of the scientific review shall be paid from Program funds.

VIII - PROGRAM FINANCES

8.1 Monsanto hereby agrees to provide to the University for the total support of the Program during the five (5) year term of this Agreement, the total amount of Twenty-Three Million, Five Hundred Thousand Dollars (\$23,500,000), to be adjusted according to Paragraph 8.2, which shall cover both direct and indirect expenses of the University. The University agrees that this funding shall be disbursed solely in support of the Program.

8.2 Payment by Monsanto to the University of the amount specified in Paragraph 8.1 shall be limited to contract year budget amounts recited in the following schedule which are subject to (i) annual adjustment for inflation in accordance with this Paragraph 8.2, and (ii) budget underruns carried forward from one year to the next with approval of the Advisory Committee

in accordance with Paragraph 8.9. The parties hereto believe the following expenditure schedule reflects the appropriate allocation of funds:

<u>Contract Year</u>	<u>Exploratory Projects</u>	<u>Specialty Projects</u>	<u>Construction and Renovation Projects</u>	<u>Contract Year Budget</u>
82/83	\$ 1,500,000	\$ 1,500,000	\$ (See Para.8.4)	\$ 3,000,000
83/84	\$ 1,600,000	\$ 2,200,000	\$	\$ 3,800,000
84/85	\$ 1,700,000	\$ 3,000,000	\$	\$ 4,700,000
85/86	\$ 1,800,000	\$ 3,800,000	\$	\$ 5,600,000
86/87	\$ 1,900,000	\$ 4,500,000	\$	\$ 6,400,000
Total	\$ 8,500,000	\$ 15,000,000	\$	\$ 23,500,000

The initial contract year shall run from the effective date of this Agreement through June 30, 1983. Subsequent contract years shall run from July 1 through June 30.

The contract year budgets above recited, commencing with the second contract year (July 1, 1983 through June 30, 1984), shall be adjusted using the GNP Deflator Index in the following manner:

- (a) A base index will consist of an average of the GNP Deflator Index figures for the four

(4) quarters from April 1981 through March 1982.

(b) An index for each contract year, commencing with the second contract year, will consist of an average of the four (4) quarterly GNP Deflator Index figures covering the period April through the following March immediately preceding the start of each contract year. (For example the index for the second contract year will be the average of the GNP Deflator Index figures for the four (4) quarters covering April 1982 through March 1983.)

(c) Each contract year budget as stated above shall be adjusted prior to the commencement of the relevant contract year by applying a multiplier derived as follows:

$$\text{multiplier} = 1 + \frac{\text{contract yr. index} - \text{base index}}{\text{base index}}$$

For purposes of this Agreement the "GNP Deflator Index" shall mean the quarterly revised Implicit Price Deflator for the Gross National Product as reported by The United States Department of Commerce, Bureau of Economic Analysis. Since it is normal for a quarterly GNP Deflator Index to be revised shortly

after it is first published, calculations herein shall be based on the final index for a quarter, if available, and otherwise on the most recent revision available on June 1 immediately preceding the start of the contract year for which calculations are made.

8.3 It is recognized that the occurrence of expenditures during a contract year is primarily dependent on Project spending plans authorized by the Advisory Committee during the current and any prior years. Nevertheless, Monsanto is not obligated to reimburse the University for expenditures incurred during, or carried forward into, any contract year in excess of the total amount of the contract year budget shown on the expenditure schedule in Paragraph 8.2, as it may have been adjusted under the provisions of Paragraph 8.2 and 8.9, unless the parties mutually agree to modify said total amount by formal amendment to this Agreement.

- 8.4 All Program funds shall be administered by the Program Director who shall allot funds, with the approval of the Advisory Committee as specified in Article IV, to Project participants. By unanimous consent the Advisory Committee may reallocate among Project types up to 10% of the total funds for any contract year specified in the schedule of Paragraph 8.2, as such annual total may have previously been modified by Monsanto under Paragraph 8.3 or by the Advisory Committee under Paragraph 8.9. Such reallocation of contract year funds may be among the

Exploratory Project type, the Specialty Project type and the Construction and Renovation Project type. The Program Director shall monitor spending of funds budgeted for individual Projects and may make adjustments among expense categories of an approved Project budget upon justified requests of Project Investigators. The Program Director shall keep the Advisory Committee informed of financial matters which might indicate a significant departure from Project plans previously approved by the Committee. The Program Director's financial records on all segments of the Program and Projects shall be available for review by any member of the Advisory Committee.

