When Framing Meets Law:

Using human rights as a practical instrument to facilitate access to medicines in developing countries

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Introduction

Over the past decade, the debate about the relationship between access to medicines and human rights has, to a large extent, come to define politics of intellectual property. This article describes how Non-governmental organisations (NGOs) seeking to draw attention to the potentially adverse effects of patents for pharmaceutical products for public health, particularly for people living with Human Immunodeficiency Virus/Acquired Immune-Deficiency Syndrome (HIV/AIDS), not only reshaped the international debate about the relationship between intellectual property rights and access to medicines by framing it as a human rights issue, but have also utilised the concrete human rights principles enshrined in national constitutional law as a practical tool in their campaigns, often to far-reaching effect.¹
Framing

A significant amount of attention has already been paid to the extent that NGOs will increase their gains if they ‘frame’ or ‘reframe’ intellectual property-related debates by using the emotive language of human rights to underpin substantive arguments.

Odell and Sell (2006, p. 87) suggest that in much the same way as powerful transnational firms and their governments had framed intellectual property protection as a trade issue during negotiations leading to the World Trade Organisation (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (the TRIPS Agreement), using the emotive language of ‘piracy’ and ‘theft’ to describe alleged violations of intellectual property rights in developing countries, critics of TRIPS have attempted subsequently to reframe the debate as a public health issue, arguing that strong intellectual property protection could be detrimental to access to medicines (and hence an infringement of human rights).

Reflecting on the negotiating history of the TRIPS Agreement, Braithwaite and Drahos (2000, p. 571-576) even argue that had the property-theft-piracy frame of industry and developed country governments been contested at the time of the negotiations, the TRIPS Agreement might not have taken the final form it did and may have been more sympathetic to the development-orientated concerns of the developing world.
Used in this way, framing becomes a tactic utilised by rights-holders and developed country
governments to demonstrate that intellectual property rights should be upheld because it is wrong to
steal or, alternatively, to demonstrate that intellectual property rights should be applied in a manner
that takes account of the need to avoid preventable deaths (Odell and Sell 2006, p. 88). However, these
subjective frames of reference imply different policy responses and the more NGOs do to win this
subjective contest and establish the dominant frame, the greater that NGOs’ negotiated gains, the
framing strategy increasing the NGOs’ credibility (Odell and Sell 2006, p. 89).

For Lang (2007, p. 147), the diffusion of human rights language into the work of NGOs must be
accompanied by degree of elaboration if it is to provide meaningful guidance to trade policy-makers
(see, for example, Abbot 2005, p. 294). Seen in this way, re-framing the debate on the impact of
intellectual property rights for development in terms of human rights performs a number of potentially
important functions, but does not provide substantial policy guidance, is not a source of new policy
ideas, and does not provide a means of choosing between competing ideas. Instead Lang argues that, to
the extent that the human rights movement can mobilise actors and groups presently marginalised and
provide effective tools to augment their political influence, framing the issue as one of human rights
may help NGOs to achieve real change. In this way, human rights add legitimacy, new constituencies and
(to a certain extent) further resources to those groups pressuring for change (Lang 2007, p 147).

Similarly, Deere (2008, p. 169) has described how framing has been deployed as a strategic tool to
influence international discourse on intellectual property issues and the outcomes of international
negotiations. For Deere NGOs, international organisations and academics working to reframe
intellectual property debates to better facilitate discussion of their public interest priorities (Deere 2008, p. 172).

Kapczynski (2008: 804) also highlights the role of ‘frame mobilisation’ in instigating, promoting, and legitimating collective action, creating areas of overlapping agreement within the coalition and establishing a language of common disagreement between itself and opposing groups. For Kapczynski (2008: 883), this explains how actors interpret their interests, build alliances, and persuade others to support their cause.

Reflecting back on the TRIPS negotiations, Drahos (2008: 269-270) has suggested that, in retrospect, drawing on public health and human rights expertise, trade negotiators interested in opposing United States (US) and European Union (EU) pharmaceutical hegemony during the TRIPS negotiations should have built a counter-frame around the principles of timely access to medicines, equity in access, and the cost-effectiveness of medicines. However, Drahos has also cautioned against viewing framing as a master mechanism and has argued that it needs the support of other strategies if it is to bring genuine structural gains in intellectual property regimes (Drahos 2008: 272).

Taking into account framing strategies in this way, this article examines how human rights have permeated the debate about the relationship between intellectual property rights and access to medicines. The chapter then pursues this theme further by highlighting the extent that human rights law (as opposed to human rights rhetoric) has been used as a practical tool by NGOs in developing countries, often with significant results.
Framing intellectual property rights and access to medicines as a human rights issue

A human rights-based approach to the debate on the relationship between intellectual property rights and access to medicines first came to prominence when international NGOs began to frame the issue by using the emotive language of human rights to underpin substantive arguments that public health, the right to health and the right to life were at risk due to the patent provisions of the TRIPS Agreement. In the run-up to the Doha Declaration on the TRIPS Agreement and Public Health in November 2001 (Matthews 2004, p. 73), international NGOs began to campaign for access to medicines by calling for the full utilisation of flexibilities contained in the TRIPS Agreement. Using human rights to frame the debate, these NGOs ultimately added moral authority to the access to medicines campaign, which in turn contributed to a greater emphasis on the importance of using in-built flexibilities in the TRIPS Agreement and the need to permanently amend of the TRIPS Agreement provisions on compulsory licensing, making explicit the link between the protection of pharmaceutical patents with key principled ideas and rhetoric of human rights discourse (see also de Mello e Souza 2005, p. 25).

This strategy proved relatively successful because the public, the media and politicians were able to engage in a relatively straightforward way with the notion that the provision of anti-retroviral drugs (ARVs) to treat people living with HIV/AIDS in the developing world was being hindered by the TRIPS Agreement. This contributed to the ability of NGOs to make explicit the link between the HIV/AIDS crisis and intellectual property rights, an issue that had resonance in both the developed and the developing world (see also de Mello e Souza 2005, p. 28).
That resonance was articulated through the framing of the issue so that intellectual property began to be seen not only or primarily as a trade issue, but also as one relevant to health and human rights (de Mello e Souza 2005, p. 10), rooted in the dignity of the other in relation to the self (Orbinski 2008, p. 373). By framing the TRIPS Agreement in terms of health and human rights, activists were able to resort to accountability politics, gaining moral leverage to pressure governments and international organizations previously committed to upholding such rights (de Mello e Souza 2005, p. 159; Schultz and Walker 2006, p. 8).

