

# Commission on Intellectual Property Rights

## Workshop 10: Research Tools, Public Private Partnerships and Gene Patenting 22<sup>nd</sup> January 2002

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**Summary:** The workshop discussions covered the most relevant aspects of the research tools debate. There were presentations on the US approach the RTs developed by the NIH, and the perspectives of the CGIAR and the MVI, both international public sector research organisations. Case studies indicating the complex layers of patents surrounding RTs, highlighted the problems such institutions face in accessing RTs for pro-poor research. There was a presentation and discussion on the strengths, weaknesses and potential collaboration between the public and private sectors. One session was devoted to a presentation and discussion on issues concerning RTs in the field of human genetic research; informed consent, benefit sharing, and access to RT information. The final session comprised of a 'tour de table' in which the attendees suggested key issues and recommendation for the commission to consider.

### **Session 1: What's the problem with research tools and what should we do about it?**

#### **Presentation by Maria Freire**

#### ***Access to Intellectual Property Rights: The Research Tool Issue***

The source of funding for development of a research tools (RTs) is of crucial significance in intellectual property management. Publicly funded research is subject to government regulations and public scrutiny and includes the obligation to share access to the invention. Privately funded research usually has greater IPR/publication restrictions. Although the NIH has no direct control over private entities, the NIH guidelines on access and control rules for RTs were meant for both public and private bodies. RTs are defined as

unique research platforms such as cell lines, animal models, reagents, or databases, which may or may not be patented. They are not usually final products available to the public, although they may be 'end products' for research firms.

The NIH working Group on research tools, convened in 1997 found that access to RTs was severely constricted and proposed the framing of guidelines for all the grantees of government funds. The Final NIH Research Tools Guidelines sets out the following core principles in the first part:

- Ensure academic freedom and publication, especially when importing RTs.
- Appropriate implementation of the Bayh-Dole act. The letter of the Act clearly seeks to move technology forward and enable economic development, but it was widely misinterpreted to imply a compulsory mandate to patent as much and as often as possible. The objectives of the Bayh-Dole Act may be achieved through publication of research results or licensing as well.
- Minimise Administrative burdens: The negotiation for Material Transfer Agreements on average took 6-8 months.
- Ensure dissemination of NIH-funded RT. The NIH backed by government regulation would decide the terms of access to RT as a pre-condition of funding.

The salient features of the NIH Guidelines focus on the following.

- In case of importation of RT from other sources for use in an NIH funded project, the IPR obligations agreed on will have to be consistent with the NIH Guidelines.
- The possibility of exclusive licenses was maintained with the qualification that the exclusivity be limited to particular 'fields of use'.
- In those cases where the RT owner is in the private sector, the possibility of 'Restricted Options' and/or 'Grant Back of intellectual property rights' is allowed although NIH grantees will have to ensure that research enterprises are not blocked by such clauses.
- A simple 'Letter Agreement Model' replaced the complicated Universal Biological Material Transfer Agreement (UBMTA).

### **Case Study: Access to Stem Cells**

The NIH funded stem cell primate studies at the WARF (Wisconsin Alumni Research Foundation) which by law allowed them some claim to the human stem cell patents as the 'conception' of the invention in the context of primates was made using NIH funds. This claim proved important in subsequent negotiations for access to the stem cell technology and exemplifies the importance of the origin of funding in the case of Research Tools.

Geron, a private company funded the human stem cell studies. WARF obtained broad patents on the primate stem cells and methods as well as the human stem cell studies and licensed 6 cell types to Geron. The license carried a stipulation that such cell lines would be distributed to the academic world for research purposes. WiCell was created for scale-up and distribution of the stem cells. These developments raised concern that access to stem cells for the purposes of academic research was being restricted and NIH had to draft guidelines to ensure academic access based on the following principles:

- Research and Commercial Uses were segregated.
- Intellectual property was to remain with inventors – no automatic ‘grant back’ or ‘reach through’ provisions.
- Materials received from third parties were also be subject to the same terms and conditions.
- These were to be the same terms for MOUs between WiCell and all Universities that are NIH grantees.

