Starting to Play by the Rules ?

Roche and access to medicines and diagnostics in developing countries

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Summary

Pharmaceutical giants have successfully lobbied for extending high level of patent protection to developing countries through the Agreement on trade-related aspects of intellectual property rights (TRIPS). The concrete effect of this 1995 World Trade Organization agreement is to delay the production and marketing of cheap generic copies of new patented medicines in the developing countries. This is ignoring the huge need in developing countries of very cheap medicines in order that poor patients can afford them and that governments can plan to scale up efficient treatment using new medicines. After some promising steps in 2001, in particular the adoption of the Doha declaration on TRIPS and public health, industrialized countries are blocking again the WTO negotiations under pressure of their pharmaceutical industry. (Part 1.)
Roche is one of the world pharmaceutical giant active in the research and development of new medicines and diagnostics. (Part 2.)
However, compared with other companies, Roche has been slow in responding to requests by the civil society to make its products more affordable in developing countries. In 2002, unlike many other pharmaceutical companies, Roche refused to answer an Oxfam-VSO-Save the Children questionnaire regarding response by the industry to the health crisis in developing countries. It took three years for Roche to reduce its prices of essential antiretroviral medicines in certain poor countries in the same proportion as other branded antiretrovirals producers. (Box 3.1. by Médecins Sans Frontières).
Are those recent prices reductions (February 2003) a sign that Roche will start to play by the rules and will become more active ? It is desirable because Roche can go further. Its essential antiretrovirals are still overpriced in many developing countries. Roche has not renounced yet to patents in developing countries with an efficient generic industry. Roche does not have any transparent price policy in developing countries regarding its HIV/AIDS diagnostics products, as well as other products. Finally Roche as well as the other Swiss pharmaceutical giant Novartis are still lobbying the government of Switzerland and other industrialized countries for strong patent protection in developing countries (Part 3). This is the reason why the Berne Declaration intervened during Roche's 2003 general assembly (see text of the intervention in the annex) and is launching with more than 40 Swiss NGOs a public campaign in Switzerland "Healthcare®: a right for all, in developing countries as well" with precise demands to Roche.

Recommendations from the Berne Declaration to Roche

Roche shall recognize that the protection of the public health shall have priority over the protection of intellectual property rights.

Roche shall recognize that the developing countries shall adapt their intellectual property protection to their level of development.
Therefore Roche shall cease to lobby in the opposite direction.

Roche shall adopt a policy where it commits itself to sell its medicines and diagnostics products in all developing countries at affordable prices, according to transparent and simple principles, without laying down inequal, unnecessary and anticompetitive conditions.

Roche shall extend its new HIV/AIDS policy for Sub-Saharan Africa and for the least developing countries (renunciation to profits and to patents) to the other developing countries, in particular to low-income and middle-income countries.

About the Berne Declaration

The Bern Declaration defends the cause of the poor populations in the developing countries since 1968. This Swiss association is politically, financially and reliously independent. The Berne Declaration is mainly active on Swiss political and Swiss economical decision-makers. Its sensibilization campaigns as well as its actions give to everyone the possibility to contribute to the construction of a fairer world, based on the respect for the human dignity and respect for the environment. The Berne Declaration is working on issues such as food and agriculture, trade, human rights, international finances, environment and health. It has 18'000 members, three regional sections (German-speaking, French-speaking, and Italian-speaking), two secretariats (in Zurich and in Lausanne) with 18 permanent collaborators.

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Part 1: Health crisis in developing countries, access to medicines, prices, patents and TRIPS

The right to health is a human right recognized by the international human rights treaties[1]. However in today's world, health is more a privilege for the rich countries than a right for every human beings. In matter of health the gap between the rich and the poor countries is manifest and has dramatic consequences. The same diseases, which are treatable or controllable in the industrialized world, often lead to serious and even fatal consequences for the sick in developing countries.

Heath crisis in the developing countries

As oppose to the situation in the industrialized countries, *communicable diseases* like pneumonia, HIV/AIDS, diarrhoea, tuberculosis, malaria and measles continue to be a major source of death and disability in the developing countries[2]. The communicable diseases, the maternal, perinatal and nutritional conditions represent together 44% of the morbidity burden in the poor countries, compared to only 7% in the rich countries[3]. HIV/AIDS, tuberculosis and malaria cause over 300 million illnesses and kill more than 5 millions people each year[4]. More than 95% of the people infected by those three diseases live in developing countries.

In 2002, 42 million people were living with *HIV* in the world. 95% of them live in the developing countries and the Eastern Europe-Central Asia region; 70% live in Sub-Saharan Africa alone[5]. In certain countries of the Southern part of Africa, infection rates range from 20% to 40% of the adult population (33.7% in Zimbabwe, 38.8% in Botswana). And the epidemic is growing quite rapidly in the Eastern Europe-Central Asia region and in the Asia-Pacific region, with respectively an estimation of 250'000 and 1 million new cases in 2002. UNAIDS suggests that the Asia-Pacific region may face 11 million new cases until 2007 if no measures are taken to prevent the spread of the epidemic. In 2002, 3.1 million people died from AIDS in the world, 98% in the developing countries and the Eastern Europe-Central Asia region, 77% in Sub-Saharan Africa alone (2.4 million people) [6]. The World Bank estimated in 2002 that per capita growth rates in Sub-Saharan Africa were reduced by 0.7% per annum between 1990 and 1997, due to the AIDS epidemic[7]. And the situation may even worsen in the future.

Malaria threats 40% of the world population. Each year it kills between 1 and 2 million people in the world. More than 90% of all cases are in Sub-Saharan Africa[8]. According to an April 2000 WHO-sponsored report, malaria has slowed Africa's economic growth by 1.3% per annum. Africa's GDP "would be up to 32% greater (…) if malaria had been eliminated 35 year ago. This would represent up to $100 billion added to sub-Saharan

[1] The right to health is mentioned in the Univeral Declaration of Human Right (art. 25 par. 1), the International Covenant on Economic, Social and Cultural Rights of 1966 (art. 12 par. 1 and par. 2), the International Convention on the Elimination of All Forms of Racial Discrimination of 1965 (art. 5 par. e IV), the Convention on the Elimination of All Forms of Discrimination against Women of 1979 (art. 11 par. 1f and art. 12), Convention on the Rights of the Child of 1989 (art. 24). For instance the International Convenant on Economic, Social and Cultural Rights, which has been ratified by a large majority of the States in the world, recognizes in its art. 12 "the right of everyone to the enjoyment of the highest attainable standard of physical and mental health" and requests from the State Parties "the creation of conditions which would assure to all medical service and medical attention in the event of sickness." For an extensive analysis of the right to health, see the General Comment No. 14 of the Committee on Economic, Social and Cultural Rights from 11 August 2000 (Document E/C.12/2000/4).
http://www.unhchr.ch/tbs/doc.nsf/(symbol)/E.C.12.2000.4,+CESCR+General+comment+14.En?OpenDocument
[2] WHO Report on Infectious Diseases: Removing obstacles to healthy development. Geneva : WHO, 1999 ; p. 1.
[3] The 10/90 Report on Health Research 2000. Geneva : Global Forum on Health Research, 2001 ; p. 69.
[4] WHO Information Fact Sheets. HIV, TB and Malaria – Three Major Infectious Diseases Threats. Background for the G8 discussions. Backgrounder No 1, July 2000.
[5] Le point sur l'épidémie du VIH/SIDA. UNAIDS 2002.
[6] In Switzerland, only 27 cases of death from AIDS were reported in 2002 (Office Fédéral de la Santé Publique, 2002)
[7] R. Bonnel. HIV/AIDS: Does it increase or decrease growth in Africa ? ACT Africa/World Bank, 2000.
[8] WHO Information Fact Sheets. Malaria. Fact Sheet No 94, Revised October 1998.

Africa's current GDP of $300 billion. This extra $100 billion would be, by comparison, nearly five times greater than all development aid provided to Africa [in 1999]." [9]

Tuberculosis (TB) kills approximately 2 million people each year, 98% of them in poor countries. The global epidemic is growing, in particular with the HIV/AIDS epidemics and the emergence of multidrug-resistant TB. More than 8 million people become sick with TB each year, 95% of them in the poor countries[10].

Other communicable diseases affects the poor countries too. For instance the African trypanosomiasis or sleeping sickness which had almost disappeared between 1960 and 1965 has regained importance: 60 million people are threatened by the disease in 36 countries of sub-Saharan Africa. In certain region of high prevalence (e.g. in some provinces of Angola, of the Democratic Republic of Congo, or of southern Sudan), sleeping sickness has become the first or second greatest cause of mortality, ahead of HIV/AIDS[11]. The Chagas disease has infected 16-18 million people in Central and South America and puts 100 million people at risk[12]. Measles is killing 900'000 people each year in the developing countries, mainly in Sub-Saharan Africa, South Asia and South-East Asia[13].

Beside this disproportionate burden of the communicable diseases in the developing countries, one should not forget the burden of the *non-communicable diseases*: the majority of the 177 million people affected by diabetes and the majority of the 150 million people affected by asthma live in developing countries[14].

Access to medicines in developing countries, prices and patents

There are multiple and interrelated causes of this public health crisis in the developing countries: poor nutrition, inadequate water and sanitation, armed conflicts, economic crises, insufficient funding allocated to health, poor local health-care systems and logistic problems, sometimes lack of willingness of governments to prioritise health-care provision, etc. The lack of access to vital and essential medicines is one fundamental factor too. According to the World Health Organisation (WHO) over one third of the world's population lacks regular access to essential drugs. In certain countries in Africa and Asia, over one half of the population does not have access[15].

The price of medicines is a crucial element of the crisis. 2.8 billion human beings in the world live with less than 2 US dollars a day, and 1.2 billion of them live with less than 1 US dollar a day[16]. However, in most of the developing countries, unlike the rich countries, the patients pay for their health expenditures in cash: 80% of the people in developing countries have to pay for their own medicines out of their pocket [17]. As a consequence, medicines often represent the largest health expenditure for families budgets in poor countries: 61% of health expenses in Azerbaijan, 76% in Bangladesh and even 80% in Mali[18] (as compared to only 20% in Switzerland[19]). Recent studies showed that the high costs of treatment and in particular of medicines are one of the major obstacle that prevent people to access the health system in developing countries[20].

