MINUTES
DEPARTMENT PATENTS BOARD
July 8, 1965

Present: Mr. James Quigley, Chairman
Mr. Peter Muirhead, OE
Dr. David E. Price, PHS
Mr. Dale S. Thompson, OS
Mr. W. B. Rankin, FDA
Mrs. Miriam Stubbs, VRA
Dr. James Cowhig, WA
Mr. Manuel B. Hiller, OGC

Also Present: Mr. Alfred Rego, PHS
Mr. Robert Hollinger, PHS
Miss Katherine Parent, NIH
Mr. Norman Latker, NIH
Mr. Benjamin Bochenek, PHS
Mrs. Sarah Spector, OGC

The meeting of the Department Patents Board took place on July 8, 1965 at 2:30 p.m. and was called to order by Chairman Quigley. The purpose of the meeting was to discuss the problem presented by the apparent inconsistency of §8.2(b) of the Department Patent Regulations with §1(a) of the President's Statement. Section 8.2(b) provides:

> "If he [the head of the agency] finds that the invention will thereby be more adequately and quickly developed for widest use and that there are satisfactory safeguards against unreasonable royalties and repressive practices, the invention may be assigned to a competent organization for development and administration for the term of the patent or such lesser period as may be deemed necessary."

Section 1(a) of the President's Statement provides:

> "(a) Where
>
> (1) a principal purpose of the contract is to create, develop or improve products, processes, or methods which are intended for commercial use (or which are otherwise intended to be made available for use) by the general public at home or abroad, or which will be required for such use by governmental regulations;

(2) a principal purpose of the contract is for exploration into fields which directly concern the public health or public welfare; or

(3) the contract is in a field of science or technology in which there has been little significant experience outside of work funded by the government, or where the government has been the principal developer of the field, and the acquisition of exclusive rights at the time of contracting might confer on the contrator a preferred or dominant position; or

(4) the services or the contractor are

(i) for the operation of a government-owned research or production facility; or

(ii) for coordinating and directing the work of others,

the government shall normally acquire or reserve the right to acquire the principal or exclusive rights throughout the work in and to any inventions made in the course of or under the contract. In exceptional circumstances the contractor may acquire greater rights than a non-exclusive license at the time of contracting, where the head of the department or agency certifies that such action will best serve the public interest. Greater rights may also be acquired by the contractor after the invention has been identified, where the invention when made in the course of or under the contract is not a primary object of the contract, provided the acquisition of such greater rights is consistent with the intent of this Section 1(a) and is a necessary incentive to call forth private risk capital and expense to bring the invention to the point of practical application."

The questions presented to the Board were:

(1) Whether the President's Statement should be broadly interpreted in the light of its overall objective to permit an 8.2(b) determination, or whether in the light of the last sentence of §1(a) it would permit such a determination only where the invention was not the primary object of the contract.

(2) If we are to retain §8.2(b) is it applicable to foreign universities?

(3) What is meant by "competent organization" in §8.2(b)?

Scope of Present Operation under §8.2(b).

Mr. Quigley asked how many determinations were made under that section in the last few years and how many requests are pending. Miss Parent replied that there were five such determinations made since 1953:

1. 3/31/53 -- In favor of University of California

   Inventor: Dr. Penn
   Invention: Synthetic Antigens for Use in the Detection of Cancer

2. 9/26/55 -- In favor of Johns Hopkins University -- asked assignment directly to inventor

   Inventor: Dr. Russell Morgan
   Invention: Low Noise Amplifiers for Use in X-Ray Screen Intensifiers of the Television Type
   System for the Translation of Intelligence at Low Signal-to-Noise Ratios

3. 10/1/59 -- In favor of Stanford University

   Inventor: Dr. Howard Pattee
   Invention: Microfluoroscope

4. 12/16/59 -- In favor of Wisconsin University

   Inventors: Green, Crane, and Lester
   Invention: Co-Enzyme Q, A New Type Quinone and Processes of its Preparation -- Not developed by exclusive licensee

5. 10/21/64 -- In favor of Jefferson Medical College

   Inventors: Nealon, Gibbon, Sandler, Kunin
   Invention: Restoration of Blood to Biochemical Normalcy by Treatment with Ion Exchange Resins.

In addition, there was an 8.2(b) determination on an invention resulting from an air pollution contract:

1958 -- In favor of Washington State University

   Inventors: Adams, Koppe and Dana
   Invention: Air Pollution testing instrument for measuring concentration of pollutants in gas

There are about 35 requests pending.

Other Solutions Available to Meet the Problem Which 8.2(b) Attempts to Resolve.

There was considerable discussion on attempting to accomplish the objectives of §8.2(b) in some other way -- such as obtaining authority to issue exclusive licenses on Government-owned inventions and thereby avoiding the need to give title to a grantee to accomplish indirectly what we cannot do directly. It was pointed out that §8.2(b) solved the problem of getting an invention developed in a very limited situation, i.e., where an invention is made under a grant or contract to a nonprofit institution. However, even if the Board decides that §8.2(b) is fully compatible with the President's Statement, there would nonetheless continue to be a need to obtain authority to issue exclusive licenses under Government-owned inventions in order to resolve similar problems generated by contracts with industrial corporations and employee research.