The NIH-WiCell MOU therefore stipulated that cells would be transferred under an MTA, for non-commercial purposes, and re-distributed only with WiCell consent. The use of stem cells could only be as provided under law (as this is a restricted area of research under US law). Further, there were to be no costs in the form of paybacks. As quid pro quo for these terms, it was agreed

- (a) that all publications by NIH scientists would acknowledge the source of the stem cells
- (b) a yearly compliance certification would be sought from WiCell, to rule out unauthorised use of the stem cells
- (c) it was agreed that for commercial uses, scientists would have to go back to WiCell for a separate license. If direct benefit of a private sector organisation was entailed, a separate license would have to be negotiated with WiCell
- (d) No third-party ‘reach through’ agreements can be entered into by NIH grantees.

### **Presentation by Victoria Henson-Appollonio *The Intellectual Property Concerns of CGIAR***

A number of case studies were presented to address the question ‘is there an effect on CG research or dissemination of products due to IPR on research tools?’. The main intellectual property concern of the CGIAR arises out of the need to ensure access to the centre’s products, to benefit subsistence level farmers, particularly those in developing countries.

**Case 1:** Positech technology covered by US Patent 5767378 awarded to Novartis (now Syngenta). This is a patent covering a process of selecting transformed plant cells. The patent claims include compositions needed to carry out the method. Syngenta made it known that the material would be available to the Centres, but this was to be only under Material Transfer Agreements (MTAs) that contains a ‘research only’ license with ‘reach

through' implications regarding new inventions. A 'research exemption' is insufficient because CGIAR needs to be able to distribute the materials. The fact that the material itself was covered by claims of the patent did not cause problems as such but the licensing agreement was the source of the dilemma.

**Case 2:** 'Golden rice' involves the use of gene sequences that result in the production of Vitamin A precursors in plants. Many pieces of intellectual property were involved in the hybridisation process. The negotiations to obtain a license for the central patents required enormous effort and ongoing research was made difficult by the publicity.

**Case 3:** The case of Xa21; use of a gene sequence to confer resistance to rice blast infection. The centre spent several years negotiating a license to use this sequence because an exclusive license had already been granted to a company by the patent owner.

**Case 4:** 'Rice genome database access' and use of proprietary information regarding the sequence of the rice (*O. japonica*) genome. One rice genome database is generated by the International Rice Sequencing Consortium, and is due to be completed by the end of 2002. The second is the proprietary database owned by Syngenta which is a much more detailed product than the one in the public domain. The licensing terms for use of this database is unacceptable to the CGIAR.

**Case 5:** 'Spatial/GIS Information access and distribution'. This comprises geographical, meteorological and other information incorporated into spatial information databases and then displayed in a graphical format. The data includes information from many countries, with security implications for those countries. Public and private institutions have restrictions over datasets that are available, many of which are very expensive. The licensing policy differs between manufacturers. New database legislation in EU countries has increased the difficulty in the centres being able to use the data and distribute the results.

**Case 6:** The Micro-arrayer: Top of the line equipment brand has 'reach through' and 'use' restrictions in the licensing agreement.

**Recommendations:**

- Encourage liberal licensing policies without 'reach through' provisions. Tax incentives that encourage liberal licensing, benefit sharing provisions (for exclusive licensing deals) might help towards this.
- Encourage public disclosure and enablement. This may take the form of patenting in keeping with the original intent of patent law.
- Discourage the keeping of trade secrets, especially commercial trade secrets. Use every opportunity to weaken enforcement of regulations that protect trade secrets.
- Encourage broad interpretation of the implied 'research license'.

- Strengthen enablement provisions of patent law.
- Support the US CAFC's decision in *Festo*.
- Encourage public institutions to disclaim (copy and database) rights over information generated with public funding.

### **Discussion**

Direct government intervention often proves detrimental to making RTs available to the public sector, and negotiation between the public sector and the RT patent holder works best. The threat to patents, (because they can be challenged or worked around) can be used as a very efficient negotiating tool. Anti trust legislation should also be considered in the case of access to RT on reasonable terms.

The definition of what is commercial is central to the NIH guidelines, although the demarcation is difficult to make. If a private entity is in a position to get 'direct benefit' from the licensing of a tool to an academic user funded by that private entity, then a university is likely to regard that use as 'commercial'. It has been recognised that 'funding arrangements' in Universities may be used to circumvent negotiations for a legitimate 'commercial use' license. The mere fact that research can result in information that may be patented or licensed does not in itself make the endeavour commercial. Recently, 'social benefit' within an American context has become central to the issue of use of public funds. This can be extrapolated to social benefit to people in the developing world as well.

