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AIDS Drug as an Unregulated Commodity: Unravelling the Limits of the Current Patent Laws

H. ANGGA INDRASWARA¹

Abstract: *One of the main issues in the global endeavour to combat HIV/AIDS is the patent rights of pharmaceutical companies on antiretroviral drugs. While pharmaceutical companies insisted that patent rights are necessary to continue research and development, Third World countries claimed that patent rights hinders universal access. Against this backdrop, this essay argues that patent rights transform antiretroviral drugs into an unregulated commodity, which is distributed based on a person's purchasing power, and thus preventing universal access. As such, to enhance the global effort to fight against HIV/AIDS, it is necessary to develop global cooperation, in which antiretroviral drugs become a regulated commodity.*

Key words: *HIV/AIDS, pharmaceutical companies, patent rights, unregulated commodity, regulated commodity, global cooperation and economic democracy.*

Despite all the advancements of contemporary globalisation, many parts of the world remain haunted by the spectres of acquired immune deficiency syndrome (AIDS) — a lethal illness caused by the infection of the human immunodeficiency virus (HIV). Without a doubt, as the death toll from AIDS reached a staggering 25 million, the endeavour to combat this global pandemic warrants not only further research and investigations in the field of biomedicine, but also in other disciplines.² In the field of International Political Economy (IPE), one dimension of the AIDS epidemic that has been a subject of debate by many scholars is the issue of patent rights *vis-à-vis* the distribution of antiretroviral drugs, whose function is to prevent HIV infection from developing into AIDS.

The locus of this debate is the inequality of access to antiretroviral drugs between wealthy and poor countries resulting from the application of patent rights by pharmaceutical companies on their drugs. In the eyes of most pharmaceutical companies, patent rights play a vital role in the global struggle against AIDS. The rationale is that patent rights provide pharmaceutical companies with the robust financial incentives needed to invest in the costly research and development (R&D) activities that can lead to the discovery of enhanced antiretroviral drugs to combat the pandemic. Many developing countries and non-governmental organisations (NGOs), however, have stated that the soaring price of antiretroviral drugs, which emanates from the monopoly allowed by the current patent laws, renders the fight against AIDS impotent as the majority of those living with HIV are unable to afford the price offered in the market.

Against this backdrop, this essay argues that the application of patent rights on antiretroviral drugs have transformed the status of antiretroviral drugs into an unregulated commodity, whose distribution depends on a person's purchasing power. As the effectiveness of the global struggle against the AIDS pandemic cannot but demand universal access to antiretroviral drugs, it is necessary to develop a global cooperation based on the values of democracy, in which access to antiretroviral drugs is determined not by a person's purchasing power, but instead by a person's need.

To present this argument, this essay will be organised into three sections. Firstly, it will explore the ways in which patent rights influence the distribution of antiretroviral drugs in Third World countries. Subsequently, based on the empirical data gathered in the previous section, it will elaborate the concept of the unregulated commodity to illustrate the limits of the patent system in countering the AIDS pandemic. Finally, it will discuss the possibility of reconciling the tension between profit-making and universal access by explicating the paramount importance of building a global cooperation based on the values of democratic accountability.

Patent rights and the AIDS epidemic: A tale of contradictions

In this section, this essay will examine the ways in which patent laws have affected the distribution of antiretroviral drugs in developing and least developed countries. In order to ensure that this task is well-placed within the landscape of the problem, it will first attempt to grasp the severity of the AIDS pandemic in both First and Third World countries.