8.5 Approved funds for individual Projects or for support of the Program shall be maintained by the University's Accounting Services Department in separate accounts for each such activity. Spending for each account shall be under the direct control of the Program Director or his delegated Project Investigator, respectively, who shall be furnished with the Accounting Services standard monthly statements of spending against their accounts.

8.6 The accounting records of Program activity shall be available for audit by Monsanto, using its own internal or outside auditors, during the normal business hours of the University.

8.7 The University shall submit monthly invoices with

supporting details to Monsanto showing actual spending by University expense category for each Project for which reimbursement of expenditures is being requested. Each invoice shall also show cumulative expenditures to date for each such Project against the approved Project budget and cumulative total Program expenditures for the contract year against the current contract year budget shown on the expenditure schedule in Paragraph 8.2 as it may have been previously adjusted under the provisions of Paragraphs 8.2 and 8.9.

8.8 Monsanto agrees to pay the University promptly upon receipt and approval of the University's invoices provided under Paragraph 8.7 up to the level of the contract year budget set forth in Paragraph 8.2, as such contract year budget may have been adjusted under the provisions of Paragraphs 8.2 and 8.9.

8.9 If in any contract year there is an overrun of the contract year budget the excess expenditures shall be carried forward and be paid from the following contract year budget. If in any contract year there is an underrun of the contract year budget (hereinafter in this paragraph "the current contract year budget"), then with the unanimous consent of the Advisory Committee the underrun amount may be carried over as an addition to the following contract year budget. The approved amount from the current contract year budget which is to be carried over shall be adjusted by a multiplier calculated by dividing the multiplier from Paragraph 8.2 for the following contract year

budget by the multiplier for the current contract year budget. The thus adjusted amount to be carried over shall then be added to the following contract year budget after the following contract year budget has been adjusted in the usual manner.

8.10 Title to all items of equipment purchased with Program funds shall vest in the University at the time of purchase.

8.11 Upon termination of this Agreement for any reason the University shall provide a final accounting of Program funds to Monsanto within ninety (90) days following such termination. During said ninety (90) days the University shall liquidate all outstanding obligations incurred prior to termination but shall not incur additional obligations. The balance of funds remaining shall thereupon be returned to Monsanto unless required for completion of Projects in accordance with Paragraph 3.3.

8.12 Indirect costs invoiced under Paragraph 8.7 shall, through June 30, 1987, be at a fixed rate of fifty percent (50%) of invoiced direct costs. Indirect costs invoiced by the University for any activity performed in whole or in part by any contractor shall not exceed the indirect costs which would have been invoiced had such activity been performed wholly by the University. If the University's indirect costs rise by ten percent (10%), i.e., to fifty five percent (55%) or more, then upon the University's request Monsanto agrees that it will negotiate the University's request to increase the rate of indirect costs from fifty percent (50%) under this Agreement, taking into con-

sideration relevant factors, including relative increases in indirect costs made in other research agreements, including government agreements.

ARTICLE IX - PUBLICATIONS AND REVIEW OF TECHNICAL DEVELOPMENTS

9.1 The University faculty members participating in Projects are at liberty to publish the results of their research subject to the provisions of Paragraphs 9.1, 9.2, 9.3, 9.4 and 9.5. Project awards will require that participants provide copies of all abstracts and articles, in the best form then available, proposed to be submitted for publication in sufficient time to permit the Program Director to provide same to a Monsanto member of the Advisory Committee at least one (1) month prior to submission to a publisher or other third party. The Program Director shall immediately determine that a Monsanto member has received a copy of each such proposed abstract and article. The Program Director shall also promptly provide to a Monsanto member a final copy of each abstract and article as submitted for publication.

9.2 Monsanto shall promptly review such proposed abstracts and articles to determine if potentially patentable Technical Developments are disclosed and shall promptly thereafter inform the University whether delay of submission for publication or other public disclosure for a reasonable time will be required to establish Patent rights of reasonable scope. Disputes concerning such delays shall be referred to the Advisory

Committee.

