

# Ethical Reasons for Intellectual Property Rights Reform:

A Report (D1.3) for **INNOVA** 

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# Ethical Reasons for Intellectual Property Rights Reform: A Report (D1.3) for Innova-P2\*

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**Abstract:** Those defending the intellectual property rights regime usually take one of two routes. Either they argue that creators and inventors have a natural right to IPR protection or they argue that, on balance, IPR systems contribute positively to human well-being, and specifically, to the development and availability of life-saving medicines. Both arguments are moral arguments, one referring to rights, the other to human flourishing and happiness. In this report, we first examine these two justifications of the IPR regime. Is there a natural right to intellectual property? Or should IPR systems be judged on their contribution to social utility? We then compare several scenarios of IPR systems to establish whether any is morally superior to others. In the last part, we focus on the duties of states and pharmaceutical companies to promote any potentially superior alternative.

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## INTRODUCTION

Human beings are social creatures. They devise rules from sophisticated etiquette to international trade regimes to facilitate co-existence. One such set of rules is the intellectual property rights (IPR) system, which grants state protection to creations of the mind so that the originator can recoup any investment by charging monopoly prices for a limited period of time. The purpose of such rules is to preserve incentives for future innovations.<sup>1</sup>

Whilst often well-intended, social rules can have grievous side effects. The effect of IPRs on access to life-saving medicines is described as follows by Anand Grover<sup>2</sup>:

[A]ccess to medicines forms an indispensable part of the right to health... Nearly 2 billion people lack access to essential medicines. Improving access to medicines could save 10 million lives a year, 4 million in Africa and South East Asia. The inability of populations to access medicines is partly due to high costs.... TRIPS [Trade-Related Aspects of Intellectual Property Rights Agreement] and FTAs [Free Trade Agreements] have had an adverse impact on prices and availability of medicines, making it difficult for countries to comply with their obligations to respect, protect, and fulfil the right to health.

Grover is the UN Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health. The above excerpt from his 2009 report expresses Grover's opinion that:

- (1) One third of the world's population do not have access to life-saving medicines. This implies that every third person may be left untreated for diseases ranging from AIDS to Yellow Fever.
- (2) Due to (1), 10 million lives are lost each year, which could be saved if access to life-saving medicines were assured. Implied in this mortality figure is immense human suffering. Parents lose their children, children their carer, husbands their wives etc. And a mortality figure does not even capture the suffering associated with avoidable ill health and morbidity.
- (3) States have obligations to respect, protect, and fulfil the right to health, which includes assuring access to life-saving medicines for all.
- (4) TRIPS and FTAs led to an increase in drug prices and an invariable decrease in the availability of generic drugs.

*Hence, Grover believes, due to (4), countries are hampered in discharging (3), thereby contributing to (1) and the result of (2).*

In other words, in his view, TRIPS and FTAs<sup>3</sup> are partly responsible for lack of access to life-saving medicines and the related deaths.

10 million premature, avoidable deaths per year are a grave ill. In general, human beings value life and want to enjoy its full length from childhood to adulthood to seniority. If a human construct (the IPR regime) contributes to so many deaths per year, it is in *very* serious need of justification.

Those defending the IPR regime usually take one of two routes. Either they argue that creators and inventors have a natural right to IPR protection or they argue that, on balance, IPR systems contribute positively to human well-being, and specifically, to the development and availability of life-saving medicines. Both arguments are moral arguments, one referring to rights, the other to human flourishing and happiness.

In this report, we shall first examine these two justifications of the IPR regime. Is there a natural right to intellectual property? Or should IPR systems be judged on their contribution to social utility? We shall then compare several scenarios of IPR systems to establish whether any is morally superior to others. In the last part, we shall focus on the duties of states and pharmaceutical companies to promote any potentially superior alternative.

## **INTELLECTUAL PROPERTY AND NATURAL RIGHTS**

### **Two Types of Social Rules**

Human communities are organised by social rules, many of which are encoded in law and administered through courts. Social rules may be understood in two main ways: they may reflect ultimate moral requirements, whether set down by God or our innate moral sense, or dictated by reason; or they may be understood as serving a social purpose within human society.

The constitutional rights of individuals are typically understood in the first way, reflecting, as John Rawls says, a person's "inviolability founded on justice which even the welfare of society as a whole cannot override."<sup>4</sup> The inviolability of these rights applies across the globe and across time, and they are often referred to as natural rights.<sup>5</sup> The right not to be killed, suitably circumscribed (to allow for self-defence, for instance), is considered such a right.<sup>6</sup> Traffic rules, on the other hand, are typically understood in the second way, in terms of their social utility as facilitators of efficient travel. Such social rules are taken to be open to thoughtful revision in order to preserve or enhance their usefulness under changing conditions. By contrast, rules expressing natural-law requirements are considered outside the power of societies to change.

With regard to some social rules, their categorisation into one of these two categories is contested. Thus, some argue that the social rule against torture is based on expediency and may therefore be revised or abolished in changed circumstances, whereas others present this rule as founded on a natural right.<sup>7</sup>

The social rules that create and define property rights are subject to similar contention: some assume that such rights should be designed to promote the common good, specified as economic efficiency, for instance, or poverty avoidance.<sup>8</sup> Others, following John Locke, regard legal property rights as implementing pre-existing natural rights to acquire things and to dispose of them as one pleases.<sup>9</sup> The two disputant groups may entirely agree on what the rules should be and yet disagree sharply on their justification.

### **Are Intellectual Property Rights Natural Rights?**

The same disagreement as outlined on the topics of torture or property rights exists with regard to IPRs. Some hold that IPRs should be shaped with an eye to the common good, striking the optimal balance between encouraging innovations and

ensuring easy access to them. Others believe that innovators have a natural right to control the use of their innovation. This dispute was in evidence in the 1990s when affluent states successfully pressured less developed states to accept TRIPS, which required them to legislate for very extensive IPRs.

Some argued that adopting US-style IPRs would benefit poor countries by making them more innovative. Others argued that poor countries were morally required to adopt extensive IPRs in order to suppress the natural-law crimes of “theft,” “piracy,” and “counterfeiting” that were being committed by copycat manufacturers within their jurisdictions.<sup>10</sup>

Which position is more defensible? Should IPRs be designed with social utility in mind or help realise creators’ natural rights? One can offer three arguments against the latter, natural-law understanding of IPRs.

