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Biotechnology Innovation and Commercialization

Key drivers and strategies

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UNITED NATIONS ESCAP
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Overview

- Biotechnology – An emerging sector
- Biotechnology indicators
- Biotech patent trends
- Biotech vis-à-vis Investor's needs
- IP protection in Biotechnology
- Biotech entrepreneurship and commercialization
- Financing and international strategy
- Concluding remarks

Biotechnology – An Emerging Sector

Issues and challenges related to:

- **Multidisciplinary and interdisciplinary** research
- **Converging** technology
- Heavily patent-oriented but throws challenges for integrating distinctly **different IP doctrines** such as patents, trademarks, copyrights, registered designs, trade secrets/know-how, plant breeders' or plant variety rights
- Development of **statistics and metrics** to measure biotechnology
- Development of **new funding models**
- **Public engagement and acceptance**

Traditional S&T Indicators

- R&D Expenditure
- Researchers in R&D
- Technicians in R&D
- Patent Applications (Resident vs. Non-Resident)
- Scientific and Technical Journal Articles
- High-Technology Exports

Key Biotechnology Indicators

Biotechnology firms

- Number of firms active
- % of small biotech firms

Private-sector Biotechnology R&D

- Biotech R&D exp. in the business sector
- Biotech R&D intensity in the business sector
- % of biotech R&D exp. by dedicated biotech R&D firms in the services sector
- % of biotech R&D expenditure performed by small biotech/R&D firms

Public-sector biotechnology R&D

- Intramural biotech R&D exp. in government and higher education sectors
- Intramural biotech R&D exp. in government and higher education sectors as % of total government and higher education sectors R&D expenditure

Biotechnology applications

- % of dedicated biotech firms by application
- % of biotech R&D by application

Biotechnology patents

- Share of countries in biotech patents
- Revealed technological advantage in biotechnologies