9.3 As to verbal presentations and discussions, the parties recognize that it is impractical to provide a complete review system for Patent purposes and that considerable discretion must be left in the investigator. It is the intent of the University and Monsanto to provide the investigators guidance sufficient to avoid any divulgations that would compromise the establishment of the best possible Patent position.

9.4 The reporting and evaluation as provided for in Paragraphs 9.1 and 9.2 notwithstanding, the Monsanto representatives on the Advisory Committee are exposed to all Program and Project plans before commencement and such representatives have full opportunity and right to follow the progress of any and all Projects. Through this mechanism the assigned Monsanto Project Scientists and Monsanto shall determine as early as practicable the potential for establishing Patent rights and its interest in obtaining a license of such rights. As soon as such potential is determined by Monsanto the parties shall cooperate on immediate actions necessary to the establishment of such rights, including, if necessary delay of publication for a reasonably brief period of time to conduct any further research or take other actions that may be necessary to file appropriate and adequate Patent applications.

9.5 All scientific publications reporting research

results from Program activities shall acknowledge that support for such research was provided by Monsanto.

9.6 Upon written request to the Advisory Committee, Monsanto shall receive adequate samples of all available scientific materials isolated or developed in the Program, and shall have the right to use the same for research and/or commercial purposes, but subject to the provisions herein with respect to confidentiality, Patents and licenses. Monsanto's rights to receive and use samples as provided in this Paragraph 9.6 shall not be denied but shall be subject to reasonable modification for good reason as deemed necessary by the Advisory Committee.

ARTICLE X - CONFIDENTIALITY

10.1 Technical Developments and Patents shall be the sole and exclusive property of the University subject to the license rights provided under Article XI.

10.2 Monsanto shall take reasonable precautions to safeguard, in a manner comparable to that used to protect its own confidential technical information, unpublished Technical Developments and not disclose the same to others for a period of two (2) years after receipt; provided, however, that Monsanto shall not be liable for unauthorized disclosure of Technical Developments in spite of such precautions. With respect to any

particular identified Technical Development for which good cause can be shown, the University may extend the two (2) year period for an additional period of two (2) years by notice in writing to Monsanto stating reasonable justification therefor and that to the University's knowledge none of the exceptions of Paragraph 10.3 is applicable. After said initial two (2) year period or extension thereof Monsanto shall be under no restrictions as to revelation of any Technical Developments. Subject to the provisions herein with respect to Patents and licenses, Monsanto shall at all times be free to use Technical Developments.

10.3 The Monsanto obligation specified in Paragraph 10.2 shall not extend to Technical Developments which:

- a) become a part of the public domain or of the public knowledge through no fault of Monsanto; or
- b) were in the possession of Monsanto prior to disclosure by the University, and such possession by Monsanto is documented; or
- c) are received by Monsanto lawfully and properly from a third party; or
- d) have been revealed in patent

applications.

10.4 Close cooperation between Monsanto personnel and University personnel in the conduct of activities required by or contributing to the purposes of this Agreement may involve the disclosure of Monsanto confidential information to such University personnel. Since, as a practical matter the University is not able to make commitments of confidentiality on behalf of its faculty nor control the confidential information disclosed to them, it shall advise all Program and Project participants that they will be required to sign in advance of receiving Monsanto confidential information personal commitments of confidentiality as Monsanto deems necessary in the circumstances.

ARTICLE XI - PATENTS AND LICENSING

11.1 Whenever the University reasonably feels a need therefor it may request Monsanto to provide in writing a preliminary indication of its current interest in commercializing Technical Developments resulting from a Project. However, Monsanto shall not be obligated to carry out commercialization.

11.2 Monsanto shall have the right and obligation to monitor progress of each Project through its representatives on the Advisory Committee and through access to University Program participants and reports, or by such other arrangements as may be

mutually acceptable to Monsanto, the Program Director, and the Project Investigators as appropriate. The primary purpose of such monitoring is to detect potentially patentable inventions as early as possible. The University shall have the obligation to disclose promptly to Monsanto all potentially patentable or scientifically novel Technical Developments.

