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ABSTRACT

This article examines the role of pharmaceutical companies in problems related to the access to drugs in many developing countries. It commences with a review of the practice of pharmaceutical companies in barring access to drugs for the HIV/AIDS pandemic and their reluctance to fund research with respect to diseases that are not profitable. It is argued that the only time developing countries are likely to have access to drugs is when their citizens are used for experimental purposes as is being suggested in the Pfizer antibiotic drugs test in Nigeria. The article concludes by calling for the World Health Organization (WHO) to take a leading role in making such pharmaceutical companies more sensitive and accountable to the plight of citizens in these developing countries. This can be achieved by setting up a mechanism modeled along the lines of the “equator principles” applicable to the International Finance Corporation (IFC) and leading financial institutions.

KEYWORDS

Human Rights – Health – WHO – Pharmaceutical companies – Developing countries



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PHARMACEUTICAL CORPORATIONS AND ACCESS TO DRUGS IN DEVELOPING COUNTRIES: THE WAY FORWARD

Justice C. Nwobike

Introduction

According to a WHO estimate, one third of the world's population lacks regular access to essential medicines with more than 50% of populations in parts of Africa and India lacking access to the most basic and essential drugs¹ Despite India's low drug prices, only 30% of the Indian population has access to medicines and even fewer people would have access with the introduction of pharmaceutical patents.²

Access to essential drugs is difficult, and is increasingly so for many of those who need them most, thus hindering a realization of the right to health in many countries.³ We see that it is not only the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement nor the World Trade Organization (WTO) alone that is causing this situation, but rather pharmaceutical companies or the governments of industrialized countries, acting on behalf of those companies. Patents affect public health provisions mainly through the impact they have on access to medicines. Granting exclusive rights on medicines to Patent holders enables them to charge a premium over and above their marginal costs of production. This makes drugs protected by patents more expensive and at the same time makes them accessible to fewer consumers than similar drugs produced in a competitive environment without patent protection in other countries. For instance 150 mg of the HIV drug fluconazole costs \$55 in India where it has no patent protection as against \$697 in Malaysia, \$703 in Indonesia, and \$817 in the Philippines where it enjoys patent protection.⁴ The role of patents in reducing access to drugs includes the fact

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that patents can hamper the production of the usually less-expensive generic versions of patented drugs, and limit or reduce the possibility for governments to allow compulsory licensing and parallel imports of pharmaceuticals.⁵

Although the TRIPS Agreement⁶ itself and the Doha Declaration on TRIPS⁷ recognize that WTO member states can adopt measures necessary to cater for their public health needs, there is still some controversy on the permissible scope of flexibility allowed to member states by TRIPS in combating their public health problems.⁸ A large number of developing countries have come under direct pressure from either the pharmaceutical companies or developed countries to provide strong patent protection on pharmaceutical products, and to refrain from allowing compulsory licensing and parallel imports.⁹ We shall consider a few such instances and thereafter examine the way forward in regulating these undue pressures.

Access to drugs in the context of HIV/AIDS¹⁰ epidemic

Access to drugs (or the lack of access), have been recurrent factors in the quest for a realization of the right to health. The enormity of the problem created by the global HIV/AIDS crisis makes this an even more compelling issue to be addressed. In large measure because of the Global HIV/AIDS crisis, the issue of access to affordable medicines in many of the worlds poor or developing countries is finally receiving the attention it deserves.¹¹ This is evidenced by the adoption of a resolution by the United Nations Security Council on the AIDS crisis. The resolution, which is the Security Council's first-ever resolution on a health issue, recognizes the efforts of the Member States which have acknowledged the problem of HIV/AIDS, and where applicable, have developed national programs. The resolution also encourages all interested Member States which have not already done so to consider developing, in cooperation with the international community and UNAIDS, where appropriate, effective long-term strategies for HIV/AIDS education, prevention, voluntary and confidential testing and counseling, and treatment of their personnel, as an important part of their preparation for participation in peacekeeping operations.¹² The Security Council resolution was followed by the General Assembly Declaration of Commitment on HIV/AIDS¹³, which recognizes the epidemic as a "global crisis" that calls for "global action."

