University IP management and science-based entrepreneurship in Japan --impact on innovation and questions for America

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Office of Technology Licensing (OTL)
Stanford University

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History of Japan's university-industry technology transfer system

- Long history of Japanese professors collaborating with companies, especially prewar.
 - Some startups: Ajinomoto, TDK, Teijin, Ebara
- In both Japan and USA, the Government owned gov't-funded inventions
 - Gen'l principle: such inventions free for all to use (no exclusive licenses).

History (cont.)

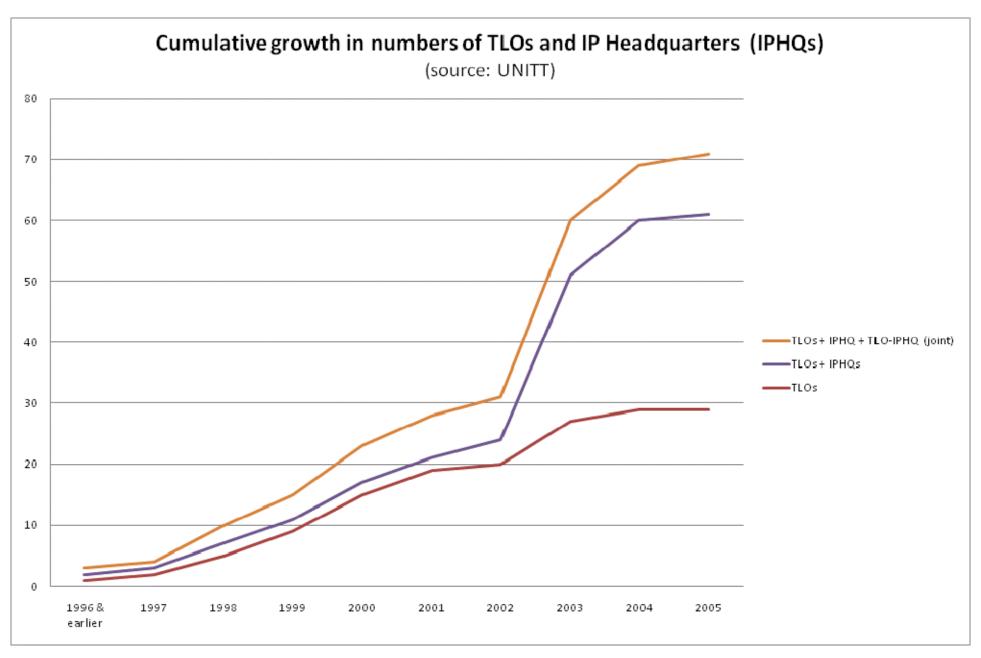
- In 1970s both countries confronted similar needs by industry for exclusive rights to some university discoveries.
- 1978: Japan decided to let inventors own inventions made with donations from companies, while government would retain ownership of inventions made with most other types of funding
 - Not surprisingly, inventors attributed almost all their inventions to donation funding, and
 - Passed these inventions directly to companies that gave donations
- 1980: America let universities own government funded inventions (Bayh Dole patent law amendments)
 - Some universities already had long experience managing non-gov't funded inventions (e.g., Wisconsin & MIT)

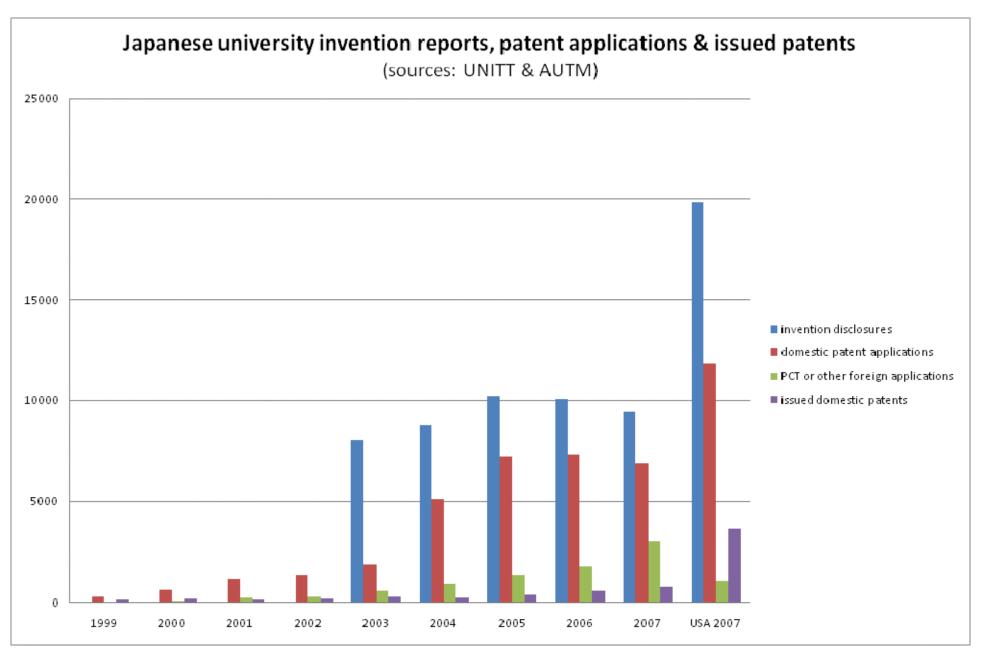
History (con't)

- 1998: Japan began to established government subsidized technology licensing offices (TLOs)
 - Based on favorable assessment of US Bayh Dole experience
 - Mesmerized by revenue streams of a few universities
 - Little understanding of Bayh Dole 's benefit for startups
 - Inventors did not have to transfer inventions to TLOS until 2004
 - Most TLOs established 1998-2004
 - many as independent for-profit entities informally affiliated with their universities
 - Currently ~30
 - but most now absorbed within their universities.
- 1999: Japan version of Bayh-Dole law
 - But not applicable to National Universities till 2004
- 2000:
 ☆Law to Strengthen Industrial Technology ☆
 - Made consulting (and thus startup formation) easier
 - Made sponsored research easier

History (cont.)

- 2003: Ministry of Ed establishes ~25 IP Management
 Offices (IP Headquarters) inside universities
 - Functions overlapped with TLOs
 - Now have absorbed their TLOs
 - Most rely on continuing subsidies from gov't.
- 2004: National university incorporation law
 - Established principle of university IP ownership
 - But overlaid on weak university administrations and tradition of professors transferring discoveries directly to companies.
 - One advantage of Japan system: universities must decide quickly to apply for patents,
 - Reversion of ownership back to inventor, rather than gov't, as is the case with US gov't funded inventions



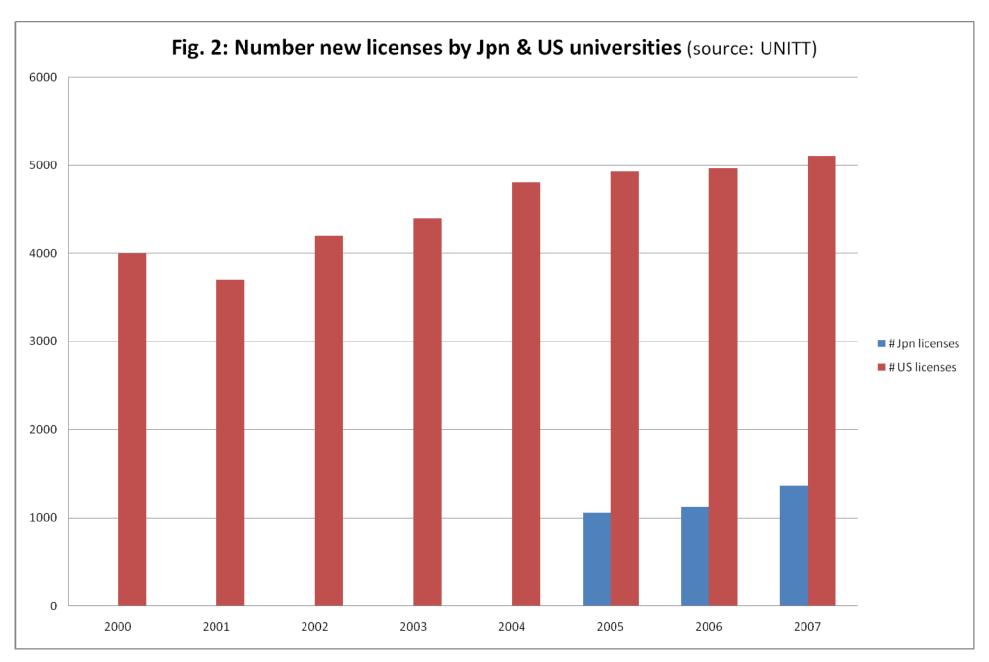


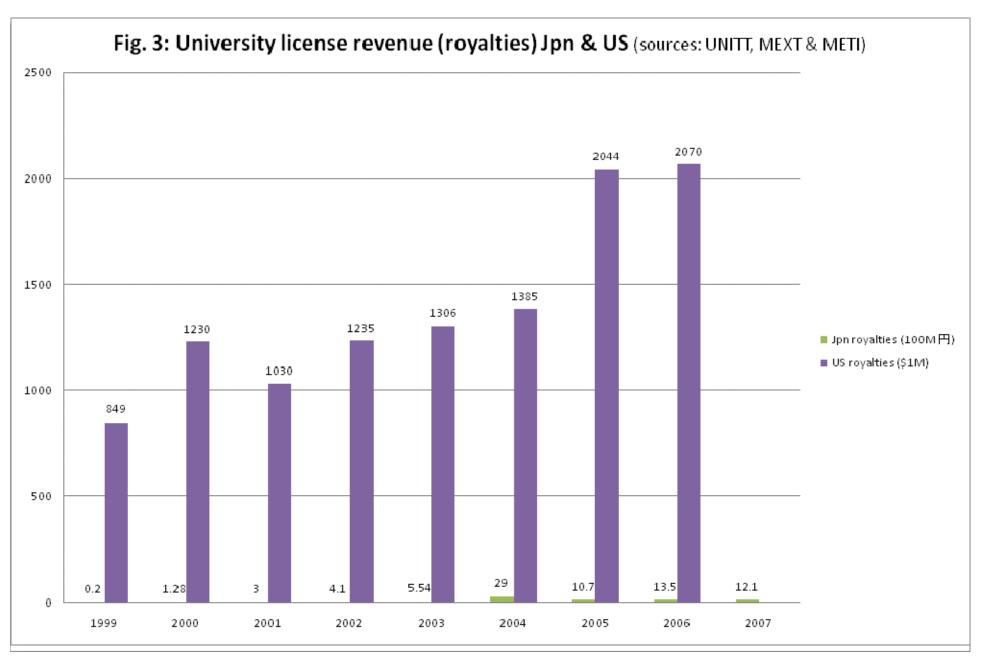
But studies by Kanama & Okuwada (2008) and Takahashi & Carraz (2009) show:

