GLOBAL COMMISSION ON
HIV and the LAW

SELECTED BIBLIOGRAPHY

MEDICINES FOR WHOM?
INTELLECTUAL PROPERTY LAW AND
THE GLOBAL FIGHT FOR TREATMENT
Selected Bibliography

Medicines for Whom? Intellectual Property Law and the Global Fight for Treatment

HIV and the Law: Risks, Rights & Health

September 2012
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Intellectual property and data protection rights on pharmaceutical products have become increasingly controversial as monopoly prices associated with these rights have made the cost of treatment for diseases, including HIV, unaffordable for many people in low and middle-income countries.

This paper outlines the historical evolution of patent and data protection and the adoption of the TRIPS Agreement, which made it a requirement for every WTO Member State to apply minimum standards on intellectual property. The paper then explores the impact of TRIPS on the balance of interests between pharmaceutical companies, governments, and the public, and describes the application of corporate pressure and the use of use of trade negotiations by wealthy nations to advance their pharmaceutical industry’s interests. Finally, the paper looks at the failure of the TRIPS Agreement to achieve its promised benefits and offers recommendations.

An increase in patent and data protection: the TRIPS Agreement
The TRIPS Agreement established minimum substantive protections and enforcement standards for intellectual property rights, including pharmaceutical patents and registration-related data. Pursuant to TRIPS WTO member states are obligated to grant patents to all comers on an equal basis, permitting patent holders to exclude competitors for 20 years. The Agreement enables patent-holders to ensure their patent rights regardless of the place of innovation, to control the site of production, and to prevent discrimination against particular fields of technology. Thus, the TRIPS Agreement limits the freedom of member states to customize national legislation in order to facilitate broader and more affordable access to medicine.

Certain developed countries have exerted enormous pressure on developing countries to forego adoption and utilization of TRIPS-complaint flexibilities, have sought to ratchet IPRs higher and higher through free trade agreements (FTAs) and economic partnership agreements (EPAs), and have retaliated when developing countries have used lawful means to increase access to more affordable medicines. Most recently, some high-income counties have reserved their right to oppose further extensions beyond 2013 of the transition period for LDCs to accede to TRIPS as well as further extensions to the 2016 transition period for the pharmaceutical patent and data protection provisions in TRIPS.

The impact of heightened intellectual property rights
The impact of the TRIPS Agreement on low and middle-income countries cannot be overstated. TRIPS has done little to promote medical innovation for diseases primarily affecting developing nations, to accelerate technology transfer, or to assure wider access to affordable medicines.

Multiple studies have catalogued how the existing intellectual property regime and R&D financing mechanisms fail to incentivize the development and sale of medicines that focus on neglected diseases in developing countries. Critics claim that the current system focuses pharmaceutical research and development on market rewards from medicines for high-income markets. Similarly, technology transfer has not been incentivized by higher intellectual property protections in most developing countries, especially those that lack absorptive capacity. Heightened IPRs may instead have led to deindustrialization in the pharmaceutical sector in countries
where importation was more economical than supporting small-scale local production. Finally, access to affordable medicines for end users in poor countries remains elusive except with respect to first-generation AIDS medicines. To date, major pharmaceutical companies have reluctantly agreed to tiered or discount pricing, mainly in response to AIDS activists and competition from generic producers.

**Recommendations**

Low and middle-income countries have turned a corner in terms of seeking a more proactive policy on intellectual property and access to medicines. They have gained a toehold for developmental issues in key multilateral institutions and have begun the arduous process of regional consultations. However, they face formidable challenges from an extremely powerful pharmaceutical industry and the upper-income countries that support it. If low and middle-income countries are going to achieve their developmental IP policy objectives, they will need to take action.

Most countries have not yet amended their legislation to take full advantage of TRIPS-compliant flexibilities because of a lack of political leadership and technical capacity or a concern about retaliation from major economic powers. Low and middle-income countries should convene stakeholder coalitions of parliamentarians, civil society representatives, and technical experts to revise national intellectual property legislation in order to incorporate TRIPS flexibilities.

One of the most promising existing opportunities for decreasing the costs of AIDS medicines is the UNITAID-affiliated Medicines Patent Pool which negotiates license agreements with multiple patent holders of antiretroviral medicines. These generic producers can then compete at efficient economies of scale to sell existing and improved formulations and combinations throughout the developing world.

Countries should streamline and amend regulatory and procurement mechanisms to increase the availability and affordability of medicines. They can expedite the registration of priority medicines by “fast-tracking” pre-qualified medication or coordinating registration standards on a regional basis. Additionally, developing countries should use existing pricing information and/or pooled procurement to purchase medicines instead of paying vastly different prices for the same medicines. Finally, countries should use competition policy to control abusive and collusive pricing.

Many countries are keen on building local and regional capacity to manufacture pharmaceutical products. When intellectual property rights stand in the way, one of the few policy options for technology transfer and local production is to promote voluntary licensing agreements. Such licenses could be transformational if they permit and capacitate local production from the manufacture of active pharmaceutical ingredients to final formulation and distribution. When voluntary licenses are not forthcoming or refused, government and private entities should consider compulsory licensing alternatives.

Finally, instead of imposing IP-maximizing policies that threaten generic competition and access to lower cost medicines, developed countries should assist developing countries in their efforts ensure access to life-saving AIDS medicines and diagnostics.


Intellectual property (IP) policy is an important structural determinant of health. Patent policy influences the rate and direction of innovation for health, playing a positive or negative role depending on how it is shaped and
implemented. Patent policy also has critical implications for access to existing medicines and medical technologies. This has been illustrated most dramatically in the context of the global HIV/AIDS pandemic. Prices for a three-drug combination of anti-retroviral (ARV) HIV therapy in 2000 from patent-holding companies exceeded $10,000 per person per year, ensuring that treatment could not be extended to the vast majority of those living with HIV around the world. Generic competition led to precipitous price reductions, so that today treatment can be provided for less than $75 per person per year. This history has contributed to the growing recognition that strong patent law applied to pharmaceuticals in developing countries undermines access to medicines and compromises the human right to health.

From both economic and human rights perspectives, the optimal patent policy in developing countries would likely be to exclude patents on medical products altogether, as many once did. In light of the contemporary framework of international agreements on IP, such a policy is no longer an available strategy for most developing countries, and is only a short-term option for least-developed countries. The most important such agreement is the World Trade Organization’s TRIPS (Trade-Related Aspects of Intellectual Property) Agreement. TRIPS establishes a high floor for IP protection for all WTO members, and crucially, introduced the requirement that members grant patents on medicines.

This paper identifies and describes the most critical TRIPS flexibilities (appropriate criteria of patentability, strong procedures to protect patent quality and effective post-grant safeguards) and describes the practical difficulties countries face in deploying these flexibilities in the context of resource limitations, continued unilateral pressure and new trade agreements that seek to restrict their use.

The paper goes on to identify barriers to the widespread use of TRIPS flexibilities in developing countries. Many countries, especially the poorest, offer IP protection that far exceeds what is required by TRIPS. In developing countries, fundamental challenges to the systematic adoption of TRIPS flexibilities exist including lack of supportive legal frameworks, resource constraints, limited coordination, continued unilateral pressure and new international agreements that reduce the scope of TRIPS flexibilities.

One of the post-TRIPS threats discussed in detail is the threat emanating from Free Trade Agreements between the US or Europe and developing countries where comprehensive trading arrangements have been made containing standards and commitments that go far beyond those stipulated under TRIPS and which restrict TRIPS flexibilities, impairing access to medicines. Other post-TRIP threats include the recent push for an IP enforcement agenda that conflates IP enforcement and drug quality control, and thereby threatens the integrity of the generic supply chain, and the recently negotiated Anti-Counterfeiting Trade Agreement.

In the growing shadow of TRIPS-plus agreements, it is clear that the existing international IP regime undermines access to medicines in developing countries and the time has come for a reassessment of the overall structure of the system. At a minimum, much more needs to be done to support the use of TRIPS flexibilities in developing countries.