First, IPRs can be shaped in myriad ways, each specifying differently their mode of acquisition, scope, or duration. The most controversial debate in this context surrounds so-called “patents on life”. Whilst patents on complex living organisms, e.g. pigs<sup>11</sup>, are regularly granted in the United States (US), the Canadian Supreme Court ruled that higher life forms can not be patented within their jurisdiction. Hence, the famous oncomouse, patented in the US by Harvard University applicants, does not fall under patent protection in Canada.<sup>12</sup> Interestingly, the European Patent Office (EPO) rejected Harvard’s patent application for the oncomouse at first, but then decided to grant the patent arguing that benefits to humanity outweighed the harm to the mice.<sup>13</sup> This means that the EPO granted the patent on grounds of social utility rather than potential natural rights of creators. The dispute is ongoing given that the German Green Party together with a large group of organisations is currently lobbying the European Parliament to prohibit patents on higher life forms in Europe.<sup>14</sup>

Here, it is also important to remember that patents on life were regarded as incompatible with US patent law in 1971, when the first case was considered. The now legendary *Chakrabarty* application (Ananda Chakrabarty had produced a genetically engineered bacteria that could clean oil spills) was first rejected by the US Patent and Trademark Office. On appeal, the patent was granted by the Court of Customs and Patent Appeals by a three over two majority. On a second appeal by the US Patent and Trademark Office to the US Supreme Court, the patent was finally granted with a five to four majority. It is clear that opinions were split almost across the middle on this issue even in the US. As Jeremy Rifkin has put it, this one case “laid the all-important legal groundwork for the privatization and commodification of the genetic commons.”<sup>15</sup> It is certainly not obvious that patents on life are a natural right of inventors as the above disagreement at supreme court level in several countries shows.

Second, like ordinary property rights, IPRs often clash with other important natural rights, such as the right to life. One of the best examples of this tension can be found in the area of access to life-saving medication, the topic of this report. As medicines under patent protection are priced under monopoly conditions, their invariably high mark-ups make them unaffordable to poor patients. Given that IPR systems provide opportunities to stop generic producers from offering cheap copies of new drugs, no alternative sources of drug supply will be available to the poor, hence conflicting with - in the worst scenario - their right to life. The question, simply put, is whether the creator of a life-saving medicine should have the legal authority to deny this medicine to those who cannot afford it. (We shall return to this topic below).

Third, IPRs are not compatible with the very natural-law understanding of property rights adduced to support them. By asserting an IPR in an innovation, the

innovator claims not merely rights to the products made from own materials, but also new property rights over materials owned by others who lose their freedom to convert their materials into the same products. Such a deprivation of freedom conflicts with the natural-law understanding of property rights in material items, which render owners immune to unilateral expropriation by others. If the rights one has to use one's own material property cannot be diminished by others without the owner's consent, then there can be no IPRs—that is, no restrictions an innovator can unilaterally impose on what others are allowed to do with their own property.

An example<sup>16</sup>: in 1995, the South African Council for Scientific and Industrial Research (CSIR) obtained a patent concerning the appetite suppressant properties of a Kalahari succulent, the Hoodia. Efforts at developing commercial products from the succulent are directed at the anti-obesity market. Since then patents have been obtained in the US, the UK, Continental Europe and Japan. Given the patent, the CSIR (or its sub-licenceses) can stop competitors from bringing to market anti-obesity products based on the Hoodia. This means that impoverished communities in Namibia, for instance, or local farmers are unable to use the Hoodia growing in their own territories for commercial gain as slimming products. As this is essentially the only viable commercial opportunity involving this succulent, it renders the plant worthless in terms of livelihoods. As a result the property right in the physical plant and with it the right to do with it as one pleases (to sell it for a specific purpose) has been taken away from physical owners in favour of intellectual property rights.<sup>17</sup> One can see here that the common natural-law understanding of physical property rights—far from showing the way to an analogous natural-law understanding of IPRs—actually provides natural-law grounds against IPRs.

The above points throw sufficient doubt on the claim that creators have natural rights to the protection of their intellectual property. It is indeed unlikely that IPRs can be justified on natural law grounds. However, before we shall move on to the social utility defence, there is an important line of reasoning, which we have not yet considered. Whilst natural law does not seem to *support* IPRs, is it possible that it might actually *mandate against* such rights?

As this is not the place for a detailed excursion into natural law theory, we shall confine ourselves to its most prominent thinker: Thomas Aquinas (1225 – 1274). According to Aquinas, laws are the dictates of practical reason. Natural law is the rational, eternal order given to the universe by divine providence. Human beings, as rational creatures, are subject to natural law “in the most excellent way, in so far as ... [they] partake... of a share of providence” through “an imprint on us of the Divine light.”<sup>18</sup> This explains why natural law and natural rights are universal, according to Aquinas, independent of local, earthly traditions that may conflict with it. For him and his followers, natural law is “our intelligent participation in God's eternal law.”<sup>19</sup> It also explains why human beings can know or recognise what is required of them by the natural law. Given that they participate in eternal law as rational beings, they are able to identify ethical demands on themselves.

The main ethical demand on human beings, according to Aquinas, is that “good is to be done and pursued, and evil is to be avoided.” In one's pursuit of the good, the most important element is the preservation of human life, or as Aquinas puts it:

inasmuch as every substance seeks the preservation of its own being, according to its nature: and by reason of this inclination, whatever is a means of preserving human life, and of warding off its obstacles, belongs to the natural law.<sup>20</sup>

The protection of human life is therefore paramount to Aquinas and the right to life is part of natural law. Another part of natural law is private property. According to Aquinas, “it is lawful for man to possess property” for three main reasons<sup>21</sup>:

First because every man is more careful to procure what is for himself alone than that which is common to many or to all: since each one would shirk the labor and leave to another that which concerns the community.

Secondly, because human affairs are conducted in more orderly fashion if each man is charged with taking care of some particular thing himself, whereas there would be confusion if everyone had to look after any one thing indeterminately.

Thirdly, because a more peaceful state is ensured to man if each one is contented with his own. Hence it is to be observed that quarrels arise more frequently where there is no division of the things possessed.

What then happens when the right to life collides with the right to property, e.g. if some have more than they need and others are starving? Or if some protect their intellectual property with the result that they are depriving the poor of life-saving medication? According to Aquinas, the right to life takes precedence over the right to property. For him,

whatever certain people have in superabundance is due, by natural law, to the purpose of succoring the poor.... Since, however, there are many who are in need, while it is impossible for all to be succored by means of the same thing, each one is entrusted with the stewardship of his own things, so that out of them he may come to the aid of those who are in need. Nevertheless, if the need be so manifest and urgent, that it is evident that the present need must be remedied by whatever means be at hand (for instance when a person is in some imminent danger, and there is no other possible remedy), then it is lawful for a man to succor his own need by means of another’s property, by taking it either openly or secretly: nor is this properly speaking theft or robbery.<sup>22</sup>

In the natural law tradition, of which Aquinas is the most prominent proponent<sup>23</sup>, the right to property or intellectual property is therefore only valid as long as it does not interfere significantly with the right to life. Whilst Aquinas promotes the concept of property and hopes that the affluent’s benevolence will help the poor, he supports the acquisition of another’s property without their consent in situations of imminent danger to life.

