

Towards a structured view of public interest IP management in the life sciences

WIPO Life
Sciences
Symposium

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Two themes

- What are the characteristics of:
 - IP management
 - IP management in the life sciences
 - IP management in the life sciences by public sector/public interest entities
- What are the lessons of practical experience for life sciences policymakers?

Two themes and one caveat

- What are the characteristics of:
 - IP management
 - IP management in the life sciences
 - IP management in the life sciences by public sector/public interest entities
- What are the lessons of practical experience for life sciences policymakers?
- Gathering factual information and sharing practical experience to help support policymakers: not endorsing or propounding any particular model or approach

ORIGINAL ARTICLE

Safety and Immunogenicity of RTS,S/AS02D Malaria Vaccine in Infants

Salim Abdulla, M.D., Ph.D., Rolf Oberholzer, M.D., Omar Juma, M.D.,
Sulende Kubhoja, M.D., M.M.E.D., Francisca Machera, A.M.O.,
Christopher Membi, A.D.M.L.S., Said Omari, D.M.L.T., Alwisa Urassa, B.P.A.,
Hassan Mshinda, Ph.D., Aiguo Lumeno, M.D., Nabuo Salim, M.D., M.M.E.D.,
Mwanja Terrell C
Marie-C
Joh:

The NEW ENGLAND JOURNAL of MEDICINE

EDITORIALS



A Hopeful Beginning for Malaria Vaccines

William E. Collins, Ph.D., and John W. Barnwell, M.P.H., Ph.D.

An effective human malaria vaccine has been sought for over 70 years, with little success.¹ A successful malaria vaccine used in conjunction with other vaccines for children (a vaccine containing diphtheria and tetanus toxoids, whole-cell pertussis vaccine). In this trial, RTS,S was given along with

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China on path to lead world in new patents -report

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By Maggie Fox, Health and Science Editor

WASHINGTON, Dec 10 (Reuters) - China has greatly stepped up its applications for new patents and will pass Japan, the current leader in new patents, by 2012, according to a report released on Wednesday by Thomson Reuters Scientific.

"In China, 16 percent of patents come from academia," Zhou told the briefing. This compares to 4 percent in the United States and 1 percent in Japan.

This article is part of Nature's premium content.

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News

Patent pledge to Indian universitie

Critics worry that push for technology transfer is moving too fast.

T. V. Padma

India's parliament will soon be scrutinizing a bill intended to help publicly funded institutes and universities commercialize their research. India's science minister, Kapil Sibal, is confident that the bill

Toc

public policy role of the patent system: the conventional public-private balance

1. promotion of innovation, directing resources towards beneficial research and development
 2. practical, equitable availability of the fruits of innovation
- challenge for IP law and policy is to find the optimal linkage between these two goals, seen in two ways:
 - a zero-sum trade off between public and private interests, or
 - a mutually-supportive harnessing of public and private interests, an encouragement to deploy resources to society's needs:
 - incentives to take risks, support research and invest in the development and dissemination of a finished product;
 - remedies and other interventions when this fails

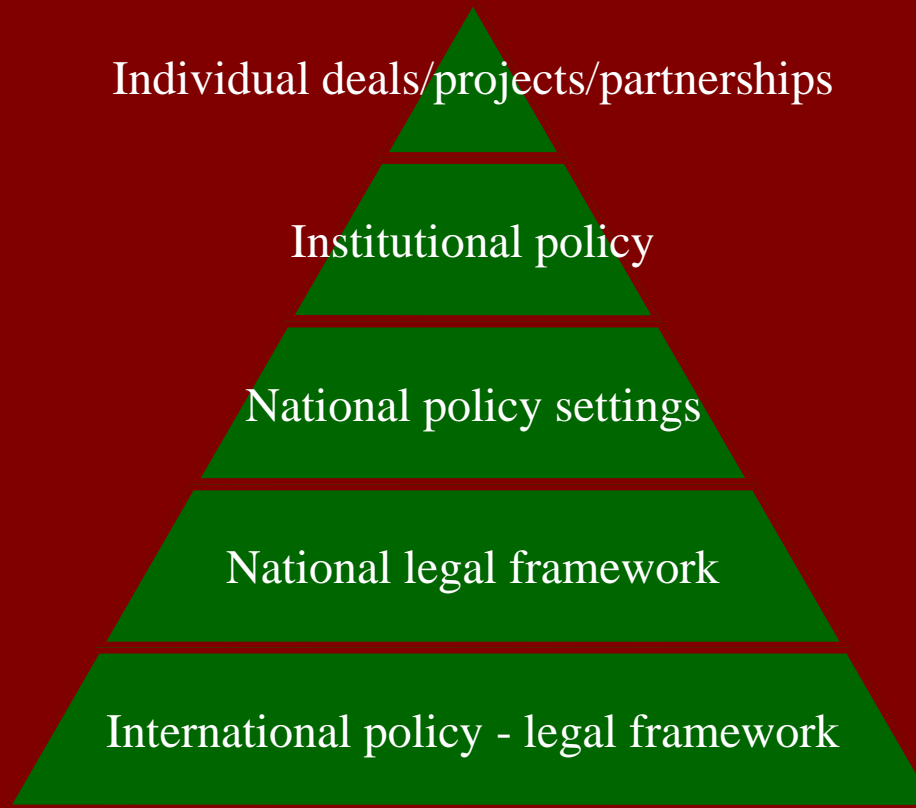
garnering and focussing resources to meet neglected health needs: what role for IP?

