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A Conversation with Dr. Anne-Valerie Kaninda

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I. INTRODUCTION

I am going to talk to you about the Campaign for Access to Essential Medicine that has been launched by MSF, which stands for Médecins Sans Frontières, the French name for Doctors without Borders.¹ This campaign was launched about three years ago.² My focus today will be on AIDS, especially AIDS in Africa.

* Kathy Cerminara: Our special guest today and, our Goodwin speaker is Doctor Anne-Valerie Kaninda, who is a medical advisor to Doctors without Borders: Médecins sans Frontières Access to Essential Medicines Campaign. Dr. Kaninda is an epidemiologist specializing in the control of emerging and reemerging diseases. She has worked with MSF since 1994, and has been with the Access to Essential Medicines campaign since April 2000. And I am sure most, if not all of you, know as an affiliate of MSF, she is with the 1999 Noble Peace Prize winning organization that is involved in sending more than 2000 medical volunteers all over the world, especially in developing countries to provide medical care.

1. MSF Access Website, at <http://www.access-med-msf.org/index.asp> (last visited Feb. 17, 2002).

2. MSF Access Website, *The Campaign: Frequently Asked Questions*, at <http://www.accessmed-msf.org/campaign/faq.shtm> (last visited Feb. 17, 2002) (“Launched in

Before we start, I would like to say just a few words about the current environment. Infectious diseases kill fourteen million people per year worldwide.³ Ninety-seven percent of these deaths occur in developing countries.⁴ Infectious disease is the leading cause of death worldwide.⁵

If you look at essential drugs, there are 306 active substances today that governments list as such.⁶ To give you a point of comparison, there are more than 5000 products today approved by the Federal Drug Administration ("FDA") in the United States, so essential drugs are only a very limited subset. According to the World Health Organization (WHO), one-third of the population is denied access to these drugs and the cost of anti-retroviral drugs is approximately \$35, the average monthly income in developing countries.⁷ So there is no way for the people, or even the government, to afford drugs to treat the people for whom it is medically required.

II. CURRENT ENVIRONMENT

Unfortunately, health care is not a priority in many developing countries. There is not a lot of money put in the health budget. In fact, a lot of developing countries have a health budget less than \$10 per year, per person, sometimes even less than four dollars per year, per person.⁸ In addition, the regulatory authorities are very weak and there is a fear of using generics. For example, when the drugs are substandard, or counterfeit, people do not like to use generic even though there are high quality generics which are much cheaper than the brand name drugs and more readily available.⁹ There are no real counter-forces to either industry or government in these societies.

November 1999, the MSF campaign has been working internationally to find long-term, sustainable solutions to this crisis.").

3. Els Torrele, *The Crisis in Drug Research & Development for Neglected Diseases*, The DND Conference (May 2001), at <http://www.neglecteddiseases.org/thecrisis.shtml>.

4. *Id.*

5. The World Health Report 2001, available at <http://www.who.int/whr/2001/archives/1998/factse.htm> (last visited Feb. 17, 2002).

6. The World Health Organization, *Essential Drugs Lists*, at http://www.who.int/ml/topics/essential_drugs_lists/en/index.html (last visited Feb. 17, 2002).

7. See generally Carmen Pérez-Casas et al., *HIV/AIDS Medicines Pricing Report. Setting Objectives: Is There a Political Will?* (July 6, 2000), available at <http://www.accessmed-msf.org/prod/publications.asp> (discussing a series of factors that influence prices).

8. The World Health Organization, *Resources for Health Services*, at <http://www.who.int/infectious-disease-report/2002/healthtext.html> (last visited Feb. 17, 2002).

9. Bernard Pécoul, M.D. et al., *Access to Essential Drugs in Poor Countries*, 281 JAMA 361 (1999).

Many of these countries have governments that are not as accountable as governments can be in wealthy nations like here.

If we look at the pharmaceutical industry in the last two decades of the twentieth century, there has been an incredible amount of consolidation within the industry, with increased competition, and an increased pressure for existing and new medicines to yield high returns.¹⁰ That means that the industry has turned increasingly into a big marketing machine, marketing their new products rather than taking a more health-oriented or research-oriented approach.