11.3 When in the judgment of Monsanto potentially patentable inventions are developed within a Project, Monsanto shall make a report of such to the University, with its views of further research that may be necessary to establish the nature and scope of these inventions, and to the extent then possible its opinion of the potential importance of such inventions to commercialization prospects, and its interests concerning the licensing by Monsanto under any Patents that may be obtained covering such inventions. The information in said report shall be retained in confidence by the University and used only for purposes of this Agreement.

11.4 When in the judgment of the University potentially patentable inventions are developed which have not yet been identified by Monsanto through the processes described in Paragraphs 11.2 and 11.3 the University shall make a report of such to Monsanto, including all available results and conclusions. Thereupon, Monsanto shall prepare and make its report to the University as specified in Paragraph 11.3.

11.5 When Monsanto has indicated its interest in a license under prospective Patent rights to an invention it shall promptly cause its patent attorneys to file and prosecute in good faith a United States Patent application on such invention. Monsanto shall also effect the filing and good faith prosecution of foreign Patent applications corresponding to the United States application in whatever countries Monsanto by written notice to the University indicates its interest in a license under prospective Patent rights.

11.6 Until such time as Monsanto notifies the University in writing that it no longer has an interest in a license, or until the expiration of the time specified in Paragraph 11.14 during which time Monsanto has not given notice of its election to take a license, Monsanto agrees to bear the cost for filing and prosecution of Patent applications under Paragraph 11.5 and the issuance and maintenance of Patents thereon. Monsanto shall not be required to prosecute any such Patent application beyond the point of final rejection by the assigned Primary Examiner in the United States Patent and Trademark Office or the equivalent stage of prosecution if a foreign application. The University, at no cost or obligation or liability to Monsanto, may take action to file or prosecute any Patent application or have issued or maintain any Patent on which Monsanto elects not to take such action. Any such election by Monsanto shall be promptly communicated to the University and in adequate time to allow the University to take such action if it so desires. Monsanto's



right to a license thereunder shall not thereby be diminished.

11.7 With respect to Patent applications filed and prosecuted and Patents issued or maintained by Monsanto under Paragraphs 11.5 and 11.6, the University at its own expense may designate and retain patent counsel of its own who shall be permitted to review such Patent applications and proposed responses to Patent Office actions thereon and issuance and maintenance of Patents and to consult with Monsanto's patent attorneys before Monsanto takes action thereon. However, the control of such filings, prosecutions, issuances and maintenances shall rest with Monsanto unless it elects to relinquish such control to the University under Paragraph 11.6 by timely written notice. The University may at any time elect by notice in writing to Monsanto to assume at University's cost those activities undertaken by Monsanto under Paragraphs 11.5, 11.6 and 11.7 on behalf of the University in regard to any Patent application or Patent, and Monsanto's right to a license thereunder shall not thereby be diminished.

11.8 Title to all Patent applications and Patents issuing thereon covering Technical Developments made only by University or non-Monsanto personnel or jointly with Monsanto personnel shall be in the University. Any royalties payable with respect to the latter shall take into consideration the relative contributions of the University and Monsanto coinventors.

11.9 The parties, including the inventors, Project Investigators and Program Director, shall do all acts necessary or desirable to provide Monsanto patent attorneys with all information and records and execution of all documents necessary or desirable in the evaluation of Technical Developments, and in the filing and prosecution of Patent applications thereon, and in obtaining the issuance and maintenance of any Patents issuing from such Patent applications.

11.10 The University shall take all necessary and desirable actions, including the signing of Agreements of Program Participants (Exhibit A) by each of the persons participating in the Program, including the Program Director, all Project Investigators, and all other persons involved in the research, to assure that it acquires sufficient title to all Technical Developments, Patent applications and Patents from those of its personnel making such so as to be entitled to grant licenses to Monsanto as specified in this Agreement. The Program Director shall maintain a file of such signed Agreements of Program Participants which shall at all times be available to Monsanto representatives and upon request the Program Director shall provide Monsanto copies of specified Agreements.

11.11 In consideration of Monsanto's financial and other support of the Program and of the Patent work and cost thereof to be undertaken by Monsanto under this Article XI, the University agrees that it will make no claims against and hereby waives any

claim it may have against Monsanto or its employees for injury, loss or damage resulting from acts of omission or commission by Monsanto, its employees or agents, in connection with the preparation, filing and prosecution of Patent applications and the obtaining and maintaining of Patents covering Technical Developments.