- the needed resources, tangible and intangible:
 - knowhow, research and product development capacity, clinical trial expertise, regulatory infrastructure, background/platform technologies and research tools, investment of public & private capital
- applying these resources towards unmet needs:
 - generating new resources
 - private: incentives, market interventions
 - public: additional funding, infrastructure development
 - better applying existing resources
 - leveraging access to technologies
 - drawing on drug development skills and R&D infrastructure
 - drawing on indigenous research and innovation capacity, and heritage of traditional medical knowledge

The question of balance in international legal standards

- The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.
 - TRIPS, art 7


Working within the policy space



Layers of IP policy for public interest IP management in the life sciences

Consider the role of IP at distinct but inter-related levels:

- practical IP management and building capacity for effective negotiations with technology partners on IP issues
- policies and strategies for IP management at the institutional or project level:
- national policy settings for public-funded or public-interest research
- specific, targeted legislative initiatives to create incentives to meet neglected welfare needs (health, food, environment)
- national innovation policy and legal settings, including IP laws and their interaction with other aspects of the regulatory system
- international cooperation, specific initiatives, standard-setting and legal framework

- 
- IP management: The set of practices determining whether intellectual property protection is in practice obtained, and how intellectual property is managed, in order systematically to achieve defined objectives, such as a firm's corporate goals or a public research agency's institutional responsibilities.
 - WIPO study on Avian Flu Patent Issues

The context of IP management

- What regulatory/legal/ethical/incentive structures guide IP management choices?
 - What are the public expectations?
- How to manage a knowledge system?
 - What overarching dynamics and strategies (before tactical choices on using IP)?
- Is some form of leverage, exclusivity or remuneration needed?
 - When is a public domain option preferable?
- If so, what kind of IP is needed? Where?
- How to manage (and pay for) that IP?
 - What kind of licensing strategies and principles?

What is distinctive about...


- IP management in the life sciences
 - human health
 - agriculture
 - biotechnology
- IP management by public sector/public interest actors
 - Publicly funded research? And development?
 - Philanthropic research? And development?
 - Hybrid partnerships (public-private)
 - Public sector or educational institutions?
 - Government agencies and departments
 - UN agencies and IGOs

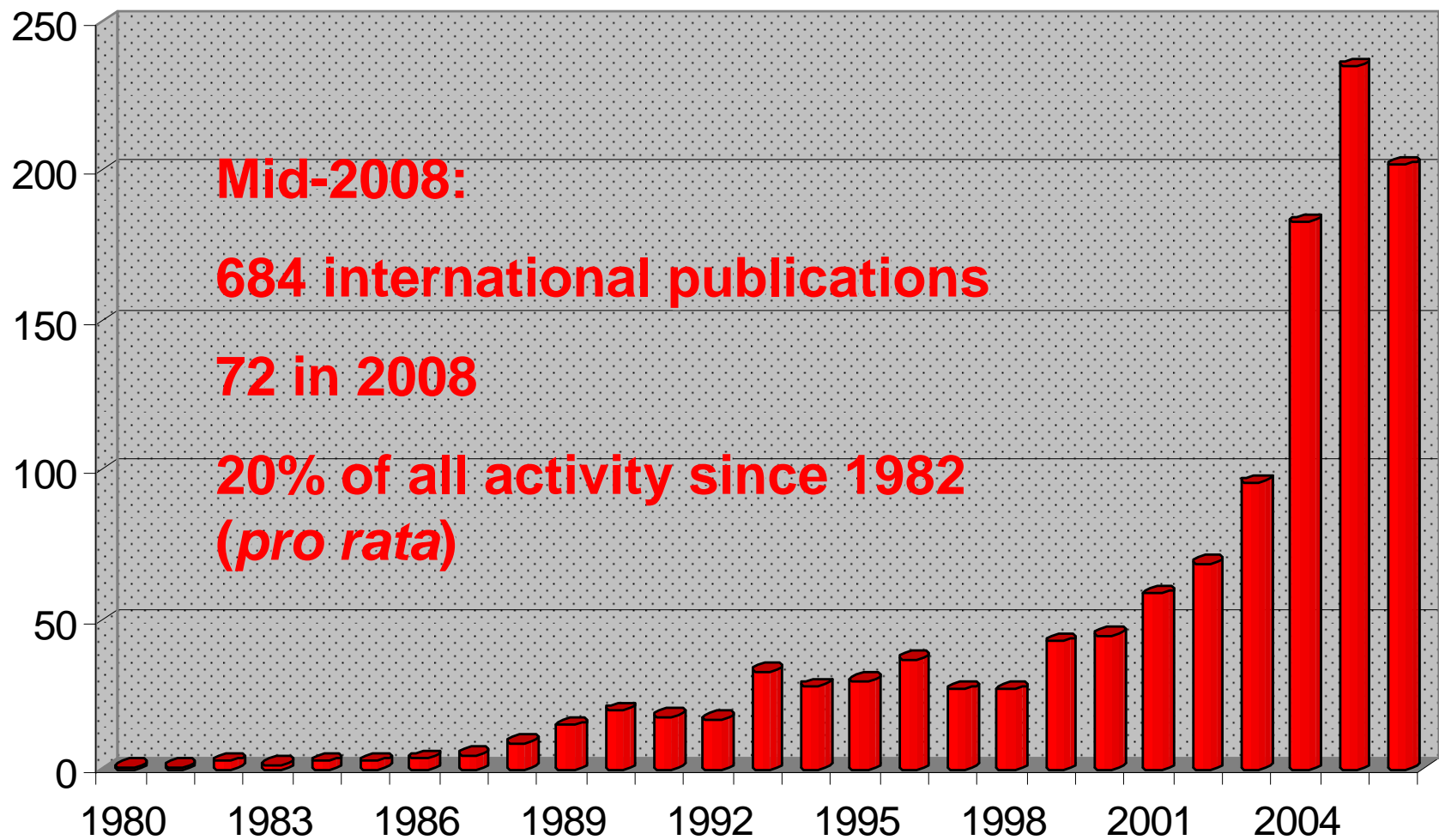
Distinctive characteristics of life sciences IP management

