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The Role of Intellectual Property Rights in Biotechnology Innovation

Workshop Report

Held at the European University Institute, Florence, Italy, October 24 & 25, 2005

Social Sciences and Humanities Research Council of Canada
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Introduction

I. The Intellectual Property Modeling Group: Project Overview and Methodology

On October 24 & 25, 2005, the Centre for Intellectual Property Policy's Intellectual Property Modeling Group ("IPMG"), a transdisciplinary group of researchers, held an international and multidisciplinary workshop entitled "The role of intellectual property rights in biotechnology innovation" in Florence, Italy. This event was the fourth of a workshop series initiated by the IPMG in the context of its research project "Legal models of intellectual property protection: a transdisciplinary approach" funded by the Social Sciences and Humanities Research Council of Canada and the Canadian Institutes for Health Research.

The purpose of this workshop was to examine the role of intellectual property rights (IPRs) in innovation over the short to medium term. Many in industry and government believe that IPRs are catalysts for biotechnology innovation. Academic research suggests, however, that the role of intellectual property (IP) in stimulating innovation is not always certain, and may actually have the opposite effect in some cases. Workshop participants from a number of disciplinary and regional perspectives considered these competing claims. The diversity of opinion and expertise was crucial to the methodology of IPMG's project since one of its interests is to uncover deeply held assumptions about the role of IP in innovation systems.

II. Workshop Structure

The workshop was framed around six panels over two days. Each panel consisted of two to three panelists with a variety of backgrounds whose research or work interests revolve around innovation and IP. The panelists discussed themes that ranged from business and economic theory of innovation to the politics and history of IP. Following the presentations, workshop members then engaged in discussion.

Panel 1 – Intellectual Property Rights in Innovation Systems

In this first panel of the workshop, we considered the role that IP plays in innovation systems. This panel provided a broad overview of IP and innovation systems in order to define terms and establish conceptual frameworks for the subsequent sessions. In addition, panelists addressed the structure of innovation systems and their components.

The first presentation by **Bjorn Asheim** discussed the potential benefits of using a regional innovation systems approach to thinking about industrial knowledge bases, territorial competence bases, and national and regional institutional frameworks. This approach can be used to unpack what makes particular contexts and environments effective for promoting knowledge creation, innovativeness and competitiveness. It also helps to explain sectoral and national differences in patenting as well as in the construction and application of IPR regimes.

The second presentation, by **Adam Holbrook**, considered innovation within the confines of a national system of innovation. A national system has five main features: Firms are part of a network of public and private sector institutions whose activities and interactions initiate, import, modify and diffuse new technologies; the system consists of formal and informal linkages between institutions; the system includes flows of intellectual resources between institutions; learning is a key economic resource and lastly, geography and location matter. In light of these features, the knowledge flow between people and institutions is the key feature of an innovation system. While there are attempts to characterize knowledge flows qualitatively, it remains an open question whether there are knowledge quanta that can be given a standard unit, counted, and tracked. IPRs might be the unit – if patents are a unit of knowledge which can be tracked and measured, and if the proxy measures of innovation (e.g. bibliometric data) and problems (knowledge flow bottlenecks) are consistent with IPRs as the basic unit of innovation.

The third presentation, by **Koichi Sumikura** examined the social context of IPRs and innovation from the standpoint of the institutions and associated practices that can bring about a desired balance between the public domain and private, exclusive rights. This discussion was couched in terms of the Japanese innovation and legal system. Dr. Sumikura noted that there are five main controls for balancing private and public interests within the Japanese patent system: public order or morality provisions in Japanese Patent Law; guidelines for patent examinations that address issues such as gene patenting and reach-through claims; grounds for exclusion from the effects of rights in cases of research exemptions; guidelines for compulsory licensing; and other operational rules that include guidelines for pooling, clearinghouses, licensing and rules for research communities.

Participants raised questions surrounding the impact of transferring and communicating information about knowledge itself. The discussion highlighted the fact that the very process of transferring information affects both the content and nature of knowledge and that this transformative effect should not be underestimated.

Participants also discussed the effects of the change in the discourse surrounding IPRs to a property/theft taxonomy from what was, historically, a discourse based on state privilege.

Panel 2 – Intellectual Property Management

Intellectual property management (IPM) is an emerging concept relating to the strategy behind the protection, use and licensing of IPRs. There is so far no universally accepted definition of IPM, a problem that the panel addressed. Fundamentally, IPM is a strategic application and ordering of IPRs within an organization.