In many respects, the reframing strategies of NGOs in the access to medicines campaign mimicked and acted as a counterweight to the framing that corporate activists had employed to such great effect when linking intellectual property to trade in the run-up to the TRIPS Agreement (Matthews 2002, p. 21; de Mello e Souza 2005, p. 25). In the run-up to the TRIPS Agreement corporate interests had portrayed intellectual property not only as a critical public policy tool for encouraging disclosure of inventions and encouraging investment in research and development (R&D), but also as an inalienable private property right. Corporate interests had also equated copying with ‘piracy’ and ‘theft’, even when this practice was entirely legal (Sell and May 2001, p. 485; Watal 2001, p. 2, quoted in de Mello e Souza 2005, p. 8).

By replicating the strategies adopted by corporate interests in negotiation of the TRIPS Agreement, the reframing strategies of NGOs weakened the public sense of legitimacy about the achievements of the TRIPS Agreement, especially in the HIV/AIDS context (Sell 2003, p. 182). While, in the 1980s, TRIPS advocates had framed it as an alternative to tolerating piracy of private property, the access to
medicines campaign compared TRIPS to a different reference point — saving the lives of poor people suffering from HIV/AIDS (Odell and Sell 2006, p. 93).

The framing strategy also facilitated contestation, with the traditional model of patents as a driver for new drug development challenged by reframing the debate using the language of ‘human rights’ and ‘the right to health’ as a threat to public health and access to medicines and, through the mobilisation of moral outrage, helped to generate a widespread sense that the TRIPS Agreement in its current form could not be justified (Lang 2007, p. 147).

NGOs were able to raise awareness that access to medicines was a trade issue, mobilising the press in developed countries and bringing the issue to the attention of the public as a means of pressurising politicians in these countries (Drezner 2005, p. 15). In part this task was made easier by developed country guilt about the post-colonial legacy, particularly in sub-Saharan Africa.

By raising awareness about the link between access to medicines and intellectual property rights issues to an extent hitherto not acknowledged, NGOs created pressure on governments in both the developed and developing world that counterbalanced the role played by industry, opening up the debate on intellectual property rights and development policy. This helped facilitate a more open discussion on the impact of the TRIPS Agreement on public health and access to medicines.
In addition to the international access to medicines campaign, NGOs in a number of prominent developing countries have gone much further than framing the discourse on intellectual property rights in terms of the language of human rights. In large, middle-income developing countries such as South Africa, Brazil and India, NGOs have actually used human rights law in substantive terms hitherto not considered by those emphasising framing strategies. NGOs in these countries have used rights enshrined in national constitutions before national courts as tools with which to challenge the scope and application of intellectual property law in a very real and tangible way.

Framing intellectual property rights and access to medicines as a human rights issue in South Africa

AIDS is the leading cause of mortality in South Africa. In 2001, approximately 200,000 people were dying of AIDS or AIDS-related illness each year (Boule and Avafia 2005, p.14) and by 2008 there were an estimated 5.7 million adults living with HIV/AIDS in South Africa, about 18 per cent of all people between the ages of 15 and 49 (UNAIDS 2008).

The wider socio-economic costs of HIV/AIDS for South Africa have also had catastrophic implications. HIV/AIDS leads to a loss of household income due to illness or death of a household member and time spent on caring. In economic terms, it is the poor who are the worst affected by HIV/AIDS since in situations of minimal income these additional costs cannot be absorbed easily by the family, resulting in increasing poverty and deteriorating food security (Boule and Avafia 2005: 14). It is often women who bear the increased responsibilities of caring for ill household members and for orphaned children, in addition to their other domestic and economic responsibilities (SIDA 2001).
The socio-economic costs of HIV/AIDS are exacerbated by AIDS denialism, social stigmatisation, fear of violence and other social realities such as exclusion. Despite the horrendous loss of human life and the socio-economic costs of HIV/AIDS for South Africa, the government’s response to the HIV/AIDS crisis was initially controversially slow. South African President Thabo Mbeki, for instance, questioned whether AIDS was caused by HIV and said that it was not certain that ARV drugs were safe and effective. He denied knowing anyone who had died of AIDS, despite so many South Africans succumbing to the virus. This institutional AIDS denialism had terrible implications for the provision of ARVs for people living with HIV/AIDS in South Africa.²

The focus for NGO activism to challenge the government’s inaction came on 10 December 1998 – Human Rights Day, when a group of about 15 people protested on the steps of St. George’s Cathedral in Cape Town, demanding ARVs for people living with HIV/AIDS (Boule and Avafia 2005, p. 15). By the end of the day a new NGO, the Treatment Action Campaign (TAC) had been created and over 1,000 people had signed up as supporters.

TAC’s formation was grounded in on a distinctly post-apartheid period of South Africa’s history when human rights issues were particularly to the fore and, by linking the right to health to human rights principles, TAC shared historical continuities with the late 1980s and early 1990s anti-apartheid and gay rights activism. The objectives of TAC were set out in clause 4 of its constitution. These included campaigning for equitable access to affordable treatment for all people with HIV/AIDS and challenging,
by means of litigation, lobbying, advocacy, and all forms of legitimate social mobilisation, any barrier or obstacle that limits access to treatment for HIV/AIDS (see also Fourie 2006, p. 130).³

To achieve these objectives, TAC’s campaigns framed access to ARVs for people living with HIV/AIDS as a human right (Boull and Avafia 2005: 23; Halbert 2005, p. 108; Mbali, 2005, p. 2) using to great effect the language and principles of human rights enshrined in the South African Constitution to do so.

