# Landmark study reports breakdown in biotech patent system

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The world's intellectual property system is broken. It's stopping lifesaving technologies from reaching the people who need them most in developed and developing countries, according to the authors of a report released in Ottawa today by an international coalition of experts.

"We found the same stumbling blocks in the traditional communities of Brazil as we did in the boardroom of a corporation that holds the patent to a gene that can determine the chance a woman will develop breast cancer," said Richard Gold, professor of intellectual property at McGill University and chair of the International Expert Group that produced the report. "Most striking is that no matter where we looked, the lack of trust played a vital role in blocking negotiations that could have benefited both sides, as well as the larger public."

The report is the result of seven years of work by Gold and his colleagues, experts in law, ethics and economics Gold said that the authors based their report on revelations that came out of discussions with policy-makers, industry representatives, scientists and academics from around the world, as well as the outcomes of a series of case studies involving Brazil, Canada, Kenya the United States, the European Union, Japan, Australia, and India. The authors portray a crucially important but increasingly dysfunctional industry that relies on a business model based on outdated conceptions of IP. In their report, the authors describe conclusions and recommendations based on data collected over the last seven years; the data itself will be released at an October 14 event in Washington, DC.

"The old IP approach of the biotechnology community has failed to deliver on its potential to address disease and hunger in both developing and industrialised nations. We need to do better, and the IT world has shown us part of the solution," Gold says. "Look at the way that change has swept through the IT world and brought benefits to millions."

While biotech's potential seems unlimited, so do its problems. The report finds that a fixation on patents and privately-controlled research has frequently given rise to controversy and roadblocks to innovation. Recent examples include: the $612 million patent suit that almost shut down the world's Blackberries; Myriad Genetics' inability to introduce its breast cancer screening test in Canada and Europe; a pharmaceutical industry with an increasingly bare medicine cabinet; an ongoing failure to deliver life-saving medications to developing countries.

"For better or for worse, biotechnology is at the heart of current debates about health care, the environment, food and development," Gold said. "It offers the promise of producing plants to resist drought and nourish the world's poor, and to offer new medicines and energy sources. Biotech is at the heart of not only today's economy but its security and well-being as well."

The current crisis in biotechnology has given rise not only to economic problems but to endemic mistrust among its actors that is stifling innovation and preventing cutting-edge technologies from helping those who can most benefit. The report and case studies provide the following as illustrations:

-- Findings from a study of stem cell researchers suggesting that those who patent the most, collaborate the least, based on a study of measures of success.

-- The reasons for the breakdown of negotiations between a US

company, which had patented human genes for breast and ovarian cancer, and Canadian health authorities. A case study reveals that talks with Canada were in crisis after Myriad delivered threatening letters to the Ontario Minister of Health from US Senator Orin Hatch and from the US Ambassador to Canada, Paul Cellucci.

-- Evidence based on a Brazilian case study that ensuring property rights to indigenous practices and knowledge has served as a significant barrier to research in Brazil and has not furthered the interests of the country's traditional communities.

-- Revelations from participants in discussions of Canada's legislation to allow emerging markets to produce drugs for poor countries—known as the Access to Medicines Regime. They said privately that they knew the regime would not work by the end of the negotiations, yet they publicly applauded it.

While exposing a number of systemic failures associated with biotech and IP regimes, the Expert Group reports that 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.

At an event on Tuesday in Ottawa, organized to present the report to Canadian policymakers, the findings of the Brazilian case study were presented by Maristela Basso of the Brazilian Institute of International Trade Law & Development (IDCID).

"NGOs in Brazil help communities sue researchers and companies that use indigenous knowledge without consent, but no one is present to help communities change the legislation or enter into agreements with those same companies in advance, so that everyone can benefit," said Basso,

an associate professor of international law at the University of Sao Paul School of Law. "This leaves behind a culture of mistrust. The NGOs and local community leaders often distrust industry and are therefore reluctant to negotiate. On the other hand, researchers and industry feel so overburdened by a maze of unworkable rules and procedures that they trust neither the government nor the local communities."

Basso noted that the authors of the new report make a number of concrete recommendations that would address the problems she and her colleagues had documented in their case study. Pointing to governments, the private sector and universities as crucial players, the authors call for better management of scientific knowledge and new ways to measure whether technology transfers are working. (See key recommendations below)

Chad Gaffield, president of the Social Sciences and Humanities Research Council of Canada (SSHRC), which funded the research activities that led to the report, noted the work of the same group in helping international organizations that are struggling with ways to improve access to biotech breakthroughs for poor countries. Most recently for UNITAID, an international governmental group, Gold and his colleagues have created the design for a patent pool to unblock patents so that needed fixed dose combination and pediatric antiretroviral medicines reach those suffering from HIV/AIDS.

"The end of our old way of doing business does not mean we don't need a system for protecting intellectual knowledge," Gold said. "We need an IP system that will support collaborations among researchers and partners in industry and academia worldwide so that knowledge gets to those who need it most. This means the laws may have to be changed, but more importantly, it means that we have a lot of work to do to change behaviors and build trust among all the players. 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."

## RECOMMENDATIONS

The report released today, Toward a New Era of Intellectual Property: From Confrontation to Negotiation, documents a series of failed attempts to expand access to both traditional knowledge and the products of modern biotechnology. The authors, members of the International Expert Group on Biotechnology, Innovation and IP make a number of concrete recommendations to address their findings. Pointing to governments, the private sector and universities as crucial players, they call for better management of scientific knowledge and new ways to measure whether technology transfers are working. The following are among their key recommendations, by the group, which is organized under the aegis of McGill University and the non-profit The Innovation Partnership:

Governments should:

-- Seek other ways to encourage innovation—not just through IP, but through health and environmental regulations, the judicial system and tax rules, for instance.

-- Work with industry to help create respected and trusted entities whose members that can be counted on to mediate disputes fairly and encourage indigenous and local communities in policy development

-- Develop Public-Private Partnerships to conduct early stage research including through the sharing of health related data to allow the sharing of risk across industry.

Patent offices should:

-- Collect standardized patent-related information, including license data as they are doing in Japan

-- Assist developing countries and NGOs in finding out which patents exist in order to enable licensing

Industry should:

-- Establish an independent, non-profit technology assessment organization to evaluate new biotechnology products from developing countries

-- Participate actively in the creation of Public-Private Partnerships and other collaborative mechanisms

-- Be transparent about patent holdings

-- Develop new business models that promote partnerships and collaborations

Universities should:

-- Develop clear principles relating to the use and dissemination of intellectual property and promote greater access and broad licensing

-- Develop measures of the success of transfer of technology based on social returns rather than on the number of patents hold

-- Enter into collaborations between developed and developing countries to ensure that developing country doctoral and post-doctoral students have opportunities to study and work at home.

Source: Burness Communications