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REPORT

A Report By The International Expert Group On Biotechnology, Innovation And Intellectual Property

TOWARD A NEW ERA OF INTELLECTUAL PROPERTY: FROM CONFRONTATION TO NEGOTIATION

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TOWARD A NEW ERA OF INTELLECTUAL PROPERTY: FROM CONFRONTATION TO NEGOTIATION

A Report from the International Expert Group on Biotechnology, Innovation and Intellectual Property

International Expert Group on Biotechnology,
Innovation and Intellectual Property
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CHAIR'S PREFACE

Seven years ago, a group of international experts foresaw an emerging sea of change in how intellectual property in the life sciences is understood. This group, which I have had the privilege to lead, realized that governments, industry, universities, researchers and NGOs were developing new views about the role of intellectual property – patents, copyrights and trade-marks – in managing life sciences innovation. With an historic financial commitment from the Canadian government, through the Social Sciences and Humanities Research Council, the International Expert Group on Biotechnology, Innovation and Intellectual Property investigated how we can collectively manage the process of biotechnological innovation to respond to the world's food, health and industrial needs.

Through a network of contributors from every continent, the International Expert Group brought together representatives from industry and NGOs, from government and universities, from richer and poorer countries to develop a novel, data-intensive and collaborative model of the role of intellectual property in innovation. Using techniques borrowed from many disciplines and drawing on the skills and insights of academics, government policy-makers, industry and university administrators, the project has culminated in this report and the rich set of case studies, articles, data, and summaries that accompany it. We make all of these materials available to the academic community, researchers, industry and NGOs alike for their non-commercial use.

None of this work would have been possible without the contributions of a large group of people. In addition to the other members of the International Expert Group, whose insights and efforts pushed the boundaries of thinking about intellectual property, an entire team of researchers, students, associates and workshop participants have ensured the depth and breadth of the work. At each stage of the project, an international team of collaborators provided peer-review, comments and criticism of the material, ensuring its quality. The International Expert Group was fortunate in benefiting from the insights of its Advisors, respected and skilled individuals from around the globe, who supported the project throughout its life. Finally, the International Expert Group was organised by the administration at the Centre for Intellectual Property Policy at McGill University's Faculty of Law. The Faculty of Law itself, its Dean and University Principal provided critical support to the Centre, its activities and this project in particular at crucial moments of the project. While all of these individuals contributed invaluably to the materials presented today, none of them other than the International Expert Group itself is responsible for their content.

At the centre of the International Expert Group's findings is the recognition that we, in high-, middle- and low-income countries, need to create new organisations to repair the lack of trust existing between those who participate in biotechnology innovation systems, whether as creator, user or manager. Putting our actions behind our words, we have created a new entity, The Innovation Partnership, or TIP (www.theinnovationpartnership.org), a non-profit consultancy with the mission of building this trust through training, independent research and the provision of strategic advice. Through TIP, the International Expert Group reaches out to indigenous, national and international communities to develop the tools and knowledge necessary for all to benefit from biotechnological innovation in the future.

E. Richard Gold
Chair
International Expert Group on Biotechnology, Innovation and Intellectual Property

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EXECUTIVE SUMMARY

OVERVIEW

Intellectual property occupies a central position in the biotechnology innovation system, the expected source of new medicines, foods and bio-energy. An international and interdisciplinary research team has convened for the last seven years in an attempt to better understand the mechanisms of intellectual property in biotechnology innovation, and to suggest improvements to the role of intellectual property in that system. This report represents the research team's core finding and recommendations.

The core finding is that policy-makers and business leaders must give shape to a new era of intellectual property to stimulate innovation and broaden access to discoveries. The current system, 'Old IP,' rests on the belief that if some intellectual property (IP) is good, more must be better. But such thinking has proved counterproductive to industry, which in health fields has seen declining levels of innovation despite increasing stakes in intellectual property. The era of Old IP has also proved counterproductive to the world's poor who await advances in health and agriculture long available to the global elite.

The International Expert Group concluded that a 'New IP' era that focuses on cooperation and collaboration is slowly emerging. Intellectual property is meant to assist in this process by encouraging cooperation among various brokers and stakeholders. The best innovative activity occurs when everyone – researchers, companies, government and NGOs – works together to ensure that new ideas reach the public, but are appropriately regulated and efficiently delivered to those who need them.

To make the transition to New IP, several things are needed:

Greater trust between actors: A lack of trust has blocked collaborations to deliver medicines to the world's poor, has led to ineffective legislative reform and has delayed the rapid introduction of new technologies. Independent trust builders who educate and encourage dialogue between industry, government, researchers and NGOs are essential.

More and better communication: The stakes are high, so the level of our conversation about IP and science and technology policy needs to be raised as well. The media have an important role to play in this regard. The media needs to step up and cover issues of science and technology policy and other actors must agree to listen in addition to talking.

New models: We need better ways to develop and deliver biotechnology products. Established companies need to help their counterparts in low and middle income countries to get financing and sell their inventions. Researchers, industry and NGOs need to work together to develop creative ways of sharing the knowledge that will lead to the next generation of products and services.

Enhancing science, technology and engineering: Most low and middle income countries, as well as indigenous peoples, face a major challenge in developing and maintaining scientific capacity. Before these countries and communities think about profiting from innovation, they need to enhance training, including in IP, better retain researchers and construct laboratories.

Cross-cutting thinking: IP has too long been looked at in isolation from other elements in the innovation system, leading to a poor understanding of IP's role in innovation. Researchers need to work across disciplines and bring together industry, users, government and scientists to understand how IP actually works in context.

Data and metrics: You get what you measure. Right now, we measure the wrong things about IP, particularly at public institutions and universities. Unless we figure out what it is

we want from innovation and how to measure it, we will not break out of the vicious cycle of Old IP.

BASIC CONCEPTS

Old IP is the current, but waning era of IP, in which companies and universities seek ever greater amounts of IP in order to protect themselves from others. It involves constructing increasingly higher walls around knowledge and controlling it tightly.

New IP is the emerging era of IP in which IP is understood within the entire context of innovation. It stresses sharing and collaboration instead of increased protection, leading not only to greater levels of innovation, but better access to new products and services.

Intellectual property (IP) is a way in which a government gives power to a person – the IP holder – to control how certain bits of knowledge will be used. A patent gives its holder the ability to control the use of the inventions. Inventions are things such as mousetraps, medicines or novel stem cells. Inventions are also ways of doing things, such as how to mix chemicals together or how to insert a gene into a cell's DNA. Copyrights cover works of art, plays, music, computer programs and databases, and give their holder a specific power: to prevent others from copying the way they expressed themselves in these works, but not in the idea of the work itself. Trademarks provide their holders with the ability to stop others from using names (Nike or Coke, for example), symbols (think of McDonald's arches) or other logos, shapes or sounds to sell products or services.

Biotechnology is the use and manipulation of living organisms and biological processes to meet various industrial, environmental, health and agricultural needs. While wine, cheese, and beer may be among the oldest forms of biotechnology, modern biotechnology involves the deliberate and measured manipulation of genes, proteins and other components of life to produce new products and services. These include the controversial – such as genetically-modified plants and stem cells originating from human embryos – and the well accepted and critical, such as the production of life-saving insulin for diabetics through genetically-modified bacteria.

An **innovation system**, described by the person who coined the term, is a local, national or international "network of institutions in the public and private sectors whose activities and interactions initiate, import, modify and diffuse new technologies."[1] Innovation systems are more circular than linear; there is no one 'beginning' and 'end' to innovation. One person – a user, researcher or company – picks up where the last left off.

A CHANGE OF ERA

Why is the Old IP Era Coming to an End?

Old IP has its roots in two developments in 1980: a US Supreme Court decision to grant a patent over genetically-modified bacterium[2] and a US statute that told universities to patent and commercialise publicly-funded scientific research.[3] Soon, patents were extended to software programs, entire animals and plants and now even ways to save on income tax. Other places, such as Japan and Europe, wishing to benefit from the biotechnology and information technology boom, brought their IP laws into line with those of the US.[4] IP became enshrined in free trade agreements, culminating in 1994, in IP rules being brought into the World Trade Organization Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPs). That agreement required countries to meet a set of minimum standards over how to protect intellectual property.

The decline of the era began soon afterward. In 1998, 39 international pharmaceutical manufacturers sued the government of South Africa, which was trying to deal with the country's ever growing HIV/AIDS crisis by allowing the country to import drugs manufactured elsewhere without the permission of patent holders. These pharmaceutical companies and their supporters claimed that South Africa should not undermine IP by allowing such measures since IP, they argued, was essential to stimulating the creation of new drugs needed to fight AIDS and other diseases. This effort by rich-country companies unleashed a major backlash from AIDS activists and low and middle income countries that shook the foundations of intellectual property and raised questions on whether the system had extended far beyond its original intent.

Towards a New IP Era

The era of Old IP had multiple flaws. It failed to recognize that knowledge leads best to new products and services if shared.[5] It wrongly assumed that companies obtain IP to protect their inventions from being copied rather than to trade or enhance their reputations.[6] It wrongly presumed that if a company has a patent right it could actually use it to prevent others from copying the invention.[7] It exaggerated the importance of patents;[8] other impediments – such as income tax rules, regulations and political and cultural understanding – may often be more important.[9] Research also showed that it was unclear whether patents actually increase inventiveness and dissemination.[10] And last, Old IP failed to come to grips with the reality of public health and public health care systems.

Because of these flaws, the era of Old IP is drawing to a close. The US Supreme Court has reversed its path and is now curtailing IP rights.[11] Countries such as France and Germany refused to fully implement new rules to expand IP rights in human genes.[12] Patent reform has become a game of choice in Washington. International organisations such as the World Intellectual Property Organization, the World Health Organization and the Organisation for Economic Co-operation and Development call for greater collaborations and adaptation. By 2007, CEOs and senior managers of pharmaceutical companies stated that their business model of establishing high IP barriers around blockbuster drugs "ha[d] been dead for two years".[13]

The twilight of Old IP does not signal the end of the importance of IP.[14] We are entering a New IP era in which IP is used to sustain and maintain collaborations and partnerships so that knowledge gets to those who need it most to produce and disseminate new products and services.

There are three elements to managing the transition to the New IP era: legal rules, practices and institutions. While legal rules surrounding patents and copyrights define the relationships between actors, they are just the beginning of the discussion. A study of US academic scientists demonstrated that they routinely ignored patent rights in conducting their research, which is widely viewed as a good thing.[15] How people behave – in other words, their practices – and the effect of practices on innovation is critical. Public and private institutions – patent offices, courts, universities, governments, corporations and industry groups – that manage, award, review and hold intellectual property also play an essential role in shaping the IP system.

The move away from Old IP requires a re-examination of how laws, practices and institutions interact to ensure that biotechnology lives up to its potential. Sanofi and GlaxoSmithKline, both large pharmaceutical companies, have, for example, entered into partnerships with the Drugs for Neglected Diseases initiative (DNDi), a non-profit organization working on medicines for developing country health needs.[16] UNITAID, an international agency that funds the purchase of medicines for HIV/AIDS, malaria and tuberculosis, is building a patent pool that would bring together the pharmaceutical industry, generic producers, national governments and NGOs to facilitate the manufacture and distribution of medicines for lower income countries.[17]

SIX THEMES FOR THE NEW IP ERA

The International Expert Group set out to build a framework through which to understand the emerging New IP era. They concluded as follows:

On trust: One of the most glaring failures of Old IP is that it continues to undermine trust. Trust among all of the players involved is essential to meeting the challenge of remaking this system so that research networks result in the creation, sharing, improvement and combination of knowledge. For now, governments do not have the capacity to step back and facilitate relationship-building. Outsiders must fill this role.

On communications: Industry and NGOs talk past one another and fail to understand each other's concerns. Lack of communication was a major cause of the failure of Myriad Genetics to develop a workable plan to introduce its breast cancer genetic test into Canada. With some exceptions, the media has done a poor job of challenging the myths of Old IP, accepting as truth statements that are often supported by nothing more than rhetoric.

On new models: Industry, governments and universities can develop new models to mobilize the innovation system to produce better results. These models will stress sharing over hoarding, and stress partnership over barriers. Examples of what these models will look like already exist. These include: a public-private partnership to develop a new

HIV vaccine through the International AIDS Vaccine Initiative (IAVI); and a pool of patents set up by UNITAID to deliver needed HIV/AIDS medications to the world's poor.

On scientific infrastructure: Low and middle income countries contribute to science and technology but with fewer resources than do rich countries. These countries need appropriate laboratories and equipment, trained scientists and technicians, access to science journals and scientific conferences, research funding and the ability to disseminate the results of research. Too many low and middle income countries lack critical infrastructure such as access to high-speed internet. And lastly, a country must also manage its biotechnological innovation system to get the greatest benefits in economic, health, agricultural and industrial needs.

On cross-cutting thinking: More attention needs to be paid to understanding how IP contributes to the overall function of the innovation system rather than deal with it in isolation. Once we better understand what most spurs innovation, we can ensure that our discussions stay focused on the potential of biotechnology to address health, agricultural and industrial needs.

On data and metrics: There is a lack of empirical data on such critical questions as to whether, how and when IP increases levels of investment in research and development. Does IP encourage or retard development in low and middle income countries? Does it facilitate or hinder the dissemination of new products and services? This data does not exist because IP is rarely the principal driving innovation. In addition, there is a lack of common standards in data collection among agencies and among countries. There is a particular dearth of data with respect to university and other public sector technology transfer and dissemination.

RECOMMENDATIONS

The International Expert Group agreed on the following actions to be taken by governments, patent offices and universities and the scientific community.

1.GOVERNMENTS SHOULD TAKE THE LEAD ON THE FOLLOWING ACTIVITIES:

1.1. They should pay at least as much attention to the environment in which innovation takes place – including regulation of the health and environmental effects of biotechnology, the independence of the judicial system, laboratory facilities, training and marketplace regulation – as they do to IP.

1.2. They should encourage, financially and intellectually, the creation of independent trust builders to mediate disputes and encourage dialogue between actors and provide training, particularly to lower income countries.

1.3. They should support independent organisations to engage indigenous and local communities at a grass-roots level in training on and policy development in relation to IP, the protection of indigenous knowledge and methods to share that knowledge while respecting the rights and autonomy of those peoples.

1.4. They should standardize the collection of important science and technology measures to permit comparisons of different models of managing IP.

1.5. Governments with public health care systems should work with industry, funding bodies and universities to develop a PPP to manage health-related data to encourage collaborations and innovation.

1.6. Government funding agencies should target the development of novel and sustainable business models and their implementation, particularly in low and middle income countries. In particular, funding should be made available to support pilot projects on commercializing and disseminating low and middle income technologies.

2. AS CUSTODIANS OF THE PATENT SYSTEM, PATENT OFFICES AROUND THE WORLD SHOULD DO THE FOLLOWING:

2.1. They should collect patent-related information in a standard form and make this available to the public for free. Data should include information that will assist in assessing patent landscapes in targeted areas of technology, such as essential medicines.

2.2. In addition to collecting patent information, they should collect data on the type and major terms of license agreements.

2.3. They should establish policy branches to investigate ways to make data more available, assist in patent landscaping and disseminate information about the patent system.

3. THE PRIVATE SECTOR SHOULD TAKE RESPONSIBILITY FOR THE FOLLOWING:

3.1. They should support the creation of trust builders and agree to submit disputes to them for mediation.

3.2. They should support the work of trust builders in organising workshops and training programmes through which stakeholders can discuss and exchange views on IP policy.

3.3. Leading private sector institutions in high, middle and low income countries should establish an independent, non-profit technology assessment organization to evaluate new biotechnology products and services originating in low and middle income countries and by indigenous and local communities.

3.4. Together with business, law and economics experts, they should develop new and sustainable business models of developing, commercializing and disseminating biotechnology products and services that are attuned to local needs and conditions. This includes greater collaboration with public sector initiatives.

3.5. They should be transparent about the patents they hold and where they are registered, and collaborate with patent offices in building publicly-available databases of this information.

