

# Pharmaceutical Patents, Human Rights and the HIV/AIDS Epidemic\*

Nathan Geffen

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## 1 Status of the HIV/AIDS Pandemic

There is likely to be consensus among the delegates at this meeting that the devastation caused by the HIV/AIDS pandemic has been tremendous. The UNAIDS report on the global HIV/AIDS epidemic of June 2000, estimates that over 18 million people have died of this disease. Furthermore, the potential exists for worse to come, unless sustainable solutions are implemented. The same report estimates that over 34 million people are living with HIV, the vast majority of them in poor and middle-income countries, especially sub-Saharan Africa. South Africa, alone, has approximately 4.7 million infections according to the government's ante-natal clinic study for 2000. There is a consensus in academic literature that the social and economic impact of allowing the status quo to continue will be catastrophic. Summarising some of the consequences from researchers, left to itself, the epidemic will result in

- life-expectancy in sub-Saharan Africa falling to 43 in 2020, instead of 62,
- reduced household incomes in families with infected adults,
- rises in medical expenditure,

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- reduced labour forces, increased absenteeism and a reduced mean age of workers,
- an enormous number of orphans – already there are over 13 million AIDS orphans; and
- an erosion of the supply of teachers in sub-Saharan Africa which is likely to dent the quality of education.

Epidemiologists and economists predict that, if nothing is done, the epidemic will negatively affect human development indices for the world's poorest countries and probably reduce their economic growth rates. Advocating for the implementation of sustainable solutions to the epidemic is therefore relevant to the WBCSD's work. [2, 3, 4, 5, 6]

While combating the epidemic is definitely going to be difficult, costly and imperfect, the Treatment Action Campaign (TAC) advocates that HIV/AIDS does not have to be a death sentence and that sustainable solutions, encompassing treatment and prevention programmes, exist which must be implemented. There is likely to be consensus among the delegates here that the obstacles to successfully combating the disease include lack of finance in poor countries, lack of political will, the debt burden of poor countries, inadequate infrastructure, lack of treatment literacy, poverty and poor nutrition. Most of these issues are addressed in the excellent, recently released, Harvard Consensus Statement[7]. TAC understands the importance of these issues and conducts campaigns around them. The point of contention in this forum is the role of pharmaceutical patents as well as the role of the multinational pharmaceutical industry in exacerbating or alleviating this pandemic. On these issues, it is TAC's contention that:

- Pharmaceutical patent abuse is a central obstacle to successfully implementing treatment programmes in many poor countries.
- HIV/AIDS is a health issue, and, therefore, a human rights issue. Health-care concerns should always supersede trade concerns.
- The production and importation of generic antiretrovirals and other essential, medicines necessary for treating opportunistic infections associated with HIV/AIDS, using voluntary and compulsory licenses where necessary, is a critical part of a successful, *sustainable* treatment programme for many countries.

It should be noted, in contrast to some misconceptions that have circulated, that this does not mean that patent-holders will not make any profits on

medicines manufactured under compulsory license. TAC has advocated for a 5% royalty on the sale price, payable to the patent-holder. In the case of medicines developed primarily with public money, royalties should go to public institutions on condition that the money is used for conducting research into diseases affecting the majority of people, and in particular the poor. Furthermore, a 1% research and development (R&D) tax has been proposed on *all* generic medicines, irrespective of the patent status of the brand-name equivalent.

The remainder of this article explains TAC's contentions in more detail and addresses pharmaceutical industry arguments, which are in most cases not supported by empirical evidence. There is an emphasis on South Africa. This is partly because TAC's expertise lies in the South Africa situation, but also because this country, along with Botswana and India, is arguably the most affected by the disease.

