

South-South Exchanges related to Patents in Developing Countries and LDCs: A Civil Society Reading

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**Second WIPO Inter-Regional Meeting on South-South Cooperation on Patents,
Trademarks, Geographical Indications, Industrial Designs and Enforcement
Cairo, 6-8 May 2013**

Outline

1. Why “South-South”?
2. How does South-South cooperation/
exchange take place?
3. Some of its aspects
4. Examples of the use of the TRIPS
flexibilities
5. Role of public interest civil society in South-
South exchange
6. Beyond patents: the wider policy space

Why “South-South”? (1)

- Acknowledgement of the growing capacities in the area of IP and development in developing countries.
- This growing expertise in the South, by nature, takes into consideration socio-economic conditions and challenges in developing countries and LDCs
- IP gets contextualised

Why “South-South”? (2)

- Safeguarding against non-development friendly IPRs
- The learning process that developing countries and LDCs are going through, has to be acknowledged and shared
- What works, what does not work

Why “South-South”? (3)

- Acknowledging both the **particularity**, and **diversity** of DCs and LDCs



South-South Exchanges: characteristics

- Are not necessarily official
 - Academia, research centres
 - Civil society networks
 - Media
- Require a credible “facilitator”

How does South-South cooperation take place?

1. Bilateral level

- Within one region, mostly
- Patent offices undertaking bilateral agreements, often for training purposes
- Visiting expert/ consultant to another country's patent office

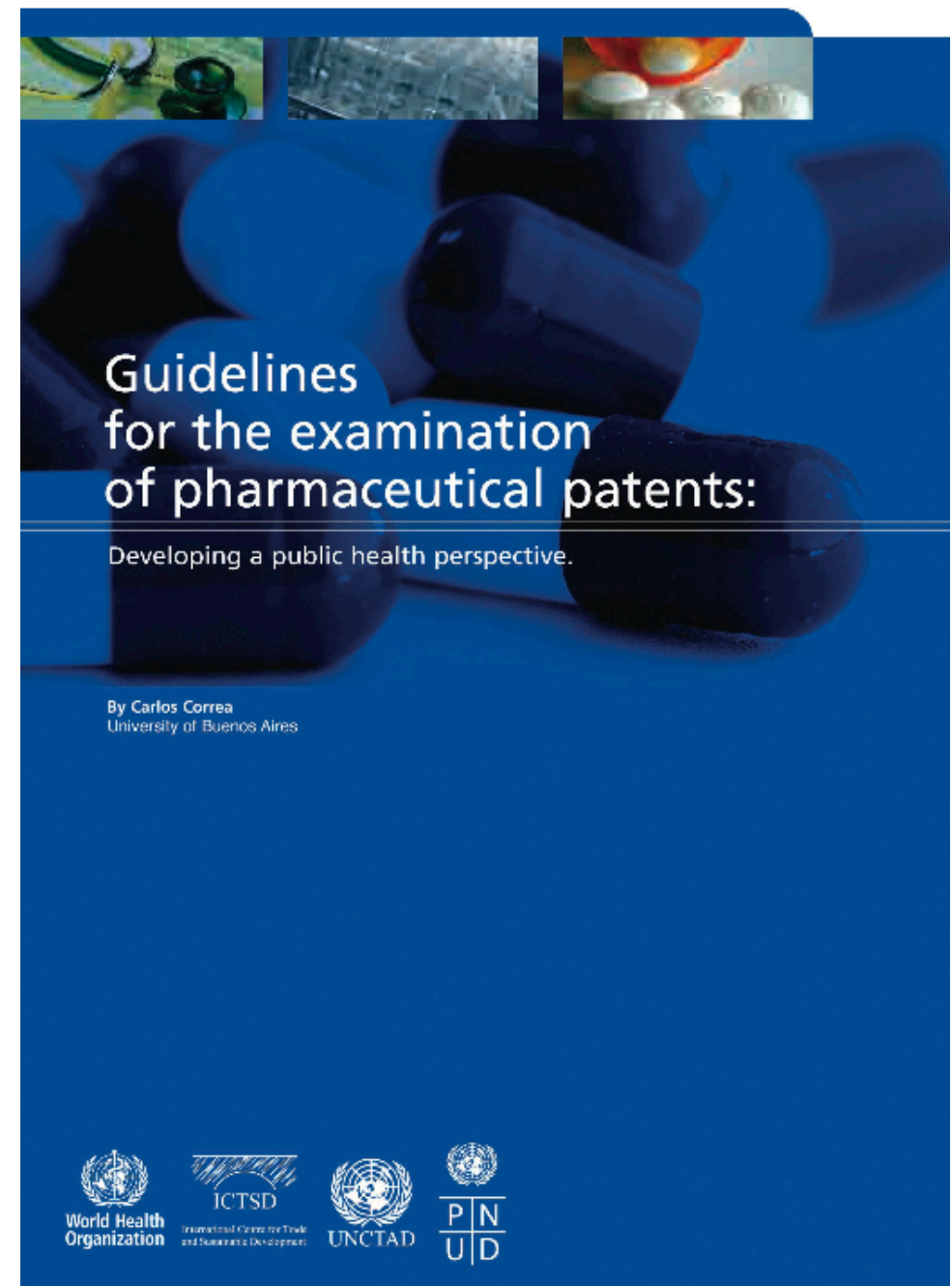
How does South-South cooperation take place?

