35 U.S.C. §§ 200 - 212[1]

Patent Rights in Inventions Made Under Federal Funding Agreements

1.0 Summary of the Law

The Patent and Trademark Laws Amendments of 1980 (Pub. L. No. 96-517, commonly referred to as the "Bayh-Dole Act") use the patent system to promote the utilization of inventions arising from federally supported research and development under "funding agreements" (procurement contracts, grants, and cooperative agreements for performance of experimental, developmental or research work funded in whole or in part by the Government).[2] The objectives of the Bayh-Dole Act are to encourage maximum participation of small business firms and nonprofit organizations in federally supported research and development efforts, promote collaboration between commercial concerns and nonprofit organizations, ensure that the Government obtains sufficient rights in federally supported inventions to meet its needs, and protect the public against nonuse or unreasonable use of inventions.[3]

Section 202 sets forth the disposition of rights between the nonprofit organization or small business firm and the Government.[4] Specifically, this section provides that each nonprofit organization or small business firm may elect to retain title to any subject invention within a reasonable time after disclosure to the Government.[5] The Government

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1 Section 200. Policy and objective.
Section 201. Definitions.
Section 202. Disposition of rights.
Section 203. March-in-rights.
Section 204. Preference for United States industry.
Section 205. Confidentiality.
Section 206. Uniform clauses and regulations.
Section 207. Domestic and foreign protection of federally owned inventions.
Section 208. Regulations governing Federal licensing.
Section 209. Restrictions on licensing of federally owned inventions.
Section 210. Precedence of chapter.
Section 211. Relationship to antitrust laws.
Section 212. Disposition of rights in educational awards.

2 35 U.S.C. §§ 200-201.

3 35 U.S.C. § 200.

4 35 U.S.C. § 202

5 35 U.S.C. § 202(c)(1).

6 *Id.*

may receive title to any subject invention if not disclosed within a reasonable time.[6] The contractor must make a written election within two years after disclosure to the Federal agency whether to retain title to a subject invention.[7] However, where publication, sale or public use has initiated the one year statutory period in which valid protection can still be retained in the United States,[8] the election may be shortened to a date that is not more than 60 days prior to the end of the one-year statutory period.[9] The one-year statutory period is set forth in 35 U.S.C. § 102(b). 35 U.S.C. § 102(b) provides that a person shall be entitled to a patent unless "the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States."

2.0 Background of the Law

Prior to enactment of the Bayh-Dole Act, U.S. companies desiring to use Government funding to develop new products and processes had to confront a bewildering array of twenty-six different agency patent and licensing policies governing patent rights in inventions developed with Government funding. This bureaucratic confusion discouraged efficient use of taxpayer-financed R&D. Government agencies were divided into "title" agencies and "license" agencies, depending upon whether they took title or merely a nonexclusive, royalty-free Government-purpose license under patentable inventions made with Government funding. There was much debate in Congress over the lack of a uniform Government patent policy and what it should be. There was deep concern by many in Congress about the ability of U.S. industry to keep pace with foreign competition in technology innovation. Many in Congress believed the problem was due, in large part, to ineffective Government patent policies that hindered the transfer of Government-funded technology to the private sector.[10]

The most common Government patent policy that existed prior to the Bayh-Dole Act was that the Government took title to inventions. It was believed that since the Government was funding the R&D, it should obtain title to patentable inventions made by contractors and the contractors should retain a non-exclusive, royalty-free license. The Government generally would not transfer title to the invention to the inventing contractor. Instead, the

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6 *Id.*

7 35 U.S.C. § 202(c)(2).

8 35 U.S.C. § 102(b).

9 35 U.S.C. § 202(c)(2)

10 H.R. 96-1307, Part 1, 96th Cong., 1st Session (1979), at 6460. See, generally, Edward C. Waterscheid, *The Need for a Uniform Government Patent Policy: The D.O.E. Example*, 3 Harv. J. L. & Tech 103 (Summer 1990). See *Technology Transfer, Administration of the Bayh-Dole Act by Research Universities*, GAO/RCED-98-125 (May 1998), at 3. See also, *The Bayh-Dole Act – A Guide to the Law and Implementing Regulations*, Council on Government Relations (September, 1999).