4. THE MEDIA HAS AN IMPORTANT ROLE TO PLAY IN IP POLICY AS WELL:

4.1. The media should develop a science policy news beat to facilitate general knowledge of science and technology issues and encourage coverage of the role of science on economic and social welfare.

5. UNIVERSITIES AND THE SCIENTIFIC COMMUNITY SHOULD DO THE FOLLOWING:

5.1. Universities should establish clear principles relating to the use and dissemination of their IP that includes ensuring greater access and the use of licensing provisions that make it easy to conduct research and development on products needed by low and middle income countries.

5.2. They should develop new measures of the success of technology transfer, development and social investment that correspond to social and economic return.

5.3. Business schools should include low and middle income country conditions and opportunities in their curriculum and should develop programmes through which their students can provide business planning assistance to low and middle income country entrepreneurs.

5.4. Universities in high income countries should collaborate with those in low and middle income countries to create educational opportunities at the doctoral and post-doctoral levels through which scientists maintain links with their countries of origin and conduct research focused on the needs of those countries. Universities in high income countries should encourage those of its professors from the Diaspora to assist their countries of origin through supervision of students, joint research projects, conducting peer review and so on.

5.5. Researchers should analyse questions of IP within the larger context of IP and innovation systems. To do so, they should use analytical tools that provide a broader, inter-disciplinary perspective on IP and innovation.

THE THEMES IN PRACTICE: A VIEW OF NEW IP

Highlighting six themes, the International Expert Group sketched out three representative ways for public and private sector decision-makers to modify IP systems.

First, decision-makers could place their emphasis on maximizing short- to medium-term levels of biotechnological innovation. The central challenge of this in the New Era of intellectual property will be to increase collaboration and the flow of basic scientific knowledge. Public sector policy-makers should focus on building collaborative relationships between public and private sector actors. Some of these relationships will rely on private financing and the appropriation of products and services emanating from these collaborative efforts while at the same time ensuring that basic knowledge and data remain free to users. Building collaborations requires, however, trust and communication. Public and private sector actors need to develop connections

to increase communication and trust. Drawing on the expertise of independent "trust builders" would be a start.

The second possible priority for decision-makers is to create and maintain a scientific infrastructure. Low and middle income countries as well as less developed regions of high income countries face the problem of catching up to the large investments made in high income regions in biotechnological innovation. The solution of adopting high income country IP systems has proved ineffective in addressing this gap. Rather than focus on increasing IP rights, as Old IP has promoted, low and middle income countries need to adapt IP systems to their technological and cultural situation. Low and middle income countries must build and disseminate new business models that better correspond to their culture and institutions. An essential step is to train managers on how to use these models.

The third possible priority involves accessing biotechnology. We found a highly antagonistic relationship between industry and NGOs in terms of getting access to biotechnological advances. The access-incentive paradigm – in which access is seen as opposite to providing an incentive – underlies much of the thinking about IP. The International Expert Group's research strongly suggests not only that this paradigm does not describe reality but that it is misleading. IP rights have only a marginal role in encouraging research; their role is significantly more pronounced in the dissemination of new products and services. Since access depends on dissemination, IP rights and access fundamentally relate to the same phenomenon: the dissemination of new products and services. The International Expert Group saw three ways ahead to help resolve the impasse: more scientific knowledge and training; access to financing and business knowledge; and access to new biotechnology products and services adapted to the needs of low and middle income countries.

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[2] *Diamond v. Chakrabarty* (1980) 447 U.S. 303.

[3] Bayh-Dole Act, P.L. No. 96-517 (1980).

[4] E. Richard Gold & Alain Gallochat, "The European Biotech Directive: Past as Prologue" (2001) 7 European Law Journal 331 at 332.

[5] OECD, *Guidelines for the Licensing of Genetic Inventions* (OECD: Paris, 2006) at 4-5, available online at: http://www.oecd.org/dataoecd/39/38/36198812.pdf.

[6] Knut Blind, Katrin Cremers & Elisabeth Mueller, "The Influence of Strategic Patenting on Companies' Patent Portfolios" (2007) Centre for European Economic Research, Discuss Paper No. 07-013 available online at: ftp://ftp.zew.de/pub/zew-docs/dp/dp07013.pdf; Knut Blind, Jakob Edler, Rainer Frietsch, Ulrich Schmoch, "Motives to patent: Empirical evidence from Germany" (2006) 35 Research Policy 655; Anthony Arundel & P. Patel "Strategic patenting", Background report for the Trend Chart Policy Benchmarking Workshop *New Trends in IPR Policy*, Luxembourg, June 3-4, 2003.

[7] E. Richard Gold & Julia Carbone, "Myriad Genetics: In the Eye of the Policy Storm" (2008) available at www.theinnovationpartnership.org.

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[11] See *eBay Inc v. MercExchange*, L.L.C. (2006) 547 U.S. 388; KSR v. *Teleflex* (2007) 550 U.S. XXX, 127 S. Ct. 1727; *Merck KGaA* v. Integra Lifesciences I, Ltd., et al., (2005) 545 U.S. 193; and *Quanta Computer, Inc. et al. v. LG Electronics, Inc.* (2008) 553 U. S.

[12] See EC, Directive of the European Parliament and of the Council on the legal protection of biotechnological inventions, 98/44, OJ L 213.

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TOWARD A NEW ERA OF INTELLECTUAL PROPERTY: FROM CONFRONTATION TO NEGOTIATION

The current era of intellectual property is waning. It has been based on two faulty assumptions made nearly three decades ago: that since some intellectual property (IP) is good, more must be better; and that IP is about controlling knowledge rather than sharing it. These assumptions are as inaccurate in biotechnology – the field of science covered by this report – as they are in other fields from music to software.

This existing system of intellectual property, or Old IP, is out-of-sync with the level and types of innovation we need. The system has not made critical inventions, such as life-saving medicines, more available to those who need them the most. The Old IP era did one thing well, however: it greatly expanded the pool of what was protected under intellectual property. This increased appetite for protection did not necessarily raise levels of innovation, creativity, or the new products that go along with it. As one observer remarked, the era of Old IP "was as much a consequence of intellectual capitalism as a cause of it, and ... was not a necessary condition for the emergence of the industries and technologies that fostered it."[1]

Intellectual property is a way in which a government gives power to one person – the IP holder – to control how knowledge will be used. A patent, for example, gives its holder the ability to control who uses inventions. Inventions are things such as mousetraps, medicines, or novel stem cells. Inventions are also ways of doing things, such as how to mix chemicals together or how to insert a gene into a cell's DNA. Copyrights cover works of art, plays, music, computer programs, and databases, and give their holder a specific power: to prevent others from copying the way the holders expressed themselves in these works. But copyrights do not give the power to control the idea of the work itself (and hence, one can prevent others from copying a Harry Potter book, but not the idea of a school for wizards or even an individual wizard with an important quest). Trade-marks provide their holders with the ability to stop others from using names (Nike or Coke, for example), symbols (think of McDonald's arches) or other logos, shapes or sounds to sell products or services. In addition to these forms of IP, other protections include plant breeders' rights (protecting the breeder of a new rose or tomato plant) and industrial designs (the form of a chair or stool, for example).

Biotechnology involves the use and manipulation of living organisms and biological processes to meet various industrial, health, environmental and agricultural needs. While wine, cheese, and beer may be among the oldest forms of biotechnology, we concentrate here on modern biotechnology, involving the deliberate and measured manipulation of genes, proteins and other components of life to produce new products and services. Some of these uses are controversial – such as the creation of genetically-modified plants and of stem cells originating from human embryos – while others are widely accepted, such as the production of life-saving insulin for diabetics through genetically-modified bacteria. Many of the products and services derived from modern biotechnology, including diagnostic tests, new medicines, new ways to produce energy and new crops, are covered by IP rights, particularly patents.

The inadequacies of the current IP era have to do more with the way that organisations use and share IP than with the technical legal rules of IP themselves. IP is used to control knowledge rather than manage it and is hoarded, not shared. People put IP on a pedestal – saying it is *the* reason why companies invest in innovation or *the* reason that people do not get needed drugs – rather than seeing it for what it is: a cog in a large system of innovation that brings researchers, universities, companies, government, non-governmental organisations (NGOs), patients and technology users together to create, improve, disseminate and use new practical knowledge. Because of these factors, innovators have tended to maintain strict control over knowledge until they can

develop and sell blockbuster products. This model's failures are illustrated by declining levels of innovation and inadequate responses to the critical health and agricultural needs of the world.[2]

As the current era of IP wanes, a new one is emerging. It centres on the principle of granting the *right* amount of IP and having the private and public sectors use those protections more effectively. We call this the era of New IP, an era in which IP becomes a servant to, and not master of, values such as equity and fairness. More specifically, it involves not only balancing patents with other ways of encouraging creativity, but also facilitating cooperation and collaboration among creators and among users of innovation. This turns out to be critical to industry, and not simply technology users, as existing business models have proved increasingly ineffective. This report examines how, in the New IP era, governments, industry, researchers and the public can better manage IP in the crucial area of modern biotechnology. While we set out in this report specific recommendations, we conclude in general that what is needed are new business models, better training in IP management, more transparent communication, and a new group of "trust builders" to better facilitate this training and communication.

This report stems from a seven year study carried out by the International Expert Group on Biotechnology, Innovation and Intellectual Property, in conjunction with hundreds of people around the globe working in the areas of biotechnology and IP from government, industry, NGOs, indigenous communities and universities. This group recognized that the era of Old IP was beginning to decline and would soon need to be replaced. It recognized a critical need to direct the change toward New IP in order to ensure the appropriate development, production and distribution of medicines, foods and industrial processes (such as the production of clean fuels). The team, which included international experts in law, management, economics, ethics, philosophy of science, political science, medicine, and biology, convinced the Canadian government[3] of the importance of this work not only for Canada but for the international community. With financial support from Canada, the team spent several years building the necessary tools and knowledge of how IP affects innovation of biotechnology so that now, as we near the end of Old IP, governments, industry and NGOs can develop better policies to increase both the amount of and access to innovation. This report represents the core findings and recommendations of the International Expert Group while other documents, referenced in the text contain the group's more detailed and technical findings.

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[1] Ove Granstrand, "Innovation and Intellectual Property Rights" in *The Oxford Handbook on Innovation,* Jan Fagerberg, David C. Mowery and Richard R. Nelson, eds. (Oxford University Press: Oxford, 2005) 266 at 278.

[2] Marc-André Gagnon, The Nature of Capital in the Knowledge-Based Economy; The Case of the Global Pharmaceutical Industry, Unpublished Doctoral Dissertation in Political Science, York University, 2008.

[3] Through the Social Sciences and Humanities Research Council (Richard Gold, McGill University, Principal Investigator) and the Canadian Institutes of Health Research (Richard Gold, McGill University, Principal Investigator). Additional funding was provided by Genome Canada (grants to David Castle, University of Ottawa, Principal Investigator and to Edna Einsiendel, Principal Investigator) and the Stem Cell Network (grants to each of Timothy Caulfield, Principal Investigator and to Tania Bubela, Principal Investigator) and Genome Alberta (Edna Einsiendel).

INNOVATION SYSTEMS AND IP

Innovation Systems

Unlike much of new technologies, from the iPhone to the BlackBerry, which are fun or useful, biotechnology touches on three essential areas of life: health, food, and energy. If appropriately developed and used, biotechnology can lead to improved health and economic development, more nutritious, environmentally-friendly and sustainable sources of food, cleaner sources of energy and better tools to clean up the environment. If inappropriately developed or used, biotechnology can potentially lead to increased economic and social disparities, greater environmental degradation, biological weapons or health crises. Which outcome will come true? This depends significantly on the social and legal context in which scientists undertake research and the way that researchers, universities, industry, and governments put new research results into practice.

Given these different potential outcomes, the role of the policy-maker is to shape the political and economic context in which biotechnology research, development and dissemination of products and services occurs. While intellectual property rights provide some of this context, they provide only a small part. What is crucial is that the entire set of actors, rules, incentives and processes that lead and direct innovation combine to support the type of results that we want rather than those that we do not want. This entire context constitutes the 'innovation system'. Described most simply and elegantly by the person who coined the term, an *Innovation System* is "the network of institutions in the public and private sectors whose activities and interactions initiate, import, modify and diffuse new technologies."[4]

Innovation systems exist locally (metropolitan areas such as the Silicon Valley in California or Hyderabad, India), nationally, and internationally. In the 1990s, most people focused their attention on innovation systems at the national level. With globalization, policy-makers have increasingly concentrated on international innovation networks. These international networks do not supplant those at the national or local level but add a new level of trade and ways of innovating. With increased use of information and communication technologies, networks of researchers from the public and private sector that span the globe can work cooperatively in advancing biotechnological innovation.

Innovation does not, however, occur uniformly around the world. There are valleys and peaks of innovative activity distributed across continents and time, among fields of technology and industry and among high- and low-income countries. Nations and regions neither succeed at innovation in the same way nor for the same reason. Successful innovation over time and across industries depends on a series of explicit policy and strategic business choices and sometimes even good fortune so that the ingredients for successful innovation – skilled individuals, resources and financing – come together.

Many actors are involved in innovation systems. The knowledge underlying innovation occurs not only through the efforts of those who invent, but those who use or improve on existing innovation. While companies spend millions on researching and developing new products and services, many of the best ideas come from the people who use the technology. According to scholar Eric von Hippel, 3M made eight times more money off products inspired by its clients than those created by its own research and development department.[5] Developing-world companies often find better formulations of medicines originally developed by large international pharmaceutical enterprises, such as when India's Ranbaxy Laboratories Limited made a one-a-day reformulation of Bayer's drug, Cyprofloxacin.[6]

The improvements brought by one actor become, in turn, the fodder for another's further innovation. Innovation systems are thus more circular and collaborative than linear and individualist; there is no one 'beginning' and 'end' to innovation and no person who invents is in isolation. As innovation begets innovation, the policy-maker and business person must pay attention to the dynamics between actors and must, specifically, ensure that innovation does not get blocked at any point.

While there is much to be learned about the right combination of policies to foster innovation, both within government and industry, we do know that innovation is a social phenomenon that depends on a diverse group of actors working in harmony. Following on John Donne's famous meditation that

no person is an island, one commentator recently noted, "A central finding in the innovation literature is that a firm does not innovate in isolation, but depends on extensive interaction with its environment."[7] To obtain the desired social, environmental and economic benefits of innovation, policy-makers need to examine and understand the complex environment in which people innovate, share their knowledge and use the innovations made by others.

Intellectual Property

A study of innovation systems turns attention to large-scale interaction of people and institutions. For individuals working within those systems, however, what matters is whether they can use or prevent others from using knowledge or a particular technology. This is the domain of IP. Depending on how it is exercised, IP can either enhance or decrease the functioning of innovation systems.[8] If the person holding the IP chooses to use it to increase partnerships and cooperation, to make new goods more easily accessible and transmit his or her knowledge to others in the network, then more innovation is likely, assuming that the people, skills and finance are otherwise available. As the OECD noted: "Research thrives on collaboration and getting the most out of the genetics revolution will rely increasingly on efficient and effective exchange between those researching and developing new innovations – as well as with those that would use these innovations." Therefore, hoarding inventions or works may lead to some short term gain for the IP holder, but in the longer term is likely to decrease the ability of the innovation system to produce new goods and services.[9] For example, the patents granted to each of James Watt over the steam engine, Thomas Edison with respect to the incandescent light bulb and the Wright brothers over the airplane, set back research in their respective fields for years.

Despite the emphasis that Old IP places on it, IP is not the principal force behind innovation. In retrospect, this appears obvious when we recognize not only the different types of actors – industry, universities, communities, technology users and individuals – that innovate, but the increasing links between these actors across frontiers, time zones and levels of economic wealth. The recognition that innovation is a social, collaborative phenomenon changes the way that policy-makers, researchers, industry and technology consumers ought to view and appreciate IP: as something to be shared and built upon rather than as something to accumulate for its own sake. In the era of New IP, the focus turns away from amassing IP and toward managing it in such a way as to enhance the functioning of innovation systems.

Findings

During the last two decades, IP systems have not spurred enough innovation, and have, at times, hampered access to new goods and services by those who need it most. Policy-makers and private sector leaders must refurbish the IP system so that it encourages the flow of innovation from one project, and one person, to another.