## 2 Globalisation of Human Rights<sup>1</sup>

In an advertisement in the Economist on 28 April, Dr Harvey Bale, Director-General of the International Federation of Pharmaceutical Manufacturers Associations (IFPMA), describes activists groups in conflict with his organisation as opponents of globalisation. While TAC cannot speak for other activist groups, the attempt to caricature us in this way is quite wrong. The TAC leadership is from a tradition that embraces globalisation. Indeed, most TAC members are not in favour of eradicating the World Trade Organisation (WTO), nor even the Trade Related Aspects of Intellectual Property Rights (TRIPs) agreement. However, unlike spokespersons for the pharmaceutical industry, TAC is consistent in embracing globalisation. Fifty-three years ago, the most important global treaty to date was adopted, the Universal Declaration of Human Rights, and has since been ratified by over 140 countries, more than the number of signatories to the WTO. Article 25 of the declaration states:

‘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* [emphasis added] and necessary social services...’

Furthermore, Article 22 states:

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<sup>1</sup>Much of this section is based on [8].

‘Everyone, as a member of society, has the right to social security and is entitled to realization, through national effort and international co-operation and in accordance with the organization and resources of each State, of the economic, social and cultural rights indispensable for his dignity and the free development of his personality.’

It *should* be uncontroversial that human rights covenants should have higher status than international trade agreements. Therefore, agreements, such as TRIPs, must be secondary in matters of health, particularly in the context of an epidemic as serious as HIV/AIDS. The human rights nature of this epidemic is established in various well-considered documents, including the *International Guidelines on HIV/AIDS and Human Rights* which has been endorsed by the director of UNAIDS and the UN High Commissioner[9]. Furthermore, the obligation upon states to protect the health interests of their citizens is described in a number of international covenants, including the International Covenant on Economic, Social and Cultural Rights(1966)<sup>2</sup>, the Convention on the Rights of the Child (1989)<sup>3</sup> and the Convention on

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<sup>2</sup>Article 12 states:

‘1 The States’ Parties to the present Covenant recognise the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.

2 The steps to be taken by the States’ Parties to the present Covenant to achieve the full realisation of this right shall include those necessary for:

- (a) the provision for the reduction of the stillbirth-rate and of infant mortality and for the healthy development of the child;
- (b) the improvement of all aspects of environmental and industrial hygiene;
- (c) the prevention, treatment and control of epidemic, endemic, occupational and other diseases;
- (d) the creation of conditions which would assure to all medical service and medical attention in the event of sickness.’

<sup>3</sup>Article 24 states:

‘1 States’ Parties recognise the right of the child to the enjoyment of the highest attainable standard of health and to facilities for the treatment of illness and rehabilitation of health. States’ Parties shall strive to ensure that no child is deprived of his or her right of access to such health care services.

2 States’ Parties shall pursue full implementation of this right and, in particular, shall take appropriate measures:

- (a) to diminish infant and child mortality;
- (b) to ensure the provision of necessary medical assistance and health care to all children with emphasis on the development of primary health care;
- (c) to combat disease and mal-nutrition, including within the framework of primary health care, through, inter alia, the application of readily available technology and through the provision of adequate nutritious foods and clean drinking-water, taking into consideration the dangers and risks of environmental pollution;
- (d) to ensure appropriate pre-natal and post-natal health care for mothers;

the Elimination of All Forms of Discrimination Against Women (1979)<sup>4</sup>

The interpretations of the internationally respected South African constitution by the Constitutional Court also confirm this view. In *S v Makwanyane and Ano* 1995 (3) SA 391 (CC) Justice Chaskalson states:

‘An individual’s right to life has been described as “the most fundamental of all human rights”...’(para 183)

He adds:

‘The rights to life and dignity are the most important of all human rights, and the source of all other personal rights in Chap 3 [of the SA Constitution]. By committing ourselves to a society founded on the recognition of human rights we are required to value these two rights above all others.’(para 144)

Justice O’Regan, in the same case, expresses that all rights must be interpreted in the light of the rights to life and dignity.<sup>5</sup>

‘The right to life is, in one sense, antecedent to all the other rights in the Constitution. Without life, in the sense of existence, it would not be possible to exercise rights or to be the bearer of them. But the right to life was included in the Constitution not

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(e) to ensure that all segments of society, in particular parents and children, are informed, have access to education and are supported in the use of basic knowledge of child health and nutrition, the advantages of breast-feeding, hygiene and environmental sanitation and the prevention of accidents;

(f) to develop preventive health care, guidance for parents and family planning education and services.

