



Institute of Economic Growth



RIS

Research and Information System
for Developing Countries

Seminar on
India and Globalization
[A Seminar in Honour of Professor N.S. Siddharthan]

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Engaging for India in the Age of
Globalization: the Case of Pharmaceuticals

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Pharmaceutical industry

- It is by now a well accepted academic claim that in the past pharmaceutical industry immensely benefited from the policy of calibrated protection in which import protection, sectoral reservation, spin-offs / spill-overs from public sector firms, patent protection for indigenous technology development, performance requirements of production from basic stage, emphasis on complete value chain development. But what is not accepted that the latest growth story too is a beneficiary of the continuation of selective protection.

Lessons for the past management of learning and innovation

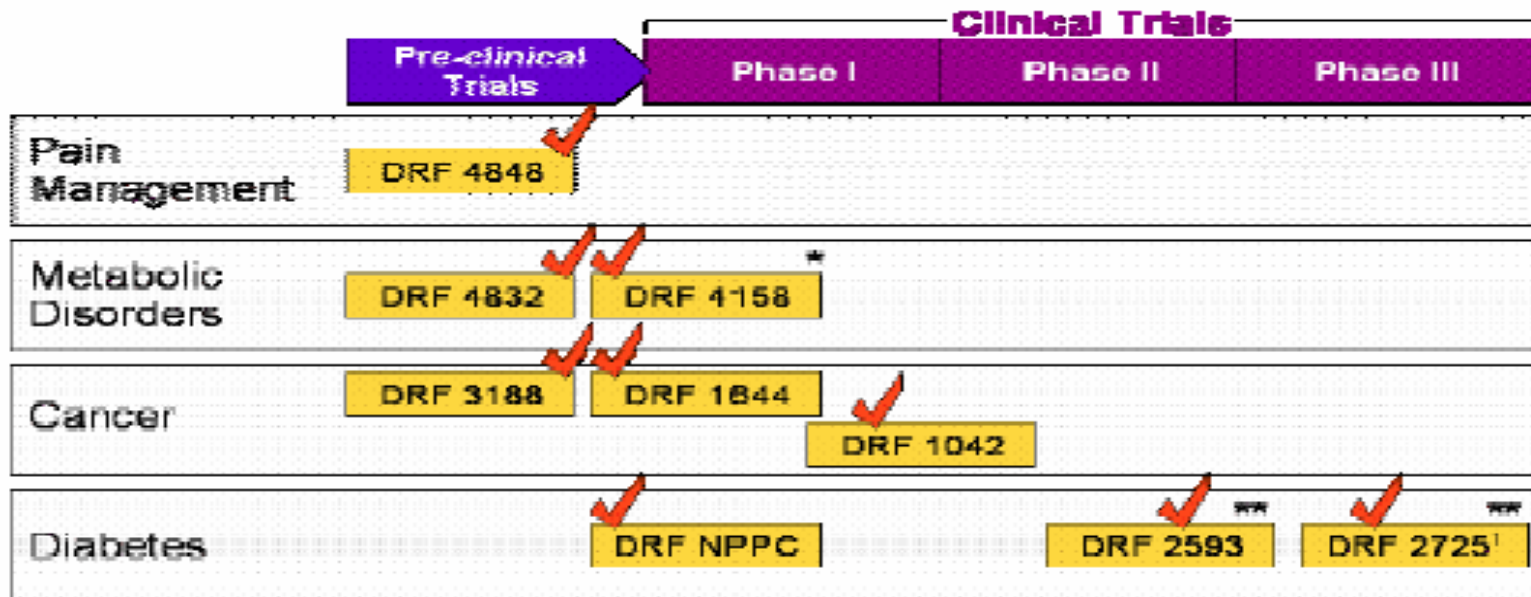
- Reinventing or creative imitation; over 57 new chemical reactions developed and linkages between publicly funded R&D laboratories and non-conglomerate specialized firms.
- Anti-infective therapeutic group was one of the key area of process innovation and growth; today the areas that are growing are anti-diabetic, Neuro/CNS, cardiac, Respiratory, pain, vitamins/nutrients