Government made such inventions available by non-exclusive license, under reasonable terms, to any party that wanted to practice them. This provided little incentive for contractors to patent inventions and resulted in a very limited flow of Government-funded inventions to the private sector.[11]

In 1980, the Government held title to approximately 28,000 patents and less than 5% of these were licensed to private industry for development of commercial products. In contrast, 25 percent to 30 percent of the small number of federal patents for which the Government had allowed the contractors to obtain title were licensed.[12]

Companies had little incentive to develop commercial products using Government-owned inventions because competitors would be free to acquire licenses from the Government to make the same or similar products. Therefore, although taxpayers were supporting the Government's large investment in R&D, they were not benefiting from the useful products or the economic development that would have occurred with the development and sale of new commercial products.[13]

After much debate, in 1980 Congress determined that the public would benefit from a uniform patent policy that would permit small businesses and nonprofit organizations to elect title in inventions made by them with federal funding. This new uniform patent policy would also permit exclusive licensing of Government-funded inventions and result in a strong incentive for licensees to commercialize products made with such inventions. This new uniform patent policy would, as a result, help stimulate the development of new technologies, products and the economy.[14]

In 1980, Congress enacted the Bayh-Dole Act, which was first uniform patent policy statute applicable to all Government agencies. The Bayh-Dole Act (Pub. L. No. 96-517) added 35 U.S.C. §§ 200-211 to the body of patent law.[15] The Bayh-Dole Act also repealed all other laws concerning Government patent policy that related to small business firms and nonprofit organizations. Thus, by enacting the Bayh-Dole Act,

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[11] Id.

[12] *Technology Transfer, Administration of the Bayh-Dole Act by Universities,* GAO/RCED-98-125 (May 1998), at 3.

[13] Note 10 supra.

[14] Id.

[15] Pub. L. No. 96-517 was first implemented by the Office of Federal Procurement Policy (OFPP) in OMB Bulletin 81-22. 46 *Fed. Reg.* 34775 (1981). Unlike the usual guidance provided by OMB or OFPP, the Bulletin was a detailed regulation. Subsequently, DOD issued Defense Acquisition Circular 76-29 (Aug. 31, 1981) to implement Pub. L. No. 96-517 and the OMB Bulletin. NASA also implemented the policy by modifying its Patent Waiver Regulations, 46 *Fed. Reg.* 37023 (1981) and its procurement regulations, NASA PRD 81-5 (July 1, 1981). 35 U.S.C. § 212 was added Nov. 8, 1984 by Pub. L. No. 98-620.

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Congress established a distinct patent policy for small business firms and nonprofit organizations.

Pub. L. No. 96-517 permits small business firms and nonprofit organizations to retain title to inventions, called "subject inventions," conceived or first actually reduced to practice in the performance of funding agreements with Federal agencies. The House Report to Pub. L. No. 96-517 stated that nonprofit organizations and small business firms were to be given preferential treatment for obtaining patent rights in inventions. The report further stated a presumption that ownership of all patent rights in Government-funded research would vest in any contractor that is a nonprofit organization or small business firm.[16] This policy substantially incorporated legislation separately introduced by the University, Small Business Patent Policy Act.[17] One of the primary purposes of the Bayh-Dole Act was to foster cooperative research arrangements among the Government, universities, and industry in order to "more effectively utilize the productive resources of the nation in the creation and commercialization of new technologies."[18]

As stated above, the goal of the Bayh-Dole Act was to establish a uniform policy on patent rights for all Government agencies for small business firms and nonprofit organizations. This patent policy has been extended to contractors that aren't small business firms or nonprofit organizations by Presidential Memorandum dated February 18, 1983 entitled "Government Patent Policy," Executive Order No. 12591 dated April 10, 1987, and Executive Order No. 12618 dated December 22, 1987.

Under the February 18, 1983 Presidential Memorandum, the Government can waive or omit any of the Government rights or contractor obligations described in Sections 202-204 of the Bayh-Dole Act, for contractors that aren't small business firms or nonprofit organizations, if the agency determines (a) that the interests of the United States and the general public will be better served thereby as, for example, where it is necessary to obtain a uniquely or highly-qualified contractor; or (b) that the funding agreement involves co-sponsored, cost-sharing, or joint venture research and development, and the contractor, co-sponsor, or joint-venturer is making a substantial contribution of funds, facilities, or equipment to the work performed under the funding agreement.

