

STATEMENT OF CONSIDERATIONS

PETITION FOR ADVANCE WAIVER OF PATENT RIGHTS BY DANISCO US, INC. ("DANISCO") UNDER AGREEMENT NO. DE-FG36-08GO18078 BETWEEN DANISCO AND DOE; W(A)-08-045; CH-1464

The Petitioner, DANISCO, has requested a waiver of domestic and certain foreign patent rights for all subject inventions that may be conceived or first actually reduced to practice under the above-identified agreement, and subcontracts thereof. The agreement is entitled "DEVELOPMENT OF COMMERCIAL ENZYMES SYSTEM FOR LIGNOCELLULOSIC BIOMASS SACCHARIFICATION." This waiver shall not impact the rights of those parties subject to Public Law 96-517, as amended, nor shall it grant any rights in inventions made by employees of the National Laboratories.

The object of the current project is to address one of the key technical barriers "Bt-G: Cellulose Enzymes Loading," with the project goal of lowering the ratio of enzymes to substrate by creating more efficient enzymes. Petitioner's approach will focus on the limitations or constraints on enzyme performance during saccharification and to improve the relevant properties of the appropriate enzymes of the cellulase mix to overcome those limitations. The end goal is to create a cocktail of enzymes optimized for efficient and cost-effective saccharification performance in real-world conditions.

The total cost of the sub-award is approximately \$22 million with the Petitioner and its subcontractors providing about 60% 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 has been investing and developing protein engineering tools for over 25 years and has applied these tools in the development of enzymes for over 10 years. Petitioner is considered a world leader in the development of enzyme technologies and in 2007 its Genencor Division launched the first commercially available biomass enzyme developed specifically for second generation biorefineries. DANISCO also invests significant amounts of its profits each year into research and development.

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 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.

Considering Petitioner's technical expertise and significant investment in this technology, including sizable cost sharing in this agreement, it is reasonable to conclude that Petitioner will continue to develop and ultimately commercialize the technology and products which may arise from this 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 attached U.S. Competitiveness provision paragraph (t). In brief, the Petitioner has agreed that any commercial product embodying any waived invention used in the processing of feedstock grown in the United States (U.S.) will be manufactured substantially in the United States unless the Petitioner can show to the satisfaction of the DOE that it is not commercially feasible to do so as described in detail in the attached U.S. Competitiveness provision, paragraph (t). Although Petitioner has agreed to domestic manufacturing provisions for commercial products embodying any waived invention used in the processing of feedstock grown in the United States, it is also important that Petitioner have the ability to locally or regionally manufacture enzymes that will be used to process feedstock originating outside of the U.S. due to the high cost of transporting large volumes of enzymes overseas. The ability of Petitioner to implement in the U.S. plants embodying any waived inventions will be accelerated if it has the ability to use the waived inventions for the development of plants overseas.

Referring to item 10 of the waiver petition, granting this waiver is not anticipated to have any adverse impact on competition. There are already numerous established enzyme manufacturers with relevant intellectual property in the area of cellulosic ethanol production.

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 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.

/Brian J. Lally/
Brian J. Lally
Assistant Chief Counsel
Intellectual Property Law Division
DOE Chicago Office

Date: August 11, 2009

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 agreement, where through such modification or extension, the purpose, scope or cost of the agreement has been substantially altered.

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| <p>CONCURRENCE:</p> <p></p> <p>Valri Anne Lightner Acting Program Manager Office of Biomass Program EE-2E</p> <p>Date: <u>12-4-09</u></p> | <p>APPROVAL:</p> <p></p> <p>Paul A. Gottlieb Assistant General Counsel for Technology Transfer and Intellectual Property</p> <p>Date: <u>12-7-09</u></p> |
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WAIVER ACTION - ABSTRACT
W(A)-08-045

REQUESTOR
DANISCO

CONTRACT SCOPE
The goal is to create a cocktail of enzymes optimized for efficient and cost-effective saccharification performance in real-world conditions.

RATIONALE FOR DECISION
60% Cost Sharing

(t) U.S. Competitiveness

The Petitioner agrees that any commercial product embodying any waived invention used in the processing of feedstock grown in the United States (U.S.) will be manufactured substantially in the United States unless the Petitioner can show to the satisfaction of the DOE that it is not commercially feasible to do so. DOE agrees that Petitioner has an expanding presence in the U.S., and that it is committed to carrying out business in the U.S. The Petitioner agrees that it, or a licensee, sub-licensee or assignee of rights to waived inventions, will make commercially reasonable attempts to commercialize the technology embodying the waived inventions in the United States within a commercially reasonable timeframe, unless the Petitioner can show to the satisfaction of the DOE that it is not commercially feasible to do so. Notwithstanding the foregoing, if a commercial product comprises more than one enzyme, Petitioner's agreement as set forth herein to manufacture in the U. S. will be met if the subset of enzyme(s) embodying any waived inventions are manufactured substantially in the United States unless the Petitioner can show to the satisfaction of the DOE that it is not commercially feasible to do so. The ability of Petitioner to commercialize products embodying waived inventions for utilization in U.S. plants will be accelerated if it has the ability to use the waived inventions for the development of plants overseas. The Petitioner and any licensee, sub-licensee or assignee thereof, agrees that it will not license, sub-license, assign or otherwise transfer any waived invention to any entity unless that entity agrees to these same requirements. Should the Petitioner 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.