Changing Biotechnology Innovation System in India

State strategies of governance in global biomedical innovation: the impact of China and India

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India holds 2% share of the global biotech market and has undergone a structural change

- Biopharma is the most dominant segment
- Bioservices and bioinformatics have emerged as new segments
- Agribio grew almost at the rate of 50% CAGR and the growth has tapered off
- The biotech industry remained export and urban oriented industry. It is for the first time that in 2012, the revenues from the domestic sources (US $ 1.93 billion) surpassed that of export sources (US $ 1.80 billion).

US $ = INR 54.6
Growth of Indian Biotech Industry

Source: Biospectrum-ABLE Survey, 2012
Sectoral Revenue Share and CAGR (2012)

- **BioPharma**: 13% CAGR
- **BioServices**: 16%
- **BioAgri**: 23%
- **BioIndustrial**: 11%
- **BioInformatics**: 10%
Is the Governance structure task different in India and China ensuring funding and knowledge transfer?
Segment-wise Share of Biotech Export (% share)

- BioAgri
- BioIndustrial
- BioInformatics
- BioServices
- BioPharma

Years: 2002-03 to 2011-12

Share values for each year:
<table>
<thead>
<tr>
<th>AgriBiotech</th>
<th>PharmaBiotech</th>
<th>Bioservices</th>
<th>BioIndustrial</th>
<th>BioInformatics</th>
</tr>
</thead>
<tbody>
<tr>
<td>BioFertilizers, BioPesticides, Seeds, Bioinoculants, Plant growth regulators</td>
<td>Drugs, Vaccines, Medical equipments and devices, Drug molecules</td>
<td>Clinical trials, CROs, clinical research on: cancer, metabolic diseases, diabetes, cardiovascular diseases, central nervous system. Custom manufacturing, data management, site management, bio equivalence, bio availability studies, toxicology studies, kpo for pharma industry, quality assurance and regulatory and medical affairs services to pharma biotech and medical device industries.</td>
<td>Enzymes</td>
<td>Data on: Genome sequencing, structural genomics, proteomics, micro-arrays, data on medical biotech eg. design of inhibitors for cholera toxin and proteomics with special reference to hepatitis, algorithm design for sequence classification,</td>
</tr>
</tbody>
</table>
Moving from Multi-tiered Regulatory Framework
i. Recombinant DNA Advisory Committee (RDAC)
ii. Institutional Biosafety Committees (IBSC)
iii. Review Committee on Genetic Manipulation (RCGM)
iv. Genetic Engineering Approval Committee (GEAC)
v. State Biosafety Coordination Committees (SBCC)
vi. District Level Committees (DLC)

to a single window clearance
The Biotechnology Regulatory Authority of India (BRAI)

Venture Capital

Drivers

- Inward and outward FDI + Exports
- City Cluster Program
- Public Private Partnership
- Special R&D Incentive for Biotechnology Sector
Biotechnology Industry Research Assistance Programme (BIRAP)

• A 200 per cent weighted deduction is available to firms that are engaged in biotechnology manufacturing or production.
• 100 per cent tax free status for Biotech Special Economic Zones (SEZs) for 5 years

Small Business Innovation Research Initiative (SBIRI)

• The Small Business Innovative Research Initiative (SBIRI) scheme of the Department of Biotechnology to fund early stage research has benefited more than 89 small and medium biotech enterprises.

Biotechnology Industry Partnership Programme (BIPP)

• The Biotechnology Industry Partnership Programme (BIPP) launched recently, has so far benefited 51 companies undertaking research in futuristic high risk technologies.
Actors

- Production Infrastructure (Firms)
- Knowledge Infrastructure (University, research institutes, private and public R&D)
- Policy Actors

Is meshwork more desirable than a network in the governance structure?
Year-wise Publication Trend by India in the Period 2001-2012 in the Research Area "Biotechnology and Applied Microbiology"

Source: ISI Web of Knowledge
Top 10 Countries Publishing in 'Biotechnology & Applied Microbiology' Research Area in the Period 2001-2012

