South Africa’s IP Policy
Way Forward?

Benefits of Substantive Examination for Pharmaceutical Patent Claims
IP Forum, South Africa, 2013
Doctors Without Borders/ Medecins Sans Frontieres

- **MSF**, is an independent international medical humanitarian organisation that delivers emergency aid to people affected by armed conflict, epidemics, natural or man-made disasters, or exclusion from health care in more than 70 countries.

- **MSF’s Access Campaign** continues to work both on improving access to existing treatments and stimulating R&D for the development of new drugs and diagnostics that take into account the needs of people in poor countries.
Local Patents linked to Local Prices

- **Patent**
  - One supplier
  - No competition
  - High prices of imported medicines

- **No patent**
  - Multiple producers
  - Competition
  - Access to low cost generic medicines
Generic competition needed to drive prices down: the example of AIDS medicines

Graph 1: Sample of ARV triple-combination: stavudine (d4T) + lamivudine (3'TC) + nevirapine (NVP). Lowest world prices per patient per year.

The Effects of Generic Competition June 2000-June 2006

Lowest Originator $10439
Lowest Originator $727
Lowest Originator $556
Brazil $2767
Cipla $350
Aurobindo $209
Hetero $201
Cipla $132
Hetero $168

Generic competition has shown to be the most effective means of lowering drug prices.
Vital Importance of Generic Competition

• Historical treatment scale up on HIV/AIDS treatment since 2000 - Today, more than 8 million people in developing countries receive antiretroviral therapy (ART)
• Treatment scale-up has been possible because of huge price drops due to generic competition
• Ministries of Health and NGOs rely heavily on generic drugs as a critical component of sustainable treatment programs:
• US - 98% of PEPFAR’s ARV are generic, up from 15% in 2005 - Generics saved PEPFAR $380 million in 2010 alone

MSF’s Use of Generic Medicines
• Most of the AIDS drugs that MSF uses worldwide are generics
• MSF routinely also relies on generic versions of essential medicines to treat TB, malaria, and a wide range of diseases
South Africa Patent system - Brief history

- Post independence high prices of medicines as lack of safeguards in national patent law

  - **Monopoly**: Thousands of product patents to MNCs has meant that local manufacturing has never really taken off

  - **Know How**: Limited capacity to manufacture

  - **Unaffordable**: Some of the highest prices in the world
Pati**ent** Registration System in South Africa

Application Filing

Outstanding documents to be submitted

Examination on formalities only by patent office

Acceptance

Publication in Patent Journal

Patent Document Issued

Rejection if all documents not filed
SOUTH AFRICA – TRIPS FLEXIBILITIES?

<table>
<thead>
<tr>
<th>COUNTRY</th>
<th>LOCAL EXAMINATION OF PATENTS</th>
<th>THIRD PARTY OPPOSITIONS</th>
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<tbody>
<tr>
<td>South Africa</td>
<td>No ×</td>
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</tr>
<tr>
<td>China</td>
<td>Yes ✓</td>
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<tr>
<td>Thailand</td>
<td>Yes ✓</td>
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<tr>
<td>Brazil</td>
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<tr>
<td>India</td>
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➔ WHAT THIS MEANS:
No challenges to weak or invalid patent claims by third parties until after they have been granted.
1987: first ARV AZT
1996: TRIPLE HAART THERAPY

2000:
Glaxo Blocks Access To Lamivudine/Zidovudine in Ghana

In letters to a drug distributor in Ghana and an Indian generic-drug maker, Glaxo said sales of generic versions of its drug, Combivir, in Ghana would be illegal because they would be violating company patents. As a result, the Indian company, Cipla Ltd. of Bombay, has stopped selling its low-cost version in Ghana, a small country in West Africa.
AIDS drug access blocked by ‘New Use’ patent on zidovudine

- **1964**: Zidovudine discovered and patented.
- **Thereafter**: Explored as anti-cancer treatment and shelved.
- **1984-85**: Discovered to work against HIV.
- **1985**: Patent granted on new use.
New use patent claims in South Africa

Cancer drug

Imatinib Mesylate Patents: Evergreening Trend

1993 + 20 (2013)
Imatinib compound and all its salts patented. (This patent expires in SA this year)

1997 + 20 (2017)
Mesylate salt of imatinib patented

2002 + 20 (2022)
New Use of Imatinib Patented
Granted in S. Africa

This patent expires in SA this year.
A number of countries have already set stricter standards of patentability.

