

Setting the scene:  
IP and regulation  
in the life sciences

- Rapid evolution in the life sciences - in biomedical research, in agricultural biotechnology - has spurred two related trends, of relevance to policymakers: sharp increases in patenting activity, and strong public interest in ensuring appropriately rigorous regulation of new biotechnologies.
- And the interaction between intellectual property protection and regulatory mechanisms in the life sciences has itself become a concern for policymakers, from the point of view of innovation policy, public interest regulatory interventions, and trade and economic relations.

- This symposium takes place within a series of policy symposia that are intended to identify and clarify the intellectual property dimension in the life sciences. They are addressed to a wide range of stakeholders, including international policymakers, government agencies, legislators, delegates, and civil society actors.
- The symposium offers an open forum for exchanging information and experiences in relation to the interaction between life sciences innovation and the intellectual property system. It is explicitly not aimed at assessing or influencing discussions in any other forum and will not produce any formal outcome.

The forms of interaction between IP and regulation of life sciences that will be surveyed include:

- the IP dimension of protection of regulatory data,
- exceptions to patent rights for regulatory processes
- the grant of patent term extensions to compensate for regulatory requirements
- the challenge of new technologies - biological pharmaceuticals
- diverse approaches to linking patent protection with regulatory approval

# Patents 101

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An Act concerning Monopolies and Dispensations with Penal Laws, and the Forfeitures thereof (*z* ).  
[A.D. 1623]

"Forasmuch as your most excellent majesty in your royal judgment, and of your blessed disposition to the weal and quiet of your subjects, did in the year of our Lord God 1610 publish in print to the whole realm, and to all posterity, that all grants of monopolies, and of the benefit of any penal laws, or of power to dispense with the law, or to compound for the forfeiture, are contrary to your majesty's laws, which your majesty's declaration is truly consonant, and agreeable to the ancient and fundamental laws of this our realm, and which your said majesty further graciously pleased to command

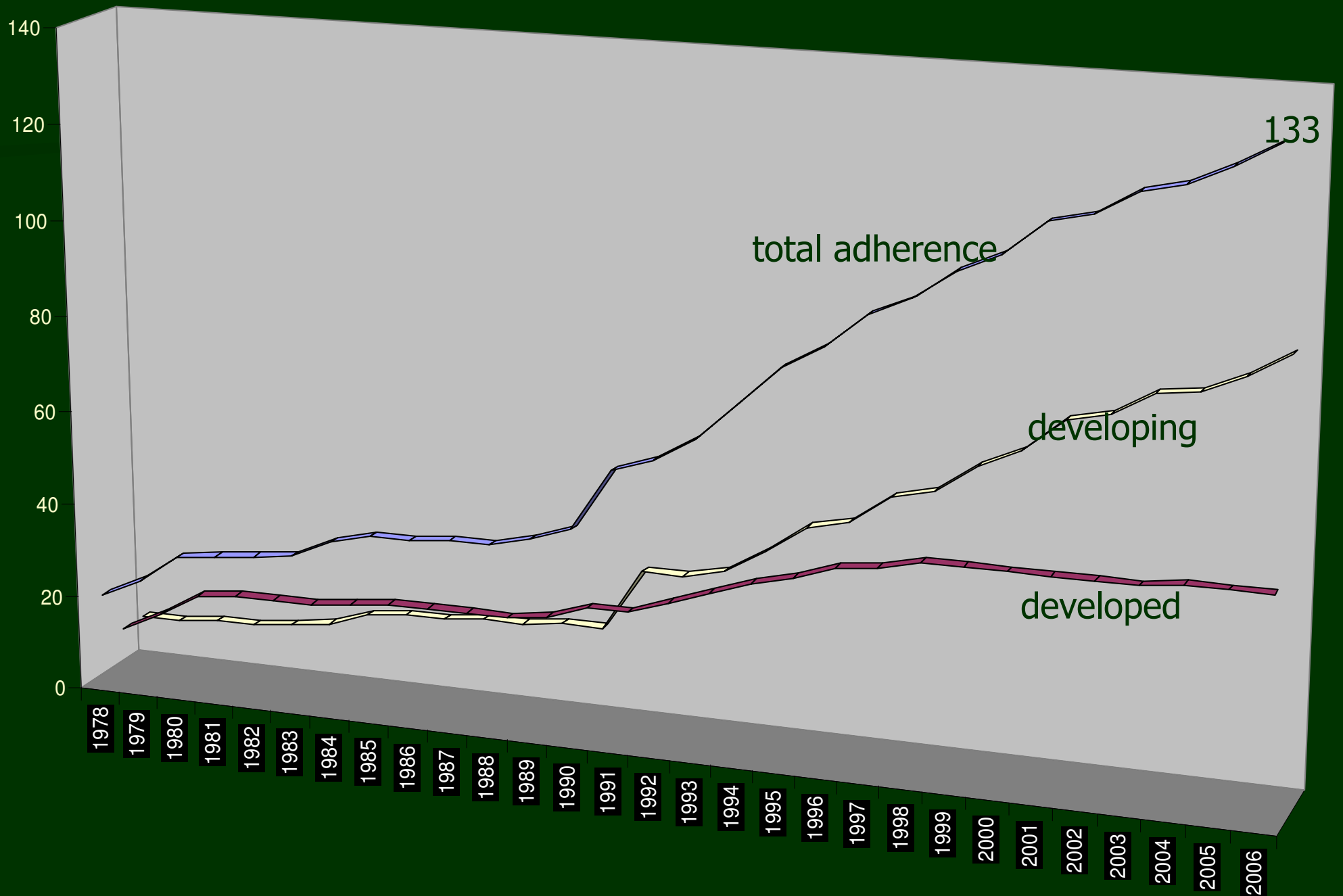
6 (*a* ). Provided also, that any declaration before mentioned shall not extend to any letters patents (*b* ) and grants of privilege for the term of fourteen years or under, hereafter to be made, of the sole working or making of any manner of new manufactures within this realm (*c* ) to the true and first inventor (*d* ) and inventors of such manufactures, which others at the time of making such letters patents and grants shall not use (*e* ), so as also they be not contrary to the law nor mischievous to the state by raising prices of commodities at home, or hurt of trade, or generally inconvenient (*f* ): the same fourteen years to be accounted from the date of the first letters patents or grant of such privilege hereafter to be made, but that the same shall be of such force as they should be if this act had never been made, and of none other (*g* )

