

Anthrax, Drug Transnationals, and TRIPs

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Against the backdrop of September 11th terrorist attacks in the U.S., the anthrax attacks in late 2001 raised highly controversial issues related to intellectual property rights. Just a few months earlier, the world had witnessed heated debates on the patent controversy when the Pharmaceutical Manufacturers' Association of South Africa (PMASA), a body representing South African subsidiaries of 39 drug transnational corporations (TNCs), took the South African government to court to prevent it from importing cheaper versions of patented drugs for patients suffering from Acquired Immuno Deficiency Syndrome (AIDS). However, under tremendous pressure generated by health activists and concerned groups around the world, the drug TNCs unconditionally dropped the lawsuit against the South African government.

No doubt, it is unfair to compare the AIDS pandemic in South Africa with the current anthrax crisis in America. As compared to over 4.7 million patients suffering from AIDS and nearly 300 AIDS patients dying every day in South Africa, the anthrax attacks in the U.S. only killed five people, made 13 others fall ill and caused more than 30,000 people to take precautionary antibiotics. Both instances relate to public health, but more importantly, the bone of contention revolves around the Trade-Related Intellectual Property Rights (TRIPs) agreement of the World Trade Organization (WTO).

Moreover, both these instances confirm the apprehensions of several developing countries—as well as health activists—that drug TNCs put profits before public health and the WTO regime severely restricts the capacity of national governments to take measures to safeguard public health.

The Price of Anthrax Drugs: Scarier than the Disease

The current controversy on patented drugs started when the first signs of anthrax attacks appeared in U.S. in early October 2001. Ciprofloxacin, an antibiotic drug, is prescribed for treating patients suffering from anthrax and other bacteria. German drug TNC, Bayer AG, holds the patent for Cipro (the brand name of ciprofloxacin) in the U.S. until December 9, 2003. Under the present TRIPs agreement of the WTO regime, it implies that no other drug company is allowed to commercially manufacture and sell the generic versions of this drug in the U.S. until the Bayer patent expires, except under extraordinary circumstances, which allow compulsory licensing and parallel importing.¹ Cipro is not only one of the best selling antibiotic drugs in the world but it is also a mega profit earning drug for Bayer. In U.S. alone, Bayer sold \$1.04 billion worth of Cipro in 1999.

As the specter of an anthrax epidemic loomed large on the horizon, people started piling up stocks of Cipro. The sudden increase in the

demand for Cipro led to a steep hike in its retail prices. With the wholesale prices of Cipro at \$4.67 for a 500 mg pill in the U.S., the retail prices went up to as much as \$7 a pill. For anthrax treatment, it is recommended that patients should take two pills a day for 60 days. Thus, the retail price for two months stock of Cipro was well over \$700, much beyond the means of poor Americans. Given the fact that two months of stock of a generic version of Cipro costs a fraction of the prevalent price in the U.S., there was uproar over the monopolistic profits made by Bayer from the public health crisis. In India, for instance, Bayer's Baycip (the brand name of ciprofloxacin in India) is available at drug stores at \$0.13 a pill. Thus, the retail price for two months stock of Baycip would be just \$17. Whereas two months of stock of a generic version of ciprofloxacin is available at a price as low as \$8 at drug stores in India (see Table 1).

In spite of higher prices, there were not adequate stocks of Cipro in American drug stores. Bayer expressed its inability to produce a sufficient supply of Cipro at a short notice as requested by the U.S. health authorities. At best, Bayer offered to produce 200 million pills within 60 days, much lower than the requirement of 1.2 billion pills. It would have taken several months for Bayer to meet the requirement. Confronted with a scenario where panic was spreading like wild fire all over the U.S., the Bush administration should have busted Bayer's patent on ciprofloxacin and allowed sale of generic versions of the drug in the country. There are a host of drug companies (including Ranbaxy, Dr Reddy's Lab, and Cipla from India) which have already received quality approval from the U.S. Food and

Table 1: Selected International Prices of Ciprofloxacin (Prices per pill of 500 mg in US dollars, October 2001)

Country	Company	Price
U.S.	Bayer wholesale	4.67
U.S.	Bayer federal government	1.83
Canada	Bayer government	1.58
Canada	Apotex generic/government	0.95
New Zealand	Bayer retail	1.29
South Africa	Bayer government	2.10
Poland	Bayer	1.51
Poland	Polfa Grodzisk generic	0.29
India	Bayer retail	0.13
India	Blue Cross generic/retail	0.10
India	FDC generic/retail	0.06

Source: Compiled by the author from several sources including Health Action International, Consumer Project Technology and retail drug stores in Delhi.

Drug Administration for manufacturing ciprofloxacin. Many of these companies were not only ready to provide ciprofloxacin to the U.S. within 60 days, but more importantly, they offered it at a fraction of the price that Bayer was charging the Americans.

