Intellectual Property, Access to Medicines and Innovation: Perspective from Médecins Sans Frontières

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Médecins Sans Frontières (MSF), founded in 1971, is an international, independent, medical humanitarian organization that delivers emergency aid to people affected by armed conflict, epidemics, natural disasters and exclusion from healthcare in nearly 70 countries.
Today, a growing injustice confronts us. More than 90% of all death and suffering from infectious diseases occurs in the developing world. Some of the reasons that people die from diseases like HIV/AIDS, tuberculosis, sleeping sickness and other tropical diseases is that---

- Life saving essential medicines are either
  - too expensive,
  - are not available because they are not seen as financially viable,
  - or because there is virtually no new research and development for priority tropical diseases.
- This market failure is our next challenge.

The challenge however, is not ours alone. It is also for governments, international government institutions, the pharmaceutical industry and other NGOs to confront this injustice.

What we as a civil society movement demand is change, not charity."
Dimensions of Access and Innovation

- **Access to existing medicines**
- **Develop and access to new medicines**

- The role of **intellectual property**, esp. patents
- Price
- Generic competition
- Follow up innovation
- Incentives for R&D for neglected population
Direct Effect on Prices of Medicines:
Competition = The Price of AIDS Drugs Fell by 99%

GRAPH 3: GENERIC COMPETITION AS A CATALYST FOR PRICE REDUCTIONS.
The fall in the price of first-line combination of stavudine (d4T), lamivudine (3TC), and nevirapine (NVP), since 2000.

Today: Still Unaffordable

**HIV**
- The price of a third-line regimen is **more than 14 times higher** than the recommended first-line.
- Middle income country dilemma with tiered pricing.

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**Graph 6: Price Comparison of Treatment Regimens**

*Note: The price of the third-line ARV regimen of US$2,006 was calculated by adding the three individual prices of the originator product.*

**Graph 4: 2013 Price Per Patient Per Year LPV/R as Component of Second-Line ARV Regimen**

Key challenges to access and innovation

- New EML faces increasing challenges of patent barriers
- Patent ever-greening continued posing barriers to competition
- TRIPS-plus provisions harmful for public health
- Limitations on voluntary measures
- Political pressures on national laws and policies
- A broken model of incentivizing R&D
Are WHO Essential Medicines Lists better off from patent barriers?
New EMLs, New challenges

• New patented medicines in 2015 edition of WHO EML list --- “…affordability is a major issue” – Nicola Magrini et al. ‘Tough decisions on essential medicines in 2015’
  – Hep C: daclatasvir, sofosbuvir
  – Cancer: trastuzumab, imatinib
  – TB: bedaquiline and delaminid

• Changing disease burden would see rising patent barriers to new EMLs with patent regime expansion

• WIPO report on patent-based analysis of WHO EML 2013
  – Disregarded the trend of disease burden and new development of EML
  – Contestable methodology – contestable conclusion
  – Wrong and limited usefulness of the data for public health decision making
  – Misleading and questionable on WIPO’s mandate

What could patent ever-greening block access to affordable medicines?
Impact of patent ever-greening

- **Case: Novartis vs. Union of India**
  - 7 years case proceeding over rejection of Novartis patent application on Imatinib Mesylate (Gleevec), a drug treating leukaemia
  - Supreme Court final decision upheld the use of Sec. 3(d)
  - Political pressure continues especially from US
Effect of Ever-greening

- Imatinib Mesylate Patents in South Africa

1993 + 20 (2013)
- Imatinib compound and all its salts patented. (This patent expired in SA 2013)

1997 + 20 (2017)
- Mesylate salt of imatinib patented

2002 + 20 (2022)
- New Use of Imatinib (GIST) Patented
  Granted in S. Africa
The Same Drug …
Before Generic Competition in South Africa

Cost of Gleevec** and Indian generics per patient per month (Imatinib Mesylate - 400mg tab)

* Public Procurement Price
**Gleevec: Novartis Brand Name for imatinib mesylate
The route of TRIPS-plus provisions?
TPP Provisions affecting Access to Medicines

• Lower requirements for patentability

• Expanded data exclusivity requirements -- at least 5 years for small molecule, 3 years for modifications, 5 years for combinations….

• Extend patent terms – beyond 20 years

• Introduce new forms of IP enforcement

• “Transparency and Procedural Fairness Chapter” restrict the ability of governments to use reimbursement or price control systems to reduce healthcare costs.