- upon misinformations and untrue pretences of public good many such grants have been unduly obtained and unlawfully put in execution, to the great grievance and inconvenience of your majesty's subjects, contrary to the laws of this your realm, and contrary to your majesty's royal and blessed intention, so published as aforesaid:" for avoiding whereof and preventing of the like in time to come,
- BE IT ENACTED, that all monopolies and all commissions, grants, licenses, charters, and letters patents heretofore made or granted, or hereafter to be made or granted to any person or persons, bodies politic or corporate whatsoever, of or for the sole buying, selling, making, working, or using of anything within this realm or the dominion of Wales, or of any other monopolies, or of power, liberty, or faculty, to dispense with any others, or to give licence or toleration to do, use, or exercise anything against the tenor or purport of any law or statute;
- ...
- are altogether contrary to the laws of this realm, and so are and shall be utterly void and of none effect, and in no wise to be put in ure or execution

# an increasingly international international system

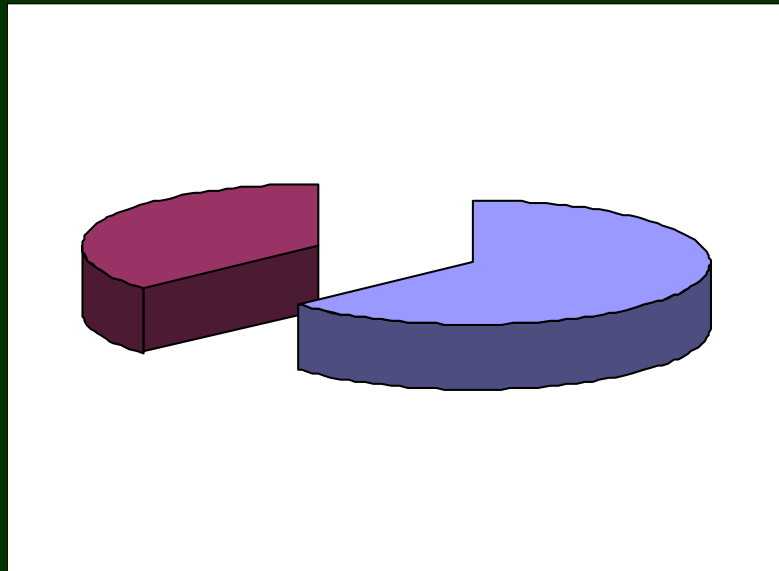
- In the past decade
  - WTO TRIPS Agreement induces considerable convergence of legal standards,
    - conspicuously in the area of pharmaceutical patents and protection of clinical trial data
  - Major growth in adherence to optional, *à la carte*, elements of the international system
  - Increasingly diverse usage of the system - by researchers in, and from, developing countries, and by public sector institutions
    - again, conspicuously so in the field of human health