The paper makes a variety of recommendations including convening an independent commission to propose amendments to the existing TRIPS Agreement. Said and Kapczynski suggest that developed countries commit to an indefinite moratorium on increased IP standards, commit to not using watch lists to threaten or pressure developing countries to apply more restrictive IP rights and support revisions to the TRIPS Agreement. They also recommend that developing countries reject TRIPS-plus obligations, explore concluding trade agreements that codify maximum IP standards and TRIPS flexibilities, act cooperatively to limit the scope of patentability and ensure patent quality, and try to build local capacity and technical expertise in patent law. Regional and South-South cooperation will be vital in helping to reduce the prices of drugs and increase access to medicines and medical technologies.

This paper examines the evolving relationship between IPR protection and pharmaceutical innovation, within the context of facilitating timely access to HIV treatment in developing countries.

Since the mid-1990s, the availability of antiretroviral (ARV) therapy as an effective treatment has transformed HIV infection from a death sentence into a chronic, but largely manageable, disease. The challenge remains to ensure affordable access to treatment for all those who need it. The introduction of generic ARVs resulted in meaningful price reductions. Had generic ARVs not been available, it would not have been possible to provide treatment for the millions who are alive today in the developing world.

The expiry of transition periods for the full implementation of the WTO TRIPS Agreement in developing countries is rapidly closing the windows of opportunity that permitted generic competition and follow-on innovations to adapt existing ARVs for resource-limited settings – key factors that have hitherto facilitated the scale up of ARV access in developing countries.

Part 3 considers the twin challenges that now arise – how to ensure innovation and access to these future health technologies. With regard to upstream innovation, the question is whether and how IP protection will impede or facilitate discovery of new treatments or adaptation of existing ones. For downstream access, the primary concern relates to the potential for reduced, or absent, generic competition and the consequences for pricing and distribution of ARVs.

There is growing recognition that meeting the needs of those living with HIV, particularly in the developing countries, will likely require alternative approaches that improve upon the present patent-driven system of pharmaceutical innovation. In this regard, the paper examines two policy dimensions – the creation of an enabling environment and the use of innovative financing mechanisms – that can serve as strategic levers to enhance sharing of knowledge for R&D and innovation, and to ensure greater affordability of the fruits of such research.

Part 4 looks at two principal approaches by which to create an enabling IP environment – tiering and pooling. While these approaches have often been used strategically on the demand side to facilitate downstream access, they also have potential for enabling innovation further upstream in the R&D pipeline. In considering the Medicines Patent Pool and GlaxoSmithKline’s patent pool, the paper draws out issues at the centre of debate. Where these are adequately addressed, this paper suggests that tiering and pooling arrangements, whether used separately or as complements, can open the door towards greater sharing of the building blocks of knowledge and thus, to innovations otherwise not possible or affordable.

Part 5 examines the role of financing mechanisms – push and pull mechanisms – with the aim of assessing their effectiveness in re-engineering the value chain of R&D and innovation, and influence downstream access. The discussion on push mechanisms addresses two related aspects; up-front funding that diminishes the risk of investing in R&D and options for the public sector’s strategic use of IPR licensing to ensure follow-on innovation
and access. On pull mechanisms, Part IV examines recent prize proposals that have garnered significant attention, namely the Advance Market Commitments and Health Impact Fund, and highlights a number of considerations that should inform the structuring of prizes.

Finally, the paper suggests that a hybrid approach to financing innovation for access may yet offer the most potential, building on the strengths while lessening the shortcomings of the various mechanisms. The evident challenge is to determine the right combination of push and pull approaches, which balance the need to ensure sufficient financial incentive for innovation with the need to do at an affordable cost. The flow of public and philanthropic funds towards the global response to AIDS necessitates a careful examination of how fair returns from the public investment in R&D may be ensured and the needs of those living with HIV can be adequately met. Drawing on a number of illustrative models, this paper proposes a metric for evaluating current and future proposals. While the obvious difficulty is that such an evaluation takes place in a context where many proposals have yet to be implemented, the aim is to provide policy makers a set of criteria and principles on which they can base their decisions.
### Case

*Minister of Health and Others v. Treatment Action Campaign and Others, 2002 SA 721 (CC) at 1 (S. Afr.)*

### Nature & Scope of Authority

“Constitutional Court: highest appellate court and occasionally court of first instance for all constitutional questions.” *The Bluebook: A Uniform System of Citation*, 389 tbl. T. 2.36 (Columbia Law Review Ass’n et al. eds., 19th ed. 2010).

### Facts & Background Law

- Appeal from high court where it was determined that the government had “acted unreasonably in (a) refusing to make an antiretroviral drug called nevirapine available in the public health sector where the attending doctor considered it medically indicated and (b) not setting out a timeframe for a national programme to prevent mother-to-child transmission of HIV.
- In 1999 the government told the Treatment Action Campaign (TAC) that they were concerned about the safety and efficacy of nevirapine.
- In 2001 the government announced that the nevirapine would be available at limited number of pilot sites which would be two per providence.
  - As a result the applicants state that doctors who did not work at one of the two sites could not prescribe the drug to patients.
- Both the Medicines Control Council and the World Health Organisation have declared nevirapine safe and suggested that it should be prescribed to women living with HIV and their child at birth.

### Issues

1) Nation-wide access to public health services and whether access to HIV medications, specifically medications that prevent mother-to-child transmission is easily available to all citizens.
2) Whether the government is providing adequate special protection for children as mandated in the Bill of Rights.
3) Whether sections 27 and 28 of the Constitution require the government to provide an effective, comprehensive and progressive programme for the prevention of mother-to-child transmission of HIV throughout the country.

### Holding

a) 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 realize progressively the rights of pregnant women and their newborn children to have access to health services to combat mother-to-child transmission of HIV.

b) The programme to be realised progressively within available resources must include reasonable measures testing pregnant women for HIV, counselling HIV-positive pregnant women on the options open to them to reduce the risk of mother-to-child transmission of HIV, counselling in general, and making appropriate treatment available to them for such purposes.

c) The policy for reducing the risk of mother-to-child transmission of HIV as formulated and implemented by government fell short of compliance with the requirements in subparagraphs (a) and (b) in that:
  a. Doctors at public hospitals and clinics other than the research and
training sites could not prescribe nevirapine to reduce the risk of mother-to-child transmission of HIV even where it was medically indicated and adequate facilities existed for the testing and counselling of the pregnant women concerned.

b. The policy failed to make provisions for counsellors at hospitals and clinics other than at research and training sites to be trained in counselling for the use of nevirapine as a means of reducing the risk of mother-to-child transmission of HIV.

**Rule, Application, and Judgment**

Government is ordered without delay to:

a) Remove the restrictions that prevent nevirapine from being made available for the purpose of reducing the risk of mother-to-child transmission of HIV at public hospitals and clinics that are not research and training sites.

b) Permit and facilitate the use of nevirapine for the purpose of reducing the risk of mother-to-child transmission of HIV and to make it available for this purpose at hospitals and clinics when in the judgment of the attending medical practitioner acting in consultation with the medical superintendent of the facility concerned this is medically indicated, which shall if necessary include that the mother concerned has been appropriately tested and counselled.

c) Make a provision, if necessary, for counsellors based at public hospitals and clinics other than the research and training sites to be trained for the counselling necessary for the use of nevirapine to reduce the risk of mother-to-child transmission of HIV.

d) Take reasonable measures to extend the testing and counseling facilities at hospitals and clinics throughout the public health sector to facilitate and expedite the use of nevirapine for the purpose of reducing the risk of mother-to-child transmission of HIV.

**Case**  

**Nature & Scope of Authority**  
Application for compulsory licence under Section 8491 of the Patents Act, 1970, in Respect of Bayer Corp’s patent No.215758.

**Facts & Background Law**

- After developing a drug that could be used to extend the life of a patient who was living with certain types of cancer, Bayer received a patent in India for the drug.
- When the patent expired, Natco, a reputed Indian generic drug manufacturer, received a licence to manufacture the drug in bulk and to market it in India.
- Natco approached Bayer to request a voluntary licence to manufacture and sell the drug, which Bayer did not grant.
- Article 27.1 of the TRIPS Agreement requires WTO Members to make patents “available for any inventions, whether products or processes, in all fields of technology”, which includes patents for pharmaceutical processes and products.

**Issue**  
- Whether the reasonable requirements of the public with respect to the
The patented invention have been satisfied,

- The patented invention is not available to the public at a reasonably affordable price, and
- The patented invention is not worked in the territory of India.

