

STATEMENT OF CONSIDERATIONS

CLASS WAIVER OF THE GOVERNMENT'S DOMESTIC AND FOREIGN PATENT RIGHTS AT SLAC NATIONAL ACCELERATOR LABORATORY'S CRYO-EM CENTER: DOE WAIVER NO. W(C)2020-004.

This Class Waiver is intended to provide for the disposition of intellectual property rights and to promote uniformity for public and private organizations (hereinafter “users”) that are using the National Center for Cryo-Electron Microscopy (Cryo-EM Center) at SLAC National Accelerator Laboratory (“SLAC”) on a non-proprietary basis. The users covered by this Class Waiver are not receiving any funds from SLAC and are not paying full cost recovery to cover SLAC’s costs for the use of the Cryo-EM Center. However, users may enter into other technology transfer agreements, for example a Strategic Partnership Program (SPP) Agreement or Cooperative Research and Development Agreement (CRADA), which require full cost recovery for the use of equipment and machines if additional research beyond the allocated time is needed, which are not covered by this waiver.

Funding of the Cryo-EM Center

The Cryo-EM Center will meet the emerging national need for cryo-electron microscopy as a tool for atomic-resolution structural biology. The National Institute of Health (NIH) will fund the Center for the purpose to: (1) establish and keep at the forefront, state-of-the-art cryo-electron microscopes to satisfy users’ needs for atomic-resolution image data, (2) archive image data with appropriate metadata, (3) provide computing resources to assess data quality in real time, (4) inform and recruit potential users across the U.S. about the public accessibility of the Cryo-EM Center, (5) establish an open, fair, transparent and efficient process to select user proposals based on scientific impact and specimen readiness, regardless of users’ geographic locations or affiliations, (6) help users to overcome technical hurdles and enable them to obtain high-resolution Cryo-EM structures quickly with a rigorous validation protocol, (7) form and facilitate a user network to exchange information seamlessly, (8) train users to become independent Cryo-EM investigators, (9) integrate user and trainee feedback into a continuous loop of facility enhancement, and (10) optimize operations to achieve the above tasks effectively and efficiently.

Cryo-electron microscopy represents an emerging key scientific tool in the field of structural biology. This Cryo-EM Center will enable external users to collect image data for atomic resolution structure determination on systems of importance to human health, and for problems of relevance to other areas of national strategic importance like sustainable energy. The Cryo-EM Center will offer a comprehensive program to train and cross-train scientists to become independent Cryo-EM investigators, regardless of their institutional affiliations.

Statutory Authority

Agreements that are the subject of this waiver do not take the form of a research contract, cooperative agreement, or grant as these terms are used in the Federal Grant and Cooperative Agreement Act of 1977 (31 U.S.C. §§ 6303-05) and implementing guidance by OMB and OFPP.

Therefore, the requirements of DOE's regulations covering contracts, cooperative agreements and grants are not applicable. Since the Government is funding the access and use of the Cryo-EM Center, these Agreements do not fall within the definition of "funding agreement" of 35 U.S.C. §200 *et seq.* (commonly referred to as the Bayh-Dole Act), and the patent policy set forth therein as applicable to small businesses and nonprofit organizations does not apply. For the same reason, the Presidential Memorandum on Government Patent Policy of February 18, 1983 and Executive Order No. 12591 of April 10, 1987, which made the policies of Bayh-Dole applicable to all other organizations to the extent permitted by law, do not apply. Although not falling within the normal concept of R&D acquisition or assistance for the user, these agreements nevertheless fall within the broad definition of "...contract, grant, agreement, understanding, or other arrangement, which includes research..." of section 9 of DOE's Federal Nonnuclear Energy Research and Development Act of 1974 (Nonnuclear Act) and the concept of "...any contract, subcontract, or arrangement entered into with ...(DOE) ..., regardless of whether the contract, subcontract or arrangement involved the expenditure of funds by the ... [DOE] ..." of Section 152 of the Atomic Energy Act of 1956, as amended (Atomic Energy Act). As a result of this broad statutory language, agreements that fall outside of normal R&D acquisition and assistance policies nevertheless fall within DOE's title-taking patent policy legislation. Although NIH funding is used, the Cryo-EM Center is operated by DOE national laboratory and therefore DOE statutory authority applies.

While collaborative uses of the Cryo-EM Center could be covered under the statutory authority for Cooperative Research and Development Agreements (CRADAs) in 15 U.S.C. § 3710a, that authority does not exclude other contractual arrangements for collaborative research. Both before and after the enactment of the CRADA law, DOE authorized other types of agreements that covered work that also could have been performed under CRADAs. These include Non-Proprietary and Proprietary User Facility Agreements under similar Class Waivers. It was recognized that there is a need to have a streamlined approach to permit users the flexibility to engage in a general collaboration without having to negotiate a CRADA, which can cause significant delays due to the commercial aspects of the transaction that may require negotiations for licensing of background intellectual property, fields of use in foreground inventions, and possible modifications to the US competitiveness provision. Furthermore, the exclusive license requirements of the CRADA may encumber Laboratory inventions and might diminish the further availability of the User Facility for others to engage in collaborative research in the same or closely-related fields of art, and could also restrict the Laboratory's ability to license its technology to others or perform work for others using the technology it develops.

