



**UNPACKING ACCESS:  
TOWARDS THE PRACTICAL IMPLEMENTATION OF BIOTECHNOLOGY**

**Workshop Report**

**Hosted by:**

*Intellectual Property Modeling Group organized through the Centre for Intellectual Property Policy (CIPP) and  
the International Centre for Trade and Sustainable Development (ICTSD)*

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## 1. Workshop Background

*Unpacking Access: Towards the Practical Implementation of Biotechnology* was a workshop organised by the Intellectual Property Modeling Group (IPMG) through the Centre for Intellectual Property Policy (CIPP) at McGill University. The workshop took place in Florence, Italy, on June 4-5, 2007 and is part of the IPMG's project *Legal Models of Biotechnological Intellectual Property Protection: A Transdisciplinary Approach* funded by Canada's Social Science and Humanities Research Council (SSHRC)<sup>1</sup>.

The workshop brought together a select group of approximately thirty participants ranging from international policy-makers, academics to non-state actors (see Appendix B for a list of participants). The discussion focused on different conceptions of access to biotechnological innovation, particularly in the health and agriculture sectors. The workshop considered these questions through the prism of challenges faced by Eastern Africa, although the discussion had broader resonance for developing countries more generally. The workshop built on a prior dialogue on access to biotechnology in East Africa that was organized by the International Centre for Trade and Sustainable Development (ICTSD), which co-hosted the *Unpacking Access* workshop with CIPP.

The workshop agenda can be viewed in Appendix A. It included updates from particular countries and organizations on IP as it relates to the larger project being conducted by the IPMG. The core of the workshop included three sessions investigating aspects of the challenge of making biotechnological innovation accessible to those most in need. The three sessions examined: access to agricultural and health-related *products*; access to agricultural and health-related *knowledge*; and access to *business & money* for agricultural and health-related biotechnology.

The workshop format encouraged dialogue and interaction between the invitees. Each of the three sessions began with an academic overview of the topic, followed by short statements by

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<sup>1</sup> You can find information about the IPMG, including reports from previous meetings and SSHRC on the following websites: [www.cipp.mcgill.ca](http://www.cipp.mcgill.ca) and [www.sshrc.ca](http://www.sshrc.ca).

participants in response to questions that were posed to them in advance. These responses were then followed by actively moderated discussions between the participants with the following questions as a guide: to what biotech products is access needed; who needs such access; how is access secured; how are access needs prioritized; and how do we mitigate the potential risks of access. This report summarizes the proceedings and discussions from the workshop.

## **2. The IPMG Modeling Group: Project Overview and Methodology**

The IPMG is a research group of international, transdisciplinary researchers organized through the CIPP. IPMG researchers from law, management, economics, ethics, philosophy, political science and the life and medical sciences are engaged in a comprehensive effort to expand our understanding of intellectual property protection for biotechnology.

The IPMG seeks to help policymakers around the world determine how best to calibrate intellectual property systems to achieve desired policy goals in biotechnology that benefit society. Specific objectives include enhancing policymakers' understanding of how laws, practices and institutions actually function, and developing creative strategies for designing more effective intellectual property systems.

The IPMG uses a rigorous empirically-based research process to address the central challenge of intellectual property systems: the need to balance conflicting interests to ensure a dynamic cultural, scientific and economic environment. IPMG researchers identify how laws, practices and institutions actually work to create or block the development of new knowledge and they have built a map showing how laws, practices and institutions work together. In addition, the IPMG has collected empirical data to interpret this map. Drawing on this work, the IPMG has built a framework for understanding how IP systems work in the real world, based on real data. This kind of research is innovative, unique and necessary.

In the fall of 2008, the IPMG will publish its findings in a report, as well as case studies examining different aspects of the biotechnological intellectual property system.

### **3. Country and Organization Reports**

The workshop opened with updates of the IP landscape for countries (Kenya, South Africa, Canada, USA) and organizations (WIPO, MSF, OECD).

Kenya enacted an IP law in 2003 and has drafted an IP policy that is being circulated as a guideline for policy-makers. While a biosafety law has yet to be passed, a biosafety policy was developed in 2003. The Plant Variety Protection Act 1978 is currently under review and will be brought into line with UPOV to address concerns about GMO crops.

The USA commentator highlighted that there are continued discussions exploring the link between patent systems and optimizing innovation. Two patent reform acts were reintroduced to the House and Senate in April 2007. The acts focus on reforms that aim to improve the quality of patents, reduce the high costs of litigation, curb potential abuses by patent speculators, and address the needs of universities, individual inventors, and small firms. Software is the key industry driving the reform. The commentator also highlighted important caselaw, noted that a private bill to ban gene patents has been introduced, and highlighted the emergence of movements to explore alternative modes of protection to increase innovation and access.

In Canada, the minority conservative government recently adopted a commercialization approach to R&D in the area of biotechnology that is favourable to the private sector and that changed the government's past extensive involvement in R&D, which funded targeted investment controlled by region and sector. Academics tend to be pursuing open access approaches, though there is debate as to whether such approaches are followed in preparing and receiving grants. In sum, the attitudes of the federal government and research communities towards commercialization are diverging.

The South African commentator noted that three issues have emerged. First, the status of the patent grant as a registration system – with no search or test for prior art – has significant implications for commercialization as companies are reluctant to adopt a patent of uncertain

validity. Second, most South Africans patent inventions in the US, a number of EU countries, and possibly Japan and Israel. This increases the costs of applying and maintaining patents, making it difficult to achieve the balance between research and maintaining a patent portfolio. Third, a bill is going before the South African parliament addressing TK in an attempt to stop biopiracy. The commentator noted that very little IP law is taught to law students in school, and none is taught to students in science, business, and medicine. This situation is problematic for building local capacity.

