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Agricultural Biotechnology and Intellectual Property: A New Framework

Workshop Report
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Workshop Report

This document is based on a two-day workshop held at the Institute of Forest Biotechnology, Raleigh, NC and was prepared by researchers at the Centre for Intellectual Property Policy (CIPP) at McGill's Faculty of Law.

The Centre wishes to thank Lori Knowles, Richard Gold and Elisa Henry for their work on this document.

This document reflects the diversity of opinions expressed during the workshop. It does not therefore necessarily represent the opinion of participants nor of their respective organisations.
It does not either necessarily represent the opinion of the CIPP nor those of its members or management board.

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North Carolina Workshop

On June 3-4, 2004 the Centre for Intellectual Property Policy's (CIPP) Intellectual Property Modeling Group (IPMG), an interdisciplinary group of researchers, convened an international, multidisciplinary workshop. This workshop was aimed at moving beyond traditional assumptions surrounding the role and functioning of intellectual property (IP) rights in respect of agricultural biotechnology (ag-biotechnology). Workshop participants included members of the international and national policy community, academics, members of international and national NGOs, and industry. These participants represented four areas of interest, although with some overlapping: economics, law, management and social policy and science.

Workshop objectives included introducing tools that the IPMG has developed to begin a more nuanced exploration of biotechnology IP. The tools, consisting of a series of questions crossing across disciplines – called 'probes' – provide the basis for moving beyond traditional assumptions and creating a transdisciplinary framework through which to study and evaluate biotechnology patent systems. Each probe provides the foundation for formulating targeted research and policy questions that more fully capture the nuances of the different disciplinary approaches and the ways that patent rights are awarded and used.

The workshop aimed to create an interdisciplinary articulation of the problems at the intersection of IP and ag-biotechnology, to explore the appropriateness and workability of the probes when applied to those problems and finally, to help expand and strengthen the probes. Although the meeting group was international, the workshop focused principally on North American perspectives on ag-biotechnology patents.

Several clear conclusions emerged from the workshop. First, despite disciplinary differences participants evidenced considerable consensus on the issues of concern raised by intellectual property rights in ag-biotechnology. Secondly, an overwhelming majority of participants concluded that domestic and international concerns involving developing countries were in most urgent need of research and resolution. Third, workshop participants concluded that the tools (probes) created by the IPMG were helpful in opening new ways to think creatively about old problems. Finally, participants suggested that the development of case studies would aid further exploration and elucidation of the function of the probes and how they interact. The development of case studies will be used in future workshops and will help elaborate how institutions, soft law and legislation can be used to address problems created by intellectual property rights in biotechnology.

Assumptions and Probes

Background work leading to the workshop focused on the discourse over patents and ag-biotechnology and how that discourse can be reshaped to break free from assumptions that impede a broad factual and conceptual understanding of how biotechnology patents function. Reframing that discourse can help focus analysis on whether biotechnology patents achieve their goal of promoting social good. This in turn can focus policy-making on aspects of intellectual property policy previously neglected.

Current discourse about biotechnology patents suffers from the lack of an interdisciplinary, integrated understanding of how intellectual property rights actually function in this context. In particular, discussions about patent protection tend to be predictable in several ways. First, the arguments used in academic literature show that the same arguments surface repeatedly according to the disciplinary background of the author. So, for example, economists focus heavily on questions of biotechnology patents and economic efficiency while ethicists focus on questions about the propriety of "owning" living material. Not only are the academic discussions predictable, but the stakeholders in ag-biotechnology, that is, the innovators (industry, universities), users (farmers, trade groups), opponents (environmental groups, organic farmers), regulators (government, international organisations) also tend to rely heavily on certain assumptions about the functioning and role of patent protections in ag-biotechnology.

While few accept all of the assumptions – some contradict others – they are all present in the literature and in discourse.

Literature searches show that discussions about the utility, necessity and appropriate application of patent protection to ag-biotechnology rely heavily on four assumptions. These assumptions (more fully elaborated in Appendix B) are:

- Patents are necessary to encourage innovation and disclosure of new inventions in biotechnology; that is, without patent protection, biotechnological innovation would cease or be significantly reduced.
- Patents are the optimal policy tool to stimulate research and development in biotechnology.
- Patents create inequities in wealth and problems of unequal wealth/benefit distribution between those who hold patents and those who do not.
- Patents are ethically neutral. They neither create nor magnify or diminish ethical concerns that already exist.

