



UNIVERSITY PATENTS, INC. · 2777 SUMMER STREET · STAMFORD, CONNECTICUT 06905 · (203) 325-2285

Cables: UPATSTAMCO

June 26, 1978

PATENT BRANCH, OGC  
DHEW

JUL 3 1978

Norman J. Latker, Esq.  
Office of General Counsel  
Department of Health, Education  
and Welfare  
Westwood Building, Room 5A03A  
5333 Westbard Avenue  
Bethesda, Maryland 20014

Dear Mr. Latker:

I am writing to call to your attention a situation which we believe undermines one of the principal reasons why the Government supports medical investigation; namely, that the work product be brought to the marketplace for the public welfare. Specifically, reference is made to intolerably long periods of time between submission of Petitions for Greater Rights for DHEW funded inventions and the receipt of definitive responses from the Agency.

As we are well aware, universities which have Institutional Patent Agreements have the power, upon identification and evaluation of an invention technology, to seek patent protection and to present it to the marketplace without extensive delay. These capabilities are of greatest significance when the investigator (as is his right) elects to publish his findings promptly. In cases where Petitions are required and DHEW fails to make its determinations known in a timely fashion, early publication destroys available foreign protection, and inordinate delays (some of which are evidenced below) jeopardize sound evaluation and may cause the loss of domestic patent protection as well.

We believe you will agree that most medical technologies, because of the enormous developmental expenses required of a licensee, must be protected by patents. When patent rights are lost through DHEW delay, the invention is unlikely to obtain commercial development. Consequently, the public's investment in funding the research is wasted.

We are listing below several technologies for which Petitions for Greater Rights have been filed, and the particulars relating to them.

1152  
File  
w/ Watson

1. University of Illinois Foundation, No. UIF 1549 - Isolation, Structure and Synthesis of Jacaranone, an Anti-Cancer Agent (Farnsworth, Cordell and Ogura).

The subject disclosure was forwarded to UPI on February 19, 1976 with information that it had been funded by a contract from National Cancer Institute, and that a paper had already been submitted for publication. Because the University IPA did not extend to contracts, a Petition for Greater Rights was deemed necessary since the invention showed promise of becoming a significant chemotherapeutic agent. A Petition was mailed on May 7, 1976. After a patentability search was completed, a nonconfidential, nonenabling presentation was prepared and submitted to thirty-five companies in October, 1976. Affirmative responses were had from eighteen companies requesting copies of the patent application. In late 1976, four companies requested samples for testing in their own facilities. Samples were finally provided through NCI in early summer of 1977, and testing concluded that the compound was not sufficiently advantageous to warrant licensing.

It should be noted that as of this writing, no final determination has been received to this Petition, twenty-five months after it was submitted. If one or more of the companies who tested the compound had become interested in licensing, the University would have been unable to proceed. In view of the varied investment demands upon a potential licensee, the opportunity to make a firm agreement might have been lost waiting for the DHEW final decision. In this case, UPI invested in a patent application without knowledge of whether it would ever have rights to transfer. It still doesn't know, although the question may be moot because of the inefficacy of the compound. UPI, with rare exceptions, will no longer invest in patent filings without prior assurance of licensable title.

2. (a) University of Arizona, No. UA 299 - New Process for the Synthesis of Amikacin (Remers and Kumar).

The subject disclosure was forwarded to UPI on May 31, 1977. A Petition for Greater Rights was submitted on July 20, 1977. No response has been received, other than a request for the clarification of two answers, provided in August, 1977.

(b) University of Arizona, No. UA 302 - Synthesis of Butirosin B and Analog (Remers and Kumar).

The subject disclosure was received by UPI on June 7, 1977. A Petition for Greater Rights was submitted on April 20, 1978. No response has been received.

(c) University of Arizona, No. UA 365 and UA 375(A) - New Mitomycin Antitumor Agents (Remers).

These disclosures were received on December 14, 1977 and March 30, 1978, respectively, and a joint Petition for Greater Rights was filed on April 20, 1978. No response has been received.