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[9] Press release WHO/28. 'Economic Costs of Malaria are Many Times Higher than Previously Estimated' 25 April 2000.
[10] Tuberculosis. WHO Fact Sheet No 104, revised August 2002; WHO Report 2002: Global Tuberculosis Control. Surveillance, Planning, Financing (WHO/CDS/TB/2002.295). Geneva: WHO, 2002.
[11] African Trypanosomiasis or Sleeping Sickness. WHO Fact Sheet N° 259, March 2001.
[12] http://www.who.int/ctd/chagas/burdens.htm [accessed on 17 February 2003]
[13] WHO Report on Infectious Diseases: Removing obstacles to healthy development. Geneva : WHO, 1999 ; p. 3. La Rougeole dans le monde en l'an 2000. Estimation des niveaux de morbidité et de mortalité. Paris: Centre français sur la population et le développement (CEPED), avril-juin 2001, n° 41.
[14] Estimations based on 2002 WHO data.
[15] WHO Medicines Strategy: Framework for Action in Essential Drug Policy 2000-2003. WHO: Geneva, 2000.
[16] Report on human development 2002. NY: UNDP, 2002.
[17] WHO, Financing Health in Developing Countries.
[18] WHO Medicines Strategy: Framework for Action in Essential Drug Policy 2000-2003. WHO: Geneva, 2000.
[19] Distribution of the health expenditure in Switzerland in 2000. Trend Analyse CAMS. (quoted from: J'achète mieux, n° 296, October 2001, p. 6).
[20] See: Boubou Cissé (INSERM): "Etude de l'accès aux soin et de l'utilisation des services de santé: une analyse comparative entre quatre capitales ouest-africaine." Study presented to the XXVI^{ème} journées des économistes français de la santé "santé et développement", Clermond-Ferrand, CERDI, 9-10 January 2003.

As often stated, there is an ambivalent relation between poverty and illness: "Much of the developing world is caught in a vicious circle: poor health causes poverty and poverty causes poor healths."[21] High cost of medicines and healthcare exposes the poorest people who cannot afford them to the risk of death or to the risk of disability which means further impoverishment. At the same time, for the poor people who can barely afford costly medicines, its heavy impact on the family resources can cause serious financial difficulties[22].

Because of the high prices of medicines, governments are hesitating to scale up efficient treatments to their population. This situation regarding HIV/AIDS is recognized by the Swiss Agency for Development and Cooperation: "For many of the worst-affected countries today, the exorbitant costs of antiretrovirals make their use in treating a broad segment of the population impossible. The healthcare systems of these countries are simply not in a position to bear the costs."[23] According to WHO, medicines already represent the second largest expenses of public health in the poor countries after human resources. In 66 countries, the total annual health expenditure (public and private) is less than 100 US dollars, in 30 countries it is even less than 50 US dollars[24].

While there is for sure a need to invest in health infrastructure in the developing countries, there is also a huge need for cheap efficient medicines in the Third World.

By granting temporary monopolistic rights to their holders, patents play a key role for the price of the newly patented medicines. Patent holders can fix their prices in the absence of competitors and prevent the production and marketing of cheap copies (generics). The case of HIV/AIDS medicines has become a symbol. Although 6 million people would today need highly active antiretroviral therapies, only 300'000 people in the developing countries (more than one third of them in Brazil) are actually being treated[25]. That is to say that 95% of people who would require treatment, does not receive any. The high cost of the patented antiretroviral medicines is one the major obstacle to the scaling up of the treatment in the developing countries.

TRIPS (Agreement on Trade-Related Aspects of Intellectual Property Rights)

Ironically, it is at the very moment when the world is faced with the HIV/AIDS pandemic, that the conditions for getting cheap medicines have worsened. The adoption and coming into force of the Agreement on Trade-Related Aspects of Intellectual Property rights (TRIPS) have strengthened and extended the level of intellectual property worldwide. This development favours above all the patent holders. With TRIPS, the Member States of the World Trade Organization (WTO) commit themselves to grant at least 20 years patent protection for products and processes in all fields of technology (article 27.1). Therefore all Members of the WTO (145 member states on 5 February 2003) and those willing to adhere to the organization have to bring their national legislation into conformity with the TRIPS agreement. The majority of WTO member states had to do so until January 2000 or have to do so until January 2005. As a consequence all WTO member states have to grant patents for pharmaceutical products to the companies that request them.

First of all, the TRIPS agreement is controversial because it is *not adapted to the level of development of the developing countries*. For the first time after decolonisation, most of the countries in the world, either industrialised or developing countries, will have to grant a high level of intellectual property protection. This will prevent the developing countries to adopt intellectual property legislations suited to their level of economic and technological development, as it was possible before, and as did during their industrialisation industrialised countries like Switzerland. In particular it will make copying more difficult, though it has always been the cheapest and simplest method of technology transfer and of development of a national industry. This is problematic since developing countries are net importers of technology. However it was the path followed by the Swiss chemical and pharmaceutical industry at the end of the 19th century and in the beginning of the 20th century, which heavely copied the products of the German industry and adapted its patent law along with its objective. It is only in 1977, once its pharmaceutical industry had reached a certain level of development, that

[21] Oxfam Company Briefing Paper on Pfizer. Formula for Fairness: patients rights before patent rights. Oxfam, July 2001; p. 16.
[22] Göran DAHLGREN. "Payer les soins de sa poche: un déterminant majeur de pauvreté" in La santé au risque du marché. Incertitudes à l'aube du XXI[e] siècle. Nouveaux cahiers de l'Institut Universitaire d'Etude du Développement de Genève n° 11. Paris: PUF, 2001; p. 123-124.
[23] Swiss Agency for Development and Cooperation. SDC AIDS policy 2002-2007. Berne: SDC, 2002; p. 8.
[24] WHO Medicines Strategy: Framework for Action in Essential Drug Policy 2000-2003. WHO: Geneva, 2000.
[25] UNAIDS 2002.

Switzerland introduced patent protection for pharmaceutical products[26]. In this study we will not go further into the debate about hazard to development caused by the TRIPS agreement.

Regarding public health, the TRIPS agreement is controversial because it *does not meet developing countriesr public health needs and priorities for cheap and effective medicines.* The TRIPS agreement obliges every WTO member states to grant at least 20 years patent protection on pharmaceutical products. This is a big change, considering that still in 1988, 49 out of the 98 States Parties to the Paris Convention for the Protection of Intellectual Property did not recognize patent on pharmaceutical products. Moreover, "until the TRIPS regime was introduced, some governments allowed local companies to produce, market, and export generics (low-cost copies of drugs patented in the industrialised countries). In this way, countries such as India, Brazil, and Egypt were able to bring down the prices of drugs for their own populations and reduce their reliance on imported products. Through their exports they were also able to keep prices down in other poorer countries, most of which do not have their own generics industries."[27] As from 1 January 2005, India, one of the major producer of cheap generic versions of new medicines in the world, will have to grant at least 20 years patent protection for pharmaceutical products.

Therefore the safeguard mechanisms provided by the TRIPS agreement have become very important for the poor countries as avenues to get cheap medicines according to their needs[28]. In view of the health crisis described above, the needs are huge. In order to counter-balance the exclusive rights of the patent holders, the states have the legal and administrative means to overcome patent holders exclusive rights when necessary. Parallel importing and especially compulsory licences are the two main instruments. Parallel importing is the possibility when a patented product is marketed at a lower price on a foreign market than to the national market, to authorize the parallel import of the product from foreign markets. A compulsory licence is the possibility to authorize other entities than the patent holder to produce, import and market a product in the national market, without the consent of the patent holder[29]. Those instruments are important not only as effective and practical ways but also as a tool to negotiate favourable lowered prices from the patent holder. The case of the negotiations between Roche and Brazil over nelfinavir (Viracept®) provides a good example: after long and unsuccessful negotiations, Roche accepted to cut the price of on its medicine by 40% in August 2001 only after the government of Brazil told the company that it will issue a compulsory licence allowing Brazilian generic companies to manufacture it.[30]

Intellectual property at WTO and trade pressures

The TRIPS agreement is part of the WTO framework. Therefore every alleged violations of the TRIPS provisions on intellectual property may open the possibility of trade sanctions. When speaking of trade threats, developing countries are in a far weaker position than industrialized countries. Unfortunately the history and the pre-history of the TRIPS agreement provides many examples for this.

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[26] France introduced patent protection for pharmaceutical products in 1960, Germany in 1968, Japan in 1976, Sweden and Italy in 1978. Dr. K. BALASUBRAMANIAM. Consumers & the WTO/TRIPS Agreement. July 1999. www.consumersinternational.org/roap/health/balapapers/wto_trips.htm; Richard GERSTER. Patent and Development. Third World Network, 2000;19 p.) On the development of the Swiss chemical industry, see: Jakob TANNER. "Property rights, Innovationsdynamik und Marktmacht. Zur Bedeutung des schweizerischen Patent- und Markenschutzes für die Entwicklung der chemisch-pharmazeutischen Industrie (1907-1928)" in Die Neue Schweiz ? Eine Gesellschaft zwischen Integration und Polarisierung./ hrsg von Andreas Ernst und Erich Wigger. Zürich: Chronos Verlag, 1996, S. 273-303; Jakob TANNER."Medikamente aus dem Labor. " in Chemie in der Schweiz, Geschichte der Forschung und der Industrie./ hrsg von Andrea Rosenbusch und Christian Simon. Basel, 1997, S. 117-146.

[27] Oxfam Briefing Paper on GlaxoSmithKline. Dare to Lead: public health and company wealth. Oxfam, February 2001; p 21.

