Strategic Implications from the Growth of Biotechnology in Korea

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Biotechnology in Korea

- Growth in R&D Levels (million US$)
- Trends in Patents (IPC=C12N)
- Industry/Firm Level Competitiveness
- Government Policies
- The IPR Regime for Biotechnology
- The Impact of IPR Regime on Biotechnology
- Strategic Implications

Growth in R&D Levels

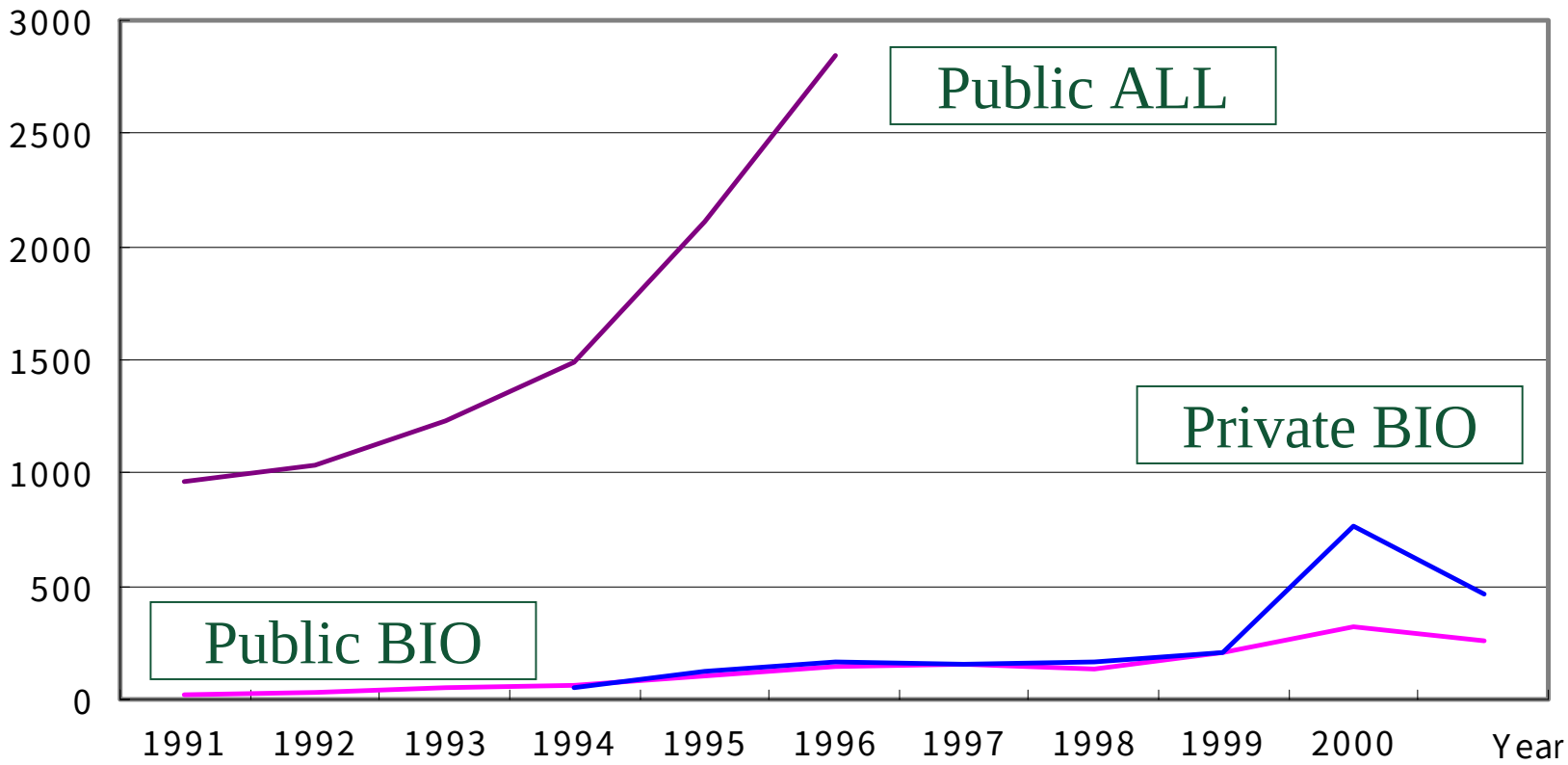
Public and Private Research Funding in Biotech