11.12 Each inventor of a potentially patentable Technical Development, no later than the time of signing a Patent application thereon, shall be requested to agree, for the considerations recited in Paragraph 11.11, to make no claims against and to waive any claims he or she may have against Monsanto or its employees for injury, loss or damage resulting from acts of omission or commission by Monsanto, its employees or agents, in connection with the preparation, filing and prosecution of Patent applications and the obtaining and maintaining of Patents covering Technical Developments. Should any inventor decline to so agree, any Patent application on such Technical Development shall be filed and prosecuted and Patents obtained and maintained by the University, at its own cost, and Monsanto's right to a license thereunder shall not thereby be diminished.

11.13 Notwithstanding any other provision of this Agreement, the University agrees to hold harmless, indemnify and defend Monsanto and its employees from all liabilities, damages, costs, expenses (including attorneys fees) and losses resulting

from any claim or any lawsuit or any settlement thereof made by the University or by Monsanto with the University's consent, by the University's employees or third party having an interest through the University or its employees, and arising out of acts of omission or commission in regard to the obligations undertaken by Monsanto or its employees under Paragraphs 11.5, 11.6 and 11.7.

11.14 The University hereby agrees to grant to Monsanto licenses to make, have made, use and sell under Patents, including the right to grant sublicenses, in such countries as Monsanto may elect. Such election for any Patent shall be made within two (2) years after the filing of a Patent application in the affected country, provided, however, that Monsanto shall not be required to negotiate the terms of a license agreement until after the relevant Patent has issued.

11.15 License grants to Monsanto of rights to Patent applications and Patents issuing thereon for inventions made solely with Monsanto support shall be exclusive for the life of such Patents. For any invention made with the joint support of Monsanto and funds provided by another sponsor, or in which there is a third party inventor, such license shall, whenever legally possible, be exclusive for the life of the Patents. However, if the University is unable to grant a license which shall be exclusive for the life of the Patent, then the University shall provide Monsanto with the maximum rights permitted by law. In connection with the transfer of Patent rights to be negotiated

under this Agreement the parties shall consider the benefits relative to licensing as distinguished from transfer of title.

11.16 The University agrees to grant and hereby grants to Monsanto an irrevocable, world-wide, paid-up, non-exclusive license, to make, have made, use and sell, including the right to grant sublicenses, on all Technical Developments which are not covered by Patents. Monsanto agrees to indemnify the University for liability arising from use of Technical Developments licensed under this Paragraph 11.16, and from use, sale or other disposition of products made by use of the said Technical Developments, by Monsanto, its affiliates, sublicensees or any party acting on behalf of same. This provision shall survive termination of this Agreement.

11.17 The University agrees to grant to Monsanto licenses on patents secured outside the Program to the extent the University has the right to so license and to the extent necessary for Monsanto to practice Technical Developments. For such patents the grant shall be on terms and conditions reasonable in the circumstances and shall include the right to grant sublicenses. Monsanto agrees to indemnify the University for liability arising from use of such patents licensed under this Paragraph 11.17 and from use, sale or other disposition of products made by use of such patents, by Monsanto, its affiliates, sublicensees or any party acting on behalf of same; this provision shall survive termination of this Agreement.

11.18 License grants to Monsanto under Paragraphs 11.14 and 11.15 shall contain at least the following terms and conditions:

a) requirement that Monsanto by its own efforts or through sublicensees during the period of exclusivity make reasonable efforts to effect the lawful introduction of Licensed Products into the marketplace as early as practicable, consistent with Monsanto's sound and reasonable business practice and judgment. The requirement for introduction of a Licensed Product into the marketplace shall be deemed met if, in the exercise of Monsanto's sound and reasonable business practice and judgment, an alternative product serving essentially the same function has been introduced into the marketplace by Monsanto and with essentially the same benefits to the consuming public.

b) the right of the University to require Monsanto to grant a non-exclusive sublicense to a responsible party on fair and reasonable terms and conditions in the event the requirement of subparagraph

a) above is not met.