This principle has been upheld by John Locke (1632-1704), one of the most eminent Western theorists on property rights. According to Locke “charity gives every man a title to so much out of another’s plenty, as will keep him from extreme want, where he has no means to subsist otherwise”.<sup>24</sup>

Does this mean that natural law mandates against intellectual property rights? We noted at the outset that 10 million people are dying every year due to lack of access to life-saving medicines and that this grave ill is partly due to the current IPR regime. Wouldn’t this suggest that natural law forbids IPRs or at least the current regime? No. The problem is more complex than this, as IPRs also save millions of lives every year given that they provide incentives for pharmaceutical research. An assessment of the natural law compatibility of IPRs would therefore



require for the loss of lives to be higher than the number of lives saved. This is a calculation that is very difficult to obtain. However, there is a more ambitious demand that could be drawn from natural law theory, and that aligns better with the purpose of this report. Ideally, not only would the lives lost be lower than the lives saved, but the lives lost would be reduced to their utmost minimum. How this could be done requires an examination of the social utility of IPR systems, a task we shall turn to now.

## **THE SOCIAL UTILITY OF INTELLECTUAL PROPERTY RIGHTS**

Given our above conclusions on natural rights, IPRs must be assessed by reference to the common good of humankind. In making this assessment, one must consider the effects of the system relative to those of its politically available alternatives. These effects depend on what the world is like: on present facts about resources and scarcity as well as on the present international economic order and distribution of wealth. Changes in the world may affect whether current IPR rules are justified—for example, the rule that gives monopoly pricing powers for 20 years to the creator of a life-saving AIDS medication.

### **No IPR Protection**

In the context of IPRs, it is sometimes pointed out what the world would look like without rewarding pharmaceutical innovations through patents. In such a world, little innovative pharmaceutical research would exist, at least as far as private companies were concerned. Their successful research efforts would almost invariably result in economic losses as soon as competitors, unrestrained by the IPR system, copied their inventions and offered the product at low prices. Given that they would not have to recoup investment costs, their prices would be much more attractive than the prices calculated to break even by the originator. As a result, it is argued that it is better to have medicines for the affluent now, which will trickle down to the less affluent after the expiration of the monopoly period, than to have none at all.

However, this comparison simplifies the problem beyond recognition. It is not sufficient to argue that the situation regarding access to life-saving medicines could be even worse. We could *all* be without access to drugs. An ethical assessment of the situation cannot focus exclusively on the worst possible scenario, but must instead consider whether the current situation can be improved upon.

### **The Pre-TRIPS Regime<sup>25</sup>**

Anand Grover clearly stated that “TRIPS and FTAs have had an adverse impact on prices and availability of [generic] medicines”.<sup>26</sup> One possible comparison to the current situation is therefore the pre-TRIPS situation, which allowed states to decide how to protect and reward their pharmaceutical industries on the basis of their own interests.

An example<sup>27</sup>: before 2005, Indian law only allowed patents on processes, not on products. As a result, India had a thriving generic pharmaceuticals industry that supplied copies of patented medicines cheaply throughout the world’s poor regions. However, in 1994 India signed up to TRIPS as negotiated in the Uruguay round of the General Agreement on Tariffs and Trade (GATT) treaty. As a result, India was required to introduce patents on products by January 2005. This change to Indian

patent rules hit the world's poor in two ways, directly by undercutting the supply of affordable medicines and indirectly by removing the generic competition that reduced the cost of brand-name medicines.<sup>28</sup> And as Grover has pointed out, this is exactly what has happened.

It is important here to remember that the poor currently face two problems when it comes to accessing life-saving drugs. First, due to monopoly pricing powers granted to innovators for considerable lengths of time, they cannot afford medicines that are still under patent protection. One can therefore speak of an accessibility problem (i.e. medicines are priced beyond the reach of the poor). However, patent protection is not the only problem endangering poor people's health in the context of pharmaceutical innovation. Given that the pharmaceutical industry operates almost exclusively within the profit-making sector, diseases that burden the poor are often not investigated in the first place. These diseases are referred to as 'neglected diseases', since they are often ignored by the international research community. Hence, the second hindrance could be termed an availability<sup>29</sup> problem (i.e. drugs are not being developed for the needs of the poor).<sup>30</sup>

The main argument against the pre-TRIPS regime is that it did not stimulate the development of medicines for use in less developed countries. Given the lack of patent protection in countries such as Brazil, India or South Africa, pharmaceutical companies could not rely on market exclusivity and were therefore unlikely to take potential profits in such markets into consideration when deciding upon research programs. Yet, these and other countries have considerable and increasing affluent sub-populations, which would be able to afford high drug prices. Such markets are estimated to include 500 million people compared to the 1,000 million of potential customers in rich countries.

The argument in favour of the TRIPS regime with regard to developing countries is therefore two-fold: first, it has the potential to awaken pharmaceutical interest in diseases that were hitherto not considered profitable, in order to serve an affluent minority. Second, after the monopoly interval such medicines would be within the reach of the poor in relevant countries.

It is too early for success stories of this kind. Most less developed countries were required to institute TRIPS by 1 January 2005, and certain "least developed" countries still have until 1 January 2016. However, in the long run, TRIPS may bring benefits to developing countries as compared to the pre-TRIPS regime, in particular in the area of so-called type 3 diseases, i.e. diseases that occur exclusively or overwhelmingly in poor countries.

Pharmaceutical companies may well increase research into type 3 diseases, secure in the knowledge of strict patent protection and the prospect of achieving high monopoly prices from affluent patients, government agencies, and NGOs. And whilst access to such drugs may initially be confined to the more affluent, much larger numbers of people will be able to benefit from their existence in the long run, after the monopoly pricing interval has expired.

Thus, the current regime is likely to have advantages over its predecessor with regard to the availability problem (i.e. drugs are not being developed for the needs of the poor). However, these advantages must be weighed against problems regarding the accessibility problem (i.e. medicines are priced beyond the reach of the poor). It is in this area, that the pre-TRIPS regime has clear advantages.

Before the TRIPS Agreement was adopted, most of the less developed countries had weak intellectual property protections or none at all, which enabled them to produce or import cheap generic versions of medicines that were still under patent protection. Relative to Pre-TRIPS, the current situation therefore imposes a

serious loss on the poor by pricing out of their reach new medicines that they could previously have obtained at generic prices.

It is difficult to estimate the relative effects of a set of social rules—that is, how various relevant groups of people fare differently under these rules than they would fare if other rules, or none, existed. Moreover, decisions about the design of social rules are rarely such that one option is unambiguously worse than another—that is, worse for some and better for none.

However, it is evident that the current situation is preferable for the population of affluent countries who gain access, on familiar terms, to additional medicines that would not have existed without the added market demand for patented medicines, now anticipated from less developed countries. The comparison is more complex in the case of affluent minorities in less developed countries. They are better off with regard to the availability problem; some new medicines would not have existed without the TRIPS Agreement. At the same time, they are worse off with regard to the accessibility problem. Whilst they are able to afford high monopoly prices, they are no longer able to benefit from the low prices of generic medicines. On balance, however, it seems plausible to argue that the additionally created medicines for local health needs make up for the financial losses.

