

Firms Battle over Anticancer Drug

Over the past 5 years, Michigan State University has become nearly \$5 million richer, thanks to its ownership of a patented drug that was originally developed from federally supported research. It is one of only a few universities to reap a generous profit from publicly funded research. The source of its riches is a drug called cis-platinum, which has now become the biggest-selling anticancer drug in the United States. The phenomenal sales success of the drug has, however, sparked a heated battle over the arrangements under which Michigan State will license future rights to exploit its patent.

In 1977, Bristol Myers Company was awarded an exclusive license to manufacture cis-platinum, but the patent agreement expires on 26 December and five other companies have petitioned for a piece of the action. Michigan State would like to renew its exclusive arrangement with Bristol Myers, but under the terms of a patent agreement between the university and the federal government, the government has the final say on how patents derived from federally funded research are licensed. The federal government is using the contest over cis-platinum as a way to encourage private companies to do more research on the drug.

The stakes are high. According to David Saks, an analyst who follows the pharmaceutical industry for A. G. Becker, sales may reach \$65 million this year and \$100 million by 1985. Cis-platinum is the mainstay of therapy for testicular cancer and is also approved to treat ovarian and bladder cancer. The drug is also currently being tested against small-cell cancer of the lung and cancer of the prostate and cervix.

The National Institutes of Health (NIH) originally funded the research that led to the discovery of cis-platinum by Barnett Rosenberg and his colleagues at Michigan State. Michigan State gained title to the patent, taking advantage of a government policy that permits universities to retain patent rights and to assign exclusive licenses. This policy is intended to encourage the development of patents. The government policy stipulates, however, that when a license expires, the government has the right to rule whether or not it should continue to be exclusive. It is under this provision that the federal government is now involved with the Michigan State patent. According to officials at the Department of Health and Human Services (HHS), this is the first time that extension of an exclusive license has been challenged.

Michigan State and its manager of the patent, Research Corporation, contend that Bristol's exclusive license for cis-platinum should be renewed for seven more years. They say that renewal would maintain Bristol's incentive to conduct more research on the drug because the company's profits will not be undercut by increased competition. Department officials say this argument is reasonable but some speculate that the university and Research Corporation also do not want to risk losing royalties by dealing with a new cast of companies. Although John Cantlon, vice president for research at Michigan State and dean of graduate studies, declined to specify the exact royalty agreement with Bristol Myers, LeRoy Randall, chief counsel at the NIH patent branch, says that institutions normal-

ly receive about 5 percent of the profits. If HHS rules that a nonexclusive license should be issued, then new royalty contracts would have to be negotiated. As things stand now, Michigan State and Research Corporation "have a bird in hand," said one department official who is involved with the discussion.

In 1977, Bristol was virtually alone in its bid for the cis-platinum license. Now five companies are challenging the renewal of its license, including Lederle Laboratories, and Adria, the maker of Adriamycin, which until last year was the top selling anticancer drug. The companies argue that Bristol Myers has enjoyed protection of its product for 5 years and that is long enough. They say that with several companies making the drug, research will become more diverse and productive. In addition, the price of the drug will drop for consumer and insurance companies. One small company, Andrulis Research Corporation, has suggested that Research Corporation require companies sharing the nonexclusive license to contribute to a common fund for cis-platinum research. The money would be managed by the National Cancer Institute or a private foundation.

Bristol, which is the leading manufacturer of anticancer drugs in the United States, acknowledges that the price of the drug will drop if it has to compete with other manufacturers. But it says that it can only continue the research if

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its profit margin is protected. Richard Crout, a former top official at the Food and Drug Administration and now head of the patent board at NIH, points out the research on a drug does tend to drop off once generic production has been approved. But he notes that recognition of a brand name product and more vigorous promotion of a product usually helps the principal drug maker maintain dominance in the market.

Two committees at NIH have reviewed the matter. An ad hoc committee, comprised of scientists from the National Cancer Institute, required all the companies to submit a research proposal for the drug and met with representatives of the various companies in June. The NIH patent board reviewed the committees' findings and then sent its recommendation on to HHS Assistant Secretary Edward Brandt. Top officials are still discussing the issue.

Cantlon of Michigan State said that, in his opinion, the other companies have not shown that they can carry out the necessary research. "If all of them could get together and do the research, that would be fine. The problem is that arrangement could lead to charges of collusion." He said Cecil Mackey, president of the university and a former government antitrust lawyer, is particularly sensitive to that issue. "We don't like to see a single company dominate the scene, but we can't see any alternative that will develop the drug's potential any better."—MARJORIE SUN