<table>
<thead>
<tr>
<th>Country</th>
<th>Count</th>
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<tbody>
<tr>
<td>USA</td>
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<td>JAPAN</td>
<td>23802</td>
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<td>GERMANY</td>
<td>17987</td>
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<td>ENGLAND</td>
<td>15693</td>
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<tr>
<td>FRANCE</td>
<td>12249</td>
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<tr>
<td>SOUTH KOREA</td>
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<td>INDIA</td>
<td>11678</td>
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<tr>
<td>SPAIN</td>
<td>10145</td>
</tr>
<tr>
<td>CANADA</td>
<td>9872</td>
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</tbody>
</table>

Source: *ibid.*
Top 10 Collaborating Countries with India Publishing in 'Biotechnology & Applied Microbiology' Research Area in the Period 2001-2012

Source: *ibid.*
Year-wise Publication Graph: India and China Collaboration in 'Biotechnology and Applied Microbiology' Research Area
India and China Collaboration: Research Areas within 'Biotechnology & Applied Microbiology'

- Genetics & Heredity: 17%
- Biochemistry & Molecular Biology: 14%
- Agriculture: 12%
- Plant Sciences: 12%
- Microbiology: 10%
- Energy Fuels: 9%
- Engineering: 5%
- Food Science Technology: 5%
- Mathematical Computational Biology: 5%
- Toxicology: 3%
- Virology: 3%
- Experimental Medicine: 3%
- virology: 3%
- virology: 3%
Indian Patent Filed in Biotechnology (2001-2012)

- 2001-2003: 466
- 2004-2006: 712
- 2007-2009: 1115
- 2010-2012: 1387
Conventional therapies manage the disease symptoms, while stem cell therapies treat the cause of the disease, and from a commercial perspective this deficit of curative treatments in conventional therapies makes stem cell research a potential goldmine.

Stem cell research also has enormous potential for cell culture. Cell culture methods ensure standardized production and propagation of highly purified stem cells and their differentiated progeny.
Segments of Stem Cell Market

- **Type**
  - Embryonic
  - Cord
  - Adult
  - Other

- **Technology**
  - Stem Cell Transplantation
  - Cord Blood Banking
  - Xenotransplantation
  - Cell Based Genomics

- **Therapeutic Area**
  - Neurology
  - Orthopedic
  - Cardiology
  - Dermatology
  - Diabetes
  - Oncology
  - Hematology
  - Other
Global Trend in Stem Cell Patenting in 2001-2012 (USPTO + EPO)

Source: Thomson Innovation (accessed and analysed on 07.03.2013)
USPTO Granted Patents in Stem Cell in the Period 2001-2012: Top 20 Countries

Source: Thomson Innovation (accessed and analysed on 06.03.2013)
Note: India is in 12th Position
EPO Granted Patents in Stem Cell in the Period 2001-2012: Top 20 Countries

Source: Thomson Innovation (accessed and analysed on 06.03.2013)

Note: India is in 17th Position
EPO Granted Patents in Stem Cell (2001-2012)
Top 25 Countries

Source: Thomson Innovation (accessed and analysed on 05.03.2013)
Note: India is in 22nd Position
Top 10 Stem Cell Patent Assignees in USPTO from India in 2001-2012

- CSIR, New Delhi: 42%
- Wockhardt Limited, Mumbai: 13%
- Reliance Life Science Pvt Ltd, Mumbai: 13%
- Biocon Ltd, Bangalore: 8%
- Ranbaxy Laboratories Limited, Gurgaon: 7%
- Torrent Pharmaceuticals Ltd., Ahmedabad: 5%
- Tsar Health Pvt Ltd, Gurgaon: 3%
- Sami Labs Ltd, Bangalore: 3%
- Maulana Azad Medical College, New Delhi: 3%
- Venues Remedies Limited, Panchkula, Haryana: 3%
- Biocon Ltd, Bangalore: 8%
## Published Patents in Stem Cell

