

STATEMENT OF CONSIDERATIONS

REQUEST BY CARGILL DOW LLC FOR AN ADVANCE WAIVER OF
DOMESTIC AND FOREIGN PATENT RIGHTS UNDER DOE
COOPERATIVE AGREEMENT NO. DE-FC36-02ID14349; W(A)-02-052;
CH-1125

The Petitioner, Cargill Dow LLC, has requested a waiver of domestic and foreign patent rights for all subject inventions arising under the above referenced cooperative agreement and subcontracts entered thereunder. The cooperative agreement is entitled "Development of Yeast for the Fermentation of Agricultural Feedstocks to Chemicals." This waiver does not apply to the rights of those parties subject to Public Law 96-517, as amended, nor does it grant any rights in inventions made by employees of National Laboratories.

The objective of the cooperative agreement is to develop a genetically engineered yeast that can metabolize sugars such as xylose into useful chemical products such as lactic acid and ethanol. It is expected that the engineered organism will facilitate the conversion of non-food agricultural products to a variety of chemicals including polylactide, propylene glycol, acrylates, ethylene and ethanol. One approach in achieving the objective will be the use of the yeast/fungal preferred route to improve the existing pathway in the yeast. The other path will be the use of the xylose isomerase route to avoid possible redox problems with the fungal pathway.

Currently, the total approved budget of the cooperative agreement is \$2.3 million, with the Petitioner providing over fifty percent (50%) cost sharing. This waiver is contingent upon the Petitioner maintaining, in aggregate, the above cost sharing percentage over the course of the agreement.

As noted in its waiver petition, Petitioner is investing about \$300 million to construct a facility to convert biomass in the form of corn sugars to polylactide polymers and lactide and holds over 110 US patents covering various aspects of this technology. Also, over the past five years, Petitioner has developed genetically modified yeast that convert sugars such as dextrose to lactic acid and ethanol, at a cost of over \$20 million. All told, Petitioner and its parent organizations, Cargill Inc, and The Dow Chemical Company, have together invested over \$100 million in developing the technology to convert corn starch to polylactide products. Considering Petitioner's technical expertise, established market position, and significant investment in this technology including sizable cost sharing in this cooperative agreement, it is reasonable to conclude that Petitioner will continue to develop and ultimately commercialize the technology and products which may arise from this cooperative agreement.

As set out in the attached waiver petition, Petitioner has also requested a waiver of patent rights in the subject inventions of its lower tier subcontractors, provided that they agree to the same terms and conditions by which Petitioner will be granted the advance waiver. It is believed that this approach will facilitate timely commercialization of the technology by furthering the establishment of business and technical relationships between the parties and providing a mechanism for obtaining meaningful cost sharing between the parties. This waiver contemplates that the parties will allocate title or other rights to inventions among themselves as they deem appropriate during the course of their association and consistent with the terms of this waiver. Accordingly, title will be waived directly to a subcontractor upon mutual agreement of the Petitioner and the subcontractor. However, this waiver will only apply to such subcontractor(s) who provide a letter to DOE acknowledging their right to ask for a waiver and agreeing to the terms of this waiver.

At present the Petitioner has identified one subcontractor, VTT Biotechnology, a Finnish company. VTT is unrelated to Petitioner and will perform certain genetic engineering work in support of this cooperative agreement.

Petitioner has agreed that this waiver shall be subject to the march-in and preference for U.S. industry provisions, as well as the U.S. Government license, comparable to those set out in 35 U.S.C. 202-204. Further, Petitioner has agreed to the U.S. competitiveness provisions as attached to this Statement. In brief, Petitioner has agreed that products embodying intellectual property developed under this agreement shall be substantially manufactured in the United States, and that Petitioner will not license, assign or otherwise transfer any waived invention to any entity unless that entity agrees to these same requirements. Additionally, Petitioner has agreed to contractor data licensing provisions as attached herein.

