GOVERNMENT PATENT POLICY

To: PAT HOYLE
From: Norm Latker

HEARINGS

BEFORE THE

JAN 10 1966

SUBCOMMITTEE ON
PATENTS, TRADEMARKS, AND COPYRIGHTS
OF THE
COMMITTEE ON THE JUDICIARY
UNITED STATES SENATE

EIGHTY-NINTH CONGRESS

FIRST SESSION

PURSUANT TO

S. Res. 48

ON

S. 789, S. 1809, and S. 1899

Pat see pgs 382-3 + 386, 387

PART 1

JUNE 1, 2, AND 3, 1965

Printed for the use of the Committee on the Judiciary



U.S. GOVERNMENT PRINTING OFFICE
54-400 WASHINGTON : 1965

Formerly, when majors were in the business of selling independents raw materials, they supplied technical information and did product development work for their customers, the independents. Now, this activity is largely proprietary. So another concern is our inability to keep up in new product development. We, and most of the other small independent fertilizer manufacturers, are almost entirely dependent upon TVA for this important function.

Will we be able to depend on TVA in the future to supply materials not available from industry, and to carry out research and do product development work for the small companies who have no facilities for this type activity? The answer to the above will have considerable bearing on our future planning. We will appreciate your carefully considered opinion.

Sincerely yours,

NELSON O. ABELL,
President.

Mr. LONG of Louisiana. Mr. President, I suggest the absence of a quorum.

The PRESIDING OFFICER. The clerk will call the roll.

The legislative clerk proceeded to call the roll.

Mr. LONG of Louisiana. Mr. President, I ask unanimous consent that the order for the quorum call be rescinded.

The PRESIDING OFFICER. Without objection, it is so ordered.

[From the Congressional Record, May 17, 1965]

PRIVATE PATENT MONOPOLIES

Mr. LONG of Louisiana. Mr. President, I have stated on many occasions on the floor of the Senate that granting private patent monopolies to the results of research paid for by the public is concentrating economic and political power in the hands of a few, is retarding our economic growth, and is stifling our capacity to protect ourselves. This is bad enough. But when the desire to make monopoly profits at the public's expense can adversely affect the health of our children, it is time to call a halt to this immoral and evil practice.

Today, I would like to present a case study which should be of great interest not only to the Congress but also to the American people.

Phenylketonuria, or PKU, is a physical condition that leads to mental retardation. It is a chemical imbalance in the blood that causes permanent brain damage if it is not detected during the first month of a baby's life. If PKU is caught in time, the damage can be prevented by altering the child's diet.

In 1962, the U.S. Public Health Service began using a simple blood test developed with public funds by Dr. Robert Guthrie at the University of Buffalo that could be given 3 days after birth to detect the presence of PKU. Thus an afflicted infant can be put on the special diet before brain damage occurs. We know now that the need for such tests is even greater than is realized, for the Guthrie test has shown that PKU is twice as common as was thought.

Louisiana, Massachusetts, New York, Rhode Island, and recently other States have made the Guthrie test mandatory for all babies born in those States within 28 days after birth. Other State health departments have made the PKU test available to their people without cost through all hospitals that provide maternal and infant care.

The Guthrie test was developed largely by governmental funds; the Public Health Service granted $251,700 and the Children's Bureau granted approximately $492,000. Total support from the Department of Health, Education, and Welfare was about three-quarters of a million dollars. Certain States have also spent considerable sums.

Information secured from the Department of Health, Education, and Welfare indicates that Dr. Guthrie did not voluntarily submit to the Public Health Service an invention report as required by the Public Health Service grant requirements.

A formal invention report was requested of Dr. Guthrie on January 10, 1962. After four followup letters and innumerable telephone conversations, an invention report was received from him on December 14, 1962, almost a year later. During this period, but 4 months after the first Public Health Service request, a patent application, serial No. 187,707, relating to this invention, was filed in Dr. Guthrie's name. This indicates that the invention had been made when the Public Health Service made its first request in January 1962. The

patent was filed 7 months prior to the actual submission of the invention report. The formal invention report was held up for almost a whole year so that a patent could be filed.

But this is not all, for shortly after Dr. Guthrie filed for a patent, he entered into an exclusive licensing agreement for the life of the patent with Miles Laboratories. This agreement was supported by the Children's Hospital in Buffalo and was approved by two voluntary health associations which had contributed a total of $50,000, but was not approved, I am glad to say, by the Public Health Service. The justification for giving Miles Laboratories a monopoly was the usual one: to induce the company to bring the product to a commercial stage and to assure the widest and most effective utilization.