Prior to 2004 and even 1998, many university inventions were being patented by individual faculty or by companies to which they had assigned their inventions:

Here are approx avg # of university inventions patented per year by individuals or by company assignees

	1995-1997	2001-2003	2005	2006
Tohoku U.	230	325	391	155
Hiroshima U.	53	95	148	51
Tsukuba U.	28	62	79	66





Current situation:

Collaborative research is the dominant mechanism of technology transfer and TLOs play a secondary role

- ~50% of all patented university inventions are attributed to joint research
- ~75% of all patented university inventions actually transferred to industry are joint research inventions on which university and company apply jointly for patents

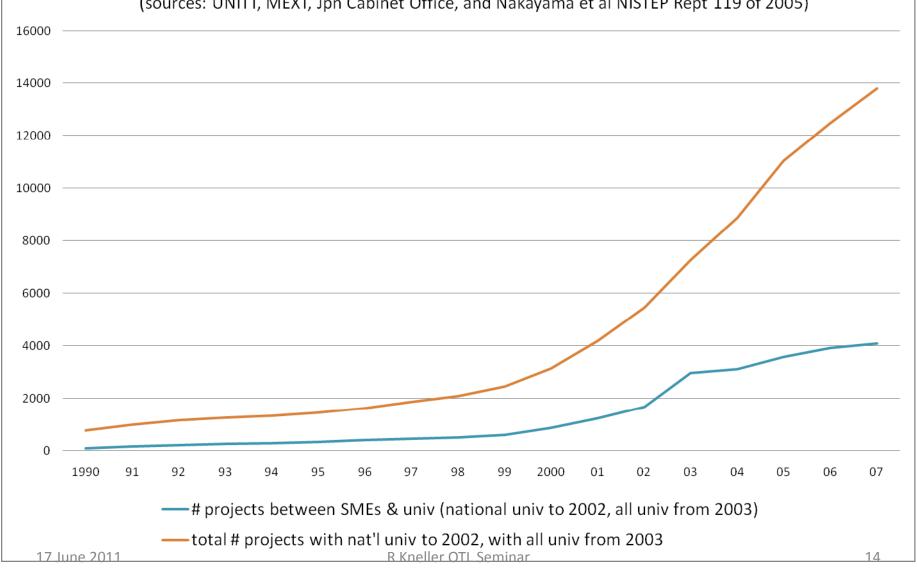
Collaborative research represents a relationship-based system of tech transfer (professor ↔ company)

- Company provides funding, commercialization outlet,
 & sometimes researchers
- Company obtains <u>exclusive</u> control over IP
- TLOs, negotiations over royalties, and negotiations over development obligations, intrude very little
- Companies have <u>considerable leeway to restrict</u>
 publications (see U Tokyo regulations in extra slides at end of file)

Under Japanese Patent Law § 73:
Co-ownership of university patents
gives partner company exclusive
control, with no royalty or
development obligations
(see text of law in extra slides at end of file)

Fig. 5: Growth in collaborative reseach with private companies (SMEs vs total)

(sources: UNITT, MEXT, Jpn Cabinet Office, and Nakayama et al NISTEP Rept 119 of 2005)

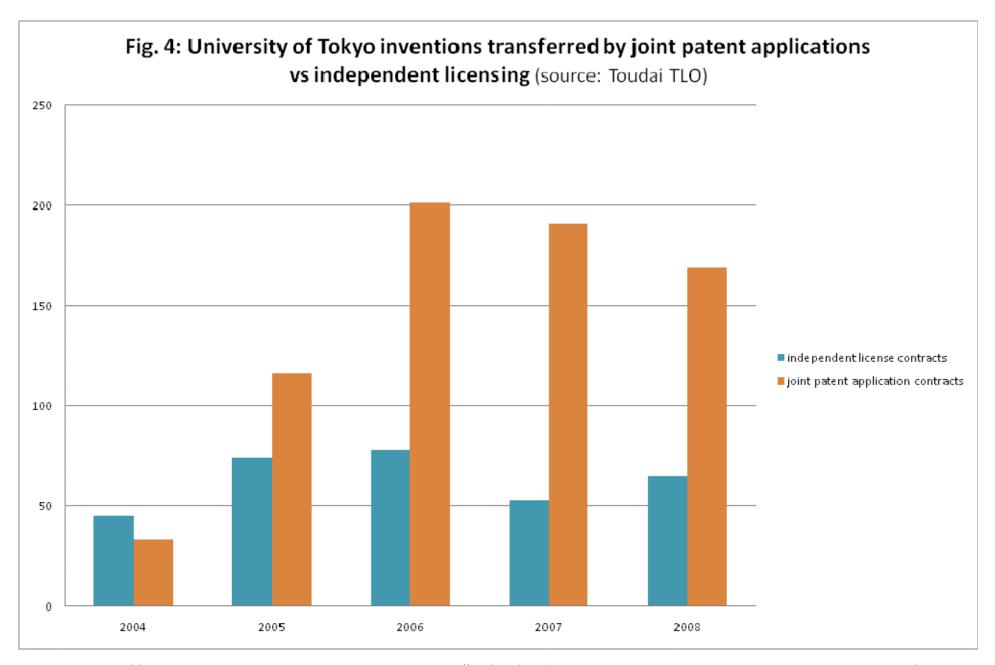


Invention disclosure form 発明等の届出書

Little oversight over who are named as co-inventors by the PI and main industry scientist

国立大学法人東京大学 総長殿

私(達)は以下内容の 職務関連発明である							で定める
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学外共同発明者等の有無		機関名・所属		氏名		発明等の	寄与分



Prevalence of industry co-ownership of university patents (compiled by R Kneller)

	A. Approx. no. US patents issued 2008/4- 2009/3 where one assignee is a university in this country	B. A (i.e. univ patents) per \$1 billion univ R&D spend	C. % of A where at least one co- assignee is a private co.	D. % of C where co- assignee is a foreign co
Canada	92	11	10	50
Germany	38	4	16	33
Japan	125	6	61	0
UK	70	9	6	100
USA	2250	48	3	0

All the Japanese companies in the above sample were large companies

MEXT data also show dominance of large companies among co-applicants of joint patents with major universities

Keio U: > 80% in both 2004 & 2005

Osaka U: ~78% "

U Tokyo: 75% in 2004, 86% in 2005

Footprint of collaborative research

- Small in the life sciences
- Large in other fields
- Moreover, in the life sciences, joint research partners are a mixture of startups, other SMEs and large companies
 - In other fields, partners are overwhelmingly large companies, at least in University of Tokyo