Emerging patterns of technology accumulation and innovation in pharmaceuticals

- Take the example of pharmaceutical industry to see the way with deregulation and global integration the big business is now beginning to behave and impacts on competition & good citizenship
- Emerging distorted pattern of technological accumulation and development in the absence of coordination of technology and markets; market rules the priorities of investments in innovation and S&T in both public & private sectors (IMDs & lifestyle diseases).
- Lacking focus on technological investments in activities providing increasing returns & synergy.
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Pattern of product development in DRL

NCE Pipeline: Driving Growth Longer-Term



* Licensed to Novartis
 ** Licensed to Novo Nordisk

¹Development status to be determined Q1/2003

Growing dependence on imports

Table: Imports of bulk drugs as percent of total availability (in Rs. 10 million)

Year	Availability of bulk drugs	Total import of bulk drugs & intermediates	Imports as percentage of total availability of bulk drugs
1988	714	328	46%
1989	878	411	47%
1990	1066	597	56%
1991	1053	519	49%
1992	1359	712	52%
1993	1658	1017	61%
1994	1933	1028	53%
1995	2329	1195	51%
1996	3452	2135	62%
1997	3891	2261	58%
1998	4450	2438	55%
1999	5066	2588	51%
2000	5802	2761	48%

Nature & Magnitude of MNC R&D in India

- Patterns of integration for global R&D by MNCs indicate limits of the route for independent pharma development.
 - R&D intensity of MNCs is lower than domestic firms' R&D intensity
 - Thrust of MNC R&D on product differentiation
 - Lack of priority for biopharmaceutical R&D
 - Patterns of outsourcing for drug discovery and clinical trials

Domestic firms

- Emphasis on non-essential & elite pattern at the level of both manufacturing & R&D.
 - A handful of Indian firms have been able to increase their R&D investments in product R&D for lifestyle diseases;
- Post-TRIPs strategies of domestic firms
 - Export of generics to the markets of developed countries
 - Contract manufacturing
 - Dedicated biotechnology firms
 - Contract R&D
 - Integrated pharmaceutical firms

Potential for export & manufacture of bio-therapeutics & diagnostics

- Strategies of domestic firms
 - Marketing for foreign firms in order to test waters; market development based on imported recombinant products;
 - Producing diagnostics, import intensive production
 - Researchers or industrialists with VCs or foreign capital into DBF establishment for contract research, production of biological products & chemicals using rDNA technology
 - Speciality chemicals-enzyme producers getting into production of chemicals using rDNA
 - Integrated pharmaceutical industry strategy
- Entry of Shanta Bharat, Panacea & Wockhardt provides competition in domestic market; Litigations expected to grow after 2005;
- Regulatory hurdles continue in US; delay in the introduction of generics.

Patterns of Contract R&D: Examples of R&D outsourcing

- Outsourcing from domestic companies for R&D in select niches & bioinformatics; For example, Syngene (BICON) & Aurigene (DRL), Chembiotec, Genequest (Nicholas Piramil) Molecular Connections (DRL) for bioinformatics
- Clinigene (BICON) for clinical research, Wellquest (Nicholas Piramil), SRL Ranbaxy, SIRO Research
- Quintiles Spectral, Siroclinpharm (accounting for 71% of the market); establish subsidiaries for healthcare management & pharmaceutical services (clinical trials, data mgm. & biostatistics).

Mercantile struggle continues for dominance of pharmaceutical supply market by the OECD Countries

- 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 in Developing Countries

- China and India remain leading APIs producers
- 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

The challenge of formulation of new pharmaceutical in India

- Domestic industry & government have to choose the goal:
 - myopic or far-sighted national innovation system access to essential medicines and long term interests of a non-myopic system of innovation innovation are co-terminus for India.
- specific assessment of requirements of network model for the changing innovation paradigm for complex innovation in India
 - Assess for the patterns of S&T funding relative importance of direct funding from government vis-à-vis VC funding
 - Importance of outsourcing investments for small biotechnology companies and Indian pharmaceuticals.
 - Appropriate policies on R&D, Manufacturing, Procurement & Pricing