While no country is immune to the AIDS epidemic, statistics reveal that Third World countries are far more vulnerable. AIDS first entered the terrain

of medical studies in 1981, when a group of American scientists discovered a type of retroviral virus — subsequently named HIV.³ HIV deteriorates the cells of the human immune system, causing those infected to develop AIDS.⁴ Since then, HIV/AIDS has transcended beyond the borders of countries across different continents, posing a health threat to the global population in a hitherto unprecedented manner. In 2009, the UNAIDS reported that there were 33.3 million people worldwide who had been infected with HIV, and that 1.8 million of whom died because of AIDS.⁵ In the developed North American, Western and Central European states, HIV infected 2.3 million people and AIDS killed 34,500 people. In Sub-Saharan Africa — the region where the HIV is most prevalent — the number is significantly higher. In this region, the UNAIDS reported that 22.5 million and 1.3 million people contracted HIV and died because of AIDS, respectively. In South and South East Asia, 4.1 million people were infected and 260.000 were killed. As these statistics suggest, the HIV/AIDS predicament lurks in both the skyscrapers of wealthy states and the slums of poor countries. The statistics, nonetheless, also reveal that the spread of HIV/AIDS is far more severe in developing and least developed countries due to the more hazardous social, economic, political and cultural milieus which envelop them.⁶

As a response to the AIDS outbreak, the field of biomedicine has been endeavouring to develop a remedy. Although it has yet to discover a cure for HIV/AIDS, the pharmaceutical industry has successfully invented antiretroviral drugs to help curb the impact of the pandemic. Antiretroviral drugs function by thwarting the multiplication of HIV within a human's body, and thus, preventing the infection from materialising into AIDS.⁷ As studies have shown, highly active anti retroviral therapy (HAART) assists those living with HIV to maintain physical and mental health. Hence, by taking antiretroviral drugs, people who contracted HIV can still continue their participation in the workforce and, this certainly improves the welfare of the society in general.⁸ Without a doubt, the R&D of such drugs require vast amount of financial resources. Certainly, this is reason why pharmaceutical companies have been ardent proponents of patent rights.

A patent grants a person with a set of exclusive rights protected by the state for a predetermined time since the application is lodged in exchange for the public disclosure of the invention.⁹ To qualify for a patent, a product must be novel, non-obvious and capable of industrial application. Its purpose is to prevent others from reproducing, using and commercialising the claimed invention. In the prevailing market system of the modern economy, patents provide a legal bastion for corporations to reap substantial profits from

monopolising the market with their new invention.¹⁰

As international trade has become the *modus operandi* of the present global economy, most states have agreed to an international agreement on patent laws under the World Trade Organization (WTO)'s Trade Related Aspects on Intellectual Property Rights (TRIPS). A product of WTO's predecessor, the General Agreement on Tariffs and Trade (GATT), the TRIPS Agreement was negotiated during the Uruguay Round between 1986 and 1994.¹¹ Its purpose is to produce an internationally agreed patent law, which previously had varied between countries, so as to minimise the potential of conflicts in international trade. Under the TRIPS Agreement, the term of protection for a patent lasts for 20 years from the date an application is submitted. A point pertinent to this essay lies in article 31 of the TRIPS Agreement, which stipulates that patent requirements can be waived by a member in the case of a national

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emergency or other circumstance of extreme urgency or in cases of public non-commercial use.¹² Additionally, the TRIPS Agreement allows for compulsory licensing, whereby a government can grant the right to another party to produce a patented product or process without the consent of the patent owner.¹³ Unfortunately, the nature of the world is such that the existence of noble

mechanism to protect the poor does not always yield the desired results. In the present case, instead of enhancing the endeavour to curb the global HIV/AIDS epidemic, what occurs is a contest of between pharmaceutical companies and poor countries.

The first phase of the confrontation between pharmaceutical companies and developing countries led to the decline of prices in antiretroviral drugs in the twilight of the 20th century. Following the logic of the patent that allows monopoly, the annual cost of HAART when it was first released in 1996 was approximately US\$10,000 per person.¹⁴ In 1997, as a part of its commitment to combat AIDS, the South African government passed a law that allows for compulsory licensing for pharmaceutical products, including antiretroviral drugs.¹⁵ Their action was undoubtedly not welcomed by the pharmaceutical companies, which had invested billions of dollars in R&D. With the backing of their governments in the Global North, these pharmaceutical companies challenged the action of the South African government, claiming it to be 'an abrogation of intellectual property'.¹⁶ Thirty-nine pharmaceutical companies decided to file a law suit against the South African government and to lobby their governments to punish South Africa with trade sanctions. Such