Innovation occurs by building on the knowledge of others and thus requires sharing and collaboration.

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[4] Christopher Freeman, *Technology and Economic Performance: Lessons from Japan*, (London: Pinter, 1987).

[5] Eric von Hippel, *Democratizing Innovation* (Cambridge, Mass: MIT Press, 2005) at 15.

[6] Kalpana Chaturvedi & Joanna Chataway, "Strategic integration of knowledge in Indian pharmaceutical firms: creating competencies for innovation" (2006) 1 *International Journal of Business Innovation and Research*.

[7] Jan Fagerberg, "Innovation – A Guide to the Literature" in *The Oxford Handbook on Innovation,* Jan Fagerberg, David C. Mowery and Richard R. Nelson, eds. (Oxford University Press: Oxford, 2005) 1 at 20.

[8] Pamela J. Smith, "How do foreign patent rights affect U.S. exports, affiliate sales, and licenses?" in *The WTO, intellectual property and the knowledge economy*, Keith E. Maskus ed. (Northampton MA: Edward Elgar Publishing, Inc., 2004) 515; Pamela J. Smith, "Patent rights and trade: Analysis of biological products, medicinals and botanicals, and pharmaceuticals" 84 *American Journal of Agricultural Economics* 495; Pamela J. Smith *et al.*, "How do copyrights affect economic development and international trade?" (2008) Manuscript, Department of Applied Economics, University of Minnesota.

[9] OECD, *Guidelines for the Licensing of Genetic Inventions* (OECD: Paris, 2006) at 4-5, available online at: http://www.oecd.org/dataoecd/39/38/36198812.pdf.

THE PROBLEM OF OLD IP

The upcoming New IP era will build on what we learned from its predecessor. By the early 1990s, it was clear that the majority of industrialized country corporate assets were no longer tangible such as factories, land and inventory, but intangible such as reputation, customer lists, credit and institutional knowledge. This was particularly true in high-technology companies such as the computer industry, and biomedical companies. Knowledge in these industries is hard to contain. Unlike the physical things that we make using our knowledge – a new hybrid variety of wheat, a plate of pasta, or the prize for winning a marathon – knowledge is elusive: it is hard to pin down, hard to trade, hard to control and hard to value. As uncertainty in business means higher risk, those industries that depended most on knowledge wanted to pin it down as best they could. Their reaction was, to protect themselves by building more and higher walls around knowledge. This time – in the 1980s and 1990s – the walls were made of laws rather than of brick or stone.

The Old IP era grew out of this reliance on legal rather than physical power. IP became the mechanism of choice to maintain control over the elusive intangible assets that lay at the heart of most companies and, hence, most industrialized economies. Through IP, companies could control who used inventions when and in what combinations.[10] This control gave assurance to investors in these companies that the companies could protect themselves from competitors. This was, however, only part of the story. As a result of increased globalization, the control over intangible assets needed was not only local or national, but in any market around the globe in which one hoped to eventually compete. Thus, some IP at home was good, but more was better at home and around the world. This has been the logic of Old IP.

One can date and locate the start of the Old IP era in biotechnology as 1980 in the United States. It began with two developments: a critical decision by the Supreme Court of the United States that genetically-modified bacteria could be patented[11] and the decision by the US Congress to pass a statute that gave universities the mandate to patent and commercialise publicly-funded scientific research.[12] Soon, patents were extended to software programs and entire animals and plants. Biotechnology and information technology companies sprang into existence. Other countries, such as Japan and Europe, wishing to benefit from the biotechnology and information technology craze, brought their IP laws into conformity with those of the US.[13] The US went even further, consolidating its judicial structure to allow a single, more consistent (and more patent-friendly) court to rule on all IP appeals – the United States Court of Appeals for the Federal Circuit.

By the late 1980s, enthusiasm over IP reached into Canada. Canada abandoned its system of generic pharmaceuticals on which the country depended to keep prices down. It did this in return for the promise – which was not fully delivered – that the major international pharmaceutical companies would invest more in research and development in Canada. This opened the door to enshrining IP rights first in the Free Trade Agreement between Canada and the US and then through the North American Free Trade Agreement between Canada, the US and Mexico. By 1994, IP rules – alone out of all legal rules governing private transactions between people and companies – become a truly international affair, when they were brought into the World Trade Organization Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPs). That agreement required countries to meet a set of minimum standards – open to interpretation yet important – over whether and how they legislate intellectual property.[14]

The Old IP era reached its pinnacle in 1998 when 39 pharmaceutical manufacturers sued the government of South Africa over its rules that permitted the importation of drugs purchased legitimately elsewhere and the manufacturing of drugs without the permission of patent holders in order to deal with the country's ever growing HIV/AIDS crisis. While going beyond what TRIPs stated, these pharmaceutical companies and their supporters, including the US government, drew on the increasing role and protection of IP to claim that South Africa had to stop these practices. They claimed that IP should be permitted to do its work by stimulating the creation of new drugs that would be needed to fight AIDS and other diseases in the future.

In short, Old IP understood patents, copyrights and trademarks to be simply mechanisms that permitted a company, having invested in research and development, to recoup its costs and make a profit before others are allowed to copy its idea. This understanding has several flaws, however.[15]

First, it fails to recognize critical differences between traditional tangible assets and knowledge.[16] A banana, house, or car is still valuable even if you are a hermit because they are physical things you can use alone. Many IP rights are only valuable, however, because of our relationships with others. A trademark only works because customers recognize it. Even a patent, which controls who is able to use which pieces of practical knowledge, is not about medicines or plants, but about the knowledge of their existence and properties. Because the value of intangibles in biotechnology – whether it be a better way of identifying mutations in a gene or the composition of a new therapeutic drug – depends on our relationship with others, IP rights need to be flexible and to take into account how people in our community use and trade knowledge.

Second, it assumes that most companies actually use IP to protect their inventions from being copied. This turns out to be only part of the story. Companies increasingly obtain patent rights, for example, for strategic reasons. These include using patents offensively to block others from entering the market by creating mine fields around a company's technology. These patents are wasteful and often of lower quality.[17] Other strategic uses include using patents to trade with other companies, obtaining patents simply to show that one is serious to outside investors or acquiring patents to increase their reputation as innovators.[18] Together, these strategic uses of patents point to the evolving nature of IP rights and the need to adapt policy to changing business practices.

While some companies seek patents for reasons other than protecting investments, other organisations, particularly in low- and middle-income countries, do not even bother to patent their inventions because they cannot afford to defend them should a high-income country company infringe it. Research institutions and small enterprises in lower income countries feel that they cannot participate in the IP system since no potential infringer would believe they would be pursued. These institutions and enterprises are the have-nots of the IP system.

Third, Old IP presumes that if a company has a patent right it can actually use it to prevent others from copying the invention. The reality is, however, that there is a significant gap between the rights the law says one has and what one can actually do in the real world. In the first place, there is the obvious problem of being able to identify cases of copying. Even if one can do so, enforcing patent rights through the courts is expensive – between $1 and $3 million in the US.[19] Beyond this is simply the impracticality of suing customers or potential customers. This is especially true with respect to health care delivery, where most purchasers are either governments and governmental institutions or large private health care providers with monopolies over entire populations of patients.[20] Myriad Genetics learned this lesson to its detriment when it found that Canadian provincial governments refused to abide by Myriad's demands to stop providing patented genetic tests. Even where the patent holder is willing to go to court, there is a very high risk that the patent will be found invalid. Statistics from the US indicate that at least one-third of litigated patents are struck down, making going to court risky.[21]

Fourth, there are bigger impediments facing competitors than just patents. Companies report that being first to sell a product or service into a market is the most important factor in ensuring their continued success.[22] Income tax laws (e.g., differential tax rates for national and foreign corporations and income tax credits for research and development), the lack of clear regulatory frameworks (such as environmental rules that apply to ag-biotech products, rules over the introduction of new medicines, and so on),[23] and appreciation for the political and social context in one's countries of operation[24] are often more critical to success than are IP rights.

Fifth, and going to the heart of the argument in favour of patents, it is simply far from clear what effect patents actually have on levels of inventiveness and dissemination.[25] While surveys of senior managers in biotechnology and pharmaceutical companies continue to rank patents high in importance for the survival of their companies,[26] the analysis of data linking patents to increased innovation is ambiguous.[27] Public policy in the 1980s and 1990s was in large measure premised on the assumption that IP was critical, if not the most critical aspect of innovation. With mounting practical evidence that innovation has proceeded strongly in the information technology field in the absence of IP and the recognition that innovation happens through the interaction of developers and users, the presumption has weakened.

Sixth, in addition to ambiguous evidence about the role of IP in innovation systems there are large gaps in the data available concerning several aspects of IP. We lack such basic knowledge as the number and types of licences issued – one of the primary means through which IP is used, the amount of total investment by industry in university research, and the amounts of money available to support basic research, development

and commercialisation of products and services. Further, data is not collected in a systematic manner across countries and across disciplines. That is, there is a lack of standardization in the way data points are defined and data collected. Together, these failures make it impossible to reach any solid conclusion about the role of IP in biotechnology innovation.

Seventh, IP rights have spill-over effects outside of the creation and distribution of new technology. For example, public health care systems are premised on the ability of their administrators to decide which tests to introduce when and how into populations. It may be more efficient to introduce a test or procedure using processes or protocols suited to the entire suite of health services on offer rather than one dictated by the patent holder. By requiring health care systems to use a particular test in a particular way, the patent holder may be thwarting the ability of health care managers to most efficiently package health services for entire populations.

A related problem is that Old IP has pushed the boundaries of the types of knowledge that are now subject to patent, IP and similar rights. At the extreme, this has meant that, in the US, it is now possible to patent ways of creating tax shelters.[28] The European Union has protected databases of scientific information virtually in perpetuity,[29] a tack so far resisted by most other countries. Other examples are subtler. They include claims by some indigenous peoples and governments that indigenous knowledge – knowledge that spans the medicinal quality of plants, animal migration paths to how thick the ice usually is – should be subject to rights in the same way as are patented inventions.[30] This approach is in evolution, however, as the limits of Old IP are becoming clear.

The logic of expansion inherent in Old IP became its downfall. The beginning of the end of Old IP was the lawsuit over South African laws brought in to respond to the HIV/AIDS crisis. The assumption that IP increases biomedical innovation came face to face with the reality that the expansion of IP rights could prevent countries from meeting their critical health needs. The South African lawsuit mobilised, in a way that all previous discussions of IP had not, NGOs and the general public to question the value of ever-increasing IP rights. The debacle at the Seattle Ministerial meeting of the World Trade Organization, at which non-governmental actors effectively blocked not only the streets of Seattle but progress on the WTO negotiations, was soon followed by a softening of IP rights at the Doha WTO Ministerial meeting in 2001. At that meeting, the primacy of health over IP rights was, if not affirmed, certainly strongly suggested. The pharmaceutical industry also dropped its lawsuit against South Africa that year, having lost both the public's and the US's confidence. By the 2003 WTO Ministerial meeting in Cancun, countries had agreed on a procedure whereby one country could issue permission to a generic manufacturer to produce medicines for another country without the permission of the patent holder, a practice formerly prohibited under TRIPs.

Other controversies beyond medicines soon emerged. Several high profile disputes in the biomedical field around genetic testing[31] and concerns over an overabundance of patents blocking agricultural biotechnology particularly aimed at developing countries[32] sapped some of the enthusiasm for IP rights among geneticists and agricultural scientists.

National governments also began showing resistance to escalating levels of IP. The US Supreme Court greatly moderated patent rights in a series of decisions dealing with injunctions,[33] the test for awarding patents,[34] exceptions from patent rights for biomedical research[35] and, most recently, the limits on patent rights.[36] France and Germany failed to fully follow European Union rules on the patenting of human genes[37] while the Canadian Supreme Court ruled that plants, animals and seeds could not be patented.[38] Patent reform in the United States became an issue of choice in Washington, with the information technology industry – wanting to curtail the expansion of IP rights – locking horns with the pharmaceutical and biotechnology industries, the traditional proponents for Old IP.

A series of international organisations also joined the movement to moderate IP rights. The World Intellectual Property Organization, which had historically represented the interests of developed countries in expanding IP rights, adopted a Development Agenda that called for the tailoring of IP rights (and even their limitation) to suit the needs of developing countries. The World Health Organization adopted a work plan in 2008 on ensuring that IP rights do not get in the way of delivering needed medications to developing countries. The Organisation of Economic Development and Cooperation (OECD), representing developed countries, adopted the Noordwijk Access to Medicines Agenda in 2007 that pointed to the primacy of access to needed drugs around the world.

The end of the Old IP era came much closer in view in 2007 when CEOs and senior managers of pharmaceutical companies stated that their business model of establishing high IP barriers around blockbuster drugs no longer worked. Jean-François Dehecq, President of Sanofi Aventis stated in December 2007, for example, that the industry's business model "has been dead for two years."[39] Joe Feczko, Pfizer's Chief Medical Officer, stated that the new business models needed by industry involve greater partnership with the public sector.[40] Ernst & Young, in its 2008 Global Biotechnology Report, concluded that "pharma companies need to fundamentally reinvent their structures and incentives to improve the productivity of their innovation efforts."[41] With fewer and fewer new drugs being put on the world market and those that are introduced showing decreasing levels of innovation (that is, an increasing percentage of drugs that copy or represent marginal increases over previous drugs), the brand-name pharmaceutical companies, the biggest advocates of increasing IP rights, admitted that IP rights by themselves, would not deliver the new products needed by either developed or developing countries.

The end of the Old IP era will not signal, however, the end of the importance of IP to biotechnological innovation: it simply signals the beginning of a more mature era in which IP is managed to encourage the type of collaborations and relationships that had always been at the core of innovation.[42] According to Ernst & Young, "[t]he real opportunity for [biotechnology] firms is to work collaboratively with big pharma, using creative business models."[43] We explore this new era of New IP next. The question will then become whether we have the policies in place – within government, industry, universities and the general public – to encourage actors to collaborate to bring forward the new products and services needed to respond to the health, agricultural, environmental and industrial needs of countries around the globe.

Findings

1. We are at the beginning of the end of the Old IP era, not only in biotechnology, but in new technologies generally.

2. We are about to embark on a novel, more cooperative era of New IP, characterised by the primacy of democratic values of equity and fairness and the careful management of IP to support collaborations and knowledge sharing.

3. Government, industry, civil society and academia have, for too long, fallen into pre-defined patterns of thinking, backed by little concrete evidence concerning the importance and role of IP within innovation systems. In particular, these actors have placed too much emphasis on the rules of IP rather than on the way that universities, corporations and governments use knowledge protected by IP.

4. While there is a growing body of empirical evidence concerning the role of IP in innovation, it continues to suffer from large gaps, a lack of standardisation and the absence of a common vocabulary.

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[10] Fabricio X. Nunez, "Market structure, intellectual property, and innovation in biotechnology" (forthcoming 2008), Ph.D. dissertation, University of Minnesota.

[11] *Diamond* v. *Chakrabarty* (1980) 447 U.S. 303.

[12] Bayh-Dole Act, P.L. No. 96-517 (1980).

[13] E. Richard Gold & Alain Gallochat, "The European Biotech Directive: Past as Prologue" (2001) 7 European Law Jounrnal 331 at 332.

[14] Jerome H. Reichman, "Compliance with the TRIPS Agreement: Introduction to a Scholarly Debate" (1996) 29 Vanderbilt Journal of Transnational Law 363; Jerome H. Reichman, "The TRIPs Agreement Comes of Age: Conflict or Cooperation with the Developing Countries?" (2000) 32 Case Western Reserve Journal of International Law 441.

[15] Several critiques have been made of the current IP system. These include Peter Drahos & John Braithwaite, *Information Feudalism: Who owns the knowledge economy?* (London: Earthscan, 2002), Adam B. Jaffe & Josh Lerner, *Innovation and its discontents: how our broken patent system is endangering innovation and progress, and what to do about it* (Princeton: Princeton University Press, 2004) and James Bessen & Michael J. Meurer, *Patent Failure: How Judges, Bureaucrats, and Lawyers Put Innovators at Risk* (Princeton: Princeton University Press, 2008).

