

life sciences symposium:
public policy patent landscaping
in the life sciences

Current issues in patent
information for public
policymakers in the life sciences:

public policy and the life sciences

Fundamental concerns:

- agriculture and food security;
- public health and pharmaceuticals;
- protection of the environment.

Crosscutting issues:

- promoting innovation – its value and direction
- ensuring equitable access to fruits of innovation
- delivering on technology transfer

Common needs:

- accessible, trusted, neutral information – not raw data

some current policy questions

- has the rice genome been privatised?
- who owns research tools in life sciences?
- who is doing stem cell research?
- what freedom to operate:
 - for agricultural research in developing countries?
 - for procurement and production of medicines?
- who is using genetic resources, where, for what purpose?
- what technologies are needed in the implementation of environmental treaties?

the context of patent landscaping for life sciences policymakers

policymakers to debate, make assessments, set policy on life sciences issues,
ideally guided by a richer information base:

what's going on
out there?

what does it
amount to?

and what
to do about it?

what can be patented,
what is patented, where,
and who is patenting it?
what genetic resources/
TK are they using?

patentability issues;
transparency;
analysis of
patenting trends

what is the impact on
access to technology *now*
- in developing world
especially

- what is the impact for
future development

- forecasting emerging
technologies

what options for

- practical IP
management

- regulatory intervention

to achieve the
required benefits
in the required way

Patent information as a tool of public policy

Policymakers look for:

clearer, more accessible and
geographically more representative
information to support policy processes.

a stronger empirical basis for assessments
on the role and impact of patents system
in key areas of life sciences technology.

two sets of questions

- Policy information
 - technology trends
 - patterns of ownership and control
 - new players
 - economic insights
 - downstream use of genetic resources
- Practical pathways
 - constructing legal and technical pathways to
 - dissemination of existing technologies
 - creation of new combinations
 - addressing neglected needs in health and agriculture

Improved analytical tools and access to patent information

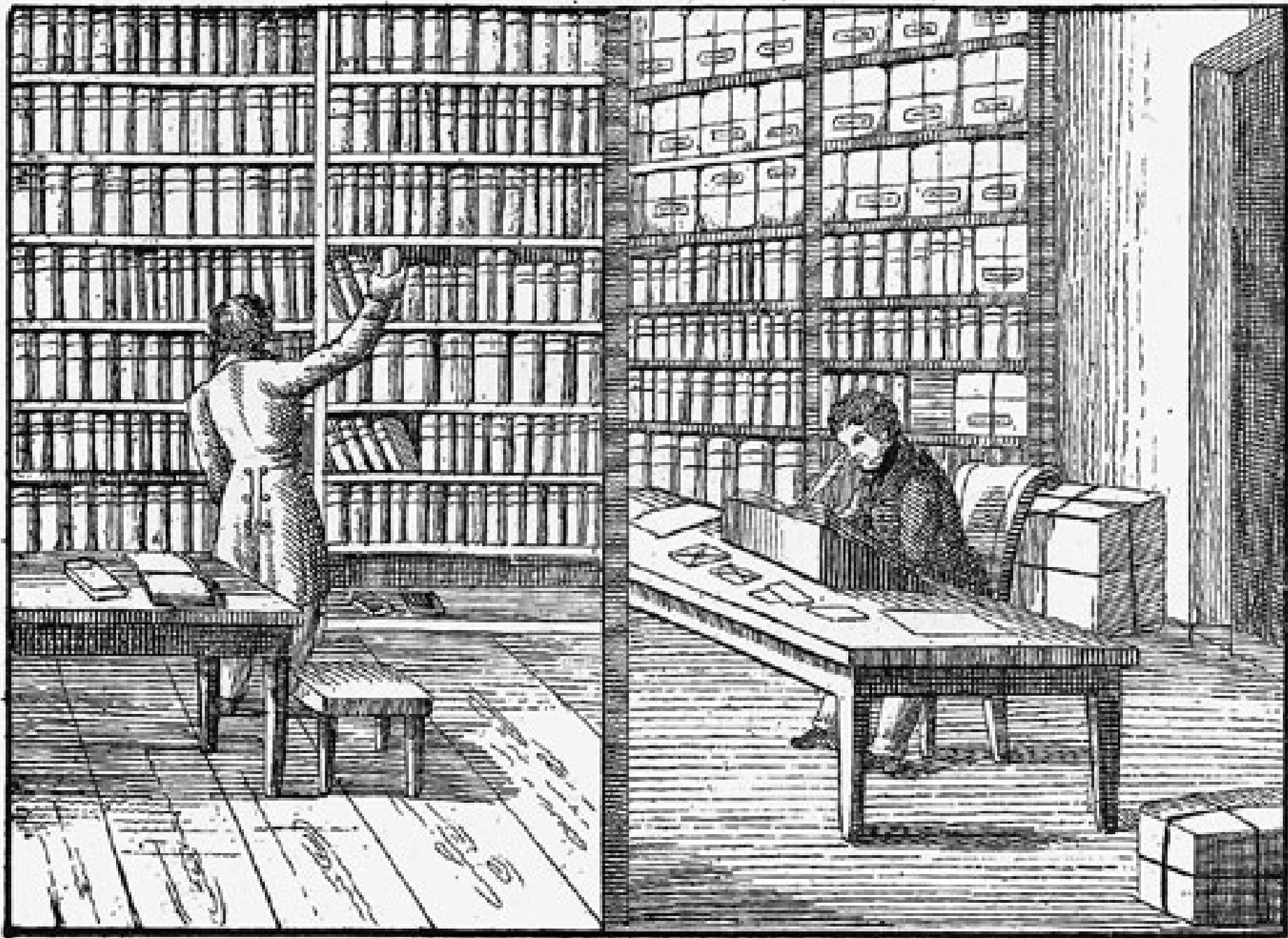
Vastly improved access to data:

- Rapid growth in the use of the patent system, and in the diversity of users, explosion of raw data on patenting activities in the life sciences

Enables raw data to become useful information:

- Availability and quality of patent information have increased.
- Analytical tools and methodologies better understood and more widely available.
- Greater practical experience harvested from recent patent landscaping initiatives.