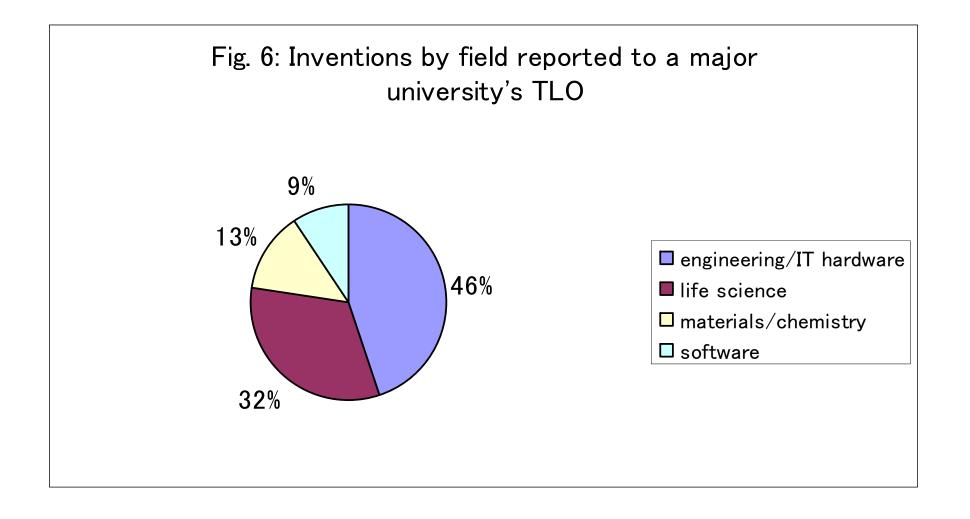


Fig. 7: Life science inventions reported to the TLO

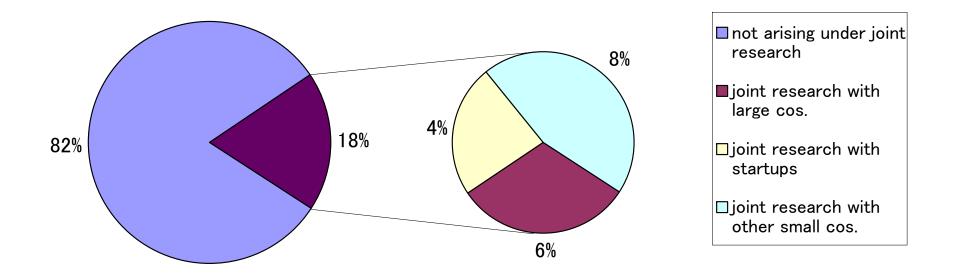
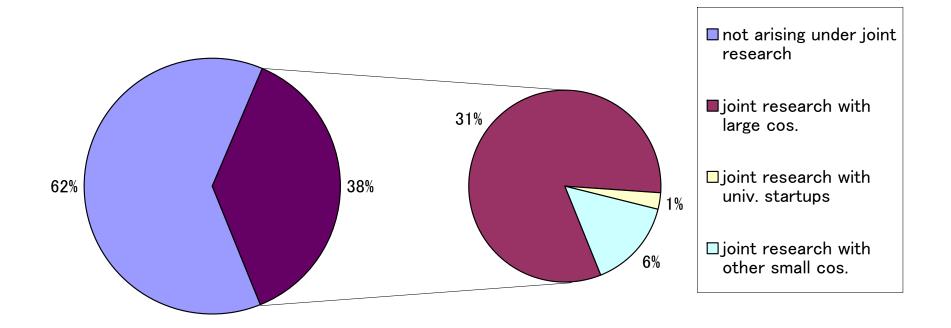


Fig. 8: Non life science inventions reported to the TLO



Benefits of Japan's system of "free pass-through of IP to joint research partner"

- Low cost, direct mechanism of technology transfer
 - often the only practical mechanism
- Probably facilitates relatively close interactions between university & industry researchers.
 - Mutual benefits

Drawbacks:

- Huge leveraging and <u>exclusive appropriation</u> of taxpayer funded discoveries by big companies <u>without</u> <u>development obligations or incentives</u>
 - Joint research < 3% of total national university R&D funding (OECD)
 - Mean joint research funding/yr/project = \$25,000 (\$50,000 in U Tokyo)
 - In US, joint research partner often pays >>\$100,000 + royalties on sales for an exclusive license.
 - In UK, joint research usually pays <u>full economic cost</u> (entire cost <u>including salaries</u>) for an exclusive license. (Lambert Agreements)
- University discoveries "sitting on the shelf" or only partially exploited by big companies is probably a major problem.

Fig. 5: Sources of national university R&D funding (excluding tuition, hospital patient charges, & support for salaries & infrastructure)

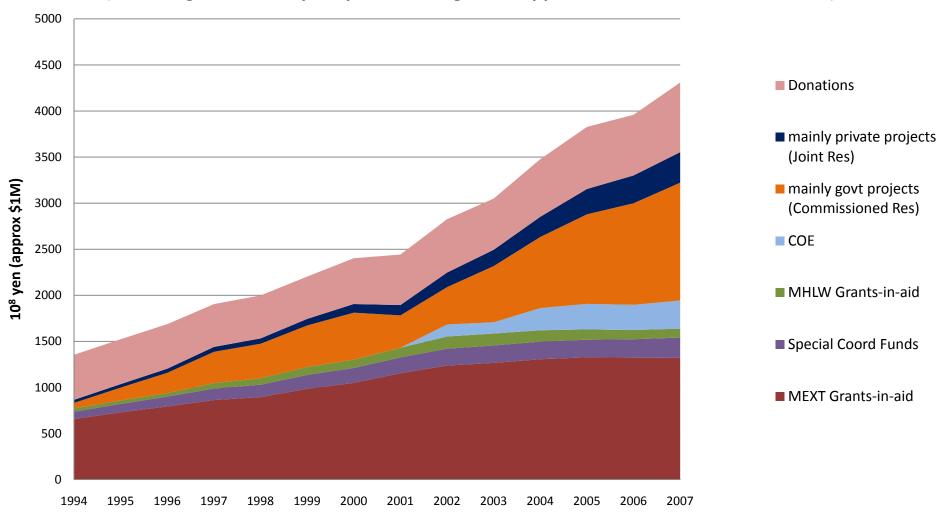


Fig. 6: Sources of University of Tokyo R&D funding (excluding tuition, hospital patient charges, & support for salaries & infrastructure)

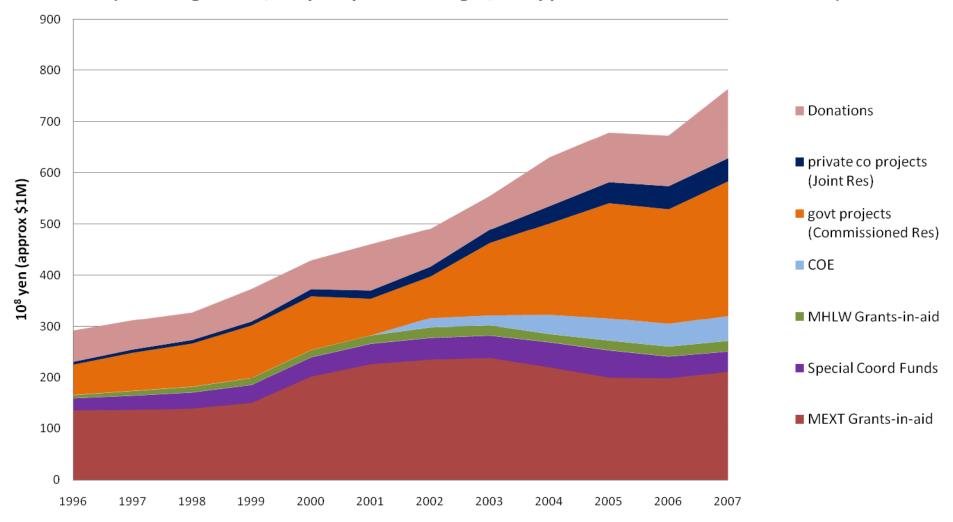


Fig. 7: All sources of national university R&D support, including salaries and infrastructure (but excluding tuition & hospital patient charges)

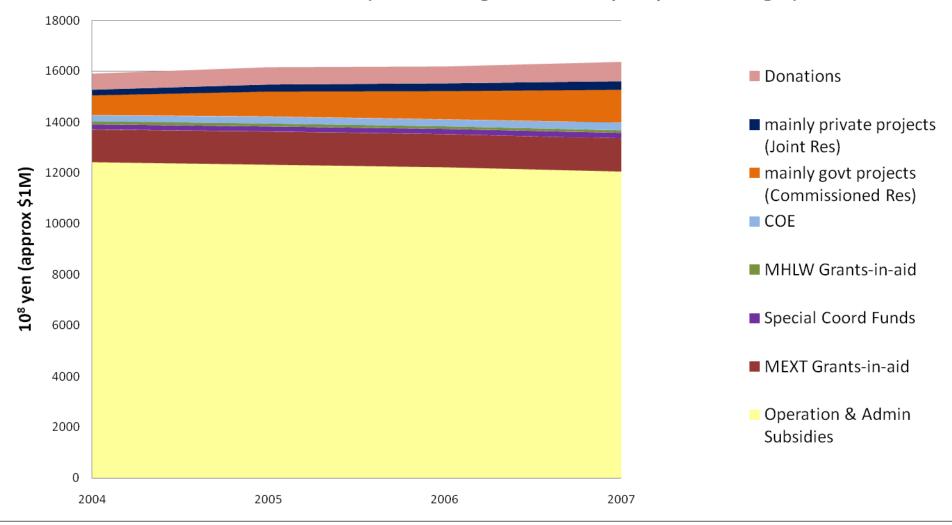
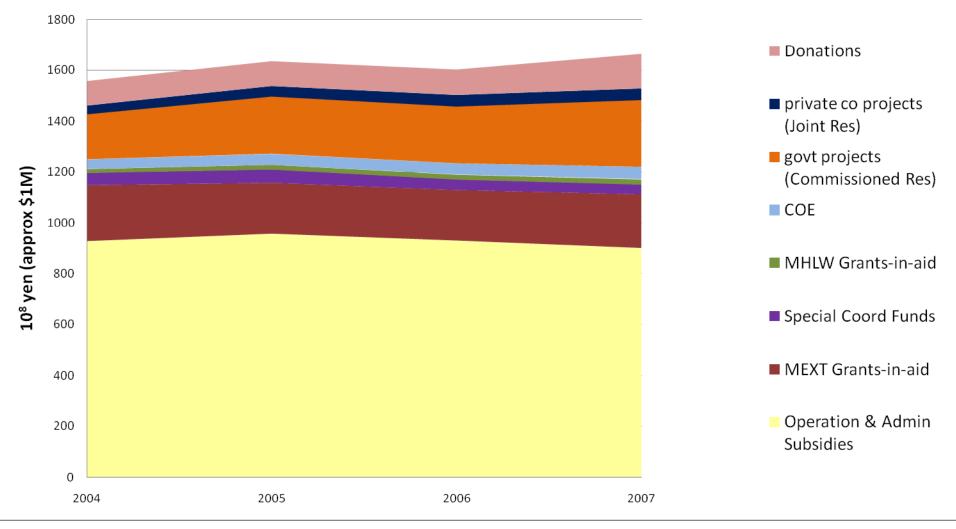


Fig. 8: All sources of University of Tokyo R&D support, including salaries and infrastructure (but excluding tuition & hospital patient charges)



Drawbacks (continued)

- Constrains the scope and incentives for entrepreneurship
 - Pre-empts faculty time and energy
 - IP of would be startups pre-empted by joint research
 - also by gov't initiated consortium research
 - Arising IP usually jointly pooled among all participants
- Reinforces graduate students' perception that collaboration with big companies is the only practical development path.