In 2003, an estimated 4.8 million people (range: 4.2-6.3 million) became newly infected with HIV. This was more new cases of HIV than in any one year before 2003. Today, some 37.8 million people (range: 34.6-42.3 million) are living with HIV, which killed 2.9 million (range: 2.6-3.3 million) in 2003, and has killed more than 20 million since the first cases of AIDS were identified

in 1981.¹⁴ In some industrialized countries, widespread access to antiretroviral medicines has fueled a dangerous myth that AIDS has been defeated. In sub-Saharan Africa, the overall percentage of adults with HIV infection has remained stable in recent years, but the number of people living with HIV is still growing.¹⁵ To date, no curative medicine or preventive vaccine has been successfully developed for the virus, however antiretroviral drugs have been developed, which promote and improve the health and well being of HIV carriers. Providing access to drugs is just one part of tackling AIDS, but it is an important part. It can significantly increase the quality and length of life of people already infected as well as aid in prevention by encouraging others to be tested, and by reducing mother-to-child transmission of the virus.¹⁶ Despite this breakthrough, access to these drugs has remained elusive for most HIV patients in developing countries. This is a direct result of the exorbitant prices imposed. Often the demand for a particular medicine is inelastic, meaning that if people cannot find alternatives they must purchase the product – even if the cost escalates. If they cannot afford the price, they must do without the product and live with the result, which in many cases is death.¹⁷

Corporate profits *versus* public health

While discussing the responsibilities of pharmaceutical corporations in relation to access to drugs it is important not to lose sight of the fact that these corporations are set up primarily for profit.¹⁸ The pharmaceutical industry and its government supporters justify patents on medicines and high prices on the grounds that both research and development of pharmaceutical drugs are extremely expensive. Thus far, there is little convincing evidence to support this claim.¹⁹ Even if this claim were supported by facts, what matters here is not that drugs are costly to develop, but rather that the rate of the return on investment is usually very high; and this leads to astronomical profits by pharmaceutical corporations. In addition, taxpayers and governmentally funded institutions often play a key role in discovering new inventions, with the pharmaceutical companies obtaining the patent and reaping the financial rewards after the basic discovery. These institutions are now becoming more reluctant to unconditionally hand over their research. In December 2000, a dispute between the US National Institute of Health (NIH) and Bristol Meyers Squibb became public. NIH is demanding \$9.1 million in royalties from the overseas sales of *didanosine*, used in the treatment of HIV/AIDS.²⁰

The most devastating impact of the AIDS epidemic takes place in sub-Saharan Africa. In South Africa, HIV/AIDS has been projected to reduce life expectancy by 20 years by the year 2010, while in Kenya one quarter of the

adult population is HIV positive but fewer than two percent receive anti retroviral treatment. If Kenya were able to import the drug *fluconazole* from Thailand, it could reduce the annual cost of treatment from over \$3,000 to \$104.²¹ Despite this alarming state of affairs, attempts by some countries to exercise certain flexibilities under the TRIPS agreement have been strongly opposed by pharmaceutical corporations and their home governments. Intense pressure is brought by very powerful countries on the governments of many other countries (mostly developing and less developed countries) that lack the requisite pharmaceutical capacity, to not adopt certain measures open to them under the Agreement.

The big pharmaceutical companies versus South Africa

A classic example of the pharmaceutical corporations opposition to the exercise of the flexibilities TRIPS offers is manifested in a lawsuit filed by 41 pharmaceutical corporations against the government of South Africa. The suit challenged a law seeking to provide access to drugs for the people in the country. The South African Parliament on 31 October 1997 passed the *Medicines and Related Substances Control Act (Medicines Act) No. 90 of 1997*. President Nelson Mandela assented to the Law on 25 November 1997. This Law, which introduced a new legal framework to ensure the availability of drugs in both the public and private health sectors, contains certain key features. The Medicines Act introduces four important elements to contain health care costs to governmental and private sectors. It provides compulsorily for the generic²² substitution of medicines that are no longer under patent. This means that the pharmacist must offer a patient the generic version of a brand name medicine unless the patient expressly refuses the substitution.²³ Secondly, it empowered the Minister of Health to establish a pricing committee that will set up transparent pricing mechanisms. Pharmaceutical companies will have to justify the prices they charge.²⁴ Another element introduced by the Act is the parallel importation provision, which allows the government to import the same drug that is being sold at a lower price by the same company – or its licensee – in another country. Finally, the Medicines Act allowed international tendering for medicines used in the public sector.²⁵ The Act did not go down well with the pharmaceutical corporations operating in South Africa, and on 18 February 1998, the Pharmaceutical Manufacturers Association (PMA) and 41 multinational pharmaceutical corporations went to court to challenge it, on the grounds that the amendments introduced amounted to unfair discrimination, were unconstitutional, *ultra vires* the Patent Act of 1978, and contrary to Article 27 of the TRIPS Agreement on Intellectual Property.

