THE PHARMACEUTICAL INDUSTRY, AIDS AND JUSTICE

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ABSTRACT:

This article offers an approximation to the broad, and complicated, framework of relationships between the Third World and pharmaceutical companies.

In the first part of this work, reference is made to the poverty of these countries, their lack of health education, the scarcity of basic hygiene, and of course, their greatly limited access to medicines, especially those for AIDS. The article then proceeds to the issue of the pharmaceutical companies’ degree of responsibility in the paucity of medicines in certain areas of the world.

One factor that most limits access to medicines is price. Many sectors propose acting upon the patents of drugs (rescinding or limiting them) in order to lower their price. The problem with patent exemption is more complicated than it seems at first glance. On the other hand, it is a measure that comes with its own risks. If for lack of funds, or the uncertainty of a return of the capital invested, the research and development of new drugs discontinue, AIDS therapy would notably worsen. It is imperative and urgent to develop new drugs against the AIDS because of its resistance to the drugs currently available.

The article concludes with the efforts of the pharmaceutical industry to research possible forms of collaboration with developing countries.
1. INTRODUCTION

A preliminary reading of the key words in the heading of this article – AIDS, social justice, pharmaceutical industry, and economy – many readers would have likely related them in this manner: “In the treatment of AIDS, many injustices are committed, most of them perpetrated out of the economic interest of the pharmaceutical industry.” It is true that the activity of the pharmaceutical industry can be, on occasion, questioned for abuses committed in the Third World or for its lack of sensitivity in the treatment of AIDS. However, neither is it ethical to generalise the actions of certain members of a collective group to that group as a whole, nor is it to base the reflection on what would clearly be an oversimplification in thinking that the problem of the propagation of AIDS in underdeveloped countries compromises pharmaceutical companies.

This work seeks to offer an approximation to the broad, and complicated, framework of relationships between the Third World and pharmaceutical companies. In order to introduce the question at hand, reference has to be made to the poverty in those countries, their lack of health education, the scarcity of basic hygiene, and of course, their greatly limited access to medicines. It is very well known in the world that there still are deprived sectors of the population that have problems in meeting their basic food needs, or in having access to an education or public health system. Needless to say, there are population groups that have great difficulties in accessing medicines. To illustrate this, 14% of the world’s population (North America, Europe, and Japan) consume 80% of medicines, while more than a third of humanity does not have access to essential medicines.

We therefore ask: what is the pharmaceutical companies’ degree of responsibility in the paucity of medicines in certain areas of the world? Undoubtedly, pharmaceutical companies must collaborate in facilitating access to medications to the underprivileged. That does not mean, however, that these companies have the maximum responsibility in this matter, or that they alone are the solution to this problem. This biased view of the conflict has resulted in many other social partners’ disclaim of the matter, when their collaboration is just as desirable as that of the pharmaceutical industry. In that sense, it has been affirmed that if companies of drinking water and bread-making companies
supplied their products to the Third World, many lives would be saved (at present, 1.1 billion people do not have access to potable water.) The impact would even be, at first, greater than what would be obtained with the best access to medicines. For example, it has been demonstrated that, on many occasions, AIDS treatments in Africa are not effective since patients do not eat sufficiently\(^1\) or because the medicaments were not conserved in the conditions required for the maintenance of their efficacy.\(^2\) As was very well pointed out by *Medicus mundi*,\(^3\) 20% of the world population lives below the poverty line in destitution, meaning more than a billion are condemned to being constantly ill. Also, it must be taken into account that health problems of underdeveloped countries do not only derive from the deficient access to medication or determinant health factors.\(^4\) Even with the availability of sufficient medicines, these are not completely effective due to the difficulty in ensuring the adherence to the treatment owing to the lack of sanitary personnel or to the inadequate level of education in the Rational Use of Drugs.\(^5\) The aforementioned affirmation can further be explained by the statistics of doctors and nurses in different countries, e.g., Mozambique has 2.6 doctors and 20 nurses for every 100,000 inhabitants; Malawi has 2 doctors and 56 nurses; Lesotho, 5 doctors and 63 nurses; South Africa, 74.3 doctors and 393 nurses (most of them in the private sector); while the USA has 247 doctors and 901 nurses.\(^6\) Based on these premises, the question of why no one holds food companies, civil engineering companies, etc., responsible for the hunger and the sicknesses derived from the lack of potable water in the Third World has to be posed. Even so, pharmaceutical companies are continually blamed for their lack of solidarity.

