IPRs in the pharmaceutical industry

The Development Implications of Intellectual Property Rights and TRIPS

Washington, DC, June 4-5, 2008
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*

*As reported by Frontline documentary “The other drug war”, June 19, 2003
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

Source: Scherer and Watal (2001)
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 pneumoccocal disease is currently being developed)
  - Innovation prizes (small-scale prizes already exist)