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Publicly Funded Patents & Technology Transfer: A Review of the Indian "Bayh Dole" Bill – Lessons for India from the U.S. Experience

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Overview

- Limitations of the Analysis – Ownership of Inventions, Not Expressions, Data,Trademarks; Not address procurement regulations and processes of federal agencies; Not address private domestic and foreign direct investment in (mainly university) R&D
- Major Benefits and Costs of the U.S. Bayh-Dole Act Experience (context of both public and private R&D)
- U.S. "Policy Levers" for Consideration
- Recent Progressive U.S. Licensing Policies
- Draft Indian Act "Policy Levers"
- Tentative Suggestions for Consideration for the Indian Experience (considering innovation models)
- Conclusions – clearer rules about use of policy levers

Major Benefits and Costs

- Benefit – increased commercialization of government funded research outputs
- Benefit – provided incentives to scientists (best identifiers) to commercialize their research
- Cost – changed norms of science and collaboration (publication; material transfers; confidentiality/COI)
- Cost – changed attitudes toward research & its markets
- Cost – imposed limitations on access for sequential research and product development (broad patents)
- Cost – created downstream effects on competition & product development, and increased prices
- Assumption of mass market, seller-based innovation v. non-uniform TT: public domain or collective management

U.S. Bayh-Dole "Policy Levers"

- Who can take title to what kinds of funded innovation and when (e.g., univ./small business; "exceptional circumstances" refusal to permit patenting)
- What obligations (e.g., reporting and transparency) and conditions (e.g., licensing terms) are imposed on owners
- What rights does the government retain (e.g. government license and scope; additional licensing authority) and when can it exercise them (march-in; compulsory license)
- What associated regulation of products (pre-marketing approvals) and use may the government employ to assure access (e.g., licensing terms or direct price regulation)
- What alternatives exist to private title and exclusive licensing (e.g., PD/subsidies; exclusive marketing)

Recent Progressive U.S. Licensing/Funding Policies

- University "Nine-Points" Policy (2007)
  - Goal of maximizing social welfare, not profit
  - Change "mission definition" of university technology transfer offices (and small businesses)
  - Key points: (1) reserve rights for universities, non-profits, and government; (2) structured exclusive licenses to permit unanticipated uses (e.g., sales but not use licenses); (3) limit rights to follow-on innovation; (4) avoid conflicts of interest; (5) ensure broad access to research tools; … (9) assure access for unmet social needs
- "Private" solutions – conditioning support on access

Draft Indian Act "Policy Levers" 1

- Section 2(c) definitions of intellectual property – all, not just inventions; 2(e) recipient – university, higher educational research institution, or non-profit scientific or education (not small business); 2(g) publicly funded by grant (but not contract, particularly copyright works for hire status?)
- Section 3(2) agreement and 3(3) disclosure by time certain (Section 4 -- 60 days of actual knowledge) and *other conditions as may be prescribed*
- Section 5 election to retain title (90 days from disclosure, extensions possible) in specified countries; exceptional circumstances order authority; title in Government otherwise; multi-Government agreements
- Section 6 non-publication and 15 days notice to file
- Section 7 application and utilization requirements and reporting; royalty sharing with creator

Draft Indian Act "Policy Levers" 2

- Section 8 prohibition on assignment without government approval
- Section 9 creator disclosure obligation immediately after creation
- Section 10 IP committee requirement to identify and assess IP having commercial potential; create a management fund; monitor licensing; *promote the cuture of innovation and publicly funded IP generation,* etc.
- Section 11 >30% royalty sharing to creator
- Section 12 no exclusive licensing in India without substantial manufacture in India
- Section 13 Government right to practice and to assign "to carry out its obligations under any international treaty"
- Section 15 annual reporting obligations, including accounts
- Section 18 (b) government licensing "on such terms and conditions as may be prescribed"

Tentative Considerations for the Indian Experience 1

- Determine conditions/entities for providing or rejecting private ownership (with public ownership or public domain status) – e.g., infrastructure, research tools, essential facilities – including government retaking title where companies fail to develop (but subject to restrictions to prevent government taking title to profitable commercial developments)
- Avoid the presumption of exclusive licensing, or better yet require non-exclusive licensing except where substantially justified (by particular industries)
- Develop policies on domestic v. foreign licensing and production (case-by-case cost-benefit analysis)

Tentative Considerations for the Indian Experience 2

- Retain greater control over taking title and licensing decisions by imposing mandatory terms (including field of use, space and time limits) by regulations or funding agreements; require development milestones reporting on licensing, and publication of terms
- Adopt a usable process for government authorization of third-party activity (whether under government license, march-in rights, or compulsory license)
- Consider "proportional" access and price regulations (of commercial development contribution relative to government funded invention) for government–funded inventions that reach the marketplace

Tentative Considerations for the Indian Experience 3

- Assure that commercial licensing/funding agreements do not unduly delay publication and dissemination (particularly of negative results), impose burdensome personnel and disclosure-approval requirements, or restrict uses of research tools or research data
- B-D does not directly regulate the university-commercial relationship – other regulatory methods
- Consider alternatives to patenting and exclusive licensing of innovations – e.g., medical biotechnology exclusive marketing rights or data compensation to recoup clinical trial costs

Conclusions

- There is a need for some private ownership and exclusive licensing, but not necessarily as a default rule; without care in structuring ownership and obligations, the cure may be worse than the disease
- It will be important to specify clear rules and expectations regarding policies – e.g., when government should retain title, what is expected of private ownership, and when the government may act to correct licensing and market practices
- Adopting the Indian Bayh-Dole Act should not be seen as a means for replacing or reducing government-funded innovation, particularly in sectors having large domestic or worldwide public benefits but small market profits