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Susan Taylor Martin

Special Report: The Fight Over Taxol

A drug company makes billions extra as cancer patients wait for a cheaper generic.

Washington Bureau Chief

By SARA FRITZ, Times Washington Bureau Chief



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© St. Petersburg Times published May 5, 2002

For more than two years, Bristol Myers Squibb Co. made \$5-million a day as the only company selling Taxol, a breakthrough drug in the treatment of breast and ovarian cancer.

It was a sweet windfall for Bristol because the giant drugmaker did not discover Taxol, nor did it hold an exclusive patent on it.

Developed entirely with taxpayer money, Taxol was given to Bristol by the U.S. government in the early 1990s in exchange for a promise that generic companies could enter the market at the end of 1997. But when the time came, Bristol instead mounted a cutthroat legal assault on its would-be generic competitors.

The government did nothing.

While the court battle raged, women with cancer were forced to pay more than \$8,000 -- twice the price of generics -- for an average Taxol treatment.

Did greed motivate Bristol to double-cross the government? Or did the company simply collect its due for the financial risk it took to bring a drug to market that saved countless lives?

* * *

The witches in Macbeth had it right when they included the bark of the yew tree in their brew. An evergreen with needle-like leaves, the yew could be poisonous or, as the Chinese and Native Americans found, it could treat ailments from arthritis to scurvy.

In 1962, 22-year-old Kurt Blum collected specimens from the Pacific yew and sent them to the National Cancer Institute, the government agency responsible for finding a cure for cancer. Blum was a foot soldier in the institute's effort to screen 35,000 plant species for possible anticancer compounds.

Using those specimens, two government-sponsored scientists discovered that an extract of the bark has antitumor properties. In



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1976, a pharmacologist at Albert Einstein College of Medicine in New York discovered how yew tree bark could stop cancer cells from dividing.

Seventeen years and \$32-million worth of government research later, the NCI was convinced it had a potent new drug in the treatment of ovarian cancer. The compound known as paclitaxel shrunk most tumors by 50 percent for at least four weeks, usually longer.

Some NCI scientists were so excited they suggested the government market the drug itself. But tradition and budget constraints prompted the NCI to give the formula to a company with expertise in anticancer drugs. Though the government discovered the drug, federal law allows a private company exclusive rights to the drug for five years in exchange for bringing it to market.

From the companies that bid, the government selected Bristol, a leader in the cancer field.

After winning the right to further test, manufacture and market Taxol, Bristol executives made it sound like they were doing the government a favor.

Bristol complained that it would cost millions to bring the drug to market, that production would take 40 weeks and that it was taking a big risk because it might not be able to find enough yew bark to satisfy demand.

At the cancer institute, they were sympathetic to the argument.

"My view was that NCI was confronted with tremendous problems in bringing to market one of the most important anticancer drugs," said Michael E. Christian, a top scientist in the NCI's cancer therapy evaluation program. "Bristol brought the critical resources at a critical time in the development of the drug."

Federal law required Bristol to sign an agreement promising it would charge a "reasonable" price.

When Bristol set an inflated price, the NCI asked the company to justify it. Bristol refused and threatened to walk.

Wall Street analysts predicted worldwide sales of Taxol would yield at least \$800-million a year. The NCI said it was confident the price would come down "as indications for Taxol's use broaden and the market expands."

Late in 1991, a contractor Bristol hired started stripping the bark from yew trees on federal land. Taxol hit the market in July 1992.

Environmentalists started bombarding Ron Wyden, an energetic Democratic representative from Oregon, with complaints that yew trees indigenous to the Pacific Northwest were being sacrificed to produce the raw material for a cancer therapy.

Wyden also was hearing from consumer advocates outraged at the inflated price of Taxol. Bristol was charging about 20 times what it was paying for the raw product.

As chairman of the House subcommittee on business

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opportunities and technology, Wyden tried to get answers. On Jan. 25, 1993, Bristol vice president Zola Horovitz told Wyden's committee that the agreement between Bristol and the NCI "imposes no requirements (on the company) with respect to submission of evidence to explain or justify the Taxol price."

Horovitz did offer some explanation. "Bristol Myers Squibb's concerns about the lack of patent protection, and about the complexity and expense of the Taxol development project, are included among the factors to be considered in connection with Taxol pricing."

Bristol needed to charge an inflated price because competition from low-priced generics was "a certainty" after five years, Horovitz said.

He added a promise: He told the committee that Bristol would not try to extend its exclusivity under the Orphan Drug Act, which offers special treatment to drugs for rare diseases. "The company voluntarily relinquished Taxol orphan drug status."

Although the NCI had conducted a complete set of trials, Bristol said it cost the company \$1-billion to conduct additional trials, win FDA approval, manufacture and market Taxol. It portrayed the task of rushing the drug to market as something equivalent to the Manhattan Project, the U.S. government research that produced the first atomic bomb.

Wyden was outraged. He said it was unconscionable that taxpayers who helped finance the discovery of a lifesaving drug were being overcharged for it and, in some cases, priced out of the market. He said government-funded scientists and drug company executives had formed a "cozy circle" that condoned giveaways of government-financed discoveries.