Transdisciplinary Probes: a new framework

To broaden and refocus the analysis of biotechnology patents, with the ultimate aim of providing a useful tool for meaningful, informed public policy, the IPMG proposes the application of seven "probes" with which to evaluate IP systems in a transdisciplinary context. Each probe generates a series of particular questions spanning the various disciplines. Not all probes will necessarily apply to all IP systems at all times. The probes and some sample questions they generate are listed below.

Probe 1: Distributive Justice

The distributive justice probe provides a more subtle and useful way to investigate the manner in which patent systems affect the distribution of the benefits and burdens of biotechnological innovation within and between nations.

- What does 'just' mean in the context of a distribution of the benefits and burdens of biotechnological innovation?
- Is there a claim that the benefits of biotechnology are *global public goods*?

Probe 2: Innovation Management

This probe focuses on the nexus between the patent system and the management or governance of innovation systems. It seeks to provide a better understanding for the context in which biotechnological innovation takes place and is used.

- Ought firms to be left free to determine the use of biotechnological innovation?
- How important are patents to attracting venture capital in different countries?

Probe 3: Knowledge Management

This probe focuses on the diffusion of information and how firms transfer knowledge between universities and industry, among industry players and also between firms internationally.

- To what extent ought one to use technology transfer to assist developing countries as opposed to more traditional systems such as the direct provision of goods and services?
- To what degree ought knowledge management questions be delegated to the private sector? Should they be regulated by the public or by the private sector?

Probe 4: Integrity of Living Things

This probe examines the way that the patent system influences perceptions of life and of living organisms. It opens a discussion rather than presuming that there is something necessarily special about the integrity of non-human life forms. The purpose is to investigate claims that too often fall outside the patent debate.

- How does one determine the normative framework in which to evaluate claims of the integrity of living organisms?
- Do domestic patent systems and/or international patent rules provide adequate mechanisms to protect the integrity of living things?

Probe 5: Sovereignty

This probe analyses the implications of patent regimes within the international legal and political context.

- Can legitimate ethical concerns be distinguished from attempts to impose non-tariff barriers to trade?

- Do international trade conventions provide an appropriate institutional structure through which to consider ethical diversity and consensus?

Probe 6: Economic Efficiency

This probe proposes a series of questions to help assess the design of patent policy for improving economic efficiency.

- How does the knowledge disclosed by patents differ across industries?
- How does the optimal strength of patent protection depend on the ease of imitation relative to innovation in an industry?

Probe 7: Risk Management

This probe examines the link between the patent system and the triad of scientific risk assessment, risk analysis and the management of various forms of environmental risk and potential harms to biodiversity.

- When new forms of harms are introduced (e.g. GMOs) what is the effect, if any, of patents in increasing/decreasing/managing these harms?
- Which institutions(s) is/are responsible for managing risk?

Given the background of the assumptions and probes, workshop participants were asked to participate in answering the following questions by the end of the workshop:

- To what extent do you agree that the four assumptions lead to inaccurate and/or incomplete analysis of how biotechnology patents function and their broader effects?
- To what degree do the probes help provide a more complete, more nuanced picture of patent systems? And,
- How might you change or elaborate these probes?

These questions can be more fully answered by applying the probes to the analysis of the problems of greatest import at the intersection of IP and ag-biotechnology as determined by the workshop participants.

Areas of concern at the intersection of agricultural biotechnology and IP

In order to articulate the issues of concern at the intersection of ag-biotechnology and IP, workshop participants were divided into four disciplinary groups: science, management and social policy, law, and economics. Each of the breakout groups was asked to articulate and prioritise issues of greatest concern in a facilitated session. While disciplinary groups articulated

and prioritised the problems differently, there was clear overlap of concerns. In large part each group articulated two types of concerns:

- Concerns about IP system design and internal functioning of IP systems including issues such as high transaction costs, differences in application of patent laws between nations, administration of patent regimes, and,
- Concerns about external impacts of the application of IP systems, including problems of anti-commons, issues of access and exemptions (such as research exemptions) and the relationship between developed and developing countries.

The disciplinary group articulations of the concerns at the intersection of ag-biotechnology and IP are reproduced below.

Concerns at the intersection of agricultural biotechnology and IP

ECONOMICS

1. *Patent system objectives*

While patents facilitate commercialisation of inventions and enhance access to technology transfer, the impact of patents in doing so are over-estimated. Patents are but one tool for providing investment incentives. Patents are not properly used as incentives for research/invention.

