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The End of the AZT Patent: A New Beginning or Too Little Too Late?

By Lindsay Frank

AIDS patients may soon find it more affordable to gain access to a drug known to extend the quality and longevity of their lives. After over seventeen years, GlaxoSmithKline's ("GSK") patent on AZT, an anti-retroviral drug used to stop the reproduction of the AIDS virus in the body and a staple in the drug regimen for those living with HIV and AIDS, has finally come to an end.¹

Critics of the patent believe that the pharmaceutical giant made their drugs so unaffordable

with HIV and AIDS.⁸ Their lawsuit against the pharmaceutical giant alleges that GSK illegally excluded competition for anti-viral drugs, such as AZT, Ziagen and 3TC, and priced their drugs so high above competitive market rates that they became out of reach for many patients.⁹ As a provider of treatment for the uninsured and patients who otherwise would not be able to afford to pay for their medication, the AIDS Healthcare Foundation also seeks damages for paying what they consider to be grossly inflated prices for AZT and other derivative AIDS drugs.¹⁰

Initially developed by the National Institute of Health in 1964 as a possible cancer drug, AZT became known worldwide as the first life-saving and life-enhancing drug for AIDS patients otherwise faced with

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that some people suffering from HIV and AIDS have died prematurely due to their inability to pay for the requisite medications.² While AIDS activists across the country are thrilled to see the end of GSK's patent, they are not convinced that it will make drugs used to fight the virus more accessible and affordable for all patients.³

GlaxoSmithKline also has a patent on Combivir and Trizivir, which combines AZT and two or three other medications in one pill.⁴ Commonly known as “drug cocktails,” these antiretroviral combination therapies (“ARVs”) make it more convenient for patients to adhere to a regular treatment plan and have become the most widely used medications among HIV/AIDS patients in the world.⁵ However, due to the rising popularity of ARVs, individual sales of AZT have declined significantly, thereby downplaying the effect of the patent's expiration.⁶

AIDS activists have been frustrated with GSK's control over the HIV/AIDS drug market for years. In fact, in April 2003, the AIDS Healthcare Foundation filed an amended patent piracy lawsuit against GSK in federal district court.⁷

The AIDS Healthcare Foundation, a non-profit organization, is the United States' largest provider of healthcare services and treatment for individuals living

almost certain death.¹¹ GSK obtained the patent for AZT in the 1980s and began pricing it well above competitive rates.¹²

Representatives from the AIDS Healthcare Foundation further claim that GSK lied to the patent office about discovering the drug.¹³ A patent on AIDS therapy drugs prohibits other companies from marketing more affordable but equally effective generic versions. This is especially detrimental to poorer countries that are forced to import their drugs from the West and pay the exceedingly high prices set by Western manufacturers.¹⁴

While optimistic about the future, Tom Myers, general counsel for the AIDS Healthcare Foundation, refused to undermine the detrimental consequences he believes GSK's patent caused in the first place.¹⁵ “We are hopeful that the end of GSK's patent on AZT means generic versions of the drug will now be more readily available, but this does not change the fact that there was an illegitimate patent in the first place,” Meyers said.¹⁶ “Our lawsuit focuses on the [irreversible] harm that has occurred over the past seventeen years.”¹⁷

On the other hand, some activist groups believe that the AIDS Healthcare Foundation's

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NEWS

\$6.7 Million Settlement in Special Education Case

By Katie D. Fletcher

An autistic child and his parents agreed to a settlement amount of \$6.7 million in their six-year long administrative and legal battle with the Manhattan Beach Unified School District ("School District") and the California Department of Education ("CDE").¹

District Court Judge Gary Allen Fees approved the record settlement amount, which represents payment to the child and his parents for the School District and CDE's failure to appropriately educate the child for more than five years.²

"This lawsuit could have been avoided and millions of dollars could have been saved had the Manhattan Beach USD and the CDE simply complied with clearly established statutes and regulations,"³ said Steven Wyner, attorney for the family.

Under the Individuals with Disabilities Education Act ("IDEA"), the School District is required to provide students with disabilities a "free appropriate public education."⁴ The federal government funds the IDEA in an effort to support the education of disabled children.⁵ In order to receive the federal funding, states and local educational agencies must have in place statutory polices and procedures that ensure identification and

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Grand View Elementary School in Manhattan Beach, CA. The Manhattan Beach Unified School District failed to provide adequate education for one of its disabled students.

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claims are misplaced. These groups believe that the pressure to get AZT out on the market as well as the research and development costs that went into the production of AZT may justify its high price. "AZT was rushed through FDA approval in record setting time, at a pace that has yet to be equaled," said Martin Delaney, founding director of Project Inform.¹⁸ "The production methods for making AZT at that time were relatively primitive and required some bizarre and expensive raw materials."¹⁹ Delaney also went on to say, "AZT is by no means a drug that stands out from the pack because of pricing."²⁰

Many generic versions of common AIDS drugs may cost between 200 and 300 percent less than their American-made brand name counterparts.²¹ For instance, the cost of treating an AIDS patient with patented drugs can cost between \$10,000 and \$15,000 per year, but a similar generic brand regime can cost \$1 per day.²² Despite the fact that drug companies such as GSK have cut the prices of AIDS drugs sold to African nations, critics argue that the drugs are still not being sold as cheaply as generic versions produced in countries such as India, Thailand and Brazil.²³

The average cost of a drug combination therapy taken by AIDS patients in the United States is \$14,000 per year.²⁴ GSK currently controls 40% of the AIDS drug market in the United States and profits from the sale of the company's worldwide sale of AIDS drugs are estimated to run in excess of \$2 billion each year.²⁵

¹ *Glaxo's Patent Protection of First AIDS Drug, AZT ends; AHF Blasts Glaxo's & Drug Industry's Greed*, PR Newswire, Sept. 17, 2005, <http://www.prnewswire.co.uk/cgi/news/release?id=153887>.

² *Id.*

³ *Id.*

⁴ *Id.*

⁵ *Id.*

⁶ *Id.*

⁷ *GSK Loses Another Key Round in AIDS Healthcare Foundation's AZT Patent Piracy Case*, PR Newswire (May 3, 2004), <http://www.prnewswire.co.uk/cgi/news/release?id=122068>.

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