

Wogart, Jan Peter

**Working Paper**

## Multiple Interfaces of Big Pharma and the Change of Global Health Governance in the Face of HIV/AIDS

GIGA Working Papers, No. 24

**Provided in Cooperation with:**

GIGA German Institute of Global and Area Studies

*Suggested Citation:* Wogart, Jan Peter (2006) : Multiple Interfaces of Big Pharma and the Change of Global Health Governance in the Face of HIV/AIDS, GIGA Working Papers, No. 24, German Institute of Global and Area Studies (GIGA), Hamburg

This Version is available at:

<https://hdl.handle.net/10419/47840>

**Standard-Nutzungsbedingungen:**

Die Dokumente auf EconStor dürfen zu eigenen wissenschaftlichen Zwecken und zum Privatgebrauch gespeichert und kopiert werden.

Sie dürfen die Dokumente nicht für öffentliche oder kommerzielle Zwecke vervielfältigen, öffentlich ausstellen, öffentlich zugänglich machen, vertreiben oder anderweitig nutzen.

Sofern die Verfasser die Dokumente unter Open-Content-Lizenzen (insbesondere CC-Lizenzen) zur Verfügung gestellt haben sollten, gelten abweichend von diesen Nutzungsbedingungen die in der dort genannten Lizenz gewährten Nutzungsrechte.

**Terms of use:**

*Documents in EconStor may be saved and copied for your personal and scholarly purposes.*

*You are not to copy documents for public or commercial purposes, to exhibit the documents publicly, to make them publicly available on the internet, or to distribute or otherwise use the documents in public.*

*If the documents have been made available under an Open Content Licence (especially Creative Commons Licences), you may exercise further usage rights as specified in the indicated licence.*

# GIGA *Working Papers*

German  Institute of Global and Area Studies  
Leibniz-Institut für Globale und Regionale Studien

GIGA Research Program:  
Transformation in the Process of Globalization

---

## **Multiple Interfaces of Big Pharma and the Change of Global Health Governance in the Face of HIV/AIDS**

Jan Peter Wogart

N° 24

June 2006

GIGA Working Papers serve to disseminate the research results of work in progress prior to publication to encourage the exchange of ideas and academic debate. Inclusion of a paper in the Working Papers series does not constitute publication and should not limit publication in any other venue. Copyright remains with the authors.

## **GIGA Working Papers**

Edited by GIGA German Institute of Global and Area Studies / Leibniz-Institut für Globale und Regionale Studien.

The Working Paper Series serves to disseminate the research results of work in progress prior to publication to encourage the exchange of ideas and academic debate. An objective of the series is to get the findings out quickly, even if the presentations are less than fully polished. Inclusion of a paper in the Working Paper Series does not constitute publication and should not limit publication in any other venue. Copyright remains with the authors. When Working Papers are eventually accepted by or published in a journal or book, the correct citation reference and, if possible, the corresponding link will then be included in the Working Papers website at:

**[www.giga-hamburg.de/workingpapers](http://www.giga-hamburg.de/workingpapers).**

GIGA research unit responsible for this issue: Research Program "Transformation in the Process of Globalization".

The research for this article has been part of the GIGA research project on "Global Health Governance: Institutional Change and the Interfaces Between Global and Local Politics in the Poverty-Oriented Fight of Diseases".

Editor of the GIGA Working Paper Series: Bert Hoffmann <[hoffmann@giga-hamburg.de](mailto:hoffmann@giga-hamburg.de)>  
Copyright for this issue: © Jan Peter Wogart

Editorial assistant and production: Verena Kohler

All GIGA Working Papers are available online and free of charge at the website: [www.giga-hamburg.de/workingpapers](http://www.giga-hamburg.de/workingpapers). Working Papers can also be ordered in print. For production and mailing a cover fee of € 5 is charged. For orders or any requests please contact:

e-mail: [workingpapers@giga-hamburg.de](mailto:workingpapers@giga-hamburg.de)

phone: ++49 (0)40 - 428 25 548

GIGA German Institute of Global and Area Studies /  
Leibniz-Institut für Globale und Regionale Studien  
Neuer Jungfernstieg 21  
20354 Hamburg  
Germany  
E-mail: [info@giga-hamburg.de](mailto:info@giga-hamburg.de)  
Website: [www.giga-hamburg.de](http://www.giga-hamburg.de)

## **Multiple Interfaces of Big Pharma and the Change of Global Health Governance in the Face of HIV/AIDS**

### **Abstract**

By using a game theoretical approach and the notion of “forum” or “regime shifting” this paper examines the multiple interfaces of the multinational pharmaceutical corporations (MNPCs) with their major counterparts at home and abroad, including the governments of the North and South, the international organizations and increasingly with national and international NGOs in the context of the spreading HIV/AIDS crisis. It shows how the execution of the MNPCs’ strategies led to significant reactions from other actors, which led to further moves and countermoves in a strategic battle between representatives of the North and the South in the global health arena.

**Key Words:** Multinational Pharmaceutical Corporations (MNPCs), HIV/AIDS, global health governance, pricing of ARVs;

**JEL Classification:** I (Health, Education and Welfare) and K (Law and Economics)

Parts of the paper have been presented earlier at Conferences of the Latin American Social Science Association (LASA) in 2004 and the Business Association of Latin American Studies (BALAS) in 2005.

### **Jan Peter Wogart**

is associated with GIGA’s research project on “Global Health Governance”, concentrating on the pharmaceutical companies and the World Bank’s health related activities. He is teaching economics and international finance at the University of Applied Sciences in Bremen, applying lessons learned from earlier teaching in the USA and Brazil and working with the World Bank Group for over 25 years.

Contact: [jpwogart@geonet.de](mailto:jpwogart@geonet.de)

## **Zusammenfassung**

### **Die HIV/AIDS-Bedrohung und die Rolle der Multinationalen Pharmabetriebe in der globalen Gesundheitspolitik**

Der Text analysiert die Interaktionen zwischen den Multinationalen Pharmazeutischen Unternehmen (MNPCs) und den Regierungen der Industrie- und Entwicklungsländer, sowie den internationalen Organisationen und den Nichtregierungsorganisationen im Zusammenhang mit der weltweiten Verbreitung der HIV/AIDS-Krankheit. Die Analyse zeigt, wie die zahlreichen anfänglichen Konflikte an allen Fronten in den letzten Jahren mehr und mehr durch Kompromisse und gemeinsame Initiativen ersetzt wurden, die die Architektur der „Global Health Governance“ entscheidend verändert haben.

## **Article Outline**

1. Introduction
2. Major Features of the Multinational Pharmaceutical Corporations
3. The Multiple Interfacing of the MNPCs: 1995-2005
4. AIDS, Doha and Revised TRIPS
5. The Battle over Drug Prices and the Southern Offensive at International Organizations
6. The Counteroffensive of the MNPCs and a Further Regime Shifting Exercise
7. Pharma and the Rise of Global Public Private Partnerships
8. The Strengthening of National Health Governance and Its Impact on Global Players at the Treatment of AIDS

## **1. Introduction**

During the last ten years, a number of spectacular confrontations between government and private sector representatives of the “North” and the “South” have been taking place in the global health arena. The rapid spread of the HIV/AIDS virus from a limited number of individuals in the industrialized countries to an ever increasing number of individuals and families in the developing countries became the igniting flash in having the national authorities of South Africa and Brazil face the multinational pharmaceutical companies (MNPCs) and their governments in an open conflict. The “South” succeeded in having the prices of anti-retroviral drugs (ARVs) against AIDS significantly lowered. At the same time, the developing countries have also been able to soften the stringent patent right protection legislated by the World Trade Organization (WTO) under the Trade Related Intellectual Property Rights (TRIPS) Agreement in 1995.

This paper will be summarizing background and implications of these two conflicts and their resolution in the context of the multiple interactions of major actors in the markets for medicines of rich and poor countries, with special emphasis on the power and politics of the large research oriented MNPCs, their current multiple problems, and the rising significance of the pharmaceutical industries in the newly industrializing countries (NICs). It will focus on four issues, which include:

- the characteristics of the main actors,
- the nature of their interfaces with the other actors in the context of the rapidly spreading HIV/AIDS crisis,
- the response of the nation states to the global health challenge, and
- the impact of the emerging institutional health governance on the very crisis, which was so instrumental for shaping the new institutional set-up.

After presenting a summary evaluation of the major characteristics of the MNPCs, a step-by-step analysis of the major interfaces the industry had with public and private entities in the face of the HIV/AIDS crisis will form the heart of the essay. The answers to questions three and four concerning the ability of nation states to withstand and/or absorb global forces and the impact of the emerging institutional setting on the pandemic's outcome are a consequence of the earlier analysis of the nature and results of the interfaces having taken place in the period between 1995 and 2005.

The examination of the MNPCs in the global health arena offers great opportunities for every social science discipline and even more for inter-disciplinary research. This analysis will use elements of strategy models, which have been increasingly used by economists, business analysts, and legal experts. It will combine those approaches with a political science framework which examines the emergence of global health governance (GHG) in the context of multi-level governance.

The research for this article has been part of the GIGA research project on "Global Health Governance: Institutional Change and the Interfaces Between Global and Local Politics in the Poverty-Oriented Fight of Diseases", funded by the Volkswagen-Foundation<sup>1</sup>. In the context of this research project Global health governance (GHG) is defined as the totality of collective regulations to deal with international and trans-national interdependence problems in health (Bartsch and Kohlmorgen, 2005). Here we go one step further and argue that GHG can be conceived as "systems of rule at all levels in which the pursuit of goals through the exercise of control has trans-national repercussions affecting health." (Buse, 2006: 14, following the global governance definition by Rosenau (2004: 45).

---

<sup>1</sup> More on the project, participants and publications can be found under: [www.giga-hamburg.de/ghg](http://www.giga-hamburg.de/ghg).

Particularly useful for analyzing the MNPCs in the multiple public and private negotiations are a game theory oriented approach and the notion of “forum” or “regime shifting” (Helfer, 2004), which the corporations and then the governments of the North used in internationalizing IPRs in the context of TRIPS, only to find out that international NGOs and representatives of the South shot back by using the same strategy in fighting for people’s access to low cost medicines. Both groups of actors have perceived their goals in a socio-political structure and an institutional setting which allowed them to pursue those different objectives and carry them out. By doing so, they have been changing the very economic and social structure of global health architecture and with its concerns, activities, and rules. In brief, the social action analyzed here has been co-determined by the property of actors and the existing socio-political structure (Sell, 2000).