TAC’s strategy of utilising the human rights principles enshrined in South Africa’s constitution (see also de Waal 2006, p. 36) and framing issues in the language of human rights and constitutional obligations (Fourie 2006, p. 163) is consistent with the personal experiences of Zackie Achmat, its chairperson. Achmat was active in the United Democratic Front (UDF) during the later apartheid years in South Africa and used non-violent methods of political activism that included strikes and demonstrations. While never ceding the legitimacy of the apartheid government, UDF activists used human rights law to challenge every aspect of racist and arbitrary rule (de Waal 2006, p. 36). Informed by experience, TAC has developed its human rights approach from an initial framing of the issues to litigation based on human rights principles enshrined in the South African Constitution, working closely with lawyers based in the Law and Treatment Access Unit of the AIDS Law Project (ALP) to achieve its objectives.

As with TAC, the ALP’s human rights approach grew out the experiences of the anti-apartheid struggle. Mark Heywood, project head of the ALP for example, was involved in the anti-apartheid movement for a decade and was also a member of the UDF. Originally based at the University of Witwatersrand in Johannesburg, the ALP believes that the progressive realisation of a set of human rights principles is
fundamental to achieving sustainable progress in tackling the HIV/AIDS pandemic. It uses a variety of legal approaches to put these human rights principles into practice in order to protect, promote and advance the rights of people living with HIV/AIDS, and to change the socio-economic and other conditions that lead to the spread of HIV/AIDS and its disproportionate impact on the poor (AIDS Law Project 2007, p. 4).

The most effective ARV for the prevention of mother-to-child-transmission (MTCT) of HIV is Nevirapine, the patent for which is owned by the German pharmaceutical company Boehringer Ingelheim (BI). In 2001 BI had offered to donate Nevirapine to South Africa at no cost. The South African government had nonetheless declined this offer and refused to adopt a full-scale Nevirapine treatment program for HIV-infected pregnant women on the grounds that the ARV’s efficacy and side-effects had not been adequately studied by the government’s pilot programs. The Ministry of Health also contended that treatment would not prevent infected mothers from transmitting the virus through breast feeding and that it did not have sufficient resources to provide the counselling and monitoring required by treatment programs (de Mello e Souza 2005, p. 247).

As a result, in July 2002, TAC brought a legal action before the Pretoria High Court in Minister of Health & Others v. Treatment Action Campaign & Others. The complaint concerned the refusal of the South African government to make Nevirapine available in the public health sector and not setting out a timeframe for a national programme to prevent MTCT of HIV.
The applicants (TAC, Dr Haroon Saloojee and the Children’s Rights Centre, together with the Institute for Democracy in South Africa, First Amicus Curiae, the Community Law Centre, Second Amicus Curiae, and the Cotlands Baby Sanctuary, Third Amicus Curiae) contended that restrictions on the availability of Nevirapine were unreasonable when measured against the human rights principles of the South African Constitution.

The Constitution commands the state and all its organs to give effect to the rights guaranteed in the Bill of Rights, in particular: sections 27(1), 27(2) and 28(1).⁶

[Open box 1]

Article 27 of the Constitution of the Republic of South Africa: Health care, food, water and social security

(1) Everyone has the right to have access to -

   (a) health care services, including reproductive health care;

   (b) sufficient food and water; and

   (c) social security, including, if they are unable to support themselves and their dependants, appropriate social assistance.
(2) The state must take reasonable legislative and other measures, within its available resources, to achieve the progressive realisation of each of these rights.

(3) No one may be refused emergency medical treatment

Article 28 of the Constitution of the Republic of South Africa 1996: Children

(1) Every child has the right-

(a) to a name and a nationality from birth;

(b) to family care or parental care, or to appropriate alternative care when removed from the family environment;

(c) to basic nutrition, shelter, basic health care services and social services;

(d) to be protected from maltreatment, neglect, abuse or degradation;

(e) to be protected from exploitative labour practices;

(f) not to be required or permitted to perform work or provide services that-

(i) are inappropriate for a person of that child’s age; or

(ii) place at risk the child’s well-being, education, physical or mental health or spiritual, moral or social development;
(g) not to be detained except as a measure of last resort, in which case, in addition to the rights a child enjoys under sections 12 and 35, the child may be detained only for the, shortest appropriate period of time, and has the right to be -

(i) kept separately from detained persons over the age of 15 years; and

(ii) treated in a manner, and kept in conditions, that take account of the child’s age;

(h) to have a legal practitioner assigned to the child by the state, and at state expense, in civil proceedings affecting the child, if substantial injustice would otherwise result; and

(i) not to be used directly in armed conflict, and to be protected in times of armed conflict.

(2) A child’s best interests are of paramount importance in every matter concerning the child.

(3) In this section “child” means a person under the age of 18 years.

[Close box 1]

Finding in favour of the applicants, the South African Constitutional Court held that sections 27(1) and (2) of the Constitution require the government to devise and implement within its available resources a comprehensive and co-ordinated programme to realise progressively the rights of pregnant women and their newborn children to have access to health services to combat MTCT of HIV. The Court also confirmed that the State is obliged to ensure that children are accorded the protection contemplated by section 28(1)(c) of the Constitution. The South African government was ordered to remove the
restrictions that prevent Nevirapine from being made available for the purpose of reducing the risk of MTCT of HIV without delay.

By seeking recourse to the human rights principles enshrined in the South African Constitution, TAC and its allies had succeeded not only in improving access to Nevirapine but also in creating an alternative moral framework for understanding the relationship between patents, access to medicines and human life.

This changed the discourse not only in South Africa but on patents and access to medicines internationally. The rights of people living with HIV/AIDS to have access to ARVs came to be more widely seen as an inalienable human right distinct from the temporary property right associated with intellectual property. Thus, the debate over the implications of intellectual property rights for access to medicines were no longer simply framed in terms of the prevention of piracy and counterfeiting and the benefits of the patent system as a stimulus for innovation, but also about balancing that system with the fundamental human rights to life and to health care.

**Framing intellectual property rights and access to medicines as a human rights issue in Brazil**

The recent history of democratic struggle in Brazil, which culminated in the end of military rule in 1985, had significant implications in terms of how NGOs have embraced and utilised principles of human rights in articulating their concerns. When military dictatorship came to an end in Brazil in the 1980s, there
followed a profound period of national self-reflection. Public policy objectives were gradually restructured around a new social agenda for the country. This social agenda was underpinned by a new democratic constitution, firmly grounded in human rights principles that should be upheld at all costs to avoid a repeat of abuses experienced during the era of military dictatorship.