A 1984 amendment to the Bayh-Dole Act[19] limited the waiver authority covered in the Presidential Memorandum. This limitation in Section 210(c) reads as follows:

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16 *See* H.R. Rep. No. 1307, 96th Cong., 2d Sess., pt. I, at 5 (1980), reprinted in 1980 U.S.C.C.A.N. 6464.

17 H.R. 2414 (S.414). S.414 was introduced by Senators Birch Bayh (D.-Ind.) and Robert Dole (R.-Kan.). The Senate passed S.414 by an overwhelming vote of 91-4.

18 Ralph C. Nash, Jr. & Leonard Rawicz, *Patents and Technical Data,* at 156 (1983).

19 Trademark Clarification Act of 1984 (Pub. L. No. 98-620).

(c) Nothing in this chapter is intended to limit the authority of agencies to agree to the disposition of rights in inventions made in the performance of work under funding agreements with persons other than nonprofit organizations or small business firms in accordance with the Statement of Government Patent Policy issued on February 18, 1983, agency regulations, or other applicable regulations or to otherwise limit the authority of agencies to allow such persons to retain ownership of inventions. Any disposition of rights in inventions made in accordance with the Statement or implementing regulations, including any disposition occurring before enactment of this section, are hereby authorized *except that all funding agreements, including those with other than small business firms and nonprofit organizations, shall include the requirements established in paragraph 202(c)(4) and section 203 of this title. (Emphasis added.)*

This change means the paid-up, nonexclusive, Government-purpose license provisions found in paragraph 202(c)(4), and the march-in rights provisions found in Section 203, cannot be waived or omitted by Government agencies in funding agreements with contractors that are not nonprofit organizations or small business firms. However, the remaining parts of Sections 202-204 of the Bayh-Dole Act can be waived or omitted by Government agencies in funding agreements with contractors that are not nonprofit organizations or small business firms.

3.0 Law in Practice

The Bayh-Dole Act encourages commercialization of subject inventions by giving the contractor the first opportunity to file for a patent. It has served its purpose well in the fact that, subsequent to its enactment, a large number of universities, small businesses, and large businesses have undertaken significant efforts to develop and patent inventions under Government funding agreements. As a result, the Government has played a key role in stimulating fundamental research other entities would not have undertaken without Government funding. In addition, many new technologies and products have been developed and commercialized with Government-funded inventions and this has greatly stimulated economic development in the United States. However, certain parts of the Bayh-Dole Act are objectionable to many commercial companies and traditional Government contractors and it is a major barrier preventing many commercial companies from performing R&D for the Government.[20]

Some of the concerns raised by commercial companies and traditional Government contractors regarding the Bayh-Dole Act include the inability to keep a patentable invention a trade secret, the breadth of the Government-purpose license, march-in rights, and the broad definition of "subject invention," which includes inventions conceived (and

[20] *See* Diane M. Sidebottom, *Updating the Bayh-Dole Act: Keeping the Federal Government on the Cutting Edge*, 30 Pub. Cont. L. J. 225 (Winter 2001); Richard N. Kuyath, *Barriers to Federal Procurement: Patent Rights*, 36 The Procurement Lawyer 1 (Fall 2000); *Pentagon Finds Fewer Firms Want to Do Military R&D*, WALL ST. J., Oct 22, 1999, at A20.

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This will result in K being
a sole source to Gov't if
Gov't is only purchaser.

possibly even patented) prior to entering into the funding agreement, but first actually reduced to practice under the funding agreement. These conditions have resulted in some commentators in Government and industry recommending that the Bayh-Dole Act be amended to address these concerns. [21]

The present Government R&D budget comprises a much smaller percentage of the total U.S. investment in R&D than it did in the 1980s. As a result, the Government no longer drives technology development as it did in the past. Many large commercial firms, which invest billions of dollars each year in internal R&D, refuse to do business with the Government.[22] Yet new national security threats and other national needs will require all Government agencies that fund research and development (such as the Department of Defense, NASA, the Department of Energy, the Department of Health and Human Services, and the Department of Homeland Security) to contract for R&D with commercial companies that are not part of the Government's traditional R&D base. Examples include pharmaceutical and biotechnology companies that are needed to develop a defense against biological and chemical warfare threats.[23] Other examples include commercial companies with technologies necessary to develop fuel cells, advanced batteries, high capacity electric transmission lines, and other alternative energy sources which will help reduce the nation's dependence on foreign oil and help reduce environmental pollution.

