

Linking medicine patent and procurement data: What can the data tell us?

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Talking points

- Data sources for procurement and international medicine patents – *challenges and opportunities*
- Discuss one example of research that's possible through linking these datasets: CL price vs Int'l price study

Some International Medicine Procurement Data Sources

International medicine procurement data

- HIV/AIDS, TB, & Malaria
 - WHO Global Price Reporting Mechanism
 - Global Fund Price and Quality Report

International medicine price data

- MSF (Doctors without Borders) Untangling the Web Publications
- Health Action International
 - International sources
 - National sources

Challenges of int'l medicine patent data

- No international medicine patent register
- Disclosure of int'l medicine patent holdings is not standard practice
- Only option is all-purpose international patent databases, like INPADOC, Derwent, and others
 - No data for many developing countries
 - Patents' legal status information is sparse and outdated
 - *How accurate can these be?*
 - *Only 46% accurate on patent numbers, expiration dates*
 - *Only 67% accurate on ave for countries with patents protection*
 - *Many false positives and false negatives*
- Conclusion => int'l patent databases alone cannot give an accurate picture globally
- **Urgent need to seek consensus on international medicine patent transparency by global suppliers**

Some International Medicine Patent Data Sources

- Methodology
 - Step 1 - US Orange Book & Health Canada medicine patent registers.
 - Step 2 - link to INPADOC, Derwent, or other int'l patent families => initial results
 - Step 3 – Verification/corrections by global suppliers (2009/11 studies were not verified by suppliers)
- Academic patent landscape studies on essential medicines
 - *Attaran, 2003 MLEM*
 - Kowalski & Cavicchi, 2009, 2011
 - *Beall & Attaran, 2013 MLEM*
- *Medicines Patent Pool database, Lawyer's Collective site for India*

Example of using linked datasets – Health Affairs Paper

HealthAffairs

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Compulsory Licensing Often Did Not Expand Produce Lower Prices For Antiretrovirals Compared To International Procurement

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Abstract

Compulsory licensing has been widely suggested as a legal mechanism for bypassing patents to introduce lower-cost generic antiretrovirals for HIV/AIDS in

