EXCLUSIVE AGREEMENTS BETWEEN FEDERAL AGENCIES AND BRISTOL-MYERS SQUIBB CO. FOR DRUG DEVELOPMENT: IS THE PUBLIC INTEREST PROTECTED?

HEARING

BEFORE THE

SUBCOMMITTEE ON REGULATION, BUSINESS OPPORTUNITIES, AND ENERGY

OF THE

COMMITTEE ON SMALL BUSINESS
HOUSE OF REPRESENTATIVES

ONE HUNDRED SECOND CONGRESS

FIRST SESSION

WASHINGTON, DC, JULY 29, 1991

Printed for the use of the Committee on Small Business

Serial No. 102-35

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

National Institutes of Health
National Cancer Institute
Bethesda, Maryland 20892

September 10, 1991

The Honorable Ron Wyden
Chairman
Subcommittee on Regulation,
Business Opportunities and Energy
B-363 Rayburn House Office Building
Washington, DC 20515

Dear Mr. Wyden:

It is our pleasure to respond to your request for additional information on the National Cancer Institute's (NCI) efforts with regard to the development of Taxol and the CRADA process. Although I was personally unable to testify at your hearing, I wish to thank you for giving Dr. Bruce Chabner, Director, Division of Cancer Treatment, NCI an opportunity to articulate NCI's commitment to drug development.

As you requested, enclosed is a folder of NCI's response to the questions you posed in your August 1, 1991 letter along with some additional background material. I hope this information addresses your concerns satisfactorily.

Perhaps we could take this opportunity to thank you for providing us an opportunity to clarify a number of issues that, in fact, could not have been presented in any other forum. We want you to know how important your support and the support of the other subcommittee members is to the success of the National Cancer Program.

Sincerely yours,

Samuel Broder

Samuel Broder, M.D.
Director
National Cancer Institute

Enclosure

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Question 5. One of the most important drugs for the treatment of ovarian cancer is cisplatin, which was originally developed with federal funds. The patent for cisplatin was licensed on an exclusive basis to Bristol-Myers Squibb for five years. In 1983, the federal government gave approval for a seven-year extension of the exclusive license to manufacture cisplatin, which was then the leading cancer drug in the United States. According to testimony at the hearing, the 1983 extension of Bristol-Myers' exclusive license was opposed by other drug companies, and was only granted after Bristol-Myers agreed to lower the price of cisplatin and fund additional cancer research. Please answer the following questions on cisplatin:

Answers (5a-i):

a. Please give the names of the drug companies that objected to the 1983 extension of the Bristol-Myers exclusive license.

Comments on the proposed extension of the cisplatin exclusive license were solicited from all interested parties. Please See "Request for Exclusive License Extension," 48 Fed. Reg. 5313 (February 4, 1983) (copy attached at Tab A). At least six companies applied for a license to cisplatin at that time:

(1) Adria Laboratories
(2) Stuart Pharmaceuticals
(3) American Cyanamid Company (Lederle)
(4) Elkins-Sinn, Inc.
(5) Andrulis Research Corporation
(6) Bristol-Myers Company

b. For how many years would Bristol-Myers have retained exclusive rights under the 1983 license extension?

Five. Please See "Decision to Extend Exclusive License," 48 Fed. Reg. 53,177 (November 25, 1983) (copy attached at Tab B). As indicated in the first paragraph of this document, the Department granted Bristol an extension of five years starting December 26, 1983.

c. Did the Bristol-Myers agree to lower the price of cisplatin in order to obtain the 1983 license extension? If so, please describe the terms of this agreement.

Yes. Please See "Decision to Extend Exclusive License," 48 Fed. Reg. 53,177 (November 25, 1983) (copy attached at Tab B). Paragraph seven of this document states that Bristol, in addition to undertaking extensive research on cis-platium, also agreed to reduce the price of cis-platium by over 30 percent during the extended period of exclusivity to reduce the cost to cancer patients.

d. Did Bristol-Myers agree to fund cancer research in order to obtain the 1983 license agreement? If so, please describe the terms of this agreement.

Yes. Please See "Decision to Extend Exclusive License," 48 Feb. Reg. 53,177 (November 25, 1983) (copy attached at Tab B). As indicated in paragraph five of Tab B, the Department felt that Bristol-Myers's proposed research and development plan met the public's need with regard to cis-platinum.

e. Testimony from the July 29 hearing suggests that Bristol-Myers agreed to finance $35 million in additional cancer research in order to obtain the 1983 cisplatin license extension, and that Bristol-Myers made regular reports to NCI explaining how this money was spent. What is the date of the last Bristol-Myers report to NCI on the progress of this research program? Did Bristol-Myers stop making these reports before it met its research commitment from the 1983 license extension? According to NCI records, how much of the Bristol-Myers research commitment was actually carried out?

The most recent report on the cisplatin research program was submitted to NCI on June 26, 1989. The report provides information about funds expended and committed for cisplatin research through December 31, 1988, the month in which the 1983 license extension expired. Bristol-Myers' reporting obligations under the 1983 license extension expired at the same time. The report shows expenditures and commitments in excess of those required under the 1983 license extension. Because some of the research grants made by Bristol-Myers were multi-year awards, certain research projects for which funds had been committed were still in progress at the time the report was filed.

f. In 1987, Bristol-Myers was given an extension of the cisplatin exclusive license for the remaining life of the patent. Please describe the circumstances under which this license extension was approved. Did any drug companies object to this extension? Did NCI provide notice of this license extension in the Federal Register? Did Bristol-Myers continue to report on research expenditures required under the 1983 license extension?

NCI had no role in the 1987 extension of the cisplatin exclusive license. With enactment of the "Trademark Clarification Act of 1984," Congress repealed prior restrictions on the length of exclusive licenses to federally-funded inventions. Since that time, grantees have had statutory authority to grant exclusive licenses for any period they wish, including the entire life of the patent. As a result of this change in the law, the government has no continuing role in the approval of exclusive licensing decisions made by grantees. Accordingly, NCI did not participate in the 1987 cisplatin license extension, did not

provide notice of that extension in the Federal Register, and has no records to indicate whether other drug companies objected.

g. What have Bristol-Myers' annual sales revenues from cisplatin been since 1983?

NCI does not have access to this information.

h. What is the average cost of a cisplatin treatment?

NCI does not compile or maintain this information.

i. Has the NCI ever asked Bristol-Myers to justify its price for cisplatin on the basis of the cost of producing the drug? If so, please elaborate on this request and any Bristol-Myers response.

No. NCI has no authority to enforce such a request.