



IPRs in the pharmaceutical industry

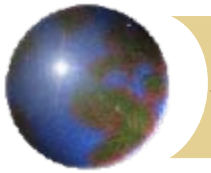
The Development Implications of Intellectual
Property Rights and TRIPS

Washington, DC, June 4-5, 2008

CARSTEN FINK

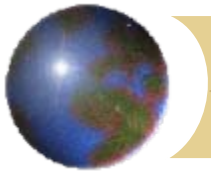


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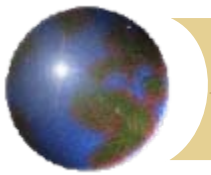


Overview

- The structure of the pharmaceutical industry
- Patents and prices
- Doha process
- The concept of differential pricing

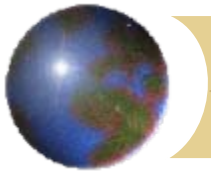


The structure of the pharmaceutical industry



Critical role of patent protection

- Long and expensive R&D process:
 - Research, development, clinical testing, regulatory approval
 - Risky process: only a small share of promising chemical entities make it to the market
 - Up to 10 years before drugs are marketed
- Without legal protection, new chemical entities are weakly appropriable from the viewpoint of the innovating firm



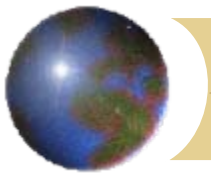
Two main industry players

● Research-based companies:

- Creates intellectual property (primarily patents, but also trademarks, clinical test data)
- Multinational in scope, relatively few number of firms
- Geographic concentration of R&D

● Generic drug companies

- Produce drugs that are off-patent
- Large number of firms, competitive market structure
- Efficient developing country producers



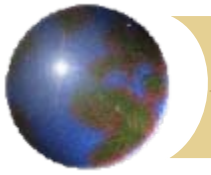
Changing IPRs environment

● WTO-TRIPS

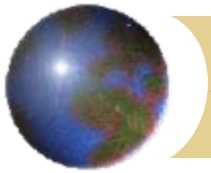
- As of 2005, developing countries are required to protect pharmaceutical patents
- Doha process

● US FTAs

- Exclusive rights to pharmaceutical test data
- Linkage between marketing approval and patent status (though watered down in May 2007)

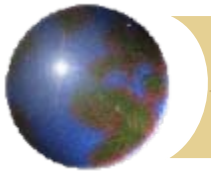


Patents and prices



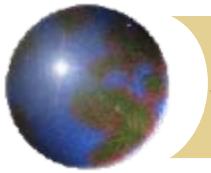
Characteristics of drug markets

- Market is therapeutic group
- Retail distribution versus public provision
- Influence of advertising and drug promotion
- In many countries, drug prices are controlled



Complex demand structure

- Up to four persons involved:
 - Doctor who prescribes the drug
 - Pharmacist who dispenses the drug
 - Insurer who (partially) pays for the drug
 - Patient who consumes the drug
- Details vary from country to country and depend on a variety of economic and institutional circumstances



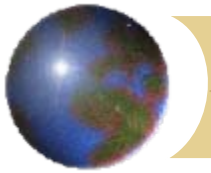
Supply structure

● Main features:

- Monopolistically competitive market for new, patent-protected medicines
- Competitive fringe of generics producers, supplying older off-patent drugs

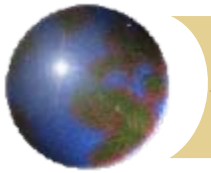
● A patent holder's pricing power depends on:

- Availability of on-patent and off-patent therapeutic substitutes
- Price sensitivity of demand (price elasticity)



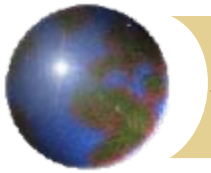
Empirical evidence

- Significant price falls documented upon expiry of pharmaceutical patents:
 - See detailed study by Caves et al. (1991) for US market
 - Example: wholesale price of Pfizer's blockbuster drug Prozac fell from \$240 to less than \$5 per bottle within six months after patent expiry*



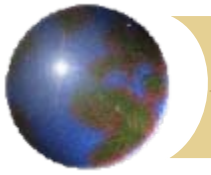
TRIPS-induced price effects

- Methodological problems:
 - Cannot talk about price increases per se, as protection does not apply retroactively, but only to new drugs entering the market
 - Difficult to predict use of TRIPS flexibilities (compulsory licensing, price controls, parallel importation)
- Fink's (2001) simulation of price effects in India points to strong role of therapeutic competition

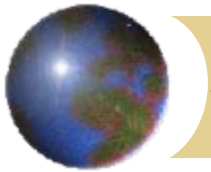


Administrative price controls

- What prices to regulate (retail, wholesale)?
- Cost-plus formula, based on:
 - ▣ Production cost, distribution margin
 - ▣ Reasonable rate of return
- Reference pricing
 - ▣ Foreign price of the same drug
 - ▣ Domestic price of similar drug