circumstances called international NGOs, such as Oxfam and Médecins Sans Frontières, to rally the public to challenge the actions of the pharmaceutical companies under the basis of profiteering from AIDS.¹⁷ Cognisant of the risk of losing their market share in developed countries from negative public image, the pharmaceutical companies could not but relinquish their patent rights in order to allow producers in developing countries to sell generic products of their patented antiretroviral drugs. As a result, by 2003, the price had declined to about US\$300 or 5% of its price in developed countries.¹⁸ The war, however, is not yet over.

The incident in South Africa led to an attempt to clarify the interpretation of compulsory licensing in the TRIPS Agreement. The governments of both developed and developing countries made a breakthrough in the Doha Declaration in 2001. As a response to the initiative made by developing countries, the ministerial round in Doha issued a declaration that stipulates that

‘The TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitments to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members’ rights to protect public health and in particular to promote access to medicines for all’.¹⁹

This declaration clarified the meaning of article 31 in the TRIPS Agreement by stating that each member ‘has the right to grant compulsory licensing’ and ‘to determine what constitutes national emergency’.²⁰ Nonetheless, although the Doha Declaration has conceived the instruments to promote universal access to patented medicines in developing countries, it needs to be noted that within the WTO structure, ministerial declarations are not legally binding.²¹ Such circumstances, inevitably, brought about the next chapter of the confrontation between pharmaceutical companies and developing countries.

The apparent success in pushing for a decline in the cost of HAART in the South African case cannot be stretched too far as to lose its tentative status in the global fight against HIV/AIDS. After all, the victory cannot change the simple fact that HIV constantly mutates within the human body. This means that after a few years of first-line treatment, a second-line regimen is required in order to allow those infected to prolong their lives.²² Unfortunately, the decline in price has occurred only for first-line regimen drugs. In 2003, the average price of second-line HAART remained as high as US\$1,100 per person per year.²³ Realising that such a price is unaffordable for many of its citizens, in

2006 the Thai government decided to grant compulsory licenses for two AIDS drugs, namely efavirenz and lopinavir/ritonavir — produced by Merck and Abbott, respectively.²⁴ According to the Thai government, such an action was justifiable since it would relieve the government budget on public health care, whilst simultaneously maintaining the size of the market for pharmaceutical industries, whose patented drugs are consumed by the upper segment of the population who subscribed to private health care services. Abbott, however, reacted by withdrawing all its applications to register new drugs in Thailand and ceasing the distribution of its new medicines, including an enhanced version of antiretroviral drugs, to the country. This development shows that the mechanism to secure universal access engraved on the TRIPS Agreement does not diminish the power of pharmaceutical companies to dictate the distribution of the drugs. As a result, the lives of the poor infected with HIV remain on peril.

The high price for second-line antiretroviral drugs is clearly an obstruction to the endeavour to provide universal HAART for the unsubsidized poor infected with HIV in developing countries.²⁵ The table below shows that in 2003 the coverage of HAART in developing countries stood at a low 7%. This is in stark contrast with the almost universal treatment in developed nations. Of the 800,000 people receiving HAART in 2002, only 300,000 were in Third World countries.²⁶ The mounting costs of second-line treatment and the inability to provide universal access to antiretroviral drugs, therefore, suggest an inherent contradiction within the current concept of patent rights. As much as patent rights drive pharmaceutical companies to produce new drugs, they also inhibit the poor from gaining access to those drugs.

