



CHALLENGES AND ISSUES IN PROTECTING GENETIC RESOURCES AND TRADITIONAL KNOWLEDGE

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Some key issues

- **Surrendering of WTO TRIPS patent exclusions and flexibilities**
- **Access and benefit sharing (CBD and Nagoya Protocol)**
 - Prior informed consent of States and indigenous peoples/local communities
 - Benefit sharing triggered by utilization of GR, including “subsequent applications and commercialization”
 - Ex situ collections of genetic resources
 - Publicly available traditional knowledge
 - “Non-commercial” research
 - Customary laws and protocols
 - Compliance – monitoring, tracking and checkpoints
- **Mandatory disclosure requirements in patent applications on GR and associated TK**
- **South-South cooperation: experiences in national regulation (ABS, mandatory patent disclosure requirements, strict standards for novelty and inventive step, etc), good practices and lessons**

Some relevant international instruments

- Convention on Biological Diversity and its Nagoya Protocol on Access and Benefit Sharing
- FAO's International Undertaking on Plant Genetic Resources for Food and Agriculture
- WTO TRIPS Agreement
- International Convention for the Protection of New Varieties of Plant (UPOV)
- WIPO Intergovernmental Committee on Genetic Resources, Traditional Knowledge and Folklore
- WIPO treaties
- UN Declaration on the Rights of Indigenous Peoples (Human Rights Council and General Assembly)
- UNESCO Conventions on Cultural Heritage, Cultural Diversity and Traditional Cultural Expressions
- At least 13 UN agencies have work on traditional knowledge

WTO TRIPS

- Nature and Scope: “...Members may, but shall not be obliged to, implement in their law more extensive protection than is required by this Agreement, ... Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice.”
- Principles: “Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.”

Patentability: TRIPS exclusion in Article 27.2

- Members 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.

Patentability: TRIPS exclusion in Article 27.3(b)

- Members may also exclude from patentability:
... **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. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.