This trend opens up enormous practical potential for improved patent information resources for public policymakers addressing the life sciences.





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PATENT INFORMATION

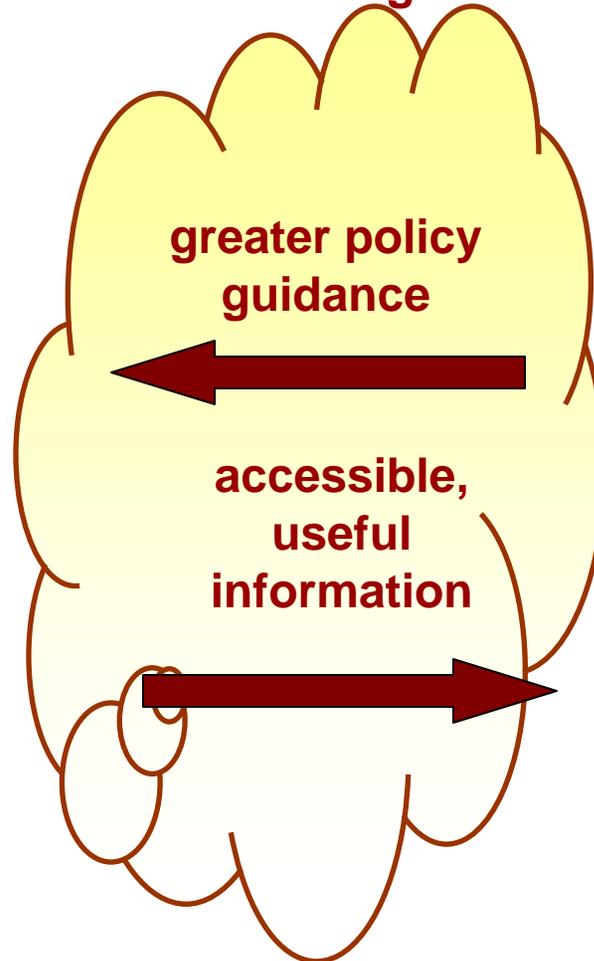
increased accessibility
of data

massive growth in data

increasing – but still
incomplete-
geographical coverage

data mining and
coordination possibilities
(Web 2.0)

what linkages?



LIFE SCIENCES POLICY PROCESSES

strong demand for
empirical data, e.g.

- neglected diseases
- control of plant
genetic resources
- use of genetic
resources under CBD

focus on practicalities
of:

- ensuring freedom to
operate
- constructing new
innovation pathways

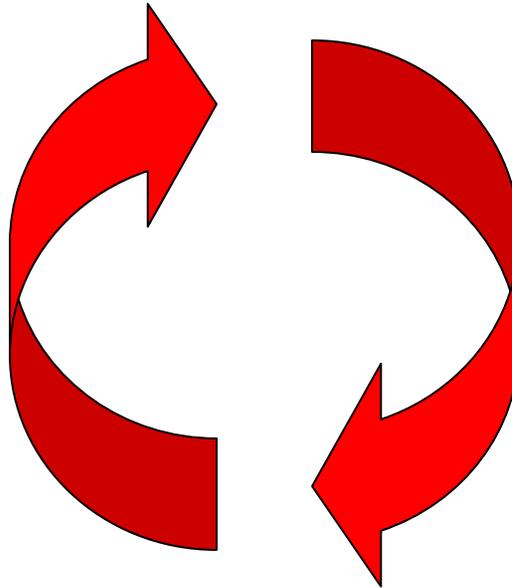
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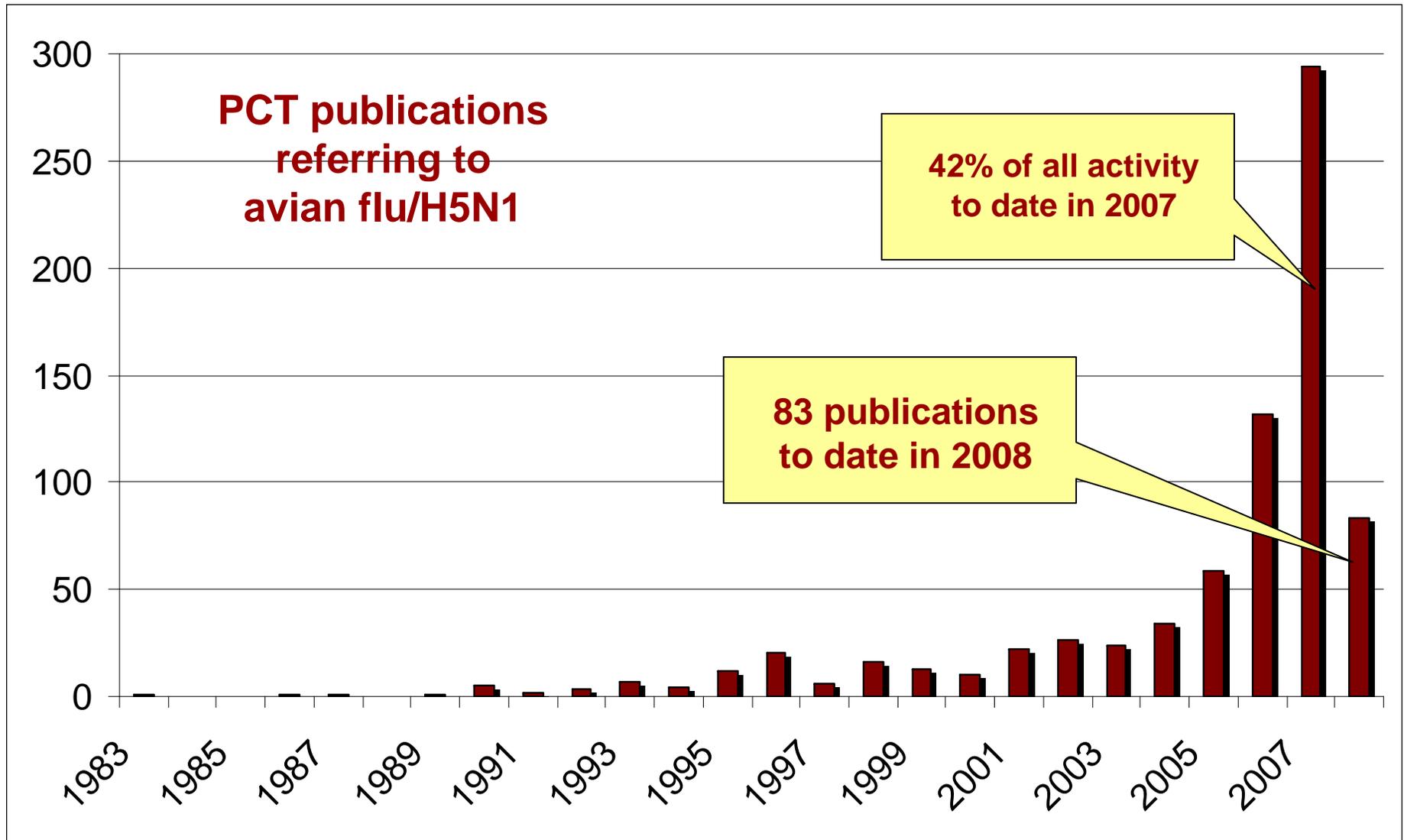
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desktop landscaping...
... some examples...