In rebuttal the South African government asserted that it has a constitutional duty to make medicines affordable for its people. The Constitution of the Republic of South Africa, 1996, provides that everyone has the right to have access to healthcare services and no one may be refused emergency medical treatment.²⁶ The suit led to a mobilization of advocacy groups against the pharmaceutical corporations. The Treatment Action Campaign (TAC) is a renowned South African Civil Society Organization working with and for People Living with AIDS. TAC applied to the Court and was granted leave to file briefs as an *amicus curie*.²⁷

In a *volte-face*, the drug companies dropped their suit in April 2001, prompted by the extraordinary wave of public protest that the suit had provoked, the possibility of failure, and perhaps crucially, the fear of a court order forcing disclosure of their real research and development costs. The specter of thirty-nine companies – whose combined profits outweighed the GDP of South Africa – moving to stop a provision of inexpensive drugs for a population in dire need, particularly in relation to HIV/AIDS, did immeasurable damage to the reputation of the drug companies. Currently large pharmaceutical companies are trying to recover from that massive loss of popularity on the ground.²⁸ Under the terms of the settlement, the South African government has confirmed that its new law will be implemented in a way compliant with the Trade-Related Intellectual Property Rights Agreement (TRIPS). In doing so, it affirmed a need for strong intellectual property protection consistent with international agreements as well as the underlying importance of intellectual property protection as an incentive to innovation. Put simply, intellectual property is not the obstacle to access.²⁹ Commenting on their withdrawal from the case, the Chief Executive of GlaxoSmithKline, *Jean Pierre Garnier* had this to say:

The key concern for the industry was that the South African Legislation was vague and ambiguous and in particular, the law appeared to give the government the freedom to override patents of any medicines at their discretion. This would have undermined the industry's ability to provide new and better medicines [...]. In the heated debate around the court case it has been difficult to convey the overwhelming truth that the most significant barriers to comprehensive treatment for HIV/AIDS in the developing world are lack of funding and public healthcare infrastructure.³⁰

The decision to drop the South African Court Case, and some recent announcements about the price reduction of anti-retrovirals can be seen as an attempt by the pharmaceutical industry to avoid having HIV/AIDS become a catalyst for an international movement seeking to address the problems in the TRIPS Agreement. It is submitted that the withdrawal of the case was a face-saving step, as a pronouncement in favor of the South African government

would have precipitated a floodgate of legislation in many other developing countries along the lines of the South African Medicines Act. The statement embodying South Africa's commitment under the terms of the settlement amounts only to a restatement of its existing obligations, under which it exercised the safeguards provided for under the intellectual property rights regime.

Developed countries: Unilateral sanctions and double standards

It is no longer in doubt that flexibilities exist within the TRIPS framework which give governments of WTO Member countries room to fulfill the public health needs of their inhabitants. However the pressure from some developed countries has made it almost impossible for developing countries to exercise these flexibilities. This problem is reflected in the nature of bilateral agreements signed with developing countries to extend patent protections over the established 20-year term³¹ or in the outright threat of an imposition of trade sanctions on countries that have adopted measures to promote public health under the intellectual property regime. The United States of America is notorious for this. A renowned human rights NGO, Human Rights Watch, has expressed concern that the U.S.-Morocco FTA will make it impossible for Morocco to use the flexibilities contained in TRIPS "to the full." According to the statement:

There are credible reports that the United States is seeking an extension to the twenty-year patent term required by the TRIPS, as well as exclusive rights for drug companies to pharmaceutical test data. Each of these provisions would diminish Morocco's ability to hasten market entry of affordable generic medicines. It is hypocritical for the United States as a member of the WTO to pursue bilateral trade policies that undercut precisely those flexibilities whose full use the Doha Declaration encourages.³²

In January 2000, the Pharmaceutical Research and Manufacturers of America (PhRMA) filed a petition with the United States Trade Representative (USTR) claiming widespread and systematic non-compliance with world patent rules in India, Egypt, Argentina and Brazil. The use of price controls and compulsory licenses allowing the generic production of brand-name drugs were identified as major problems, especially in India. Four months later, the USTR placed Brazil and Argentina on the 'Special 301' Priority Watch List – in effect, a short-list of candidates for unilateral trade sanctions. The annual 'Special 301' review also warned that future actions would be brought against other countries, including Israel, Egypt and the Dominican Republic.³³

Another strategy that has been ‘creatively’ developed by pharmaceutical corporations to extend their patents is to produce a variation on a drug already under an existing patent, and then obtain a patent for the new product, which in any case would not have cost much in terms of research and development when compared with the cost of their initial research. In 1999, Smithkline Beecham (now GlaxoSmithkline) secured a new patent on its 20-year-old best-selling drug, Augmentin, by modifying the pediatric version.³⁴ Although the old form will be available off-patent, extensive marketing is likely to induce doctors to prescribe the new drug when it comes on the market.

It is interesting to note that when faced with similar situations of disease threat, developed countries, in a bid to promote and enhance the public health of their own citizens, have adopted measures identical to measures they consistently seek to prevent developing countries from adopting. During the period following the terrorist attacks of September 11, 2001, a few anthrax cases in the US raised fears of biological terrorist attacks. The United States and Canada threatened to issue compulsory licenses for the manufacture of *Cipro* – the only known cure for anthrax – which is produced under patent by Bayer, a German pharmaceutical company, unless it was sold to them at discounted prices. According to Sarah Joseph, it is interesting to note how quickly the United States and Canada acted to threaten the Bayer patent, and how quick media commentators were to question Bayer’s profit margin on *Cipro* at a time when the United States had thirteen anthrax cases with three deaths, and Canada had no cases at all. The North American anthrax threat was not an emergency on par with the devastating effects of HIV/AIDS in the developing world. The North American response was probably legitimate under the circumstances. However, it blatantly displayed hypocrisy on the part of the West regarding their acceptability of patent relaxation in the context of health emergencies confronting “us” in the developed world, as opposed to the context of the health emergencies constantly confronting “them” in the developing world.³⁵

In spite of the pressure, the crusade to make the drugs used for the treatment of HIV/AIDS related diseases continues to record modest achievements. Recently, GlaxoSmithKline, one of the world’s leading manufacturers of ARV medicines, granted a voluntary license under its patents for the manufacture and sale of antiretrovirals (ARVs) containing *Zidovudine* and/or *lamivudine* in the public and private sectors in Kenya and other countries in East Africa to Cosmos Limited, a Kenyan pharmaceutical company. GSK currently sells *zidovudine* (sold as *Retrovir*®), *lumivudine* (sold as *Epivir*®) and the combination of the two molecules (sold as *Combivir*®) across the region.³⁶ However, a lot still needs to be done by pharmaceutical companies to ensure an increased access to HIV/AIDS drugs to complement the WHO and UNAIDS initiatives in tackling the epidemic.

