Access to Medicines, Patent Information and Freedom to Operate

linking empirical data to policy processes:
strengthening the base for
policymaking on access to medicines

Article 7
Objectives

The protection and enforcement of intellectual property rights should mutual advantage of producers and users of technological knowledge transfer ...ucers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.

Article 29
Conditions on Patent Applicants

1. Members shall require that an applicant for a patent shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art and may require the applicant to ... carrying out the invention known to ...

from data to policy to outcomes

Public health and access to medicines policy concerns:

- directions of innovation vis-a-vis public health needs
- optimal focusing of research and development resources
- freedom to operate in product development
- freedom to operate in access to medicines

Crosscutting issues:

- promoting innovation – its value and direction
- ensuring equitable access to fruits of innovation
- promoting technology diffusion

Common needs:

- From raw data, to…
- … accessible, trusted, neutral and relevant information
- … that informs and illuminates policymaking processes
- … and practical innovation and procurement strategies

current policy questions

- How neglected are neglected diseases? Is this changing?
  - Who is undertaking research?
  - What are the trends in research?
  - Is research bearing fruit – progressing down the drug development pipeline?
- Who owns biomedical research tools? Diagnostic tools?
- Who is using traditional medical knowledge as the basis of research?
  - What are they doing with it?
- Freedom to operate:
  - for medical research and development?
  - for procurement and production of medicines?
- e.g. HIV AIDS treatments:
  - patent holdings on current treatments
  - is this different for new treatment regimens? How? Where? Who?

...ellectual property-related technolog...
... the mandate of an appropriate WIPO body.

30. WIPO should cooperate with other IGOs to provide to developing countries, inc... LDCs, upon request, advice on how to gain access to and make use of intellectual property-related information on technology, particularly in areas of special interest to the requesting parties.

31. To undertake initiatives agreed by Member States, which contribute to transfer of technology to developing countries, such as requesting WIPO to facilitate better access to publicly available patent information.

To have within WIPO opportunity for exchange of national and regional ex... ...ormation on the links between IPRs and comp...

...ES
...eative ...
...blic P...

Cluster F: Other issues

...eloping countries

(c) facilitate widespread access to, and promote further development of, including, if necessary, compiling, maintaining and updating, user-friendly global databases which contain public information on the administrative status of health-related patents, including supporting the existing efforts for determining the patent status of health products, in order to strengthen national capacities for analysis of the information contained in those databases, and improve the quality of patents.

... stimulate collaboration among pertinent national institutions and rele... ...ment departments, as well as between national, regional and int... ... to promote information sharing relevant to public h...

WTO: 2010 NEWS ITEMS

2 March 2010
INTELLECTUAL PROPERTY

Members ask: Is the 'Par.6' system on intellectual property and health working?

WTO: 2010 NEWS ITEMS

26 and 27 October 2010
TRIPS

Little-used 'Par.6' system will have its day,

The 26—27 October 2010 meeting of the WTO intellectual property
acquire generic versions of patented medicines, but with little cha
biopiracy and on developments outside the WTO on intellectual pro

NOTE: Par.6. The Trade-Related Aspects of Intellectual Property Rights (TRIPS) Council reviews the so-called Paragraph 6 system annually, but for the first time since the system was agreed in 2003, a whole day was set aside for WTO members to discuss this agenda item in a more structured way, the length of the debate on this and other topics taking the meeting late into the evening of 27 October.

JARGON BUSTE

- CBD: Convention Biological Diversit
- geographical indications (GIs): names (or words associated with a used to identify

the context of patent landscaping for public health policymakers

policymakers to explore issues, make assessments, set priorities, make policy on health policy 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 is patented; where and where not; and by who? and what are the trends: •upstream technologies •research tools •vaccines •diagnostics •treatments •adaptations	Implications for research and development access and procurement in developing world especially - what is the impact for future developments - forecasting emerging technologies -e.g, new vaccine technologies	illuminating the options for • practical IP management •innovation policy •procurement strategies •regulatory intervention •use of flexibilities and policy options

Patent information as a tool of public policy

Policymakers look beyond the raw data 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 health innovation and access to medicines.