- Inherent public interest in these technologies
 - They address basic human needs
 - Bioethics and broader public scrutiny
- More complex legal environment, and necessarily stringent regulatory context
 - Addressing regulatory demands of product development a major factor in IP management
 - Legal context of genetic inputs
- Informatics and complexity of analysis
 - Freedom to operate assessments
 - (WIPO symposium on life sciences landscaping)

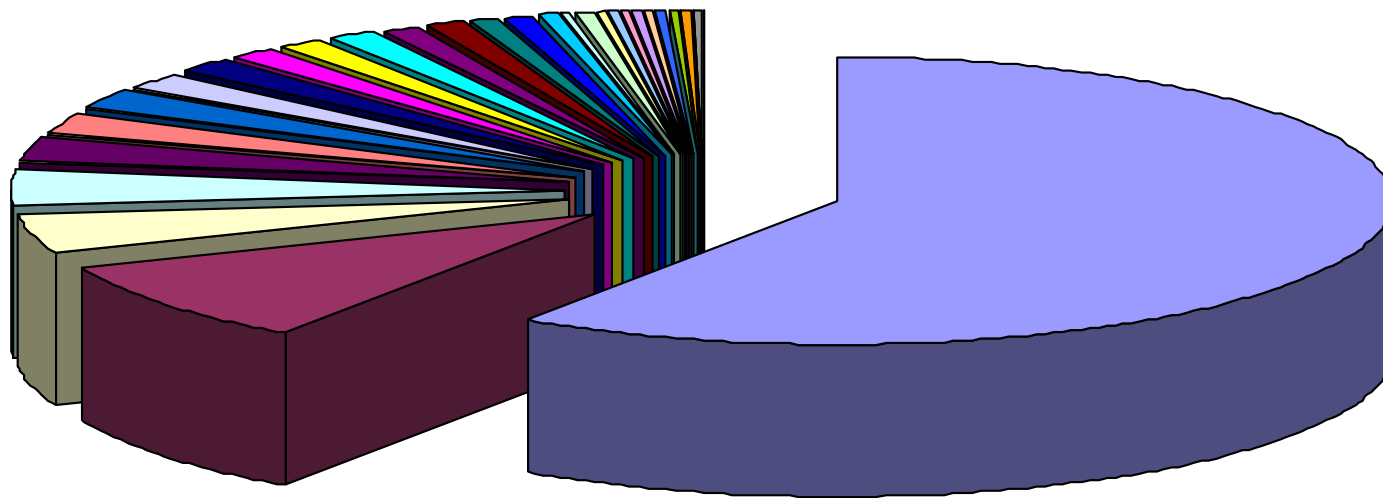
Distinctive characteristics of life sciences IP management by public sector/ public interest entities

- High levels of public/philanthropic investment in research
 - Expectations of a return from investment measured in terms of equitable human welfare gains, not (only) commercial returns
- Complex interrelationship with private sector and other partners to bring research to the public
 - Public sector players rarely undertake full product development, regulatory approval and dissemination alone
- Distinctive public policy/philanthropic requirements
 - From servicing the local economy...
 - ...to meeting global health, food and environmental needs
- Obligations under international agreements to transfer publicly managed technologies?