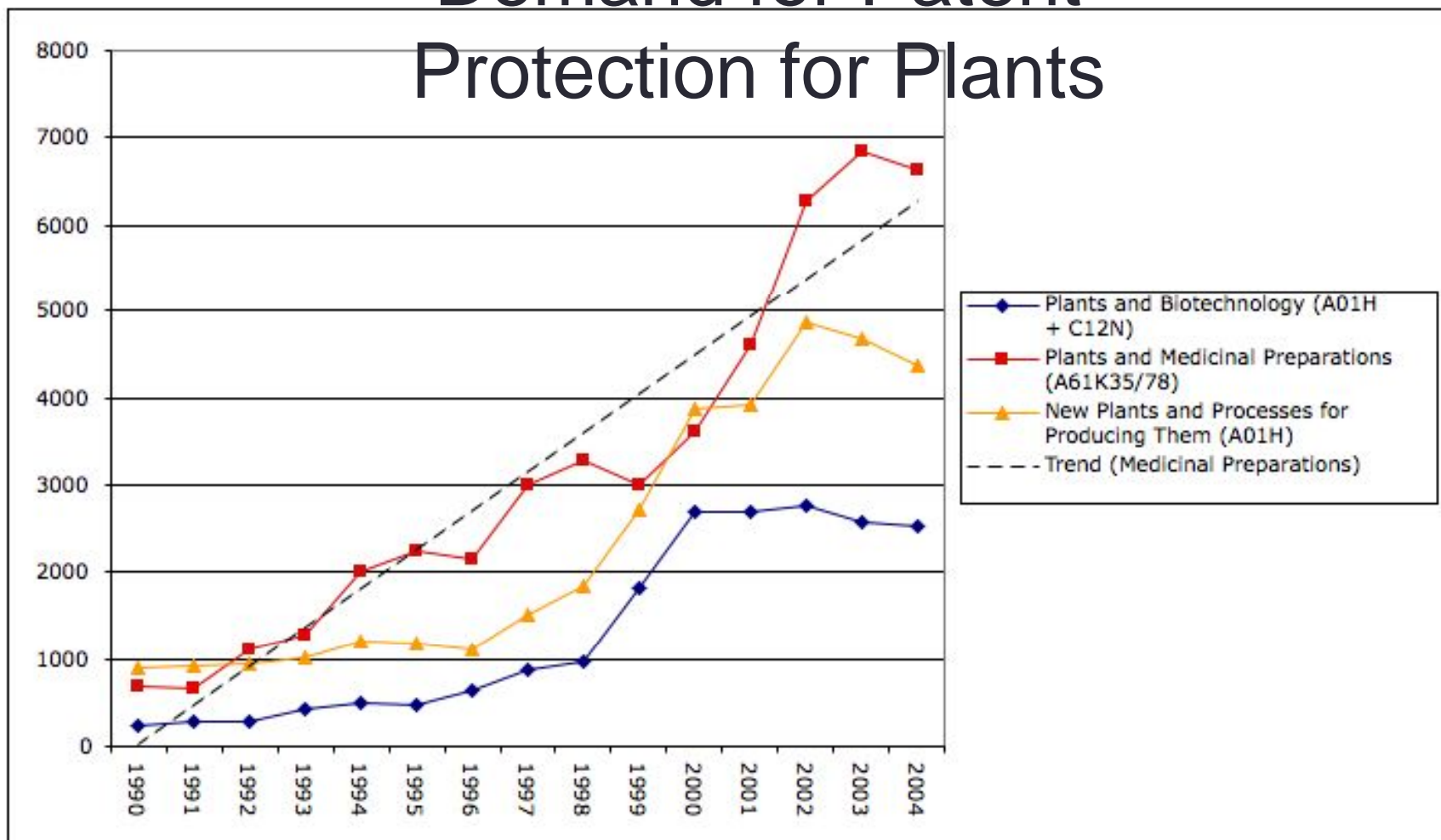
Exercising flexibilities

- Patentability criteria determined by national legislation (“novelty” and “inventive step”)
- Interpretation of “microorganisms” in national implementation; whether gene sequences are patentable
- Protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof

Review of Article 27.3(b)

- Proposal by Kenya on behalf of the African Group in August 1999: questioned the TRIPS' requirement for mandatory patenting of some life forms and some natural processes. It proposed a clarification that plants, animals and microorganisms should not be patentable. It sought a clarification that a "sui generis" system of plant varieties protection can include systems that protect the intellectual rights of indigenous and farming communities. It also asked that TRIPs be made to harmonise with the Convention on Biological Diversity and the FAO's International Undertaking on Plant Genetic Resources for Food and Agriculture (later revised to be the International Treaty on PGRFA).

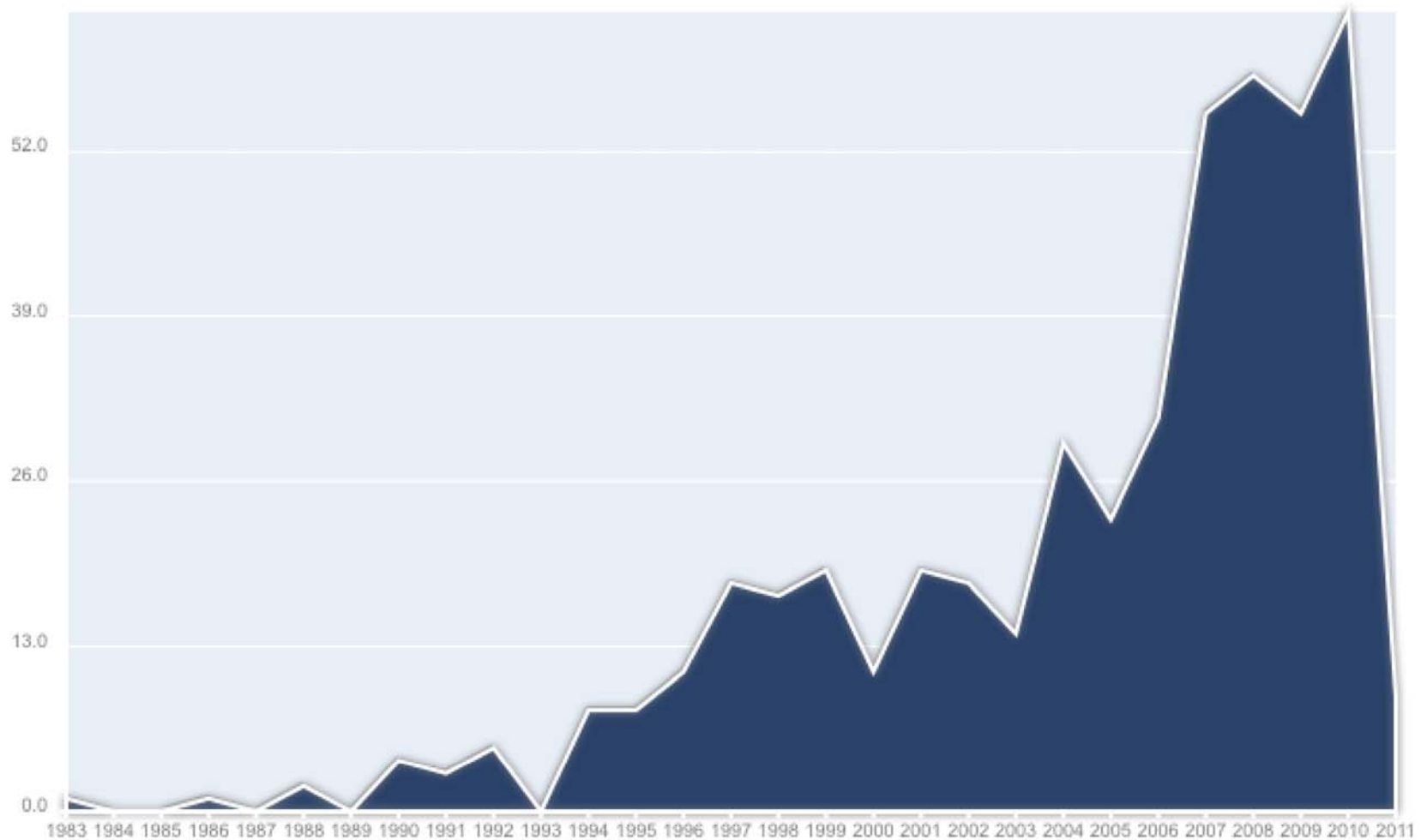
- International Trends in Demand for Patent Protection for Plants