H5N1 – Avian flu



... is this recent patent activity...

- a very welcome indication of the massive investment of resources on a pressing public health need?
 - many new players (over 100), and a rich blend of public and private activity
- a potential obstacle to an effective global response to a pandemic – due to complexity and difficulty of analysis?
- or both?
- how to promote the former as against the latter?

many international players

1	VIROGENETICS CORPORATION	17	24	MEDICAL RESEARCH COUNCIL	4
2	MEDIMMUNE VACCINES, INC.	15	25	OCULUS INNOVATIVE SCIENCES, INC.	3
3	NOVARTIS VACCINES AND DIAGNOSTICS SRL	9	26	ISIS PHARMACEUTICALS, INC.	3
4	REGENTS OF THE UNIVERSITY OF MINNESOTA	8	27	AKZO NOBEL N.V.	3
5	SYNTRO CORPORATION	7	28	BOGOCH, Samuel	3
6	MERIAL LIMITED	6	29	YALE UNIVERSITY	3
7	CRUCCELL HOLLAND B.V.	6	30	WYETH	3
8	AGENCY FOR SCIENCE, TECHNOLOGY AND RESEARCH	6	31	UNIVERSITY OF MASSACHUSETTS	3
9	AVENTIS PASTEUR LIMITED	5	32	NORTH CAROLINA STATE UNIVERSITY	3
10	BAYER HEALTHCARE AG	5	33	ABIC LTD.	3
11	BIOVERIS CORPORATION	5	34	MASSACHUSETTS INSTITUTE OF TECHNOLOGY	3
12	DOW AGROSCIENCES LLC	5	35	MERIAL	3
13	ISIS INNOVATION LIMITED	5	36	BIOSCALE, INC.	3
14	UNIVERSITY OF GEORGIA RESEARCH FOUNDATION, INC.	5	37	EMBREX, INC.	3
15	KIMBERLY-CLARK WORLDWIDE, INC.	5	38	CONNAUGHT LABORATORIES, INC.	3 \
16	RECEPTORS LLC	5	39	BIOCRIST PHARMACEUTICALS, INC.	3
17	WISCONSIN ALUMNI RESEARCH FOUNDATION	4	40	NOVARTIS VACCINES AND DIAGNOSTICS GMBH & CO KG	3
18	ST. JUDE CHILDREN'S RESEARCH HOSPITAL	4	41	CORNELL RESEARCH FOUNDATION, INC.	2
19	GLAXOSMITHKLINE BIOLOGICALS S.A.	4	42	AUCHINCLOSS, Thomas, Ralph	2
20	SONG, Chang Seon	4	43	INTERVET INTERNATIONAL B.V.	2
21	LG ELECTRONICS, INC.	4	44	COMMONWEALTH SCIENTIFIC AND INDUSTRIAL RESEARCH ORGANISATION	2
22	THE UNIVERSITY OF HONG KONG	4	45	PROTEIN SCIENCES CORPORATION	2
23	VANDERBILT UNIVERSITY	4	46	OVAVAX, INC.	2
			47	CHIRON CORPORATION	
			48	CROSSBETA BIOSCIENCES B.V.	2
			49	BOYCE THOMPSON INSTITUTE FOR PLANT RESEARCH	
			50	NIMAN, Henry, L.	

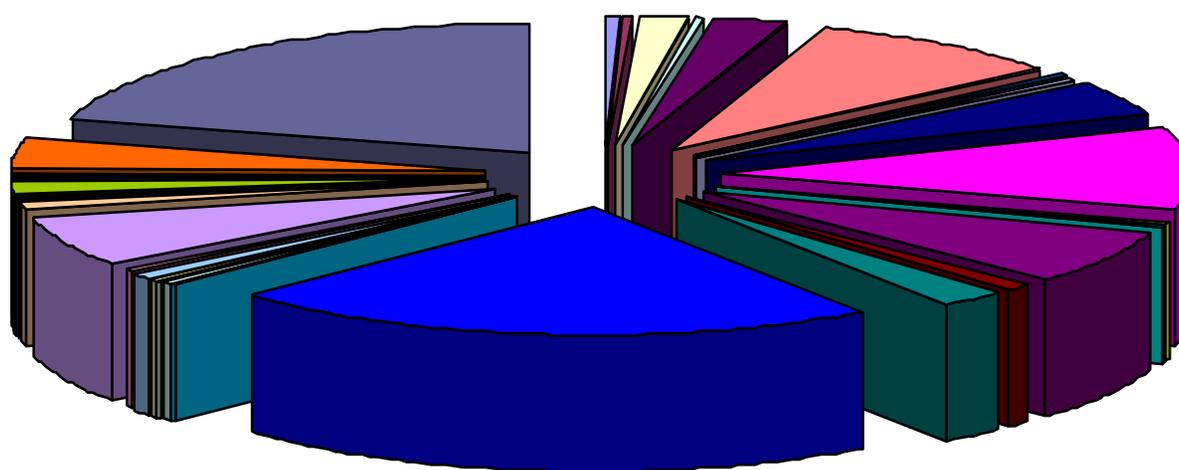
unresolved questions

there are many recent patent *applications*, but it is still necessary to clarify:

- what is the actual geographical reach of this surge of recent activity?
 - what implications for developing countries?
- what is the likely scope of patents that would be granted?
 - what differences between
- to what extent do they use genetic material from virus specimens?
- to what extent do they claim genetic material from virus specimens?

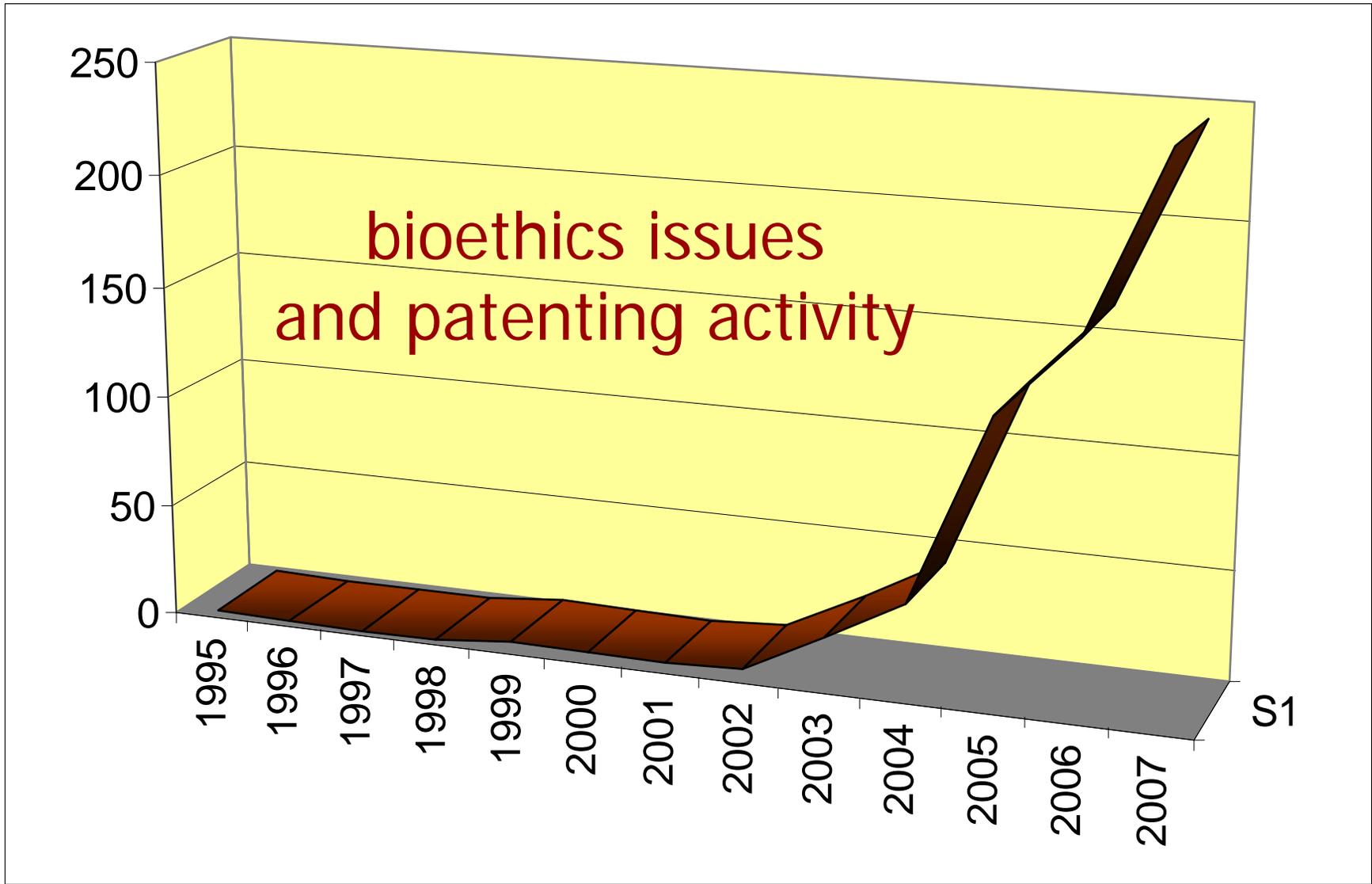
TK-GR patenting activity

medicinal substances derived from plants*
PCT applications published in 2005



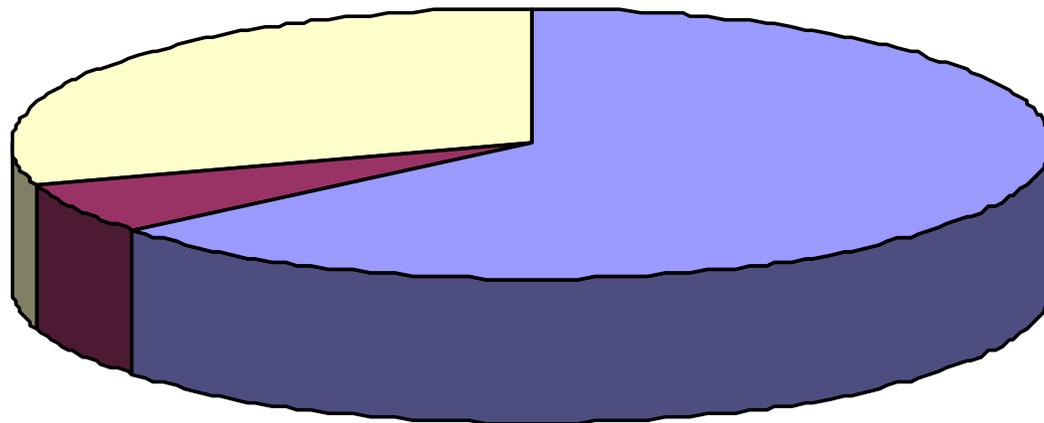
**2005 PCT publications: Medicines
derived from traditional plant sources**