2. Regional level (1)

- Allowing for wider participation
- Wider context for exchanges on IP challenges and best practices
- Creation of informal networks to support official work

2. Regional level (2)

- Series of regional training workshops for pharmaceutical patent examiners
- South African countries, Cape Town, Nov 2008
- MENA countries, Cairo, April 2009



2. Regional level (3)

- Project on “Enhancing Access to Treatment: Intellectual Property Protection and AIDS” in EMR/MENA countries, 2007-2008

- Partners:

WHO/EMRO, WHO/HQ

UNDP HIV/AIDS Regional Programme in the Arab States

UNDP Arab Initiative on Trade, Development and Economic Governance

Third World Network

2. Regional level (4)

- Outcomes:

IP regime/A2M

Assessment Tool +
national country
studies

Assessment tool for IPR regime, infrastructure and related procedures at country level

This assessment tool has been developed through collaborative efforts of WHO (East Mediterranean Regional Office and Headquarters), UNDP - HIV/AIDS Regional Programme in Arab States - (HARPAS) and Asia-Pacific Trade and Investment Initiative, UNDP Regional Centre in Colombo and Third World Network. In its present form, the tool has been developed to use in a joint multi-country project of these three organizations: "Enhancing Access to Treatment: Intellectual Property Protection and HIV/AIDS". A committee of representatives of these organizations has jointly developed this assessment tool. The assessment tool is accompanied by a User Guide and Explanatory Notes. For more information please contact: mirzaz@emro.who.int August. 2007

Part I Contextual Background

- A. General macroeconomic and trade environment
- B. State of the domestic health care system
- C. Pharmaceutical Situation
- D. HIV/AIDS situation and access to treatment

Part II Intellectual property right protection regime

- A. Non-WTO Members
- B. WTO Members: Implementation of IPR requirements under TRIPS
- C. Incorporation of public health safeguards and TRIPS flexibilities in patent law
- D. Membership of other trade agreements

Part III National IPR and market authorization Infrastructure.

- A. National Patent Office
- B. Market Authorization

Part IV Procedures and processes

- A. Patents
- B. Compulsory License

2. Regional level (5)

- Regional workshop on “Access to Essential Medicine: Patent and the Law”, Alexandria 15-16 May 2013.
- Bibliotheca Alexandrina and International Development Law Organisation (IDLO)

How does South-South Cooperation take place?