• Introduce Investor-State Dispute Settlement to risk substantive patent law flexibilities under attack

MSF Briefing and Open Letter to TPP countries:
• http://www.msfaccess.org/content/msf-open-letter-tpp-countries-dont-trade-away-health

MSF Open Letter to ASEAN on TPP:
http://www.msfaccess.org/content/msf-open-letter-asean-governments-dont-trade-away-health
Could voluntary license bring the cure?
Issues with Voluntary License

- Transparency – Publication vs. secrecy
- Coverage:
  - Coverage for what? --- production, sale, API supply
  - Who is in and who is out? And why?
- Royalty rate: free? Tiered? Not tiered?
- ‘Indirect coverage’? --- option for excluded countries; the use of CL; nexus with patent opposition?
- Termination: relation with tech transfer terms
- Anti-diversion: where is the limit?
- Framing: does signing a VL bring access?
New Challenges ahead with Access

Hepatitis C: global prevalence

About 180m people are infected with hepatitis C and 350,000 people die each year from related liver diseases.
Cont. issues with Gilead’s voluntary license


- Exclusion of many Middle-income countries
- Restriction on API sourcing by India generic companies

The Licensing Agreement Excludes the Following 50 MICs:

Albania  
Algeria  
Argentina  
Armenia  
Azerbaijan  
Belarus  
Belize  
Bosnia Herzegovina  
Brazil  
Bulgaria  
China  
Columbia  
Costa Rica  
Dominican Republic  
Ecuador  
El Salvador  
Georgia  
Grenada  
Hungary  
Iraq  
Jamaica  
Jordan  
Kazakhstan  
Kosovo  
Lebanon  
Libya  
Macedonia  
Malaysia  
Marshall Islands  
Mexico  
Micronesia  
Moldova  
Montenegro  
Morocco  
Panama  
Paraguay  
Peru  
Philippines  
Romania  
Serbia  
St. Lucia  
Syria  
Thailand  
Tunisia  
Turkey  
Ukraine  
Venezuela  
West Bank & Gaza  
Yemen
Cont. issues with Gilead’s voluntary license

- ‘Anti-diversion’ programme in developing countries through its distributors and licensees (generics companies that have signed a voluntary license with Gilead).
- These policies violate patient privacy and autonomy, undermine confidentiality of patient data, introduce coercion and police upon medical providers.
- The policies may result in treatment interruptions for patients.


http://www.msfaccess.org/sites/default/files/HepC_Gilead_anti-diversion_FINAL.pdf
Is the patent centric model indispensable for medical innovation?

MSF new report: ‘Lives on the Edge’
Do more patents bring more innovation on medicines?

Figure 1. Patent applications worldwide

Source: WIPO World Intellectual Property Indicators, 2015

Global patent filings on pharmaceuticals have increased by 7.3% from 1995-2013.

Source: WIPO World Intellectual Property Indicators, 2015

The 5 largest pharma companies spent $60 billions on marketing.
Myth of R&D cost and prices of medicines

- 2004-2015, 19 of the largest pharma companies spent $226 billions repurchasing their own shares = 51% of the R&D expenditure (Lazonick W. et al, 2016)
Myth of R&D cost and prices of medicines

- Unjustifiable high launch price
- Voluntary tiered price leaves millions in need without access
Example: Antimicrobial Resistance - AMR

A truly global public health problem

Available National Data* on Resistance for Nine
Selected Bacteria/Antibacterial Drug Combinations, 2013

*National data means data obtained from official sources, but not that data necessarily are representative for the population or country as a whole.

Source: WHO Global report on AMR, 2014
• Diagnostic methods are based on principles that are over 75 years old!

• Diagnostic devices not adopted to resource limited settings

• No promising pipeline of new antibiotics

• Why? Antibiotics market is less profitable
  • Patent centric model does not work for AMR R&D
Example: Drug-Resistant TB

The next epidemic in the making?

Countries that had notified at least one case of extensively drug-resistant tuberculosis by the end of 2012

The boundaries and names shown and the designations used on this map do not imply the expression of any opinion whatsoever on the part of the World Health Organization concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted and dashed lines on maps represent approximate border lines for which there may not yet be full agreement.

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The issues – Multi Drug Resistant (MDR)-TB treatment

**Medicines:**
- **Old** – ‘newest’ drug in current regimens was introduced 50 years ago; Two new drugs... **no new regimens.**
- **Expensive** – Can cost up to $5000 in drug costs alone

**Treatment:**
- **Long** – Treatment takes two years and
- **Toxic** – extreme side effects include deafness, psychosis, constant nausea and vomiting, weight loss and more; and
- **Complex** – different treatment regimens for individual resistance patterns; about 5 different drugs (14,000 pills), including 8 months of painful injections
- **Inadequate** – high default rates and low cure rates (~50%) contribute to further resistance; no paediatric formulations

**Funding:** Private funding decrease; lacking interests of accelerating clinical trial

**Patent centric model does not work for TB R&D**
Time for TB to do something new

3P Project - Push, Pull and Pooling

**FIGURE 9:**
THE 3P PROJECT: AN OPEN, COLLABORATIVE APPROACH TO TB REGIMEN DEVELOPMENT

**PUSH**
Direct upfront funding to finance R&D activities (i.e. through grants)

**PULL**
Incentivize R&D through the promise of financial rewards if certain objectives are met (i.e. through prizes)

**POOL**
Share intellectual property (IP) and data to ensure open collaborative research and affordability of the final products.

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• Thank you!

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