- 
- Public sector/public interest/publicly accountable patent holders particularly pronounced in the life sciences field...
 - A glance at recent patterns of international patent filings on cell lines
 - A key research tool, but rarely a finished or stand-alone medical or agricultural product



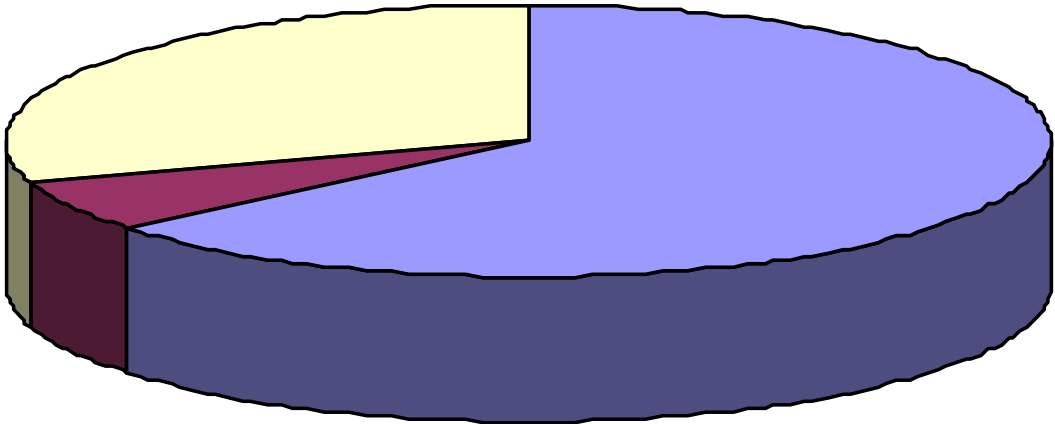
International patent applications on human, animal or plant cell lines by year of publication (Source: Patentscope) to mid-2007



C12N-5/08 - Human cells or tissues
PCT – nationality of principal applicant

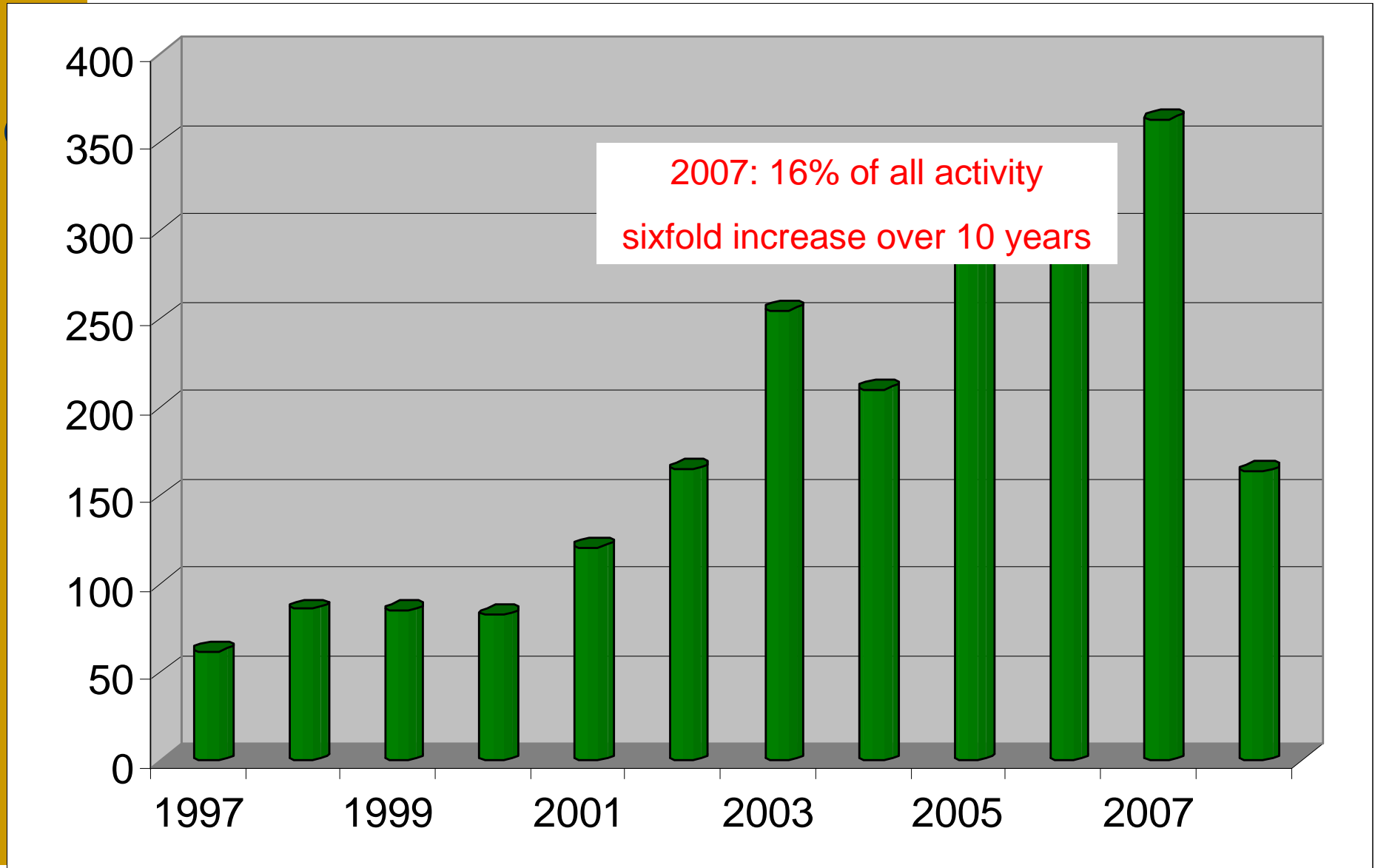
- US
- JP
- DE
- GB
- FR
- IL
- CH
- CA
- AU
- DK
- NL
- EP
- KR
- SE
- IT
- SG
- CN