Sharon Oriel was the first panelist to speak in the group at the workshop. Oriel has been involved in the implementation of IPM within corporations for many years, including a significant period of time working on IPM at Dow Chemicals. She began her presentation by setting out definitions of IP, intellectual assets and intellectual capital – terms that are often misapplied and used as if they are interchangeable, but are in fact distinct categories of intangibles. Giving examples from Dow, Oriel illustrated that a management strategy for each category of intangibles will have a unique character, directly related to the nature of the category of asset or property.

Oriel noted that the field of biotechnology is different from others due to its focus upon competitive advantage. This grows from the nature of biotech companies, which are often start-ups with a singular focus on their product and no thought given to diversification. In Oriel's opinion, these attributes are significant as firm culture has a significant influence on which IPM strategy is most appropriate. In biotech, IPM strategies often emphasize small scale IPRs (e.g. national patents rather than global patent portfolios achieved through PCT patent filings) and concentrate on value to "stakeholders" not simply "shareholders". Oriel's use of the term stakeholders points to the importance of moving from a concern over a narrow group of parties who hold shares in a company to the wider group with an interest in the company's ability to succeed.

The second speaker in the panel was **Richard Gold**, the Director of the Centre for Intellectual Property Policy of McGill University. Gold discussed the application of IPM to the realm of policymaking. He argued that a dynamic approach to IPM can instigate industry-wide strategies, such as pooling, contracting models and lobbying. These activities may shift the emphasis of IPM from single corporations to a wider sphere of organizations participating in a common market or sphere of innovation. Some of the implications of moving IPM beyond the boundaries of the traditional firm may be that the pool of decision-makers would expand to include policy-makers. This change could widen the range of IPM tools available so as to encompass public policies, industry practices, international treaties and the regulatory environment. The goal of dynamic IPM may be stated as competition through cooperation.

Patrick Sullivan was the final member of the panel. He began by pointing out that the understanding of what constitutes the category of IPR from a legal standpoint may differ greatly from that of a business approach. The business understanding equates IPRs with business assets. Sullivan described IP as having two main forms of value: defensive and offensive. A collaboration of multi-national accounting bodies with whom Sullivan has been involved is attempting to develop new ways to measure the value of intangible assets. This value is not simply revenue value but includes cost-reduction value, strategic value and position value. Intangibles only have value within a particular context as different people make different uses of the same asset.

Several common themes ran through all of the presentations. Foremost amongst these is the observation that the category of intangibles includes more than merely the class of IPRs. For this reason it is crucial that an IPM strategy identify the group of intangibles that it is to address. All of the speakers agreed that culture has a significant impact upon IPM and shapes the strategies as it influences the goal of an entity. Linked to this issue is the fact that IPM should remain open to new methods and not become static. Open source initiatives may be an example of a progression that can be integrated into IPM and may therefore merit further consideration.

A first comment related to the citation of public domain sources in patent documents. It was suggested that the reasons underlying this phenomenon were mostly strategic: inventors would not necessarily rely on those sources but would cite them in order to avoid possible lawsuits by their competitors.

A second set of comments highlighted that the intellectual property model enacted by Columbia University and Waterloo University, which consists in empowering individual inventors with intellectual property rights instead of retaining it within the institution or sharing it between the institution and the inventor, was an interesting and effective one.

Panel 3 – Intellectual Property Rights in Relation to Other Measures of Innovation

This panel addressed the challenging issue of measuring levels of innovation and, in particular, measuring returns on patents relative to other forms of IPR protection. Innovation measures can relate to different units of analysis. These innovation measures can reflect inputs as well as outputs. Measurement implies that an innovation, whether a product, a process, an organization, or a market, can be quantified with homogeneous and standardized units of measurement. There are several conceptual and empirical issues associated with innovation measurement, and these are easily overlooked as measures of patents are not sufficient. The papers presented in this panel look at this issue from alternative perspectives.