Doha process



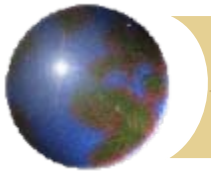
TRIPS obligations

● Article 27:

- Patents to be awarded without discrimination among fields of technology
- Patents to cover both processes and products
- Patents to be protected for 20 years from the date of filing

● Transition periods

- 2005 – for developing countries
- 2016 – for LDCs (may be extended)



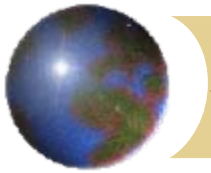
Doha Declaration

● Background:

- Spreading HIV/AIDS pandemic in large parts of the developing world
- General concern that there may be conflicts between TRIPS and public health objectives

● Content:

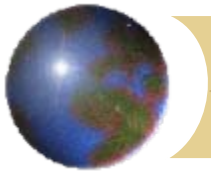
- Confirms TRIPS flexibilities (political endorsement)
- Extension of implementation deadlines for LDCs
- Unresolved issue: compulsory licensing when manufacturing capacity is insufficient



Compulsory licensing

● Conditions established in TRIPS:

- Shall be considered on individual merit
- Need to make effort to obtain a voluntary license first – however, this requirement can be waived in *"the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use"*
- Right holder shall be paid adequate remuneration
- Use shall be *"predominantly for the supply of the domestic market"*



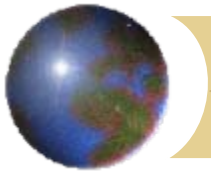
2005 TRIPS Amendment

● Problem:

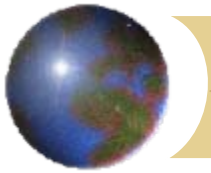
- TRIPS Article 30/31 (f): legal uncertainty to what extent generic versions of patented drugs can be exported

● August 2003 Decision/TRIPS Amendment:

- Article 31 (f) is waived if importing country has established that it has insufficient manufacturing capacities
- Safeguards and reporting requirements

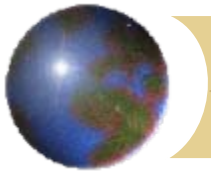


The concept of differential pricing



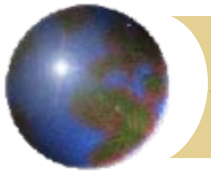
Definition and terminology

- Differential pricing describes the practice of a firm of setting different prices for the same product in different markets
- Terminology
 - Discriminatory pricing
 - Tiered pricing
 - Equity pricing



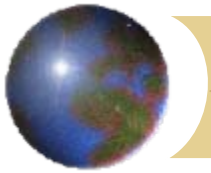
Economic theory

- Three conditions need to hold for discriminatory pricing to occur:
 - Companies must have pricing power
 - Demand conditions must vary across markets
 - Markets must be segmented
- A profit-maximizing firm will set higher prices in markets, in which the price sensitivity of demand is lower (consumers have a lower price elasticity)



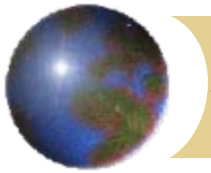
Consistent with equity objectives?

- Does the price sensitivity of demand (price elasticity) vary inversely with per-capita income?
- Companies may focus on rich or insured population segments in low income countries
- What is an equity-consistent price? Note that lowest prices may still be above competitive levels



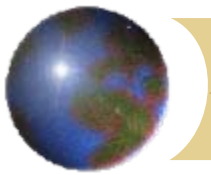
Why the simple model may fail

- Firms may not set prices to purely maximize (short term) profits:
 - Philanthropic considerations
 - Pressure from NGOs and the media
- Monopsony power of large buyers
- Markets may not be perfectly segmented
 - Physical leakage of products (parallel trade)
 - Information spillovers (reference pricing)