Patent Publication counts as an indicator of demand.

Source : Paul Oldham, 2006

PCT patent applications (1983 to March 2011): flu vaccines



PCT patent applications: flu vaccines

Top Recent Applicants!! (Total for 2001-2011 YTD)

Novartis ⁸	35
GlaxoSmithKline	15
Merck ⁹	10
AstraZeneca ¹⁰	8
Medicago Intl.	6
Crucell	6
Avir Green Hills	5

Recent Applications by Year!

2001	19
2002	18
2003	14
2004	29
2005	23
2006	31
2007	55
2008	58
2009	55
2010	62

Convention on Biological Diversity

- **Objectives:** conservation of biodiversity; sustainable utilization; fair and equitable sharing of benefits from such utilization (including appropriate access to genetic resources and to technology) taking into account “all rights” over those resources and to technologies, and by appropriate funding
- Link between patents and CBD objectives – (1) what can be patented; (2) Mandatory disclosure requirements

CBD Article 15: Access and Benefit Sharing

- Sovereign rights of States over natural resources; national authority to determine access to GR subject to national legislation
- “Endeavour to create conditions to facilitate access”
- Access to be on mutually agreed terms
- Access is subject to Prior Informed Consent of Party providing GR
- Scientific research with full participation of Party providing GR; where possible in providing country
- Fair and equitable sharing of results of R&D, and of benefits arising from **the commercial and other utilization of GR** with Party providing GR (as well as “subsequent applications and commercialization”: Nagoya Protocol on Access and Benefit Sharing)

SOME RECENT “BIOPIRACY” CASES

- **Medicinal Plants and Cosmetics**

- The Avon Lady comes collecting Asian medicinal plants
- Rutgers University chases profit from West African Medicinal Plants
- Food Giant Nestlé Claims to have Invented stomach soothing use of *habbat al-barakah* (*Nigella sativa*)

- **Agriculture, Food, and Fuels**

- Marker-assisted biopiracy
- Agrochemical giant DuPont to sell Bolivian Sorghum Gene
- Chinese Sorghum to Enrich Texas Agrofuel Industry
- US Researcher Files for Patent on the lucuma fruit, a “flagship product” of Peru
- Smithsonian seeks to patent Panama research and claims work of others as its own

- **Microbes**

- The Patenting Professor: Montana’s Rebellious Microbe Man

- **University Intellectual Property Policies and “Non-Commercial” Access to Genetic Resources Under the Nagoya Protocol**

- (*Edward Hammond, Prickly Research, to be published*)

