STATEMENT OF CONSIDERATIONS

REQUEST BY NOVOZYMES BIOTECH, INC. (NOVOZYMES) FOR AN ADVANCED WAIVER OF DOMESTIC AND FOREIGN PATENT RIGHTS UNDER SUBCONTRACT NO. NREL-ZCO-1-30017-02 UNDER CONTRACT NO. DE-AC36-99GO10337, CH-1061, W(A)-01-008

The Petitioner, Novozymes Biotech, Inc. (Novozymes), has requested a waiver of domestic and foreign patent rights for all subject inventions under DOE Subcontract No. NREL-ZCO-1-30017-02, entitled, "Cellulase Cost Reduction for Bioethanol", which is governed by NREL Prime Contract NO. DE-AC36-99GO10337. This subcontract pertains to the development of an economical process for the conversion of low-value biomass to sugars and ethanol utilizing a cellulase enzyme.

The objectives of this subcontract are to locate a cellulase having novel saccharifying cellulolytic activity through protein engineering of the cellulase enzyme, such that cost of bioethanol produced will be in the range fo 5-10 cents per gallon, and to develop the overall production technology for the novel cellulase. Specifically, this subcontract is directed to the development and implementation of a technical plan that defines the sequence of activities and metrics required to achieve a ten-fold improvement in cellulase enzyme cost. The initial plan and implementation thereof may be modified upon review of the project results at the completion of each phase of the subcontract.

It is anticipated that this subcontract will be performed in three phases over a period of approximately three years. Phase I of the subcontract runs from December 19, 2000 to an anticipated completion date of September 18, 2001, at a cost of $6,891,387.00, of which the Petitioner's cost share is $1,378,277.00 or an approximate 20%-cost share. The total overall value of the subcontract is projected at $14,781,651.00, with participation by Novozymes to be $2,956,330.00, or approximately 20%-cost share. It is contemplated that Novozymes will complete all three phases contingent upon approval of the contracting officer. Further, it is anticipated that this waiver will be applicable over all three phases of the subcontract, provided that the Petitioner maintains, in aggregate, substantially the same cost sharing percentage over the course of the subcontract (i.e., 20%).

The Petitioner is clearly competent in the field of technology relating to this agreement as demonstrated in the Petitioner's response to questions 5 and 6 in the attached copy of its waiver petition. As noted in its waiver petition, Petitioner, as a wholly owned research and development subsidiary of Novozymes A/S, is the world's largest producer of industrial enzymes. Novozymes A/S had annual sales of more than $600,000,000.00 of formulated enzyme products in 1999. In the United States, Novozymes employs approximately 30 scientists in the field of molecular biology, protein chemistry, chemical engineering, and microbial physiology. Novozymes' business is focused on identifying and engineering new industrial enzymes for application to industrial processes. Exemplary of Novozymes technical expertise is a list of more than 100 US patents and access to more than 4,000 proprietary enzyme-related inventions that are patented or where patent applications have been filed. A list of the US patents is included at the end of Novozymes' petition.

Novozymes through its parent Novozymes A/S is the world's leader in technical enzyme production, with a 44%market share. Total annual sales of cellulase-containing products surpass 1000 tons, comprising a range of products from a number of different source organisms (*Humicola, Trichoderma, and Aspergillus*) having a wide range of applications (textiles, detergents, food and feed). Novozymes A/S's worldwide fermentation capacity is measured in thousands of cubic meters, with a significant portion of that capacity located at its U.S. production facility located in Franklinton, North Carolina. Additional production capacity, which includes laboratory-scale, pilot plant, and full scale manufacturing facilities are located at the company headquarters in Bagværd, Denmark, and facilities in Kalundborg, Denmark, Davis, California, as well as their North Carolina facility. At this time no known sales are made to the U.S. Government.

Considering the Petitioner's technical expertise, established market position, and significant investment in this technology, including substantial cost sharing under this agreement, it is reasonable to conclude that the Petitioner will develop and ultimately commercialize the technology arising from this agreement.

This advance waiver of the Government's rights in inventions is subject to the usual advanced patent waiver and background data licensing provisions. The terms of the advanced patent waiver include the usual Government license, march-in rights, and preference for U.S. industry provisions set out in 35 U.S.C. 202-204. The advance patent waiver also includes the attached U.S. Competitiveness clause (paragraph t) which requires products embodying any waived invention or produced through the use of any waived invention be manufactured substantially in the United States unless the participant can show to the satisfaction of DOE that it is not commercially feasible to do so. The Petitioner further agrees to make the above condition binding on any assignee or licensee or any entity otherwise acquiring rights to any waived invention, including subsequent assignees or licensees. Should the Contractor or other such entity receiving rights in any waived 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 DOE.

The grant of this waiver is not expected to result in adverse effects on competition or market concentration, as the novel cellulase enzyme, identified as the goal of this subcontract, is not produced commercially at this time. Rather the waiver will create a new process, which should in time enhance competition and growth of the technology in the United States. DOE has the right to require reports of the utilization or the efforts at utilization that are being made for the waived inventions. If a participant which has obtained title is not making reasonable efforts to utilize a waived invention, DOE can exercise its march-in rights and require licensing of the background inventions and data.

Considering the foregoing, and in view of the statutory objectives to be obtained and the factors to be considered under DOE's statutory waiver policy, all of which has been considered, it has been determined that this waiver as set forth above will best serve the interest of the

United States and the general public. It is recommended that the waiver be granted, providing Novozymes maintains at least 20 percent cost sharing, in aggregate, over this and subsequent phases of this agreement.

[redacted]

Thomas G. Anderson
Assistant Chief Counsel
Office of Intellectual Property Law

Date: 8/2/01

[redacted]

Mark F. LaMarre
Patent Attorney
Office of Intellectual Property Law

Date: August 2, 2001

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 will not apply to any modification or extension of the contract, where through such modification or extension, the purpose, scope or cost of the contract has been substantially altered.

CONCURRENCE:

[redacted]

John Ferrell, Director
Office of Fuel Development,
EE-31

Date: 8/30/01

APPROVAL:

[redacted]

Paul A. Gottlieb
Assistant General Counsel for Technology
Transfer and Intellectual Property, GC-62

Date: 8-31-01

U.S. COMPETITIVENESS CLAUSE

(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.

WAIVER ACTION - ABSTRACT
W(A)-01-008

REQUESTOR	COOPERATIVE AGREEMENT SCOPE OF WORK	RATIONALE FOR DECISION
Novozymes Biotech, Inc.	Identify a cellulase having novel saccharifying cellulolytic activity through protein engineering of the cellulase enzyme, such that cost of bioethanol produced will be in the range fo 5-10 cents per gallon, and to develop the overall production technology for the novel cellulase. .	Significant experience in the production of modified cellulase enzymes - 20% cost sharing.