

## An Overview of the AIDS Drug Industry and Drug Access Policy in Lower Income Countries

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### Introduction

The pharmaceutical industry spans many nations and is represented by numerous firms of various sizes. These companies produce medicines for a myriad of illnesses and medical conditions. However, this paper will focus on those firms that produce drugs that work specifically with regard to HIV, the virus that causes AIDS, and opportunistic diseases (OI) that develop as a result of HIV infection. With 40 million HIV/AIDS patients worldwide, there is a substantial market for these medicines.

<b>Major pharmaceutical firms</b>	GlaxoWellcomeKline (UK) Pfizer/Agouron (US) Hoffman-La Roche (Switzerland) Merck (US) Abbott, Boehringer-Ingelheim (Germany) Bristol-Myers Squibb (France) Gilead (US)
<b>Firms that produce generic brands</b>	Biolab Company (Thailand) Ranbaxy (India) Cipla (India) Hetero Drugs (India) Far-Manguinhos (Brazil) Aspen Pharmacare (South Africa)
<b>Main anti-AIDS drugs</b>	[nevirapine (NVO) + lamivudine (3TC), + zidovudine (AZT) = generic triple therapy], zalcitabine (ddC), stavudine (d4T), efavirenz (EFZ), indinavir (IDV)

**Table 1: Major pharmaceutical companies and the brand name AIDS drugs they produce**

### Industry Structure

The pharmaceutical industry which deals with the production of AIDS drugs can be described as a monopolistically competitive one. It is such because there are many sellers that compete for customers who need AIDS medications, and there is no restriction on new firms entering the market. Also, although there is some overlap and substitutes are produced, many firms offer products that the others do not. The pharmaceutical industry is also slightly oligopolistic in that when new drugs are developed, patented and produced for the market, the firms that produce the new class of drugs are usually very few in number (Danzon, 1997, p. 303). Gradually, as other companies begin to produce the drugs, this number increases. There is some evidence, however, that an even more competitive structural type is developing.

Because pharmaceutical firms hold patents for their discoveries and have been the sole producers of particular drugs, as long as there were no substitutes available, they have been price makers,

able to set the prices consumers will have to pay. Pharmaceutical companies often argue that prices are high because they need the revenue to invest in R&D for new drugs, and to offset losses of those drugs that ultimately did not reach the market. It has been estimated, however, that pharmaceutical firms' investment in R&D is, in fact, less than that in marketing (Barrett, et. al., 1999; Harris, 2000). Still, according to one pharmaceutical firm's senior vice president, it costs about a billion dollars to see one drug through from discovery to market ("Q&A Pfizer's" 2004). Be that as it may, these firm's are reaping substantial yearly profits. From its AIDS drugs alone, GlaxoWellcomeKline (UK), the world's largest manufacturer of HIV/AIDS drugs, saw sales reach \$1.76 billion in 2001 (Naik, 2002).

Over the 20-year history of anti-retroviral (ARV) drug development, most leading pharmaceutical firms have had the luxury of deciding their own prices, but prices have come down considerably due to progress in technological innovations, new developments in AIDS research, and pressure from AIDS activist groups and NGOs. For example, in 1987, when Burroughs Wellcome first announced its AZT, the price was \$10,000/year. That fell to \$6,400 in 1989, and is now available in the U.S. for \$3,659/year. 3TC, available in the U.S. for \$5,800/year ("Formula", 2001) in only two years has come down to about \$3,000 as of July 2003 (Kresge, 2003). As more substitutes have begun to enter the market, there has been increasing competition, but mainly among the major players in the industry, which indicates that the industry is monopolistically competitive. Continuing pressure from international organizations such as WHO, NGOs, and from shareholders themselves, has resulted in further price decreases. "Over 1999-2003, prices were lowered by more than 90% and yet likely still allowed a mark-up many firms in other industries would be envious of" (Vachani and Smith, 2004).

### **Power over Production**

It is growing more difficult for pharmaceutical giants to keep producing breakthrough drugs in high numbers in their own laboratories. Firms are finding they have to promote existing products harder and are increasing their advertising and sales forces in order to do so. Still, to produce enough new medicines and maintain investors' confidence, many drug companies are forming alliances with smaller biotech firms that can come up with new drugs quicker. The giants are also forming mergers, or sometimes purchasing entire biotech firms (Harris, 2000).

### **Generics: the real competition**

Currently, prescription AIDS drug prices are subject to wide price differentials based on geography. By this "tiered pricing" system, major drug firms "set a pricing scheme that is inversely proportional to the development index of the recipient country" (Baker, 2001, p. 36). Under this system, consumers in middle and higher-price countries will be paying what is, in effect, a subsidy for the discounts allowed in lower-price countries, an arrangement that will probably receive opposition in the U.S. considering there is no universal access to lower-priced medicines there (ibid).

