

Patent system 'stifling science'

By James Morgan
Science reporter, BBC News

Life-saving scientific research is being stifled by a "broken" patent system, according to a new report.

"Blocking patents" are delaying advances in cancer medicine and food crops, says the Canada-based Innovation Partnership, a non-profit consultancy.

The full benefits of synthetic biology and nanotechnology will not be realised without urgent reforms to encourage sharing of information, they say.

Their findings will be reported next week to UK policymakers and NGOs.

The report is compiled by the Innovation Partnership's International Expert Group on Biotechnology, Innovation and Intellectual Property.

It cites examples of medical advances which have been delayed from reaching people in need - in both the developed and developing world.

These include HIV/Aids drugs and cancer screening tests.

In pharmacy, we no longer see much discovery - we see firms playing safe and holding onto their turf
Pat Mooney, ETC Group

The authors offer guidelines for a transition from "Old IP" to "New IP", in which companies, researchers and governments recognise that sharing information is mutually beneficial.

"If we are to turn the atoms of publicly funded discovery into molecules of innovation... we have to make sure research avenues stay open," said the report's lead author, Professor Richard Gold.

"That doesn't mean there will be no patents. It simply means that patents don't become a barrier to early stage research.

"We do not want to end up in the same situation with nanotechnology that we are in with genetics."

Fortress IP

The traditional view is that strong patent protection stimulates innovation, reassuring companies that it is safe to invest in research without fear of being stung by rivals.

Under this "old" model of intellectual property (IP), biotech firms raced to file a "fortress" of patents around newly discovered genes, closing off avenues of research for their competitors.

But this strategy is ultimately counter-productive for both industry and consumers, argues the report, not least because it deters grass roots research in universities.

Work on the BRCA1 and BRCA2 genes that can cause breast cancer has been held up by legal disputes over patents held on the genes by Myriad Genetics, a biotech firm based in Utah, US.

Meanwhile, patients in European countries were denied access to the cancer screening kits, because national health services were unwilling to meet the cost.

The Myriad case is "an anatomy of old IP gone wrong", said Dr Gold, Professor of Intellectual Property Law at McGill University in Montreal.

"Myriad is not the exception - it is the rule. Others are following and will continue to follow, unless we drastically change things."

To facilitate sharing of information, he believes companies should be encouraged to form "patent pools", allowing them to cross-license their technologies without losing out on royalties.

An example is the pool established by the international partnership Unitaid to provide HIV patients in developing countries with access to affordable anti-retroviral drugs.

Partnerships

Governments should develop public-private partnerships to conduct early stage research, and seek other ways to encourage innovation - via tax credits, for instance.

Meanwhile, patent offices must standardise their information gathering and do more to help firms in developing countries gain access to accurate patent information, the report recommends.

Reform now would ensure that society feels the full benefit of new fields such as synthetic biology, a discipline that could lead to cells with novel genomes which perform useful functions, such as making biofuels or absorbing greenhouse gases.

Dr Craig Venter, the man who led the private sector effort to sequence the human genome, has already raised eyebrows by applying to patent the method he plans to use to create a "synthetic organism".

Fears that these patents may be too broad have been raised by the ETC Group, which campaigns for the reform of biotech patenting.

"The patenting system is not functioning. It is more of a barrier than an incentive," said Pat Mooney, the organisation's executive director.

"In pharmacy, we no longer see much discovery - we see firms playing safe and holding onto their turf.

"Meanwhile, in nanotechnology, we have seen some dangerously broad patents, which cut off whole areas of research.

"Patent offices must get up to speed with new areas of science, so they know exactly how much they are giving away."

Story from BBC NEWS:

<http://news.bbc.co.uk/go/pr/fr/-/2/hi/science/nature/7632318.stm>

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Patent wars hurting life sciences

[Print](#)

By Clive Cookson in London

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The drive to accumulate and defend patents is stifling innovation, particularly in biotechnology and healthcare, according to a Canadian-led international study.

Richard Gold, a law professor at McGill University in Montreal who chairs the International Expert Group on Biotechnology, Innovation and Intellectual Property, presented the study's findings in London on Tuesday, and called for a more collaborative and trusting approach in the life sciences.

"The old [intellectual property] 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 [information technology] world has shown us part of the solution," said Prof Gold.

"Look at the way that change has swept through the IT world and brought benefits to millions."