Following a brief discussion, commentators provided updates on the activities of various organizations, beginning with the WIPO representative. He commented that in the area of TK protection, WIPO is working on new norms to protect against the misuse and misappropriation of knowledge. It is also developing legal provisions for more effective and equitable IP norms. An international framework is emerging that supports national policy making and TK communities. This is happening alongside strengthening the capacity of communities to document knowledge, which is important to determining its equitable use. This process has examined the IP aspects of TK protection and has placed indigenous and local communities' interests at the centre of the work, leading to a cultural shift in the organization. Two broad policy goals that have emerged are preservation of TK and supporting the cultural structures within which TK is created. There have been discussions over developing a treaty which is at the stage of a draft set of objectives and principles. The most important principle is preventing misappropriation, which includes illicit acquisition, breach of prior informed consent, wrongful assertion of IP rights over TK, gainful use of TK at odds with equity, and moral and spiritual rights over TK. WIPO has been working with other international organizations in areas such as bioethics to help policy makers navigate the ethical issues that arise with IP.

The representative from MSF noted that its Access to Essential Medicines Campaign emerged amidst concerns regarding the impact of patents on access to existing medicines and the development of new medicines. MSF has been responding in part to observations that smaller biotechnology firms are often interested in applying their knowledge and technologies to develop drugs for parasitic or other diseases, but these interests quickly fade when larger pharmaceutical companies buy them out. MSF is also interested in fundamentally questioning current paradigms

for stimulating innovation in order to develop different models, such as alternative incentive mechanisms, that address the links between R&D costs and the cost of medicines. MSF also notes the emergence of a global student movement based in universities that is persuading universities and public sector researchers to adopt patent policies that do not inhibit access to medicines.

The representative from the OECD noted that the 30 advanced industrialized nations that comprise the organization discuss good government practices that encourage trade and economic growth for members. The OECD has been examining changes in innovation cycles, regulatory structures, increasing the number of participants in the innovation cycle, and securing clinical R&D funding. These projects are primarily focused on making innovation available and, to some extent, accessible. The OECD began to consider public health issues when the human genome was being sequenced and has been concerned with how to create an environment in which the genome sequence could be diffused as broadly as possible, not whether it should or should not be patentable. This led to a project that ended in 2006 considering best practices with respect to incentive structures, licensing guidelines, and avoiding patent-related blockages. Another area of interest is in collaborative mechanisms, like open source, clearinghouses, patent pools, consortia, and the concrete cases in which they can be applied. A project focusing on neglected and emerging diseases has created a forum to address what can be done to accelerate the research cycle and prime the pipeline for cheaper drugs, vaccines, and diagnostics for infectious diseases that affect developing countries. In contrast to MSF's notion of decoupling pricing from the actual funding of R&D, the OECD is interested in reducing the cost of R&D so that it is possible for businesses to make the necessary financial investment. Thus R&D must be shared, interactive, and updatable. A parallel discussion on creating cheaper and more effective innovation systems for infectious diseases proposes that industry do 'pro-bono' work through developing infrastructure to share tools such as libraries, parallel studies, and toxicology studies. The OECD hopes that what can be implemented for infectious diseases may also lead to innovative practices with respect to non-infectious diseases.

An animated discussion followed the reports from organizations opening with the question of how patent landscapes can be made more transparent. This is increasingly happening through

the proliferation of appropriate information technology, public policy processes that are demanding relevant information, and major efforts to digitize patent information. It was noted that while encouraging industry to share its research may reduce the costs of research, this may not have an impact on costs associated with other activities. The major cost of drugs, for example, is attributable to marketing and advertisement, and not to research. Thus these costs will not likely decrease even if sharing increases. Participants noted that the OECD's attempt to reduce the costs of R&D and search for new business models is complementary to MSF's efforts to arrive at a different financing model. The OECD reiterated that dialogue on these issues must include NGOs in addition to big pharmaceuticals and country politicians.

#### **4. Panel Discussing Access to IP Knowledge**

The workshop then moved to the first set of panelists discussing access to agricultural and health-related IP Knowledge. Julian Kinderlerer of the University of Cape Town, South Africa provided the introductory overview to the topic. He highlighted that in South Africa, access to clean water, adequate housing, food, drugs for major diseases, and hospitals are priorities for healthcare particularly when dealing with the HIV/AIDS pandemic. Access to both governmental and non-governmental information is central to access to knowledge initiatives. Weak internet connections in many areas of Africa prevent people from gaining access to information. Since one cannot obtain patent information online, one has to refer to a book instead. For example, the anti-GM movement has had to apply to court several times to obtain information that is theoretically available on the internet. Moreover, while the University of Cape Town has some journals online, it has far fewer than what is available at institutions in the US or Europe.

Rose Ndegwa of the International Livestock Research Institute, Kenya was tasked with answering the question of whether patent protection can get in the way of accessing knowledge. She highlighted that the last couple of decades have seen changes in the intellectual property arena, driven largely by increased privatization of agricultural research and development, expansion of IP scope to cover non-traditional areas like life forms, and liberalization of markets. These have had an impact on the public sector's role in agricultural research and in delivery of

research products to relevant beneficiaries, primarily the resource poor. Against this background, public research institutions have to establish collaborative links with advanced laboratories in order to access technologies; ensure product development and delivery; and guard against misappropriation of resulting technologies. She noted that patenting is regarded as a Western concept that conflicts with African concepts of communal ownership and that activists believe that patents play little role in incentivizing innovation. The complexity of navigating through these challenges for researchers has led some to believe that IP rights are incompatible with the ideals of public research and development, specifically because they hinder access to those technologies covered by IP. Public institutions can build their capacity to access knowledge through means such as establishing collaborative links and ensuring product development and distribution.