# Participation in the international system: adherence to the Patent Cooperation Treaty

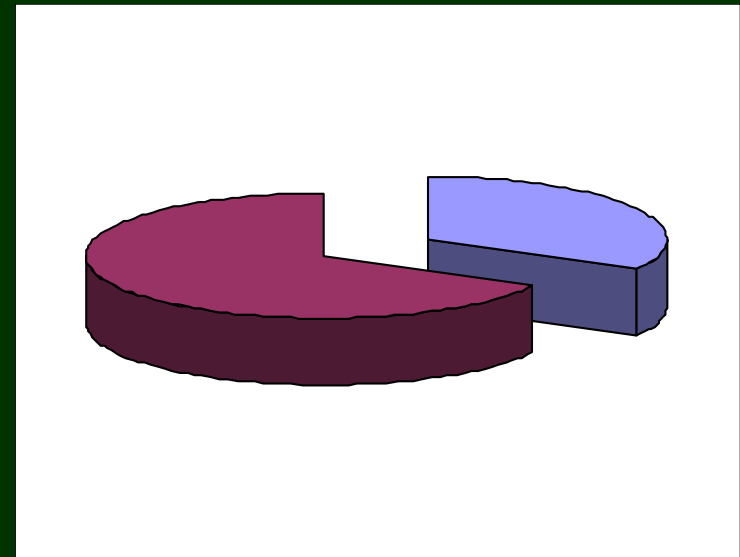


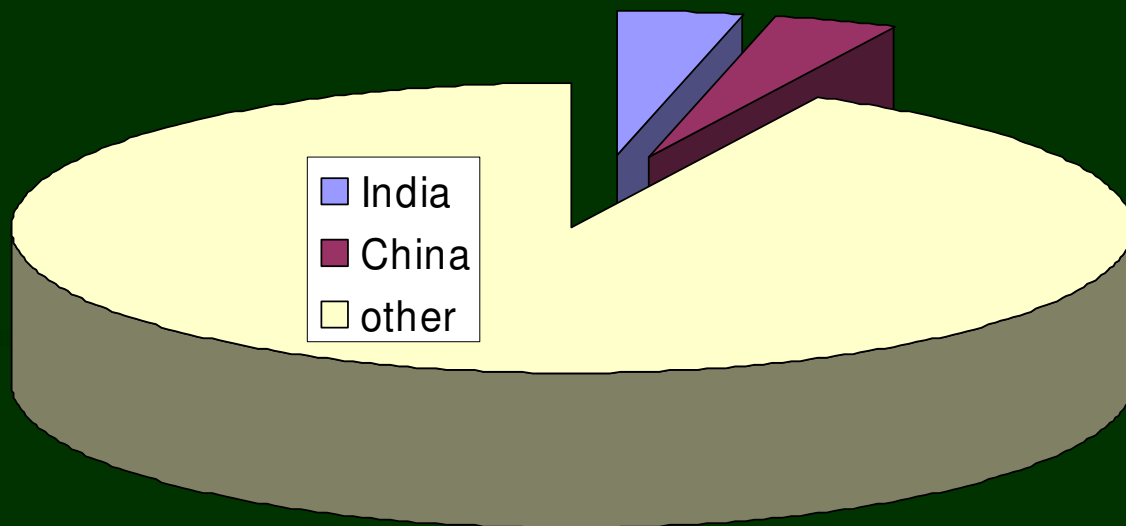
# Participation in the international system: PCT adherence developing countries : developed countries