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
    - effective procurement strategies
    - dissemination of existing technologies
    - research and development
    - packaging and combining technologies
    - addressing neglected needs in health

Improved analytical tools and access to patent information

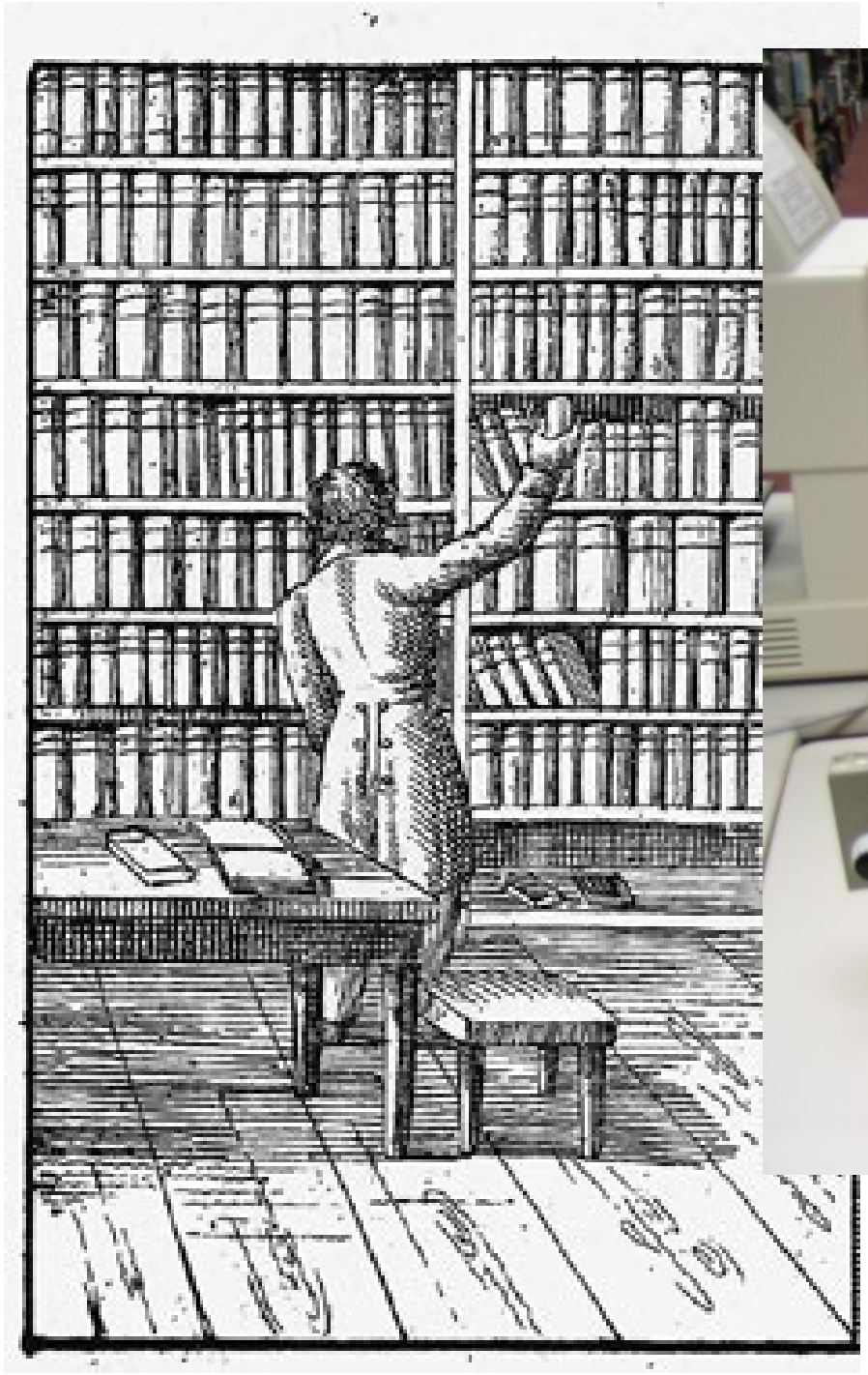
A lot more data, but also vastly better access to it:

- Rapid growth in the use of the patent system
  - and in the diversity of users,
- matched by better tools for synthesizing and probing these data

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 public health issues.