The first presentation by **Marco Ceccagnoli** addressed two main questions: (1) whether it is appropriate to use financial returns of patents as a way to measure innovation and (2) whether returns on patents provide an incentive to innovate. The first question looked at the estimation of the average patent return, that is the innovation premium, and at inter-industry measures. The second question looked at the impact of increasing the patent premium on an incumbent's R&D investments. Ceccagnoli employed a series of econometric estimates of an innovation production function looking at the measurement of these returns for product innovations. This analysis used 1994 data for 790 U.S. manufacturing firms conducting R&D. The results indicate that an increase in patent premium leads to an increase in patents and in R&D investments and also in the patent/R&D investment ratio. In industries where there is a low return on patents such as in semiconductors, the impact is much more significant in patenting and on R&D investment. Hence, the results indicate that patent protection provides some R&D incentive even in the semiconductor industry where firms rely mainly on alternative IPR mechanisms to manage their innovations. The opposite result was observed in the biotechnology sector where the patent/R&D investment ratio increases more than in high premium R&D investment. This could provide some explanation as to why the patent/R&D investment ratio does not rise as much in the life sciences as in information technology.

The second presentation by **Clinton W. Francis** provided an agenda for a model of innovation valuation. Francis argued that there are distortions in the way the valuation of innovation is conducted. Indeed, this distortion comes from the lack of interpretative complexity from an innovation in its natural and historical contexts which limit the ability to appropriately value an innovation in current market-based contexts and organizational settings. Francis offered three main lines of arguments to call for a re-examination of the way we value innovation: (1) IPR-based evaluations, (2) market-based evaluations, and (3) value-chain-based evaluation. IPR-based valuations, which attempt to attach a monetary value to IPRs held by an enterprise, run into several problems. These include the fact that today's technologies cannot be valued in the same way as previous technologies (as each generation acts quite differently), making historical comparisons of little value, that IPRs only protect a portion of the value of a new technology and that society adapts to new technologies. To address the valuation of innovation issue, and the potential for hierarchical confusion in the evaluation of the innovation, Francis presented a model called Language System 3.0, which is an application of a semiotics analysis to complexity with the goal of suggesting a method of innovation valuation that is hierarchically orthogonal, as much as is possible, to the subject matter to avoid the inversion of dependent hierarchies that could limit the competitive advantage bias against emerging innovations.

A first set of comments related to the methodology used in surveys referred to in Ceccagnoli's presentation. Given that the methodology involved interviews, there was concern that answers given by people surveyed were perhaps biased toward their position within a given company and that certain tools should be used to avoid this bias.

Panel 4 – Beyond Patent-Length

This panel examined which features of the patent system – beyond simply the number of years that the patent lasts – may influence levels of innovation and distribution. The panel thus moved beyond traditional economic analysis to investigate different ways that patents may operate to stimulate desired activity.

The first presentation by **Walter Park** focused on the analysis of "open source" as a possible solution to stimulate innovation and diffusion in biotechnology. Park started with a contextualization of the main issues at stake, talking about the growing number of IPR claims in the field of biotechnology and mentioning some of the concerns associated with this proliferation (for example, increasing cost of innovation, slowing progress, negative effect on developing countries, biopiracy concerns, possible proprietary rights over discoveries, patent thickets and under-use of knowledge). This led Park to explore the 'open source" model as an alternative non proprietary solution to those problems, referring to existing movements, especially examples arising from the software industry. He presented three varieties of open development possibilities: 1) open standards (technological, useful to coordinate innovation efforts), 2) open innovation (innovation findings shared freely even when patented) and 3) open licensing (compatible with patent, royalty free license for patented good and its improvements). Park then explored the relevance of those strategies to modern biotechnology, studying similarities and differences between the software and the biotechnology industries. He examined some of the underlying principles that could make open source work for biotechnology such as free revealing (reduction of future transaction costs), collective invention (collaboration, complementarities, sharing) and user innovation (knowledge about specific needs), highlighting some concerns and uncertainties associated with the application of those strategies in some specific spheres of biotechnology. Park concluded his presentation with a special focus on the application of open source in developing countries, especially with regards to issues relating to neglected diseases and biopiracy.