## 2. Major Features of the Multinational Pharmaceutical Corporations

The purchasing price of pharmaceuticals, sales of which make up about 15% of total health expenditures in the rich countries but are estimated to reach between 20 and 25% in the poor countries, can vary by hundreds of percent, depending on which class of drugs they belong to and in which country they are sold. The “innovator” drugs are protected by patents, granting the producer a monopoly rent in compensation for past and future research and development efforts. While not officially disclosed, after passing a series of tests and approval from public regulatory authorities, the MNPCs base and rationalize their pricing decision not on short and long run costs but on the degree of competition from similar drugs, the elasticity of demand, and the extent that the new patented drug substitutes for earlier treatments of the disease, many of which have been expensive, especially when it entailed medical treatment in hospitals (Neukirchen, 2004: 93).<sup>2</sup>

In the past the industry has been reaping the benefits of that type of pricing and the protection granted them by law rather extensively, even if governments intervened with price controls. In the US the authorities have refrained from direct market intervention. Instead, the firms enjoy a great number of positive incentives, ranging from tapping results from superior public sector institutions to tax reductions for locating in special US territories.<sup>3</sup> The fa-

---

<sup>2</sup> Increased competition has narrowed the wide differences among various international markets. We are still far away from the convergence to one price, but the globalisation of markets working into that direction in OECD countries. “The ten oldest drugs, launched before 1988, are up to four times more expensive in America than elsewhere, the ten newest drugs, launched after 1997, are only twice the price.” (The Economist, 2005a: 12)

<sup>3</sup> For a critical discussion, see Young and Surrasco (2001); The Economist (2005b); Abramson (2004).

avorable policy framework has made it possible for the major firms to be consistently top financial performers of all industrial branches, irrespective of profitability being measured by return on revenues or on assets. Despite recent legal problems concerning negative side effects of some of their “blockbuster” medicines, the pharmaceutical industry’s net revenues averaged close to 30% of shareholders’ equity, remaining one of the leading industries in the annual ranking of *Forbes’ Magazine* in 2003 and 2004. Large legal departments make sure that nobody infringes on the patents and try to prolong them by applying for additional patents if innovations can be added on to the existing drug.

For an industry which is facing high fixed costs in research and development, merging and acquisition to reach ever larger economies of scale is a must. As a consequence, the concentration of the industry has taken on a rapid pace in the last two decades.<sup>4</sup> While there were still over 30 major pharmaceutical companies engaged in R&D in the 1980s, that number has shrunk to just over a dozen, all of them concentrating on the goal to invent, produce and sell a “blockbuster”, i.e. a drug which reaches annual sales of over US 1 billion.<sup>5</sup>

As Table 1 indicates, the largest sixteen research oriented pharmaceuticals had annual sales averaging \$18 billion in 2004, with some of their major products ringing up over \$1 billion per year. The statistics on the stock market value of those companies’ stocks, however, reveal that the majority of them have faced significant buyers’ sell-offs in the recent past, reflecting the growing competition from the generic industries, the problem with negative side effects showing up after their drugs have been pushed to the market too rapidly, and the increasing wave of informal marketing channels at discount prices, of which the Canadian imports into the U.S. is only the most prominent example.<sup>6</sup>

---

<sup>4</sup> In the last two decades of the 20<sup>th</sup> century, there were close to 50 mergers in the pharmaceutical industry, valued over US\$ 1 billion, 17 of which crossed the \$5 billion mark. (Zeller, 2001)

<sup>5</sup> The most successful “blockbuster” drug is Lipitor, an anti-cholesterol medication which provided its producer Pfizer with annual sales of over \$3 billion in 2004. Its patent is currently challenged by India’s largest manufacturer Rambaxy in various courts around the world. For a discussion of the battle in British courts see, *The Washington Post*, October 13, 2005.

<sup>6</sup> For good summary of the major issues facing big pharma, with special emphasis on the problems in the largest and most profitable US market, see *The Economist*, June 18, 2005.

**Table 1: Vulnerable Giants: Sales, Market Value and R&D Expenditures of the Large Pharmaceutical Companies (US\$ Billion)**

| Rank         | Name                | Sales 2004 (a)       | Market Value |              | R&D Spending |
|--------------|---------------------|----------------------|--------------|--------------|--------------|
|              |                     |                      | 2000         | 2004         |              |
| 1.           | Pfizer              | 45.2 (51.1)          | 290          | 201          | 7.5          |
| 2.           | GlaxoSmithKline     | 30.6 (32.8)          | 178          | 145          | 4.5          |
| 3.           | Sanofi-Aventis      | 25.0 (27.4)          | 49           | 128          | 4.0          |
| 4.           | Johnson&Johnson     | 21.8 (24.7)          | 146          | 200          | 4.7          |
| 5.           | Merck               | 21.7 (23.9)          | 216          | 71           | 3.8          |
| 6.           | AstraZeneca         | 21.4 (21.7)          | 89           | 69           | 3.4          |
| 7.           | Novartis            | 20.9 (22.9)          | 128          | 131          | 3.8          |
| 8.           | Roche/Genentech     | 15.7 (17.8)          | 91           | 112          | 4.0          |
| 9.           | Bristo-Myers Squibb | 14.9 (15.6)          | 146          | 50           | 2.5          |
| 10.          | Eli Lilly           | 13.1 (13.7)          | 105          | 66           | 2.6          |
| 11.          | Wyeth               | 13.1 (14.3)          | 83           | 58           | 2.1          |
| 12.          | Abbot Labs          | 11.2 (14.3)          | 75           | 75           | 1.6          |
| 13.          | Amgen               | 10.4                 | n.a.         | n.a.         | 1.9          |
| 14.          | Takeda              | 10.4                 | n.a.         | n.a.         | 1.1          |
| 15.          | Schering-Plough     | 6.3 (6.9)            | 83           | 29           | 1.6          |
| 16.          | Bayer               | 5.6 (6.4)            | 39           | 25           | 1.1          |
| <b>Total</b> |                     | <b>287.3 (314.3)</b> | <b>1718</b>  | <b>1,360</b> | <b>50.2</b>  |

Note: Sales data are for prescription medicines and generics, numbers in brackets include OTC sales; if health care products and diagnostics are included, some companies such as Bayer and Roche easily doubled their total sales in 2004.

Sources: IMS Health; Thompson Data Stream, The Economist, June 2005.

An increasing part of pharmaceuticals are generics, which enter the markets at significantly lower prices, once the patents are terminated. Their development in the US was favored by the 1984 Hatch-Waxman Act, which allows the producers of generics to use the research results and the long series of tests of the R&D companies to be ready for their own production once the patent has been terminated.<sup>7</sup> Other countries followed with similar legislation, and recent examples of more intense competition can be found everywhere, with some those industries becoming particularly prominent in Europe.<sup>8</sup>

Production of generic pharmaceuticals in the South is mainly taking place in the larger industrializing economies and is undertaken both, in private and public sector firms. In Brazil, for example patented products are imported or receive only the final touches by the

<sup>7</sup> At the same time, the Hatch-Waxman Act also granted a number of benefits to the research oriented pharmaceutical companies, among others longer time periods for patents. (see Angell, 2004)

<sup>8</sup> Out of EUR 25 billion of pharmaceutical products being sold in Germany in 2000, over 70% were bought on prescription, of which only 22% being protected by patents. The sales and consumption of generics has grown substantially during the last 15 years, especially in Germany, where their share rose from less than 20% in the mid 1980s to close to 50% in 1999. (Zeller, 2001). Price differences among the various countries are less pronounced, with the US market offering often lower prices than Europe.

MNPCs' local plants. Legal generics are just starting to establish themselves, and have reached market shares of about 10%. An estimated 40% of consumption of pharmaceuticals are still produced in many small and some large local plants and are called "similar", i.e. unauthorized copies of patented drugs. It is that part of production which the MNPCs have been fighting against by arguing that they are not only violating patents but that they are also potentially dangerous to patients.<sup>9</sup> Indeed, both industry and independent sources estimate that counterfeit drugs make up 25% of medicines sold in developing countries, with specific drug counterfeits reaching 40% in some Latin American and Asian markets.<sup>10</sup>

Production, distribution and exports of generics have been more important in India and China than in the advanced Latin American countries. By declaring patents only being valid for processes rather than products, India's major pharmaceutical companies have achieved specialized manufacturing capabilities through reverse engineering, producing generic drugs from antibiotics to Viagra, including medication against AIDS. While the 14 leading companies' sales only reached US\$ 2.9 billion in 2003, or about 1% of the above mentioned MNPCs, the plants of India's leading firms have become significant suppliers of active ingredients for the European and US generic industries, ringing up export revenues of over US\$1.5bill. during the same year.<sup>11</sup>

Most of the drugs sold in other developing countries have also been copied from patented medication without the local producer holding a license from the original producer of the drug. While the amount of sales was too small to really hurt the big Pharma companies in the past, the MNPCs and their legal departments have actively supported the introduction of new and tough intellectual property rights (IPRs) legislation in the developing world for years, and they were successful when the World Trade Organization (WTO) set international rules not only for trade of goods but also for services, of which the IPRs became an important part, and which were incorporated into the 1994 Trade Related Intellectual Property Rights (TRIPS) Agreements, to be discussed below in some detail.

As a consequence of the many different suppliers, international price comparisons of the very same drug are difficult, even before the multiple interventions of governments and/or insurance companies take place. Nevertheless, there is a list of essential generic medicines (EDL), put together by the World Health Organization (WHO), which not only provides specific classification of each drug, but also its availability and price. Moreover, the NGO Doctors without Borders (MSF) has been researching the prices of important drugs fighting

---

<sup>9</sup> Clearly stated in a letter by PhRMA to the Office of the US Trade Representative on February 15, 2002.

<sup>10</sup> For a summary review of the counterfeit problem, see Seiter (2005a).

<sup>11</sup> Financial Times, January 22, 2004. The leading companies are Ranbaxy, Dr. Reddy's, Aurobindo, and Lupin. Those four firms are responsible for 70% of total Indian sales.

major diseases in developing countries, which the organization is posting regularly on the internet (MFS, 2004).