This belief in the primacy of human rights, particularly the right to health enshrined in the Brazilian Constitution, impacted subsequently on the decision of NGOs to mobilise in support of the Brazilian government in its attempts to achieve a balance between the patents for pharmaceutical products and the right to health through the compulsory licensing provisions of federal law. Those provisions were subject to a US complaint to the WTO and in turn led to sustained and detailed engagement with issues relating to patents, public health and access to medicines on the part of the Brazilian NGO community.

The period from 1985 to 1989 then saw a rapid growth in the number of NGOs in Brazil acting for and on behalf of people living with HIV/AIDS. In particular, these NGOs made explicit the link between the protection provision of ARVs and the fundamental human rights of people living with HIV/AIDS. This link had profound resonance in a Brazilian society still recovering from the painful legacy of twenty-one years of military rule.

Articulate and well-educated people living within the gay community took the lead in these NGOs, advocating that the government make the provision of ARVs for people living with HIV/AIDS a priority (Smallman 2007, p. 80). Prominent amongst these new NGOs was Grupo de Apoio à Prevenção à AIDS (GAPA - AIDS Prevention Action Group), founded in São Paulo in 1985, the Associação Brasileira
Interdisciplinar de AIDS (ABIA - Brazilian Interdisciplinary AIDS Association) and Grupo pela Valorização, Integridade e Dignidade do Doente de AIDS (Grupo pela VIDDA - Group for Life), founded in Rio de Janeiro in May 1989. This was followed, in 1995, by the founding of the Brazilian Network of People Living with HIV-AIDS (RNP+), which today has a membership in excess of 2,500 people. In total there are now more than 600 different NGOs working on issues related to HIV/AIDS in Brazil under the umbrella of the State Forum of AIDS NGOs (Távora dos Santos Filho 2000).

These Brazilian NGOs are responsible for a number of significant initiatives that advocate improved access to ARVs. In the early 1990s, for instance, the Grupo pela VIDDA and GAPA sued the federal and state governments to assure access to medication for HIV/AIDS patients in hospitals (Távora dos Santos Filho 2000).

A key strategy of the NGOs campaigning for improved access to ARVs in Brazil was Article 196 of the 1988 Constituição da República Federativa do Brasil (Constitution of the Federal Republic of Brazil) which enshrined the right to health in federal law.

[Open box 2]

Article 196 of the Constitution of the Federal Republic of Brazil.
Health is a right of all and a duty of the State and shall be guaranteed by means of social and economic policies aimed at reducing the risk of illness and other hazards and at the universal and equal access to actions and services for its promotion, protection and recovery.

[Close box 2]

Using strategies that had worked to such good effect in opposition to the previous military regime, these HIV/AIDS NGOs began to use human rights principles to frame the health policy on the right to health care as a right for all (see also Galvão 2005, p. 112). The right to health enshrined in Article 196 of the Brazilian Constitution quickly became the focus of attention for NGOs representing people living with HIV/AIDS seeking to articulate the universal right of access to ARVs.

In fulfil the constitutional right under Article 196, the Sistema Único de Saúde (SUS – Unique Health System) was set up to provide healthcare to approximately 123 million Brazilians (74 per cent of the total population) who cannot afford private health care plans (Cohen and Lybecker 2005, p. 216) and is regulated by Laws 8.080/90 and 8.142/90. These laws also established the three founding principles of the SUS. First, that it should be universal, meaning that no citizen could be excluded from SUS coverage. Second, that it should be characterised by equality of access with no discrimination regarding the public health services and products provided to users. Third, that it should provide full health care coverage, from the most basic to the most complex health care needs.
These three principles of universality, equality and integrated health care define the Brazilian state’s promotion of health as a fundamental social right and, although the Brazilian constitution does not mention specifically access to medicines as part of the right to health, it is generally acknowledged that the right to access to medicines is derived from this implementing legislation (see, for instance, Rosina et al 2008, p. 170). Specifically, Article 6(l)(d) of Law 8.080/90 provides that SUS “must be responsible for promoting full medical assistance, which includes pharmaceutical assistance.”

In line with this obligation, in 1990 the federal government began free delivery of Azidothymidine (AZT), one of the first ARVs, to the citizens of Brazil. Initially, the Brazilian federal government purchased AZT from Burroughs-Wellcome Company (now GlaxoSmithKline), the multinational pharmaceutical company that had undertaken research and development work and had subsequently been granted patents on the drug.

As the number of people living with HIV/AIDS increased and demands for treatment became more pressing, the federal government struggled to provide free ARV treatment to its citizens. The high prices of patented pharmaceutical products then started to come to the fore. Given the costs associated with purchasing large consignments of these patented pharmaceutical products at the market price, in 1993 the federal government instead began to purchase ARVs manufactured by Brazilian pharmaceutical companies which produced cheaper, equally effective, generic versions of AZT and other patented medicines.
By November 1996, this policy of universal access to ARVs at no cost to patients had become a legislative right for all Brazilian citizens as a result of Federal Law 9.313/96. This guaranteed that the SUS had a federal responsibility to provide ARV treatment to all Brazilian citizens and made it mandatory for the SUS to provide ARV treatment to all citizens living with HIV/AIDS (see also Galvão 2005, p. 112; Rosina et al 2008, p. 189). As a result, Brazil became one of the few countries in the world with a policy of universal free access to ARV treatment.

While 1996 saw the adoption of Federal Law 9.313/96 and marked the beginning of a policy of universal access to ARVs in Brazil, it also marked the point at which awareness grew about the relationship between intellectual property rights, public health and access to medicines. This occurred with the adoption of Industrial Property Law 9.279/96, which introduced patent protection for an area of technology - pharmaceutical products – not previously patentable in Brazil.