Parallel importation is another suggested solution by which a product that is legally marketed in another country is imported by the company that holds the patent or by another authorized agent, for the purpose of promoting price competition. Many major drug companies oppose parallel importation "because it limits companies' ability to charge whatever a local market will bear" (ibid, p. 43). Some have suggested this system be a voluntary one. One problem with this is that, as with cartels, there must be agreement among the pharmaceutical companies that they would not import drugs sold in lower-price countries back to their higher-price countries.

Millions of AIDS patients live on less than a dollar a day cannot possibly afford even drugs that have already been discounted by multinational drug companies (see Appendix 1, Appendix 2). To deal with the gap in access to ARVs, there has been a growth of generic brands produced in developing countries, and this has been the major obstacle for the pharmaceutical industry so far. It is soon to become an even greater thorn in the side of multinational drug corporations, as patents valued at more than US\$80 billion will expire by 2007 (Sixth Asia Pacific, 2004). For years, various developing countries have been producing generic AIDS drugs in order to stem the tide of AIDS deaths occurring each year. Brazil and India have been leaders in developing and distributing such drugs, stimulating a strong reaction from major drug firms that cite violations of patent laws.

Since Brazil never had restrictive patent laws which limit the use of generic drugs in, for example, South Africa or Guatemala, it started making its own nucleoside analogues such as AZT, ddI, etc., in the mid-1990s.... Brazilian made generic nucleoside analogues have brought the prices of those drugs down by 72%, while the prices of brand-name protease inhibitors and NNRTIs has dropped by just nine percent (Treatment Action Group, 2000).

The TRIPS agreement developed by the WTO covers rules for intellectual property rights. From January of this year, India, for example, will have to grant product patents to pharmaceutical companies. Up to now, competition among Indian pharmaceutical firms has kept drug prices low. For example, the cost of an AIDS “cocktail” combination of three anti-retrovirals is 90% that of brand-name combinations (“Changes”, 2004). In fact, “According to a World Bank study in the mid-1990s prices for four typical drugs were ten times more expensive in neighboring Pakistan, 17 times more expensive in Britain and 37 times more expensive in the United States than in India” (“Health”, 2004).

### **Reshaping industry structure: Which way will it go?**

As more low-income countries begin to fight back against the high prices leveled at them by major pharmaceutical companies, there is a chance that the AIDS drug industry may slowly change from a monopolistically competitive structure to one that is more competitive, with buyers and sellers becoming price takers. As a greater number of producers offer generic brands at far lower prices, the market in lower-price countries may be able to push multinationals out. For the major players, such low prices would make the market for AIDS drugs the target of arbitrage from countries where prices are lower to those where they are more expensive.

On the other hand, if IP protection is strictly enforced, and if multinational drug firms establish their own production facilities and distribution systems in lower-income countries, greatly reducing the tariffs, and distribution costs, the firms might be able to maintain control over the market, sustain quality of the products sold, and ensure continuity in product availability. As an alternative to this, major pharmaceutical companies have been moving in the direction of granting licenses to generic firms to produce AIDS drugs. As TRIPS agreement deadlines are reached, it will be interesting to see what road major firms will choose, and how their decision will affect the structure of the industry.

### **Probable effects of CAFTA**

The Central American Free Trade Agreement, which passed the House of Representatives in July 2005. Provisions in this agreement will further restrict generic drug manufacturers from developing much-needed AIDS medicines in countries including Guatemala, Nicaragua, El

Salvador, Costa Rica, Honduras, and the Dominican Republic, countries which already have significant problems in employment, health and education. According to Dr. Manuel Munoz, director of Medecins Sans Frontieres' AIDS treatment program in Honduras, "HIV/AIDS kills one person in Honduras every two hours because the vast majority of people with HIV/AIDS cannot afford life-saving AIDS medicines" (Weissman, 2004).

When a drug is approved, the pharmaceutical company has to produce test data to show the drug's safety and efficacy. Generic drug companies up to now have relied on this registration data and have shown that their generic compound is chemically equivalent and will have the same efficacy, without having to spend the millions of dollars required to repeat the original studies.

CAFTA includes a number of provisions that establish an array of special monopoly protections for regulatory data. The meaning of these provisions is that generics will effectively be barred from entering the market -- even if patent terms have expired, and even if countries have issued compulsory licenses that would otherwise enable them to sell on the market while a product is on patent -- until the monopolies on use of the data expire (Weissman, 2004).

As the effects of these international trade policies take root, more and more people in Central America will join the ranks of those who are unable to afford AIDS treatment, unless governments in those regions are able to find loopholes that will allow them to develop or import AIDS drugs at drastically lower costs.