III. DRUG DEVELOPMENT

In general, drug companies focus their research and development in areas where the prospect of high returns on their investments is favorable.¹¹ Between 1975 and 1997, among the 1223 new chemical entities that were brought into the market worldwide, only one percent treat tropical diseases.¹² That is thirteen drugs.¹³ Out of those thirteen drugs, most were coming from army research on malaria, such as, the compounds from the Walter Reed Army Institute of Research, or from laboratories with public funding.

Now, if you look at the annual reports from the pharmaceutical companies in terms of market sales in 1999, the projected worldwide pharmaceutical market for Africa and Asia represented 10.6% of the total market.¹⁴ Approximately seventy-two percent of the population lives in Africa and Asia today, and they consume 10.6% of the pharmaceutical market.¹⁵ The pharmaceutical industry's three largest companies are multinational, but they have headquarters in the United States. Considering these companies' annual reports, they have revenues in the billions of dollars. When you compare the amount the companies spend on marketing versus the amount they spend on research and development, at least twice as much is spent on marketing than what is spent on research.

10. *Id.* at 364.

11. Patrice Trouillier et al., *Drugs for Neglected Diseases: A Failure of the Market and a Public Health Failure*, 6 TROPICAL MED. & INT'L HEALTH 945, 946 (2001).

12. Bernard Pécoul, M.D. et al., *supra* note 9, at 364.

13. *Id.*

14. Patrice Trouillier et al., *supra* note 11, at 946.

15. *Id.*

In 1994, 130 countries signed a General Agreement on Tariffs and Trade (GATT) agreement¹⁶ and created the World Trade Organization (WTO). This treaty included an agreement on intellectual property protection. All the countries that signed this agreement and are now members of this World Trade Organization, have to change their national laws to become compliant with the Trade-Related Intellectual Property Rights (TRIPS) agreement.¹⁷ In this agreement, pharmaceuticals are considered as any other goods, like Barbie dolls, CDs, etc. This means the countries that signed the agreement have to grant patents on pharmaceuticals. In many developing countries, pharmaceuticals were not covered by patents. In some countries, they were simply not patentable. Now, this all has to change. This agreement sets the minimum standard for intellectual property protection. It will have a negative effect on drug availability in developing countries because countries that have strong generic industries, such as India or Argentina, will no longer be able to make high-quality copies of medicine for a cheaper price until the patent expires. So this means the Agreement will delay the introduction of cheaper medicines into many developing countries.

In recent years, what we have seen is that the United States and European Union have lobbied poor countries to create national laws that restrict the safeguards included in this TRIPS Agreement. These safeguards include compulsory licenses and parallel imports.¹⁸ Compulsory licenses provide that if a country can not have access to a product because the patent order sets it at a price which does not make it available to the majority of the public, or the product is not available, and the country is in an emergency situation, then the government can issue a license. This, in effect, overrides the rights of the patent order and grants a license to a third party to locally produce the product or import it from a generic manufacturer from the outside in exchange for a reasonable royalty. Of course, pharmaceutical companies hate this safeguard because they see it as a threat to the intellectual property of their patent.

The use of parallel importing is another safeguard that allows governments to do some comparison shopping. If a company, the owner of a patent product, sells its product in country A for a certain price and in country B for a lower price, then the government of country A is allowed to go and buy it

16. *InterAm Database*, International Treaties—GATT (General Agreement on Tariffs and Trade), at <http://www.natlaw.com/treaties/gatt.htm> (last visited Jan. 27, 2002).

17. The TRIPS Agreement. A Guide for the South, The Uruguay Round Agreement on Trade-Related Intellectual Property Rights, at <http://www.southcentre.org/publications/trips/toc.htm> (last visited Jan. 27, 2002).

18. MSF Access Website, *supra* note 2.

for the lower price in country B. This is another safeguard the pharmaceutical companies do not favor. Parallel imports, by the way, are not allowed here in the United States.

All of our amendments allow generic manufacturers to start preparing their file for registration to obtain a generic products license before the patent is expired, so that the very day the patent expires, the product is all ready to enter the market. The generic manufacturers do not have to wait until the day that the patent expires to start doing what is called reverse engineering: start work on the product; learn how to make the product; and provide all the necessary tests and records for the regulatory authorities to get the registration approved.

