

UNITAID Patent Pool for Medicines

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What is a patent pool?

- Patent pools are mechanisms for the collective management of IPR by grouping patents and other intellectual property assets related to a particular technology and making them available to third parties as “one stop shop”, in exchange for royalty payments.
 - When licensing agencies exist, they manage the licenses, the negotiations with right holders and the receipt - distribution of royalties.
 - Patent Pools are created to facilitate more systematic transfer of technology and competition (downstream) and/or to promote innovation (upstream).
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Examples of Patent Pools



Patent Pools examples

“Survey of Patent Pools Demonstrates Variety of Purposes and Management Structures”. David Serafino. KEI Research Note 2007:6

- Summary of 35 patent pools from 1856 - present
 - There is no single reason for creating a patent pool; no single way to manage a patent pool
 - May be managed by Licensing Agencies or have an in-house / *ad hoc* management structure
 - Patent pools have been organized by a wide variety of actors
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History of Patent Pools

Sewing Machine Combination (1856)

- Set up by sewing machine manufacturers to avoid litigation
- Ability to mass-produce sewing machines and sustain artificially high prices
- Simple licensing structure - royalty of \$15/machine

Manufacturers Aircraft Association (1917)

- Set up in response to U.S. Government production needs before World War I
- Before: high royalty rates (\$1000/plane); wide spread litigation; low production
- After: lower royalty rates (\$200-\$100/plane); fulfillment of government orders

“Survey of Patent Pools Demonstrates Variety of Purposes and Management Structures”. KEI Research Note 2007:6



Pools for Standards

DVD3C (1998)

- Set up to provide “one-stop shopping” for licenses essential for manufacture of DVD products
- Royalty payments set by “Ground Rules for Royalty Allocation”
- Grant-back provision: future essential patents belonging to licensors are automatically added to the pool

Open Invention Network (OIN) for Linux software (2005)

- Set up by several investors in Linux, an open source software
- Purpose is to facilitate innovation and promote use of Linux to create complementary products
- OIN licenses any patent, royalty free but licensees in turn cannot assert their patents against the Linux environment

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Patent Pools for biomedical technologies

The SARS IP Working Group (proposed 2005)

- Proposal to institute a patent pool to promote the R&D of a treatment or vaccine for SARS
- This “Upstream” patent pool will aim to avoid delays and complications in SARS research and development arising from the multiplicity of patents

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UNITAID Patent Pool



UNITAID

- International purchasing facility for HIV-AIDS, Malaria and TB drugs and diagnostics for the developing world.
 - Created in September 2006 by France, UK, Norway, Chile and Brazil.
 - Innovative financing mechanism based on a solidarity tax on airline tickets.
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Chronology