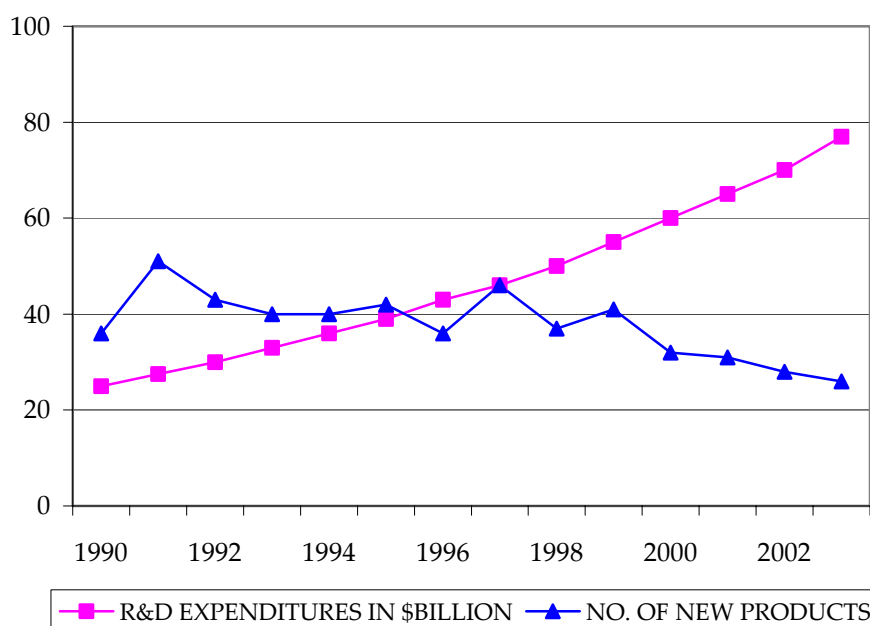
As Table 1 has indicated, the major MNPCs' annual outlays for R&D average over \$3 billion, amounting to 17% of their sales. These expenditures, even if some of them could be partly allocated to marketing, are a significant amount both in absolute and in relative terms, routinely used for the industry's claim for the high prices they cover for innovator drugs. While the industry's quoted cost of each new drug development amounting to \$800 million has been questioned, there is no doubt that the industries R&D outlays have advanced rapidly in the last 10 years, reaching close to \$80 billion in 2004, which was double the size a decade earlier.<sup>12</sup> However, what has perplexed the industry and the public is the fact that the results in terms of new products and licenses has not caught up with the expenditures but shows a declining trend, falling from an average of 40 in the mid 1990s to less than 30 in the earlier years of this decade, as illustrated below.

There would seem to be several reasons that, in spite of running faster and faster, the industry is losing ground in providing the public with innovative products. Among them, the more important problems would seem to be:

- Essential drugs against killer diseases like diphtheria and tetanus with relatively simple cause and effect relationships have been developed and are on the market. The more recent diseases like cancer and AIDS are more complicated and harder to fight, requiring substantially larger R&D resources
- The deciphering of the human gene promises great advances in the future, but the change from scientific research to practical application is requiring many more years than originally anticipated
- The extensive marketing has put the R&D Departments into a position to come up with ever more effective medication, which are far above the required inputs of human and financial resources used in the past

---

<sup>12</sup> The \$800 mill. R&D spending on each new drug was taken from a Tuft's University study funded by the industry, which also supplied selected data from ten of their major firms. A thorough examination by the Public Citizen Congress Watch came to the conclusion that average R&D cost for each new product came closer to \$100 million during the late 1990s (Young and Surrusco, 2001). In addition, significant basic research is done in public hospitals and laboratories. For good account of that issue see Goozner (2003).

**Graph 1: R&D Outlays and New Pharmaceutical Products**

Source: European Federation of Pharmaceutical Industries and Associations, Yearbook 2004.

Higher research outlays require more funds, which the companies get from the capital markets. Investors in those markets follow closely the industry's development quarter by quarter, looking at the production and pipeline of profitable products that sell in the rich countries. Under that institutional set-up, there is little incentive for the industry to engage in large scale research of medication required by the less developed countries. As a consequence, there were only four new medicines for tropical diseases coming to the market between 1975 and 1997, at a time when the industry licensed over 1,200 drugs worldwide. Most of the major pharmaceutical companies had closed their research labs for tropical and other diseases of poor people in the 1980s and 1990s. The rate of return was too low (Neukirchen, 2004: 215).

Unfortunately, there has been a rapid upturn of infectious diseases which were expected to be under control for some time. One example is tuberculosis, the germs of which have currently infected about one third of the world population, with two million people dying every year. Most of the germs have become resistant against antibiotics, which were once hailed as an effective weapon to wipe that illness off the planet. For over 40 years, there has been no attempt to research for new therapies. Similar problems have occurred in the case of

dengue fever and malaria, two well known tropical diseases affecting each year over 360 million people, who mostly live in the developing countries. (WHO, 2000b).<sup>13</sup>

### 3. The Multiple Interfacing of the MNPCs: 1995-2005

While the major concerns of the MNPCs have remained to expand and strengthen their position in the OECD countries in the recent past, they have been working consistently on internationalizing patent rights for a long time. The strategy of the multinational pharmaceutical companies (MNPCs) has been to stop the increasing spread of illegal copying and generic production of pills by introducing enforceable international legislation around the world, which would seem to be a perfectly legitimate and reasonable undertaking from their point of view. They have also found the full support of the governments of the North, but they failed to convince the developing countries fighting infectious diseases with insufficient scientific, human and financial resources.

The ensuing action and interactions between the MNPCs and the other major actors in the global and national health arena have been analyzed in earlier contributions.<sup>14</sup> They are summarized below, and some of “the deadly games” are then discussed in detail afterwards. In principle, there were numerous encounters, some of them memorable, while others were not. Most of them occurred at the time the HIV/AIDS virus spread around the globe and were part and parcel of the worldwide discussion to fight the disease, with the governments in LDCs taking on the responsibility and costs of preventing and treating the disease.

- *Overture*: The MNPCs getting other (hi-tech) industry and government support in OECD countries for strengthening international IPRS in international bodies (WIPO)
- *Act 1*: Initiated by the MNPCs, the North is practicing regime shifting from WIPO to WTO, drafting and implementing the Trade Related Intellectual Property Rights (TRIPS) with effective enforcement of IPRS through potential trade sanctions (game 1: MNPCs win without serious opposition).

The South’s Response to TRIPS: strengthening escape clauses and affirmation of safeguards, resulting in the Doha Declaration of 2001 and integrated to be integrated into TRIPS in 2005. The North fights to keep the original TRIPS in tact, prolonging and

---

<sup>13</sup> The most recent changes in tackling those “neglected diseases” both within the industry and in the new institutional set-up of public-private partnerships (PPPs) will be discussed below.

<sup>14</sup> For the conflict between Brazil and the MNPCs, see Wogart and Calcagnotto (2006); for the discussion on TRIPS see Wogart and Hein (2006).

and delaying discussions on crucial para. 6 of the Declaration regarding compulsory licenses (CLs) . (game 2: a loss by MNPCs because of “soft” evasion clauses)

- *Act 2:* MNPCs going to Court in South Africa to fight against law allowing domestic production of generics (game 3: MNPCs lose, as they decide to withdraw under pressure of world opinion and NGO action).

Negotiating with Brazil on ARV pricing and agree on substantial price cuts after being threatened with the issue of CLs by the country(game 4: loss for MNPCs)

- *Act 3:* The MNPCs forming of GPPPs and increase involvement in fighting neglected diseases (game 5: outcome too early to tell, but may become a win-win situation)

A second regime shifting of the North and increased emphasis on bi-lateral trade agreements with TRIPS + (game 6: won by the North and MNPCs against serious but unsuccessful NGO opposition)

- *Act 4:* The Southern/NGO response with own regime shifting of IPRS issues from WTO back to WIPO by introducing development agenda (game 7: uncertain outcome)

Simultaneous introduction of medical R & D Treaty into WHO, amplifying world-wide discussion on the use and abuse of patents and access to knowledge (game 8 could also produce two winners and hopefully an increasing amount of people’s lives being saved and/or improved).

These events took place between 1995 and 2005, some of which have also been highlighted in contributions of a recent Joint WHO-GIGA Workshop<sup>15</sup> What is unique in this case is that the MNPCs were both directly and indirectly not only the major actor in the fight over prices of the ARVs against AIDS, but they were also responsible for the introduction and negotiations of TRIPS and TRIPS + in the bi-lateral treaties, although those were officially pure governmental interfaces. Those involvements in turn were based on the fact that MNCs have not only vast resource based power, both material and immaterial, but got also fully involved in the decision making and formal norm setting process, normally reserved for government negotiations.

---

<sup>15</sup> For most of the interfaces between the MNPCs and the Brazilian and South African Government, see v. Soest, Calcagnotto and Weinel (2006); for the discussion of TRIPS developments and the role of MNPCs, see Wogart and Hein (2006).

As a consequence, the MNPCs found themselves in a number of interfaces, ranging from organizational and legal ones like the encounters with South Africa over the programmatic ones, which entailed the drafting of the TRIPS legislation and its discussion with USTR, to resource transfer based interfaces occurring in the fight over drug price with Brazil and increased efforts to support R&D of neglected diseases.<sup>16</sup> With the MNPCs using their vast financial resources quite extensively on all fronts, most of the encounters were really a combination of at least two or three of those types of interfaces. By putting perhaps too much emphasis on the legal interfaces at the beginning of the “access to medicine in poor countries discussion”, they did not get the expected results, as they admitted quite openly afterwards.<sup>17</sup>

The pharmaceutical industry analysts have long used game theory in their strategic thinking and advice to management. In the case of deciding about alternative large research projects, which not only faced the risk of failure but also the possibility of strong competition even after many years of successful R&D, management used game theory approaches, helping them to decide which projects to sponsor and which to drop or delay.<sup>18</sup> In the case of internationalizing IPRs the MNPCs chose the “regime shifting” approach, which they deemed was secure, since it had the backing of the US Government. That strategy did seem to work out well at the beginning, when the shift of a new legal and enforceable base for IPRs from WIPO to WTO was accomplished without major opposition, as highlighted in Graph 2.