The social utility of the poor, who cannot afford monopoly prices, is the most difficult to assess and they ought to be accorded great moral weight in any calculations, given that, according to Anand Grover, 10 million lose their lives each year due to lack of access to life-saving drugs.<sup>31</sup>

The extension of strong intellectual property rights through TRIPS into less developed countries, burdens the poor disproportionately as they lose access to generic copies of drugs that are still under patent protection. On the other hand, this extension of intellectual property rights may benefit the poor of the future, given that additional incentives are being provided to address health needs in developing countries. Initially, poor people would not be able to afford new medicines. However, they may benefit from purchases made on their behalf by aid agencies and governments, and eventually the relevant patents will have expired and prices will drop to just above the marginal cost level. This latter benefit could begin to materialise in 2025, 20 years after strong IPR protection was instituted.

The magnitude of these burdens and benefits is enormous and decisions of social utility are difficult to make. Currently, as Anand Grover, has pointed out, 10 million deaths per year can be attributed to lack of access to life-saving medicines. At least part of this problem is due to TRIPS and high monopoly prices, according to Grover. The exclusion of the poor from access to advanced medicines will exact a heavy toll of disease and death for the indefinite future. On the other hand, millions of people may survive or be healthy in the future thanks to the generic availability of medicines that would not have existed without TRIPS.

Human rights focused philosophers may argue that it is morally impermissible to cause severe harms, including deaths, to poor people now for the sake of protecting millions of poor people from similarly severe harms later on. They would therefore endorse the pre-TRIPS situation, given only these two choices. Yet, one cannot be satisfied with such an outcome in view of all the harm that stimulating new drug development could avert from so many future lives. From a utilitarian perspective one might therefore argue that the overall benefits outweighed the overall losses.

Most importantly, though the three scenarios we have discussed so far (no IPRs, pre-TRIPS, TRIPS) are not the only alternatives.

## IPR Reform

The problems of access to life-saving medicines are not new. In our first report, we summarised proposals for intellectual property rights reform<sup>32</sup>, aimed at resolving the accessibility problem (i.e. medicines are priced beyond the reach of the poor) and/or the availability problem (i.e. medicines are not being developed for the needs of the poor).<sup>33</sup> The following table shows again a summary of the main reform proposals.

**Table 1. Intellectual Property Rights Reform Plans and Related Efforts**

	Addresses accessibility problem	Addresses availability problem
Donation of drugs	YES	NO
Differential pricing	YES	NO
Bulk buying	YES	NO
Compulsory licensing	YES	NO
<b>Publicly funded research</b>	<b>YES</b>	<b>YES</b>
Public private partnerships	Not fully	YES
Priority Review Vouchers	NO	YES
<b>Advance Market Commitments</b>	<b>YES</b>	<b>YES</b>
<b>Health Impact Fund</b>	<b>YES</b>	<b>YES</b>

We concluded that three proposed solutions (in bold) address both the accessibility and the availability problem, namely publicly funded research, Advance Market Commitments<sup>34</sup> (AMCs) and the Health Impact Fund<sup>35</sup>. All three are dependent on individual donations, taxpayers' contributions or funding from non-governmental organisations (NGOs). Publicly funded research suffers from the typical drawback of push mechanisms<sup>36</sup>, namely that it expends funds on unsuccessful research attempts. The other two proposals do not suffer from this drawback, as they are both pull mechanisms<sup>37</sup>. However, the focus of Advance Market Commitments is very restricted and to date only one type of treatment (vaccine) for one disease (pneumococcal disease) has been covered by an AMC. By contrast, the Health Impact Fund is a pull mechanism, which is much broader in scope and open to all types of treatments for all diseases. Its current disadvantage is that it still needs to find a solid funding base.

When assessing the social utility of the current IPR system, it is important to consider all alternatives, not just the most radical (abolition), those referring to the status quo (TRIPS) and those referring to the past (pre-TRIPS).

Of the three workable reform plans, only one – the Health Impact Fund – is broad enough to provide a real reform alternative. The following gives a brief summary of the fund.

### The Health Impact Fund

The Health Impact Fund seeks to stimulate research and development of life-saving pharmaceuticals to provide wide access to the most effective pharmaceuticals,

without endangering incentives. The proposed Fund is an optional mechanism that offers pharmaceutical innovators a supplementary reward based on the health impact of their products, if they agree to sell those products at designated low prices.

*How would it work?*

Pharmaceutical innovators holding valid patents can elect to sell their product globally at a low price agreed with the Fund. In exchange, they will be paid by the Fund annually for ten years based on their product's assessed health impact. Participating firms will also offer zero-priced relevant licenses following the ten years.

*How much would each firm earn?*

The low price will be set to cover manufacturing costs, so firms' profits will derive solely from payments from the Fund. Each year, the Fund will have a fixed pay-out – \$6bn to begin with – to be distributed among the products firms elect to register. This annual pay-out will be shared among firms in proportion to the assessed global health impact of their drugs in the preceding year. Thus, products will be rewarded strictly in proportion to their health benefits (pay for performance).

*What drugs would be included?*

The Health Impact Fund would be most attractive for products that are expected to have a large global health impact but relatively low profitability under monopoly pricing. For example, a drug treating a disease mainly afflicting poor people will be an excellent candidate for registration, since typically such products cannot earn high profits, though they could benefit many people. Thus, the Fund will provide important additional incentives to develop drugs for neglected diseases.

*How would it affect consumers?*

Consumers will benefit from the availability of new drugs at low prices: through reduced cost for national health systems, reduced insurance premiums, and reduced prices at the pharmacy. They will benefit further from increased medical knowledge and better protection against invasive diseases, from the increased concern of pharmaceutical companies with the health impact of their products rather than merely with sales, from reduced counterfeiting incentives, and from massive reductions in the global burden of disease with associated gains in economic productivity world-wide.

*How would health impact be assessed?*

Health impact can be assessed in terms of a variant of quality-adjusted life years (QALYs), a metric that has been extensively used for more than a decade. Taking the preceding state of the art as a benchmark, the assessment would estimate to what extent the new drug has improved public health worldwide by improving the health of patients who otherwise would have consumed an inferior medicine or none at all. The estimate would be based on data from clinical trials, including pragmatic trials in real-life settings, on tracking randomly selected packages to their end users, and on statistical analysis of sales data as correlated with global burden of disease data. These estimates would necessarily be rough, at least in the beginning. But so long as

any errors are random, or at least not exploitable by registrants, the incentives provided by the Fund would be disturbed only minimally.

*Would patent rights be affected?*

No. Innovators retain their patent rights. They can elect to give up the freedom to charge monopoly prices in exchange for Health Impact payments from the Fund. Firms will probably make this choice only when they expect higher profits from these payments than from monopoly prices.