Canon
Scanner 400
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- Territoriality and data asymmetries

countries for which data critically needed

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countries for which data is available

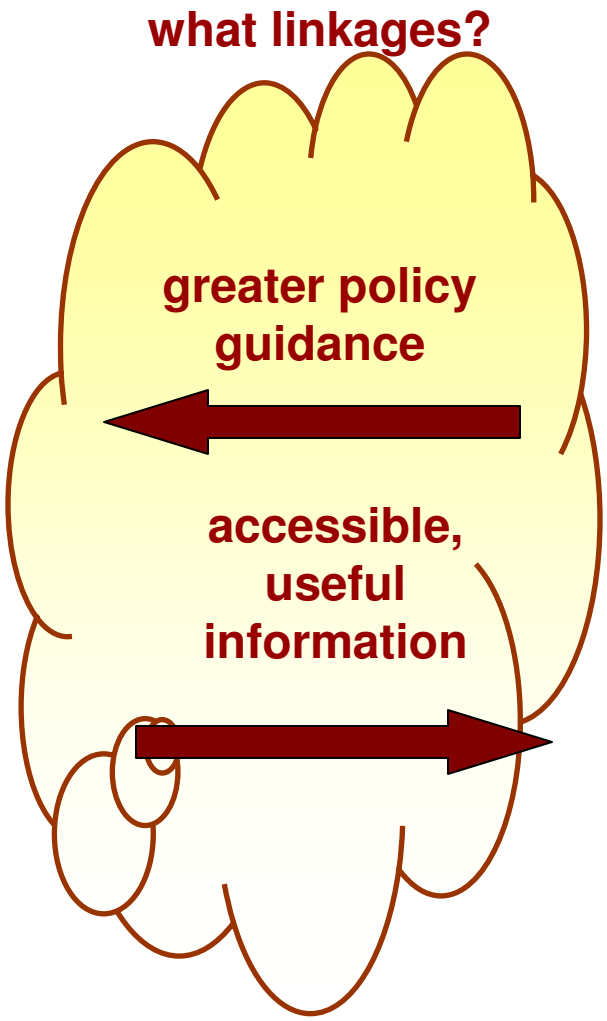
PATENT INFORMATION

increased accessibility of data

massive growth in data

increasing – but still incomplete- geographical coverage

data mining and coordination possibilities (Web 2.0)



PUBLIC HEALTH POLICY PROCESSES

strong demand for empirical data, e.g.
- neglected diseases
- ARVs, vaccines

focus on practicalities of:

-ensuring freedom to operate in research and development

-optimizing drug procurement strategies

- constructing new innovation pathways

PATENT INFORMATION

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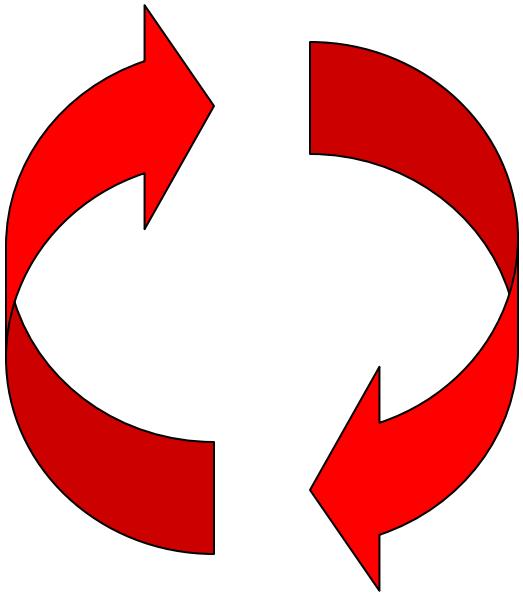
a policy dialogue