Pharmaceutical corporations and neglected diseases

Neglected diseases are those diseases that “affect almost exclusively poor and powerless people living in rural parts of low income countries”.³⁷ The UN Special Rapporteur on the right to health has undertaken pioneering work on human rights and neglected diseases. He states that neglected diseases result from several problems which include: the lack of access to medicines and mechanisms for neglected diseases for poor people living in developing countries because of the high cost of the drugs; scarcity of resources; geographical inaccessibility, particularly in rural areas; and the inadequacies of the health systems.³⁸ Another reason is the “so-called 10/90 gap, which refers to the phenomenon whereby only 10% of global health research is focused on the conditions which account for 90% of the global burden of disease.”³⁹ Diseases which occur mainly in the poor communities of developing countries have attracted particularly little research and development. The market mechanism, which increasingly determines research and development, fails to respond to these so-called “neglected diseases” since they do not promise a good return on investments.⁴⁰ A great deal of research and development is put into drugs for chronic, ongoing conditions, like heart disease or high cholesterol, as opposed to cures and vaccines which do not have the same ongoing market potential.⁴¹

The essence of the intellectual property regime is to guarantee a reward for the invention to the inventor, as well as an opportunity to recover the investments for research leading to the invention. Intellectual property protection can, however, affect the enjoyment of the right to health and related human rights in a number of ways. Importantly, intellectual property protection can affect medical research, and this can bear upon access to medicines. For example, patent protection can promote medical research by helping the pharmaceutical industry shoulder the costs of testing, developing and approving drugs. However, the commercial motivation of intellectual property rights encourages research, first and foremost, towards “profitable” diseases, while diseases that predominantly affect people in poor countries - such as river blindness - remain under-researched.⁴²

The possibility of recouping research and development costs by excluding competition from the market through the use of intellectual property rights assumes that there is a market for new medicines in the first place. That neglected diseases are overwhelmingly suffered by poor people in poor countries underlines the fact that there is little or no market potential for medicines to fight these diseases, simply because the sufferers are unable to pay. Intellectual property protection does not provide any incentive to invest in research and development

in relation to neglected diseases. Given that the adoption of the TRIPS Agreement has placed incentives for medical research squarely on the trade agenda, the question of the enjoyment of the right to health for people suffering from neglected diseases has now also become a trade issue.⁴³

Pfizer's antibiotic drugs test in Nigeria: A case study

In 1996, there was an outbreak of meningitis in Kano, Northern Nigeria. On learning of the outbreak, Pfizer sent in a six-member research team to the infectious disease hospital in Kano. The drug company utilized the opportunity of the crisis to conduct medical experimentation of its antibiotic, *trovan*, as part of its effort to determine whether the drug, which had never been tested on children, would be an effective treatment for the disease. Under the experiment, 100 children were treated with *trovan*, while another 100 were treated with *ceftriaxone*, the standard drug for the treatment of meningitis.⁴⁴ When *trovan* was developed in 1996, tests were carried out, and when it was introduced into the market in 1998 it became one of the most prescribed antibiotics in the United States, earning more than \$160 million the first year. However, reports of liver damage led the U.S. Food and Drugs Administration to recommend in 1999 that it be used only for severely ill patients in institutions. Its use on children had not been approved.⁴⁵

Of the children who took part in the trial a total of 11 died, and others suffered different forms of disabilities – including brain damage, paralysis and deafness.⁴⁶ More than 30 families whose children took part in the drug test have sued Pfizer in a Federal District Court in Manhattan under the Aliens Tort Claim Act seeking damages and continuing medical care for the children involved, and an order restraining Pfizer from conducting illegal experimentation anywhere in the world.⁴⁷ Plaintiffs allege that Pfizer selected their children to participate in a medical experiment for a new, untested and unproved drug without their prior and informed consent. They claim that Pfizer failed to inform them that they had an option for an alternative treatment, as Doctors without Borders were providing free treatment in the same hospital with *Chloramfenicol*, a cheaper antibiotic that is internationally recommended for bacterial meningitis; nor were they informed that they were free to refuse to be part of the exercise.⁴⁸ This practice was in violation of the Nuremberg Code of 1947 and the World Medical Association Declaration of Helsinki,⁴⁹ which require that anyone seeking to conduct medical tests on human subjects must explain the purpose, risks and methods of the study and obtain each subject's voluntary consent to participate. Pfizer maintains that the tests were conducted fairly and

professionally, and that the clinical trials were effective in saving lives.⁵⁰ The company produced a letter from the hospital stating that the hospital's ethics committee had approved the *trovan* study. Interestingly, the plaintiffs contend that the letter was written a year later and then backdated – and that at the time of the Pfizer trial the hospital had neither an ethics committee nor the letterhead on which the letter was written.⁵¹