Anthony Taubman from the World Intellectual Property Office, Geneva, answered the question of how useful traditional knowledge is to the scientific community and how best the interface between the traditional and scientific communities can be dealt with. He proposed that this interface must be understood by examining the relationship between holders of TK and the scientific community and by reference to the principles that this relationship ought to be built upon, namely respect, recognition and equity. First, the relationship must be built on respect, which has both a technical and legal aspect; that is, to build the system around recognition of values and the customary laws that apply within the community from which the knowledge originates. Second, the relationship must be built on recognition; recognition is a matter of shifting value systems but, above all, the intellectual contribution of the TK holder needs to be recognized on par with any other participant in the process. Finally, the relationship must be built on equity and sustainable forms of partnerships.

IP is often criticized as a form of commodification of TK. In reality, if we speak of IP rights in the knowledge, we are talking about mechanisms that entitle the community to decide when, to whom and how knowledge is to be used and applied; however, IP rights can never be a stand alone solution but only one part of a broader discussion. Recognizing that the people who develop, sustain and exercise TK should have a say over how that knowledge is put into practice is fundamental. Taubman considered the meaning of the idea of protection of TK. While he

stated that the discussion often focused on the public domain he noted that one must be conscious of the source of TK. Finally, he argued that we cannot continue to benefit from TK knowledge without recognizing it as a legitimate form of innovation.

Tania Bubela from the University of Alberta, Canada then answered the question of whether the scientific community should have access to traditional knowledge. She pointed out the irony in the fact that the scientific community is embracing the norms of open access to information at the same time as indigenous communities are asserting stringent property rights over TK. This position is a backlash against what indigenous peoples consider the appropriation of TK without acknowledgement and appropriate sensitivity to the cultural context of that knowledge. This paradoxical situation is illustrated, in the Canadian context, by the International Polar Year (IPY). IPY is a major international publicly funded scientific research initiative on the Poles. It includes socio-cultural and health research. The data management policy at the Canadian and international level calls for the immediate public availability of all metadata, data and publications, wherever possible. One of the few exceptions to open access is when dissemination of TK interferes with the rights of knowledge holders. At the same time, science projects are required to consult with communities and to integrate TK. Unfortunately, in the current political climate, meaningful collaboration and trust-building between TK holders and the research community may not be possible. The scientific community must recognize that it does not have unfettered rights of access to information from any community, including the TK of indigenous peoples. TK should be accorded the same respect and protection as other forms of information and the degree of respect must be determined, on a case-by-case basis, by the holders of that knowledge. At the same time, holders of TK must recognize that unless TK is available, it will not contribute to the scientific assessment that will shape government policies and future investment.

Discussants responding to the presentations noted that a distinction can be made in TK debates between equitable access to content and an equitable process by which one acquires the content. They noted that many cases of misappropriation have resulted from a failure to work within the cultural framework of the source community and build trust. Community involvement raises issues of governance and individual consent particularly since there is a tendency to impose

conceptions of knowledge on communities through IP rather than considering their customary practices in handling knowledge. Major errors can occur when one paradigm does not align with another. For example, a chief may not have any greater or lesser rights than the rest of a group with respect to knowledge, thus such a chief may not be able to represent the community in negotiations. Some discussants noted that many NGOs arrive with views that perpetuate their own paradigm or agenda, and need to adapt culturally and environmentally if they want to be effective and viewed as legitimate. Issues also arise when different tribes have claims over the same piece of knowledge; attributing ownership based on chronology may not work as both communities may have arrived at the same knowledge from different approaches.

Discussants further noted that NGOs and others must also take care not to impose knowledge management assumptions on TK communities. In TK communities 'rights' talk can be an erroneous approach in that there can be a responsibility to pass on the knowledge or distribute it that is inextricably linked with the 'right'. In this case, proper knowledge management would require that a distinction be made between knowledge that is shared and knowledge that is proprietary. For example, farming knowledge is shared because it is important to the survival of the community. Unique seed varieties are exchanged so that they can be revived if they are destroyed. Similarly, knowledge important to the identity of a community also carries special responsibilities. Thus one could consider sharing as the norm and proprietary access as the exception. In this context the debate shifts from public interest arguments to appropriation.

Additionally, knowledge may be compartmentalized within communities. For example, sometimes community members will only gain access to knowledge that resides with elders when they have developed some of their own wisdom and maturity. Thus, even within a framework of sharing, norms other than proprietary ones determine access. These observations highlight the recognition that knowledge functions as a system, where pieces used out of context may be dangerous. TK thus has much to offer in terms of understanding different possible forms of access. In the end, however, when a sharing system is contrasted with a proprietary system, it is the community that engages in sharing that stands to lose from the restrictions that can be imposed when knowledge moves into the proprietary domain.

Several discussants also noted that a number of major initiatives in knowledge generation have taken place in East Africa in the last few years. Research has been under strict field trials or in labs as biosafety laws are not yet in place. Monsanto is engaged in GM research with the bioarm project, looking at generating new knowledge through the development of new varieties. In addition, Biosciences eastern and central Africa (BecA) is developing and applying bioscience research and expertise to “produce technologies that help poor farmers secure their assets, improve their productivity and income and increase their market opportunities.”<sup>2</sup> BecA is endorsed by NEPAD and is intended to be a hub for the African scientific community to address agricultural problems relating to poverty and promoting development. It is currently involved in bioinformatics and medical research. The research center has had an IP unit for the last 3 years but since goods are produced for the public good there is a reduced need for patent protection. For example, a diagnostic test for HIV it has developed is widely in use.

