PHARMACEUTICALS

- Characteristics
  - Prescription (ethical) and Over-the-Counter
  - Price inelastic (especially when insured)
  - Agent/principal problems (physician/patient)
  - High R&D, and high promotion
- Regulation: Safety and Efficacy
  - Trade-off between speedy introduction and introduction of unsafe drugs
- The Need for Patents
  - Profits to pay for R&D
  - Low natural imitation barriers (pure information)
  - Ease of generic manufacture
- The Incentive to “Free-Ride” or “Cheap-Ride”
  - The economics
  - Under-developed countries
  - And developed ones: Canada
    - 1969-1987, Compulsory Licensing
    - 1987-1993, 7-10 years patent protection
    - 1993-present, same as regular patent (20 yrs)
- Generic Competition
    - "Bifurcation of the market"
    - "Pseudo-Generics
- Today - Trying to Control Health Care Costs
    - Agent-principal rearrangement
      - US: HMOs, Medicare
      - Canada: the Provinces (BC's Pharmacare)
    - Instruments
        - Co-payments
        - Formularies
        - Reference based pricing
        - Physician education & monitoring
        - Patented Medicine Prices Review Board (PMPRB)

Canada: Manufacturers' Sales of all Drugs and Patented Drugs for Human and Veterinary Use, 1990-1998; and Human Use 1999-2004

	Total ($billions)	Patented ($billions)	Patented Drugs as % of total %
2004	15.9	10.9	69%
2003	15.1	10.1	67%
2002	13.1	8.8	67%
2001	11.5	7.5	65%
2000	10.0	6.3	63%
1999	8.9	5.4	61%
1998	7.8	4.3	55%
1997	7.0	3.7	53%
1996	6.6	3.0	45%
1995	6.0	2.6	43%
1994	5.9	2.4	41%
1993	5.4	2.4	44%
1992	4.8	2.2	46%
1991	4.4	2.0	45%
1990	3.7	1.7	46%