By simultaneously pressing for the internationalization of IPRs at WIPO, into which the US Government introduced the Sustained Patent Treaty (SPT), attaining a successful introduction and legislation of the TRIPS Agreement at WTO, and insisting on even tougher (TRIPS +) IPRS regulations in various bi-lateral treaties, the governments of the “North” in general and the USTR in particular followed the script designed and proposed by the high tech MNCs, among which the MNPCs played a crucial role.<sup>19</sup>

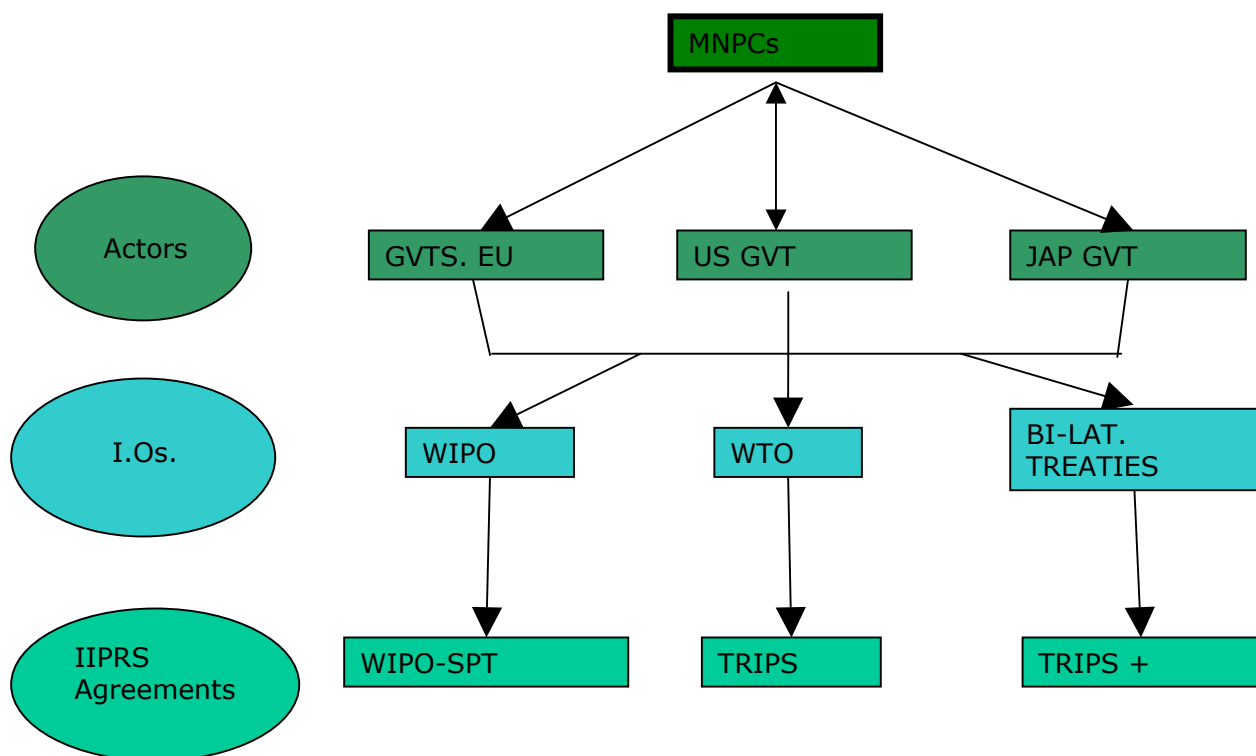
---

<sup>16</sup> They were also involved in discursive interfaces, both through their major associations on the national and international level (PhRMA and IFPMA) and also top executives of the major companies taking part in major discussions with public and other private partners and opponents

<sup>17</sup> *The Economist* (2005b).

<sup>18</sup> See for example Senn’s game theory approach to project prioritisation in the pharmaceutical industry (Senn 1996).

<sup>19</sup> For an extensive discussion of the MNPCs role in drafting the TRIPS Agreement, see Sell (2000) ; for a close examination of MNC involvement in follow-up on TRIPS, see Jawara and Kwa (2003).

**Graph 2: Internationalizing Patents Rights as proposed by the North**

The WTO Secretariat was quick to point out that

“TRIPS attempts to strike a balance between the long term social objective of providing incentives for future inventions and creation, and the short term objective of allowing people to use existing inventions and creations.” (WTO, OMC. 2001: 1)<sup>20</sup>.

Many of the developing countries saw it differently. Respected free-trade advocates like Jagdish Bhagwati described the WTO’s intellectual property protection as a tax that most poor countries pay on their use of knowledge, “constituting an unrequited transfer to the rich producing countries.” (Sexton 2001: 10).

#### 4. AIDS, Doha and Revised TRIPS

It was the rapid spread of the HIV/AIDS virus in developing countries and the NGO campaigns which made officials in the developed and developing countries aware that the stringent conditions of the IPRs in the TRIPS Agreement made it difficult to finance the treatment of the HIV/AIDS infected patients in their countries. As a consequence, discussions over poor countries’ access to low cost medicines against serious diseases endangering the public

<sup>20</sup> They were, however, also quick to point out that it was not an official interpretation of the WTO agreements or members’ positions.

health of the country got underway in the late 1990s and led to the Doha Ministerial Declaration on the TRIPS Agreement and Public Health in November of 2001.<sup>21</sup>

The Doha Declaration attempted to clarify the relationship between the protection of patents and its limitation in the context of public health emergencies. It stated that WHO members had a right and duty to protect the health of their populations, making it possible for them to get access to medication at lowest possible prices, if necessary through the issuing of compulsory licenses. In addition para 6 of the Declaration instructed the TRIPS Council to find an expeditious solution for issuing of CLs in those countries which did not have the capacity to produce pharmaceuticals.

To soothe the fear of the MNPCs and their governments in the developed countries, however, the General Council's Chairperson underlined the fact that that the

“system that will be established by the Decision should be used in good faith to protect public health and, without prejudice to paragraph 6 of the Decision, not be an instrument to pursue industrial or commercial policy objectives” (WTO News, 2003).

It took another two years before stipulating a binding agreement on the issue proposed by the famous paragraph 6 of the Doha Declaration, allowing countries to issue compulsory licenses for generic production, both domestically – if the production capacity was available – or abroad, if the domestic economy was not in the position to produce that drug.<sup>22</sup> Brought forward by the NGOs (in particular MSF and their Access to Essential Medicines Campaign) and the ensuing worldwide moral indignation, the South pressed for and succeeded in getting changes in the TRIPS agreements, which would allow them to import AIDS medication from the lowest priced source, but prohibit re-export of that medication to third countries.

During those negotiations, the North tried to split the Southern vote, by offering the least developing countries special trade advantages if they would not join the middle income countries' quest for altering the original TRIPS Agreement (Jawara and Kwa, 2003). That strategy of “divide and rule” has been used many times by dominant countries outwitting the majority of its opponents and leads itself to a game theoretical approach.<sup>23</sup> In this context, some of the African countries were indeed considering to trade their support for the LDC re-interpretation of the TRIPS Agreement in favor of increased access of their products

---

<sup>21</sup> Declaration on the TRIPS Agreement and Public Health (Nov. 14, 2001).

<sup>22</sup> The 2003 Decision actually took the form of a waiver related to the obligations of the Member countries under Articles 31f and 31h of TRIPS (For a detailed legal interpretation and a discussion on the relationship between the Decision and the Amendment see, South Centre and CIEL, 2006).

<sup>23</sup> It has also been used in the context of Marxian economics, with business confronting different groups of organized labour (see B. Philip, 2005).

in developed markets, but after some deliberation they fell in line with the rest of the developing world.

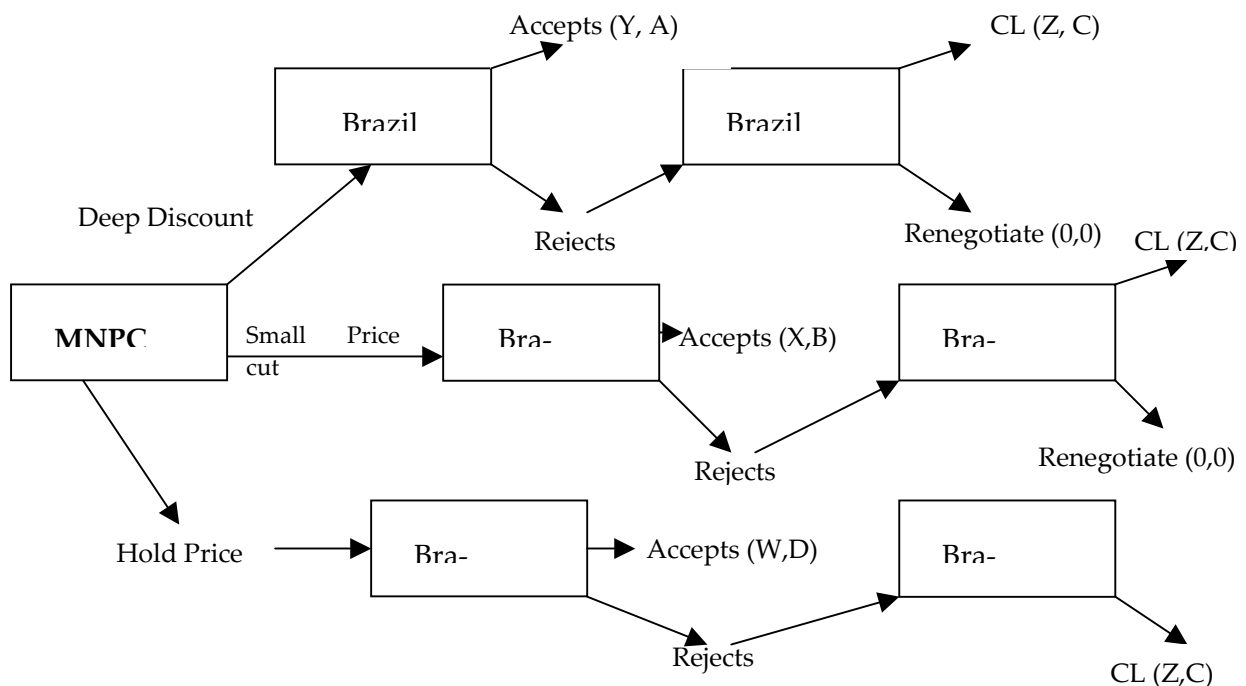
## 5. The Battle over Drug Prices and the Southern Offensive at International Organizations

As the negotiations over the TRIPS Amendments in the halls of the WTO in Geneva became ever more entwined in the definition and interpretation of specific clauses and paragraphs, the real battles took place in the market place for ARVs. As Latin America's leading industrializing country Brazil had an ongoing discussion with the US government regarding the enactment and implementation of full blown legislation covering patents. That issue became a major point of disagreement, when the government's sponsored generic industry started to produce two of the twelve ARVs needed by Brazil to effectively treating HIV/AIDS.

The federal and some local government authorities had been getting seriously involved in starting up production of ARVs in the late 1990s. During that time period, Brazil had already been able to cut mortality rates of AIDS by half, lower the hospitalization of the victims by 80% and reduce the mother-to-child transmission significantly. Since the Brazilian Government provided the treatments free of charge to every patient in need, the case for lowering the public sector costs of the patented ARV medicines became a priority for Brazilian policy makers.

Encouraged by the willingness of the North to respect the Southern demands for issuing compulsory licenses in the case of a national emergency, Brazil entered into negotiations with a number of MNPCs to ask them for significant price reductions or face the threat of the country issuing those compulsory licenses. That encounter obviously led itself to a perfect game scenario with possible moves and countermoves, containing considerable downward risks on both sides should they lose that battle. For the Brazilian challenger, there were considerations beyond the payments of royalties for the license, starting with a serious test of the production capability and cost containment of its government owned laboratories, and ending with the availability and costs of the required ingredients. For the MNPCs, adherence to the stipulated prices was facing the possibility of the firms to be shut out of a large and growing market of a major emerging economy and the undesirability to set a precedent for compulsory licenses detested by most MNPCs.