Internationally, there has been a shift from a focus on public research towards translating research into products that can be commercialized. There is also a growing recognition of the benefit of maintaining and enforcing public benefit goals. Thus the question becomes how to balance the interests of public institutions with the desire to move products into the market and, as a subsidiary question, whether IP protection is required to achieve this. Further questions remain, particularly in Africa, as to how one stimulates (sometimes non-existent) private sector actors to take up product development, manufacturing, and distribution. In the end, technology transfer can include building the capacity of public institutions in areas from the development of vaccines to the development of business models.

Technology transfer offices are thought to play this role in commercialization, although the returns are not always clear after tallying investments in lawyers, patent fees, and other costs. Licensing is normally conducted for continuing trials where the technology is imported, but there is a sense that research for noncommercial purposes should be exempted from infringement. Further, there are areas of research where researchers are motivated by a common humanitarian goal. For example, the community of researchers searching for an AIDS vaccine has engaged in a collaborative model of research and the players have long-term relationships. It would be

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<sup>2</sup> From the BecA website at: [http://www.biosciencesafrica.org/about\\_BecA.htm](http://www.biosciencesafrica.org/about_BecA.htm)

interesting to explore whether it would be possible to create such collaborative relations in other areas of research where people have a common humanitarian goal and have developed relationships of trust with one another. The US Bayh Doyle university technology transfer model, which at least accompanied increased investment in biotechnology in the US, is thought to have limited applicability to the developing world.

## **5. Panel Discussing Access to IP Products**

This panel discussing access to IP products opened with an introductory overview by Richard Gold from the IPMG. He pointed out that the question of access goes beyond access to a product towards access to an entire infrastructure. Access to infrastructure depends on factors such as national priorities and regulatory frameworks. He argued that negotiating the strength of IP is a process of optimizing access to products both now and in the future. In this context, Gold discussed IPMG case-studies that examine plant derived vaccines, Myriad Genetics, and the Mouse consortium. A strong conclusion emerging from these case studies is that, in order to enable access to the new products of biotechnology, one must consider the entire system – from research infrastructure, financing opportunities to diffusion platforms – that allows products and services to be disseminated rather than simply considering making a product available. In sum, IP may not be the primary stumbling block to access.

Discussion then turned to panelists who answered pre-posed questions. Marie Chamay from ICTSD, Switzerland answered the question of whether policies may be needed to regulate trade and access to biotechnology products. She responded that first governments should analyse and identify their short, medium and long term needs, policy gaps and priorities related to biotechnology. Countries' policies and strategies for biotechnology development should be based on clearly identified objectives that are specific and formulated through participatory processes. These could include: ensuring food security; increasing agricultural productivity, prioritizing rural development and poverty alleviation; promoting economic growth through diversification into high-value products and technological development; promoting public health and food safety; and conserving, sustainably using and equitably sharing the benefits of biodiversity.

Achieving these objectives will entail addressing and integrating a range of policy areas and instruments in order to develop a coherent biotechnology policy framework. Countries must simultaneously ensure compatibility of their regulations with WTO rules, such as those governing the application of sanitary and phytosanitary measures. Moreover, countries wishing to grow biotechnology crops will need to set up systems to comply with stringent labeling and traceability requirements of trading partners such as the EU or China.

Chamay argued that national policies relevant to access to biotechnology include policies aimed at creating an enabling environment for the development of biotechnology through making explicit government support for biotechnology, implementing IP regulatory mechanisms, establishing a biosafety regulatory framework, and developing local R&D capacity.

Kent Nnadozie from the CIPP/McGill University, Canada then answered the question of what are the key issues of technology transfer from North-South, South to North, or South to South. He noted that there exists a need in Eastern Africa to deal with structural and systemic issues particularly as the region faces the challenges of a rapidly changing legal, ethical and political landscape, an externally set and driven agenda, and insufficient or weak scientific, legal and institutional capacity. For both the short term and long term, good governance is critical.

The key issues he raised were capacity, access and cost; international legal regimes, international relations and politics; asymmetry of resources and knowledge and, therefore, power; appropriateness or suitability of technology; policy coherence and development of priorities and strategies for intervention; and cascading developments in technological fields that render specific rules and regulations quickly obsolete. These are important, he argued, because of the increasing convergence of trade, food & agriculture, health and technology transfer issues; international policy developments that increasingly determine national policy and research activities; dwindling funding/resources for public research; and increasing private sector involvement and clout in international agenda-setting.

Bénédicte Callan from the OECD then answered the question about the extent to which developed countries are the problem or the solution to the issue of access to biotechnology in

Eastern Africa. She argued that access is not an end in itself, but rather the goal is to create domestic scientific capacity to serve domestic needs in the areas of health and agriculture. She separated types of access into access to scientific knowledge, access to materials, access to know-how, access to products, and access to innovation. She pointed out that access can be static or dynamic and that recognizing different conceptions of access can promote holistic solutions to access issues. She argued that while there has been much discussion of whether the IP regime itself is a problem – there is little evidence one way or the other – OECD countries will not solve access issues through IP and trade. They might relieve pressure to enact IP regimes but this would have to be supported by hard economic data. Similarly, the work being done on open source mechanisms could also present an alternative to the current IP system if empirical evidence shows where and when they work, and the extent of their utility.

