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COMPTROLLER GENERAL OF THE UNITED STATES
WASHINGTON D.C. 20548

B-204687

October 16, 1981

The Honorable Albert Gore, Jr.
Chairman, Subcommittee on Investigation
and Oversight
Committee on Science and Technology
House of Representatives

Dear Mr. Chairman:

You have requested GAO to undertake a legal analysis of a contract signed in May 1981 between Massachusetts General Hospital (MGH) and Hoechst Chemical Company of West Germany (Hoechst) and the impact of the Act approved December 12, 1980, Public Law No. 96-517, 94 Stat. 3015 (Act), which amended the patent and trademark laws, upon the contract. Since MGH receives more than $30 million per year in research funding from the National Institutes of Health (NIH), a possibility exists that Hoechst will gain title, in violation of the Act, to inventions that have been partially funded with Federal dollars.

Section 6 of the Act added sections 200 through 206 to title 35, United States Code. (References hereafter to sections are to title 35, as amended by the Act, unless otherwise specified.) Basically, those sections give nonprofit organizations and small business firms a first right of refusal to title in inventions they have made under funding agreements with Federal agencies (sections 202(a), 202(c)(2)); give the Federal agencies a nonexclusive license to practice an invention to which the nonprofit organizations or small business firms elect to retain title (section 202(c)(5)); restrict nonprofit organizations' assignment of rights and granting of licenses in their inventions (section 202(c)(7)); give to the Federal agencies "march-in rights" to force development or application of inventions not utilized (section 203); and mandate a preference for United States industry in the manufacture of the inventions in certain circumstances (section 204).

These requirements are not self-executing; they must be effectuated with appropriate provisions in any funding agreement with a small business firm or nonprofit organization. Section 202(c). While we have not received the agreement between NIH and MGH, a nonprofit organization as defined in the Act, we assume that the annual $30 million NIH provides to MGH is done under "funding agreements" as that term is defined in section 201(b), that is, through grants, contracts, or cooperative agreements for performance of research.

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The contract MGH signed with Hoechst will provide MGH with substantial funds over 10 years to establish a molecular biology laboratory in return for licenses to exploit any patents generated by the research funding. You wish us to discuss the respective rights of the Federal Government and Hoechst in any invention MGH makes resulting from research which both the Government and Hoechst have funded.

Any potential conflict between the contract MGH has with Hoechst and sections 200 through 206 of title 35 would only exist after July 1, 1981, the effective date of those sections. See section 8(f) of the Act, 94 Stat. 3028. Any funding agreement entered into after that date is required to embody the principles of those sections. Section 202(c). Conversely, funding agreements entered into before July 1, 1981, would not be governed by these sections, even if the agreement extended beyond July 1, 1981, because they lack the provisions required by the statute. In other words, the enactment of sections 200 through 206 did not, in itself, have any effect on MGH's pre-existing contract with Hoechst.

Assuming that NIH has entered or will enter into a funding agreement with MGH after July 1, 1981, incorporating the requirements of the Act, the Act still would not affect the contract if MGH produced an invention using funds provided exclusively by Hoechst. The Act applies to "subject inventions," defined as those conceived or reduced to practice "in the performance of work under a funding agreement." Section 201(e). An invention made solely with Hoechst funding would not fall within this definition.

This result is consistent with the contract between MGH and Hoechst. Section 6.3B(a) of the contract stipulates that if MGH patents an invention using funds exclusively given it by Hoechst, then Hoechst will be given an exclusive worldwide license for the life of the patent. Care must be taken, however, that no Federal funds directly or indirectly support the research leading to an invention if MGH is to claim that the terms of a funding agreement do not apply. This may very well mean that MGH must account separately for all expenses leading to an invention including the cost of research itself as well as indirect or overhead costs to be able to show that the expenses were paid with funds provided by Hoechst. In the event MGH is unable to prove that NIH funding was in no way involved, the terms of the Act, as embodied in a funding agreement, would apply. 1/