[28] This problem is not limited to medicines. Other patented products related to public health are also concerned, like for instance vaccines or diagnostic kits.

[29] For a more complete discussion about intellectual property rights and the developing countries, see: Commission on Intellectual Property Rights (CIPR). Integrating Intellectual Property Rights and Development Policy. London: CIPR, September 2002; 178 p.

[30] Jane GALVÃO. "Public health: Access to antiretroviral drugs in Brazil", The Lancet, 7 December 2002.

The inclusion of intellectual property issues within the GATT Uruguay Round negotiations (that lead to the establishement of WTO) was a mixture of negotiation tactics and trade pressures[31]. It had been strongly advocated by the pharmaceutical industry (along with the cinema and software industries). It was imposed and put on the agenda by the industrialised countries in spite of the opposition by many developing countries. Most of the negotiations took place between a small number of industrialised countries (USA, European Economic Community, Japan, Canada, Switzerland, Australia) in the so-called "Green room talks". It was only when an agreement was reached in those talks that the results were presented to other countries. The developing countries which were opposed to it, became subjects to bilateral trade pressures regarding their intellectual property legislations until they agreed.

The USA played a prominent role in these bilateral pressures. The section 301 of the US trade law allows US companies to request to the US trade office the inscription on a 'watch' list of countries accused of infringing the rights and commercial interests of the companies. Then those countries may face US trade retaliation if they fail to comply with the US trade office's requests. PhRMA, the business association of the American pharmaceutical industry[32], used that procedure against countries reluctant to accept higher international standard of intellectual property rights in the GATT negotiations (Brazil, India, Argentina, Egypt and Yugoslavia). In 1990, two years after the introduction by the USA of tariff penalties on certain Brazilian products, the Brazilian president announced that he accepted the intellectual property legislation changes that the USA asked for.

After the signature of the TRIPS agreement in 1994, those pressures continued. At the request of PhRMA, the USA has used bilateral pressures or threatened to initiate WTO Dispute Settlement procedures against countries accused of non-compliance with the TRIPS agreement (Thailand, Brazil, Argentina, etc.). On a more discrete level, other industrialised players (like the European Union or Switzerland) have also relied to bilateral pressures related to patent protection.

2001: Promising steps in South Africa, Brazil and Doha

2001 saw promising steps in order to shift the balance in favour of the protection of the public health before the protection of patents.

In South Africa, 39 pharmaceutical companies had sued the South-African government for its new medicines law, stating that certain provisions were infringing the Constitution and the TRIPS agreement. Both Swiss pharmaceutical giants, Novartis and Roche, were plaintifs. Because of the worldwide protest caused by this trial against a country severely confronted with the HIV/AIDS epidemic (19.9% of the South African adult population was infected by HIV in 2001), the pharmaceutical companies withdrew their case on 19 April 2001.

Following a request by the USA , the WTO accepted in February 2001 to set up a panel to discuss the compliance of the provisions on compulsory licences in the Brazilian law with the TRIPS agreement. The USA were acting at the request of PhRMA, the business association of the pharmaceutical industry in the USA. Once again, confronted with worldwide protests, the USA finally withdrew their request for a panel in the WTO in June 2001.

The most important step happened during the WTO ministerial conference in Doha/Qatar. At the request of the developing countries, the 143 WTO member States adopted a Declaration on the TRIPS agreement and public health on 14 November 2001 (hereafter the Doha Declaration). This declaration recognized the concerns about the effects of intellectual property rights on prices (paragraph 3). The Doha Declaration stated that "the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health" and affimed that "the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all" (paragraph 4). The Doha Declaration also clarified the way the TRIPS agreement should be interpreted and implemented, in particular regarding compulsory licences, national emergency, and exhaustion of intellectual property rights (paragraph 5b, 5c, 5d).

[31] For a more detailed account of the prehistory of TRIPS, see: (1) on the GATT negotiations: Peter DRAHOS. Negotiating Intellectual Property Rights: Between Coercion and Dialogue. Paper presented at Oxfam international seminar on intellectual property, Brussels, 20 March 2001; (2) on the role of the pharmaceutical industry: Oxfam Company Briefing Paper on Pfizer. Formula for Fairness: patients rights before patent rights. Oxfam, July 2001; pp. 31 to 35.

[32] The Swiss pharmaceutical companies Roche and Novartis are active paying members of PhRMA. See below Box 3.2.

At the WTO ministerial conference in Doha, it was also decided to extend the implementation deadline for the Least Developing Countries (LDCs) to 2016 (paragraph 7 of the Doha Declaration). But the impact of this measure may remain limited: 70% of the population of the LDCs as a whole live in countries which already protect patents on pharmaceutical products, and 27 of the 30 African LDCs have already patent laws in conformity with the TRIPS requirements.

Paragraph 6 of the Doha Declaration decided to open new negotiations:
"We recognize that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002." (Hereafter this point is referred to as paragraph 6).

This is an important point. Two thirds of the developing countries import 100% of the medicines they use or have very limited manufacturing capacities in the pharmaceutical sector[33]. Today, those countries can take advantage of the generic manufacturing in countries like India where there are still no patent on pharmaceutical products. But in 2005 this window will be closed since India will have to grant patents on pharmaceutical products[34]. That is the reason why it is important to find a solution for those countries with insufficient or no manufacturing capacity in order to be able to use effectively the compulsory licence provisions of the TRIPS agreement after 2005.

2002 and today: reneging the Doha Declaration

The deadline to resolve this point could not be meet in December 2002, although the developing countries accepted a complicated and insatisfying ad hoc mechanism negotiated throughout 2002. At the request of its pharmaceutical industry, the USA opposed the proposed mechanism because they wanted to restrict it to HIV/AIDS, malaria, tuberculosis and other epidemics of same scale and gravity. The other industrialized countries like Switzerland, the European Union, Japan, Canada and Australia have accepted the proposed solution but with the understanding of restricting the scope of diseases of the ad hoc mechanism. However this contradicts what had been discussed and agreed in Doha: i.e. the Doha Declaration addresses all public health problems in the developing countries and is not limited to HIV/AIDS, malaria, tuberculosis and other epidemics of same scale and gravity. Moreover no industrialised countries objected when Japan insisted that vaccines should not be part of the proposed mechanisms, even though vaccines are one of the most useful and cost-effective means to fight epidemics. It's still unclear whether vaccines will be part of the proposed mechanism or not.
Paragraph 6 of the Doha Declaration is still unresolved today and is expected to be one of the main points of discussion during the next WTO ministerial conference in Cancún/Mexico in September 2003.

This situation creates a profound inequality between the countries. The countries with sufficient manufacturing capacities can use the compulsory licence under the conditions set out in the TRIPS agreement and for all public health problems they regard as important. In contrast, the countries with insufficient or no manufacturing capacities in the pharmaceutical sectors will be allowed to use the compulsory licences only for a limited number of public health problems and under the very restricted conditions stated in the ad hoc mechanism. This inequality is not acceptable.

At the same time, the USA, the European Union and Switzerland continue to conclude bilateral or plurilateral treaties with developing countries asking them to comply with high standards of intellectual property protection. They also target countries which are not members of the WTO requesting them to comply with the TRIPS agreement[35].

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[33] Commission Macroéconomie et Santé. Des faits et des Chiffres (taken from: Macroéconomie et Santé: investir dans la santé pour le développement économique: Rapport de la Commission Macroéconomie et Santé). 20 December 2001.
[34] India has already amended its negotiation to make it compliant to the TRIPS agreement.
[35] See for example the treaties being negotiated in the Western Hemisphere under the Free Trade Areas of the America. Switzerland has also a very active policy of bilateral and plurilateral treaties with developing countries related to intellectual property rights. See Bernhard HEROLD, "Propriété intellectuelle. La position de la Suisse", Se Soigner®: un droit pour tous. Sida, Suisse et pays pauvres. Lausanne: Déclaration de Berne, 2003; pp. 22-23. For US bilateral agreements until 2001, see also: Peter DRAHOS. Bilateralism in Intellectual Property. 2001; 20 p.

2000-2002: generic competition as the most efficient way to get cheap medicines

The last 3 years have demonstrated the importance and efficiency of generic competition in order to get the cheap medicines needed by the sick in the poor countries. Generic competition proved more efficient than relying only on low differential prices for developing countries voluntarily offered by the patent-holding companies. The significant price falls of antiretrovirals against HIV/AIDS provide a good example. In May 2000 the lowest international price for a widely used combination of first regimen antiretrovirals (stavudine + lamivudine + nevirapine) was 10'439 US dollars per patient a year by relying on products from the patent holders. In December 2002, the lowest international price was 727 US dollars per patient a year for the patented products and only 201 US dollars for a combination made by an Indian generic producer[36]. Without generic competition, the patent-holding companies would not have lowered their prices in such a large proportion (-93%)[37]. Moreover, in most of the cases, low-priced branded products remain more expensive than generic products[38]. Generic competition was precisely possible because those pharmaceutical products were not yet patented in developing countries with a performing generic industry like India, Brazil or Thailand. This situation will change in the future for new pharmaceutical products patented for 20 years in those countries.

[36] Médecins Sans Frontières. Untangling the web of prices reduction. Geneva: MSF, December 2002; p.5

[37] This is consistent with the result of a WHO study that showed that prices tend toward the lowest achievable when there are five or more competing equivalent products on the market (WHO Secretariat. Background paper for the WHO-WTO Secretariat Workshop, "More Equitable Pricing for Essential Drugs", April 2001).

[38] Médecins Sans Frontières. Untangling the web of prices reduction. Geneva: MSF, December 2002; pp.7-11.

Part 2: Roche's general profile 2002

F. Hoffmann-La Roche (hereafter Roche) belongs to the top list of pharmaceutical companies in the world. In 2000 Roche ranked in 9th position with an estimated 3.4% share of the global pharmaceutical market[39]. The Swiss company, whose headquarters are in Basle, has recently improved its position by acquiring 50,1% of the Japanese company Chugai (effective since 1 October 2002)[40].