Until 15 May 1997, when Law 9.279/96 came into force, Brazilian pharmaceutical manufacturers were permitted to legally reverse-engineer and manufacture cheaper, generic versions of pharmaceutical products that were subject to patent protection elsewhere in the world. This practice was permitted prior to 1997 under previous legislation, Industrial Property Law 5.772/71 that came into force on 21 December 1971 and, as a result, during the 1970s many private firms, such as Aché, Farmasa, Libbs, Sintofarma and public sector manufacturers, such as Fiocruz in Rio de Janeiro and FURP in São Paulo, were able to supply generic pharmaceutical products in this way (Cohen and Lybecker 2005, p. 215).
In the pre-TRIPS era, this was permissible under international law because countries were not required to grant patents to all areas of technology, such as pharmaceuticals. This changed with Article 27.1 of the TRIPS Agreement which required all WTO Members, after the expiration of transitional periods, to make available patents in all fields of technology (including pharmaceutical products).

Only a year after the TRIPS Agreement had come into force and well in advance of the applicable transitional period coming to an end, Law 9.279/96 was introduced in Brazil to provide for the protection of pharmaceutical products by patent law (see also Rosina et al 2008, p. 183). In fact, the legislation was introduced despite concerns that patent protection for pharmaceutical products would increase the financial burden on the SUS, given its obligation to purchase ARVs and provide these drugs free of charge to all citizens living with HIV/AIDS. Nevertheless, Law 9.279/96 also sought to achieve a balance between the patents accorded to pharmaceutical products and the right to health, in particular, the need to ensure the adequate provision of ARVs to people living with HIV/AIDS in Brazil.

The mechanism used to achieve this balance was compulsory licensing. Law 9.279/96 allowed the government to issue a compulsory licence where a patent holder exercises patent rights in an abusive manner, or by means of an abuse of economic power proven by an administrative or court decision. Other instances were also specified where compulsory licences may be issued, particularly under Article 68 and 71.

Under Article 68, the holder of a patent in Brazil was required to ‘work’ the subject matter of a patent, either by producing the patented good in the country, or by allowing the patented process to be used in
Brazil. If this requirement was not met within three years of the issuance of the patent, the government could issue a compulsory licence allowing others to utilise the patent against the patent holder’s wishes. Article 68 also stated that if a patent owner chooses to utilise the patent though importation rather than the local working of the patent, then others besides the patent holder would be allowed to import the patented product or products obtained from the patented process.

Under Article 71, compulsory licences could also be issued by the federal government in cases of national emergency or public interest (see also Shadlen 2009, p. 48). A Presidential Decree on Compulsory Licensing 3.201/99 was subsequently issued in 1999 to define, in Article 2, what might constitute such situations of national and public interest in which compulsory licences could be issued for patented products. Yet despite these legislative developments, in policy terms the relationship between intellectual property rights and access to medicines at that time remained a topic largely unknown to NGOs in Brazil, particularly given the legal complexity of the issues involved.

This changed 2001 when, faced with the challenge of carrying on its HIV/AIDS programme at a considerably higher cost, the Brazilian federal government opted to initiate negotiations with a number of the major pharmaceutical companies designed to reduce the price of ARVs. These negotiations were backed by the threat of compulsory licensing, with the possibility of using in particular the procedures mandated by Articles 68 and 71 of Law 9.279/96.

Using the threat of compulsory licences as a negotiating tool, by 2001 the Brazilian federal government had been able to agree substantial price reductions for ARVs with several pharmaceutical
manufacturers, including a 64.8% price reduction for Indinavir, 59% for Efavirenz, 40% for Nelfinavir and 46% for Lopinavir. In addition, a technology transfer agreement was established between Merck and the Ministry of Health’s main national laboratory Farmanguinhos (Love 2006, p. 2) to enable local working of some of Merck’s patented pharmaceutical products.

Then, on 9 January 2001, the US requested that the WTO Dispute Settlement Body (DSB) establish a panel to resolve its complaint against Brazil in relation to the provisions of Law 9.279/96 that authorise the use of compulsory licences and parallel importation to promote the local working of patents. In what was widely viewed as a reaction to the Brazilian federal government’s interference on the production and pricing of highly profitable ARV drugs patented by or exclusively licensed to US-based pharmaceutical multinationals, the US government then began consultation procedures.

The US complaint focused on Article 68 of the 1996 Brazilian Industrial Property Law 9.279/96. The US complained that Article 68 violated the TRIPS Agreement which set out the principle of non-discrimination in the protection of patent rights and the exclusive rights to be enjoyed by patent holders by discriminating against US owners of Brazilian patents whose products are imported into Brazil but not locally produced and curtailing the rights of these owners to utilise the patents. The US demanded from Brazil written guarantees that it would not issue compulsory licenses for products patented or exclusively licensed to US companies. Following the refusal of the Brazilian government to meet these demands, the US requested the opening of a WTO panel against Brazil, on 1 February 2001. The DSB then established a WTO dispute settlement panel to report on this matter on 30 May 2001 (see also de Mello e Souza 2005, p. 201).
For HIV/AIDS NGOs in Brazil, the US complaint was a catalyst that focused attention on the fact that intellectual property rights can act as a barrier to access to medicines, particularly for people living with HIV/AIDS in developing countries. Brazilian NGOs such as GIV and ABIA articulated their opposition to the US complaint by using the language of human rights and the right to health enshrined in Article 196 of the Brazilian Constitution to claim that the complaint by the US to the WTO had the potential to infringe the human rights of people living with HIV/AIDS. In recognition of the fact that the Brazilian HIV/AIDS programme had been a success and should be protected, HIV/AIDS NGOs in Brazil were quick to support their federal government, and, on 7 March 2001, began to demonstrate against the US outside the US Embassy in São Paulo.

This was the first time that the relationship between intellectual property rights and access to medicines had been discussed openly by NGOs in Brazil and the timing of this meeting was significant. Faced with the need to respond to the US complaint against Brazil at the WTO, Brazilian HIV/AIDS NGOs began to act and, driven by the objective of protecting human rights, they began to collaborate with their international counterparts, particularly Médecins Sans Frontières (MSF) and Oxfam, on the implications of the TRIPS Agreement for public health and access to medicines.