Demonstrating the fact the Government is not gaining access to the latest state-of-the-art technologies, a recent study compared DoD research, development, test, and evaluation (RDT&E) contract awards with the *Business Week* R&D scorecard and the *Fortune 500* Industrials. This study found that more than 92 percent of the industry leaders that invested the greatest percentage of their sales in R&D received insignificant or no DoD RDT&E awards. These firms were usually the leaders in their industry in technology development.[24] As previously mentioned, one of the major barriers preventing these commercial companies from performing R&D for the Government is Government patent rights mandated by the Bayh-Dole Act.

The Department of Defense has special authority under 10 U.S.C. § 2371 to enter into

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21 *See* Diane M. Sidebottom, *Updating the Bayh-Dole Act: Keeping the Federal Government on the Cutting Edge*, 30 Pub. Cont. L. J. 225 (Winter 2001); Richard N. Kuyath, *Barriers to Federal Procurement: Patent Rights*, 36 The Procurement Lawyer I (Fall 2000).

22 *Pentagon Finds Fewer Firms Want to Do Military R&D*, WALL ST. J., Oct. 22, 1999 at A20.

23 39 Gov't. Cont. Rep. (CCH) ¶ 421 (Aug. 27, 1997).

24 Robert C. Spreng, *Increasing the Effectiveness of Government/Industry R&D Investment*, CONT. MGT., May 1997, at 28.

25 *Department of Defense Other Transactions: An Analysis of Applicable Laws* (American Bar Association Monograph, 2000), at A-37 through A-43.

R&D agreements called "other transactions" that are not subject to the Bayh-Dole Act.[25] The Department of Defense has successfully used this special authority to enter into "other transaction" R&D agreements with commercial companies that otherwise would not do business with the Government. Since "other transactions" are not subject to the Bayh-Dole Act, the Department of Defense has been able to negotiate and modify the standard Government patent rights clause in its "other transaction" agreements to eliminate the major concerns of commercial companies. Likewise, traditional defense contractors and the Government have negotiated modified patent rights clauses under "other transaction" agreements that eliminate the concerns of traditional defense contractors. Examples of such modifications that can be made to the standard patent rights clause include:

a. Permitting the contractor to keep the patentable invention as a trade secret, such as when that is the contractor's standard commercial practice, a "process patent" is involved (the infringement of which cannot be easily detected), or where a background trade secret would have to be revealed in a patent application due to the "best mode" requirement in 35 U.S.C. § 112.

b. Narrowing the Government-purpose license so that (1) it applies to only one agency (versus the entire Government), or (2) it can be used only to make weapon systems.

c. Eliminating march-in rights or placing further limitations on their exercise than currently apply under existing laws and regulations.

d. Eliminating the "or first actually reduced to practice" provision in the definition of "subject invention."

When the patent rights clause required by the Bayh-Dole Act has been a barrier to obtaining the technologies it seeks, the Department of Defense has used "other transactions" as the funding instrument instead of a procurement contract, grant, or cooperative agreement. Since the Bayh-Dole Act does not apply to "other transactions," the DoD has the flexibility under "other transactions" to negotiate patent rights that meet the needs of both parties. In recent reports, the General Accounting Office found that 72 of 97 DoD "other transaction" agreements reviewed incorporated tailored patent rights clauses in order to obtain technology not available using standard Bayh-Dole Act patent rights clauses. *See Intellectual Property: Information on the Federal Framework and DoD's Other Transaction Authority,* GAO-01-980T, July 17, 2001 (examples at 8-9); *Acquisition Reform: DoD's Guidance on Using Section 845 Agreements Could Be Improved*, GAO/NSIAD-00-33, April 2000 (examples at 46-48). At this time, however, only the DoD, the Department of Transportation and NASA have "other transaction" authority, and only DoD has used it extensively. The vast majority of Government R&D continues to be funded under procurement contracts, grants and cooperative agreements,

[25] *Department of Defense Other Transactions: An Analysis of Applicable Laws* (American Bar Association Monograph, 2000), at A-37 through A-43.

which are subject to the Bayh-Dole Act. Therefore, it is desirable for the Government to have the option under the Bayh-Dole Act to negotiate patent rights under procurement contracts, grants and cooperative agreements in the same manner as with "other transactions." This flexibility will help enable the Government to gain access to the latest in state-of-art technologies.