- Australia
- Belgium
- Brazil
- Bulgaria
- Canada
- China
- Czech
- Egypt
- France
- Germany
- Hungary
- Iceland
- India
- Israel
- Italy
- Japan
- Madagascar
- Mexico
- Netherland
- Norway
- NZ
- Philippines
- ROK
- Russia
- Serbia
- South Africa
- Spain
- Sweden
- Switzerland
- UK
- USA

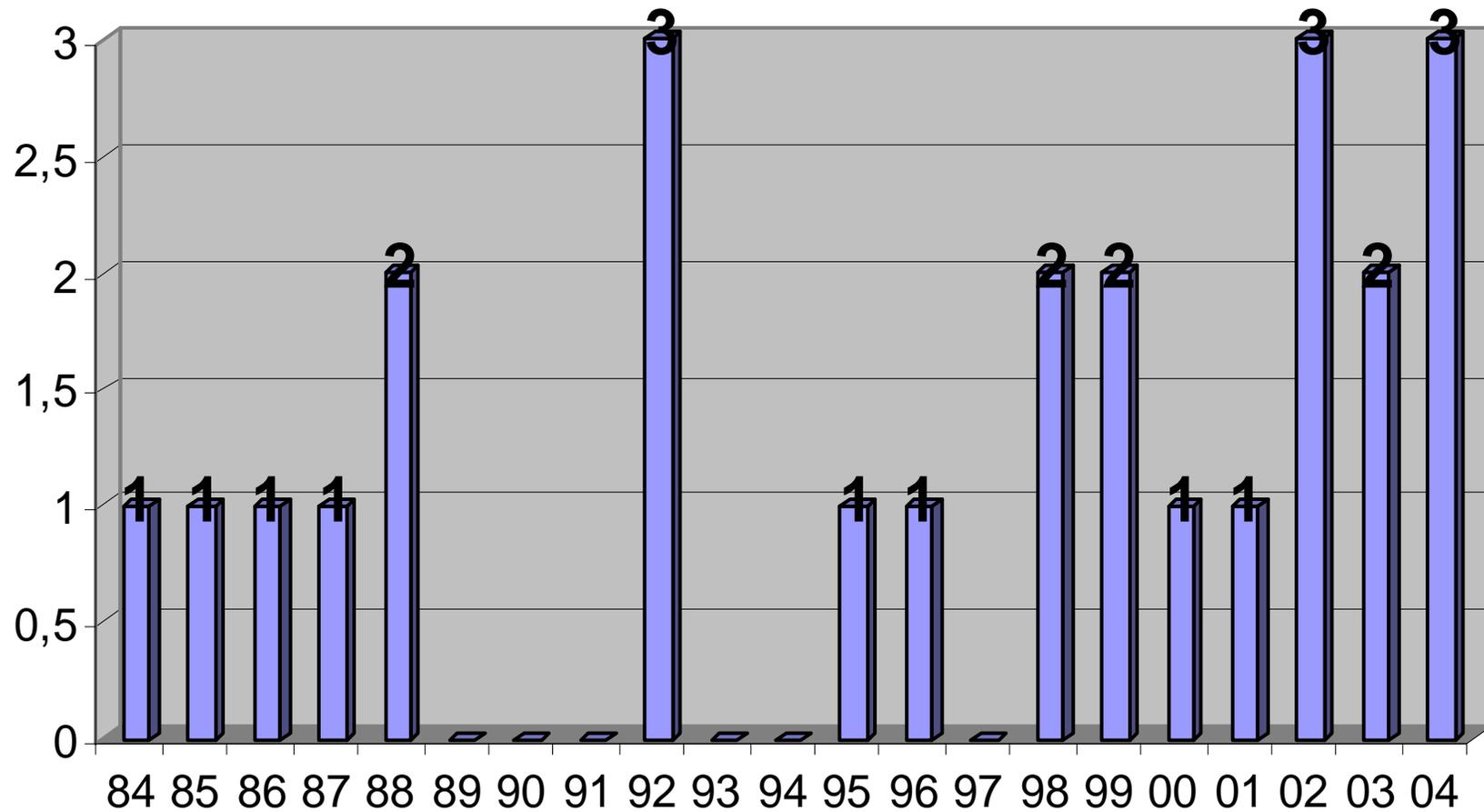


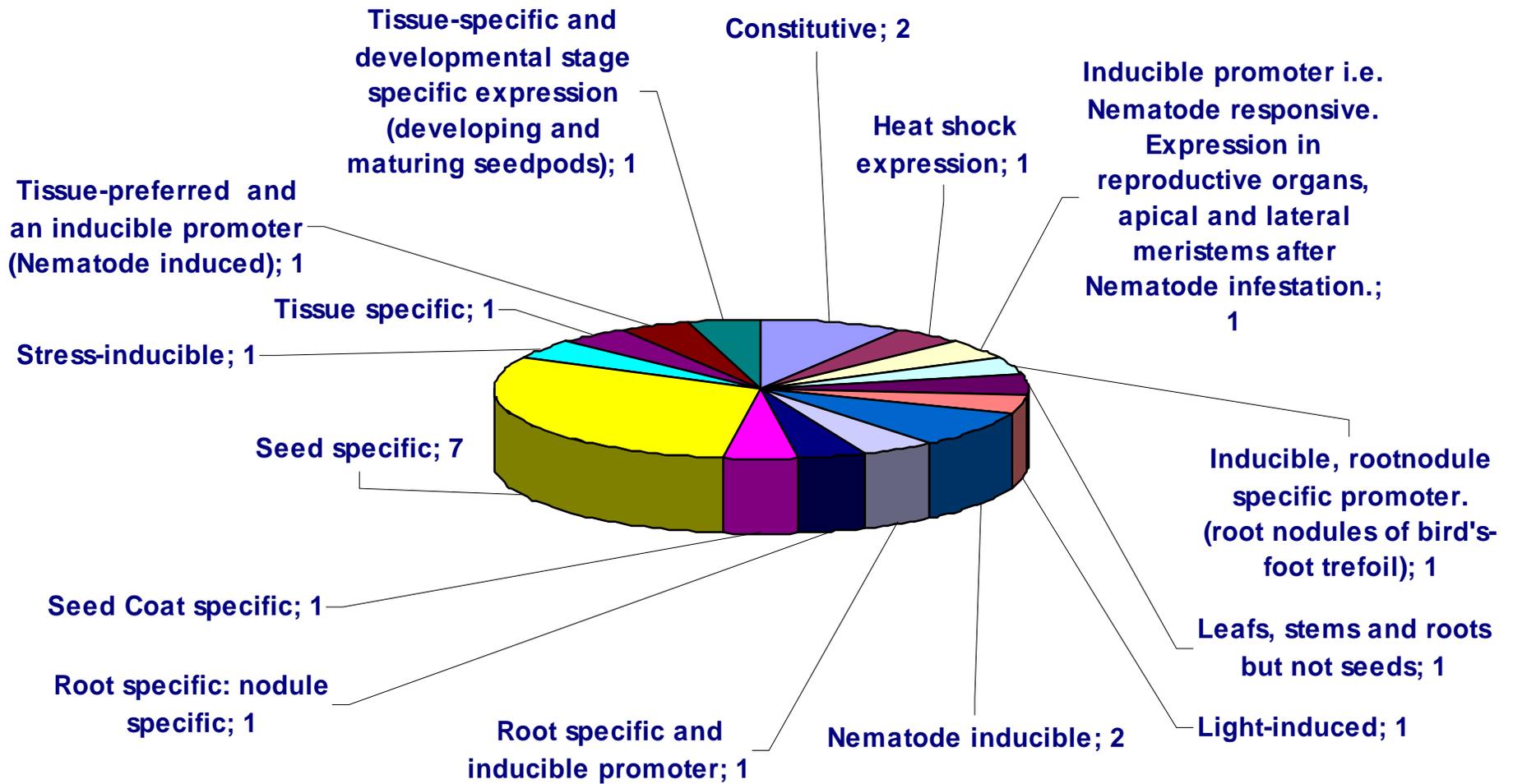
International patent applications on human, animal or plant cell lines by year of publication (1995 – 2007) (Source: Patentscope)

