

STATEMENT OF CONSIDERATIONS

REQUEST BY MOTOROLA MANUFACTURING SYSTEMS FOR AN ADVANCE WAIVER OF DOMESTIC AND FOREIGN PATENT RIGHTS UNDER LBNL SUBCONTRACT NO. 6443828; DOE WAIVER NO. W(A)-96-027; SAN-670

The Petitioner, Motorola Manufacturing Systems (MMS), has requested an Advance Waiver of the Government's domestic and foreign rights to inventions made under the above cited research and development contract (R&D Contract).

The objective of the R&D Contract, which is issued by the Lawrence Berkeley National Laboratory (LBNL) on behalf of DOE's Office of Health and Environmental Research (ER-70), is to provide consulting services to support planning activities toward the eventual creation of a next generation DNA sequencing facility. More specifically, the R&D Contract will prepare technical roadmaps to improve the directed sequencing process. These roadmaps will identify needed systems, technologies, and methods, such as production scheduling, automation, Computer Integrated Manufacture (CIM), quality control, materials inventory management and staffing that are necessary over the period of the facility funding plan. Models will be completed for the future process and for operational costs. Alternative layouts will be developed which describe how the operation will be organized. An extensive analysis will be conducted to determine the best plan and estimates will be made of facility and operational costs.

The programmatic requirements of LBNL for this R&D Contract suggest a very narrow field of vendors who could provide the proposed service. As noted in the Sole Source Justification Memorandum prepared for this LBNL procurement, there are no organizations or facilities in the field of genomics that approach the scale of the anticipated ramp up required by the DOE sequencing effort. See Exhibit A, section D. Industrial partners that LBNL could select are segmented in the following narrow fields: the pharmaceutical industry; the biotechnology industry; the diagnostic industry; the equipment suppliers; informatics companies; genomics companies; microfabrication companies; and manufacturing companies. See Exhibit A, section C. LBNL has discussed the possibility of performing the type of work proposed in this R&D Contract with many of the companies actively working in these fields. See Exhibit A, section C. However, most of these companies fail to have the combination of an established manufacturing facility and requisite manufacturing knowledge that would be appropriate for completing this contract. See Exhibit A, section C, fifth paragraph. In fact, several companies that are operating a high-throughput manufacturing facility consider this combination of skills to be proprietary and do not offer this knowledge to others on a commercial basis. The personnel of the Human Genome Center (HGC) at LBNL consulted with a broad variety of their colleagues, who all agreed that Motorola was the logical and sole source to complete this Contract. See Exhibit A, Section C, fifth paragraph.

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Motorola, Inc. (Motorola) is a manufacturer of telecommunications products and semiconductors and has expertise in manufacturing and manufacturing-related technologies. Motorola has a manufacturing facility in Illinois that uses robotics and process engineering techniques that would be directly applicable to expanding the existing sequencing effort of HGC at LBNL. See Exhibit A, section D. Thus, Motorola has significant hands-on experience in operating and staffing manufacturing operations in an industry that has similar technical requirements in regard to throughput and cost control. Over the past five years, Motorola has invested over \$100 million in developing and maintaining a staff of manufacturing experts which can be accessed for work on this project. See Exhibit C, statement 10. The inherent difficulties of high throughput have been solved by using robotics as related to the manipulation of small sub-assemblies and workstations for manufacturing personnel. The in-line use of CIM, which Motorola uses in its own manufacturing facility, is a key growth area of the HGC production process. See Exhibit A, section D. In addition, Motorola uses sophisticated process modeling software to plan the start-up and expansion of existing manufacturing lines. The model is important to prevent the waste of time and money in the construction of facilities that do not maximize throughput and minimize costs. See Exhibit A, section D. The rigorous evaluation of process bottlenecks is the driving force behind improving operations. See Exhibit A, section D. Motorola's expertise in world class manufacturing techniques, specifically the creation and management of project teams oriented around continual improvement of the manufacturing process, is necessary to complete this R&D Contract.

To achieve a close working relationship with other Motorola divisions, MMS has proposed a project team approach to carry out this R&D Contract. MMS, which is a corporate staff department of Motorola, proposes to use its team of engineers and consultants to confer with other divisions of Motorola in order to assist with development of software, automation, materials management, and facilities projects. Exhibit C, statement 7. The proposed fixed price lump-sum contract should last 16 weeks at a cost of \$250,000 and would not necessitate MMS to track costs or bill hours to reimbursable accounts. Thus, if a novel and patentable process were developed during this R&D Contract, it would be difficult for Motorola to substantiate which project team activity conceived of the novel process. Therefore, this Advance Waiver will protect Motorola's interest by permitting retention of title to their Subject Inventions without creating the necessity for establishing a direct link between the development of the novel process and the funding source under this R&D Contract. Without this Advance Waiver, MMS will be hindered in discussing and conferring with other divisions of Motorola without the guarantee that title to any Subject Invention that Motorola may conceive or

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reduce to practice is retained by Motorola. In fact, Motorola has stated that it will not enter into this contract without an advance right to them retain title to and practice inventions conceived by its employees. See Exhibit C, statement 5.

It should also be mentioned that the Patent Rights clause negotiated with MMS does not include either a Background Patents or a U.S. Competitiveness provision. Due to the short term (16 weeks) nature of this contract, which involves only a preliminary evaluation of the proposed plant and facilities requirements, such provisions were not deemed necessary. The assessment to be prepared by MMS under the current contract will not involve the detailed design for a building nor is its purpose to develop commercializable products or processes. Requiring that any waived inventions be manufactured substantially in the United States may make Motorola less competitive given that they already have manufacturing operations in several foreign countries that are believed to be essential for access to overseas markets which comprises more than half of their sales revenue. Finally, omission of the Background Patent provision is in accordance with regulation 48 CFR 927.302 (Policy) which state that such provision "should normally be deleted for contracts with an estimated cost and fee or price of \$250,000 or less and may not be appropriate for certain types of study contracts (or) for planning contracts".

LBNL, by way of Exhibit B (HGC letter Re: Motorola Subcontract), is in support of this patent waiver grant. After this initial Contract is completed and the Funding Plan is submitted to LBNL, Motorola may be included in future follow-on contracts over the next few years to assist in further development of a Joint Genomics Institute, which will involve the participation of Lawrence Livermore and Los Alamos National Laboratories. However, this Advance Waiver and the terms of the intellectual property clauses included within the subject R&D Contract are meant to cover the scope of the work under this particular project and shall not serve as precedent for any follow-on work to be negotiated separately by the Parties in the future.

For the foregoing reasons, and in view of the objectives and considerations set forth in 41 CFR 9-9.109-6, all of which have been considered, it is recommended that the requested waiver be granted for this R&D Contract.



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Based on the foregoing Statement of Considerations, it is determined that the interests of the United States and the general public will best be served by waiver of the United States and foreign patent rights as set forth herein, and therefore, the waiver is granted. This waiver shall not apply to a modification or extension of the contract where, through such modification or extension, the purpose, scope or DOE cost of the contract has been substantially altered. This waiver shall not affect any waiver previously granted.

CONCURRENCE:



Ari Patrinos
Associate Director for
Health and Environmental Research

Date: 12/30/96

APPROVED:



Paul Gottlieb, Assistant General Counsel
for Technology Transfer and Intellectual Property

Date: 12-30-96