In fact, there are legal provisions in the U.S. that allow compulsory licensing. Under U.S. Federal law (28 USC 1498), the U.S. can purchase products like ciprofloxacin for official use from manufacturers other than the patent holder. In addition, the U.S. government can also promulgate HR 1708 that exempts it from paying any compensation to Bayer for suspending its patent.

Not only the health activists and anti-corporate campaigners in the U.S., even politicians like Charles Schumer, a Democrat senator from New York, strongly demanded the suspension of Bayer's patent. In a letter addressed to Tommy Thompson, U.S. Secretary of Health and Human Services, Ralph Nader (consumer advocate and former presidential candidate) along with his colleague,

James Love, called upon the administration to immediately authorize generic production of ciprofloxacin. In the letter, they pointedly asked the U.S. Health Secretary, "your official responsibility is to protect the public's health, and not to defend large profiteering pharmaceutical companies, which are already making a fortune because of our country's current problems. How do you define the patriotic choice here?"

Abject Surrender

Despite extensive domestic support to suspend Bayer's patent on Cipro, the response of Bush administration was outrageous. Tommy Thompson considered it "illegal" to suspend Bayer's patent on Cipro and he preferred to enter into negotiations with Bayer with the sole intention of lowering the price of Cipro. Facing an unprecedented public embarrassment, Bayer agreed to lower the price of Cipro for government purchase from \$1.77 to \$0.95.

Dubbed as "historic victory" in official U.S. circles, it would be absurd to view this agreement as a major

accomplishment of the Bush administration. Rather, it was a major victory for Bayer because the agreement is based on the condition that the company would continue to remain the sole supplier of the drug in the U.S. till December 2003. Further, the agreement with Bayer only covers government purchases of Cipro from the company, while the drug will be sold at hospitals and drug stores at normal price. Even on discounted price, Bayer is still making profits from huge orders placed by the health authorities. Meanwhile, perturbed over this lopsided agreement with Bayer, consumer activists and concerned groups in several states have filed a lawsuit asking the court to scrap the agreement that gives monopoly rights to Bayer.

Had the Bush administration suspended Bayer's patent and allowed the commercial manufacture and sale of generic versions of Cipro as per existing national laws and international agreements, the real beneficiaries would have been the American people, who would have procured drugs in time and at reasonable prices. This episode confirms the allegations of anti-corporate activists that drug TNCs are being rewarded by the Bush administration for their large financial contributions to the Republicans during the election campaigns.

While these developments were taking place, allegations of price manipulations by Bayer have also come to light. It is alleged that the U.S. subsidiary of Bayer AG signed illegal agreements with three of its competitors—Barr Laboratories, Rugby, and Hoechst-Marion Roussel—to prevent them from challenging its patent rights over Cipro. According to anti-corporate activists, Bayer has paid a total sum of \$200 million to date to

these companies for not manufacturing or marketing a generic version of Cipro, thereby neutralizing competition to protect monopoly profits.

Canada's Flip-Flop Posture

Watching these developments in the U.S. from close quarters, neighboring Canada announced on October 18 that it would suspend Bayer's patent on Cipro and allow generic drug makers to manufacture and sell this drug in the country. The Canadian authorities also approached a domestic generic drug maker, Apotex, to produce one million pills, as Bayer was unable to meet the required allotment of Cipro. Apotex agreed to sell its generic version at \$0.95 per pill to the health authorities, which was significantly lower than the \$1.59 charged by Bayer. This move by the Canadian health authorities sent shock waves through the entire pharmaceutical industry. The drug industry was taken aback by the sudden change in the Canadian stance because the country had consistently supported the U.S. position on the intellectual property rights issue in the past. Bayer, in collusion with several lobby organizations, used all kinds of pressure tactics, including a threat to sue the Canadian government, for reversing this position. Within hours, the Canadian authorities reversed their stand again and announced that they would honor Bayer's patent on Cipro and would buy the drug only from the company. This sordid episode demonstrates the shady role played by the drug companies and their lobby organizations to stifle competition from low cost generic drug manufacturers.

The U.S. Administration: Hand in Glove with the Drug Giants

The Bush administration did not suspend Bayer's patent largely because it was more concerned with the wider implications of such an action, particularly on the ongoing negotiations at the WTO. Realizing that scrapping Bayer's patent would set a precedent that could give legitimacy to the growing demands of the poor and developing world for more flexibility on patent issues, the U.S. has given a clear message to the world that patents are more important than public health. Such a calculated move was not only meant to serve the corporate interests of drug TNCs, but it also conveyed the message to the developing nations that Washington would continue its discriminatory policy on the issue of patents.