Source: http://www.oecd.org/sti/inno/keybiotechnologyindicators.htm

Biotech Patent Filing

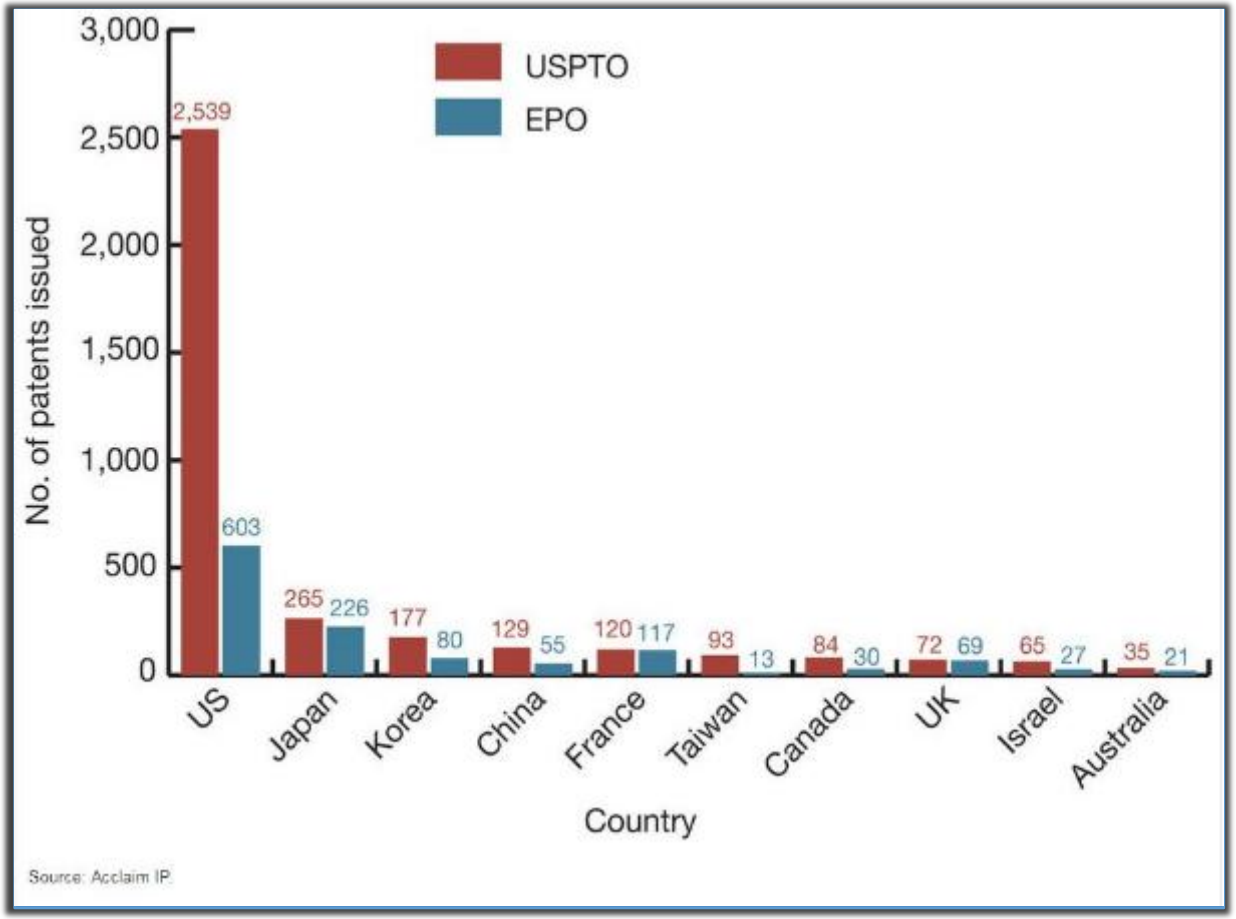
- During 2010-2013, only **7** Asia-Pacific countries together shared about **24.9 percent** of all biotechnology patents filed within the top five IP Offices (5IP).

- **Japan** (11.9%), **Republic of Korea** (5.9%), **China** (3.5%), **Australia** (1.3%), **India** (1%), **Singapore** (0.8%) and **Malaysia** (0.1%)

Note: The members of IP5 are EPO, JPO, KIPO, SIPO and USPTO. The IP5 Offices together handle about 80 per cent of the world's patent applications, and 95 per cent of all work carried out under the Patent Cooperation Treaty (PCT).

Source: OECD, STI Micro-data Lab: Intellectual Property Database, http://oe.cd/ipstats, October 2016

Research Biotech Patents Issued by Country, 2012-2016



Top 10 most active non-US universities by number of issued biotech patents, 2016

University	USPTO	EPO	Total
Kyoto University (Japan)	25	19	44
University of Tokyo (Japan)	22	19	41
Tel Aviv University (Israel)	24	9	33
University of British Columbia (Vancouver, Canada)	21	10	31
National University of Singapore (Singapore)	23	5	28
Osaka University (Japan)	16	12	28
Hebrew University of Jerusalem (Israel)	17	8	25
Paris Descartes University (France)	8	12	20
Kyushu University (Japan)	9	11	20
Université de Montpellier (France)	12	6	18

USPTO, US Patent and Trademark Office; EPO, European Patent Office.

Source: Acclaim IP. Query terms: university, college, research foundation, research organization, institute, school, plus our keyword and CPC-based searches.

Source: http://www.nature.com/nbt/journal/v35/n8/full/nbt.3829.html?foxtrotcallback=true

Biotech in the Shoes of Investors

- Biotech ventures are **capital-intensive** and investments have **long payback period**.
- Some countries have developed **venture capital funds** that are focused exclusively on biotech sector. Ex. Biotechnology Venture Fund (of the Andhra Pradesh Industrial Development Corporation)
- Investors look for **strong and capable management team**, a **risk-diversified approach** and **clear ownership of Intellectual Property (IP)**
- Investors are well aware of the **centrality of patents** in the biotech industry and will conduct a thorough **due diligence** prior to taking a decision to invest.
- Investors will seek to determine whether the company will have **freedom to operate**, i.e. whether it will be able to commercialize the product **without any IP infringement**.

