



COUNCIL ON GOVERNMENTAL RELATIONS

Eleven Dupont Circle, Suite 480 Washington, D.C. 20036 (202) 861-2595

Bumer

January 26, 1984

TO: Patents, Copyrights and Rights in Data Committee
FROM: Milton Goldberg *MG*
SUBJECT: Cisplatin

On April 4, 1983 COGR responded to a solicitation for public comment as to whether Bristol-Myers should receive a seven year extension of its exclusive license to make, use and sell Cisplatin compounds as anti-cancer agents. COGR supported the Bristol-Myers request. Our letter is attached.

DHHS has ruled in Bristol-Myers' favor, but extended exclusivity for only five years rather than seven and did so with certain conditions, including one to monitor expenditures for research.

I will send you the details when they are made available.

Enclosure

cc: Sheldon Steinbach, ACE
Thomas Kennedy, AAMC
V. Wayne Kennedy

COGR

an organization of research universities

COUNCIL ON GOVERNMENTAL RELATIONS

Eleven Dupont Circle, N.W., Suite 480
Washington, D.C. 20036
(202) 861-2595

April 4, 1983

BOARD OF MANAGEMENT
KENNETH W. SLOAN, CHAIRMAN
The Ohio State University

LESTER H. BURY
University of Alabama
in Birmingham

RAYMOND J. CLARK
Princeton University

STUART H. COWEN
Massachusetts Institute
of Technology

ROGER G. DITZEL
University of California
Systemwide Administration

GENE A. FRICK
Purdue University

RONALD GEBALLE
University of Washington

ANN H. GREENBERG
New York University

J. ROBERT R. HARRISON
University of Delaware

V. WAYNE KENNEDY
University of California
at San Diego

ANTHONY MERRITT
University of Pennsylvania

JULIE T. NORRIS
University of Houston

THOMAS O'BRIEN
Harvard University

DON S. OUSTERHOUT
University of Arkansas

CORNELIUS J. PINGS
University of
Southern California

ROBERT B. PRICE
The University of Texas
Health Science Center
At San Antonio

THOMAS E. STELSON
Georgia Institute of
Technology

RICHARD L. VAN HORN
Carnegie-Mellon University

EXECUTIVE DIRECTOR
MILTON GOLDBERG

ASSISTANT EXECUTIVE
DIRECTOR
GEORGE B. BUSH

Mr. Leroy Randall
Chief, Patent Branch
Office of the General Counsel
National Institutes of Health
Westwood Building, Room 5A03
Bethesda, Maryland 20205

Dear Mr. Randall:

This letter responds to the solicitation for public comments published in the Federal Register, Friday, February 4, 1983 on whether the government should approve a seven year extension of an exclusive license issued to Bristol-Myers Company to make, use and sell cisplatin compounds as anticancer agents.

The three specific questions proposed by the Department are treated below:

1. Would the public best be served by extending the existing exclusive license to Bristol-Myers to further develop the product?

It is the collective conclusion of the universities which are members of the Council on Governmental Relations, an organization of 120 leading research universities, that extension of the license would best serve the public. The reasons for this conclusion are the following:

a. It is our understanding that Bristol-Myers under an extension of the exclusive license is willing to commit additional millions for needed research and development to explore and expand the application of cisplatin to the treatment of other types of cancers and that this effort would increase the use of the compound approximately nine-fold. Importantly, the increased usage is directly equated with the number of patients who could benefit from such treatment and who could be given some hope for the future.

b. The performance of Bristol-Myers under the exclusive license appears to have been exemplary. That Company spent substantial sums in developing the compound for use in the treatment of certain types of cancers and timely made the invention available to the public for its use and benefit.

Mr. Randall
Page Three
April 4, 1983

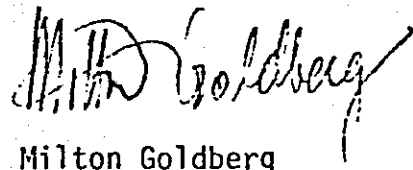
3. How should the government exercise its rights with respect to this invention in a manner that would best promote the public health?

COGR believes that public health would best be promoted by extending the exclusive license which Bristol-Myers now has for the following reasons:

- a. Bristol-Myers is willing to make a current substantial commitment to the additional research and development necessary to expand the uses of cisplatin against other forms of cancer.
- b. Bristol-Myers is in the position to expeditiously carry forward such research and development because of its past experience. Therefore, the public would have the benefit of access to the results of such research and development in the shortest possible time.
- c. The past record of Bristol-Myers under the exclusive licensing arrangement speaks loudly as to its capabilities, intentions and willingness to commit to a rather extensive research and development effort - an effort which is wholly in the public interest.
- d. The requested extension of time for the exclusive license is not for the remaining period of patent life and the further efforts by Bristol-Myers to expand the applications of cisplatin will permit the later entry of other companies into a broadened market.

In summary, and although there is a possibility that extension of the exclusive license might delay reductions in the cost of therapy utilizing cisplatin for the present patient population, extension of exclusivity would appear to be the only way to insure a timely commitment to further research and development necessary to benefit many more patients. In balance, the latter consideration outweighs the former and will permit the kind of continuing cooperative arrangement which will lead to full utilization of the potential of the technology which has been licensed to Bristol-Myers.

Sincerely,



Milton Goldberg