Given the dubious patentability of some RTs, particularly with respect to industrial applicability, it was debatable whether third world countries are obliged under the TRIPS agreement to allow patents on RTIs. It was suggested that developing countries are required under TRIPS to provide patent protection for human gene sequences and there are no special exclusions for RTs. The central question seems to be that of what amounts to an invention. In a European context an 'invention' is patentable, but a 'discovery' is not. Under US law, an invention includes a discovery. In practice there is no difference in effect between the two positions.

MTAs and licenses under which the material is made available are often more problematic than patents on RTs. Considerable resources are spent negotiating for broader and 'customised' research exemptions. It was recommended that ways of institutionalising or codifying this process in law should be investigated. For example, under the American Inventors Patent Act passed in 1999, a researcher working independently on something that is subsequently patented by another entity can continue to use that technique and such use will not amount to infringement of the patent. It was pointed out that any resolution on access to RTs would have to take note of the distinction between intellectual property rights and tangible property rights. The right to use the patent without infringing it does not extend to access to the actual

material, which is subject of a separate contract. Both kinds of rights are reflected in the NIH Guidelines.

The RTs question may resolve itself as commercial enterprises stop bothering to negotiate 'use licenses' unless there is a real prospect of a commercial product. However many CGIAR scientists feel thwarted by the lack of access to RTs, specifically, 'Geographical Information System' and 'database rights' could potentially cause severe difficulties for the functioning of CGIAR. Centres like CGIAR should be situated in parts of the world where the reach of US patent law is minimal. CGIAR is a special case as they provide a lot of material to farmers. In this context it was agreed that the specifics of the legislation being introduced in developing countries in accordance with the TRIPS agreement is crucial. Strong rights to compulsory licenses scope for research must be maintained. To ensure access to RT, unreasonable valuation of RT by small private companies and inflation of what is allowed within the claims of the patent itself are two particularly insidious problems.

## **Session 2 – What are the IPR issues in public-private partnerships?**

**Presentation by Richard Mahoney**

***Intellectual Property, R&D, Public-private partnerships***

The specific question addressed was 'Can better management of IP in product R&D have an important impact on health in developing countries?'

The two prominent inequities in health, are that of 'cost' of new products, that acts as a barrier to the poor, and 'availability', as products needed predominantly by the poor receive much less attention. The use of IP in the public and private sectors is lopsided. The private sector has highly sophisticated abilities to manage IP, and uses IP effectively for their corporate objectives. In the public sector there is little clarity on the importance of IP and how it can be used to realise public sector objectives.

These findings led to the specific question of why and how better public sector IP management can address problems of cost and availability? The private sector has limitations and cannot be expected to assign high priority to products for the poor in developing countries. Conversely, a lack of such products indicates that the public sector has not fulfilled its responsibilities. Intellectual property is important because it provides opportunity for reward to risk capital in the private sector. Regulation is pervasive, affects all aspects of R&D, and is expensive to comply with. The prospect of reward acts as incentive for the investment for the private sector.

The following high priority needs were identified:

- Identification and codification of 'best practices' for licensing to achieve the goals of the public sector. These include:
  - Fields of use – reserve options for products likely to be for the poor.

- Territory – reserve options for developing countries
- Price – help ensure affordable price for the poor.
- ‘White Knight’ – specific benefits for the public sector and/or poor.
- Royalties – maximise benefit for the licensor; minimise burden on the poor.
- Training for scientists and administrators of universities, research institutes and product-specific groups in both developed and developing countries.
- Consulting services (delivery of best practices) to developing and developed country groups concerned with research and product development.

Other needs that have to be fulfilled include the establishment of IP databases, policy analysis and research, information collection and dissemination, brokering, patent pooling (for platform technologies, for example), and IP value assessment. The interim conclusions of the study proposed that an independent centre (MIHR) be set up as a consultative organisation that would work in collaboration with existing or emerging organisations. It would function as an IP management initiative addressed to developing country health needs. Expanded consultation is being currently provided, and it is hoped that the entity is created in early 2002.

The aims and objectives of the International Vaccine Institute is a case in point. The IVI is an autonomous international organisation under the Vienna Convention and is hosted by Korea. The IVI is a non-profit research centre that carries out many of the same research activities as private industry. However, unlike industry, the IVI accords highest priority to vaccines for the poor in developing countries. Its purpose in collaborating with industry is to assume a significant portion of the risk of vaccine development to meet the needs of the poor in developing countries. The major research programs span DOMI (Diseases of the most impoverished, bacterial diseases of Asian children, Vector borne diseases, and other enteric infections funded by various bodies. In the context of the IVI, and given these major research initiatives, IP is a matter of high priority. Some of the points of special protection are international agency access, and the need to maintain incentives for the private sector.