Source: PMPRB and IMS Health

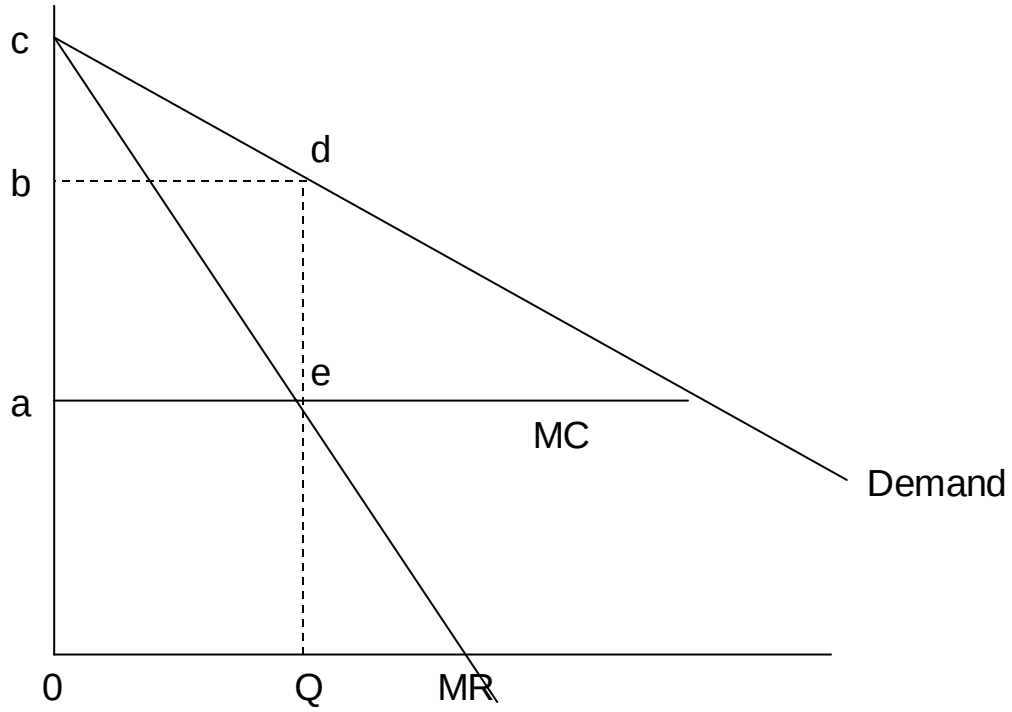
Issue: the speed of approval

Null Hypothesis: the drug is **not** safe or effective

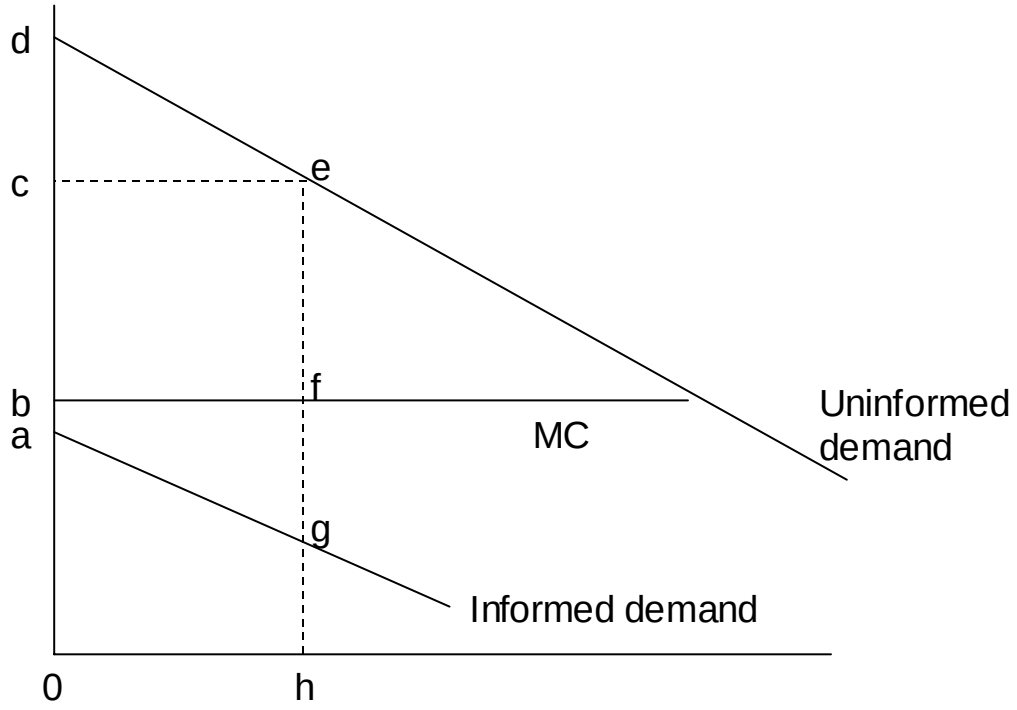
Type I Error: reject the null hypothesis when it is true (i.e., allow dangerous drugs onto the market -- example, Thalidomide in Europe).

Type II Error: accept the null hypothesis when it is not true (i.e., do not allow an effective drug to be marketed).

Type II: Society foregoes net benefits of acde for every period the drug is not allowed