Feasibility of Limiting Use of §8.2(b) to Invention which is not Primary Object of Contract.

The question was raised whether we should adopt a strict construction of the President's Statement by permitting §8.2(b) determinations only if the invention is not the primary object of the contract. It was pointed out by Mr. Latker that one of the largest areas in which an 8.2(b) determination is needed is in the synthesizing of compounds, a situation in which the invention is the primary object of the contract or grant. This need to issue exclusive licenses is also present where an employee may have synthesized 100 compounds and be unable to obtain testing either in or out of the Government because of the patent problem. Mr. Thompson queried why such testing could not be performed in-house. Dr. Price explained that only pharmaceutical companies can accumulate the extensive clinical data required by FDA for a new drug application. Only in the field of cancer research and psychopharmacology does NIH, through special authorization, have facilities for this endeavor. There is some question whether the Government should assume responsibility in every case where there is hope that some significant utility might result to organize such testing, or whether as a matter of policy the Government should permit private enterprise to use its own resources.

In cancer screening, there was a policy decision to perform this work at NIH. Do we wish to make the same policy decision in the remainder of the drug development field? If so, it was felt by Dr. Price that we would be embarking upon an astronomical program. Mr. Thompson asked why we could not pay industry to screen for us and retain patent rights. While there are some laboratories who do nothing but this work for a fee, pharmaceutical companies prefer to use their resources to test their own drugs as incidental to finding uses for their proprietary compounds and will not divert their

facilities for testing purposes without some hope of obtaining patent rights. In the long run, Dr. Price expressed the view that it was more economical for the Government to let industry do the clinical work in the hope that on the rare occasion they will discover a use for a compound to which they can obtain patent rights which will reimburse them for all their other effort.

There was some discussion concerning the legal concept that an 8.2(b) determination is permissible while an exclusive license issued under a Government-owned patent is not. When an invention results under a grant or contract, an affirmative act of assignment is required in order to vest title in the Government. It does not become Government property but is the property of the inventor until the determination is made and the assignment takes place. Therefore, the failure of the Government to assert its own right to title does not constitute the giving away of Government property.

Under §8.2(b) the inventor is requested to assign his proprietary interest to a grantee who, in turn, will issue an exclusive license to a commercial organization. The Government retains control over the licensee and the invention by the conditions it imposes under §8.2(b) and the President's Statement. However, if an exclusive license is issued under a Government-owned patent, an old decision of the Attorney General (34 Op. Atty. Gen. 320; 1924) has created the impression that such action would be a disposition of Government property. Until this is clarified, no Government agency is issuing such licenses without statutory authority. Mr. Bochenek pointed out that in the field of water pollution there is need to encourage private industry to bring inventions that are developed by the PHS forward to ultimate marketability. These inventions are the primary object of a contract as are other inventions of hardware, such as research in the artificial heart field. It was felt that interpretation of §301 of the PHS Act (42 U.S.C. 241(a)) gave to PHS the responsibility to see to it that inventions are made available to the point of practical application, and, therefore, that we do have a responsibility which can be implemented only by §8.2(b) at the present time.

It was the consensus of the Board that it was not feasible to make determinations that some inventions were or were not the primary objects of a contract or grant. This is especially true in the grant field where a grantee investigator, in pursuit of his scientific bent, may deviate from the line of inquiry promised in his grant application. Additionally, this condition is irrevelant in assessing the need for an 8.2(b) determination.

The Conclusions of the Board.

Mr. Hiller summarized the consensus of the Board as follows:

1. That we are not disposed to eliminate §8.2(b) now as irreconcilably in conflict with the President's Statement.

2. The first few paragraphs of the President's Statement, particularly as coupled with the objectives expressed in the Memorandum and in 42 U.S.C. 241(a), would permit a broad interpretation of the President's Statement so as to allow 8.2(b) determinations and would be incompatible with a strict interpretation of the succeeding sections of the Statement which would prohibit §8.2(b) determinations on "incidental" inventions.

3. Notwithstanding the availability of §8.2(b) on a limited basis, the Department will nevertheless request from the Attorney General a formal opinion on the question of exclusive licensing of Government-owned inventions.

4. If we do get affirmative confirmation to issue exclusive licenses, we are disposed to giving exclusive licenses only after public notice and hearing, and would establish a central board to determine whether to issue such licenses. We would then dispense with §8.2(b).

What is a "competent organization"?

Dr. Price said that when §8.2(b) was drafted the term competent organization was intended to go beyond the grantee and to include non-profit organizations such as research corporations.

Foreign Grantees.

This question was raised by a request from McGill University of Canada to obtain title and to enter into an exclusive licensing arrangement with Schering Corporation, a domestic corporation. It was the consensus of the Board that McGill University would qualify since it was a grantee, it was a Canadian corporation, the proposed exclusive licensee is a domestic corporation. Each request from a foreign grantee should be handled on a case by case basis. The grant of such request should not be foreclosed solely because the request comes from a foreign grantee.

The meeting was then adjourned.

Sarah H. Spector

Sarah H. Spector
Deputy Patents Officer