



Food and Drug Administration  
Division of Freedom of Information (HFI-35)  
Office of Shared Services  
Office of Public Information and Library Services  
5600 Fishers Lane  
Rockville, MD 20857  
Fax: 301-443-1726 or 301-443-1719

October 9, 2009

**Re: Freedom of Information Act Request**

This is a request under the Freedom of Information Act, 5 U.S.C. § 552, for documents relating to the use, requests to use or consideration of the government right's as contemplated in the Bayh Dole Act.

The Bayh-Dole Act reserved certain rights for the government to ensure that the government and the public will have access to inventions developed with the support of taxpayer. Specifically, the federal government retains the following rights:

- A nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States any subject invention throughout the world, also known as a nonexclusive royalty-free license. (35 U.S.C. §202(c)(4))
- A "March-In" authority. Under this authority, the federal agency that funded the development of an invention has the right to require the contractor or exclusive licensee to grant a license in any field of use to a responsible applicant upon terms that are reasonable under the circumstances (in other words, to issue a compulsory license), if the agency determines that: the contractor has not made, and is not expected to make, efforts to commercialize the invention within an agreed upon time frame; public health or safety needs are not reasonably satisfied by the contractor or licensee; the use of the invention is required by the federal government and the contractor or licensee cannot meet the government's requirements; or the owner of an exclusive license is not ensuring that the invention is "manufactured substantially" in the United States and has not obtained the necessary waivers to do so. (35 U.S.C. §203)

There is some additional information about the exercise of such rights in the July 2009 GAO publication (GAO-09-742), titled "Report on Information on the Government's Right to Assert Ownership Control over Federally Funded Inventions."

Knowledge Ecology International (KEI) is conducting an investigation of the use of these provisions by different federal agencies, with the explicit purpose of examining in more detail the cases where federal agencies have considered or been asked to consider the exercise of federal rights. KEI will use the

information received through this request for disseminating information to the public and to policy makers in several ways, including through the publication of articles in popular blogs and magazines, academic articles, and in policy memoranda circulated to policy makers and published on the KEI web site.

In submitting this FOIA request, KEI is encouraged by the Transparency Memorandum issued by President Obama in January 2009 which declared that "My Administration is committed to creating an unprecedented level of openness in Government" and that "Openness will strengthen our democracy and promote efficiency and effectiveness in Government".

Request:

In order to conduct our investigation and serve the public interest, KEI requests all documents, including email, letters, faxes and other communications, memorandums, power point presentations, and any other information which addresses the use, request to use or the possibility of using U.S. government rights in patents under provisions of the Bayh-Dole Act, including but not limited to possible or actual exercise of the right to a nonexclusive royalty-free license to use an invention, or the exercise March-in rights. This request also includes any cases where the agency has used or considered using the process laid out in the Commerce Regulations 37 C.F.R. 401 to resolve a dispute about the use of the invention.

The time period of our request dates from 12 December 1980 to the present.

When possible, we prefer that the documents be submitted in electronic form in order to avoid the cost of duplication of documents, and to assist in the dissemination of the documents.

Knowledge Ecology International is incorporated under the laws of the District of Columbia as a non-profit corporation with the purpose of undertaking research, exploring new ideas, and proposing new solutions for the management of knowledge resources that better align the interests of consumers with those of creative and inventive communities. This request is made for a scholarly or scientific purpose and not for commercial use.

We request a waiver of all fees for this request, on the grounds that the use of the information is not for any commercial purpose, and will contribute significantly to public understanding of the operations or activities of the government, and a deeper understanding of how billions of dollars in taxpayer funded research is managed.

Thank you for your consideration of our request.

Sincerely,

Judit Rius

Knowledge Ecology International

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