The group did not oppose the principle of patent protection for discoveries. It was concerned at the confrontational way in which companies and universities amassed and defended as many patents as possible.

Case studies showed that aggressive patenting was counterproductive. One example concerned controversial patents awarded to [Myriad Genetics](#), a Utah-based company, for breast cancer genes. If the company and opponents in European and North American public health services had taken a less confrontational attitude, it was suggested, both sides would have benefited.

Prof Gold said reform of the world's intellectual property laws to encourage collaboration would not be realistic. Governments could make more use of existing provisions to enforce licensing and "march-in rights" when patent holders were behaving unreasonably, but change would be most effective if it came from the life sciences industry itself.

Attitudes were beginning to change, particularly in pharmaceutical companies. "I think the leadership is more likely to come from the pharmaceutical than the biotechnology industry," he said. "I have talked to biotech executives who say the message we are giving is the right one, but [they] cannot afford to say so openly."

The expert group backed the idea of more public-private partnerships to share risks during early stages of research, and more patent pooling during the later stages of development and commercialisation.

"The IT industry does it better because IT encountered the limitations of the old business model sooner," he added. "You can see it in the rise of a sustainable open source movement and in the way companies like IBM changed their attitude and now license out IP quite liberally."

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Canada

INTELLECTUAL PROPERTY

Patent system seen stifling medical breakthroughs

A more collaborative approach is needed to bring research to market, McGill professor says in report

BY CAROLINE ALPHONSO

An outdated intellectual property system is preventing life-saving medicines and cutting-edge technologies from reaching those who need them the most, a leading expert on patents asserted yesterday.

"If things don't change, we're going to all have fewer medicines to treat whatever the next diseases are," warned E. Richard Gold, director of the Centre for Intellectual Property Policy at McGill University. "Not only will we not develop those drugs for cancer and heart ... but we won't get the innovative breakthrough drugs unless we change."

From communities in Brazil to corporate boardrooms, Dr. Gold and his team found an endemic mistrust among those involved in the patent system that is stifling innovation and

preventing technology from entering the market and helping those in both developed and developing nations.

He and his colleagues presented their report, which was seven years in the making, to civil servants and industry observers in Ottawa yesterday.

The report found that the heavy-handed control on patents resulted in much controversy – and that change is needed.

Talks between Myriad Genetics of Salt Lake City, Utah, for example, and Canadian officials broke down in 2003 after the company claimed intellectual property rights over the BRCA1 and BRCA2 genes, which contain information that can reveal a woman's risk of developing hereditary forms of breast and ovarian cancer.

In Brazil, meanwhile, non-governmental agencies help

residents sue companies that use indigenous knowledge without consent, but don't even consider helping them enter into agreements instead, which results in a level of mistrust on all sides, Dr. Gold said.

"The era of old IP [intellectual property] had multiple flaws," the report states. "It failed to recognize that knowledge leads best to new products and services if shared. It wrongly assumed that companies obtain IP to protect their inventions from being copied rather than to trade or enhance their reputations. ... Old IP failed to come to grips with the reality of public health and public health-care systems."

Dr. Gold said that, if anything, the biotechnology community needs to learn from the information-technology sector, which has become



If things don't change, we're going to all have fewer medicines to treat whatever the next diseases are.

E. Richard Gold, director of the Centre for Intellectual Property Policy, McGill University

more collaborative.

"Obviously, there is innovation happening, but we're not getting as much as we should," he said. "Clearly, there are technologies that are being marketed today because of the intellectual property system we have. But there are equally technologies that are never developed or not delivered be-

cause of the intellectual property system we have. We need to adjust the way we think of intellectual property rights."

Biotechnology advocates have warned that changing the patent system will be bad for business and science, because companies will not conduct research that they cannot commercially protect.

Dr. Gold dismissed the suggestion. "If they actually won, in the long term that would actually hamper their success," he said, adding that it would limit the number of new products and technologies that enter the marketplace.

He said that in talking with officials in the industry, many say they would like to find ways to work together with government and non-governmental agencies. And he said the Canadian government

should encourage collaboration through incentives such as tax credits and direct funding.

"We don't need to strengthen patent laws, we need to better use patents," he said. "The Canadian government should resist claims to increase the life of a patent or to make injunctions easier to get."