Mandatory disclosure requirements

- *Patent applications that involve genetic resources and/or associated traditional knowledge*
- WTO TRIPS Council – relationship between TRIPS and the Convention on Biological Diversity
- Nagoya Protocol on Access and Benefit Sharing – issue debated; WIPO argued by developed countries as the proper forum
- WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC) – differences between developed and developing countries remain (US, Canada, Japan and South Korea reject disclosure)

Nagoya Protocol on Access and Benefit Sharing to CBD (adopted October 2010)

- As of 27 February 2013 – 15 ratifications and 92 signatories. Entry into force requires 50 ratifications
- Africa – 6 ratifications and 27 signatories
- Signed: Algeria, Benin, Burkina Faso, Cameroon, Cape Verde, Central African Republic, Chad, Congo, Cote d'Ivoire, Dem. Republic of Congo, Djibouti, Egypt, Ghana, Guinea, Guinea-Bissau, Kenya, Madagascar, Mali, Mauritania, Mozambique, Niger, Nigeria, Senegal, Somalia, Sudan, Togo, Tunisia
- Ratified: Botswana, Ethiopia, Gabon, Mauritius, Rwanda, South Africa

Nagoya Protocol

- “Derivatives” of GR included in the scope
- Ex situ collections of GR – can “subsequent applications and commercialization” be interpreted as new and continuing uses?
- “Non-commercial research” and simplified procedures for access to be provided in national law (PIC and benefit sharing not exempted)
- Publicly available TK
- “Appropriate, effective and proportionate” compliance measures
- Global Multilateral Benefit Sharing Mechanism

Access to TK associated with GR

- **Nagoya Protocol on ABS Article 7** : In accordance with domestic law, each Party shall take measures, as appropriate, with the aim of ensuring that traditional knowledge associated with genetic resources that is held by indigenous and local communities is accessed with the prior and informed consent or approval and involvement of these indigenous and local communities, and that mutually agreed terms have been established.

GR and/or associated traditional knowledge

- CBD Article 8(j): Subject to national legislation,
- Respect, preserve and maintain knowledge, innovations and practice of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biodiversity
- Promote their wider application with the approval of the holders of such knowledge, innovations and practices
- Encourage the equitable sharing of benefits arising from the utilization of such knowledge, innovations and practices”
- **Nagoya Protocol Article 5: Legislative, administrative or policy measures on benefit sharing with ILCs from utilization of GR held by ILCs; and from utilization of TK associated with GR held by ILCs**

Demands/Concerns of indigenous peoples and local communities (CBD forum)

- Statutory recognition of customary law and practices
- Respect for, protection and promotion of traditional knowledge
- Risks in Registers of TK and information that is in public domain or publicly available
- Prevention of Biopiracy through National Legislation and policies
- Enforcing compliance in user countries

Sui Generis Protection for Traditional Knowledge

- Intellectual Property Rights systems alone cannot effectively protect traditional knowledge and respect for customary law
- The idea behind *sui generis* systems is that while patents, trademarks and trade secrets are tools in the existing IPR regime that can help protect traditional knowledge, new mechanisms that add further protection for indigenous peoples should also be developed.

Meaning of “protection and promotion”

In UNESCO terminology, “protection” refers to the adoption of measures aimed at preservation, safeguarding and enhancement.

That is the sense in which the term is used in various instruments such as the Convention concerning the Protection of the World Cultural and Natural Heritage (1972), the Convention on the Protection of the Underwater Cultural Heritage (2001) and the Convention for the Safeguarding of the Intangible Cultural Heritage (2003).

The term “protection” in this context has none of the connotations that it may evoke in the commercial sphere.

Meaning of “protection and promotion”

When used in conjunction with the term “promotion”, it implies the need to keep alive cultural expressions imperilled by the quickening pace of globalization.

“Promotion” calls for perpetual regeneration of cultural expressions to ensure that they are not confined to museums, “folklorized” or reified.

Furthermore, the paired terms “promotion and protection” are inseparable.

Protecting traditional knowledge - some issues

- Lack of land security
- Development projects (mining, infrastructure, etc)
- Material poverty, especially to access basic services
- Lack of social services which encourages migration to cities
- Recognition of indigenous peoples and their rights
- **Challenge:** establishing appropriate roles and relationships between customary law, national legislation, and international recognition in the protection and promotion of TK