

## Friend or Foe: CIPLA and Health Care in the Age of Intellectual Property Rights

- Cast of Characters:   World Trade Organization (148 members)  
                          World Health Organization  
                          European Union  
                          Western Pharmaceutical Manufacturers  
                          Generic Pharmaceutical Manufacturers (principally Cipla)  
                          Governments of Developed Nations  
                          Governments of Developing Nations  
                          Least Developed Countries  
                          Sub-Saharan Africa (48 nations; 24 million living with HIV/AIDS)  
                          Medicins Sans Frontier  
                          HIV/AIDS patients (42 million worldwide)
- Forces:                Patent Laws  
                          *Patentability*  
                          *Pre-Grant Opposition*  
                          *Evergreening*  
                          Trade Related Intellectual Property Rights (TRIPS)  
                          Doha Declaration  
                          Compulsory Licensing

Yusuf Hamied, CEO of Cipla, a pharmaceutical company headquartered in India, feels no need to temper his language when he speaks of international patent laws and their effect on the pricing of essential medicines for a global market. “Trading in Death” is one of the phrases he uses to characterize the Indian government’s recent assurance to the World Trade Organization that it would revise its patent laws, in operation since 1972, to bring them in line with the increased emphasis on protecting intellectual property rights. In his view, the pharmaceutical companies in the West—specifically the United States and Europe—are arch villains, and the governments of various nations are held hostage to the economic might of these multinational corporations (MNC). Although the pharmaceutical industry in the West sees him as a pirate and a thief, Hamied is unapologetically defiant, insisting that he has broken no laws (see below for his justification). His stand on the pricing of essential medicines (for tuberculosis, malaria, and

HIV/AIDS) is nothing short of revolutionary. Hamied is proof that a single individual can take on the extremely complicated machinery of the international pharmaceutical industry and the World Trade Organization (according to the consumer advocacy group Public Citizen, from 1997 to 2002, the pharmaceutical industry spent nearly \$478 million on lobbying; see Shah) and force it to interrogate its practices and positions. Admittedly, he is no ordinary man on the street, but in the fierce resistance he has encountered to his pioneering offer of inexpensive antiretrovirals to countries in sub-Saharan Africa, one realizes the extraordinary courage of his position and the rarity of the sentiment underlying his gesture.

CIPLA is the leading pharmaceutical company in India, having posted net profits of approximately \$90,000,000 this past fiscal year (figures from the Cipla Annual Report). A significant portion of this profit can be attributed to the sale of generic drugs that Cipla manufactures, and so one could argue that his economic power and influence within the Indian pharmaceutical industry stem from ill-gotten gains. But Hamied sees his company as performing an essential humanitarian service, a responsibility that the western pharmaceuticals and western governments have abdicated. Patents are a favor, not a right that a government grants to an innovator, he notes. It's a present, and that present can be recalled or suspended at any time, should circumstances arise that necessitate such a move. The current world health crisis is such a circumstance argues Hamied: "We are dividing the people of the world into those who can afford life-saving drugs and those who cannot. This amounts to a systematic denial of people's right to life and health in the poorer parts of the world." Patent laws are national laws, not international laws, says Hamied; no two countries will have the same patent laws, because these are need-based to the country. For instance, he observes, in the United States, one cannot patent anything connected with the atomic or nuclear industry.

“I’m not against patents, but against monopolies,” Hamied asserts. One could say that he has a “Robin Hood” complex, or even that he is on a self-mythologizing mission. Whatever his motivation—altruistic or selfish, or a combination of both—one cannot deny that without Hamied’s intervention the move to cut drastically the prices of anti-retroviral (ARV) medications might have been delayed indefinitely. It is not an exaggeration to say that a large percentage of AIDS patients in sub-Saharan Africa owe their lives to him; in 2003, the World Health Organization approved the triple-drug cocktail Triomune, manufactured by Cipla. Medication regimens that prior to 2001 cost as much as \$12,000 per patient annually dropped in price to \$1,200 per patient annually and further, through Cipla’s offer to Medicins Sans Frontier, to as low as \$300 per patient annually. “If, through my action, I have forced the western pharmaceutical multinationals to cut their price to 1/10<sup>th</sup> of what they were originally charging governments in Africa, then I can be satisfied that I have done my service to humanity,” says Hamied. That these MNCs had done nothing to address the high cost of the drugs before he made his offer to the world in 2001 is proof, according to him, that the western pharmaceutical industry is devoid of heart.