Academic experts brought in by international NGOs were able to highlight the fact Articles 204 and 209 of Title 35 of the US Patent Code, which specified local manufacturing of publicly-financed patented products and products patented by the US government, were remarkably similar to those that the US had challenged Brazil on at the WTO. The US countered this by arguing that, whereas the
aforementioned articles of its Patent Act referred to contractual terms for publicly-financed projects, Article 68 of Brazil’s Law 9.279/96 was a blank requirement applicable to all patented goods, regardless of their origin. Nevertheless, international NGOs and the academic experts associated with them had provided crucial information on the US Patent Code and had also brought pressure to bear on the US by means of protests with ample media coverage.

On 25 June 2001 in the face of enormous negative publicity from international and Brazilian NGOs and legal arguments about the similarity between Articles 204 and 209 of Title 35 of the US Patent Code and Article 68 of Brazilian Law 9.279/96, the US withdrew the complaint. It did so after receiving assurances that it would be notified before any products patented by or exclusively licensed to US companies were subject to compulsory licensing in Brazil (de Mello e Souza 2005, p. 203). Brazil and the US also agreed that, before using the disputed provision in Article 68 of Brazilian Law 9.279/96 against a US patent holder, a ‘Consultative Mechanism’ would be initiated in an attempt to resolve the matter bilaterally (see also Deere 2008, p. 166).15

Alongside the technical inputs from academic experts brought on board by international NGOs, Brazilian NGOs proved adept at framing the dispute in terms of the human rights of people living with HIV/AIDS who would be adversely affected by the continued use of patents for pharmaceutical products in Brazil. With public perception that the human rights of people living with HIV/AIDS in Brazil would be undermined by the US complaint to the WTO, the US WTO case against Brazil looked increasingly unsavoury (Sell 2003, p. 158).
In June 2001 the US announced that it was officially withdrawing its case against Brazil on the first day of the first United Nations Special Session devoted to a public health issue - the context was HIV/AIDS. The session culminated in “The Declaration of Commitment” on HIV/AIDS on June 27, 2001. The Declaration framed the issue in terms of access to medicines and human rights to explain why it was of such crucial significance (Sell 2003, p. 158; de Mello e Souza 2005, p. 214). The US and Brazil subsequently notified the WTO DSU that a mutual agreed understanding had been reached to settle the dispute but, in effect, the US had stepped back from further confrontation on this issue, subject to a bilateral understanding to the effect that, should Brazil seek to issue a compulsory licence on grounds of failure to work the patent locally, it would consult the US before doing so. The continued existence of the safeguard provisions on compulsory licences in Articles 68 and 71 of Law 9.279/96 in Brazil has been described by the Report of the UN High Commissioner on the impact of the TRIPS Agreement as helpful in improving the implementation of the country’s HIV/AIDS treatment programme. Moreover, while no compulsory licence was actually issued under Brazilian Law 9.279/96 until 2007, the provisions were nevertheless instrumental in negotiating lower prices with the owners of patents on pharmaceutical products. The Report of the High Commissioner concluded that: “on the facts that have been provided by the Government of Brazil, it is possible to say that the Brazilian case demonstrates how the provisions of the TRIPS Agreement can be implemented in ways that respect, protect and fulfil the right to health. Through careful legislative implementation of TRIPS provisions...the Brazilian IP law supports the implementation of national health policy aimed at providing essential drugs to those who need them.”

20
Framing intellectual property rights and access to medicines as a human rights issue in India

Human rights have also played an important role in defining the way that Indian NGOs have engaged with the impact of intellectual property rights on access to medicines. When India’s struggle for independence from British colonial rule ended in 1947, human rights and in particular the right to life enshrined in the Indian Constitution formed the basis of the report on the future of the patent system prepared by the Committee on the Revision of the Patents Laws (1957-1959), known as the Ayyangar Committee. The Committee looked more specifically at poverty issues, noted the high mortality rates in India and recommended that granting patents in critical areas such as food and medicines be curtailed since the high price of patented products could deny Indian citizens access to resources and violate the right to life, enshrined in Article 21 of the Constitution of India (Ragavan 2006, p. 285). The Committee’s reasoning for this recommendation was that the prohibitively high price of patented products could violate the right to life.

[Open box 3]

*Article 21 of the Constitution of India: Protection of Life and Personal Liberty*

No person shall be deprived of his life or personal liberty except according to procedure established by law.
Of particular concern to the Ayyanger Committee was the fact that, at that time, foreign pharmaceutical companies supplied almost 85 per cent of medicines in India and, according to the United States Senate Subcommittee on Anti-Trust and Monopoly (the Kefauver Subcommittee), by 1961, prices for pharmaceutical products in India were amongst the highest in the world (Keayla 2005, p. 2).

So, in order to protect the constitutional right to life and promote industrial development in India, the Ayyanger Committee recommended that product patents should not be granted in critical areas such as food and pharmaceutical products.\textsuperscript{23} Instead, patent protection should be limited to the method of making food, pharmaceuticals and chemicals, leaving the final products free from patent protection and consequently allowing local generic drug companies to manufacture without infringing patent rights (Ragavan 2006, p. 286). The Ayyanger Committee also recommended that India ensure that patented inventions were worked locally to facilitate industrial development, with the government giving powers to revoke patents or issue compulsory licenses in order to redress instances where foreign patent owners were not working the invention locally (Ragavan 2006, p. 287).

As a result of the Ayyanger Committee’s recommendations, the Patents Act of 1970, which came into force on 20 April 1972, was designed as a response to growing concerns in India about how best to strike a balance between patents rights as incentives to innovate on the one hand and how best to protect the public interest and promote industrial development in India on the other. In line with the Ayyanger Committee’s recommendations, Section 5 of the Act introduced differential treatment of food,
pharmaceutical and chemical inventions by making available patent rights only for the processes of manufacture (Chaudhuri 2005, p. 37). By excluding protection of the end product, several manufacturers could each own patents for different processes of manufacturing the same pharmaceutical products (Rangnekar 2005, p. 4; Ragavan 2006, p. 289).

