Final Report Certification
for
CRADA Number ORNL-03-0671

Between

UT-Battelle, LLC

and

Protein Discovery

(Participant)

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PW
8-13-07

Instructions:

Mark the appropriate statement in 1a or 1b below with an 'X.' Refer to the articles in the CRADA terms and conditions governing the identification and marking of Protected CRADA Information (PCI).

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2. The final report does not contain Proprietary Information.

3. By the signature below, the Participant has no objection to the public distribution of the final report due to patentable information.

For the Participant:

(Name)
President
(Title)
7/31/2007
(Date)

CRADA Final Report ORNL—03-0671

Molecular Comb

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No protected CRADA information

July 17, 2007

Abstract

This CRADA was developed to enable ORNL to assist Protein Discovery, Inc. to develop a novel biomolecular separation system based on an ORNL patent application "Photo-electrochemical Molecular Comb" by Thundat, Ferrell, and Brown. The Molecular Comb concept is based on creating light-induced charge carriers at a semiconductor-liquid interface, which is kept at a potential control such that a depletion layer is formed in the semiconductor. Focusing light from a low-power illumination source creates electron-hole pairs, which get separated in the depletion layer. The light-induced charge carriers reaching the surface attract oppositely charged biomolecules present in the solution. The solution is a buffer solution with very small concentrations of biomolecules. As the focused light is moved across the surface of the semiconductor-liquid interface, the accumulated biomolecules follow the light beam. A thin layer of gel or other similar material on the surface of the semiconductor can act as a sieving medium for separating the biomolecules according to their sizes.

Statement of Objectives

The objective of the CRADA was to demonstrate a chip-based, miniature biomolecular separation device that uses low voltage. Unlike gel electrophoresis system, which is bulky and uses high voltages, the Molecular Comb device uses low voltages (4-5 V). Protein Discovery, Inc. licensed the Molecular Comb technology from ORNL. Protein Discovery is a life sciences company headquartered in Knoxville, TN and develops, manufactures, and sells sample preparation solutions for clinical mass spectrometry. The objective of the CRADA was to demonstrate and develop a system using the Molecular Comb technology. Protein Discovery, Inc. obtained both private and public (SBIR) funds to initiate this CRADA. All related experiments and developments were carried out at ORNL under this CRADA.

Under this CRADA, ORNL trained five Protein Discovery scientists such that they were authorized to perform experiments at ORNL. Protein Discovery, Inc. is now located in their own labs in downtown Knoxville.

Benefits to the Funding DOE Offices' Mission

DOE is pursuing Nano technological ideas for biotechnology and environmental monitoring and remediation. The Molecular Comb technology will be ideal for concentrating extremely small concentrations of analyses in ground water. The technology, therefore, can also be used for environmental research. The Molecular Comb technology once developed may be able to replace gel electrophoresis systems for selected applications.

Technical Discussion of work performed by all parties

Protein Discovery, Inc. was responsible for

1. Acquiring the license from ORNL
2. Developing and building a prototype device

3. Supplying the primary human and capital resources to demonstrate feasibility of the technology

ORNL was responsible for

1. Helping to design the prototype
2. Helping with lab work for demonstration
3. Helping to take data
4. Providing scientific and technical assistance for instrument development
5. Interpreting data

Protein Discovery-ORNL team has written a seminal paper on this technology that appeared in the *Proceedings of the National Academy of Sciences (PNAS)* in April 2006.

The above tasks were accomplished during the course of this CRADA (Feb. 19, 200_ - Feb. 4, 2007.)

Commercialization possibilities

Feasibility of the system was demonstrated for separation of biomolecules for subsequent analysis via mass spectrometry, which was the application for which Protein Discovery obtained its license. However, Protein Discovery has since terminated its license to the Molecular Comb technology, as it has developed an alternative system more appropriate for its commercial target application. However, with feasibility demonstrated, a working prototype developed, and a seminal publication in a leading scientific journal, the technology should be ripe for commercialization in an appropriate application (e.g. environmental testing, etc.).

Plans for future Collaboration

Plans for future collaborations with Protein Discovery are currently on hold.

Conclusions

The study achieved its interim goals. ORNL met its commitment to the project. The potential of the Molecular Comb technology for concentrating and separating analytes has been demonstrated under this CRADA.