Commission on Intellectual Property Rights

Workshop 3: Genetic Resources, Gene-based Inventions and Agriculture

19th November 2001

Participants: Michael Blakeney (University of London), Linda Brown (DFID), Peter Button (UPOV), John Mugabe (ACTS), Patrick Mulvany (ITDG), Dwijen Rangnekar (University of London), Suman Sahai (Gene Campaign), Clive Stannard (FAO), Geoff Tansey (Consultant), Ruchi Tripathi (ActionAid).

Commissioners: Sandy Thomas (Chair), Daniel Alexander, Carlos Correa and Ramesh Mashelkar.

Secretariat: Charles Clift, Tom Pengelly, Phil Thorpe, Rob Fitter.

Summary: The first session of the workshop comprised presentations by the authors of the two study papers commissioned on this topic, followed by a response by a discussant and a general discussion of the paper. The first Paper by Blakeney focused on recommendations regarding TRIPS Article 27.3(b), and prompted a discussion on the understanding of TRIPS in this context and its relationship with the CBD. The second paper, by Rangnekar, reviewed the evidence available on the impacts of IPRs on agricultural development and initiated a debate on *sui generis* options for PVP and their access implications. The second session looked into issues such as the flexibilities within TRIPS, *sui generis* alternatives, food security and the global agricultural system, and technological R&D in the public and private sectors. The third session dealt with the relationships between the various international agreements concerning genetic resources, their implementation and impact on access to the common resource base. Disclosure of origin was a further major topic of debate. The final session drew together the different strands of the workshop discussions, highlighting the most important areas for the commission to concentrate on and suggesting potential recommendation.

Glossary

ACTS	African Centre for Technology Studies
CBD	Convention on Biological Diversity
CGIAR	Consultative Group for International Agricultural Research
COFAB	Convention of Farmers and Breeders
DFID	Department for International Development (UK)
DUS	The criteria for PVP: Distinctiveness, Uniformity and Stability
EPC	European Patent Convention
FAO	Food and Agriculture Organisation (UN)
GFAR	The Global Forum on Agricultural Research
GM	Genetic Modification
GURTS	Genetic Use Restriction Technologies
IP	Intellectual Property
IPR	Intellectual Property Rights
ISNAR	International Service for National Agricultural Research
ITDG	Intermediate Technology Development Group
ITPGR	International Treaty on Plant Genetic Resources (FAO)
IUPGR	International Undertaking on Plant Genetic Resources (FAO)
LDC	Least developed country
MNC	Multi-national company
MTA	Material transfer agreement
OAU	Organisation of African Unity
PPP	Public – Private Partnership
PVP	Plant Variety Protection
R&D	Research and Development
TK	Traditional Knowledge
TRIPS	Agreement on Trade-Related Aspects of Intellectual Property Rights (WTO)
UPOV	Union Internationale pour la Protection des Obtentions Vegetales (International Union for the Protection of New Varieties of Plants)
WTO	World Trade Organisation

Session 1: Presentation and discussion of the study papers

Blakeney Presentation

Professor Blakeney put forward the following propositions as a means to stimulate discussion:

The Link Between Article 27.3(b) and Development

Recommendations

a. Review the impact of biotech patents on agricultural research in developing countries.
b. Review the breadth of claims permitted in biotech patenting.
c. Review the extent of the utilisation of Southern genetic resources and public germplasm collections (e.g. the CGIAR collection).
d. Establish an International Institute to provide technical assistance to developing countries on genetic resources management.

Technical Issues Relating to Patent and Plant Variety Protection Under Art.27.3(b)

Recommendations

a. Preserve the right of any country to exclude plants and any parts, including gene sequences and fragments, from patentability.
b. Adopt clear rules indicating that naturally occurring plant materials, including genes and gene sequences, should not be patentable.
c. Define the novelty requirement to exclude from patenting, any subject matter which is available to the public as a written description, used in indigenous communities, or in a germplasm collection.
d. Establish commitments by governments not to grant, or to cancel, IPRs on materials obtained from international germplasm collections where such materials are in violation of any Material Transfer Agreements.
e. Define plant varieties under Article 27.3(b) to permit a dual system of protection which includes both modern as well as farmers' varieties.
f. Allow an exception for experimentation on patented plant materials.