Drawbacks (continued)

- Limitations on publication freedom
 - See text of U Tokyo regulations in extra slides at end of file
 - Some (many?) joint research findings never published
 - But professors try to avoid impact on student publications.
 - Does ability to keep research secret nudge overall research towards applications orientations?

Is constrained entrepreneurship and favoring of established companies a problem?

- Probably yes
 - Almost certainly in pharmaceuticals and medical devices.

Summary of findings from analysis of 252 new drugs approved by the US FDA 1998-2007

- 215 new molecular entities (NMEs, mostly small molecules)
 - 98 priority approved NMEs (provide substantial benefit over existing drugs)
 - 117 standard approved NMEs
- 37 new therapeutic biologics (NTBs, large protein-based drugs)

Biotech drugs are more innovative than pharma drugs

- 67% of drugs discovered by new companies (biotechs), or universities that transfer new active compounds to biotechs (U>B), have new mechanisms of action or offer substantial benefits over existing drugs,
 - Compared with 36% of drugs discovered by established pharmaceutical companies
- Together B and U>B discovered drugs account for about half of all innovative drugs.
 - But only 20% of follow-on drugs
- Biotechs play a significant role in drug discovery only in the US, Canada and Australia

Biotechs also important for later stages of drug development

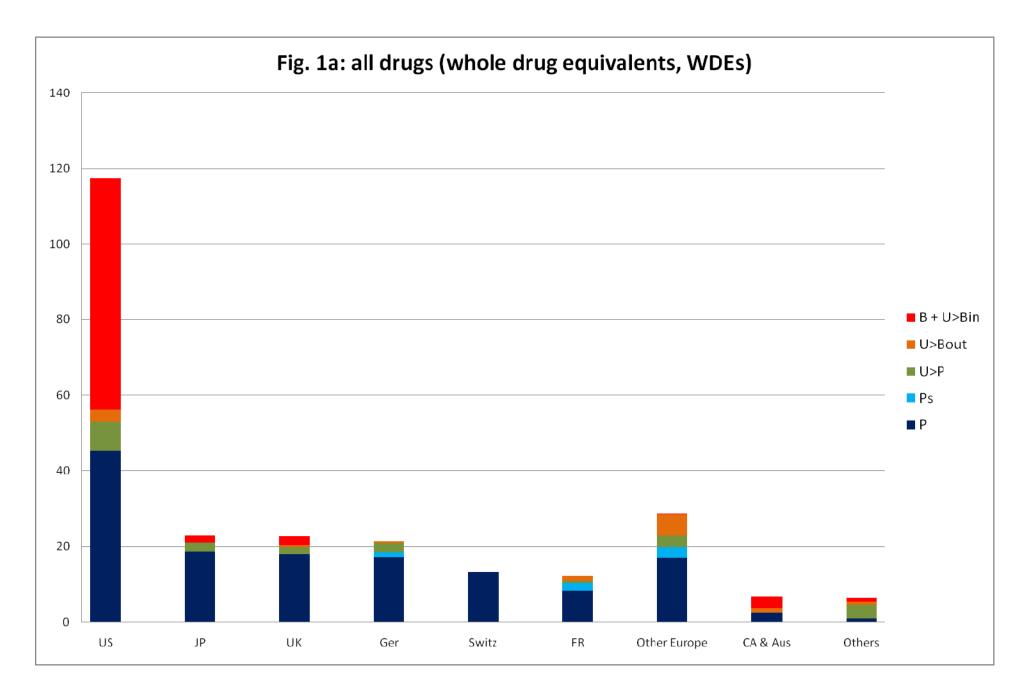
- At FDA application (NDA) stage, and
- During first year of marketing in the US.
- Genentech, Amgen, Genzyme and Biogen (the oldest and largest biotechs) are important but do <u>not</u> dominate discovery or development by biotechs.

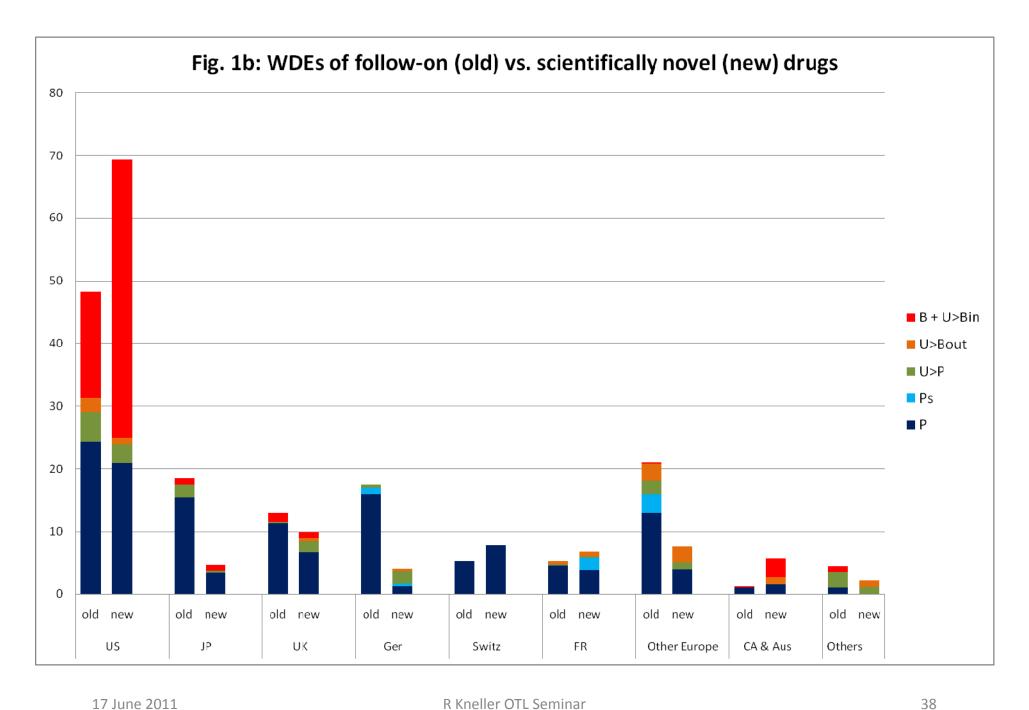
Biotechs especially important for early development of scientifically novel university drugs

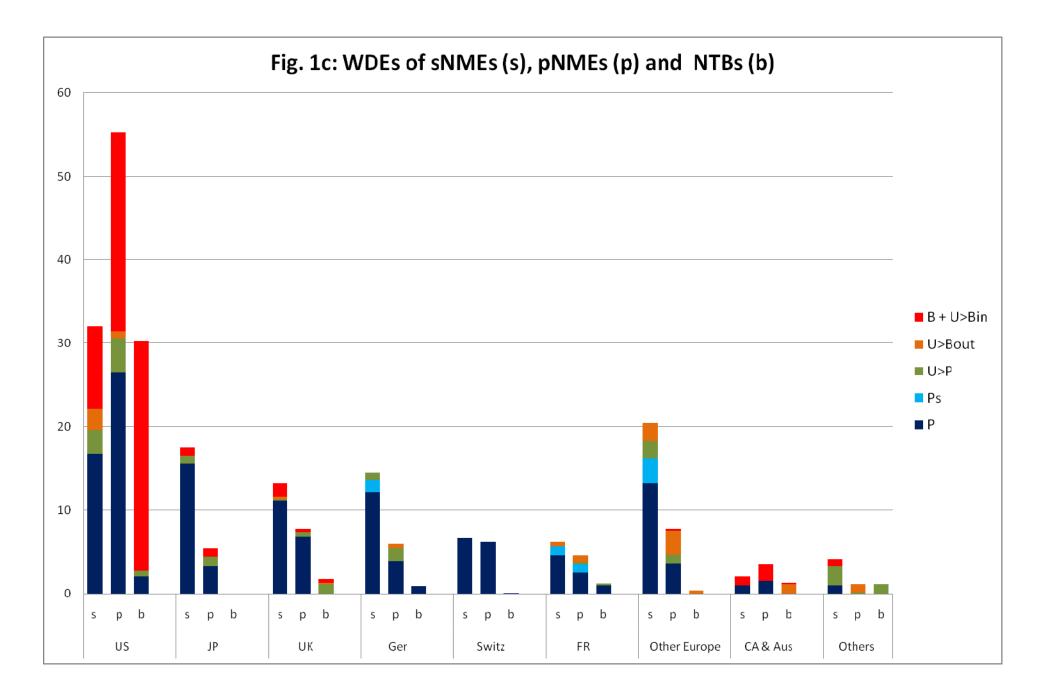
- U>B drugs are more innovative than U>P drugs.
- Early development by major multinational pharmas of scientifically novel university drugs is very rare.
 - Big pharmas are averse towards developing novel university therapeutic discoveries.