Kate Hoyer from the University of Ottawa, Canada then answered the question of what access means in dominant narratives and models. She argued that the Bayh-Dole Act in the US and open access both value the same thing, “access”, but that the two value different aspects of access. Bayh-Dole intended to remove administrative hurdles to commercialization by technology transfer at universities, rather than remove IP barriers to researcher access to technology. Prior to the Act, the dominant narrative was that industry would develop products based simply on the publication of research, in turn increasing economic competitiveness. This turned out not to be the case, giving rise to the need for a bridge between universities and industry: the technology transfer office. The Bayh-Dole Act simplified the process through which universities could transfer technology. However, the original purpose of the Act was soon lost. The narrative shifted to the largely unsupported notion that IP and its exclusive licensing by technology transfer offices would lead to job and wealth creation. This narrative is particularly strong, and particularly misleading, when something akin to the Bayh Dole Act is legislated outside the US. Countries that do not share the same historical concerns of inter-institutional IP red tape and university structure as in the US, would be unlikely to benefit from such legislation. She remarked that Bayh-Dole addressed open access in its own narrow way, however, by showing that open access can create roadblocks in the wrong hands. Thus, simply placing innovation on the internet is not enough to achieve access as others may use it to block access to resulting inventions.

Finally Ellen t’Hoen from Médecins sans frontières, France answered the question of whether we can fix the problem of access to health care products without legislative change. MSF has made three observations with respect to drugs that people in need cannot access. First, there is a clear link between R&D and access issues in that many drugs are not available because they simply have not been developed. Second, products may be available but are not available in the forms that are needed (combination, pediatric, and heat stable therapies). In these cases, the technology exists to make such drugs available but market incentives fail to justify production. Third, IP protection and patents in particular make products unaffordable in spite of the availability of drugs. She thus observed that patent monopolies are creating barriers and allowing the private sector to dictate and shape much of the public health landscape. In the short term, NGOs and other market actors can be of assistance. She gave two examples. First, prices for anti-retroviral treatments can be reduced with the introduction of generic competition into the market. It is thus critical that mechanisms be found to ensure such competition as soon as possible. Second, Roche has a patent on an effective drug for treatment of an infection in the eye that leads to blindness if left untreated. MSF was able to negotiate a special pricing agreement to make the treatment available only for NGOs and exclusively for use in developing countries.

To address concerns in the longer term, however, she argued that we need to implement rules that already exist and revise other rules appropriately. The TRIPs Agreement’s clear public policy objectives need to be implemented as they are often ignored even in the face of the additional interpretive force of the Doha Declaration. She observed that many countries have not had an easy time implementing compulsory licensing or paragraph 6 of the Doha Declaration (which allows for the export of generic drugs to countries that do not have the capacity to manufacture their own). Alternatively, there are barriers to implementing compulsory licensing created by article 31(f) of TRIPS that could contribute to increasing access to treatment if appropriately revised.

A broad-ranging discussion followed the remarks of the panelists, focusing on the need to consider how the patent system works to support getting products to market. Commentators identified two types of access barrier: first, complete market failure (as in the case for neglected

diseases) or second, ensuring that IP does not promote trade barriers. One commentator raised transgenic soybeans grown in Argentina as an example of the second type of barrier. These do not yield royalties for Monsanto because they did not patent it in Argentina. Production of soybeans has increased significantly as a result of Argentina farming them. Recently Argentina's exports to Europe were challenged in the Dutch courts because the variety is patented in Europe even though it is not patented in Argentina. In this case, the patent system may be stopping the export of a major product grown legally.

Discussants pointed to the need to consider revising metrics used to assess technology transfer offices to be more subtle than merely royalties and number of licences issued as technology transfer offices are motivated to meet metrics. There is a dearth, however, of information being collected on alternative practices that could be used as metrics such as humanitarian licensing, which creates a distorted picture of what is actually happening. Similarly, if we were to measure innovation by the pharmaceutical industry as the number of new therapeutic drugs introduced rather than as the number of patent applications filed, we would conclude that innovation from the industry has actually decreased in spite of an increase in both patents and funding. Clarity on how innovation is measured is useful to discussing the problems with the current system.

Some discussants further noted that while there is economic evidence of the link between patent rights and the ability to economically afford a product, there is little evidence demonstrating that patent rights motivate industry to develop therapeutic drugs or participate in foreign direct investment (FDI). While the aggregate of drug prices for low or middle income countries did not increase with the introduction of TRIPS, there is evidence that patents increase price and the introduction of generics decreases price. According to these discussants, more evidence of the systemic effects of TRIPs is, however, needed in order to renegotiate the agreement. Any reform proposals must account for the need to foster a research-based innovation system that may require monopolies. Renewed IP policy-making should, according to these discussants, focus on the need for broad management of essential medicines, rather than relying on management from the patent holder alone.

## **6. Panel Discussing Access to Money and Funding**

Anthony So of Duke University, USA provided the overview to the panel discussing access to markets, business & money for agricultural and health-related biotechnology. He posited that systematic market failures have led to a need for creative approaches to innovation in the area of access to medicines. He also argued that it is useful to conceptually distinguish frameworks for access. For example, financial access is a significant barrier to therapeutic access. He further raised the importance of questioning whether new approaches match global health priorities and remarked on a number of public sector interventions that make creative use of private sector capacities: tax credits, R&D funding, dual market solutions etc. He also argued the importance of considering alternatives like advanced market commitments for late stage vaccines, supplementing the patent system through prizes, and thinking of push and pull mechanisms that will prompt the innovation system to produce what the future demands, with particular attention to developing vaccines for developing country contexts. He further questioned whether we should be delinking the price of drugs and IP, and whether the R&D chain should be reengineered.