Scope of Class Waiver

This waiver is directed to non-proprietary research at the Cryo-Em Center for users to gain a familiarity with the capabilities of the equipment or to advance their own general state of knowledge. The users:

- (1) will have a general scope of work in which SLAC's and user's tasks will be directed toward non-proprietary research that advances the state of the art in the user's area of interest and familiarity with cryo-electron microscopy as a tool for atomic-resolution structural biology;

- (2) intend to publish their research results in the open scientific literature; and
- (3) do not require the data protection available in a CRADA or Strategic Partnership Project.

SLAC will initiate a process of selecting users within the scope of NIH funding requirements. Once selected an allocated time of the equipment, the User will advance nonspecific commercial interests, or gain a familiarity with the capabilities of cryo-electron microscopy. This waiver is intended to cover public and private organizations which are using the Cryo-EM Center in the following situations:

- (1) where a user is given access to the equipment to perform research without interacting with SLAC scientists and personnel, except for technical assistance in operating the equipment;
or
- (2) where a user intends to engage in some degree of collaboration with SLAC scientists when using the equipment or other aspects of the Center.

In both of the foregoing cases, the Department (through NIH funding) pays for the full cost of operating the equipment and for the SLAC scientists and other personnel, but does not provide funds directly to the users, who will be covering their own costs. This waiver is also available to foreign entities, provided they are granted access to the Cryo-EM Center pursuant to other applicable laws and regulations.

The Allocation of Patent Rights

A. SLAC

In accordance with its Management and Operating Contract, SLAC may elect title to its Subject Inventions. SLAC has the second option to elect the user's Subject Inventions when the user declines to elect its Subject Inventions (in accordance with paragraph B below) within one year of reporting to DOE. If SLAC or DOE seeks to protect the Subject Invention, the user shall retain a non-transferable, royalty free, commercial license to use the invention for its own purposes, without the right to sublicense.

B. The User

This Class Waiver grants the user the right to elect title from DOE to any user Subject Inventions, which is defined as any invention or discovery of the user conceived or first actually reduced to practice in the course of, or under, the user Agreement. The Government retains the standard Government Use License, which is a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States, the user's Subject Invention throughout the world. In addition, the user's Subject Inventions will be subject to statutory March-in Rights (48 C.F.R. 27.304-1(g)), the requirements with respect to preference for U.S. industry pursuant to 35 U.S.C. § 204, and reporting requirements.

C. Other Agreements Overriding Above Rights Allocation

To the extent that the user is directly supported by funding from a federal agency (for example, user's salaries), including DOE, or an international agreement, the agreement with the agency or the international agreement will provide for the disposition of patent rights in user Subject

Inventions deemed necessary to satisfy the agency's statutory or regulatory requirements. In view of the Bayh-Dole Act, the 1983 Presidential Memorandum on Government Patent Policy and Executive Order 12591, the disposition of rights in a funding agreement with the Government will normally be identical to those of this Class Waiver. The user agreement may need to be modified accordingly to reflect the other agreement and approved by DOE.

The Allocation of Data Rights

The Government, SLAC and user have unlimited rights in technical data first produced or specifically used in the performance of the user agreement. The user must agree to furnish data to DOE when: (a) specified to be delivered in the Statement of Work; (b) essential to the performance of work by DOE or Contractor personnel; or (c) necessary for the health and safety of such personnel in the performance of the work.

SLAC Non-Proprietary User Agreements

SLAC currently has several DOE Designated User Facilities where users can execute one agreement and use different SLAC facilities based on allocated time. SLAC's users follow applicable foreign visits and assignments requirements for access to the facilities. Since the Cryo-EM Center has similar goals to SLAC's Designated User Facilities and a user must have allocated time at the Center in order to perform work, SLAC may allow users to access the Center under current SLAC User Agreements (User Agreements). Current DOE policy does not require a foreign review for access to DOE Designated User Facilities. It would be burdensome and cause delays to conduct a foreign review for users to access the Center. Therefore, the DOE policy for access to the Cryo-EM Center for domestic and foreign entities shall follow current DOE policy for access to Designated User Facilities. If an entity has not entered into a User Agreement with SLAC, the standard SLAC user agreement may be executed for access to the Cryo-EM Center.

General Indemnity in User Agreements: Since DOE Program considers the use of the Designated Non-Proprietary User Facility is to advance DOE's research program mission by funding the activity of the user, a narrower General Indemnity provision is used where the user is responsible for only its own negligent acts. This standard will apply to Cryo-EM Center Agreements funded by NIH. However, the Deputy Secretary Memorandum (dated October 23, 2018) entitled "Decision on Recommended Technology Transition Reforms Related to Indemnity Requirement in Laboratory Partnering Agreements with Domestic Entities" applies to User Agreement and is applicable for the Cryo-EM Center agreements with domestic entities when reserving General Indemnity and Intellectual Property Indemnity.