1/ An invention made by an MGH scientist using NIH funds, whether patented or not, could be used as a "building block" for an invention made through research funded exclusively by Hoechst. The

After reviewing the terms of the Hoechst-MGH contract, we believe it is possible for MGH to segregate the research funded by Hoechst from other research conducted by it. The contract calls for the establishment of a separate "Department of Molecular Biology" (Department) at MGH (contract, section 4.1) which will initially occupy two floors of an existing building, and then the upper four floors of a new research building. Contract, Exhibits A and B. Funds for renovating the space in the existing building as well as for constructing the space the Department will occupy in the new research building will be provided by Hoechst, as will the funds for equipment and furniture. Id., sections 2.1, 2.2. In addition, Hoechst will provide MGH with funds for the annual operating costs of the Department. Id., section 2.1.

Under section 3.2 of the contract, Hoechst has guaranteed a minimum annual funding level and has reserved the right to fund all additional research at the Department. Only if Hoechst decides not to exercise this option may MGH seek funding from other sources. Section 3.2 also stipulates that MGH will do nothing in the renovating, construction, and initial equipping of the Department that would allow third parties, expressly including the United States, to acquire any rights or equity in any work solely accomplished in the Department by personnel of the Department. It is apparent, then, that if MGH and Hoechst desire, the Department of Molecular Biology can be established, equipped, and run with funding solely provided by Hoechst. The rights to any invention to come out of such an arrangement would be determined pursuant to the contract between MGH and Hoechst and the requirements of the Act would not come into play because no Federal funds would be involved. The possibility exists, despite the precautions, described above, that the parties may not be able to agree that a particular invention was funded by Hoechst, with no NIH involvement.

Alternatively, Hoechst might decide not to exercise its option to fund research above the guaranteed amount. In that case, MGH might seek Federal funding for the additional research under a funding agreement incorporating the requirements of the

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1/ invention made exclusively through Hoechst funding may of course be patentable also, provided it produces a new and useful result in a substantially different way. Abbott v. Barrentine Manufacturing Co., 255 F. Supp. 890, 899 (N.D. Miss. 1965). The rights to the patent of the newer invention, in such a case, would be determined between MGH and Hoechst. The Government could not claim patent infringement.

Act. This situation would not appear to raise the possibility of conflict between the contract and the statute because the additional research, since it would not be funded by Hoechst, would not be covered by the contract.

Assuming that a funding agreement is signed by NIH and MGH after the effective date of sections 200 through 206, incorporating the required provisions, then the terms of those sections would apply to any research carried on by MGH which is funded, at least in part, with Government monies. Consequently, if some of the NIH money is to be used for research by the Department, NIH should not sign a funding agreement with MGH if the agreement's required terms are in conflict with the terms of the MGH-Hoechst contract. A review of the Hoechst contract does reveal certain potential conflicts assuming that both the Government and Hoechst fund research by the Department. 2/

Section 6.2 of the MGH-Hoechst contract is entitled "Patent Rights." Under the terms of this section, MGH notifies Hoechst of any invention arising out of research sponsored in whole or in part by Hoechst. 3/ If the two parties decide to file patent applications, the applications will be in the name of MGH. This provision is consistent with section 202(a) which gives to small business firms and nonprofit organizations the right to retain title to an invention produced at least in part with Government funding. 4/

2/ We recognize that the contract between MGH and Hoechst was effective on May 14, 1981, and the effective date of sections 200 through 206 was July 1, 1981. We do not believe, however, that those sections create an impairment of contract in violation of the 5th Amendment. Century Arms, Inc. v. Kennedy, 323 F. Supp. 1002, 1014 (D. Vermont 1971). Sections 200 through 206 do not, in themselves, alter the contract between MGH and Hoechst. They only operate through provisions of a funding agreement. If MGH does not believe that the principles embodied in section 200 through 206 are in its best interest, it can choose not to sign a funding agreement with NIH. Cf. Pfile v. Corcoran, 287 F. Supp. 554, 559-560 (D. Colorado 1968).