Unit:million US$

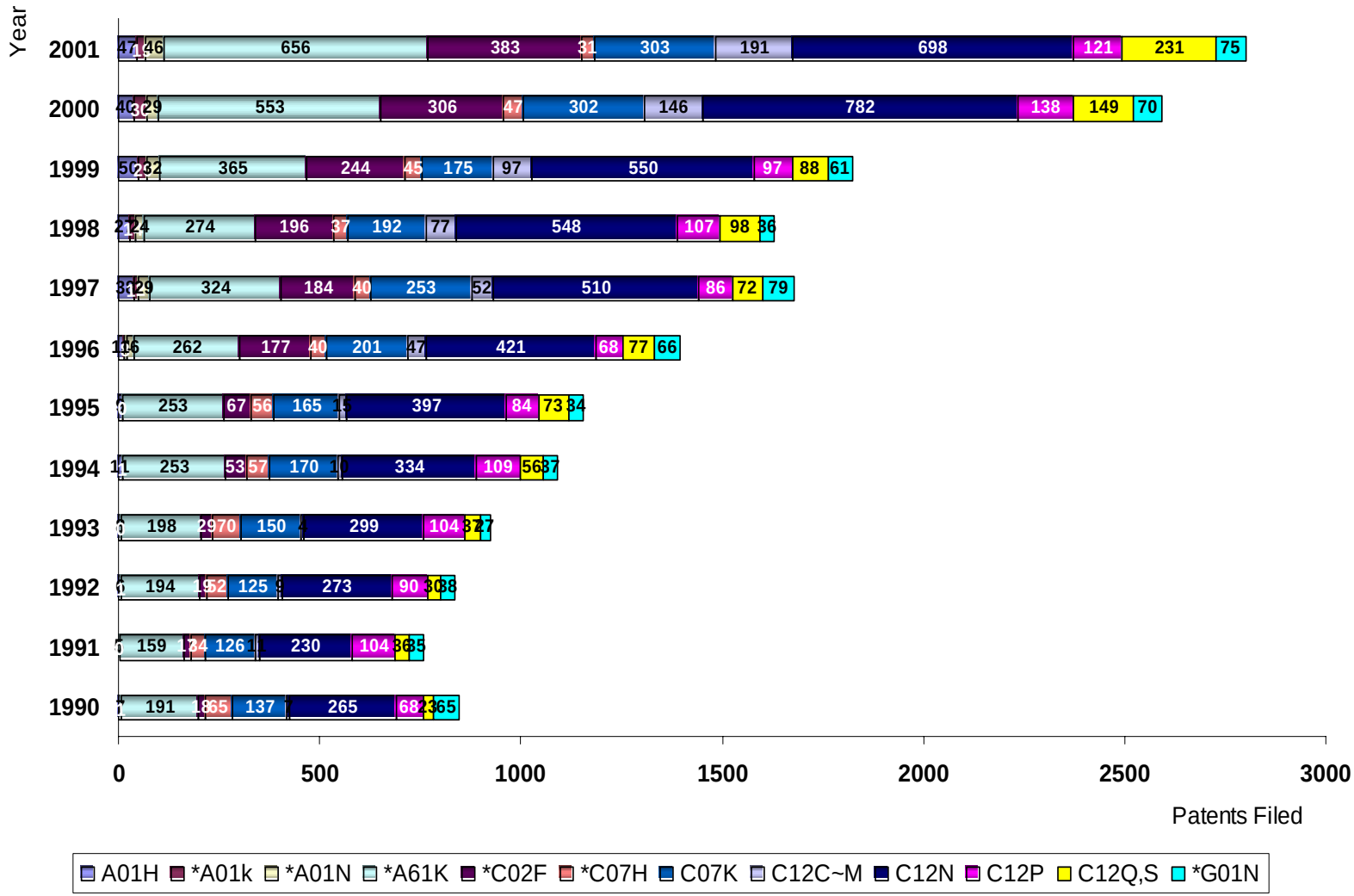
Year	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001 (estm.)
Public BIO	24 (2.48)	29 (2.80)	55 (4.47)	64 (4.29)	103 (4.89)	146 (5.14)	154	138	204	324	262
Public ALL	966	1,037	1,231	1,493	2,108	2,840					
Private BIO				57	126	162	160	163	205	763	469

Source: MOST, Ahn et al (1998: 41)

Growth in R&D Levels



Patents Filed in Korea (Korean Patents Only)



Trends in Patents: Patents Filed in the US

Country	'91-'95 (4,828 patents)			'96-2000 (11,677 patents)			2001 (2,782 patents)		
	Patents	Ratio of total (%)	Ratio to US held patents (%)	Patents	Ratio of total (%)	Ratio to US held patents (%)	Patents	Ratio of total (%)	Ratio to US held patents (%)
US	2,993	62.0	100	9,274	79.4	100	2,131	77.0	100
Japan	741	15.3	24.8	1,056	9.0	11.3	207	7.4	9.6
Germany	220	4.6	7.4	437	3.7	4.7	126	4.5	5.8
France	87	1.8	2.9	382	3.3	4.2	94	3.4	4.4
UK	27	0.6	0.9	329	2.8	3.5	150	5.4	7.0
Austr.	39	0.8	1.3	126	1.1	1.4	45	1.6	2.1
Korea	20	0.4	0.7	67	0.57	0.7	26	0.9	1.2
China	2	0.04	0.1	6	0.05	0.1	3	0.1	0.1