Shahid Yusuf from the World Bank, Switzerland was the first panelist and considered what the relationship is between access to knowledge and economic growth in health and agriculture. He stated that modern agriculture is a resource, energy and knowledge intensive activity employing a tiny fraction of the workforce. Through interdisciplinary research by public and private entities, yields across a broad spectrum of commodities are increasing and crop characteristics are being continuously modified to facilitate storage and to minimize transportation costs. Crop protection against disease and pests is also registering steady progress. He argued that three challenges will require a redoubling of research effort and the rapid assimilation of findings by producers: first, the anticipated growth in population and the expectation of a continuing convergence in nutrition levels among countries; second, impending climate change; and third, increasing energy costs. He predicted that biotechnology and ICTs will make a strong contribution to dealing with these challenges. Health care will face similar challenges including population growth, urbanization, the rising average age of the population, emergence of virulent disease organisms, and the threats posed by global warming and associated extreme climatic events. In sum, he argued that the need

for investment in knowledge and the effective application of this knowledge has never been greater.

Moustapha Kamal Gueye from ICTSD, Switzerland then addressed the question of what the barriers are that FDI contributes to access in the area of biotechnology. He stated that as a technology and capital intensive industry, the biotechnology sector requires significant levels of investment. While many developing countries are endowed with important genetic and other natural resources that are essential to the biotechnology industry in its various applications, deficient infrastructure and limited financial resources hinder the development of that potential by means of domestic resources alone. Foreign investment can play a crucial role, not least because it could allow inflow of resources, but also the transfer of technology capacities through the process of relocation of R&D and productive functions in developing countries.

FDI in biotechnology shows a high-degree of geographical concentration in line with the general pattern of geographical distribution of FDI in which FDI investment is concentrated in those countries with the most advanced level of technology in an industry. Leading developing country locations include Singapore, South Korea, China, and India. Historically, biotechnology companies have tended to congregate around a common location of interconnected firms, specialised suppliers and providers, and associated institutions such as research institutions. This observation is being realized at the policy level in developing countries. Singapore, for example, has invested \$8 billion in its Biopolis, and China is developing two centers at an investment of \$500 million. These sites offer prospective tenants grants for research and development costs, in addition to tax incentives and venture capital. Biotech parks alone are unlikely to attract sufficient FDI. Biotech companies also tend to seek locations with strong IP protection. It is reported that interest in investing in India has increased after its product patent regime came into force in January 2005. Apart from providing incentives, government FDI policies need to strike the right balance between access and benefit sharing to ensure sustainable development.

Joseph Wekundah from the Biotechnology Trust Africa, Kenya then answered the question about the extent to which micro credit can jump-start biotechnology commercialization in Eastern Africa. He argued that access to credit by farmers is still a major problem. The risks associated

with farming coupled with complicated land laws and tenure systems that limit the use of land as collateral, make the financing of agriculture by financial institutions unattractive. Cooperatives support farmers through supplies and credit but, due to mismanagement, most have collapsed in Kenya. Currently, small-scale farmers obtain credit from projects implemented by NGOs and CBOs. Biotechnology products are expensive, and farmers require credit to access them which could be in the form of inputs such as seedlings. NGOs have developed a model for providing this support without asking farmers for collateral. They organized the farmers into small groups from the same area with the purpose of guaranteeing each other. Farmers are given credit to make purchases, they pay back the credit when they profit at which time further credit is available. Farmers have a grace period of three months before they have to start making repayments. In some places this model has been used to establish village banks. This model has yielded in an increase in household incomes. For example, in one project providing TC banana seedlings in Kenya, this mechanism increased baseline income by 38% per farm with a repayment rate of 95%. Similarly providing a Newcastle Disease Vaccine to farmers three times a year generated, on average, an income of between US\$563 and US\$1000 per household. Credit is thus important to providing farmers with small scale access to biotechnological products. These types of credit schemes could be transferable from Kenya to East Africa as a whole.

Betty Kiplagat from the Kenya Agricultural Research Institute, Kenya rounded out the discussion on this panel by considering what (if anything) distinguishes Eastern Africa as a region in its technology transfer policies. She highlighted that technology transfer currently occurs through both informal and formal means. Informally, knowledge exchanges and local training occur through conservation initiatives, sharing of indigenous knowledge and students returning from study abroad. Formally, organizations like BIO-EARN, ASARECA, ECABIO and BecA facilitate technology transfer. She noted, however, that there is yet to be adopted legislation, regulations, and policy to govern technology transfer. She also pointed to a need to increase IP management capacity, risk assessment, and funding for technology transfer particularly in light of the number of innovations flowing from the South, pointing to the examples of artemisinin and sweet worm wood. She favourably raised the example of the Gates Foundation that has required groups receiving funding to agree that IP will be bypassed for

product distribution in the developing world. She further raised the importance of South-South technology transfer that will enable independence from the North as a knowledge centre. She concluded that research agendas should be taking a broad view of IP and accounting for ideas in *The Next 4 Billion* report<sup>3</sup> that sees the 4 billion people in the South as representing a market. IP needs to be thought of in this broader context as a means of fostering new ways to unlock and codify knowledge from the South so that the rest of the world can learn continually and sustainably from the knowledge produced.

Discussion followed the presentation of the panelists and centered on concerns specific to building capacity in Eastern Africa. These include retention concerns when nationals are sent abroad for education as well as problems with aid from international partners that come with preconditions and goals articulated without consultation with locals. Most discussants agreed that country, not donor, priorities should be the focus of aid. Further, educating policy makers and farmers about key questions that need to be asked before funding is received is important to addressing local needs and building capacity: for example, how to market products and how sustainable are products introduced. Developed countries have generally failed to work with technology and people on the ground and have been slow to realize the importance of interpersonal relationships and evaluating whether or not the relevant knowledge exchange has taken place. Discussants were divided on whether it was good policy or sustainable to rely on aid, and raised the examples of Gates and Rockefeller as sparking a rethinking about how private sector expertise is applied to the public sector. Questions also remained for the discussants about the value and effect of regulatory frameworks.

