
# Access to HIV/AIDS Pharmaceuticals and the Issue of Rights[1]

**Lee Gillespie-White**

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Some of you might have read the article Amir Attaran of Harvard and I wrote for JAMA, which deals with the patent status of HIV/AIDS pharmaceuticals in sub-Saharan Africa and the impact of this on access to those pharmaceuticals. In broad detail what the study concluded was that if one were to view the continuum of how a drug reaches those in need, one finds that the breakdown is not due to the patent system.

The point the JAMA paper makes is essentially an empirical one: where patents do not exist (as in many Sub Saharan African countries) they obviously cannot be considered as barriers to drug access, at least insofar as the manufacture and distribution of drugs in that country is concerned. Other factors, such as affordability (lack of sufficient finance for drug purchases), poor health delivery systems and so on are the chief barriers to access. This does not translate into the normative proposition that patent laws – and the IP system as a whole – are illegitimate or should be done away with in order to make drugs more accessible. One way of illustrating this is by asking you to assume, for the purposes of argument, that all the non-patent barriers to AIDS-drug access in a given Sub Saharan African country had been dealt with (i.e. the government had sufficient funding to purchase such drugs, it had solved its delivery problems and so on) and patents had been registered on AIDS medications. Would we suggest that, under these conditions, these patents – and the IP system- simply be scrapped? No, we would not.

[1] Note, this paper incorporates elements of a speech given for the World Intellectual Property Organization in New York, New York on June 11, 2002.

Since South Africa, my home country is one of the key exceptions to our findings, I should like to examine the situation there in the hope that used as an example the real impediments to access to these drugs will be highlighted.

South Africa has had considerable difficulty in dealing with what its Department of Health refers to as: "The [pandemic which] has claimed millions of lives, is inflicting pain and grief, causing fear and uncertainty and threatening the economy."[2]

Before I go into the detail of the way the country has dealt with the crisis of the HIV/AIDS pandemic, it is worth stressing that the right to health is enshrined in the South African Constitution which provides that: "Everyone has the right to have access to health care services"[3]. It also provides that: "The State must take reasonable legislative and other measures, within its available resources, to achieve the progressive realisation of each of these rights."[4]

It is further worth stressing that the South African law protects intellectual property, particularly patent rights in accordance with international standards and norms.

These features –and particularly their existence in tandem - are not necessarily characteristic of many developing countries and they have had a vital impact on access to drugs and therapies for South Africans and on the debate surrounding these issues.

There are three instances of this. Though the South African courts have become most famous in the health sphere for cases related to HIV/AIDS drugs, there is, in fact, another case of equal if not greater importance. In 1997 Mr Soobramoney approached the Constitutional Court on the basis of the right enshrined in the Constitution of access to health care services and his right not to be refused medical treatment. The Constitutional court had to weigh up these rights against the obligation imposed on the State to provide access to health care within its available resources.

The Appellant, an unemployed man in the final stages of chronic renal failure had approached a hospital to provide him with emergency medical care. The hospital refused him admission to its renal unit. Its reason for doing so was said to be that it followed a set policy in regard to the use of its dialysis resources. The primary requirement was eligibility for a kidney transplant. To be eligible for a kidney transplant the patient had to be free of other "significant disease". The Appellant, who suffered from other conditions including heart disease, failed to meet this requirement.

The Appellant had unsuccessfully approached a local division of the High Court for an order directing the hospital to provide him with the treatment he desired and interdicting the hospital from refusing him admission to the renal unit of the hospital. The application was dismissed and the Appellant thereafter appealed to the Constitutional Court on the basis of his rights enshrined in the South African Constitution.

[2] South African Department of Health publication 2000
[3] Section 27 (1) (a) of the Constitution of South Africa
[4] Id ss (2)

The Constitutional Court found, however, that those rights were not absolute and that the sections of the Constitution providing for access to housing, health care, food, water and social security had to be qualified to the effect that the State must take reasonable legislative measures within its available resources.