*How would the Fund be financed?*

Governments and other donors would commit to long-term funding. Some of the Fund's cost to taxpayers will be offset by savings on medicines that would otherwise have been bought at much higher prices.

The Fund's greatest benefit is that patients will gain access to important medicines that, without the Fund, would have been too expensive for them, or even non-existent. In this regard, the Fund addresses both the accessibility and the availability problem.

As the Fund is currently the only reform plan, which avoids expending public resources on unsuccessful research attempts and which is not restricted to particular diseases, it must be regarded as the most promising approach to mitigating the detrimental effects of the TRIPS regime. Importantly, the Fund does not require a weakening of intellectual property rights, which may lead to fewer medicines in the future, thereby putting the affluent and the poor at risk. On the contrary, it preserves the advantages of the TRIPS regime, namely that pharmaceutical companies are now likely to consider the affluent section of developing country markets in their research programs, whilst allaying its main problems for the poor. Through its two-tiered system of providing incentives for the pharmaceutical industry, the Fund meets the requirements of both social utility and natural law (focusing on the right to life) better than any existing regime.

For the remainder of the report, we shall discuss whose obligation it is to push for such reform in order to avoid unnecessary deaths.

## **THE RIGHT TO HEALTH – STATE OBLIGATIONS**

We have just seen that there is an alternative to both the pre-TRIPS and the TRIPS regime, which has the potential to avoid millions of unnecessary deaths. The Health Impact Fund presents a feasible reform plan, which has the potential to preserve the strengths of the TRIPS regime whilst mitigating its disastrous impact on the poor.

More than sixty years ago, the governments of the world came together to assert that each human being has a right to the enjoyment of the highest attainable standard of physical and mental health (even though it was not phrased so complexly at the time).<sup>38</sup> On 10 December 1948, the United Nations General Assembly affirmed that state parties have pledged to respect and observe the human rights listed in the Universal Declaration of Human Rights. The right to health has since been enshrined in both binding and non-binding legal instruments, as the following table shows.

**Table 2. Legal Instruments – Right to Health**

Government obligations towards their own citizens:	Government obligations for international assistance:
Universal Declaration of Human Rights, Art.25(1) <sup>39</sup>	Declaration of Alma-Ata, Art.II <sup>43</sup>
International Covenant on Economic, Social and Cultural Rights, Art.12 <sup>40</sup>	UN Committee on Economic, Social and Cultural Rights E/C.12/2000/4, General Comment No.14. <sup>44</sup>
Convention on the Elimination of All Forms of Discrimination against Women, Art.12 <sup>41</sup>	Millennium Development Goals 4, 5 and 6 <sup>45</sup>
Convention on the Rights of the Child, Art.24(1-3) <sup>42</sup>	Convention on the Rights of the Child, Art.24(4)

As Anand Grover has rightly noticed in the report which criticises TRIPS' effect on access to life-saving medicines<sup>46</sup>:

States have an obligation under the right to health to ensure that medicines are available, financially affordable, and physically accessible on a basis of non-discrimination to everyone within their jurisdiction. Developed States also have a responsibility to take steps towards the full realization of the right to health through international assistance and cooperation.

It is also worth quoting from the International Covenant on Economic, Social and Cultural Rights, a legally-binding multilateral treaty adopted by the United Nations General Assembly on 16 December 1966 (in force since 3 January 1976). The treaty commits state parties to work toward the granting of economic, social, and cultural rights to individuals, with Art. 12 referring to the right to health. As the comment on the implementation of this article explains<sup>47</sup>:

Health is a fundamental human right indispensable for the exercise of other human rights. Every human being is entitled to the enjoyment of the highest attainable standard of health conducive to living a life in dignity. The realization of the right to health may be pursued through numerous, complementary approaches, such as the formulation of health policies, or the implementation of health programmes developed by the World Health Organization (WHO), or the adoption of specific legal instruments. Moreover, the right to health includes certain components, which are legally enforceable.

Signatories to the International Covenant on Economic, Social and Cultural Rights must strive towards securing the highest attainable standard of health for all their citizens. The obligation covered in this Covenant therefore refers to duties within the borders of states.

In 1978, these national duties were complemented by the Declaration of Alma-Ata, which requests international assistance for developing countries. In particular it notes in Art II that<sup>48</sup>:

[t]he existing gross inequality in the health status of the people particularly between developed and developing countries as well as within countries is politically, socially and economically unacceptable and is, therefore, of common concern to all countries.

Even though one may be sceptical about the power of non-binding declarations, reading this declaration in 2009 is particularly depressing, as Art X expresses the hope that

[a]n acceptable level of health for all the people of the world by the year 2000 can be attained through a fuller and better use of the world's resources, a considerable part of which is now spent on armaments and military conflicts.<sup>49</sup>

It is time that state parties resolved to collaborate to enable their citizens to enjoy the highest attainable standard of physical and mental health, which requires access to life-saving drugs. It is morally unjustifiable to uphold the current IPR system without sustained attempts at mitigating its detrimental effects on the poor. The relevant commitments of states have been made over 60 years ago and since then regularly repeated. There is an opportunity now to preserve the advantages of TRIPS and resolve some of its problems.

States might be supported in this undertaking by the pharmaceutical industry, as we shall see in the next and final section.

## **THE RIGHT TO HEALTH - PHARMA OBLIGATIONS**

Should the pharmaceutical industry shoulder a share of the responsibility for supplying life-saving drugs to the poor? Disagreements about the obligations of pharmaceutical corporations could not be more extreme than on the topic of providing life-saving drugs to the poor.

On the one hand, some recognise no such obligation at all. Most broadly, Economics Nobel Laureate Milton Friedman declared: "The social responsibility of business is to increase its profits."<sup>50</sup> This position is re-emphasised in the context of life-saving medicines by Bernard Lemoine, Director-General of France's National Pharmaceutical Industry, when he says:

I don't see why special effort should be demanded from the pharmaceutical industry. Nobody asks Renault to give cars to people who haven't got one.<sup>51</sup>

On the other hand, some NGOs and academics make very substantial demands. For instance, Oxfam devoted a 56-page report to demanding that the pharmaceutical

industry must put access to medicines at the heart of its decision-making and practices... [S]ociety expects pharmaceutical companies ... to develop necessary products at prices that are affordable... The pharmaceutical industry is expected to fulfil these requirements reliably and sustainably, and by so doing, play its part in the wider responsibilities to improve the health of all.<sup>52</sup>

Amongst academics, Thomas Dunfree, for instance, demands that



[f]irms possessing a unique human catastrophe rescue competency have a moral obligation to devote substantial resources toward best efforts to aid the victims of the catastrophe... These duties apply to the global pharmaceutical companies in the context of the AIDS pandemic in sub-Saharan Africa.<sup>53</sup>

It would go beyond the space of this report to detail all justifications given in support of the above positions. These range from excessive profits<sup>54</sup> to 'you must, if you can'<sup>55</sup>, to enlightened self-interest<sup>56</sup> and a co-responsibility for the human right to health<sup>57</sup>.