1980



2006



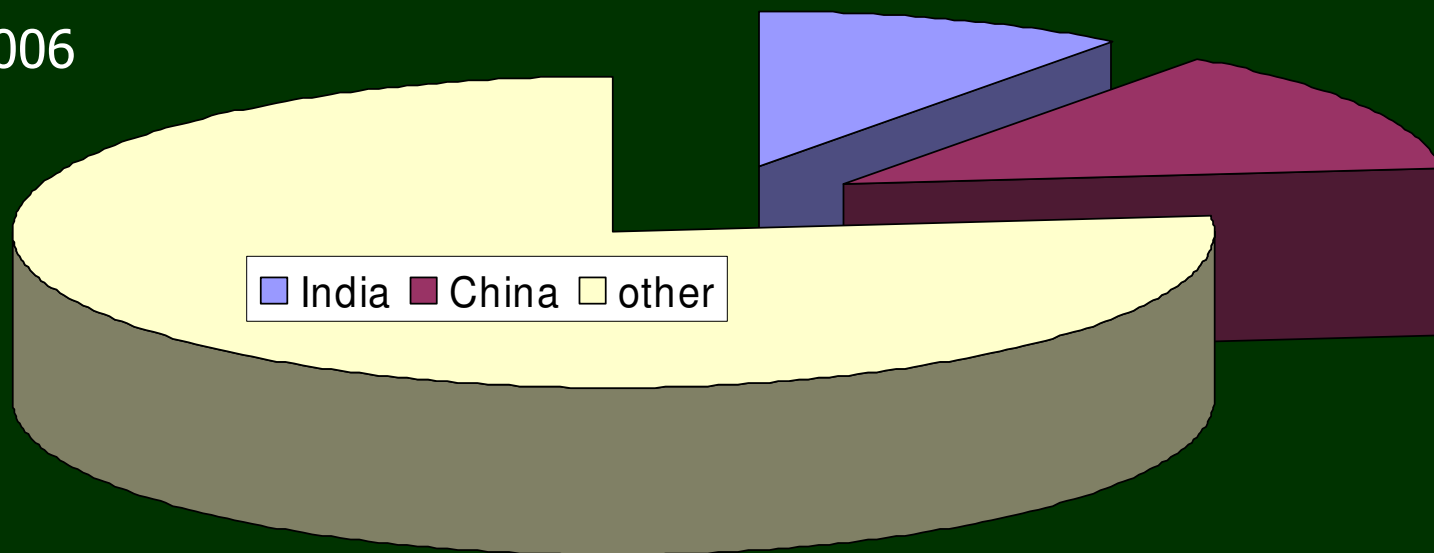


Overall participation in the international patent system:  
PCT publications by nationality of applicant:

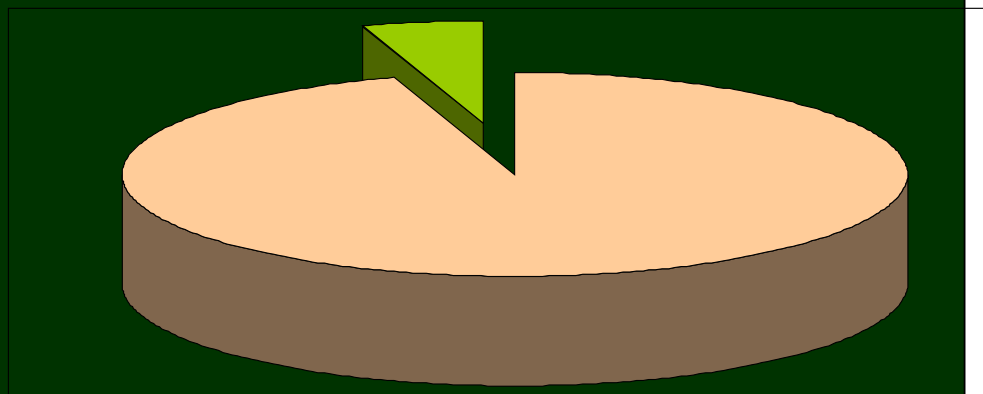
IPC Class A61K:  
*Preparations for medical purposes*

1998

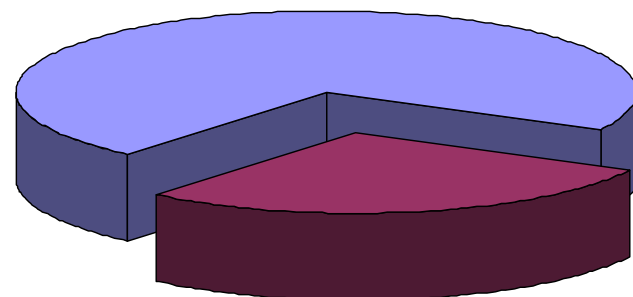
2006



# international patent activity in 2002-3 publications: developed: developing countries



all technological fields



plant-derived medicinal substances

A61K 35/78, 35/80, 35/82 and 35/84

# IP and biotechnology: some recurring questions

- Can a chemical compound be novel if it is identical to a compound that already exists in nature?
- When is it a 'mere discovery' or a true invention to isolate a compound (e.g. DNA sequence) that already exists in nature?
- Is it a true invention (non-obvious, inventive) to use standard techniques to derive practical knowledge of chemical compounds (e.g. gene sequencing?)
- When is it non-obvious to derive a new form or derivative of a known compound - polymorphs, new salts, new dosage forms?
- What are the moral/bioethical issues - do they concern the technology itself, or ownership of exclusive rights over isolated chemical structures, or how those exclusive rights are exercised, to what end?
- What is different about the chemistry of life - genes/DNA fragments and the proteins they code for? Are they 'just' chemical compounds or something more?

