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**Public Sector IP Management for Public Health Outcomes:
Implications for Statistical Analysis and Valuation**

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“Public Sector IP Management for Public Health Outcomes: Implications for Statistical Analysis and Valuation”

Informal Discussion Paper presented at the UN Statistical Division’s Conference on the “Creation, Recognition and Valuation of Intangible Assets”

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Introduction

“On agit sur la réalité, en agissant sur sa représentation.” (Michel Foucault)

Reporting systems, statistical analysis influence society’s perception on a given topic. Data is often used to legitimate or dismiss a specific position. As such, statistics may not only be viewed as a language in and by itself, one that has its own grammar and vocabulary and one that can only be “spoken” by trained professionals, but it also takes an important role in the economic and political discourse. As such, the way we measure, the approach we take to a certain question determines our judgment, position and views.(1)

The UNSD interest in exploring existing best practices and infrastructure that support intellectual asset (IA) creation, recognition and valuation in view of developing joint guidelines for the compilation of R&D statistics in the national accounts so to give a more appropriate view of R&D will undoubtedly impact the perception on the contribution of R&D to economic wellbeing and social welfare. Modifications with regard to reporting the contribution of R&D to the economy as a whole may possibly also have benefits at the firm level. Current accounting standards, established to provide a fact-based analysis of firm behavior tend to punish R&D intensive companies since these firms are not provided with a full range of opportunities to document their value.

We hope to gain from this conference a better understanding on current methodologies with respect to measuring and capturing the value of IP and other intangibles. Historically

1 Foucault Michel: L’Ordre du Discours, Edition Flammarion, Paris 1971

insufficient weight has been given to the role of intangibles, particularly if they are held by public sector bodies or academic institutions.

Core Question

In line with the purpose of this conference, this research project reviews reporting systems that allow the analysis of the contribution of publicly funded research to public health. Publicly funded research related to health, which takes an important part in developing drugs, providing knowledge on healthy life styles, as well as the development of medical equipment for diagnosis, should benefit the public. We further believe that policy makers have a responsibility to assure access to health for all and assure that the privatization of research findings is a pathway for health for all. Questions related to access should therefore matter as early as the selection of the research topic. There are two distinct questions:

- How can the impact of public health outcomes of publicly funded research be captured? In this context the potential use of data from the PCT (Patent Cooperation Treaty, administered by WIPO) may serve as a proxy.
- How can adequate measurements be leveraged as means to improve technology management so to optimize welfare outcomes from publicly funded research?

The rationale for this undertaking is similar to any other type of reporting:

To better manage disposable resources, to correct current perceptions that focus on monetary returns rather than public health and to equip policy makers with a language that allows to conceptualize adequate policy measures.

Working Hypothesis

- Established reporting concepts do not allow policy makers to capture the public health benefit of publicly funded research since emphasis is put on monetary returns. The UNDP's human development, measuring human security and welfare distribution rather than GDP/capita may form a best practice example for this research project.
- Context, information provided and the risk rate assumed (in case of valuations) are crucial for adequate reporting systems. The challenge lies more in identifying the right information than in the mathematics. ("trash in, trash out")
- Public funding is crucial for health markets, which, like other innovation markets, are associated with high levels of risks and investments. Public-private interaction happens primarily during two stages of the value chain. During drug development and drug approval. Depending on how the interaction is managed it may either be a source for public health or create further disparities within and between populations.(2)
- The particularities of health markets require public private partnership where interaction mainly happens through IP. IP is however not primarily a price rewarding the inventor or a monopoly, but an entrance ticket to the market-based economy.

2 Taubman Antony: Public-Private Management of Intellectual Property for Public Health Outcomes in the Developing World: The Lessons of Access Conditions in Research and Development Agreements, The Initiative on Public-Private Partnerships for Health, Geneva 2004, http://www.globalforumhealth.org/filesupld/ippph_cd/START.HTM

Network externalities may give rise to a monopoly, but not IP in and by itself.(3)
Ignoring IP may mean to give up strategic choices and letting the private sector pick and chose from public research findings.

Capsule of Main Trends on Measuring Health Gains from Public Research

Previous studies have taken various approaches differing primarily in scope. The US National Institute of Health (NIH) cites several studies demonstrating the correlation between an overall improvement in the status of public health and advancement of science. Publicly funded research not only helped to fight diseases, but also reduce the economic costs of illness and improve the value of life. The NIH estimates that in the US the total economic costs of illness are 3 trillion USD or 31% of GDP and continues further that increases in longevity between 1970 and 1990 created annual net gains worth about 2.4 trillion USD. If only 10% of these incidences can be attributed to NIH funded research it indicates that public funds paid of more than 15 times. (4)

Literature in health economics is rich in calculations of the economic gains of a healthy, long living labor force and the loss of talent due to disease, illness or social behavior (such as violence or smoking) causing disability or shortened lives. Nordhaus for examples values the contribution of extended life expectancy between 1975 and 1995 and finds that economic gains are as high as the growth in consumption of all other goods and services.⁵ While a variety of factors, such as social conditions, political stability or hygiene have contributed to health gains over time, the progress in science against disease is an important element contributing to public health.(6)

Advances in knowledge can help society to lead better and longer lives, but can the scope of measuring the spillover effects of publicly funded research on public health be narrowed? Respectively, how can the role of licensing agreements and patents filed by the public sector be approached, so to ascertain to which extent the public benefited from innovation related to health?