MC/C12N-5/08 PCT publications 1995-2007 by applicant



- Public
- Public/Private
- Private

International patent activity relating to stem cell research



top ten filings in stem cell patenting

- 1 SEOUL NATIONAL UNIVERSITY INDUSTRY FOUNDATION
- 2 WISCONSIN ALUMNI RESEARCH FOUNDATION
- 3 VIDACARE CORPORATION
- 4 THE GENERAL HOSPITAL CORPORATION
- 5 STEMLINE THERAPEUTICS, INC.*
- 6 CEDARS-SINAI MEDICAL CENTER
- 7 UNIVERSITY OF FLORIDA
- 8 TRUSTEES OF COLUMBIA UNIVERSITY IN THE CITY OF NY
- 9 RIKEN
- 10 PARK, Hyun Sook

*: Licensee of University of Cambridge

also in the top 50

- VRIJE UNIVERSITEIT MEDISCH CENTRUM (VUMC)
- UNIVERSITY OF SOUTHERN CALIFORNIA
- UNIVERSITY OF SHEFFIELD
- UNIVERSITY OF ILLINOIS
- UNIVERSITA' DEGLI STUDI DI TORINO
- UNIVERSIDAD DE SALAMANCA
- THOMAS JEFFERSON UNIVERSITY
- THE WALTER AND ELIZA HALL INSTITUTE OF MEDICAL RESEARCH
- THE UNIVERSITY OF UTAH
- THE UNIVERSITY OF MEDICINE AND DENTISTRY OF NEW JERSEY
- THE UNIVERSITY COURT OF THE UNIVERSITY OF EDINBURGH
- THE UNIVERISTY OF KANSAS
- THE TRUSTEES OF PRINCETON UNIVERSITY
- THE TRUSTEES OF COLUMBIA UNIVERSITY IN THE CITY OF NEW YORK
- THE SECOND MILITARY MEDICAL UNIVERSITY
- THE REGENTS OF THE UNIVERSITY OF MICHIGAN
- THE REGENTS OF THE UNIVERSITY OF COLORADO
- THE REGENTS OF THE UNIVERSITY OF CALIFORNIA
- THE QUEEN'S UNIVERSITY OF BELFAST
- THE OHIO STATE UNIVERSITY RESEARCH FOUNDATION
- THE JOHNS HOPKINS UNIVERSITY
- THE J. DAVID GLADSTONE INSTITUTES
- THE GOVERNING COUNCIL OF THE UNIVERSITY OF TORONTO
- THE BOARD OF TRUSTEES OF THE LELAND STANFORD JUNIOR UNIVERSITY
- THE BOARD OF SUPERVISORS OF LOUISIANA STATE UNIVERSITY AND AGRICULTURAL AND MECHANICAL COLLEGE
- THE BOARD OF REGENTS OF THE UNIVERSITY OF TEXAS SYSTEM
- TECHNION RESEARCH & DEVELOPMENT FOUNDATION LTD.
- SUOMEN PUNAINEN RISTI, VERIPALVELU
- SUN, DongMing