Cohen and Lybecker (2005) have developed a scenario, borrowed from simple game theory, which reflects well the options one of the MNPC faced by bargaining with the Brazilian government authorities. A slightly changed version of their diagrammatic presentation is depicted below.

**Graph 3: Price Bargaining for Prescription Drugs**

Note: Letters in brackets show the preferences of the two parties. In the case of the MNC outcome W is best before X, which is better than Y, and Z is the worst. For Brazil A is to be the top, followed by B and C, with D actually not being seriously considered.

It is fairly easy for the MNPC to realize that it would not make sense to immediately go for a deep discount, especially since the companies believed to have the U.S. government support behind them. On the other hand, while it might have been possible to bluff and hang tough, believing that the issue of CL is even more distasteful to the Brazilians than it is to the industry, it might be the best strategy to start with a relatively small discount, which will not have the best outcome (after all X is less favorable than W but better than Y and Z), but may find Brazil's willingness to agree, since that outcome is at least second best for the country (B is worse than A but better than C). In case Brazil rebuffs the offer of a small discount, further negotiations would seem a probable outcome rather than an immediate issuing of a CL.

What is missing here, are the probabilities attached to the expected reaction of the Brazilian policy makers and with it the outcome of the game. Clearly, the deep discount would have a fairly high probability to be accepted, but leave no room for any further maneuvers to improve the outcome for the MNPC. On the other hand, the probability of the government's willingness to come back to the bargaining table with the MNPC not being willing to give in an inch would also be low and lead straight away to the issuing of a CL. So to start with a relatively small price reduction would seem not only to provide both parties with interme-

diate outcomes and room for further negotiations, it would also seem the choice with the highest probability attached.

The actual negotiation between Brazil and Hoffmann-La Roche over the ARV Nefivair did indeed take that route. The company started off with a 13% price reduction which the government of Brazil rejected. At the same time as the state-owned Far-Manguinhos prepared for the production, the Health Minister asked the company to cut prices by 40%. Roche replied with a 30% discount, but saw its situation further weakened by other MNPCs granting significantly larger price reductions, with Merck leading the pack, offering reductions of over 60%. (Rich, 2001).

Three further factors contributed to Roche eventually giving more generous price reductions: First, the earlier attack of the MNPCs in the South African High Court against Medicine and Related Substances Control Amendment Act had led to the MNPCs eventual withdrawal under the strong protest of the international health community, especially such NGOs as Oxfam and MSF. Secondly, the continued public pressure of both, the local and international civil society converged in Brazil to a powerful movement, encouraging Health Minister Serra to ride the wave of popular support by challenging the MNPCs and with it increase his chances as a Presidential candidate.

Thirdly, the trump card of the MNPCs to have the US Government to invoke trade sanctions to have Brazil punished for going beyond the Article 31 of the TRIPS Agreement and Paragraph 6 of the Doha Declaration with legislation of its own supporting and protecting its own pharmaceutical industry rather than protecting human life failed, The USTR withdrew its complaints against Brazil at the WTO in mid-2001.<sup>24</sup>

The success on the national front encouraged Brazil and the NGOs also to play an increasingly more active and demanding role at the international global health arena. The outcomes were realized in two initiatives at the WIPO and WHO. After successfully renegotiating TRIPS, the developing countries under the leadership of Argentina, Brazil, and Kenya introduced a "Development Agenda" into WIPO, hoping to provoke further discussion of the value and the best timing of IPRS legislation in developing countries. At the same time, the same countries took a plan from one of the NGOs concerning the change of patent rights in the light of the need to increase not only the peoples' access to medicines at reasonable prices but also the access to knowledge (A2K) in general.

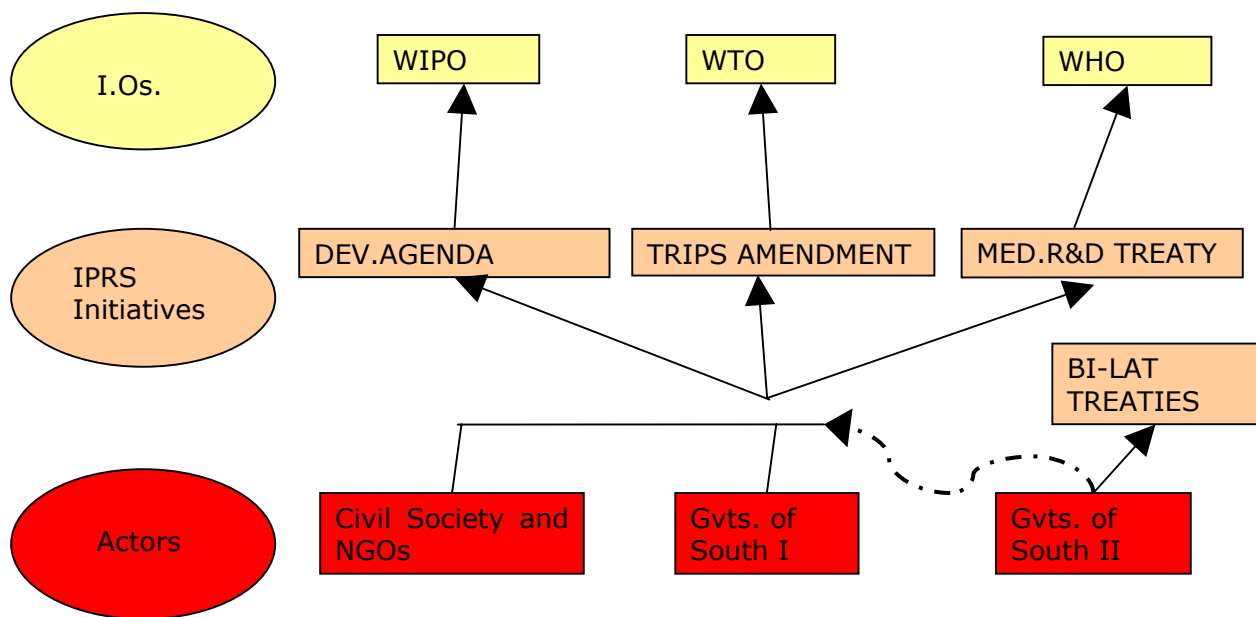
By also using the strategy of forum shifting, the South countered the initiatives of the North with an increasing number of initiatives, which transferred the limelight of global health issues in general and the patent issue in particular from the WTO to the WHO, where it

---

<sup>24</sup> As the then president F.H. Cardoso stated in his memoirs, "I have no doubt that this favourable outcome was decisively influenced by global public opinion." (Cardoso, 2006: 217)

would seem to belong. That scenario is depicted in Graph 4. The latter initiative was undertaken by the NGOs, which were increasingly looking for alternatives to the existing IPRs, drafted for private sector development but not to solve public health issues (Love and Hubbard, 2005). Kenya, Argentina and Brazil officially introduced the Medical R&D Treaty into the WHO in 2005.

**Graph 4: Initiatives of the South in the Global Health Arena**



## 6. The Counteroffensive of the MNPCs and a Further Regime Shifting Exercise

At the time of the conclusion of the TRIPS Agreement, the USTR had also begun to introduce strict IPRs legislation into bi-lateral trade treaties. Starting with the NAFTA Agreement, the strengthening of the original TRIPS to become TRIPS + was the basis for almost all trade negotiations the USTR undertook either with individual countries or a group of countries in the South. In the case of Latin America, the pressure put on the small countries “south of the border” became particularly severe and provide a good example of the continuous strength of the MNPCs. Negotiations between the U.S government authorities and the five Central American economies plus the Dominican Republic went for well over three years. Although trade with those economies is a fraction of the overall US exports and imports, President George W. Bush made it a major policy issue and lobbied Congress for passing the bill. While the usual interest groups of the agricultural sector (sugar, cattle) and in-

dustry (textiles) were the major opponents and nearly had the bill toppled, the IPRs issues in general and the patents legislation in particular became important points in the debate in the US Congress.

Supported by assessments of the major NGOs Oxfam and the Doctors without Frontiers (MSF), the Committee on Government Reform prepared a report for a number of Congress members, who had been fighting the excessive influence of the pharmaceutical industry in Government for some time (Committee on Government Reform, 2005).<sup>25</sup> That report summarized the major concerns, found in almost all IPRs negotiated in other Free Trade Agreements the U.S. has recently undertaken.<sup>26</sup> Analyses by the UNCTAD-ICTSD Project on Intellectual Property and Sustainable Development arrived at similar conclusions (UNCTAD-ICTSD, 2005).

Issues included restrictions of compulsory licensing, which limit the circumstances under which the CACM countries (and also most other nations negotiating FTAs with the US) can issue those compulsory licenses authorizing generic manufacturers to produce low cost versions of patented drugs. Closely related to it is the prohibition of parallel importation, preventing developing countries from importing patented drugs from the most favorable available source. The other two issues revolve around the extension of patent protection for new uses of already patented products and the requirements to have the drug regulatory authorities in the CACM countries to adjudicate patents, despite their lack of expertise in the area of patent enforcement.

On the other hand, there are no provisions that would promote greater access to affordable medicines, such as: the “Bolar-type” provision to ensure that countries permit testing and experimental work required for the registration of a generic medicine during the patent period of the original product so that generics can enter the market immediately after the expiration of the patent. There are also no requirements for patent holders to disclose the “best mode” for reproducing an invention so that society can benefit from it after the patent expires. Finally, there are no caps on patent extensions for delays in the issuance of a patent or the marketing approval process.

The report concludes:

“Taken together, these trade provisions will significantly impede the ability of developing countries to obtain access to inexpensive, life-saving medications. Contrary to the Doha Declaration, these provisions in the trade agreements advance the financial

---

<sup>25</sup> That report served as a base for a letter Congressman Waxman and 13 other Congress members wrote to the head of the USTR in 2005.

<sup>26</sup> These are mainly smaller middle-income countries, including Singapore, Jordan, Morocco, Chile, and Peru. Larger economies such as Colombia and Thailand are still negotiating in particular the IPRs part of the agreement.

interests of large multinational drug companies at the expense of the developing world's ability to address public health problems." (Committee on Government Reform, 2005: 5).<sup>27</sup>

In short, while the MNPCs and the US government retreated in their negotiations within the WTO and showed some flexibility with the large emerging economies, they more than compensated for that compromise by strengthening the IPRs rules in the negotiations with the smaller middle income countries. It can be expected that once more and more of those countries are signing those bi-lateral trade agreements, the pressure on nations like Brazil, India and China to fall in line with the rest of other emerging economies and follow tougher IPRS implementation rules will increase.