Moreover, what we have seen in the field so far is that our patients die because drugs become increasingly ineffective. When you use drugs, especially to treat infectious diseases, ultimately you will see resistance to the drug. That is the case with any drug, any antibiotic, antiparasitic or anti-retroviral drug. Thus, we have drugs that were introduced in the first half of the last century that are increasingly ineffective. There are no new drugs brought on the market to replace these drugs. In some cases, the production of existing drugs is abandoned because they are not deemed profitable enough by the pharmaceutical companies, especially drugs which treat diseases affecting poor people in poor countries. These diseases include sleeping sickness, or types of meningitis that do not occur here, in Europe, or in Japan, and other diseases which occur in both the wealthy nations as well as the developing world.

There are new drugs but these drugs, are usually patented and expensive or inaccessible, so people do not have access to the drugs and they die. Over the years we have seen research decrease. That is why we launched this campaign. The objective of the campaign is to stimulate research and development into neglected diseases, to ensure the production of abandoned and endangered drugs, and also to establish a normal system that allows essential medicines to be cheaper in poor countries.

IV. AIDS

Out of the 36 million people infected with the Human Immunodeficiency Virus ("HIV") worldwide, ninety-five percent are in the developing world.¹⁹ Overwhelmingly, the majority of patients do not have access to

19. The World Health Organization, *Profiling the Killers*, at <http://www.who.int/infectious-diseases-report/2002/textintroduction.html> (last visited Feb. 17, 2002).

treatment; treatment for opportunistic infections, but more specifically anti-retroviral treatment. This is really the treatment that has made the difference in the last three years here, in Europe, and in other wealthy nations. As the Health Minister of Zimbabwe said at last year's World Health Organization assembly, there are treatments in the north and the patients are in the south and there is no crossover.

Another paradox with AIDS, is that for the developing world and the majority of the people infected with the virus today, we have been stuck over the last ten to fifteen years with the promotion of "prevention-only" strategies. The ideal prevention would be not to get infected. That is the best way to stay healthy, but this strategy does not always work. Prevention-only methods have not been able to control the course of the epidemic. We still continue to say that the answer is prevention, but I am not sure that this is an ethical medical attitude to have. Another problem is that the newer anti-retrovirals, as of today, are not included in the World Health Organization's model list of essential drugs.²⁰ Of the anti-retrovirals, only zidovudine (AZT) and nevirapine were listed as essential drugs in 1999.

Finally, another paradox is that in the very few local initiatives, where treatment has been introduced—we have seen and witnessed this first-hand in our own projects in the field—when you start treating people, people come and get tested because there is hope for them. Each time you offer treatment, you maximize the effectiveness of your prevention activities. If you do not offer treatment to people, they do not want to know because it is a death sentence for them and then there is another stigma associated with this disease. That is, they are rejected and marginalized by their societies and families and they just end up in a miserable, destitute state and die. However, when you offer treatment, people are more open to the prevention messages that you give them, and they come to get tested.

Today, less than ten percent of the people infected with the virus know or suspect that they are infected with the virus. How can you do effective prevention if people do not even know that they are infected? Also, when you look for treatment, and especially if the treatment combination is highly active anti-retroviral therapy, you decrease the amount of virus that replicates in the bodies of people and they become less infectious and less likely to transmit the disease. So why not treat people? For the answer to this question, you have to look at the industry rhetoric on the issue.

20. JOINT UNICEF-UNAIDS-WHO/EDM-MSF PROJECT, SELECTED DRUGS USED IN THE CARE OF PEOPLE LIVING WITH HIV: SOURCES AND PRICES 10 (2000).

V. INDUSTRY RHETORIC—HIV/AIDS

If you listen to the industry rhetoric, the pharmaceutical companies will say that patents are not the issue, rather, the rhetoric is that intellectual property protections are fundamental to the way the industry works because they have to invest a lot of money in research and development. Out of the several thousand compounds screened, only one will be brought on the market. Yet, so much money is spent on marketing that could be put to better use in research and development.