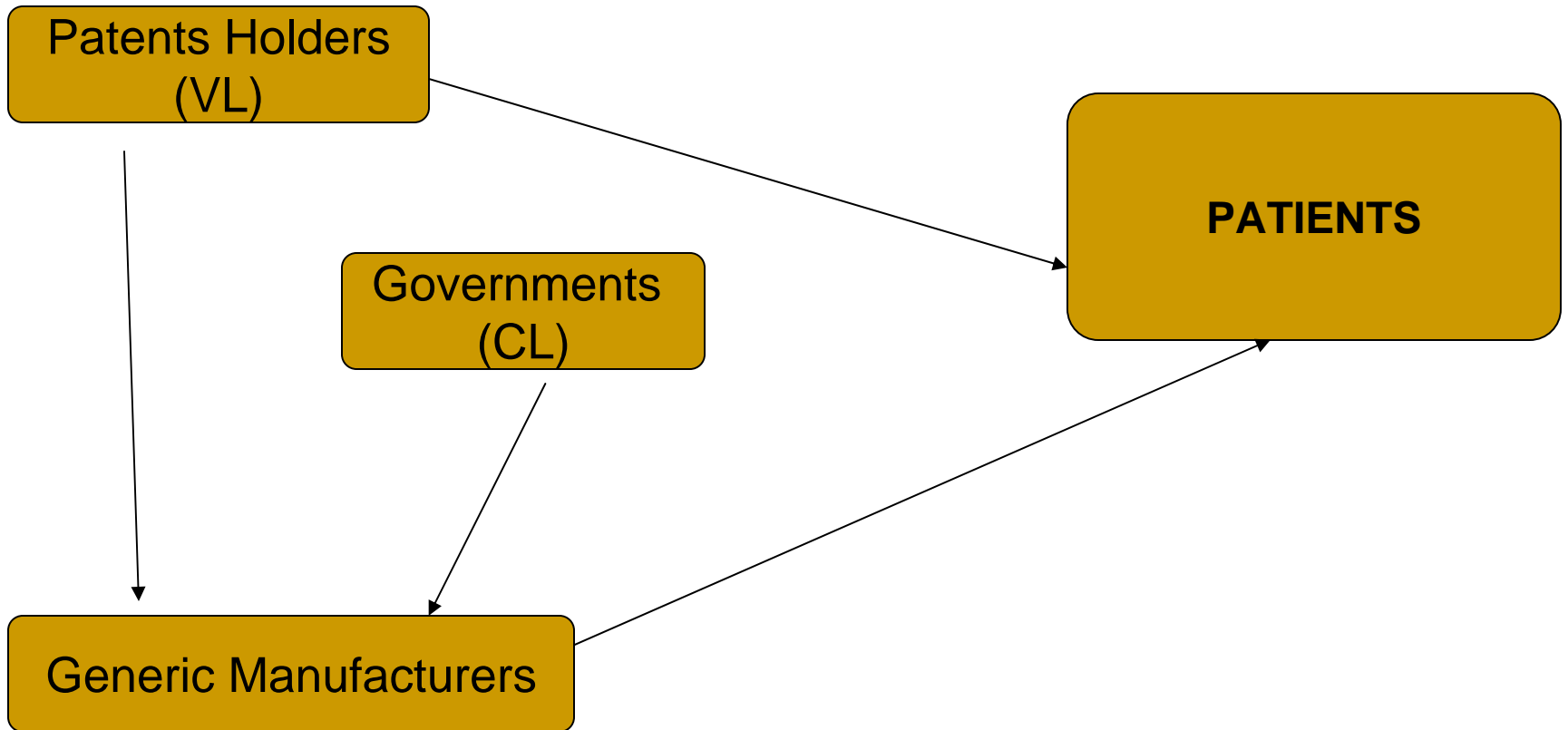
- 2002: AIDS Conference in Barcelona
 - 2005: several Essential Information proposals
 - June 2006: MSF & KEI Proposal to UNITAID
 - July 2008: UNITAID Executive Board
 - Approved the principle of establishing a voluntary patent pool
 - An initial focus in ARVs pediatric & fixed doses combinations
 - With the aim to provide patients in low and middle income countries with increased access to more appropriate and affordable medicines
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UNITAID Patent Pool

- Create a Patent Pool on IP rights required for
 - The production and distribution of generic versions of medical technologies in the developing world, and
 - The development & innovation of better adapted formulations, such as fixed-dose combinations and paediatrics ARVs.
 - The goal is for patent and other IPR rights held by companies, universities & government institutions to voluntarily be brought together (pooled) and made available on a non-exclusive basis to generic manufacturers and other third parties in exchange of royalty payments.
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Current Situation