## **Conclusion**

The situation of the AIDS drug industry, and the production and distribution of anti-AIDS pharmaceuticals, is unique when compared to other industries in that it has ethical aspects that involve values and moral judgments about human life in a way that is unlike the production of non-vital goods or commodities. It is also different because, unlike malaria or polio, it has millions of potential consumers in low, middle, and high-income countries, which means that there is a wide variety of consumer surplus totals with regard to pricing. How drug companies should determine pricing schemes with regard to lower-income countries is a complicated one. They cannot afford to lower costs without guarantees they will not lose profits in high-income countries, or to assume that differential pricing will not produce diversion of their products to wealthier countries, and yet they cannot run the risk of generic brands taking away large portions of the market.

Still, there is another justification for large pharmaceutical firms to urgently consider changes in drug access policies. HIV is a virus that can mutate easily if treatment programs are not followed consistently. If treatment is stopped and no alternative medicines made available, new strains of the virus are likely to find their way into the population, rendering current medicines ineffective. Of course, severe problems with infrastructure in low-income nations contribute greatly to treatment of HIV/AIDS patients. However, by working cooperatively to allow production of their drugs at prices that people in developing countries can afford, pharmaceutical firms can ensure that there will still be a market for their drugs because they are still effective. From a business perspective, it is in their own interests, and those of their investors, that major drug companies should take a proactive stance. From an ethical standpoint, it is vital if we are to end the scourge of AIDS worldwide.

## Resources

Baker, Brook. 2001. "African AIDS: Impacts of Globalization, Pharmaceutical Apartheid, and Treatment Activism." Health GAP Papers. Available Jan. 29, 2005 from <[http://www.healthgap.org/press/releases/01/040301\\_BBAKER\\_PPR\\_SA.pdf](http://www.healthgap.org/press/releases/01/040301_BBAKER_PPR_SA.pdf)>.

Barrett, Amy, E.Licking, J. Carey, K. Capell. 1999. "Addicted to Mergers?; Dealmaking may not be the right prescription for drugmakers." *Business Week*. New York. Dec. 6., Iss. 3658; pg. 84. Available Jan. 29, 2005 from <<http://www.businessweek.com/archives/1999/b3658148.arc.htm>>.

"Brazilian generic ARV drugs in South Africa - the background: A historical account of the use of Brazilian drugs in MSF's antiretroviral programme in South Africa." *Medecins Sans Frontieres Access Web Site*. 29 January, 2002. Available Aug. 2, 2005 from <<http://www.accessmed-msf.org/prod/publications.asp?scentid=29120021037154&contenttype=PARA&>>.

"Changes in Indian Patent Laws Could Drive Up Prices of AIDS Drugs in Africa." 2004. *Business CustomWire*. Dec. 16, 2004. Available Jan. 28, 2005 from <<http://search.epnet.com/logging.aspx?direct=true&db=bwh&an=CX2004351X6891>>.

Danzon, Patricia. 1997. "Price Discrimination for Pharmaceuticals: Welfare Effects in the US and the EU." *International Journal of the Economics of Business*, Vol 4 No 3. Available Jan. 29, 2005 from <<http://www1.worldbank.org/hnp/hsd/documents/iHEA%20paper.pdf>>.

"Formula for Fairness: Patient Rights before Patent Rights" 2001. Oxfam. Available Jan. 29, 2005 from <[http://www.oxfam.org.uk/what\\_we\\_do/issues/health/cb\\_pfizer.htm](http://www.oxfam.org.uk/what_we_do/issues/health/cb_pfizer.htm)>.

Harris, Gardiner. "Drug Firms, Stymied in the Lab, Become Marketing Machines." *The Wall Street Journal*. Jul. 6, 2000. Available Jan. 29, 2005 from <<http://www.karlloren.com/biopsy/p18.htm>> (original at: <<http://interactive.wsj.com/archive/retrieve.cgi?id=SB96283441531664841>>).

"Health: Goodbye to Cheap Indian Aids Drugs?" 2004. *Business CustomWire*. Nov. 29, 2004. Available Jan. 28, 2005 from <<http://search.epnet.com/logging.aspx?direct=true&db=bwh&an=CX2004334U0297>>.

Kresge, Kirsten. 2003. "FTC's Approval Adds to Growing Number of Once-a-Day Drugs" AMFAR. Available Jan. 29, 2005 from <<http://www.amfar.org/cgi-bin/iowa/td/newsan/record.html?record=98>>.

Naik, Gautam. 2002. "Glaxo Faces U.S. Lawsuit Over AIDS-Drug Pricing." *The Wall Street Journal*, July 1, 2002. Available Jan. 29, 2005 from <<http://www.aegis.com/news/wsj/2002/WJ020701.html>>.

