

US challenge to AZT patent

- AIDS treatment too costly
- AZT discovered in US lab

Washington

THE patent for AZT, at present the only drug licensed for the treatment of AIDS, is being challenged by the US government and two Canadian companies in an attempt to wrest it from the hands of Burroughs Wellcome, the British pharmaceutical company that has made a fortune from it.

At issue is the price of the drug, and the profits Burroughs has taken from its sale. Three years ago, when Burroughs first introduced AZT, it charged more than \$3.00 per capsule. For the average AIDS patient, that meant an annual cost of some \$10,000. Under pressure from AIDS activists, the company has since cut the price by two-thirds, to \$1.20 per capsule, but critics say it is still overpriced.

Because medical costs quickly impoverish many people with AIDS, government subsidies usually end up paying for most of the AZT. So far, those subsidies have amounted to some \$420 million of the \$700 million spent on the drug. Much of that money, critics say, could have gone to research instead.

Burroughs has refused publicly to disclose the cost of making AZT, saying only that research and development has cost the company "hundreds of millions of dollars" and that the price of the drug reflects that. But US health officials and congressional investigators are now disputing what Burroughs says: they say that government scientists at the National Cancer Institute (NCI) first discovered AZT more than two decades ago, and then in 1985 proved it killed the human AIDS virus.

Burroughs' major contribution, according to NCI researchers, was to pick AZT — at that time a failed cancer drug — among some four dozen other compounds in the public domain to be tested in collaboration with NCI for possible AIDS applications. AZT turned out to be surprisingly effective.

NCI also turned over its supply of an essential and rare compound — thymidine, which is found naturally only in herring sperm — so that Burroughs could produce the AZT. In 1985, Burroughs won an exclusive patent on the drug. There was no mention of the role of the US scientists.

Among other options, lawyers at the US National Institutes of Health are considering challenging the patent on the grounds that the US government should have been listed as a co-inventor, accord-

ing to a spokesman. The American Civil Liberties Union and Public Citizen, a non-profit litigation group, are also considering legal action. And, as first reported by the US television network ABC last week, two Canadian companies — Apotex Inc. and Novopharm — have challenged the Burroughs patent in Canada.

Apotex already has large quantities of AZT and has begun shipping it for \$0.89 per capsule — two-thirds of the Burroughs price — to countries such as the Bahamas, where Burroughs does not have a patent. Canadian researchers believe they can make AZT as cheaply as \$0.50 per capsule.

"We are virtually certain we will win", says Apotex president Barry Sherman. "There was no invention, and even if it were an invention, [Burroughs] was not the inventor. If a product in the public domain proves useful for AIDS, that is a scientific effect, not an invention." He expects similar patent challenges in the United States within months. A Burroughs spokeswoman said only that "we are confident in our patent."

The large fraction of government AIDS money that has gone to AZT has drawn the attention of Congressman Ted Weiss (Democrat, New York), head of the House of Representatives human resources investigative subcommittee. Although initially spurned in his request for an accounting of Burroughs' AZT costs, Weiss scored a victory last month when the company provided the figures under a promise of confidentiality. Weiss's staff is now analysing those figures and may hold a hearing, but Weiss has already made his mind up on one point: AZT costs too much and the fault lies both with the government and with Burroughs.

"For several years the federal government did nothing to enforce its ownership right to AZT", Weiss says. "Government inaction allowed Burroughs Wellcome to reap excessive profits from persons suffering from AIDS who need the drug to lengthen their lives. There will be no reason for Burroughs Wellcome to lower the inordinately high price of AZT until the federal government exerts its rights, including a share in past profits".

Although the onslaught seems sure to wrest concessions — if not outright control of the patent — from Burroughs, the news may not be all good for the AIDS community. The price of AZT is likely to drop, from competition if nothing else,

but the strong-arm tactics used by activists and legislators alike may send a worrying signal to the rest of the industry. "You can't go too far; you don't want to discourage companies from getting involved in AIDS-related research", warns Pat Christen, director of the San Francisco AIDS Foundation. Burroughs (or the company that ends up manufacturing the drug once the patent disputes are resolved) must be allowed a fair profit. Just how much profit is fair, and who should decide, remain the pressing questions.

Christopher Anderson

ASTRONOMER ROYAL

New man will speak his mind

London

ARNOLD Wolfendale, professor of physics at the University of Durham, is Britain's new Astronomer Royal — an honorary position dating back to the seventeenth century. A vocal critic of the low British spending on astronomy and space science, Wolfendale promises that his official appointment will not prevent him from speaking out in future: "I may need to be more circumspect, but the message will be the same".

Wolfendale's research centres on cosmic rays and high-energy solar particles. He replaces the radioastronomer Sir Francis Graham-Smith, who resigned the post after his retirement from the University of Manchester.

Wolfendale has been chairman of the Astronomy and Planetary Science Board of the Science and Engineering Research Council (SERC) since 1988. British astronomers hope that the outspoken Wolfendale will fight their corner as support for 'big science' projects comes under scrutiny in the council's search for ways to release more money for small project grants.

Last month, the usually apolitical Royal Astronomical Society voiced its concern about the damage to the "first-class" British presence in astronomy and space physics that would result from any reduction in support. Astronomy has borne the brunt of SERC's immediate cost-cutting to prevent a cash shortfall of £40 million in 1991-92: two important projects — a collaboration with the United States and Canada to build two 8-metre optical telescopes, and the British contribution to a gravity wave observatory to be built in Germany — have been delayed for at least two years.

The post of Astronomer Royal has had no set duties since the link with the directorship of the Royal Greenwich Observatory was severed in the early 1970s, but the Astronomer Royal is meant to represent the British astronomical community.

Peter Aldous