c) requirement that during the period of exclusivity Monsanto submit a product development plan specifying its reasonable estimate of the schedule of key events to market entry and provide periodic reports of significant modifications to the plan and progress against the plan to the University until market entry is achieved, and requirement that the University retain in confidence the information in said plan and reports and use only for purposes of the license.

d) right of Monsanto to sublicense others provided the University is notified to whom the sublicense was granted.

e) a royalty schedule based on net selling price of Licensed Product sold by Monsanto or its sublicensees. The University and Monsanto recognize that patent protection is only one factor contributing to commercial success of a product or process and that other factors, for example other patented

inventions, unpatented know-how, technical and marketing skills, financial contribution and risk, nature and extent of market, nature and extent of competition, normal trade practices, and condition of the economy also play an important part. Accordingly, rather than attempt at this time to establish royalty rates, the University and Monsanto declare their intentions to negotiate in good faith at the time of licensing, reasonable and fair royalties payable to the University by Monsanto on the commercial practice by Monsanto and its sublicensees of each Technical Development covered by a Patent licensed under this Article XI, taking into account the various factors contributing to the commercialization. If the University and Monsanto are unable to agree on royalty rates within six (6) months of the commencement of negotiation, the matter may be submitted to arbitration by either party and if so submitted by either party, shall be finally settled by arbitration conducted in accordance with the then-existing

rules of conciliation and arbitration of the American Arbitration Association. Any such arbitration shall take place in St. Louis County, Missouri, before three (3) arbitrators, one of whom shall be designated by Monsanto, one by the University and the third by the two so designated. If one party fails to designate an arbitrator within thirty (30) days after the designation of an arbitrator by the other party, the arbitrator who should have been chosen by the other party shall be appointed by the American Arbitration Association as soon as possible. In the event that the said two arbitrators designated by the parties are unable to agree upon a third arbitrator within thirty (30) days after the nomination of the last of the said two arbitrators, the third arbitrator shall be appointed by the American Arbitration Association as soon as possible. None of the arbitrators need be designated from any panel published by the American Arbitration Association or any other arbitration association. The arbitrators shall apply the laws of the

State of Missouri. The decision by the arbitrators shall be binding and conclusive upon the parties, their successors and assigns and they shall comply with such decision in good faith. The University and Monsanto each shall pay its own costs and one-half of the costs of the arbitration.

f) provision that when a Licensed Product is sold but not as such and constitutes significantly less than all of the thing sold, an equitable adjustment shall be made in the net selling price of the thing sold to arrive at the net selling price for royalty calculations. When a Licensed Product is manufactured by or used in a process and the process is only a minor factor in the manufacture or use, an equitable adjustment shall be made in the net selling price.

g) provision that Monsanto payments required to be made to a third party for the right under a third-party dominating patent to make, use or sell a Licensed Product licensed hereunder shall be credited

against one-half of the royalties due the University hereunder from sales of the same Licensed Product.

- h) right of annual audit to confirm royalties on behalf of the University by a firm of accountants to which Monsanto has no reasonable objection.
- i) indemnification of the University by Monsanto for liability arising from the manufacture, use, sale or other disposition of Licensed Products, by Monsanto or its affiliates, sublicensees or any party acting on behalf of same. This provision is to survive termination of the license agreement.
- j) law of Missouri shall apply.
- k) such other provisions as the parties may mutually desire, and, in the case of an exclusive license of an invention jointly supported by the government, such provisions as the government may have validly required the University to include.

1) Patent Infringement procedures:

(1) If at any time a third party shall infringe a Patent licensed to Monsanto hereunder, then Monsanto may either (i) obtain a discontinuance of such infringing operations; (ii) bring suit at Monsanto's expense against such infringer in the name of Monsanto, or in the name of the University and Monsanto if the University is a legally indispensable party; or (iii) permit the University at its option to bring such suit at its own expense. The party who brings suit shall control the prosecution and any settlements thereof, and the other party shall be entitled to be represented therein by counsel of its own selection at its own expense.

(2) From any recovery from such suit or settlement thereof there shall first be paid the expenses of the party

bringing the suit, then the expenses of the other party hereto if represented by counsel, and the balance shall be divided two-thirds to the party bringing the suit and one-third to the other party, unless the parties agree otherwise.

(3) Before bringing suit Monsanto shall fully inform the University, and give careful consideration to the views of the University in making its decision whether or not to sue.

