CENTRE FOR INTELLECTUAL
PROPERTY POLICY

HEALTH BIOTECHNOLOGY AND INTELLECTUAL PROPERTY: A NEW APPROACH

Workshop Report

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I. Introduction

1. The Intellectual Property Modeling Group's project and methodology – an Overview

On October 27-28, 2004, the Centre for Intellectual Property Policy's (CIPP) Intellectual Property Modeling Group (IPMG), a transdisciplinary group of researchers, convened an international, multidisciplinary workshop on health biotechnology and intellectual property (IP) in Florence, Italy. The goal of the workshop was to present and advance research that is part of a four year project, *Legal Models of Biotechnological Intellectual Property Protection: A Transdisciplinary Approach,* funded by the (Canadian) Social Sciences and Humanities Research Council and the Canadian Institutes for Health Research. The workshop provided important validation for not only the general approach of the IPMG research project, but of its research methodology and, in particular, its choice of research tools.

Governments, industry and many commentators have noted with enthusiasm the potential of biotechnology to address human health needs in both developed and developing nations. Countering some of this enthusiasm, others have pointed to concerns over the ethical and social effects of this technology. Some of these concerns relate to how IP rights over biotechnological inventions allocate benefits and burdens within and across countries, may lessen access to important research tools, or interfere in the decision-making process within public health systems.

One of the goals of the IPMG is to provide policy-makers with tools through which to ensure that the IP regime best meets the needs of countries, regions

and the world. IPMG will also provide academics and policy-makers with a better understanding of the inter-relationship between IP, innovation policy, health care systems and agriculture. It will provide alternative proposals – within existing international frameworks – from which policy discussion and academic analysis can proceed.

At a first workshop held in Raleigh, North Carolina in June 2004,[1] IPMG engaged international and national members of policy communities, academics, members of NGOs and industry in discussions that moved beyond traditional assumptions surrounding the role and functioning of IP rights related to agricultural biotechnology. Several conclusions emerged from the North Carolina workshop. First, despite disciplinary differences, it was clear that participants shared similar concerns about the role that IP rights play in ag-biotechnology. Second, and as an example of this, an overwhelming majority of participants concluded that domestic and international concerns involving developing countries were in urgent need of research and resolution. Third, workshop participants concluded that the tools created by IPMG were helpful in opening new ways of thinking creatively about existing problems. Finally, participants suggested that the development of case studies would aid further exploration and elucidation of and the research tools developed by IPMG.

Following on the North Carolina workshop, IPMG presented the next phase of its research at the Florence workshop, the focus of this report. The research group designed this workshop to start a discussion about biotechnology IP in the health care field so as to examine not only the formal aspects of IP law but also practices and institutions that underlie the IP system. Workshop participants once again included national and international members of policy communities, academics, members of NGOs and industry and represented various regions (with a focus on Europe and Africa) and disciplinary perspectives.

[1] See Centre for Intellectual Property Policy, *Agricultural Biotechnology and Intellectual Property: A New Framework Workshop Report*, June 3-4, 2004 available online at http://www.cipp.mcgill.ca/db/published/00000004.pdf.

Picking up on the suggestions of workshop participants in North Carolina, IPMG members introduced new research and research tools by means of a case study surrounding the implementation of a novel biotechnological event (plant-derived vaccines). Through this case study, participants discussed the various issues that arise at the cross-section of IP and biotechnology, identified relationships involved in these issues and mapped out those relationships in the form of an influence diagrams in order to achieve a better understanding of the system.

2. Workshop Structure

The Florence workshop was held over a two day period. IPMG members first introduced workshop participants the IPMG project and presented a case study concerning the introduction of a new agricultural-based biotechnology. Participants then divided into four disciplinary groups (policy, law, management/economics and science) in which they identified and then discussed issues related to the case study. This was followed by a report back session during which participants drafted a list of the most pressing issues identified.

The next day, participants divided into four interdisciplinary groups, as opposed to the disciplinary groups of the first day. Each group focused on one of the issues discussed the previous day and worked to identify the relationships that underpinned the issue it was addressing.

The workshop concluded with a report back session during which participants shared their experience of working with influence diagrams as well as their general comments and suggestions about the workshop and the research project.