Source: Ministry of Science and Technology (2002)

Industry Level Competitiveness

Unit: 100 million won

	1997	1998	1999	2000	2001	Annual Average Growth
Production	5,879	8,198	9,130	11,795	13,950	24.1
Exports	3,018	4,815	4,543	6,101	6,363	20.5
Domestic	4,246	5,085	6,701	9,000	11,783	29.1
Import	1,385	1,702	2,114	3,306	4,196	31.9

Source: KDI (2003)

Firm Level Competitiveness

Annual Average	1990	1995	2000	2002
sales (won)	2,460 mil	40,976mil	54,511mil	54,314mil
No. emp	421.25	424.92	315.53	307.9
Profit/sales	8.50%	4.23%	9%	4.14%
Fin Exp/sales	7.10%	8.94%	5.51%	2.64%
SMEs	16	24	30	31
No. of firms	28	34	40	42

Government Policies

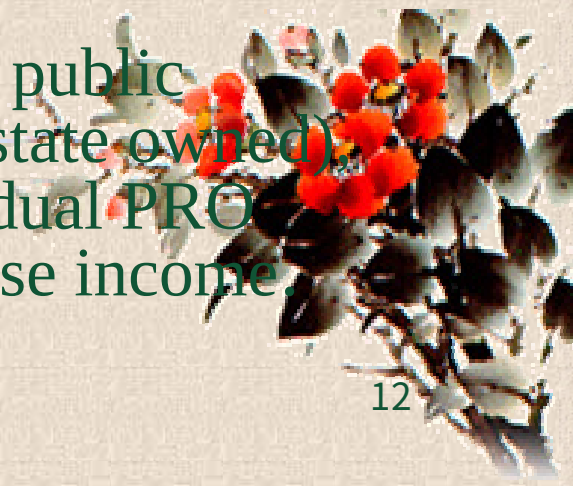
- 1982: Gov't begins to include biotech as major sub-programs in national R&D
- 1985: Legislation of the *Genetic Engineering Promotion Act*, KRIBB set up
- 1992: Launches the HAN Project to strengthen indigenous technological capability and industrial competitiveness

- 1994: Launches “Biotech 2000.” A 14 year national biotech development program (R&D funding), involving various ministries. 3 Stages (1994-97, 98-2001, 2002-2007). Currently under evaluation.
- 1995: MOAFF launches R&D program for agricultural biotech, MOHW launches R&D program for new drug development
- 1998: “Braintech 21” launched to promote research on the human brain.

The IPR Regime for Biotechnology in Korea

- 1987: Product (or material) patents allowed.
- 1988: Joined Budapest Treaty (effective in Korea as of 1990).
- 1997-2000: Series of revisions to comply with TRIPS.
  - 1997: Seed Industry Law (jointed UPOV in 2002) to protect sexually reproduced plant varieties.

- 1998: Established current patent approval criteria in biotechnology
- 1998: *Special Measures on Venture Firms* allows PRO scientists to own equity and directly participate in venture businesses. With permission, PRO scientists can hold joint positions in venture businesses or take temporary leave.
- Date?: *SME Start-Up Support Act*, designating PROs as venture incubation centres
- 2000: *Technology Transfer Facilitation Law*: management decentralisation of license income for PROs, public funding of TTOs.
- 2001: *Patent Law amendment*: allowed public universities to own patents (previously state owned), and benefit from license income. Individual PRO innovators are also to benefit from license income.



The Patent Approval Criteria

Category	Subject Matter	Patentability	Note
Material	Gene (DNA sequence)	Patentable	- Only if usefulness is proven. - Simple genome sequence is not patentable - Must submit computer readable sequence (since 1999)
	Protein (Amino-acid sequence)	Patentable	
	Single cell life forms (virus, bacteria)	Patentable	Must deposit patented microbe, which can be used by third parties. (Patent Law Art 42.3; Implementation Rules Art. 2-3.)
	Animals	Patentable, if it does not violate public moral	- New Approval Guidelines Development for Animal Patents
	Plants	Only asexually reproducing plant variety is patentable	- Patent Law Art. (Plant Inventions)
	Parts of Human body	Not patentable	- Inventions which violate human dignity is not patentable subject matter