"The taxpayer is paying twice -- once in development and again as consumers," Wyden said. "American consumers who have funded drug development through the gift of corporate tax credits and federal lab research should not be bludgeoned by price gouging."

"Bristol Myers and other companies claim that if the government insists on answers to basic questions about pricing, that they will walk away from the table and that Americans will die as a result. They have, in effect, said do it our way or no way, betting on the prospect that our desire for new cures is so great that no one will insist on data justifying the taxpayer expenditures."

Horowitz told Wyden's committee that Bristol executives were offended that anyone would question their integrity. He said the criticism made them "question the wisdom of participation in similar projects in the future."

"Taxol was never patented and no patent is even possible," he testified. "The only exclusive protection afforded the company is the five years of protection from generic competition granted under (the law) to every new chemical entity."

Even as Horovitz was testifying, records show the company was preparing to patent Taxol through the back door by claiming exclusivity over the castor oil solution used to administer the drug intravenously.

In the first five years, Bristol sold nearly \$5-billion worth of

Taxol. Time was up in December 1997, the exclusivity period was over. But now Bristol broke its agreement with the NCI and worked to retain control of the drug.

Aware that by reneging it would take a public relations beating, Bristol retained the Washington consulting firm of Democratic media mastermind Bob Squier. To rally support, it donated hundreds of thousands of dollars to cancer activist groups. To keep generic upstarts at bay, its lawyers prepared to sue.

Seattle-based Immunex Corp. was selling a generic version of Taxol in Canada, where patent laws are less stringent. When Immunex filed a petition with the Food and Drug Administration to market it in the United States, Bristol sued Immunex for patent infringement, even though Bristol had no patent for Taxol. Under law, the suit won Bristol an automatic 30-month delay of the Immunex petition.

"Keeping the generics off the market even an extra day or a week can mean millions of dollars in sales to them," said Clay O'Dell, spokesman for the Generic Pharmaceutical Association.

The authors of the 1984 law that governs drug patents, Democratic Rep. Henry Waxman and Republican Sen. Orrin Hatch, say they included the provision for a 30-month delay to protect companies against patent infringement. They say they never intended that it be used to extend exclusivity.

Earlier in 1997, IVAX had moved to get FDA approval to use Taxol under the Orphan Drug Act for treatment of Kaposi's sarcoma, an AIDS-related cancer. Bristol's lawyers beat them by filing a similar petition one month earlier.

Drug companies commonly invoke the Orphan Drug Act to extend exclusivity. Bristol, however, had specifically pledged in 1992 that it would not. The company paid no consequence for not honoring its pledge. Congress gave no federal agency the power to penalize companies that violate drug patent laws.

In the 30 extra months, Bristol sold more than \$4-billion in Taxol. The extension expired in April 2000. Again IVAX and Immunex prepared to introduce generic versions of Taxol; again Bristol outmaneuvered them.

A California firm, American BioScience, announced it intended to sue Bristol for Taxol patent infringement. Industry analysts saw it as a sham suit because American BioScience, like Bristol, did not have a patent on Taxol. Though Bristol was getting sued, it wound up ahead: The FDA put approval of the generic on hold until the case was resolved.

IVAX president Neil Flanzraich alleges that Bristol, running out of legal options, prevailed upon American BioScience to file a bogus infringement case to keep the generic off the market while the case was being litigated.

Flanzraich remembers the day he learned about the American BioScience suit as if it were yesterday. IVAX stock fell more than 30 percent; Bristol's rose 5 percent.

"They really snookered you," a CNBC commentator joked when Flanzraich arrived for a televised interview.

A diminutive, bespectacled man, Flanzraich was visibly shaken.

"Is this a society in which we applaud someone for playing tricks with the public interest?" he demanded. "Is this a good thing?"

Even after the FDA granted IVAX permission to begin selling generic paclitaxel in September 2000, Bristol continued its litigation in courts around the country. It wasn't until Jan. 25, 2002, after winning court victories over Bristol and American BioScience, that IVAX announced that the courts and the FDA had upheld its right to market the generic version.

In all, Bristol extended its five-year exclusivity period by nearly three years -- generating nearly \$5-billion in additional sales.

In the first 10 weeks that Onxol -- IVAX's version of Taxol -- was on the market, IVAX reported sales of more than \$30-million. Almost overnight, the price for one vial of the drug at Moffitt Cancer Center in Tampa dropped from \$1,435 to \$750, pharmacology director Philip Johnson said.

Most patients use about six vials during treatment, which means the cost fell from \$8,600 to \$4,500.

Where was the government in this? Should some agency have been tougher on Bristol?

The FDA approves drugs sold in the United States, but it does not have the authority to intervene in disputes between brand name and generic companies. The National Institutes of Health, including the NCI, cannot control how drugs discovered by the government are marketed after they are given to a private company.

If the generic companies lose in court, the only place to turn is the Federal Trade Commission, which investigates anticompetitive activities in every industry.

With no government enforcement, Flanzraich said, it has fallen to generic manufacturers to challenge brand name companies that overcharge consumers: "We act in the public interest.

