

Patents vs. Patients: AIDS, TNCs and Drug Price Wars

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On April 19, 2001, 39 drug transnational corporations' (TNCs) association, which had taken the South African government to court over patent laws, dropped the lawsuit unconditionally. The case was filed by the Pharmaceutical Manufacturers' Association of South Africa (PMASA), a body representing South African subsidiaries of 39 drug TNCs. The Association challenged the Medicines and Related Substances Control (Amendment) Act which allows compulsory licensing and parallel importing of Acquired Immuno Deficiency Syndrome (AIDS) drugs and other drugs as well.

Compulsory licensing permits the South African government to license local companies to produce cheaper versions of drugs whose patents are controlled by foreign drug companies. Local companies can produce and sell drugs in South Africa after paying a reasonable royalty on sales to the foreign drug companies. By increasing competition in the market, compulsory licensing can significantly lower the prices of drugs. Parallel importing allows South Africa to import cheap, generic versions of drugs without permission from the patent holders. For instance, a South African company can import drugs from an Indian company and then sell them in South Africa. Since the prices of drugs are lower in several countries, parallel imports can help in lowering the prices of drugs. Recent experience shows that both these measures can be helpful in promoting access to drugs at affordable prices.

The South African Parliament passed this Act in 1997. There are 4.7 million South Africans suffering from AIDS. Faced with higher prices of drugs, particularly those related to AIDS, this

Act was meant to make available drugs at affordable prices to South Africans. The South African government defended the Act on the ground that providing equal access to health care (which also means affordable drugs) is a constitutional obligation. Further, the government announced that it would use the provisions of this Act as per the rules of the World Trade Organization (WTO). It is noteworthy that only four members of the PMASA — Merck, Glaxo-SmithKline, Bristol-Myers Squibb and Boehringer Ingelheim — are involved in AIDS drugs but the remaining thirty five members also decided to be a party in the lawsuit against the South African government. Surprisingly, one of the defendants in the lawsuit included Nelson Mandela, who was the President of the country when this Act was passed.

Dropping the lawsuit: No altruism

It is important to emphasize here that the drug TNCs unconditionally dropped the lawsuit not because of their sudden change of heart or altruistic feelings towards the poor South Africans suffering from AIDS. Rather, it was the result of a sustained campaign by a number of health activists and groups which included *Medecins Sans Frontieres* (Doctors without Borders) and *Treatment Action Campaign* (TAC), a South African group started by Zackie Achmat. Achmat is a HIV-positive patient but he consistently refused to take anti-retroviral drugs until they were made accessible to all South Africans. An important dimension to the lawsuit was added when Judge Ngoepe appointed TAC as *amicus curiae* (friend of the court).

These groups campaigned tirelessly to get the drug companies to drop the lawsuit against the South African government. The health activists and groups were successful in spreading the message across the world that drug TNCs have been putting profits before poor people's lives. They highlighted various arm-twisting strategies adopted over the years by the drug TNCs to block attempts by the poor and developing countries to supply cheap drugs to their patients.

Medecins Sans Frontieres launched the global 'Drop the Case' petition that was signed by nearly 2,85,000 citizens from 130 countries calling upon the drug TNCs to drop the case. The petitioners included people from diverse backgrounds, from slum dwellers in Nairobi to Dr. David Ho, the winner of 1996 *Time* magazine "Man of the Year" award for his path-breaking research in the anti-retroviral drugs for AIDS. In the US, students also organized protests within the university campuses against drug pricing and patent regimes. Given the fact that some US universities hold patents on several AIDS drugs (for instance, University of Minnesota holds the patent for Zidgen manufactured by Glaxo-SmithKline and Yale holds patent of Zerit manufactured by Bristol-Myers Squibb), the campaign was instrumental in pressurizing the TNCs to drop the lawsuit as well as lower the prices of drugs in the poor countries.