3. Global level

- Initiatives/ programmes organised by intergovernmental organisations (IGOs) e.g. UN organisations; or international NGOs
- South Centre (IGO of developing countries)
- Research (importance of documentation)
- Civil society networks e.g. WHO Watch project of People's Health Movement (including faith-based organisations)
- Media: News, Mailing lists and virtual think tanks

South-South Exchanges: aspects

1. Technical and legislative

- Creating an orientation towards development
- Capacity development pertaining to the use of patents in a developing country context
- Incorporating TRIPS flexibilities in national legislation
- Making full use of TRIPS flexibilities
 - Strict Patentability Criteria
 - Pre and post grant opposition systems
 - Compulsory License/Government Use Licenses
 - Parallel Importation
 - Exceptions to patent rights (e.g. Bolar exception)

Finally, the patients prevail

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The Supreme Court has denied Novartis a patent for its anti-cancer drug Gleevec. This leaves the door open for Indian pharmaceutical companies to produce their own versions of the drug. Since these are sold at roughly one tenth of the patented brand price, for thousands of cancer patients it means the difference between medicine and no medicine at all.

It is not just cancer patients that will benefit, but millions of people dependent on medicines for survival, including those with HIV, diabetes, hepatitis and more. Had the judgement gone the other way, it would have set a precedent for other big pharmaceutical companies to simply make minor modifications to any existing medicines to receive fresh patents. The message from the court is clear: India will grant pharmaceutical companies extended market monopoly only if a medicine is genuinely innovative.

It's not that Gleevec is not an excellent medicine. It is a lifesaving

NEWS » NATIONAL

April 7, 2013

DRUG PATENTS

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SAKTHIVEL SELVARAJ

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The Supreme Court's patent denial to Novartis for its anti-cancer drug Gleevec leaves the door open for Indian pharmaceutical companies to produce their own versions of the drug.

The Hindu

South-South Exchanges: aspects

2. Political

- Political and Positive:
 - Use of TRIPS flexibilities in a large number of developing countries and LDCs
 - Politically sensitive to use; none in Arab/MENA region
- Political and negative:
 - Political influence leading to signing of FTAs and going beyond the minimum standards of IP protection set by the TRIPS Agreement

Examples of Use of TRIPS Flexibilities (1)

- **Pre-Grant Opposition** filed in India in 2006 against GlaxoSmithKline (GSK)'s application for a patent on Combivir - a combination of two existing drugs in one pill
- GSK withdrew its patent applications in India as well as in other countries
- Resulted in improved access to generic versions of Combivir.

Examples of Use of TRIPS Flexibilities (2)

- Governments have the right to determine grounds for **compulsory licence**
 - negotiations to obtain a license on reasonable terms and conditions from the patent holder failed
 - public interest,
 - national emergencies,
 - public health nutrition,
 - failure to exploit or insufficiency of working
 - to remedy anti competitive practices
- **Not just for emergencies** and not limited to certain diseases

Examples of Use of TRIPS Flexibilities (3)

- **Zimbabwe:** CL in 2003
- **Zambia:** CL in 2004 to Pharco Mozambique to manufacture ARV combination lamivudine, stavudine & nevirapine
- **Mozambique:** CL in 2004 to manufacture same combination
- **Ghana:** GU in 2005
- **Eriteria:** imported ARVs in 2005 for public non-commercial use

Examples of Use of TRIPS Flexibilities (4)

- **Malaysia**
 - In 2002, issued a Government Use licence to import generic version of patented ARVs from India
 - Treatment cost per patient per year dropped by 81%
- **Indonesia**
 - GU in 2004, to manufacture ARVs
- **Thailand**
 - GU in 2006, 2007 to import/ manufacture ARVs
 - 2008, issued 3 GU licences

Examples of Use of TRIPS Flexibilities (5)

- **India**

- CL in 2013 for Sorafenib
- Grounds: not available at a “reasonably affordable price”
- 97% reduction in treatment cost

THIRD WORLD RESURGENCE

The compulsory licence on sorafenib: A right step to ensure access to medicines

The decision by the Indian Patent Office to grant a local company a compulsory licence to produce a generic version of an anti-cancer drug patented by Bayer on the grounds that it was not available at a 'reasonably affordable price' is a major step to ensure access to medicines.