[16] E. Richard Gold *et al.* "The Unexamined Assumptions of Intellectual Property: Adopting an Evaluative Approach to Patenting Biotechnological Innovation" 18 Public Affairs Quarterly 299.

[17] Knut Blind, Katrin Cremers & Elisabeth Mueller, "The Influence of Strategic Patenting on Companies' Patent Portfolios" (2007) Centre for European Economic Research, Discuss Paper No. 07-013 available online at: ftp://ftp.zew.de/pub/zew-docs/dp/dp07013.pdf.

[18] Knut Blind, Katrin Cremers & Elisabeth Mueller, "The Influence of Strategic Patenting on Companies' Patent Portfolios" (2007) Centre for European Economic Research, Discuss Paper No. 07-013 available online at: ftp://ftp.zew.de/pub/zew-docs/dp/dp07013.pdf; Knut Blind, Jakob Edler, Rainer Frietsch, Ulrich Schmoch, "Motives to patent: Empirical evidence from Germany" (2006) 35 Research Policy 655; Anthony Arundel & P. Patel "Strategic patenting", Background report for the Trend Chart Policy Benchmarking Workshop *New Trends in IPR Policy*, Luxembourg, June 3-4, 2003.

[19] Fabricio X. Nunez, "Intellectual property litigation and mergers and acquisitions in biotechnology: Methodological overview" (2008) Manuscript, Department of Applied Economics, University of Minnesota; "Patent Litigation: Is it Worth the Expense? If Rights Are Uncertain, Pursuing Licensing with Alleged Infringer Might Be Best Option" (2006) 26 Genetic Engineering & Biotechnology News, available online at: http://www.genengnews.com/articles/chitem.aspx?aid=1454 (estimating costs at between $1 and $3 million); John R.S. Orange, "Costs – an Issue for Whom" paper presented at the World Intellectual Property Organization Conference on the International Patent System March 25 - 27, 2002 available on-line at: http://www.invention-ifia.ch/Costs_orange.pdf (estimating a cost of between $2 and $4 million); Philip Brook's Patent Infringement Updates, "Costs of Patent Infringement Litigation" July 1, 2008, available online at: http://www.infringementupdates.com/2008/07/costs-of-patent-infringement-litigation.html (estimating costs at $1.3 million).

[20] E. Richard Gold & Julia Carbone, "Myriad Genetics: In the Eye of the Policy Storm" (2008) available at www.theinnovationpartnership.org.

[21] Kimberly A. Moore, "Judges, Juries, and Patent Cases: An Empirical Peek inside the Black Box" (2000) 99 Michigan Law Review 365 at 390 (finding that patents were held invalid in 33% of all decisions, whether before a jury or a judge); John R. Allison & Mark A. Lemley, "Empirical Evidence on the Validity of Litigated Patents" (1998) 26 AIPLA Q.J. 185 at 205 (finding that 46% of patents litigated all the way to a written judgment were held invalid in the US).

[22] Knut Blind, Jakob Edler, Rainer Frietsch, Ulrich Schmoch, "Motives to patent: Empirical evidence from Germany" (2006) 35 Research Policy 655 at 661.

[23] David Castle & J. Dalgleish, "Cultivating fertile ground for plant-derived vaccines" (2004) 23 Vaccine 1881; David Castle, Kira Kumagai, L. Martin Cloutier & E. Richard Gold, "A model of regulatory burden in technology diffusion: the case of plant-derived vaccines" (2008) Proceedings of the Portland International Center for the Management of Engineering and Technology; David Castle et al., *Plant Derived Vaccines: Innovations and Regulatory Burdens* (New Jersey: John Wiley and Sons, forthcoming under contract, 2009).

[24] Gold & Carbone, *supra* note 20.

[25] Bronwyn H. Hall, "Patents and patent policy" (2007) 23 Oxford Review of Economic Policy 568; Matthew Herder & E. Richard Gold, "Intellectual Property Issues in Biotechnology: Health and Industry" a report prepared by The Innovation Partnership for the OECD International Futures Project on 'The Bioeconomy to 2030: Designing a Policy Agenda' (2008) available on-line at: http://www.oecd.org/dataoecd/16/9/40181372.pdf.

[26] Knut Blind, Jakob Edler, Rainer Frietsch, Ulrich Schmoch, "Motives to patent: Empirical evidence from Germany" (2006) 35 Research Policy 655 at 661.

[27] Gold et al, *supra* note 16.

[28] Brant Hellwig, "Questioning the Wisdom of Patent Protection for Tax Planning" (2007) 26 Virginia Tax Review 1005.

[29] European Community, Directive of the European Parliament and of the Council on the legal protection of databases, 96/9, OJ L 77. While protection technically lasts only 15 years, it is renewed any time a substantial change is made to the database. Given that scientists continually, however, add information to the database, this effectively means that there is perpetual protection over the database.

[30] Tania Bubela et al., *Respecting, Promoting, and Protecting Traditional Knowledge: A Comparative Case Study of Brazil, Kenya, and Northern Canada* (2008) available online at: www.theinnovationparternship.org.

[31] See Gold & Carbone, *supra* note 20.

[32] Michel Trommetter, "Intellectual Property Rights in Agricultural and Agro-food Biotechnologies to 2030" a report prepared by The Innovation Partnership for the OECD International Futures Project on 'The Bioeconomy to 2030: Designing a Policy Agenda' (2008) available on-line at: http://www.oecd.org/dataoecd/11/56/40926131.pdf.

[33] *eBay Inc* v. *MercExchange, L.L.C.* (2006) 547 U.S. 388.

[34] *KSR* v. *Teleflex* (2007) 550 U.S. ____, 127 S. Ct. 1727.

[35] *Merck KGaA* v. Integra Lifesciences I, Ltd., et al., (2005) 545 U.S. 193.

[36] *Quanta Computer, Inc. et al.* v. *LG Electronics, Inc.* (2008) 553 U. S. ____.

[37] See EC, Directive of the European Parliament and of the Council on the legal protection of biotechnological inventions, 98/44, OJ L 213.

[38] *Harvard College* v. *Canada (Commissioner of Patents)*, [2002] 4 S.C.R. 45. See also Canadian Biotechnology Advisory Committee, *Human Genetic Materials, Intellectual Property and the Health Sector* (Ottawa : CBAC, 2006) based, in part, on Timothy Caulfield, Abdallah S. Daar, Hamet P, Kroeger A, Ling V, McPherson A, Morrow J, Slater B, Closson T. *Human Genetic Materials: Making Canada's Intellectual Property Regime Work for the Health of Canadians* (Ottawa: CBAC, 2005).

[39] Yves Mamou, « Le lancement de nouveaux médicaments est de plus en plus coûteux et rapporte de moins en moins: Les laboratoires sont contraints de révolutionner leur recherche » *Le Monde*, January 3, 2008, p. 10.

[40] Joseph Feczko, presentation at the Organisation for Economic Co-operation and Development High-Level Forum – Medicines for Neglected and Emerging Infectious Diseases: Policy Coherence to Enhance their Availability, Noordwijk-ann-Zee, The Netherlands, June 21, 2007.

[41] Ernst & Young, "Record venture capital and heated deal environment propel global biotechnology industry forward in 2007", Press Release, May 20, 2008 available online at: http://www.ey.com/global/content.nsf/International/Media_-_Press_Release_-_Beyond_Borders-_Global_Biotechnology_Report_2008.

[42] Fabricio X. Nunez, "Do mergers and acquisitions deter innovation?: The case of biotechnology" (2008) Manuscript, Department of Applied Economics, University of Minnesota; Fabricio X. Nunez, "Intellectual property, knowledge capital, and mergers and acquisitions in biotechnology" (2008) Manuscript, Department of Applied Economics, University of Minnesota; and Fabricio X. Nunez, "Mergers and acquisitions and innovation in biotechnology: Methodological overview" (2008) Manuscript, Department of Applied Economics, University of Minnesota.

[43] Ernst & Young, *Beyond Borders: Global biotechnology report 2008* (London: EYGM Limited, 2008).

UNDERSTANDING IP SYSTEMS

Once we understand that IP affects relationships between people acting within an innovation system, we can examine more carefully how it does so. Certainly the legal rules surrounding patents and copyrights help to define the relationships between actors. Other legal rules (such as those dealing with anti-trust or competition law, regulating companies and so on) amplify these relationships by expanding or curtailing the scope of IP laws (consider, for example, the effect of anti-trust law on the exercise of a patent right).

Together, legal rules constitute a first component of an analysis of how IP acts, but they are not alone. Not only do people frequently ignore what IP law says – think of music downloading, which, despite not being permitted in most countries without a licence, is commonplace – but the entire set of rules about IP is premised on the fact that people will do so. A world in which all IP is always observed would soon be barren of creativity. This is not the world in which we live. Not only do we accept widespread violations of the letter of the law, we actually celebrate it. A study of US academic scientists demonstrated that, in conducting their research, they routinely ignored patent rights.[44] Far from being decried, this has been taken as evidence that the IP system works and does not limit creativity. In fact, companies often want academics to conduct research on their inventions – even without consent – since the academics may find something that increases the value of their patents.[45]

What this points to is that IP law should only be the beginning, not the end, of any analysis of how IP affects actors working within an innovation system. As discussed above, how actors behave in the face of IP rights is perhaps more critical to what is innovated and used than the law itself. Beyond simply ignoring the law, actors also manipulate it in various ways. We have previously seen that companies frequently obtain patents not to protect their inventions, but in order to trade or to set IP traps for potential competitors. Actors can, however, also act more constructively. They can, for example, allow others to use their inventions through a contract or by working on a collaborative research project.

Patents also affect the behaviour of competitors or users. Competitors may invest in technologies to circumvent a patented invention or hire lawyers to determine whether putting a product on the market will infringe another's patent. Users may refrain from sharing their adaptations of an invention for fear of attracting the attention of the patent holder. How people behave – in other words, their practices – and the effect of practices on innovation thus constitutes a second important aspect of how IP affects innovation.

There is a third component of the relationship between IP and innovation: the public and private institutions that manage, support, award, review and hold IP. These include, on the public side, the patent office, courts and other tribunals but also universities, research institutes, government funding agencies, organisations of university technology transfer offices (such as AUTM in the US or ACCT in Canada), government departments and international governmental organisations such as the World Intellectual Property Organization. Private institutions comprise everything from private corporations, to private think tanks and industry groups such as BIO (advocating on behalf of many biotechnology companies), the Licensing Executives Society (representing lawyers and other professionals involved in the licensing of technology) and PhARMA (an advocacy group representing brand-name pharmaceutical and heath biotechnology companies). Collectively, these institutions play a critical role not only in shaping the law but in defining the behaviours of actors in respect of patents and other IP rights.

Thinking about IP as a system of three domains – laws, practices and institutions – provides a comprehensive way to examine how IP affects knowledge production, sharing and use within biotechnology innovation systems.[46] It points to ways in which laws, practices and institutions confirm one another, such as when patent offices do a good job of applying the legal criteria of what constitutes an invention. It also shows how these laws, practices and institutions can complement one another, for example, when broad infringement by researchers is tolerated by patent holders in order to offset what would otherwise be a harsh rule. Finally, these three components can contradict one another, as when the high cost of litigation undermines the ability of a user to invalidate a patent that should never have been granted in the first place. Such an approach also provides the opportunity to examine different paths to reach the same goal by differentially modifying laws, practices or institutions. For example,

one can reduce the number of poor patents by altering legal rules (for example, the US legal rules with respect to patent prosecution estoppel), eliminating quotas on patent grants at patent offices or by establishing a less expensive means through which to challenge a patent held by another.

The move from Old IP to New IP involves more than letting go of the notion that the only effect of patents on innovation is to protect inventors against copying. It requires a re-examination of the ways that laws, practices and institutions interact to help ensure that biotechnology lives up to its potential. For example, both Sanofi and GlaxoSmithKline, large pharmaceutical companies, have entered into partnerships with the Drugs for Neglected Diseases initiative (DNDi). DNDi is a non-profit and independent organisation working on research and development of medicines for developing country health needs, and their work will be to develop medicines against targeted diseases.[47] UNITAID, an international agency that funds the purchase of medicines for HIV/AIDS, malaria, and tuberculosis, is building a patent pool that will bring together the pharmaceutical industry, generic producers in developing countries, national governments, and NGOs to facilitate the manufacture and distribution of new formulations of medicines for low- and middle-income countries.[48]

These are only the beginnings of the New IP era. To fully enter it, policy-makers, industry and university leaders, researchers, farmers and health care providers will need to expand their approach to IP systems and biotechnology innovation.

Findings

1. An analysis of IP laws alone gives a distorted understanding of how IP facilitates innovation and dissemination. Such an analysis must be complemented by an understanding of business and governmental practice as well as the public and private institutions and entities that create, grant and govern IP.

2. In the transition from Old IP to New IP, more attention must be paid to altering the behaviours of public and private actors in order to build collaborations and more broadly share knowledge.

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[44] John P. Walsh, Ashish Arora & Wesley M. Cohen, "Science and the Law: Working Through the Patent Problem" (2003) 299 *Science* 1021.

[45] See Gold & Carbone, *supra* note 20, for example. Of course, companies may be less happy with research that points out complications or negative side-effects of their products.

[46] Wendy Adams, "A transdisciplinary ontology of innovation governance" (2007) Artificial Intelligence and Law. DOI 10.1007/s10506-007-9060-2, available online at: http://www.springerlink.com/content/ck47615683 6j440h/?p=144cdf54346c4a9eb7b4f59aff60e920&pi=1.

[47] DNDi, Press release, March 6, 2008, available online at; ttp://www.dndi.org/cms/public_html/insidearticleListing.asp?CategoryId=166&SubCategoryId=167&ArticleId=463&TemplateId=1; DNDi, "DNDi-Sanofi Aventis sign agreement on AS/AQ" (2005) 10 *DNDi Newsletter*, available online at: http://www.dndi.org/newsletters/10/partnership.htm.

BUILDING A METHOD TO ANALYSE BIOTECHNOLOGY IP

While identifying the three domains of IP systems – laws, practices and institutions – may provide a more accurate understanding of the interaction between IP and innovation systems, it also greatly complicates policy-making. Those who make decisions within government, universities, industry and non-governmental organisations require tools and approaches that, while capturing the interactions between IP systems and innovation systems, also simplify them. This requires the analytical tools to do the work of figuring out those interactions while presenting them in a straightforward manner.

The challenge in building such tools is the vast amount of knowledge that needs to be considered in their construction. No one academic or real-world discipline possesses that knowledge alone. Lawyers may know how to interpret laws, but are not expert in economics or management. Managers and economists often have a fairly cursory understanding of IP law but understand why people do things. Philosophers of science bring an understanding of how science actually progresses while ethicists can lay out the critical and difficult decisions that need to be made. Political scientists can describe the processes of public decision-making but do not usually appreciate the various ways that companies may deploy IP rights. Scientists, doctors, and agricultural researchers can evaluate the science and predict where advances are likely to emerge. What is needed, in short, is a combination of these skills.

Recognizing the need to bring disciplines together is easy. Putting them together has proven extremely difficult. As noted by one writer, "One obstacle to improving our understanding is that innovation has been studied by different communities of researchers with different backgrounds, and the failure of these communities to communicate more effectively with one another has impeded progress in this field."[49] Bringing disciplines and actors from various walks of life together presents problems of conflicting and incomplete assumptions, different vocabularies and, finally, different ways of determining which relationships are worth examining. With the growing interest in IP systems, many fields have advanced knowledge significantly and there is an increasing interdisciplinary examination of the role of IP in innovation. Nevertheless, these efforts, while promising and useful, are incomplete.

The International Expert Group that assembled to develop the tools to help guide the movement from Old IP to New IP, recognized that if these tools are to assist policy-makers, they must build on a common understanding of IP and innovation systems. The International Expert Group thus went about constructing such an understanding based around the following three principles:

- They would construct a single framework for understanding the role of IP systems within biotechnological innovation systems that was common to all disciplines, industry, government, and the public and that could help answer a wide set of questions.