\(^1\) The UN estimates that a sixth of the population that receives antiretroviral drugs need better nutrition. This is the aim of the Academic Model for Prevention and Treatment of HIV/AIDS (AMPATH,) one of the first projects to offer assistance against AIDS and manages a large-scale agricultural farm.


\(^4\) Arbeláez points out that the expected results of the measures taken by the Colombian government that tend to achieve equality as far as accessibility and availability in the health system are quite discouraging, “not only from the point of view of the availability of health care, but more so, in relation to the basic determinant factors of health (potable water and basic sanitation) whose coverage indices are certainly precarious and indicate profound inequalities.” Arbeláez M. “Evaluación de la eficacia del derecho a la salud en Colombia a partir del proceso de descentralización sanitaria” (Evaluation of the effectiveness of law on health in Colombia from the process of health decentralisation.) *Derecho y Salud*, 15 (1), (2007), 60.


As regards the access to medicines in underdeveloped countries, there is another question that remarkably draws attention. This is the question of taxes, bureaucratic red tape, obstacles, bribes, and corruption on the part of the authorities of those countries upon the entry of the medicines. It is alarming, and concerning, that even donations made by the international community are levied. Those taxes are a way to collect money (it is calculated that this duty ranges around 1% of the health budget in those countries), one way to fill the nation’s coffers, which at the same time hinders access to medicines. Therefore, it has to be asked why no one holds governments of underdeveloped countries responsible for placing obstacles in the distribution of medicines, or the international organisations for not involving themselves enough, or more, in the elimination of these bureaucratic impediments. In the meantime, pharmaceutical companies are continually attacked for their lack of involvement in the needs of Third World populations.

In preceding paragraphs, it has been sought to demonstrate that the problem of the lack of medicines, being solely, or mainly, that of pharmaceutical companies, is not realistic. Furthermore, the cited assertion overlooks a fundamental fact, which is the last premise to be expounded in this introduction, and this is that pharmaceutical companies are not charitable institutions, but lucrative companies with stakeholders and stock market activity. It is precisely because of this that it be in the social interest that these companies achieve good dividends. This would allow the shareholders – who are risking their money – to reach their objectives and in this way, continue to disburse funds for research and development of new medications.

In conclusion, the problem of access to medicines of the people in developing countries does not depend only on pharmaceutical companies’ more or less altruistic activity. It will also depend on united, coordinated, and decisive action of different agents on different fronts – among them the pharmaceutical companies – in a common undertaking. Each one has its own degree of responsibility depending on its formation.

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8 Which is not in conflict with “organisations, echoing the concerns of their employees and shareholders, have the right to contribute to the collective effort to limit the effects of poverty and inequality, and contribute to the possible development of peoples.” Francés, P., Borrego, A., Velayos. C. *Códigos éticos en los negocios*. Ediciones Pirámide, Madrid, 2003; 259.
(company, NGO, international organisation, etc.) and its capacity to produce effects (economic, political, social, et al.)

2. PRICE AS A LIMIT TO ACCESS MEDICINES.

One of the first questions that arise in relation to the access to medicines, posed by economically disadvantaged sectors, is that of patents. The pharmaceutical industry makes enormous efforts in research and development of new drugs, in the hopes of recovering their investment with profit later on. In order to help the company with its goals there exists a period in which their efforts are rewarded through controls arbitrated by the patents of the new products. Patent duration usually lasts around 20 years from the day of the application in the competent organisations. Notwithstanding, “because the process of development of the new pharmaceuticals is long as a result of more normative demands every day, and because the duration of the registration process in all lasts anywhere from 12 to 14 years, the effective period of the patent is reduced to 6 to 8 years.”

Within this period, companies have to recover their investment in research and development. Moreover, not only must what was invested in that molecule that is now in the market in the form of a drug be compensated, but also everything else invested in the other molecules that have been ruled out at some phase of the synthesis, clinical tests, etc.

There are resolute efforts from different sectors so that patents are not applied in developing countries, or at least so that they are adapted to the requirements and respective situations of those areas. It is certainly a laudable aspiration that seeks the common good. Nevertheless, these measures, as will be made evident later on, in order to be effective have to distance themselves from mere “populist” plans and approach the issue with rigour, dealing with the measures employed and the intended subjects. In this sense, Monge maintains, “the traditional patent system, indispensable for business

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10 Somoza, A., De la Figuera, A., Martínez, P. “La especialidad farmacéutica desde la síntesis a la Farmacia.” *(Pharmaceutical specialty from the synthesis of Pharmacy.)* *Auladelafarmacia*, 1 (2), (2004), 11.

and the diffusion of science, should take into consideration upcoming situations.” That is to say, a balance must be struck among all the interests involved.