Examined individually, standard justifications for the obligation to provide life-saving medicines to the poor do not hit the crux of the matter. For instance, excessive profits in the car industry do not lead to demands to provide cars to the poor. Of course, one can point out that life-saving medicines provide for basic human needs, cars do not.<sup>58</sup> However, exorbitant prices on basic foods, another prerequisite for human survival, do not normally lead to requests on the food industry. Instead state action is demanded, as in August 2009, when the Indian Communist Party (CPI-M) presented demands to the government on how to deal with the high prices for rice.<sup>59</sup> 'You must, if you can' does not also lead to demands on food producers to supply sustenance to the starving. Philanthropy is good business for all within affluent societies and not limited to pharmaceutical corporations. And no other corporate sector is regularly being made co-responsible for the attainment of human rights in a positive, enabling rather than refraining form. The following will clarify further.

The UN Global Compact<sup>60</sup>, the most powerful initiative to foster corporate social responsibility, has outlined ten principles. Nine of them revolve around labour standards, environmental concerns<sup>61</sup>, anti-corruption policies and complicity in human rights abuses. Essentially, businesses are asked to refrain from harmful behaviour, for instance, the employment of children, violence by company security forces, discrimination, pollution or bribery. These actions put limits onto what businesses can do to increase their profits. Whilst child labour may be cheaper than adult labour, it is unethical to employ children.

Only Principle 1 is more general. It says: "Businesses should support and respect the protection of internationally proclaimed human rights."<sup>62</sup> Examples given of how companies can discharge this obligation are very specific, though, and they are all connected to workers and immediate communities (rather than distant strangers). For instance, companies are asked to provide "safe and healthy working conditions", prevent "the forcible displacement of individuals, groups or communities" and, in the context of this report, provide "access to basic health, education and housing for the workers and their families, if these are not provided elsewhere."<sup>63</sup> Hence, the UN Global Compact does not demand that a pharmaceutical company contributes to the provision of life-saving medicines to the poor, except for company workers whose health care is not covered otherwise.

What then is the crux of the matter? This is best illustrated by comparing a company that produces anti-retrovirals (ARVs) with a company that produces food. In 2008, the yearly cost of providing second-line ARVs to AIDS patients was \$US1105 per patient in low income countries.<sup>64</sup> These drugs were still under patent protection. Hence, no cheap generic alternatives were available. According to NGO figures, to feed a child to protect him or her from starvation or severe malnutrition costs US\$630-US\$1260 per year, depending on the country and the setting and assuming the child has no additional medical complications.<sup>65</sup> Both the right to health and the right to food are enshrined in the same article of the Universal Declaration of Human Rights. Art. 25(1) says:

Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including **food**, clothing, housing and **medical care** and necessary social services, and the right to security in the event of unemployment, sickness, disability, widowhood, old age or other lack of livelihood in circumstances beyond his control.<sup>66</sup>

Why then is Unilever, one of the largest multinational food producers, not asked regularly and pressingly to contribute to global food security? What is the difference to, let's say, Pfizer, Merck and Glaxo Smith Kline's potential to contribute to global health? They both service basic human needs and the costs of achieving survival are comparable. Essentially one word: patents, or more broadly, intellectual property right protection. Barring entry to copied products for a specified interval provides innovators with a chance to charge monopoly prices. Amongst those who benefit from intellectual property rights protection, the pharmaceutical industry is the *only* industry that trades almost exclusively in goods that are required to satisfy basic human needs.

In line with Art.25(1) above, we take basic human needs to comprise: food, clothing, housing and medical care.

Films, software, books, designs, circuit layouts, computer programs, new technical inventions etc.; none of these satisfy basic human needs. The only exception is the seeds industry, which does benefit from intellectual property rights protection whilst providing for basic human needs. However, considerable farmers' rights against multinational corporations have been established under the International Treaty on Plant Genetic Resources for Food and Agriculture ("ITPGR"). This treaty exempts a number of basic food and seed crops from patenting and makes them accessible to all member states through a facilitated system.<sup>67</sup> As there are no such exemptions for the pharmaceutical industry and the compulsory licensing exemption is hardly ever evoked, the pharmaceutical industry is unique in benefiting from monopoly pricing powers at the same time as providing for a basic human need.

Whilst states are the main duty bearers when it comes to providing access to health care for their citizens or international assistance to poor states, the support of an IPR reform plan, such as the Health Impact Fund, could show corporate social responsibility on the part of pharmaceutical companies, given that they are the only commercial entities that provide for essential human needs under the protection of patents. This also aligns with the position on moral obligations of pharmaceutical companies with regard to access to life-saving medicines as supported by the current Director of the Novartis Foundation, Klaus Leisinger. He wrote:

I perceive it to be in the enlightened self-interest of a pharmaceutical company to be part of the solution to the access-to-medicines problem, by committing to a human-rights-aware, innovative, and creative portfolio of assistance to the poorest 2.5 billion people in the world. I consider this first of all to be the 'right thing to do'. To contribute to the solution of a problem that claims millions of lives every year will (probably) also contribute to a corporation's social acceptance and hence to its longterm license to operate.<sup>68</sup>

## CONCLUSION

Every year, 10 million human beings die because they do not have access to life-saving medicines. Some may not have access to doctors or pharmacies; others may be so poor that they cannot even afford cheap generic drugs, yet others – as the UN Special Rapporteur for the Right to Health has confirmed – die because they are unable to pay high monopoly prices for drugs in a world changed by the TRIPS agreement.

The human right to health has been enshrined in the Universal Declaration of Human Rights for over sixty years. The sheer scale of the challenge of securing it for all is no excuse for paralysis. That one cannot resolve all problems at once (e.g. access to doctors *and* affordable drug prices) does not mean that one can rest and ponder. In this report, we have shown that intellectual property right systems have to be designed with overall human well-being and flourishing in mind. They are not mandated to secure natural rights of inventors to have their mind creations protected. In fact, there are no such natural, universally valid rights to IPRs. Any benefits to inventors need to be weighed up against benefits to humankind.

The Pre-TRIPS regime had certain advantages over the TRIPS regime. It allowed the production and distribution of cheap copies of patented drugs by generic manufacturers, mostly from India, South Africa and Brazil. As a result, some poor patients had access to life-saving drugs that are no longer available to them today. Yet, the Pre-TRIPS regime did not provide the pharmaceutical industry with incentives to consider neglected diseases, diseases occurring mostly in developing countries. As a result, not even the affluent in developing countries had their health needs served. Both systems therefore show some social utility, but also room for improvement. Yet, as we have noted, these two are not the only alternatives.