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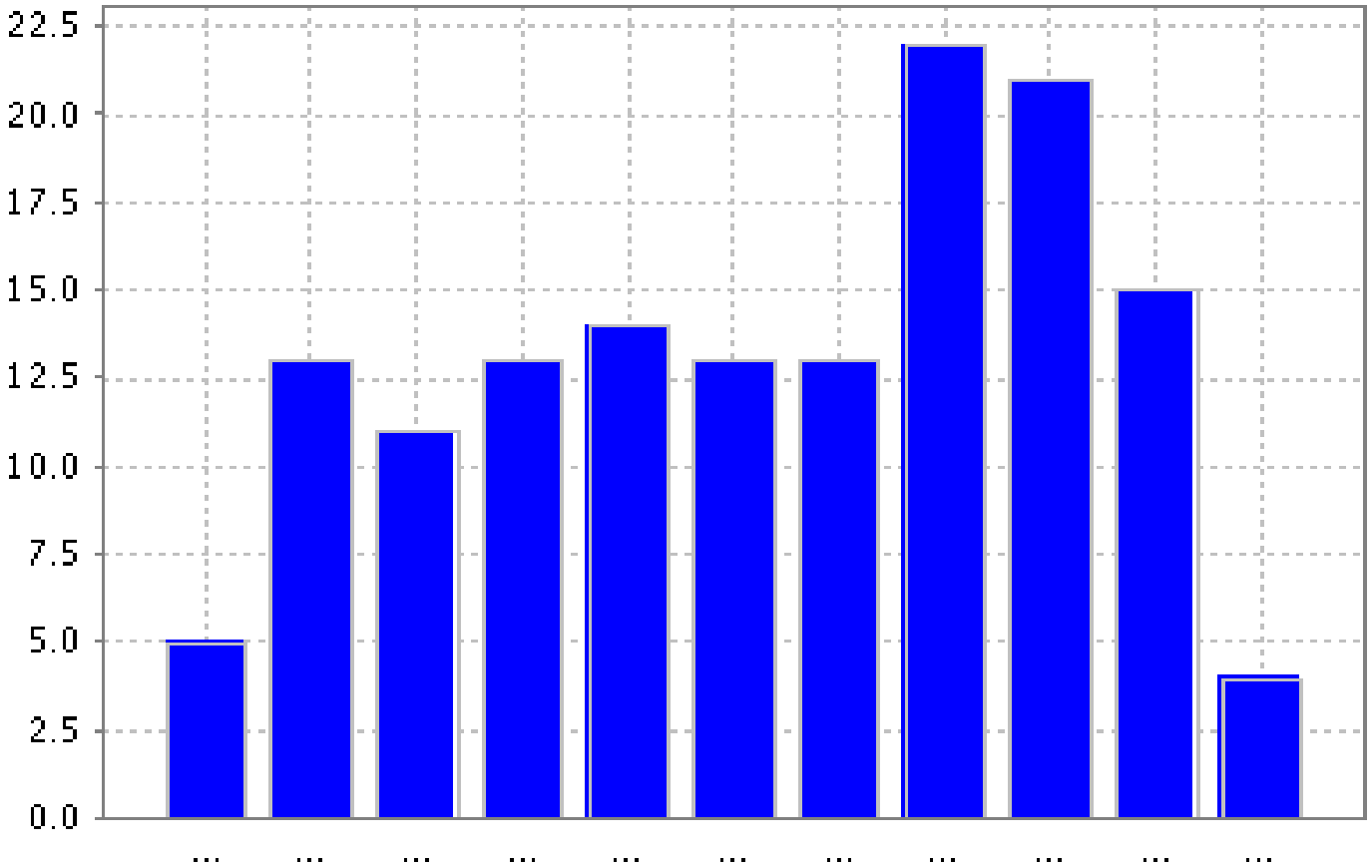