## 7. Pharma and the Rise of Global Public-Private Partnerships

While the MNPCs played only an indirect though important role in the bi-lateral trade agreements, they also reacted on other fronts of developing countries' concern more forcefully after the public attacks and surprising losses against players of the South.

Since the major clash with South Africa and Brazil, the pharmaceuticals have been engaged in an increasing number of partnerships, both with public agencies and private NGOs, to fight infectious diseases. In the case of AIDS there were eighteen of those networks active in October of 2004, and in the case of tuberculosis and malaria there were eight and eleven respectively (IPFMA, 2004b). Table 2 provides an overview of some the partnerships the companies are involved in the case of AIDS.<sup>28</sup>

---

<sup>27</sup> A real controversy arose in the negotiations between the USTR and Guatemala, the Congress of which had introduced and approved legislation, which denied the data exclusivity provision. Although directly contradicting the WTO Ministerial Declaration on the TRIPS Agreement and Public Health (the Doha Declaration), the US made that provision a must for the trade negotiations and threatened Guatemala to delay ratification of the CAFTA Agreement. Different from Brazil, the Guatemalan Congress gave in and issued Decree 31-88, overruling the previous legislation

<sup>28</sup> In addition, there are also a growing number of them being very active in supporting the fight against malaria and TBC as well as such tropical diseases as dengue fever, or join in the Global Alliance to Eliminate Leprosy, The Sleeping Sickness Program and the International Trachoma Initiative. They are also actively participating in important initiatives against vaccine preventable diseases as the Global Alliance for Vaccines and Immunization (GAVI) and the Vaccine Fund (VF).

**Table 2: Involvement of Pharmaceutical Firms in Public-Private Partnerships Against HIV/AIDS**

| Program                                                          | Pharmaceutical Firm                                                                                  | Partner                                                                      | Public Health Objective                                                                 |
|------------------------------------------------------------------|------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| <b>Disease: HIV/AIDS</b>                                         |                                                                                                      |                                                                              |                                                                                         |
| ACADEMIC ALLIANCE for AIDS CARE and PREVENTION in AFRICA (AAACP) | Pfizer                                                                                               | Makarere University, Uganda                                                  | Training of medical personnel in HIV/AIDS                                               |
| Accelerated Access Initiative (AII)                              | Abbot, Boehringer-Ingelheim, Bristol-Myers Squibb, GSK, Gilead Sciences, Merck, F. Hoffmann-La Roche | UNAIDS, WHO, UNICEF, UN Population Fund, World Bank                          | Preferential pricing of retrovirals for prevention and treatment of AIDS                |
| DIFLUCAN® PARTNERSHIP PROGRAM                                    | Pfizer                                                                                               | Governments and NGOs in Africa, Asia, the Caribbean and Latin America        | Donation of its antifungal medicine, Diflucan®                                          |
| GLAXOSMITHKLINE'S POSITIVE ACTION ON HIV/AIDS                    | GlaxoSmithKline                                                                                      | Community-based organizations around the world                               | Capacity building, strategic management, leadership, advocacy                           |
| SECURE THE FUTURE®                                               | Bristol-Myers Squibb and the Bristol-Myers Squibb Foundation                                         | Government leadership and local organizations in southern and western Africa | Food security and poverty alleviation; epidemiological and medical research in HIV/AIDS |

The first results of research and development in the field of neglected diseases by large and small pharmaceutical companies as well as by private public partnerships have been undertaken and have now been evaluated. In a 2005 report, entitled “The New Landscape of Neglected Disease Drug Development,” researchers at the LSE Health and Social Care Unit reported that the ongoing debate over the lack of research and development for those illnesses no longer holds true (Moran et al., 2005). Between 2000 and 2004 over 60 projects have been tackling those “neglected” diseases. Two new drugs are now at the registration phase and 18 new products in clinical trials, half of which is at stage III.<sup>29</sup>

The MNPCs are conducting about half of those projects, of which half again they are doing on their own and the other half within a PPP.<sup>30</sup> Even in the case of their own research, the idea is to finally test and market the product with public partners, because of the public sector character of the market for those medications. The R&D concentrates on ma-

<sup>29</sup> Testing of pharmaceuticals proceeds in several stages, of which stage III is the last and most comprehensive one with human beings.

<sup>30</sup> Most of the work is done by four companies: GSK, Novartis, Astra-Zenica, and Sanofi-Aventis.

laria and tuberculosis but also includes the search for medication and vaccination for dengue fever, onchocerciasis and visceral leishmaniasis.

Of the \$250 million “public” funding to support the PPPs, only 16% comes from governments, while the Gates Foundation alone has contributed nearly 60%. Since Mr. Gates has paid much attention to the Foundation’s money being spent efficiently, the evaluation has been on top of the many R&D attempts in this area. With respect to health outcomes, the PPP model showed superior results than the industry-alone developed medication. In short, the rapidly increasing PPPs may become the major provider for low cost medicines of the formerly neglected diseases.<sup>31</sup>

It is still premature to provide a comprehensive evaluation of those efforts, since most of them have only started recently. Some public sector involvement has led to high administrative costs and poor management of such programs. The legal status, corporate governance, and operational efficiency are issues which will have to be analyzed in some detail, before a solid judgment can be made. However, for the pharmaceutical companies participating in the PPPs, one would expect an efficient execution of the commitments undertaken combined with the necessary supply logistics, storage and documentation.

From a purely financial contributions’ point of view, it would seem to be relevant to note that the engagement of the big pharmaceutical companies amount to over one third of the total public US healthcare assistance to the third World. In addition, the industry is claiming that

“our partnership with leading academic, governmental, multilateral, non governmental and community-based organizations exceeds or rivals in total size the annual budgets of the World Health Organization and the World Bank’s health programs, among others” (IPFMA, 2004a).

That leaves the question to the emerging suppliers of low cost generic drugs from advanced developing countries, particularly Indian and/or Chinese producers. Indian suppliers of lowest cost ARVs have played an important role in reducing the costs of treating AIDS in the past 5 years. However, in cases of future health emergencies at home, those firms will have first to supply the large populations of their own country. In order to compensate for that commitment, the companies would rather turn around and sell to prosperous markets than to their poor neighbors. One recent example of delivery problems of AIDS medication

---

<sup>31</sup> Four country studies on the impact of PPPs in addressing access to low cost medicine issue provided similarly encouraging findings. (Caines et al., 2004). While the researchers admitted that the quantification of benefits for public health derived from such donation programs as AIDS medication to prevent mother-to-child transmission of HIV were difficult, several indicator showed that the program had led to short term favorable results. A similar positive evaluation was given to the joint Novartis-WHO discounted drug program for tropical diseases.



A broader perspective of how the increasing responses of the South interacted with the initiatives of the North is provided in Graph 6, which brings together the multiple interfaces among the major actors in the health arena of today. From earlier discussions regarding the MNPCs' interactions with and influences on the governments of the North in pressing for internationalizing IPRs in various fora and the response from the developing countries to fight for an amendment on TRIPS and introduce new initiatives at WIPO and the WHO, it has become clear that those major pillars of the global health architecture have changed substantially.

They will continue do so in the near future. While neither the MNPCs nor the NGOs belong to those "pillars", their actions and interactions have played a major role in bringing about that change of such venerable institutions as the WHO and World Bank, the WIPO and the WTO, the latter two of which would have not imagined to become part of wide ranging discussions and decisions concerning global health issues 15 years ago.

The confrontation and dialogue between the Northern and Southern representatives have not limited themselves to exchanging legal opinions and issuing threats, but on many other levels, both formally and informally. In addition to the discussion within the international organizations and in the government buildings in New York, Geneva, Washington, Brasilia, and New Delhi, there were numerous meetings, which had senior representatives of the WTO, the respective governments, the MNPCs, and the NGOs discuss the major issues. Sponsored by the Foreign Policy Centre in London, a report issued in 2001 stated that,

"despite dissonance over many of the fundamentals, the seminar opened several doors for potential solutions among which were:

- The introduction of a tiered patenting system,
- increased flexibility of TRIPS for developing countries,
- the creation of an international fund to support the consolidation of health systems in those parts of the developing world hardest hit by the AIDS virus" (Walters et al., 2001).

By 2003, two of those proposals were translated into reality. The Doha Declaration gave a wider and much more flexible interpretation of the TRIPS Agreements and the Global Fund against AIDS, Malaria, and TB (GFAMT) has been installed to grant financing for prevention and treatment programs against those diseases in the affected developing countries. In the meantime, experts of intellectual property rights are rethinking some of the rules written into the legislation of both the developed and developing countries, and the multinationals are trying to figure out how to manage a multi-tiered price system, which benefits the poor in the developing countries but not traders who are re-exporting the discounted drugs to the high priced markets of developed countries.

These are indeed accomplishments of a growing consensus of the need for closer co-operation in global health issues by all nation states involved. That the national health governance can gain in importance in the face of a major global health crisis has been shown in the case of Brazil, but while that country has become a model for developing countries' AIDS policies, its replication in the smaller and poorer countries is far from ascertained. As mentioned above, the stringent IPRS rules will make it more difficult to receive the required medication in those countries having bi-lateral trade agreements with the U.S. Even in the larger economies, the treatment of HIV/AIDS has not yet received the attention of policy makers it deserves.

With all the heat created over the pricing of ARV drugs, proponents of fighting the MNCs over monopoly rights, participants of the debate tend to forget or to play down the fact that drug prices are but one part of the story, as many poor countries have found out when they had to administer the ARV therapy. Similar to earlier statements of industry representatives and their associations, the authors of the Hudson Institute brought home the point by stating that

"ARV therapy is only effective if there is a healthcare infrastructure – doctors, nurses, clinics, supplies, storage and distribution systems. This infrastructure is often lacking in developing countries, where the majority of the AIDS victims live."(Adelman et al., 2004: 1).

Many developing countries have pledged in their Poverty Reduction Strategy Papers (PRSPs) to improve the infrastructure of their health care systems, both by allocating more resources to the sector and by making the current systems more efficient. In the context of following up on the Millennium Development Goals for Health, the participants of wide ranging multiple discussions in Washington, Ottawa, Geneva and Lagos in 2003 and 2004 have identified the poor countries' access to pharmaceuticals as one constraint among many others. They include the lack of credible and resource based health strategies, scarcity of qualified human resources, and the need to mobilize individual households and families, who are the key and underrated actors in the health sector (Wagstaff and Claeson, 2004).