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

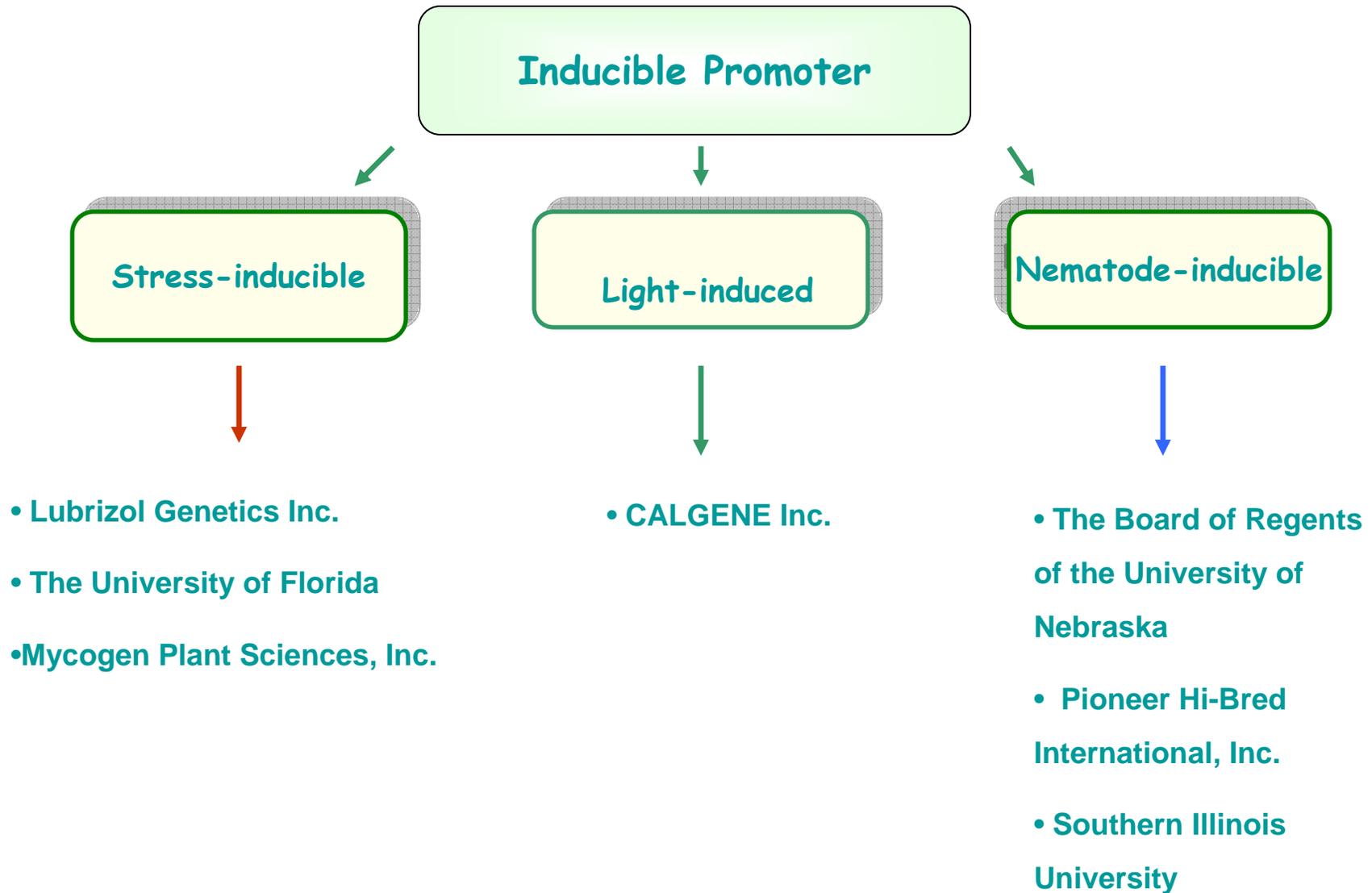


Access to and use of plant genetic resources: gene promoters in soybeans