The second presentation by **Christopher May** analyzed the issue of biotechnology patent scope within a political context. May started with a contextualization of the issues, referring to the recent globalization of IPRs (WTO and TRIPs/ WIPO and SPLT) and its constraining effects on national patentability flexibilities and diversity. He then referred to the challenge of recognizing and differentiating between concepts of *invention* and *technology* in fast moving fields of activity such as biotechnology. He referred to different and interconnected international normative documents (TRIPS, UPOV and CBD), their inbuilt flexibilities in relation to patentability and to their possible influence on developing countries' domestic laws and practices. This led him to conclude that the patent system was not actually working to balance public and private interests and to protect the public realm (for example, there is a strong tendency to grant numerous patents over a single technology and to assume that the judicial process will address mistakes, without considering associated costs). May then discussed the recent WIPO initiative to negotiate further IPR related treaties, with the purpose of raising IPR standards and enforcement. These initiatives would ultimately lead to a fully harmonized and globalized patent regime that goes well beyond TRIPs. May put IPRs in a broader context as trade related knowledge in opposition to human rights or non-trade knowledge. To this end, he referred to IPRs as creating scarcity where none would necessarily exist and allowing the imposition of a price on what would otherwise be non rival knowledge goods. He explored areas of action to reform global IP such as improving patent quality, reducing uncertainly, controlling costs, setting up pre-grant opposition processes and establishing fair-use measures.

The third presentation by **Scott Keiff** focused on identifying elements that make different agents unhappy with IP institutions, using the New Institutional Economics (NIE) as a theoretical approach.[1] Keiff's main goal was to focus on what he viewed as a too often neglected area of the IPR debate: the role of IPRs in coordinating activity. Kieff argued that property rights help coordinate among complementary users to ensure the best use of assets (with ease of negotiation, improved diversity and socialization). He contrasted this with the view that IPRs act as an incentive mechanism of rewards and as a way to reduce transaction cost and problems related to monopolies. He concluded by presenting some implications of his approach for further research, in particular on research tools. He also noted that thinking about IPRs in terms of coordination could have a positive effect on the UN's development agenda.

A first set of comments related to the open source movement in the biotechnology sector. Contrary to the operation of open source models in the information technology sector which aims at disclosing software's source code, in biotechnology the goal is to provide access to innovation itself. It was also noted that that the open source is becoming a business model for several companies while most research in developing countries was performed by public institutions. It would therefore be interesting to explore how the public sector could be involved in open source property models.

A second set of questions related to the complex nature of IPRs and their impact on accessing research tools in the public sector. It was argued that transaction costs involved in using protected research tools had the effect of limiting innovation. According to Kieff, this argument was a valid one for simple research tools but should be reevaluated in light of the coordination role played by IPR in respect of complex research tools.

[1] NIE: field that focuses on the impact of institutions (law, rules norms) and of their enforcement on human interactions and on economic development.

A third set of comments involved the restrictive effects played by patents in the biotechnological innovation process. Public opinion has demonstrated a reluctance to permit the patenting of living organisms and a discomfort of the way that wealth is distributed through patents. However, it was noted that the absence of criminal sanctions in the case of patent infringement combined with the laisser-faire business practices of several patent owners tend to limit patents' restricting effects on innovation.

Panel 5 – Innovation Governance

This panel discussed the wider social context in which scientists and industry create and distribute innovation. Public opinion, our ability to regulate the use of technology and other concerns all play a role in shaping what innovation occurs and how it is introduced.

Tim Caulfield introduced discussion through his analysis of the problems surrounding public trust in both biotechnology research and in the products of biotechnology. The image of the mad scientist abounds in popular culture and in the public consciousness. Maintaining public trust is crucial for any kind of research, especially biomedical research because of the need for dedicated public funds over the long-term.

Correctly, or incorrectly, biotechnology patents have become a flashpoint for the public as well as being the focus of policy debates. Public agencies fund biomedical research to address specific health and social policy problems. However, in the fields of human genomics and stem cell research (especially with respect to embryonic stem cells), commodification emerges as a clear public and policy concern. Anti-commodification and human dignity concerns have emerged as the primary policy constraints on stem cell research in particular, e.g., EPO interpretation of *ordre public* etc. There is also significant jurisdictional variation on stem cell patenting with different jurisdictions having opposing views (EPO refuses it, Australia limits it, UK allows it but there is a public policy limit, US allows it completely, Canada allows it with limitations but no embryonic stem cell patents have been issued). The EU Commission report in July 2005 offered no clarity on the position of the EPO.

If we probe the generalized public angst around commodification of biomedical research, public survey data suggests that people are concerned about patenting life (56% were uncomfortable with this notion in 2002) and the issue of access to technologies (see Myriad Genetics cliché). There is a plethora of evidence that public trust in biomedical research is very fragile and that the research is carried out without taking into consideration the public's interests and values. There are significant issues around the credibility of researchers and policy makers/politicians in the field of biotechnology. Publicly funded scientists are considered credible sources of information. However, this may be contrasted with industry scientists, biotechnology executives and public-institution scientists who receive private research funding who are low in trust rankings. Politicians are not trusted (e.g., see CBAC survey 2005). Focus group studies show that the US public in general supports stem cell research when they know more about it, but remain concerned about gene modification, especially when moral concerns are mortgaged. If the public considers that the public interest goals of the research are limited, then support drops (See Walsh, Cho, Cohen, 2005 in Science).