3/ Under the terms of a funding agreement, MGH would also have to notify NIH of an invention within a reasonable time after it is made. Section 202(c)(1).

4/ Under section 202(a) of the Act, a funding agreement need not allow a nonprofit organization or small business firm the right to retain title to its inventions

Under section 6.2 of the contract, if MGH does not wish to file a patent application with respect to a particular invention, or does not wish to file patent applications with respect to specific countries, then Hoechst has the right to file in its own name. If an invention were developed with both Government and Hoechst funding, a refusal by MGH to file an application would be in conflict with the provisions in a funding agreement effectuating sections 202(c)(2) and 202(c)(3) of the Act. The former section gives to the United States the option to retain title to any invention funded at least in part by a funding agreement if the small business firm or nonprofit organization does not choose to retain title. The latter section gives to the United States the right to receive title to inventions in any country where the small business firm or nonprofit organization has not filed patent applications within a reasonable time. MGH might therefore have to file an application to be in compliance with its funding agreement.

Additionally, under section 6.2 of the contract, if Hoechst is not interested in having patent applications filed, then MGH can file for patent rights, dispose of them, or release them to the inventor, as it deems fit. Under the terms of a funding agreement, however, MGH's exercise of those options would be limited. For example, as was pointed out earlier, the Government can elect to retain rights in inventions if the nonprofit organization or small business firm does not so choose.

Section 6.3 of the contract spells out the types of licenses Hoechst will obtain in a patented invention of the Department, the research for which has been funded, at least in part, by Hoechst. It states in pertinent part:

"B. The license granted * * * shall be:

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4/ in three circumstances: (1) when the funding agreement is for the operation of a Government-owned research or production facility; (2) in exceptional circumstances when the agency determines that restriction or elimination of the right to retain title to an invention will promote the objectives of the Act; or (3) in certain national security situations. The first exception does not apply here. For the purpose of this letter, we are assuming that NIH will not invoke either of the other two.

> "(b) with respect to any Patent resulting from collaborative research funded in part by the Company, an exclusive world-wide license for the life of the Patent whenever possible, and when not possible the most favorable license obtainable but in any event a nonexclusive world-wide license for the life of the Patent;
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> "(c) with respect to any Patent claiming an Invention conceived during the term of this Agreement as a result of Sponsored Research but first reduced to practice within the 30 months next following the termination of this Agreement, the most favorable license obtainable but in any event a nonexclusive world-wide license for the life of the Patent."

By definition, "Sponsored Research" includes research funded either in whole or in part by Hoechst. Contract, section 1.2.

These provisions would thus come into play, among other situations, should the parties agree that a particular invention was the result of collaborative research. 5/ Since the granting of exclusive licenses by MGH for the life of the patent is not a requirement under the contract, these contract provisions would be in conformity with the terms of a funding agreement.

Basically, section 202(c)(7)(B) prohibits nonprofit organizations from granting exclusive licenses (except to small business firms) for a period in excess of 5 years from first commercial sale or use of the invention or 8 years from the date of the exclusive license, whichever is earlier, unless the Federal agency involved approves a longer license. Thus, as

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5/ As mentioned above, the determination whether an invention was jointly funded or not could be the occasion for disagreement between the parties. The rights created by the Act would be dependent on the outcome of that dispute since, if the invention is funded without Government involvement, the Act does not apply. Alternatively, the parties might agree that Government funding was not involved, while there might be reason to believe it was.

to an invention subject to a Federal funding agreement, Hoechst would only be able to obtain an exclusive license in the United States for the stated time period unless NIH approved a longer period. (There are no restrictions in sections 200 through 206 on the terms of nonexclusive licenses.) However, section 204 of the Act requires nonprofit organizations granting exclusive licenses to use or sell an invention in the United States to get from the grantee its agreement that products using the invention or produced through the use of the invention will be substantially manufactured in the United States unless the Federal agency, based on statutory criteria, waives this requirement.