3 States’ Parties shall take all effective and appropriate measures with a view to abolishing traditional practices prejudicial to the health of children. 4 States’ Parties undertake to promote and encourage international cooperation with a view to achieving progressively the full realisation of the right recognised in the present Article. In this regard, particular account shall be taken of the needs of developing countries.’

<sup>4</sup>Article 12 States:

‘1 States’ Parties shall take all appropriate measures to eliminate discrimination against women in the field of health care in order to ensure, on a basis of equality of men and women, access to health care services, including those related to family planning.

2 Notwithstanding the provisions of paragraph 1 of this Article, States’ Parties shall ensure to women appropriate services in connection with pregnancy, confinement and the post-natal period, granting free services where necessary, as well as nutrition during pregnancy and lactation.’

<sup>5</sup>These arguments are taken from [8], which explains the precedence of human rights issues over all other legal matters in more detail than presented here.

simply to enshrine the right to existence. It is not life as mere organic matter that the Constitution cherishes, but the right to human life: The right to live as a human being, to be part of a broader community, to share in the experience of humanity. The concept of human life is at the centre of our constitutional values. The Constitution seeks to establish a society where the individual value of each member of the community is recognised and treasured. The right to life is central to such a society.

The right to life, thus understood, incorporates the right to dignity. So the rights to human dignity and life are entwined. The right to life is more than existence - it is a right to be treated as a human being with dignity: Without dignity, human life is substantially diminished. Without life, there cannot be dignity.’ (paras 326 - 327)

The consequence of this argument in the context of this discussion is described in TAC’s heads of argument in the highly publicised recent court case between the Pharmaceutical Manufacturers Association (PMA) and the South African Government[8]:

‘Section 7(3) of the Constitution places a duty on the State to “respect, protect, promote and fulfill the rights in the Bill of Rights.” If the State were to stand by when efficacious drugs for the treatment of HIV/AIDS and associated infections are placed beyond the reach of most people in this country, it would ignore a profound threat to the fundamental rights of millions of South Africans to human dignity (s 10), health care (s 27), basic health care services for children (s 28(1)(c)) and to life itself (s 11). There is accordingly a pressing constitutional obligation on the State to take all measures at its disposal to reduce the price of these drugs.’

The Constitutional Court has gone as far as to invoke an unratified (by the SA government) international human rights treaty in a recent ruling<sup>6</sup> to inform its interpretation of the constitution. It upheld that the South African government should be guided by the rights espoused in the following quotation from a report by the United Nations Committee on Economic, Social and Cultural Rights.

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<sup>6</sup>Government of the Republic of South Africa and Others v Grootboom and Others 2000 (11) BCLR 1169 (CC)

‘On the basis of the extensive experience gained by the Committee, as well as by the body that preceded it, over a period of more than a decade of examining States’ Parties’ reports the Committee is of the view that the minimum core obligation to ensure the satisfaction of, at the very least, minimum essential levels of each of the rights is incumbent upon every State Party. Thus, for example, a State Party in which any significant number of individuals is deprived of essential foodstuffs, of essential primary health care, of basic shelter and housing, or of the most basic forms of education, is *prima facie*, failing to discharge its obligations under the Covenant. If the Covenant were to be read in such a way as not to establish such a minimum core obligation, it would be largely deprived of its *raison d’être*. By the same token, it must be noted that any assessment as to whether a State has discharged its minimum core obligation must also take account of resource constraints applying within the country concerned. Article 2(1) obligates each State Party to take the necessary steps ‘to the maximum of its available resources’. In order for a State Party to be able to attribute its failure to meet at least its minimum core obligations to a lack of available resources it must demonstrate that every effort has been made to use all resources that are at its disposition in an effort to satisfy, as a matter of priority, those minimum obligations.’