### **Presentation by Melinda Moree**

#### ***Intellectual Property and Neglected Diseases: Help or Hindrance?***

The mission of the Malaria Vaccine Initiative (MVI) is to accelerate the development of malaria vaccines and ensure their availability and accessibility for the developing world. While the clinical and preclinical expenditure in the development of a malaria vaccine is similar to that of any other vaccine, the profitability of malaria vaccines is significantly lower than the normal profitability of a vaccine. The strategic approach of MVI is to pull together various entities working in an academic, government or biotechnology firm into an ‘industrial model of management’ towards vaccine manufacture. Time is of utmost importance, thousands of children die every day due to malaria, and negotiating MTAs takes time. The major players in the field are

complicated entities with multiple stakeholders in academia, government and biotechnology companies. These stakeholders moreover, are distributed all over the world. Each of the patent stakeholders individually are entitled to small pieces of royalty that cumulatively make up about 30% of costs.

The case of one antigen (MSP-1) was used to illustrate the complexity. There are currently 34 MSP-1 patent 'families' that describe and claim the antigen, process the fragments and constructs, as well as deal with production and delivery of the antigen. The patent landscape that establishes the value of patents and the 'freedom to practice' risk for a product or technology in this case is very complicated. Within the MSP-1 patents there is little IP heritage to be found; there are very limited backward or forward citations. Most importantly, qualitative questions are raised about the validity and enforceability of the MSP-1 'patent families'. This case illustrates that although IP ownership is critical for commercialisation and investment, it can also prevent access for research into neglected diseases. High transaction cost in terms of time and money for access to the use of the subject matter of these patents leads to 'avoidance'.

The Malaria Vaccine Initiative's approach to the problem is based on the following:

- Vaccine developer retains 'ownership' of the project and the IP.
- In some cases an up-front license is requested.
- In all cases 'back-up rights' are requested if the vaccine developer ceases development of the malaria application.
- The MVI plays the role of a neutral broker and advises on IP strategies.

### **Discussion**

Compulsory licensing is irrelevant at the R&D stage where most of the hindrance exists. Although publicly embarrassing the groups that thwart important research maybe an effective way of dealing with the situation, it is often the cumulative effect of patents that is detrimental to further research. An effective solution may be to locate such research in the developing world where such patents may not have been taken out.

Any viable solution to the problem will have to take account of the following

- Doing away with the patent system in health research may prove counterproductive as the cost of regulations in the field and the resultant need to ensure return on investment could lead to such information being guarded as trade secrets.
- Special exemptions for 'neglected diseases' technologies may not be effective as in many cases technologies are developed for another use and then its use in 'neglected diseases' is realised.

The dubious quality and validity of some of these patents, called for guidelines on 'appropriate patentability' that patent examiners should enforce. The re-examination of patents is a very useful process and it should be applied liberally as it is easier to challenge the validity of a patent at the re-

examination (or application stage) rather than at a later (infringement stage). The American system does not adopt a re-examination procedure prior to the granting of the patent. It was pointed out that the problem is spread over various regulatory bodies and hence more difficult to solve.

## **Session 3 – What is the problem with human gene patents and what can we do about it?**

**Presentation by Sivaramjani Thambisetty**

***Informed Consent and Benefit Sharing in Patent Law: Incompatible or Necessary?***

Four central issues were raised.

### **1. How is informed consent related to patent law?**

Firstly, informed consent may include explicit consent to patenting of a resulting invention that arises out of or comprises human genetic material. Truly 'informed' consent protects the autonomy of the human subject, and in some cases 'conveys' property rights where limited property interests in genetic material are recognised. Secondly, patent law may play a role in enforcing requirements relating to prior informed consent for many reasons. Patents are a form of property and many developing countries have established 'sovereign rights' over human genetic material making authorisation for research necessary. The patent system affords an opportunity to put in place minimum requirements as to informed consent as oversight of compliance is difficult any other way. On the contrary, a major reason for not introducing such requirements in patent law is that this body of law is particularly unsuited to take morality into account. The increased costs and uncertainty in patentability may be detrimental to the bio-industry.