In the facts of the case, the court found that that the Appellant had not shown that the State's failure to provide renal dialysis facilities for all constituted a breach of its Constitutional obligations and the appellant was not entitled to the relief he sought. Some weeks later Mr Soobramoney died.

In its most recent judgment on the issue of balancing the right to health against state resources, the Constitutional Court found in The Minister of Health et al vs Treatment Action Campaign et al that the state had not taken reasonable measures in limiting its programmes for the prevention of mother-to-child-transmission to two sites per province and that it was within the state's means to provide Nevirapine to public hospitals and clinics.

Then there was the case against the South African government by the Pharmaceutical Manufacturers Association in respect of certain provisions in its Medicines and Related Substances Control Act of 1997. As you are probably aware, that case was settled, and arguably should never have been brought in the first place. The "certain circumstances" under which the discretionary powers could have been exercised in terms of section 15C of the Act had never been tested and may or may not have proved to be inconsistent with TRIPS.

These three cases illustrate the two fundamental legal themes that run throughout the debate, the policy, the law-making and the litigation surrounding the availability of HIV/AIDS drugs (and other therapies) in Africa, these are:

- Balancing individual socio-economic rights (in this case to health and children's rights to health) against competing needs (including competing rights) in the society; who gets what claims on the limited resources available to the state; and, above all, who determines policy on these matters (i.e. the balance between the legislature, executive and judiciary); and
- Intellectual Property rights –the impact of IP laws and countries' commitments to international agreements.

I will deal with each of these. The South African Constitutional Court has taken a fairly cautious approach to the issue of the impact of government policies and resource-allocation decisions on the right to health. This is illustrated in the Soobramoney case and in the following quote from the Nevirapine case: *"Courts are ill-suited to adjudicate upon issues where court orders could have multiple social and economic consequences for the community."*[5]

But the issue is rarely settled and perhaps the issue here is not really about health at all, but about difficulties that countries face in addressing socio-economic issues through constitutional means. The way this issue plays out in the health arena in South Africa is going to be absolutely fascinating, and of great educative value to other countries facing this crisis.

[5] Paragraph 38 of Case CCT 8/02

The second theme is that of the impact of IP laws on the right to health in the form of access to medications. Some propositions in this regards are as follows;

- In a recent Harvard working paper – "The Impact of Patents on Access to HIV/AIDS Drugs in Developing Countries" [6] which looked at the short-term impact of patents on access to AIDS medications and found that, while patent restrictions do constrain market coverage in a relative sense, because market coverage or access in many Developing Countries is so low to begin with, "patents cannot be blamed for the lack of access of the vast majority of patients in developing countries." (p. 21-22) In the sample studied in the paper (34 low and middle income countries 1995-99), without patents market coverage would only have increased from 0.88% to 1.15% in the period under study (p.5) In other words the impact of patents on aggregate access in poor countries is marginal, particularly for the poorest: The authors found that patents have no practical effect to access to drugs in the poorest countries in their sample such as Bangladesh, French West Africa, India and Pakistan" (p.23)

- Which brings me to the second proposition – non-IP factors are far more important than IP factors in limiting access to therapies such as AIDS medications. In the JAMA we postulated that a variety of barriers are more responsible for impeding access to antiretroviral treatment than patents and patent laws, including but not limited to, the poverty of African countries, the high cost of antiretroviral treatment, national regulatory requirements for medicines, tariffs and sales taxes and above all a lack of sufficient international financial aid to fund treatment. What we did not touch on and this is something that particularly applies to South Africa, since it is the exception to our findings in that report, that is the question of government policies.

- The third proposition is that obviously if there were no patents there would be no – or very few profits – and no incentives to innovate – the drugs would not be available in the first place (the Harvard paper pointedly avoided this issue.)