- The framework would integrate a large set of quantitative data (e.g., statistics, polls and so on) and qualitative data (such as interviews, case studies and expert opinion) to overcome the lack of empirical knowledge on IP systems.

- The framework would be validated through the participation of experts in academia, industry, government, the research community, and the public through peer-review workshops, interviews and a reading of scholarly and policy publications.

The construction of this framework followed five steps.

First, the International Expert Group identified problems in the current analysis of IP crossing their various fields (law, economics, management, philosophy, ethics, political science, natural sciences and medicine). These included a failure to appreciate the ambiguity of the role of IP in facilitating innovation, an overemphasis on patenting and licensing to the detriment of collaboration and informal ways of sharing knowledge, a lack of appreciation of the spill-over effects of patents on social and ethical concerns in both health and agricultural biotechnology and general confusion about what IP is and how it works.[50]

In the second step, the International Expert Group entered into a process of, in turn, identifying key elements of interaction between IP and biotechnological innovation, and ranking

them. Through this effort, they developed a series of seven overarching areas of inquiry, including the role of IP in economic growth, the differential impact of technologies on high- and low-income countries, and ethical issues relating to certain biotechnologies.[51]

The third step involved drawing on the seven areas of inquiry to identify relationships that link IP systems with innovation systems. In total, the International Expert Group identified approximately 120 different variables involved with those relationships. The group then mapped those relationships and variables out and drew links between them.[52]

Following on the creation of this map (called an influence diagram), the International Expert Group collected data from a variety of sources.[53] These included publicly available statistics on IP and innovation, case studies, qualitative evaluations of legislation and politics as well as expert opinion. Borrowing on the same idea of simulation games, such as the Sims and SimCity, the team entered the data and relationships into a computer to simulate how changes in the variables would alter the structure and output of biotechnology innovation systems.[54]

The last step involved creating a bridge between the map and simulation and the type of policy-choices that those in government, industry and the public can make with respect to IP systems and innovation. This bridge links, on the one hand, the factors identified in the map and, on the other, a list of policy options derived from a search of the academic, governmental and other literature. This bridge also identifies complementary policy paths to reach the same outcome and potentially unintended consequences of policy choices.[55]

This five-step approach to understanding IP and innovation systems provides a single, flexible, empirically-based method to examine not only the ways in which IP affects innovation, but how various choices are likely to help policy-makers, industry, NGOs and others achieve their innovation goals.

Findings

Intellectual property should be understood horizontally, that is, as cutting across academic disciplines, government and industry departments and fields.

Tools are needed in order to permit public and private sector decision-makers to better use IP systems.

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[48] UNITAID, Minutes to Eighth Board Meeting (Geneva, 2-3 July 2008), http://www.unitaid.eu/en/Eighth-Board-Meeting-Geneva-2-3-July-2008.html; Richard Gold, Tina Piper, Jean-Frédéric Morin, L. Karen Durell, Julia Carbone and Elisa Henry, *Preliminary Legal Review of Proposed Medicines Patent Pool* (Montreal: The Innovation Partnership, 2007) available online at: http://www.theinnovationpartnership.org/data/documents/00000003-1.pdf.

[49] Jan Fagerberg, "Innovation – A Guide to the Literature" in *The Oxford Handbook on Innovation,* Jan Fagerberg, David C. Mowery and Richard R. Nelson, eds. (Oxford University Press: Oxford, 2005) 1 at 21.

[50] Gold *et al*. *supra* note 16; E. Richard Gold, David Castle, L. Martin Cloutier, Aballah S. Daar & Pamela J. Smith, "Needed: models of biotechnology intellectual property" (2002) 20 *Trends in Biotechnology* 327.

[51] See Gold *et al, supra* note 16. The seven areas of inquiry are: distributive justice; innovation management; knowledge management; integrity of living things; sovereignty; economic efficiency; and risk management.

[52] See, in general, www.theinnovationpartnership.org for information about this mapping.

[53] See, in general, www.theinnovationpartnership.org for the data used.

[54] See, in general, Céline Bérard, L. Martin Cloutier, Luc Cassivi, "Design and Model Documentation of the Intellectual Property Modeling (IPMG) Dynamic Simulation Model: Documentation of Group Modeling Design and Research" (2008) Documentary Report, University of Québec at Montréal and Université Paris-Dauphine; Lorie Bouchard, Luc Cassivi, L. Martin Cloutier, "Intellectual Property Modeling in Health and Agricultural Biotechnology: Documentation of Variables, Measures, and Data" (2008) Documentary Report, University of Quebec at Montreal; Céline Bérard, "Dynamique des systèmes et modélisation en groupe : Analyse des cadres opératoires" (2007), présentation at the XVIème Conférence Internationale de Management Stratégique (AIMS), Montréal; L. Martin Cloutier, Céline Bérard & Luc Cassivi, "Diffusion of an innovative biotechnology : The case of plant-derived vaccines using system dynamics" (2005) International System Dynamics Conference, Boston (MA) (July 17-21); Niranjan R. Calindi & L. Martin Cloutier, "Strengthening Intellectual Property rights in Biotechnology Innovation: Learning from a System Dynamics Synthesis" (2006) International System Dynamics Conference, Nijmegen, The Netherlands; Céline Bérard & L. Martin Cloutier, "Decision-making's double complexity in intellectual property Management: Group Model Building using System Dynamics" (in preparation for the European Journal of Operational Research); L. Martin Cloutier, Céline Bérard & Luc Cassivi, "Diffusion of an innovative biotechnology: The case of plant-derived vaccines using system dynamics" (2005), presentation at the International System Dynamics Conference, Boston.

[55] Adams, *supra* note 46.

RECOMMENDATIONS FOR MOVING TOWARD NEW IP

Drawing on the framework it developed, the International Expert Group mapped out how public and private sector decision-makers can proactively plan for the approaching era of New IP. In doing so, they recognized the importance of taking a holistic approach to the role of IP within innovation systems. That is, rather than analyse the small sub-components of the IP system in isolation, the international experts adopted the standpoint of an 'intellectual architect', a person who sees not only a country's "innovations, but also the foundations that ensure their free flow, such as licensing arrangements, funding mechanisms like government grants and tax rules, technology clustering, universities, immigration rules, and training of technology-related business managers."[56]

The International Expert Group concluded that an intellectual architect would examine biotechnology innovation and IP using six themes as follows:

- Trust
- Communications
- New Models of Collaboration and Dissemination
- Scientific Infrastructure
- Cross-Cutting Thinking
- Data and Metrics

This report deals with each in turn.

The Importance of Trust

One of the most glaring failures of Old IP is its continuing outcome of undermining trust. The mentality of Old IP – that IP is to be held tightly and not shared – has led to fear of it not being respected and to distrust of those who hold it. The research carried out by the International Expert Group found that a lack of trust lay at the bottom of virtually all major controversies surrounding biotechnological innovation. Examples include the following:

Brand-name pharmaceutical companies and NGOs involved in delivering health services to low- and medium-income countries distrust one another so much that they avoid becoming involved in otherwise worthwhile projects that would require collaboration.[57]

Companies with new biotechnology products distrust the decisions that public-health administrators make on how to introduce, monitor, and pay for new health services while the public officials distrust the motives of those companies.[58]

Indigenous communities distrust their own governments' intentions when it comes to protecting their traditional knowledge, fearing that the central government will take away their rights and culture.[59]

Staff members of the World Intellectual Property Organization so distrusted their Director General that he was forced to resign.[60]

Health, trade and industry bureaucrats distrust one another on IP issues. For example, high-income countries, such as the US, distrust that World Health Organization to play a key role in ensuring that IP increases, rather than decreases, health innovation and access.[61]

Low-income countries fear that high-income countries push for an expansion of IP rights in order to have the poor subsidize the rich while high-income countries claim that low- and medium-income countries turn a blind eye to the widespread piracy of their companies' IP.[62]

Trust is essential to meeting the challenge of New IP. Innovation is furthered in the long run by sharing knowledge, not by hoarding it. Increasing attention to private-public partnerships (PPPs) – in which government, private foundations, industry and research institutions work collaboratively to develop new products or services – can only function if there is trust between the partners. For example, Sanofi's drive toward partnerships, in which IP is shared and not taken over by the company, requires trust. If UNITAID, an international governmental organisation established to provide medicines to the poor, is to succeed in encouraging industry to participate in a novel approach to produce medicines targeted to the needs of the poor through a patent pool (see Box A), it will need the trust of both industry and NGOs delivering health services. In the longer term, building the

research networks that will result in the creation, sharing, improvement and combination of knowledge will happen only if actors trust one another.

BOX A

In order to supply medications to fight HIV/AIDS, malaria and tuberculosis in low- and medium-income countries, France decided to create a fund out of an airplane ticket tax. In 2006, France, together with other countries such as Brazil, the UK, philanthropic foundations and NGOs, created UNITAID, an international governmental organisation housed by the World Health Organization. While UNITAID's principal function is to assist organisations on the ground to purchase medications, it also wanted to ensure that the medicines needed were available and reasonably priced. It therefore began a pilot project to build a patent pool around fixed-dose combinations and paediatric doses of anti-AIDS drugs. With the expert assistance of The Innovation Partnership and the participation of NGOs, UNITAID will sponsor a new non-profit agency to license the right to manufacture these drugs from brand-name pharmaceutical companies and provide those licenses to manufacturers and distributors in low- and medium-income countries. Through this process, drugs in a form not otherwise available will be delivered to those most in need.

A lack of trust is particularly evident in the relationship between indigenous peoples and their governments. Governments and researchers have concentrated much more on using the natural resources and, on some occasions, the knowledge of indigenous peoples than on respecting their autonomy. In order to build trust, governments will need to support the building of autonomous indigenous institutions with the capacity to sustain and develop indigenous knowledge and to apply their laws and practices, particularly when interacting with non-indigenous groups, including researchers, corporations and governments. They will also need to develop a legal framework in which to protect the autonomy and land rights of indigenous people.[63] Similarly, low- and middle-income countries with high levels of genetic diversity, such as Brazil, Indonesia and Kenya, will need to balance economic development based on the use of natural resources (particularly when involving indigenous people) with the needs of communities. Local economic development and targeted research in those countries should aim to generate sufficient economic resources to lead to the conservation of their biological and cultural diversity.[64]

Innovation systems, as we have seen, involve a large and complex variety of actors in the private and public sectors. Trusted individuals and organisations that can bridge the views of the various actors are critical in order to fulfil the promises of New IP. So far, however, governments have failed to build this trust. Having bought into Old IP for too long, governments do not currently have the capacity to step back and facilitate relationship-building. The International Expert Group recommends that, at least until governments develop this capacity, they should do the following:

Recommendation 1: Governments, industry and NGOs should encourage the creation of independent trust builders – individuals or firms that are independent from the major stakeholders and who have knowledge in the field – to mediate disputes, encourage dialogue between actors and develop joint research initiatives. Each of the above actors will need to contribute financially and intellectually to the efforts of the trust builders. In particular, those actors should agree to submit disputes to the trust builder for mediation and should support the trust builder in organising workshops on key issues of joint interest.

Recommendation 2: Governments should support independent, non-governmental and non-industry organisations to engage indigenous communities at a grass-roots level in training related to a host of issues around access and benefit sharing agreements, contracting and intellectual property. This training should include ways through which these communities can protect indigenous knowledge and methods to share that knowledge while respecting the rights and autonomy of those peoples. Support can take the form of funding and access to documentation, but should not be tied to the manner in which the training is to be delivered or the substance of that training. Communities should be involved in both the delivery and substance of the training.

Communications

Communication is a critical ingredient to building trust. During the era of Old IP, industry and NGOs talked past one another, failing to understand the other's concerns.[65] Further, communication failures were a major cause for Myriad Genetics in developing a workable plan to introduce its breast cancer genetic test into Canada and much of Europe. Similarly, such failures have strained the

relationships between indigenous peoples, researchers, industry and the public.

We have been overrun by rhetoric. Each actor freely spouts its views in the hopes that others will become convinced, yet fails to listen to what others say. Dead-end outcomes result, such as Canada's access to medicines regime which was adopted knowing it would fail, [66] and it has.[67]

It is not only the principal actors involved in health innovation and health care delivery that are responsible for communication failures: the media must also share some of the blame. With some exceptions, the media has done a poor job of challenging the myths of Old IP, accepting as truth statements that are often supported by nothing more than rhetoric. These include the assertion that IP has been essential to the development of new drugs, that countries that take a different view of IP encourage 'piracy' or that, on the other extreme, patents are the primary reason why HIV/AIDS medications do not get to the poor. Further, the International Expert Group's research illustrates how the media's attention to controversies, such as that between Myriad Genetics and Canadian provinces, deepened the crisis rather than helped to resolve it through enhanced communication.[68]

Part of the problem underlying a failure of communication is a lack of understanding of what IP is and how it works. In the waning days of Old IP, it is clear that IP has never been about creating new inventions.[69] While this may come as a surprise to those who have been spoon-fed this assertion, the overwhelming weight of evidence suggests that IP is about how people transfer knowledge and not how they create it.[70] IP needs to be demystified and become the subject of democratic reflection and debate if governments, industry, researchers, and the public are to actively use it within a vibrant innovation system.

Several actors have a role to play in enhancing communication.[71] First, as the example of Myriad Genetics illustrates, the media can do a better job of enhancing understanding not only of science but of the relevance of science in meeting important social goals. One study found that out "of 500 US health news stories over 22 months, between 62%–77% of stories failed to adequately address costs, harms, benefits, the quality of the evidence, and the existence of other options when covering health care products and procedures."[72] Second, independent actors can help build understanding of IP and its significance to research and to product development among scientists, policy-makers, industry, and NGOs. Third, scientists themselves should make greater pains to communicate with the media, especially since surveys suggest that they find these encounters positive and that reporters usually present their work fairly.[73] Given this, the International Expert Group recommends as follows:

Recommendation 3: The media should consider covering issues of *science policy* – how innovation systems function and their effect on social and economic outcomes – more thoroughly to facilitate general knowledge of science and technology issues and, in particular, the governance of knowledge and innovation. Scientists should also be willing to engage the media in order to assist them in understanding not only the science but its implications.

Recommendation 4: Governments, industry, universities, and NGOs should engage the trust builders proposed in Recommendation 1 in developing workshops and training programmes through which stakeholders and the public can actively debate the role of biotechnology in health, agriculture and industry.

Innovative Models

"At this point," according to Ernst & Young, "neither biotech nor big pharma (nor, for that matter, big biotech) is getting it entirely right."[74] There is a once-in-a-generation opportunity to propel innovation into the New IP era. Each of industry, universities and governments have felt the bite of the failure of Old IP models to generate the products, services, reputation, and funding that they have been seeking. The pharmaceutical industry is producing fewer and fewer new products each year and those that it produces represent fewer real advances.[75] Universities find that the riches they were promised from protecting IP have not materialized. Instead, universities have, overall, lost money after over 20 years of commercialisation activities.[76] Governments hoping to spur economic growth and productivity increases, by relying significantly on increasing IP, wonder why they are not yet seeing the benefits.

With what is now known – thanks largely to the study of the failures of Old IP – industry, governments, and universities can develop new models of how to mobilize the innovation

system to produce better results. These models will stress sharing, not hoarding, and partnership, not barriers. Examples of what these models will look like already exist. These include the following efforts:

- A PPP to develop a new HIV vaccine through the International AIDS Vaccine Initiative (IAVI);[77]
- A PPP devoted more generally to vaccines through the GAVI Alliance;
- Partnerships between each of Sanofi and GSK with DNDi;
- A patent pool to be established by UNITAID for anti-retroviral drugs to combat HIV/AIDs;
- The Structural Genomics Consortium, a PPP aimed at discovering the structure of proteins and making these structures freely available to all (see BOX B);
- A university initiative to bring together all patents relating to agricultural biotechnology that may be of use in developing food for low- and middle-income countries (PIPRA);
- A fund set up by Italy, Canada, Norway, Russia and the United Kingdom that will pay for the delivery of a vaccine against pneumococcal virus;
- The Human Genome Project, an international collaboration of public research centres, funded by government agencies, that sequenced the entire human genome and placed that information in a free, publicly-available database;
- The Single Nucleotide Polymorphism (SNP) Consortium, an international collaboration of foundations, industry, and public research centres to create a free, public database of single mutations of interest in health research.