International Declaration that codify informed consent requirements are, UNESCO Declaration on the Human Genome and Human Rights, 1997, The Charter of fundamental rights of the European Union, 2000, The Convention on Biological Diversity, 1992 and recital 26 of the European Biotechnology Directive, 1998. National access regulations in India, China, the Andean Pact nations, and the Organisation of African Unity, also require informed consent. Many Indigenous peoples declarations also articulate this. It was pointed out that 'Peer pressure' within academia and industry can also act as an enforcement mechanism.

**Recommendation:** A 'certificate of compliance' to the effect that local laws and regulations were obeyed and that informed consent was taken from participants, whose origin and location are specified should be appended to all patent applications that describe human gene sequences and products derived therefrom.

### **2. Is 'benefit sharing' important in commercialisation of human genetic research?**

Two propositions were discussed in relation to 'Benefit sharing'. Firstly, that it may be a viable alternative to 'direct financial gain' to participants in genetic research. Secondly, the possibility that it may be made a component to patent law. Remuneration or 'direct financial gain' for participants in genetic research is prohibited. Given that developing countries may not have the financial or technological resources to undertake genetic studies themselves, but are however keen to use biotechnology as a spur for economic development, the question of 'returns' for participation in genetic studies assumes great importance. Access legislation in developing countries describe mechanisms for 'equitable sharing of benefits' such as technology transfer, humanitarian development work, immediate medical benefits, share in intellectual property etc. (for example, India, China, Tonga). In contrast, many developed country policy documents articulate a 'gratuitous model' of 'donation' of human genetic material to pre-empt any subsequent claims on the commercial benefits of the research. There are some documents like the HUGO statement on benefit sharing in 2000, that suggest that 1-3% of profits out of genetic research should be donated towards humanitarian work in developing countries. The Human Genome Diversity Project's Model Ethical Protocol suggests three principles of benefit sharing – legality, honesty and appropriateness of scale.

**Recommendation:** Development of an international consensus on the need for and mechanisms of benefit sharing. Profit making entities (patent holders) are actively encouraged to commit a percentage of profits from genetic research to developmental activity in participating target countries.

### **3. What does it take to keep 'genomic information freely available to scientists everywhere'?**

The most obvious way to keep gene sequences freely available is to deny their patentability. But genomic information in various forms is increasingly coming under monopoly control via patents. So far the internet has played a very important role in making genomic information available but empirical data shows that access by scientists in developing countries is substantially lower than those in the west. Data was collected on the number of times the 'ensembl' website was accessed from different locations to show this. Given that genomic information is in fact patentable in most developed countries means that most gene sequences will be patented by entities in the developed world, leading to a loss of access to discoveries for further research in the developing world.

**Recommendation:** Patents granted for application of genomic information should be limited to 'use claims' and should not extend to the gene sequence itself.

### **4. Does special legislation for pharmacogenetics raise any issues?**

Special legislation for 'Orphan drugs' is to be found in the US, Japan, Singapore, Australia and most recently in Europe that provide for broader

protection than patents. Pharmacogenomics offers the opportunity to 'genetically profile' patient populations and predict the therapeutic value of drug(s). This information can in turn be used to render a 'conventional' drug 'orphan'. This could lead to monopolies on drugs that are already in the public domain because of expired patents or to extend existing monopoly of patented drugs.

**Recommendation:** Careful scrutiny of market exclusivity provided to conventional drugs under the orphan drug legislations is called for.

### **Discussant**

Informed consent in patent law is 'necessary but not sufficient' and cannot be a substitute for fairness in all dealings between countries and individuals undertaking research. Benefit sharing should be incorporated into a mandatory scheme. It is unfair to expect corporations to be socially responsible and put the onus of voluntary compliance on them. An international regulatory framework should therefore replace notions of corporate responsibility towards benefit sharing.

In terms of keeping genomic information freely accessible, three remedies were suggested. Firstly, there was no justification for patents on gene sequences to cover all uses of the sequence. Secondly, discoveries of gene sequences should not be granted patents. Thirdly, more can be done to disseminate technology, especially to spread the use of bioinformatic tools. Such a need was 'desperate' as developing countries should have the capacity to study the genetic bases of diseases that concern them the most.

All gene databases, not just human, should be kept in the public domain. An insidious aspect of proprietary databases is that re-distribution of the information is prevented. This unreasonably inhibits research by restricting communication between researchers and publications. The need for public databases is absolutely necessary not only for developing countries but also researchers everywhere.