"Q&A Pfizer's Martin Mackay on drug research" 2004. *The Boston Globe*. Jun. 6, 2004. Available Jan. 29, 2005 from <[http://www.boston.com/business/articles/2004/06/06/qa\\_pfizers\\_martin\\_mackay\\_on\\_drug\\_research/?rss\\_id=Boston%20Globe%20--%20Business%20News](http://www.boston.com/business/articles/2004/06/06/qa_pfizers_martin_mackay_on_drug_research/?rss_id=Boston%20Globe%20--%20Business%20News)>.

“Report on the Global HIV/AIDS Epidemic.” Joint United Nations Programme on HIV/AIDS (UNAIDS) 2000. Available Jan. 29, 2005 from <[http://www.aegis.com/files/un aids/WADJune2000\\_epidemic\\_report.pdf](http://www.aegis.com/files/un aids/WADJune2000_epidemic_report.pdf)>.

Sixth Asia Pacific Pharmaceuticals Roundtable (Programme). 2004. *New tactics for profitable growth*. Grand Hyatt Shanghai. Available Jan. 29, 2005 from <[http://www.economistconferences.com/roundtable/public/con\\_common.asp?rtID=720&area=2&preview=&rtRegion=2&fprevrt=>](http://www.economistconferences.com/roundtable/public/con_common.asp?rtID=720&area=2&preview=&rtRegion=2&fprevrt=>)>.

Treatment Action Group (TAG). 2000. “Brazil: What Went Right?” TAGLine, 7:9. Available Jan. 29, 2005 from <[http://www.aegis.com/pubs/tag/2000/TG0012\\_01.html](http://www.aegis.com/pubs/tag/2000/TG0012_01.html)>.

Vachani, Sushil and N. Craig Smith. 2004. “Socially Responsible Pricing: Lessons from the Pricing of AIDS Drugs in Developing Countries.” *California Management Review*. Vol 47 No 1. Available Jan. 27, 2005 from <<http://harvardbusinessonline.hbsp.harvard.edu>>.

Weissman, Robert. 2004. “CAFTA: Recolonizing Central America: Dying for Drugs--How CAFTA Will Undermine Access to Essential Medicines.” *Multinational Monitor*. April 2004 - Vol 25 No 4. Available Aug. 2, 2005 from <<http://multinationalmonitor.org/mm2004/04012004/april04corp2.html>>.

World Health Organization. 2000. “WHO Medicines Strategy: 2000-2003; Framework for Action in Essential Drugs and Medicines Policy.” Available Jan. 29, 2005 from <<http://www.who.int/medicines/strategy/strategy.pdf>>.

## Appendix 1

### Antiretroviral Drug Prices (“Brazilian generic ARV drugs”, 2002)

Difference between proprietary company offers and generic producer prices

Price of AZT/3TC:

- GlaxoSmithKline (proprietary company), special discount price: US\$ 2 per day
- FarManguinhos (generic): US\$0.96 per day (52% cheaper)

Price of Nevirapine:

- Boehringer Ingelheim (proprietary company): US\$1.19 per day
- FarManguinhos (generic): US\$0.59 per day (50% cheaper)

Price of AZT:

- GlaxoSmithKline (proprietary company): US\$1.6 per day
- FarManguinhos (generic): US\$0.09 per day (94% cheaper)

Price of 3TC:

- GlaxoSmithKline (proprietary company): US\$0.64 per day
- FarManguinhos (generic): US\$0.41 per day (36% cheaper)

## APPENDIX 2

Drug	Defined daily dose	USA (1)	Côte d'Ivoire (2)	Uganda (3)	Brazil	Thailand (6)	
Zidovudine	100 mg	600 mg	10.12	2.43	4.34	1.08 (4)	1.74
Didanosine	100 mg	400 mg	7.25	3.48	5.26	2.04 (4)	2.73 (7)
Stavudine	40 mg	80 mg	9.07	4.10	6.19	0.56 (4)	0.84
Indinavir	400 mg	2400 mg	14.93	9.07	12.79	10.32 (5)	NA
Saquinavir	200 mg	1200 mg	6.50	4.82	7.37	6.24 (5)	NA
Efavirenz	200 mg	600 mg	13.13	6.41	NA	6.96 (5)	NA

(1) Prices, 2 April 2000, from [www.globalrx.com](http://www.globalrx.com), a US mail-order pharmacy that offers proprietary antiretrovirals with a minimum mark-up (shipping not included).

(2) End-user prices, UNAIDS Drug Access Initiative, Côte d'Ivoire, March 2000.

(3) End-user prices, UNAIDS Drug Access Initiative, Uganda, March 2000.

(4) Generic drugs produced in Brazil (US\$1 = R\$ 1.8).

(5) January 2000 cost to the Brazilian Government of imported drugs (US\$ 1= R\$ 1.8).