The drug TNCs were really finding it difficult to counter the campaigns launched by these activists and groups. The drug TNCs even tried to force their viewpoint by raising the specter of negative economic consequences of dropping the lawsuit against the South African government. They argued that dropping the case would lead to an exodus by the drug TNCs from South Africa and consequently, the entire country may suffer. However, there were few takers of such arguments in both the government and the civil society which together fought the battle against the drug TNCs.

In order to divert the attention from the real issues, the drug TNCs also launched a misinformation campaign by arguing that the problem with AIDS in Africa is not due to highly priced drugs but due to lack of health infrastructure including computers; as if lack of computers had caused this pandemic.

For the oligopolistic drug industry, this episode was perhaps the worst ordeal as their international reputation took a severe beating. The drug TNCs had never anticipated such a strong international backlash to the lawsuit. As later admitted by Rick Lane, President of Bristol-Myers Squibb, "I think we underestimated the capacity to be made villains."¹

The real motives of drug TNCs

The drug TNCs opposed the Act tooth and nail on the grounds that it violates the Trade-Related Aspects of Intellectual Property Rights (TRIPS) under the WTO agreement. But this position taken by drug TNCs is erroneous because there are provisions within the TRIPS, which allow governments to take special measures to protect the health of their citizens. Both compulsory licensing and parallel imports are allowed under the TRIPS. In fact, a number of developed countries including Japan and the European Union regularly take resort to these provisions.

In fact, the intentions of drug TNCs were something else. The stakes of the drug TNCs were much higher than the market for AIDS drugs in South Africa, which is just one percent of the global drug sales. The drug TNCs were concerned more about the wider implications of this Act. They were apprehensive that if the South African law is allowed to retain its stand, other countries may be encouraged to enact similar legislation. In particular, TNCs were quite worried about the adverse impact of this fallout in the US markets where they earn bulk of their profits. They feared that if the poor and the developing countries were allowed to buy low-priced drugs, American consumers may similarly demand lower prices. Already, a number of

1 Quoted in Gardiner Harris, "Aids gaffes in Africa come back to haunt drug industry in the US," *The Wall Street Journal*, April 23, 2001.

US-based health activists and groups are demanding massive cuts in skyrocketing drug prices.

At another level, the drug TNCs were equally concerned that if AIDS is the issue today, tomorrow it may extend to heart, cancer or for that matter any other disease. Fearing substantial slide in their profits in the near future, the US-based drug TNCs cartel, Pharmaceutical Research and Manufacturers of America (PhRMA), was the first one to deplore this Act.

The shady role of US

In recent years, the US administration has been actively pushing the interests of drug TNCs, particularly the American ones, in several bilateral and multilateral trade agreements. The US administration has been endorsing the enforcement of a global monopolistic regime of patent rights as well as restricting the capacities of nations to go in for compulsory licensing and parallel importing. For instance, the US-Jordan Free Trade Agreement, completed in fall 2000 and expected to be considered by Congress in 2001, sharply limits the grounds for compulsory licensing.² The position of the US on the intellectual property rights section of the proposed Free Trade Agreement of the Americas (FTAA) contains a variety of measures that would effectively extend patent terms, interfere with compulsory licensing, and undermine efforts by poor countries to make medicines more accessible.³ The US has also been the strongest advocate of even more stringent protection for patents under the so-called “TRIPS plus” measures.⁴

The PhRMA exercises great influence over the US administration, particularly the office of the United States Trade Representative (USTR). In recent years, several countries including India, Brazil, Argentina and Dominican Republic have been threatened with trade sanctions under “Section 301” of national trade legislation by the USTR. The threats were issued when these countries failed to comply with the terms dictated by PhRMA members. It is no coincidence that members of PhRMA spent \$236 million in lobbying the US Congress and the government between 1997 and 1999. With the help of Joseph Papovich, the Assistant Trade Representative of the US, TNCs have been exercising undue influence over developing countries to protect their patent rights. In the words of none other than Peter Scher, Chief of Staff at the Trade Office under President Clinton, “Joe Papovich viewed his responsibility simply: carry out the agenda of US companies.”⁵

2 Robert Weissman, “AIDS and developing countries: Facilitating access to essential medicines,” *Foreign Policy in Focus*, Vol. 6, No. 6, February 2001.