II. Identifying the Issues at the Cross-Section of Health-Biotech and Intellectual Property

To help identify the issues that arise at the cross-section of health-biotechnology and IP, IPMG members presented a case study to participants involving the possible introduction of a new technology, plant-derived vaccines (PDV), in India. By being forward-looking – in the sense that the technology has not yet been introduced – the case study offered workshop participants with the opportunity to imagine different scenarios and policy options. After the presentation, participants divided up into four disciplinary groups to discuss the issues that would have to be addressed when introducing plant-derived vaccines in India.

PDV is a new method for producing and administering vaccines. Plants genetically modified to contain sub-unit vaccines can be grown, processed and administered orally in a method that departs significantly from cell-cultured vaccines that are costly to produce and administered by injection.. The benefits of PDVs over traditional methods include lower production costs, potential for *in situ* production, and ease of distribution because they do not require the maintenance of a cold chain. PDV can be viewed as an ethical and socially responsible health care tool if they result in wider vaccination and overcome one of the most significant health care challenges: the reduction of infectious disease burden in developing countries.

Vaccines generally comprise less than 2% of the annual global investment in pharmaceutical research and design. As yet, there is no major corporate backer or angel investor for PDVs. Nevertheless, PDVs are a proven research concept and are undergoing clinical trials. Consistent with other forms of biotechnology R&D, there are a number of published patent applications and issued patents relating to PVD inventions which have been filed with the patent offices of the United States and India, among others. The majority of these patents and patent applications have been invented by and owned by residents of the United States. A significant number of PDV patents are held by private companies although

governmental bodies such as the US Health Department and universities also hold PDV patents. The existing patents and patent applications cover a variety of aspects of PVD technologies, including platform technologies, and disclose methods of immunization against viruses such as Hepatitis A, Hepatitis B and human papillomavirus (HPV).

PDVs have not yet been introduced in India, and so India provides an interesting forward looking case study to examine what issues may arise when introducing a new technology into a developing country. India is of particular interest since it has both a physical capacity (relatively large biotechnology industry) and a regulatory capacity (signatory to numerous international treaties such as the WTO, *Protection of Plant Varieties and Farmer's Rights Act, the Convention on Biological Diversity* and the *FAO Treaty on Genetic Plant Resources* and also has several institutions such as the *Recombinant Advisory Committee, Review Committee on Genetic Manipulation, Institution Biodiversity Committee* and the *Genetic Engineering Approval Committee*) to support the introduction of a new technology.

To stimulate discussion, IPMG members discussed four possible options for the introduction of PDVs in India. The options include technology transfer through licence from a US to an Indian firm, technology transfer through foreign direct investment, sale of the product produced in the US to India through international trade or technology transfer through mediated aid whereby, for example, the US transfers the products and technology to India through an international organization such as the WHO. Participants then discussed, in break-out groups, the following question: What strategy for deploying the PDV technology ought to be adopted to ensure that PDVs can be used in India in a manner which is sustainable from a business standpoint, mindful of IP issues, compliant with existing regulations, while ensuring the highest level of access to Indian citizens? IPMG members stressed that the question was to help structure discussion only and participants should feel free to move beyond it.

1. Group Discussions on Introducing PDVs

Participants split into four break-out groups: policy, law, management and economics, and science.

a. Policy

In examining the question, the policy group emphasized the complexity of the issues involved in introducing a new technology. Some participants expressed their desire for more knowledge about developing countries in order to fully grasp the issues. In the end, the group identified four primary issues. First, the group discussed the impact of different interpretations of IP law in different jurisdiction on the introduction of new technologies such as the way in which novelty and inventiveness standards are interpreted. More general questions arose about how the public sector and universities use IP. The second issue identified was the need to discuss research agendas. Questions arose about who is setting the research agenda, what are the structures and what is the regulatory framework within which research is being conducted as well as what incentives that are driving research. Third, participants identified the issue of building partnerships both between sectors of the economy and between countries. Fourth, focus was placed on looking at the geopolitical context in which the technology was being deployed.

b. Law

The law group decided to structure their discussion around the stages of technology deployment. The group thus first addressed the framework within which new technologies are introduced, in particular the specific goal driving the introduction of the technology. For example, is the goal of introducing PDVs to cure as many people as possible, to build a scientific infrastructure or to make a

profit? It is important, participants noted, to keep the goal in mind as it will affect the way in which the technology is developed.