Realizing that the system is flawed, the U.S. Supreme Court has achieved a better balance in the American patent system by allowing researchers to do certain work and not be sued, he said. And agencies, such as the Organization for Economic Co-operation and Development, are calling for greater collaboration.

"It's not getting rid of patent rights," Dr. Gold said. "It really is about thinking what we want to do with them."

Le Monde

Mercredi 10 septembre 2008

SANTÉ

Un groupe d'experts recommande de repenser les règles du droit des brevets

LES RÈGLES qui fondent la propriété intellectuelle dans le domaine de la pharmacie et des biotechnologies doivent cesser d'être des outils de confrontation pour évoluer vers plus de coopération et de négociation. Telle est la thèse qui a été défendue, mardi 9 septembre, à Ottawa par Richard Gold, professeur à l'Université McGill de Montréal (Canada), qui présentait, au nom du « Groupe international d'experts en biotechnologie », un rapport intitulé « Vers une nouvelle ère de propriété intellectuelle : de la confrontation à la négociation ».

Ce rapport, initié voilà sept ans par M. Gold à l'Université McGill, a été financé par le gouvernement canadien. Ce travail est le résultat de sept ans de recherches menées par ce groupe international d'experts en droit, en éthique, en sciences, en gestion et en économie.

Sa thèse principale est qu'en matière de sciences du vivant les règles de la propriété intellectuelle ont vécu. Elaborées dans les années 1980 aux Etats-Unis, celles-ci ont d'abord facilité l'essor de la recherche sur les sciences du vivant. L'autorisation donnée par la Cour suprême américaine de breveter les modifications génétiques d'une bactérie a servi de base à un édifice juridique complexe destiné à protéger l'énorme investissement consenti annuellement par le budget fédéral américain en faveur de la recherche en biologie. Tout progrès de la connaissance devait pouvoir être protégé. « Les brevets furent ainsi étendus aux logiciels, aux animaux, aux plantes... » Parallèlement, en Europe et au Japon, les gouvernements ont adapté leur législation. Progressivement, les règles furent intégrées à l'Organisation mondiale du commerce (OMC).

Favoriser la coopération

Le Groupe international d'experts estime que le procès intenté par 39 laboratoires à l'Afrique du Sud à la fin des années 1990 pour empêcher l'importation de génériques de médicaments antisida encore protégés par des brevets a sonné le glas du système. Depuis dix ans, les conflits Nord-Sud se sont multipliés, obligeant tantôt les gouvernements à élaborer des dérogations au droit des brevets, tantôt les laboratoires à négocier des compromis au coup par coup. Plutôt que de maintenir un système caviardé par un nombre croissant de transgressions, les rapporteurs proposent de revoir en profondeur un droit des brevets qui aboutit aujourd'hui à « détruire la confiance » au lieu d'engendrer la coopération.

Parmi leurs nombreuses recommandations, ils proposent aussi la création d'intermédiaires ou « bâtisseurs de confiance » qui pourraient jouer un rôle de médiateur dans les conflits liés à la propriété intellectuelle. Ils demandent que les administrations qui enregistrent les brevets facilitent l'accès aux données et proposent que le secteur privé joue le jeu de la transparence « quant aux brevets qu'il détient et quant aux pays où ces brevets sont en vigueur ». Ils réclament que le monde scientifique prenne ses responsabilités et impose aux milieux d'affaires des transferts de savoir-faire et des collaborations en direction des pays les moins développés. ■

YVES MAMOU

POLICY BRIEFING - BIOTECHNOLOGY

Time to fix, modernize innovation gap, say biotechnology industry stakeholders

Feds' science and technology strategy released last year 'sent the right message,' but Canada's biotechnology environment needs to be modernized.

By BEA VONGDOUANGCHANH

More needs to be done to fix and modernize an innovation gap in skills and regulatory systems and it must be done in a collaborative way, say biotechnology industry stakeholders.

Richard Gold, McGill University innovation and intellectual property associate professor, says Canada's biotechnology industry should be moving toward a "new era" of collaboration between academia, the private sector and the government.

"What's needed is to understand that innovation is a circle, not a line," said Prof. Gold, who also chaired the International Expert Group on Biotechnology, Innovation and Intellectual Property which released a report two weeks ago on its findings of a seven-year study on "the emerging sea of change in how intellectual property in the life sciences is understood."

