
INTERNATIONAL INTELLECTUAL PROPERTY INSTITUTE

# Health and Patents: The Rights Issue

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Though the courts of my home country, South Africa, have recently become famous in the health sphere for cases related to HIV/AIDS drugs, there is in fact, a case heard by South African courts equal, if not greater in importance.

In 1997, Mr Soobramoney approached South Africa's Constitutional Court on the basis of the right provided by our Constitution concerning access to health care services and his right not to be refused medical treatment. Mr Soobramoney, the Appellant, was an unemployed man in the final stages of chronic renal failure had requested that a hospital provide him with emergency medical care. The hospital responded by refusing him admission, citing a set policy in regard to the use of its dialysis resources. The primary requirement for use of dialysis resources was eligibility for a kidney transplant. To be eligible for a kidney transplany 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 Constitutional court had to weigh up the obligation imposed on the State to provide access to health care within its available resources.

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 for refusing him admission to their renal unit. The application was dismissed and the Appellant thereafter appealed to the Constitutioanl Court on the basis that it is enshrined in the South African Consitution that no one may be refused emergency medical treatment and that everyone has the right to life.

The Constitutional Court found, however, that those rights were not absolute and that of 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 Constitutional Court found that the Appellant had not shown the State's failure to provide renal dialysis facilities for all constituted a breach of the State's Constitutional obligaitons, and the appellant was not entitled to the relief he sought. Some weeks later Mr Soobramoney died.

The South African Constitution is known for its progressive character. Yet even under this dispensation, the right to health care – which in this case amounted to the right to life - is not absolute. The Constitutional Court had to make a tough decision, as a result of which a man died. In final analysis, the Constitutional Court found that in order to preserve many lives in the long term, a life was sacrificed in the short.

The question of access to drugs – including, but not only HIV/AIDS drugs – is normally dealt with as a trade-off between competing rights – the right to health care versus the right to property. The right to health care is seen as requiring access to drugs at affordable costs. Property rights – specifically intellectual property rights – are seen to jeopardize this by creating monopolies that drive prices up. The starting point for the debate on IP rights in drug manufacturing and distribution is thus commonly taken as an ongoing, and often absolute, conflict between these two rights.

This is neither a strictly accurate nor a very constructive way of approaching the matter. The issue really is not only how to ensure that these rights are secured in themselves (i.e. both the right to property and the right to health care are intrinsically "good" and require protecting), but how they can be virtuously related. Here the economic logic of intellectual property cannot be avoided. It is only from the protection of the intellectual property invested in new drug development that the incentive to innovate arises. And without this incentive, new drugs will not be produced and the right to health care will be increasingly insecure.

This brings us to the whole debate around the issue of accessibility to drugs and whether the patent system and TRIPS are to blame for the lack of access to HIV/AIDS drugs by poor countries.

In 2000 and under commission by WIPO, IIPI produced a paper on the patent status of HIV/AIDS pharmaceuticals in Sub-Saharan Africa and the effect on access to those drugs.[1] We found that very few patents for antiretroviral treatments had been obtained in African countries. This study was followed up by second review of patents for HIV/AIDS pharmaceuticals that appeared in the Journal of the American Medical Association which found that only 21.6% of possible patents had been obtained in Africa.[2]

On examination of the issue as far as Sub-Saharan African countries are concerned, first and most concretely, in those Sub-Saharan African countries where patents have not been registered they cannot be eliminated. It thus clearly makes no sense to talk of getting rid of something that

[1] *Patent Protection and Access to HIV/AIDS Pharmaceuticals in Sub-Saharan Africa*-International Intellectual Property Institute 2000

[2] Amir Attaran and Lee Gillespie-White: *Do Patents for Antiretroviral Drugs Constrain Access to AIDS Treatment in Africa?* JAMA 2001

does not exist in the first place. This is a trite point, however, and does not take us very far. The real issue here goes to what so many health activists mean when they call for the elimination of patents.

The point the IIPI and JAMA papers make 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. However, 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.

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 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.