The hospitals in Massachusetts and in other States were producing a kit for testing 500 infants, including all costs, for $6. The granting of a license to Miles would prevent the manufacture of such kits by anyone except Miles Laboratories. And Miles Laboratories' price was $262, over 40 times the cost to Massachusetts, Louisiana, and other States.

The Chief of the Children's Bureau protested the issuance of the exclusive license as contrary to the public interest. A number of States were contemplating setting up the Guthrie tests on a routine basis and were planning to produce their own materials. Financially they could not carry out a statewide program unless they manufactured the necessary materials themselves. If Miles secured the monopoly and was able to force the States to pay through the nose, this would prevent many States from carrying out their plans. None of these States could afford to institute a program if they had to purchase the kits from the Ames Division of Miles Laboratories at the price demanded or if they had to pay royalties on the materials they would manufacture themselves.

The exorbitance of the Miles' price is magnified by the fact that the Guthrie test kit had already been developed, promoted and tried. A charge which is 40 times what it cost Dr. Guthrie to produce the kits for the field trials, especially when all of the basic development and promotion had already been done, is, in my judgment, an outrage.

Further investigation by the Public Health Service disclosed that at least five companies were interested in obtaining a license and producing the kits at a cost similar to Dr. Guthrie's.

Accordingly, the Public Health Service determined that ownership to the invention belonged to the United States and the proper action was taken. Credit for this action on behalf of the public must be given to Dr. Luther Terry, the Surgeon General, Dr. David E. Price and all those staff people connected with this action. Dr. Guthrie himself was appalled by the price Miles wanted to charge.

This case, Mr. President, illustrates several points:

First. Allowing private patents on Government-financed research will inevitably result in delaying disclosure of new knowledge, inventions, and discoveries, at least for as long as it takes to prepare patent applications and file them. In most cases the delay will be much longer. I have already pointed out that firms in the aerospace industry withheld information for as long as 5 years. In the field of health a delay is especially reprehensible.

Second. Allowing universities, hospitals, and nonprofit institutions to control and administer patents resulting from publicly financed research is contrary to the public interest. This activity is a Government function and must not be delegated to any nongovernmental institution. In the Guthrie case which I have just described, neither the university nor the Children's Hospital at Buffalo had the knowledge, the background, or the sophistication to know what is or is not in the public interest. It was also disclosed that Dr. Guthrie's application was filed by a patent attorney who was hired by the State university system of New York for this purpose, but who was actually a patent attorney for Miles Laboratories.

Educational institutions are not sacrosanct. They have withheld information from the public; they have also violated the antitrust laws. A well-known case is the development of vitamin D at the University of Wisconsin with Government funds. The patent was assigned to the Alumni Foundation, against which the Department of Justice brought an antitrust suit and won. The Comptroller General of the United States revealed a few years ago how this same university—after having received almost $3 million from the Government, the American Cancer Society, and other nonprofit organizations—assigned patent rights on 5–FU, a cancer drug, to a company which, in turn, charged exorbitant prices even to the Government. The Department of Health, Education, and

Welfare in this case, also, had to intervene and reclaim the patent on behalf of the public.

With the Government paying for construction, equipment, and other facilities to universities and giving them grants for all kinds of research programs, there is no reason to give them patent rights, also.

I cannot see why we should set them up in the business of patent licensing. If they are educational institutions and wish to take advantage of that status, they should stay out of business.

Third. The third point is the falsity of the reason given for granting a monopoly. Further development was unnecessary. Creation of a new market was unnecessary. No unusual risks were involved. Other companies were willing to produce the Guthrie kits for testing of 500 infants for $6; and they would still be making a profit.

Fourth. The case also illustrates what happens when a private company gets a monopoly. In this case its price was so exorbitant that many States would have had to curtail their programs with the ultimate sufferers being innocent, mentally retarded children, who could have been saved.

Dr. Guthrie and the hospitals in Louisiana, Massachusetts, and other States could produce kits for testing 500 infants, including all costs, for $6. Miles Laboratories wanted $262 for the same thing. If this is not blood money, extracted at the expense of the taxpayer, I should like to know what is.

Mr. President, it is very important for the American people to know about these governmental activities. Therefore, I ask unanimous consent that some of the documents concerning the subject which I have discussed be printed at this point in the Record.

There being no objection, the documents were ordered to be printed in the Record, as follows:

U.S. GOVERNMENT MEMORANDUM

NOVEMBER 5, 1963.

To: Mr. Herschel Clesner, Inventions Coordinator, Office of the Surgeon General, PHS.