Patent pools may be one governance structure for commercialization which maintains public support. The benefits of patent pooling are risk spreading, decrease in transaction costs, and increase in investment possibilities. The criticisms are that it takes away incentives, increases monopoly control, and may be difficult to negotiate, especially in academic publicly funded research. However, if patent pools are structured so that they have an Independent Governance Scheme, they may address the public's concerns about commodification, conflicts of interest and trust in the independence of the research community.

The second presentation b y **Jasper Bovenberg** focused on the accessibility of biological data. The study of common complex disorders requires links to be made between genotype and phenotype; between abstract genomic data and concrete patient medical records. This, in turn, requires that these data be made accessible to those who were not necessarily the primary producers of these data. There is a spectrum of accessibility to genomic and phenotypic data from large-scale collections of abstract genomic data produced by publicly funded scientists (e.g., the Human Genome Project) to small-scale collections of phenotype data collected by individual scientists, typically in a hybrid clinical/research setting. These collections tend to be only conditionally accessible, as the primary producers often feel that they have earned an exclusive right to use 'their' collection.'

Two unrelated developments might impact on the current degree of accessibility of these data. First, large-scale projects are moving from assembling raw genomic data with little or no "utility" in the patent sense, to producing "functional data" with increasing utility. The increased "patentability" of these novel data may undermine the data release policies of these projects. Second, data in the small-scale collections are increasingly being assembled by the research participants themselves. Consequently, traditional proprietary claims by individual researchers may come under pressure from claims by research participants.

Human Genome Project data is governed by the Bermuda Principles base on an ethos of academic sharing of research results and publication related data. This ethos is reinforced by the prospect of reciprocity. The Bermuda Principles have served as a point of reference for publicly funded large-scale sequencing projects. The principles have been reinforced, with some modifications to address technical issues, by a number of funding agencies. To date, these policies are claimed to have secured open access to at least 548 public genetic databases worldwide, available on the internet, including the large international nucleotide databases

(EMBL and GenBank). At a meeting in 2003, convened by the Wellcome Trust, an international group of data producers, users, database personnel, journal editors and funding agency representatives unanimously agreed that pre-publication release of large-scale genome sequence data had been of tremendous benefit to the scientific research community. They further recommended that the Bermuda Principles be extended to all types of sequence data and "community resource projects" , including the International Human genome Sequencing Consortium, the SNPs Consortium, the International HapMap Project and, recently, the Encyclopaedia Of DNA Elements (ENCODE) Project

The attendees of the Wellcome Trust meeting considered that beyond those large-scale ‘community resource projects’ many valuable small-scale data sets could come from other sources. Since those resources emerge from research efforts whose primary goal is not resource generation, the contribution of their data to the public domain is more a voluntary matter. However, there is a clear benefit to be derived from converting these ‘small-scale’ data sets into community resources as rapidly as possible and, ideally, the producers of such data should release them into the public domain voluntarily.

A number of problems have emerged from the Bermuda Principles and the Wellcome Trust Tri-Partite Policy. The first is they fail to address the problem of free-riding by other scientists and commercial researchers, e.g., the International HapMap Project. To prevent this from happening, the HapMap Project developed a licensing strategy in the form of the HapMap Click Wrap license, whereby researchers are granted a non-exclusive license to access and conduct queries of the Genotype Database. However, such a license offers only limited protection because it operates only between the licensor and the licensee and second it is unclear whether the condition of the license could be effectively enforced in case of a violation of any or more of the terms of the license, e.g., filing a patent application.

Increasingly, patient groups have become key players in the promotion, facilitation and acceleration of studies of the causal role of genetics in diseases, creating and maintaining databases with epidemiological, medical and other information about the relevant families. Biomedical researchers depend heavily on the long-term participation and co-operation of cell and tissue donors. Thus there is a strong case that the active participation and substantive contributions of tissue/cell donors justify that they retain title to the collection they have amassed.