### Holding

Compulsory licence agreement was granted to Natco with the price of the drug not to exceed Rs.8880 for a pack of 120 tablets, required for one month’s treatment.


High Court of Kenya ruled that sections of the Anti-Counterfeit Act 2008 will not apply to generic medicines, that the Constitution of Kenya 2010 promotes the contention that intellectual property should not override right to life, right to health and right to human dignity. Patent holders will not be able to use the act to block the import of generic medicines.
Legislative Authority


Nature, Scope and Source of Authority

- This is the first report to the General Assembly since the High-level Meeting on HIV/AIDS, held in June 2011.
- Reports are not binding and it is up to the Member States to adhere to the recommendations made in the report.

Substance

At the meeting, which reviewed progress made during the previous decade, Member States pledged to deliver antiretroviral therapy to 15 million people living with HIV; work towards eliminating new infections in children and substantially reducing maternal AIDS-related deaths; reduce by 50 percent new infections from sexual transmission and among people who inject drugs; substantially increase HIV funding, with the goal of mobilizing $22 billion to $24 billion annually; meet the needs of women and girls; and eliminate stigma and discrimination.

The report summarizes the key targets for 2015:

- Reduce sexual transmission of HIV by 50 percent;
- Reduce HIV transmission among people who inject drugs by 50 percent;
- Eliminate new infections in children and substantially reduce AIDS-related maternal deaths;
- Reach 15 million people living with HIV with antiretroviral treatment;
- Reduce tuberculosis deaths among people living with HIV by 50 percent;
- Close the global AIDS resource gap and reach a significant level of expenditure;
- Meet the specific needs of women and girls, eliminate gender inequalities and gender-based abuse and violence and increase the capacity of women and girls to protect themselves from HIV;
- Eliminate stigma, discrimination and violence against people living with and affected by HIV and HIV-related travel restrictions, through laws, policies, strategies and programmes that advance human rights; and
- Eliminate parallel systems for HIV-related services to strengthen integration of the AIDS response.

1) Treaty Article


Nature, Scope & Source of Authority

Brazil has had immense success in implementing a free antiretroviral drug programme through public networks in its country. There are over 400 AIDS drugs dispensing units in Brazil and over 350 hospitals accredited for HIV/AIDS care.

Substance

- The quality control of the antiretrovirals distributed by the Ministry of Health (MoH) is done by: (1) statement (mandatory) from the competent health authority of the country where the product is manufactured, certifying that the plant complies with the Good Manufacturing Practices (GMP); (2) preliminary inspection of the pharmaceutical plant before the first delivery of the product; (3) monitoring of the production of the first batches; (4) analysis of batches
purchased, in the early phases of the provision contract, at laboratories accredited by the National Health Surveillance Agency/MoH; and (5) starting in 2001, mandatory bioequivalence testing for all drugs purchased.

- As a result, there are currently 95,000 infected individuals on antiretroviral treatment; 95 percent are adults and adolescents and 5 percent are children under 13 years old. As a comparison, in January 1997, approximately 23,000 people were benefiting from the free access policy. The analysis of data at the MoH has shown a significant drop in the number of hospitalization/patient; it estimated that approximately 234,000 AIDS-related hospital admissions were prevented in the period 1997-2000, with a savings of 677 million (U.S. dollars) for the Unified Health System.

- A considerable part of the success achieved by the Brazilian drug distribution programme is due to the development of quality generic antiretroviral drugs by Brazilian manufacturing laboratories, at costs significantly below those practised in the international market. Brazil has stated that they can, at the present time, promote the transfer of technology for the establishing of industrial antiretroviral drug manufacturing poles, including the training of technical staff.

### Treaty Article


### Nature, Scope & Source of Authority

- Meeting was hosted by Maastricht University and the International Commission of Jurists to discuss economic, social and cultural rights.
- The Maastricht Principles on Extraterritorial Obligations of States was adopted by international human rights treaty bodies, regional human rights bodies, and former and current Special Rapporteurs of the United Nations Human Rights Council.
- Principles were based on legal research conducted over a decade.
- Drawn from international law, these principles aim to clarify the content of extraterritorial State obligations to realize economic, social and cultural rights with a view to advancing and giving full effect to the object of the Charter of the United Nations and international human rights.

### Substance

- These commitments include the obligation to realize progressively economic, social and cultural rights given the maximum resources available to States, when acting individually and through international assistance and cooperation, and to guarantee these rights without discrimination on the basis of race, colour, gender, sexual orientation and gender identity, language, religion, political or other opinion, national or social origin, property, birth, disability or other prohibited grounds in international law.
<table>
<thead>
<tr>
<th>Nature, Scope &amp; Source of Authority</th>
<th>WTO member states were concerned about how the TRIPS Agreement would impact their ability to protect intellectual property rights while at the same time providing low-cost medicines to the public for epidemics such as HIV/AIDS, tuberculosis, malaria etc.</th>
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<tbody>
<tr>
<td></td>
<td>As a result, the WTO members declared the following TRIPS Agreement flexibilities:</td>
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<tr>
<td></td>
<td>o In applying customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles.</td>
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<tr>
<td></td>
<td>o Each member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.</td>
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<tr>
<td></td>
<td>o Each member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those related to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.</td>
</tr>
<tr>
<td></td>
<td>o The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each member free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions of Arts. 3 and 4.</td>
</tr>
<tr>
<td></td>
<td>The declaration stated that the Council for TRIPS would need to find an expeditious solution to the problem that WTO members who are unable to manufacture or who have insufficient manufacturing capabilities are facing with the effective use of the compulsory licensing under the TRIPS Agreement.</td>
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<tr>
<td></td>
<td>Least-developed country members are not obliged, with respect to pharmaceutical products, to implement or apply Sects. 5 and 7 of Part II of the TRIPS Agreement or to enforce rights provided for under those sections until January 1, 2016.</td>
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<tr>
<td><strong>Nature, Scope &amp; Source of Authority</strong></td>
<td>Decision of the General Council. Created in response to the statement in the Declaration on the TRIPS Agreement and Public Health that the Council needed to come up with a solution for countries that do not have manufacturing capabilities or whose capabilities are insufficient.</td>
</tr>
</tbody>
</table>
| **Substance** | • Establishes waivers in relation to pharmaceutical products from the obligations set out in paragraphs (f) and (h) of Art. 31 of the TRIPS Agreement.  
• Obligations shall be waived with respect to the grant by it of a compulsory licence for the purposes of production of a pharmaceutical product(s) and its export to an eligible importing Member(s) as long as:  
  o The eligible importing Member(s) has made a notification to the Council for TRIPS, that:  
    ▪ Specifies names and expected quantities of the product(s) needed;  
    ▪ Confirms that the eligible importing member in question, other than a least developed country Member, has established that it has insufficient or no manufacturing capacities in the pharmaceutical sector for the product(s) in question in one of the ways set out in the Annex to this Decision; and  
    ▪ Confirms that, where a pharmaceutical product is patented in its territory, it has granted or intends to grant a compulsory licence in accordance with Art. 31 of the TRIPS Agreement and the provisions of this Decision.  
  o The compulsory licence issued by the exporting Member under this Decision shall contain the following conditions:  
    ▪ Only the amount necessary to meet the needs of the eligible importing Member(s) may be manufactured under the licence and the entirety of this production shall be exported to the Member(s) which has notified its need(s) to the Council for TRIPS;  
    ▪ Products produced under the licence shall be clearly identified as being produced under the system set out in this Decision through specific labeling or marking.  
    ▪ Before shipment begins, the licensee shall post on a website the following information:  
      • The quantities being supplied to each destination; and  
      • The distinguishing features of the product(s).  
  o The exporting Member shall notify the Council for TRIPS of the grant of the licence, including the conditions attached to it.  
• Where a compulsory licence is granted by an exporting Member, adequate remuneration shall be paid to that Member.  
• To ensure that the products imported under this established system, eligible importing Members shall take reasonable measures within their means, proportionate to their administrative capacities and to the risk of trade diversion to prevent re-exportation of the products that have actually been imported. |
imported into their territories under the system.

- Members shall ensure the availability of effective legal means to prevent the importation into, and sale in, their territories of products produced under the system set out in this Decision and diverted to their markets inconsistently with its provisions, using the means already required to be available under the TRIPS Agreement.

