Section by Section Analysis of the Bayh-Dole Act of 1980
(P.L. 96-517, as amended)

Sec. 200: Policy and objectives

"It is the policy and objective of the Congress to use the patent system to promote the utilization of inventions arising from federally supported research or development; to encourage maximum participation of small business firms in federally supported research and development efforts; to promote collaboration between commercial concerns and nonprofit organizations, including universities; to ensure that inventions made by nonprofit organizations and small business firms are used in a manner to promote free competition and enterprise without unduly encumbering future research and discovery; to promote the commercialization and public availability of inventions made in the United States by United States industry and labor; to ensure that the Government obtains sufficient rights in federally supported inventions to meet the needs of the Government and protect the public against nonuse or unreasonable use of inventions; and to minimize the costs of administering policies in this area."

Sec. 201: Definitions

Defines federal agencies, funding agreements, inventions, etc. For purposes of the Act, anyone receiving federal grants or contracts is referred to as a "contractor."

Sec. 202: Disposition of rights

Each nonprofit organization or small business making an invention with government support can elect to own the invention, unless they are not located in the United States or do not have a domestic place of business. The contractor must report the invention to the funding agency in time that a patent may be filed or the government can take ownership.

When the contractor elects to own the invention, the federal agency has a non-exclusive, non-transferable, irrevocable royalty-free license to use the invention for or on behalf of the

United States throughout the world. Funding agreements can give the government additional rights if they are needed to meet its obligations under international treaties or agreements. The agency can also require the contractor to file periodic reports on steps they are taking to license or develop the discovery. Such reports must be treated by the agency as confidential and not releasable under the Freedom of Information Act.

Nonprofit organizations must give a preference to small businesses when licensing their inventions.

Nonprofit organizations cannot assign their patent rights to another party without approval of the federal agency funding the research.

Nonprofit organizations must share royalties or income they receive under the Act with their inventors, and remaining royalties — after paying expenses related to managing the invention — must be used to support research or education at the institution.

In cases where the contractor is managing a government-owned facility (e.g. a federal laboratory), the same royalty sharing provisions apply. However, if such a contractor received royalties during any fiscal year that "exceeds five percent of the annual budget of the facility, that 15 percent of such excess shall be paid to the Treasury of the United States and the remaining 85 percent shall be used for the same purposes described above in this clause."

If the contractor elects not to retain ownership, the agency may do so itself or allow the inventors to own the patent.

If a federal employee co-invents an invention with a contractor, the agency may assign licensing rights to the contractor.

No funding agreement with a small business or nonprofit organization shall require them to license inventions they made without federal support to third parties, unless the head of the agency can justify such actions in writing. This authority cannot be delegated.

In exceptional circumstances where an agency believes government ownership of the invention better promotes the objectives of the law, contractor ownership can be denied. However, the agency must justify its decision to the Secretary of Commerce (who oversees Bayh-Dole) within 30 days. If the Secretary of Commerce disagrees, the head of the requesting agency will be notified. If it appears that there is a pattern of agency abuse of this provision, regulations are authorized to prohibit such abuse.

Agencies may also deny automatic contractor ownership if it is required to protect foreign intelligence or counterintelligence needs, or if the invention originates in a Department of Energy naval nuclear propulsion or weapons program.

Sec.203: March-in rights

Federal agencies may require contractors, an assignee or an exclusive licensee to grant licenses to other parties in four specific circumstances. In those cases, the contractor is required to license responsible applicants "upon terms that are reasonable under the circumstances." If the contractor refuses, the agency may grant such licenses itself.

Contractors have the right to appeal any decision to march in against them through an agency administrative procedure and can file a petition within 60 days to the U.S. Court of Claims. Agency decisions to march in are "held in abeyance pending the exhaustion of appeals or petitions filed under the preceding sentence."

Note that the first provision below ***only applies to the patent owner (normally an academic institution) while the others apply to the patent owner and the licensee:***

1. "Action is necessary because the contractor or assignee has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention in such field of use."

a. Twenty years after enactment, critics of the Bayh-Dole Act claimed that this provision allows the government to march in if the price of a product is not "reasonable," citing the definition of "practical application" which includes the phrase "that the invention is being utilized and that its benefits are to the extent permitted by law or Government regulations available to the public on reasonable terms." However, like its previous usage in this Section, "reasonable terms" refers to the terms of the license, not how the product is sold. A product's price is determined by the licensee, not the patent owner, which under Bayh-Dole is normally an academic research institution.

