TRIPS II, Asia and the Mercantile Pharmaceutical War: Implications for Innovation and Access

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The TRIPS II Agenda

- High levels of intellectual property and related regulatory protection
- Principally championed by the United States, but supported by EU, Japan, Switzerland, Australia with different levels of intensity
- Achieved through bilateral and regional "free trade" negotiations, and in bilateral WTO accession negotiations
  - "Second-best" alternative to multilateral agreement at WTO
- Addresses new generation of competitive threats
  - Emerging market industries capable of producing globally competitive high quality products
  - Audio-visual content and pharmaceutical-agricultural chemical principal drivers
  - Focus here on pharmaceutical sector

Problems of Innovation and Access

- "Access to medicines" issues widely studied and addressed
  - WTO public health debate leading to Doha Declaration, August 30, 2003 waiver and TRIPS Amendment
  - WHO Commission and WHA R&D Resolution
- Economic focus on market failure resulting principally from disparities in income and wealth
  - Research skewed toward "diseases of the North"
  - Market and regulatory failures lead to concentration on incremental innovation rather than breakthrough
  - Differential pricing allegedly impeded by threat of parallel trade
- Remedies include developed country subsidization of research and purchase, public-private research partnerships, restrictions on parallel importation (at least cross-regional)

Alternative Context: Mercantile Struggle for Dominance of Pharmaceutical Supply Market

- Small number of highly capitalized OECD-based enterprises face increasingly strong competition from emerging market, and principally Asian, pharmaceutical enterprises
- OECD government and industry efforts to constrain emergence of competition leading to highly restrictive regulatory regime with potentially adverse global public welfare impact
- Consideration of Asian emerging market response

Pharmaceutical Industry Structure: OECD

- OECD-based companies are preponderant developers and owners of pharmaceutical technology
- OECD-based companies dominate OECD internal markets in sales of originator and, to a marginally lesser extent, generic products
- Revenues from originator markets far outweigh revenues from generics markets
- OECD dominance in pharmaceutical sector heavily subsidized by OECD governments
  - $28 billion US National Institutes Health budget
  - Medicare Part D program
  - Maintenance of costly regulatory framework
  - New bio-weapon and pandemic vaccine subsidy programs
  - Other OECD governments less supportive than US, but pharmaceutical R&D and purchase heavily subsidized
- OECD pharmaceutical industry is *not* a private market economy – it is a heavily subsidized and regulated competitor in the global market

Pharmaceutical Industry Structure: India

- Historically concentrated on supply of generics to developing country markets
- Increasingly penetrating high-value OECD generics markets
  - Hatch-Waxman patent challenges and 180 marketing exclusivity
  - Purchasing OECD generics suppliers
- Valuation of major Indian pharma companies rapidly increasing
- Indian government funding pharmaceutical R&D
- Growth of clinical trial subindustry
- Capacity to emerge as successful competitor in global originator market

Pharmaceutical Industry Structure: India

- Indian regulatory structure undergoing transformation based on implementation of TRIPS I requirements
  - Implementation of pharmaceutical product patent protection
  - Nine thousand "mailbox" applications under review
    - Pre-grant opposition proceedings
    - Sui generis prior user's right allows continued generics production
  - Increased patent office funding
  - Debate on new price control regime
- OECD Pharma response
  - R&D joint ventures (e.g., Glaxo-Ranbaxy)
  - Acquisitions and greenfield investments so far limited
    - Potential targets include mixed producer drug portfolios
    - Experts expect acquisitions once originator products emerge

Pharmaceutical Industry Structure: China

- Various market advantages
  - Government promotion of technical education
  - Significant production capacity
  - Traditional cultural interest in medicines
  - Large domestic population with growing income and wealth
  - Increasing access to capital markets
  - Local industry increasing export sophistication
- Relatively non-transparent regulatory and industry structure as compared with India
- Widely shared perception China to emerge as strong global pharmaceutical industry competitor

Pharmaceutical Industry Structure: Others

- Indonesia, Malaysia, the Philippines and Thailand house significant generic production capacity
- South Korea is a leading producer of bulk chemicals, and investing substantially in biotechnology-related R&D and production
- Singapore investing heavily in biotechnology research, including establishment of Biopolis research complex
- Bangladesh "least developed" generics export platform
- China and India remain leading APIs producers

