

Current issues in IPRs and Public Health

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*IFPMA Brief on WHO IGWG, Sep 2007



Patents vs. Patients?

Is Intellectual Property a zero-sum game?

- If not, is it possible to get a fair and mutually beneficial deal?
- How to correctly distribute benefits and responsibilities amongst the different players in order to make it possible the "enjoyment of the highest attainable standard of health" by everyone?

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Is IP a barrier to public health?

- 95% of the Essential Medicines List are off patent worldwide and up to 99% in sub-Saharan Africa.
- The differential pricing scheme allows research-based companies to sell at cost or even at loss most of the patented drugs in the LDCs. For instance, some second-line drugs from originators are actually cheaper than the generic versions.
- When they feel that their technology will be protected, many companies do grant voluntary licensing for the production of some drugs.

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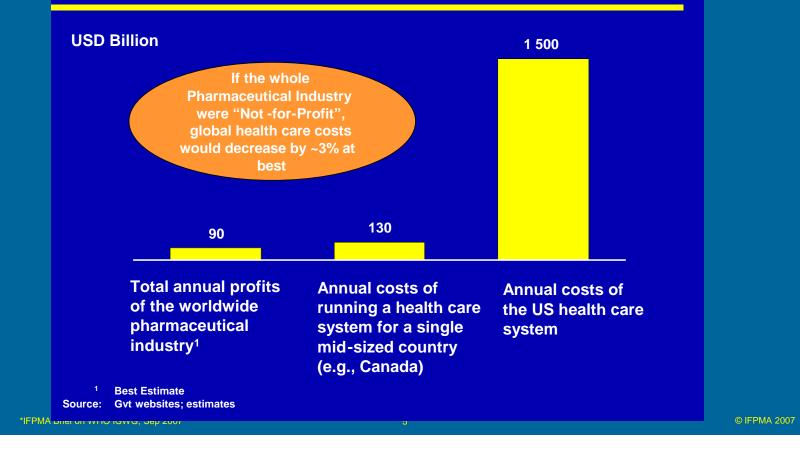


- The TRIPS has given the LDCs a large period to enforce the IPRs.
- In case a country has truly public health needs and the manufacturer is unable to supply the drugs, it can use the *ad hoc* TRIPS flexibilities to import or produce locally generic versions patented drugs.
- Is it aways economically advantageous to produce locally? Is public health the main concern behind the recent IP & heath debate?

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Is it really either profit or access?

Even Giving Away All Profits Would Not Change the Picture





- Incentive to the R&D of new drugs
- Inspire confidence for Industry to engage in technology transfer initiatives, as well as in partnerships for the R&D of drugs without a viable market.
- Incentives for investments (both foreign and domestic) in more technology intensive industries

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IPR-based R&D System Addressing Global Burden of Disease

Disease	Health Burden (% of global deaths/DALYs)	Existing treatments developed by R&D pharmaceutical industry			
HIV/AIDS	4.9/5.7	All 21 drugs in 4 different classes			
Respiratory Infections	6.9/6.3	All recent and effective antibiotics			
Cardiovascular disease	29.3/9.9	All drugs in 8 different classes			
Cancer	12.5 / 5.1	All most effective drugs in 8 classes			
• FPMA Brief on WHO IGWG, Sep 2007	0 / 4.5	All recent drugs in 4 different classes			



Market-based company and PPPs R&D for developing country health needs

- AIDS: 35 new ARVs, at least 6 additional pediatric formulations for ARVs and 19 vaccines
- Tuberculosis: 17 medicine projects, 2 vaccine projects
- Malaria: 18 medicine projects, 2 vaccine projects
- Other Tropical Diseases: 8 medicine projects, 2 vaccine projects

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Some access activities

- Mectizan Donation Program: over 1.8 billion tablets worldwide (with an estimated value of USD 2.7 billion) and more than 530mi cumulative treatment since 1987.
- International Trachoma Initiative: 252 thousand or surgeries performed, 44mi treatments donated.
 Some countries are moving towards erradication.
- GAELF: 6 billion preventive albendazole treatments donated. WHO estimates that 100 million people have begun to be protected from LF.

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Are IPRs enough? Are good drugs enough?

The Cycle of Health and Wealth of a Nation

Infrastructure	Culture	Culture Natural resources					
Drugs/medical products		Education					
Health Health professionals		Wealth	Trade				
Hygiene		G	eographic location				
Infrastructure	Regulations	Po	litical system				
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Shared benefits, shared responsibilities

- All countries benefit from a new drug. It is only fair that they contribute to the financing of this process, acording to their resources.
- Developing countries should not be seen as passive receipient of foreign aid, but as key partners, responsible for the health of their people.
- Developed countries should help developing countries to establish performing and sustainable healthcare systems with their expertise and some start-up finance.

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Governments Need to Rise to the Challenge

Development aid as % of GDP 2004

Medicine access programs as % of 2004 sales company A

2.00

0.87

UN objectives for developed nations (0.7)

0.37



Source : OECD

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Just the tip of the iceberg...

Price Components

Table 14: Example of Price components in the Private sector

Nigeria

Example 1: Medicine Name	Medicine Strength	Dosage Form	l arget Pack Size	Dispensed Quantity	Type of Charge	Charge Basis	Amount of Charge	Price of Dispensed Quantity	Cumulative % Mark-up
Co-trimoxazole suspension	8+40 mg/ml	millilitre	70	50	Cost, insurance, freight (CIF) price	NA	NA	51.71	0.00%
					Port charges, clearance, inspection Importer's margin Distributor's margin Retailers' margin	percent percent percent percent	30% 20% 10% 30%	67.22 80.67 88.73 115.35	30.00% 56.00% 71.60% 123.08%

Ghana

*IFP

Table 12: Summary of calculated mark-ups for selected medicines

	Item	Public	Public patient	Private patient	Mission patient	
	Item	procurement	charge	charge	charge	
	Ciprofloxacin 500mg tab	25.00%	233.33%	387.59%	122.22%	
	Nifedipine retard 20mg tab	4.11%	177.78%	216.53%	185.71%	
	Cotrimoxazole suspension	53.88%	246.26%	27.35%	66.67%	
	Glibenclamide 5mg tablet	16.67%	233.33%	150.00%	106.25%	
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An "inclusive" debate

- Must ensure that policies for improving "public health" or "development" do not stifle innovation
- Thus, dialog among IP experts and those creating intellectual property is vital, especially with creators of IP in developing and least-developed countries
- Look at realities, not ideology

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