## STATEMENT OF CONSIDERATIONS

REQUEST BY MOTOROLA MANUFACTURING SYSTEMS FOR AN ADVANCE WAIVER OF DOMESTIC AND FOREIGN PATENT RIGHTS UNDER LBNL SUBCONTRACT NO. 6443828-CHAMGE ORDER NO. 3; DOE WAIVER NO. W(A)-97-012; SAN-672

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 Change Order (Third Contract Modification) to Lawrence Berkeley National Laboratory's (LBNL) research and development Contract No. 6443828 (R&D Contract). The objective of the R&D Contract, which was issued 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 required the preparation of technical roadmaps, i.e., for automation, scheduling, quality control, materials inventory management, etc., to improve the directed sequencing process. An Advance Waiver W(A)-96-027; SAN-670 was initially granted for the underlying R&D Contract on December 30, 1996. However, that Advance Waiver was not to be applied "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." Therefore, MMS must petition DOE for another Advance Waiver each time this R&D Contract is modified.

The first extension (Change Order No. 1) of the R&D Contract was a no-cost, two-week extension, which did not require another Advance Waiver determination. However, on April 22, 1997, an Advance Waiver W(A)-97-006; SAN-671 was granted for the second extension (Change Order No. 2) of the R&D Contract. This Second Contract Modification extended the R&D Contract until July 15, 1997 with an increase cost of \$249,500. At the completion of the Second Contract Modification, MMS will deliver a Ramp Plan report that details the acceleration of activity through 1998 and provides a corresponding process analysis. MMS will deliver a Process Control Procedures report that documents process control procedures for critical processes and analysis of material handling needs. MMS will deliver a Quality Awareness and Training Plan for all LBNL Human Genome Center employees. MMS will deliver an Automation Sourcing Strategy and Procedures report. Lastly, MMS will deliver a Work-In Progress (WIP) Tracking Requirements Specification report documenting the requirements specification for a WIP tracking system.

LBNL proposes this Third Contract Modification to extend the R&D Contract until October 7, 1997 with an increase cost of \$250,000. MMS will perform several activities during the performance of the Third Contract Modification. MMS will create user requirements for a materials management system through quality awareness and training of materials management methods. MMS will make an

assessment of critical points in the process and determine proper defect tracking methodology by creating a plan for tracking defects, which will be documented in a Defect Tracking Plan report. For the MMS process control procedures for critical production processes developed in the Second Contract Modification, MMS will now demonstrate a Design of Experiments methodology on a given critical process. MMS will form plans for computer systems disaster recovery, which will be documented in a System Disaster Recovery Plan. In the Second Contract Modification, MMS created the requirement specifications for WIP tracking system. In this Third Contract Modification, MMS will survey applicable WIP tracking software and deliver a WIP Tracking Software Survey report to LBNL. See Exhibit A, the Petition, Statement 2.

As discussed in the previous collateral DOE Waiver No. W(A)-96-027, the programmatic requirements of LBNL for the R&D Contract suggest a very narrow field of vendors who could provide the proposed service. As noted in the Sole Source Justification Memorandum, which was attached to DOE Waiver No. W(A)-96-027, there are no organizations or facilities in the field of genomics that approach the scale of the anticipated ramp up required by the LBNL sequencing effort. In fact, most companies fail to have the combination of an established manufacturing facility and requisite industrial engineering knowledge that would be appropriate for completing this contact. Because Motorola has adequately performed the work in the R&D Contract and the Second Contract Modification, LBNL believes that Motorola is the logical and sole source to complete this Third Contract Modification.

Motorola, Inc. (Motorola) is a manufacturer of telecommunications products and semiconductors and has expertise in manufacturing and manufacturing-related technologies. Motorola will continue to apply its previously acquired knowledge and expertise in manufacturing products for its markets to this subcontract. 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 A, Statement 10. As discussed in DOE Waiver No. W(A)-97-027, Motorola's expertise in world class manufacturing techniques, specifically the creation and management of project teams oriented around continual improvement of the manufacturing process, was necessary to complete the initial R&D Contract and will be instrumental in completing the Third Contract Modification. In addition, it is expected that the relationship with Motorola will play a key role in facilitating the collaboration between LBNL, Lawrence Livermore National Laboratory (LLNL) and Los Alamos National Laboratory (LANL) as it establishes the DOE Joint Genome Institute. See Exhibit A, Statement 4.

To achieve a close working relationship with other Motorola divisions, MMS will continue to use a project team approach to carry out this Third Contract Modification. MMS, which is a corporate staff department of Motorola, uses 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. See Exhibit A, statement 7. The proposed fixed price lumpsum extension of the current contract will last another 12 weeks at a cost of \$250,000. In accordance with established accounting practices, MMS is not being required to track costs or bill hours directly to reimbursable accounts for this project. Thus, if a novel and patentable process were developed during this Third Contract Modification, 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 Third Contract Modification. Without this Advance Waiver, MMS will be hindered in discussing and conferring with other divisions of Motorcla without the guarantee that title to any Subject Invention that Motorola may conceive or 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 retain title to and practice inventions conceived by its employees. See Exhibit A, statement 5. It should be noted, however, that LBNL has verified that no inventions were developed during the performance of the either initial R&D Contract or the First Contract Modification. Furthermore, LBNL confirmed that no inventions have been developed during the performance of the Second Contract Modification.

It should also be mentioned that the Patent Rights clause negotiated with MMS did not include a Background Patents provision and that the Rights In Data clause did not include a Contractor Licensing provision. Omission of the Background Patent provision is in accordance with regulation 48 CFR 927.302 (Policy) which state that such provision "...may not be appropriate for certain types of study contracts (or) for planning contracts". Similarly, the Contractor Licensing provision was omitted because no proprietary information was identified by MMS as being utilized in performance of the contract. However, if the data provided to LBNL under the R&D Contract requires the use of MMS's proprietary data or background patents, then LBNL will need to license this technology from MMS. While the process and systems assessment to be prepared by MMS under the proposed Third Contract Modification is not likely to involve MMS's proprietary data or background patents, MMS has agreed to bring this to the Government's attention in advance should such material be necessary to incorporate. In addition, LBNL does not believe that any commercializable products or processes will be developed during this Third

Contract Modification. Thus, the U.S. Competitiveness provision, which requires that any waived inventions be manufactured substantially in the United States, was removed from the Patent Rights clause because it may make Motorola less competitive worldwide 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.

LBNL supports granting this advance patent waiver to MMS. After the R&D Contract and each modification is completed, 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 and subsequent contract modifications 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 Third Contract Modification.

Date: 6/30/97

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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 another 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:

Date:

Health Effects and Life Sciences Research Division
Office of Health and Environmental Research

APPROVED:

Paul Gottlieb, Assistant General Counsel

for Technology Transfer and Intellectual Property