TRIPS II Commitments

- Bilateral and regional trade agreements negotiated by the United States, in force or signed with Jordan, Singapore, Chile, Australia, Morocco, Central America – DR, Bahrain, Oman, Peru, and Colombia, and under negotiation with Thailand, Southern Africa Customs Union (SACU), South Korea and others
- WTO accession negotiations which are characterized by bilateral demands for concessions on pharmaceutical protection, see, *e.g.*, Cambodia and Russia negotiations

TRIPS II Commitments

- Patents
  - New uses of known compounds (*e.g.*, second medical indications)
  - Plants and animals
  - Patent term extension based on regulatory approval or patent office delay
  - Regulatory review exemption narrowed
  - Grounds for compulsory licensing limited
  - Prohibition of parallel imports
- Marketing exclusivity
  - Based on foreign submissions and/or approvals
  - Expand scope of covered products beyond new chemical entities
  - Extend term based on new clinical trials
  - Patent-regulatory review linkage
- Price Controls
  - Right to challenge Australia PBS reimbursement scheduling
  - Negotiations with South Korea

TRIPS II Commitments

- Major shift from private patent holder enforcement of rights to government-imposed market exclusivity regimes
- Overcomes problem of patent invalidity
- Complexity overwhelming for developing country regulatory authorities
  - Lead to application of simplified more highly restrictive procedures compared to Hatch-Waxman
  - Avoidance of trade disputes with US
- Developing country governments recognize elevated pharmaceutical cost of concession to US
  - *Ex ante* and *ex post facto* impact assessments confirm
  - Trade-off for improved access to US market in agricultural products, textiles, etc.
  - World Bank, WHO, other development agencies recommend against conceding public health flexibilities

U.S. Policy Objectives

- Increase US technology rents by foreclosing competition from emerging market pharmaceutical producers
- US pays significant political price for agreements
  - Antipathy of foreign government officials
  - Public protest
  - Latin American political shift
- TRIPS MFN extends "benefits" to all WTO Members
  - EU, Japan free ride on political cost
- Mercantile "winners" are large Pharma companies based in the OECD
- Mercantile "losers" are generic manufacturers which do not hold patent portfolios or control regulatory data, including from emerging Asian markets

Policy Outcome

- Reinforce dominance of major OECD-based Pharma companies
- What is rationale for reinforcement?
- Does the OECD Pharma-centric system function well?
  - 15% revenue directed to R&D
    - High proportion directed to lifestyle drugs – weight loss, cosmetic skin care, etc.
    - Patents predominantly for incremental innovation – sometimes suspect – new forms of same substance, dosages, delivery systems
    - Breakthrough drug pipeline fallow – low number of NCEs
    - Under-investment in diseases of poor
  - High percentage of Pharma expense to advertising and promotion, administration
    - Direct to consumer advertising
    - Promotion to physicians
  - Market incentive for increasing sales irrespective of patient interest
    - *E.g.*, recent high level of prescription sleep medication sales
- Why reinforce this system through increased technology rents?
  - Best of less than ideal alternatives
    - Mechanism for attracting capital in competitive market
    - Protects against under-investment in R&D

Policy Outcome

- Negative impact
  - Increases cost of medicines, disproportionately affecting less affluent parts of population worldwide
    - Restricts introduction of generic medicines
  - Reduces access to innovative technologies
    - Assumes that technology "leakage" an adverse event
    - Assumes innovation will increase based on limiting drug development to small number of highly capitalized market actors
- Emergence of Chinese and Indian competitors may be inevitable, but may be delayed for 5, 10 or 15 years
- Alternative models for promoting pharmaceutical innovation required
  - Separating inventive function from distribution function
- Oligopolistic market with 5 Asian participants not necessarily an improvement
  - Problem is market structure

Asia's Response

- Concessions in pharmaceutical sector must be balanced with higher public health expenditure, otherwise done at expense of patient-consumer
- Adoption of more aggressive regulatory posture
  - Application of competition law
  - Strict review of patent applications and claims for marketing exclusivity
  - Promote challenge in patent-regulatory review linkage
  - Exercise vigilance over prices, including adoption of price oversight mechanisms
- Increase public funding of R&D to compete with US NIH-based system
- Restrict level of foreign penetration of pharmaceutical producer market
  - Necessary to maintain competitive market in face of highly subsidized foreign participants
- Encourage market entry of generic products with, *e.g.*, 180-day market exclusivity periods as per Hatch-Waxman
- Retain and use TRIPS I flexibilities, *e.g.*, compulsory licensing for domestic and export markets

Conclusion

- Matter of achieving appropriate balance
- Asian emerging market economies have self-interest in promoting local R&D and production, and providing affordable medicines to public
- Caution should be exercised in accepting TRIPS II commitments