When we ask companies to decrease their price for poor countries, they are very reluctant to do so. At least until very recently, because they say that the money is needed for research and development. But if you look at it, what appears to drive their agenda is really the wealthy market. They actually recoup their costs and investments in this wealthy market.

So, what we are asking for is some extra production in markets where they do not sell anything anyway today, where they are not interested in selling anything. What is the point of protecting the intellectual property in these markets if they are not interested in selling? At least they should let other people, like the manufacturers of generics, sell the drugs. But, they argue that intellectual property protections are fundamental and patents are not the issue.

The pharmaceutical industry claims that with AIDS, the problem is not drugs, the problem is infrastructure. Even if you had the drugs for free, you would not be able to use them because you do not have transportation means, you do not have distribution systems, you do not have clean water, and you do not have human resources. You do not have the basic necessities. This is a blanket statement. There is a huge heterogeneity among different countries in the developing world, and there are countries today that are ready to start treating people if they had the drugs. Countries like South Africa and Thailand, for instance, could do a lot today.

Within these countries, too, there is a huge heterogeneity. Even in the least developed countries, in the large urban areas, there exists a minimum of laboratory facilities and health care. It is not in the best shape of course. If we had the drugs for free today, although we would not be able to cover 100% of the needs of the entire population of these countries, we could do something. We could start. We need not do nothing or everything; there is a significant something in between where we could start. That is what we should be doing today. Infrastructure is a constraint, but it is not an excuse for not doing anything.

Another issue is compliance. Some will argue that these are complicated regimens and poor people in poor countries will not be able to comply. They will not be able to take the drugs. This is simply not true. The evidence consists of really limited experiences. But in Brazil, or in Senegal, or in Uganda, for instance, it shows that if you offer drugs to people and they are sick they are going to take the drugs. Of course, if you use a drug-dumping program, just give the drugs and then leave, then people are not going to take their drugs. But if you have a quality program, rational use of drugs, and if you are careful with what you are doing, then people are as able to take the drugs in that setting as they are able to take the drugs in the United States.

Next, an issue which is often brought up is the issue of resistance. You are not going to have good compliance if you do not have the proper facilities to monitor the drugs. Then you are going to create super resistant germs that will spread from country to country. With respect to anti-retroviral drugs on a wide scale, of course we are going to create resistance, but what is the point of having effective drugs if you are not going to use them?

Today, there are more than 100 compounds which are in the pipeline; new drugs for AIDS. The drugs for which the virus is going to become resistant are going to be replaced by new compounds in the next year or so. In Europe, in the western world, we have started to create resistance by using the highly active anti-retroviral therapy. When protease inhibitors have been introduced we have seen a whole bunch of patients in which the viral load was starting to increase and be resistant, but who still had a clinical benefit and have been maintained on this therapy, just because the clinical benefit was still there. If we are accepting the creation of resistance here, why would we not accept it overseas in developing countries?

The final argument is that there is no political leadership in developing countries. That is true. There is no political leadership. However, wealthy nations lack political leadership on this issue as well. We have to push for strong political commitments. We cannot accept this as a reason or an excuse for doing nothing. We have to treat people. Today, needed drugs are prohibitively priced because of monopolies in other developing worlds.²¹ Monopolies are one factor responsible for the high prices of drugs. Patents in many of the developing countries, such as Thailand or South Africa, are responsible for monopolies.²² The anti-retrovirals are registered and patented, and in this case, it is an issue.

21. See generally Pérez-Casas et al., *supra* note 7.

22. *Id.* at 15.

Anti-retroviral drugs are not patented in most of the least developed countries; this is true. In many of these countries, they are not registered and they are not available. Pharmaceutical companies do not even bother to register their products in some of these countries. They are not interested in selling them there. Lack of information is always very important in terms of monopolies. In some countries, we see generics sold at the same price as brand name products. And when you look at it, they are the only ones, so you can have several sources of generic, but only one is registered there, so why would choose one generic over another brand?