Berger summarises this point succinctly:

‘The Constitution expressly rejects the characterization of a Bill of Rights “as a shield and not as a sword”. It does this not merely by entrenching justiciable social and economic rights, but also by mandating the state to “respect, protect, promote and fulfil the rights in the Bill of Rights.” These obligations apply to all rights, whether classified as civil, political, social or economic.’<sup>[1]</sup>

We argue, therefore, that where a conflict arises between human rights covenants and trade agreements, the rights to life and health-care take precedence. In concrete terms, if a government is a signatory to both the TRIPs Agreement and any of the above-mentioned human rights covenants, by international standards it should be able to take action to enforce the protection of human rights, even if this means breaching the TRIPs Agreement. Consequently human health should not be subject to international trade law.

## 3 Pharmaceutical Patents and Access to Treatment

### 3.1 The Status Quo Favours the Pharmaceutical Industry

Having established that if a conflict exists between health-care and international trade agreement, health-care takes precedence, we need to consider whether such a conflict does exist. However the question is more complex than whether the TRIPs Agreement in and of itself contains obligations which are a barrier to treatment access. TRIPs is a complex, often poorly worded, document informed by many interests, but mainly those of business. The ambiguity on the interpretation of critical issues, such as parallel importation, compulsory licenses, exporting of medicines manufactured under compulsory license and the agreement's exemptions on grounds of health and security has spurred numerous legal and academic papers interpreting these aspects of the agreement. Where such ambiguity exists, litigation is bound to occur.

Now consider the following[10, 11, 6]:

- The combined sales of the largest pharmaceutical companies exceed the combined GDPs of the whole of sub-Saharan Africa.
- The pharmaceutical industry has demonstrated that it is prepared to act in unison against states, such as the recent case between 40 corporations and the South African government. Generic manufacturers are regularly threatened with litigation without just cause, as the recent Glaxo SmithKline letter to Cipla over its AZT/Lamivudine donation to Ghana demonstrated.
- The industry has enormous experience with litigation and has access to the best intellectual property lawyers.
- The industry reportedly has one lobbyist for every two US Congress representatives. It has contributed more money to the US Presidential elections than any other interest group. This has resulted in intimidating tactics being used by the US government to protect the interests of this industry. When South Africa introduced the Medicines and Related Substances Control Amendment Act No 90. of 1997(Medicines Act), it was placed on the 301 Watch List. Though the action was eventually withdrawn, it contributed to delaying the implementation of this legislation for over three years. The US has also laid a complaint at the WTO against Brazil's new patent legislation. Brazil's treatment

programme, which relies on generic antiretrovirals, has been cited by UNAIDS as a best practice[12].

- European governments, also not immune to drug company lobbying, pressurised the South African government not to enact the Medicines Act.<sup>7</sup>
- Industry spokespersons regularly make assertions in favour of TRIPs-plus legislation, by denouncing the few favourable measures allowed by the agreement favourable to developing countries such as compulsory licenses and parallel importation[13][14].

All of this leads to the inescapable conclusion that the balance of power with respect to interpreting TRIPs is strongly weighted in favour of the pharmaceutical industry. While TAC advocates that compulsory licenses on antiretrovirals and other HIV/AIDS medicines are obtainable within the limits of the agreement, this is unlikely to occur without an expensive, protracted and risky legal battle. Given the multitude of trade and legal threats that third-world countries receive from the US government, European Union governments and powerful drug companies, it becomes apparent why most of them lack the political will to fight the pandemic, Brazil and Thailand being notable exceptions.

Fred Abbot[15] captures the situation precisely:

‘The decision by the United States government to use its economic power as a weapon against developing countries fighting a battle against a deadly plague would plausibly lead developing country government officials and common citizens to question the economic, social and political foundations of the TRIPs Agreement.’

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<sup>7</sup>On 23 March, 1998, Sir Leon Brittan, vice-president of the European Commission sent a letter to vice-president Mbeki indicating that the Medicines and Related Substances Control Amendment Act "would negatively affect the interests of the European pharmaceutical industry."