- Peru, Bolivia, Columbia and Ecuador already exclude new use patents. India and Brazil exclude new use and new formulation patents.

**Impact on medicine prices:**

**Imatinib (cancer)** costs R867 per tablet in South Africa where it is patented, but only R86 in India where the patent was rejected because it is a new formulation of an old medicine. Linezolid (TB) cost R264 per tablet in the public sector and R676 per tablet in the private sector. The product patent is set to expire in 2014 but an additional patent on the crystal form of the medicine was granted in 2002. It is not clear if this will block generic entry after 2014, until 2022. In India, generic versions are already available for as little as R9.
Globalisation of Patent Rules

• 1995 WTO Trade related aspects of intellectual property rights agreement (TRIPS)
• “minimum” standards of protection of intellectual property rights
• 20 year patents on pharmaceutical products
• No differentiation between lifesaving medicines and trivial goods
• 2005 Indian amended its patents act to be compliant with TRIPS and starts to grant product patents (transition period ends).
Patent Filing Trends in India

• Major Increase in the number of patent applications filed at the Indian Patent Office (IPO)
• PCT is the favorite filing route
  —~60% applications filed with the IPO were national phase filings under PCT
• Majority of filers are foreign residents (Bayer, Gilead)

Source: Annual Reports of the IPO
2005: India parliament inserts safeguards against patent abuse

<table>
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<tr>
<th>Local Examination of patent applications by patent office</th>
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<tr>
<td>Pre grant/post grant opposition of patent applications and invalid patents</td>
</tr>
<tr>
<td>Patentability criteria &gt; What is not patentable: new use of an old drug, or simply derivatives of old drugs or combinations of old drugs (companies have to prove enhanced therapeutic efficacy)</td>
</tr>
<tr>
<td>Compulsory license (license to generic companies to produce &amp; market) and automatic licensing for drugs already in production</td>
</tr>
<tr>
<td>Government use (public non-commercial use)</td>
</tr>
<tr>
<td>Bolar exception (preparation for generic launch i.e. production for marketing approval &amp; marketing approval)</td>
</tr>
<tr>
<td>Parallel importation</td>
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STAGES OF PATENT EXAMINATION IN INDIA

1. Filing of Application
   - Provisional / Complete

2. Publication of Application

3. Request for Examination
   - Promptly after 18 months

4. Examination
   - Issue of First Examination Report
     - Pre Grant Opposition

5. Reject/Grant of Patent
   - All objections to be completed within 12 months

6. Decision of Controller
   - Post Grant Opposition (Within 12 months)

7. Appeal

8. Appellate Board

9. Revocation/Amendment
Darunavir Patent Applications in India

Base compound application ineligible for filing in India

Combination with Ritonavir

Pseudopolymorph

Preparation of Key intermediates

Combination with Ritonavir and Tenofovir

No. of years patent monopoly has been avoided

Year of patent grant and expiry

Rejected following opposition

Withdrawn after opposition
Developing countries & TRIPS

➢ Reserve IP incentive for new compounds i.e. active ingredients that represent a fresh contribution to the stock of products available for medicinal use

➢ But not all patent applications relate to new compounds. Majority are for existing drugs (new use, new forms and new formulations)

➢ These can be rejected as such inventions that are common knowledge and practice in the pharmaceutical field
Novartis patent application on life saving cancer drug – CPAA files opposition in 2005

Glivec’s patent 1993 application on the base compound was not eligible for an Indian filing because India joined the WTO only in 1995.
Cost of **Gleevec** and Indian generics per patient per month (Imatinib Mesylate - 400mg tab)