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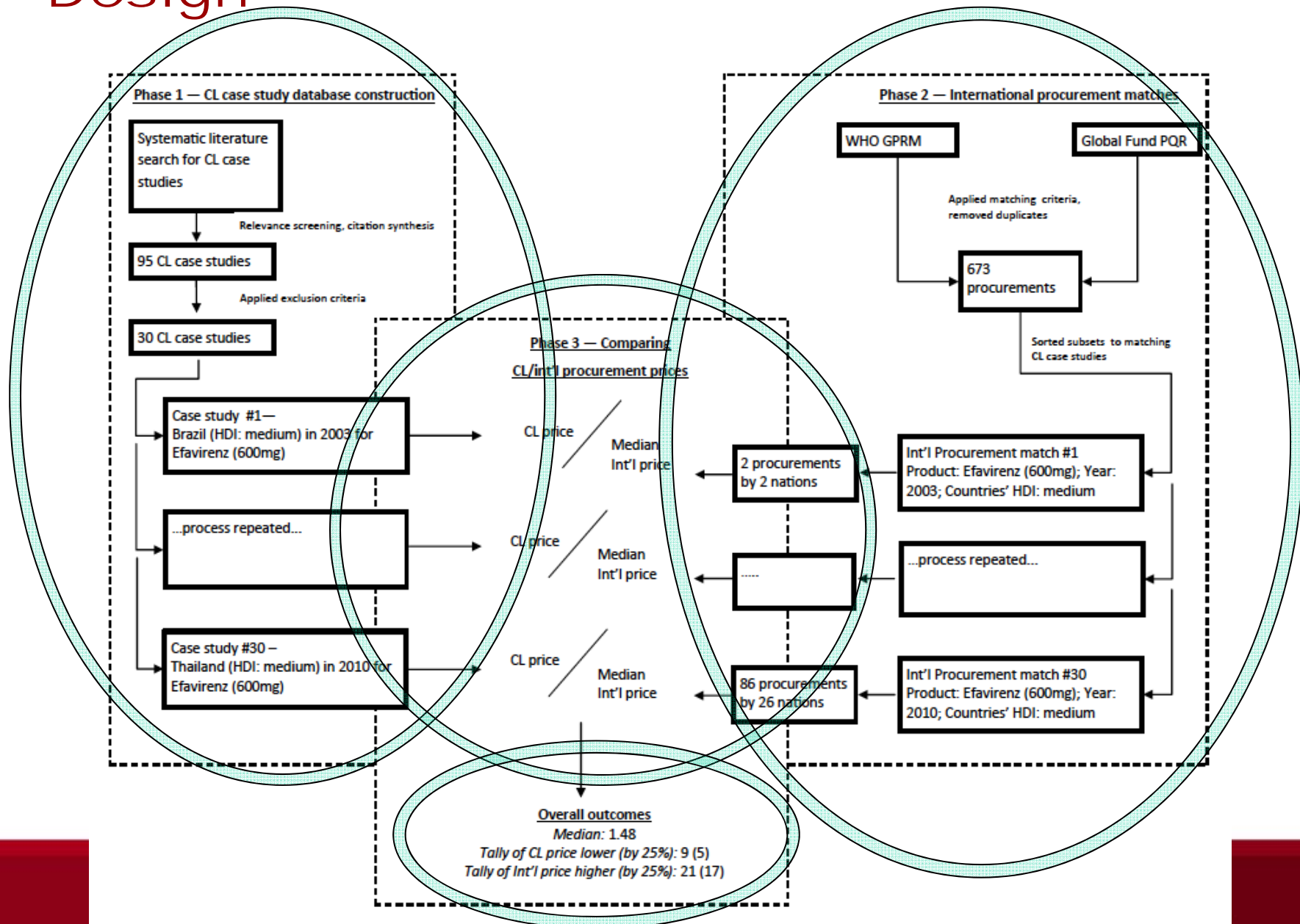
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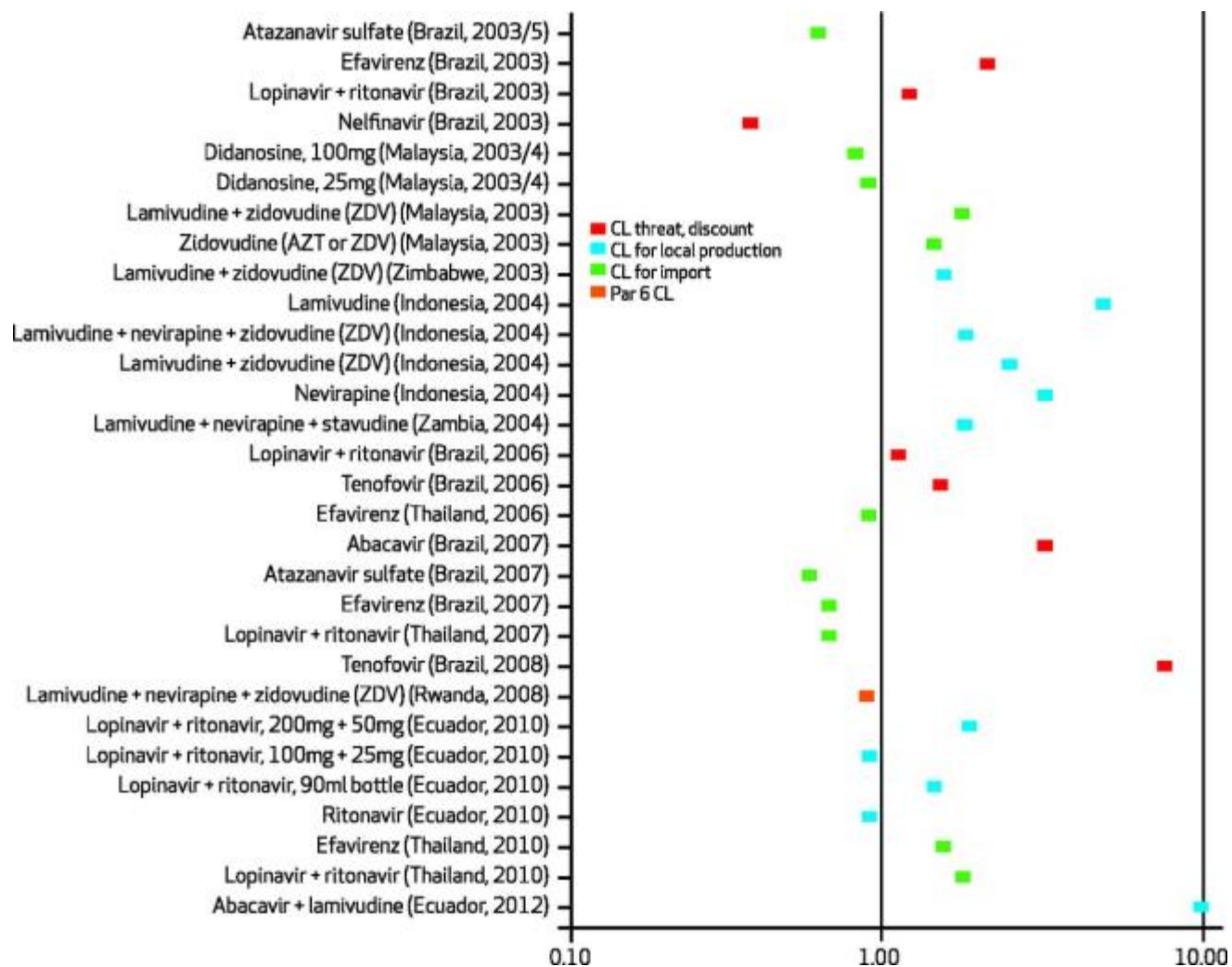
Background of study on compulsory licensing