A recent example of debate on the applicability of an AIDS drug patent is the issuance by the Brazilian government of an obligatory licence that permits the importation of generic versions of efavirenz, which is still protected under patent. The Brazilian government justified its decision appealing to “public interest.” The process underwent arduous negotiation wherein the pharmaceutical company only acceded to lower their product’s price by 30% (the Brazilian government demanded a reduction of 60%).

Merck’s last offer was the sale to Brazil of $1.50 a unit. Meanwhile, the same pharmaceutical company is selling to Thailand at $0.65 a unit. The generic drug of this product, which is produced in India, sells for $0.45. The Brazilian government claims that it was negotiating a reduction in price with Merck as of November 2006. In April 2007 it warned the pharmaceutical company that unless Brazil could purchase efavirenz at the same price that was recently offered to the Thai government, it would issue a compulsory licence in seven days. On Tuesday, 3 May, the Brazilian government rejected the 30% price cut offer and proceeded to issue the obligatory licence the next day. The posture of Merck & Co. in the media was made out to be intransient and not solidaristic. In its defence, the pharmaceutical company alleged that in its proposal it took into account that Brazil is the twelfth biggest economy in the world, therefore it has a greater capacity to pay for HIV medication than poorer countries or countries more affected by the infection.

In other words, Merck applied a criterion of economic proportionality upon determining the final price of its products in different countries.

Some countries, upon limiting or outright not admitting patents, are becoming outstanding manufacturers of generic, low cost drugs. India has transformed into one of the outstanding areas in this field (for instance, an Indian court recently turned down a demand made by the pharmaceutical Novartis against the national law that prevented it from patenting a new formula of Glivec.) The production of low cost generics in underdeveloped countries implies a series of risks. Among these, that they can come to be “commercialised, in a more or less legal manner, all over the world, which would

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surely encourage other governments to follow suit so that they improve the conditions of their populations and at the same time, favour the local pharmaceutical companies who do not do R&D nor take any risks.”\textsuperscript{14} This situation can put a stop to the research of new medicines and create such paradoxical scenarios such as what is currently occurring in India. On the one hand, they demand the exemption from patents because of poverty, but on the other hand, they are becoming a world pharmaceutical power spreading significantly not only in the more underprivileged countries, but they are also making their incursions into more developed countries.

Another problem associated with the question of patents is the criteria to adopt in order to establish the poverty limit in a country. It was stated earlier that the pharmaceutical industry could not afford to generate losses. So, if it loses money, (or generates less revenue) because of the aid it gives to poor countries, it would have to displace these economic losses to the wealthier countries. This idea can be a source of injustice since this price increase would give rise to isolated population groups in developed countries that would have serious problems in accessing certain drugs.\textsuperscript{15} In line with this, Buela reminds us that in the United States for example, “in the world’s first economy, if you cannot pay for healthcare, you will not receive any, even if it is available.”\textsuperscript{16} On this premise, it would be quite unfair that the pharmaceutical industry finance the treatment in far off countries, while some citizens in the surrounding areas where the company is located do not have the possibility of availing of these treatments. A population, it should be recalled, who at a more prosperous point in its history was able to finance the basic research with its taxes.

Definitely, the problem of patent exemption is far more complicated than at first glance. There is no doubt acting upon them – limiting, annulling – might be a good way to provide that everyone has access to pharmaceutical treatment. Yet, it is not the only means available to achieve end. At the same time, it must be remembered that it is a measure that comes with its own risks. Indeed, it is a genuinely dangerous to choke the main means of economic stability of the companies, the means the companies have in order to realise a return on their research investments. Case in point: we have Sanofi-

Aventis that closed 2006 with an increase in sales of 3.6%. If it did not lose the patents of four products in the US, it would have reaped 8.2% more benefits.\textsuperscript{17} If for lack of resources, or the uncertainty of a return on investment, research grinds to a halt as with the development of new medicines, AIDS therapy would be seriously aggravated owing to the fact that it is peremptory to develop new drugs against the AIDS virus, since resistance to present-day drugs surface every day.