I am not certain whether the health activists who call for the elimination of patents accept this legitimacy in respect of commodities other than drugs (such as music and software). If they do not, they may be commended for consistency, but would then need to accept the consequence of their view – which is the software they use to write their many missives, the cars they drive and the TV programmes they watch would not exist. Perhaps one could conceive some sort of agrarian utopia such as this, but it is not a prospect in our lifetimes. Such a view need not be taken seriously.

If, on the other hand, the health activists do accept the legitimacy of IP rights for non-drug commodities, then the onus is on them to demonstrate that the factors that justify IP in respect of these other things do not apply to the realm of pharmaceuticals. In particular, they should be

asked to demonstrate that a dissolution of the IP rights of those who have the resources to invest successfully in producing drugs to ameliorate, prevent and even cure AIDS, will not have exactly the same effect they would in other areas; i.e. disinvestments and disintegration of the industry. The question which needs to be asked is whether in their enthusiasm to make existing AIDS drugs available to all by eliminating the IP rights of the drug companies, they have not inhibited ongoing investment in AIDS research and thus slowed progress towards prevention and cure of this disease.

Everything in the above needs 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 be avoided.

This, in essence, is the problem, and is probably as good a way of describing the profound difference that separates those of us who believe in the legitimacy of intellectual property rights (whether applied to drugs or other commodities), and those "health activists" who apparently do not. They wish IP to bear the burden of making access to AIDS drugs widely available at cheap prices. Dissolve patent rights on AIDS medications, they argue, and many lives will be saved. To me and to others, this is a short-sighted view that courts disaster; you may be successful with existing drugs for a short while, but you will kill the ongoing development of remedies. In the long term, many more lives will be lost.

So, to come back to our hypothetical African country in which all non-patent barriers have been dealt with. I would not support the scrapping of patent law in respect of drugs (or any other commodities) there. But I would be very much in favour of pursuing all possible means – including negotiating down profit margins on the sale of these drugs (which is what is effectively happening in a number of Sub Saharan African countries). However, dispensing with IP as a way of achieving reduced prices would be self-defeating; the human cost is simply too high.

Thus it is clear that conflicts between these fundamental rights exist and trade-offs have to be made. These trade-offs he detailed, messy and prosaic business of formulating specific rules and making judgments over the specific application of IP is the very stuff of which the governance of intellectual property is comprised. It falls to international organisations and governments to ensure that this is done properly but note (i) the assumption here is that IP exists and is legitimate, and (ii) that IP rights can be good for health care rights, if the regulation of both is done properly. The art of good government is to optimise the degree to which the rights of property (IP) and health care are virtuously rather than viciously related.

One of the key problems at the moment is that IP is being asked to shoulder too much of the burden of the right to health care. This is a burden it cannot bear. The system will crack if it is required to do so, and if it cracks new drugs will not be produced and future advances in health care will be jeopardized.

There is a need to start disentangling the right to health care, in countries with high HIV infection rates for example, from an obsession with eliminating intellectual property. It must be realized that 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 (for example, making it easy to establish whether there is a patent on a certain drug); (ii) Companies shouldn't 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 (an example of this is the recent action by 29 states against Bristol-Myers Squibb, where the company is being accused of illegally profiting from its monopoly over the cancer drug, Taxol. Bristol-Meyers Squibb is attempting to delay production of a generic of this drug, notwithstanding that the patent is about to expire) (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 contributions from the pharmaceutical industry in fighting poverty and disease have totaled $1.9 billion since 1999, which is of similar magnitude to the international community's efforts through the Global Fund for HIV/AIDS, TB and Malaria.[3] There is a need to negotiate an overall framework of strategies, obligations and burdens: drug companies need to agree to reduced profit margins on certain drug lines (effectively, some drug companies are doing this already – an example is Boeringer's offer of free AZT for 5 years to South Africa – but there is no doubt that they could do more); Donor countries need to agree to certain levels of aid, part of which ensures that drug companies find manufacturing and distribution of subsidized products sustainable (without some sort of return, their interest will surely shrivel); developing country governments need to 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 AIDS Fund. But tripartite agreements like these are

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

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