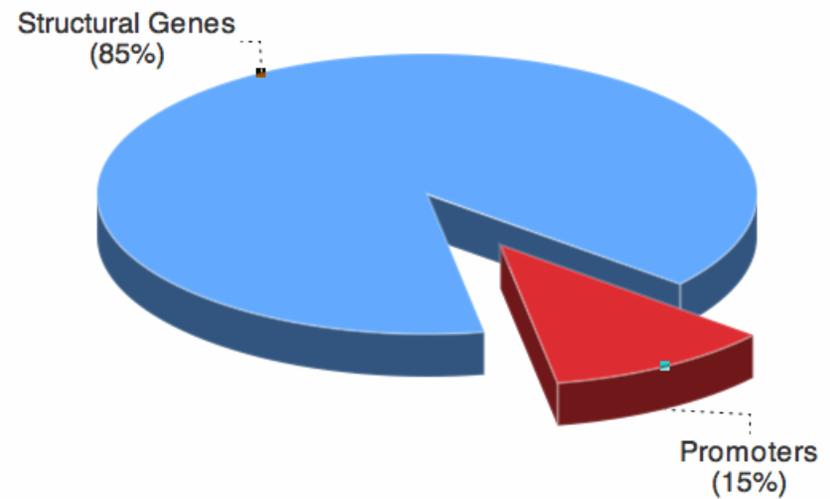
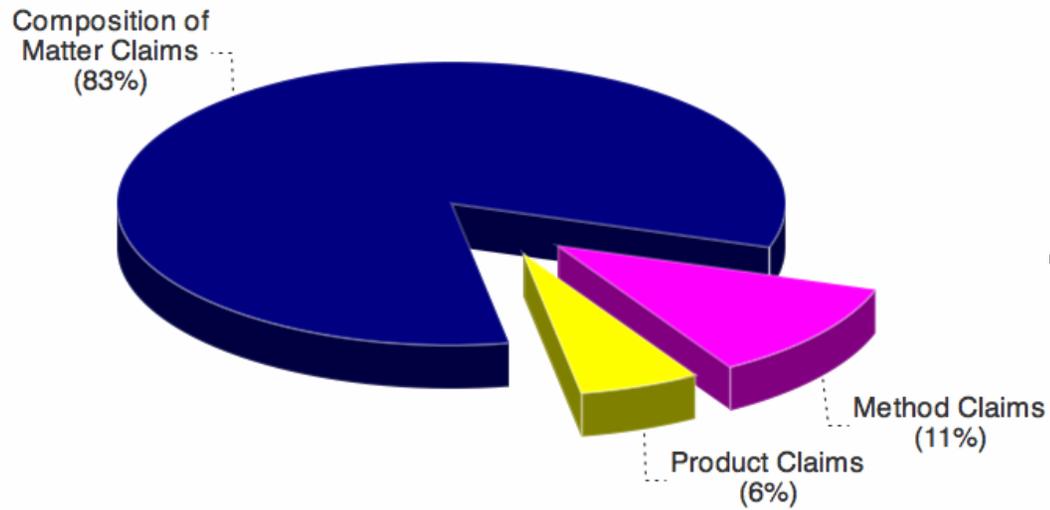




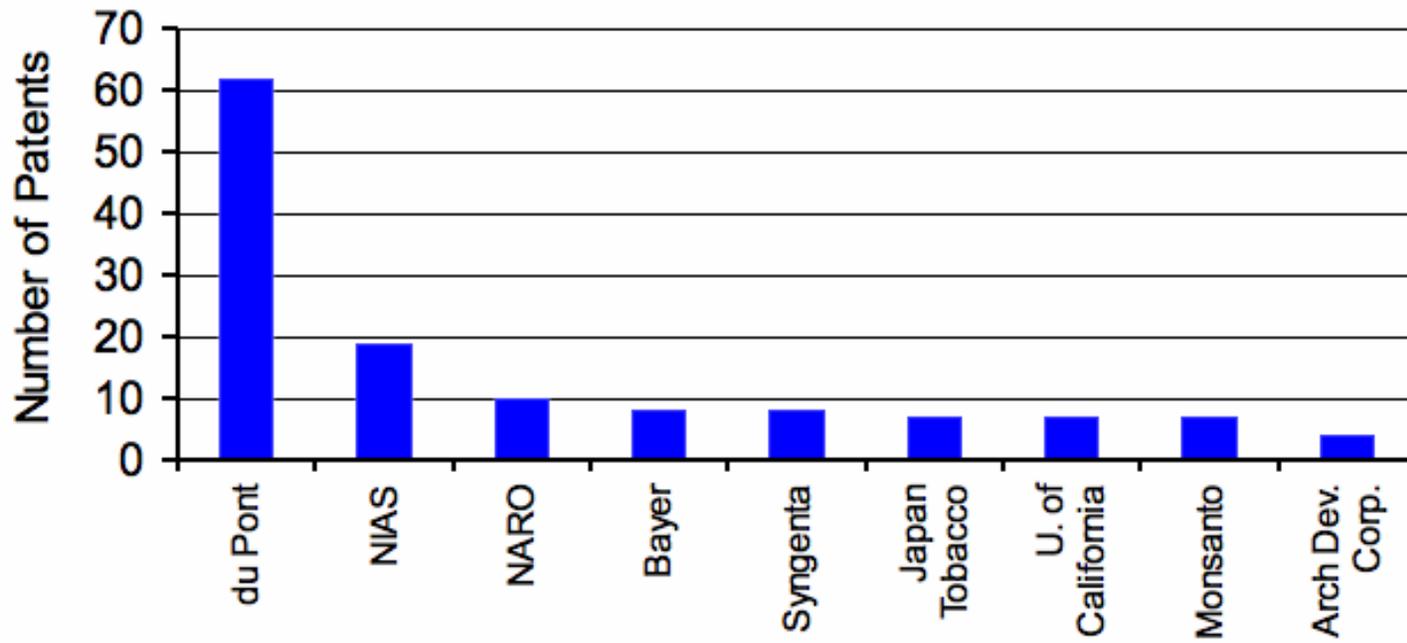
Major Assignees - Inducible Promoters of Soybean