The foregoing group of disclosures represent improvements and variations in an on-going program with aminoglycoside antibiotics. Since the inventor has a relationship with Bristol Laboratories, his work has been screened by them as it has materialized. No patent applications have been filed on any of these inventions, and none will be filed by the University or UPI, unless DHEW first releases title to the University. In the event Bristol determines that one or more of the foregoing merit intensive research and development, no program can be initiated until we, and Bristol, know that licensing will take place. Not until DHEW acts, will this be determined.

3. University of Arizona, No. UA 294 - Predictive Bioassay for Human Anticancer Treatment (Salmon and Hamburger).

The subject disclosure was forwarded to UPI on April 26, 1977. A Petition for Greater Rights was filed on July 20, 1977. No final response has been received to date. An article which described the technology was published in SCIENCE in July, 1977. UPI submitted a presentation of the work to fifty-three potential licensees in early August, 1977, accompanied by reprints of the above-mentioned article. Evidence of interest was clear, although many believed the work was too early in its development to merit investment in licensing. The patent filing dilemma was pinpointed by DHEW's letter to the University on September 9, 1977, in which it was stated that further action would be deferred "until supplemental information was received." The inventors were working, but there was no assurance of when sufficient information to meet NCI's judgmental standards would be available. We do not yet know if the materials submitted by the inventors as late as May 1, 1978 satisfied those demands.

UPI was of the opinion initially, and remains of the opinion, that the subject work may be of the greatest value. If it had rights, UPI would have filed for patent protection. An indication of peer recognition of the inventors' efforts is attested by an article by them on this subject published this month in the prestigious New England Journal of Medicine.

Technicon Instruments Corporation, one of the firms to whom the technology was presented, has constantly monitored the work, through direct contact with the inventors. It is noteworthy that Technicon has evidenced a very strong degree of interest in the progress which has been made. We believe a research and development contract, incorporating a license for commercialization, could be negotiated with Technicon, if the University was able to assure rights.

4. Arizona State University, No. ASU 111 - Isolation and Characterization of Sphyrnastatins 1 and 2 (Pettit and Ode).

The disclosure was received by UPI on December 27, 1976. Publication was made on May 11, 1977. A Petition for Greater Rights was filed on May 12, 1977. A decision, that the Government would retain rights, would not patent and considered the aforementioned publication sufficient, was rendered on May 2, 1978. We believe that this technology was not of sufficient merit to warrant protection and agree with the DHEW conclusions. However, we would point out that if it was, indeed, of great value, the time at which a decision was rendered was almost precisely one year after the enabling publication: patent rights, both domestic and foreign, were forfeited. If DHEW had rendered its decision promptly after receipt of the Petition, we might have been able to obtain industrial screening and evaluation in time for protection to have been obtained-- had that been shown to be appropriate.

5. Arizona State University, No. UA 113 - Isolation and Characterization of Strongylostatin (Pettit, Herald, Ode and Vanell).

The disclosure was received by UPI on February 22, 1977. A Petition for Greater Rights was filed June 13, 1977. No response has been received. There has been no publication (to our knowledge) of this work.

6. University of Arizona, No. UA 165 - Breast Cancer Detection: Method, System and Apparatus (Boone).

The subject disclosure was forwarded to UPI on June 20, 1974. A patent application was filed at UPI's expense on September 22, 1975. A Petition for Greater Rights was submitted on April 22, 1977, as well as a Petition for an exclusive license to U.S. Patent No. 3,960,138, which is assigned to the DHEW. However, during July of 1977, it was determined that no DHEW funds were used in either the conception or reduction to practice of the subject disclosure. A letter was written on June 22, 1977 withdrawing the University's waiver petition but reemphasizing its request for an exclusive license to U. S. Patent No. 3,960,138.

The technology relates to a special brassiere that is outfitted with a temperature sensor and a data storage device. Thus, the brassiere may be utilized in the detection of breast cancer in high risk patients.