(4) If Monsanto decides to sue and University is a legally indispensable party, the University shall have the right to assign to Monsanto all of the University's rights, title and interest in the Patent or Patents concerned, in which event suit by Monsanto on such Patent or Patents shall thereafter be brought or continued solely in its name if the University is no longer an indispensable party. Patents so assigned by the University to

Monsanto shall remain subject to the same royalty and all other terms and conditions of this Agreement.

11.19 Commencing with the fourth and subsequent years in which royalties are due to the University pursuant to licenses contemplated under this agreement, Monsanto shall be entitled to a credit, not to exceed 25% of the gross royalties due for the commercialization of Licensed Products in each year, (a) of Monsanto's cumulative out-of-pocket costs (excluding the costs of Monsanto's employees) for patent activities under Paragraphs 11.5 and 11.6 and (b) 50% of all payments made prior to the date of crediting by Monsanto to the University under Article VIII hereof, which payments can be related to the cost of development of those commercialized Licensed Products.

11.20 Should Monsanto not indicate interest to take a particular license from the University, or subsequently decide not to enter into the license agreement, or terminate the license agreement, or should such agreement be justifiably terminated by the University without challenge or objection by Monsanto, then the University shall be free to license to others the subject matter so released, without further obligation to Monsanto. However, such licenses to others shall exclude Licensed Products directly competitive with or substantially equivalent to those Monsanto has licensed.

11.21 Upon the indication by Monsanto of an interest in any Technical Developments and that Monsanto desires to commence activities directed at transferring such technology to its laboratories, then the Program Director shall participate with Monsanto representatives, the Project Investigators and others as may be appropriate to work out mutually acceptable actions to be taken to effect such technology transfer, including activities contemplated under Paragraphs 6.2 and 9.6, all at no added cost to Monsanto.

ARTICLE XII - TERMINATION

12.1 This Agreement shall terminate on June 30, 1987 unless extended by mutual agreement of the parties under the provisions of Paragraph 3.2; or unless earlier terminated under the provisions of Paragraphs 4.3, 12.2 or 12.3.

12.2 In the event that either party to this Agreement defaults or breaches any of the provisions hereof, the other party reserves the right to terminate this Agreement upon ninety (90) days written notice to the defaulting party; provided that if the defaulting party, within said ninety (90) day period cures the said default or breach, this Agreement shall continue in full force and effect.

12.3 If either party shall become insolvent, or shall make any assignment for the benefit of creditors, or shall be

adjudged bankrupt, or if a receiver or trustee of the property of either party is appointed, the other party on thirty (30) days written notice may terminate this Agreement.

12.4 Notwithstanding the termination of this Agreement for any reason, the provisions of Articles X, XI and XIII shall remain in effect subject to Paragraph 12.5.

12.5 If the University exercises its rights under Paragraphs 12.2 or 12.3 and validly effects the termination of this Agreement it shall be under no further obligation to grant further licenses to Monsanto and Monsanto shall promptly transfer to the University the prosecution of all pending Patent applications and the maintenance of all Patents not yet licensed to Monsanto and which Monsanto is prosecuting or maintaining hereunder.

ARTICLE XIII - INDEMNIFICATION

13.1 Monsanto agrees to hold harmless, indemnify and defend the University from all liabilities, demands, damages, expenses and losses arising out of use by Monsanto or by any third party acting on behalf of or under authorization from Monsanto, of information or materials received from University or out of any use, sale or other disposition by Monsanto or by any third party acting on behalf of or under authorization from Monsanto of products made by use of information or materials received from University.

13.2 The University warrants that it carries sufficient Worker's Compensation insurance to comply with the laws of Missouri and any other state where any of the work pursuant to this Agreement is performed with respect to the University's personnel. Except as provided under Paragraph 13.3 it is expressly understood and agreed that Monsanto shall not be responsible for or obligated in any manner to reimburse the University or to pay any compensatory, special, exemplary or consequential or other direct or indirect damages in respect of any loss, property damage, personal injuries or loss of life incurred in performance of the research work under this Agreement other than that attributable in whole or in part to Monsanto's fault or negligence, and the University shall defend, indemnify and hold Monsanto harmless (using funds other than those paid to University pursuant to the provisions of Article VIII hereof) from any and all claims, costs or liability for any such loss, damage, injuries or loss of life, other than that attributable in whole or in part to Monsanto's fault or negligence.