cambia mapping of rice genome



Top Rice Sequence Assignees



- 182 granted US patents recite rice sequences;
 - 151 (83%) have claims that explicitly claim rice sequences or sequences highly similar to rice.
- only 0.26% of the rice genome and less than 1.0% of coding sequence is claimed in these U.S. patents.
- more patent applications - 313 U.S. applications - that recited rice sequences in claims, the sequences encompass about 74% of the rice genome.
- high degree of genome coverage is largely due to “bulk sequence applications” that are published with claims to large numbers of sequences.
- Despite the large fraction of genome coverage, it is unlikely that more than a tiny number of these sequences will actually be claimed in granted patents; already approximately 30% of the patent applications have been abandoned and U.S. patent law currently only allows one sequence to be claimed in a patent.
- assignee with the largest number of rice sequence patents is du Pont, which includes Pioneer Hi-Bred. Monsanto has filed a large number of the bulk sequence applications.

from data...
to information...
to knowledge...
for life science policymakers

- Trends in patenting activity for key technologies
- Access to knowledge: patents as disclosure
- Freedom to operate/opportunities for partnership and technology transfer
- Tracking use of genetic resources

some technical obstacles

- search focus: false positives/false negatives
- search capacity: the human element
- timeliness: towards real time legal status?
- geographical reach: coordination of data, digitization of diverse records
- claims applied for vs. claims as granted
- claims vs. disclosure: technical knowledge or knowledge of legal state of play
- bioinformatics: DNA, polypeptide sequence data

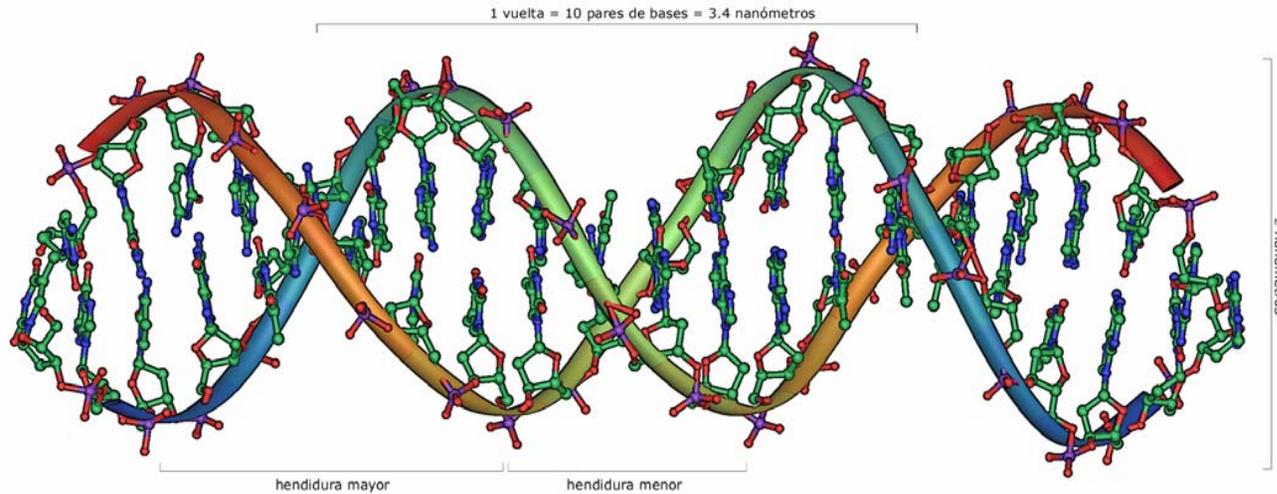
some policy obstacles

- greater clarity and precision of policy questions
- what technologies matter most?
- what are the needs?
 - trend information, identifying new opportunities
 - implications for technology transfer
 - patents as a signal of willingness to offer technology?
 - an obstacle, or a spur to invent around?
 - ‘freedom to operate’
 - but at the macro or micro level? one product, or a field of technology?
 - but freedom to do what? plant, breed, research, transform?
 - diversity in outcomes
 - geographically
 - from applications into granted patents

what is distinctive about life sciences patent landscaping?

- Fundamental policy issues:
 - health, food, the environment
- ‘Reach through’ issues:
 - impact of research tool patents on downstream products
- Strong bioethical flavour
 - patent information as a means of technology monitoring
- Concerns about equities of using genetic resources
 - tracing, surveying use patterns of specified genetic resources

what is distinctive about life sciences patent landscaping?



Could the greatest challenge – grappling with voluminous sequence data – potentially become the greatest opportunity?

-using sequence data to link between patent documents and

- records of accessions to genetic resources
- licensing information
- prior art
- plant varieties

what is distinctive about life sciences patent landscaping?

not a zero sum
game...