*Table 1: Coverage of Adults in Developing Countries
Receiving Antiretroviral Therapy by WHO Region 2003²⁷*

Region	Number of People on Treatment	Estimated Need	Coverage
Africa	100,000	4,400,000	2%
Americas	210,000	250,000	84%
Europe (Eastern Europe, Central Asia)	15,000	80,000	19%
Eastern Mediterranean	5,000	100,000	5%
Southeast Asia	60,000	900,000	7%

Western Pacific	10,000	170,000	6%
All WHO Regions	400,000	5,900,000	7%

Antiretroviral Drugs as an Unregulated Commodity

Having examined the ways in which patent laws allow pharmaceutical companies to influence the distribution of antiretroviral drugs in poor countries, it becomes clear that the issue of patent rights poses a conundrum. One issue worthy of further investigation is the relevancy of patent rights vis-à-vis the fight against the AIDS epidemic.

To begin its inquiry, this section will look at the rationale behind the application of patent rights on drugs. Hettinger notes that the proponents of patent rights claim that patent provides the financial incentives for people to continue to innovate.²⁸ Not only does patent fairly compensate the innovator for the labour exerted on the invention, it also prevents other people from ‘free-riding’ someone else’s invention. This is of paramount importance in ensuring that the society in general will continue to have the desire to innovate and create progress.²⁹ Moreover, from a utilitarian perspective, Resnik argues that since patent rights would expire after a period of twenty years, the overall society will benefit for two reasons. First is that the pharmaceutical industry will continue to innovate so as to bring more enhanced medicines, and second is that everyone in the society will have cheaper medicines once the patent has expired.³⁰ These arguments are also augmented by statistical data.

A glance at the cost paid by pharmaceutical companies on their R&D show that patent rights are indeed necessary. According to the Pharmaceutical Research and Manufacturers of America (PhRMA), the average cost of researching and developing a new medicine, and making it available to patients is approximately US\$1.3 billion.³¹ Moreover, it is estimated only 33% of new drugs developed by pharmaceutical companies are profitable.³² This is precisely why for pharmaceutical companies, patents hold a sacrosanct status. Nonetheless, one must not lose its care to discern the relevance of what is general in a particular case such as antiretroviral drugs.

One useful question to begin the investigation is whether the disappearance of patent rights actually weakens the effort to combat the AIDS epidemic. A study by Bakan suggests that the profit of pharmaceutical companies from the selling of antiretroviral drugs is largely made in the market of North America, Europe and Japan – 20% of the world’s affluent populations that constitutes 80% of the drug market’s targeted demographics.³³ The statistics, therefore, suggests that pharmaceutical companies will not lose substantial profit if they relinquish their patent rights through compulsory

licensing in poor countries.

Moreover, given the profit-seeking nature inherent in any modern-day corporation, the application of patent rights on antiretroviral drugs does not necessarily lead to new innovations that can bolster the global effort to combat the AIDS epidemic. Bakan observes that of the 1,400 drugs developed between 1975 and 1999 only 13 were manufactured to treat tropical diseases. In 2000 there were no drugs developed to treat tuberculosis, compared to eight for impotence and seven for baldness.³⁴ As such, it appears that the logic of maximising profit embraced by pharmaceutical companies will drive them to produce drugs that are more profitable in the market in developed countries. Indeed, the nature of maximising profit is such that it is what is profitable in the market that really determines what the pharmaceutical companies produce, and not the severity and the scale of an epidemic. In other words, the production of antiretroviral drugs rests on the voluntary action of the pharmaceutical industry.

It is precisely at this point where the importance of patent rights in driving the innovation of antiretroviral drugs becomes obsolete. Hank McKinnel, CEO of Pfizer, explains that 'our primary mission is to sustain the enterprise, and that, of course, requires profit'.³⁵ In other words, even though many pharmaceutical companies have now adopted corporate social responsibility (CSR) programmes and become involved in charity activities, such as drug donation, the decision as to whether the company should utilise the profit obtained from patented antiretroviral drugs depends solely on whether it serves the corporation's economic interest.³⁶ Should pharmaceutical companies decide that there is more profit in investing in a new antiretroviral medicine, they would allocate funding for researching and developing that drug. However, should they decide to utilise their resources on more profitable drugs, they could proceed with such a decision without any other institution to hold them accountable.³⁷ This analysis, therefore, reveals that the notion of innovation that stands as the *raison d'être* of patent rights is problematic. They claim that the patent rights applied on AIDS drugs are necessary to drive innovation, but at the same time, the trajectory of R&D is determined by what is profitable in the market. These are indicative of the logic on which pharmaceutical companies distribute their medicines.