Technical Issues Relating to the *Sui Generis* Protection of Plant Varieties

Sui generis Options

a. Landraces should be excluded from IP protection.
b. Material in germplasm collections should be protected through publication, and collected materials protected by material transfer agreements.
c. For medicinal plants, a certificate of novelty should be required for PVP.
d. PVP should not be obtained for wild species.
e. After purchase the PVP right will be exhausted and any further transactions with the seed will be permissible.

Ethical Issues Relating to the Patentability of Life forms

Recommendations

a. Consult stakeholders on the ethical impact of IPRs on living materials.
b. Develop policy guidelines for IP offices on the balancing of public and private interests in the area of biotechnology.

Relationship of Article 27.3(b) to the Conservation and Sustainable Use of Genetic Material

Recommendations

a. The CBD be granted observer status on the Council for TRIPS.

Relationship of Article 27.3(b) with the Concepts of Traditional Knowledge and Farmers' Rights.

Recommendations

a. *Sui generis* possibilities for Farmers Rights legislation (c.f. African Model).
b. Develop options for seed saving for different categories of farmers.
c. Establish a central fund from which the breeder is paid on the basis of the area grown, and in exchange, farmers are permitted to save, exchange and trade the seed from the protected variety on a non-commercial basis.
d. Provide assistance to developing countries in formulating legislation to assist farmers in contributing to the evolution, conservation, improvement and sustainable use of plant genetic resources for food and agriculture.
e. Formulate measures for credit facilities and market provisions governing farmers' access to plant genetic resources for enhancing traditional genetic resources, development the exchange systems.

Discussant

A potential problem for implementing the Article is that it runs counter to elements of the European Biotechnology Directive and could therefore be difficult for European governments to agree to.

In response to many of the recommendations made to the Commission, it was unclear who would be able to undertake the extensive reviewing suggested. The Commision has limited time to prepare its report and is unlikely to be able to address these recommendations. Other initiatives, such as the conversion of the International Undertaking to a Treaty, were starting to deal with issues relating article 27.3(b) with development, and ISNAR is developing technical assistance regimes. The Commission should focus on what is can achieve in its time frame.

It was recognised that there is little understanding in the international community of the TRIPS 27.3(b), and the Commission could play an important role by explaining clearly the different interpretation options and flexibilities (such as the importance of a research exemption), and the meaning of phrases (such as non-biological processes). Defining terms in the Article needs to be very precise, qualifying terms like 'plants ' with 'as they exist in nature'. Questions were raised

about the exclusion of landraces in the Article, and the effect this has on the level of protection by IP or from IP (through restricted access). Clarification was recommended.

The discussant agreed with the ethical issues raised in the presentation, especially in regard to stakeholder involvement.

Discussion

The relationship between TRIPS and the CBD is thought to be conflicting by some developing countries. However the CBD only refers to IP in a way that does not jeopardise the objectives of the CBD, and the flexibilities in the two agreements mean that they can be implemented to either complement or conflict, as required. But whatever the interpretation, there must be precision in determining where there are possible conflicts.

The use of 'disclosure of origin of materials' as a requirement for IP application could be held by some to conflict with TRIPS, which states that only the standard three requirements; novelty, non-obviousness and industrial applicability, need be met. And if naturally occurring material is not patentable, why should the isolation of parts of that material be grounds for granting a patent?

The FAO International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGR) is in harmony with the CBD, covering the specific needs of agriculture and holds the middle ground between the CBD (environmental) and TRIPS (trade). Article 9 deals specifically with Farmers' Rights.

Rangnekar Presentation

Evidence from Developed Countries

There is evidence of only a modest and uneven impact of PVP on R&D investment across crops and companies. Evidence from the US suggests older companies are more successful at accumulating knowledge resources and major market crops are subject to the most intense IP focus.

Evidence suggests increases in number of varieties released, but issues concerning varietal quality and planned obsolescence remain. And there seems to be no link between rate of protection of varieties and number released.

There is an increase in the degrees of market concentration and exercise of market power (e.g. seed price and royalty rate increases); but questions of causal mechanisms remain.

Evidence from Developing Countries

There is a tendency to focus on select crops (high value/low volume), narrow production niches (post-Green Revolution areas), and GM-crop research. A greater dominance of IP and private sector research seems to be leading to investment in crops and traits that are of limited use to the poor.

Evidence that an absence of IPRs hindering access to varieties and germplasm from abroad is mixed, but there is suggestive evidence of 'controlled access' and privatisation of public varieties.