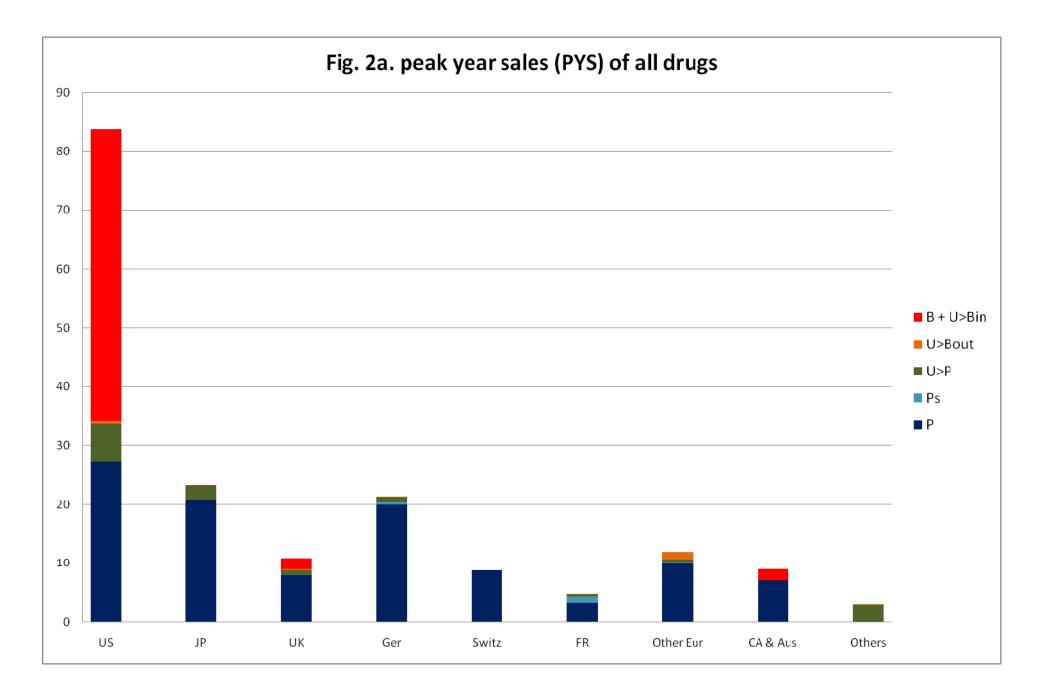
Marketed drugs arising from collaborations between Japanese or Continental European universities and established companies

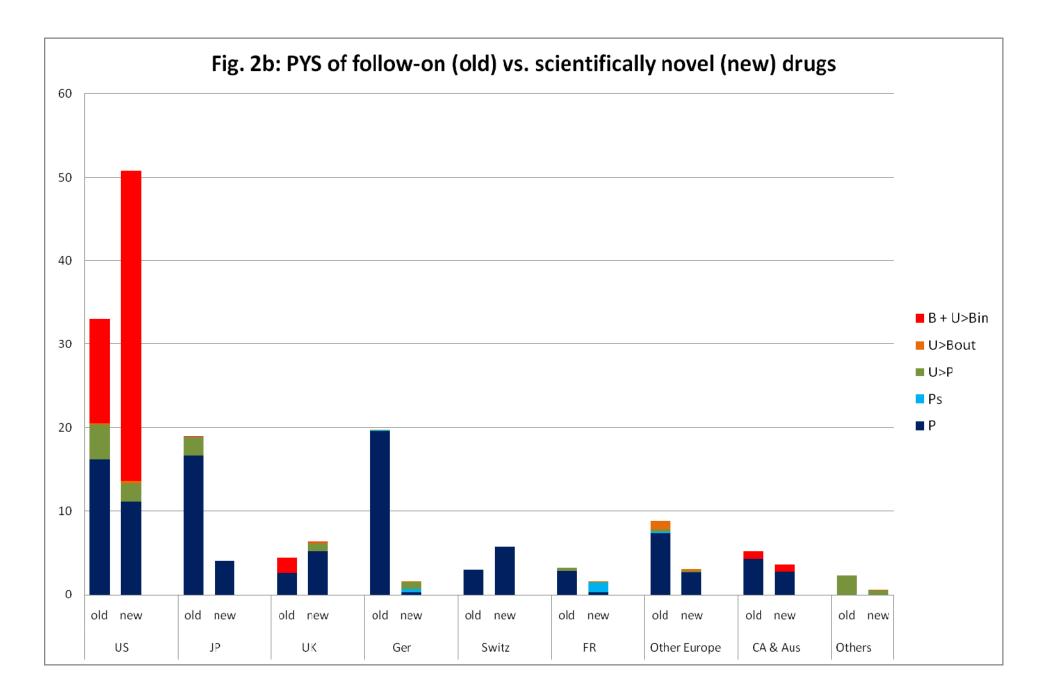
- No more innovative than average for these countries
- History suggests few innovative drugs will reach market from such joint research collaborations.