## **7. Workshop Consolidation**

Overall, parties to the workshop agreed that defining the terms of discussion is necessary to enable progress. Key terms include “access”, “knowledge”, “markets” and “products”. Discussants ranged from the view that if we get the IP system right then we can resolve access problems, to the contention that the IP system is fundamentally flawed and needs to be

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<sup>3</sup> available at [http://www.wri.org/business/pubs\\_description.cfm?pid=4142](http://www.wri.org/business/pubs_description.cfm?pid=4142)

overhauled and we should be looking for something entirely different. Resolving which presents the better vision moving forward is a question of evidence, creating reliable metrics and developing meaningful relationships, as well as listening to all parties in the debate about important concerns regarding the role of aid, TK and regional priorities. Thus IP may or may not be a barrier to access, depending on the situation being examined. IP can be a useful tool with a particular purpose somewhere in a long chain of events. Properly understanding when and when not to patent and licence, under appropriate institutional supervision, may bypass massive failures. Acknowledging the failures of the IP system increases our ability to use the IP system for its intended purpose. The more skeptical view regards the IP system as a necessary evil and thus our efforts should concentrate on simply minimizing its negative impact. There was general agreement, however, that IP is just one small piece of the picture of innovation and maybe even irrelevant to innovation in many cases. At a minimum, the legal language of IP is a common language that can be used in discussions about access.

## 8. Appendix A – Workshop Agenda



### ***Unpacking Access: Towards the Practical Implementation of Biotechnology***

European University Institute, Florence, Italy

June 4-5, 2007

Refectory of the Badia

### **AGENDA**

| <b>MONDAY JUNE 4</b> |  |
|----------------------|--|
| <b>9:00-9:45am</b>   | <b>Welcome and Introductions</b>   |
|                      | <i>Welcome address – purpose of workshop, agenda, etc.</i><br>Tina Piper (McGill University, Canada) |
|                      | <i>Introduction of ICTSD</i><br>Marie Chamay (ICTSD, Switzerland)                                    |
|                      | <i>Participants' Introductions</i>   |
| <b>9:45-10:30am</b>  | <b>Country/Regional Updates</b><br>Facilitator: oline Twiss (McGill University, Canada)              |
|                      | <i>Kenya</i><br>Betty Kiplagat (KARI, Kenya)   |
|                      | <i>USA</i><br>Julia Carbone (Duke University, USA and McGill University, Canada)                     |
|                      | <i>Canada</i><br>David Castle (University of Ottawa, Canada)   |
|                      | <i>South Africa</i><br>Julian Kinderlerer (University of Cape Town, South Africa)                    |
| <b>10:30-11:00am</b> | <b>Morning break</b>   |
| <b>11:00-11:45am</b> | <b>Organization Updates</b>  |
|                      | World Intellectual Property Organization<br>Antony Taubman (WIPO, Switzerland)                       |

|                        |  |
|------------------------|--|
|                        | <a href="#">Médecins Sans Frontières</a> /NGOs<br>Ellen 't Hoen (MSF, France)  |
|                        | Organization for Economic Cooperation and Development<br>Bénédicte Callan (OECD, France)   |
| <b>11:45am-12:30pm</b> | <b><i>The Intellectual Property Modeling Group (IPMG) Project and Access</i></b><br>Richard Gold (McGill University, Canada)   |
| <b>12:30-2:00pm</b>    | <b>Lunch break</b>   |
| <b>2:00-3:00pm</b>     | <b>Access to agricultural and health-related knowledge</b><br>Moderator: David Castle (University of Ottawa, Canada)   |
|                        | Overview<br>Julian Kinderlerer (University of Cape Town, South Africa)   |
|                        | <i>Does patent protection get in the way of accessing knowledge?</i><br>Rose Ndegwa (International Livestock Research Institute/CGIAR, Kenya)  |
|                        | <i>How useful is traditional knowledge to the scientific community and how best can the interface between the two be dealt with?</i><br>Antony Taubman (WIPO, Switzerland)   |
|                        | <i>Should the scientific community have access to traditional knowledge? If so, under what conditions?</i><br>Tania Bubela (University of Alberta, Canada)   |
| <b>3:00-3:30pm</b>     | <b>Afternoon break</b>   |
| <b>3:30-4:30pm</b>     | <b>Discussion</b><br>Facilitator: Abdallah Daar (University of Toronto, Canada) <ul style="list-style-type: none"> <li>• how do we mitigate potential <i>risks</i> of access to knowledge?;</li> <li>• to <i>what</i> knowledge is access needed?;</li> <li>• <i>who</i> needs such access?;</li> <li>• <i>how</i> is access secured?; and</li> <li>• <i>how</i> do we prioritize access needs?</li> </ul> |
| <b>5:00pm</b>          | <b>Adjournment</b>   |