Seeds and Seed System Transformations

Seeds are the critical input into agriculture and the delivery mechanism for agricultural technological developments. A review of public and donor sector policy should recognise the role of the private sector and withdraw from activities which the private sector can recover its investments.

IPRs and Public Sector Plant Research

Emergent trends include:

a. stagnating public research expenditure
b. increasing presence of private sector
c. growing collaborative ventures between public and private sectors

Access to research tools

Evidence suggests extensive use of proprietary tools (i.e. transformation systems, selectable marker genes, promoter genes), but there is a lack of clarity on terms of access/use, and on obligations concerning dissemination of derived products. Plant breeding requires a range of research tools and cannot function in a protectionist environment.

The TRIPs Agreement

Although TRIPS was designed to achieve global parity in IP standards, it dictates minimum standards only, and since there is no obligation to adopt identical practices, many key concepts are undefined and ambiguous. Many countries have TRIPS-plus legislation, standards vary across jurisdictions and there is possible disharmony.

The UPOV Approach

In light of the history of the UPOV system of PVP, a current option is for a dual system which would include modern varieties and farmer varieties, but prohibit IP on wild species or traditional varieties.

Options for Implementing Article 27.3(b)

a. Exclude plants and plant varieties from patentability and establish *sui generis* system for plant varieties
b. Not exclude plants and plant varieties from patentability
c. Not exclude plants from patentability and provide for protection of plants/plant varieties through a dual IPRs system (e.g. the US)
d. Exclude only plant varieties from patentability and establish *sui generis* system (e.g. EPC)

Components of *Sui Generis* System

Options include: modifying the DUS system and introducing 'identifiability', 'merit' via agronomic requirements, stronger novelty criterion, and tying in CBD principles (e.g. declaration of geographical origin). All plant species and botanical genera must be included within the coverage of law. There are many outstanding problem concerning the scope and strength of rights of farmers and breeders which need to be addressed

<u>Discussant</u>

IPs must be analysed in their economic, technological and access contexts. The paper was thought to deal with IPRs without looking at access issues. Access to genetic resources under the CBD was usually regulated by contractual agreements, and these could me an impediment to further access. Moreover, in classical plant breeding, it is difficult and often impossible to decide how to value the inputs of the sometimes tens of varietal stocks contributing to a variety, after many years of breeding. Moreover, the transaction costs of negotiating contracts, tracking the use of material, and litigating for the enforcement of rights is probably higher than the benefits that might be obtained: there is already evidence that transaction costs and uncertainties associated with contracts.

In terms of how IPRs themselves affected access to the genetic resources in a protected product, it was necessary to distinguish between patents over plant varieties and PVPs. Under the UPOV PVP regime, only the variety is protected, and by the "breeders' exemption" free access to the genetic resources is allowed. The biotech model of patent protection is not easily applicable to traditional plant breeding, and, for various reasons, pushes the seed industry in countries using variety patents towards high cost, high tech solutions, which cannot address the needs of small farmers, This factor, and capital concentration in the industry in general means that it is not profitable for the private sector to invest in research on small-scale crops or those with small markets, and so much of the R&D is focusing on input and labour reducing traits. Thus the responsibility of supplying the needs of the poor, and developing minor crops and crops for small environmental niches, weighs increasingly heavily on the chronically under-funded public sector, which is finding it increasingly hard to work with a private

sector that controls not only important genetic material under patent, but the "enabling technologies" needed for biotechnological plant development. Governments need to look at the effect of IPRs within the specific context of agriculture, and of the needs of developing countries.

The ITPGR recognises that countries are interdependent with respect to the most important crops for food security. It therefore establishes a Multilateral System of Access and Benefit-sharing for a list of crops supplying about 80% of world calorie intake. Countries agree to pool their resources of these crops, and to arrange benefit-sharing on a multilateral basis. There is therefore no link between the country of origin and benefit. There is a clash between access legislation and IPRs; an option is to have a pool of information and rules to regulate access to it rather than proprietary rights over material.

Technological protection mechanisms e.g., GURTS, are a further method of protecting material, but if applied as an appropriation strategy, are likely to undercut rational IP systems. There were good policy reasons for banning their use as an appropriation mechanism on these grounds. It was however necessary to distinguish between their use as an appropriation strategy, and ways in which genetic use restriction technologies may have a production potential, and not confuse the two.