From: Katherine B. Oettinger, Chief, Children's Bureau.

Subject: Miles Laboratory request for exclusive commercial arrangement to develop Guthrie PKU kit.

We have considered the above request in the Children's Bureau and at this point would strongly recommend to the Surgeon General that such exclusive commercial rights not be granted to Miles Laboratories. In making this recommendation, we have taken into account the following factors:

1. Expenditure of public funds in the development, promotion, and distribution and trial of this kid. In addition to funds expended by the Public Health Service for the development of the assay which is utilized in these kits, the Children's Bureau has invested a total of $242,792.27 since fiscal 1962 in the actual development of the kit, in the promotion of field trials to test the efficiency of this screening method, and in the manufacture and distribution of sufficient kits to screen 550,000 newborn infants as a part of these field trials. These field trials are currently underway with over 300,000 babies already screened (32 babies detected and confirmed as having phenylketonuria). They involve 33 States and approximately 600 hospitals. In order to carry out the field trials, we estimate that the participating States will have spent an additional $250,000 of maternal and child health funds to collect the blood samples, to actually run the assays in the laboratories, and to run confirmatory tests on the presumptive positives which the screening procedure turns up. From our point of view therefore, approximately $492,000 of public funds will have been utilized in order to develop, promote, distribute, and try out these kits when the field trials are completed.

2. Current plans of the States. While the field trials have not as yet been completed, a number of States have already made a decision that from their point of view and regardless of the overall outcome, this screening procedure is worth while and should be developed within the State as a routine screening for all newborns. As you know, the State of Massachusetts instituted this some time ago, and at present all babies born in the State are screened for PKU with this procedure. In doing this, Massachusetts is manufacturing its own materials used for this screening. A number of other States contemplating setting up this type of screening on a routine basis have indicated that they too would manufacture their own materials. Financially they feel that they could not

PAT HOYLE

carry out a statewide program unless they manufactured the necessery materials themselves. It seems to us that the granting of exclusive commercial rights to the Miles Laboratories would prevent Massachusetts and some of the large States now contemplating setting up this screening as a routine, from carrying out their plans. None of these States could afford to institute a program if they had to purchase the kits commercially at the contemplated price, or if they had to pay royalties on the materials they would manufacture themselves.

3. The suggested sales price at which Miles would make these kits available appears somewhat exorbitant in view of the fact that these kits have already been developed, promoted, and tried. A charge which is 40 times what it cost Dr. Guthrie to produce these kits for the field trials seems to us to be out of line when all of the basic development and promotion has already been done.

While we feel strongly that, particularly for some of the smaller States, a commercially available source of these kits is essential if these States are to develop a screening program, it does not seem that an exclusive arrangement with Miles Laboratories would result in such commercial availability at a reasonable cost. There are indications that a number of laboratories would be willing to manufacture these kits with adequate quality control at a reasonable cost if Miles were not granted an exclusive commercial arrangement.

It is our feeling that the rights to this screening kit should be retained by the Government in view of the investment of public funds. Retention of such rights at this time would, we feel, allow a number of States to proceed with the manufacture of their own materials for statewide programs and would allow other commercial laboratories to produce the kits for some of the smaller States at a more reasonable price.

STATE UNIVERSITY OF NEW YORK AT BUFFALO, SCHOOL OF MEDICINE,
DEPARTMENT OF PEDIATRICS, CHILDREN'S HOSPITAL,

Buffalo, N.Y., December 4, 1963.

RUDOLPH HORMUTH,
Specialist in Services for Mentally Retarded Children, Division of Health Services, Department of Health, Education, and Welfare, Washington, D.C.

DEAR RUDY: With reference to your letter of November 21, 1963, here are the answers to your questions to the best of my knowledge:

1. Our cost to produce a kit for the testing of 500 infants, including estimates of all costs (labor, materials, rental and maintenance of space, etc.), and not including materials for collecting blood spots or urine impregnated paper in the hospitals, $6.

2. During my visit to Miles Laboratory last June I was told that their price for the same kit to test 500 infants would be $262. This was explained to me as only 50 cents per test.

3. Other companies who have indicated their interest in producing kits are: Fischer Scientific, Pittsburgh, Pa.; Baltimore Biological Laboratories; Difco Laboratories; Sylvana Co., New Jersey: Dade Laboratories, Miami, Fla.

I think this answers all your questions; if not, please feel free to call on me.

Very truly yours,

ROBERT GUTHRIE, Ph., D., M.D.

THE COMMONWEALTH OF MASSACHUSETTS,
DEPARTMENT OF PUBLIC HEALTH, DIAGNOSTIC LABORATORY,
December 13, 1963.

