Policy, Markets and Knowledge: Strategic Synergies in Indian Pharmaceutical Firms

The Open University, Milton Keynes

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Agenda

Policy  Market  Research  Opportunities

Patent regimes  Structural composition  Status and approach

Existing and Emerging
Phase I (1950-1970)

Policy

- The Patents & Design Act 1911
- Industrial Policy 1948
- First DPCO 1970

Market

- Foreign Ownership
- Drug Prices high
- High import for essential drugs

R&D

- Technology import
- Industrial know-how & Capital import
- No bulk production
- Research non-existent
The PDA 1911 and Industry Growth

25-30
Chem Pharma
Indo Pharma
Unichem
Sarabhai
IPCL
Zandu
CIPLA
East India
Bengal Immunity
Alembic
Bengal Chemicals

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Public

Private

Pfizer....80 MNCs
Wyeth
G.Remedies
Abott
Smithkline
Boehringer
Ciba-Geigy
Merck
Sandoz
Rhone
Nicholas
Roche
Bristol Myers
Hoechst
Burroughs
Parke Davis
Boots
Glaxo
FERA
Phase II (1970-90)

Policy

- The Patents Act 1970
- New Drug Policy 1978, 1986
- Revised DPCO 1979, 1987
- Hatch Waxman Act 1984
- NIP 1991 (Liberalization)

Emergence of domestic sector
(small, medium and large Pvt. sector)
Public Sector decline
Increased production
Import substitution-self sufficiency
Lower Drug prices
Exit of MNCs

Market

Reverse Engineering
Large scale production capacities and capabilities (generics)
Non-infringing processes

R&D
Dynamic Changes

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<thead>
<tr>
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<tbody>
<tr>
<td>Western Multinationals</td>
<td>80</td>
<td>50</td>
<td>39</td>
</tr>
<tr>
<td>Indian Public Sector</td>
<td>10</td>
<td>2</td>
<td>1</td>
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<tr>
<td>Indian Private Sector</td>
<td>10</td>
<td>48</td>
<td>8000+</td>
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- In 1976, among the top 20 firms, (which held 57.19% of the pharmaceutical market in India), there were only 4 Indian firms.
- By 1995, only 7 MNCs (including their subsidiaries) figured among the top 20 pharmaceutical firms in India.
- Among the top 50 in 1995-96 only 12 MNCs figured in the list.
Phase III (Since the 1990s)

**Policy**
- TRIPs Agreement 1995
- DPCO 1995
- Schedule M enforcement
- Schedule Y amendments
- National Pharmaceutical Policy 2006 draft
- Continued growth of the domestic Sector
  - (Mainly large pharma)
  - Net exporter of low-cost, high-quality generics
  - Entry in regulated markets
  - Reawakening of PRIs, Laboratories
  - Return of Western MNCs

**Market**
- Innovative R&D (NCEs, NICEs)
  - (greater investment, patent filings)
  - Greater Innovation in generics
    - (branded and bio-generics)
  - Science based in-house infrastructure

**R&D**
Product patent regime and industry growth

Market share of local Indian companies and MNCs
## Phase I+II+III (1950-2000...)

<table>
<thead>
<tr>
<th>The PDA 1911</th>
<th>The Patents Act 1970</th>
<th>TRIPs Agreement 1995</th>
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<td>First DPCO 1970</td>
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<tr>
<th>Foreign Ownership</th>
<th>Emergence Pvt. Sector</th>
<th>Domestic Sector</th>
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<tbody>
<tr>
<td>Drug Prices high</td>
<td>Public Sector decline</td>
<td>(Mainly large pharma)</td>
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<tr>
<td>High import</td>
<td>Increased production</td>
<td>Net exporter</td>
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<td>Import substitution</td>
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<td>Reawakening of PRIs,</td>
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<td>Return of Western MNCs</td>
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<tr>
<th>Technology import</th>
<th>Reverse Engineering</th>
<th>Innovative R&amp;D (NCEs, NICEs)</th>
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<tr>
<td>Capital import</td>
<td>Large-scale production capacities (generics)</td>
<td>Greater Innovation in generics (branded and bio-generics)</td>
</tr>
<tr>
<td>No bulk production</td>
<td>Non-infringing processes</td>
<td>Science based infrastructure</td>
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<tr>
<td>Research non-existent</td>
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India’s capability creation and value progression chain