3 *Ibid.*

4 Robert Weissman, ““Free Trade” and medicines in the Americas,” *Foreign Policy in Focus*, Vol. 6, No. 13, April 2001.

5 Quoted in Helene Cooper, Rachel Zimmerman and Laurie Mcginley, “AIDS epidemic puts drug firms in a vise: Treatment vs. Profits,” *The Wall Street Journal*, March 2, 2001.

The crucial role played by PhRMA to influence the Clinton administration to threaten trade sanctions against South Africa is well known. Since early 1998, Papovich and other US officials eagerly took up the cause of drug TNCs with South African officials. The Clinton administration also raised the drug TNCs grouse against the Act during the President's visit to South Africa in March 1998.⁶ A variety of arm-twisting tactics were used against South Africa to re-amend the Act. In 1998, for instance, the USTR suspended additional benefits under the Generalized System of Preferences, a trade scheme that allows poor countries to export products to the US at reduced duties. In April 1999, USTR office placed South Africa on the Special 301 "watch list." US also tried to "bribe" African countries not to undertake compulsory licensing.⁷ The Export-Import Bank of the US announced in July 2000 that it would make \$500 million in loans available to African countries each year for buying AIDS medicines. But with the proviso that these loans could only be used to purchase drugs from the US TNCs.⁸

However, US administration started reversing its stand on this issue in mid-1999, when health activists and groups started raising these issues and turned the heat on during the Presidential election campaign. It was only in the later half of 2000 that Clinton administration issued an executive order, which stipulated that US would not challenge TRIPS-compliant policy measures to make AIDS drugs available anywhere in Africa. It needs to be mentioned here that the executive order is limited by application only to sub-Saharan Africa and only to AIDS drugs.

How the drug price war started

AIDS drug price war started when Cipla Limited, a medium-sized drug company in India, offered a cocktail of three anti-AIDS drugs (lamivudine, stavudine and nevirapine) for an annual price per patient of US\$350 to the *Medecins Sans Frontieres*. Cipla, a leading generic drug maker in India, offered this special offer to *Medecins Sans Frontieres* through a three-tier pricing mechanism, under which the same combination drugs will be offered at \$600 per patient per year to governments and \$1,200 to distributors. The offer by Cipla created ripples in the international drug industry because the prices of these drugs in the US and other developed countries are between \$10,000 and \$15,000 per patient per year.

It has been estimated that there are over 30 million patients suffering from AIDS in the World. Most of these patients are poor and therefore, cannot afford the exorbitant prices charged by the drug TNCs. Fearing an intense competition in drug prices in the coming days because their

6 "South Africa's bitter pill for world's drug makers," *The New York Times*, March 29, 1998.

7 Robert Weissman, op.cit.

8 *Ibid.*

prices were much higher, drug TNCs launched a massive offensive against the offer by Cipla.

If one goes by the arguments of the proponents of drug TNCs, Cipla had committed an “un-ethical” act by lowering drug prices for the poor patients. Last year, Glaxo accused Cipla of infringing upon its exclusive patent rights of Combivir in Ghana. As a result, Cipla immediately stopped supply of its generic version of Combivir drug to Ghana. But now Glaxo admits that it had no valid patent in Ghana and an “overzealous” company official made the mistake.⁹

Cipla has also been accused of stealing “intellectual property right” of drug TNCs. On being branded as a “pirate” by J P Garnier, chief executive of Glaxo, Yusuf Hamied, the CEO of Cipla, replied, “If we’re pirates, (let them) litigate against us...Where is the question of piracy when we abide by the laws of the land?”¹⁰