To attract more commercial companies to perform R&D for the Government, all agencies of the Government should have similar flexibility with respect to the ability to negotiate patent rights under procurement contracts, grants and cooperative agreements that the Department of Defense has with respect to "other transaction" agreements. This may be accomplished by amending 35 U.S.C. § 210(c) in two ways:

First, delete the requirement presently in 35 U.S.C. § 210(c) that all funding agreements with contractors that are not small business firms or nonprofit organizations must include the requirements in paragraph 202(c)(4) (paid-up, Government purpose license) and section 203 (march-in rights). As a result, in accordance with the President's Memorandum to the Heads of the Executive Departments and Agencies entitled "Government Patent Policy" dated February 18, 1983, the Government will be able to waive or omit, in whole or in part, any of the rights of the Government or obligations of the contractor described in 35 U.S.C. §§ 202-204 in funding agreements with entities that are not (a) small business firms or nonprofit organizations, or (b) subject to the Atomic Energy Act of 1954 (42 U.S.C. § 2011 et seq.), the Federal Nonnuclear Energy Research and Development Act of 1974 (42 U.S.C. § 5901-5915), or the National Aeronautics and Space Act of 1958 (42 U.S.C. §§ 2451-2459, §§ 2471-2476).

Second, amend Section 35 U.S.C. § 210(c) to provide that if a funding agreement is made with (1) a contractor that is a nonprofit organization or small business firm that is subject to the Bayh-Dole Act (35 U.S.C. §§ 200-212), or (2) a contractor that is not a nonprofit organization or small business firm and that is subject to the Atomic Energy Act of 1954 (42 U.S.C. § 2011 et seq.), the Federal Nonnuclear Energy Research and Development Act of 1974 (42 U.S.C. §§ 5901-5915), or the National Aeronautics and Space Act of 1958 (42 U.S.C. §§ 2451-2459, §§ 2471-2476), any rights of the Government or obligations of the contractor relating to patents described in (a) 35 U.S.C. §§ 202-204, (b) 42 U.S.C. § 2182 covering any invention or discovery useful in the production or utilization of atomic energy, but excluding any invention or discovery useful in the production or utilization of special nuclear material, (c) 42 U.S.C. § 5908, or (d) 42 U.S.C. § 2457 may be waived or omitted, in whole or in part, if the head of the contracting activity determines that the interests of the United States and the general public will be better served thereby. Further, any of the foregoing rights of the Government or obligations of the contractor relating to patents (excluding any invention or discovery useful in the production or utilization of special nuclear material) may be negotiated between the Government and the contractor to reduce such Government rights or contractor obligations, if the head of the contracting activity determines that the interest of the Government and the general public will be served thereby. This same right to negotiate reduced Government rights or reduced contractor obligations relating to

patents shall apply to those contractors that are not nonprofit organizations or small business firms and that are subject to the Statement of Government Patent Policy issued on February 18, 1983.

Examples of when such waivers, omissions, or negotiations would be appropriate include, but are not limited to, where such waiver, omission, or negotiation is necessary to obtain a uniquely or highly qualified contractor, or the funding agreement involves co-sponsored, cost sharing, or joint venture research and development, and the contractor, co-sponsor, or joint venturer is making a substantial contribution of funds, facilities, or equipment to the work performed under the funding agreement.

It is intended that when this new authority under 35 U.S.C. 210(c) is used, in most cases it will be to negotiate reduced Government rights or reduced contractor obligations relating to patents, rather than to waive or omit an entire standard Government right (e.g., the Government-purpose license). Examples of lesser Government rights that may be negotiated include (1) a narrower Government license in the invention (e.g., to make weapons), and (2) a narrower definition of subject invention ("invention conceived in performance of work" instead of the definition in 35 U.S.C. 201(e), i.e., "invention conceived or first actually reduced to practice in the performance of work"). An example of a lesser contractor obligation that may be negotiated is a contract term that presumes that the contractor will elect title to the subject invention, instead of the obligation under 35 U.S.C. 202(c)(2) that the contractor must elect title in writing within two years after disclosure to the Federal agency. However, under appropriate circumstances, the Government may waive or omit an entire Government right (e.g., the Government-purpose license in 35 U.S.C. 202 (c)(4)) or an entire contractor obligation (e.g., the obligation, under 35 U.S.C. 204, when the contractor grants an exclusive license to use and sell a subject invention in the United States, to require the licensee to agree that any products embodying the subject invention, or produced through use of the subject invention, will be manufactured substantially in the United States).