Cockburn and Henderson (1997) looked at 21 drugs identified by 2 experts as having the most impact on therapeutic drugs and found that only 24% (6) were developed with no public sector input into the basic or applied research that was necessary to bring the product to the market, suggesting hence that public research is essential to private sector drug discovery.(7)

Along the same line of argument the US based NIH cites that out of 47 drugs that reached the 500\$ million per year threshold in annual sales in the U.S., 4 were clearly released with the support of publicly owned IP. Subject of measurement, was the number of compounds licensed out by public research organizations that could be identified in FDA approved drugs in a given period of time. The findings may however have been distorted by the fact that there

3 For further discussion see: Gans Joshua S./Williams Philip L./Briggs David: Intellectual Property Rights: A Grant of Monopoly or an Aid to Competition? Intellectual Property Research Institute of Australia, Working Paper Nr. 07/02, December 2002, <http://www.ipria.org>

4 Office of the Chairman of the National Institute of Health Connie Mack: The Benefits of Medical Research and the Role of the NIH. May 2000, <http://jec.senate.gov>, p.17

5 Nordhaus William D.: The Health of Nations: the Contribution of Improved Health to Living Standards. NBER Working Paper No. 8818, http://www.econ.yale.edu/~nordhaus/homepage/health_nber_1.doc

6 *ibid*, p.18

7 Cockburn Iain/Henderson Repecca: Public-Private Interaction in Pharmaceutical Research, Proceedings National Academy of Science USA, Vol. 93, pp. 12725-12730, November 1996, Colloquium Paper, <http://www.pnas.org/cgi/content/full/93/23/12725>

is no need under current regulation to make the proportion of publicly funded IP in a given drug explicit.(8)

Background

In 1980, US Congress passed Patent Law 96-517, Amendments to the Patent and Trademark Act (commonly referred to as the Bayh-Dole Act). Under this law, “title to inventions made with government support is provided to the contractor if that contractor is a small business, a university, or other non-profit institution.” The aim of this law is to leverage patent ownership as an incentive for private sector development and the commercialization of federally funded R&D. The law encourages the commercialization of new technologies through cooperative ventures between and among the research community, small business, and industry, which should result in new products and processes for the marketplace. “(9)

This legislation has caused a worldwide debate on how to deal with public research outcomes. While until the 1970s there was a widespread believe that outcomes of publicly funded research should remain fully in the public domain through means of publications in academic journals, current thinking in this area relies on the belief that public research that is not patented may not only prevent product development, but also allow the private sector to pick and chose as it pleases. Rather than leaving knowledge goods unmanaged in the public domain, the question arises how patented knowledge can be managed so to maximize health gains. Similar to the fair trade debate, the point is not to prohibit trade, but to manage it in a way beneficial to all participants. Patenting knowledge means gaining ownership over choices, making knowledge explicit and putting it in a format that it can easily be exchanged between interacting participants, hence fostering knowledge sharing.

While the Bayh Dole act succeeded in fostering licensing agreements between the public and the private sector and spurring patenting activities at universities in general, it is not certain to which extent universities profit from licensing their technology out. According to an AUTM (Association of University Technology Managers) study, universities in the US make on average an annual profit of 5% from licensing arrangements, however the study did not look at costs, so it can not be ascertained that the universities did have a profit. Most universities license technology out at a very early stage, hence no exceedingly high fee can be expected. The profitability of technology commercialization for universities is further hampered by inadequate patent portfolios.(10)

According to the Congressional Research Service, the think tank of US Congress, the Bayh Dole Act has successfully met the objective of commercializing public research outcomes, however critics assert that the private sector is receiving benefits to the detriment of the public interest. Other issues raised concern “conflict of interest, redirection of research, less openness in sharing of scientific discovery, delays in publications, and a greater emphasis on

8 University Working Group: University Working Group Observations on NIH Report on Return on Investment in Drug Research, <http://www.aaua.edu/research/NIH8.20.01.html>

A similar approach has been taken by: Heher Antony H.: Implications of International Technology Transfer Benchmarks for Developing Countries, Journal of Technology Management and Sustainable Development Vol 31 Issue 4 July 2006, p.1-21

9 Schacht Wendy H.: The Bayh-Dole Act: Selected Issues in Patent Policy and the Commercialization of Technology, Congressional Research Service Report for Congress, Order Code RL 3207 Penny Hill Press, September 2003, <http://penhyhill.com>, p.1

10 Association of University Managers, AUTM Licensing Survey, Fiscal Year 1991 and 2001, <http://www.autm.net>

applied rather than basic research.”(11) The role of the Bayh Dole Act in improving public health is subject debate, in this context it can only be emphasized that the conditions according to which public private partnerships are structured is crucial to determining the winners of such deals.

