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NIH censured for Taxol deal

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US auditors released a study on Friday (June 6), criticizing the deal theNational Institutes of Health (NIH) struck with drug giant Bristol-Myers Squibb (BMS) to get the anticancer drug Taxol to market quickly.

The report by the General Accounting Office (GAO) said NIH's pact with Bristol-Myers Squibb recovered only $35 million in royalty payments for Taxol after taxpayers spent $484 million to develop the best-selling cancer drug in history.

Further, federal auditors said NIH failed to get adequate proof that BMS would sell Taxol at a reasonable price before handing over exclusive rights to make and market the drug developed by government-funded research. The company's sales revenue from Taxol was $9 billion between 1993 and 2002.

In a response, NIH said the auditors failed to recognize all the public benefits derived from NIH funding of the basic science behind paclitaxel, the active compound in Taxol. The GAO failed, for example, to include in its computations the $400 million in royalties Florida State University collected for a method to manufacture Taxol, the NIH response said.

"Our company met or exceeded every responsibility under the agreement [with NIH]," BMS spokesman Robert Hutchison said, commenting on the GAO report. "We are proud of our history with Taxol."

GAO's critique of the bargain NIH struck comes in the wake of settlements ending litigation that pitted all 50 states, five territories, and the District of Columbia, as well as hospitals and insurance companies, against BMS over the high price of Taxol. Those suits and an action by the Federal Trade Commission (FTC) accused the company of abusing the legal process to prolong its profitable monopoly on Taxol sales in the United States.

When NIH struck its deal with BMS in 1991, neither the federal agency nor anyone else knew the company planned to pursue patents on Taxol, said Meredyth Andrus, assistant attorney general in Maryland and one of the lead attorneys in the case against the drug maker.

"The negotiations with NIH were based on the fact that generics were going to come on the market once the 5-year period of exclusivity was over, so Bristol-Myers needed a price that would enable them to recover their marketing and manufacturing costs," Andrus said. "Everybody expected that would happen."

It did not happen because BMS was able to use its allegedly baseless patents to keep generics out of the market for years.

The GAO's report comes out as Canadian lawmakers wrestle over a regulatory scheme that seems to have handed BMS a chance to replay a similar scenario north of the border—one in which it gets a monopoly on Taxol and puts a tiny Canadian competitor with a low-priced alternative out of business.

BMS admitted no wrongdoing in the series of US Taxol settlements, including a recent one in which it agreed to return $135 million to the states, hospitals, and insurance companies who claim they were bilked on the price of Taxol. In April,the company came to terms with the FTC and agreed to refrain from asserting Taxol-related patents against generic rivals as part of a deal to end accusations that it had pursued baseless patents on the drugs after promising the NIH it would not and that it had used the patents to keep others out of the market.

But BMS is using patents it took out on Taxol in Canada against Biolyse Pharma, which wants to offer its naturally derived paclitaxel to cancer sufferers. The US drug giant won court victories against Biolyse that have kept the rival out of the market for years. In Canada, as in the United States, patent holders can invoke special protections to hold generic drug makers at bay for years.

"It's the same story, Canadian version," said Biolyse President Brigitte Kiecken. "Except it's worse in this scenario because we did our own research—15 years of research on this product." Biolyse scientists ran their own clinical trials and created a drug that is not simply a generic version of Taxol, she said. "Health Canada from the start always considered our product a novelty and a new drug," Kiecken said. "It's manufactured from a different species, and they said we can't assume it's the same; we have to show safety and efficacy through separate clinical trials."

Biolyse is prepared to sell its natural paclitaxel at a price that is less than one third of the price BMS is charging in Canada, she added.

June 2–4 saw a series of hearings in the House of Commons Industry Committee in which critics pointed to BMS's grip on the Taxol market as evidence of flaws in the Canadian patent system. "What it comes down to is that Bristol is dictating to our health authorities who gets what cancer treatment and at what price," Kiecken said. BMS declined to comment on the Canadian dispute.

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