The European database-right could serve as a model. The European Database-right was introduced in 1996 by the European Union. The right vests an exclusive right in the producer of a database to grant permission to extract and re-utilize the contents of the database. The database-right confers an exclusive right in a *collection* of data. It does not bar anyone from collecting the same data to create his own database. Second, if owned by an individual scientist or group of scientists, the database-right could indeed be used as an instrument to legitimize and enforce data-exclusivity. However, the database-right typically will not vest in a single scientist or even a group of scientists. The database-right vests in the *producer* of the database. Under the European Database-right the producer is the person who bears the *financial risk* of the investment in the database. Third, while the database-right is said to undermine the public domain, the Directive provides that the database-right does not prejudice existing rights to access public documents. The rationale behind this provision is that public works, produced by the public authorities should in principle be part of the public domain. Fourth, the Directive provides for a research exemption, allowing the lawful user to use the database for research purposes, without the consent of the owner of the database.

In conclusion, while traditional IP plays no role as regards the protection of collections of data, the recognition of a database-right in large-scale collections of abstract (post) genomic data could provide a meaningful remedy, enforceable against all users who misappropriate or threaten to restrict the use to be made by others of the data collection, protecting the interests of researchers and patient groups who have invested substantial resources in the collection of valuable data and deserve a meaningful and enforceable positive right to exploit or control the collection.

This presentation by **Sachin Chaturvedi** addressed Emerging Trends in Patent Regime: Plant Patents, Utility Patents, Patenting of Research Tools; the Current State of Play: Convention on Biological Diversity (CBD) and TRIPs; New Incarnation of WIPO; Substantive Patent Law Treaty (SPLT); Free-Trade Agreements (FTAs) and TRIPs Regime; and Policy Challenges to Innovation, Access to Knowledge, and Impact on local Seed Industry.

Plant variety protection (PVP) and patents have emerged as two important forms of IPRs. Both patents and PVP provide exclusive monopoly rights over a creation for commercial purposes for a limited period of time. Though the criteria for a patent is defined as novelty, inventiveness (non-obviousness), utility, and reproducibility along with provisions for compulsory licenses (CL), patent offices now grant biotechnology patents on microorganisms and, in some countries, on all life forms with no provisions for CL. In contrast, the intellectual property regime for plant variety protection emerged with a strong commitment to the public interest, including provision for CL.

Plant variety protection has worked well as a mechanism to promote the interests of plant breeders for developing new varieties through giving them proprietary rights, on the one hand, and treating plant breeders as custodians of public rights of access and use of genetic material, on the other hand. PVP encourages cross licensing between a holder of PVR and a holder of a patent. Under the breeders' exemption of plant variety rights anyone may use protected material for breeding purposes. However, the patent regime does not reciprocate. In the patent regime the interpretation of research exemption is much narrower than that of the breeders’ exemption in PVR. Thus, for instance, if a breeder wants to produce a new variety and needs a compulsory cross-license from a patent holder, the breeder has to demonstrate that the breeding programme will produce technical progress, which, given the nature of plant breeding, is almost impossible. Thus for all practical purposes PVR ends up protecting small advances in the breeding process while the patent regime leads to the protection of bigger leaps in technological achievements.

A directive from European Community on the protection of biotechnology inventions (Directive 98/44EC) contains specific provisions on the patentability of genetically engineered biological material including plants and animals. The most significant feature of the directive is the provision pertaining to the patentability of biological material including inventions relating to plant and animal varieties, human body and sequences or partial sequences of genes. The explanatory notice published in the OJ EPO records that since the early 1980’s, the EPO has received about 15000 applications in the field of biotechnology, for which about 3000 patents have been granted. 1500 applications relate to transgenic plants, 600 to transgenic animals, and 2000 to DNA sequences. The Biotech Directive had to be implemented into national law by the 30th of July 2000.

Private-sector research expenditures for plant breeding have increased from $6 million in 1960 to $400 million in 1992 (Klotz. Fugile, and Pray, 1995; Fugile, Klotz, and Gill, 1995). Nearly 70 per cent of private-sector plant breeding research expenditure in 1989 was for corn, vegetables, and soybean. Private firms have also reacted to changes in IPR’s by investing heavily in biotechnology techniques. The number of utility patents issued has grown very rapidly in the US. By December 1994, 324 Utility Patents had been issued for new plants or plant parts and 38 were issued for animals. As with Plant Variety Protection Certificates, most utility Patents were awarded to the private sector.