On January 27, 1998, the Executive Board of the World Health Assembly recommended the adoption of a Revised Drug Strategy resolution, put forward by Zimbabwe. The resolution states that members should "ensure that public health rather than commercial interests have primacy in pharmaceutical and health policies and to review their options under the Agreement on Trade Related Aspects of Intellectual Property Rights to safeguard access to essential drugs." The resolution was attacked by EU governments. A more detailed account on the EU shenanigans surrounding this proposal can be found on the Consumer Project on Technology website, <http://www.cptech.org/ip/health/sa/sa-timeline.txt>.

In the paper from which the above quotation is taken, Abbot stresses the importance for the future of organisations like the WTO that agreements such as TRIPs not be abused to further the commercial interests of rich countries at the expense of poor ones. TAC advocates that if this is to happen, then, at a minimum, TRIPs must be reformed. The short-sighted and short-term profit interests of one industry threaten the system of multilateral agreements and intellectual property rights. Ambiguities on critical issues should be resolved within the framework of human rights covenants in order to reduce the possibility of legal action – and the possibility of success of legal action – aimed at undermining states and organisations introducing measures to protect human rights. The preamble to the agreement needs to affirm that any measure taken to fulfill the requirements of the Universal Declaration of Human Rights, even if they come into conflict with clauses in TRIPs, are acceptable and encouraged.

HIV/AIDS activism has resulted in the development of a social movement concerned about the abuse of intellectual property rights. There is much evidence to suggest that intellectual property protection has gone too far and become counter-productive to innovation and detrimental to developing countries<sup>8</sup>. The opportunity exists now to reform TRIPs, not only to deal more adequately with the HIV/AIDS pandemic and not only to deal with pharmaceutical products, but to critically revisit the agreement and improve it on the basis of empirical research into the economic costs and benefits of patents. Intellectual property rights are not sacred. They are necessary for the public good and to fairly reward innovators. Berger explains this concept clearly:

‘In short, the patent system should provide sufficient incentive to innovate, but no more. The public interest is served by ensuring access to essential drugs for all, not just for the wealthy or those with drug insurance. If people do not have access to life-saving drugs it does not make sense to provide incentives for their innovation.’[1]

### **3.2 Competition will Lead to Lower Prices and Greater Access**

TAC advocates the use of compulsory licenses because there is overwhelming evidence that with generic competition, drug prices fall substantially, and approach their marginal cost. This will result in more people gaining access

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<sup>8</sup>See [16, 17, 11].

to essential HIV/AIDS medicines and those who already have access, having more disposable income. Local generic production also offers some protection to developing countries against exchange rate fluctuations, since internationally produced drugs are usually priced in US dollars. For a country like South Africa, whose currency has steadily declined over the last two decades, this is a critical issue. Furthermore, the economies of scale created by added generic production will result in further drug price reductions. Medicins sans Frontieres (MSF) estimates that Farmanguinhos, Brazil's national pharmaceutical producer is operating at 50% capacity. If given access to African markets, their per-unit price of production will come down. The Brazilian government has offered to sell medicines to countries with large epidemics at cost-price, but pressure emanating from the multinational pharmaceutical industry has resulted in this offer being rescinded. A by-product of compulsory licenses is that some developing countries will develop stronger generic pharmaceutical industries, one of the few advantages they will receive from an otherwise devastating disease.

It is interesting to examine the IFPMA's arguments against compulsory licenses, because when the evidence is considered, one finds that the opposite of what it argues is usually the case. In the advertisement referred to previously, Bale asserts that (1) stronger patent protection is needed in developing countries to reduce the gap with developed countries, (2) patent protection in developing countries has not had a "significant negative impact on access to medicines", (3) "even at the lowest prices many of the world's poorest people do not have access to treatments for malaria, TB and other common diseases" and (4) there are not monopolies on antiretroviral medicines. Other arguments often made by the industry include (5) the need for the pharmaceutical companies to recuperate their R&D costs and (6) the recent spate of reduced drug-price offers from pharmaceutical companies rendering the need for generic competition unnecessary. All of these arguments are examined and found to be inadequate. One argument that is not examined is the contention that poor people are not in a position to adhere to their treatments. This is rebuffed in the Harvard Consensus Statement[7] and by the pharmaceutical industry's experience in drug trials throughout South Africa and other developing countries.