The Health Impact Fund leaves intact strong incentives for the pharmaceutical industry around the globe, thereby preserving the TRIPS advantages, whilst mitigating its main challenge, namely to block access to life-saving medicines to the poor. By registering a patented medicine with the Fund, a firm would agree to sell it globally at cost. In exchange, the firm would receive, for a fixed time, payments based on the product's assessed global health impact. The arrangement would be optional and it would not diminish patent rights, it therefore aligns the interests of pharmaceutical companies with the interests of poor patients. Such a win-win situation has to be welcomed! By supporting the Fund, governments would discharge part of their obligation towards the right to health, whilst pharmaceutical companies could follow the path of enlightened self-interest in increasing the social acceptance of their corporations.

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## ENDNOTES

<sup>1</sup> Danzon, Patricia M. and Towse Adrian (2003) Differential Pricing for Pharmaceuticals: Reconciling Access, R&D and Patents, *International Journal of Health Care Finance and Economics*, Vol.3:183-205, p.185.

<sup>2</sup> Grover, Anand (2009) Promotion and Protection of all Human Rights, Civil, Political, Economic, Social and Cultural Rights, including the Right to Development, a Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, United Nations, A/HRC/11/12, pp.6, 7, 28.

<sup>3</sup> We shall concentrate on TRIPS henceforth.

<sup>4</sup> Rawls, John (1999) *A Theory of Justice*, Cambridge, Mass.: Harvard University Press, p. 3.

<sup>5</sup> Brown, Brendan F. (Ed.) (1960) *The Natural Law Reader*, New York: Oceana Publications.

<sup>6</sup> Finnis, John (1980) *Natural Law and Natural Rights*, Oxford: Clarendon Press, p. 281.

<sup>7</sup> Brecher, Bob (2007) *Torture and the Ticking Bomb*, Oxford: Blackwell Publishers.

<sup>8</sup> Rawls, John – see note 4.

<sup>9</sup> Nozick, Robert (1974) *Anarchy, State, and Utopia*, New York: Basic Books.

<sup>10</sup> Yet, others asserted pressure by promising a social utility bargain independent of IPR mechanisms, namely trade liberalisation (e.g. reduction of subsidies on agricultural products). However, this is not relevant here.

<sup>11</sup> Jentzsch, Christian (2006) *Patent for a pig -- the big business of genetics : a film*, HTTV Production for WDRWestdeutscher Rundfunk.

<sup>12</sup> Canadian Environmental Law Association (not dated) *Life Patents – The Oncomouse Case*, <http://www.cela.ca/collections/celacourts/life-patents-oncomouse-case>, accessed: 25 November 2009.

<sup>13</sup> Irwin, Aisling (1995) *Patent Battle Over Life*, *Times Higher Education*, <http://www.timeshighereducation.co.uk/story.asp?storyCode=95686&sectioncode=26>, accessed: 25 November 2009.

<sup>14</sup> Institute of Science in Society (2009) *Europe's Uprising Against GMOs and Patents on Life* <http://www.i-sis.org.uk/EuropesUprisingAgainstGMOs.php>, accessed: 25 November 2009.

<sup>15</sup> Rifkin, Jeremy (1998) *The biotech century: Harnessing the gene and remaking the world*, New York: Jeremy P. Tarcher/Putnam, p.43.

<sup>16</sup> Wynberg, Rachel and Chennells, Roger (2009) *Green Diamonds of the South: An Overview of the San- Hoodia Case*, in: Wynberg, Rachel; Schroeder, Doris; Chennells, Roger (Eds) (2009) *Indigenous Peoples, Consent and Benefit Sharing*, Springer, Berlin, 89-124.

<sup>17</sup> One might argue that the above example has not been explained in all its complexity given the restraints imposed on patent applicants by the Convention on Biological Diversity (CBD). However, this is irrelevant for the clash between property and intellectual property rights under discussion. In fact, one could even argue that one of the main results of the CBD is that it prioritises physical property rights over intellectual property rights by legislating for non-human genetic resources to fall under the national sovereignty of states.

<sup>18</sup> Aquinas, Thomas (1947 [1274]) *Summa Theologica – Of the various kinds of law*, <http://www.sacred-texts.com/chr/aquinas/summa/sum229.htm>, accessed: 25 November 2009.

<sup>19</sup> May, William (2000) *Contemporary Perspectives on Thomistic Natural Law*, in: *St. Thomas and the Natural Law Tradition*, John Goyette, Mark Latkovic, and Richard Myers (eds), Washington, D.C.: The Catholic University of America Press, 2004, pp. 138-184, p.132.

<sup>20</sup> Aquinas, Thomas (1947 [1274]) *Summa Theologica – Of the natural law*, <http://www.sacred-texts.com/chr/aquinas/summa/sum232.htm>, accessed: 25 November 2009.

<sup>21</sup> Aquinas, Thomas (1947 [1274]) *Summa Theologica – Of theft and robbery*, <http://www.sacred-texts.com/chr/aquinas/summa/sum322.htm>, accessed: 25 November 2009.

<sup>22</sup> Ibid.

<sup>23</sup> Murphy, Mark (2008) The Natural Law Tradition in Ethics, Stanford Encyclopedia of Philosophy, <http://plato.stanford.edu/entries/natural-law-ethics/>, accessed: 25 November 2009.

<sup>24</sup> Locke, John (1823) Two Treatises of Government, Book 1, London: Thomas Tegg; W. Sharpe and Son;p.31, <http://socserv.mcmaster.ca/econ/ugcm/3ll3/locke/government.pdf>, accessed: 25 November 2009.

<sup>25</sup> This section draws heavily on Pogge, Thomas and Hollis, Aidan (2008) The Health Impact Fund – Making New Medicines Accessible to All, Incentives for Global Health, pp.52-54.

<sup>26</sup> Grover, Anand (2009) See note 2, p. 28.

<sup>27</sup> From Pogge, Thomas and Schroeder, Doris (2009) Why We Need A New Approach to Pharmaceutical Innovation – A Pragmatic Answer to a Moral Question, in: Marc Noppen and Marleen Wynants (eds.) In *Sickness and Health – The Future of Medicine*, Brussels: Vrije Universiteit Brussel Press, 197-213, p.202.

<sup>28</sup> Editorial (2005 January 18). India's Choice. The New York Times.

<sup>29</sup> Grover uses the term differently, in all likelihood referring to the non-availability of generic drugs.

<sup>30</sup> Selgelid, Michael and Sepers, Eline M. (2006) Patents, Profits, and the Price of Pills: Implications for Access and Availability, in: Illingworth, P., Schuklenk, U. and Cohen, J.C. (eds) *The Power of Pills: Social, Ethical and Legal Issues in Drug Development, Marketing and Pricing Policies*, Pluto Press, pp.153-163, p.153.

<sup>31</sup> Grover, Anand (2009) See note 2, pp.6, 7, 28.