Second, the law group addressed issues surrounding the conduct of clinical trials. Questions included: who owns the technology, who will carry out the trials and where will the trials be conducted? Discussion of the clinical trial phase then led to a discussion about standards (human subject and environmental standards) and biosafety issues. Participants raised questions about the level of standards and who would be responsible for setting those standards.

Once the PVD is produced, the next question becomes transport issues and liability concerns in relation to the provision of vaccines to human subjects. There may also be transborder issues in terms of which states give permission for trials as well as political and cultural issues about clinical trials and what technology is deemed acceptable. Once one gets to the end of the clinical trials, there may also be new IP rights that arise.

Finally participants discussed issues of PDV manufacturing. Different issues will arise depending on whether the funding for the initiative is public or private. Accessibility may be compromised if PDVs are manufactured with the help of private sector funding because private actors may be expected to place greater emphasis on profitability than on access. Participants also discussed the possibility of a public facility for manufacturing vaccines and the possibility of producing the PDV in an area other than where it will be consumed. Bioequivalence was viewed as a peripheral issue during the discussions.

In general, participants felt that IP did not play the most significant role in the deployment of this new technology. Participants stressed that the most important element is accessibility and affordability.

c. Management and Economics

Participants began by discussing what is involved in stimulating innovation. Participants agreed that in the case of PVDs in India, the main stimulus for innovation is a local public health problem (some participants making the analogy to the US Bioshield effort). In the case of the PDVs, the local health problem being addressed is Hepatitis B (whereas the Bioshield model focused on addressing Ebola). Consequently, innovation will be stimulated by a threat. Participants also identified the need for sufficient political commitment to address the threat before significant innovation and implementation can occur. For example, following September 11th, the US government set up a major initiative and funded $6 billion dollars worth of research relating to terrorism. The NIH was involved, for example, through a commitment to develop drugs to prevent bioterrorists attacks.

Once there is sufficient political commitment, it is then necessary to consider the various ways in which the need can be addressed. For example, if the goal is to build a scientific base to produce vaccines for a present danger, the state may need to focus on strengthening the country's science base and thus lead to thinking about points of entry to do so.

In terms of research and development levels, participants felt that adoption of a clear R&D policy is fundamental to moving knowledge from the research phase to the market as a product. Such a policy is particularly important as a tool to correct market failures such as, for example, by reducing risks in order to stimulate innovation. IP cannot be the only solution but must be part of a broader R&D policy.

The fourth issue discussed was the idea that once developing countries build up a significant manufacturing capacity they may be able to partner in the production of PDVs. However, developing countries would have to prioritize which partnerships are most advantageous to them, particularly since they have limited

resources. For example, given the cost and the existence of other types of vaccines, it may not be worth developing PDVs.

In general, the group placed emphasis on the need to consider all possible alternatives when deciding whether (1) to introduce a new technology and (2) how to introduce a new technology.

d. Science

At the beginning, participants sought to clarify the working assumptions behind the PDV case study. First, capital investment is low in these vaccines. Second, the amount of tacit knowledge required for production of PDVs is relatively low except when dealing with the original genetically-modified plants. Third, the key patent holders over the PDV technology are not motivated by profit-seeking but by doing good.

Participants noted that the adoption of a business model was necessary to the deployment of a new technology. It is important to keep in mind that the business model chosen will be affected by the low marginal production but high marketing distribution costs. For example, because of the low profit, manufacturing may not attract the big pharmaceutical companies. One participant raised UNICEF's experience with measles as an example of this.

Two interesting models include the public-private partnership model whereby initial stages are publicly funded and then, as the project enters later stages, funding becomes increasingly private. There are, unfortunately, few such models in developing countries. It is usually a developed country approach.

Participants stressed the importance of looking at the specific characteristics of the country before selecting a strategy to introduce PDVs. Political will in establishing a program is central. Other important factors include market

structure and means of delivery. In terms of the market, participants raised questions about whether IP was even necessary in the case of PDVs. There are ways to control use of the plant, for example by rendering it sterile, without using patents to protect the technology. Biosafety, the public and informed consent were also considered key issues. In terms of delivery, there are civil society issues such as means of encouraging delivery, for example, through traditional healers and the church.