Cell line patent applications published in 2008 to date

- 1 THE REGENTS OF THE UNIVERSITY OF CALIFORNIA 10
- 2 RIKEN 10
- 3 THE TRUSTEES OF COLUMBIA UNIVERSITY IN THE CITY OF NEW YORK 8
- 4 ARIUS RESEARCH INC. 8
- 5 SUOMEN PUNAINEN RISTI, VERIPALVELU 7
- 6 Kyowa Hakko Kirin Co., Ltd. 7
- 7 CEDARS-SINAI MEDICAL CENTER 7
- 8 WYETH 6
- 9 THE REGENTS OF THE UNIVERSITY OF MICHIGAN 6
- 10 TAKARA BIO INC. 6
- 11 SEOUL NATIONAL UNIVERSITY INDUSTRY FOUNDATION 6
- 12 OSAKA UNIVERSITY 6
- 13 THE UNIVERSITY OF TOKYO 5
- 14 THE GENERAL HOSPITAL CORPORATION 5
- 15 PRESIDENT AND FELLOWS OF HARVARD COLLEGE 5
- 16 GENENTECH, INC. 5
- 17 DUKE UNIVERSITY 5
- 18 BAYLOR RESEARCH INSTITUTE 5
- 19 ANTHROGENESIS CORPORATION 5
- 20 YALE UNIVERSITY 4
- 21 WISCONSIN ALUMNI RESEARCH FOUNDATION 4
- 22 UNIVERSITY OF ROCHESTER 4
- 23 THE TRUSTEES OF THE UNIVERSITY OF PENNSYLVANIA 4
- 24 TECHNION RESEARCH & DEVELOPMENT FOUNDATION LTD. 4
- 25 STEMPEUTICS RESEARCH PRIVATE LIMITED 4

In 2008:

12% of all historic activity

Since 2005:

Over 50% of all activity

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- 28 JAPAN SCIENCE AND TECHNOLOGY AGENCY 4
- 29 CHUGAI SEIYAKU KABUSHIKI KAISHA 4
- 30 YOKOHAMA CITY UNIVERSITY 3
- 31 TOKYO UNIVERSITY OF SCIENCE EDUCATIONAL FOUNDATION ADMINISTRATIVE ORGANIZATION 3
- 32 TOKYO METROPOLITAN ORGANIZATION FOR MEDICAL RESEARCH 3
- 33 THE UNIVERSITY OF QUEENSLAND 3
- 34 THE UNIVERSITY OF HONG KONG 3
- 35 THE UNIVERSITY OF CHICAGO 3
- 36 THE JOHNS HOPKINS UNIVERSITY 3
- 37 THE J. DAVID GLADSTONE INSTITUTES 3
- 38 THE BRIGHAM AND WOMEN'S HOSPITAL, INC. 3
- 39 STEM CELL SCIENCES (UK) LTD 3
- 40 SCHERING CORPORATION 3
- 41 REVERSE PROTEOMICS RESEARCH INSTITUTE CO., LTD. 3
- 42 OREGON HEALTH & SCIENCE UNIVERSITY 3
- 43 ONCOTHERAPY SCIENCE, INC. 3
- 44 NOVARTIS AG 3
- 45 NATIONAL INSTITUTE OF ADVANCED INDUSTRIAL SCIENCE AND TECHNOLOGY 3
- 46 MOUNT SINAI HOSPITAL 3
- 47 MEDTRONIC, INC. 3
- 48 MEDIMMUNE, LLC 3
- 49 MASSACHUSETTS INSTITUTE OF TECHNOLOGY 3
- 50 Japan Science and Technology Agency

