



THE INNOVATION PARTNERSHIP



## EXECUTIVE SUMMARY

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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PROPERTY POLICY

# THE INTERNATIONAL EXPERT GROUP ON BIOTECHNOLOGY, INNOVATION AND INTELLECTUAL PROPERTY

## **Richard Gold, McGill University, Chair**

Wendy Adams, McGill University  
Louise Bernier, Université de Sherbrooke  
Tania Bubela, University of Alberta  
Luc Cassivi, Université du Québec à Montréal  
David Castle, University of Ottawa  
Ghislaine Cleret de Langavant, AETMIS (until 2006)  
L. Martin Cloutier, Université du Québec à Montréal  
Abdallah S. Daar, University of Toronto  
Hélène Delerue, Université du Québec à Montréal  
Amy Glass, Texas A&M University  
Elisa Henry, McGill University  
Lori Knowles, Health Law Institute, University of Alberta  
Jean-Frédéric Morin, Université Libre de Bruxelles  
Tina Piper, McGill University  
Pamela J. Smith, University of Minnesota

## **ADVISORS**

Maristela Basso, University of Sao Paolo (Brazil)  
Timothy Caulfield, University of Alberta (Canada)  
Robert Cook-Deegan, Duke University (United States)  
Iain Gillespie, Organisation for Economic Cooperation and Development (France)  
Julian Kinderlerer, University of Cape Town (South Africa)  
Marnie McCall, Industry Canada (Canada) *in her personal capacity*  
Kent Nnadozie, SEAPRI (Kenya)  
Anthony So, Duke University (United States)  
Koichi Sumikura, National Graduate Institute for Policy Studies (Japan)

## **ASSOCIATE EXPERTS**

Michael Adcock, University of Sheffield  
Alain Gallochat, Consultant  
Scott Kieff, Washington University  
Peter Phillips, University of Saskatchewan  
Arti Rai, Duke University  
Edson Beas Rodriguez, IDCID

## **RESEARCHERS**

Cécile Bensimon, University of Toronto  
Céline Bérard, Université du Québec à Montréal  
Lorie Bouchard, Université du Québec à Montréal  
Julia Carbone, McGill University / Duke University  
Hélène Delerue, Université du Québec à Montréal  
Karen Durell, McGill University  
Kate Hoye, University of Ottawa  
Fabricio Nunez, University of Minnesota

## **ASSOCIATE RESEARCHERS**

Maria Chan, University of Alberta  
Melanie Forcier Bourassa, McGill University

Shawn Hagen, University of Alberta  
Yann Joly, McGill University  
Liesel Knall, University of Alberta  
Gene Kruger, McGill University  
Kira Kumagai, Ottawa University  
Pavel Matrosov, McGill University  
Dipesh Mistry, University of Alberta  
Thomas Moran, University of Alberta  
Jyoti Mistry, Ottawa University  
Rhiannon Noble, University of Alberta  
Sven Poysa, McGill University  
Jeff Roberts, McGill University  
Andreas Stromann, University of Alberta

## **ADMINISTRATION AND LOGISTICS**

Monique Cavalleri, European University Institute  
Hélène Hamou, McGill University  
Monique Leblanc, McGill University

## **VISITING FELLOWS**

Emile Bienvenu, National University of Rwanda  
Emmanuelle Bourgois, Food and Agriculture Organization  
Rabogajane Busang, Medical Research Council (South Africa)  
Maria-Teresa Lavalle, University of Buenos Aires (Argentina)  
Isabel Lopez, Universidad Rey Juan Carlos, Madrid, (Spain)  
Jackline Nyaga, University of Nairobi (Kenya)  
Graciela de Ortuzar, National University of La Plata (Argentina)  
Niranjan C. Rao, Centre for Economic and Social Studies (India)  
Antoinette Rouvroy, European University Institute

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## 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 on Biotechnology, Innovation and Intellectual Property 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.

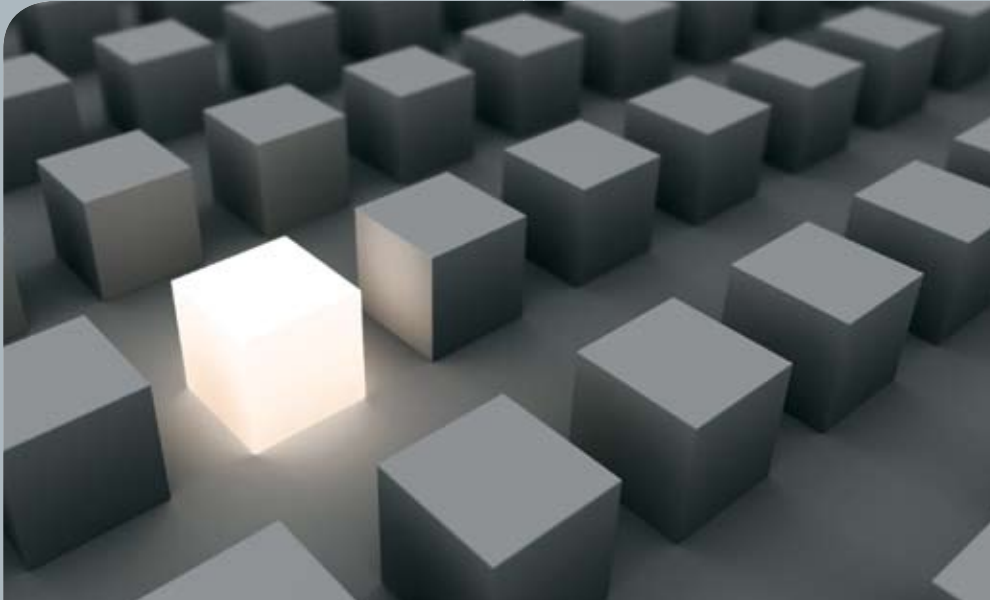
**New models:** We need better ways to develop and deliver biotechnology products. Established companies need to help their counterparts in low and middle income countries to get financing and sell their inventions. Researchers, industry and NGOs need to work together to develop creative ways of sharing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



