HADDAD OSLO TALK (PART 1)

TITLE: ***"BACK TO THE FUTURE"***

In this talk I will address the question posed to me by Harvey Bale: How and why I am here? I will discuss Cipla and their offer and tell you a little about a remarkable man, Dr. Yusuf Hamied. I will address differential pricing using the pharmaceutical industry's current practices. I will question the convoluted, structured and often subsidized academic logic presented at this Conference and elsewhere in this debate and suggest this is "déjà vu all over again," a continuation of what has happened to competition in the pharmaceutical industry in the past. Finally, I will outline current and contemplated European community actions that now hinder and shortly will dramatically impact the delivery of new pharmaceuticals to the HIV/AIDS community. I will suggest TRIPS MINUS and TRIPS north/TRIPS south as possible solutions to current and future problems in the delivery of affordable, quality pharmaceuticals in crisis situations. I will address the question of whether it is ethically, morally or legally correct for the rich nations of the world to dictate policies for poor nations where local leaders must make life and death decisions.
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the headline: "AIDS Epidemic Traps Drug Firms in a Vise: Treatment vs. Profits" was this lead paragraph: "Can the pharmaceutical industry inflict more damage upon its ailing public image? Well, how about suing Nelson Mandela?" (WSJ 03/02/01.) Guess what? They did.

To our surprise, the multinationals surrendered and with the Secretary General of the UN issued their third statement: we are coming. This time it rings true.

Further, Cipla offered Nevirapine free to governments to erect the wall between transmission from mother to child. We are pursuing a pilot project for 100 hospitals. Both UNAIDS and Boehringer told us here they have made the same offer for the last several years, but with few takers. Maybe their experience will enable us to do better, but time will tell. Thanks to MSF our first triple cocktails are being shipped as we talk.

A recent New York Times editorial summed it up: "...just nine months ago, people in the third world could expect to pay the same $10,000 for triple therapy that Americans pay. Today, thanks to the competition from generics and the pharmaceutical companies' need to repair a public image as AIDS profiteers, every African government will soon be able to buy brand-name triple therapy for $1200 a year or a generic version for half to a third of that." End of story.

We popped no champagne. The joy of accomplishment is dramatically diminished when we realize how many children died painfully in the interim.

CIPLA AND DR. HAMIED

I have been asked by people at this Conference about Dr. Hamied and Cipla. Let me quote from the WSJ:

"Yusuf K. Hamied is a man with impressive humanitarian credentials. His pharmaceutical company, Cipla, Ltd., runs a free cancer-care hospital in India...when a devastating earthquake recently struck Gujaret State, Dr. Hamied ordered his company warehouse opened, on a holiday, to supply free medicine...(his offer at providing triple combination anti-retroviral AIDS drugs) is transforming the debate of how to provide critical medicines to poor nations...(with a Cambridge, Ph.D., Chemistry) Dr. Hamied showed a special brilliance for decoding the foreign companies' newly invented drugs. Colleagues in the industry recall seeing him scribble from memory all the steps needed to synthesize a particular molecule."

Personally, I find Dr. Hamied to be a modest, almost shy person with deep convictions and commitment. When the brown people of India were denied life saving essential drugs because they could not afford the international pricing, he developed and sold them generically. Perhaps that is the reason he understands the problems of Africa today.

Cipla is India's third largest pharmaceutical company and exports its products to 125 nations. It manufactures almost all of the anti-retroviral AIDS drugs and is currently testing products that may simplify their use by patients. Cipla has transferred its technology to the United States, Canada, Germany, the UK and Israel, as well as to Ecuador, Ivory Coast and Saudi Arabia. The company has joint marketing ventures in Australia, Ireland, South Africa and Europe. It has provided free technical assistance to Cuba and trained Cuban technicians in both India and Cuba. Cipla supplies basic raw materials to the generic industry in the United States. Its facilities have been approved by all the major western and international authorities including the US FDA.

And, Harvey, I am a volunteer for this effort.

DIFFERENTIAL PRICING

Differential pricing is a normal condition of business in the branded pharmaceutical community.

Let me narrow the discussion: the issue is differential pricing in markets protected by pharmaceutical patents and lower priced competition is excluded during a crisis. Patent holders fear differential pricing in Africa will create a precedent for lowering prices in their other more affluent markets compounded by the

realistic concern of black market transshipment of their lower priced product to other more pricey markets. The pandemic in Africa and the exclusion of generic competition into markets the patent holders cannot serve, all but makes the this discussion academic. The current decision to meet generic prices will, for the moment, avoid the issue. Nevertheless, those benefiting from the patent holders lower price policy, must assume some responsibility to address these concerns. Succinctly, the pandemic in Africa supersedes all theoretical or academic discussions. There are two obvious alternatives if price remains a barrier to life saving medicines. Patent holders routinely use voluntary licensing for a fixed fee in markets too small to exploit. Cipla has offered to license the patented AIDS products for use in South Africa for a universally accepted fee.