- Eligible importing Members and exporting Members are encouraged to use the system set out in this Decision to help build the pharmaceutical sector to overcome the problem identified in the Declaration.

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**Treaty Article**


**Nature, Scope & Source of Authority**

The South Centre (the Centre) is an intergovernmental organization of developing countries established by an Intergovernmental Agreement (Treaty) which came into force on July 31, 1995 with its headquarters in Geneva.

**Substance**

- This policy brief seeks to examine the implementation of the Doha Declaration in the ten years since its adoption and the constraints that have occurred in preventing effective implementation of the Declaration.

  - Constraints:
    - The Doha Declaration is not self-executing and requires amendments to national legislations to make full use of the TRIPS flexibilities.
    - The TRIPS plus standards, regional trade, investment agreements, and WTO accession agreements can significantly undermine the existing TRIPS flexibilities for developing and least-developed countries.
    - At the time that this article was published, only a limited number of countries have adopted legislation to implement the August 30th Decision as an exporting country. And there has been very limited use of the system. Only one importing country (Rwanda) used the mechanism to import cheaper life-saving medicines.
    - There has been no substantial progress towards realizing the fundamental objective behind the extension of the transition period in order to provide least-developed countries with sufficient policy space to create a ‘viable technological base’.

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**Treaty Article**

Medicines and Related Substances Control Amendment Act 90 of 1997 (S. Afr.).

**Nature, Scope & Source of Authority**

- Purpose of the act is to provide a method through which antiretroviral agents could be made cheaper and more available to people in South Africa living with HIV.

- Enacted by the Parliament of the Republic of South Africa and assented by the President of South Africa.

**Substance**

- In general, to provide for procedures that will expedite the registration of essential medicines, the re-evaluation of all medicines after five years, to enact
measures for the supply of more affordable medicines, require labels to be approved by the council, prohibit bonusing and sampling of medicines, regulate control of medicines and scheduled substances, provide the licensing of certain persons to compound, dispense, or manufacture medicines, provide generic substitution of medicines, establishment of a pricing committee, regulate the purchase and sale of medicines by wholesalers, make provisions for appeals against decisions of the Director-General or the council, regulate the powers of inspectors, increase magistrates’ jurisdiction in relation to penalties of this Act, provide council ability to acquire and appropriate funds, regulate anew Minister’s power to make regulations, and provide for the rationalization of certain laws relating to medicines and related substances.

**U.S. Federal Regulation**

**Exec. Order No. 13155, 65 Fed. Reg., 30521 (May, 10, 2000).**

**Nature, Scope & Source of Authority**

- Issued by the President of the United States and has the full force of the law.

**Substance**

- Purpose is to support any intellectual property law or policy that benefits a sub-Saharan African country in regulating HIV/AIDS pharmaceuticals or medical technologies as long as the law or policy of the country:
  - Promotes access to HIV/AIDS pharmaceuticals or medical technologies for affected populations in that country, and
  - Provides adequate and effective intellectual property protection consistent with the TRIPS Agreement.
- Prohibits U.S. Government from taking action pursuant to section 301(b) of the Trade Act of 1974 with respect to any law of policy in beneficiary sub-Saharan African countries that promotes access to HIV/AIDS pharmaceuticals or medical technologies and that provides adequate and effective intellectual property protection consistent with the TRIPS Agreement.
- Allows U.S. Government to evaluate, determine, or express concern about whether such a law or policy promotes purposes described above or is consistent with the TRIPS Agreement.
- Allows U.S. Government to consult with or otherwise discuss with sub-Saharan African governments whether such law or policy meets the conditions set forth in this order.
- Also allows U.S. Government to invoke dispute settlement procedures of the WTO to examine whether any such law or policy is consistent with the Uruguay Round Agreements.

**Treaty Article**


**Nature, Scope & Source of Authority**

In accordance with Paragraph 8 of the Decision on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, the Council for TRIPS annually reviews the functioning of the System set out in the
### Decision to ensure its effective operation.

<table>
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<th>Substance</th>
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| The report provides:  
- Information on implementation and use of the System established under the Decision;  
- A discussion on the operation of the System established under the Decision;  
- Information on the Protocol Amending the TRIPS Agreement;  
- The experiences of Members who have used or have considered using the system;  
- Information on the implementation of the system into domestic legislative and regulatory framework;  
- Procedural requirements of acceptance and current status of acceptances of the amendment to the TRIPS Agreement;  
- Information on the annual review of the technical cooperation and capacity building on the Paragraph 6 System and related TRIPS flexibilities;  
- Any alternatives to the use of the Paragraph 6 System to achieve the objective of access to medicines, procurement policies, and other related aspects affecting access to medicines; and  
- Next steps and recommendations made by the Council and Members |

### Communication Article

<table>
<thead>
<tr>
<th>World Trade Organization (WTO), European Union and a Member State-Seizure of Generic Drugs in Transit, Request to Join Consultations, WT/DS408/7 (June 3, 2010).</th>
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<tr>
<th>Nature, Scope &amp; Source of Authority</th>
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<tbody>
<tr>
<td>Communication that was from the delegation of Japan to the delegation of the European Union, the delegation of India and the Chairman of the Dispute Settlement Body.</td>
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<th>Substance</th>
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<tr>
<td>Japan requested to be a part of the consultations about the seizure of consignments of generic drugs.</td>
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### Treaty Article

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<table>
<thead>
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<th>Nature, Scope &amp; Source of Authority</th>
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<td>Concerning customs action against goods suspected of infringing certain intellectual property rights and the measures to be taken against goods found to have infringed such rights.</td>
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<th>Substance</th>
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| Article 1, 1. This Regulation sets out the conditions for action by the customs authorities when goods are suspected of infringing an intellectual property right in the following situations:  
  - (a) when they are entered for release for free circulation, export or re-export in accordance with Article 61 of Council Regulation (EC) No 2913/92 of 12 October 1992 establishing the Community Customs Code (3);  
  - (b) when they are found during checks on goods entering or leaving the Community customs territory in accordance with Articles 37 and 183 of Regulation (EEC) No 2913/92, placed under a suspensive procedure within the meaning of Article 84(1)(a) of that Regulation, in the process of being re-exported subject to notification under Article 182(2) of that Regulation or placed in a free zone or free warehouse within the meaning of Article 166 of that Regulation. |
2. This Regulation also fixes the measures to be taken by the competent authorities when the goods referred to in paragraph 1 are found to infringe intellectual property rights.

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<td>Nature, Scope &amp; Source of Authority</td>
<td>The South Centre (the Centre) is an intergovernmental organization of developing countries established by an Intergovernmental Agreement (Treaty) which came into force on July 31, 1995 with its headquarters in Geneva.</td>
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| Substance | • New mechanisms are needed in order to simultaneously and effectively promote innovation and access to medicines, particularly for diseases that mainly affect developing countries. A binding international instrument or international treaty on R&D, to be negotiated under the auspices of the WHO, can provide the adequate framework to define priorities and ensure the coordination and sustainable financing of R&D on drugs that could be made available at affordable prices in developing countries.6
• This article suggests the following objectives for a global instrument on research and development of pharmaceutical products:
  o Develop sustainable financing mechanisms;
  o Prioritize R&D on the basis of health needs;
  o Coordinate public R&D; and
  o Promote the research capacity of developing countries.
• Author suggests a paradigm shift to promote R&D to meet the needs of public health in the long and medium term, especially in developing countries.
• Also, the adoption of a binding instrument could help the WHO regain its leadership in this area and redefine global health governance. |

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<td>Nature, Scope &amp; Source of Authority</td>
<td>Recognizes that least-developed country Members have special economic, financial and administrative constraints and are in need of flexibility to create a viable technology base. Least-developed country Members of the WTO are required to comply with TRIPS by July 2013. However, they may further postpone the treaty’s application to pharmaceutical products until January 2016.</td>
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| Substance | • Least-developed country Members shall not be required to apply the provisions of the Agreement, other than Articles 3, 4 and 5, until 1 July 2013, or until such a date on which they cease to be a least-developed country Member, whichever date is earlier.
• With a view to facilitating targeted technical and financial cooperation programmes, all the least-developed country Members will provide to the Council for TRIPS, preferably by 1 January 2008, as much information as |
possible on their individual priority needs for technical and financial cooperation in order to assist them taking steps necessary to implement the TRIPS Agreement.