For example, the generic form of an anti-fungal drug used in the treatment of cryptococcal meningitis is sold at twenty-nine cents per tablet in Thailand.²³ In South Africa, the price of the same brand product by Pfizer is approximately four or five dollars per tablet.²⁴ Therefore, the cost of maintenance and treatment per year for 10,000 patients, if you buy the product from Thailand, would cost a little over \$1,000,000.²⁵ If you buy them in South Africa, you would have to spend almost \$30,000,000 for exactly the same number of patients and the same treatment.²⁶ Alternatively, if you look at the number of patients treated per year with a \$1,000,000 budget, there are approximately 10,000 people treated with the Thailand product compared to 350 people treated with the Pfizer product in South Africa.

VI. THE AIDS PROGRAM IN BRAZIL

Brazil decided in 1997 that it would provide free anti-retroviral treatment for its population infected with HIV/AIDS when it is medically required.²⁷ Today, that is almost 100,000 patients.²⁸ They used local, generic production and the threat of compulsory licenses when the drugs were patented and no generic was available to decrease the price. They were able to decrease the price for triple combination therapy on average, to about

23. *Id.* at 12.

24. *Id.*

25. *See id.*

26. *See supra* note 21, at 12.

27. *See Roy Wadia, Brazil's AIDS Policy Earns Global Plaudits* (Aug. 16, 2001), at <http://www.cnn.com/2001/WORLD/americas/08/14/brazil.AIDS/index.html>.

28. "The World Health Organization's latest figures estimate 540,000 people live with HIV and AIDS in the country." Cristiana Mesquita, *Brazil to Break Patent, Make AIDS Drug* (Aug. 22, 2001), at <http://www.cnn.com/2001/WORLD/americas/08/22/aids.drug>.

\$3000 per year, per patient, compared to a cost of between \$10,000 and \$15,000 per patient, per year here.²⁹

The program has been quite successful. They have halved their death rate between 1997 and 1999.³⁰ They have decreased hospitalizations for opportunistic infections by sixty to eighty percent.³¹ Between 1997 and 2000, the program has saved a little over \$600,000,000 in hospitalization costs.³² Furthermore, because these people are not hospitalized and continue to stay healthy for a while, they can still go to work and lead productive lives. This benefit is not even included in the savings.

Presently, the United States is taking Brazil in front of the World Trade Organization (WTO) to challenge their patent legislation.³³ The article they are particularly challenging states that Brazil will grant a patent to a product, but there is a local working requirement; the patent owner has three years to produce the drugs locally if they want the patent to continue to remain in effect. After three years, if the company is not able to produce the drug, or the company cannot prove that there is no way that it can produce the drug locally, the government can then issue a compulsory license and resort to generic production.

For Brazil, it is very important to have the local working requirement because it is a way to attract technology and knowledge in their country instead of granting patents to companies which are going to produce somewhere else and just import the product into the country. It is not clear-cut whether this is or is not allowed under the TRIPS agreement and this is why the dispute settlement has been initiated. The director of Brazil's AIDS program is arguing that the country really needs this particular provision. In particular, the country wants to be allowed to issue a compulsory license after three years if the drug is not produced locally. Brazil also provides for compulsory licenses in case of a health emergency.

29. Kaiser Family Foundation, Kaiser Daily HIV/AIDS Report, *Amid 'Increasingly Bitter' Dispute, WTO Reviews Legality of Brazil's Generic Drug Law* (Feb. 6, 2001), at <http://report.kff.org/archive/aids/2001/2/kh010206.4.htm>.

30. See The World Health Organization, *Brazil*, at <http://www.who.int/infectious-disease-report/2002/healthtext.html> (last visited Feb. 17, 2002).

31. *Id.*

32. *Id.*

33. See Wadia, *supra* note 27.

VII. CIPLA OFFER

Recently, you may have heard, that there was an Indian generic manufacturer that offered to provide HIV treatment combination therapy for \$600 per year, per patient, to the South African government.³⁴ So far, that is the lowest that is available. This is good news because last year in Durban, at the International AIDS Conference, we set a target goal of \$200 per year, per patient, for treatment combination therapy and we were far away from that. The lowest price at that time was approximately \$1000 per person, per year, for a brand name product and then came this generic offer, which was really good news. Cipla even offered what they called a humanitarian price, for MSF of \$350 per patient, per year.³⁵

We are not only campaigning for our programs, we are campaigning for everyone, other “NGOs,” or non-governmental organizations. Anyone involved in the treatment and care of people in the developing world should have access to these affordable prices. If the generic manufacturers can offer a lower price than the brand name industry, with it’s increased market share should be able to offer a lower price as well.