Discussion

Would the absence of any IP make a difference to poor people? The current situation is that there is a flow of genetic resources away from the diverse heritage of small farmers which is being concentrated under the control of large multinational companies. The threat is that the resultant access restrictions will damage the genetic biodiversity which is the basis for evolution and crop adaptation, and thus affect the ability of small farmers to adapt to local environments.

Questions were raised as to whether *sui generis* systems that make specific arrangements for different species and categories of plants, for example open or self-pollinated plants, could be useful. But it was argued that this distinction could be dangerous, as arbitrary or unnatural isolation of groups of species could prevent vital genetic out-mixing. The question was deemed to be unclear and requiring more research.

Biotechnology and chemical companies are taking over from the plant breeding industry and this is reflected in the increasing dominance of the patent system. The IPR system that exists today developed from industrial practice of determining ownership over material goods, and this is not relevant for live, natural, evolving materials. Thus a different system is needed which is sensitive to the peculiarities of biological material.

It was suggested that the Indian PVP law could be used as a model for other developing countries, as it has good Farmers' Rights elements, but must be adapted to suit national circumstances. The ITPGR provided that the operationalisation of Farmers' Rights was to be done at national level.

The political reality is that TRIPS is signed and is being enforced, and the CBD has not even been ratified by the US. The International Treaty promotes the free exchange and access to genetic resources, and is in harmony with both the CBD and IP regimes.

Session 2: Food Security and Technology Development

Flexibilities in TRIPS and alternatives

It was asked whether the approach in Article 27 3 b) was the right one for both developed and developing countries? There were flexibilities in the Article, but were they sufficient to meet the needs of developing countries? Plants were not like software in that they were not easy to copy. There was some debate as to whether the Indian Patent Amendment Bill which requires disclosure of origin, and recognises oral knowledge, is TRIPS incompatible.

Sui generis Systems and Alternatives

LDCs are not homogeneous, some are innovators and benefit from IP protection, other have no innovation capacity as yet, but could develop an IP system to suit their stage of technical development. It was suggested that the UPOV regime was sufficiently flexible to be fitted to current national development circumstances. But it was also argued that UPOV was developed for industrial scale temperate agriculture and is not suitable for tropical subsistence farming; for example there is no concept of proactive farmer rights (as opposed to "exceptions" to protect farmers". The distinction between modern and farmer plant varieties is not viable as most new varieties source traits from the great agro-biodiversity maintained by farmers. There are no readily available alternative *sui generis* systems for developing counties to adopt and there is thus considerable pressure to plump for UPOV. Moreover, the UPOV model was often promoted through bilateral trade agreements. It was suggested that a review of the applicability of UPOV to developing countries should be undertaken. The Convention of Farmers and Breeders (COFAB) was suggested as a potential non UPOV alternative. This would be a new platform to incorporate farmers and breeders rights and secure access to and exchange of seeds and varieties. Similarly the suitability of the OAU legislation required to be considered, as also the new Indian legislation on plant varieties.

Global Food System

Food security depends not only on seed saving but the ability to exchange and sell seed. These practices are economically essential and necessary to maintain the gene flow and the selection responsible for agro-biodiversity. But the global food system is driven by the developed world. IP rights in these areas have been developed to serve the needs of Northern researchers and breeders. Poor farmers are of little importance in determining the direction of agricultural change, and the economic power is concentrated in the MNCs. The evidence of increasing market concentration in North and South was considerable. This was described as a public policy issue; a choice between supporting small farmers with a public research infrastructure, or letting market opportunities in rich countries determine agro-industrial R&D.

Applicability of IPRs to Developing Country Agriculture

Because of the high transaction costs of the application and enforcement, IP is more feasible in a developed country where these costs are comparatively small. The complementary procedures required to implement a system of PVP were arduous for developing country administrations. There is little evidence of developing countries being able to use the IPR system to stimulate innovation. Moreover, in some cases there was a poasitive downside. For instance, in the Basmati case, it required the effort of the Indian Government over several years to challenge patent claims that could have severely affected India's rice exports. While IP protection might be relevant to stimulating innovation in the chemical and pharmaceutical industries, the case was much less clear in the agricultural sector.