This case raises a number of issues. The pertinent question is, “does Pfizer have any right-to-health-related duties to the subjects of its experimentation?” If a duty does exist, has it been breached? A sedate perusal of the relevant human rights instrument will reveal some interesting provisions. Article 7 of the ICCPR provides that: “no one shall be subjected to torture nor to cruel, inhuman or degrading treatment or punishment. In particular, no one shall be subjected, without his free consent, to medical or scientific experimentation.” The Human Rights Committee explains that article 7 expressly prohibits medical or scientific experimentation without the free consent of the person concerned. The Committee notes that the reports of State parties generally contain little or no information on this point. More attention should be given to the need and the means of ensuring an observance of this provision. The Committee also observes that special protection in regard to such experiments is necessary in the case of persons not capable of giving valid consent,⁵² and in particular, those under any form of detention or imprisonment. Such persons should not be subjected to any medical or scientific experimentation that may be detrimental to their health.⁵³

The Nuremberg Code, which was developed by the judgment of the War Crimes Tribunal in Nuremberg, lays down 10 standards to which physicians must conform when carrying out experiments on human subjects. The Code provides *inter alia*:

The voluntary consent of the human subject is absolutely essential. This means that the person involved should have the legal capacity to give consent, should be so situated as to be able to exercise free power or choice, without the intervention of any element of force, fraud, deceit, duress, overreaching or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved to enable him to make an understanding and enlightened decision.⁵⁴ The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs or engages in the experiment. It is a personal duty and responsibility, which may not be delegated to another with impunity.⁵⁵

Without pre-empting the outcome of the hearing, an analysis of the facts

from the prism of the right to health will reveal that it is difficult to hold that Pfizer has discharged the onus of the company. Before the general outbreak of meningitis in Kano, there had been sporadic and sparse cases and the company had initiated no intervention. It is curious that the company did not deem it fit to enter into consultations with the relevant authorities and obtain the prior and informed consent of the subjects. The circumstances of the general disease outbreak and the company's intervention; the situation of families whose children were sick and desperately in need of a medical treatment which many of them could not afford because of poverty, would seem to suggest that it was impracticable to obtain the nature of consent which the instruments mentioned above envisage. While the suit is still pending in court, the fallout of the exercise has had more grave negative implications for the realization of the right to health in Nigeria. Most states in the Northern part of Nigeria have continued to boycott the nationwide polio vaccination exercise as a rumor has spread that the vaccinations have side effects that are detrimental to health and can lead to disabilities and damage to health. The Pfizer tests in Kano continue to be cited as an example, and in a society where the literacy level is low and the degree of poverty is high, millions are not able to take advantage of the benefit of the free immunization offered by the government. This undoubtedly will affect the progressive realization of the right to health of Nigerians and the UN Millennium Development Goals (MDGs).

Conclusion: The way forward

It is important to state that while pharmaceutical companies qualify as multinational corporations, the time has come to begin to treat issues relating to them differently from other classes of transnational corporations. This is because beyond the general principles of human rights, which cut across the operations of such corporations, the specific rights involved, as well as the manifestations of their violations, are obviously different. A corporation involved in the extractive industry will confront issues like environmental degradation, suppression of locals with private security outfits, and other labor issues. These do not in anyway involve intellectual property, which is at the crux of the duty of pharmaceutical companies in relation to an access to drugs.

It is important to take a cursory look at the views of pharmaceutical corporations themselves. Daniel Vasela, President and CEO of Novartis, argues there are three dimensions of responsibility with differing degrees of commitment. The first is the fulfillment of responsibility in the context of normal business activities, which he refers to as essential. The second is ambitious

corporate citizenship standards, and last are the additional desirables which the company is not expected to undertake, but which it may engage in.⁵⁶