2. *Differences between regions and nations in application of patent systems*

Countries and regions differ substantially in terms of breadth and scope of patents granted, exemptions, examination systems, burdens of proof for challenging patents, vulnerability of system to political abuse. Thus, one must not assume that the impact of one system is the same as others.

3. *Use and abuse of patent systems*

Existing systems are used imperfectly by market players. There is a need to define best practices to reduce what are significant transaction costs, imprecise licensing language, the use of patents to block access and so on. These best practices may include patent swapping, clearinghouses and clusters. We need to conduct research on the concentration of patents within industries and the amount of rights withheld from the market. We also need to address our knowledge gap concerning the structure and use of patent systems in developing countries.

4. *Unintended and negative impacts*

While recognising that patents are only part of a larger incentive system, issues such as a lack of parity of access, problems of the anti-commons, negative externalities, the restriction of knowledge diffusion and the role of patents in emphasising applied rather than basic research are some of the unintended and potentially negative impacts of patent systems.

Concerns at the intersection of agricultural biotechnology and IP

LAW

1. *International issues*

Two sets of issues arise at the international level. First, the place of patent systems in international treaties is uncertain. There are undefined areas at the intersection of such treaties such as TRIPs and the Convention on Biological Diversity and tensions between the spirits of these conventions. Second, the role of patent systems in mediating relations between developed and developing countries raise important questions of trade and equity. These include technology transfer from developed to developing countries, perceptions of imperialism in relation to the imposition of developed country patent systems on the developing world, control over research agendas in developing countries and problems of infrastructure in developing countries that may be exacerbated by developed country patent systems. There are additional questions about how developing countries can make positive use of patent systems within their countries: How should they use their limited funds? Should they protect their genetic resources? In which areas should they invest in innovation? Should they permit copying or should they enforce compliance with patent laws?

2. *Patent system issues*

Important questions remain about the internal administration of the patent system and its mechanics of operation. These include issues relating to the functioning of patent offices, the interpretation and application of patent criteria, the scope of rights granted to patent holders and exemptions and exclusions to patent rights and what constitutes abuse of rights. Additionally concerns exist pertaining to the costs of obtaining patent rights, enforcing those rights, challenging the award of patent rights and defending against infringement claims.

3. *Market issues*

There are many empirical questions that remain unanswered concerning ag-biotechnology such as claimed anti-commons concerns, the effect of patents on research and access, whether market power dominates over market expansion and whether there is a problem with licensing of technology. Issues also arise with respect to the strategic behavior of patent holders and the application of public choice approaches to patents.

Concerns at the intersection of agricultural biotechnology and IP

SCIENCE

1. *Access to technology and knowledge*

One of the primary areas of concern surrounds questions of access to technology and knowledge. There is a need to enable access to platform technology for small markets and a need for humanitarian uses and research exemptions to ensure the continuation of ag-biotech research. Concerns around restrictions on the communication and dissemination of knowledge to the public domain as a result of IP rights, for example, academic journal rules regarding disclosure of protected information may unduly restrict research. Licensing practices and their impact on technology dissemination need also to be examined.

2. *Research Agendas*

The availability of funding drives the research agenda and threatens to skew the balance between basic and applied research (that is, public vs. private science)

3. *Patent Scope*

There is a need to fix and harmonise an appropriate scope to patent rights that are neither too narrow nor too broad and a need to harmonise an approach to patenting of higher life forms.

4. *Bioprospecting and benefit sharing*

Defining the nature of benefit sharing obligations with respect to biodiversity and indigenous knowledge and their relation to IP systems needs to be undertaken.

5. *Process*

Several process issues relating to the granting of patents also need to be addressed. These include the cost and time it takes to challenge issued patent claims and the lack of specialisation of patent office staff and the judiciary, particularly in respect of emerging technologies.

Concerns at the intersection of agricultural biotechnology and IP

MANAGEMENT AND SOCIAL POLICY

1. *Lack of Knowledge*

IP law, institutions and practices are not well understood and there is a general lack of empirical knowledge on the distribution of patent rights and access to patented inventions. We also lack historical knowledge that would help guide policy today.

2. *Risk management and liability*

There is a need to analyse the various forms of risk presented by ag-biotechnology including public exposure to risk (health risks, environmental risks) and business risks. We also need to better examine extra-legal forms of controlling technology (e.g., 'Terminator' technology) as well as ways to harmonise biosafety rules with IP systems.