In 2002 Roche's global sales amounted to 29.725 billion Swiss francs, a growth of 2% compared to 2001. During the year the sales in Roche's core activities (pharmaceuticals and diagnostics) grew even faster than the global market (+3%). These core activities also experienced a double-digit increase of their operating profit (+22% in local currencies, +12% in Swiss francs). The profit margins also grew for pharmaceutical products from 19.5% in 2001 to 21.5% in 2002 and for the diagnostics products from 14.4% in 2001 to 15.6% in 2002. However Roche announced a consolidated net loss of 4.0 billion Swiss francs in 2002. This loss resulted from the sale of the vitamins and fine chemicals division, from further charges to cover the liabilities due to the vitamins scandal (see below Box 1.1.) and from the impairment of the company's equity portfolio. According to Roche's president and CEO, Mr. Franz B. Humer, this loss shows "[Roche's] vigorous action to address significant unresolved issues from the past"[41]. In contrast, in 2001 Roche's net income had been 3.697 billion Swiss francs (13% of the sales).

Though Roche sells its products in most countries in the world, its main markets remain North America (40% of the sales), Europe (37%) and Asia (13% - with Japan being the biggest Asian market)[42]. Latin America represents 7% of the sales and the other regions (including Australia) 3%. Those figures are consistent with the general pattern for the world pharmaceutical industry: approximately 80% of the sales of the industry are made in North America, Europe and Japan[43] which count together for only 20% of the world population.

Roche's main activities in 2002 were pharmaceutical products (65% of sales), diagnostics (24%) and vitamins and fine chemicals (11%). In 2003 Roche sold its vitamins and fine chemicals division to the Dutch company DSM (see below Box 1.1.). This operation will be completed in 2003. Roche is the world leading company for diagnostics (18% of the global market share in 2001[44]). In pharmaceutical products, Roche holds strong positions in oncology, virology, inflammatory and auto-immune diseases, and diseases of the central nervous system. Roche has an active policy of acquisition of products and technologies from other companies. Roche's best sold prescription products included in 2002: MabThera® / Rituxan® (rituximab, non-Hodgkin's lymphoma), Rocephin® (ceftriaxone, antibiotic), NeoRecormon® (epoetin beta, anemia), CellCept® (mycophenolate, transplantation), Herceptin® (trastuzumab, breast cancer), Roaccutane® / Accutane® (isotretinoin, severe acne), Xenical® (orlistat, obesity)[45].

At the end of 2002 Roche employed 69'659 people in 60 countries. Roche had manufacturing facilities in 35 countries in the world, mainly in Europe, North America, Asia and Latin America.

In 2002, Roche spent 14% of its sale (4.257 billion Swiss francs) for research and development (R&D). At the same time it spent double that amount for marketing and distribution (29% of the sales, 8.538 billion Swiss francs), and 4 % for administration (1.295 billion Swiss francs).

Box 2.1. The vitamins cartel: a burden for Roche's reputation and finances

Roche has been recently penalized in the USA and the European Union for its involvement in a series of illicit cartels for vitamins products (vitamin A, E, B1, B2, B5, B6, C, D3, Biotin (H), Folic Acid (M), Beta Carotene

[39] Le Temps, 16 July 2002.
[40] Scrip, N° 2787, 4 October 2002, p. 10.
[41] Roche annual report 2002, p. 4.
[42] See the detailed sales by region for pharmaceutical products (41% North America, 33% Europe, 9% Japan) and for diagnostics (36% North America, 42% Europe, 5% Japan). (Roche Annual Report 2002)
[43] 2001 Global pharma sales by region. IMS health (www.ims-global.com/insight/news_story/0204/news_story_020430.htm [consulted 10 June 2002])
[44] Dr. Erich Hunziker. Turning innovation into customer benefit. Switzerland Roadshow. Geneva, 4 December 2002.
[45] Roche annual report 2002.

and carotinoids) which operated during the late 1980s and the 1990s. Through secret agreements, Roche and the other companies involved worked together to fix prices and quantities and to share the markets. They also discussed together the means to prevent access to market to new competitors, in particular Chinese vitamins producers. Roche, which was then the largest vitamins producer in the world, with some 50% of the global market, has been pointed by the competition authorities as leading participant and as main beneficiary of the cartels.

In the USA where the vitamins cartels have been first discovered and investigated, Roche was imposed a payment of 500 million US dollars by a court in Denver/Texas in May 1999. In 2002 the company had paid 1707 million US dollars to settle civil charges. Roche has already reached agreement with all direct US customers and a majority of its indirect US customers, and is still trying to reach out-of-court settlements with the others[46].

In the European Union Roche and 7 other companies (BASF, Aventis (as successor of Rhône-Poulenc), Solvay Pharmaceuticals, Merck KgaA, Daiichi Pharmaceuticals, Eisai Co Ltd, Takeda Chemical Industries Ltd) were penalized by the European Commission for their participation in illicit agreements for vitamins products (Case COMP/37.512). As pointed out by Mario Monti, European Commissioner for competition on 21 November 2001: "This is the most damaging series of cartels the Commission has ever investigated due to the sheer range of vitamins covered which are found in a multitude of products from cereals, biscuits and drinks to animal feed, pharmaceuticals and cosmetics"[47]. He added: "The companies' collusive behaviour enabled them to charge higher prices than if the full forces of competition had been at play, damaging consumers and allowing the companies to pocket illicit profits. It is particularly unacceptable that this illegal behaviour concerned substances which are vital elements for nutrition and essential for normal growth and maintenance of life". Roche, who was the leading participant involved in every agreement, received the largest fine (462 millions euros), more than one half of the total amount of 855.22 million euros imposed on the 8 companies. The Commission found that some of its most senior executives were involved in these practices, and suggested that the arrangements were part of a strategic plan conceived at the highest levels to control the world market in vitamins by illegal means[48].

As a consequence of those worldwide illicit agreements, Roche and the other participants have to face other investigations and possible sanctions by competition authorities outside the USA and the European Union. For instance, the Brazilian competition authorities started in 1999 investigation on subsidiary companies of Roche, BASF and Aventis (as successor of Rhône-Poulenc) for illicit agreements on vitamins A, E, betacaroten[49]. Even in Switzerland Roche as well as BASF and Rhône-Poulenc (now Aventis) were sentenced by the Swiss Competition Commission, but due to the weakness of the national competition law Roche was not fined[50]. Following the scandal, Roche initiated an internal program "Behaviour in business" for more than 8000 managers worldwide to ensure compliance with all national competition laws.

Unfortunately it was not the first time that Roche had been penalized for anticompetitive practices in the vitamins market. In the 1970s the European Commission had fined the company for its system of fidelity contracts with its major buyers of vitamins (secret rebates in exchange of buying all or most of their requirements from Roche)[51]. Stanley Adams, a former employee of Roche who had provided the European Commission with informations about those practices, had also reported illicit agreements between Roche and his principal competitors to fix prices and quantities in the vitamins market. However, at that time the European Commission had not gone further about this[52]. Ironically, those anticompetitive practices did not prevent Roche

[46] Scrip, n° 2790, 16 October 2002, p 10; Le Temps, 11 February 2003.
[47] Press release of the European Commission IP/01/1625, 21 November 2001. Available at: http://www.health.fgov.be/WHI3/krant/krantarch2001/kranttekstnov1/011122m13eu.htm [consulted on 15 January 2003]
[48] Ibid. On 5 December 2001 Roche was again sanctioned by the European Commission for its participation with 4 other companies to an illicit agreement for sharing the citric acid market. The 5 companies were fined 135 million euros. Roche again was a leading participant (Case COMP/36.604. Cf Press release of the European Commission IP/01/1743, 5 December 2001).
[49] CNUCED TD/B/COM.2/CLP/26 - 18 April 2002.
[50] Decision from 19 April 2001 of the Swiss Competition Commission (Commission fédérale de la Concurrence).
[51] Decision of the European Commission from 1 July 1976, confirmed by the European Court of Justice from 13 February 1979.
[52] Stanley ADAMS. Roche versus Adams. London: Fontana/Collins, 1985; pp. 14-26, 76-78. Because he had released information and documents to the European Commission, Mr. Adams was arrested, jailed and sentenced in Switzerland for disclosure of trade secrets and economic spying to a foreing country.

to be a long standing member of the European Round Table of industrialists (ERT), a European forum of transnational corporations aiming among other things at promoting competition and competitiveness on a European scale[53].

These late 1980s and 1990s vitamins cartels continue to have financial, industrial and reputation consequences for Roche today.

This scandal has already cost to the company 3.6 billions Swiss francs in payment of fines and indemnities to plaintiffs. But the final total costs are expected to be higher, around 5 billion Swiss francs. In order to face this, Roche had to make provisions of 2.460 billion Swiss francs in 1999, 760 million Swiss francs in 2001 and again 1.770 billion Swiss francs in 2002[54].

Another consequence was the sale by Roche of its vitamins division to the Dutch company DSM[55]. In February 2003 it announced that the contract between the two companies had been signed to a transaction price of 1.95 billion euros (2.85 billion Swiss francs)[56]. All present and future liabilities from the vitamins cartels will remain with Roche. This put an end to the presence of Roche on the vitamins market where it had been since 1934. Roche was even the first company to make the industrial synthesis of vitamin C and had acquired a dominant position in the world. Analysts explained this decision by the decreasing profit margin in the vitamins markets due to the end of the vitamins cartel and the coming of new Chinese competitors[57].

But the vitamins scandal impacts Roche's reputation. Even without its vitamins division, it casts a shadow on the company's reputation for the coming years.

[53] About the ERT: see Europe Inc. Regional & Global Restructuring and the Rise of Corporate Power. Edited by Belén Balanyá et al. London: Pluto Press in association with the Corporate European Observatory, 2000; xv-256 p. See also ERT's website: www.ert.be
[54] Le Temps, 4 and 11 septembre 2002.
[55] Scrip, n° 2790, 16 October 2002, p 10.
[56] Le Temps, 11 February 2003.
[57] Le Temps, 4 septembre 2002.