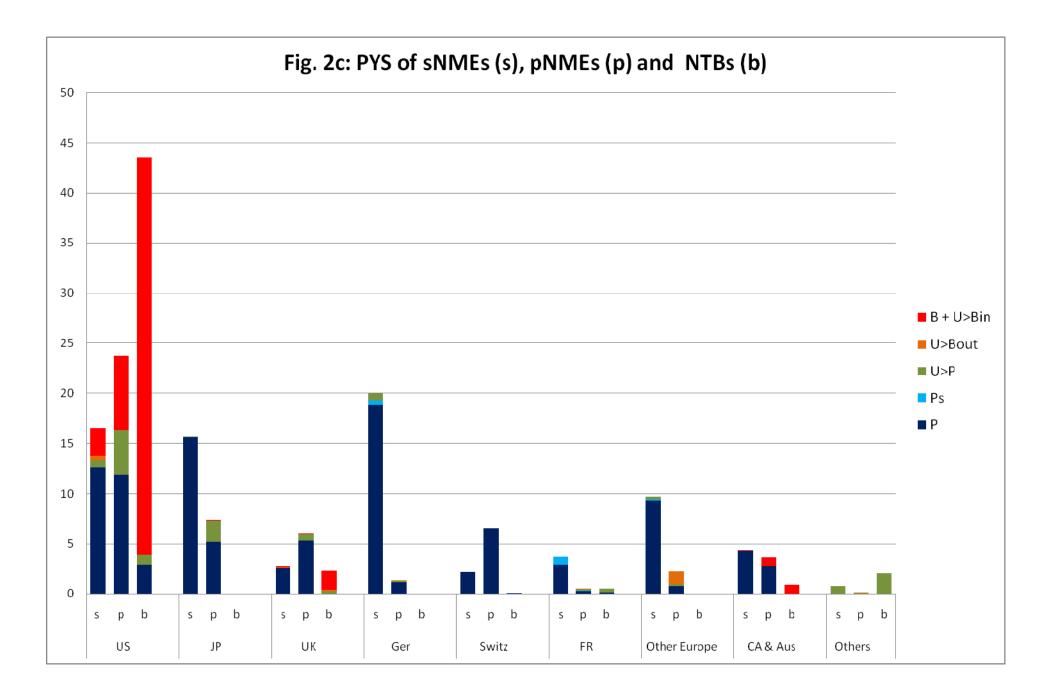


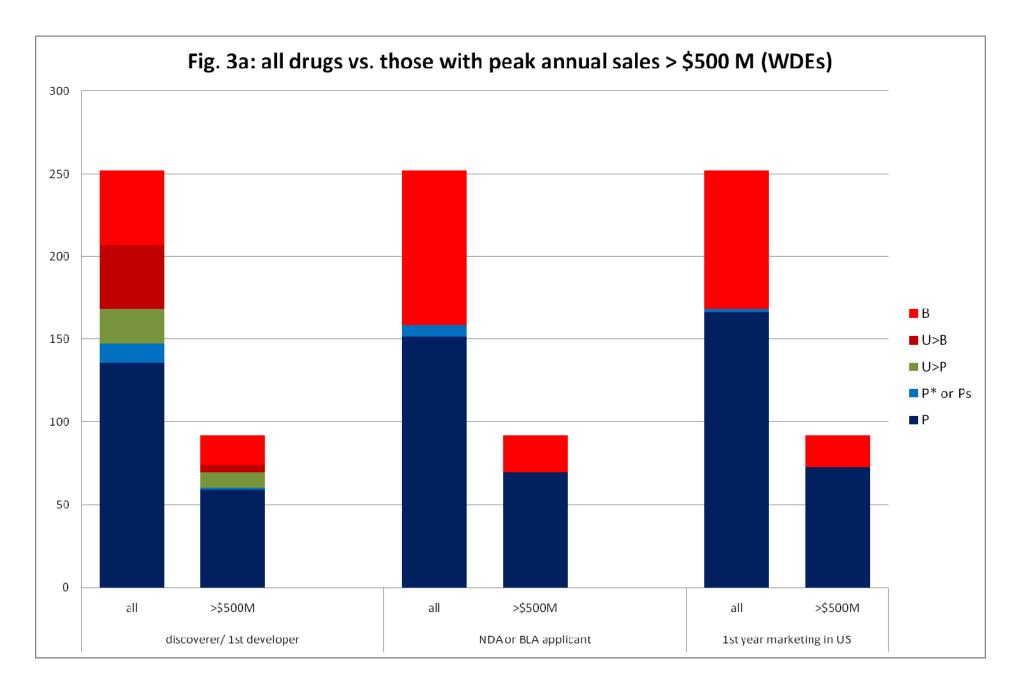


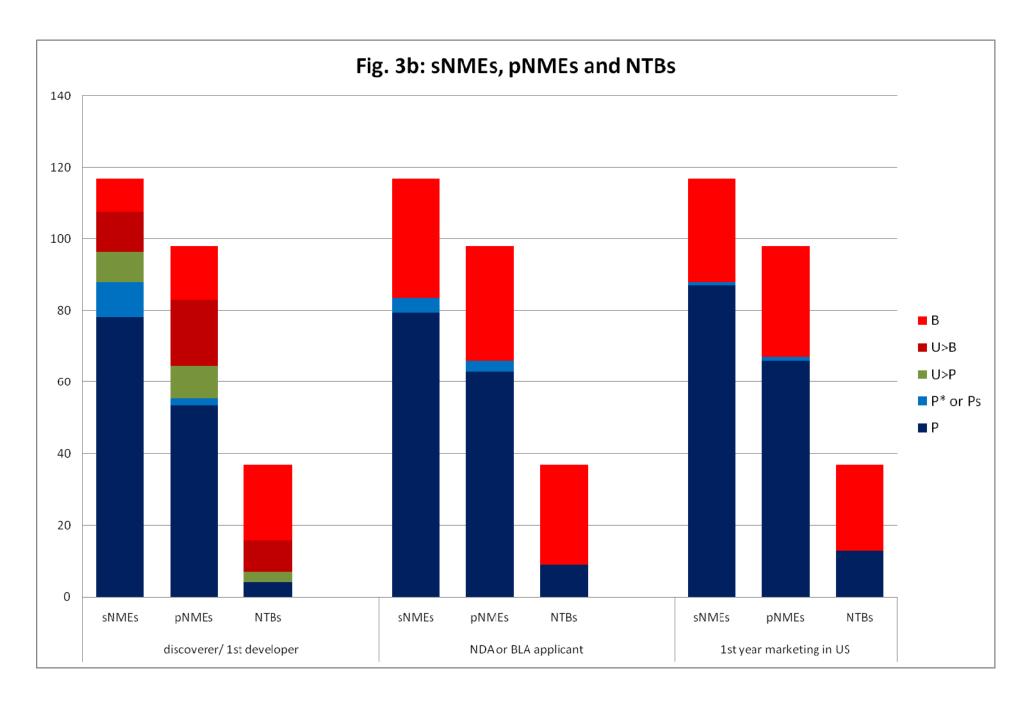












Key points

Ecosystem also important

(NIH funding, large numbers of well trained/mobile researchers, capital availability) Nevertheless:

- New companies are vital for pharmaceutical innovation and public health.
 - Especially with respect to university-discovered compounds, biologics, and orphan drugs.
- Little evidence large companies can substitute for new companies with respect to innovative drugs.
- Why should other technical fields be different?
 - such as medical devices, bio materials, regenerative medicine, material science, etc.

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Recall: Under Japanese patent law, co-ownership of university patents gives partner companies exclusive control, with no royalty or development obligations

- <u>But</u> Japan not unique (USA is <u>the</u> exception)
- Nevertheless, Japanese co-ownership rates much higher than Germany, UK or Canada

Why is Japan different from UK, Canada & Germany?

- Traditional practice prior to 2004
- Strength of professor-company relationship
- Weakness of university administrations/TLOs
 - Universities don't act as independent entrepreneurial entities.
- No entrepreneurial alternative.
- (?) Shared conviction "This is good for Japanese industry."
- (?) Japanese university research more oriented towards needs of existing companies.

10 reasons Japanese S&T startups are weak

($\stackrel{>}{\simeq}$ => relatively amenable to change by gov't policy)

- 1. Insufficient personnel & mobility (hesitancy to work in startups and to change jobs)
 - Aging population

 - Social and family prejudices
 - Barriers to 2-career families (risk if sole breadwinner has an unstable job)
 - Company pension systems (pensions non-transferable for pre-2000 h;
 - Emphasis on generalists over specialists in in-house company training & promotion
 - and BS/MS over PhDs in new hires
 - → The Unfair Competitive Practices Law
 - Psychological discouragement due to narrow gate a success
 - "If I don't get into the University of Tokyo (v pility)'s low and I can't amount to much."
- 2. Difficulty communicating in English () international alliances & information flow)
- 3. ☆ Insufficient access to capital
- 4. Autarkic (self-reliant 有首位 innovation strategy in large companies
- 5. \Leftrightarrow Pre-emption o ersity researchers' discoveries & time by large companies
- 6. Entrepreneurs prefer service or value-chain companies to disruptive gazelles
- 7. System of gov't funding for univ. R&D and patronage-based univ. recruitment & promotion discourage ground breaking research
 - Scientific peer review is done poorly
 - Large proportion of funding distributed through "eminent professors"
- 8. $\stackrel{\star}{\sim}$ Concentration of resources in a few universities creates anti-entrepreneurial academic caste system
- 9. Culturab& institutional barriers to horizontab, intermorganizational information sharing 49
- 10. Closed distribution systems (e.g., influence of keiretsu on market access)

Rays of hope with respect to Japanese biotechs

- In 2004, about 135 Japanese biotechs were developing new medical therapies about 5 had new drugs (or other therapies) on the market or in clinical trials.
- In 2009, about 115 therapeutic oriented biotechs had ~45 new Japan-discovered therapies on the market or in clinical trials.
- Probably better than France or Italy
 - maybe even Germany.

But outside of biomedicine, Japanese university startups on a growth trajectory are rare

Exceptions that prove the rule

- U Tokyo: ASM, Morpho
- Tohoku U: Ideal Star, MEMS Core
- Keio U: SIM-Drive & Soundpower
- Nagoya Institute of Technology: DDS
- Tsukuba University: Cyberdyne
- Saga University: Xenesys
- There are others But are there many?

10 reasons Japanese S&T startups are weak

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 - − ☆ Limited immigration
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 - "If I don't get into the University of Tokyo, my ability is low and I can't amount to much."
- 2. Difficulty communicating in English (barrier to international alliances & information flow)
- 3. \Rightarrow Insufficient access to capital
- 4. Autarkic (self-reliant 自前主義) innovation strategy in large companies
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Should Japan even try to change?

Is an American (Silicon Valley) startup-driven national innovation model sustainable?

- Scarcity/high cost of capital for early stage startups
- IPO window closed
- Reverse brain drain
- Risk averse regulatory agencies
- Basic research funding stagnation/cutbacks
- Difficulty recreating Silicon Valley in other parts of America, much less other countries.

Should Japan change (con't)?

- Germany relies mainly on established companies and currently is doing well
- Japanese component manufacturers remain nearly unassailable (?? considering how non-Japanese automakers have resourced components from ex Japan sources)
- Intravation/corporate spinoffs <u>occasionally</u> work
 - Canon: semiconductor manufacturing steppers
 - Fujitsu/Fanuc: computer controlled robotics
 - Beckton Dickinson: cell flow cytometers

Nevertheless

 Probably dangerous for any developed country to rely solely on established companies for innovation.

What changes might be help?

- Greater use of due diligence clauses and development obligations in university licenses
 - No company should have free, exclusive control of a university invention, in perpetuity, unless it goes forward with development.
- Increase interdisciplinary communication in universities
 - BioDesign Fellowships

Changes that might be practical (con't)

- De-emphasize government co-funded large university-industry consortium projects, where IP is controlled by the large companies in the consortium
 - Let companies compete for access to large government funded projects
- METI's new \$10 billion Industrial Innovation
 Fund (INCJ) should invest some of its capital in
 the Japanese VC funds that have a track
 record of early stage investments.

Facilitate the development of Japanese discoveries by overseas startups

Or by Japanese startups that establish operations overseas.

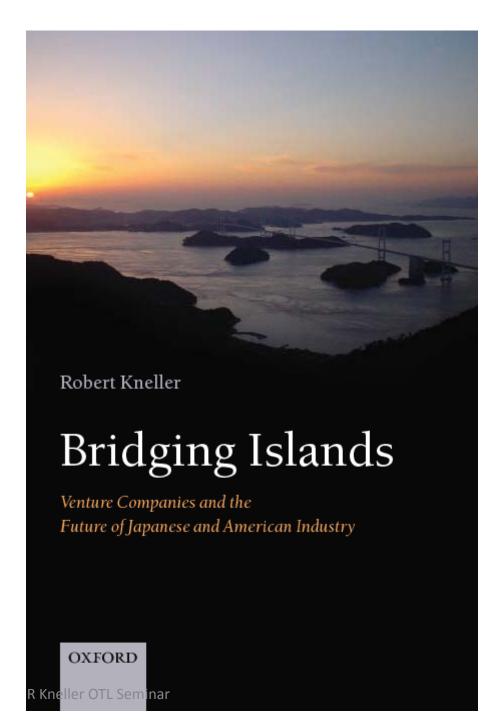
Lessons/questions for collaborative research and IP management in US Universities