<sup>32</sup> Schroeder, Doris and Singer, Peter (2009). *Intellectual Property Rights Reform Plans – A Report for Innova*, [www.uclan.ac.uk/innova](http://www.uclan.ac.uk/innova) accessed: 12 October 2009.

<sup>33</sup> Selgelid, Michael and Sepers, Eline M. (2006) See note 30, p.153.

<sup>34</sup> Advance Market Commitments create incentives for pharmaceutical innovation by removing the risk that nobody will be interested in the result. A group of sponsors, e.g. governments or NGOs, join forces and promise to buy a certain quantity of products at fixed prices with a given specification (e.g. a vaccine against disease x).

<sup>35</sup> For a description of the fund see below and also Hollis, Aidan and Pogge, Thomas (2008) *The Health Impact Fund – Making Medicines Accessible for All, Incentives for Global Health*.

<sup>36</sup> Push and pull mechanisms are incentive tools to achieve certain goals. A push mechanism provides funds to an individual or a specified group according to a given brief. For instance, a research institute is awarded a grant to develop a malaria drug. If the institute fails to achieve the goal before the grant runs out, the failure was funded by public funds. Pull mechanisms, on the other hand, only pay for the result, i.e. they will pay a promised amount to the first who delivers the goal as set in the brief.

<sup>37</sup> See note 36 for explanation of push mechanism.

<sup>38</sup> The Universal Declaration of Human Rights (1948) <http://www.un.org/en/documents/udhr/>, accessed: 25 November 2009.

<sup>39</sup> The Universal Declaration of Human Rights (1948), see note 38.

<sup>40</sup> International Covenant on Economic, Social and Cultural Rights (1966) <http://www2.ohchr.org/english/law/cescr.htm>, accessed: 25 November 2009.

<sup>41</sup> Convention on the Elimination of all Forms of Discrimination Against Women (1979)

<http://www.un.org/womenwatch/daw/cedaw/text/econvention.htm>, accessed: 25 November 2009.

<sup>42</sup> Convention on the Rights of the Child (1989)

<http://www2.ohchr.org/english/law/crc.htm>, accessed: 25 November 2009.

<sup>43</sup> Declaration of Alma-Ata (1978)

[www.who.int/hpr/NPH/docs/declaration\\_almaata.pdf](http://www.who.int/hpr/NPH/docs/declaration_almaata.pdf), accessed: 25 November 2009.

<sup>44</sup> Committee on Economic, Social and Cultural Rights (2000) Substantive Issues Arising in the Implementation of the International Covenant on Economic, Social and Cultural Rights,

[http://www.unhcr.ch/tbs/doc.nsf/\(symbol\)/E.C.12.2000.4.En](http://www.unhcr.ch/tbs/doc.nsf/(symbol)/E.C.12.2000.4.En), accessed: 25 November 2009.

<sup>45</sup> Millennium Development Goals (2000)

<http://www.un.org/millenniumgoals/bkgd.shtml>, accessed: 25 November 2009.

<sup>46</sup> Grover, Anand (2009) See note 2, p.6.

<sup>47</sup> International Covenant on Economic, Social and Cultural Rights (1966), see note 40.

<sup>48</sup> Declaration of Alma-Ata (1978), see note 43.

<sup>49</sup> Ibid.

<sup>50</sup> Friedman, M., (1995). Legitimacy and Responsibility, in: Hoffmann, W. / Frederick, R. (eds), *Business Ethics – Reading and Cases in Corporate Morality*, 3rd edition, McGraw Hill, New York, pp.137-141.

<sup>51</sup> Joseph, Sarah (2001) Pharmaceutical Corporations, Access to Drugs, and Human Rights,

<http://www.law.monash.edu.au/castancentre/conference2001/papers/joseph.html>, note 87, accessed: 25 November 2009.

<sup>52</sup> Oxfam (2007) Investing for life - Meeting poor people's needs for access to medicines through responsible business practices, [http://www.oxfam.org/en/policy/bp109\\_investing\\_for\\_life\\_0711](http://www.oxfam.org/en/policy/bp109_investing_for_life_0711), accessed: 25 November 2009, pp.3f.

<sup>53</sup> Dunfee, Thomas W. (2006) Do firms with unique competencies for rescuing victims of human catastrophes have special obligations? Corporate responsibility and the aids catastrophe in Sub-Saharan Africa, *Business Ethics Quarterly*, v16 i2, p185(26), pp, 185, 190.

<sup>54</sup> Joseph, Sarah (2003) Pharmaceutical Corporations and Access to Drugs: The Fourth Wave of Corporate Human Rights Scrutiny, *Human Rights Quarterly* 25(2)425-452.

<sup>55</sup> Dunfee, Thomas W. (2006), see note 53, p.185.

<sup>56</sup> Pogge, Thomas and Schroeder, Doris (2009), see note 27.

<sup>57</sup> The Lancet (2009) Editorial: Right-to-health responsibilities of pharmaceutical companies, Vol.373, p.1998.

<sup>58</sup> Except for the car of the midwife or other health care workers who need to cover a large rural area with no public transport.

<sup>59</sup> Thaindian News (2009) CPI-M to launch agitation against price rise, drought, [http://www.thaindian.com/newsportal/politics/cpi-m-to-launch-agitation-against-price-rise-drought\\_100238934.html](http://www.thaindian.com/newsportal/politics/cpi-m-to-launch-agitation-against-price-rise-drought_100238934.html), accessed: 25 November 2009.

<sup>60</sup> United Nations Global Compact (2000) The Ten Principles, <http://www.unglobalcompact.org/AboutTheGC/TheTenPrinciples/index.html>, accessed: 25 November 2009.

<sup>61</sup> It may sound as though Principle 9 “Businesses should encourage the development and diffusion of environmentally friendly technologies” is not about

refraining from unethical action but about actively promoting new technologies. However, when one reads the explanatory details, one realises that the principle is addressed at polluters who are requested to cut down on detrimental environmental impact.

<sup>62</sup> United Nations Global Compact (2000), see note 60.

<sup>63</sup> United Nations Global Compact (2000), see note 60.

<sup>64</sup> Avert (not dated) Aids, Drug Prices and Generic Drugs, <http://www.avert.org/generic.htm>, accessed: 25 November 2009.

<sup>65</sup> Personal communication Miltos Ladikas, figures from Action Contré La Faim (ACF), Paris on 29 October 2009.

<sup>66</sup> The Universal Declaration of Human Rights (1948), see note 38 (our emphasis).

<sup>67</sup> Helfer Laurence (2004) Intellectual property rights in plant varieties - International legal regimes and policy options for national governments, Part IV, <http://www.fao.org/docrep/007/y5714e/y5714e05.htm>, accessed: 25 November 2009.

<sup>68</sup> Leisinger, Klaus (2009) Corporate Responsibilities for Access to Medicines, *Journal of Business Ethics* 85:3-23, p.5.