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- What are the moral issues - do they concern the technology itself, or ownership of exclusive rights over isolated chemical structures ('gene patenting' or 'nucleotide patenting')?
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as use of the patent system broadens in scope - geographically, culturally - with more diverse actors, (public institutions, public-private partnerships) - will these questions be answered in different ways?

- Patent law is inherently dynamic, responsive to the shifting technological landscape
- Centripetal convergence or centrifugal diversity in the core conception of what kind of innovation merits the grant of exclusive rights, in the broader interests of society?

## ... yet ...

- the interplay between biomedical innovation and intellectual property raises complex questions, with deep roots...
- ...which range over many areas of public policy...
  - (e.g. policy and regulation concerning pharmaceuticals, food and agriculture, ethics (reproductive technologies & stem cell research), publicly funded research, use of genetic resources, Indigenous rights and interests)
- ... and may be considered, resolved and reconsidered in diverse ways in different countries and cultures...
- this symposium can't attempt to capture them all..

# two paradoxes

1. The central paradox of IP law:  
Promoting the production of public goods  
by restraints on the public domain:  
exclusive rights or rights of remuneration
2. The challenge of technology neutrality:  
Biotechnological innovation is “just the  
same” as any other field of innovation, but  
is entirely different

# Why single out life sciences?

- Social and economic factors:
  - ethical concerns about the technology
  - ethical concerns about *patenting* the technology
  - concerns about environmental impact
  - technology addresses fundamental human needs: food & health
  - public funds account for a significant proportion of research, including fundamental research
  - makes use of genetic resources - human, agricultural, biodiversity - raising questions of ownership and control of resources, prior informed consent, benefit-sharing
  - strong North-South dimension
- Technological factors...

# Why single out life sciences?

- Again, this concerns fundamental human needs: health, food, the environment
- Regulatory questions:
  - safety, efficacy of medical treatments
  - health and environmental impact of agricultural chemicals
  - environmental impact of GMOs
  - regulation of food
  - ethical concerns

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# biomedical innovation & IP

- Is biomedical innovation different?
  - How is it different?
  - Do the differences matter?
  - And what does that mean for the patent system?
- Current debates about IP & biomedical innovation
  - Scope of protection and scope of exceptions
  - *Morality and ordre public* issues
  - Interaction with other forms of IP and non-IP law (including the regulation of pharmaceuticals)
  - Reach of claims (research tools)
  - IP management in the public interest
  - Compulsory licensing and government use provisions

# The rules: the TRIPS Agreement

- patents available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.

# The rules: the TRIPS Agreement

But may exclude from patentability:

inventions, the prevention within their territory of the commercial exploitation of which is necessary **to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment,**

*provided that* such exclusion is not made merely because the exploitation is prohibited by their law.

# The rules: the TRIPS Agreement

They may also exclude from patentability:

(a) **diagnostic, therapeutic and surgical methods for the treatment of humans or animals;**

(b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes.

However, Members shall provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof.

# Some symptoms of perceived differences

- Specific restrictions on patentable subject matter (e.g. methods of medical treatment, 'essentially biological processes' - TRIPS Art.27)
- TRIPS amendments to facilitate compulsory licensing for pharmaceutical products, for those countries with limited manufacturing capacity
- Budapest system for deposit of microorganisms for patent purposes
- Disclosure of origin or consent for genetic resources and traditional knowledge

# Is biotechnology in the IP system...

... much the same as any other technology?

The same rules & principles:

- patentable subject matter
- no patents on mere discoveries
- novelty, non-obvious, inventive step
- sufficiency of disclosure
- regulation of technology distinct from patenting

... totally different, needing unique responses?