KM Gopakumar

THE Indian Patent Office (IPO) made a landmark order on 12 March to grant domestic drug company Natco Pharma a compulsory licence (CL) to produce the generic version of multinational pharmaceutical firm Bayer's anti-cancer medicine sorafenib.

This order would allow sorafenib to be made available for Rs8,800 (\$173.93) per box that contains 120 100 mg tablets for a month's treatment, against Bayer's price of Rs280,000 per box.

However, Natco is not the first generic company to bring this medicine at a lower price. India's leading pharmaceutical company Cipla had introduced its generic version earlier, only to be subjected to a patent infringement suit by Bayer. The Patent Office order now ensures that low-cost sorafenib would be available in India even if Bayer wins the patent infringement suit. Further, Natco's price is even lower than Cipla's price of Rs28,000 per pack.



Intellectual Property Watch

<http://www.ip-watch.org/>

India's First Compulsory Licence Upheld, But Legal Fights Likely To Continue

By Patralekha Chatterjee for Intellectual Property Watch on 04/03/2013 @ 8:59 pm

New Delhi – India's Intellectual Property Appellate Board (IPAB) today upheld the country's first compulsory licence on a pharmaceutical product. The much-awaited verdict by Justice (Ms) Prabha Sridevan upholds the compulsory licence issued to Hyderabad-based Natco Pharma Ltd, an Indian generic drug manufacturer, which sells a much cheaper version of German pharmaceutical company Bayer AG's kidney and liver cancer drug Nexavar in the market.

[Update:] Bayer on 5 March announced it will appeal the decision ([IPW, Developing Country Policy, 5 March 2013](#) ^[1]).

Sridevan cited affordability and product access as the reasons for the decision to dismiss Bayer's appeal against the compulsory licence (CL). However, the Chennai-based IPAB hiked the royalty which Natco would have to pay to Bayer (under the terms of the CL) from 6 per cent to 7 per cent.

Mr. Madineedi Adinarayana, company secretary and general manager of Legal and Corporate Affairs at Natco Pharma Ltd, told *Intellectual Property Watch* that the IPAB decision is "very significant" and he is "happy" that the CL had been upheld. But, he said, "This is unlikely to be the end of the legal battle."

"The only relief that Bayer has got is a rise in royalty," Adinarayana said, adding that the company did not wish to comment on its plan of action for the future. "We will have to see what happens in the coming days," he said. "We will decide about our legal options after studying the IPAB decision in detail, and after seeing what Bayer does."

If Bayer wants to continue the legal fight, it has the option of going to the High Court in Mumbai, or in Chennai, or going to India's Supreme Court.

At the time of writing, the full text of IPAB judgment on the Nexavar case, was not public. Public health advocates and intellectual property rights experts shared their initial thoughts with Intellectual Property Watch. Bayer has yet to issue an official reaction to the IPAB decision, and not yet responded to inquiries.

Background

Bayer holds an Indian patent for the chemotherapy drug sorafenib tosylate, sold under the trade name Nexavar. On 9 March 2012, the then Indian Patent Controller issued the first-ever compulsory licence to Natco Pharma to manufacture an affordable generic version of sorafenib tosylate. Bayer promptly filed an appeal against the compulsory licence order before the IPAB in Chennai. Meanwhile, the CL had a dramatic effect on the drug's price – bringing it down to 8,800 rupees (approximately USD 160) for a month's dose – a fraction of Bayer's price of 280,000 rupees (approximately 5,098 USD). Under the terms of the compulsory licence, however, Bayer got a six per cent royalty on sales by Natco.

The mechanism of compulsory licence, which has generated a lot of heat globally, is embedded in India's patent law. Section 84 of India's Patents Act provides that an interested person may apply for a compulsory licence to work the patented invention on any of the following grounds: the reasonable requirements of the public with respect to the patented invention have not been satisfied; the patented invention is not available to the public at a reasonably affordable price; or the patented invention has not been worked in the territory of India.