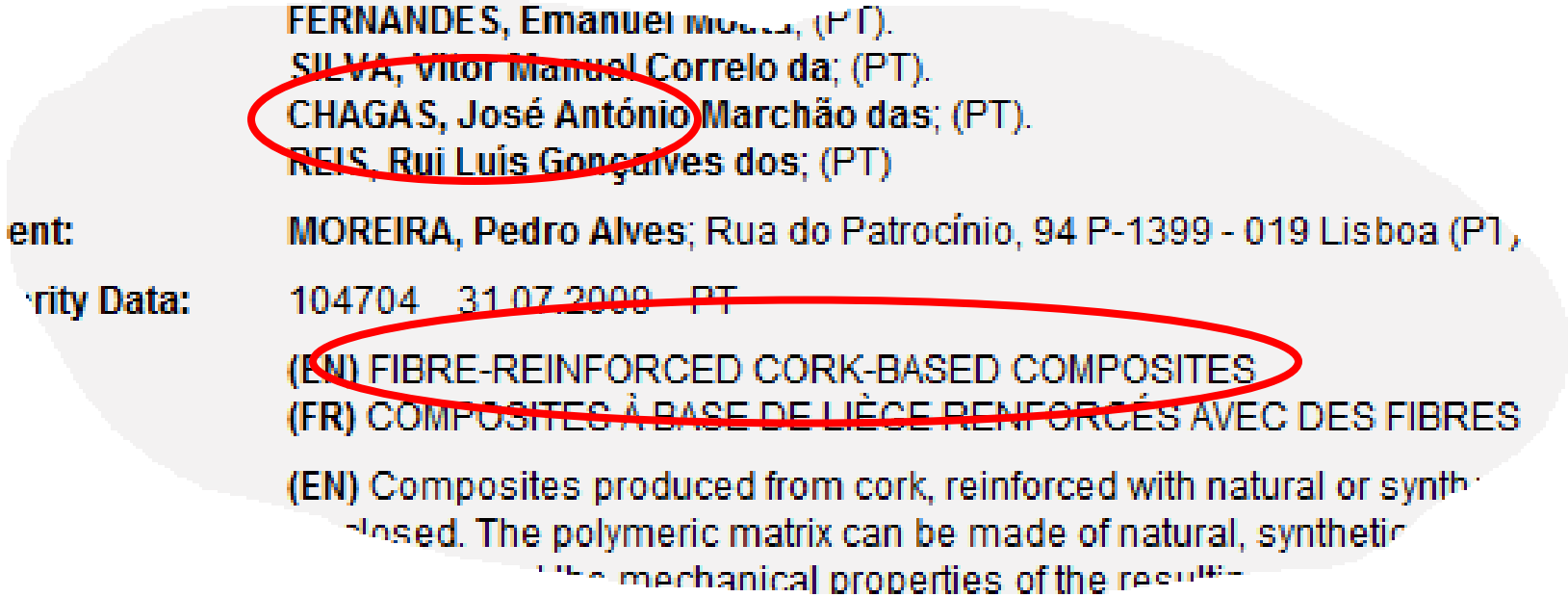
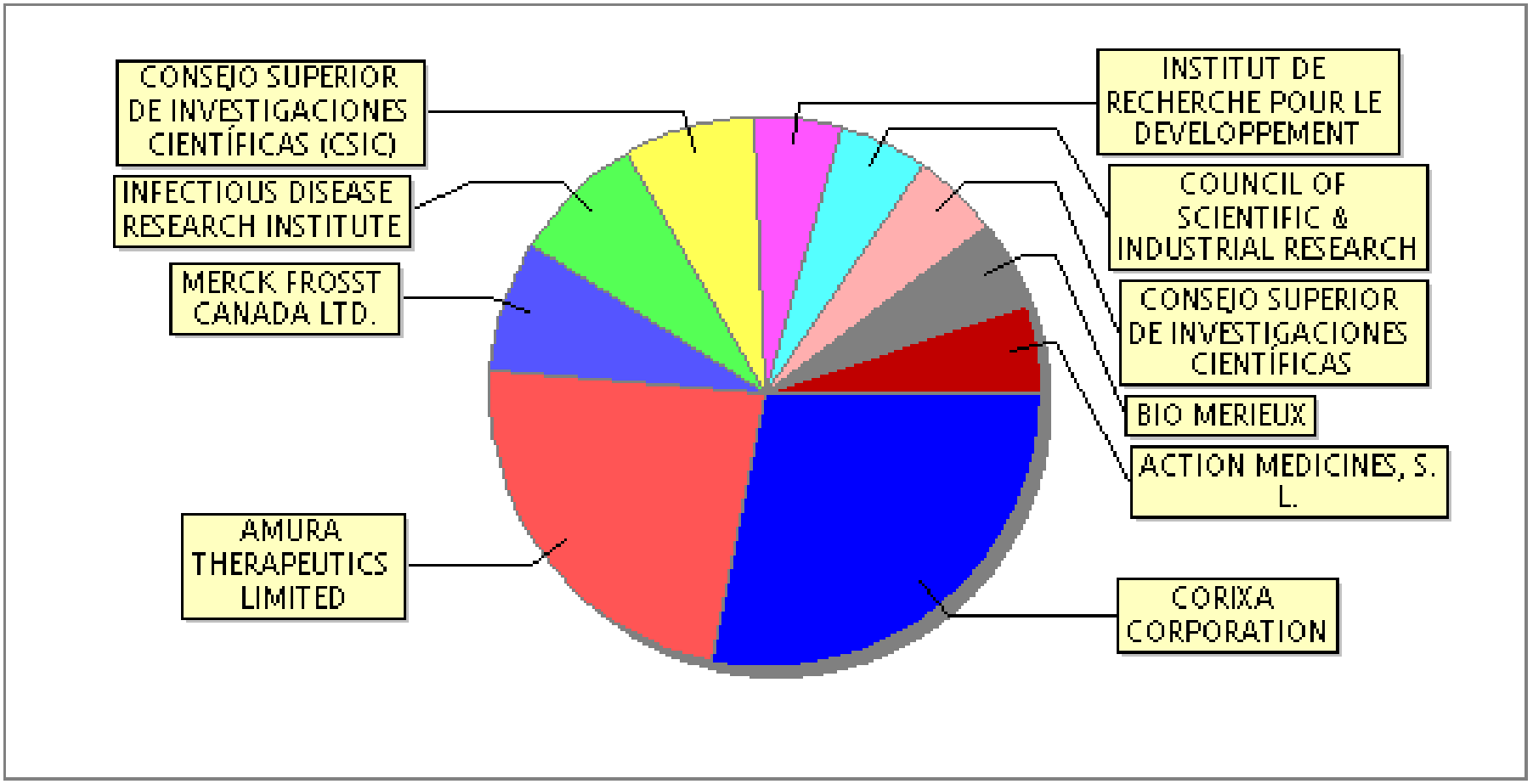
15 minute desktop landscaping…