HERSCHEL F. CLESNER,
Inventions Coordinator, PHS, Department of Health, Education, and Welfare, Washington, D.C.

DEAR MR. CLESNER: Your letter to Dr. Edsall, which is concerned with a proposal that a certain company be granted a license for the exclusive marketing rights for the Guthrie PKU kits, has been referred to me. Since, as you state in your letter, the Commonwealth of Massachusetts does require the PKU test by law and we do make up our own kits in this laboratory for the assaying procedure here, we are appreciative of your courtesy in inviting our comments.

First, I would have some reservations about parts of the sentence you quote in the first paragraph in your letter which reads, "That such time and expenditure is warranted and justified in order to have the company produce the product under the most exacting conditions of quality control in order to insure a high

order of quality and consistency of reproducibility from batch to batch, also the company will have to continue development research on the product to the point of developing modifications or even substitution in order to provide a better diagnostic aid and that it will have to conduct an extensive educational and promotional effort to obtain the widest possible distribution and usage of the product." Actually, we have not found it particularly difficult to purchase and set up the various ingredients which go into the media used, nor the other supplies to complete the testing kits. We would feel that any properly qualified and reasonably resourceful laboratory would be able to adjust and standardize the reagents used and quite economically, as they perform the tests according to the published directions of Dr. Guthrie. Furthermore, a considerable educational and promotional effort has already taken place in one way or another resulting in more than half the States now trying out the test, although of course a much wider use of the screening test is greatly to be desired.

Since the test is now mandatory and performed on a practically 100 percent basis in Massachusetts, we continue to find it most efficient and economical to make up our own kits in our laboratory here. We would be very strongly opposed, and I think with good justification, to the granting of any license which in any way prevented or curtailed our making up the ingredients and supplies into laboratory assaying kits. Our present system of preparing from available commercial sources the finished materials for doing the testing is working superbly well, and quite inexpensively. Indeed, our entire cost of running the PKU tests, including professional, subprofessional, and clerk salaries and the costs of making up both the laboratory kits and the hospital collecting kits we estimate as about 50 cents per baby tested. Of this total cost only a quite small portion goes into the laboratory assay kits. Dr. Guthrie, for instance, had told me that his costs have been $6 for producing kits to do 500 tests in the laboratories, i.e., 1.2 cents per test and our costs would be roughly comparable.

In our opinion, it would not be in the public interest for any patent or license to in any way prevent or curtail our laboratory or any qualified laboratory in the manufacturing of PKU kits for its own use. Further, since we have a number of ethical, competing firms that produce a variety of excellent biological products and media, the problems and complexities many of which are as great or greater than for PKU kits, I would seriously question granting exclusive rights to any one firm. By so doing, it seems to me, we arbitrarily keep out of the market other firms that might conceivably produce a better product at a lower cost.

Yours sincerely,

ROBERT A. MACCREADY, M.D.,
Director, Diagnostic Laboratories.

THE COMMONWEALTH OF MASSACHUSETTS,
December 23, 1963.

MR. HERSCHEL F. CLESNER,
Public Health Service, Department of Health, Education, and Welfare, Washington, D.C.

DEAR MR. CLESNER: On returning last week from an overseas trip I found at hand your letter to me of November 27 and Dr. MacCready's reply. I completely agree with everything Dr. MacCready has said, but I feel that an even stronger statement could be added. In my considered opinion the proposal to grant a license for the PKU kit to a private commercial firm,[1] with exclusive marketing rights for 5 years, would be against the public interest and would be contrary to the existing principles regarding patents and similar "exclusive rights" provisions.

The proposal is against the public interest because it could furnish the basis for a costly monopoly on an essential public health supply item, and because, I am certain, the granting of such exclusive rights for a device developed with the support of an NLH research grant would be contrary to the spirit—if not the letter—of the unwritten rules that govern the use of such public money.

The proposal would, in my opinion, be unallowable because the device and the procedure in question have been in the public domain for well over a year,

[1] Your letter says "Miles" but it has been my understanding that the Ames Co. was scheduled to be granted the exclusive rights in this case. They already have a "kit" on the market.

hence the granting of exclusive rights to any one firm would violate the spirit, if not the letter, of the laws governing such arrangements.

My legal references and opinions may be subject to legal question since I am not a lawyer. However, I believe that the views I express are shared by the majority of scientists, health workers, and educators, and I imagine that most lay persons would take the same position as regards public policy and the public interest.