BOX B

The Structural Genomics Consortium (SGC) is a true public-private partnership with substantial ($20 million out of the $120 million total funding) investment from pharmaceutical companies with the remainder provided by governments and private foundations, in particular, the Knut and Alice Wallenberg Foundation, the Karolinksa Institutet and the Wellcome Trust. The SGC was able to attract industry investment by promising them, as well as all the public-sector participants, with the right to create a wish-list of proteins to investigate. These lists are kept private but are used to determine what work is done within the consortium. All protein structures actually investigated are, however, put into publicly accessible and free databases. So far, the SGC has released over 700 protein structures into the public domain. SGC launched a new effort during the summer of 2008. It recognized a need to identify and describe molecules to inhibit reactions in cells that could be used in industrial and academic biomedical research. Usually, only industry has access to these molecules or inhibitors. The SGC realized, however, that these inhibitors could be used to identify specific proteins that contribute to disease. The identification of these inhibitors would, in turn, encourage industry to invest in expensive, drug discovery programs. GlaxoSmithKline, the National Institutes of Health, and the University of Oxford launched a new program in which the partners will develop novel, selective, and freely available chemical inhibitors of human proteins in the area of epigenetics. What is particularly novel about this initiative is that the partners agreed that none of them would commercialise the inhibitors identified and would in fact, use patent rights to block others from doing so. Nevertheless, they will ensure that the compounds will be available for use by the scientific community.

Other models are in the works. The World Health Organization has agreed to examine alternative ways to finance the development of medicines for low- and middle-income countries. One such method is the creation of a prize system in which companies would receive compensation out of a general fund based on how much they increased the health of individuals around the world. Another is the Collaboration for AIDS Vaccine Discovery (CAVD), established with funding from the Bill & Melinda Gates Foundation, in which AIDS vaccine researchers agree to collaborate with one another, share research results and, in some cases, pool their intellectual property. Others involve adapting open-source licenses available on such software as Mozilla, Linux, and the Apache server to the needs of biotechnology.[78]

The examples of success are still too few and too far between. To move New IP toward reality, innovation is needed in business, not only in biotechnology. However, IP has hampered business innovation: it has been less expensive and more expedient so far for companies to invest in lobbying for increases in IP rights than to develop and implement new ways of doing business based on sharing, rather than on hoarding knowledge.

This pattern of lobbying over innovation has not been restricted to biotechnology. The music industry, for example,

fought the effects of the Internet by trying to build higher IP walls with greater penalties for music sharing rather than by constructing new business models that use the power of the Internet to disseminate music. Similarly, the film industry initially fought the introduction of videotape recorders – going as far as the Supreme Court of the United States to take these machines off the market[79] – until it realized that it makes more money from video and now from DVD rentals than it does from ticket sales at theatres.[80] The pharmaceutical industry continues to call for increased patent rights – for example, longer terms and automatic injunctions – despite the fact that the last time they did so (in Canada), the promised increased investment never fully materialized and has, in fact, sunk to old levels.[81]

The pharmaceutical industry has begun, however, to realize that its business models no longer serve themselves or the public. While some positive efforts have been made, this realization has yet, however, to fully translate into actual and significant changes in behaviour. Until the brand-name pharmaceutical industry and other actors figure out how to actually build sustainable models – for both industry and user communities – nothing will change.

Another problem of the era of Old IP is the presumption that only developed country actors are capable of developing the next generation of biotechnology products and services. With the advent of substantial and growing developing world biotechnology and pharmaceutical companies – Biocon and Serum Institute, to name just two – and non-profit pharmaceutical companies (such as the Institute for OneWorld Health), this presumption should no longer exist. The recent sale of a majority stake in India's Ranbaxy to the Japanese pharmaceutical firm, Daiichi Sankyo, illustrates the growing significance of developing country firms.[82]

While most research continues to require expensive labs that only high- and higher-middle-income countries can afford, the International Expert Group identified promising research in many low- and middle-income countries, including in South Africa (a fibre to treat AIDS-related diarrhea, paediatric diarrhea and irritable bowel syndrome), Indonesia (a leaf to treat Dengue fever) and Kenya (a mosquito repellent) that are ripe for development. Low- and middle-income country institutions and enterprises need assistance in both accessing money and in acquiring the skills necessary to mobilize IP more effectively. The International Expert Group therefore recommends as follows:

Recommendation 5: Leading private sector institutions in high-, middle- and low-income countries should establish an independent, non-profit *technology assessment* organisation to evaluate new biotechnology products and services. This organisation would assess technology proposed by start-up enterprises and universities in low- and middle-income countries and start-up enterprises formed by aboriginal communities with the view to providing them with increased visibility and credibility in attracting private sector financing.

Access to financing appears to be a declining problem in high-income countries as new sources of public and private funding become available. There still appears, however, in many of these countries, difficulty in matching those with money with those needing it. The difficulty often is the lack of networks through which those with money, particularly angel investors, are put in touch with those with good ideas. Beyond supporting those investors – through vehicles such as tax laws – building local communities of university managers, small companies and investors is useful to developing raw research into tangible products and services.[83]

The research of the International Expert Group also illustrates how the public sector has an important role in developing and distributing innovation to low- and medium-income countries. Through a new plant-based vaccine technology that the International Expert Group evaluated, the World Health Organization and donors can draw on cutting edge technology to develop vaccines for hepatitis and other diseases.[84] Public sector researchers developed the technology and have the interest and capacity to put it into practice. What is now required is the political will and business capacity to harness the benefits of this technology.

A prerequisite to creating new business models for biotechnology, bringing forth technology developed in low- and middle-income countries and developing and using promising technology by the public sector, is leadership in establishing clear goals for health, agricultural and industrial innovation. Governments and public sector institutions have, for the most part, failed to provide this leadership (for exceptions see Box C). Universities around the world have been joining the Old IP bandwagon by patenting more of their research and assigning or licensing it out to commercial partners without thinking through whether and how this contributes to the university's objectives of education, knowledge creation and public service, and developing countries. In fact, the vast majority of

universities have no clear policy on why they protect their research through IP and why they commercialise it.[85] A group of US-based universities began the process of addressing this lacuna by setting out, in March 2007, a set of nine points to address in licensing their IP.[86] These points include ensuring that licensing practices enhance research and that universities specifically give themselves the right and the responsibility to provide access to technology to meet the needs of low- and middle-income countries.[87]

Further, universities and public institutions measure the success of their efforts at disseminating research based largely on the number of patents held, the revenues they obtain from licensing technology to industry and the number of spin-off companies they helped create. These measures derive not from their importance but from their ease of calculation. They are easily manipulated – by obtaining several patents to cover the same innovative idea and by structuring licence agreements to pay high up-front fees – and say little about the social and economic effects of public investment in university research. Further, as indicated earlier in this report, universities and public institutions do poorly on such measures, as technology transfer activities cost more than they provide in revenues.

BOX C

The University of California, Berkeley, has been progressive in its licensing and patenting practices and in its relationships with the biotechnology industry.[89] Not only is UC Berkeley home to PIPRA, an initiative that is bringing together all public sector owned patents relating to agricultural biotechnology that may be of use in developing food for low- and middle-income countries, it also has developed access and benefit sharing agreements for collaborative research with indigenous peoples. For example, it entered into an agreement with the island of Samoa for the development of the new AIDS and cancer drug, prostatin, derived from native uses of the mamala tree. The agreement allows for benefit sharing with various villages in Samoa. The University has committed itself to "exert reasonable efforts in licensing such patents or copyrights for public benefit, keeping in mind UC Berkeley's and Samoa's mutual goals of providing low cost therapies for free, at cost, or with minimal profit in the developing world". The University has also been at the forefront of developing PPPs. For example, Artemisin, a traditional herbal remedy in Chinese medicine, is a proven treatment for malaria, particularly in combination with other drugs. A research team at the university developed a process to extract this compound, working with a small biotechnology company, Amyris Biotechnologies. Backed by a $42.6 million grant from the Bill & Melinda Gates Foundation, the Institute for OneWorld Health forged a non-profit partnership with UC Berkeley and Amyris Biotechnologies. Under the arrangement, Amyris committed to taking "no profit from the sales of this product to the developing world".

Following the lead of UC Berkeley, the University of British Columbia has been one of the only universities in the world to explicitly set out its goals and how it will measure success. It has adopted principles that include not only promoting teaching and learning, but ensuring global access to the results of its research. Success is to be measured not by the number of patents held, but by delivery of product to low- and middle-income countries at a reasonable cost. The British Columbia Cancer Agency, the province's public-sector agency involved with the treatment of and research on cancers in British Columbia, sees beyond the necessity to use patents. Rather, it uses its database of cancer-related information to build partnerships with public and private sector actors in order to expand the data and to identify potential treatments and diagnostics. Through these collaborations, the data is enhanced and made available to other researchers – instead of being sold off to only one company – that leads to promising treatments that partner companies can patent, further develop, and market.

The era of New IP requires that public institutions measure success of their use of IP not simply in terms of revenues but in the number of collaborations, partnerships, research platforms, students trained, and exchanges that result from IP. These indicators of success more closely match the public mission of universities and the reasons that governments fund research: to develop new knowledge and to harness the social and economic returns from that knowledge. More research will be needed to develop clear and uniform measures through the study of social networks, patterns of researcher collaboration (as indicated through joint publications, presentations and funding requests) and how ideas in science and technology move about between researchers, industry, and the public. The International Expert Group has been able to develop ways of

tracking knowledge production and dissemination that go far beyond counting patents and adding revenues.[88] These can serve as the basis of developing more accurate measures. The group therefore recommends the following:

Recommendation 6: Working together, governments, universities and industry should develop new measures of the success of technology transfer, and other means of development and social investment that better correspond to desired social and economic return. They should specifically abandon traditional measures such as the number of patents held and licensing revenues and replace them with indicators of a social return on investment.

The private sector has done no better in demonstrating leadership in the biotechnology sector. While many enterprises have established donation programs and other efforts at corporate social responsibility, few have engaged communities and countries in developing new platforms to spur innovation creation and management as has occurred in other sectors (see Box D). While welcome, the efforts to date have hardly put a dent into addressing the needs of the majority of the people on this planet. Until recently, brand-name pharmaceutical companies have even resisted attempts to contemplate alternative models. Even now, with the realization that their models do not work for themselves, let alone low- and middle-income country populations, the biotechnology and pharmaceutical industries have yet to actively engage governments, researchers and communities in developing collaborative and inclusive models of innovation, including through participation in the public product development initiatives.[90] To fill this gap, the International Expert Group recommends the following:

Recommendation 7: Industry and academics in business, law, economics and other disciplines should develop new and sustainable business models of developing, commercialising and disseminating biotechnology products and services that are attuned to local needs and conditions. Business schools should include low- and middle-income country conditions and business opportunities in their curriculum and should develop programmes through which their students can provide business planning assistance to low- and middle-income country entrepreneurs.

Recommendation 8: Funding agencies should target the development of novel and sustainable business models and their implementation. In particular, funding should be made available to support pilot projects on commercialising and other dissemination of low- and middle-income technologies. Governments should increase funding to these funding agencies, counting such investments as part of their aid development budgets so as to meet international targets on these budgets.

Recommendation 9: Governments with public health care systems, funding agencies and universities should develop a PPP to manage research and development of health data. Such a PPP would license out the use of data to private actors on condition that such actors collaborate with public sector actors and contribute new data to the PPP for further use.

BOX D

For over 100 years, the Tata Group, India's largest private sector industrial group, has been at the forefront of integrating social leadership with private enterprise. This includes targeting its products to the needs of the communities it serves, such as the $2,500 Nano car that is safe, affordable and with low carbon emissions (although not as low carbon as the bicycles it can be expected to replace), and providing community services as through the Tata Consultancy Services's computer-based literacy project in India. According to its policy on corporate sustainability, Tata Group companies are to "[c]reate sustainable livelihoods and build community through social outreach programs in Health, Education, Empowerment of Women & Youth, Employee Volunteering, that can be measured in terms of their having more lasting benefits, serving a larger national or regional purpose, and also making it more meaningful to all involved." To measure compliance with its goals, the Tata Group has developed and implemented an Index for Sustainable Human Development that it uses to assess each of its companies' performance in enhancing communities.[91]

Scientific Infrastructure

Innovation is global. Korea proved this not long ago and India[92] and China[93] have growing biotechnology sectors. Similarly, South Africa, Kenya, Brazil, Venezuela, Cuba, Indonesia, Rwanda, and Malaysia, are active and promising biotechnological innovations.[94] These may be less omnipresent, involve less high-technology (but not always)

and be funded with lower amounts of money. They have significant potential not only for health, agriculture, and industry, but also for economic and social development.

In order to facilitate greater levels of biotechnological innovation, countries must possess the basic capacity to conduct research and develop products. There are three components of this capacity related to generating knowledge and managing IP: 1) an environment in which to conduct science; 2) retaining and recruiting scientists; and 3) skill and experience in managing IP.

On the first point, a country needs appropriate laboratories and equipment, trained scientists and technicians, access to science journals and scientific conferences, research funding, and the ability to disseminate the results of research, whether through publication, licensing or collaborative activities. Cuba disseminates its research and the products it develops well. With relatively few resources, it has a well organised health and agriculture biotechnology industry, enters into partnerships with large international companies and takes care to protect and promote the country's name-brand products. An example of this is its development of a meningitis B vaccine.[95] It is now working with GSK to take this vaccine through clinical trials and to develop it for the international market.

On the other hand, many low- and middle-income countries lack critical components of a sustainable research environment. For example, most African countries lack sufficient access to high-speed Internet connections. With increasing pressure on high-income country scientists to publish in free on-line journals, the lack of Internet access in Africa puts some of the continent's scientists at a severe and increasing disadvantage.

Beyond physical infrastructure, low- and middle-income countries face a more serious impediment: A 'brain drain' of highly educated individuals who leave the country in favour of greater opportunities elsewhere, such as graduate programs in high-income country universities. These individuals soon become integrated into their new environments, both scientifically and personally, and thus establish themselves in their new countries. While those scientists may continue to conduct research in areas of interest to their country of origin, they do not pass on their training to others who must, in turn, leave their countries to obtain training. There are two ways to counter the effects of the brain drain and to start to reverse it.

First, a country can invest in creating environments that encourage doctoral students to study at home. Such investments include not only laboratories and equipment, but world-class training programs at home. A country can accomplish the latter, for example, by encouraging high-income country universities to require only short residency requirements at those universities so that doctoral candidates can return home to conduct their research. This not only lessens the cost of training – by reducing the time abroad – but maintains the student's links to his or her home country. The high-income university benefits by being able to attract students from a wider pool of candidates and by increasing its reputation around the world.

Second, a country's scientific diaspora – those living abroad – can assist it by training the next generation of scientists at home. A report to the African Union in 2007 concluded that there is a "wellspring of opportunity that diaspora communities present."[96] These communities can train students, agree to joint appointments at universities in their countries of origin, maintain dual citizenship and residence, participate in scientific review panels in their country of origin, create research partnerships between their former and new countries and so on. Rather than insist that scientists who have moved abroad return home permanently – which is, in most cases, unrealistic – the diaspora scientists can supplement and assist local scientists. The International Expert Group therefore recommends as follows:

Recommendation 10: Universities in high-income and in low- and middle-income countries should create educational opportunities at the doctoral and post-doctoral levels for scientists through which those scientists maintain links with their countries of origin and conduct research focused on the needs of those countries. Universities in high-income countries should encourage those of its professors from the diaspora to assist their countries of origin through supervision of students, joint research projects, conducting peer review and so on.

Beyond ensuring that it has the capacity to conduct scientific work, a country must also manage its biotechnological innovation system in order to benefit its economic, health, agricultural, and industrial needs. This means ensuring that

research results are used and disseminated in a way that responds to the country's priorities. IP is one means through which to do this, but only if it is managed with care. Knowing whether and what to protect through IP, what to leave in the public domain, how and to whom to license technology, how to build collaborations that leverage existing knowledge and how to build common research platforms requires skill, one that low- and middle-income countries lack to a greater extent than do high-income countries. Even in South Africa, which has placed considerable emphasis on IP and commercialisation, individuals trained in IP management, both in theory and in practice, are few and far between. Without this expertise, countries cannot hope to develop and implement models to manage the biotechnology they produce.