Compulsory licensing under TRIPS is permitted but not understood. *I was disturbed to learn from the*

coded cartel minutes in Latin America. The cartel members paid $200,000,000 in fines, but no one went to jail. Memories faded as tetracycline and miracle drugs became affordable.

What did not fade into the night was Phama's desire to restrict competition even when patents expired. Years later, using New York's subpoena power and legislative hearings, I was to learn that 160 essential drugs with expired patents had no competition. As I began to explore the reasons, an academic report prepared by the medical school of a famous University arrived in Congress claiming that patent life had been cut in half by bureaucratic restraints. It was untrue, but ninety Senators (out of a hundred) and two-thirds of our House of Representatives sponsored "remedial" legislation to extend patent life for seven years for all existing and future patents effectively ending generic competition.

At a critical and desperate moment, fate intervened. I received a handwritten letter from a credentialed woman who claimed to have been hired to conduct the academic survey only to find it had been written before she arrived and had been secretly financed by the pharmaceutical association. She and her deputy had resigned in protest. She said she had the confirming records.

Bottom line: her story was true, she had the records, hearings were held and instead of the restrictive legislation, the Drug Price Competition and Patent Restoration Act emerged (Hatch-Waxman, named after its sponsors). That law created the U.S. generic industry and today serves as the model for most nations. Generic market share after a patent expired jumped from eight percent to seventy-five percent.

There are two key provisions of that legislation that relate to our discussions here. One established, by law, the scientific process for cloning and approval. We had been denied approval *because FDA said it had no process to approve generic clones.* The other was the so-called Bolar provision that permitted the generic companies to import just enough raw material to create the clone and have it developed and approved before a patent expired, a three to four year process.

With the United States committed to competition, Pharma turned to a gullible Europe and the team that brought you TRIPS, went to work. First they bypassed Bolar by prohibiting through legislation raw materials to be shipped from Europe...the major source of our raw material...until after the product patent had expired, essentially adding three to four years of life to a patent worldwide. You will notice the full impact when India and some other countries conform to TRIPS.

This team...based in Brussels...also succeeded in extending patent life for Europe ... and within TRIPS ... from seventeen to twenty years. Using the so-called "harmonization" concept of TRIPS, the United States accepted the twenty-year patent life providing an immediate multibillion-dollar windfall for Pharma companies.

PERPETUAL PATENTS

The worst is yet to come. We now have "perpetual patents" for the emerging generation of pharmaceuticals. Until the nineties most pharmaceuticals were developed from a chemical base. Today and into the future most breakthrough drugs will be biologically based, the so-called biotech drugs. Because the FDA does not have a process to clone them (sound familiar?), the biotech drugs remain on patent forever and a day. Hard to believe, but that is the truth.

Many of these drugs, some used to treat AIDS and downstream medical complications, are already cor ah95m2 TD 03o5 0 TD 0

Let me repeat: no community will be more impacted than AIDS patients waiting patiently for either a cure or a vaccine. We have made nearly affordable the anti-retroviral drugs, but unless current law is changed, we will be back where we started, cures and vaccines out of the reach of most persons...including millions in the United States. These drugs now cost between $3000 and $300,000 a year! When and if the US Congress approves a prescription drug program for the elderly, the price of these life saving off patent products will not be on the list of medicines they can receive. In one sense, they will join with the millions in Africa who are now denied treatment. That is not an overstatement, but a fact of life.

ACADEMIC ARGUMENTS

Given the history of academia and the generic drug industry, I have very little patience with studies and reports that are used to impress the uninformed about how the pharmaceutical industry functions. I was

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Sixth, assist poorer nations in adopting bilateral "memorandums of understanding" with developed nations to expedite the approval of imported or locally manufactured medicines. The U.S.-Russian model, now copied by Canada and France, provides the workable guidelines and protects national integrity. There is no need to reinvent the wheel.

Seventh, a program I call "Have Plant Will Travel," a series of interlocking modular built inexpensive generic plants built to world standards that can be expanded by market demand and produce the full range of essential drugs at barometer prices. (I will make available the plans to those who are interested.)

Eighth, urge the United States Pharmacopoeia to prepare monographs for AIDS cocktails. Such a procedure will enable companies to clone AIDS cocktails to world standards. Patents require disclosure of information and increased competition can lower prices.

Ninth, Block the contemplated harmonization of European data disclosure with the United States. Data disclosure enables competition and eliminates the need for expensive studies. Europe enables pharmaceutical companies to withhold data from six to ten years. The U.S. standard is five years. The U.S. disclosure requirement expedites competition.

Tenth, international agencies should negotiate umbrella worldwide contracts for purchase of raw materials that will enable smaller nations to participate at what can be dramatically reduced than those negotiated individually.

Thank you.