3. RESPONSIBILITY IN THE FACE OF DEVELOPING COUNTRIES.

The not so well deserved notoriety of the industry as an ogre that seeks to take advantage of depressed countries is, as was pointed out previously, a simplification of the issue at hand. The error is in lumping together the mistaken notion of a company’s responsibility to employ identical criteria for rich and poor countries alike, and the misconception that the pharmaceutical industry alone is capable of solving all the health problems of the Third World. What is more, research and pharmaceutical distribution are usually mistaken to be one and the same, when actually they are two separate things altogether with different solutions.\textsuperscript{18}

Pharmaceutical companies defend themselves from the media harassment to which they are being subjected by deviating the attention to other sectors. So, it is claimed that governments of wealthier countries (sometimes, even the governments of the developing countries themselves for the poor management and distribution of resources) and international organisations in charge, and not the private companies are the ones mainly responsible for the unjust distribution. That is, the health issue goes beyond the price of a particular drug, to the extent that it cannot be resolved without active participation of governments, international organisations, NGOs, and something we normally forget, the very citizens of those communities that should be aware that


they have to cooperate for their own good. Along this line, Pastors\textsuperscript{19} shows that there are four factors and five groups of actors that have to be considered to solve the health problems of the Third World. The factors are the choice and rational use of the medicines, accessible cost of drugs, sustainable financing, and the health system and reliable supply. The main players are developing countries’ governments, governments of industrialised countries, pharmaceutical companies, consumer groups and NGOs, and the international agencies and foundations. Recall the words of Pope John Paul II to the participants of the G-8 summit. In his speech, he admonished them to commit themselves “to promoting a culture of solidarity that allows for concrete solutions to the problems that most affect our brothers in life and relations with others: peace, poverty, health, and the environment.”\textsuperscript{20}

Nonetheless, pharmaceutical companies should not evade their responsibility. Not demanding from them certain actions or conduct is totally compatible with censure and seeking that they avoid committing abuses. Among the denounced abuses that can be cited are:

a) The use of different criteria in the distribution of medicines.\textsuperscript{21} The case of Bayer and the antibiotic Cipro is an example of an industry’s difference in attitude when a developed country or a developing country seeks their “altruistic” aid with respect to price reductions of medicines.\textsuperscript{22} The prolonged and systematic resistance of laboratories to lowering prices of AIDS drugs in Third World countries has previously been pointed out. On the other hand, US and Canadian governments were able to quickly close deals with the multinational Bayer for them to be supplied amounts worth millions of the antibiotic Cipro to combat anthrax at prices far lower than the existing prices before the bacteriological attacks by post. The argument wielded was the state of emergency. Nevertheless, the threat of said countries not to respect patents appealing international treaties that allow for the manufacture or importation of generics in case of

\textsuperscript{19} Pastors, B. “Promover acciones prácticas con respecto al poder de las industrias farmacéuticas.” (Promoting practical actions with respect to the power of the pharmaceutical industries.) Dolentium Hominum 49 (1), (2002), 97.

\textsuperscript{20} Message of pope John Paul II to the participants of the G-8 summit in Genoa, 19 July 2001.


\textsuperscript{22} Pincock, S. “Drug company to offer new malaria drug cheaply in Africa”. BMJ 327, (2003), 360.
national emergency regardless of existing patents must have influenced in the decision of the laboratory.

b) Carrying out unauthorised clinical test by ethics committees of developed countries. Bear in mind that certain aspects such as the benefits derived from the participation in the test or economic benefits can become a form of “coercion” for people in Third World countries. For example, in February 2003, the European Group on Ethics (EGE) in Science and New Technologies, presented its seventeenth report in which an exception is made to a general rule contained in the Helsinki Declaration, establishing that the testing of new drugs should compare to the best therapy available. The reason behind this exception is that, in cases of certain diseases such as AIDS, its compliance impedes testing less effective drugs than what are available in developed countries but accessible in developing countries. Notwithstanding, two of the twelve members of the EGE oppose this criterion because they deemed it sets a “double standard” when it comes to dealing with rich countries or poor countries. Following this line, a case that sparked much controversy was that of the zidovudine clinical test. In the United States and France it was proven that a complex treatment regimen based on zidovudine reduced HIV transmission from mother to child. After obtaining these results, another study was done in an underdeveloped country comparing a less complex treatment with a placebo.

c) Commercialising in the Third World medicines prohibited in Europe and the United States. An example to illustrate this is that of an affiliate of Bayer, which in the 80’s continued to sell to Asian and South American countries a haemophilia drug despite being aware of the high risks its employment posed for the transmission of AIDS. In 1982, the Centre for Disease Control in the United States warned there was