2. Plenary discussions

Following the disciplinary group discussions, participants reconvened, reported on their discussions and formed a list of the most important questions and issues to address when introducing a new technology, such as PDVs, in a developing country. The following is the list of questions/issues (in order of discussion):

1. What is the best way to constitute public-private partnerships at the national and international level?
2. What is the cross-cultural impact of research agendas at the national and international levels?
3. What is the effect of patents on platform technologies and reach through rights on downstream innovation?
4. What are the mechanisms to ensure the bilateral flows of information between sectors and between developing and developed nations?
5. How should regulatory oversight be coordinated at the national and international level?
6. What are the distribution channels for PDVs in developing nations?
7. What is the extent of political commitment regarding PDVs?
8. Who bears responsibility for environmental, social and health harms?
9. What type of knowledge and information management decisions made upstream will have significant downstream effects?

10. What effect do governmental IP and regulatory mechanisms have on R&D decisions?
11. What effect does public purchasing of PDV products have on innovation choices?
12. What mechanisms exist or can be created to balance the interests of public health needs and industry expectations for profit
13. What is the best way to build R&D capacity in developing countries?
14. What is the impact of different national innovation systems on the implementation of PDVs?
15. What is the relationship between health protection legislation and environmental protection with respect to PDVs?
16. How should government policy take into account alternative technologies to PDV?
17. How should decision-making be structured when technologies are developed in the developed world for the developing world?
18. What is the policy capacity of developing nations regarding PDVs?
19. What mechanisms for partnerships and revenue sharing with communities are required to implement PDVS?

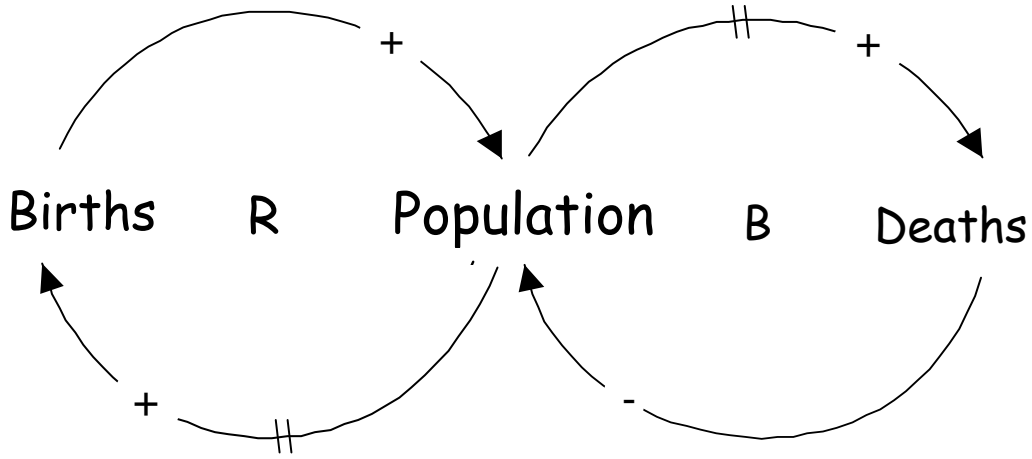
These questions and issues then served as a basis for developing influence diagrams that map out the different relationships that come into play when addressing the issues and answering the specific questions.

III. Identification of Relationships & Creation of Influence Diagrams

During the second part of the workshop, participants were divided into four interdisciplinary groups. Each group focused on one question listed above and worked to identify relationships and factors involved in addressing this issue. Once the relationships were identified, the groups attempted to map out these relationships using influence diagrams.

Influence diagrams help users gain insight into research questions by providing a means of mapping the different factors at play and how they relate to each other. Influence diagrams are an especially useful tool to integrate disciplinary knowledge as they create a shared model of a problem and serve to build a common language and knowledge base in order for a group of people from different disciplines to form the same, transdisciplinary understanding of how the system works. In addition, influence diagrams capture tacit knowledge about different relationships and how these interact with one another.

