PATENTS AND COVID-19 MEDICINES: AN ECONOMIC PERSPECTIVE

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Some Basics of Medicine Economics: 1. Rationale for Patents

Ideal of Market-based Economies:

- Competition drives prices to marginal cost (MC)
- Patents grant limited monopoly to innovators, to enable price above MC (P > MC), to recoup fixed costs of R&D
- *Optimal* patent length/breadth: balance *cost to current consumers* from P >MC vs. *benefit of future new products*

Reality: WTO TRIPS 20 year patent + country "flexibilities"

- No evidence 20 yrs. is optimal, even on average
- For medicines in practice: country-level follow-on patent rules + regulatory details determine patent life and incentives

2. Affordability/Access: Insurance and Reimbursement Affect Pricing + Patent Value

- Public +Private Insurance (e.g. NHS) pays for most medicines
- Insured patients are financially protected and price-insensitive => producers raise prices unless payers limit reimbursement
- Payers ex-USA limit *reimbursed* price, usually based on the new drug's incremental benefit or cost-effectiveness
  - e.g.UK NICE: Cost per QALY $\leq$ £30,000 ("Threshold")
- Pricing Issues: In general and especially for COVID
- What Costs and Benefits to include?
- Should Threshold be higher/lower for COVID therapies?
- Should public funding of R&D constrain price?

COVID Medicines:1. Testing Established Drugs: Patents, Regulations and Incentives Matter

- Testing existing drugs requires only Ph. II/III trials
- But financial incentives may be weak *except* for biologics
- Patentability of new attributes, formulations is allowed in US => "evergreening" concerns, esp. for biologics
- E.g. Enbrel patents expire 2028 in US vs. 2015 in EU
- FDA Data Exclusivity is most effective bar to generics entry, but
- US: 5 yrs. for small mols. vs. 12 yrs. for biologics; EU: 10 yrs

=> Weak incentives to adapt older small mol. drugs for COVID

=> Public trials may be needed + outlicense to generic producers

COVID Medicines: 2. New Therapeutics

- R&D costs are relatively modest: Covid-19 pathways known; known compounds can be adapted; Regulatory fast-track
- Volume: potentially large, depends on indication + off-label use
- Price/reimbursement based on standard formulae:
  - Incremental health gain (QALYS) + medical costs averted

=> Modest prices vs. “cures” for chronic, fatal disease e.g. Hep C

- Affordability an issue for payers IFF multiple therapeutics are used in cocktails, especially for early stage/mild disease

COVID-19: 3. Vaccines: HIC vs. LDC Issues

- R&D costs relatively modest: Existing vaccines/techniques adapted quickly to address this virus + regulatory fast-track
- Public funding + private pharma collaborations underway
- Higher Income Countries (HICs): Affordability within current health budgets will be the main challenge => issue for pricing
- Less Developed Countries(LDCs) Huge global volumes => investment in production capacity will require LDC producers
  - Indian, Vietnamese producers are main suppliers of most vaccines and therapeutics for UNICEF
- LDCs will likely require GAVI funding for mass vaccination
  - As for other “essential” vaccines

HICs: Reducing Threshold on Cost-per-QALY for Value-based COVID Vaccine Price

- Assuming annual, universal vaccination: COVID vaccine will pose ongoing new budget challenge for health payers…. But
- Decline in GDP + huge other demands on public budgets =>
- Higher opportunity cost => lower threshold + prices optimal
- R&D incentives for high-volume vaccines will remain
  - Prices are constrained *because* volumes are high
- Also: Public funding for COVID vaccines has been significant
- US: Setting a value-based price, with a reasonable threshold, assures public ROI, while preserving incentives for future R&D
- Such Value-based pricing is preferable to march-in rights that must still determine a fair price + set an uncertain precedent

Less Developed Countries (LDCs): Voluntary Licensing (+ Compulsory License Back-up)

- Voluntary licensing and/or differential pricing (roughly based on GDP per cap.) enabled affordable supply for Hep. C drugs
- LDC vaccine producers may license Covid vaccines …and/or develop their own vaccines
- GAVI funding + UNICEF purchasing provide an established framework for negotiating prices for LDCs
- PAHO negotiates vaccine prices and supply for LATAM
- With time, multiple similar vaccines should provide choice for customers and competitive pressure on supplier prices, also for middle income countries outside purchasing frameworks