So what exactly did Hamied do? He earned the piracy charge by declaring that Cipla would make available a cocktail of three ARV drugs—Stavudine, Nevirapine, and Lamivudine. In a 2004 address at the Vatican, Hamied explained that these three drugs are produced by three different companies—Bristol-Myers Squibb of the United States, Boehringer-Ingelheim of Germany, and GlaxoSmithKline of the United Kingdom, respectively. The individual companies could not combine the separate medications into one tablet, but in India Cipla could do so legally (because India operated under process patent rather than product laws until recently). The combination medication, Triomune, was Cipla’s innovation, and the company applied for WHO

approval of this cocktail. But the development of the ARV cocktail Triomune was not the principal reason for the attack on Hamied. It was the price at which he was ready to make it available that led to his being branded a thief. Hamied's offer of reduced prices came in stages. In September 2000, at the European Union's High Level Round Table on Communicable Diseases (held in Brussels), Hamied announced his readiness to offer the triple-drug combination at \$800 per patient per year as against the price at the time of \$10,000 per patient per year. Hamied recalls that "We also offered totally free, technology to any Third World government wanting to produce their own ARV drugs. Subsequently, we also offered to supply free worldwide the single dose drug Nevirapine capable of stopping the transmission from mother to child. Surprisingly, the world watched silently and there was no response." In February 2001, he took another bold step and announced that Cipla would offer Triomune at under \$1 per patient per day. Hamied claims that with this dramatic price reduction, "awareness to the problem of HIV/AIDS became a worldwide phenomenon and it opened up the much larger subject of access to medicines at affordable prices. It dawned on one and all that anti-AIDS drugs were not only available from generic companies, but also affordable. The absolute power of patents and drugs and monopoly was clearly exposed." The decision to make ARV drugs affordable to patients in developing and least developed countries has won Hamied a great deal of international fame and notoriety. Whatever his critics and supporters might say about him, he insists that fundamentally he is a businessman and a scientist. He believes that innovation should be rewarded, but urges governments to consider seriously how much the reward should be and for how long. For his own part, he declares that he has no desire to make money on AIDS medications. His company manufactures 800 drugs, and if he does not make money on six drugs, why should he worry, he asks.

The current international attitude on pricing and patents in the realm of health care is schizophrenic. On the one hand, activists and governments of developing countries are beginning to voice their outrage at the western MNCs' refusal to recognize their global obligation to balance the drive for profit with humanitarian concerns. The Doha Declaration of November 2001 (at the Fourth Ministerial conference of the World Trade Organization) was a major victory for countries seeking exceptions to trade related intellectual property rights (TRIPS). On the other hand, the push for protection of intellectual property rights by MNCs in developed countries has intensified, and the United States, in particular, is wielding a heavy hand in forcing governments of developing nations to comply and is making it increasingly difficult for them to avail of the flexibilities built into TRIPS. The recent move by the Indian Congress to approve a revision to its patent laws is clear evidence of the impact of this coercive force by Western governments (the powerful players in the World Trade Organization), which are in turn being lobbied by the MNCs within their borders.

Hamied and many others within the Indian drug industry are deeply angered at the Indian government's capitulation to WTO pressures. They believe that the government's obsession and enthrallment with Information Technology ascendancy and its desire for dominance in this realm has led to the abandonment of India's healthcare commitment not only to its poor but to the world's disenfranchised populations. Says Hamied, "Of the 38 million people worldwide who have HIV, currently only 1 million are actually being treated. Of this group, 500,000 are being treated by Indian drugs, and of this number 250,000 are being treated by Cipla manufactured drugs." It was Hamied's hope that Indian generic drug industry could serve the healthcare needs of developing nations at prices that they could afford. But the new patent laws have jeopardized that hope. Eager to welcome investment in Information Technology by MNCs like Microsoft

and GE, the Indian government has passed patent laws that appear not to take advantage of the flexibilities built into TRIPS. Dilip Shah, Secretary General of the Indian Pharmaceutical Alliance urges the Indian government not to overlook the provisions within TRIPS that grant necessary latitude to governments in how they implement patent laws. He warns that there are forces at work to design the law “to allow the patenting of marginal changes in the known substances (*patentability*) and to deny the patent examiners an opportunity for informed decision making (*pre-grant opposition*). The TRIPS Agreement permits member countries to define *patentability* in their national laws.”

For good reason, the Indian Pharmaceutical Alliance is proud of its achievement in the last 30+ years. The rise of Cipla is illuminative of the causes for this success. Hamied tells the story eloquently: his father, a strong anti-colonialist, founded the company in 1935, and in 1939 when Mahatma visited the company and urged it “to produce medicines for the Indo-British war effort,” Cipla realized the value of “self-reliance” and “self-sufficiency” (India was under colonial rule until 1947). Hamied recalls that in 1960 when he returned to India from Cambridge University to begin his career in the pharmaceutical industry, he found that the MNCs had a monopoly on drug manufacturing in India. “[E]very major drug we wanted to manufacture was covered by patents.” It wasn’t until 1972 that India, thanks to Indira Gandhi’s realization that in the areas of food and medicine national self-reliance was critical, passed the Indian Patent Act that gave Indian pharmaceutical companies the freedom to manufacture domestically any drug required by the country that was available on the international market, provided that the process of production did not duplicate that of the patent holder’s. In other words, Indian drug manufacturers were bound by process patents, not product patents. Hamied is emphatic that he never broke any laws. He was accountable to Indian laws, and these he observed scrupulously.