Part 3: Roche's response to the health crisis in developing countries regarding access to medicines and diagnostics

Through their successful lobbying on the governments of industrialized countries, Roche and the other giant pharmaceutical companies have obtained through the adoption of the TRIPS agreement the extension of high standards of intellectual property protection to all WTO member states including the developing countries (see Part 1.). This means that all WTO member states have to accord to all requesting pharmaceutical companies a minimum 20 years protection for new pharmaceutical products and processes. These measures mainly benefit the giant pharmaceutical companies like Roche who detain patents or exclusive licences for the great majority of the new medicines. But this new world patent regime gives to those giant pharmaceutical companies a direct responsibility regarding access to new medicines in the developing countries, and therefore regarding the health and life of millions of people in the developing countries. However this new responsibility had not been foreseen by those giant pharmaceutical companies when they were asking for this new world patent regime.

This part will examine how Roche has been responding to the health crisis in developing countries regarding access to its pharmaceutical products.

Philanthropy or responsibility ?

In its 2002 annual report and on its website[58], Roche mentions its 'social involvement' and its 'good corporate citizenship'. Under those expressions, Roche mainly refers to its contributions to several philanthropic projects like for example a train clinic in South Africa, a program for distribution of vitamin A in Sub-Saharan Africa, community projects in HIV/AIDS caring in Africa, India, Thailand, Brazil.
Although these programs are certainly positive for the people who benefit from them, they are not what is primarily expected from a company like Roche, especially after the new world patent regime created by the TRIPS agreement. Indeed, in view of the public health crisis and of the limited resources in the developing countries (see Part 1), a world leader in pharmaceutical products and diagnostics will be primarily judged along its daily business practices. In particular Roche is expected to sell in the developing countries useful, efficient and safe products which fulfil essential health care needs[59] at affordable prices according to simple and transparent principles.

Moreover, compared to other companies, Roche has been slow into responding to requests by the civil society to make its products more affordable in developing countries. In 2002, unlike many other pharmaceutical companies, Roche refused to answer an Oxfam-VSO-Save the Children questionnaire regarding response by the industry to the health crisis in developing countries because it invoked not disclosable proprietary informations[60].

Roche's HIV/AIDS products

Roche is one of the leading companies in HIV/AIDS therapy. It has discovered, developed and produced several important antiretroviral medicines. Roche is also a leader in diagnostics measuring the viral load of people infected with HIV. On 13 March 2003, the Food and Drugs Administration (FDA), the American medicines control authority, approved the marketing of enfuvirtide (Fuzeon®), the first antiretroviral of a new class of treatment (fusion inhibitor)[61]. Submission of marketing authorization is also pending in the European Union, Switzerland, Australia and Canada. But Roche's announcement of the very high price of enfuvirtide in the

[58] See: Roche Group Annual Report and Group Accounts 2002. Basle: Roche, 2003; pp. 53-55, www.roche.com/home/company/com_soc_com_intro.htm
[59] This precision is important: a 1989 inquiry of the BUKO-Pharma Kampagne and Berne Declaration had revealed that 50% of the Roche's medicines sold in developing countries were at that time unuseful, inefficient or unsafe. (Robert Hartog. Das Schweizer Arzneimittelangebot in der Dritten Welt. Bestandeaufnahme und pharmkologische Bewertung. Zürich: Hrsg. Erklärung von Bern, 1989; 51 p.)
[60] Beyond Philanthropy. The pharmaceutical industry, corporate social responsibility and the developing world. Oxford-London: Oxfam-VSO-Save the Children, 2002; p. 11. Personal communication from Jo Nickolls, Oxfam, 8 November 2002.
[61] Trimeris & Roche press release, 13 March 2003.

European Union, 18'980.- Euros per patient per year in Europe (27'770.- Swiss francs)[62], has already raised concerns and protests among AIDS activists because it may place this medicines out of reach for many patients[63]. Roche is explaining this high price for the enfuvirtide by its costs of production and of research and development[64]. In fact as long as Roche and the other pharmaceutical companies are keeping secret their accounting books, it is impossible to check the real costs.

Late and controlled price reductions for essential antiretrovirals in developing countries

Roche holds exclusive production and marketing rights in developing countries for two protease inhibitor antiretrovirals that were inscribed on the WHO model list of essential medicines in April 2002 and recommended by WHO as first or second HIV/AIDS regimen in resources-limited settings[65]: saquinavir (Invirase® / Fortovase®) and nelfinavir (Viracept®). (See Box 3.1. Bowing to pressure)

On 13 February 2003 Roche announced from 1 March 2003 a double pricing policy for certain developing countries for saquinavir and nelfinavir: "non-profit" prices for Sub-Saharan Africa and least developing countries and higher prices for other countries that are considered as "low-income" and "lower middle income" by the World Bank[66]. Subsequently the treatment with nelfinavir costs now respectively 900 US dollars per patients per year (a price reduction of 85% compared with the price in Switzerland) and 3000 US dollars per partient per year (a price reduction of 48%). This decision is definitely a positive step since Roche gives up its previous complicated pricing policy for Sub-Saharan Africa and least developing countries. Moreover the other developing countries are not excluded anymore: until 1 March 2003, the price of nelfinavir was higher in Guatemala and Ukraine than in Switzerland! (see Box 3.1.)

Though positive, this decision is very late. In May 2000, Roche was one of the 5 companies to start the Accelerated Access Initiative, a 'partnership' of pharmaceutical companies with the United Nations[67] aiming at facilitating the contacts between the manufacturers of branded antiretrovirals and the government of developing countries. But Roche needed almost three years to bring down its prices in a similar proportion to the other participating pharmaceutical companies (i.e. between 87% and 95% compared with the prices in industrialized countries). In April 2002, Mr. Nabarro, executive director in the WHO, recognized that "he had problems with some companies" and "wished Roche would start to play by the rules" as soon as possible[68]. Roche could certainly maintain its high prices for its two protease inhibitors for so long because the company did not have to face any serious generic competition, especially since it had concluded in August 2001 a special price reduction with Brazil (40%), the largest single market for antiretrovirals among the developing countries. But even this agreement with Brazil had not been easy to achieve: Roche finally agreed to reduce its prices only when Brazil, after unsuccessful price negotiations, announced that it would issue a compulsory licence[69]. The 2003 price reduction was mainly due to the protests by health professionals and activists in the industrialized countries, in particular Médecins Sans Frontières with members of the Société Suisse d'Infectiologie (see Box 3.1.).

Box 3.1. *Bowing to public pressure, Roche lowers AIDS drug price*

[62] Roche press release, "European Price Announced for AIDS Drug Fuzeon", 24 February 2003. On 16 April 2003 a group of AIDS advocacy groups has launched a campaign to pressure Roche to lower price for Fuzeon®: http://www.kaisernetwork.org/daily_reports/rep_index.cfm?DR_ID17205

[63] Act Up New York Press Release, "Act up creates 'Fuzeon® graveyard' at Roche [US] headquarters", 13 mars 2002.

[64] For an estimation of enfuvirtide R&D cost, see: Bob HUFF. "What Does R&D Really Cost ?", Gay Men's Health Crisis Treatment Issues, Vol. 15, Number 7/8, July/August 2001. (http://thebody.com/gmhc/issues/julaug01/r_and_d.html)

[65] Scaling up. Antiretroviral therapy in resource-limited settings. Guidelines for a public health approach. Geneva: WHO, June 2002.

[66] Roche Media News. "Roche updates pricing policy for protease inhibitor AIDS drugs within Accelerating Access Initiative. Basle, 13 February 2003 (http://www.roche.com/med-corp-detail-2003?id=937&media-language=e)

[67] In fact UN specialised agencies like UNFPA, UNICEF, WHO and UNAIDS, with the World Bank. The participating companies are: Boehringer-Ingelheim, Bristol-Myers Squibb, GlaxoSmithKline, Merck Sharp & Dome, Roche, and Abbott.

[68] Act Up Press Release, "Accelerating Access: serving pharmaceutical companies and corrupting health systems", 11 May 2002.

[69] Jane GALVÃO. "Public health: Access to antiretroviral drugs in Brazil", The Lancet, 7 December 2002.

By Elisabeth Le Saoût, Médecins Sans Frontières

After one year of pressure over the price of its antiretroviral drug nelfinavir (brand-name Viracept®) in developing countries, Swiss pharmaceutical giant Roche announced on February 13th that it would slash the price of its drug in poor countries. A victory for the patients in countries most affected by the epidemic.

A sad reality: an essential drug at an unaffordable price

Although generic competition and differential pricing have led to significant price reductions for first-line therapies in developing countries, the price of second-line therapies remains 6 to 15 times more expensive. One of the reasons for this discrepancy is the high price of an essential component of second-line triple therapy, Roche's Viracept® (nelfinavir). A WHO-recommended component of combination treatment, nelfinavir is considered an ideal protease inhibitor for resource-poor countries – its use requires no eating restrictions, and does not require refrigeration. MSF uses Viracept® in several of its antiretroviral treatment programmes.

Roche, along with other companies, announced the intention to decrease prices by up to 90% when committing to the Accelerating Access Initiative (AAI) in the year 2000. Following this initiative, most products from multinationals were offered at a 87-92% reduction for least developed countries. But Roche's best offer for Viracept® was US$ 3,130 per patient per year (ppy) for least developed countries (LDC) and sub-Saharan Africa – a reduction of only 40-50% off the French and Swiss retail prices. Other companies' offers for the same category of medicine were more generous: Merck reduced the price of indinavir to US$ 600 ppy (85% reduction) and Abbott offers lopinavir at US$ 500 ppy (93% reduction).

In addition, middle-income countries were forced to negotiate Viracept® prices on a case-by-case basis, as Roche only had a published price for least developed countries. As a result, Viracept® was offered at US$ 8,358 ppy in Guatemala and US$ 7,110 in the Ukraine, while patients in Switzerland pay just US$6,169 ppy. Roche also often charged governments a much higher price than NGOs for the same medicine.