In mapping out relationships, influence diagrams reveal feedback loops. Collections of interacting feedback loops represent complex systems and all decisions that affect a system are made within these loops and affect the loops. An example of an influence diagram is seen with the mapping out of a basic population dynamics model. The population size is most fundamentally affected by births and deaths. Population decreases with deaths and increases with births. Arrows indicate the direction of the relationships and the + and – signs indicate whether the relationship is positive (e.g. births increase the population) or negative (e.g. deaths decrease population). As population increases, the number of births also increases as does the number of deaths. Consequently, feedback loops are created.



Once created, influence diagrams become a hypothesis about how a given system works. They thus can be used as the starting point for empirical investigation. Empirical data will include both current and historical econometric data as well as other quantitative and qualitative data (e.g. surveys). An advantage of using influence diagrams over other mapping methodologies is that they identify links and definitions precisely.

Influence diagrams have become a central part of the IPMG research project. IPMG researchers have been constructing a map of the IP system – comprising law and legislation, practices (business, government, NGO) and institutions – in order to provide academics and policy-makers with a better understanding of the context within which IP operates. Based on the identified structure of the IP system described in the diagrams, it will be possible to design and empirically test different configurations of IP systems.

Based on the issues identified, participants were asked to contribute to the research process by defining and identifying variables and relationships within the context of the questions identified on the first day of the workshop. The purpose of using influence diagrams was to demonstrate how the different factors discussed during the issue identification break out sessions interrelate,

raise new questions and also capture the participants' tacit knowledge and expertise.

1. Breakout Group Influence Diagrams

Each of the four break-out groups discussed one of the questions identified on the first day of the workshop.

a. Group 1 – What is the best way to constitute public/private partnerships at the national and international level?

In creating the influence diagram to explore the relationships between the factors involved in constituting a public/private partnership at the national and international levels, participants identified the fact that such partnerships bring together players that do not usually work together. They bring industry, philanthropists and researchers together to address a common set of problems.

Participants identified that the ultimate aim of PDVs is to eliminate certain diseases. They discussed both the push and pull mechanisms needed to achieve this goal.

Push mechanisms include, for example, tax breaks to stimulate investment. Pull mechanisms include public sector guarantees to purchase a drug, thus attracting industry investment.

In forming public-private partnerships, participants identified a balanced feedback loop. Legal entities that have contracting expertise take responsibility for IP and provide a coordination function. If the legal entity has a great degree of expertise, then the coordination increases in efficiency, transaction costs decrease and more stakeholders will want to invest. However, an increased number of stakeholders also increases transaction costs. Tax breaks illustrate this reinforcing feedback loop. The more tax breaks there are, the more people will be interested in investing. Increased investment will in turn increase funding. This funding is important for research and development and the more funding

there is, the more drug development there will be which is the very purpose for which tax breaks are granted in the first place.

Participants divided IP into input IP (e.g. pooling of IP that already exists) and output IP (IP over a drug). Licensing was deemed a very important factor in the financing of PDVs. Cheap licenses will increase access to the medicines.

b. Group 2 – What is the cross-cultural impact of research agendas at the national and international levels?

Participants first concentrated on focusing the question. They began with the idea that there are two kinds of health research outputs: 1) health research outputs aimed at addressing the needs of poor countries and 2) health research outputs for rich countries. A central question is whether this difference has an impact on research agendas.

Participants next addressed private/public funding models. Possibilities for public/private funding models include matching funds (e.g. dollar to dollar) or private/public funding that is staged depending on the phase of development.

The value of IP to its holder is what the holder can expect to obtain from the exclusivity provided by the patent over the patent's life. If one wishes to increase the returns from the patent – so as to provide an incentive to invest more into research – one can do so by changing the regulatory framework. Decreasing costs or time required to put a product into the market increases revenues to the patent holder, thus increasing the effect of the patent system on investment.

Private investment can significantly affect culture due to the influence of marketing. One example is marketing drugs directly to the consumer. Tools such as trade marks can be used to increase public acceptance. Culture is also a strong determinant of the value of IP.

Participants felt that the level of disease burden influences the extent of investment. This, in turn, increases health research output and creates a market. However, when there is no market because the disease is neglected, public

investment is needed. Incentives to innovate and invest can be created through government purchase. The government may engage in research and development directly or stimulate R&D by guaranteeing a market.

c. Group 3 – What is the effect of patents on platform technologies and reach through rights on downstream innovation?