   As noted previously, this provision only applies to the patent owner. The language means that efforts are being made to license the invention and resulting agreements contain provisions conducive to commercialization, so that good faith efforts are made to bring the product to the marketplace where it is available for public use.

2. "Action is necessary to alleviate health or safety needs which are not reasonably satisfied by the contractor, assignee, or their licensees;

3. "Action is necessary to meet requirements for public use specified by Federal regulations and such requirements are not reasonably satisfied by the contractor, assignee, or licensees; or

4. "Action is necessary because the agreement required by section 204 has not been obtained or waived or because a licensee of the exclusive right to use or sell any subject invention in the United States is in breach of its agreement obtained pursuant to section 204." (Sec. 204 is the domestic manufacturing preference)

Sec. 204: Preference for United States industry

The law requires that the contractor shall not grant an exclusive license for the U.S. market unless the licensee "agrees that any products embodying the subject invention or produced

through the use of the subject invention will be manufactured substantially in the United States. However, in individual cases, the requirement for such an agreement may be waived by the Federal agency under whose funding agreement the invention was made upon a showing by the small business firm, nonprofit organization, or assignee that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible."

Sec. 205: Confidentiality

Agencies are authorized to withhold for a reasonable time from public disclosure any information they may have which could jeopardize the ability of the contractor to file for a patent.

Sec. 206: Uniform clauses and regulations

The Secretary of Commerce is charged with issuing regulations and standard funding agreements after they have been made available for public comment.

Sec. 207: Domestic and foreign protection of federally owned inventions

Agencies are authorized to file patents on inventions made by government employees, both in the United States and abroad. They are also authorized to license their inventions for commercialization. The Secretary of Commerce is authorized to assist the agencies in these efforts.

Sec. 208: Regulations governing Federal licensing

The Secretary of Commerce is authorized to promulgate regulations for the terms under which federally owned inventions may be licensed.

Sec. 209: Licensing federally owned inventions

When licensing their inventions, agencies should do so with applicants which commit to developing the invention within a reasonable time. Agencies should also determine that granting such licenses will not lessen competition. If the government owns a foreign patent on its invention, the agency should determine that granting the license enhances the interests of the government or U.S. industry.

Agencies must give a preference when licensing their inventions to small businesses and those who pledge to substantially manufacture resulting products in the United States.

Agencies may also require that licensees periodically report on their utilization efforts, with such reports being treated as commercial and financial information, not subject to release under the Freedom of Information Act.

Agencies are required to provide a public comment period of at least 15 days of their intention to issue an exclusive or partially exclusive license.

Licenses may be terminated if the licensee is not taking reasonable steps to achieve commercialization or violated the pledge to manufacture resulting products substantially in the U.S. Agencies may also terminate their licenses if "necessary to meet requirements for public use specified by Federal regulations issued after the date of the license, and such requirements are not reasonably satisfied by the licensee; or the licensee has been found by a court of competent jurisdiction to have violated the Federal antitrust laws in connection with its performance under the license agreement."

Sec. 210: Precedence of chapter

Lists the old laws regarding ownership of federally funded inventions, which the Act supersedes. It also specifies that no future law supersedes Bayh-Dole unless that statute specifically cites Bayh-Dole.

Sec. 211: Relationship to antitrust laws

"Nothing in this chapter shall be deemed to convey to any person immunity from civil or criminal liability, or to create any defenses to actions, under any antitrust law."

Sec. 212: Disposition of rights in educational awards

"No scholarship, fellowship, training grant, or other funding agreement made by a Federal agency primarily to an awardee for educational purposes will contain any provision giving the Federal agency any rights to inventions made by the awardee."

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Joseph P. Allen is Executive Director of the Bayh-Dole Coalition and helped enact the law as Senator Birch Bayh's staffer on the Senate Judiciary Committee. Mr. Allen later oversaw implementation of the Bayh-Dole Act at the U.S. Department of Commerce.