In an another interview, Yusuf Hamied stated, “I am not a westerner marketing drugs for western markets. I represent the Third World and its needs and aspirations. I also represent the capabilities of a country with a billion population. Please do not link up the problems of the Third World and India with those of the West. We haven’t broken any laws...the main reason for reasonable drug prices in India is the absence of monopoly because of the Patents Act, 1970.”¹¹ Hamied further added, “The average cost of the AIDS cocktail in the West is \$10,000 to \$15,000 per patient per year – not because the drugs are prohibitively expensive to produce; they’re not. It is the drug pricing structure imposed by multinational manufacturers, which makes the drugs prohibitively expensive. Secondly, the international patent and trade regime at present seeks to choke off any large-scale attempt to produce and market the drugs at affordable levels.”¹²

Allegations against Cipla are baseless because the company has not violated any national or international laws. In India, the current laws only recognize process patents and not product patents. Thanks to the Patents Act of 1970, the drug prices in India have come down dramatically as there is more competition and the real beneficiary of these measures is the public at large. Cipla has managed to produce these drugs at a lower cost through “reverse engineering.” Even in the Indian markets, Cipla has drastically reduced its prices of AIDS drugs by over 30 per cent to ensure that the poor needy can afford the drugs. Besides, the company also provides the Indian government free drugs for the prevention of mother to child transmission of AIDS. But

9 “Glaxo withdraws charge,” *The Hindu Businessline*, April 24, 2001.

10 “Cipla dismisses Glaxo ‘piracy’ allegation,” *Indian Express*, March 14, 2001.

11 “A cocktail that cures,” *The Times of India*, March 1, 2001.

12 *Ibid.*

it needs to be emphasized here that Cipla has not indulged in any charity act for the poor people by reducing the prices of AIDS drugs. The company still continues to make profits.

The immediate fallout of Cipla offer has been very positive. Almost every drug TNC was forced to announce substantial cuts in their drug prices. Table 1 reveals the drastic cuts announced by several drug TNCs in response to Cipla offer. Merck, which earlier refused to take part in a pilot program by the UN to provide HIV drugs at lower prices to several developing nations, was the first to offer massive discounts on its drugs, namely, Crixivan and Stocrin. This cut was on top of sharp reductions announced last year by the company. Merck also abandoned its earlier country-by-country price negotiation policy and offered these drugs immediately to any government, charitable organization, or employer in poor nations. Merck admitted that its earlier policy of country-to-country negotiations failed as few people (less than 2,000 people in Rwanda, Senegal and Uganda) could avail the lower-priced drugs.

Following Merck's decision, other big drug TNCs including Roche, Pfizer, Glaxo-SmithKline, Abbott Laboratories, Bristol-Myers and Boehringer-Ingelheim also announced drastic cuts in

Table 1: The Price War

Drug (Company)	US Price	Cipla	Hetero	Latest Company <i>Offer in Africa</i>
Zerit (Bristol-Myers)	3589	70	47	252
3TC (Glaxo)	3271	190	98	232
Crixivan (Merck)	6016	N.A.	2300	600
Combivir* (Glaxo)	7093	635	293	730
Stocrin (Merck)	4730	N.A.	1179	500
Viramune (Boehringer)	3508	340	202	483

Note: Prices are for AIDS drugs per patient per year in the US and Africa offered by large drug makers and two Indian generic drug companies.

Prices are in US Dollars.

*AZT and 3TC.

N.A. – not available.

Source: *The Wall Street Journal*

their drug prices in Africa. Another generic drug manufacturer from India, Hetero Drugs Limited, further intensified the price war by offering the same cocktail of AIDS drugs for \$347 per year per person. Hetero also tied up with a large South African generic drug firm, Aspen Pharmacare Limited, to distribute drugs in the country once the South African government declares AIDS a national emergency and grants compulsory licenses to make generic AIDS drugs.¹³ Already Hetero has received orders to supply a basket of AIDS active pharmaceutical ingredients (APIs) to Brazil and Argentina.¹⁴

Thanks to competitive pricing by Cipla and Hetero, the international drug industry is going to witness fierce price wars and massive restructuring in the coming days. The drug TNCs will have no other option but to fall in line and drastically reduce the prices of drugs, even in the developed countries.