Worse still, Roche's price reduction was not always applied, even in those countries which are most in need. For instance, Cameroon – a sub-Saharan country where per capita income is just US$ 570 – was eligible for Roche's lowest price. Yet Roche sold Viracept® there at US$ 4,124 ppy – almost US$ 1,000 more than the purported price for least developed countries.

Experience has shown that generic competition is the single most effective strategy to reduce drug prices to more affordable levels for developing countries. But because generic nelfinavir is not yet available in most countries, Roche's product is the only option. Given the absence of significant competition, MSF estimated that Roche had a responsibility to lower its price, and took different steps to influence the company's policy.

One-year pressure campaign on the company

In a face-to-face meeting with Roche representatives in Basel in April 2002, we urged Roche to lower its price for nelfinavir to match discounts by other companies; apply the same pricing schemes to NGOs, governments and institutional providers; put in place a system of policy implementation that ensures the drugs reach recipients at the promised price; abandon its policy of time-consuming case-by-case negotiations; and address the lack of a price policy in middle income-countries.

On September 30, leading Swiss researcher Prof. Dr. Hirschel and a group of concerned scientists wrote to Roche asking the company to adjust its position. So far, Roche responses have been incomplete and unconvincing. Roche claims that their licensing agreement with Pfizer prevents them from reducing their prices and that they are selling at cost. Yet in a letter to MSF, Pfizer explained that "the royalty licensing agreement is based on a percentage of sales, and that Roche has the flexibility to price Viracept® as they determine on a country by country basis", adding that "[the] royalty would be reduced proportionately with any price

reductions". In addition, according to information from a raw material supplier and generic maker, it seems that nelfinavir could be sold for half the current Roche price – including profit margin.

Responding to continuing pressure at the Glasgow international congress on drug therapy in HIV infection held last November, Roche at last publicly committed to addressing this issue – but gave no date or details of a change.

Roche cuts price of nelfinavir

On February 13th, the company finally announced a drastic price reduction. With this new discount, Roche will now charge approximately US$ 900 per patient per year for least developed countries and sub-Saharan Africa. At just over 85% off Swiss prices, this discount is equivalent to those offered by other multinational pharmaceutical companies. Roche has also established a price of just under US$ 3,000 per patient per year for middle-income countries, unfortunately only 48% off Swiss prices.

These measures are consistent with our demands previously addressed to Roche, but it is important to note that Roche's published prices are "ex-factory": additional fees for freight and insurance will be added to the drug price, raising the price by around 20% for the customer. Published prices by other pharmaceutical companies such as Merck and Bristol-Myers Squibb already include these charges. Our task now will be to check if this price is well applied in the countries where we work.

Generic competition remains the most effective means to push prices down. However, for newer drugs for which no generic equivalents are available, a system of affordable prices from originator companies is critical. The long struggle to reduce the price of this Roche drug is proof of the limitations of a fully voluntary system. For new drugs, there needs to be an internationally-supported enforceable system that reduces prices to affordable levels in developing countries.

Elisabeth Le Saoût, Médecins Sans Frontières

Roche can go further

Though positive, those price reductions are not sufficient. At a price of 3000 US dollars per patient per year, the treatment with nelfinavir remains very expensive for the majority of the patients in developing countries other than sub-Saharan Africa and least developed countries. For example, the annual gross national income per capita is 520 US dollars in Armenia, 420 US dollars in India, 390 US dollars in Vietnam or 850 US dollars in Honduras[70]. This aspect is important at a time where the HIV/AIDS epidemic is growing in the Eastern European and Central Asian region, Asia and Central America. It would be irresponsible to wait until the epidemic reaches catastrophic prevalence rates like in sub-Saharan Africa before selling nelfinavir and saquinavir at "non-profit" prices in those countries.

Moreover, even at "non-profit" price of 900 US dollars per patient per year, nelfinavir remains expensive for many patients in Sub-Saharan Africa and least developed countries, especially since the price is from direct supply from Roche's headquarters in Basle and does not include the cost of freight, import, duty, taxes, distribution ad inventory. Nathan Geffen from the Treatment Action Campaign notes than in South Africa Roche's saquinavir and nelfinavir are still more expensive than the other branded antiretrovirals of the same class (protease inhibitors). With the new price policy adopted in March 2003, the price of a pack of 270x250mg pills of nelfinavir dropped from 2363 Rands (304 US dollars) to 681 Rands (88 US dollars), VAT excluded. This price remains expensive in a country where half of households earn less than 1500 Rands per month (193 US dollars). A reasonably affordable price in line with the reduced price of other branded protease inhibitors would therefore be 300 Rands (38 US dollars)[71]. Roche says that its "non-profit" prices do not reflect research and development costs, marketing costs, distribution costs or company overheads. Once again, as long as Roche does not open its accounting books, it's difficult to really estimate what is comprised in the "non-profit" price.

Half concession on patents on antiretrovirals

[70] World Development Report 2002. Washington D.C.: the World Bank, 2002.
[71] Personal communications with Nathan Geffen from the Treatment Action Campaign, February and March 2003. (Exchange rate on 11 April 2003: 1 US dollars = 7.7663 Rands)

Nelfinavir is patented in 24 African countries (and saquinavir is patented in 3 African countries)[72]. Both products are patented in South Africa. In April 2002 Roche adopted a "no patent policy" for its HIV/AIDS medicines in Sub-Saharan Africa and in the least developed countries: Roche committed itself in these countries not to act against infrigement of patents it holds on HIV/AIDS medicines, and not to file patents on new or investigational HIV/AIDS medications.
This "no patenting" policy is only an half concession that does not cost too much to Roche. Indeed with the exception of South Africa, none of the sub-Saharan African countries and none of the least developed countries has an efficient generic industry able to seriously compete with Roche. Countries with a generic industry able to produce on a large scale (like India, Brazil, China, etc.) are excluded from this policy. Moreover, this declaration of principle does not offer the sufficient legal security to Indian, Brazilian or even South African generic producers for starting production in or exporting to a Sub-Saharan African country or to a least developed country. This is a real concern for the generic producers in the developing countries[73].

Therefore this "no patent" policy for HIV/AIDS medicines should be extended to the other developing countries, in particular to countries with a performing generic industry. Since Roche is ready to renounce to making profits for its HIV/AIDS products in developing countries, it is logical that it renounces also to its patents in these countries. Today, even at "non profit" prices, Roche's nelfinavir and saquinavir costs almost the double that of the other antiretrovirals in the same class (protease inhibitors). In fact only a real generic competition will lead to the very low prices affordable to patients in poor countries. The sacrifice is not unreasonable for Roche since the company sells the huge majority of its products in countries in Europe, in North America and in Japan (83% of the global sales in 2002[74]).

HIV/AIDS diagnostics: several assistance projects but no transparent policy

Roche is a leader in the diagnostics market (see Part 1). Regarding HIV/AIDS Roche holds the patent of one of the technologies used to measure the viral load of patients (polymerase chain reaction, PCR) and produces both apparatus and reagents.

In the industrialized countries, viral load monitoring belongs to the best standards of healthcare and is commonly used to monitor the evolution of the patients under highly active antiretrorviral treatment. Even though it recognizes the utility and importance of the viral load tests, WHO does not recommend them yet in resource-limited countries because they are still very expensive and because their high technicality necessitates adequate infrastructure and staff[75]. However WHO notes that these tests could be considered in the central level of the health system in poor countries[76] (for example one laboratory in the capital city could do the tests with blood samples collected in the country).

Today Roche's viral load tests are very expensive (both apparatus and reagents). In Switzerland, the COBAS AMPLICOR™ analyser costs 60'000.- Swiss francs (around 43'100.- US dollars) and reagents for an individual HIV viral load tests cost 170.- Swiss francs (around 122.- US dollars) (market prices). When one adds the maintance, redemption and staffing costs, it makes the price of individual test expensive, especially for patients in countries where the people are poor and have to pay healthcare out of their pocket. The final price for the patient of one viral load test (price of reagent, maintenance and recouping the cost of the apparatus, staffing) costed 165.- US dollars in Guatemala (price for MSF) in January 2003. In Honduras the price was 250.-

[72] Data taken from: P. Boulet, J. Pierrens, F. Renaud-Théry. Patent situation of HIV/AIDS-related drugs in 80 countries. Geneva: UNAIDS/WHO, January 2000, pp. 11-15; A. Attaran, L. Gillepsie-White. "Do Patents for Antiretroviral Drugs Constrain Access to AIDS Treatment in Africa", The Journal of the American Medical Association, 17 October 2001, vol. 286, n° 15, p.1888.
[73] See for example a recent interview in the Financial Times: "M. Brar [director of the Indian generic producer Ranbaxy] said that generic companies would only invest insubstantial new capacity for producting AIDS drugs for Africa if there were guarantees that they would not face legal challenges and if there was sufficient public funding in place to purchase the drugs." (Georg Dyer, "Drug groups need not fear deal", Financial Times, 11 mars 2003)
[74] Roche Annual Report 2002.
[75] WHO recommends the CD4+ lymphocyte count, although there is an urgent need of simple and low-cost CD4 technology. (Scaling up. Antiretroviral therapy in resource-limited settings. Guidelines for a public health approach. Geneva: WHO, June 2002; p. 83) Moreover alternative technologies to PCR technology exists, such as NASBA technology or antigenemia p24.
[76] Scaling up. Antiretroviral therapy in resource-limited settings. Guidelines for a public health approach. Geneva: WHO, June 2002; pp. 83-84.