It is intended that this new authority under 35 U.S.C. 210(c) to waive or omit, in whole or in part, any Government right or contractor obligation relating to patents, or to negotiate reduced Government rights or reduced contractor obligations relating to patents, shall also apply to subcontractors performing experimental, developmental or research work under funding agreements. It is intended that the subcontractor will negotiate the waiver, omission, or reduced Government rights or reduced contractor obligations with the Government, through the prime contractor.

With respect to subcontractors that are small business firms or nonprofit organizations, prime contractors shall continue to be prohibited from using the leverage of award of the subcontract as a way of extracting rights, in the subcontract agreement, to their subcontractor's subject inventions developed under the subcontract. No change is being made to the current requirement for an exceptional circumstance determination to be issued by the funding agency under 35 U.S.C. 202(a)(ii) as the only way for the prime contractor to obtain rights, in the subcontract agreement, in subject inventions of small

business firm or nonprofit organization subcontractors developed under the subcontract. An exceptional circumstance determination can only be issued in such a situation when the funding agency has determined that granting the prime contractor the right to obtain rights, in the subcontract agreement, in subject inventions of small business firm or nonprofit organization subcontractors developed under the subcontract will better promote the policy and objectives of the Bayh-Dole Act.

A prime contractor remains free to negotiate a separate licensing agreement, supported with separate consideration, with a subcontractor that is a small business firm or nonprofit organization, under which the prime contractor obtains rights in the subcontractor's subject inventions. An exceptional circumstance determination is not required in such a situation.

The authority to waive, omit, or negotiate any right of the Government or obligation of the contractor relating to patents under 42 U.S.C. § 2182 shall include only those inventions or discoveries useful in the production or utilization of atomic energy. Such authority under 42 U.S.C. § 2182 shall not include the right to waive, omit, or negotiate any right of the Government or obligation of the contractor relating to inventions or discoveries useful in the production or utilization of special nuclear material, as that term is defined in 50 U.S.C. § 47f(c).

These revisions made to 35 U.S.C. § 210(c) will also benefit traditional Government contractors by incentivizing them to patent and commercialize inventions developed using Government R&D funding. Because the Government obtains a paid-up, Government-purpose license under 35 U.S.C. § 202(c)(4) and the 1983 Presidential Memorandum to any invention conceived or first actually reduced to practice by the contractor in the performance of a funding agreement, and because such license can be used, on a royalty-free basis, by any competing Government contractor or subcontractor for Government purposes, there currently is little or no incentive for many traditional Government contractors to patent inventions developed under funding agreements. This is particularly the case where the traditional Government contractor's principal or only customer is the Government.

Strong arguments have been made that most technology is best spread through private businesses developing it with rights to protect it through the patent process. To the extent the standard Government patent rights substantially reduce the ability of a business to protect its investment in developing and marketing such technology, the likelihood a business will make such investment is also reduced. The counterbalancing consideration is that, to the extent a business can patent such inventions, competition may be reduced, resulting in higher prices both to the Government and to other buyers. The Integrated Dual Use Companies believe that the tradeoff is justified in this instance because it may result in more competitors and more competing technologies.

The current statutory scheme hinders the Government from incenticizing commercial companies and traditional Government contractors through the granting of patents. If,

under appropriate circumstances, the Government is willing to negotiate lesser Government rights or contractor obligations relating to patents, the incentive for many commercial companies and traditional Government contractors to patent and commercialize inventions made under funding agreements could be greatly increased. In this regard, it should be noted that the General Accounting Office has found that the paid-up licenses to subject inventions retained by the Government are of little, if any, use in Federal procurements.[26]

The revisions made to 35 U.S.C. § 210(c) will further benefit traditional Government contractors because many of them have the same concerns as commercial companies, such as the inability to keep a patentable invention a trade secret, march-in rights, and the broad definition of "subject invention," which includes inventions conceived (and possibly even patented) prior to entering into the Government funding agreement, but first actually reduced to practice under the funding agreement.