### **3.2.1 Stronger Pharmaceutical Patent Protection Contributes to Inequality and Reduces Access to Medicine**

Bale offers no evidence that stronger patent protection is needed to reduce the gap between developed and developing countries. Perhaps underlying this argument is the belief that patent protection will give incentives to pharmaceu-

tical companies to develop treatments for under-researched diseases affecting third-world countries. The reality, however, is that developing countries do not have wealthy enough markets for privately funded profit-driven research companies to invest in medicines for diseases that only have noticeable effects on poor countries. South Africa offers an excellent counter-example to Bale's assertion. It has had a patent system as strong as most developed countries for over a century. It also has one of the worst TB epidemics in the world, and a not insignificant malaria problem. Yet no new TB medicines have been developed in the last thirty years. (Multi-drug resistant TB is examined later.) Research into new malaria treatments is also inadequate.

Critically South Africa, because of its strong protection of pharmaceutical patents has not been able to produce generic antiretrovirals. Less than 10,000 South Africans of the 4.7 million people with HIV, receive antiretroviral treatment. However, Brazil, which did not recognise pharmaceutical patents until 1997, via the production of generic antiretrovirals treats over 100,000 patients according to MSF and the Brazilian Ministry of Health (see[18, 12]). Since the introduction of generic production of antiretrovirals in Brazil, prices of these medicines have fallen by an average of 70%. Thailand represents another country with a partially successful response to the epidemic made possible through generic production. There is not a single example, however, of a developing country that has improved access to HIV/AIDS medicines as a result of patent protection, whether increased or static over the last decade. The table below compares US\$ per capsule prices between some antiretrovirals in Brazil and South Africa.

Medicine	1996 Brazil Price	2000 Brazil Price	2001 Brazil Price	2000 Best SA Price
AZT(100mg)	0.5	0.18	0.15	0.32
AZT(300mg)+lamivudine(150mg)	3.3	0.72	0.68	2.74
ddI (100mg)	1.8	0.51	0.49	1.00
lamivudine	2.8	0.83	0.35	3.12
d4T	2.2	0.28	0.27	3.51
nevirapine	Not produced	2.68	1.25	4.35

The evidence, not only fails to verify Bale's assertion; it actually demonstrates the opposite: stronger pharmaceutical patent protection contributes to inequality. The above examples also destroy Bale's assertion that patent protection does not have a significant impact on medicine access. While it is true that many poor countries up until now have been unable to afford even the lowest priced generic medicines, HIV/AIDS has highlighted the generally iniquitous distribution of health-care between rich and poor countries. As a result, there is a move under way by UNAIDS to establish a global trust fund for treating HIV/AIDS in poor countries. Poor people in poor countries might finally start benefitting from lower-priced treatments. Medicine prices will be a critical factor in ensuring its success. The Harvard Consensus Statement estimates that medicines will comprise over half the cost of a worldwide treatment programme. There is every reason to shop for the cheapest prices. Not only will it save taxpayers in rich countries money, but it will also allow more people to be treated.

Bale's argument that "even at the lowest prices many of the world's poorest people do not have access to treatments for malaria, TB and other common diseases" is true for many countries, but makes the common mistake of lumping all poor countries together. It is not true in South Africa (where some of the world's poorest people live), Botswana or in many other countries. While South Africa's TB treatment programme is not perfect, it reaches a significant portion of the population<sup>9</sup>. Tens of thousands of people would die without it. Yet clinics struggle to treat multi-drug resistant TB, because the necessary medicines are patented and unaffordable. A similar situation exists in Russia. Furthermore, the new global awareness of the inadequate health-care situation in many poor countries will hopefully result in more financing for treating other major diseases in these countries. If this happens, then the need to shop for the lowest prices will once more assert itself.