3. *Distribution and Access*

The fundamental policy issues underlying patent rights relate to the distribution of the benefits and burdens of ag-biotechnology. Unfortunately, the actual discussion of IP systems is dominated by economic efficiency instead of distribution. Distributional effects of IP systems for both developed and developing countries are not well understood and their interaction even less so. Despite this, there is a drive for harmonisation (e.g.TRIPs) although there exist no consensus about what the appropriate distribution would look like or what the capacity is to receive innovation in developing countries.
Access is often limited by transaction costs. There is either vagueness in or an absence of non-market use exemptions for humanitarian research or for research aimed at the public good. It is unclear whether public and private patent pools are actually in the public good. The public good may be eroded by IP rights in different ways such as the value of displaced technologies being lost and possible loss of traditional knowledge.

Areas of concern prioritised

Following the breakout sessions, workshop participants reconvened. Each breakout group presented its outcomes following which participants synthesised and prioritised the issues of concern with respect to patents and ag-biotechnology.

By overwhelming majority, the workshop participants found that the constellation of concerns relating to **developing countries** was the issue of paramount concern. This constellation of concerns includes issues internal to developing nations, such as the need for innovation in orphan crops and markets, issues of infrastructure capability and technological needs and concerns over where and how to spend limited financial resources to participate in IP systems. Another facet of

this area of concern relates to the relationship between developed and developing countries, including issues of benefit sharing and access to both technology and products of biotechnology. Related concerns of an international nature are how to protect and value the indigenous knowledge that often reveals economically valuable properties in biological materials. Finally, there is an urgent need to find a balance between preserving and exploiting biodiversity, particularly in the developing world.

Workshop participants considered concerns about **patent system design** to be the second highest priority with particular emphasis on the need to examine and perhaps expand and create further exemptions and exclusions for research, to respect farmers' rights, public order, humanitarian use, and higher life forms. While participants did not determine the exact shape these exclusions and exemptions might take, there was consensus that patent systems needed to re-examine the need for such exemptions to ensure its goal of serving the public interest is met. A related issue of how patent systems might be structured to take into consideration elements such as indigenous knowledge was raised.

There was also widespread agreement that the efficiency of the patent system, together with concerns about the broad scope of patent protection granted, needed to be addressed. The ability to use and abuse the system for private gain and the need to avoid undesirable impacts such as the creation of monopolies that subvert the public interest were seen as issues of concern while some participants raised the need to position these concerns through study of how patent systems compare to other means of achieving exclusivity, such as through lobbying and regulation.

Finally, the **relationship between public and private science and research**, **licensing practices and policies** and **transaction costs** were also considered important areas for research and policy investigation. With respect to public and private research, there is increasing concern about research that is forgone now that the award of patents has become a criterion for the awarding of research grants and for the management (for example, through Technology Transfer Offices) of public innovation. Heavy reliance on the private sector to determine research priorities and needs will skew the important balance between private and public participation in biotechnological innovation.

Workshop participants agreed that many issues that appear to be issues about patent systems are actually concerns about the interaction of patent systems with licensing practices and policies. Licensing practices and soft law shape the impact of patent systems to a large extent. Consequently there is a need to re-examine the perception that existing problems can be best solved through reshaping patent regulations and laws alone and a related need to examine how licensing agreements contribute to many problems at the intersection of IP and ag-biotechnology. The solution to many of the concerns will likely lie in some mixture of changing patent law and business, management and licensing practices.

Finally, there is a need to examine the transaction costs involved in participating in IP systems. In particular there is a need for good empirical data that can reveal transaction costs for specific products, specific markets and specific regions.

Probing issues of IP and ag-biotechnology

The concluding sessions of the workshop aimed at assessing whether the seven probes constitute comprehensive, meaningful tools to engage in a broad transdisciplinary exploration of the role and function of IP systems. There was general agreement among participants that the seven probes provided a more subtle and contextual analysis of IP questions relating to biotechnology. The participants also agreed that each of the seven probes was important and yielded interesting questions at the intersection of the traditional discourse. Some participants wondered whether an additional probe was needed to specifically address developing country issues while others believed that these issues were subsumed within the existing probes, in particular, Distributive Justice and Sovereignty.