See handout

References

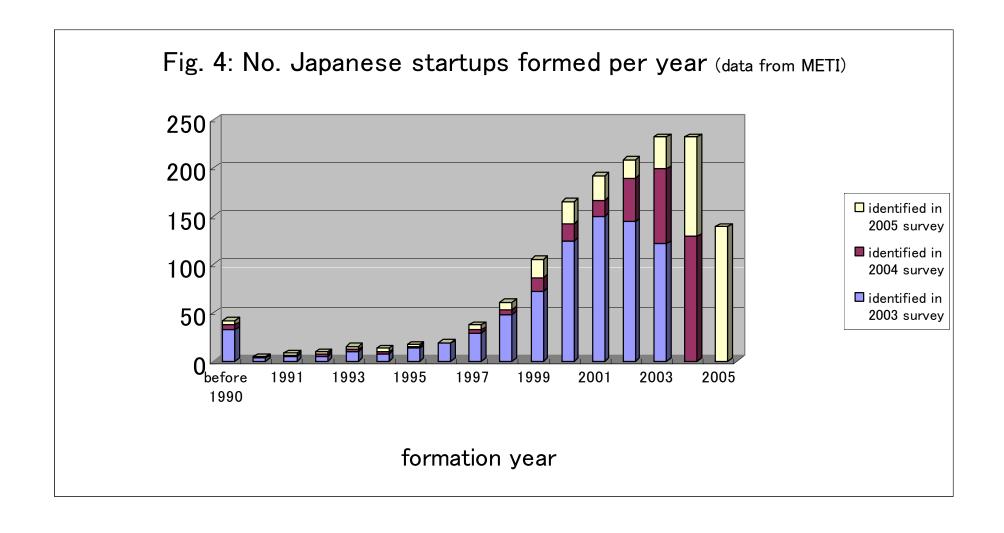
- *Kneller, Robert. 2010. Importance of new companies for drug discovery: origins of a decade of new drugs. Nature Reviews Drug Discovery 9 (November) 867-882.
- *Kneller RW 2010, 'The changing governance of Japanese public science', In R. Whitley, J. Gläser & L. Engwall (eds), *Reconfiguring Knowledge Production: Changing Authority Relations in the Sciences and Their Consequences for Intellectual Innovation,* Oxford: Oxford U. Press (in press, publication scheduled for July).
- **Kneller, RW. 2007. *Bridging Islands: Venture Companies and the Future of Japanese and American Industry*. Oxford U. Press.
- *available via <u>www.kneller.asia</u>
- ** chapter on industry-university cooperation available via www.kneller.asia

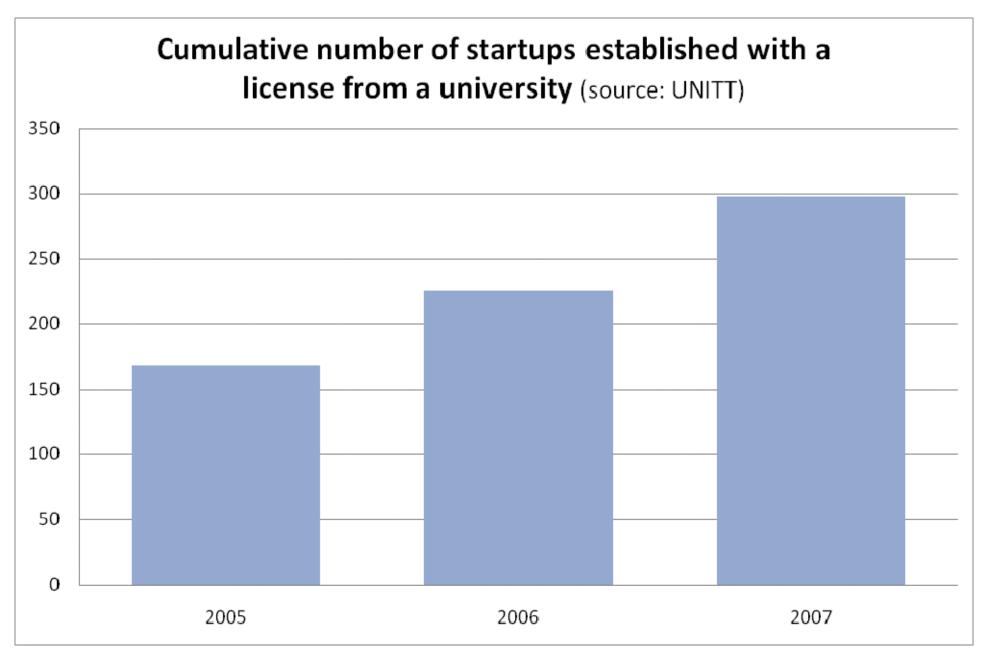
Thank you for your consideration and attention!



Extra slides

- background data
- information on special topics
 - Japanese patent law
 - University regulations regarding sponsor's rights
 - University regulations regarding sponsor's ability to restrict publication
 - Concentration of R&D resources in a few universities





Japan Patent Law Article 73 (Jointly owned patent rights)

- (1) Where a patent right is jointly owned, no joint owner may assign or establish a right of pledge on the said joint owner's own share without the consent of all the other joint owners.
- (2) Where a patent right is jointly owned, unless otherwise agreed upon by contract, each of the joint owners of the patent right may work the patented invention without the consent of the other joint owners.
- (3) Where a patent right is jointly owned, no joint owner may grant an exclusive license or non-exclusive license with regard to the patent right to any third party without the consent of all the other joint owners.

Official Japanese text of Patent Law § 73

特許法(共有に係る特許権)

- 第73条 特許権が共有に係るときは、各共有者は、他の共有者の同意を得なければ、その持分を譲渡し、又はその持分を目的として質権を設定することができない。
- 2 特許権が共有に係るときは、各共有者は、契約で別段の 定をした場合を除き、他の共有者の同意を得ないでその特 許発明の実施をすることができる。
- 3 特許権が共有に係るときは、各共有者は、他の共有者の同意を得なければ、その特許権について専用実施権を設定し、又は他人に通常実施権を許諾することができない。

University of Tokyo's model joint research contract showing attempt to get around joint owner's exclusive control over patents bestowed by Patent Law § 73 東京大学の共同研究契約書(第三者に対する実施の許諾)第21条

3. 乙が本件知的財産権に関して非独占実施を希望する場合、甲は、甲知的財産権について自由に第三者に対し実施の許諾をすることができ、又、共有知的財産権については当該共有知的財産権を出願等したときから、乙の書面による同意を得て第三者に対し実施の許諾をすることができるものとする。なお、正当な理由なく、かかる同意を拒んではならないものとする。

University of Tokyo's model joint research contract showing broad latitude to designate joint research results as trade secrets (know how) and for the sponsor to prevent their publication:

東京大学の共同研究契約書(ノウハウの特定)第25条

- 1. 甲及び乙は、本共同研究の結果、ノウハウに該当するものが生 じた場合は、協議の上、速やかに書面にて特定するものとする。
- 2. 前項に従って特定されたノウハウは、相手方の書面による承諾な 〈第三者に開示、漏洩してはならない。ノウハウを秘匿すべき期間 は、ノウハウを特定した日から表記契約項目表12.の期間終了日 までとする。ただし、ノウハウの特定に当たり、甲乙協議の上、表 記契約項目表12.の期間とは異なる期間を定めることができるもの とする。甲及び乙は、ノウハウの特定後において必要があるとき は、協議の上、秘匿すべき期間を延長し、又は短縮することができ る。

University of Tokyo's model joint research contract showing broad latitude of sponsor to restrict publication of joint research results until at least one year after end of project:

東京大学の共同研究契約書 (研究成果の公表) 第30条

- 3. 前項に基づき通知を受けた相手方は、通知された公表内容に、自らの将来期待される利益を害するおそれがあるものが含まれると判断されるときは、当該通知受理後15日以内に公表内容の修正を書面にて公表希望当事者に通知するものとし、公表希望当事者は、相手方と十分な協議をしなくてはならない。公表希望当事者は、研究成果の公表により相手方から将来期待される利益を害するおそれがあるとして、本項に従い通知を受けた部分については、相手方の同意なく、公表してはならない。ただし、相手方は、正当な理由なく、かかる同意を拒んではならない。
- 4. 本共同研究終了日の翌日から起算して1年間を経過した後は、公表希望当事者は、第2項に定める相手方に対する通知を行うことなく、研究成果の公表を行うことができるものとする。ただし、甲乙協議の上、この期間を延長し、又は短縮することができるものとする。

Part 6: Concentration of resources in a few universities

- Negative implications for science
- Perpetuation (maybe strengthening) of an academic caste system
 - Probably with anti-entrepreneurial effects

• Reference:

Kneller RW 2010, 'The changing governance of Japanese public science', In R. Whitley, J. Gläser & L. Engvall (eds), Reconfiguring Knowledge Production: Changing Authority Relations in the Sciences and Their Consequences for Intellectual Innovation, Oxford: Oxford U. Press (in press, publication scheduled for July).

U of Tokyo, Kyoto U, Osaka U & Tohoku U, receive the largest share of all types of competitive research funds:

- 1. 44% of all MEXT Grants-in-Aid (GIA 科研費) to National University Corporations (NUs, 国立大学法人) 2006-2008, 35% of GIA to all Japanese universities.
 - U Tokyo received 16% of 2007 GIA to NUs.
- 2. 47% of Commissioned Research (受託研究費) for NUs 2007-08.
- 3. 42% of 2008 donations (寄付金) to NUs
- 4. 43% of Joint Research (共同研究費) for NUs 2008
- 5. 51% of 2007-08 MEXT Global COE funding for all Jpn U.
- 6. 41 % of 2007 MEXT Special Coordination Funds (振興調整費) for NUs

But only 21% of General Operation and Administration Subsidies (O&A subsidies, 運営交付金).

Funding concentration is increasing.