The Experience of the Indian Seed Industry, measured by the Research and Information System for Developing Countries Seed Industry Study shows the following results: (1) indigenous seed firms in India find it difficult to access relevant genes for development of new varieties in their biotechnological research as their sequence has already been patented by just one Trans National Company; (2) introduction of Bt characteristic without license even in other plants is completely impossible; (3) license fees are not regulated, are arbitrary and are incredibly expensive, and (3) consolidation of the industry is driving out of smaller firms.

The discussion focused on the presentations of Caulfield and Bovenberg who presented in person.

There was a general consensus that patent pools, especially those with an independent governance structure would be a useful mechanism for improving public perceptions of biotechnology. This may be further facilitated if patent pools are first established in areas of biotechnology perceived as having high social value such as forest biotechnology and the preservation of heritage trees.

In Europe, however, it may be difficult to separate public concerns over GMOs *per se* and biotechnology patenting. Some examples highlight the distinction. There was general public outrage when Monsanto attempted to patent terminator technology and this played out in the media as a patenting issue. Ironically, however, self-help strategies such as terminator technology and trade secrets are chosen by innovators when patent protection is weak and there is a feat that patents will not be enforced.

It is also interesting that the profit motive is so distrusted by the public when many studies have indicated that other motivations have a much greater effect on scientific research, e.g., self-aggrandizement and the building of large institutions. It seems strange that the public mistrusts a private biotechnology company with $100,000 in assets but trusts a multi-billion dollar institution such as Harvard that styles itself as a not-for-profit educational foundation. The Walsh study found that individual desire to move forward academically had a more profound impact on data sharing than patents. Patents were not a significant factor in non-disclosure and the largest factor was career advancement. Other studies have shown race and gender effects.

Dr. Bovenberg suggested that without access to data there could be no scientific revolutions. This was explored from a historic perspective. Did this statement come from a view of the past where there was open access to data between members of the scientific research community that in fact never existed? From a historical perspective, there was a massive growth in mathematical science, chemistry and mechanics and the patent system/property rights from 1870-1914. At that point there were few mechanisms for technology transfer. However, the illustration of patents and Watt's invention of the steam engine is actually more interesting from the perspective of what was not patented. Watt did not patent the efficiency measuring mechanisms he had in his works. Instead, he kept it a trade secret because is enabled him to gauge and understand what he was doing. It is likely that if that steam gauge would have been made public, it would have done most of the work of diffusing the invention rather than stifling it for, what some people argue, as long as 31 years. Thus, the issue about how technology moves forward is not simply about patenting but also the access or non-access to the means that allow evaluation of the technology or science.

From an economic perspective, the term for innovation is a subplot because the useful life of a technological innovation is shorter and shorter. In industry, valuation is not possible for longer than 5-6 years of market value because the discount rate drops to 0 after 5-6 years. Thus, duration is of decreasing importance.

The question of who should own academic data collections has many alternative answers such as scientists, funding agencies, government, research projects and institutions. Problems may arise when these different actors have different rules and cultures around managing IPRs. However, the better question may be *should anyone own it*. It may be better to set up a system of attribution through meta-tagging. One could argue that authorship is both a way of ensuring attribution and certification. Communities could develop standards such that the meta-tagging would be accommodated within protocols for communication of data.

Gold summed up the discussion to that point. The discussion points had moved from innovation to commercialization. Few participants were still talking about IPR as an incentive for innovation but were seeing IPRs as a facilitator for the movement of information from place to place. Viewed thus, the question becomes to what extent are patents necessary to do so and to what extent are there other as yet unexplored methods to do so?

The central question is the compatibility of patent and non-patent systems for different forms of information. Do patents overwhelm other methods once they are introduced? In terms of the question asked at this workshop – What is the role of IPRs in innovation? — the answer is likely very little at the creation stage. However, patents have a role in moving knowledge around with the caveat that our knowledge is incompletely leaving the answer uncertain.

That said, in the business context, patents protect investment. Industry does not want to bring out a product that can be easily imitated. Industry pushes for innovation that it can take to the market and patenting is the mechanism that gives assurance for that investment. From this standpoint, we could argue that patents encourage business-driven innovation. Other forms or areas where society wants innovation are a separate issue – patenting is helpful for commercializing ideas and at that level they spur innovation.

There may therefore be a distinction in the role of patents in industry versus public science. In the industrial realm, patents play a role in moving information to a commercial setting. Patents may provide an incentive to industry to move information around. However, do patents have a negative effect on distributing other forms of knowledge, are these systems in parallel, do they conflict, or is there any relationship at all?