In general, User Agreements are expected to be used only as long as the scope of work is directed toward non-proprietary research that advances the state of the art in the user's area of interest, rather than toward producing a specific commercial end result (*e.g.*, a marketable product). If the duration of a User Agreement extends for a considerable period of time or the DOE allocation of use of a facility becomes extensive, the SLAC should consider concluding the work under the User Agreement and begin negotiating a CRADA to continue a more specific commercial project.

Required DOE Reviews

Approval for use of a User Agreements is subject to any other requirements for approval provided in the DOE Contract for the operation of SLAC for other matters such as ES&H requirements, cyber security and export controls.

Expiration of this Class Waiver

NIH has committed to funding the Cry-EM Center for six years until April 30, 2024. If successful, NIH may extend funding to the Center and this waiver will stay in effect. However, if NIH funding ceases, this waiver will expire and access to the Center by the private sector will be by traditional SPP and CRADA. If DOE determines to continue this Center as a Designated User Facility, the appropriate procedures will be followed to designate the Cryo-EM Center as a DOE Designated Non-Proprietary User Facility.

Conclusion

User Facilities were established not only for utilization by DOE to further programmatic missions, but also for advancing research by offering these unique capabilities to the research efforts of profit and nonprofit organizations, as well as other Government entities. The grant of this waiver, therefore, reflects the guidance provided to DOE in Section 9 of the Nonnuclear Act and Section 152 of the Atomic Energy Act. Furthermore, the grant of the waiver does not conflict with the legislative intent of Bayh-Dole as implemented by DOE regulations governing the granting of patent waivers, in the 1983 Presidential Memorandum on Government Patent Policy, and Executive Order No. 12591.

It is believed that providing exclusive rights to users in their patentable inventions made by the users would best encourage such utilization, as well as further development of the technology by the user. If additional funding is necessary to continue the research and carry it through to commercial utilization, exclusive patent rights will normally be useful in encouraging the investment of the required capital expenditures. If additional, more commercial collaboration is needed between the user and SLAC, this Class Waiver will facilitate further collaboration in a CRADA or other authorized transaction. The Class Waiver should, therefore, promote the commercial utilization of subject inventions and make the benefits of the Cryo-EM Center widely available to the public in the shortest practicable time. Accordingly, this Class Waiver is consistent with the objectives and considerations of DOE's waiver regulations set forth in 10 CFR 784.

For its contribution, the Government will receive a royalty-free, nonexclusive license to each invention made under these agreements, the standard march-in rights and U.S. preference terms under Bayh-Dole, and the right to publish the results of the sponsored research. DOE will also have unlimited rights in all data generated from work under these agreements, and contemplates that all such data will be made public.

Finally, in view of the fact that this Class Waiver will mostly apply to basic research performed in facilities available to all of the scientific and technical communities, there appears to be little chance this Class Waiver would cause an adverse effect on competition.

Accordingly, in view of the objectives to be attained and the factors to be considered under DOE's statutory waiver policy, all of which have been considered, it is recommended that a waiver of U.S. and foreign patent rights, to this class of users at the Center, and in the situations described above, will best serve the interests of the United States and the general public. It is therefore recommended that this Class Waiver be granted.

_____

Date: August 4, 2020

Gary Drew
Assistant Chief Counsel for Intellectual Property
Office of Science

Pursuant to the authority provided in Section 152 of the Atomic Energy Act of 1954, as amended (42 U.S.C. 2182), Section 9 of the Federal Nonnuclear Energy Research and Development Act of 1974, as amended (42 U.S.C. 5908), and the implementing regulations promulgated thereunder for waivers of patent rights, it is in the best interests of the United States and the general public to grant a waiver of patent rights to the class represented by users of the SLAC Cryo-EM Center.

Therefore, it is ordered that a waiver of U.S. and foreign patent rights to users of the Cryo-EM Center is hereby granted. This Class Waiver is limited to inventions of the user which are conceived or first actually reduced to practice in the course of or under an agreement for the use of the Cryo-EM Center, and is subject to all the limitations, terms, and conditions set forth in the foregoing Statement of Considerations. The Assistant General Counsel for Technology Transfer and Intellectual Property shall be responsible for issuing instructions for implementation of this waiver in accordance with DOE regulations for the waiver of patent rights.

CONCURRENCE:



R. Todd Anderson for Sharlene Weatherwax

Date: 8/26/2020

Sharlene Weatherwax
Associate Director of Science for
Biological and Environmental Research (BER)
Office of Science

APPROVAL:



Date: 8.27.2020

Brian Lally
Assistant General Counsel
for Technology Transfer and Intellectual Property