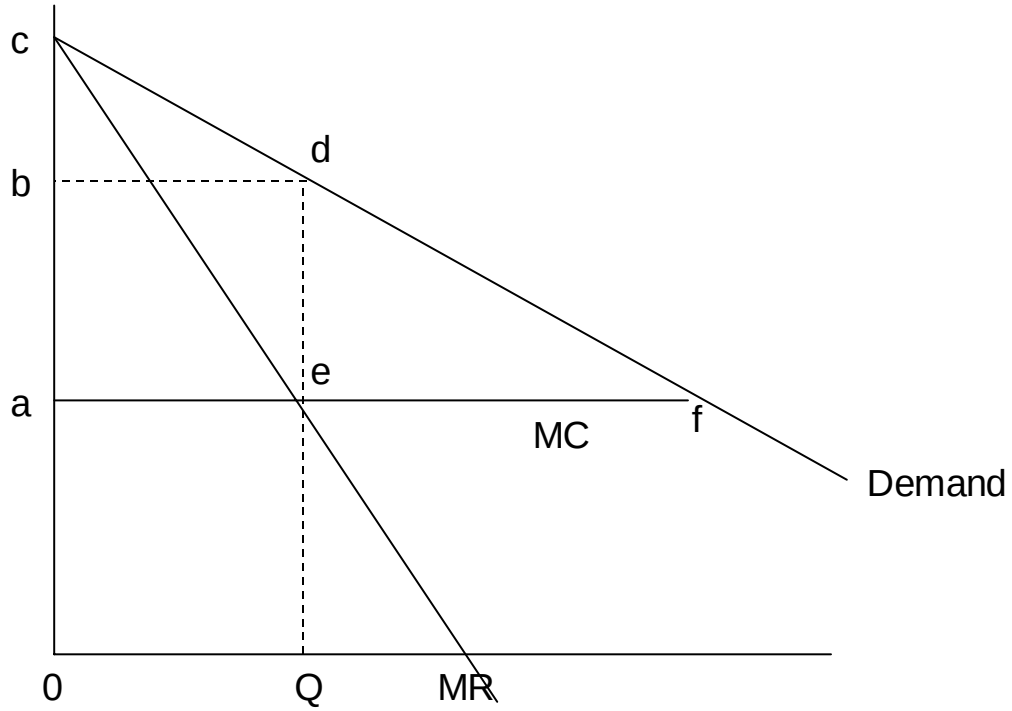
Type I: Society incurs deadweight loss of abfg



Note consumers pay 0ceh, but receive 0agh in benefits.

Note, if the drug is very dangerous, the demand curve could be below the horizontal axis (i.e., a negative price).

Issue: How much patent protection?



Once the drug is discovered, each period the patent is in force leads to a deadweight loss of edf. (Note, MC is likely very low for pharmaceuticals)

The NPV of abde must be large enough to pay for the investment in R&D, otherwise not even bcd will be obtained by consumers (the drug will not be discovered).

ALTERNATIVES

Invention without property rights

- Natural imitation lags
- Advantage of competitive product leadership
- Non-patent barriers to imitation

Variable life of property rights

SOCIAL COSTS

- allocative inefficiency
- extension of monopoly power across products
- extension of monopoly power through time
    - improvement patents
    - pharma: "new indications" (i.e., new application of an existing drug)
- suppression of patented innovation
- suppression of diffusion
- cross-licensing (i.e. cartels)
- inequities between big and small firms

CANADIAN SYSTEM

1. “First to File” (not first to invent)
2. “Absolute Novelty” but one year grace period
3. Term = 20 years
4. Abuse provisions: patent can be canceled if,
    a) not worked in Canada
    b) inadequate supply (i.e., exorbitant price)
    c) an industry is “prejudiced” because of refusal to license

GENERIC COMPETITION

- "Bifurcation of the market"
- "Pseudo-Generics
    - Definition
    - Anti-competitive effects: first mover advantage again

recall:
Vo = perceived value of the first mover
Po = price of the first mover
Vn = perceived value of the entrant's product
Pn = price of the entrant's product
Ef = the probability that Vn < Vo
For the first mover to sell the product the following must hold:

(Vo - Po) > 0

for the entrant to sell its product:
(Vn - Pn) - Ef(Pn) > (Vo - Po)