Fallacious claims of drug TNCs laid bare

The developments in South Africa have brought to the fore the real motives of drug TNCs, which put profit before people's lives. The present crisis has unveiled the secrecy maintained by the drug industries for decades about their real profits, which are several times more than their actual costs of manufacturing and distribution.

The usual claims by the drug TNCs that their products are highly priced because they make huge investments in research is questionable on several grounds. First, several of the patented drugs were never "discovered" by the TNCs. Publicly funded universities and research institutions had carried out the initial research and development of several drugs. The National Institutes of Health (NIH) has estimated that in 1995 the contribution of private industry to overall US health research and development was just 52 per cent and the NIH alone accounted for 30 per cent.¹⁵ In the initial research of AIDS drugs too, there has been substantial involvement of publicly funded research institutions of the US. For instance, the NIH was instrumental in the discovery of 3TC, Invirase, Ziagen, Zerit and Viramune.¹⁶ In December 2000, the NIH demanded \$9 million in royalties from Bristol-Myers Squibb for overseas sales of didanosine, used in the treatment of AIDS.¹⁷

13 Gauri Kamath, "Aspen could give Cipla tough fight in South Africa," *The Economic Times*, March 16, 2001.

14 Anju Ghangurde, "Hetero takes anti-AIDS battle into rivals' turf," *The Financial Express*, March 11, 2001.

15 "Patent Injustice: How world trade rules threaten the health of poor people," *Oxfam Briefing Paper*, February 2001, <http://www.oxfam.org.uk/cutthecost/patent.pdf>

16 *Ibid.*

17 *Ibid.*

Further, the drug companies have rarely disclosed to the public the costs of making a particular drug, and the public has little idea of the exact amount spent on research by TNCs. This is despite the fact that governments have been offering generous grants and tax breaks for research and development to the drug industry. A 1998 investigation by the *Boston Globe* concluded that 45 of the 50 top-selling drugs approved in the US between 1992 and 1997 had received government funding at some stage of development.¹⁸

Even the claim made by the drug TNCs that they are incurring huge losses due to non-compliance of intellectual property rights are not corroborated by facts. The drug industry is one of the most profitable industries in the world. According to an Oxfam report, even prior to the full implementation of TRIPS, operating profits in the drug industry were over 20 per cent.¹⁹ Another report by Oxfam reveals that Glaxo has earned sales revenues to the tune of \$1.5 billion on Combivir since this product was introduced in the market in 1997.²⁰ By making an operating profit of nearly \$450 million on this drug within three years, the company has reaped a huge largesse.²¹ In fact, most of the TNCs spend more money on marketing than on research and a substantial part of their expenditure is geared towards maintaining monopoly structures. To cite a few examples. Pfizer's production costs were 17 per cent of the total sales in the year 2000, research and development costs accounted for a mere 15 per cent, whereas marketing and other costs were as high as 39 per cent, and the company reaped 30 per cent profit.²² While in the case of Glaxo-SmithKline, production costs accounted for 21 per cent of total sales, research and development costs amounted to only 14 per cent, marketing and other costs registered 37 per cent, and as a result, the company recorded a high profit margin of 28 per cent.²³

Even the argument that patents are instrumental in stimulating investments in research and development of drugs does not stand scrutiny. Only 10 per cent of the global research and development is directed towards diseases of the poor.²⁴ Of the 1,233 new drugs that reached the market between 1975 and 1997, only 13 were approved specifically to treat tropical diseases.²⁵ Thus, it is the lack of market, not patent protection, which restricts the drug TNCs to invest in research and development on drugs directed towards diseases of the poor. While billions of

18 *Ibid.*

19 *Ibid.*

20 "Dare to lead: Public health and company wealth," *Oxfam Briefing Paper*, <http://www.oxfam.org.uk/cutthecost/dare.pdf>

21 *Ibid.*

22 "Implausible denial: Why the drug giants' arguments on patents don't stack up," *Oxfam Policy Papers*, April 2001.

23 *Ibid.*

24 Oxfam, op. cit., February 2001.

25 *Ibid.*

dollars are pumped each year into research and development of drugs related to obesity, depression, hypertension, impotency, etc.