Workshop conclusions

Breakout sessions illustrated that despite differences in articulations of concerns about ag-biotechnology and IP according to disciplinary background, considerable agreement exists on substantive issues for future research and on prioritisation of issues of concern. Substantial agreement across disciplines exists that research of international focus between developing and developed nations is imperative in responding to the explosion of biotechnology patents in both agriculture and health.

With respect to the probes presented as tools for facilitating future research and policy in this area, workshop participants were able to articulate several conclusions. The probes do open new ways of thinking through issues of conflict and concern and help move beyond traditional assumptions. Further exploration of both the function and the interaction of the probes is warranted in future workshops. Using examples and case studies will help elucidate how the probes work individually and in aggregate. Beyond case studies, there may be tools from the various disciplines that are helpful in addressing the question of the comprehensiveness of the probes.

Workshop participants were supportive of asking the larger theoretical questions that were opened up by the probes about the value of patent systems and whether such systems are meeting the stated system goals of promoting public benefit. It was noted, however that there is a dearth of literature examining patents and IP systems from a non-utilitarian perspective which will make this challenging.

Future workshops should focus on concrete examination of the intersection between the probes and the legal models that will be created. In addition, continued focus and elaboration of both legislative and soft law solutions to the needs clearly articulated in the initial workshop is merited. Finally, additional discussion of institutional responsibility and capacity for implementing those solutions should be undertaken.

With the help of partners and workshop participants, the project goal to facilitate public policy debate nationally and internationally on ways to encourage biotechnological research that achieves a socially acceptable and self-consistent balance between the goals identified for a given IP regime will be actualised.

Appendix A

Grant Background

The Centre for Intellectual Property Policy (CIPP) of McGill University is conducting 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. This project involves an international effort to reexamine intellectual property rights relating to biotechnological innovation in the health and agricultural sectors.

While biotechnology's capacity to solve problems in human health and nutrition, agriculture and the environment is often highlighted, there is increasing concern over the ethical and other social effects of this technology. Among these concerns is the role and impact of intellectual property (IP) rights that establish rights of control over biotechnology research results, the impact of IP rights on the development of scientific infrastructure in developing nations and the effect of IP rights on ensuring access to biotechnological innovation. Different legal regimes for IP offer solutions to the problem of balancing competing social interests by providing different levels of protection for, and access to, these innovations. The CIPP aims to systematically review the nature and scope of protection granted to health and agricultural biotechnological innovation in existing legal models for IP regimes, and to develop and evaluate alternative legal models of these regimes.

The project involves three main research objectives:

- Using a transdisciplinary methodology, to develop and disseminate three alternative legal models that integrate ethical, economic and legal perspectives for the protection of health and ag-biotechnology innovation. Each model will represent a different balance of ethical, management, political and economic concerns.
- To develop and disseminate critical analyses of the ethical, legal, management, political and economic facets of each of the legal models. These critiques will incorporate the interests and feedback of academic, regulatory and business communities and especially developing countries.
- To use the three models to spur more constructive and focused debates over the appropriate nature and scope of protection granted over biotechnology-based innovation.

Appendix B

The Assumptions

Assumption 1: Economic Efficiency

> *Patents improve economic efficiency by encouraging innovation and disclosure of new inventions. Without patent protection, biotechnological innovation would cease or be significantly reduced.*

The foundation of this assumption is that for innovation to occur an innovator must expect a stream of profits sufficient to compensate it for the costs of its innovation efforts. The right to exclude others offered by patent protection increases the size and duration of these profits and thereby increases the incentive to innovate. Absent such exclusionary rights, the market for innovations would operate inefficiently resulting in fewer innovations than is socially beneficial. An additional facet of this assumption is that the disclosure of the innovation required by law increases the dissemination of innovation and in turn sponsors additional innovation.

Although economic and, to a lesser extent, ethics literature adopt this economic efficiency assumption, it is the uncritical acceptance of this assumption in the legal literature and leading case law (particularly in the United States but also in Canada) that is particularly striking. In the debate over patents and ag-biotechnology, inventors and industry rely heavily on this assumption. This is reflected in claims that patents are needed for competitive advantage, to attract and maintain a thriving agricultural research community, to encourage the flow of investment capital, to avoid a chilling-effect on development of new and important biotechnological inventions and to keep bringing useful technologies to the marketplace. Users of ag-biotechnology, particularly trade organisations, also voice claims that patents are important for disclosure that will encourage additional research and innovation in agriculture.