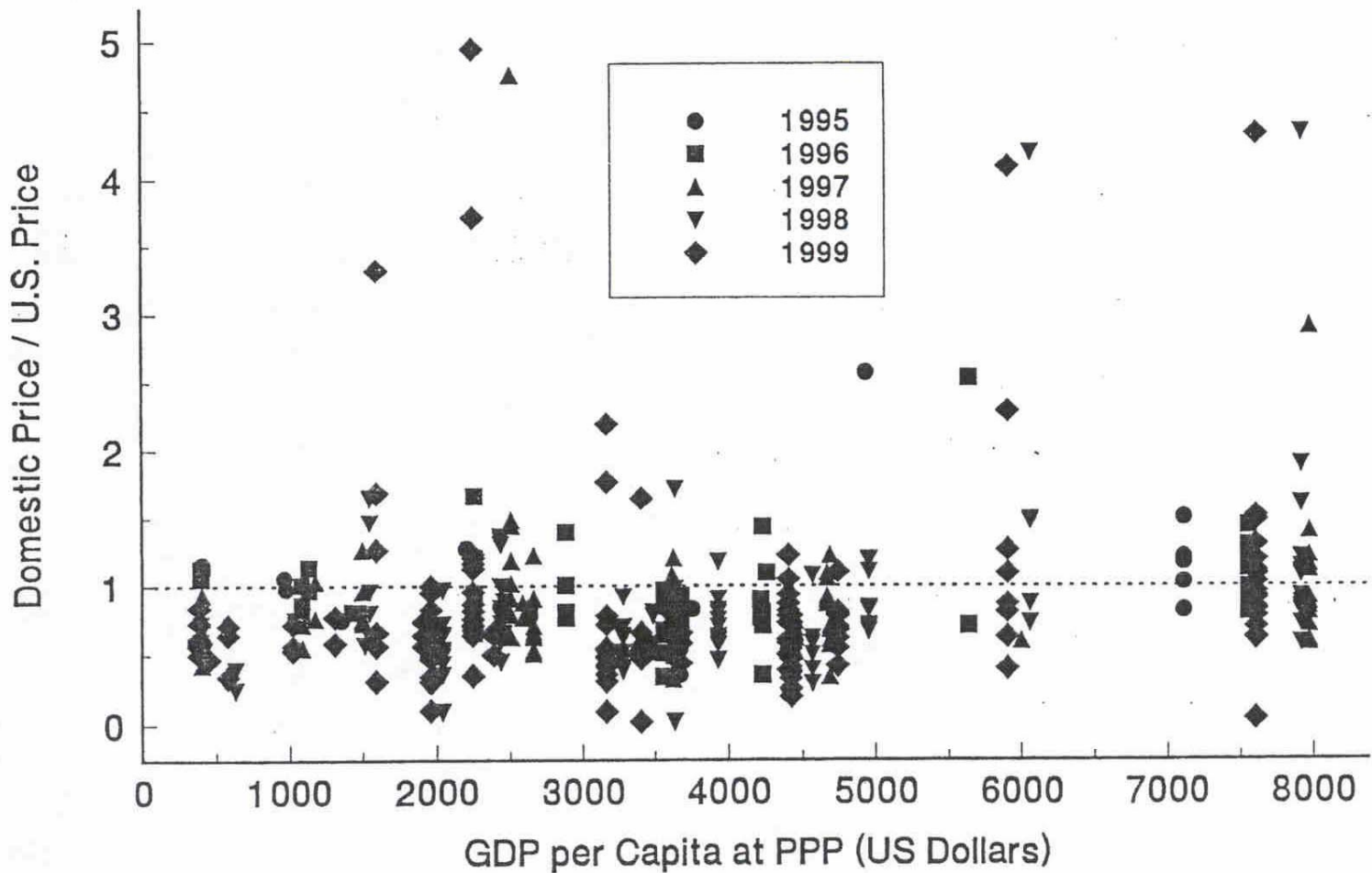


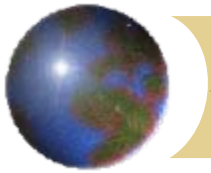
Empirical evidence: retail prices

- Obvious question, but empirical evidence is scarce
- Study by Wong (2003) finds a positive correlation between income inequality and wholesale drug prices
- Study by Scherer and Watal (2001) finds no (or at best a weak) correlation between national wholesale prices for 15 anti-retroviral drugs and per-capita income between 1995 and 1999



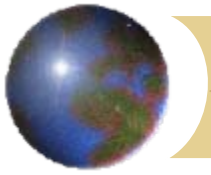
Pricing of ARVs



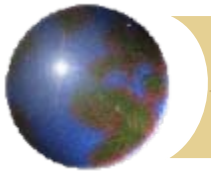


Special offers to public sector

- 'Doctors with Borders' regularly publish price discounts offered to developing country governments, NGOs, and certain international organizations
- Discounts may be influenced by generic competition

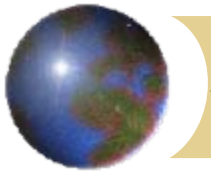


Some final considerations



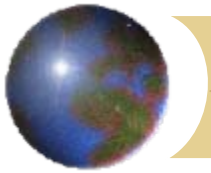
Other obstacles to drug access

- Funding: despite increasing commitments to fight AIDS, Malaria and Tuberculosis, available resources are estimated to be insufficient
- Lack of complementary health infrastructure (hospitals, doctors, nurses, distribution systems)
- Control of drug quality



Research into LDC-specific diseases

- Little research conducted into diseases, for which burden falls on poor countries (Malaria, Dengue, Polio, Syphilis, Diarrhoeal diseases, Measles, and others)
- Even with patent protection, developing country markets remain small:
 - Developed countries account for more than 85 percent of the \$625 billion of global pharmaceutical sales
 - LDCs account for less than 2 percent of global sales



Policy responses

● Push mechanisms:

- Research funded/undertaken by the public sector
- Public-private partnerships (e.g., Global Alliance for Tuberculosis Drug Development)

● Pull mechanisms:

- Advance market commitments (pilot project to develop a vaccine for pneumococcal disease is currently being developed)
- Innovation prizes (small-scale prizes already exist)