The Indian Patents Act of 1970 also limited the term of protection for process patents on food, pharmaceutical and chemical inventions to five years, with a license of right authorising any person to manufacture a patented product, notwithstanding the patentee’s approval, available for food, pharmaceutical or chemical inventions after three years. With the objective of encouraging local manufacturing of inventions, the Indian Patents Act of 1970 also introduced powers for the Comptroller of Patents to issue compulsory licences based on the patent owner’s ability to work the invention in India to the public’s advantage.

This system of not granting patents for inventions that related to food, pharmaceutical or chemical products prevailed until the coming into force of the TRIPS Agreement and allowed the Indian pharmaceutical industry to develop considerable expertise in reverse engineering and developing new methods of manufacture in order to become highly efficient producers of generic medicines.

This human rights approach in turn informed the subsequent strategy of NGOs working to ensure that amendments to India’s patents legislation utilised to the full extent flexibilities contained in the TRIPS Agreement. In the post-TRIPS implementation period, as other NGOs become involved with patents and
access to medicines issues, it was once again an underlying concern that the human rights of people living with HIV/AIDS were being abused which informed their approach.

The Indian government did not seek the views of NGOs or other stakeholders before undertaking initial negotiations on the TRIPS Agreement in the late 1980s (Daz 2003, p. 38). Nevertheless, a number of well-informed individuals came forward to articulate concern about the increased cost of pharmaceutical products that would result from new international norms requiring patent protection regardless of the products in question (Matthews 2002, p. 31). In particular, the National Working Group on Patent Laws provided the focal point for informed debate in India (Rangnekar 2005, p. 7).

In 1993 the National Working Group on Patent Laws convened the first People’s Commission. It consisted of three former judges of the Supreme Court, together with a retired chief justice of the Delhi High Court.28 Crucially, the Commission’s report made explicit reference to the fact that the impact of the TRIPS Agreement on drug prices and access to medicines in India could conflict with the right to life enshrined in Article 21 of the Constitution of India (see Krishna Iyer et al 1996, p. 61). Pointing out that the Supreme Court of India had concluded that the right to health, including access to medical treatment, is a fundamental right,29 the report argued that the Indian Patents Act 1970 could not be rewritten to allow the grant of patents for pharmaceutical products since this would constitute a violation of Article 21 of the Constitution (see Krishna Iyer at al 1996, p. 62). So, from the outset, the National Working Group on Patent Laws was adept at framing concerns about the impact of the TRIPS Agreement on access to medicines as a human rights issue.
This led in turn to NGOs originally versed in human rights law to engage to a greater extent with the technical aspects of patent law. They began initiating pre-grant patent oppositions against pharmaceutical product patent applications in a way these groups could not have foreseen when they originally began campaigning on human rights issues associated with HIV/AIDS some years earlier.

As NGOs in India began to use human rights to good effect to frame their arguments about the impact of intellectual property rights on access to medicines, this in turn, contributed to a policy-making climate in which, since 2006, the Indian government has been markedly more receptive to concerns raised by NGOs on these issues. By framing the issue in terms of human rights, NGOs are of the opinion that their viewpoints are now taken more seriously by the Indian government.

**Conclusion**

This chapter has sought to demonstrate that the extent that human rights have been used by NGOs seeking to highlight the adverse impacts of intellectual property rights on access to medicines is far greater than was previously thought.

This human rights-based approach first came to prominence a decade ago when international NGOs began to frame intellectual property-related issues by using the emotive language of human rights to underpin substantive arguments that public health, access to medicines, the right to health and the right to life were at risk due to the patent provisions of the TRIPS Agreement. International NGOs began to
campaign for access to medicines through the full utilisation of flexibilities contained in the TRIPS Agreement and framed the issue in terms of human rights. By so doing, the human rights frame ultimately added moral authority to the access to medicines campaign, which in turn contributed to a greater emphasis on the importance of using in-built flexibilities in the TRIPS Agreement and the need to permanently amend of the TRIPS Agreement provisions on compulsory licensing.

However, while the strategy of international NGOs in framing the access to medicines campaign as a human rights issue has been recognised widely, rather less attention has been paid to the parallel activities of NGOs that have been using similar human rights-based approaches in developing countries. NGOs representing people living with HIV/AIDS in South Africa, for instance, have used strategies that had worked previously to such good effect during the anti-apartheid struggle and highlighted primacy of human rights principles under the country’s constitution. In Minister of Health & Others v. Treatment Action Campaign & Others, human rights principles enshrined in the South African Constitution were used to overturn the decision of the South African government’s refusal to make Nevirapine available in the public health sector and to set out a timeframe for a national programme to prevent MTCT of HIV.

Similarly, following the ending of military rule in Brazil, NGO activists used their knowledge of human rights acquired during the struggle for democracy to campaign successfully for universal access to ARVs for people living with HIV/AIDS. This belief in the primacy of human rights, particularly the right to health enshrined in the Brazilian Constitution, impacted subsequently on the decision of NGOs to mobilise in support of the Brazilian government in its attempts to achieve a balance between the patents for pharmaceutical products and the right to health through the compulsory licensing provisions of federal law. Those provisions were subject to a US complaint to the WTO and in turn led to sustained
and detailed engagement with issues relating to patents, public health and access to medicines on the part of the Brazilian NGO community.

Human rights have also played an important role in defining the way that Indian NGOs have engaged with the impact of intellectual property rights on the poor, the disadvantaged and vulnerable sectors of society. When India’s struggle for independence from British colonial rule ended in 1947, human rights and in particular the right to life enshrined in the Indian Constitution formed the basis of the Ayyangar Committee’s recommendation that granting patents in critical areas such as food and medicines be curtailed. The Committee’s reasoning for this recommendation was that the prohibitively high price of patented products could violate the right to life. This human rights approach in turn informed the subsequent approach of NGOs working to ensure that amendments to India’s patents legislation utilised to the full extent flexibilities contained in the TRIPS Agreement. In the post-TRIPS implementation period, as other NGOs become involved with patents and access to medicines issues, it was once again an underlying concern that the human rights of people living with HIV/AIDS were being abused which informed their approach. This led in turn to NGOs originally versed in human rights law to engage to a greater extent with the technical aspects of patent law, particularly by initiating pre-grant patent opposition proceedings against pharmaceutical product patent applications in a way that they could not have foreseen when they originally began campaigning on human rights issues associated with HIV/AIDS some years earlier.