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46 MOUNT SINAI HOSPITAL 3

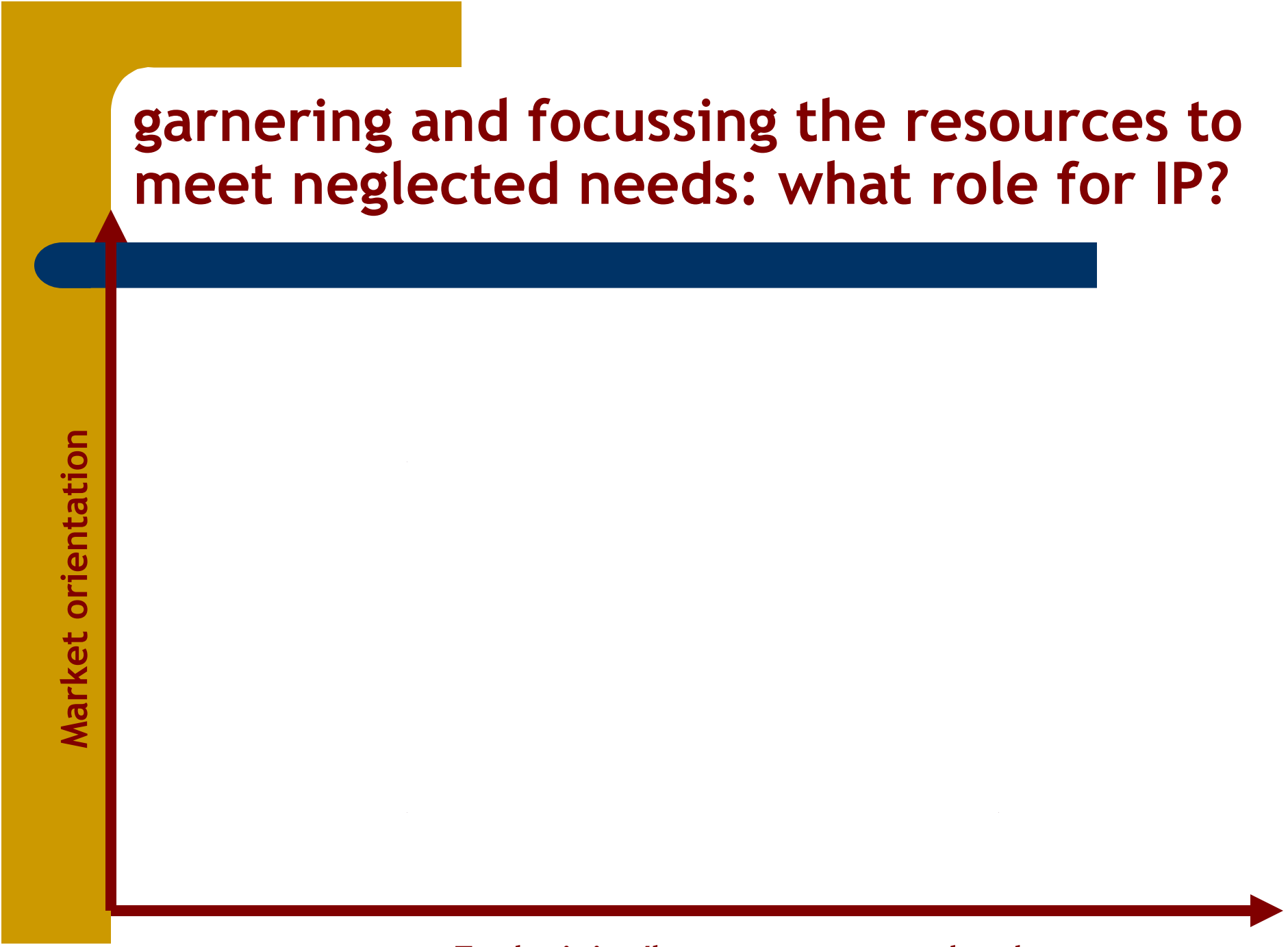
49 MASSACHUSETTS INSTITUTE OF TECHNOLOGY 3

50 Japan Science and Technology Agency

garnering and focussing the resources to meet neglected needs: what role for IP?

Market orientation

Exclusivity/leverage over technology



garnering and focussing the resources to meet neglected needs: what role for IP?