  The reason is the obvious one and goes to the basic ethical and economic justification for the existence of intellectual property rights. We recognize that such rights need to be protected both as an ethical imperative (i.e. because individuals and institutions have rights to the results of intellectual labour) and because, unless such rights are protected, there will be no financial incentive for ongoing investment in any given area. At this abstract level, drugs are no different to computer software or songs. If you do not protect the rights of those who design or create them, and instead allow their designs or creations to be stolen (i.e. to be subject to infinite copying), you destroy the key reason

[6] Joan-Ramon Borrell and Jayashree Watal. CID Working Paper No. 92 May 2002

people have for continuing to produce these goods. Of course this right needs to be weighed against the social benefit that can be attained from infinite copying for free. The only practical mechanism that exists to conduct this balancing act is the granting of a temporary monopoly to the designer or creator, during which period the initial investment can be recouped and profit can be made. There is, of course, scope for argument over the details of this balance and hence over the character and extent of this monopoly. Such arguments are ongoing and their results are translated into IP law, either by statute or by court precedent. But they rest on an acceptance of the validity and legitimacy of intellectual property in the first place.

However this needs to be subject to a critical disqualification. Earlier I said "At (the) abstract level, drugs are no different to computer software or songs". Concretely, however, drugs – and particularly AIDS drugs – are crucially different to songs. They save lives, millions of which are under threat from the AIDS pandemic. For this reason, there is clearly a case to be made that access to existing AIDS medications should be treated differently from access to CDs. To take an obvious example, it is clearly justifiable – indeed imperative- to devise ways for rich countries to subsidize purchases of AIDS drugs in poor countries; it makes no sense to develop aid programmes to subsidize CD purchases. Many avenues – aid programmes, technical assistance, pressure on drug companies to cut their huge profits – are available to expand the delivery of these AIDS drugs to the places and people that need them most. But the effort should not place IP rights in jeopardy if broader progress on the drug development front is to continue.

There is a need to start disentangling the right to health, in countries with high HIV infection rates for example, from an obsession with intellectual property. Dealing satisfactorily with IP matters is an important part – but only a part – of the overall issue. What are the key elements of a remedy?:

- (i) Improvements to the IP system (so for example it is easy to establish whether there is a patent on a certain drug); (ii) Companies shouldn't cynically attempt to subvert the system through recourse to obviously illegitimate (even if legally meritorious) court appeals, and the system should make this behaviour more difficult (iii) Assistance to developing countries and transition economies to develop IP systems and become "good" at IP governance; (iv) The provision of financial assistance necessary to create a market for new drugs aimed at the disease burden of developing countries.

- In parallel, initiatives to deal urgently with specific crises or issues and ways to distribute the associated burdens must be carried out properly. In the fight to provide access of HIV/AIDS drugs to developing countries, the overriding perception is of the enormous profits drug companies are making (more profitable than other industries) at the very time that millions of people, particularly poor people, are dying. This perception persists notwithstanding that contributions

from the pharmaceutical industry in fighting poverty and disease have totalled $1.9 billion since 1999, of similar magnitude to the international community's efforts through the Global Fund for HIV/AIDS, TB and Malaria.[7] There is a need to negotiate an overall framework of strategies, obligations and burdens: drug companies agree to reduced profit margins on certain drug lines; Donor countries agree to certain levels of aid, part of which ensures that drug companies find manufacture and distribution of subsidized products sustainable (without some sort of return their interest will surely shrivel); developing country governments agree to policies and programmes which can get drugs delivered rapidly to those who need them.

The issues are complex and there have been some efforts in this regard, obviously notable amongst them is the setting up of the Global Aid Fund but tripartite agreements like these are point of departure only.

All of this involves a recognition, even an endorsement, of IP and IP rights. It does not imply that any existing system of IP rights is perfect – indeed ongoing improvement of the actual systems is one of the key reforms that I've suggested and this issue is being partially tackled by the TRIPS council following the Doha Declaration– but (i) the fact and virtue of IP needs to be taken as a point of departure, and (ii) a sensible distribution of burdens needs to be negotiated across a number of different dimensions, recognizing that the difficulties of securing the right to health are far more complex and weightier than simply an "IP problem."

9/8/02

[7] Source: Mr Jean Jacques Bertrand, Chairman of Aventis Pasteur at a forum conference in Brussels –"Global Healthcare and Development" 4 June 2002