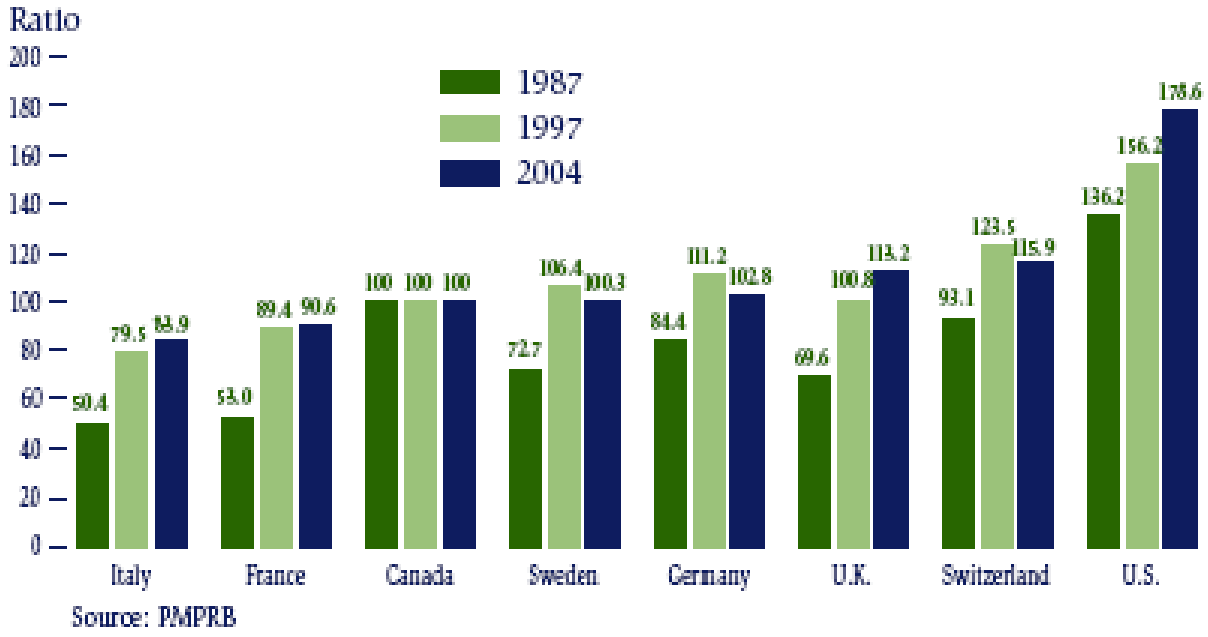
- Patent holder can introduce the pseudo-generic first
    - Entrant incurs sunk costs and time delays (bio-equivalence studies, chemical analysis, manufacturing set-up).
    - Entrant must file "notice of allegation" patent holder can dispute and trigger 2 year delay
- Commonly patent holder introduces pseudo-generic only when entry is imminent.
- Evidence of strong first mover advantage in the generic market

POLICIES TO CONTROL PHARMA COSTS: CANADA

- Note: prescription drugs not universally covered by public sector plans (e.g., in BC, Pharmacare covers elderly, those on social assistance)
- Instruments
    - Co-payments (common with insurance cos.)
    - Formularies (public sector lists acceptable drugs)
    - Reference based pricing (public sector will only pay the lowest price in the formulary)
    - Physician education & monitoring (miscellaneous application)
    - Patented Medicine Prices Review Board (PMPRB
        - Created in 1987 when patents extended
        - Deals with patented drugs
        - Intended to control "excessive pricing"
            - Most new patented drug prices are limited so that the cost of therapy is in the range of the cost of therapy for existing drugs sold in Canada used to treat the same disease;
            - Breakthrough drug prices are limited to the median of the prices for the same drugs charged in other specified industrialized countries (France, Germany, Italy, Sweden, Switzerland, U.K. and the U.S.).
            - Existing patented drug prices cannot increase by more than the Consumer Price Index (CPI);
            - Canadian prices of patented medicines can never be the highest in the world.
        - Monitors R&D spending (no enforcement)
        - 1987, major Canadian Pharma's "promised" brand name pharmaceutical industry would increase its annual R&D expenditures as a percentage of sales to 10% by 1996. In 2002, the R&D-to-sales ratio was 9.9%
            - Result, public sector (e.g., university) researchers regularly support strong pharma patents

Figure 9

Average Foreign to Canadian Price Ratios, Patented Drug Products, 1987, 1997 and 2004



Source: PMPRB