Sincerely yours,

GEOFFREY EDSALL, M.D.,
Superintendent, Institute of Laboratories.

U.S. GOVERNMENT MEMORANDUM

MARCH 25, 1964.

Case No.: N-G116-62.
Grants B-1960 and B-3935.
To: Mr. Herschel Clesner, Inventions Coordinator, PHS.
From: Miss Katharine A. Parent, special assistant for extramural patents, DRG.
Subject: Grantee Invention—GUTHRIE, Children's Hospital, Buffalo. "Bacteriologic testing method ('inhibition assay') for estimating the level of phenylalanine in blood":

Attached is a determination on the subject invention. The invention report was not subjected to independent scientific review because of the involvement of the Children's Bureau and the National Institute of Neurological Diseases and Blindness. Also, the question of patenting was not an issue, since patent application had been filed before submission of the invention report.

Support background is as follows:

PHS support:	
B-1960: Jan. 1, 1959-Dec. 31, 1963	$152,375
B-3935: Dec 1, 1961-Nov. 30, 1963	99,325
Committed support	None
Other support:	
NARC: Sept. 1, 1958-Aug. 31, 1963	25,000
AACC: Sept. 1, 1958-Aug. 31, 1963	25,000
Commercial Solvents Corp.: Mar. 1, 1962-Feb. 28, 1963	15,000
National Foundation: Jan. 1, 1962-June 30, 1963	20,672
Playtex Foundation: Oct. 1, 1958-Sept. 30, 1960	15,000
Children's Bureau: Indeterminate amount of funds allocated to State programs for field trial of the kits	?

Comments: It should be noted that we requested a formal report of invention from Dr. Guthrie on January 10, 1962. We did not, however receive the report until December 14, 1962, after four followup letters and telephone conversations. Please also note that the patent application was filed by their attorney on April 16, 1962, 4 months following the first request for a formal invention report and 7 months prior to submission of the report.

MARCH 30, 1964.

MISS KATHARINE A. PARENT,
Division of Research Grants, NIH, Through: Dr. Eugene Confrey, Chief, DRG, NIH, and Norman J. Letker, Patent Adviser, OD, NIH:

Grantee invention—Guthrie, Children's Hospital, Buffalo: "Bacteriologic Testing Method (inhibition assay) for Estimating the Level of Phenylalanine in Blood."

Your determination on the disposition of invention rights for this major breakthrough indicates that the grantee's request for a period of exclusive patent rights have been subjected to a thorough evaluation and is denied. Your determination further indicates that U.S. patent application, Serial No. 187,707 should be asigned to the U.S. Government.

There is nothing in the file indicating upon what your evaluation and determination is based. Further, there is no indication as to the disposition of foreign patent rights which are equally as important as the domestic rights. Has Miles Laboratories filed in foreign countries?

What are your intentions as to reimbursing Miles Laboratories for their cost of patent preparation? This is a cost that the Government would obviously had to have incured if Miles had not filed. (This is exactly the same situation ignored in the McKean case.)

Has Miles incurred expenses for a new drug application? If so, have you investigated our obligation for reimbursing them? This, again is an expense that the Government would have had to incur if Miles had not.

Your determination in essence destroys an investment by Miles Laboratory that is in the thousands of dollars, yet you provide not a word justifying the Government's position (your position).

APRIL 1, 1964.

Re N-G116-62.

To: NORMAN J. LATKER, Patent Adviser, OD, NIH.

From: Miss Katharine A. Parent, Special Assistant for Extramural Patents, DRG, NIH.

Subject: Grantee Invention—Guthrie, Children's Hospital, Buffalo: "Bacteriologic Testing Method ('Inhibition Assay') for Estimating the Level of Phenylalanine in Blood."

In view of your memorandum of March 30, 1964, regarding the determination made on the Guthrie case, Children's Hospital, Buffalo, the determination is being sent direct to Mr. Clesner along with a copy of your memorandum, since the questions raised were answered many months ago; in fact many months before you joined the National Institutes of Health.

I should like to make the following comments: (1) There is no mutuality between the Public Health Service and Miles Laboratories. We made no arrangement with them to file patent application. We were not a party to any agreement between the grantee institution, the investigator, and Miles Laboratories. This whole arrangement was a fait accompli when we finally got our invention report. I do not believe, therefore, that we are under any obligation to reimburse Miles Laboratories for anything. (2) There is, in my opinion, absolutely no analogy between the Guthrie case and the McKean case. (3) The State of Massachusetts has been manufacturing and distributing their kits to hospitals in the State for many months. This type of screening is mandatory in Massachusetts hospitals. The New York State Legislature has just passed a bill making such tests mandatory in New York hospitals. A number of other States are contemplating setting up this type of screening. (4) No further development needs to be done by Miles or any other one commercial firm to market the kits. It has been completed; hence the terminology in the determination. (5) Miles intended to charge an exorbitant price for their kits—40 times what it cost Dr. Guthrie to produce the kits for the field trials. Under the circumstances, there appears to be no justification for an exclusive license to Miles.