Referring to item 10 of the waiver petition, granting this waiver is not anticipated to have any adverse impact on competition. The chemical products of interest, such as lactic acid and ethanol, in this cooperative agreement are already being produced by other suppliers in both the US and the world. There are various fermentation processes and methods using petroleum feedstocks for producing these chemical products. The success of this cooperative agreement may provide a cost advantage to Petitioner in some areas, but is not expected to place Petitioner in a dominant position in the field.

Considering the foregoing, it is believed that granting this waiver will provide Petitioner with the necessary incentive to invest its resources in the commercialization of the results of the cooperative agreement in a fashion which will make the above technology available to the public in the shortest practicable time. Therefore, upon evaluation of the waiver petition and in view of the objectives and considerations set

forth in 10 CFR 784, all of which have been considered, it is recommended that the requested waiver be granted.



Daniel D. Park
Assistant Chief Counsel
Office of Intellectual Property Law

Date: 6/30/03

Based upon the foregoing Statement of Considerations and representations in the attached waiver petition, it is determined that the interests of the United States and the general public will best be served by a waiver of patent rights of the scope described above, and therefore the waiver is granted. This waiver shall not apply to any modification or extension of the cooperative agreement, where through such modification or extension, the purpose, scope or cost of the cooperative agreement has been substantially altered.

CONCURRENCE:



Douglas Kaempt
Douglas Kaempt
Office of the Biomass Program
EE-2E

APPROVAL:



for Paul A. Gottlieb
Paul A. Gottlieb
Assistant General Counsel
for Technology Transfer and
Intellectual Property

Date: 8/12/2003

Date: 8/12/2003

WAIVER ACTION - ABSTRACT
W(A)-02-052

REQUESTOR

Cargill Dow LLC

CONTRACT SCOPE OF
WORK

Development of yeast for the
fermentation of agricultural
feedstocks to chemical
products

RATIONALE FOR DECISION

50% cost sharing

(t) U. S. Competitiveness

The Contractor agrees that any products embodying any waived invention or produced through the use of any waived invention will be manufactured substantially in the United States unless the Contractor can show to the satisfaction of the DOE that it is not commercially feasible to do so. In the event the DOE agrees to foreign manufacture, there will be a requirement that the Government's support of the technology be recognized in some appropriate manner, e.g., recoupment of the Government's investment, etc. The Contractor agrees that it will not license, assign or otherwise transfer any waived invention to any entity unless that entity agrees to these same requirements. Should the Contractor or other such entity receiving rights in the invention undergo a change in ownership amounting to a controlling interest, then the waiver, assignment, license, or other transfer of rights in the waived invention is suspended until approved in writing by the DOE.

Rights in Data - General (JUN 1987), is amended by adding paragraph (k) as follows:

(k) Contractor Licensing. Except as may be otherwise specified in this contract as data not subject to this paragraph, the contractor agrees that upon written application by DOE, it will grant to the Government and responsible third parties, for purposes of practicing a subject of this contract, a nonexclusive license in any limited rights data or restricted rights software on terms and conditions reasonable under the circumstances including appropriate provisions for confidentiality; provided, however, the contractor shall not be obliged to license any such data if the contractor demonstrates to the satisfaction of the Secretary of Energy or designee that:

(1) Such data are not essential to the manufacture or practice of hardware designed or fabricated, or processes developed, under this contract;

(2) Such data, in the form of results obtained by their use, have a commercially competitive alternate available or readily introducible from one or more other sources;

(3) Such data, in the form of results obtained by their use, are being supplied by the contractor or its licensees in sufficient quantity and at reasonable prices to satisfy market needs, or the contractor or its licensees have taken effective steps or within a reasonable time are expected to take effective steps to so supply such data in the form of results obtained by their use; or

(4) Such data, in the form of results obtained by their use, can be furnished by another firm skilled in the art of manufacturing items or performing processes of the same general type and character necessary to achieve the contract results.