Panel 6 – National and international comparisons

There were three complementary presentations in this session that examine the role of IPRs in innovation in the developing world.

Ian Inkster's presentation made the argument that IPR systems have been enormously varied over time and have worked in different ways in different countries. In fact, IPR systems in the form of patents, in particular, have served to stimulate innovation in a relatively small number of industrial modern nations, a group that reached its basic mass and density around 1914 and continued to exist as such to around 1971. In such favoured nations, IPR systems have become imbedded into very elaborate innovation cultures, organizations and institutions, themselves parts of wider financial, legal, and scientific infrastructures. In late-developing nations such as Russia or Japan around 1900, heroic efforts towards technology transfer-in were made by centralized political regimes, involving strategic developments and manipulations of patent systems adopted/adapted from systems generated initially by USA, UK and France.

In the great majority of less developed nations from that point on, an absence of these wider elements, as well as intrinsic features of patent systems themselves, assisted in the process of underdevelopment that dominated the years circa 1918-1971. Only from around the early 1970s with the OPEC crisis, when new micro-electronic, biotechnical, marine and environmental industries combined with rapid changes in international payment systems, did new windows of opportunity emerge that allowed another group of newly industrializing countries to participate in the manufacture of steel and chemicals and to establish institutions governing IPRs, knowledge creation, diffusion, and application. There is little evidence from the overall statistics of patent registration at a global or comparative level that patent systems post-1850 were ever generally conducive to industrial development outside the favored group of nations that had emerged already by 1914-1918. One lesson that we can draw from this is that reformers of the global patent systems must take into account the historical fact that IPR systems have also been information systems and technology transfer systems, and that it would be unwise to radically reform IPR systems without simultaneously improving ancillary information systems. Over the whole range of history it might well be that most patent systems have been at their best as information systems and at their worst as IPR systems.

The second presentation by **Richard Y. Boadi**, of the African Agricultural Technology Foundation noted that there is evidence that IPRs have indeed helped to stimulate innovation in the developed world, particularly in the United States, in the past two decades in the area of plant biotechnology. There has not, however, been as much innovative activity in developing countries over the same time period. In fact, there is evidence that most applications for IPR protection in African countries had been filed by entities based in developed countries. There is, nonetheless, increasing awareness that the transfer, adaptation and use of IPR-protected biotechnologies could play a major role in improving agricultural productivity and the overall development of African countries where agriculture remains the key source of food, incomes, employment and often foreign exchange. The World Bank reports that yields of the major staple crops (maize, sorghum, millet, cassava, cowpea, bananas/plantains) of smallholder farmers in Africa have been stagnant or even declined in the past 40 years due to numerous biotic and abiotic constraints such as diseases, pests and drought. Local research efforts to overcome these stresses are hampered by declining financial support for agricultural research and limited access to elite genetic material and other technologies protected by IPRs. Therefore, a new initiative, the African Agricultural Technology Foundation (AATF), has been established to address this challenge by negotiating access to proprietary technologies and facilitating their delivery to smallholder farmers in Africa.

The third presentation by **Tina Piper** examined the medical use exception in patent law. Initially drafted to account for the needs of industrializing England, this exception to patentability has remained in the UK's patent law ever since. It is currently being imposed through TRIPs and other harmonization efforts on developing countries without any evidence (historical or otherwise) that it satisfies its purported effect of ensuring that valuable medical technologies are available to medical practitioners. Finally, the medical methods exception has been used to block a range of biotechnologies while it is also used as a normative argument that patent law does in fact ensure that valuable medical technologies are not patented.

Participants discussed two fallacious assumptions commonly relied upon in discussions about IPRs and developing countries. The first assumption is that IPRs operate in the same way in developing countries as they do in developed countries. The second is that IPR solutions used in developed countries could be imported in developing countries without taking into consideration the specificities of local resources and needs.

Workshop Conclusions

The workshop concluded that current discussions about the role of IPRs in furthering innovation are loaded with often false assumptions about how IPRs operate, on what they operate and how they interact with the larger social, political and economic context in which innovation is created and disseminated. While IPRs may be a useful tool in innovation and dissemination – and the empirical evidence on this is as yet unsatisfactory – it is at best one tool among many. Even that tool needs to be adapted to new technologies, communities of innovation and the needs of particular countries and regions.