MAY 25, 1964.

Case No. N-C116-62.

DR. MOIR F. TANNER,
Director, The Children's Hospital,
Buffalo, N.Y.

DEAR DR. TANNER: Reference is made to the report of invention titled "Bacteriologic testing method (inhibition assay) for estimating the level of phenylalanine in blood," developed by Dr. Robert Guthrie during course of work under Public Health Service research grant B-1960.

It is my understanding that patent application, Serial No. 187,707, was filed on April 16, 1962, 7 months prior to submission of the formal report of invention. The Service was notified of this filing on October 23, 1962. It is also my understanding that an agreement was made between Dr. Guthrie and Miles Laboratories, Inc., dated June 11, 1962, relating to the tests for estimating the level of phenylalanine in blood. Copies of the patent application and the agreement have been made available to the Public Health Service.

The agreement under which funds were made available for the support of the research from which this invention arose provides that the applicant will refer to the Surgeon General, for determination, the question of whether such invention should be patented and the manner of obtaining and disposing of the proposed patent in the public interest. This responsibility is exercised in accordance

with general policy directives included in the enclosed patent regulations of the Department of Health, Education, and Welfare.

Section 3.2(b) of the regulations provides that an invention may be assigned to a competent organization for development and administration, if it is determined that the invention thereby will be more adequately and quickly developed for widest use and that there are satisfactory safeguards against unreasonable royalties and repressive practices. Consideration of such a determination by the Surgeon General requires the submission of an acceptable proposal laying a factual basis for assignment of an invention to a grantee institution for administration. The proposal submitted in your letter of August 12, 1963, has been subjected to a thorough evaluation. As a result of this evaluation, I have concluded that the proposal does not meet the criteria of section 32(b) and that the best interests of the public will not be served by granting an exclusive license to a single manufacturer: rather, the invention should be offered to any qualified manufacturer, health service, or laboratory interested in carrying out the program necessary to manufacture or distribute the PKU kit for the market.

In the light of the foregoing conclusions and consistent with section 8.2(d) of the Department regulations, it is my determination that insofar as the invention may be patentable, the equitable ownership of all rights, both domestic and foreign, shall be in the United States, and that assignment of rights in U.S. patent application, serial No. 187,707 filed on April 16, 1962, shall accordingly be obtained. The form of assignment to be executed by the inventor is enclosed. It is my further determination that based on the possible public health significance of this invention, patent protection is in the best interest of the public. The Public Health Service will arrange for the necessary prosecution of U.S. patent application, serial No. 187,707.

Pursuant to this assignment and in accordance with the patent policy of the Department of Health, Education, and Welfare, licenses under the patent application or any patent which may issue thereon will be granted by the Department to all applicants on a nonexclusive, revocable, royalty-free basis, subject only to such controls as to condition of manufacture and quality of the product as may appear needed to protect the public interest.

You are requested to acknowledge receipt of this determination by signing and returning one copy to the Special Assistant for Extramural Patents, Division of Research Grants, National Institutes of Health, Bethesda, Md., 20014. Please include with the signed determination (1) as original and three copies of the duly executed assignment to the Government, (2) a substitute power of attorney to our patent attorneys on the attached form to be signed by your patent attorney, and (3) copies of all actions taken thus far on U.S. patent application, serial No. 187,707.

Sincerely yours,

DAVID E. PRICE,
Acting Surgeon General.

U.S. GOVERNMENT MEMORANDUM

OCTOBER 9, 1964.

To: Files.
From: Mr. Clesner.
Subject: Guthrie.

Many have urged obligatory PKU blood tests for newly born babies.

The test is the Guthrie bacteriologic test (inhibition assay) for estimating the level of phenylalanine in blood.

The test is extremely important as a diagnostic aid for the detection of the condition of phenylketonuria, which mental disease, while having a low incidence rate, has serious consequences both to the individual concerned and to society in general. The mental retardation caused by this disease can be completely prevented by use of a low phenylalanine diet which has been available in the United States and abroad for several years. However, to be completely effective the diet must be started within the first 1 to 3 months of life. It is this early diagnosis which is the purpose of the mass screening of newborn infants before leaving the hospital nursery a procedure made possible for the first time by the "inhibition assay" procedure for blood phenylalanine. The test has application both in this country and foreign countries, since the gene for phenylketonuria has worldwide distribution.