VIII. WHO CHANGE OF POSITION

Recently, there was an official breakthrough with the World Health Organization (“WHO”) change of position. Dr. Gro Harlem Brundtland, the WHO Director-General, said in essence in an editorial in the international Herald Tribune that anti-retrovirals are essential drugs, which was really good news.³⁶ In addition he said anti-retroviral drugs can be administered effectively in Africa without the Western standard of monitoring and follow up.³⁷ This was really good news because one way you can kill the initiative for treating patients in Africa is by setting up very high standards for monitoring and follow up, knowing that there is no way that you can monitor a viral load every other week for patients who live in the middle of the bush, 1000 kilometers away from the center. The World Health Organization now also supports offering the drugs at lower prices in developing countries.

34. Press Release, MSF, *AIDS Triple Therapy for Less Than \$1 a Day* (Feb. 7, 2001), at <http://www.doctorswithoutborders.org/pr/2001/02-07-2001.shtml>.

35. *Id.*

36. Gro Harlem Brundtland, M.D., *Cheaper Drugs Offer Hope in the War Against AIDS*, INT’L HERALD TRIB., Feb. 14, 2001, Opinion, available at <http://www.lexis.com>.

37. *Id.*

IX. *PMA v. NELSON MANDELA*

Then there was the South African lawsuit, *PMA v. Nelson Mandela*. PMA stands for Pharmaceutical Manufacturer Association.³⁸ The Pharmaceutical Manufacturer Association is the South African brand name industry. First, you have to understand that the patent legislation for pharmaceuticals in South Africa was inherited from the apartheid era.

At one time, industries, not only pharmaceutical industries but all of them, were highly discouraged to invest in South Africa. So the South African government passed legislation in 1965 directed at the pharmaceutical industry which gave really sweet deals to brand name companies as an incentive to invest in South Africa.³⁹ After the end of the apartheid, the South African government tried to rectify this legislation to allow the government access to cheaper drugs.⁴⁰ The Medicines and Related Substances Control Amendment Act signed by Nelson Mandela in 1997 provides for things like parallel importation and compulsory licensing. Compulsory licensing was already possible under the previous law, but the new law gave it a broader scope.⁴¹ Generic substitution, or measures like that, would enable the South African government to increase access to cheaper drugs.

Two to four months after that legislation was signed, thirty-nine companies within the Pharmaceutical Manufacturer Association of South Africa sued the government over this legislation.⁴² In effect, this really blocked the enactment of the legislation.⁴³ Since then, the legislation has been signed but it cannot be enforced until the lawsuit is settled. The case was finally starting to be heard on March 5th.⁴⁴ On March 6th, the case was suspended again until April 18th, to allow companies to prepare information regarding pricing

38. For information about the lawsuit between PMA and Nelson Mandela, *see, e.g.*, Josey Ballenger, *Zuma's Health Laws to Be Contested in Court*, BUS. DAY, Feb. 19, 1998, available at <http://lists.essential.org/1998/pharm-policy/msg00005.html>.

39. Medicines and Related Substances Control Act 101 of 1965.

40. Medicines and Related Substances Amendment Act (amending Act 101 of 1965). *See also* Robert Block, *Big Drug Firms Defend Right to Patents on AIDS Drugs in South African Court*, WALL ST. J. (New York), Mar. 6, 2001, at <http://www.aegis.com/news/wsj/2001/WJ010304.html>.

41. § 15C of Medicines and Related Substances Amendment Act.

42. *See SA Victory in AIDS Drugs Case* (Apr. 19, 2001), at http://news.bbc.co.uk/hi/english/world/africa/newsid_1285000/1285097.stm.