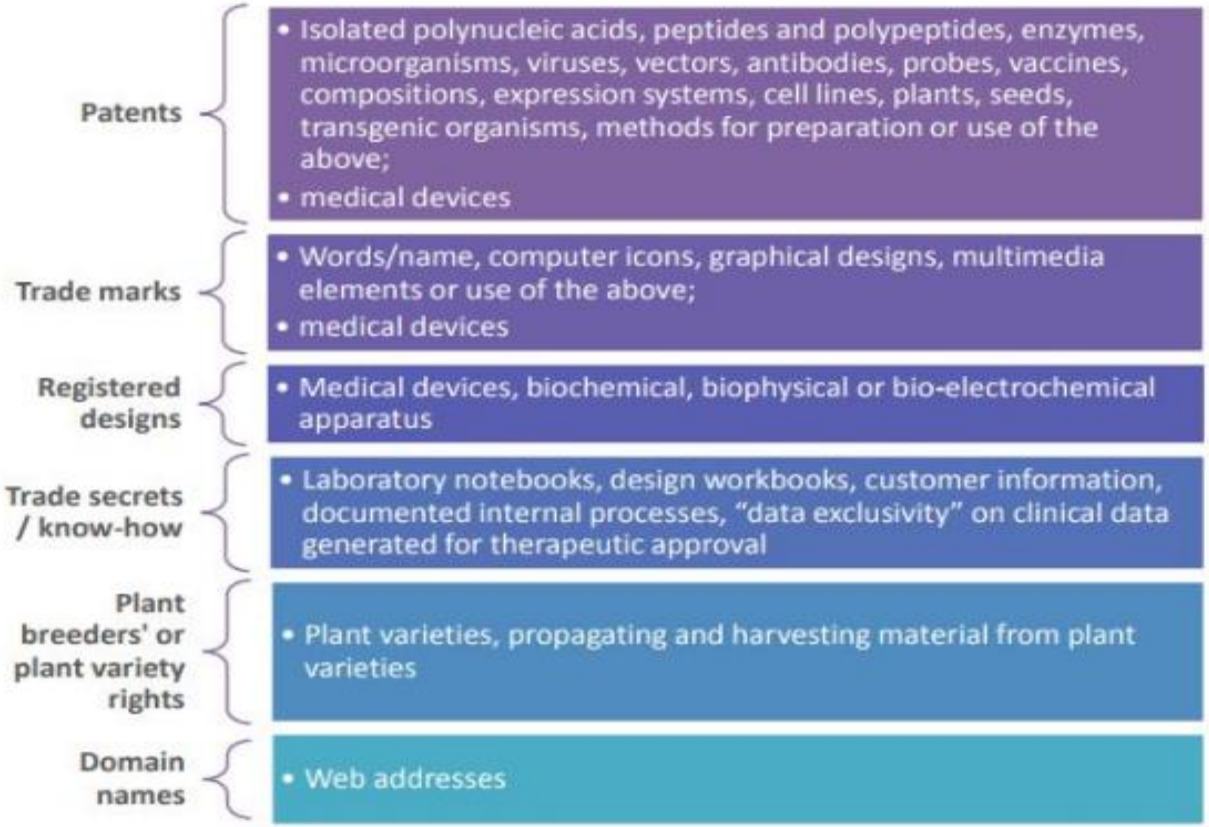
Source: http://www.wipo.int/sme/en/documents/patents_biotech_fulltext.html

Tracking Biotech Market Trends

Certain trends in '**healthcare sector'** an investor/company tracks:

- **Aging population and their healthcare needs**
- **Global reach of certain diseases**
- **Global trends in vaccination coverage**
- **Obesity and diabetes trends**
- **Technological advances**

IP Protection in Biotechnology



IPR can help in -

- Patent protection
- Revenue generation
- Maintaining investment cycle
- Rewarding researchers

Source: https://www.iprhelpdesk.eu/sites/default/files/newsdocuments/IP_in_Biotechnology.pdf

Patents at the Core of Biotech Business

As in any other field, biotechnology inventions need to fulfill the **three basic requirements of patentability**:

- Novelty
- Inventive step or non-obviousness
- **Industrial application or utility**

These should be borne in mind while:

(a) Drafting patent applications

(b) Devising R&D strategy for commercialization

Source: http://www.wipo.int/sme/en/documents/patents_biotech_fulltext.html

Biotech Trial of the Century - Case of CRISPR

Crispr (clustered regularly interspaced short palindromic repeats) is a revolutionary **genome-editing technique**

Potential benefits across human health, agriculture and industrial biotechnology

In 2015, Crispr technology moved beyond academia attracting **investment** from – **Novartis, AstraZeneca, Juno Therapeutics, Vertex Pharmaceuticals, Regeneron Pharmaceuticals, DuPont**

Patent battle casting a shadow over the technology's future commercial potential:

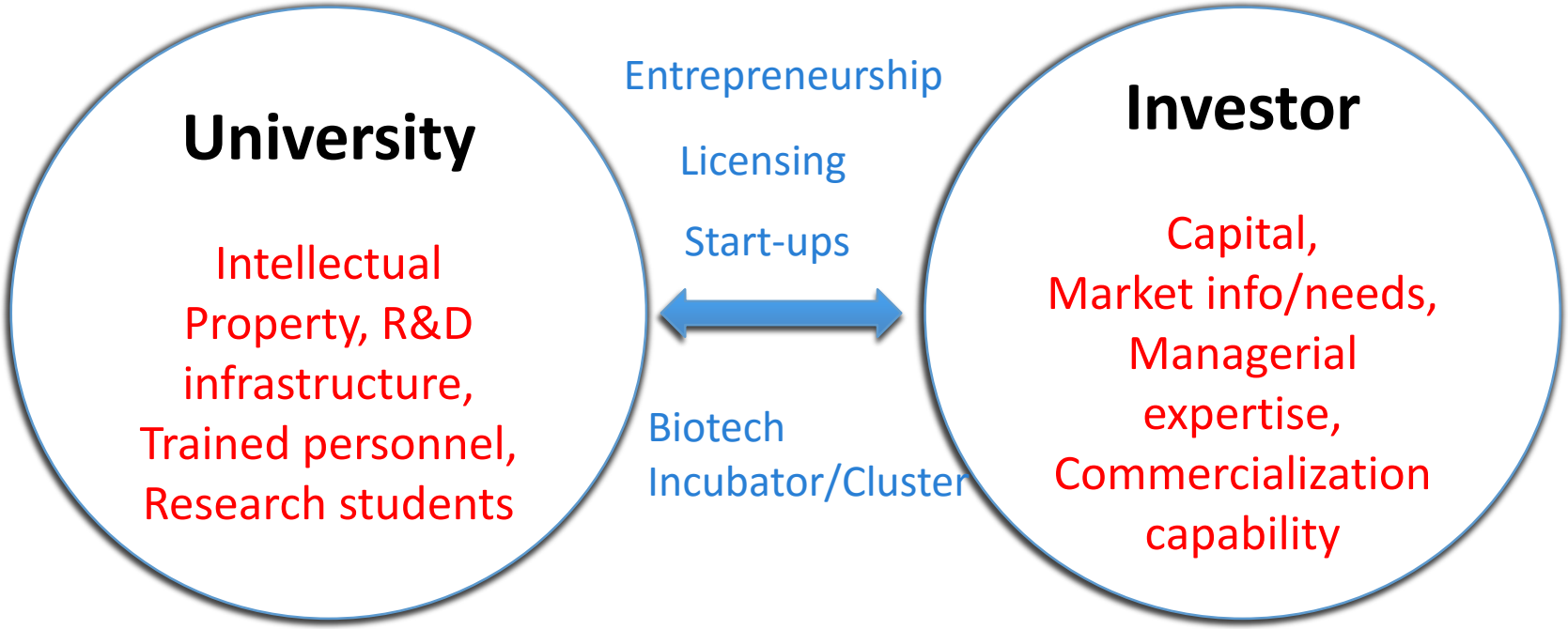
a) In 2012, Doudna and Charpentier (UC Berkeley) filed a **patent application**, followed seven months later by a separate patent application by Zhang (Broad Institute of Harvard and MIT).

