IPRs and Access to “New Essential Drugs”

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Fact check

- Patents provide temporary exclusivity
- Patents provide pricing power – if the patented product is attractive to buyers
- Patents create an incentive for innovation
- ..but are not sufficient to ensure innovation
- ..and can even inhibit innovation if fragmented
- Absence of patents does not ensure competition or low prices
- Competition and “low” prices do not ensure access for the poor
Insider View on Patents

- A patent has a life cycle: claim submission, grant, challenge, modification, rejection or confirmation
- The value changes sometimes dramatically over the life cycle
- It is a rough world out there – a patent can be worthless if you are not willing to defend it
- Big companies fight for patent rights but happily violate other patents if it suits them – and they think they can afford it
- Patents create a platform for start-ups originating mainly from academia
- Small companies try to maximize their value by claiming much more IPR than they will ever get
- Patents and licenses are a key currency in corporate deal making
Assumptions

- The pro/contra pharmaceutical patents debate will go on for a while without final resolution.
- Several “new essential drugs” will be launched on the global market over the next years.
- Regulators and payers will be confronted with the dilemma of providing access to these drugs without compromising other services or fiscal stability.
- Compulsory licensing will not solve all access (affordability) problems.
- LICs with negligible for-profit markets will continue getting special access prices (cost based) from major manufacturers (MNCs*).
- MNCs will maintain a profit interest in (fast growing) MICs but will also be willing to cooperate on access issues.
- Domestic industry and some politicians linked to it may try to highjack the “access” argument to conceal profit motive.

*Multi-National Companies
Alternative Options to Improve Access to “New Essential Drugs”

- Market segmentation
- Differential pricing
- Making profit from selling to the rich; making no loss from selling to the poor
Potential Models

- Individual patient assistance programs
- Institution/channel based segmentation
- Dual brand strategy with/without licensing to local manufacturer
- Bundling of goods and/or services
Patient Assistance Program

- Example: Gleevec “GIPAP” program available in > 80 countries
- Chronic myeloid leukemia (CML) – relatively rare disease, progressing slowly but fatal without treatment
- Gleevec is highly effective but also very expensive – beyond reach even for middle class in many countries

**Diagram:**

1. Diagnosis CML
2. Country eligibility
3. Clinical eligibility
4. Means assessment
5. Delivery for free or limited copayment

- High transaction costs
- Low risk of leakage
Market Segmentation

- Private sector/public sector
- Specific delivery channels (e.g. NGO clinics, specialized hospitals)
- Price to the low-income channel can remain confidential, higher income channel priced at international level
- Monitoring to avoid arbitrage, ensure adequate targeting
- Can be used for drugs with larger patient populations if health system provides segmentation possibility
Dual Brand Strategies

- Original drug targeting wealthy segment; licensed generic or originator secondary brand targeting the low income segment
- Problematic if segments overlap too much – targeting becomes difficult; potential acceptance problems
- Usually combined with channel segmentation
Provider-Controlled Targeting

- Example Sanofi-Aventis malaria drug ASAQ
- Pharmacist has two offers – profitable brand at high price and no-brand at low price (minimal profit for pharmacist, no profit for manufacturer)
- Pharmacist decides which version to sell, based on subjective assessment of patient income
- Limited to residents in pharmacy neighborhood, who have to register and get a rebate card
- Underlying objective: low-cost version should not cannibalize profits from high-cost version; but create additional sales to patients who otherwise would buy cheaper, outdated malaria medicines
Bundling Options

- Several drugs and diagnostic services offered as a package – for example for diabetes (insulin, oral antidiabetics, glucose test sticks)
- Cost of each component hidden in package price
- Defined service delivery points needed
- Potentially complex contractual situation (multi-party)
Parameters Influencing Program Design

- Structure of health system in a country
  - Payer & provider structure
  - Hierarchy and decision making
  - Control mechanisms
- Perception of patients and providers
- Characteristics of the pharmaceutical product
  - Large/small patient population
  - Primary care/specialty care
Limitations for Tiered Pricing/Access Programs

- Arbitrage, diversion
- Reference pricing systems
- Transparency, political pressure
- Targeting
- Transaction costs
- Marketing costs