Given the rationales behind the application of patent rights on antiretroviral drugs, it appears that pharmaceutical companies view and distribute their drugs according to the logic of the unregulated commodity. This essay defines the concept of unregulated commodity as goods and services that are traded in the market according to a person's purchasing power. Certainly,

this is the case with most goods available today, such as cars and jewellery. A quick glance at the world today will undoubtedly suggest that patent laws have functioned relatively well to drive the innovation of these goods, and thus, improving the livelihoods of the society in general. The application of patent rights on antiretroviral drugs with the aim of attaining profit, therefore, indicates that pharmaceutical companies distribute their life-saving drugs in the same way any other company distributes its product.

The problem is that the importance of antiretroviral drugs for those living with HIV is inherently dissimilar to the other goods that are distributed and traded in this logic. Should the market fail to distribute cars or jewellery to the poor living with HIV, who cannot afford them, they would still be able to sustain a dignified human life. In contrast, should the market fail to distribute antiretroviral drugs to the poor living with HIV, there could not be any dignified human life. Indeed, for those living with HIV, the importance of antiretroviral drug as a constitutive *sine qua non* of life is such that lower purchasing power does not bring lower demand for AIDS medications.

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Securing Universal Access through Democratic Cooperation

After unravelling the limits of patent rights, the last section of this essay will attempt to envisage the path to be travelled next. To begin with, it is necessary to discuss the relevance of the Liberal theory in IPE that underpins the concept. This exercise is of paramount importance so as to ensure that the solutions that this essay seeks to propose are grounded on both empirical data and theoretical ideas. As a child of history, patent laws are predicated upon the Liberal assumption that the market system is the most effective and efficient way of regulating the economy. Owing its origins to the works of Adam Smith, Liberal IPE theorists contend that the invisible hand of the market will ensure an efficient and equitable distribution of goods and services across the world economy.³⁸ In this sense, Liberal theorists suggest that if each economic actor pursues his/her own self-interests, society and the global political economy will enter a new realm of prosperity and harmony.³⁹ Indeed, it is within this context that liberal theorists call for a non-interventionist state. The state's role, they argue, is merely to utilise its monopoly on violence to establish and protect private property rights, the rule of law and institutions of freely functioning markets and trade, which will subsequently generate the growth required to

improve citizens' overall welfare.⁴⁰ As Wolf has observed, however, if left to its own devices, the market is bound to produce distributional inequity since its *modus operandi* is oblivious to the stark inequalities between the wealthy and the poor.⁴¹ With regards to the distribution of antiretroviral drugs, therefore, the market needs to be regulated so as to secure the pursuit of universal access.

While the Liberal idea of the free market as the *modus operandi* par excellence has its limits, the Liberal notion of cooperation is of particular significance. Given the magnitude of AIDS as a global pandemic, it is instructive to build a global cooperation that distribute antiretroviral drug as a regulated commodity. As a regulated commodity, antiretroviral drugs are distributed based on a person's need, rather than his/her purchasing power. As many Liberal theorists in IPE have noted, international cooperation is of paramount importance since cooperation amongst states and non-state actors is likely to be beneficial for all participating party.⁴² Nonetheless, as the aforementioned discussion has revealed, cooperation has not worked optimally to ensure universal access.