Despite wide acceptance of the truth of this assumption, it is increasingly subject to challenge in current economic literature, particularly at the international level. Economic efficiency arguments do not account for situations in which most research and development involves new entrants improving on existing products. In such cases innovation may occur despite a lower social benefit than the cost of the innovation. Similarly, where the duration of patent protection is too long, this may provide more benefit to the innovator than is actually required to induce innovation through monopoly distortions that are economically inefficient. Likewise, where patents are overly broad they may needlessly block related innovations. This has been seen several times in the healthcare field. The patent length that maximises economic efficiently in one industry may be of a longer duration than that for other industries.

In addition, the role of patents in knowledge dissemination varies across industries. The nature of innovation for some products may be easily revealed through reverse engineering, such that disclosure provides minimal social benefit in that regard. Also, some innovators may choose to patent only portions of an innovation preferring to protect vital aspects through other mechanisms such as trade secrets. Although in this situation the innovator assumes a risk, it effectively circumvents full disclosure so that other innovators cannot build upon the underlying

innovation to which that patent protection attaches. Thus, it is quite possible that patents may not play a substantial role in the diffusion of knowledge in some cases.

Finally, there are structural reasons to believe that one can never know for certain whether patents actually encourage or discourage innovation. These include differences between markets for different products and the fact that industry rarely relies solely on a single patent to secure its inventions. It is customary to use a combination of patents, trade secrets, and even trademarks to protect industry innovations as well as other mechanisms to gain advantage over competitors. All these intellectual property management mechanisms make isolating the effect of patents on innovation difficult if not impossible. Further research is therefore needed to distinguish the line between patents and innovation in unique sectors such as biotechnology.

Assumption 2: Optimising R&D

> *Patent protection provides the optimal tool for encouraging and promoting research and development (R&D) in biotechnology. It is the ability to gain patent rights that spurs scientific research and development.*

This assumption is related to the economic efficiency assumption (Assumption 1) but differs in an important respect. First, Assumption 1 merely advocates patents as necessary to encourage innovation and dissemination of knowledge. Assumption 2, however, goes further by suggesting that governments looking to promote innovation should place reliance on patents rather than other measures. Assumption 2 requires acceptance of Assumption 1 *and* institutionalises acceptance of patents as a public policy tool.

The assumption that intellectual property and patents are the optimal tools to promote R&D in biotechnology is a prominent assumption in policy literature and public policy discourse and decision-making. In making award decisions, granting agencies rely increasingly on the ability of grant-seeking researchers to obtain patents and to commercialise innovations. The Canadian National Research Council granting policy relies heavily on the ability of universities and colleges to provide intellectual property for business development. In the United States the Bayh-Dole Act (1980) provided universities the right to gain patents on innovations resulting from federally-funded research.

It is often claimed that the Bayh-Dole Act together with the US Supreme Court decision in *Diamond v. Chakrabarty* (allowing the first patent of a genetically-modified organism) prompted the biotechnology revolution. In reality, industry only became interested in commercialising genetic and biotechnological innovations once governments, universities and not-for-profit research centers (largely subsidised by federal funding) had spent decades developing the technology to the point where it could be commercially exploited.

Despite increasing governmental reliance on patents to promote privately sponsored R&D, without publicly funded research there would be no biotechnology industry. Stakeholders in ag-biotechnology rarely discuss the role of public research in bringing about innovations. Industry and trade associations rely on the assumption about the primary importance of the private sector for research and innovation. Claims are often voiced that without the ability to patent innovations

in ag-biotechnology, research and development would move to other sectors or be significantly reduced.

The increasing reliance on university-industry partnerships and patenting in the area of biological research has changed university research agendas. The question needs to be posed as to whether this change is for the better. Do these relationships that fragment intellectual property rights between various industry-university collaborations hinder the development of mature technologies and down-stream research? In addition, university research may be moving away from its traditional role in conducting basic research toward conducting applied research. This prompts concerns about whether universities can remain accountable to the public and hold the public's trust. These concerns require further analysis of the assumption that promoting patents optimises R&D. Do such policies promote *balanced* R&D agendas? Framed otherwise, should patent systems be evaluated on their ability to bring about a balanced approach to research that promotes both necessary basic and applied research?