- Competitive research funding (especially commissioned and joint research) has been increasing.
 - Now over 25% of total university budgets
- While general subsidies are being cut
 - source of salaries and most infrastructure
 - More evenly distributed than competitive funds

In contrast in 2000-01, Oxford, Cambridge, Imperial College, and U. College London received:

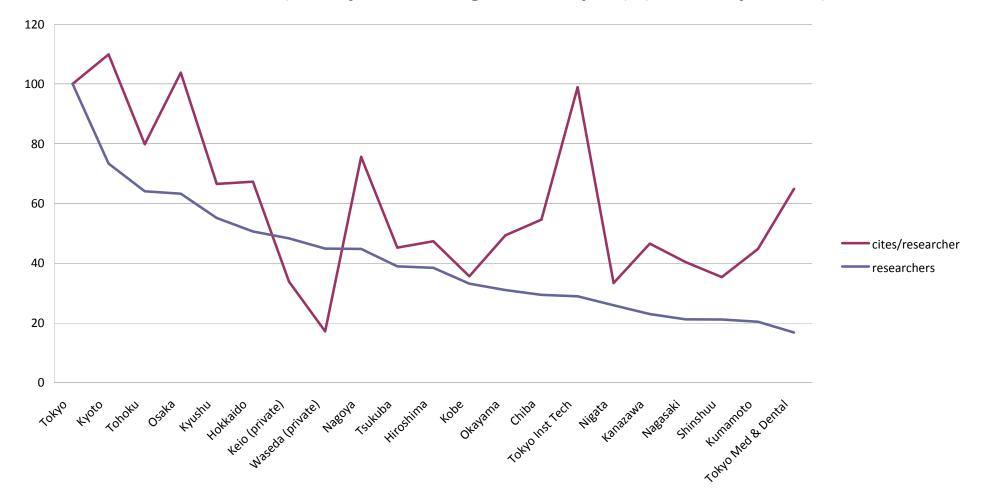
- 25% of UK research grants and contracts (equivalent to competitive research funding)
- 9% of Funding Council grants (equivalent to O&A subsidies).
- In other words, funding concentration in Japan is about <u>twice</u> that in the UK.

Citation analysis (引用の分析) provides insights into the impact of funding concentration on science

Citations per university researcher (Fig. 1)

- The universities with more researchers (i.e., the better funded universities) tend to have more citations per researcher.
- So far, no suggestion that concentrating resources in a few universities is harmful.

Fig. 1: 2006-07 cites to 2003-07 pubs (apportioned by univ) / full time 2005-06 researcher (faculty + doctoral graduates/year) (Univ Tokyo = 100)

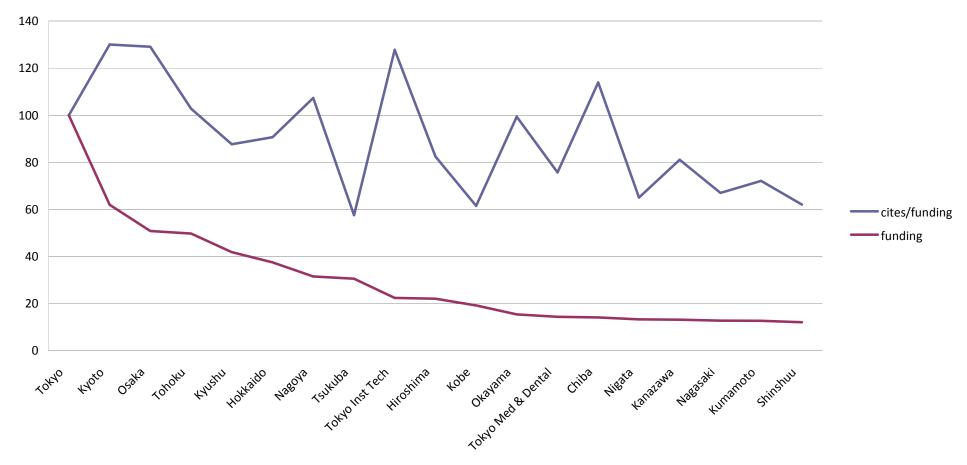


Citations per total funding (Fig. 2)

(general subsidies + competitive research funding + donations)

- Inconsistent downward trend from better funded to less well funded universities
 - Kyoto, Osaka, Nagoya, Tokyo Inst. of Tech. and Chiba Universities are better than U. of Tokyo.
- Concentration of funding does not seem harmful, but neither is it clearly beneficial
- Competitive research funding is modifying the strong positive association between numbers of researchers (or general subsidies alone) and citations

Fig. 2: 2006-07 cites to 2003-07 pubs (apportioned by univ) / \$1M total 2004-05 funding (excluding tuition payments and patient hospital charges) (Univ Tokyo=100, national universities only)

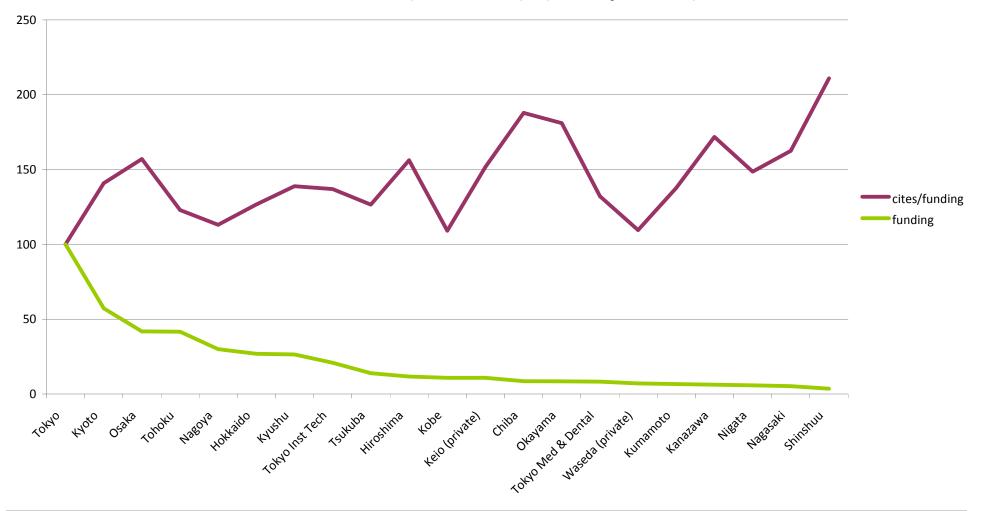


Citations per unit of grants-in-aid (科研費) (Fig. 3)

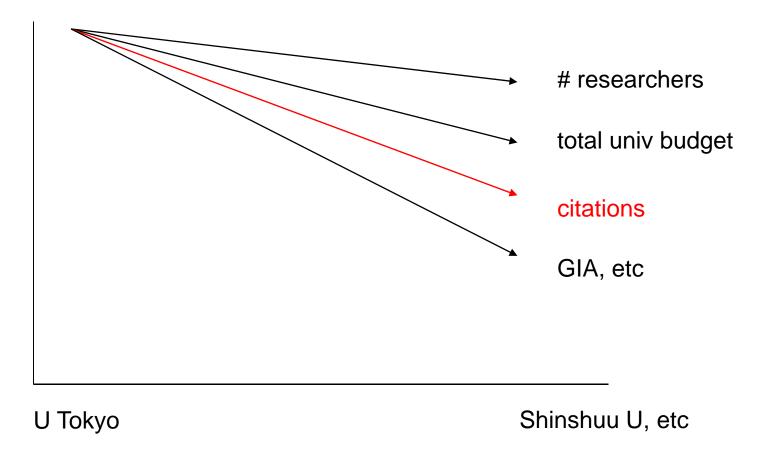
(Results are similar per unit of <u>any major type of</u> <u>competitive research funding</u>, e.g. commissioned research or Centers of Excellence)

- Clear inverse relationship: citations per unit of GIA (or any type of competitive research funding) are higher for universities that receive fewer such funds.
- This suggests some capable researchers in smaller universities are starved of such funding
 - Japanese researchers would receive more citations overall if competitive research funding were allocated more evenly.

Fig. 3: 2006-07 cites to 2002-07 pubs (apportioned by univ) / \$1M MEXT Grants-in-aid (2001-2006) (U Tokyo = 100)



Interpretation requires caution. These graphs simply mean the relative trends moving from large to small universities are as follows:



Nevertheless, these graphs suggest the following hypothesis:

- In the smaller universities, faculty tend to be older and to spend more time on teaching than research, thus Fig. 1.
- Competitive research funding (mainly for equipment, data access and networking (e.g. travel), but <u>not salaries</u>) modifies the above (Fig. 2), suggesting <u>the advantage of the best</u> <u>universities is due more to brains than economies of scale</u> <u>from more equipment, data, etc.</u>
- Fig. 3 tends to confirm the modifying effect on the Fig. 1
 phenomenon of giving the talented, energetic researchers in
 smaller universities access to equipment, data and networking
 opportunities. It also suggests:
 - diminishing returns from additional concentration of equipment, data access and networking opportunities in the large universities, and
 - peer review committees often overlook good researchers in lesser known universities.

Even if increasing economies of scale no longer exist in the largest universities with respect to equipment and networking opportunities,

 might they nevertheless exist with respect to people/brains?

In other words, do more talented researchers provide the elite universities with an <u>additive</u> or <u>multiplicative</u> advantage?

- Anecdotally, little evidence for a multiplicative effect.
 - Japanese universities have been described as "Worlds of closed doors with limited opportunities for cross-communication between labs."
- Also some statistical evidence against a multiplicative effect:
 - The inverse correlation between COE funding (much of which provides stipends for young, non-permanent researchers) and citations is at least as strong as the inverse correlation between GIA funding and citations.
 - But maybe there has not been enough time for COE funding to produce cited publications.

If the advantage is not multiplicative,
Japan would not be hurt by
distributing competitive funding and
talent more evenly among universities.

In fact, a more equal distribution would likely help Japanese science and entrepreneurship

- Institutional competition would likely increase, leading to
 - more varied & novel approaches
 - more opportunities for young researchers to pursue their own research plans
- Likely reduction of the psychological perception that the paths to successful careers are few, the gateways to success narrow, and university admissions exams are infallible predictors and of long term ability.
- Greater empowerment of (and scope for) individual initiative and creativity.