- Developed country Members shall provide technical and financial cooperation in favour of least-developed country Members in accordance with Article 67 of the Agreement in order to effectively address the needs identified in accordance with paragraph 2.
- In order to assist least-developed country Members to draw up the information to be presented in accordance with paragraph 2, and with a view to making technical assistance and capacity building as effective and operational as possible, the WTO shall seek to enhance its cooperation with the World Intellectual Property Organization and with other relevant international organizations.
- Least-developed country Members will ensure that any changes in their laws, regulations and practice made during the additional transitional period do not result in a lesser degree of consistency with the provisions of the TRIPS Agreement.
Persuasive Authority


This article examines the connection between a country’s GDP and the strength of their patent protection laws. Based on research by other researchers, the authors determined that a negative and statistically significant estimated coefficient on ln GDP per capita and a positive and statistically significant estimated coefficient on [ln GDP per capita]-are consistent with a U-shaped relationship between GDP and patent strength. It was also stated that the u-shaped relationship is robust to the addition of other explanatory variables to the model, such as measures of openness to trade, lagged school enrollment, total CDP, the proportion of scientists and engineers in the labour force, and British and French colonial origins. The authors also state that as poorer countries grew, their ability to imitate inventions also grew and the legislatures would decrease patent protection as a result.


The report reviews progress made until the end of 2010 in scaling up access to health sector interventions for HIV prevention, treatment, care and support in low-and middle-income countries. It also monitors key components of the health sector response to the HIV epidemic. It provides an update on the HIV epidemic; selected health sector interventions for HIV prevention; knowledge of HIV status, scaling up treatment and care for people living with HIV; scaling up services for key populations at higher risk of HIV infection; scaling up HIV services for women and children; towards elimination of mother to child transmission and improving maternal and child health in the context of HIV. The report also provides statistics on the key indicators of the HIV epidemic. In addition, it outlines a roadmap for 2015 and the ways in which Member States can meet their goals.


This article discusses the crucial role that Brazilian civil society organizations have played in the implementation and sustainability of universal access to AIDS drugs in the country. It emphasizes the effort of nongovernmental organizations (NGOs) that work together in the fields of public health, HIV/AIDS, and intellectual property. The article discusses the Brazilian response to the HIV/AIDS and the role of NGOs in the area of intellectual property and access to medicines from the perspective of a Brazilian civil society group called The Working Group on Intellectual Property (GTPI) of the Brazilian Network for the Integration of Peoples (REBRIP). It outlines the problems and challenges that GTPI has dealt with in the field and how GTPI has maintained a balance between intellectual rights and the right to health through certain measures.

The authors discuss Brazil’s large-scale universal antiretroviral distribution program. It is the first of its kind and provides free antiretroviral medication to about 125,000 patients, which reflects coverage of virtually all people living with HIV/AIDS with some form of treatment indication. They state that results achieved are telling: from 1996 to 2002, more than 60,000 AIDS cases, 90,000 deaths and 358,000 AIDS-related hospital admissions were averted. Financially, the balance is also positive: the savings in out-patient and hospital costs outrun the costs of implementation by more than US$ 200 million. Their conclusion is that these results demonstrate that it is feasible to extend the availability of ARV treatment to the millions of people in need, even in a resource-poor setting where the ideal infrastructure might not be in place. The broad political and sociological context in which the Brazilian response evolved cannot be underestimated, but it is fair to say that the Brazilian experience is based on a concerted early government response, the strong and effective participation of civil society, a multisectoral mobilization, a balanced prevention and treatment approach and the advocacy of human rights in all strategies and actions.


This report provides data on new global AIDS-related statistics, information about the last two decades of what occurred in relation to the AIDS epidemic, and global milestones, commitments, investment and accountability, treatment access, HIV prevention and safer sex, preventing new HIV infections among children, male circumcision, women and girls, men who have sex with men, people who inject drugs, sex workers, and punitive laws and practices statistics from the last decade. It also discusses the AIDS epidemic in relation to the UN’s Millennium Development Goals (MDG), specifically goals 4, 5, and 6.


Each year, UNAIDS and the Kaiser Family Foundation collect and analyze data to document international assistance for AIDS in low-and middle-income countries. It represents funding levels reflecting budgeting decisions that occurred during the current global economic crisis.

Financing a sufficient and sustained response to the HIV epidemic in low-and middle-income countries has emerged as one of the world’s greatest health and development challenges, and one that will be with us for the foreseeable future. International assistance from donor governments, through bilateral aid and contributions to the Global Fund to Fight AIDS, Tuberculosis and Malaria (the Global Fund) and other financing channels such as UNITAID (the international drug purchase facility) is a critical part of this response. Other funding sources include multilateral institutions, the private sector, and domestic spending by many affected-country governments and the households and individuals within them. Although funding from all these sources has risen significantly over the past decade, the gap between UNAIDS’ estimate of resources needed to combat the HIV epidemic and resources available was approximately $7.7 billion in 2009, up from a $6.5 billion gap in 2008. Moreover, after years of funding increases for AIDS from donor governments, this report finds that funding was essentially flat between 2008 and 2009.

In this report, the Commission on Intellectual Property Rights considers whether and how intellectual property rights (IPRs) could play a role in helping the world meet their targets – in particular by reducing poverty, helping to combat disease, improving the health of mothers and children, enhancing access to education and contributing to sustainable development. Also whether and how they present obstacles to meeting those targets and, if so, how those obstacles can be removed.

The Commission discusses the following questions:

- What can we learn from the economic and empirical evidence about the impact of IP in developing countries? Does the historical experience of developed countries hold any lessons for developing countries today? How can technology transfer to developing countries be facilitated? (Chapter 1)
- How does the IP system contribute to the development of medicines that are needed by poor people? How does it affect the access of poor people to medicines and their availability? What does this imply for IP rules and practices? (Chapter 2)
- Can IP protection on plants and genetic resources benefit developing countries and poor people? What sort of systems should developing countries consider for protecting plant varieties while safeguarding farmers’ rights? (Chapter 3)
- How could the IP system contribute to the principles of access and benefit sharing enshrined in the Convention on Biological Diversity (CBD)? Can it help to protect or promote traditional knowledge, biodiversity and cultural expressions? Can the extension of Geographical Indications (GIs) benefit developing countries? (Chapter 4)
- How does copyright protection affect developing countries’ access to knowledge, technologies and information that they need? Will IP or technological protection affect access to the Internet? How can copyright be used to support creative industries in developing countries? (Chapter 5)
- How should developing countries frame their own legislation and practice on patents? Can developing countries frame their legislation in ways that might avoid some of the problems that have occurred in developed countries? What would be the best position for developing countries in relation to patent harmonisation? (Chapter 6)
- What sort of institutions do developing countries need to administer, enforce and regulate IP effectively and how can these be established? What complementary policies and institutions are necessary, in particular in relation to competition? (Chapter 7)
- Are the international and national institutions involved in IPRs as effective as they could be in serving the interests of developing countries? (Chapter 8)


The author explains how new global rules for pharmaceutical patenting impact access to medicines in the developing world. The book gives an account of the current debates on intellectual property, access to medicines, and medical innovation, and provides historical context that explains how the current system emerged. The author supports major policy changes in the management of pharmaceutical patents and the way medical innovation is financed in order to protect public health and, in particular, promote access to essential medicines for all.

A policy agenda for access and innovation is sorely needed and should address both immediate steps to be taken, as well as tackle the fundamental question of how to create incentives for R&D that do not create access barriers.
Ensuring lower prices for medicines and other health care products requires the full implementation and use of the provisions of the Doha Declaration. Furthermore, the WTO should extend the 2016 deadline for LDCs to comply with obligations in the TRIPS Agreement to provide pharmaceutical product patents and protect undisclosed test data; it should also review the August 30th decision on production for export under a compulsory license. Finally, the international community, including patent-holding and generic pharmaceutical companies, should consider supporting patent pools as a tool for improving the management of IP for access and innovation.

In the longer term, medical research should be targeted in the direction of greatest need. Some alternatives currently being tested and/or debated include: a not-for-profit drug development model, prize funds that reward innovation based on health impact; and an R&D treaty that focuses on equitable contributions to the cost of R&D through multiple means – not exclusively through the granting of patent monopoly rights.