Even in the narrower confinement regarding the supply to essential medicines, price is only one variable. Without strategic procurement, improved logistics, and training of pharmacists, the reliable supply of drugs cannot be achieved. The OECD countries and the multilateral institutions have launched an increasing amount of support programs to provide that framework. Among others, the Global Fund to fight AIDS, TB, and Malaria (GFATM) is looking for new networks among developing countries to improve production techniques trade logistics, including storing and delivery techniques. Here, both the traditional and the

emerging pharmaceutical industries will have to play a crucial role to make the Fund's programs successful. (Attridge and Preker, 2005)

The buildup of the national, state and local social infrastructure will take time. The summary statistics show how far the fight against AIDS has been proceeding in the recent past, indicating also how far away the majority of the countries are in treating current victims. Table 3 indicates the amount of people in developing countries on the five continents requiring treatment in 2005 in descending order. Out of the 6.5 million people, over 72% come from Africa, followed by Asia's much larger population, the share of which requiring treatment would still seem to be relatively modest in relative terms, but is believed to increase rapidly in the years to come.

**Table 3: Increased Efforts and Waiting for Better Results. Regional Estimates of AIDS and its Treatment in Developing/Transitional Countries**

| Region                          | People Need Treatment | People Receiving Treatment | Treatment Coverage (percent) |
|---------------------------------|-----------------------|----------------------------|------------------------------|
| Sub-Saharan Africa              | 4,700,000             | 500,000                    | 11                           |
| East, South and South-East Asia | 1,100,000             | 155,000                    | 14                           |
| Latin America and the Caribbean | 465,000               | 290,000                    | 62                           |
| Europe and Central Asia         | 160,000               | 20,000                     | 13                           |
| North Africa and Middle East    | 75,000                | 4,000                      | 5                            |
| <b>Total</b>                    | <b>6,500,000</b>      | <b>970,000</b>             | <b>15</b>                    |

Source: [www.aert.org/aidsdrugs.htm](http://www.aert.org/aidsdrugs.htm).

Columns 3 and 4 show the treatment in each continent in absolute and relative terms, reflecting the much more active role of private and public sector efforts in Latin American health sectors, which reached a 62% coverage compared to rates between 5 and 15% on the other continents. However, even the Latin American health workers in general and the Brazilian ones in particular are aware that there is still some way to go to reach the Millennium Development Goals of bringing the illness to a standstill by 2015.

In that context it is worthwhile to remember that like in any other country facing a sudden health crisis, which spread rapidly from a few individuals in the metropolitan centers to whole families all over the country, Brazil's national policy makers were ill prepared to move decidedly against the disease. Were it not for the active and vocal NGOs and some local governments, especially in the city of Sao Paulo, the national authorities would rather left the crisis lingering for some time. The close relationship the authorities had with the multilateral agencies in general and the World Bank in particular provided the impetus for an organized and well financed program against AIDS in the early 1990s, which then pro-

vided a basis for a joint front of national and local authorities, local and international NGOs, as well as international agencies to pull together.

The fight over price and patent issues Brazil had with the MNPCs helped the country to strengthen the national resolve to get AIDS under control. To what extent the early inroads and successes can be maintained remains to be seen. While the current government is committed to pursue the same goals as its predecessor, it seems to lack the human and financial resources the previous authorities could muster. Many of the highly qualified personnel, who worked with the central government in the AIDS campaigns in the 1990s and early 2000s have left the public sector, and the recent negotiations with the MNPCs have dragged on for much longer periods than had been expected. In addition, with newer and better drugs being developed in the years to come, it can be expected that the difficult encounters to negotiate favorable prices for ARVs with the MNPCs will heat up again.

## Bibliography

- Abbott, Thomas, III. (1995): Price Regulation in the Pharmaceutical Industry: Prescription or Placebo?, in: *Journal of Health Economics*, No. 14.5, pp. 551-567.
- Abbott, Frederick M. (2005): The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health, in: *The American Journal of International Law*, Vol. 99, pp. 317-358.
- Abramson, John (2004): *Overdosed America*, New York: Harper/Collins.
- Adelman, C.C. et al. (2004): *Myths and Realities on Prices of AIDS Drugs*. Hudson Institute White Paper, Washington, D.C.
- Angel, Marcia (2004): *The Truth about the Drug Companies*. New York: Random House.
- Attridge, James; Preker, Alexander (2005): *Improving Access to Medicines in Developing Countries*. HNP Discussion Paper, Washington, D.C.: The World Bank.
- Buse, Kent (2006): How Does the Private Sector Govern Global Health?. Paper presented at the GOI/WHO workshop "Defining and Shaping the Architecture for Global Health Governance", February 22-24, 2006, Hamburg: Deutsches Übersee-Institut.
- Buse, Kent; Walt, Gill (2000a): Global Public-Private Partnerships, Part I: A New Development in Health?, in: *Bulletin of the WHO*, No. 78 (4), pp. 549-561.
- Buse, Kent; Walt, Gill (2000b): Global Public-Private Partnerships, Part II: What are the Health Issues for Global Governance?, in: *Bulletin of the WHO*, No. 78 (5), pp. 699-709.
- Caines, Karen; Lush, Louisiana (2004): *Impact of Public-Private Partnerships Addressing Access to Pharmaceutical Drugs in Selected Low and Middle Income Countries: A synthesis Report from Botswana, Sri Lanka, Uganda, and Zambia*. Geneva: The Initiative on Public-Private Partnerships for Health.
- Cardoso, Fernando Henrique (2006): *The Accidental President of Brazil. A Memoir*. New York: Public affairs.
- Cohen, Jillian Clare; Lybecker, Kristina M. (2005): AIDS Policy and Pharmaceutical Patents: Brazil's Strategy to Safeguard Public Health, in: *World Economy*, Vol. 28.2 (February), pp. 211-230
- Cohen, Jilian Clare (2000): Public Policies in the Pharmaceutical Sector: A Case Study of Brazil, in: *LCSHD Paper Series*, No. 54, Washington, D.C.: The World Bank.
- Comanor, William S. (1986): The Political Economy of the Pharmaceutical Industry, in: *Journal of Economic Literature*, No. 24, pp. 1178-1217.

- Commission on Intellectual Property Rights (2002): Integrating Intellectual Property Rights and Development Policy, in: [www.iprcommission.org/home.html](http://www.iprcommission.org/home.html).
- Cool, Karel; Schendel, Dan (1987): Strategic Group Formulation and Performance: The Case of the Pharmaceutical Industry 1963-82, in: *Management Science*, No. 9 (1987), Vol. 33, pp. 1102-1124.
- Curat, Luis J. (1999): The Global Forum for Health Research: An Overview, in: Secretariat of the Global Forum for Health Research, Geneva, N° 10/90, Report on Health Research, p. 23-29.
- DiMasi, Joseph A. et al. (1991): The Cost of Innovation in the Pharmaceutical Industry, in: *Journal of Health Economics*, No. 2, Vol. 10, pp. 107-142.
- Dodgson, Richard; Lee, Kelley; Drager, Nick (2002): Global Health Governance: A Conceptual Review, LSHTM/WHO Discussion Paper No. 1, in: [www.lshtm.ac.uk/cgch/globalhealthgovernance.pdf](http://www.lshtm.ac.uk/cgch/globalhealthgovernance.pdf).
- Drahos, Peter; Mayne, Ruth (eds.) (2002): *Global Intellectual Property Rights. Knowledge, Access and Development*. Basingstoke: Palgrave.
- The Economist (2005a): The Drugs Industry, Can Big Drug Companies Recover from a Recent String of Problems, in: *The Economist*, No. 17, London.
- The Economist (2005b): Prescription for Change, A Survey of Pharmaceuticals, in: *The Economist*, N° 18, London.
- Gates Foundation; McKinsey (2002): *Developing Successful Global Health Alliances*. Seattle: Bill & Melinda Gates Foundation.
- Goozner, Merrill (2003): *The 800 Million Pill, The truth behind the cost of new drugs*. Berkely and Los Angeles: University of California Press.
- Griffin, Charles (1989): Strengthening Health Services in Developing Countries through the Private Sector. IFC Discussion Paper, No. 4, Washington, D.C.
- Hein, Wolfgang (2002): The Interfacing of Developing Countries' National Strategies with Global Governance, Conflicts and Co-operation in the Health Sector, in: *Nord-Süd aktuell*, No. 3, Vol. 16, pp. 484-493.
- Helfer, Laurence R. (2004): Regime Shifting, The TRIPS Agreement and New Dynamics on International Intellectual Property Lawmaking, in: *The Yale Journal of International Law*, Vol. 29, pp. 1-83.
- Initiative on Public-Private Partnerships for Health (IPPPH) (2002): *Good Practices for the Establishment and Operation of Public-Private Partnerships*. Geneva: IPPPH.

- International Federation of Pharmaceutical Manufacturers and Associations (2004a): Research and Development for Neglected Diseases, Lessons Learned and Remaining Challenges, in: [www.ifpma.org/news/publications.aspx](http://www.ifpma.org/news/publications.aspx).
- International Federation of Pharmaceutical Manufacturers and Associations (2004b): Building Healthier Societies through Partnerships, in: [www.ifpma.org/news/publications.aspx](http://www.ifpma.org/news/publications.aspx).
- International Federation of Pharmaceutical Manufacturers and Associations (2004c): Joining Forces for Change: The Pharmaceutical Industry in HIV/AIDS, in: [www.ifpma.org/news/publications.aspx](http://www.ifpma.org/news/publications.aspx).
- Jacobzone, Stéphane (2000): Pharmaceutical Policies in OECD Countries, Reconciling Social and Industrial Goals, Labour Market and Social Policy Occasional Paper, No. 40, Paris: OECD.
- Jawara Fatoumata; Kwa, Aileen (2003): Behind the scenes at the WTO: The real world of international trade negotiations. London: Zed Books.
- Kaul, Inge et al. (2002): Providing Global Public Goods, Managing Globalization. New York: Oxford University Press.
- Kickbusch, Ilona; Quick, James (1998): Partnerships for Health in the 21<sup>st</sup> Century, in: World Health Statistics Quarterly, No. 1, Vol. 51, pp. 68-74.
- Kremer, Michael (2002): Pharmaceuticals and the Developing World, in: Journal of Economic Prospects, No. 4, Vol. 16, pp. 62-90.
- Langer, Gerhard (1974): Können multinationale Unternehmen international kontrolliert werden?, in: Kebschull, Dietrich; Mayer, Otto G. (eds.), Multinationale Unternehmen – Anfang oder Ende der Weltwirtschaft, Frankfurt/Main, pp. 219-244.
- Lee, Kelley; Buse, Kent; Fustukian, Suzanne (eds.) (2002): Health Policy in a Globalising World. Cambridge: Cambridge University Press.
- Levin, Richard et al. (1987): Appropriating the Returns from Industrial Research and Development, in: Brookings Papers on Economic Activity, No. 3, pp. 783-831.
- Love, James; Hubbard Tim (2005): Paying for Public Goods, in: Ghosh, Rishab A. et al. (eds.), Collaborative Ownership and the Digital Economy, Cambridge: Leonardo, pp. 207-228.
- Médecins Sans Frontières (2004): Untangling the Web of Price Reductions, A Pricing Guide to the Purchase of ARVs for Developing Countries, in: [www.accessmed-msf.org/documents/untanglingtheweb%208.pdf](http://www.accessmed-msf.org/documents/untanglingtheweb%208.pdf).
- Moran, Mary (2005): The New Landscape of Neglected Disease Drug Development. London School of Economics and Wellcome Trust. London: London School of Economic and Political Science.