- Specific international compulsory licensing rules
- Public interest exceptions to patentable subject matter
- Morality & ordre public
- Limited reach of claims
- Unique legal mechanisms for deposit of microorganisms and disclosure requirements

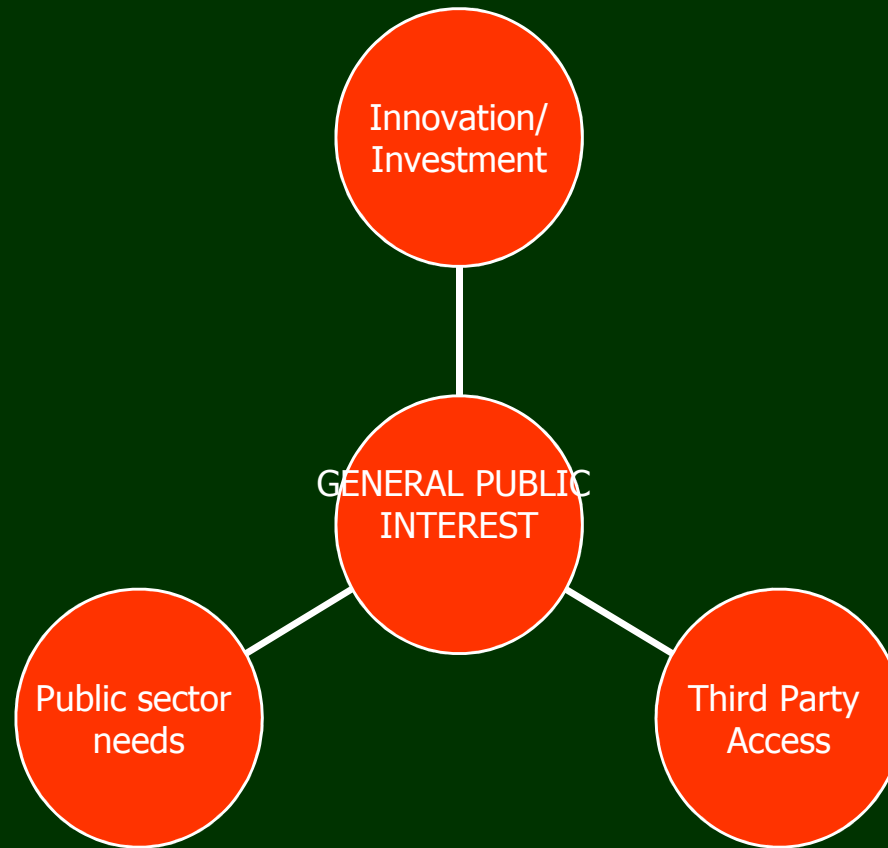
# Resolving the contradictions

- Broad principles have proven to be adaptable to emerging technologies
  - But tensions will arise as new technologies wash through the patent system
  - A practical challenge, but one with profound
- Patenting activities will be subject to particular scrutiny because they represent the tip of the iceberg of technological development
- But it's no minor task to adapt and apply these principles when law, technology and their social and economic context overlap and evolve:  
*a dynamic challenge* for policymakers
- Balancing necessary regulatory diversity with a core conception of the public interest as captured in the fundamental principles of patent law

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# and the IP balance:



The dynamic balancing of interests for overall equitable outcomes

# Regulatory data

- Test data as a public good
  - data from clinical trials
  - data from field trials of agricultural chemicals
  - information that is vital for sound public policymaking
  - to some extent, funded by private firms
- New products, new applications as a public good
- What structures, what mechanisms for
  - generating these data, creating new products
  - ensuring fair access to and use of these data?
- What form of exclusion serves the overall public interest?
- Where does the balance lie?

# two paradoxes & the IP balance

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# the impact of new technologies

- new technologies can lead to review or recalibration of the equitable balance
  - sound recording led to performers' rights
- once the equitable balance is established for regulatory data - e.g. clinical trial data
  - how about biosimilars or follow-on biologics?
  - the same treatment as generic small-molecule drugs

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# the impact of regulatory approval

2. The challenge of technology neutrality:  
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\* Rigorous regulatory procedures in the life  
sciences mean:

- longer lead time to come to market; delays  
generic entry - a de facto extension of patent term  
- does this merit exceptions to patent rights?
- longer lead time to come to market; reduces the  
effective patent term - a de facto reduction of  
patent term - does this merit extensions of term?

# the impact of regulatory approval

2. The challenge of technology neutrality: Biotechnological innovation is “just the same” as any other field of innovation, but is entirely different

\* Rigorous regulatory procedures in the life sciences open up possibilities for:

- linkages between the approval of drugs, generic entry, and the exercise of patent rights
  - the ‘Orange Book’
- linkages between the regulation of drugs and the grant of patents on drugs
- and no linkages!

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