The challenges ahead

The dropping of lawsuit by the drug TNCs cartel is an important victory for the people of South Africa and the global campaign to make drugs more affordable. Undoubtedly, it has conveyed the message that people's lives are more important than patents. This victory is certain to boost the morale of the people, particularly in the poor and the developing world, to demand medicines at affordable prices. After suffering such a humiliating defeat, it is unlikely that drug TNCs will launch a similar lawsuit in any other country in the near future. With their bargaining power significantly weakened, the drug TNCs would also find it difficult to persuade the US administration to push their agenda in the international trade agreements.

Despite such a positive outcome, it would be a serious aberration to consider this victory as an end in itself. After winning the first round, the real battle for affordable AIDS medication in South Africa has just begun. After working in close alliance with the South African government against the drug TNCs; TAC and other activist organizations should now pressurize the South African government to allow parallel importing and compulsory licensing. Otherwise, this victory would be of little value for the poor AIDS patients. The South African government should launch a widespread program to provide AIDS medication to its poor citizens. However, this is not an easy task since it requires a fundamental shift from the neo-liberal economic policies being pursued by the Mbeki administration.

At the same time, public-spirited health critics are arguing for further slashing of drug prices for poor AIDS patients because there are millions of poor people who cannot even afford the Cipla offer of annual price per patient of \$350. This is an issue which requires immediate attention, given the fact that a large number of AIDS patients earn less than one dollar a day.

At the international level, the next battlefield must be Brazil that is fighting against AIDS despite pressures from the drug TNCs and the US government. In January 2001, the US government made a formal complaint to the WTO regarding Brazil's new patent legislation. It is an open secret that PhRMA was instrumental in pushing Clinton administration to prevent the Brazilian drug industry to produce reasonably priced generic drugs to support government-run universal program for AIDS treatment. The Brazilian government has repeatedly refuted these charges on the grounds that it has only exercised the exemptions granted under Article 31 of the TRIPS agreement of the WTO.

The publicly funded Brazil health program has yielded positive results and is therefore considered a model for AIDS treatment. Brazil has shown to the world how drug prices could be lowered through generic production. Activists and organizations have to put pressure on the US government to drop its impending World Trade Organization tribunal case against Brazil for producing cheap AIDS drugs for its own people.

The US has also prompted WTO action against Argentina on a number of issues which will adversely impact her policy of making drugs accessible to the poor people. In fact, much of the US emphasis under the just concluded FTAA negotiations was to restrict the possibility of Latin American countries emulating Brazil's successful anti-AIDS program.²⁶

The recent developments in South Africa will have tremendous international ramifications. This episode is likely to shift the balance of power in favor of the poor and the developing countries. Now the onus is on these countries to take advantage of this case and enact national patent legislation protecting their interests while demanding suitable changes in the international trade agreements. In particular, the developing countries must demand a comprehensive review of TRIPS, including reduction in the duration and scope of patent protection for medicines that are essential for public health. The real challenge, therefore, lies in resisting and reversing the international agreements related to patents that were introduced at the behest of TNCs. It is high time that the primacy of national health policy over international agreements, including the WTO, be restored.

In the light of these developments, the Indian government should reexamine its commitment to amend the Indian Patents Act. Successive Indian governments have assented to amend the patent laws to conform to the regulations under the WTO. A monopolistic patent regime will have serious implications for the poor in India because drug prices will rise phenomenally. One needs to remind policymakers that in spite of lower drug prices, still over two-thirds of India's population is unable to afford drugs.

By bringing highly technical issues into public arena, this episode has clearly exposed how TRIPS and the concomitant patent regime can adversely affect the lives of AIDS patients in the poor and the developing world. Universal health programs and other public funded interventions notwithstanding, it is also necessary that monopolies in the drug industry be dismantled so as to ensure that crucial drugs are made accessible to the poor patients at affordable price.

26 Robert Weissman, *op. cit.*, April 2001.