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24 Diario Médico, 6 February 2003.
26 Mahmood, K. “Runaway drug prices in Pakistan”. *Lancet* 342, (1993), 809. At times, leaders in developing countries are accused of fostering this abuse, and this, in turn, points to the pressure exerted by the industry. This is the case of the Peruvian Health Minister in 1989 when he declared that the problems of Third World countries, in this aspect, is due to the fact that “this industry is more powerful than the ministers” Cf. Gilson, M, Gilson, S. “A different drugs scandal”. *Lancet* 21 October 1989, 970.
strong evidence AIDS was transmitted through the blood. At that moment measures were taken all over the world to try and avoid infection through the blood. Nonetheless, the New York Times had access to internal documents proving Culter Biological continued selling a product meant for haemophiliacs obtained from donated blood in spite of having full knowledge of the extremely high HIV infection risk. This practice was only carried out in the geographic areas mentioned because the same company had a safer version of the same drug since the beginning of 1984, although it was destined exclusively for the European and North American markets. Another example is that which took place in India, where the government went so far as to threaten to boycott certain pharmaceutical industries in order to force them to cease commercialisation of certain preparations already prohibited in the West.

d) Offering different information on the labels and prospectuses of medicines.

Every user, regardless of what country they hail from, has the same right to receive complete information on the medicine they are using.

The cited cases (being only a sample of a broad range) have generated much widespread debate on the activity of companies in the pharmaceutical sector. It is because of this that pharmaceutical companies are concerned about their activity being under constant scrutiny. They deem this pressure exerted on them could jeopardise their image resulting in a decrease in revenues. From this rationale arises the pharmaceutical companies’ response: to seek to work with permanent ethical criteria (thus their involvement in Corporate Social Responsibility); and to try to offer compensation through solidarity projects.

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27 El Mundo, 22 May 2003.
30 This year Pfizer has been questioned for the experimentation carried out in 1996, during a meningitis epidemic. Lanzer, J. “Nigeria files criminal charges against Pfizer”. BMJ 334, (2007), 1181.
31 “When the pharmaceutical industry brought the South African government to court in 2001 for its patent legislation, just as the AIDS epidemic began to break out in the region, it brought upon itself the image of a villain, until then reserved only for tobacco companies. Public clamour was so fierce that executives began to fear the backlash they could suffer as a consequence of the controversy on the AIDS treatment in Africa could undermine its credibility and benefits in the wealthier countries. The sector therefore abandoned the suit against South Africa and intensified the offers to cut prices of its anti-HIV and other drugs in developing countries.” Diario Médico, 26 May 2003, 27.
4. THE SOLIDARISTIC RESPONSE OF PHARMACEUTICAL COMPANIES.

There are many examples of the pharmaceutical industry’s efforts in exploring possibilities to collaborate with developing countries. Among them, there is the study espoused by International Federation of Pharmaceutical Manufacturers’ Associations (IFPMA) entrusted to Dr. Klaus Leisinger, who at the time was heading international relations of Ciba-Geigy, on the responsibility of the pharmaceutical industry in the Third World.

Another interesting proposal is the Mectizan Donation Program. Merck, Sharp & Dohme discovered the value of ivermectin to treat onchocerciasis (river blindness.) Ivermectin is an antihelmintic used in veterinary medicine. The pharmaceutical company deemed its commercialisation as a remedy for humans not economically feasible. Nevertheless, the pharmaceutical company, heeding its social importance, carried out the necessary development. Since 1987, ivermectin has been included in the Control Programme, as a key element in the therapeutic regimen. MSD has donated ivermectin all over the world, for the treatment of persons afflicted with onchocerciasis for however long this drug will be needed.

Pfizer Laboratory has undertaken a firm resolution to social commitment, wherein their efforts in concrete actions to the benefit of the underprivileged are manifest. Their positive battle against AIDS can be highlighted in the form of measures such as the contribution of $11m for the creation of a health information and training centre for health professionals in Africa, or the institution of a program to eradicate trachoma.

From the year 2000 to 2007, under the auspices of Novartis, 4 million lepers have been cured thanks to the free distribution of the drug for this disease. The programme will continue until 2010, as they have acceded to offer to the WHO free treatment.

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The examples portrayed above are only the tip of the iceberg of the social involvement of pharmaceutical companies.

Nevertheless, this chapter cannot end without posing two reflections.

1) Are these gestures of benevolence truly an expression of the concern for the needy, or are they simply another marketing strategy of multinational companies in the pharmaceutical sector? At times, it has been pointed out that donating money or carrying out a timely campaign is easier than to maintain a consistent positive attitude in this matter.

2) Are the problems posed not formulated with the mentality of developed countries, and that they are erroneously designed because they cannot be applied with the same ethical criteria in developed countries and developing countries?36

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