_AIDS and Governance, (Nana K. Poku, Alan Whiteside, and Bjorg Sandkjaer, eds, June 2007)._  
The political impact of HIV/AIDS varies greatly and is difficult to map. States depend on how governments choose to manage the political implications of HIV and AIDS, both those stemming from the erosions of its own capacity as well as those that originate from their changing relationship on a national and international level. With the epidemic showing scant signs of slowing down, this innovative volume assesses how HIV/AIDS affects governance and, conversely, how governance affects the course of the epidemic. In particular, the volume employs a compelling analytical and polemic framework for mapping the multiple dynamic mechanisms of governance and HIV/AIDS, brings together contributions from renowned international scholars from a variety of disciplines, draws on comprehensive and detailed perspectives of the roles of actors, institutions and structures, provides an incisive study of a global plague which threatens existing social, economic and human interrelations.

_Brenda Waning, Ellen Diedrichsen, & Suerie Moon, A Lifetime to Treatment: The Role of Indian Generic Manufacturers in Supplying Antiretroviral Medicines to Developing Countries, 13 J. of the Int'l AIDS Soc'y 1 (Sept. 2010)._  
Background: Indian manufacturers of generic antiretroviral (ARV) medicines facilitated the rapid scale up of HIV/AIDS treatment in developing countries though provision of low-priced, quality-assured medicines. The legal framework in India that facilitated such production, however, is changing with implementation of the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights, and intellectual property measures being discussed in regional and bilateral free trade agreement negotiations. The authors utilized transactional data containing 17,646 donor-funded purchases of ARV tablets made by 115 low- and middle-income countries from 2003 to 2008 to measure market share, purchase trends and prices of Indian-produced generic ARVs compared with those of non-Indian generic and brand ARVs.

They discovered that Indian generic manufacturers dominate the ARV market, accounting for more than 80% of annual purchase volumes. Among paediatric ARV and adult nucleoside and non-nucleoside reverse transcriptase inhibitor markets, Indian-produced generics accounted for 91% and 89% of 2008 global purchase volumes, respectively.

From 2003 to 2008, the number of Indian generic manufactures supplying ARVs increased from four to 10 while the number of Indian-manufactured generic products increased from 14 to 53. Ninety-six of 100 countries purchased Indian generic ARVs in 2008, including high HIV-burden sub-Saharan African countries. Indian-produced generic ARVs used in first-line regimens were consistently and considerably less expensive than non-Indian generic and innovator ARVs. Key ARVs newly recommended by the World Health Organization are three to four times more expensive than older regimens.
The authors determined that future scale up using newly recommended ARVs will likely be hampered until Indian generic producers can provide the dramatic price reductions and improved formulations observed in the past. Rather than agreeing to inappropriate intellectual property obligations through free trade agreements, India and its trade partners - plus international organizations, donors, civil society and pharmaceutical manufacturers - should ensure that there is sufficient policy space for Indian pharmaceutical manufacturers to continue their central role in supplying developing countries with low-priced, quality-assured generic medicines.


The researchers assessed the budget impact of the Thailand government’s use licences policy (which are a form of compulsory licensing) on seven patented drugs. They compiled data from the Thai government agencies on the number of patients who needed treatment with each drug and the costs of treatments of both original and generic versions. The impact of the government’s budget was estimated within a 5-year period after the introduction of the licences policy. The study indicated that the use of generic drugs under the policy could save the government budget approximately $370 million over 5 years. It was also determined by the researchers that each drug had a different effect on budget saving depending on the number of patients treated, the difference in drug costs between original and generic drugs, and the lag time from the introduction of the policy to the availability of the generic drugs on the market. They concluded that the introduction of the government use licence policy in Thailand would provide significant benefits for the study timeframe. It was noted, however, that there were several key facts that affected the budget impact.

One of those factors was the number of patients in need of the drugs in question. If a more expensive drug was in higher demand then a cheaper generic version of the drug available would save the government more than if a cheaper drug is available, but there are fewer people who need that drug. The researchers noted that most of the drugs were delayed for one year from the year of policy introduction and therefore the potential benefits could have been greater if the importation of generic drugs occurred more quickly. Because of this, the researchers suggested that the policy implementation should be well prepared and the government should coordinate with the generic manufacturers to ensure quick importation. It was acknowledged by the researchers that there were some limitations of the study, one of them being the assumption that all patients had access to the drugs under the policy, which may not always be the case. Some patients may not seek treatment because of the fear of stigma or discrimination. In addition, factors not considered in the study would need to be considered, such as the subsequent reduction in market returns of pharmaceutical industries which might undermine innovation for the research and development of new drugs in the future. The researchers suggested that there would need to be long-term monitoring of the policy and assessments about its effect on the drug market.

Donald Harris, TRIPS After Fifteen Years: Success or Failure, as Measured by Compulsory Licensing, 18 J. Intell. Prop. L. 367, (Spring 2011).

Goal of the article is to determine whether or not TRIPS has been effective, to determine its impact on the global intellectual property standards, determine whether TRIPS is still relevant, whether TRIPS has been successful, and to evaluate TRIPS’ compulsory licensing provision. There are indicators on both sides of the argument of whether TRIPS is still relevant. The indicators that TRIPS is relevant are Member’s continued implementation of TRIPS obligations, the continued use of the WTO dispute settlement system to resolve TRIPS-related disputes, and compliance with recent adverse TRIPS’ decision. From the viewpoint of TRIPS’ objectives and principles, TRIPS has been successful. However, from the view of the Dispute Settlement System, TRIPS has not met its objectives and therefore has failed. In his conclusion, the author considers whether TRIPS thus far has been a success or failure is not clear. In its fifteen years, its message has been mixed. While there have been many positive developments,
negotiations for further advancement have stalled. In looking at the issue that arguably has garnered the most attention and has generated the most controversy--compulsory licensing--we also come away with mixed feelings. Significant progress has been made. Much more can be made. Nonetheless, the WTO has made remarkable strides in advancing compulsory licensing so that it is poised truly to address the needs for which it was created.


This Article explores key functions of pharmaceutical arbitrage, including its impact on access and innovation and its implications for the implementation of the TRIPS Agreement and other government interventions affecting pharmaceutical prices and distribution. Part I of the Article establishes a theoretical framework for understanding pharmaceutical markets and innovation, using the heuristic device of optimal pharmaceutical rents to explore pharmaceutical arbitrage. Part II of the Article applies this framework to two situations: the global pricing of antiretroviral drugs and the issue of Canadian-U.S. cross-border arbitrage. The primary conclusions of this Article fall into two clusters. First, the heuristic indicates that several forms of pharmaceutical arbitrage are beneficial, delivering lower prices to consumers without harming innovation. More broadly, the heuristic indicates that optimal economic incentives for innovation can be maintained while providing low income populations with greatly expanded access to patented medicines. Consistent with global optimal pharmaceutical rents, access can be expanded to all categories of global diseases, including cancer and heart disease, without damaging innovation. In the second cluster of conclusions, the author determines that the threat of pharmaceutical arbitrage is overstated and rarely observed empirically. This Article describes the legal and commercial frameworks which generally obstruct arbitrage, and argues that the most dangerous threat to innovation and public health comes from counterfeit medications, not from arbitrage. Resources now being expended to limit diversion in donor programmes and differential pricing schemes could be more profitably reallocated to anti-counterfeiting initiatives within high income markets. A prime example of a misdirected anti-arbitrage effort is the initiative within the President’s Emergency Plan for HIV/AIDS Relief (PEPFAR) to establish its own supply chain and procurement policies.