### **Discussion**

There were three central questions raised. Firstly, whether informed consent in developing countries should be regarded differently than in developed countries. Secondly, whether informed consent should be looked at within the ambit of patent law at all, rather than looking at it from the completely different perspective of protection of human subjects of research. Thirdly, in what way is the wider debate on informed consent and the need to specify sources in the case of patents on traditional knowledge different or similar to the requirement of informed consent in human genetic studies where it works as protection of the human subjects of research?

Most policy documents deal with traditional knowledge differently from human genetic material. The principles behind both are quite different. The notion of protection of the human subject is key to informed consent directed at the individual or community. The International Convention on Biological Diversity does not directly refer to human genetic material, and at the second meeting

of the conference of parties, it was decided that the CBD should not apply to human genetic material. This in itself makes the two issues separate. This was put in place because of the apparent repugnancy to the idea that one could trade in human genetic material. It was pointed out that the use of CBD-like arrangements in developing countries for access to human genetic material is contradictory to what was agreed at COP. Perhaps what can only be borrowed from CBD is a framework of arriving at an international consensus and then leaving it to national laws to implement a broad agreement.

The idea of 'moral rights' in copyright might provide a model to implement similar rights in patent law to do with protection of the human source of genetic material. Such a measure might be effective as there is theoretical precedence for it within Intellectual property law itself. But to term these as 'moral' requirements may undermine them as the patent system has shown itself to be averse to arguments based on morality.

Informed consent, is an indeterminate doctrine in itself and notoriously difficult to implement. The provider of the consent has an opportunity to negotiate some benefit sharing although there are often circumstances that cannot always be foreseen at the point at which informed consent is given. In such cases, other laws like anti trust legislation on consumer protection should be brought into effect. Because of the moral position that the body should not be subject of 'direct financial gain', the community gains prominence as a focal point for benefit sharing. Community consent can take many forms. In Iceland and Tonga, for example, population gene databanks have been set up under law. This may be construed as 'political consent'.

The question of compatibility of additional requirements like origin of the source, and informed consent with TRIPS, Art 27 (3) (b) was met with the possibility that it could be interpreted to fall within the public order and morality exception. There is no internationally agreed precedent for interpreting this clause and this may well work in favour of developing countries and 'local' interpretation. It was suggested that under TRIPS this was only applicable to 'commercialisation of the invention' and not grant of the patent itself. It was pointed out that the legal status of recital 26 of the European Biotechnology Directive which requires that 'informed consent' should be taken wherever possible is a source of disagreement between European countries.

Possible commercialisation via patents, as well as through exclusive licensing, should be disclosed to the provider of informed consent upfront. 'Inappropriate licensing' was a cause for concern for example, when the lung cancer vaccine, including the gene sequences, that were taken originally from two lung cancer patients were subsequently licensed exclusively to Japan Tobacco. It was pointed out that many people do not understand the implications of the patents. In such a case the efficacy of explaining the notion of patents to research participants is doubtful.

Genes can be used as diagnostic tools as in the case of the breast cancer genes, there are also patents on therapeutic proteins that incorporate the

gene sequences itself as in the case of EPO, and there is also the case of RTs where subsequent research can be done on the gene sequences. It was suggested that given that the European Biotech Directive is already in place, there is scope only to suggest incremental changes. Some of the aspects that require changes are the distinction between inventions and discoveries, the unjustified breadth of some of the patents, overlap of patent rights leading to huge transaction costs for useful research, patenting of RT that is a matter of concern for many pharmaceutical companies, the emphasis on protection of investment rather than invention, and other ethical concerns.

A number of remedies emerged during the discussion. It was strongly emphasised that the commission has an opportunity to improve the situation with respect to the invention-discovery distinction. This could take the form of guidelines. Inventions or discoveries happen as a process, and guidelines would help to characterise the process. This could extend to the function/utility aspect as well.

A distinction has to be made between the undesirable subject matter of the patent itself and the breadth of the patents (which may be solved by enablement doctrines, for example). In the specific context of the BRCA patent, the question of whether a narrower patent that would maintain the incentive effect while allowing further inventive activity around it, would be acceptable was posed. A more appropriate BRCA patent would be one that would not prevent development of a cheaper or more appropriate diagnostic device.

With respect to the discovery – invention dichotomy the theoretical basis of patents was raised. It was also strongly recommended that any guidelines aimed at corporate behaviour should be mandatory as anything else is unlikely to be effective given the lobbying power of MNCs and their objective to make profit.