**Intellectual property is a way in which government gives power to a person – the IP holder – to control how certain bits of knowledge will be used.**

**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”.<sup>1</sup> 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<sup>2</sup> and a US statute that told universities to patent and commercialise publicly-funded scientific research.<sup>3</sup> 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.<sup>4</sup> 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.<sup>5</sup> It wrongly assumed that companies obtain IP to protect their inventions from being copied rather than to trade or enhance their reputations.<sup>6</sup> It wrongly presumed that if a company has a patent right it could actually use it to prevent others from copying the invention.<sup>7</sup> It exaggerated the importance of patents;<sup>8</sup> other impediments – such as income tax rules, regulations and political and cultural understanding – may often be more important.<sup>9</sup> Research also showed that it was unclear whether patents actually increase inventiveness and dissemination.<sup>10</sup> 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.<sup>11</sup> Countries such as France and Germany refused to fully implement new rules to expand IP rights in human genes.<sup>12</sup> 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”.<sup>13</sup>

The twilight of Old IP does not signal the end of the importance of IP.<sup>14</sup> 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.<sup>15</sup> 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.<sup>16</sup> 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.<sup>17</sup>



## 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.

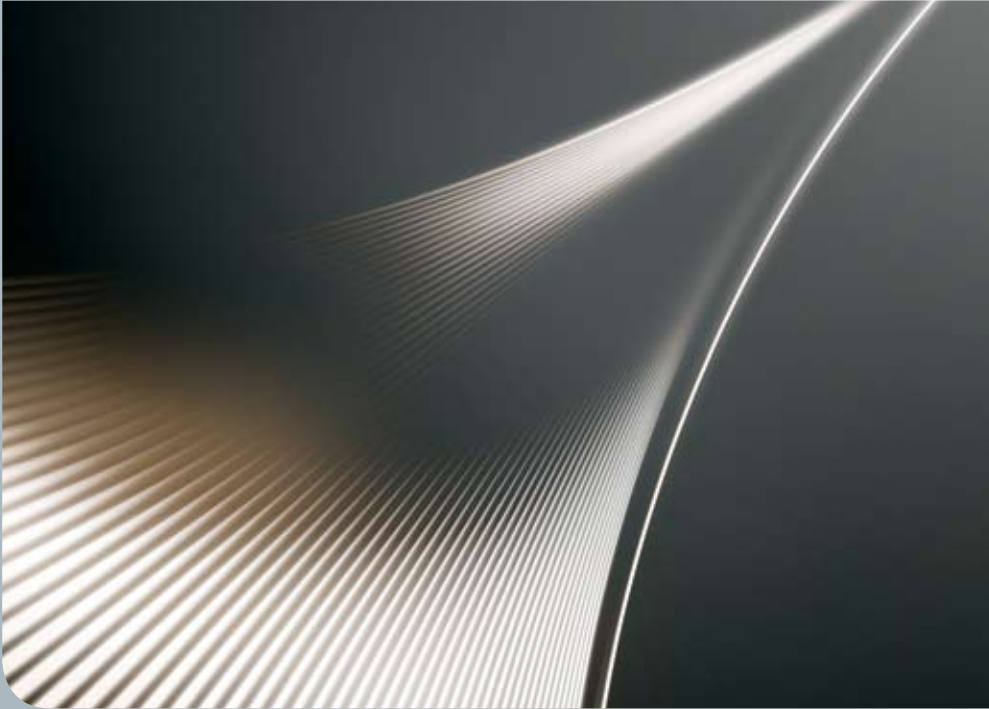
**On communications:** Industry and NGOs talk past one another and fail to understand each other's concerns. Lack of communication was a major cause of the failure of Myriad Genetics to develop a workable plan to introduce its breast cancer genetic test into Canada. With some exceptions, the media has 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.



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.

# 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 organizing 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, interdisciplinary 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.

<sup>1</sup> Christopher Freeman, *Technology and Economic Performance: Lessons from Japan*, (London: Pinter, 1987).

<sup>2</sup> *Diamond v. Chakrabarty* (1980) 447 U.S. 303.

<sup>3</sup> Bayh-Dole Act, P.L. No. 96-517 (1980).

<sup>4</sup> E. Richard Gold & Alain Gallochat, "The European Biotech Directive: Past as Prologue" (2001) 7 *European Law Journal* 331 at 332.

<sup>5</sup> 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>.

<sup>6</sup> 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.

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

<sup>8</sup> Knut Blind, Jakob Edler, Rainer Frietsch, Ulrich Schmoch, "Motives to patent: Empirical evidence from Germany" (2006) 35 *Research Policy* 655 at 661.

<sup>9</sup> 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).

<sup>10</sup> 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>.

<sup>11</sup> 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.

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

<sup>13</sup> 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.

<sup>14</sup> 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.

<sup>15</sup> John P. Walsh, Ashish Arora & Wesley M. Cohen, "Science and the Law: Working Through the Patent Problem" (2003) 299 *Science* 1021.

<sup>16</sup> DNDi, Press release, March 6, 2008, available online at: [http://www.dndi.org/cms/public\\_html/insidearticleListing.asp?CategoryId=166&SubCategoryId=167&ArticleId=463&TemplateId=1](http://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>.

<sup>17</sup> 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>.