US dollars (price for the government) and 180.- US dollars (price for MSF) in March 2002[77]. However, in the Hôpital Cantonal et Universitaire in Geneva/Switzerland, the price of an individual test is 275.- Swiss francs (around 197.- US dollars) in March 2003[78]. That is to say that prices are more or less similar between Switzerland and developing countries where GDP per capita is much lower than in Switzerland: 1690.- US dollars in Guatemala and 850.- US dollars in Honduras as compared with 38'120.- US dollars in Switzerland. In South Africa, the cost of a test was 400.- Rands (around 51.- US dollars) in March 2003. According to Nathan Geffen from the Treatment Action Campaign, Roche should reduce the price of its reagents to 180.- Rands (23.- US dollars) for one test[79].
Roche communicates that it provides its viral load apparatus and its reagents at low prices or even for free to different punctual programs in several developing countries (in Thailand, South Africa, Uganda, Tanzania, Zimbabwe, Botswana, Senegal, Kenya, Ivory Coast, Peru). Such programs are laudable but insufficient. Donations do not respond to the long term needs of the developing countries. It is time for Roche to adopt a policy to sell its diagnostic products in the developing countries at affordable prices according to simple and transparent principles.

Not only HIV/AIDS products

The same problem of patents and affordability can be said for products not directly related to HIV/AIDS.

For instance a survey by Health Action International gives the case of Roche's ceftriaxone sodium (Rocephin®), one of Roche's blockbusters (1.548 billion Swiss francs sales in 2002). Roche's patent on different formulation of ceftriaxone has expired or is expiring but until recently it was patented in many countries [80]. Although ceftriaxone sodium can be used in the treatment of acute respiratory tract infections that led to 3.45 million deaths in 1998, its price in 1999 was on average 30% more in Latin America than in developed countries[81].

Roche is consolidating its position as a leader in diabetes care, a market perceived as promising by the company in view of the estimated 150 million people affected worldwide and of the 300 million people predicted to be affected worldwide by 2025[82]. However, in its forecasting, Roche should consider that the majority of diabetes patients live and will live in developing countries. Diabetes is not the main health care priority in the developing countries yet, but Roche should already commit itself to provide its products at affordable prices, according to simple and transparent principles.

On 31 March 2003, Roche announced that it will give to the Brazilian government the patent rights and the technology on a essential medicine, benznidazole, used to treat the Chagas disease. Once handed to the Brazilian government, Roche will cease production. It's certainly a positive step to hand over the production of benznidazole to the Brazilian government rather than just stopping it. But it is not at all a concession regarding the patent, since benznidazole which was first marketed more than 20 years ago in 1980, is off patent[83].

Lobbying for strong protection of patents in developing countries

Swiss pharmaceutical giants like Roche and Novartis for years have been lobbying for the highest level of protection of intellectual property worldwide, even in developing countries. Usually this action is not publicized. However it became highly visible with the trial of 39 pharmaceutical companies and business associations against the South African government for its new medicines law, where both Novartis and Roche were plaintiffs, the latter participating even twice, as mother company F. Hoffmann-La Roche AG and as South-African subsidiary Roche Products (Proprietary) Lted.

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[77] Personnal communication from Elisabeth Le Saout, Médecins Sans Frontières, 12 March 2003.
[78] Personal communication from Prof. Luc Perrin, Hôpital Cantonal et Universitaire de Genève, 20 March 2003.
[79] Personnal communication from Nathan Geffen, Treatment Action Campaign. March 2003.
[80] Patent on ceftriayone sodium expired in 1999 in the USA and in Europe (P. Boulet, J. Pierrens, F. Renaud-Théry. Patent situation of HIV/AIDS-related drugs in 80 countries. Geneva: UNAIDS/WHO, January 2000; p.11).
[81] K. Balasubramaniam & K. Sagoo. "Patents and Prices", HAI News, n° 112, April/May 2000; Oxfam Briefing Paper on GlaxoSmithKline. Dare to Lead: public health and company wealth. Oxfam, February 2001; p 18.
[82] For an estimation of people affected by diabetes mellitus, see: Press release by the International Diabetes Federation, "Rising Global Pandemic", 2002 (http://www.idf.org/home/index.cfm?node=204)
[83] "Roche to hand Brazil patent for anti-Chagas drug", Reuters, 31 March 2003. "Roche donates medicine to Brazilian Government to fight tropical disease", Roche press release: Basel, 2 April 2003.

Usually, this lobby for a maximum patent protection worldwide is carried out discretely, either directly or through a web of lobby associations that uses their influence on the industrialized countries (Switzerland, USA, European Union) (see Box 3.2.). This lobby is nothing new, as the case of Indonesia in the beginning of the 1990s shows[84]. The TRIPS agreement is a direct result of the lobbying of the pharmaceutical giants (see Part 1). The strong and efficient lobby of the Swiss pharmaceutical giants also explains the hardline position of Switzerland for a strong patent protection in developing countries in the World Trade Organization negotiations as well as in the Swiss bilateral policy[85]. One is always struck to find in the official Swiss position the arguments of the industry lobbyists[86].

The declaration on TRIPS and public health adopted during the WTO ministerial conference in Doha/Qatar worried both the Swiss pharmaceutical industry and the Swiss government. In Doha Swiss negotiators had opposed it until the last minute. In the Wall Street Journal, Daniel Vasella, president and chief executive officer of Novartis, expressed its concerns about the Doha declaration: "I am concerned. It's important that the compromise express care for developing countries. But without patents, profits aren't possible, and research suffers."[87]

This attitude is characteristic of the Swiss pharmaceutical giants Roche and Novartis. As they are lobbying for strong rules on patent protection worldwide that do not make any difference between industrialized and developing countries, they are regarding any questioning of strong patent protection in developing countries as a threat to patent protection in industrialized countries too, and therefore to their very existence. In a letter to the Berne Declaration from 11 July 2001, Roche wrote: "It is too easy to criticize unilaterally the pharmaceutical industry. The sector is faced with contradictory requirements: on the one hand, the requirement for new medicines more efficient, more sure and cheaper (…), and on the other hand the necessity to provide least developed countries and the patients from the rest of the world with medicines at the lowest price possible. In the same time, some people are requesting the abolition of patent protection as well as the introduction of the authorization of parallel importing in Switzerland of cheaper medicines from low production costs countries. (…). This is just an impossible task." (translation by the author)[88]. And as stated the director of Roche's

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[84] "In 1989 the Indonesian government drafted a proposed patent law in response to criticism from the Swiss pharmaceutical and the United States. The American Embassy immediately had the text of the draft law translated from Indonesian into English, and supplied it to interested parties. "Interpat", an informal consortium of large European and American chemical concerns, commented on the draft proposal. National industrial associations – such as the Swiss Association for the Chemical Industry "Schweizerische Gesellschaft für Chemische Industrie") then lobbied their governments to intervene at the diplomatic level. Representatives of the USA, Switzerland, the EU were thus able to present the Indonesian government with proposed changes to the draft law that were co-ordinated and consistent in content. Indonesia finally adopted patent legislation, not as the result of careful study but of extreme pressure from foreign countries." (Richard GERSTER. Patents and Development. Lessons learnt from the economic history of Switzerland. Third World Network, 2000; pp. 6-7)

[85] Switzerland has an active policy of concluding with developing countries bilateral agreements and plurilateral (through the European Free Trade Agreement) agreements with strong intellectual property rights components. (See: Bernhard HEROLD, "Propriété intellectuelle. La position de la Suisse", Se Soigner®: un droit pour tous. Sida, Suisse et pays pauvres. Lausanne: Déclaration de Berne, 2003; pp. 22-23.)

[86] Compare for example the intervention of Felix Addor, one of the persons in charge within the Swiss administration with bilateral and multilateral negotiations regarding intellectual property, and the intervention of Thomas B. Cueni, the general secretary of Interpharma, the lobby group of the pharmaceutical industry, during the 11 October 2001 workshop on patents organized by Interpharma. Felix ADDOR. "Versorgung mit Medikamenten in Entwicklungsländern. Patentschutz: nicht das Problem, sondern Teil der Lösung" (http://wwww.interpharma.ch/themen/ghpolit/archiv/pdf/ptt-addor2.pdf) & Thomas B. CUENI. "Der Zugang zu Medikamenten" (http://wwww.interpharma.ch/themen/ghpolit/archiv/pdf/ptt-cueni.pdf)

[87] Wall Street Journal, 14 November 2001.

[88] Complete original quotation: "Il est trop facile de critiquer unilatéralement l'industrie pharmaceutique. Le secteur est en butte à des exigences contradictoires: d'une part, la demande en faveur de médicaments nouveaux, encore plus efficaces, plus sûrs et plus avantageux économiquement, dont le développement est extrêmement long et requiert d'énormes investissements, et d'autre part, la nécessité d'approvisionner les pays les moins développés et les patients du reste du monde en médicaments le moins chers possible. Simultanément, des voix s'élèvent en faveur de l'abolition de la protection des brevets ainsi que l'autorisation de l'importation parallèle en Suisse de médicaments meilleur marché en provenance de pays à faibles coûts de production. En outre l'industrie est censée garantir une certaine garantie de l'emploi et étendre ses activités de recherche. Autant dire que l'exercice relève de la quadrature du cercle." (Letter from Horst Kramer, head of corporate communication, to Déclaration de Berne, 11 July 2001.)

pharmaceutical division, William M. Burns, in an article about AIDS in Africa: "For us as research-oriented enterprise, patent protection and fair prices are the key to our future business success and therefore to our long term security of existence." (translation by the author)[89].

Pharmaceutical lobby groups have a direct responsibility in the present paralysis of WTO negotiations on paragraph 6 of the Doha declaration on TRIPS and public health. Companies continue to lobby the governments of industrialized countries, in particular the USA, Switzerland, the European Union and Japan, to take a tough stand and limit as much any concessions to developing countries[90]. This shows that the pharmaceutical giants are still seeking for maximum patent protection in the developing countries, and that they want to prevent the production and the marketing of generic copies of patented medicines in developing countries, especially in countries with an efficient generic industry, such as India, Brazil, China, Thailand for example, even though such attitude will hinder the supply of the very cheap medicines needed by the sick in poor countries.