Bale's assertion that antiretrovirals are not operating in monopoly conditions in countries with patent protection is absurd. His reasoning is that there are multiple drugs in each antiretroviral class to choose from. The table of prices above offers counter-evidence to the assertion that monopolistic pricing practices are not taking place, but more importantly Dr Bale should be aware that medicines in the same antiretroviral class have different properties. Patients are often allergic to some but not to others. Furthermore, resistance patterns are different between them. At times, resistance to one does not automatically imply resistance to others in the same class.

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<sup>9</sup>Latest statistics indicate 80% coverage.

### 3.2.2 The Cost of R&D and Fair Compensation

R&D is a significant cost in the development of new medicines. The risk of failure associated with R&D is the basis for rewarding intellectual property, though it does not justify excessive protection. When one considers the argument by industry advocates that compulsory licensing will hinder innovation, it is important to note:

- Many antiretrovirals, e.g. AZT, ddI, ddC, d4T and abacavir, were invented using US taxpayer money in public institutions. The same applies to many other essential medicines, e.g. Taxol which is patented by Bristol-Myers Squibb. An affidavit by James Love for the previously mentioned South African court case describes in detail the perturbing situation of pharmaceutical companies using publicly funded research to reap huge profits at the expense of consumers[19]. In many cases, corporations have invented antiretrovirals, such as the protease inhibitors and non-nucleoside reverse transcriptase inhibitors, but even in these cases the US government has made significant direct contributions to drug trials and fundamental research into these medicines was carried out in public institutions.<sup>10</sup>
- Drug companies receive enormous tax-breaks for R&D, which is a form of government subsidy that leads to them exaggerating their R&D expenditure[11, 20]. It is interesting that in 1988, the US National Cancer Institute estimated that it spent on average between 2.3 and 6 million US dollars to research and develop a new drug through to the end of Phase III trials. This does not include adjustments for inflation, the opportunity costs of capital or risk adjustments for failed drugs. But even taking these into account, drug company estimates for the R&D of a new drug of over US\$500 million imply either massive inefficiency or exaggeration[20].
- Fundamental research necessary for developing new drug molecules is done in public institutions around the world. New drugs, like any innovation, are not developed in a vacuum.

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<sup>10</sup>Much R&D by pharmaceutical companies is going into non-essential products like hair-replacement agents and impotence treatments such as Viagra. TAC does not demand compulsory licenses for these. The current patent-based reward system for pharmaceutical innovation gives little incentive to research and develop medicines for third-world diseases. Of over 1200 medicines produced between 1975 and 1997, only 13 were for tropical diseases that affect mainly the third-world. Of these 13, only four were specifically developed by drug companies directly for the purpose of treating a tropical disease. [11, 17]

- The pharmaceutical industry has an average profit-to-capital ratio of 15%, almost double the ratio of all of industry. Despite their R&D costs, they are very profitable<sup>11</sup>.
- Sub-Saharan Africa accounts for approximately just over 1% of pharmaceutical company sales, most of this in South Africa.
- Compulsory licenses are usually accompanied by royalty payments.

In this light industry's concern about not being being adequately rewarded for their R&D expenditure fall flat. If anything the current patent system fails by providing incentives to drug companies to spend money on non-essential medicines for wealthy markets, but not on under-researched diseases. As Berger writes:

‘Although the pharmaceutical industry often claims that theirs is a risky game, statistics paint a somewhat different picture. Whether viewed on the basis of return on revenues, assets or shareholders' equity, the industry is the most profitable of all sectors. As Angell argues: “An industry whose profits outstrip not only those of every other industry in the United States, but often its own research and development costs, simply cannot be considered very risky.”’.

He further states:

‘Intellectual property that is being used only to reap profits and not to benefit the public good amounts to a use of such property that undermines the rationale behind the extension of IP protections in the first place.’[1]

### 3.2.3 Recent Drug Company Offers

Much has been made of recent drug company price reduction offers to developing countries. The most publicised of these is the so-called UNAIDS offer by the big five. Other important concessions have included:

- Pfizer has donated fluconazole to the South African public sector for the treatment of systemic thrush and cryptococcal meningitis, but not vaginal thrush (Pfizer donation).