IP and Research Investment

There is little evidence to prove a causal relationship between IP and innovation in developing countries. The nature of agricultural research in developed and developing countries was very different. IP rights might be appropriate in developed countries for "industrial" agriculture where research is predominantly in the private sector, but this was not the case in developing countries.

It was agreed that an active public sector is vital for developing countries, but as the public sector did not seek to benefit from patenting its 'pro-poor' innovations, it had not hitherto used the IPR system. However, the relationship between the public and the private sector is changing, and there has been a rapid trend towards more private sector research. Public science provides the basis for much private research. Information in the public domain can be used by anyone as they wish, but this information was increasingly used as the basis for downstream patenting.

Commercial practices within public R&D

As a result, the incentive to place knowledge or material in the public domain is decreasing. It was argued that some countries are now unwilling to supply genetic resources to the CGIAR centres for fear of losing control of these potentially valuable national resources to private sector appropriation. Moreover, there was apparently a declining use of CGIAR held material by others. The restriction of access to enabling technologies is encouraging public R&D centres to patent their work, either to "protect " it for the public sector or as a bargaining chips to gain access to patented technologies held by others. This is changing the research ideals of openness and information sharing, as it becomes more necessary to control access to this 'public' resource. The significant growth in PPPs has introduced new issues of IP ownership and further complicated the aims and practices of public and private sector research. The significance of transaction costs in getting "freedom to operate" was arguably an increasing burden for research institutions. Overall, the operating ethos of the public sector had changed.

The Global Forum on Agricultural Research (GFAR) website **www.egfar.org** was recommended as a useful resource.

Session 3: TRIPS, the ITPGR and the CBD

Relationship between the CBD and the FAO International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGR)

Developing countries had been concerned about the loss of bio-resources, and the CBD reaffirmed national sovereignty over a country's genetic resources. This should not be confused with the assertion of property rights. There was no implication that sovereignty should be equated with IP. It was contended that the CBD was designed to allow countries (or communities?) to make a fair return for making available national genetic resources, but this was based on a mining/extractive industry model, which is less appropriate to agriculture. Hence the ITPGR fulfills a specific need in relation to accessing agricultural genetic resources.

The ITPGR

The ITPGR is believed to be in harmony with both the CBD and TRIPS, and go some way to securing free exchange of genetic material, and implementing a global plan of coordinated action. It offers support to the public CGIAR system of agricultural research by conserving a selection of crop genetic material in the multilateral system from direct patentability. It was recognised that the maintenance of open access to genetic resources in regions of high crop diversity is vital for developing country food security, as sustaining the momentum of crop development relies on this diversity to source new traits and

genes. However the ITPGR only covers 35 genera of plants, and a potential problem is that the rest are covered by the not wholly satisfactory provisions of the CBD.

It was claimed that the US would not block the ITPGR as it keeps genetic resources accessible to industry. But it also dictates that industrial applications based on this 'common' material are covered under material transfer agreements which require benefit sharing and payment of mandatory royalties. ITPGR Article 12.3(d) states that "all genetic parts and components" are protected from patenting but "in the form received". This qualifier could be interpreted to allow a gene which has been isolated and its function determined, to be patented. The decision on how to interpret this ambiguity will be made by national governments, but concerns were raised over TRIPS compatibility. Nevertheless, the benefit of the ITPGR was the potential escape from "gene by gene privatisation" in the crops covered, and the support for farmers' rights and the protection of traditional knowledge.

Implementation of the CBD, ITPGR and TRIPS

There was concern that the CBD, ITPGR and TRIPS isolated the interconnected elements; farmers rights, traditional knowledge and genetic resources, and treated them separately. It was suggested that these three international agreements should be implemented at a national level within the same framework so that they can have practical effects. The Africa group was highlighted as leading the way by producing model legislation. But there was concern that the model legislation is in conflict with many African countries' national legislation, which do not recognise common property rights. And additionally, genetic resources are never truly common as there are always some restrictions to access. Therefore the greatest tensions and conflicts are not within the three international agreements, but between them and national law and practice.

It was noted that MTAs were a godsend for lawyers, but a nightmare for researchers and breeders.

Plant collections

There was a debate as to whether the pre CBD and pre ITPGR gene banks and plant collections, such as the CGIAR collections are outside protection for common resources. There was also debate over what qualifies as a public collection; whether this is an issue of national government discretion, and it was suggested that if private collections now want to access the public/common resource pool, they must join and be governed by the ITPGR. The danger of bringing environmental issues into the trade arena is that, as observed in Doha, it is politically unpopular in developing countries.