One way of reinvigorating global cooperation in the fight against AIDS is by reinvoking the ideals of democracy. The aforementioned examples of South Africa and Thailand show how pharmaceutical companies can opt to place the financial interests of their shareholders above the need of the people whose lives depend on them. These incidents are actually indicative of a larger trend in the present globalisation, in which multinational corporations become colossal entities, whose massive powers are not held accountable by any democratic means. As explained by Chandler and Mazlish, 'multinational corporations have an impact on almost every sphere of modern life from policymaking on the environment to international security, from issues of personal identity to issues of community, and from the future of work to the future of the nation-state and even of regional and international bodies and alliances.'⁴³

From the perspective of democracy, these circumstances call for the re-summoning of equality as the moral compass of any decision making. This should be done not simply in the fields of politics, but also in the terrain of economy. For democracy is not simply a system. It is a *modus vivendi* that presupposes that everyone's judgment deserves an equal weight in the shaping of a community and in the exercise of power.⁴⁴ A democracy void of equality in decision making is a democracy losing its constitutive *sine qua non*.

Finally, the revival of democratic values in the global political economy as a way of securing universal access to antiretroviral drugs requires a

redefinition of the purpose of corporation. For this intention, White's design principles offer a starting point. Primarily, White argues that 'the purpose of the corporation is to harness private interests in service to the public interest'.⁴⁵ Accordingly, 'corporations and their shareholders shall accrue a fair share of investment returns, but not at the expense of the legitimate interests of other stakeholders'.⁴⁶ In this sense, competition and innovation in the market will continue, but it will also have a new meaning as their purpose is no longer the accumulation of wealth, but 'the welfare of all ranks of society', including those living with HIV in poor countries.⁴⁷ This model is not without trial since it is prevalent in Scandinavian countries in which corporations are viewed as an organic entity where all participants, namely shareholders, creditors, employees and consumers, have a harmonious purpose to improve the economic development of the entire society.⁴⁸ Through a transformation of corporate role, it can be expected that the pharmaceutical companies owe a responsibility not only to their shareholders, but also to the poor living with HIV. No less importantly, the attempt to combat AIDS will have an entirely new trajectory, in which helping the poor living with HIV is not a simply spill-over effect of accumulating profit, but instead, an intended consequence of a global endeavour to eradicate AIDS by all pertinent actors.

Re-embedding Pharmaceutical Business

So far it is evident that the application of patent rights has transformed the status of antiretroviral drugs into an unregulated commodity, which is distributed based on a person's purchasing power. Statistics reveal that the AIDS pandemic is far more severe in poor countries. Despite the fact that the majority of those living with HIV are unable to afford patented drugs, as well as the Doha Declaration, which asserted the right of developing countries to exercise compulsory licensing, pharmaceutical companies maintain that patent rights should be upheld. While such an attitude may be relevant for goods, such as cars and jewellery, it needs to be emphasised that the importance of antiretroviral drugs as a constitutive sine qua non of life for those living with HIV is such that lower purchasing power does not bring lower demand for the drugs. In addition, as pharmaceutical companies obtain their resources from the ownership of private property, there is no guarantee that the profit acquired from patented antiretroviral drugs will be used to develop more enhanced versions of the medicine to better fight the AIDS pandemic. Seen in this light, it appears that patent rights are simply a legal masquerade for pharmaceutical companies to reap profits, even at the expense of the poor.

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While this analysis reveals a limit to the Liberal IPE theory about the supremacy of the market, its concept of cooperation remains pertinent in the struggle against an epidemic with such a global magnitude. To ensure that this cooperation can work for the benefit of all ranks of the global society, it is necessary to invoke the democratic values of equality in the economic sphere, and to redefine the purpose of the corporation to serve the public interests.

Having come full circle, this essay will now end by acknowledging that the solutions proposed here are more grounded more on theoretical ideas than on practical reality. Nonetheless, it has attempted to offer some signposts to the ways in which the global pharmaceutical industry should develop its trajectory since the present framework is more about reaping profits than serving the public interests. This is of course a mirage of ideals, for a human science, such as the one applied by pharmaceutical companies, emptied of human needs cannot but lose its *raison d'être*. What this essay has attempted to show is that pharmaceutical companies can only serve public interests if they are re-embedded in the lives of the communities in both developing and developed countries.

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