b) Despite being second to submit, Zhang was awarded the patent based on his **claimed invention date**.

c) In February 2017, the US Patent Trial and Appeal Board ruled in favour of Board Institute.

Source: https://www.chemistryworld.com/business/crispr-goes-commercial/9359.article

Academic/University Entrepreneurship in Biotechnology



Stanford, Purdue, MIT and Cambridge have been particularly successful in nurturing start-ups through establishing **Biotech Clusters.**

Towards More Entrepreneurial University

Recruit star faculty – (a) Engaged in activities beyond research and teaching; (b) Possess strong publications and citation records; (c) Command a position in the university hierarchy; (d) Display qualities of a role model; (e) Possess business education and experience

Develop links with industry – (a) Research projects sponsored by industry; (b) Industry consulting; (c) Setting up university startups for commercial exploitation of research; (d) Licensing of patents

Create an appropriate incentive structure - Appropriate rewards and incentives to motivate faculty and students to innovate, network and connect with industry.

Source: https://link.springer.com/article/10.1057/jcb.2011.22

Funding Options for Biotechnology

Stage of Development	Funding Options
R&D phase	Public funding schemes, Equity capital, R&D tax credits
Commercialization phase	Public funding schemes, Equity capital, Debt from non-traditional lenders (Venture Capital, Private Equity), R&D tax credits, Limited sales revenue
Maturity phase	Sales revenue, Royalty revenue, Debt from traditional lenders

Key Success Factors for Biotech Startups

Funding - Have a diverse funding base and constantly seek out alternatives to mitigate the risk of investor withdrawal.

People - Allow the research and technical teams to evolve. Ensure expertise is aligned to the stage of development.

Forecasting - Ensure sufficient cash flow, and foresight long term demand.

Assets - Ensure that any internally generated intangible assets can be adequately protected and exploited.

Source: http://www.mcgrathnicol.com/biotechnology-market-challenges-success-factors/

Strategies for International Participation

- Strengthen **financing channels** and resolve the problem of difficult financing through Govt. funds & credit, fiscal incentives, venture capital, equity
- Build and promote **Biotech clusters with international operations**
- Capitalize on **self-advantages** to find a position in the global value chain – **low manufacturing cost**
- Improve technology **innovation** and **shift to the high end of value chain**
- Learn from **international experiences** and continue to improve **managerial skills and expertise**

Source: Tech Monitor, Jul-Sep 2012

Concluding Remarks

- Identify **critical problems in SDG sectors** which could be addressed through developing innovative biotech solutions
- Use of appropriate **biotech indicators** for policy making at national level and R&D / innovation / commercialization strategy planning at institutional levels
- R&D and innovation be driven by **market trends and needs**
- **Strong patents with wide industrial applications and utility** is key to attracting investment and commercial success
- Need to promote and strengthen **Academic/University entrepreneurship** through Technology Business Incubators (TBIs)
- **Success factors** for biotech commercialization – Strong patents, International strategy and networking; Academic/university entrepreneurship; Start-ups; TBIs; Biotech clusters; Innovation financing

Thank you

For more information, contact

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