The test was developed with the following support background as indicated by official NIH grant files.

Public Health Service:	
Grant No. B–1960 (National Institute of Neurological Diseases and Blindness) Jan. 1, 1959, to Dec. 31, 1963	$152,375
Grant No. B–3935 (National Institute of Neurological Diseases and Blindness) Dec. 1, 1961 to Nov. 30, 1963	99,325
Total	251,700
Other support:	
National Association for Retarded Children Inc. (NARC) Sept. 1, 1958, to Aug. 31, 1963	25,000
Association for the Aid of Crippled Children (AACC) Sept. 1, 1958, to Aug. 31, 1963	25,000
Other possible support:	
Commercial Solvents Corp., Mar. 1, 1962, to Feb. 28, 1963	15,000
National Foundation, Jan. 1, 1962, to June 30, 1963	20,673
Playtex Foundation, Oct. 1, 1958, to Sept. 30, 1960	15,000

Children's bureau up to November 1963. Not disclosed in NIH records.

Approximately $492,000 has been utilized in order to develop, promote, distribute, and try out these kits when the field trials, involving 33 States and approximately 600 hospitals, are completed.

Dr. Guthrie did not voluntarily forward to the Public Health Service an invention report as required by PHS grant agreements B–1960 and B–3935. A formal invention report was requested of Dr. Guthrie on January 10, 1962. After four followup letters and innumerable telephone conversations an invention report was received from him on December 14, 1962. In the interim, patent application serial No. 187,707 relating to this invention was field in Dr. Guthrie's name on April 16, 1962. This was 4 months following the initial request for a formal invention report and 7 months prior to the actual submission of the invention report. Shortly thereafter Dr. Robert Guthrie entered into an exclusive licensing agreement for the life of the patent with Miles Laboratories which was approved by two voluntary health associations involved, but not by the Public Health Service. The agreement called for royalty proceeds (a small percentage of net sales) that may result from the license agreement to be assigned to one or more of the sponsoring charitable organizations. Dr. Guthrie and Children's Hospital of Buffalo petitioned the Public Health Service to leave exclusive rights to Miles. No reference was made of the massive Children's Bureau contribution. Study disclosed that Ames Division of Miles Laboratories intended to sell the test kit for 40 times the price that Guthrie and Children's Hospital of Buffalo, N.Y.; Massachusetts State Public Health Biological Laboratories; and other contractors were charging the Children's Bureau. Therefore, if such a patent issued with such an exclusive license, Miles Laboratories could have excluded all other, including the Massachusetts State Public Health Biological Laboratories, from manufacturing, distributing and using the test kits or force all others to pay substantial royalties to Miles.

The States of Massachusetts and New York presently require this PKU blood test to be given to all infants newly born in the respective States. The Massachusetts State Public Health Biological Laboratories provides these kits for use of Massachusetts hospitals and doctors. Upon disclosure of the amounts that Miles intended to charge for the test kit. Dr. Guthrie became helpful in attempting to destroy his existing, though non-Public Health Service ratified, agreement with Miles.

He further orally disclosed that the patent application was filed by a patent attorney who was hired by the State university system of New York for this purpose but who actually was Miles' outside patent attorney. He and the children's hospital also orally refuted their petition to the Public Health Service that Miles be given an exclusive license. He also disclosed that three or more companies were interested in obtaining a license and producing the kits at cost similar to his own. Accordingly, the Public Health Service (Deputy Surgeon General) determined that ownership to the invention belonged to the United States and an assigment to the patent application has been since received and recorded.

The patent advisor, NIH, objected to this determination stating that there is nothing in the file (without reading the file) to indicate the basis of the evaluation and determination, nothing to indicate the disposition of the foreign rights, even though the publications present in the grant file and referred to in

the determination file were sufficient to bar filing in most foreign countries. He indicated that the Government should reimburse Miles for the cost of patent preparation even though there is nothing of record to indicate that Miles paid such costs or was a party in interest to such filing. He also raised the question whether Miles had incurred expenses for a new drug application and, if so, has the PHS investigated our obligation to reimburse them stating "This, again, is an expense that the Government would have had to incur if Miles had not."

"Your determination in essence destroys an investment by Miles Laboratories that is in the thousands of dollars, yet you provide not a word justifying the Government's position."

