License to ddI

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The anti-HIV drug ddI -- didanosine, sold as Videx -- faces a watershed in October when its 10-year license expires, and not only maker Bristol-Myers Squibb (BMS) but all of Big Pharma is anxiously tracking this to see which way the wind blows. In one corner we have BMS, which wants to extend its rights to manufacture and ensure that its second-biggest-selling AIDS drug (its cash cow is d4T, or Zerit) will remain the company's exclusive property. In the other corner we have activists, who charge that the license should be allowed to expire so that cheaper, generic versions can be marketed without fear of trade sanctions.

Like its older brother AZT, ddI was invented by government researchers. But while the National Institutes of Health (NIH) holds the patent for ddI, it needed a company's capital to bring the drug to market. So in an October 1991 agreement, BMS was given a decade exclusive to sell the product worldwide, and ddI hit the shelves.

A cornerstone of many anti-HIV combos, ddI had global sales totaling $205 million in 1999, as compared to d4T's $635 million. (A year's ddI supply costs about $2,800, or $7.70 a day.) "DdI is one of our most significant products, and we'll do everything to protect it," said John Kouten, BMS's associate director of public affairs, adding: "Providing ddI to patients is our priority."

An official at the NIH's Office of Technology Transfer, the department that licenses such drugs, would not comment on how the decision will be reached, except to say, "We will consider and evaluate any request by the company to extend the terms of the license." But even if the NIH rips up the agreement, the matter is complicated by subsequent patents secured by BMS for specific formulations, including a more expensive, easier-to-take, once-daily capsule approved by the Food and Drug Administration (FDA) late last year. Patents on brand-name drugs typically last 20 years.

Still, advocates are pressuring the NIH to let the license lapse. "The gravy train should stop," said Jamie Love, director of the Nader-founded Consumer Project on Technology. "BMS invested very little in developing ddI and have benefited very much." Others argue that the FDA should use its limited regulatory power to press BMS into slashing the price of its AIDS meds in developing countries. Meanwhile, such nations as Thailand and Brazil have been manufacturing a generic ddI powder at a cost of about $1.50 per day.

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