13.3 Monsanto agrees to defend, indemnify and hold the University harmless from any and all claims, costs or liability for any loss, damage, injury or loss of life, other than that attributable in whole or in part to the University's fault or negligence, arising as a result of any Monsanto Employee working in the laboratories of the University as provided under Paragraph 6.2.

ARTICLE XIV - TRANSFER OF INTEREST

14.1 Neither this Agreement, nor any of the rights and obligations stated herein or resulting therefrom, may be assigned, transferred or otherwise disposed of by either party without the prior written consent of the other unless such assignment, transfer or disposition is to a successor to all the business of the transferor which pertain to the subject matter of this Agreement, and provided that such successor shall agree in writing with the other party to assume all the obligations of the transferor to the other party.

14.2 Should it become necessary or desirable for the University to subcontract any of the Program research to others, such research shall be performed under a formal subcontract satisfactory to Monsanto by which the subcontractor accepts all appropriate provisions of this Agreement and other such provisions as are necessary.

ARTICLE XV - NOTICE

15.1 Any notice or report required or permitted to be given under provisions of this Agreement shall be in writing and be sent by first class mail or hand delivered:

a) If to Monsanto, to:

G. Edward Paget, M.D.
Director, Health Care Development
Monsanto Company, 02F
800 North Lindbergh Boulevard
St. Louis, Missouri 63167

with a copy to:

Mr. John E. Maurer
General Patent Counsel
Monsanto Company, E2NA
800 North Lindbergh Boulevard
St. Louis, Missouri 63167

b) If to the University, to:

David M. Kipnis, M.D.
Chairman, Department of Medicine
Washington University School of Medicine
660 South Euclid Avenue
St. Louis, Missouri 63110

with a copy to:

Mr. Edward L. MacCordy
Associate Vice Chancellor for Research
Washington University
Lindell & Skinker Boulevards
St. Louis, Missouri 63130

15.2 Either party may change the address or the person(s) designated to receive notice by notifying the other in writing of the change.

ARTICLE XVI - GENERAL PROVISIONS

16.1 Except as provided in Paragraph 9.5, neither party shall use the name of the other party, its affiliated organizations or its personnel in advertising or promotional materials or news or press releases pertaining to the subject matter of this Agreement without prior written consent of such other party.

16.2 This Agreement shall be construed under the laws of the State of Missouri.

16.3 No waiver of any default, condition, provisions or breach of this Agreement shall be deemed to imply or constitute a waiver of any other like default, condition, provision or breach of this Agreement.

16.4 The Article headings used in this Agreement are for convenience only and form no part of the Agreement.

16.5 This writing constitutes the entire Agreement between the parties hereto relating to the subject matter of this Agreement and there are no understandings, representations or warranties of any kind except as expressly provided herein. Neither this Agreement, nor any term or provision thereof, may be discharged, waived, released, abandoned, changed or modified except by an instrument in writing signed by a duly authorized representative of each of the parties to this Agreement. If either party desires a modification or change of any kind in this Agreement, the parties shall, upon reasonable notice of the proposed modification or change by the party desiring the change, confer in good faith to determine the desirability of such modification or change.

16.6 The parties agree that it is the intention of neither party to violate any valid federal, state and local laws and regulations; that if any sentence, paragraph, clause, or combination of the same in this Agreement is in violation of any applicable law or regulation, or is unenforceable or void for any reason whatsoever, such sentence, paragraph, clause or combinations of the same shall be inoperative and the remainder of the Agreement shall remain binding upon the parties.

IN WITNESS WHEREOF, the parties have caused this Agreement to be executed in duplicate by their duly qualified officers.

THIS CONTRACT CONTAINS A BINDING ARBITRATION PROVISION WHICH MAY BE ENFORCED BY THE PARTIES.

WASHINGTON UNIVERSITY

By W^m Danforth
William H. Danforth
Chancellor

Date 6/1/82

MONSANTO COMPANY

By John W. Hanley *JWH*
John W. Hanley
Chairman of the Board

Date 6/3/82