Under section 6.3D of the contract, if Hoechst has not begun actual commercial development of an invention to which it has been given exclusive license within 3 years after the date of MGH's filing of the patent application, the license will become nonexclusive. The 3-year exclusive holding period could potentially be in violation of Office of Management and Budget regulations promulgated under section 203 of the Act, "March-in rights." Among other things, that section gives to the Federal agency involved in the funding agreement the right to require the holder of an exclusive license to grant either a nonexclusive, partially exclusive, or exclusive license to applicants if the Federal agency decides that the holder is not diligently pursuing practical application of the invention. The question of whether "march-in rights" would be triggered before Hoechst's 3-year exclusive holding period ended would depend on the circumstances surrounding each invention.

Under section 6.4 of the contract, royalties paid by Hoechst to MGH for any licenses granted will be allocated among the inventor, the Department, the inventor's laboratory, and the general research funds of MGH in accordance with a predetermined schedule. This provision appears to comply with sections 202(c)(7)(C) and (D) of the Act which require, respectively, that the royalties received by nonprofit organizations be shared with the inventor and that the balance of royalties after payment of expenses be utilized for the support of scientific research or education.

Finally, under Article VIII of the contract, MGH can assign its rights and obligations to any corporation controlling, controlled by, or under common control with it. If this option is meant to include assignment of MGH's rights to inventions which have been at least partially funded by a funding agreement, MGH may not do so. Section 202(c)(7)(A) prohibits a nonprofit organization from assigning its rights to such an invention in the United States, without the approval of the Federal agency involved, except in one limited circumstance.

In conclusion, before NIH signs another funding agreement with MGH, it should make clear that the Federal monies involved are not to be used in conjunction with monies provided under the MGH-Hoechst contract. In the alternative, if the Federal monies are to be used with MGH-Hoechst contract monies for research, the contract should be modified to be in accord with any funding agreement NIH signs with MGH.

This letter contains information of a proprietary nature since it extensively cites the contract's provisions. Therefore, we are constrained to inform you that further release of the letter may be prohibited by 18 U.S.C. §1905.

Sincerely yours,

MILTON J. SOCOLAR

For the Comptroller General
of the United States

cc: Mr. Myers, PAD
Ms. Moore, PAD

DIGESTS:

1. Sections 200-206 of title 35, effective July 1, 1981, describe terms that must be in funding agreements--grants, contracts, or cooperative agreements for performance of research--Federal agencies have with small business firms and nonprofit organizations. Basically, those sections spell out rights small businesses and nonprofit organizations have in inventions they have produced through research funded, at least in part, by Government monies. Funding agreements entered into before July 1, 1981, would not be governed by those sections, even if agreements extended beyond July 1, 1981, because they lack provisions required by statute.

2. Since sections 200-206 of title 35 only apply to "subject inventions," defined as those conceived or reduced to practice "in performance of work under funding agreement," rights to invention made solely with private funding would not be subject to those sections.

3. Review of terms of contract Massachussetts General Hospital has with private chemical company indicates it is possible for MGH to segregate research funded by chemical company from other research funded by other sources including National Institutes of Health through funding agreement. Rights to any invention to come out of research funded exclusively by chemical company would be determined pursuant to contract between MGH and chemical company.

4. Assuming that funding agreement is signed by NIH and MGH after effective date of sections 200 through 206, incorporating required provisions, then terms of those sections would apply to any research carried on by MGH which is funded, at least in part, with Government monies. Consequently, if some of NIH money is to be used for research which will also be funded by chemical company, NIH should not sign funding agreement with MGH if agreement's required terms are in conflict with terms of MGH's contract with chemical company.