It is noted that there may be certain circumstances where waiver or omission of certain standard Government rights (such as "march-in rights") would be inappropriate. An example would be where a company is performing research under a Government funding agreement for a purely public purpose such as the development of a vaccine to prevent AIDs. In such a case, the company could develop under the funding agreement and patent an effective vaccine to prevent the disease, but not want to commercialize the vaccine because it has been determined that a certain small percentage of the persons vaccinated will develop the disease as a result of the vaccination. This could result in lawsuits being made against the inventing company for making and selling the vaccine. Failure to commercialize the vaccine under these circumstances would thwart the public purpose for the Government funding the research. However, there may be another company willing to make and sell the vaccine under these circumstances. In such a case, it would be both appropriate and prudent for the Government to retain "march-in rights" in order to have the right to require the inventing company to license the other company under reasonable terms under the inventing company's patent to make and sell the vaccine to alleviate public health needs which are not being reasonably satisfied by the inventing company.

Any regulations and policy guidance issued to implement this amendment to 35 U.S.C. § 210(c) are to be written in a manner to provide maximum flexibility to the head of the contracting activity to (1) waive or omit, in whole or in part, any right of the Government or obligation of the contractor relating to patents, and (2) negotiate the terms and conditions of the patent rights clause in the funding agreement to fit the particular circumstances involved.

Proposed Amendment to 35 U.S.C. 210(c)

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[26] *Intellectual Property: Information on the Federal Framework and DOD's Other Transaction Authority* (GAO-01-980T, July 17, 2001), at 4.

(c) Nothing in this chapter is intended to limit the authority of agencies to agree to the disposition of rights in inventions made in the performance of work under funding agreements with contractors other than nonprofit organizations or small business firms in accordance with the Statement of Government Patent Policy issued on February 18, 1983, agency regulations, or other applicable regulations or to otherwise limit the authority of agencies to allow such contractors to retain ownership of inventions. Any disposition of rights in inventions made in accordance with the Statement or implementing regulations, including any disposition occurring before enactment of this section, are hereby authorized. . In addition, if the funding agreement is made with (1) a contractor that is a nonprofit organization or small business firm that is subject to this chapter, or (2) a contractor other than a nonprofit organization or small business firm that is subject to the Atomic Energy Act of 1954 (42 U.S.C. § 2011 et seq.), the Federal Nonnuclear Energy Research and Development Act of 1974 (42 U.S.C. §§ 5901-5915), or the National Aeronautics and Space Act of 1958 (42 U.S.C. §§ 2451-2459, §§ 2471-2476), any of the rights of the Government or obligations of the contractor relating to patents described in (1) 35 U.S.C. §§ 202-204, (2) 42 U.S.C. § 2182 covering any invention or discovery useful in the production or utilization of atomic energy, but excluding any invention or discovery useful in the production or utilization of special nuclear material, (3) 42 U.S.C. § 5908, or (4) 42 U.S.C. § 2457 may be waived or omitted, in whole or in part, if the head of the contracting activity determines that the interests of the United States and the general public will be better served thereby. Further, any of the foregoing rights of the Government or obligations of the contractor relating to patents (excluding any invention or discovery useful in the production or utilization of special nuclear material) may be negotiated between the Government and the contractor to reduce such Government rights or contractor obligations, if the head of the contracting activity determines that the interests of the Government and the general public will be served thereby. This same right to negotiate reduced Government rights or reduced contractor obligations relating to patents shall also apply to those contractors that are not nonprofit organizations or small business firms and that are subject to the Statement of Government Patent Policy issued on February 18, 1983. This subsection 210(c) makes no change in the requirements set forth in subsections 202(a)(ii) and 202(b)(i) of this chapter for an exceptional circumstance determination to be made by the agency before a prime contractor will be permitted to obtain rights, in its subcontract funding agreements, in inventions made under its subcontract funding agreements by nonprofit organizations or small business firms, and creates no separate authority for a prime contractor to obtain rights, in its subcontract funding agreements, to inventions made under its subcontract funding agreements by nonprofit organizations or small business firms.