- Compulsory license (CL) = “when a government allows someone else to produce the patented product or process without the consent of the patent owner”
- Previous studies show that CLs save money.
- How do CL prices compare to prices gained through procurement from the international market in cooperation with third parties (e.g. PEPFAR, UNICEF, Clinton Foundation)? (HIV medicines only)

Design



Ratios Of Compulsory Licensing (CL) To International Procurement Prices For Antiretroviral Drugs.



Reed F. Beall et al. Health Aff 2015;34:493-501

HealthAffairs

The results

- **Both CL and int'l procurement save money, but the non-CL strategies combined saved just as much or even more**
 - Compared to a notional “pre-CL price”, CL saved 71%, but int'l procurement saved 79%.
- CLs for local manufacturing in low income countries was always more expensive than int'l procurement

Caveats

- Only HIV/AIDS medicines
- Small sample of CLs – inclusion of new or unpublished CLs may or may not change the picture
- Study period during time when generic equivalents from India were available on the market, but this could be different for new medicines in the future
- This study was to broadly compare two strategies globally
 - the point is *not* to say Country X, should or should not have used CLs.
 - Rather, the point: international procurement system was often able to deliver prices comparable to CL prices

Conclusions and take-aways from the CL study

- Do not assume CL is always the cheapest solution; other solutions may save more \$\$
- Use price transparency data whenever possible
- The right to CL should remain, equalizing power at negotiating table is critical
- Int'l procurement tactics were effective at reducing cost => can this serve as prototype for other essential medicines?

Medicine patent/procurement transparency on essential medicines

International medicine procurement data

- Procurement data can inform buying decisions and inform policy decisions
- Global campaign for HIV medicine access can serve as a prototype/template for more essential medicines?

International medicine patent data

- Accurate patent data on essential medicines is not available in most countries
- Imprecision in this area => suboptimal policy & health outcomes
- Heightening patent transparency on essential medicines by global suppliers – **a consensus statement?**

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Medicine patent transparency – A Trilateral consensus statement?

- Transparency in middle-income, medicine-exporting countries, e.g., India, China
- Voluntary disclosure by brand/generic companies
- Information ideally disclosed for life-saving/-sustaining drugs
 - What MLEM products are patented (including strength, route, and formulation)
 - Kind of protection (compound, formulation, method, process, device)
 - Where companies have patents they intend to enforce (including patent numbers and expiration dates)
 - Information on steps the supplier is taking to ensure affordable access
- Central database? The WTO's TRIPS and Public Health dedicated webpage for notifications? Medicines Patent Pool? IFPMA?