This problem is exacerbated because low- and middle-income countries have tended to rely on training provided by high-income countries or international organisations such as WIPO. These countries and organisations approach IP management from the perspective they know best: that of a high-income country. While these strategies may arguably be appropriate in the US, Europe, or Japan, they are unlikely – given different institutional structures, ways of doing business, levels of financing, reliability of the judicial system, and culture – to work in most low- and middle-income countries. These countries need strategies specifically adapted to their needs and environments rather than hand-me-downs from their richer colleagues (see Box E). Because of their reliance on high-income countries and international organisations, however, low- and middle-income countries often blindly implement strategies that simply do not work for them. To build better training programs, the International Expert Group recommends as follows:

BOX E

The Innovation Partnership, together with its partners the African Insect Science for Food and Health Institute, the University of Nairobi, the Kenya Intellectual Property Office and the Centre for Intellectual Property Policy at McGill University, jointly developed a training programme for 25 senior scientists from Eastern Africa in June-August 2007. Funded by the Foundation for Sustainable Enterprise and Development, the programme trained these scientists on IP and IP management based on a programme that took into account the particular interests and needs of the region. Training was provided to the extent possible by local experts, leaving behind a support network for participants. On returning to their home institutions, participants conducted an audit of those institutions' IP policies and practices. The scientists presented their audits and set out milestones for action. A follow-up training programme is contemplated at which participants will evaluate success in meeting those milestones.

Recommendation 11: Governments, industry and public institutions should sponsor capacity building programmes on technology transfer and IP management for low- and middle-income countries and for aboriginal communities in high-income countries. This training should be provided by independent organisations, such as described in Recommendations 1 and 2 working jointly with researchers and communities in those countries to address their specific institutional, social and economic needs.

Cross-Cutting Thinking

Much of the debate over biotechnology and commercialisation has focused on individual components of the IP and innovation systems but few have taken a more holistic and global approach. For example, while much ink has been spilled on the thorny issue of whether it is appropriate in the abstract to patent human genes or stem-cells derived from embryos, there is relatively little study of the practical effect of deciding one way or another on research and development. Consider the European debate over embryonic stem cell patents. While Europe has largely decided, for ethical reasons, to withhold patents over the cells, this seems to have little or no effect on the use of embryonic stem cells in research on the continent.[97] Conversely, in the US, where patents continue to be granted over stem cells, a federal ban on funding embryonic stem cell research has slowed research.

Similarly, the continuing debate over whether commercial enterprises should be permitted to patent and profit from government-supported research is often debated separately from discussions of how best to disseminate this research. Some consider it unfair that a private actor should be able to appropriate the benefits of something created through public funding. If, however, the models of dissemination developed through Recommendations 7, 8, and 9 require private participation, it may not only be fair but appropriate to accord some IP rights to private actors in order to facilitate that dissemination.

According to its research, the International Expert Group found that the question of *how* to manage IP rights has a greater impact on what is innovated and for whom than the question of *who* can patent what. After all, the very same patent right can be used either to exclude or to include researchers, firms, and patients in low- and middle-income countries. Given this, it is impossible to determine the implications of particular IP rules in the abstract. It is therefore critical that the questions we ask relating to IP be examined in the larger context of how innovation systems function and how people actually behave.

The International Expert Group examined biotechnology IP systems in this larger context. It asked, for example, how IP can be used to provide new products to address low- and middle-income health needs. As noted earlier, it examined how a promising new technology to produce vaccines in plants – at significantly lower cost and in a much more stable form – can be used to reduce the incidence of hepatitis B in India. The International Expert Group found that delays, costs and uncertainties associated with IP have the potential to be significant hurdles in deploying the technology, particularly when the technology is transferred from one country to another. Moreover, other factors, such as the lack of clear regulations in relation to the environmental and health aspects of the technology in India, can cause even more significant delays.[98] The International Expert Group concluded, therefore, that it is critical to examine IP systems within the larger context of innovation systems and also to pay attention to the general economic and social context in which innovation is developed and deployed. It therefore recommends as follows:

Recommendation 12: Public and private sector researchers should analyse questions of IP within the larger context of IP and innovation systems. To do so, they should use analytical tools that provide a broader, inter-disciplinary perspective on IP and innovation, whether those developed by the International Expert Group or their own.

Recommendation 13: Governments need to pay as much attention to the environment in which innovation takes place – including regulation of the environmental and health effects of biotechnology, the independence of the judicial system and marketplace regulation – as they do to IP. IP only functions where there is a stable and functioning marketplace that addresses the social and economic impact of new technologies.

Data and Metrics

One of the most frustrating features of analyzing IP systems is the lack of empirical data on such critical questions as whether, how, and when IP does any of the following: 1) increases levels of investment in research and development; 2) encourages or retards development in low- and middle-income countries; and 3) facilitates or hinders the dissemination of new products and services. Further, we possess only a sketchy statistical picture of the types of licence agreements being employed and whether these lead to increased levels of innovation and use. There is so little actually known about the functioning of the patent system that it is not credible to come to any firm conclusion on how it works and on its effects.

The dearth of knowledge has not, however, prevented actors at various times from making strident statements for or against the IP system. The International Expert Group's research revealed the persistence of strong assumptions about IP that cannot, on any reasonable empirical basis, be justified. These include, on the one hand, the assumption that increases in IP in the early 1980s were the necessary precondition for the subsequent biotechnology boom (or, in other eras, the chemical, pharmaceutical or information technology booms) or, on the other hand, that IP is the principal reason why patients in low- and middle-income countries cannot obtain HIV/AIDS medicines. While most industry representatives and NGOs take a more moderated view on IP, their public statements occasionally give the impression that IP is more central to the problem at hand than the evidence supports.

Perhaps the most important reason why it has proven impossible to draw firm conclusions about the role of IP in innovation systems is that IP is rarely the most significant factor driving innovation. According to one study, IP and licensing together account for less than 20 percent of the dissemination of research ideas originating in universities.[99] Many technology fields have advanced well in the absence of IP. This was true of the information technology sector in the 1970s as well as the semiconductor industry.[100] In most industries, being first to market and having skilled managers significantly outweighs the importance of IP in the success of a company.

Of all the sectors studied, however, the pharmaceutical and the biotechnology industries have placed the most emphasis

on IP. Part of the reason for this is the significantly longer time it takes to bring a pharmaceutical and many (but not all) biotechnology products to market due to the need for extensive health and safety testing of new health and agricultural products. Further, the biotechnology sector has been influenced by the continued practice of venture capitalists to insist on patents despite their limited practical value. Because of this, biotechnology firms continue to apply for patents.

Even if, however, IP actually plays a more significant role in the pharmaceutical and the biotechnology industries than in other industries, the empirical evidence available strongly indicates that it is not sufficient to bring about an increase in the number and innovativeness of new products and services. Once again, however, we lack sufficient data about the role that IP plays in the overall pharmaceutical and biotechnology innovation systems.

Another factor inhibiting the collection of empirical information is the lack of common standards in data collection among agencies and among countries. Individual researchers and organisations currently collect data in an *ad hoc* manner reflecting their particular interests, making comparison difficult. Common definitions of what information needs to be collected as well as standard methods of collecting that information and measuring results need to be established. Without such common standards, it is difficult to compare effects between industries, between time periods and between countries and regions. Since the effects of IP systems are so wide ranging and cross so many borders, data needs to be collected across a wide variety of countries if we hope to discern the effects of IP systems on biotechnological innovation. The International Expert Group therefore recommends the following:

Recommendation 14: Government, industry and the research community should standardize the collection of important science and technology measures to permit country, regional and temporal comparisons of different models of managing IP. The Organisation for Economic Cooperation and Development may be best placed to lead this effort given its expertise in economic measures.

While all data collection needs to be encouraged, there is a particular dearth of information with respect to university and other public sector technology transfer and dissemination. Much policy attention has, over the past decade, focused on the role of universities and research institutions in ensuring that the research they develop is put to use. Underlying much of this attention have been three assumptions: 1) that the best way to put knowledge to use is by transferring it to the private sector; 2) that strong IP protection is necessary in order to accomplish this; and 3) that technology transfer will provide public institutions with needed revenues. All of these assumptions turn out to be untrue, at least in most cases. Not only do most universities and research institutions lose money on technology transfer but there is no guarantee that the private sector will do any better in disseminating research than do universities. Further, there exist some promising models that show the potential of public-private interaction, such as that employed by the Structural Genomics Consortium (see Box B) and the British Columbia Cancer Agency (see Box C), in which IP plays a lesser role.

The International Expert Group has identified particular knowledge gaps that need to be filled in order to assist research institutions in measuring the impact of their dissemination efforts. Data on patent grants, fields of technology, and applications are currently impossible to collect on an international level. Even within the US, patent data is only available through private providers such as Delphion, while the best citation data (whether an article or patent has been cited in subsequent work, indicating its relevance and impact) is available through another private provider, Scopus. Patent offices around the world are best placed to build publicly-available databases of patent information that can be used to better track the impact and effectiveness of not only the IP system, but of particular methods of dissemination.

Of particular concern to international governmental organisations and NGOs operating globally to provide medicines to the world's poor is better information on whether, where and how those medicines are subject to patent rights. Current patent databases make such searches difficult. Industry can assist in this by being more transparent about the patents they hold, including those over pharmaceutical and biotechnological products. Patent examiners, as they review patent applications could, in addition, indicate in the database whether the invention being examined is related to key medicines. Further, information could be collected on whether these patents are subject to any licences and, if so, the principal terms of those licences. The International Expert Group therefore recommends as follows:

Recommendation 15: Industry and patent offices around the world should collect patent-related information in a standard form and make this available to the public for free. Data should include information that will assist in assessing patent landscapes in targeted areas of technology, such as essential medicines. Patent databases should be linked so that a user can identify not only the patents in one country but related patents in other countries. These databases should also be easily searchable.

Recommendation 16: In addition to collecting patent information, patent offices should collect data on the type and major terms of licence agreements. A pilot project at the Japanese Patent Office on creating such a database should be expanded and spread to patent offices around the world.

Recommendation 17: To better enable patent offices to respond to the needs of the public sector, these offices should establish policy branches that would investigate ways to make data more available, assist in patent landscaping and disseminate information about the patent system.

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[56] E. Richard Gold, "Innovation and Productivity: the Need for an Intellectual Architect", *Policy Options*, October 2006, 75 at 77.

[57] Jean-Frédéric Morin & E. Richard Gold, "Consensus-Seeking, Distrust, and Rhetorical Action: The WTO Decision on Access to Medicines" (2008) under review.

[58] Gold & Carbone, *supra* note 20.

[59] Bubela *et al*, *supra* note 30.

[60] E. Richard Gold & Jean-Frédéric Morin, "From Agenda to Implementation: Working Outside the WIPO Box" in *Implementing WIPO's Development Agenda,* Jeremy de Beer, ed., (Waterloo, ON: Wilfred Laurier University Press, forthcoming 2008).

[61] ICTSD, "WHO Adopts Strategy on Public Health, Innovation and Intellectual Property" (2008) 12:19 Bridges 11 at 12.

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[65] E. Richard Gold, "Finding common cause in the patent debate" (2000) 18 *Nature Biotechnology* 1217.

[66] Morin & Gold, *supra* note 57.

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[70] Ibid. See also Gold *et al., supra* note 16.

[71] Louise Bernier, "Dialogue et élaboration de normes dans le domaine de la propriété intellectuelle: l'influence grandissante des citoyens et groupes d'intérêts" (2008) Séminaire du pôle Innovation du laboratoire Cemantic, Centre d'études en Management et Technologies de l'information et des télécommunications Sud Paris, Evry, Paris.

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[78] See, for example, BiOS, a project of Cambia, online at: http://www.bios.net/daisy/bios/home.html. Cf. David Castle, "Open Source and Patent Pooling in Canadian Science and Biotechnology Policy: A Report for Health Canada" (2006).

[79] *Sony Corp. of America* v. *Universal City Studios, Inc.* (1984) 464 U.S. 417.

[80] Theatrical revenues only account for 25% of revenues whereas those from video and DVD account for 40%. Malcolm Ritchie, "Revenue Flow and Making Money out of Film", *SkillSet Film*, available online at http://www.skillset.org/film/knowledge/article_5103_1.asp.

[81] The Canadian brand-name pharmaceutical industry agreed to increase spending on research and development in Canada in the late 1980s to over ten percent of revenues – which was, in any event, significantly below the level of investment in the US, France, UK and other OECD countries – if the federal government abolished automatic compulsory licences. The government did so. While industry did increase investment to over 12% of revenues for several years, the promise was short lived. Not only was the vast majority of investment in the far less clinical rather than basic research, but industry investments returned to late 1980s levels. The latest figures, from 2007, indicate that all those holding patents invested 8.3% of revenues into research while the brand name pharmaceutical companies invested 8.9% of revenues into research. However, only 20.3% of this investment went into basic research. Patented Medicines Prices Review Board, *Annual Report 2007* (Ottawa: PMPRB, 2008) at 42-44, available online at: http://www.pmprb-cepmb.gc.ca/CMFiles/PMPRB-AR07-english42LFK-6182008-8285.pdf.

[82] Ranbaxy, Press Release, June 11, 2008, available online at: http://www.ranbaxy.com/news/newsdisp.aspx?cp=889&flag=LN.

[83] Kate Hoye, Richard Gold, and David Castle, "Workshop Report: Bridging the Invention-Innovation Gap in the Commercialization of Publicly-Funded Research: Four Recommendations" (2008) available online at www.cipp.mcgill.ca.

[84] Castle *et al, supra* note 23; L. Martin Cloutier, Céline Bérard, & Luc Cassivi, "Diffusion of an innovative biotechnology: The case of plant-derived vaccines using system dynamics" (2005) presentation at the International System Dynamics Conference, Boston.

[85] Karen L. Durell & E. Richard Gold, "An All-Asset Approach to Canadian Technology Transfer" (2008) A Study for Industry Canada; Kate Hoye & David Castle, "Understanding Technology Transfer in Canada" (2008), Report for Industry Canada.

[86] California Institute of Technology et al. "In the Public Interest: Nine Points to Consider in Licensing University Technology" March 6, 2007, available online at: http://news-service.stanford.edu/news/2007/march7/gifs/whitepaper.pdf.

[87] *Ibid*, points 1-3 and 9.

[88] Tania Bubela & Andreas Strotmann, "Designing Metrics for Impacts and Social Benefits of Publicly Funded Research" (2008) available at www.theinnovationpartnership.org.

[89] Anthony D. So, Arti K. Rai, & Robert M. Cook-Deegan, "Intellectual Property Rights and Technology Transfer: Enabling Access for Developing Countries" (N.p.: WHO Commission on Intellectual Property Rights, Innovation, and Public Health, 2005).

[90] The International Expert Group on Biotechnology, Innovation and Intellectual Property recognizes, however, that BIO, the biotechnology industry lobby group, supported alternative funding arrangements to encourage the development of health products aimed at meeting low- and middle-income country needs. See BIO, "BIO Applauds World Health Assembly's Global Strategy on Public Health, Innovation and Intellectual Property", Press Release, May 30, 2008, available at: http://www.bio.org/news/newsitem.asp?id=2008_0530_01.

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[95] Thorsteinsdottir H, Saenz TW, Quach U, Abdallah S. Daar, Singer PA. Cuba—innovation through synergy. *Nature Biotechnol* 2004 Dec;22 Suppl:DC19-24.

[96] High-Level African Panel on Modern Biotechnology, *Freedom to Innovate: Biotechnology in Africa's Development* (South Africa: Africa Union, 2007) at 89.

[97] Herder & Gold, *supra* note 25.

[98] Castle *et al, supra* note 23.

[99] Ajay Agrawal and Rebecca Henderson, "Putting Patents in Context: Exploring Knowledge Transfer from MIT" (2002), 48 *Management Science* 44.