There is a need to clarify that legislation under TRIPS can specifically exclude gene sequences from being patentable. Anglo-American patent terminology used in recent legislation in developing countries could in effect make such sequences patentable. The alleged contradiction between developing country rhetoric and practice was pointed out. Many developing countries seem keen to patent their own biodiversity in first world countries including the US, precisely because there is a market for it and there are profits to be made. At the same time many of these countries would not allow such patents in their own jurisdictions. It was suggested however, that this was due to the pressure of a lopsided system, similar to the way universities have been driven to aggressive patenting undermining their own academic objectives in the process.

#### **Session 4: Tour de table - Key issues and themes for the Commission**

- Commission has a key and timely opportunity to influence thinking about intellectual property rules and practice.
- Developing countries need institutional capacities to design appropriate IP regimes under TRIPS to take note of specific concerns dealt with in this workshop.
- Licensing of IPRs often has unintended consequences in limiting access. Undesirable clauses like 'exclusive rights in all fields of use' should be identified.
- Negotiating licenses and of access takes inordinate time and resources. Compulsory licenses should be considered as a viable alternative, irrespective of industry sensitivity to it. On the downside use of compulsory licenses can also be counter-productive, barring many potential partnerships with IPR owners.
- Inclusion of mechanism for pre-grant opposition periods in national patent laws should be considered. Bad patents may be prevented by greater attention to the role of patent examiners. Review of patent examination practice and possible audit of patent grants to look for overly broad or incorrect claims should be considered.
- There is need for greater transparency about how patents function. Misunderstandings can be particularly detrimental when consent is required from research subjects and licensing agreements for use of technology are being negotiated.
- A 'best practice' approach for licensing should be developed.
- Public-private partnerships have a negative affect on the IP policies of the public sector. There is a need to re-articulate the objectives of these institutions. IP policy for publicly funded research should maximize access to the knowledge generated.
- The correct mandate and obligations of developing countries with respect to gene patents under TRIPS should be clarified.
- The Commission should consider special measures for technology transfer to those countries suffering pandemic diseases in terms of public health related products.
- The commission should be wary of emphasizing the Consent issue, as this is largely based on the mistaken belief that potential windfall benefits are to be gained from genetic information.
- Patent law and ethical concerns should be kept separate. The latter is better dealt with elsewhere, as patent law is designed to reward

innovation. Tampering with this objective can be ineffective and raise transaction costs.

- Rather than target big pharmaceutical companies as the cause for the plight of public health of poor people, it would be more constructive to deal directly with neglected diseases. There are many good aspects of the current system that can be exploited through public-private partnerships.
- Although the case of MVI exemplifies the problems of licensing the enormous and (overlapping) range of different IPRs, it also means the necessary knowledge has already been created and exists as intellectual property because of the patent system. The patent system cannot be condemned in entirety as detrimental to developing platform technologies.
- The Commission should consider broadening research exemptions in patent law, by making these unambiguous (in the EU), or making a case for their inclusion where they are not currently incorporated (in the US)
- Commission should look at the UNESCO Declaration on the Human Genome and Human Rights (1997), as this already reflects a minimum level of international consensus on issues like consent, benefits sharing and technology transfer.
- Commission should consider recommending that countries stop a minimum level of international consensus. giving product patents on (human) gene sequences and restrict this to granting of 'use' claims.
- The commission should consider both sides of the invention-discovery dichotomy. The distinction appears irrelevant as the social purpose of the patent system is to encourage the development of useful technologies and their availability for use by people. And whether these are invention or discovery makes no difference. But patents on the discovery of human genes can fundamentally restrict future competition in (possibly better/cheaper) application technologies by restricting 'inventing around'.
- Patenting of research uses needs to be addressed by narrowing the scope of claims.
- Commission should consider the serious problem of the growing use of 'reach through' clauses in patent claims and in IP license agreements.
- Natural altruism is the expected norm (by ordinary people) in terms of benefit sharing of the use of human genetic material in commercial research, this should be institutionalised as a core part of the notion of 'consent'.

- The commission should use evidence and case studies as far as possible to inform debate and point to what the real issues are.
- Strengthening regulations requiring informed consent for use of human genetic material in medical research could have the undesirable effect of increasing costs and slowing the delivery of treatments and vaccines for neglected diseases in developing countries.