Assumption 3: Differences in Distribution

> *Patents create inequities in wealth and problems of unequal wealth/benefit distribution between those who hold patents and those who do not.*

Ethics literature argues that patents create disparities in distribution, advantaging holders of patent rights to the detriment of others. While it is clearly true that patent systems create differences in distribution of goods, more research is needed to analyse whether these differences within and between societies are unjust. Some differences, which favour groups or individuals, may not harm others. Clearer analysis and development of criteria to determine the just or unjust effects of the distributional effects of patent rights in biotechnology must be developed.

Industry and user stakeholders in ag-biotechnology vigorously criticise this distributional assumption. These stakeholders claim that despite holding private rights in the underlying innovations, there will be broad distribution of the benefits flowing from those innovations. Claims are often made that by promoting innovation in ag-biotechnology (Assumption 1 and Assumption 2) patents will benefit citizens around the globe. Claims are made that innovations in ag-biotechnology will not only help feed the poor and hungry but that patents also help protect the biodiversity or indigenous biowealth in developing regions of the world. Opponents of patent rights argue that this privatisation fosters "biopiracy" of the genetic resources of the developing world by industrialised countries. They argue that intellectual property regimes should recognise centuries of traditional knowledge that has often discovered useful properties of nature's wealth.

Clearly claims about biopiracy need to be "unpacked". Claims about rewarding traditional knowledge may not fit into traditional notions of property, and may not be necessary if patents are properly awarded to "novel" innovations. Further analysis is needed to determine if it is true that the application of patents to biotechnology or living material is unjust policy. Where unjust distributions exist, is it the patent law or patent *administration* that creates the injustice? Could different administration of patent law help create greater equity between nations by, for example, facilitating technology transfer? Further analysis of competing rights that might constrain the

positive use of patent rights (rights to use and exploitation rather than rights to exclude others) is needed.

Assumption 4: Ethical Neutrality

> *Patents are ethically neutral. They neither create nor magnify or diminish ethical concerns that already exist.*

Ethical consideration of biotechnology patents has not kept pace with the explosion in the number of patents during the 1980s. Ethics literature in this field tends to lack a conceptual and methodological robustness provided by the interdisciplinary analysis. Much of the ethics work to date concentrates on worthwhile but narrow issues such as the special status of DNA and its role in patents and the effect of patents on the distortion of science toward profit, and subordinate issues such as whether "living material" including genes, plants and animals ought to be the object of patent rights. Ethical discourse about patent systems must be broadened and informed by other disciplines.

Legal literature and case law adopt the assumption that patents are ethically neutral. This assumption holds that distributional inequities come from the nature of market economies and not from patent rights. It is the application of the underlying technologies or the use of licenses that have ethical implications but not the mere existence of the patent rights themselves. This implies that where unethical or social concerns arise out of biotechnological research, commercialisation and access, (apart from more general concerns about distributional justice addressed in Assumption 3), they are not related to the patent system *per se*. Patents function simply as a regulatory mechanism for reconciling the simultaneous and contradictory objectives of achieving maximum levels of innovation and maximum access to the products of innovation.

Belying this assumption, many developed nations (but not Canada, the US or Australia) provide for ethical review within their patent regimes. Most commonly, provisions in patent law provide for exceptions to patentability where the award of patent rights would run contrary to "ordre public" or morality. Other exceptions also exist in international agreements such as the TRIPs agreement. Clearly these exclusionary clauses and the assumption of ethical neutrality are contradictory. An interdisciplinary analysis of this assumption is needed. Questions about the accountability and responsibility of patent holders with respect to use of patent rights and effects on related public policy concerns need to be addressed. Additionally, issues of institutional responsibility have not been adequately analysed. Which institutions and groups should be responsible for raising ethical concerns related to patent regimes? What bodies have legitimacy and competence to analyse and/or to create policy that mediates between property rights and rights that affect public welfare?

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Unchallenged and uncritical reliance on these four assumptions by academics and policy-makers leads to an incomplete and inaccurate analysis of the real functioning and impact of patent regimes as applied to biotechnology. In particular, reliance on these assumptions works to

conceal emergent ethical, social and economic consequences of the patent system in various spheres of life. Lines of inquiry that conflict with an assumption are neglected. For example, questions about how to best use the patent system to maximise innovation are studied while questions about the effect of biotechnology patents on basic scientific research, and the larger impact this might have on society, are largely neglected.

Appendix C

Workshop Participants

Our profound thanks to the following individuals who attended and participated in the initial workshop of Legal Models of Biotechnological Intellectual Property Protection: A Transdisciplinary Approach:

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