In answer to these objections the Special Assistant to the Chief, DRG, NIH, pointed out:

"(1) There is no mutuality between the Public Health Service and Miles Laboratories. We made no arrangement with them to file patent application. We were not a party to any agreement between the grantee institution, the investigator, and Miles Laboratories. This whole arrangement was a fait accompli when we finally got our invention report. I do not believe, therefore, that we are under any obligation to reimburse Miles Laboratories for anything. (2) There is, in my opinion, absolutely no analogy between the Guthrie case and the McKean case. (3) The State of Massachusetts has been manufacturing and distributing their kits to hospitals in the State for many months. This type of screening is mandatory in Massachusetts hospitals. The New York State Legislature has just passed a bill making such tests mandatory in New York hospitals. A number of other States are contemplating setting up this type of screening. (4) No further development needs to be done by Miles or any other one commercial firm to market the kits. It has been completed; hence the terminology in the determination. (5) Miles intended to charge an exhorbitant price for their kits—40 times what it cost Dr. Guthrie to produce the kits for field trials. Under the circumstances, there appears to be no justification for an exclusive licence to Miles."

Mr. MANUEL B. HILLER,
Department Patents Officer.
HERSCHEL F. CLESNER,
Inventions Coordinator, PHS:

Inventions derived from cosponsored PHS and other DHEW research support.

This will confirm our recent telephone conversations in which you were advised that there are examples of inventions derived from cosponsored "PHS and other DHEW agencies" where the other DHEW agency did not utilize a patent clause, whereas PHS did.

This is difficult to explain to the institution and the grantee investigator when they ask why. This also makes it difficult to require reporting of such inventions.

You asked for actual examples. The best and most readily available example is the Guthrie case. There are at least four inventions involved: (1) the Guthrie inhibition assay test for phenylketonuria, (2) the Guthrie inhibition assay test for maple sirup disease, (3) the Guthrie inhibition assay test for galactosemia, and (4) the Guthrie inhibition assay test for histidimemia.

The background support for Dr. Guthrie is as follows:

Public Health Service support:

B–1960; Jan. 1, 1959–Dec. 31, 1963	$152,375
B–3935; Dec. 1, 1961–Nov. 30,, 1963	99,325
No known committed support after Dec. 31, 1963.	
Total Public Health Service support	251,700
Other DHEW support, Children's Bureau, approximately	492,000
Total DHEW support	743,700
Other support:	
NARC, Sept. 1, 1958–Aug. 31, 1963	25,000
AACC, Sept. 1, 1958–Aug. 31, 1963	25,000
Commercial Solvent Corp., Mar. 1. 1962–Feb. 28, 1963	15,000
National Foundation, Jan. 1, 1962–June 30, 1963	20,672
Playtex Foundation, Oct. 8, 1958–Sept. 30, 1959	15,000
Total other than DHEW support	100,672

Initially, Dr. Guthrie did not submit a formal report of invention. A formal report of invention was requested from Dr. Guthrie on January 10, 1962, by the Division of Research Grants, NIH. The report was received on December 14, 1962, after four follow-up letters and telephone conversations. The patent application was filed by the patent attorney associated with Miles Laboratories, on April 16, 1962, 4 months following the first request for a formal invention report and 7 months prior to the submission of the report.

Although Dr. Guthrie has orally informed us that he has also conceived and reduced to practice assay tests for maple syrup disease, galactosemia and histidimenia, the Public Health Service has never received invention reports concerning these tests. The Children's Bureau issued the following report: "A Report on Children's Bureau Health Service Activity under the 1963 Amendments to the Social Security Act." This publication discloses the referred to tests on page 9. The bibliography or reference list on pages 18 and 19 indicates publication or immediate publication for these tests. The tests for maple syrup disease and galactosemia are already being conducted as of August 19, 1964, on newborn infants in Massachusetts in connection with the Massachusetts phenylketonuria detection program. As the Public Health Service support expired as of December 31, 1963, it is possible that the latter three inhibition tests were conceived and reduced to practice under Children's Bureau tests were conceived and reduced to practice under Children's Bureau support rather than the PHS support.

All the tests relate to the inborn errors of metabolism which may cause early death or mental retardation among survivors. If detected early, these conditions can be prevented by early treatment. It should be expected that all the tests, if found to be as practical or reliable as the phenylketonuria test, would find widespread use both in domestic and foreign programs. At present, the phenylketonuria tests is required either mandatorily or permissibly by approximately 10 States or areas.

Under all the circumstances it appears that the Public Health Service and other Department of Health, Education, and Welfare policies and practices ought to be as consistent as possible with one another and that cooperation should exist in order to carry out DHEW responsibilities.