- Mossinghoff, Gerald J. (2000): Brazil's Pharmaceutical Industry, in:  
[www.usinfo.state.gov/products/pubs/intelprp/Brazil.htm](http://www.usinfo.state.gov/products/pubs/intelprp/Brazil.htm).
- Musgrove, Philip (ed.) (2004): *Health Economics in Development*. Washington, D.C.: The World Bank.
- Neukirchen, Heidi (2004): *Der Pharma Report, Das große Geschäft mit unserer Gesundheit*. Muenchen: Droemer.
- Organization of Pharmaceutical Products of India (2004): *Pharmaceutical Industry Profile 2004*; Mumbai, India: OPPI.
- Oxfam (2002): *Beyond Philanthropy, The Pharmaceutical Industry, Corporate Social Responsibility and the Developing World*, in: <http://publications.oxfam.org.uk>
- Perlmutter, Howard V. (1972), *The Multinational Firm and the Future*, in: Blake (ed.), *The Multinational Corporation*, *The Annals of American Academy of Political and Social Sciences*, No. 403, pp. 139-152 .
- Philp, Bruce (2005): *Reductions, Rationality, and Game Theory in Marxian Economics*. London and New York: Routledge.
- Preker, Alexander S.; Harding, April (2000): *The Economics of Public and Private Roles in Health Care: Insights from Institutional Economics and Organization Theory*, HNP Discussion Paper. Washington, D.C.: The World Bank.
- Reich, Michael R. (1987): *Essential Drugs: Economics and Politics in International Health*, in: *Health Policy*, No. 2, pp. 186-191.
- Reich, Michael. R.. (ed.) (2002): *Public-Private Partnerships for Public Health*. Cambridge: Harvard Center for Population and Development Studies.
- Rich, Jennifer L. (2001): *Brazil will Defy Patent on HIV/AIDS Drug Made by Roche*, in: *New York Times*, August 23, 2001.
- Rosenau, James N. (2004): *Strong Demand, Huge Supply: Governance in an Emerging Epoch*, in: Bach, Ian; Flinders, Mathew (eds.), *Multi-level Governance*, Oxford: University press, pp. 31-48.
- Sachs, Jeffrey D. (2001): *Macroeconomics and Health, Investing in Health for Economic Development*, Report of the Commission on Macroeconomics and Health. Geneva: WHO.
- Scharpf, Fritz W. (2000): *Interaktionsformen, Akteurzentrierter Institutionalismus in der Politikforschung*. Opladen: Leske + Budrich.
- Scherer, Frederic M. (1993): *Pricing, Profits and Technological Progress in the Pharmaceutical Industry*, in: *Journal of Economic Perspectives*, No. 3, Vol. 7, pp. 97-115.

- Seiter, Andreas (2005a): Pharmaceuticals, Counterfeits, Substandard Drugs and Drug Diversion, HNP Briefing Paper 2, Washington, D.C.: The World Bank.
- Seiter, Andreas (2005b): Pharmaceuticals: Local Manufacturing, HNP Briefing Paper 3, Washington, D.C.: The World Bank.
- Seiter, Andreas (2005c): Pharmaceutical Drug Regulation in Low and Middle Income Countries, HNP Briefing Paper 4, Washington, D.C.: The World Bank.
- Seiter, Andreas (2005d): Pharmaceuticals: Quality Assurance in the Distribution Chain, HNP Briefing Paper 6, Washington, D.C.: The World Bank.
- Sell, Susan (2000): Structures, Agents and Institutions, Private Corporate Power and the Globalization of Intellectual Property Rights, in: Higgot Richard (ed.), *Non-State Actors in the Global System*, London: Routledge, pp. 91-106.
- Senn, Stephen (1996): Some Statistical Issues in Project Prioritization in the Pharmaceutical Industry. *Statistics in Medicine* 15(24) 2689-2702
- Sexton, Sarah (2001): Trading Health Care Away? GATS, Public Services and Privatization. The Corner House Briefing 23, Dorset, U.K., in: [www.thecornerhouse.org.uk/pdf/briefing/23gats.pdf](http://www.thecornerhouse.org.uk/pdf/briefing/23gats.pdf).
- Simmons, Ann M. (2001): South Africa, Manufacturers Settle Over AIDS Medication. *Pretoria: Los Angeles Times*.
- South Centre and Center for International Environmental Law (2005): Quarterly update-Fourth Quarter 2004, The TRIPS Agreement at a crossroad: Intellectual property and development Concerns in the lead up to Hong Kong Ministerial, in: [www.ciel.org/Publications/pubipqu.html](http://www.ciel.org/Publications/pubipqu.html).
- Subramanian, Arvind (2004): Medicines, Patents and TRIPS, in: *Finance and Development*, No. 1, Vol. 41, pp. 22-25.
- UNCTAD (1996): *The Trips Agreements and Developing Countries*. New York and Geneva.
- UNCTAD-ICTSD (2005): *Resource Book on TRIPS and Development*. New York: Cambridge University Press.
- United States House of Representatives, Washington Committee on Government Reform – Minority Office (2005): *Trade Agreements and Access to Medication under the Bush Administration*. Washington, D.C.
- Von Soest, Christian; Calcagnotto, Gilberto; Weinel, Martin (2006): *Between Conflict and Cooperation, Global-National Interfaces and the Fight against HIV/AIDS in Brazil and South Africa*. Paper presented at the GOI/WHO workshop “Defining and Shaping the

- Architecture for Global Health Governance", February 22-24, 2006, Hamburg: Deutsches Übersee-Institut.
- Wagstaff, Adam; Claeson, Mariam (2004): Rising to the Challenges – The Millennium Development Goals for Health. Washington, D.C.: The World Bank.
- Walters, James; Perenyi, Sofia; Griffith, Phoebe (2001): Pharmaceuticals and Intellectual Property: Overcoming the Impasse, in: <http://fpc.org.uk/articles/99>.
- Wogart, Jan Peter; Calcagnotto, Gilberto (2006): Brazil's Fight Against AIDS and its Implications for Global Health Governance, in: *Journal of World Health and Population* 1/2006, pp. 1-16
- Wogart, Jan-Peter; Hein, Wolfgang (2006): TRIPS and the Pharmaceuticals Facing AIDS and Shaping Global Health Governance. (Paper presented at the GOI/WHO workshop, Defining and Shaping the Architecture for Global Health Governance, February 22-24, 2006). Hamburg: Deutsches Übersee-Institut.
- World Bank (1993): World Development Report 1993, Investing in Health. Washington, D.C.: The World Bank.
- World Bank (2000): World Development Report 2000/2001, Attacking Poverty. Washington, D.C.: The World Bank.
- World Health Organization (2000a): The World Health Report 2000, Health Systems: Improving Performance. Geneva: WHO.
- World Health Organisation (2000b): Report on Infectious Diseases 2000, Overcoming Antimicrobial Resistance. Geneva: WHO.
- World Trade Organization (2002): WTO Agreements & Public Health. Geneva: WTO.
- World Trade Organisation OMC (2003): TRIPS and Pharmaceutical Patents, WTO Fact Sheet. Geneva: WTO.
- Young, Bob; Surrusco, Michael (2001): RX R&D Myths: The Case Against the Drug Industry's R&D Scare Card. Washington, D.C.: Public Citizen Congress Watch.
- Zeller, Christian (2001): Globalisierungsstrategien – Der Weg von Novartis. Berlin: Springer.

## Recent issues:

- No 23 Daniel Flemes: Brazil's Nuclear Policy. From Technological Dependence to Civil Nuclear Power; June 2006
- No 22 Leany Barreiro Lemos and Mariana Llanos: The Politics of Senatorial Confirmations: A Comparative Study of Argentina and Brazil; May 2006
- No 21 Matthias Basedau and Wolfram Lacher: A Paradox of Plenty? Rent Distribution and Political Stability in Oil States; April 2006
- No 20 Esther K. Ishengoma and Robert Kappel: Economic Growth and Poverty: Does Formalisation of Informal Enterprises Matter?; April 2006
- No 19 Anika Oettler: Guatemala in the 1980s: A Genocide Turned into Ethnocide?; March 2006
- No 18 Heike Holbig: Ideological Reform and Political Legitimacy in China: Challenges in the Post-Jiang Era; March 2006
- No 17 Howard Loewen: Towards a Dynamic Model of the Interplay Between International Institutions; February 2006
- No 16 Gero Erdmann and Ulf Engel: Neopatrimonialism Revisited – Beyond a Catch-All Concept; February 2006
- No 15 Thomas Kern: Modernisierung und Demokratisierung: Das Erklärungspotenzial neuer differenzierungstheoretischer Ansätze am Fallbeispiel Südkoreas [*Modernization and Democratization: The Explanatory Potential of New Differentiation Theoretical Approaches on the Case of South Korea*]; January 2006
- No 14 Karsten Giese: Challenging Party Hegemony: Identity Work in China's Emerging *Virreal* Places; January 2006
- No 13 Daniel Flemes: Creating a Regional Security Community in Southern Latin America: The Institutionalisation of the Regional Defence and Security Policies; December 2005
- No 12 Patrick Köllner and Matthias Basedau: Factionalism in Political Parties: An Analytical Framework for Comparative Studies; December 2005
- No 11 Detlef Nolte and Francisco Sánchez: Representing Different Constituencies: Electoral Rules in Bicameral Systems in Latin America and Their Impact on Political Representation; November 2005
- No 10 Joachim Betz: Die Institutionalisierung von Parteien und die Konsolidierung des Parteiensystems in Indien. Kriterien, Befund und Ursachen dauerhafter Defizite [*The Institutionalisation of Parties and the Consolidation of the Party System in India. Criteria, State and Causes of Persistent Defects*]; October 2005
- No 9 Dirk Nabers: Culture and Collective Action – Japan, Germany and the United States after September 11, 2001; September 2005

All GIGA Working Papers are available as pdf files free of charge at [www.giga-hamburg.de/workingpapers](http://www.giga-hamburg.de/workingpapers). For any requests please contact: [workingpapers@giga-hamburg.de](mailto:workingpapers@giga-hamburg.de).  
 Editor of the Working Paper Series: Bert Hoffmann.