Disclosure

The discussion on disclosure of origin of genetic material in patent applications raised the argument that compulsory disclosure may not be consistent with TRIPS as it represents an extra, 4th requirement for patent application (the Colombian proposal was cited in reference to this problem). But the response to this was that UPOV has 5 application criteria and there are ways of avoiding legislative problems (such as the Danish legislation, where failure to disclose does not invalidate a patent). Several other national policy positions on this issue were stated: the Indian Patent Amendment Bill requires disclosure of origin by a patent applicant; and the British policy is to push for the inclusion of disclosure of origin as a secondary system but not as a requirement for patent application. However, the policy of disclosure could also be seen as an important way of linking CBD and TRIPS.

Disclosure of origin was thought to be important in preventing biopiracy and could facilitate setting up benefit sharing arrangements. It could prevent the misgranting of patents, on the grounds of prior art. The Indian government, based on a sample survey of US patents, has estimated that about 40% of US patents might not have been granted, because of prior art considerations. However there are serious problems in determining the origin of biological material, living material has very different properties to mechanical objects, as it is the product of thousands of years of evolution, selection and genetic intermixing, and is in the process of continuous change. This is, for instance, a problem with the CBD definition of country of origin, which the ITPGR avoids by bringing them into the multilateral system.

Session 4: Conclusions and Recommendations

Particular themes stressed were the need to maintain access to technologies and resources for the public sector, to benefit poor producers. There was a concern that IP in this area was more about appropriation than innovation, and about investment rather than innovation. The issue for the Commission was how IPRs can be used as a tool to achieve development goals? There was also concern about how to deal with technological protection mechanisms, such as GURTS.

The Commission could usefully help, inter alia, by proposing an agenda for the Governing body of the IUPGR.

Theory of patents: the conceptual relationship between IPRs to public goods

- Genetic resources and the techniques of innovating with natural evolving life forms have special characteristics that are not accounted for by IPRs, which were developed for inanimate mechanical products in industry.

- IPRs can be used to either support innovation or to appropriate value (or both simultaneously). IPRs are becoming commercial tools, emphasising appropriation not innovation.

- IPRs should be considered in the context of other technological protection mechanisms (such as GURTs), and the interrelationship of different forms of IP protection in the food industry (PVP, Patents, Trademarks, etc.)

- IP provides privileges not rights.

IPRs divert private R&D away from poor country agriculture

- For Northern agriculture, the profit potential of the large and lucrative market motivates the private sector to greater efficiency. In this area public sector R&D may not be as effective. And in some niche markets in poor countries, private sector seeds (protected by IPRs) can be effective. However, IPRs as a policy tool are not necessarily effective in encouraging agricultural R&D for poor farmers in developing countries, where other investment factors such as market potential are weak.

Changes in public sector research

- Public sector needs more funding for R&D if it is to provide an alternative to the north-centric private sector. But is public sector R&D also out of touch with the needs of poor farmers? Is it realistic in the current political environment to revert to a public R&D system?

- Access legislation: The public sector need to have access to 'platform and process' R&D technologies:
    - Knowledge (TK)
    - Genetic resources
    - Tools and techniques

Impact of private control of biodiversity through IPRs on poor farmers

- Does IP have any positive impact on the poor in an agricultural context?

- Concerns about broad patenting of genetic resources. 70% of poor farmers use saved seed so retention of knowledge and freedom of exchange is essential for them. Patenting of general features of staple crops like rice may restrict essential access in developing countries.

- Reduction of agro-biodiversity through the private sector system of industrialised 'monocultures' damages the resource base from which future agricultural development could be based. Focus on animals and microorganisms as well. Pig and chicken companies buy up varieties and

leave them to die if the genes are not immediately valuable (animals exhibit more rapid extinction than seed bearing plants)

TRIPS, the IUPGR and the CBD

- What are the flexibilities within TRIPS and are they enough?

- Disclosure of origin issues: If a patent application is valid and legal then there should be nothing to hide. And this might go some way to increasing the proportion of wrong patents challenged prior to granting. Benefit sharing mechanisms could be developed in cooperation with disclosure legislation.

- Flexibilities in international rules should be interpreted by national governments to suit their development requirements, and not enforced by the WTO appellate body.

- Access legislation and technology transfer.