Market orientation

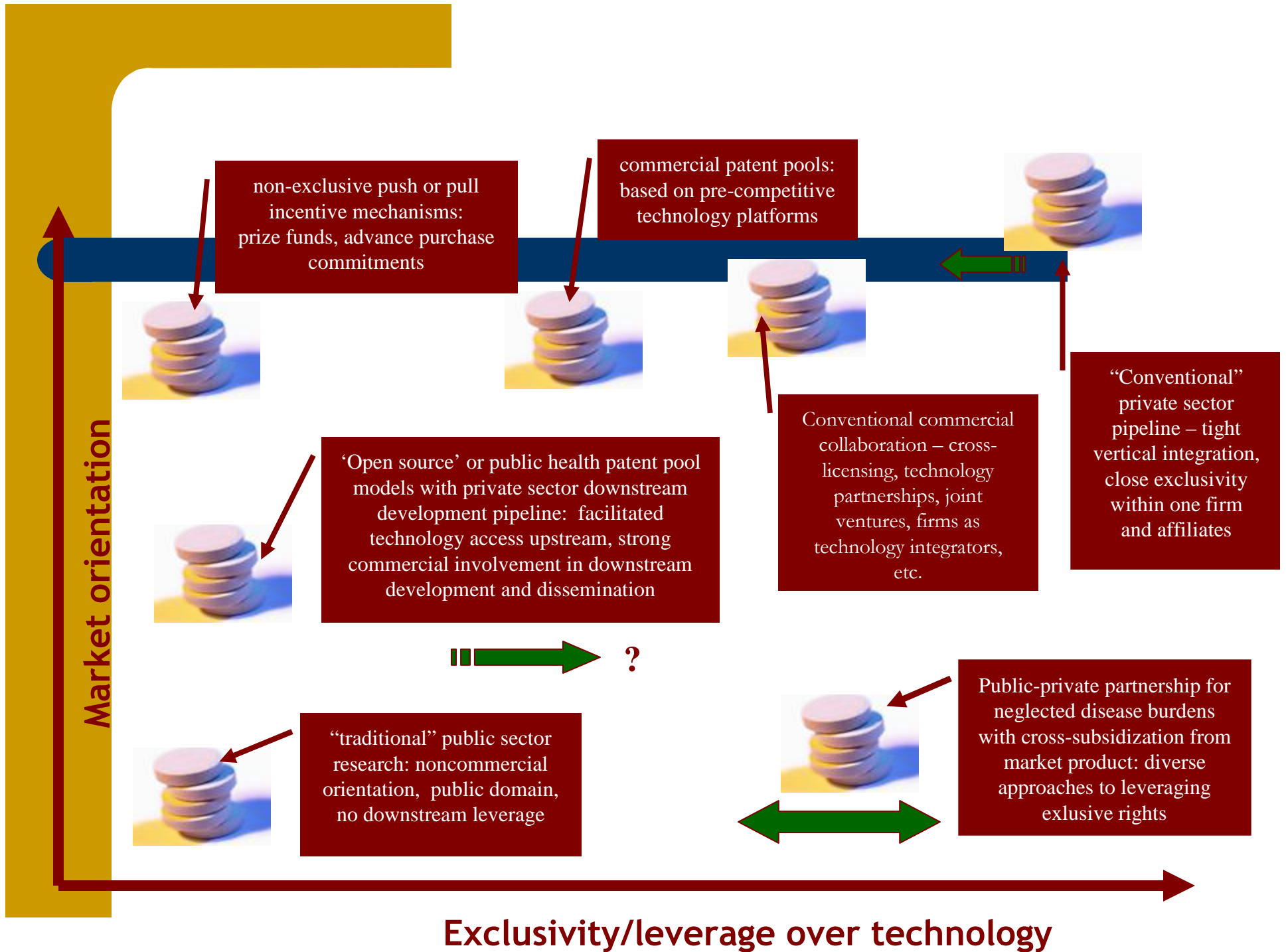
Private



Public

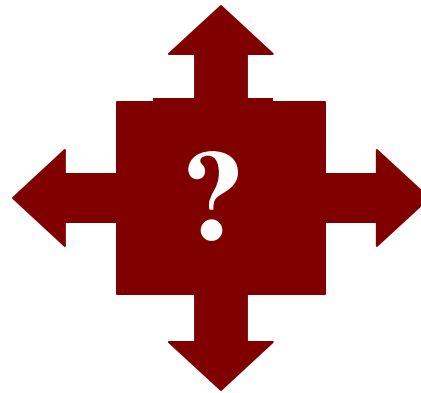


Exclusivity/leverage over technology



Defining the policy space

scope and
exclusivity of
rights over
technology



stringency of
post-grant
regulation
of patent use:
public safeguards

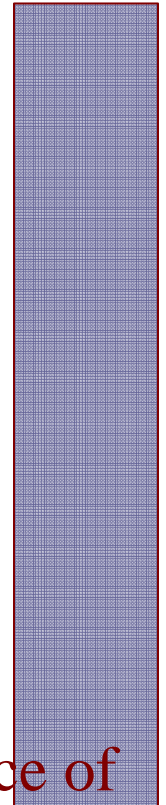
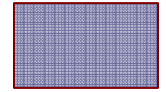
... and filling the policy space...



multiple technological, legal,
infrastructure, regulatory inputs

consider
the development
over time
of an actual product

de facto practice of
increasing private
sector intervention
towards delivery end
of pipeline



Two key demands ...

- **Public interest management of knowledge to deliver new public health outcomes:**
 - what are the lessons of practical experience?
 - what structures or partnerships, what ways of blending incentives and safeguards, what forms of IP management and leveraging have been effective?
 - ‘work in progress,’ but a vital new skill set is emerging
- **Enlarging the base of innovation, and broadening the development pipeline:**
 - bolstering indigenous innovative and product development capacity in developing countries
 - empowering developing countries to extract maximum benefit from their research activities, leveraging access to technology
 - respect for and recognition of traditional knowledge systems

a dynamic, practical challenge

- IP system one component of a broader set of national and international policy settings that determine how public and private resources are garnered and channeled to serve public health needs.
- its role, ideally, is to harness private interest and to channel productive investment, so as to serve the broader interests of society.
 - A balancing of specific private interests and broader public policy objectives, a dynamic process that is conducted at various levels: by the policymaker and legislator, by the regulator or judicial authority, and by the public sector funding agency or public health program.

Reviewing the role of patents as a policy tool

- A deliberate use of exclusive rights
 - legally-structured policy-driven exclusions from the public domain
- to promote the production of public goods
- ...harnessing private interest for the public benefit...
- The ultimate impact results not from international standards, nor national patent laws, nor even decisions on patent grant
 - But an accumulation of numerous choices
 - to patent or not (and where)
 - And how to exercise patent rights once granted
- Given the scale of public sector/public interest patenting activity, and the importance of key upstream life sciences technologies,
- choices of public sector IP managers will have significant impact on public welfare outcomes...