In this connection, it is worth remembering that TRIPS compliancy requirements could result in the criminalization of actions of member nations responding to domestic health crises. The new Indian product patent law that went into effect in January 2005 has seriously altered this picture for Indian drug manufacturers.

Hamied and Shah have both separately addressed the vexing issue of evergreening, the process by which patent holders prolong indefinitely the patent on a product beyond the 20-year period, the legal time that a patent remains in effect. Evergreening takes place, says Hamied,

by appending numerous patents which apply to multiple aspects of a single product, that expire at different times. The best example for this is the AIDS drug AZT. It was invented in 1963, but a patent on its use against AIDS was filed only in 1985. This patent is to expire internationally in 2005. But the license holder, GSK [GlaxoSmithKline], then combined Lamivudine (whose patent expires in 2007) with AZT and filed a patent for this fixed dose formulation in 1998, which will last until 2018. So here you have a drug originally invented in 1963, which is under patent directly and indirectly until 2018. It's a monopoly of more than half a century. (*The Little Magazine*, 47)

Dilip Shah also takes up the issue of AZT in a review of Marcia Angell's book *The Truth about Drug Companies*, but he offers the revealing historical background. The research that led to the synthesis of the AZT molecule took place at the Michigan Cancer Foundation. Its effectiveness against AIDS was discovered in 1985 by a team of scientists at Duke University and the National Cancer Institute. Shortly thereafter, Burroughs Wellcome patented the drug and won FDA

approval for it in 1987. GSK acquired the patent from Burroughs Wellcome. Angell, says Shah, makes the point that

Burroughs Wellcome did not develop or provide the first application of the technology to determine whether a drug like AZT could suppress live AIDS virus in human cells. Nor did it develop the technology to determine at what concentration such an effect might be achieved in humans. Nor was it the first to administer AZT to an AIDS patient. Nor did it perform the first clinical studies. Nor the immunological and virological studies necessary to infer that the drug might work, and was therefore worth pursuing in further studies. (Shah, 74).

Cipla's pricing strategy for ARV drugs is now enshrined in a case study at the Harvard Business School. What began as a study on pricing quickly metamorphosed into a case study on the "tensions between pricing as a reward for investment in R&D versus making a product available to poor people who will die without it," (Hanna 38) says Rohit Deshpande, the author of the HBS case study. His students were polarized by the discussion, he observes. The Cipla case study is part of HBS's Leadership and Corporate Accountability Program. In a curious assertion about the effect of the case in his classroom, Deshpande reveals what could be the problem with the business world today:

"This [pricing of AIDS drugs] was an issue that took the discussion beyond the realm of typical products and services and the normal laws of supply and demand. It's not a career-oriented case that lends itself to helping students set up for interviews. And yet it touched the hearts and minds of students, which is gratifying." (Hanna 38)

Whether or not Deshpande intended to drive a wedge between career interests and the heart, or to posit the two as irreconcilable, that is certainly the implication of what he says.

Yet, Hamied shows that the customary opposition between the two can be bridged. It's always dangerous to speculate on the motivations that prompt a businessman to exhibit heart, but Hamied's actions reveal that one need not feel crushed by the inexorable logic of excessive profit. The qualifier "excessive" is key, because Hamied is by no means calling for an abolishing of the fundamental tenet of capitalism. He is, first and foremost, a businessman. But he is a businessman who asks, "What do you want in life?" and then declares emphatically, "There is a lot of soul-searching that needs to be done by the pharma industry in the West."

Cipla's headquarters is located on a street in Mumbai that signals unmistakably the great poverty of the majority of the Indian citizenry. As the cab I was in entered the street, I looked everywhere for a plush building, the edifice of success. I didn't see it, and I was convinced that I had got the address wrong. Though I had grown up in India, I had come to expect that corporate headquarters of an internationally known company would be located in an affluent setting akin to mid-town Manhattan or Boston's financial district. Cipla's headquarters, which I found only after I got down from the cab and walked the street and asked people (who pointed to what at first appeared to be nothing, a phantasm), lies behind tall metal gates smack in the midst of a ramshackle overcrowded messy Mumbai road. The gates themselves are nondescript, hardly imposing or arresting. At the end of my hour-long conversation with Hamied, it made perfect sense to me that Cipla should be located where it is.

Notes

I met with Yusuf Hamied on August 18, 2005 and with Dilip Shah on August 17, 2005. Both meetings took place in Mumbai, India.

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