* Public Procurement Price
**Gleevec: Novartis Brand Name for imatinibmesylate
India
High prices of patented drugs in TRIPS regime (post 2005)

Raltegravir:
Patented HIV drug used by MSF in its Mumbai clinic to treat patients who develop resistance costs about 1800 USD per person per year

First patent 2002 -2022

2nd patent application in 2007 (+ 5 yrs if granted)

Compound patent 212400

Potassium Salt application 4187/DELNP/2007 (Patent opposition filed)
One time costs: the Government of India embarked upon a plan to modernize and strengthen the intellectual property (IP) offices in the country as part of the ninth five-year plan (1997-2002), during which 2.5 million USD/22 million ZAR was spent on the development of the infrastructure of IP offices.

During the eleventh five year plan (2007-12), the Government earmarked addition 56 million USD (485 million ZAR) for human resource development.

During 2009-2010, the Indian patent office generated revenue of Rs. 142.62 crore (230 million ZAR) while its expenditure (including design administration) amounted to Rs. 21.87 Crores (35 million ZAR). Therefore, the revenue surplus during this period amounted to Rs. 120.75 Crores (195 million ZAR).

The revenue is generated through collection of fees on various activities related to filing of applications, their examination and the maintenance of patents that are awarded.
The expenditure provided in the budget for routine activities of the government are called non-plan expenditure. Its examples are expenditure incurred on administrative services, salaries and pension etc.
EXAMINATION SYSTEM

- IT enabled to ensure a transparent IP system
- 337 sanctioned posts of Examiners and 94 posts of Controllers of Patents and Designs
- Master’s degree in Physics/Chemistry/Bio-Chemistry/Micro Biology/Bio-Technology or a degree in Engineering/Technology
- Institutional training for examiners.

(Has led to employment generation)
“Policy makers in the health area, as well as patent examiners, should be aware that decisions relating to the grant of a patent...can directly affect the health and lives of the people of the country where the patent is granted and enforced.” – WHO/UNCTAD ‘Guidelines for the examination of pharmaceutical patents: Developing a public health perspective.’
Compulsory licensing
Indian Patent Act

Specific Provisions:
Sec. 84 – On application by generic companies
Sec. 92 – notification by central govt for public non-commercial use/national emergency/ extreme urgency
Sec. 92A – for export
Sec. 100 – govt use
Natco Pharma requested for a CL for the anti-cancer drug Nexavar (Sorafenib Tosylate), patented by Bayer.

Not for drug supplied to the Public sector but actually sold in The private sector

Granted in March 2012:
- Bayer’s import was grossly inadequate to the needs (hardly 2%)  
- No import in certain years  
- Price not reasonably affordable to the public. Bayer price 5210 USD for 120 tabs for a month; Natco 164 USD
No R&D for ‘poor’ markets

“Keeping the cold chain to conserve the vaccines at the right temperature, when it’s 45 degrees Celsius outside is a major challenge. You can imagine how many icepacks are needed, so even getting the vaccines out to the villages is a huge logistical effort in itself.”
Dr. Michel Quéré, MSF Medical Advisor for programmes in Niger, Chad and DRC

“One important antiretroviral drug for children is lopinavir/ritonavir. It exists as syrup which has to be stored at a temperature between two and eight degrees until the moment it is dispensed. The syrup tastes terrible to children and contains more than 40 per cent alcohol, so it really is not optimal to be offering this to a young child. We urgently need another solution.”
Dr. Marianne Gale, MSF Medical Advisor for paediatric tuberculosis & HIV

“A number of previously treatable diseases - including major childhood killers in Africa - are becoming far more difficult and expensive to treat because of antibiotic resistance. In practice, this may mean that many of these diseases may not be treated at all.”
Nathan Ford, Medical Coordinator, MSF Access Campaign
WHY SOUTH AFRICA
SHOULD EXAMINE PHARMACEUTICAL PATENTS

How legislative reform could boost the affordability and accessibility of medicines for South Africans

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