## Tuesday June 5

|               |   |
|---------------|---|
| 9:00-9:30am   | <b>Day 1 highlights</b><br>Tina Piper (McGill University, Canada)   |
| 9:30-10:30am  | <b>Access to agricultural and health-related products</b><br>Moderator: Tina Piper (McGill University, Canada)  |
|               | Overview<br>Richard Gold (McGill University, Canada)  |
|               | <i>What policies may be needed to regulate trade in and access to biotechnology products?</i><br>Marie Chamay (ICTSD, Switzerland)  |
|               | <i>What are the key issues of technology transfer from North-South, South to North, or South to South? Why?</i><br>Kent Nnadozie (McGill University, Canada)  |
|               | <i>To what extent are developed countries the problem or the solution to the question of access to biotech in Eastern Africa?</i><br>Bénédicte Callan (OECD, France)  |
|               | <i>What is commonly overlooked in the formulation of policies governing technology transfer and access to products?</i><br>Kate Hoyer (University of Ottawa, Canada)  |
|               | <i>Can we fix the problem of access to health care products without legislative change?</i><br>Ellen 't Hoen (MSF, France)  |
| 10:30-11:00am | <b>Morning break</b>  |
| 11:00-12:00pm | <b>Discussion</b><br>Facilitator: Jean-Frédéric Morin (McGill University, Canada) <ul style="list-style-type: none"> <li>• how do we mitigate potential risks of access to products?;</li> <li>• to what products is access needed?;</li> <li>• who needs such access?;</li> <li>• how is access secured?; and</li> <li>• how do we prioritize access needs?</li> </ul> |
| 12:00-1:30pm  | <b>Lunch break</b>  |
| 1:30-2:30pm   | <b>Access to markets, business &amp; money for agricultural and health-related biotechnology</b><br>Moderator: Lori Knowles (Research Practice Institute, USA)  |
|               | Overview<br>Anthony So (Duke University, USA)   |
|               | <i>What is the relationship between access to knowledge and economic growth in health and agriculture?</i><br>Shahid Yusuf (World Bank, USA)  |
|               | <i>What are the barriers that foreign direct investment contributes to access in the area</i>   |

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|                    | <p><i>of biotechnology?</i><br/>Moustapha Kamal Gueye (ICTSD, Geneva)</p>  |
|                    | <p><i>To what extent can micro credit jump-start biotechnology commercialization in Eastern Africa?</i><br/>Joseph Wekundah (Biotechnology Trust Africa, Kenya)</p>  |
|                    | <p><i>What (if anything) distinguishes Eastern Africa as a region in its technology transfer policies?</i><br/>Betty Kiplagat (KARI, Kenya)</p>  |
| <b>2:30-3:00pm</b> | <b>Afternoon break</b>   |
| <b>3:00-4:00pm</b> | <p><b>Discussion</b><br/>Facilitator: oline Twiss</p> <ul style="list-style-type: none"> <li>• how do we mitigate potential <i>risks</i> of access to markets, business &amp; money?;</li> <li>• to <i>which</i> markets, businesses &amp; money is access needed?;</li> <li>• <i>who</i> needs such access?;</li> <li>• <i>how</i> is such access secured?; and</li> <li>• <i>how</i> do we prioritize access needs?</li> </ul> |
| <b>4:00-4:30pm</b> | <p><b>Consolidation and wrap up</b><br/>Tina Piper and Richard Gold</p>  |
| <b>4:30-5:00pm</b> | <b>Closing, thanks, adjournment</b>  |

## 9. Appendix B – List of Participants

- ❖ **Bénédicte Callan**, Organisation for Economic Co-operation and Development (OECD)
- ❖ **Marie Chamay**, Programme Officer Trade and Natural Resources International Centre for Trade and Sustainable Development (ICTSD)
- ❖ **Moustapha Kamal Gueye**, Senior Programme Manager Environment Cluster International Centre for Trade and Sustainable Development (ICTSD)
- ❖ **Ellen ‘t Hoen**, Director Policy Advocacy Médecins Sans Frontières
- ❖ **Julian Kinderlerer**, Professor of IP Law University of Cape Town
- ❖ **Betty Kiplagat**, Administrative Legal Officer Kenya Agricultural Research Institute
- ❖ **Rose Ndegwa**, Intellectual Property Manager International Livestock Research Institute
- ❖ **Anthony D. So**, Director, Program on Global Health and Technology Access Terry Sanford Institute of Public Policy Duke University
- ❖ **Antony Scott Taubman**, Director Global IP Issues Division WIPO
- ❖ **Joseph Muyalah Wekundah**, Executive Director Biotechnology Trust Africa
- ❖ **Shahid Yusuf**, Economic Adviser The World Bank Group

### Members of the Intellectual Property Modeling Group

- ❖ **Tania Bubela**, Assistant Professor School of Business University of Alberta
- ❖ **Julia Carbone**, Researcher Centre for Intellectual Property Policy Faculty of Law McGill University
- ❖ **David Castle**, Professor and Canada Research Chair in Science and Society University of Ottawa
- ❖ **Martin Cloutier**, Professor Department of Management and Technology University of Quebec at Montreal
- ❖ **Abdallah Daar**, Professor of Public Health Sciences & Professor of Surgery University of Toronto
- ❖ **Richard Gold**, Director Centre for Intellectual Property Policy Faculty of Law McGill University
- ❖ **Elisa Henry**, Executive Director Centre for Intellectual Property Policy Faculty of Law McGill University
- ❖ **Kate Hoye**, Post-doctoral Fellow University of Ottawa
- ❖ **Lori Knowles** Senior Research Fellow Research Practice Institute
- ❖ **Jean-Frédéric Morin** Post-Doctoral Research Fellow Centre for Intellectual Property Policy McGill University
- ❖ **Kent Nnadozie**, Ph.D Student Centre for Intellectual Property Policy McGill University
- ❖ **Tina Piper**, Assistant Professor Faculty of Law McGill University
- ❖ **oline Twiss**, Student Faculty of Law McGill University