The human rights responsibilities of pharmaceutical companies are therefore to include the respect of human rights within their operations. To this end, they must observe international human rights norms as one of the organs of society mentioned in the preamble of the 1948 Universal Declaration of Human Rights (UDHR). For a corporation, the duty to respect the right to health may require the corporation to abstain from operations that may cause environmental problems that are detrimental to the health of employees, and to people residing on the land where the corporation operates. Moreover, where corporations knowingly market unhealthy products, a violation of their obligation to respect the right to health will occur. An example of the latter is the aggressive marketing of powdered milk by multinationals in developing countries. For pharmaceutical corporations this includes a duty to not carry out medical experimentation on human subjects without obtaining their prior and informed consent, as required by various human rights instruments. The pharmaceutical companies should also have an obligation to make drugs affordable, especially in the context of epidemics like AIDS. This requires them to make their drugs available and affordable through low-cost pricing of drugs, and through the granting of voluntary licenses to other pharmaceutical companies to produce affordable drugs for consumption, especially in developing countries. They are also duty bound not to insist on the enforcement of intellectual property regimes that inhibit States from abiding by any obligations they have under international human rights instruments. A human rights approach further establishes a requirement for the state to protect its citizens from the negative effects of intellectual property. To do so, governments need to undertake a very rigorous and disaggregated analysis of the likely impact of specific innovations, as well as an evaluation of proposed changes in intellectual property paradigms, and to utilize these data to assure non-discrimination as the end result. When making choices and decisions, it calls for particular sensitivity to the effect on those groups whose welfare tends to be absent from the decision-making calculus about intellectual property: the poor, the disadvantaged, racial, ethnic and linguistic minorities, women, rural residents.

The duty to protect the right to health will come into play especially with regard to the underlying determinants of the right to health such as food and nutrition, housing, access to safe potable water and adequate sanitation, safe and healthy working conditions, and a healthy environment. The duty to protect may require a corporation to adopt guidelines in order to

ensure that its activities and the activities of its business partners will not lead to violations of any other individual's right to health.⁵⁷

To this end, it is recommended that the World Health Organization (WHO), which is the UN agency charged with health promotion, play a leading role. Although it has been involved in initiatives with private partnerships, a sector-wide, comprehensive, and all embracing mechanism needs to be established. This mechanism should be modeled along the lines of, and draw from the experience of – the “equator principles”. The principles embody commitments adopted by the International Finance Corporation (IFC) and leading financial institutions, as a framework for managing environmental and social issues in project financing.⁵⁸ The speed with which financial institutions are adhering to the principles shows that the industry has come to accept them as very desirable. From the preamble, banks commit to “not provide loans directly to projects where the borrower will not or is unable to comply with our environmental and social policies and procedures.”⁵⁹

Under this arrangement, the issue of access to drugs and neglected diseases can be addressed. The establishment of a fund, to which pharmaceutical corporations would be required to contribute an agreed percentage of their profits – which would in turn be devoted to research for neglected diseases – would ensure research even when there is no profit involved. Also, the reliance on a specific percentage of profits as contributions would ensure equity, as each company would contribute in accordance with its size and resources. The development of this mechanism will have to be gradual, and participation of all stakeholders, particularly pharmaceutical companies, is indispensable. This will promote greater compliance among the companies.

The idea that businesses have obligations corresponding to human rights is relatively new, still controversial, and involves some revision of the thinking that is expressed in the central instruments of international human rights law.⁶⁰ Companies ought to respect human rights, avoid being complicit in human rights abuses, and within their sphere of influence, do what they can to promote human rights principles. On this there is widespread agreement.⁶¹ The question remains, how can this be enforced?

Attempts at developing codes of conduct that rely purely on voluntarism have not been totally successful in ensuring the accountability of multinational corporations. If self-regulation and market forces were the best means of ensuring respect for human rights one might expect, since this has been the dominant paradigm, the number of abuses attributable to companies to have diminished.⁶² But this is not yet the case. Accordingly, there is need to evolve a mandatory mechanism within the international

human rights system. The time has come for a stronger international framework for corporate accountability, and the UN Human Rights Norms for Business are a significant contribution to this. By bringing together in one place all the major international human rights, labor rights, and environmental laws and standards pertaining to global business, and by surveying key international instruments and best practices, the UN Norms provide helpful guidance and leadership opportunities for businesses willing to comply with their legal and ethical responsibilities.⁶³ It is hoped that the transition from voluntary to mandatory enforcement of the human rights responsibilities of corporations is achieved much sooner than later.

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