Participants focused on the relationship between platform technologies and the relationship to downstream arrangements and discussed the various relevant policies and arrangements between the players. The groups discussed the various different patent holders, e.g. patents held by public institutions, private actors or joint public/private partnerships. The group also looked at the relationship between private and public granting, government policies and the concept of legal certainty. Participants identified the need for legal certainty in terms of the extent to which patents are enforceable and whether the scope is appropriately narrow or broad and the amount of litigation. For example, the *Schmeiser* case in Canada may have significant impact on the funding from private granting agencies. The process downstream is particularly affected by the climate of legal certainty.

d. Group 4 – What are the mechanisms to ensure the bilateral flow of information between sectors and between developed and developing nations?

The group's discussion can be divided into three phrases. The first phase involved identifying the actors that generate research and development in industrialized countries. The second phase was to identify how information is channeled to developing countries. Once this was mapped out, the focus shifted to how these influences can be qualified or quantified. The majority of the influences were positive.

In general, the entire map was conceived as operating between sovereign states. This distinction could be softened by thinking of institutions that penetrate across sovereignty lines. For example, participants clearly identified a link between private/public partnership and industry, government and universities in various states.

Participants focused on the need to identify ways to encourage technology uptake, the need to recognize the importance of having people on the ground and the need to collect information. The group thought that public uptake could be influenced through regulatory institutions that act as trusted authorities and thus influence public opinion. The group also felt that there was a lot of be added to the diagram about networking and feedback loops. For example, media focus on GMO activism can have a significant impact on public opinion while other kinds of pro-GMO publicity comes out of international agencies behind the development. These relationships must be further articulated.

Other factors that participants identified included how a number of generic qualifiers could be integrated, including cross-cultural understandings, building of trust and understanding, repetition of contact, facilitation of knowledge exchange and moving tacit knowledge around, understanding of cultural determinants of technology, uptakes, transaction costs and the way that institutions are responsible for following norms and laws.

2. Summary of the Building of Influence Diagrams

There were certain common issues raised within all the groups. These included: 1) the role of IP in regulating behavior and opinion; 2), the role of the market (some groups took the market as a given whereas others tried to address market failures) in determining outputs; 3) the importance of identifying the specific actors involved, their role and their effect on the system, allowing one to take into account feedback effects; 4) concern on a more macro level about

institutions such as industry and investment; 5) micro elements such as how the mechanisms work to bring stakeholders together and lower costs and how this leads to research and development and 6) the link between the micro and the macro (one of the benefits of the influence diagrams).

On a more procedural level, it became clear that work on the influence diagrams facilitated discussion about both the PDV case study and the role of IP in health biotechnology in general. The influence diagrams accomplished this forcing people with different backgrounds and approaches to sit down and define with some precision the question being posed. Different groups create different diagrams that all answer the same general issue but from different angles. Groups made great efforts to build diagrams and create links to elucidate the questions and to come to a joint understanding of relationships and factors. One of the most difficult tasks was to create feedback loops.

In focusing on specific questions, group work helps refine and focus models. When building models, the goal is to outline the underlying structure. Then, with each case, such as the PDVs, the model is refocused and this allows a decision maker to apply the knowledge gained from the model.

Of course, the biggest challenge faced by the groups was limited time. Nevertheless, participants succeeded in achieving a substantial amount of insight into the policy question underlying the introduction of PDVs and similar technologies.

IV. Conclusions

Overall, participants found the workshop highly productive. In particularly, the influence diagrams were very well received and viewed as not only an excellent teaching tool but as a very effective way to bring people together from many different backgrounds to generate fruitful discussions. The importance for academics and people representing diverse organizations of learning to speak the same language was thought fundamental. Participants appeared particularly

interested in the community that the IPMG is attempting to build through its research project.

Participants from developing countries were very interested in the final products and wanted to ensure that their governments would be aware of the research produced. They also emphasized the importance of looking at the particular socio-cultural and political structure of developing countries and ensure that this is taken into account.

Participants were very keen to see the final product and were interested in how the research would put into practice. These concerns will be addressed in a workshop to be held in Montreal, from June 24-29, where research and the tools that will come out of the research will be presented to policy makers.

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