Global trade rules agreed upon in 1994 required many developing countries to begin offering patents on medicines for the first time. The World Trade Organization's Doha Declaration on the Agreement on Trade-Related Aspects of Intellectual Property Rights and Public Health affirmed that patent rules should be interpreted and implemented to protect public health and to promote access to medicines for all. Since Doha, more than 60 low- and middle-income countries have procured generic versions of patented medicines on a large scale. Despite these changes, however, a "treatment timebomb" awaits. First, increasing numbers of people need access to newer antiretrovirals, but treatment costs are rising since new ARVs are likely to be more widely patented in developing countries. Second, policy space to produce or import generic versions of patented medicines is shrinking in some developing countries. Third, funding for medicines is falling far short of needs. Expanded use of the existing flexibilities in patent law and new models to address the second wave of the access to medicines crisis are required. One promising new mechanism is the UNITAID-supported Medicines Patent Pool, which seeks to facilitate access to patents to enable competitive generic medicines production and the development of improved products. Such innovative approaches are possible today due to the previous decade of AIDS activism. However, the Pool is just one of a broad set of policies needed to ensure access to medicines for all; other key measures include sufficient and reliable financing, research and development of new products targeted for use in resource-poor settings, and use of patent law flexibilities. Governments must live up to their obligations to protect access to medicines as a fundamental component of the human right to health.
High prices of patent-protected medicines have become a major public health concern in developing countries, especially since the coming into force of the World Trade Organization (WTO)’s TRIPS Agreement, which sets stringent patent norms for WTO member states. Nevertheless, despite providing for the patenting of medicines, the TRIPS Agreement does allow certain exceptions and flexibilities which are in line with the public interest. This paper examines the TRIPS-permitted flexibilities (compulsory licensing, government use and parallel importation) which developing countries can make use of to override drug patents and make available more affordable medicines. Recent examples (from Malaysia, Indonesia, Thailand, Zimbabwe and Ghana) are provided of individual developing countries’ use of compulsory licences or government-use orders or other flexibilities to produce and import cheaper generic versions of patented drugs. The author also cautions, however, that a new wave of bilateral “free trade agreements” (FTAs) between developed and developing countries effectively erode these flexibilities by imposing even stricter patent standards than those in the TRIPS Agreement. If left unchecked, the trend towards such “TRIPS-plus” FTAs threatens to undermine access to essential medicines by poor patients throughout the developing world.

The Guide is part of our work under UNDP’s mandate to provide capacity development support to governments to implement good practices in intellectual property law and policy with focus on public health and south-south cooperation. The Guide is to be used as an instrument to support national initiatives for protecting, upholding and fulfilling the universal right to the best attainable standards of health. The Good Practice Guide analyses each of the public health flexibilities in the TRIPS Agreement and provides examples where and how have they been used by national governments. The Guide also provides some examples on the effect of adopting intellectual property protection measures, which exceed the minimum requirements of TRIPS and which are often introduced through bilateral trade instruments. An extensive bibliography allows further research on any of these matters. The Guide discusses ways in which these provisions and safeguards can be used in a flexible manner. It provides examples of how they have been applied by governments in various countries, and what effect such utilization has achieved thus far.

This paper reviews how countries can successfully use the flexibilities of the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) to increase access to HIV treatment. It gives an overview of the AIDS epidemic and the amount of people who are using antiretroviral treatment. The brief also outlines successful strategies that other countries have employed in utilizing the TRIPS flexibilities. It also outlines provisions that have been included in bilateral and regional trade agreements to maximize TRIPS flexibilities. In addition, the paper outlines possible actions that can be taken by high-income governments, low- and middle-income governments, and international organizations.

This paper considers India’s continued role as a supplier of affordable medicines since five years ago when it complied with the TRIPS Agreement. It examines both the Indian pharmaceutical industry and legal system roles in creating a system that is compliant with TRIPS, but can still provide affordable medicines. Topics covered in the study ways in which the Indian government has included flexibilities in their Patent law to promote a generic industry, the importance of keeping that industry going, and the development of the “mailbox” system in India. In addition, the authors state that the report can be used as an entry point towards exploring strategic south-south cooperation mechanisms on seeking solutions for health innovation to meet human development goals.


The authors of this statement think that the August 30, 2003 mechanism that was adopted by the TRIPS Council and the General Council needs to be tested and shown to work before becoming a part of the TRIPS Agreement. They state that it if it doesn’t reach its goal of giving access to affordable medicines for least-developed countries, then the amendment should be rejected and the WTO should come up with another alternative.


The authors think that developing countries need to improve medicines regulation rather than intellectual-property enforcement to ensure quality medicines are available. They argue that new intellectual property rules can undermine access to affordable generic medicines and damage public health. The article makes several recommendations for developed and developing countries, and for the World Health Organization (WHO). It is suggested that developed-country governments should increase drug-regulatory authorities, stop pursuing TRIPS-plus enforcement measures, and that developing countries should expand public health-care infrastructure, promote generic competition in national medicines policies. For the WHO, they recommend prioritizing the program that provides access to affordable, quality medicines for its Member States, including expansion of capacity and adequate funding, in addition the WHO should disband IMPACT.


This article states that since the TRIPS Agreement was enacted, the USA has imposed increasingly high levels of intellectual property protection on developing countries, most specifically Jordan. Medicine prices in Jordan have increased over the last ten years due in part to the country’s inability to generate generic medicines, the high cost of medicines that are produced in the country and the lack of foreign direct investment. Oxfam suggests several objectives for Jordan, the USA and other countries to reduce the burden on Jordan.

The authors considered how the proposed European Union (UN) language in a comprehensive trade agreement between Canada and the EU would affect Canada’s pharmaceutical market. They found that the period of exclusivity for innovative drugs in Canada would be lengthened considerably and higher drug costs would be placed on consumers, businesses, unions and government insurers. About 45 percent of total prescription drug spending in Canada is done using a government drug plan, so a substantial share of the costs would fall onto those plans. The study also determined that the additional costs to Canadians would be considerably more than the development investment into new drugs.


This is the third survey report published by G-Finder and investigates the 2009 global investment into research and development of new products for neglected diseases. HIV/AIDS research and development comprised 35.7 percent of global funding in 2009. The bulk of funding was provided by both public and philanthropic funders. Research shows that there was an overall shift towards public funding with emphasis on basic research, rather than higher-risk product development.


This report characterizes the level of innovation of all the new branded medicines that entered the U.S. market from 1989 to 2000, excluding vaccines and other biologics products. It also assesses the specific contribution made to spending growth from 1995 to 2000 by new drugs at each level, from breakthrough technology to incrementally modified products providing no significant clinical improvement to older medications. Finally, the report considers the structural forces that have shaped the direction of pharmaceutical innovation. In particular, it examines how modifying branded products approaching patent expiration can enable manufacturers to delay the threat of generic competition.


It analyses the relationships between intellectual property rights, innovation and public health, mobilizing the available evidence and analysis and the perspectives of different stakeholders. It makes recommendations aimed to promote innovation (i.e. new diagnostics, vaccines and medicines) relevant to the needs of sick people in developing countries, and the accessibility of health-care products in developing countries. The Commission was asked to submit a final report with concrete proposals to WHO’s Executive Board. Its detailed terms of reference were to summarize the existing evidence on the prevalence of diseases of public health importance with an emphasis on those that particularly affect poor people and their social and economic impact, review the volume and distribution of existing research, development and innovation efforts directed at these diseases, consider the importance and effectiveness of intellectual property regimes and other incentive and funding mechanisms in stimulating research and the creation of new medicines and other products against these diseases, analyse proposals for improvements to the current incentive and funding regimes, including intellectual property rights, designed to stimulate the creation of new medicines and other products, and facilitate access to them, produce concrete proposals for action by national and international stakeholders.

This statement remarks on the Global Fund to Fight AIDS, Tuberculosis and Malaria’s November 2011 cancellation of their annual round of funding due to their own financial situation. The cancellation is a reflection of the global HIV funding crisis even though science, medicine and other programmes are making progress in relation to the HIV epidemic. The UNAIDS Reference Group makes several recommendations to improve the funding situation of HIV prevention, treatment and care services. It suggests that states should recommit to funding the HIV response, UNAIDS should advocate more strongly for human rights based programmes and resources for those affected by HIV, the UNAIDS Executive Director and other staff should continue to advocate for financial support for the global AIDS response, which includes the Global Fund, and UNAIDS should implement innovate long-term funding mechanisms for the global HIV struggle.


The 14th edition of this report is the most recent guide to the prices of AIDS medicines, provides evidence of how increasing access to HIV/AIDS medicines can decrease the number of people living with HIV, offers suggestions on how to increase access to HIV/AIDS medicines and the history and World Health Organization’s guidance for each of the antiretroviral drugs that are profiled in this report. This report focuses on the high prices that pharmaceutical companies are charging in middle-income countries and examines specific companies, discusses how the price of tenofovir (TDF) continues to fall, but the price of fixed-dose combinations containing TDF hamper treatment scale-up, how paediatric formulations of ARVs for children are not being researched by companies, newer medicines are still too costly, and pharmaceutical companies should employ voluntary measures to increase access to medicines.