<table>
<thead>
<tr>
<th>Paradigms</th>
<th>Shifts</th>
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<tbody>
<tr>
<td>Knowledge Base</td>
<td></td>
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<tr>
<td>Minimal Information</td>
<td>3D-Information</td>
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<tr>
<td>Minimum Knowledge</td>
<td>Complex - Knowledge (Tacit)</td>
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<tr>
<td>(Explicit)</td>
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<tr>
<td>Research</td>
<td></td>
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<tr>
<td>Duplicative Imitation</td>
<td>New Innovation</td>
</tr>
<tr>
<td>R&amp;D: Reverse Engg</td>
<td>R&amp;D: Generics, Chiral Synthesis</td>
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<tr>
<td>Process Development</td>
<td>R&amp;D: NDDs and Analogue Research</td>
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<tr>
<td></td>
<td>New Innovation</td>
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<td>R&amp;D: NCEs</td>
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<td>Drug Development Capabilities</td>
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<tr>
<td>Primitive Formulations-Manufacturing</td>
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<td>Intermediate Chemical Synthesis Skills</td>
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<td>Semi-Advanced Complex technologies</td>
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<td>Advanced New Knowledge-edge fields</td>
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<tr>
<td>Timescale</td>
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<tr>
<td>15 – 24 yrs</td>
<td>Decreasing Cycle Time</td>
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<tr>
<td>10 – 12 yrs</td>
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Leveraging strengths to move up

- Horizon 1: Generics in Regulated Markets
- Horizon 2: Formulation Exports
- Horizon 3: R & D Based Products

- API Exports
- Formulations
- APIs
- Export of domestically produced generics
- Chemicals
- R&D - led Business Models

**TIME**

**VALUE**
Research Networks

Top 10 corporations = 37 % market share, 8 out of 10 are Indian Firms

- 250-300 firms account for 70% of products
  - Ranbaxy, DRL, NPIL, Sun, Lupin, Cadila, Zydus, Cipla, Wockhardt, Torrent Aurbindo, Glenmark, Matrix, Alembic, Divis, Sarabhai, Dabur …..
  - GSK, Novo Nordisk, Astra, Pfizer, Merck, Eli Lilly, Roche ….
  - Siro-Clinpharm, lambda, i-Gate, Aurigene, Wellquest, Syngene ….
  - Biocon, Bharat Serum & vaccines, Panacea, Shantha Biotech, ….
  - Wipro, TCS, IBM, ORACLE, Accenture, Satyam, Intel ….

- Central Govt, State Govt, Regulatory authorities
  - MOH, ICMR, DCGI, DBT, DST, Maharashtra, Karnataka, Andhra-Pradesh, Gujarat,
The PDA 1911 and Industry Growth

Pfizer....80 MNCs
Wyeth
G.Remedies
Abott
Smithkline
Boehringer
Ciba-Geigy
Merck
Sandoz
Rhone
Nicholas
Roche
Bristol Myers
Hoechst
Burroughs
Parke Davis
Boots
Glaxoaxo
FERA

CSIR Labs
State-owned (6)
IDPL
HAL
Tech-Institutions
Public

25-30
Chem Pharma
Indo Pharma
Unichem
Sarabhai
IPCL
Zandu
CIPLA
East India
Bengal Immunity
Alembic
Bengal Chemicals
Private
Research Findings: Industry Landscape

- Emerging Innovation Model
  - Technology push + Market pull
  - Generics + NDD (hybrid models)
  - R&D led Service business models
- Guiding Principles
  - knowledge integration
  - Cooperate where cannot compete
- In Transition
  - Process to Product regime (Policy)
  - Imitation to Innovation (Research)
  - Non to semi-regulated markets (Market)
  - In-sourcing to out-Sourcing, Captive investment, partnerships (Strategy)
Three Act Play

(Beginning of advanced R&D in India)

• First Act
  advanced development for products

• Second Act
  Basic research

• Final Act
  R&D Power house ??

Where will Indian drug companies be in 5 years?
Everywhere – if they innovate!!

(Knowledge @ Wharton)
Thank You

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