The subject disclosure is in interference with the Government's issued patent. There appears to be a question of derivation on the part of the Government employees (inventors of U. S. Patent 3,960,138) from the University employees/inventors (see file affidavits).

At the time of our original waiver request, UPI had one potential licensee. Due, in part, to the long determination time taken by DHEW, the licensee has lost interest in pursuing this project further. To date, we have had no formal response from DHEW on this subject.

7. University of Arizona, No. UA 277 - Birefringent Optical Thermometer (Cetas).

The subject disclosure was forwarded to UPI on September 28, 1976. The original device, a Birefringent Crystal Thermometer, was conceived, assembled and a patent application filed therefore, while Dr. Cetas was an employee of the National Bureau of Standards working under a contract with the Bureau of Radiological Health, FDA, DHEW. Dr. Cetas felt that the original thermometer, as disclosed in the DHEW patent application (Ser. No. 660,349) was not sufficiently stable for practical commercial production. Therefore, after joining the University of Arizona, Dr. Cetas continued to do development work on the thermometer to overcome the stability problems. As a result of his efforts, an improvement utilizing the teachings of his original invention was conceived and reduced to practice. The University, desiring to establish the strongest possible patent position so that a successful licensing effort could be mounted, decided (after a meeting with you) to file a C.I.P. to the original application, rather than filing a new application on the improvement. Thus, the C.I.P. was assigned: 1/2 to the Government and 1/2 to the University. UPI is presently paying the expenses involved in prosecuting the application.

A request for an exclusive license with the right to sublicense under the Government's 1/2 interest in the C.I.P. was made on May 31, 1977.

Technicon Instruments Corporation, one of the firms to whom the technology was presented, has evidenced a very strong interest in the technology. A research development contract, incorporating a license for commercialization, could be negotiated if the University's petition is granted. Further delay by DHEW in its determination could jeopardize the transfer of this technology.

Norman J. Latker, Esq.

June 26, 1978

Page Six

8. University of Colorado, No. CU 10 - Optical Cell for Spectroscopy Studies of Oxygen Binding to Hemoglobin (Mahoney).

The subject disclosure was forwarded to UPI on September 20, 1976 and publication of the technology was made on June 30, 1977. A Petition for Greater Rights was filed on August 10, 1977.

The invention deals with a thin-layer sample cell for the examination of the spectra of hemoglobins at various degrees of gaseous-ligand saturation.

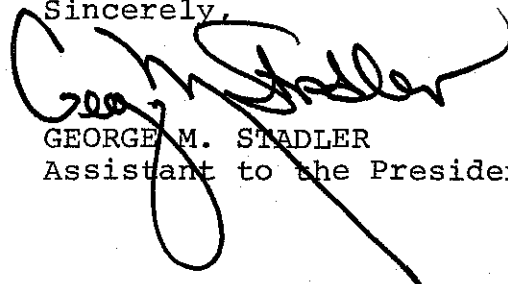
Due to DHEW's delay in the subject waiver determination, there is not enough time to properly protect the invention. It will be dedicated to the public. Since there is no patent protection, the chances of eventual commercialization are remote.

In addition to the foregoing, it is our understanding that two of our client universities--University of Arizona and the University of Chicago--have filed applications for an IPA with the DHEW, having met all the department's (DHEW's) requirements for the IPA. Neither University has received an approved Agreement. Since the DHEW has granted and administers over 70 similar agreements with U. S. universities, I do not think the delay in granting the IPA's to the University of Arizona and the University of Chicago is justifiable. These two Universities, in my opinion, are being discriminated against. Their only alternative appears to be bringing this matter to the attention of their Congressional representatives to obtain expeditious determinations.

In closing, I would like to emphasize that UPI has long enjoyed an excellent working relationship with your office. It has only been quite recently that we have noticed delay or impedance to the technology transfer process rather than promotion of the flow of technology to the public.

If there is anything that I can do to help expedite the decision-making process, please let me know. After all, the real winner in the transfer of Government developed technology is the public.

Sincerely,



GEORGE M. STADLER  
Assistant to the President

GMS: sb