43. *Id.*

44. Claire Keeton, *SAfrica-AIDS: S. Africa's Treatment Action Campaign Advances Fight Against AIDS*, AGENCE FRANCE-PRESSE, Mar. 21, 2001, at <http://www.aegis.com/news/afp/2001/AF0103A2.html>.

policies. What the AIDS activists in South Africa have done was to use the case of AIDS and use the focus on AIDS to demonstrate how the prior legislation was really affecting and hurting people living with HIV/AIDS. A group of activists, the Treatment Action Campaign or TAC of South Africa has presented evidence to the court that was not included initially and the pharmaceutical companies asked for more time to prepare the case.⁴⁵

On March 5th and 6th, the international media were present in Pretoria, and filed reports that really hit the news big time. So the reaction from the pharmaceutical companies came very quickly. On March 16th, the European parliament passed an emergency resolution calling all companies to drop the lawsuit in South Africa.⁴⁶ The WHO also made a press release backing the South African policy on drug patents. So, there is a lot of political support for the South African government in that particular case.⁴⁷

X. INDUSTRY REACTION

These developments probably explain the recent industry reaction because they have been really bloodied in the press and public opinion is really not in their favor right now. So Merck, a large pharmaceutical company, came very quickly with the offer of decreasing the prices of two anti-retrovirals that they produce in the market.⁴⁸ Their offer is a little bit puzzling. For the first time it put forth a press release that said it will offer these products for \$500 per year per patient, which is normally \$600 per year per patient in developing countries.⁴⁹ However, Merck said this is not for Brazil, so Brazil is excluded from the deal. It is only for Africa. With Asia, we do not know. So it appears they might be going one step in the right direction, but then two steps back.

Then you look at the price and they say they are offering it at cost, but it is really hard to tell if it is accurate. If you look at Cipla, it is offering a

45. *Id.*

46. Joint News Release, Oxfam & MSF, *European Parliament Demands That Drug Companies Drop Case Against South African Medicines Law* (Mar. 17, 2001), at <http://www.oxfam.org.uk/whatnew/press/cutcost-sa5.htm>.

47. The case was eventually dropped by all thirty-nine companies. See *SA Victory in AIDS Drugs Case*, *supra* note 42.

48. *US Firm Offers Cheap AIDS Drugs* (Mar. 7, 2001), at http://news.bbc.co.uk/hi/english/world/newsid_1207000/1207571.stm.

49. *Id.*

combination of three drugs for \$600 per year, per patient.⁵⁰ So, if Merck is offering one drug for \$500 per patient, per year, it is a little hard to believe it is at cost. It is not clear what they include in calculating cost, but it is hard to believe Cipla is losing any money when they are offering \$600 per year, per patient, on that triple combination therapy.

Then there are the raw materials. If you calculate the quantity of raw material needed per year per patient, then you come up with more than 1000 dollars for the treatment. They probably have discounts when they buy raw material, but it could be ten percent or ninety percent. We do not know since there is no price comparison. It is really hard to tell whether or not these drugs are really offered at cost.

Bristol Myers Squibb is another story. They have exclusive licensing agreements for two drugs and the patents are held by Yale University and the National Institute of Health (NIH). Since they have exclusive licensing agreements, they act as the patent owners and have monopolies. We asked them for a price decrease for many years for both of these drugs for Thailand and South Africa, but they have refused. They have refused, up until very recently.⁵¹ We hooked up with some Yale law school students and told them that their university owns the patent rights on these drugs, we need the drugs, and asked for their assistance. The students went to the Dean and asked to see the original contract. They started making some noise, and made the point that if a professor at the university develops a drug, in the licensing agreement there are usually fair pricing provisions that are not enforced. That is OK here, because this country is rich and can afford the higher price of the drugs, but that is not the case for other countries.

The South Africa media circus, combined with the investigation by the students, made Bristol Myers Squibb announce last week that they were giving an emergency relief patent right and they would make sure, finally, that no patent would stand in the way of access to drugs. In addition, Glaxo last week made a press release or short statement saying that they would provide one of the drugs for \$2 per day, per treatment.⁵²

50. *Indian Firm Offers Cheap AIDS Drugs* (Feb. 7, 2001), at http://news.bbc.co.uk/hi/english/health/newsid_1158000/1158637.stm.