"That's the way the laws have cast us. Our interest becomes the public interest. In most cases, the only one representing the public is the generic company."

Retired, Zola Horovitz spends his winters in Boca Raton. He remembers testifying before Wyden's subcommittee in 1993 but does not remember promising the committee that the company would not oppose the introduction of generics in 1997. Nor does he recall pledging not to invoke the Orphan Drug Act.

He says Bristol took a big risk by agreeing to manufacture Taxol. "The NCI wasn't giving us very much, except some early clinical data," Horovitz said.

Because the law governing drug patents allows a company to go to court to defend its exclusivity, Horovitz said Bristol would have shortchanged its stockholders if it hadn't done so for Taxol.

Why did Bristol mount a fierce legal battle instead of honoring its agreement with the government?

"I don't think we knew back then (1992) the range of promise of Taxol," said Wilson Grabill, Bristol's director of corporate affairs.

"It's one thing to say something at a point in time when you don't know the potential of what you are talking about. This miracle drug has bloomed, producing many uses that weren't anticipated back then."

Bristol's critics say that makes it worse: With its better-than-anticipated windfall, the company had even more of an obligation to keep its promise.

"The value of the package Bristol received from NCI was greater than the tens of millions of dollars that the government spent developing Taxol," said Jay Shapiro, a Miami lawyer who represents IVAX.

"Not only did they get the benefit from all the clinical trials, toxicology studies and purification, but they got exclusive access to federal lands to pick bark from the yew trees. How do you put a dollar value on that?"

O'Dell, the generic drugs spokesman, said the Taxol case cast Bristol as "the poster child of patient abuse." Former NOW president Patricia Ireland described it as "a truly reprehensible example of corporate welfare and greed." Securities analyst Jeffrey Kraws called it "the most despicable thing I've seen in 12 years as an analyst on Wall Street."

Uwe E. Reinhardt, health care economist at Princeton University, says morality is not at issue, Bristol merely fulfilled its obligation to its stockholders.

In an economic system where health care decisions result from a struggle for profits between drug companies and insurers, Reinhardt said, the outcome does not likely favor the patient.

"Somehow," he said, "the patient and doctor are innocent bystanders in this whole battle."

Many women with ovarian and breast cancer owe their lives to Taxol; more than 1-million cancer patients have been treated with it since 1992.

Patients with comprehensive health insurance have ready access to Taxol, of course. Some uninsured women can take advantage of private or government programs that help pay for treatments, one of them run by Bristol. When someone gets Taxol through these programs, the high prices add to costs shouldered by consumers, employers, insurers, charities and government agencies that fund health care.

Finding such a program can be difficult.

It took Terri Mullis, an uninsured hairdresser in Danville, Va., more than a year to find a free program after she was diagnosed with breast cancer. When she finally began treatment at the University of Virginia Hospital, the tumor in her breast was plainly visible.

Mullis says it humiliated her to beg for help: "It was the most degrading experience of my life."

About the time Taxol became available, 34-year-old Sue Kocsis of Omaha, Neb., found a lump in her breast. Her cost-conscious HMO doctor refused to take her complaint seriously, saying she

was too young to have breast cancer.

At the time, Taxol was the most expensive cancer drug on the market. Insurers saw it as a high-priced therapy that threatened to undermine their profitability, and Kocsis was convinced that's why her HMO turned her away.

It wasn't until she changed health plans 20 months later that she was properly diagnosed and treated with Taxol. She died in July 2000, leaving a husband and three daughters.

Julie Seguin, a 40-year-old dental technician in Houston, was treated with Taxol for breast cancer in 1999 and 2000, after Bristol's five-year period of exclusivity had expired and during the time it kept generics off the market. She says she and her husband owe \$10,000 for costs her insurance did not cover.

The stories of people who couldn't afford Taxol have fueled a backlash against Bristol. Even the pharmaceutical industry agrees people should not be denied access to a drug discovered with tax dollars.

The FTC is investigating complaints that Bristol violated antitrust laws by manipulating the legal system to delay the marketing of generic drugs.

Sens. John McCain, R-Ariz., and Charles Schumer, D-N.Y., have proposed a bill to eliminate the 30-month patent extension for brand name companies that go to court to block generics. The senators say too many drug manufacturers are using the extension and other legal maneuvers to retain exclusivity of their best-selling drugs for as long as possible.

A newly organized coalition of state governors, major employers and labor unions also wants to end the extension.

"No policymaker in the nation can claim the system is working as it was intended," Vermont Gov. Howard Dean said.

The pharmaceutical lobby, PhRMA, which represents the industry with arguably the most influence in Washington, says changing the law would stifle drug development.

Richard I. Smith, PhRMA vice president, said the group will oppose any change "with every ounce of strength, resolve and purpose that we can muster because to fail to do so puts in jeopardy the future of pharmaceutical genius and the lives of countless patients who depend upon us to keep alive the promise of new and better drugs."

Even if Congress changes the law, Princeton's Reinhardt says, the interests of patients always will be secondary.

"The drug manufacturers and insurance companies will speak movingly about saving a patient's life, but that's not their primary social obligation," Reinhardt said. "It's all about money."



Past 14 Days

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