continued …/

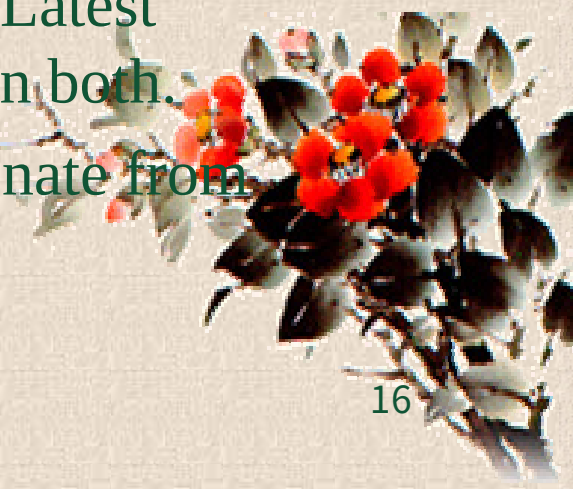
Category	Subject Matter	Patentability	Note
Process (Methods)	Operations, medical treatments	Not patentable for human, patentable for animals	- Human medical treatment of does not embody commercial usefulness (Patent Law Art. 29.1)
	Genetic treatments	Not patentable for human, patentable for animals	
	Diagnostic technique	Not patentable for human, patentable for animals	

Source: KIPO (2004).

The Impact of IPR Regime on Biotechnology

- The pharmaceutical sector
  - General conclusion for Korea: there is initial loss of welfare but there is greater competition and incentive for R&D. But paucity of dynamic, causal analysis of impact of patents on R&D, welfare, competitiveness.
  - La Croix & Kawaura (1996): an event study of stock market values for pharmaceutical firms during 1986-1989 show welfare reduction (excess return of –74%).

- Lee (1992), Song (1993), Lee (1995), Park (1997): examine impact of material patent in the pharmaceutical industry. Shows general increase in R&D, and greater competition in general.
  - But there is market segmentation between domestic and MNCs or JVs. Former market is competitive and focused on the retail market, the latter is concentrated and focused on hospitals. Latest change have made the latter dominant in both.
  - Product patent effect is difficult to alienate from many other factors.



- Experience in other countries:
  - Japan (La Croix and Kawaura 1995): introduced product patents in 1975. Overall welfare gains (esp. by large pharmaceutical companies with R&D programs)
  - Italy (Scherer & Weisburst 1995): legitimization of drug product patents did not induce market shift from generics to innovative drugs. Drug R&D expenditure growth did not accelerate after the patent regime transition, the number and character of new product launches did not change significantly, and Italian firm's increased patenting of drug chemical entities in the US is mainly due to increased propensity to patent.
  - Turkey (Kirim 1985): studied abolition of pharmaceutical patents. Found this had no effect on FDI, licensing, domestic R&D, levels of entry barrier and anti-competitive activity.
  - Number of studies on India (Watal 2000: welfare loss, Lanjouw and Cockburn 2000: ambiguous)

- The impact of changed IPR management rules: decentralised IP-policies for PROs.
  - Seems to have a positive role in increased patenting activity and technology transfer from PROs to the private sector.
  - Long gestation gap between patenting and licencing. Follow-up research and additional patenting activities to draw attention by a private firm wishing to license needs a lot of capital. But current per project R&D funding is too low.
  - Successful commercialisation would need firms with annual sales of at least $10 billion. This requires targeting large multinationals, but the lack of adequate basic research prevents technology that is high-tech enough to allure drug firms of international stature.
  - So, Korean PROs and bio-firms have to specialize in certain stages of R&D phase and then network with global biotechnology players. This prevents Korean firms from fully appropriating the final fruits of the invention, where the highest profits are made. But this may facilitate technology accumulation (eg electronics).

Strategic Implications from the Korean Experience

- Strong government support for the industry
- But in general, the bulk of R&D is being done by private firms: both positive and worrying. Given bio patents are very science based, public R&D should focus much more on basic science. There isn't sufficient stock of technology to be transferred to the private sector (the floundering TTOs …). Much needs to be done still on the supply side.

Strategic Implications from the Korean Experience

- Some policy considerations
  - increasing the level of R&D scale per project.
  - Institutional strengthening: greater resources to the Patent Office, patent subsidy should be provided for renewal and maintenance rather than for filing.
- Need more angels: long gestation gap between first patenting and product development. Need to fund the intermediate period (patent-to-product development).
- Hooking on to the international division of labor in R&D can be one strategy.

Strategic Implications from the Korean Experience

- Raising IP standards too early compared to levels of R&D causes initial welfare loss but may stimulate greater competition and higher incentive to do R&D in the long run.
  - Providing a lot of market information, identifying windows of opportunity may help minimize welfare losses .