international applications on neglected diseases: Chagas, trypanosomiasis leishmaniasis



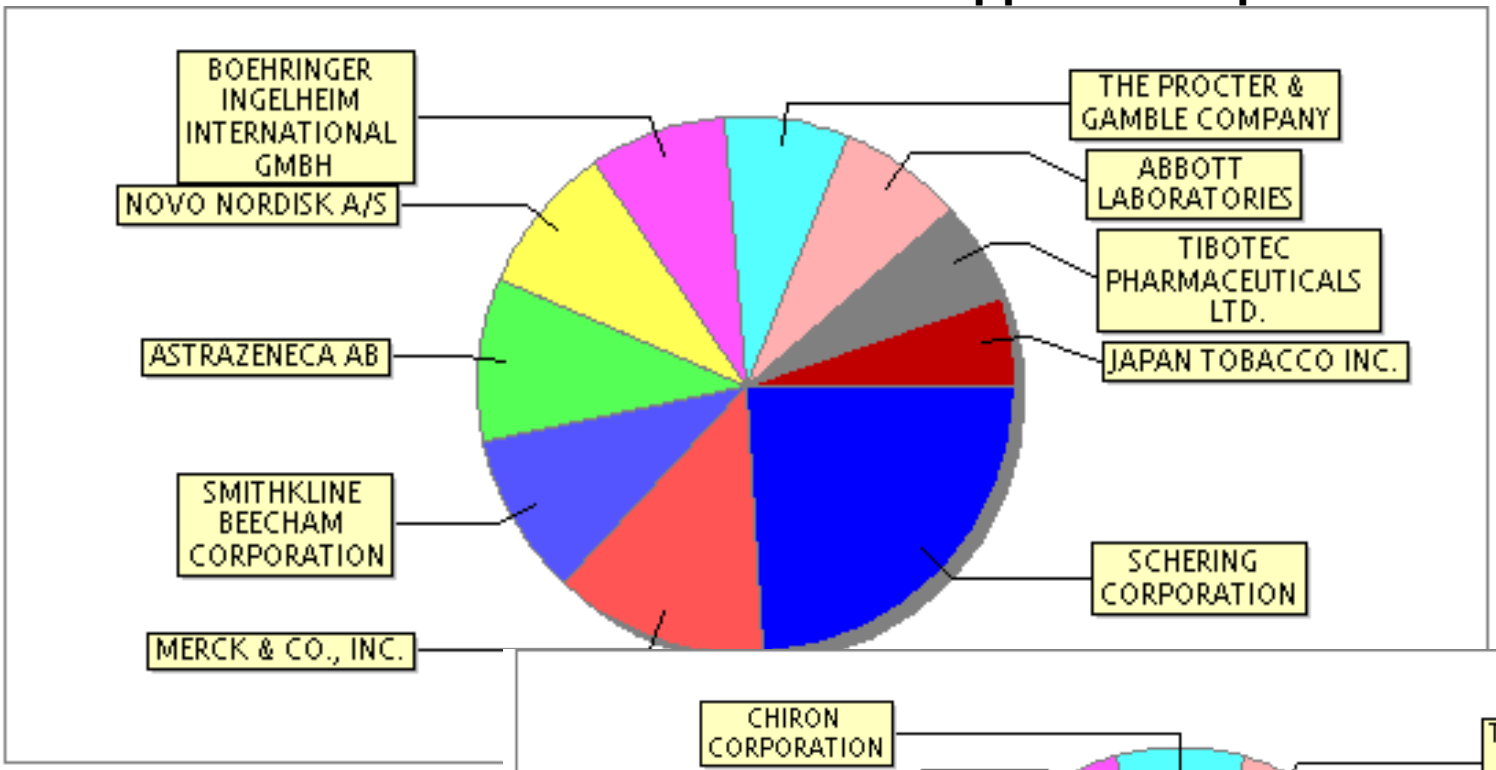
beware false positives



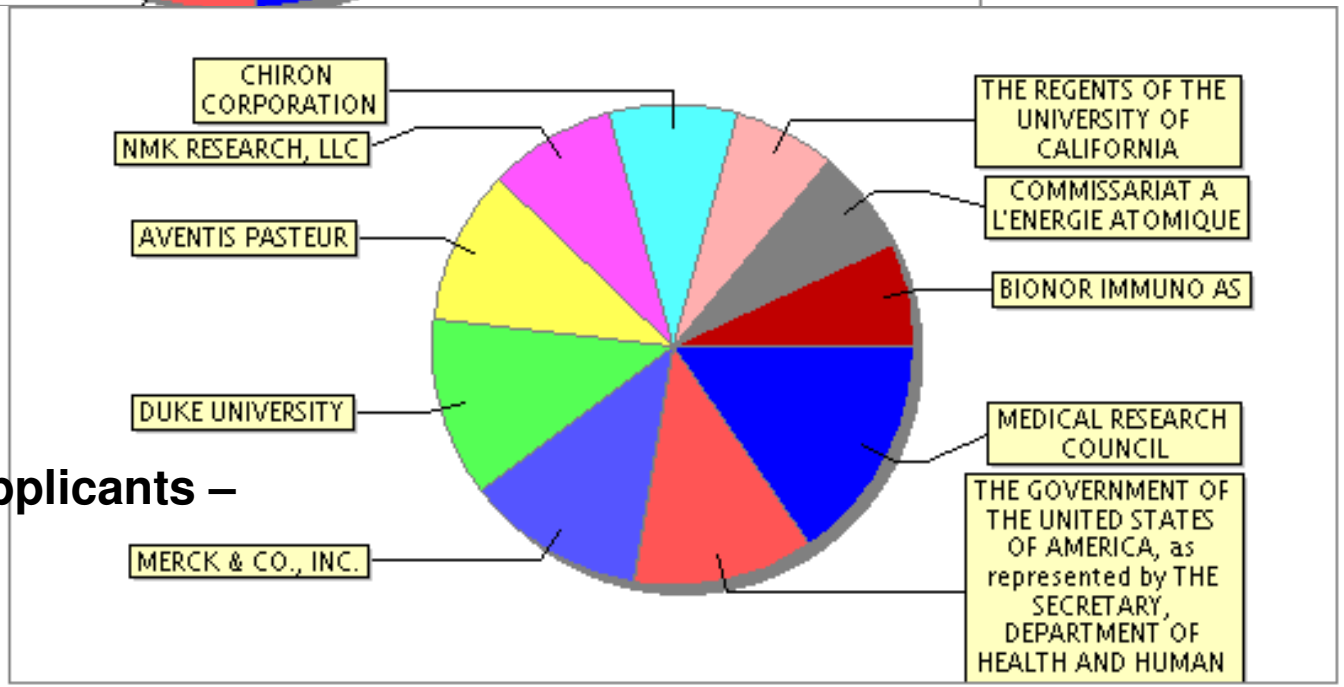


key international applicants

Main international applicants – protease inhibitors

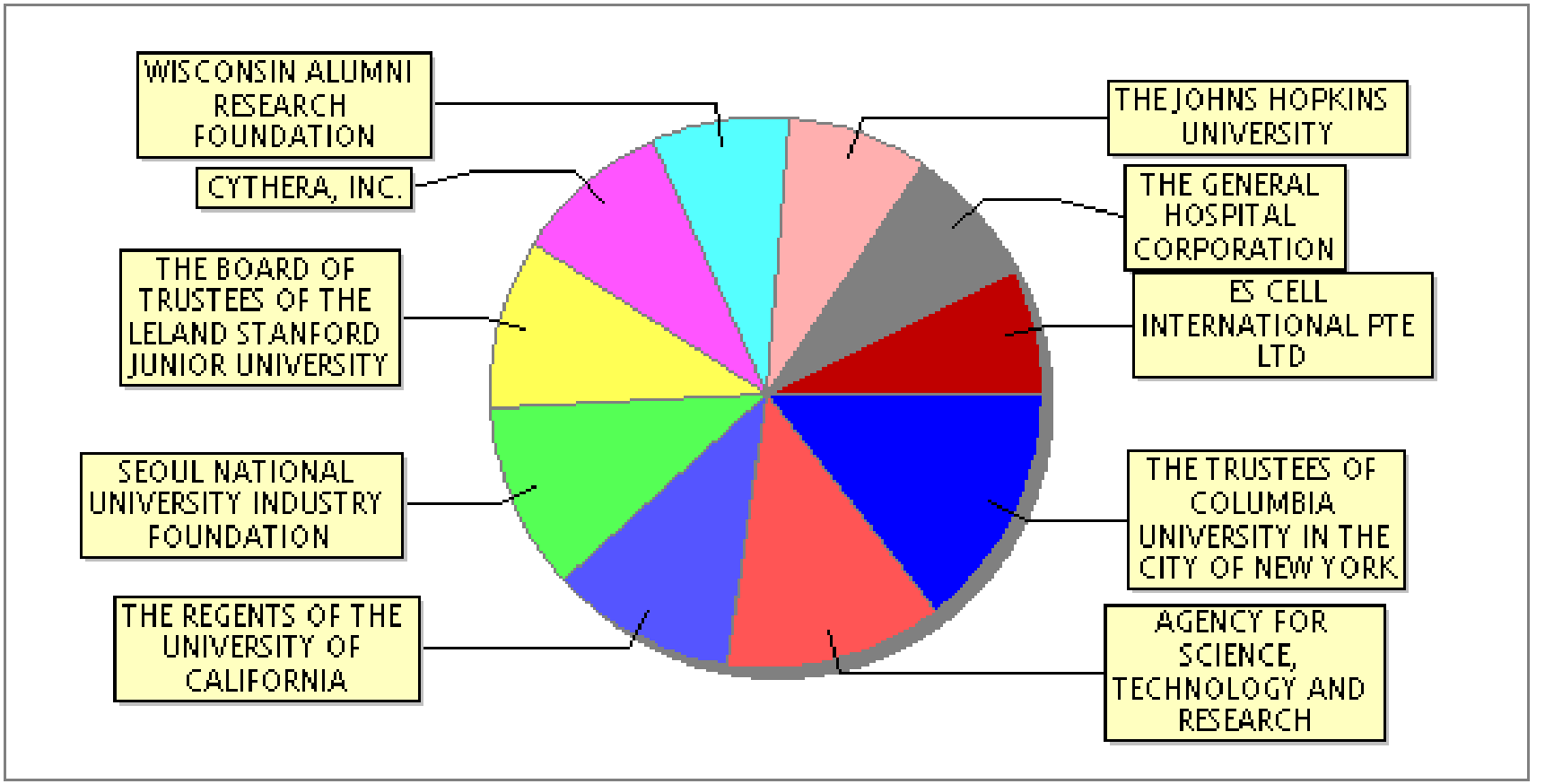


Main international applicants – HIV AIDS vaccines



research tools and cell lines

top international applicants on human, animal & plant cell lines



from data…
to information…
to knowledge…
for health policymakers

- Trends in patenting activity for key technologies
- Access to knowledge: patents as disclosure
- Freedom to operate/opportunities for partnership and technology transfer
- Informed and effective

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? procure, compete, research, transform?
  - diversity in outcomes
    - geographically
    - from applications into granted patents