51. Michael Waldholz & Rachel Zimmerman, *Bristol-Myers Squibb Offers to Sell AIDS Drugs in Africa at Below Cost*, WALL ST. J. (New York), Mar. 15, 2000, at <http://www.aegis.com/news/wsj/2001/WJ010312.html>.

52. *Glaxo Offers Cheaper AIDS Drugs* (Feb. 21, 2001), at http://news.bbc.co.uk/hi/english/business/newsid_1182000/1182652.stm. See also Mark Schoofs & Michael Waldholz, *Price Wars Breaks Out over AIDS Drugs in Africa As Generics Present Challenge*,

XI. WHAT'S NEXT?

So, what is next? Triple combination therapy is probably going to be made available for \$500 to \$600 dollars per patient, per year for the least developed countries. This is probably where we are headed, hopefully by the end of this year. The question is, who will pay for these drugs? At this price level, the least developed countries do not have the resources necessary to treat their patients, especially those who have between ten to twenty percent of their adult population infected. They do not have the resources, so wealthy nations have to come up with the money. Once you start implementing treatment programs, it is really a long-term commitment. You can not start a treatment program and say, "Ok, I am going to put people on anti-retroviral therapy," and a year later say, "I am not going to pay anymore; I am not giving any money, find your treatment somewhere else." Once you start treating people, it is for life.

XII. SO WHAT HAPPENS WITH GENERICS?

What about generics? Generic companies are in business to make money, exactly like the brand name, research-based pharmaceutical companies, but so far what has driven the prices down is public opinion and competition. It might be tempting for wealthy nations to say they are going to give money, but on the condition that you buy the drugs you need from companies that are in those countries. That policy favors the research-based companies. This would be a big mistake because the developing world has to be part of the solution, as well. Right now, the only pharmaceutical industry that is producing drugs in the developing world is the generic industry.

The generic industry serves as a tool to drive prices down and is needed even if we reach low drug prices today. What about tomorrow when the world's drug needs are going to increase? We will still need to continue to drive the prices down. So, for this reason and because the developing world has to be part of the solution, generics should be included in the equation. Finally, what about the developing countries that are excluded as with the Merck offer? The pharmaceutical companies come up with something that

WALL ST. J. (New York), Mar. 6, 2001, at <http://www.aegis.com/news/wsj/2001/WJ010306.html>.

will make them look generous, but they immediately restrict it to poor African countries, not Brazil, not Thailand, and not South Africa.⁵³

XIII. REASONS FOR HOPE

There is, however, reason for hope. You have to understand that the United States is probably the only or one of the only countries on earth where there is no pharmaceutical prescriptive drug price control. In Europe, there is some level of prescriptive price control in all of the countries. Therefore the United States is the most profitable market for them. Here, we pay on average almost twice to ten times as much for the exact same drugs that are available in France. What industries worry about is if they engage heavily in these deferential pricing schemes, it could be used as a tool against them, forcing them to decrease their price in the wealthy markets, which is all they are concerned about.

In February, Oxfam launched a campaign for access to essential medicines. It is an international campaign, but for now, the UK has launched its campaign and its first target is Glaxo. They made it very clear to Glaxo that since they own some stock in the company, they made it very clear to them that they were going to attend the shareholders meetings and start challenging Glaxo on their pricing policy in the developing world. The same day or the very next Glaxo issued a press release saying yes, this was indeed a problem and they had some inconsistent policies so far but that they were working on a solution and they were a very responsible company. It is really good news to see that those companies can react quickly when the right argument is used.

Human rights advocacy groups are also interested in taking up the issue and domestic organizations have also expressed interest. So things are probably going to move this year. This campaign is not only about AIDS, it is really about what we call neglected diseases and essential medicines in the developing world.⁵⁴

53. In some cases aid comes with strings attached. See Michael Waldholz, *Bristol-Myers's AIDS Relief is Hitting Hurdles in Africa*, WALL ST. J. (New York), July 7, 2000, at <http://www.aegis.com/news/wsj/2000/WJ000701.html>.

54. For information about additional diseases, see generally MSF Access Website, at <http://www.accessmed-msf.org> (last visited Feb. 17, 2002).