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<sup>11</sup>For details on this, see the Oxfam study[11].

- Bristol-Myers Squibb (BMS) has stated that it will reduce the combined price of ddI and d4T to \$1 per day in sub-Saharan African countries (BMS reduction).
- Boehringer Ingleheim has made a substantial reduction to the price of nevirapine. They have also donated nevirapine to poor governments for mother-to-child transmission prevention (mtctp) (BI donation and price reduction).
- Merck has substantially reduced the price of efavirenz in South Africa (Merck reduction).

Any offer that will result in more people being treated is better than nothing, but only a naive person would believe these offers have arisen from pharmaceutical company generosity. They have come about as a result of activist pressure, particularly the threat to use compulsory licenses. Furthermore, except for the BI donation and price reduction, all of the above have serious shortcomings and conditions attached. But even the BI price reduction still leaves Viramune more expensive in South Africa for non mtctp use than generic versions. The UNAIDS price reduction, which was accompanied with much fanfare but few details, does not match generic medicine prices and will only benefit a few thousand people at most. Critically however, it was clear from the outset that the offer had strings attached. It is an attempt to prevent developing countries from exercising their compulsory license rights under the TRIPs agreement. The offer has not been made to private sectors, the only significant points of distribution in African countries. A genuine no-strings attached offer would mean making the reduction across the board.

In large part, the Pfizer donation came as a result of an intense campaign. TAC did not demand a donation. Charity is unlikely to be a sustainable method for combating health problems. TAC's demands were that Pfizer grant a voluntary license to the state to produce and import generic fluconazole or reduce the price to R4 per capsule (from R100), more than double the price of generic versions. When this campaign began, fluconazole was approximately 50 times more expensive in the South African private sector than the price at which a safe Thai generic is sold. In the private sector it still is, therefore TAC's fluconazole campaign continues. Note that it took almost a year from the initial offer to its implementation. While some of the responsibility for this delay lies with the South African government, TAC was party to the initial negotiations and witnessed the Pfizer negotiator acting in bad faith by placing unreasonable conditions on the offer. The most pernicious aspect of the Pfizer offer has been reduced pressure on the company to lower their prices in the poorest countries.

The statement concerning the BMS reduction was made by that company on 14 March in the middle of the previously mentioned court case and an intense campaign to get the prices of these medicines reduced, which were not developed by BMS. It then transpired that the company was only making the offer to African governments, none of which distribute antiretrovirals on a significant scale, and NGOs, few of whom, if any, have the capacity to distribute antiretrovirals. The private sector was once more ignored. As a result of TAC highlighting BMS's broken promise, the company backtracked. The reduction reached the South African private sector on 17 May. Unbelievably, BMS made a price reduction offer to the South African government on the 1st of March and less than a month later used the offer as evidence of the SA government's lack of commitment to their offers in the PMA's affidavit to the court case, a clear example of expedient pharmaceutical company behaviour. The Merck offer also came in the midst of the court case. At least it was implemented without delay.

Drug price reductions in this context are not sustainable nor adequate. If activist pressure is alleviated within the next few years, there will be nothing to stop prices from being increased again. The negotiations and compromises involved in these reductions are aimed at stifling criticism and removing the few rights that developing countries have under the TRIPs agreement. What is needed is competition, and only generic production can provide this. Also critical is a co-ordinated strategy between governments, NGOs, brand-name companies, generic manufacturers and international agencies to get essential medicines to people.

Pfizer vice-CEO C.L. Clemente recently stated 'We are for-profit companies. We are not the Red Cross.' TAC agrees. The consequence of this is that in the situation where an industry produces an essential product and has special legislative protection which insulates it from competition, there is necessity to implement measures to prevent abuse. In this case these measures must at a minimum include voluntary and compulsory licenses.

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