It is ironic that the U.S. administration abandons its responsibility when it comes to protecting its own citizens from public health calamities while it acts as a supercop when the drug industry's patents and profits are at stake. In international economic negotiations, Washington has been one of the strongest allies of the global drug industry. Acting on the behest of drug TNCs, the U.S. played a key role in initiating the Uruguay round of GATT negotiations where several agreements including TRIPs were pushed forward. The U.S. has challenged various countries at the WTO tribunal and has even threatened trade sanctions against several countries including Thailand, India, South Africa, and Brazil for breaching TRIPs. Although the TRIPs agreement does allow member countries to take compensatory measures to counter the effective monopolies of companies owning patents, undue pressure has been put on many devel-

oping countries to refrain from exercising their rights of compulsory licensing and parallel import. The dispute settlement case lodged by the U.S. against Brazil in the WTO in relation to its Industrial Property Law and the lawsuit filed by 39 drug TNCs against the South African government are some of the instances of pressure tactics.

Particularly in the past couple of years, the U.S. has been advocating imposition of stringent measures for protecting patents under the so-called "TRIPs-Plus" mechanism. Therefore, it is not surprising that the U.S. has been vehemently opposed to a document on patents and drug issues prepared by nearly 50 WTO member countries, including the Africa Group, Brazil, and India. Concerned with poor peoples' lack of access to affordable medicines due to high prices of patented drugs and the resultant public health crisis, this document seeks suitable changes in the present TRIPs agreement. The document clearly states that "nothing in the [TRIPs] agreement shall prevent governments from taking measures to protect public health."

Lip Service at Doha Conference

The wider concerns for protecting public health were expected to usher in substantial changes to the existing TRIPs agreement at the Fourth WTO Ministerial Conference in Doha, Qatar held November 9-13, 2001. Not only health activists and NGOs, but also several poor and developing countries had shown determination to raise this vital issue at the Doha conference. But the outcome of the Doha conference was disastrous for the world's poor because it provides few concessions on the drug patents issue. Except for providing

least-developed countries an additional 10 years to implement TRIPs and giving autonomy to governments to define public health emergencies in which TRIPs could be suspended, the Doha conference failed to resolve the fundamental conflicts between patents and public health. The lip service approach to this vital issue can be gauged from the fact that the declaration on the TRIPs agreement and public health was issued separately, not as part of the main Ministerial Declaration. With the key issues related to drug patents remaining unresolved, the world is likely to witness patents versus poor patients conflicts in the coming years.

The agreement reached at Doha for a new round of negotiations is a significant achievement for the U.S., the EU, and Japan as it opens up new opportunities for TNCs to further expand their global reach. It is important to highlight the hypocritical stand of Indian authorities on WTO issues, which was completely exposed during the Doha Conference. A few weeks before the Doha conference, Indian authorities took a strong posture seeking drastic changes in the TRIPs agreement as well as opposing any new round of negotiations until contentious issues related to the implementation of Uruguay round of negotiations were resolved. Not only the poor and developing countries, but also several Indian and international NGOs joined the ranks in support of Indian authorities. But within hours after asserting that "a new round of trade talks at the WTO is not necessary, it is evil," India's Commerce Minister, Murasoli Maran, agreed to a new round of formal negotiations without any major gains in key areas such as textiles, agriculture, TRIPs, and transfer of technology. This is hardly surprising given the fact that the same Indian

government is not just pursuing amendments in domestic patent laws to conform with the WTO regime but also is pushing a liberalization agenda in several sectors of economy (for instance, financial sector) that are well beyond the purview of WTO.

Wider Ramifications

Several inferences can be drawn from the anthrax crisis in the U.S. First, by sacrificing the public health concern of its own citizens to protect the private interests of drug TNCs, the U.S. has unabashedly acknowledged the supremacy of patents over public health. Second, the present patent regime not only poses a grave danger to public health in the poor and the developing world, even the developed world is also not immune to it. Hence, this episode should serve as a wake up call to the rest of the developed countries who usually follow the footsteps of the U.S. on patent issues. Poor and ordinary people, whether they live in New York or New Delhi, have a basic right to sound health, and therefore, safeguarding public health must take precedence over patents and monopoly profits of the drug TNCs.

Third, apart from universal health programs and other publicly funded interventions, it is of utmost importance that monopolies in the drug industry be dismantled to ensure that crucial drugs are made accessible to poor patients at affordable prices. Therefore, strict regulation of drug TNCs must be an integral component of building a public health system in the developed as well as the developing world.

Fourth, with critical support from the developed countries not forthcoming, the responsibility for demanding a comprehensive review of TRIPs,

including reduction in the duration and scope of patent protection for drugs that are essential for public health, rests with the poor and developing countries. This calls for greater unity and solidarity among the poor and the developed world on issues of common interest at the WTO and other international economic negotiations.

Finally, it is high time that the primacy of national health policy over international agreements, including the WTO, be restored.

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Endnote:

1 Under compulsory licensing, a government can allow local companies to produce cheaper versions of drugs whose patents are controlled by foreign drug companies. Local companies can produce and sell drugs in the country 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, while parallel importing

allows countries to import cheap, generic versions of drugs without permission from the patent holders. For instance, the U.S. government can import drugs from an Indian company to sell them in the country. Since the prices of drugs are lower in several countries, particularly in developing ones, 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. But the scope of using these measures is severely restricted under the present TRIPs regime.