[100] Bronwyn H. Hall and Marie Ham, "Patent Paradox Revisited: Determinants of Patenting in the U.S. Semiconductor Industry, 1980-94" (1999), Competition Policy Center. Paper CPC99-005, available online at: http://repositories.cdlib.org/iber/cpc/CPC99-005.

EXAMPLES OF POLICY STRATEGIES IN THE NEW IP ERA

Drawing on the above six themes – trust, communications, new models, scientific infrastructure, thinking outside the box, and data and metrics – the International Expert Group sketched out three representative ways in which public and private sector decision-makers could modify IP systems to facilitate the passage from the era of Old IP to that of New IP. These alternative policy strategies take into account the complex ways in which IP and innovation systems interact as well as the variety of policy goals that actors pursue.

Each strategy represents a starting point for discussions of policies available for institutions, companies, and governments to manage the transition toward New IP. While there is time to make the transition – Old IP has not yet fully left the stage – there is not much time. Increasing attention to the failure of Old IP to deliver innovation and to meet the needs of low- and middle-income countries means that the transition will occur. How well it will occur will depend on the willingness of all actors to understand and manage it.

The International Expert Group selected three strategies to examine, each revolving around separate goals: 1) to maximize short to medium term levels of biotechnological innovation; 2) to build and maintain the scientific infrastructure necessary to carry on biotechnological innovation; and 3) to maximize access to existing and future biotechnology. While not mutually exclusive, each strategy focuses on a key policy area. We present a brief overview of each strategy here, leaving the details to online materials.[101]

Maximizing Short to Medium Term Innovation

The central challenge of ensuring innovation in the era of New IP will be to increase collaboration and the flow of basic scientific knowledge. Where knowledge hoarding is common in the Old IP era, the International Expert Group foresees that New IP will usher in a period marked by the creation of new partnerships and other forms of collaboration. Given this, public sector policy-makers would be wise to focus on building collaborative mechanisms through which to link public and private sector actors. These should be designed to ensure that basic knowledge and data remain free to use. That is, while individual companies will be able to commercialise particular molecules or plants developed through collaborations, the new research and data they generate in doing so will remain a shared resource. Recommendations 7, 8, and 9 are particularly apt in addressing this need.

Building collaborations requires, however, both trust and communication. As the International Expert Group noted earlier, these are in short supply. Public and private sector actors need to develop mechanisms through which to increase communication and trust. Drawing on the expertise of independent "trust builders", as suggested in Recommendations 1 and 2, would be a start.

The expert group further noted the lack of managers with a specific understanding of biotechnology. Good management, more than good IP, is essential to the success of any biotechnology enterprise, whether in the public or private sector. Without a large cohort of well-trained and experienced managers, it will be difficult to construct and implement the creative business models that will be necessary in the New IP era. Those with experience in managing biotechnology companies will contribute to this, but more individuals are needed, particularly those with experience building new business models. Such individuals may need to be found in sectors other than biotechnology, such as information technology, in which more experimentation has occurred.

It will also be critical, in moving from Old IP to New IP, that industry lobby groups catch up with the reality faced by their members. Those who actually conduct research and deliver products within large and small biotechnology and pharmaceutical companies understand the changing landscape and the need to adapt. On the other hand, both national and international industry associations and some of those in charge of government relations within individual companies have yet to understand the necessity of change. Instead of helping to manage the smooth transition to New IP, as would be in the long-term interests of their constituents, they too often stand in the way. Those with foresight in industry need to push their colleagues speaking on their behalf to adapt to the change of era.

Increasing trade opportunities for biotechnology products and services will also be important, according to the International Expert Group. Trade enhances investment in the corporate sector and provides revenues for local enterprises to fuel their growth. While unhampered trade could be disruptive, opening markets to biotechnology products through lower tariffs and the reduction of regulation on investments should increase investments in biotechnology.

Scientific Infrastructure

Low- and middle-income countries, as well as less developed regions of high-income countries, face the problem of catching up to the large investments made in high-income regions in biotechnological innovation. These investments range from physical infrastructure, such as laboratories and training facilities, to equipment and skilled people. The solution of adopting high-income country IP systems has proved ineffective in addressing this gap. Rather than focus on increasing IP rights, as Old IP has promoted, low- and middle-income countries need to adapt IP systems to their technological, institutional, economic, and cultural situation.

The export of the US Bayh-Dole Act to low- and medium-income countries illustrates this well. Throughout the 1990s and early 2000s, high-income country governments and industries encouraged low- and middle-income countries to adopt the Bayh-Dole formula that research institutions be given the mandate of obtaining IP protection over inventions made at those institutions and to transfer that IP to the private sector. The goal of this strategy was to both provide additional revenue – chiefly through licence fees – to those institutions and to ensure that the technology would be commercialised for the economic benefit of the country. These benefits are unlikely to occur for low- and middle-income countries.[102] There are several reasons for this including the following:

Simply obtaining IP rights is inadequate to commercialisation. It misses the need of having established companies ready to receive the technology with the skill, networks, and financing necessary to develop it further.

Universities do not, overall, make money through technology transfer. While there are some high profile cases where universities profited from the technology they commercialised, such as Gatorade, these are the exceptions, not the rule.

Low- and middle-income countries lack access to venture financing, angel investors, and those skilled in managing biotechnology companies. Without access to financing, technology transfer is ineffective.

While the Bayh-Dole legislation may fit into the cultural and institutional structure of the US – in which there are numerous balancing features that provide government with the tools to step in when necessary in the public interest – it does not do so in other countries. Too often, low- and middle-income countries copy parts of the US patent system without also emulating counterbalancing rules.

The experience of exporting policies to low- and middle-income countries shows that a different approach is necessary. Those countries need to concentrate less on technology transfer than on building and maintaining the capacity to do biotechnological research and development. This means drawing on those countries' diaspora of researchers, finding ways to train doctoral students and post-doctoral fellows at home, and providing opportunities for students to conduct research on fields related to the needs of their home countries.

Low- and middle-income countries must also build and disseminate new business models that better correspond to their culture and institutions. This will sometimes require new commercial models while, at other times, require partnerships with a marginal commercial component. Building successful models and sharing them will accomplish more than the blind enhancement of IP rights and licensing.

Building new models of dissemination is, however, only the beginning. Training managers on how to use those models will prove essential if low- and middle-income countries hope to overcome the biotechnology gap. The International Expert Group's Recommendation 11 is of particular relevance here.

Spending on education, research, and training will be critical to maintaining and enhancing scientific infrastructure. As suggested by Recommendation 8, increased spending by development and aid agencies in high-income countries earmarked for research partnerships with low- and middle-income countries could provide one mechanism through which to address this funding gap.

Indigenous peoples, whether located in high-, middle-, or low-income countries generally have less education and fewer opportunities in science and technology. While overcoming the years of marginalisation faced by these people is beyond the scope of this report, opportunities exist to improve the situation. Many indigenous peoples possess knowledge about their environment, plants, and animals that could provide a lever for getting involved with research and development. Through sharing this knowledge in ways that affirm their autonomy and rights – such as through obligations on researchers to ask permission, to report back on research results, and to engage members of the community in scientific projects – indigenous peoples can increasingly become participants in biotechnology. Recommendations 2 and 11 will assist indigenous peoples to take these steps.

Accessing Biotechnology

The research conducted by the International Expert Group highlighted the antagonistic manner in which access to biotechnology is contrasted to protecting biotechnological inventions through IP. This antagonism comes from both industry, which views calls for access as ignoring industry's need to recoup and profit from its investments, and from NGOs, which claim that industry's use of IP has prevented many people from obtaining life-saving medicines and other products.

The access-incentive paradigm – in which *access* is seen as incompatible with providing an *incentive* – underlies much of the thinking about Old IP. The International Expert Group's research strongly suggests that this paradigm does not describe reality and is, actually, misleading. IP rights have only a marginal role in encouraging research; their role is significantly more pronounced in the dissemination of new products and services. Since access depends on dissemination, IP rights and access fundamentally relate to the same phenomenon: the dissemination of new products and services.

With this more holistic account of access and IP, as suggested by Recommendation 12, the International Expert Group noted three forms of access that are necessary for both the progress of science and for ensuring that those in need of products and services can obtain them.

The first form of access is to scientific knowledge and training. This means more than simply the free availability of scientific information but, as noted earlier, the infrastructure necessary to access it. As well, information beyond that ordinarily published in scientific journals – such as compound libraries – needs to be made available.

Second, the International Expert Group noted the importance of access to financing and to business knowledge. The mechanism suggested in Recommendation 5 would be a good start. As discussed in the previous section and in Recommendations 7, 8, and 9, there is a need to develop business models that work in low- and middle-income countries. This requires training and a greater willingness of venture capitalists to invest in low- and middle-income countries.

The third form of access is to new biotechnology products and services adapted to the needs of low- and middle-income countries. The International Expert Group concluded that, so far, high-income country governments and enterprises have done a poor job of providing those products and services. Part of the reason for this is the relatively smaller market power – due to a variety of factors including poverty, corruption, and lack of infrastructure – in many low- and middle-income countries. But a large part of the problem remains the failure to adapt business models to be more collaborative and to better engage the public sector. Existing public-private partnerships have, to a certain extent, filled this gap. However, many of these rely on a single source of financing – the Bill & Melinda Gates Foundation – and thus do not represent sustainable business models for two reasons. First, while the particular partnerships may be stable, one cannot use them as models to build new partnerships since the subject areas may fall outside of the interests of the Gates Foundation. Second, these models are similar in structure and ethos because of their funding source. If we hope to provide truly robust endeavours, a diversity of approaches will be needed, requiring a diversity of funders and funding mechanisms.

To achieve all three forms of access requires a holistic approach to policy development. In particular, the IP system should not be viewed in isolation but as part of larger national and international innovation systems. Recommendations 4, 6, and 9 set out the parameters for such an approach.

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[101] See, generally, www.theinnovationpartnership.org.

[102] Sara Boettiger and Alan Bennett, "The Bayh-Dole Act: Implications for Developing Countries" (2006) 46 IDEA: The Intellectual Property Law Review 259.

CONCLUSION

"The answer, quite simply, is that things are only inevitable as long as we are unwilling to change them." So remarked Ernst & Young looking at the biotechnology industry in the summer of 2008.[103] The International Expert Group on Biotechnology, Innovation and Intellectual Property has set out what it would mean to undertake change. In this report, the group provides an overview of its research findings and, more importantly, practical recommendations that respond to the critical need to develop policy tools and approaches to manage the transition from Old IP to New IP. The success of this transition – measured in terms of increased social, health, agricultural, and economic benefit derived biotechnology – will depend on the political will of governments and the long-term vision of companies and NGOs to fully engage in greater collaborations, partnerships and knowledge sharing. If countries and private actors retain their narrow and unsuccessful models, biotechnology will more likely be a bane than a benefit to us all.

Soon will be the time to bury Old IP and in its place the era of New IP will begin. By aligning IP policy with democratic values of equity and fairness, as suggested by this report and its recommendations, governments, researchers, universities, industries, and NGOs can embrace the future.

[103] Ernst & Young, *supra* note 43.

LIST OF RECOMMENDATIONS

Recommendation 1: Governments, industry and NGOs should encourage the creation of independent trust builders – individuals or firms that are independent from the major stakeholders and who have knowledge in the field – to mediate disputes, encourage dialogue between actors and develop joint research initiatives. Each of the above actors will need to contribute financially and intellectually to the efforts of the trust builders. In particular, those actors should agree to submit disputes to the trust builder for mediation and should support the trust builder in organising workshops on key issues of joint interest.

Recommendation 2: Governments should support independent, non-governmental and non-industry organisations to engage indigenous communities at a grass-roots level in training related to a host of issues around access and benefit sharing agreements, contracting and intellectual property. This training should include ways through which these communities can protect indigenous knowledge and methods to share that knowledge while respecting the rights and autonomy of those peoples. Support can take the form of funding and access to documentation, but should not be tied to the manner in which the training is to be delivered or the substance of that training. Communities should be involved in both the delivery and substance of the training.

Recommendation 3: The media should consider covering issues of *science policy* – how innovation systems function and their effect on social and economic outcomes – more thoroughly to facilitate general knowledge of science and technology issues and, in particular, the governance of knowledge and innovation. Scientists should also be willing to engage the media in order to assist them in understanding not only the science but its implications.

Recommendation 4: Governments, industry, universities, and NGOs should engage the trust builders proposed in Recommendation 1 in developing workshops and training programmes through which stakeholders and the public can actively debate the role of biotechnology in health, agriculture and industry.

Recommendation 5: Leading private sector institutions in high-, middle- and low-income countries should establish an independent, non-profit *technology assessment* organisation to evaluate new biotechnology products and services. This organisation would assess technology proposed by start-up enterprises and universities in low- and middle-income countries and start-up enterprises formed by aboriginal communities with the view to providing them with increased visibility and credibility in attracting private sector financing.

Recommendation 6: Working together, governments, universities and industry should develop new measures of the success of technology transfer, and other means of development and social investment that better correspond to desired social and economic return. They should specifically abandon traditional measures such as the number of patents held and licensing revenues and replace them with indicators of a social return on investment.

Recommendation 7: Industry and academics in business, law, economics and other disciplines should develop new and sustainable business models of developing, commercialising and disseminating biotechnology products and services that are attuned to local needs and conditions. Business schools should include low- and middle-income country conditions and business opportunities in their curriculum and should develop programmes through which their students can provide business planning assistance to low- and middle-income country entrepreneurs.

Recommendation 8: Funding agencies should target the development of novel and sustainable business models and their implementation. In particular, funding should be made available to support pilot projects on commercialising and other dissemination of low- and middle-income technologies. Governments should increase funding to these funding agencies, counting such investments as part of their aid development budgets so as to meet international targets on these budgets.

Recommendation 9: Governments with public health care systems, funding agencies and universities should develop a PPP to manage research and development of health data. Such a PPP would license out the use of data to private actors on condition that such actors collaborate with public sector actors and contribute new data to the PPP for further use.

Recommendation 10: Universities in high-income and in low- and middle-income countries should create educational opportunities at the doctoral and post-doctoral levels for scientists through which those scientists maintain links with their countries of origin and conduct research focused on the needs of those countries. Universities in high-income countries should encourage those of its professors from the diaspora to assist their countries of origin through supervision of students, joint research projects, conducting peer review and so on.

Recommendation 11: Governments, industry and public institutions should sponsor capacity building programmes on technology transfer and IP management for low- and middle-income countries and for aboriginal communities in high-income countries. This training should be provided by independent organisations, such as described in Recommendations 1 and 2 working jointly with researchers and communities in those countries to address their specific institutional, social and economic needs.

Recommendation 12: Public and private sector researchers should analyse questions of IP within the larger context of IP and innovation systems. To do so, they should use analytical tools that provide a broader, inter-disciplinary perspective on IP and innovation, whether those developed by the International Expert Group or their own.

Recommendation 13: Governments need to pay as much attention to the environment in which innovation takes place – including regulation of the environmental and health effects of biotechnology, the independence of the judicial system and marketplace regulation – as they do to IP. IP only functions where there is a stable and functioning marketplace that addresses the social and economic impact of new technologies.

Recommendation 14: Government, industry and the research community should standardize the collection of important science and technology measures to permit country, regional and temporal comparisons of different models of managing IP. The Organisation for Economic Cooperation and Development may be best placed to lead this effort given its expertise in economic measures.

Recommendation 15: Industry and patent offices around the world should collect patent-related information in a standard form and make this available to the public for free. Data should include information that will assist in assessing patent landscapes in targeted areas of technology, such as essential medicines. Patent databases should be linked so that a user can identify not only the patents in one country but related patents in other countries. These databases should also be easily searchable.

Recommendation 16: In addition to collecting patent information, patent offices should collect data on the type and major terms of licence agreements. A pilot project at the Japanese Patent Office on creating such a database should be expanded and spread to patent offices around the world.

Recommendation 17: To better enable patent offices to respond to the needs of the public sector, these offices should establish policy branches that would investigate ways to make data more available, assist in patent landscaping and disseminate information about the patent system.

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