This double game of the pharmaceutical industry is not acceptable. Roche cannot on the one hand concede some price reduction and abstain to defend its patents in some countries, and one the other hand continue to lobby Switzerland and the other industrialized countries for international rules for a maximum protection of its patents in the world, including the developing countries. Companies are also accountable for the lobby they are doing. It's time that Roche, Novartis and the other pharmaceutical companies recognize that the developing countries should adapt their level of intellectual property protection to their level of development. They must also recognize that the protection of public health has priority on the patent protection. Roche, Novartis and the other pharmaceutical companies must stop lobbying in the opposite direction.

Box 3.2. Swiss pharmaceutical industry in the national, European, American and global network of lobbying associations

Swiss pharmaceutical giants Roche (29.725 billion Swiss francs sales in 2002) and Novartis (32.412 billion Swiss francs sales in 2002) are influential global players. In order to defend their interests, both companies can rely on a efficient network of professional associations at the national, European, American and international levels.

In Switzerland, Interpharma plays a key role in the lobbying of the Swiss federal authorities (administration and parliament)[91]. This association represents the interest of its three full members: Novartis, Roche and Serono (1.546 billion US dollars sales in 2002). Another important Swiss professional association, also active in lobbying activities, is the Swiss Association for the Chemical Industry (SGCI - Schweizerische Gesellschaft für Chemische Industrie; SSIC – Société Suisse des Industries Chimiques)[92].

Swiss pharmaceutical companies are also present at the European level (European Commission and European Parliament). Franz B. Humer, chairman and CEO of Roche, is one of the two vice-presidents of the European Federation of Pharmaceutical Industries and Associations (EFPIA), one person from Novartis chairs the Intellectual Property Policy Committee, the secretary general of Interpharma chairs the Economic and Social Policy Committee[93]. Roche, Novartis and the SGIC are also members of the European Chemical Industry Council (CEFIC), the "forum and the voice of the European chemical industry"[94].

In the USA, Roche, Novartis and Serono are full paying members of PhRMA, the Pharmaceutical Research and Manufacturers of America[95]. Representatives from Roche, Novartis and Serono (Ernesto Bertarelli, the CEO of

[89] Original quotation: " Für uns als forschungsorientiertes Unternehmen sind der Patentschutz und faire Preise der Schlüssel zu unserem künftigen Geschäftserfolg und damit zur langfristigen Existenzsicherung." ("AIDS in Afrika: was tut Roche ?", Roche Magazin, n° 68, Oktober 2001, p. 21)
[90] On the lobby on the USA: "The pharmaceutical industry raised $60m for the Republican war chest for last year's mid-term elections. Its lobbying group, PhRMA (Pharmaceutical Research and Manufacturers of America) is pressing for a tough line on the Doha talks. Individually, Pfizer, Merck, Roche and Bristol-Myers Squibb are also thought to be demanding that the [US] government defends their interests." (Sarah Boseley and Charlotte Denny in Geneva, "WTO conference Deadlock as US shows no sign of loosening veto on pharmaceutical patent rights", The Guardian, 20 February 2003)
[91] http://www.interpharma.ch
[92] http://www.sgci.ch
[93] http://www.efpia.org/1_efpia/structur.htm [accessed on 18 April 2003]
[94] http://www.cefic.org
[95] http://www.phrma.org

Serono) are members of PhRMA's board of directors. This influential association requires and obtains from the US government that it issues trade sanction against countries accused of not respecting PhRMA's interpretation of the TRIPS agreement (see Part 1.)[96].
Because of the US lobby disclosure act, figures for lobbying in the USA are known (in opposition to Switzerland and the European Union where they are not disclosed). In 2001 the pharmaceutical industry had spent 78 million US dollars for lobbying expenditure on the US Congress (brand-name manufacturers accounted for 97% of the total amount, and the generic manufacturers for the remaining 3%) and had employed 623 lobbyists[97]. PhRMA spent 11.2 million US dollars for lobbying US Congressmen and employed 82 lobbyists in 2001. Swiss pharmaceutical companies have been quite active in lobbying activities: in 2001, Roche spent 2.9 million US dollars for lobbying (+213% since 1997) and employed 17 lobbyists[98]; Novartis spent 2.6 million US dollars (+167% since 1997) and employed 33 lobbyists; Serono spent 180'000 US dollars (+450% since 1997) and employed 17 lobbyists. Regarding the political expenditures, the pharmaceutical industry in the USA strongly supported the Republican administration in the recent legislative and presidential elections. According to provisional figures for the 2002 elections cycle, PhRMA gave 95% of its 3 million US dollars contributions to the Republicans. Regarding Swiss pharmaceutical corporations, Novartis gave 79% of its 600'000 US dollars contribution to the Republicans and Roche gave 51% of its 120'000 US dollars contribution to Democrats and 49% to Republicans[99].

At the international level the Swiss pharmaceutical industry is one ot the "permanent members" of the board of the International Federation of the Pharmaceutical Manufacturers Associations (IFPMA)[100]. This association is active with the international organizations in Geneva (WTO, WTO, WIPO, etc.). Daniel Vasella, chairman and CEO of Novartis, is one of the two vice-presidents of the IFPMA council.

Beside those specific pharmaceutical or chemical associations, Roche and Novartis belong individually to several business associations at the national, European or global level such as for instance the International Chamber of Commerce (Novartis) or the European Roundtable of Industrialists (Roche).

[96] For a current list of the submission of PhRMA to the US trade secretary: http://www.phrma.org/international/
[97] The Other Drug War II. Drug Companies Use an Army of 623 Lobbyists to Keep Profits Up. Washington: Public Citizen's Congress Watch, 12 June 2002; ii-49 p.
[98] This figure does not comprise Genentech, a US biotech company in which Roche detains 60% of the shares. In 2001, Genentech spent 1.2 million US dollars for lobbying (+94% since 1997) and employed 34 lobbyists.
[99] See the data from the Center for Responsive Politics: http://www.opensecrets.org/industries/contrib.asp?ind=H4300&Cycle=2002 [accessed on 25 February 2003] (In the previous election cycles from 1998 to 2000, both Novartis (previously Sandoz and Ciba-Geigy) and Roche had also given predominantly to Republicans.)
[100] http://www.ifpma.org

Recommendations from the Berne Declaration to Roche

Roche shall recognize that the protection of the public health shall have priority over the protection of intellectual property rights.

Roche shall recognize that the developing countries shall adapt their intellectual property protection to their level of development.
Therefore Roche shall cease to lobby in the opposite direction.

Roche shall adopt a policy where it commits itself to sell its medicines and diagnostics products in all developing countries at affordable prices, according to transparent and simple principles, without laying down inequal, unnecessary and anticompetitive conditions.

Roche shall extend its new HIV/AIDS policy for Sub-Saharan Africa and for the least developing countries (renunciation to profits and to patents) to the other developing countries, in particular to low-income and middle-income countries.

Abbreviations

CEFIC	European Chemical Industry Council
EFPIA	European Federation of Pharmaceutical Industries and Associations
ERT	European Roundtable of Industrialists
EU	European Union
HIV/AIDS	Human Immunodeficiency Virus/Acquired Immune Deficiency Syndrome
IFPMA	International Federation of Pharmaceutical Manufacturers Associations
MSF	Médecins Sans Frontières
NGO	Non Governmental Organization
PhRMA	Pharmaceutical Research Manufacturers of America
SGCI	Schweizerische Gesellschaft für Chemische Industrie
TRIPS	Agreement on Trade-Related Aspects of Intellectual Property Rigths
UN	United Nations
VTA	Value Added Tax
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

Annex:

Text of Bern Declaration's intervention to Roche's General Assembly on 1 April 2003
(English translation from French)

Mr. Chairman,

I would like to intervene today on Roche's position regarding access to medicines in developing countries in view of the public health crisis in those countries.

Firstly let me express my relief for the price reduction of your two protease inhibitors (Fortovase® and Viracept®) in favour of sub-Saharan Africa countries and Least Developed countries. Though late this price reduction is a very positive step from you, a first step, we hope, will encourage Roche to finally distinct itself as one of the most proactive entreprises regarding access to medicines in the developing countries.

However, at 3000 US dollars per patient a year in the other developing countries, treatment with Viracept® (nelfinavir) remains too expensive for the great majority of the sick in the other developing countries. One should keep in mind that annual gross national income per capita is 520 US dollars in Armenia, 420 US dollars in India, 390 US dollars in Vietnam, 850 US dollars in Honduras. Is it really necessary to wait until the HIV/AIDS epidemics has reached catastrophic prevalence rates in those countries before you start to extend your "not profit" prices to these countries ? This is my question: are you ready to extend to the other developing countries your "not profit" prices ?

One other thing: you have decided not to protect your patents on HIV/AIDS medicines in the countries of sub-Saharan African and in the Least Developed Countries. Again, this is a positive move but that should go further. The great majority of those countries do not have any pharmaceutical industry efficient enough in order to produce the very cheap medicines needed by their sick. However countries that may produce them, like India, China, Brazil, are excluded from your policy. Since you are renouncing to make profits in developing countries with your anti-AIDS medicines, why don't you renounce to patents on those anti-AIDS medicines in all developing countries ? This would give the legal security necessary to generics producers in those countries for starting production.

The same kind of interrogation is worth for your other medicines and diagnostics products too. Are you ready to adopt affordable pricing policies that rely on simple and transparent principles for all your useful, efficient and safe products, that respond to essential health needs in the developing countries ?

I can understand that Roche protects its patents in the industrialized countries where is the essential part of its market, in order to finance the research and development of new medicines. But I cannot understand why Roche worked and is still working to extend high level of intellectual property protection to the developing countries, that is in countries where the great majority of the population do not have the financial means to buy expensive medicines. This quest for a maximum patent protection in developing countries is problematic because you strongly delay the introduction of generic competition. However recent experience has shown that generic competition is the most efficient mean to get the very cheap medicines needed by the sick in the developing countries.
Are you ready to recognize that the protection of the public health shall have the priority over patent protection and that the level of patent protection in developing countries shall be adapted to their level of development ?

I thank you in advance for your reply.

Julien Reinhard, Déclaration de Berne, 1 April 2003.