Difficulties

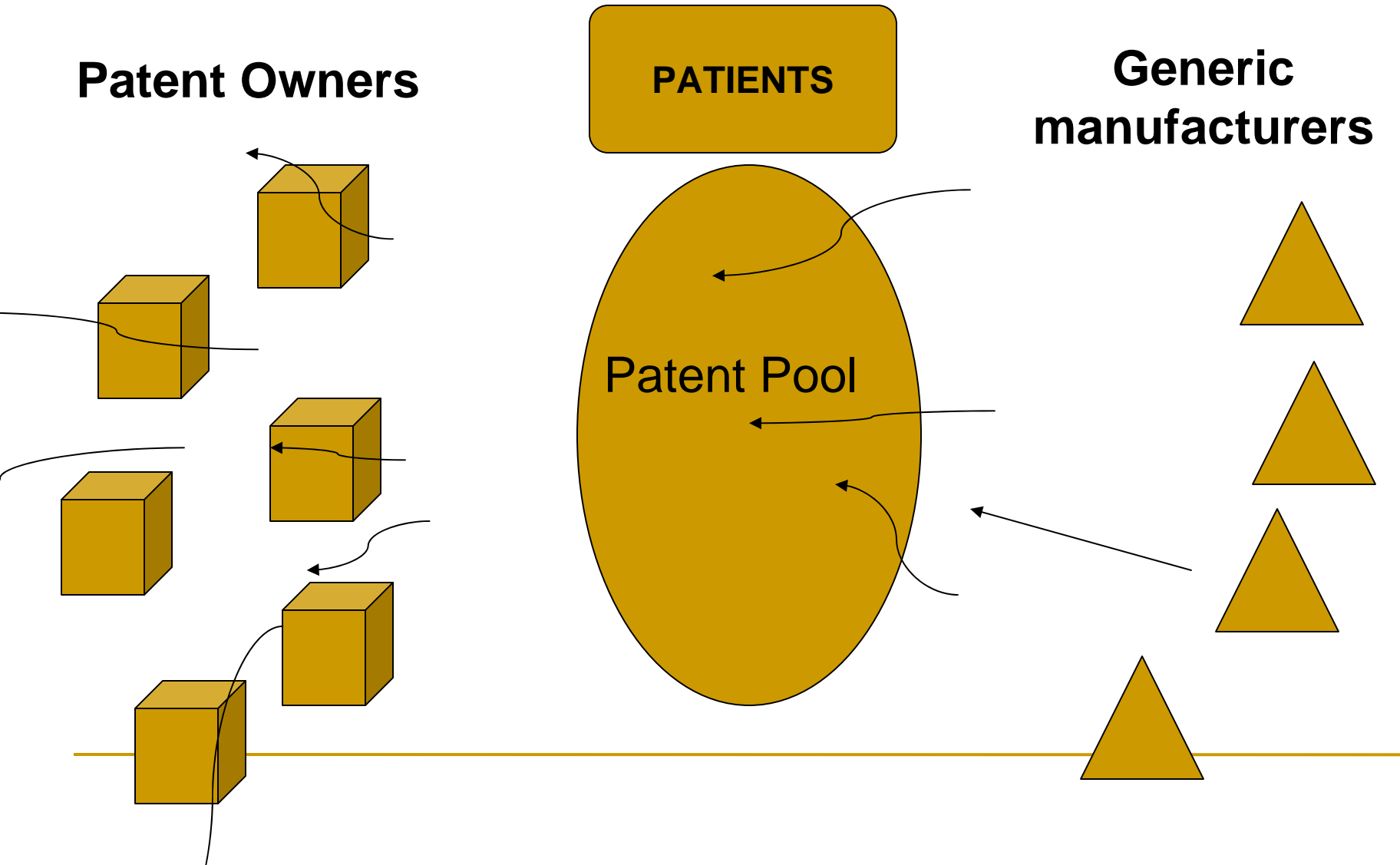
- **Case by case solution:** drug by drug, company by company, country by country
 - Micro-negotiations with high transaction cost
 - Fatigue for activists, donors, companies and governments
 - Difficulties in setting best licensing and royalty practices (e.g. Gilead VL)
 - **Uncertainty** over size of market & export potential, inhibits generic scale up and prevents economies of scale
 - **Fragmentation of rights** (e.g. Fixed Dose Combinations)
 - **Pro-monopolist retaliation** (e.g. Abbott v. Thailand CL/ USTR Special 301 List)
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Post-TRIPS

- Newer HIV-AIDS regimes
 - 4 to 11 fold increase in price compared to old regimen
 - Post - 2005 India patent law = less sources of generic supply
 - Post - 1996 Brazil patent law = less purchasing power - Brazil buys brand-name for second generation ARVs
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Pool collects royalties from the generic manufacturers and distributes to right owners



Potential benefits I

- ACCESS: facilitates generic competition
 - INNOVATION
 - Facilitates development of better adapted technologies & management of fragmentation of rights (e.g. Fixed Dose Combinations)
 - Practical & Efficient
 - One-stop licensing that reduce transaction costs
 - Best Practices
 - Rule of law, Transparency, Registration, Quality
 - Global norms on Contractual & Licensing Terms
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Potential benefits II

■ Economic

- ❑ Multi-country pool can create sufficient economies of scale to induce entry & efficient generic competition

■ Political/ Activist

- ❑ Pool is the visible actor, with a leadership position and countries move together as a group
 - ❑ Civil society can unify message: encourage patent owners to license to the pool
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Next Steps

- Design the “appropriate” licensing terms and governance structure
 - Get the patents & other IPR from companies, universities and governments
 - Ensure success & broad geographic scope including middle income economies. E.g. Donor prize proposal
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