Turning Science into Business?(12)

The words “health” and “markets” create a challenging dichotomy. While health is essentially considered a public good (in the strict sense of economics it would be considered a publicly provided private good), markets are the result of operations conducted by individual profit maximizing firms. The textbook argument for government interaction is that markets for health do by themselves not provide socially optimal outcomes. This contradiction prevails any type of discussion related to technology management having a public health focus.

If health innovation is not only to advance technology, but also to bring along public health, health markets -as they work today- do not fully meet their purpose. While important resources are being spent on drugs with relatively little incremental therapeutic value (e.g. viagra), a relatively moderate fraction of funds available is spent on developing medication affecting the global poor.(13) The global fund has expressed this problem as the 10/90 health research gap, where only 10% of global research funds are being spent on research related to diseases affecting the poor. In line with that argument Trouiller, Olliaro et al. found that between 1977 and 1999 only 16 out of 1393 chemical entities marketed for tropical diseases.(14) Malaria, for example, spread in many developing countries, is primarily considered a potential market because it may affect travelers leaving for these countries for leisure or military purposes. This means that patients in developing countries may not receive drugs that best serve their purpose or that these drugs do not even exist due to a lack of research effort invested in them.(15)

More questions rather than a Conclusion

“Innovation is not black or white, on or off. Innovation is a matter of degree.”(16)

Innovation is a cumulative process built continuously on previous knowledge. Public research organizations are much more than the depository of “secrete facts”. They are neither dictionaries nor databases. They are the “know how” and “know why” organizations of a society.(17) Organizational knowledge, knowledge embedded into social context is the

11 Schacht Wendy H., p.3-5

12 OECD Secretariat: Turning Science into Business: Patenting and Licensing at Public Research Organisations, OECD, Paris 2003, www.oecd.org/document/2/0,2340,en_2649_34797_2513917_1_1_1_1,00.html

13 Hollis Aidan: An Efficient Reward System for the Pharmaceutical Innovation, Discussion Paper of the Department of Economics, University of Calgary, October 2004, <http://econ.ucalgary.ca/hollis.htm>

14 Trouiller Patrice/Olliaro Piero et al.: Drug Development for Neglected Diseases: A Deficient Market and a Public Health Policy Failure. *Lancet* 2002. 359:2188-2194

15 Keusch Gerald T/Nugent Rachel A.: The Role of Intellectual Property and Licensing in Promoting Research in International Health: Perspectives from a Public Sector Biomedical Research Agency. Commission on Macroeconomics and Health Working Paper Nr. WG2: 7, p.26- 28

16 Office of Health Economics Consulting: A Review of IP and Non-IP Incentives for R&D Diseases of Poverty. What Type of Innovation is Required and How Can We Incentivise the Private sector to Deliver It? Final Report for the WHO Commission on Intellectual Property Rights, Innovation and Public Health. WHO, Geneva April 2005, p.7

17 Ryan Michael P./Ghafele Roya: Do Patent Reforms Stimulate Innovation in Developing Countries? Intellectual Property and Bio Medical R&D in Brazil and Jordan, June 2006, submitted for Journal Publication, p.26

ultimate value proposition of public research institutions. The private sector does not simply reap the harvest of public research activity, rather the private and the public sector interact with each other at the various stages of the research process. Knowledge generation is a continuous process and –contrary to physical property- knowledge property does not have diminishing returns. The more property on knowledge is in use, the richer it gets. Measurement approaches need to capture this characteristic of IP if they are to be appropriate.

- Data from the Patent Cooperation Treaty, a treaty administered by WIPO helping to assure international patent protection, indicates that developing countries are building up national assets related to health. While overall filing by developing countries with the PCT lies by 2%, developing countries' share of patents related to health is by 8% and patents referring to plant based compounds for medication even make up 20% of total filings with the PCT. Public institutions in India, China and Korea are the main patenting institutions driving this disproportional trend. Can we observe a correlation between increased patent ownership in these countries and health indicators, such as life expectancy or DALYs?(18)
- If there is an overall positive correlation between an improved status of health and ownership over a systematic patent portfolio related to health, how can the dependent variables be defined that may help understand this trend? How do indicators need to be defined so to capture managerial approaches to public private partnerships that promote public health, e.g. non-exclusive licenses or license agreements allowing a price differentiation of medical products adjusted to incomes of a given population?

It is a policy choice to assure property rights on public research break the equation between public research and the public domain. Legislation like the Bayh Dole Act has helped to assure that public research findings were better fed into products that reached the market. Current challenges are hence primarily related to determining how public private partnerships need to be structured so to assure health benefits to society and how these type of partnerships can be described in a quantitative way.

Roland Barthes sees in statistics a language that suits a world conceptualizing itself as “myth free”. As such mythology has captured statistics as a whole and the discipline serves all together the various social constructions we live by.(19) In this sense reporting tools capturing the public health impact of publicly funded research may possibly just help to construct another myth, but this in and by itself may be considered a helpful tool for policy makers.

18 DALY means disability adjusted life years. The DALY attempts to compile a burden of premature death and lives lived with disease related disability into a single estimate of society's disease burden.

19 Barthes Roland: Mythologies, Editions du Seuil, Paris 1957