Role of public interest civil society in SS exchange (1)

- Distinction between “public-interest” and “business-interest”: PINGOs and BINGOs
- Informal networks across the globe
- High level of expertise
- On-going research in specialised areas such as access to medicines and health policy (specialised NGOs and think tanks)
- Fast flow of information and strong advocacy tools

Kenyan court ruling upholds access to generic drugs

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NAIROBI | Fri Apr 20, 2012 12:24pm EDT

(Reuters) - Kenya's High court ruled on Friday that lawmakers must review legislation that could threaten the import of generic drugs,

allowing Kenyans to continue receiving affordable medicine.

Role of public interest civil society in SS exchange (2)

- Strong presence in global health trade and IP negotiations at intergovernmental level (observers) defending positions of the “South”
- Influenced outcomes of negotiations to the interest
 - TRIPS Agreement,
 - WHO Global Strategy on Public Health, Innovation and IP,
 - WIPO Development Agenda

Role of public interest civil society in SS exchange (3)

- Influencing discussions on substandard medicines at the WHO, shifting the focus from the counterfeit/IP angle to a more health-related one
- Strongly advocating for LDCs extension at WTO



NEWS

South African campaigners defy HIV drug patents

Nicky Lewis

31 January 2002 | EN

South Africa's Treatment Action Campaign (TAC) has defied the country's patent laws — and the stance of its government — by bringing generic versions of widely-used anti-HIV drugs into the country from Brazil.

Although the drugs in question are currently manufactured in South Africa in their proprietary form, these cost twice as much as generic versions, making them prohibitively expensive for most HIV/AIDS patients. The Brazilian drugs cost just US\$1.55 per patient per day.

By deliberately infringing patent laws, the campaigners say they are challenging the South African government to allow the generic production of HIV drugs in the country. For example, they argue, the government could issue compulsory licences that by-pass the authorisation to manufacture drugs that is normally required from patent holders.

"The South African government should pursue compulsory licensing to ensure that generic antiretrovirals can be produced and/or imported in South Africa," says Zackie Achmat, chair of TAC.



3rd People's Health Assembly, Cape Town, July 2012



3rd People's Health Assembly, Cape Town, July 2012

Attack on affordable medicines continues in EU-India trade negotiations

Posted by REPOST on April 11, 2013

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Photo: Delhi Network of Positive People

Health groups rally in Delhi as protests spread across the developing world.

[Posted on the [Don't Trade Our Lives Away](#) blog, 10 April, 2013, New Delhi] Thousands of people living with HIV, cancer patient groups & public health activists rallied on the streets of Delhi today calling on the Indian government to reject the EU's demands in the European Union–India Free Trade Agreement (EU–India FTA) negotiations. The protests coincide with the visit of the the Hon'ble Prime Minister to Germany to meet German Chancellor, Dr. Angela Merkel with the FTA at the top of the agenda. On 14-15 April, the Hon'ble Commerce Minister will be in Brussels for ministerial level negotiations to finalise the FTA.

As both sides push for the early conclusion of the FTA , the latest leaks of the negotiating text show that the EU's demands for harmful intellectual property & investment provisions have not stopped. The provisions require India to go beyond its WTO commitments and will have an adverse impact on access to medicines across the developing world.

Mr. Y.K. Sapru of Cancer Patients Aid Association, said "The Supreme Court has kept Section 3(d) alive & intact in a case that has captured global attention & sparked off global debates on the need for developing countries to protect only genuine innovations in medicines & not evergreening. Having failed to get their way at the Supreme Court in the Novartis case, we can expect the EU to push its industrv's demands for changes in the Indian law to curb the Indian iudiciarv."

Beyond patents

Sharing experiences of the wider policy space at national level

- Constitutional support of public interests
- Health insurance schemes
- Medicine pricing and procurement mechanisms
- Rational use of medicines (esp. antimicrobials)
- Pharmaceutical manufacturing capacity
- Role of public interest civil society organisations at national level

Thank you

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