The purpose of this case study is to provide successful examples of technology transfer and integration into the world economy that are best practices and can be used by other developing countries to build their technological capacity. This study considers the performance of the Indian pharmaceutical industry and how the government’s focus on building the technological aspects of the pharmaceutical industry contributed to its current success. The first two chapters provide a broad overview of the industry, and the third chapter provides a case study on Ranbaxy Laboratories, which is a leading company in the industry. The case study is an example of the how the Indian pharmaceutical industry performed through the developing policy regime.

Brazil’s AIDS treatment program guarantees free access to highly active antiretroviral therapy for all people living with HIV/AIDS in need of treatment and as a result, the program is considered one of the most successful AIDS program in the developing world. This study considers the ARV cost trends in Brazil and how they compared in other low- and middle-income countries. The authors considered the overall changes in expenditures to compare the relative impacts of changes in drug prices and drug purchase quantities. They also considered the excess costs that are due to the difference between prices for generics in Brazil and the lowest global prices for the drugs and Brazil’s estimated savings that are a result of their reduced prices for patented drugs.


The AIDS Law Project launched a complaint on behalf of individuals living with HIV/AIDS, health care workers, Congress of South African Trade Unions, the Chemical, Energy, Paper, Printing, Wood and Allied Workers’ Union and the AIDS Consortium in attempt to lower the costs of essential HIV/AIDS drugs. The complaint was filed against GlaxoSmithKline and Boehringer Ingelheim and asserts that the excessive prices that the companies charge for their ARVs are responsible for premature, predictable and avoidable death of people living with HIV/AIDS. This report discusses HIV/AIDS in South Africa, ARVs and how they work, implications of paying for treatment in South Africa, the complaint to the Competition Commission of South Africa, and the authors suggestion for moving forward.


The objective of this report is to consider how Sub-Saharan African countries have handled TRIPS flexibilities in their legislation and how that has affected the costs of providing medicines to that region of the world. The authors review 39 national legislations of the Sub-Saharan African countries and finds that in general, very few countries have taken advantages of the TRIPS flexibilities to exclude new pharmaceutical patents, create a patent rights regime to permit parallel imports, to exempt research activities from patent infringement actions, permit the early working exception and to limit the level and type of test data protection.


When the Thai Ministry of Public Health announced the Government Use of Patents on three patented drugs (Efavirenz, Lopinavir+Ritonavir, and Clopidogrel), there was much confusion among the public. The purpose of this publication is to answer the top issues that need to be addressed. Its aim is to inform and educate the Thai and Global Society as a whole on the issue of pharmaceutical patent and public health. The paper discusses the government’s decision to use the Government Use of Patents on the three drugs, how it will affect the Thai people, and other questions that have been raised in relation to their decision. It also includes several relevant documents such as the TRIPS Agreement, Doha Declaration, patents, licences, and government announcements.

Beginning in 2006, the joint project developed a methodological framework for assessing the impact of TRIPS-Plus provisions contained in Free Trade Agreements (FTAs) on the price of medicines. The objective is to offer guidance to governments (e.g., trade and health ministries), research institutes as well as civil society organizations, in empirically evaluating the effects of these new IP obligations. Such a methodology can serve several purposes, including: (i) strengthening the overall negotiating capacity of governments in FTA negotiations; (ii) identifying areas where flexibilities in negotiations on new IP standards may be warranted; and (iii) identifying areas where complementary policies may help alleviate possible adverse public health implications of TRIPS-plus standards.


This presentation covered the MFN clause in TRIPS and regional trade agreements, why industrialized and developing countries engage in FTA with IP provisions, TRIPS Flexibilities and FTAs/EPAs, comparing IP provisions in recent FTAs/EPAs, assessing the impact: the case of Costa Rica and Dominican Republic, recommendations for negotiations, and lessons from the assessment.


This article offers a discussion of the probable effects of a Worldwide Patent System for developing countries. It draws upon insights from the ongoing processes in the World Intellectual Property Organization and elsewhere relevant for the global patent system and discusses these features from a developing country perspective. For scientifically advanced developing countries the effect in their most advanced and most global enterprises is potentially positive as they will benefit as much as other multinational companies. In areas of research and development where these most advanced developing countries do not possess a high level of technological capacity, a Worldwide Patent System is unlikely to create any benefits for them. For countries with the ability to copy and produce inventions made by others a Worldwide Patent System will have a negative effect as inventors will have little opportunity to utilise the system, whereas they will be bound by a larger number of exclusive rights narrowing down their space for innovation. For the least developed countries an additional problem arises: it might become even more difficult to import essential goods because patents will be in force in these countries even though there is no production of that product in the country.


One of the goals of this assembly was to remove intellectual property barriers on research and development for public health. The global strategy has various elements which aim to assess the public health needs of developing countries, identify their research and development priorities at regional, national and international levels, promote necessary research and development needs and capabilities, promote technology transfer between
developed and least-developed countries, remove barriers that prevent the delivery of and access to all health products and medical devices, improve financing mechanisms for research and development, and monitor this strategy and plan of action.


WIPO Member States adopted 45 recommendations made by the Provisional Committee on Proposals Related to a WIPO Development Agenda (PCDA) at the 2007 WIPO General Assembly. The recommendations are divided into five difference clusters: technical assistance and capacity building; norm-setting, flexibilities, public policy and public domain; technology transfer, information and communication technologies and access to knowledge; assessment, evaluation and impact studies; institutional matters including mandate and governance; and other issues. Each cluster covers different a different area of the development agenda.


The Administration's top priorities outlined in this report involve addressing weak IPR protection and enforcement, particularly in China and Russia. Although this year's Special 301 Report shows positive progress in many countries, rampant counterfeiting and piracy problems have continued to plague China and Russia, indicating a need for stronger IPR regimes and enforcement in those countries. In this year’s review, USTR highlights the need for significantly improved enforcement against counterfeiting and piracy, Internet piracy, counterfeit pharmaceuticals, transshipment of pirated and counterfeit goods, requirements for authorized use of legal software by government ministries, proper implementation of the TRIPS Agreement by developed and developing country WTO members, and full implementation of TRIPS Agreement standards by new WTO members at the time of their accession. The report also discusses countries that have positive progress on IPR protection and enforcement in 2007.


This report mentions the “indigenous innovation” policies that the U.S. considers an unfair disadvantage to U.S. rights holders in China and other copyright issues involving the Internet in countries such as Canada, Spain, Italy and Russia. The report is divided into two sections with one section focused on global developments of intellectual property rights protection and enforcement and how USTR and country reports which outline specific issues of concern with the partners that the U.S. trades with. In addition, the report announces that USTR has a new initiative in 2011 where it invites any trade party that’s on the Special 301 Priority Watch List to negotiate a mutually agreed action plan designed to lead that trading partner’s removal from the relevant list.

**Bernhard Schwartländer, et al., Towards an Improved Investment Approach for an Effective Response to HIV/AIDS, 377 The Lancet 2031, 2031-2041 (2011).**

Substantial changes are needed to achieve a more targeted and strategic approach to investment in the response to the HIV/AIDS epidemic that will yield long-term dividends. Until now, advocacy for resources has been done on the basis of a commodity approach that encouraged scaling up of numerous strategies in parallel, irrespective of
their relative effects. The authors propose a strategic investment framework that is intended to support better management of national and international HIV/AIDS responses than exists with the present system. Their framework incorporates major efficiency gains through community mobilisation, synergies between programme elements, and benefits of the extension of antiretroviral therapy for prevention of HIV transmission. It proposes three categories of investment, consisting of six basic programmatic activities, interventions that create an enabling environment to achieve maximum effectiveness, and programmatic efforts in other health and development sectors related to HIV/AIDS. The yearly cost of achievement of universal access to HIV prevention, treatment, care, and support by 2015 is estimated at no less than US$22 billion. The authors contend that implementation of the new investment framework would avert 12·2 million new HIV infections and 7·4 million deaths from AIDS between 2011 and 2020 compared with continuation of present approaches, and result in 29·4 million life-years gained. They also state that the framework is cost effective at $1060 per life-year gained, and the additional investment proposed would be largely offset from savings in treatment costs alone.