Over the past decade, therefore, NGOs have played a critical role in reappraising the relationship between intellectual property and access to medicines through the frame of human rights principles in a range of ways that will continue to have profound implications for many years to come.
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Endnotes

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2 While other large developing countries like Brazil had begun offering large scale public health treatment programmes as early as the 1990s, the South African Cabinet only announced a national treatment plan in 2003 after years of ever-increasing mortality rates and NGO activism.


4 Nevirapine is a non-nucleoside reverse transcriptase inhibitor for use against mother-to-child transmission of HIV which has been shown to reduce MTCT of HIV in approximately 50 per cent of cases.


7 Public health service delivery is shared equally by the different levels of government: federal, state, municipal and the national health system (Sistema Único da Saúde - SUS). In practice, the delivery and management of health services is increasingly being decentralised to the state and municipal levels, reflecting the government’s sensitivity to the population’s preference for more local governance. The federal level of government defines the policies and regulations, grants technical and financial support for the states and municipal governments and provides some service delivery. These governments in turn contribute the remainder of the health budget and share responsibility for health service delivery (Cohen and Lybecker 2005, 214).
In 2003 an additional Presidential Decree 4.830/03 clarified the scope of these situations under Article 71 further. These revisions provided clearer definitions of national emergency and public interest and simplified the mechanism for issuing compulsory licences by giving the Ministry of Health greater authority to act. According to Shadlen (2009, p. 48), Presidential Decree 4.830/03 crucially stipulates that private firms supplying the government constitutes “public use” and is thus acceptable under Article 71, and also requires patent owners to transfer technological knowledge in the case of compulsory licences, thus increasing the Ministry of Health’s capacity to leverage price reductions from patent-holding pharmaceutical firms.

A notable exception was the statement made by then Minister of Health the previous year Statement of José Serra, Minister of Health, to the 2001 USTR Special 301 Report, 3 May 2001. Available at:

The Ministry of Health’s budget for purchasing antiretroviral drugs in 2007 was R$984 million. Authoritative estimates demonstrate that 80% of this money is used to acquire patented medicines and 20% is spent on generic drugs that are manufactured domestically by Brazilian companies. The fact that such a huge portion of the budget is being spent on patented medicines has put the sustainability and universality of this healthcare policy in jeopardy.

http://www.wtocenter.org.tw/SmartKMS/fileviewer?id=73103. See also Press Communiqué by the Government of Brazil, 25 June 2001, in which Brazil maintained its conviction that Article 68 is fully consistent with the TRIPS Agreement and an important instrument available to the Government, in particular in its efforts to increase access of the population to medicines and to combat diseases such as AIDS. Available at:


Jorge Beloqui, interview with the author, 19 March 2006.
“Notwithstanding any other provision of this chapter, no small business firm or nonprofit organization which receives title to any subject invention and no assignee of any such small business firm or nonprofit organization shall grant to any person the exclusive right to use or sell any subject invention in the United States unless such person agrees that any products embodying the subject invention or produced through the use of the subject invention will be manufactured substantially in the United States. However, in individual cases, the requirement for such an agreement may be waived by the Federal agency under whose funding agreement the invention was made upon a showing by the small business firm, nonprofit organization, or assignee that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible.”


16 Ultimately, however, Oxfam retained its distance from the core group. ActionAid, meanwhile, subsequently withdrew from access to medicines issues in Brazil altogether in a move described by some Brazilian HIV/AIDS activists interviewed for this book as “pitiful”.


19 On 4 May 2007, Brazil finally issued a compulsory licence for the ARV Efavirenz after failing to reach agreement with the patent owner, Merck, to lower prices of the drug. Announcing the compulsory licence, the Ministry of Health said that the action would reduce the cost of purchasing Efavirenz, currently used by 75,000 of the 180,000 people living with HIV/AIDS in Brazil, by up to US$240 million between 2007 and 2012, when Merck’s patent
expires. Meanwhile President Luiz Inácio Lula da Silva, signing the decree granting the compulsory licence, said
‘between our business and our health, we are going to take care of our health’. *Brazil Issues Compulsory Licence
for AIDS Drug*, Bridges Weekly Trade Digest, Vol. 11, Number 16, 9 May 2007. In other instances, the Brazilian
government has opted for voluntary agreements with multinational pharmaceutical companies. On 9 May 2006,
for instance, Minister of Health Agenor Álvares and the Vice-President of Gilead Science, Joseph Steele, signed an
agreement that resulted in a 51 per cent price reduction of the ARV drug tenofovir. The price of each capsule
consequently reduced from US$7.68 to US$3.80, representing an immediate saving to the Brazilian National STD
and AIDS Programme of US$31.4 million per annum. *Brazilian deal on tenofovir – translation of Ministry of Health


21 High mortality rates had been identified in India’s First Five Year Plan in 1950.

22 The Supreme Court has held subsequently in *Bandhua Mukti Morcha v. Union of India* (AIR 1984 SC 802) that
the right life in Article 21 includes the right to health. The Supreme Court has also made clear in *State of Punjab v.
Mohinder Singh Chowla* (1997 2 SCC 83) and that the Indian government has a constitutional obligation to provide
health facilities. It stated in *Paschim Banga Khet Mazdoor Samity v. State of West Bengal* (AIR 1996 SC 2426 at
2429 para 9) that failure to provide a patient timely medical treatment a violation of the patient’s right to life, and
in *State of Punjab v. Ram Lubhaya Bagga* (1998 4 SCC 117) that there is an obligation on the State to maintain
health services (Mathiheran 2003).

23 N. Rajagolala Ayyangar, Repoprt on the Revision of the Patents Law (1959), paragraph 101.

24 Section 53(1)(a) of the Indian Patents Act 1970.

25 Section 88 of the Indian Patents Act 1970.

26 Section 87(1) of the Indian Patents Act 1970.

27 Section 84 of the Indian Patents Act 1970.


29 *Vincent v. Union of India* (AIR 1987 SC 990).