<table>
<thead>
<tr>
<th>Assignee/Applicant</th>
<th>Type of Stem Cell</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reliance Life Sciences Pvt. Ltd.</td>
<td>Embryonic Stem Cell</td>
<td>19</td>
</tr>
<tr>
<td></td>
<td>Adult Stem Cell</td>
<td>8</td>
</tr>
<tr>
<td></td>
<td>iPSC</td>
<td>1</td>
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<tr>
<td>Stempeutics Research Private Limited, Bangalore</td>
<td>Embryonic Stem Cell</td>
<td>9</td>
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<tr>
<td></td>
<td>Adult Stem Cell</td>
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<tr>
<td>Smt. G R Doshi and Smt. K M Mehta Institute of Kidney Diseases and Research</td>
<td>Adult Stem Cell</td>
<td>2</td>
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<tr>
<td>Patki Research Foundation &amp; Hospital</td>
<td>Adult Stem Cell</td>
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<tr>
<td>Advanced Neuro-Science Allies Private Ltd.</td>
<td>Adult Stem Cell</td>
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<td>Geeta Shroff, New Delhi</td>
<td>Embryonic Stem Cell</td>
<td>29</td>
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<tr>
<td>Arundhati Mandal</td>
<td>Embryonic Stem Cell</td>
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</tr>
<tr>
<td>CTRI Number</td>
<td>Cell Type Used</td>
<td>Condition Treated</td>
</tr>
<tr>
<td>-------------</td>
<td>----------------</td>
<td>-------------------</td>
</tr>
<tr>
<td>CTRI/2008/091/000046</td>
<td>Autologous BMMNCs</td>
<td>Acute Ischemic Stroke</td>
</tr>
<tr>
<td>CTRI/2008/091/000232</td>
<td>Bone marrow stem cells</td>
<td>Acute Myocardial Infarction</td>
</tr>
<tr>
<td>CTRI/2009/091/000176</td>
<td>Ex Vivo Cultured Adult Allogenic MSCs</td>
<td>Myocardial Infarction</td>
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<tr>
<td>CTRI/2009/091/00437</td>
<td>Ex Vivo Cultured Adult Allogenic MSCs</td>
<td>Dilated Cardiomyopathy</td>
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<tr>
<td>CTRI Number</td>
<td>Cell Type Used</td>
<td>Condition Treated</td>
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<td>-------------</td>
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</tr>
<tr>
<td>CTRI/2009/091/000590</td>
<td>Stem Cells</td>
<td>Heart Diseases</td>
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<tr>
<td>CTRI/2011/05/001742</td>
<td>Cardiopoietic Stem Cells</td>
<td>Chronic Heart Failure</td>
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<tr>
<td>CTRI/2010/091/000626</td>
<td>Autologous MNCs</td>
<td>Coronary Heart Disease</td>
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<td>CTRI/2010/091/000643</td>
<td>Autologous</td>
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<td>CTRI/2010/091/000644</td>
<td>Autologous</td>
<td>Myocardial Infarction</td>
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Indian Stem Cell Patent Assignees (EPO) in 2001-2012

- CSIR, New Delhi: 6 patents
- Sami Labs Limited, Bangalore: 2 patents
- Piramal Life Sciences Ltd, Mumbai: 2 patents
- Panacea Biotec Ltd, New Delhi: 2 patents
- Wockhardt Limited, Mumbai: 1 patent
- USV Limited, Mumbai: 1 patent
- Torrent Pharmaceuticals Ltd, Ahmedabad: 1 patent
- Reliance Life Sciences Pvt. Ltd, Mumbai: 1 patent
- Lupin Limited, Mumbai: 1 patent
- Dr. Reddy's Laboratories Ltd, Hyderabad: 1 patent
- Cipla Ltd, Mumbai: 1 patent
Yearwise Graph of Indian Stem Cell Patent Grants (USPTO)
Indian Stem Cell Granted Patents (USPTO) in 2001-2012

- 2001-2003: 23
- 2004-2006: 17
- 2007-2009: 15
- 2010-2012: 23
## Indian Stem Cell Granted Patents (EPO) in 2001-2012

<table>
<thead>
<tr>
<th>Period</th>
<th>Patents</th>
</tr>
</thead>
<tbody>
<tr>
<td>2001-2003</td>
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<td>2004-2006</td>
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<td>2007-2009</td>
<td>7</td>
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<tr>
<td>2010-2012</td>
<td>12</td>
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</table>
Thank you