BIOTECCanada president and CEO Peter Brenders told *The Hill Times* last week that although the federal government's science and technology strategy released last year "sent the right message," Canada's biotechnology envi-

ronment needs to be modernized. "I'm not sure our competitiveness is as strong as it once was," he said. "It's tough to see a lot of our companies looking for investments in other jurisdictions south of the border. It's tough for the introduction of new technologies. It's one thing to invest, but can it be adopted? For example, health technologies when they come to market, don't get easily adopted in Canada."

The Conservative government's strategy, *Mobilizing Science and Technology to Canada's Advantage*, states that "Canada's overall productivity gains are below those of other trading nations with whom we compete [and] the need to encourage greater private-sector S&T investment is a national priority."

To address this, the government announced changes to the Scientific Research and Experimental Development program which would increase the expenditure limit for tax credits from \$2-million to \$3-million; facilitating university, business and government collaboration through an \$82.4-million investment in the Networks of Centres of Excellence; and R&D investments through the Industrial Research Assistance Program.

In a speech to the Montreal Neurological Institute and Hospital in February, Industry Minister Jim Prentice (Calgary Centre-North, Alta.) said the S&T strategy would help Canadians gain skills for the knowledge-based economy, give researchers more resources "to stay at the forefront of international research and discovery" and create a strong business environment to help products get to the market.

"We know that the future belongs to countries that invest aggressively in innovation," Mr. Prentice said. "In

looking at where we are going, it is evident that the stakes for R&D leadership have been

raised in this global knowledge-based economy. It is clear, as well, that the government of Canada has an obligation to respond, and that we intend to do so."

Although the strategy puts science and technology on the front burner, Prof. Gold said that it's still "linear" and needs to focus more on collaborative efforts.

"We actually have quite a good scientific infrastructure. We invest in our universities, we have top-level universities with good levels of equipment, federal grants and provincial grants available for it," he said. "What we're not good at is having that knowledge transform itself into real economic growth and new products and services and that's because we're working on this old model where universities are doing a good job generating ideas but then it doesn't go anywhere."

Prof. Gold said that innovation is declining and cited an example from the pharmaceutical industry. Between 1961 and 2005, there has been a global decline in the number of chemical product introductions from approximately 440 to 160, according to research by Marc-André Gagnon, a post-doctoral fellow at McGill.

"If our innovation system were working, we should be able to sustain levels of innovation, but we actually have declining levels of innovation within the pharmaceutical sector and even the number of products they've put on the market is going down, they're less innovative," Prof.

Continued on Page 17

'What we're not good at is having that knowledge transform itself into real economic growth and new products and services and that's because we're working on this old model where universities are doing a good job generating ideas but then it doesn't go anywhere.' —Richard Gold, McGill University

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In-House Research

Source: Research and Development (R&D) Expenditures on Therapeutic Health Products, by type of organization
Statistics Canada, Industrial Research and Development 2006, intentions, Catalogue No. 88-202-XIE, November 2007.

*Including Research-Based Pharmaceutical Companies, Biopharmaceutical and Biotechnology Companies



ECO - Un groupe d'experts appelle à une "nouvelle ère de propriété intellectuelle"

NEW YORK, 9 sept 2008 (AFP)

Un groupe d'experts internationaux a appelé mardi à une "nouvelle ère de propriété intellectuelle", estimant que le régime actuel des brevets était un frein au développement de l'innovation et à la diffusion de nouveaux produits, spécialement dans le domaine de la santé.

"La conclusion principale est que les décideurs politiques et les dirigeants d'entreprise doivent donner corps à une nouvelle ère de propriété intellectuelle afin de stimuler l'innovation et d'élargir l'accès aux découvertes", notamment dans les pays en développement, relève le Groupe international d'experts en biotechnologie, innovation et propriété intellectuelle.

"Les activités les plus novatrices ont lieu lorsque tous, chercheurs, entreprises, gouvernements, ONG, travaillent ensemble pour s'assurer que les nouvelles idées soient transmises au public tout en étant encadrées de façon appropriée et diffusées efficacement à ceux qui en ont besoin", précise le groupe présidé par Richard Gold, de l'Université McGill de Montréal, auquel ont participé quinze autres universitaires, pour la plupart basés au Canada, sous l'égide de l'organisation TIP (Partenaires dans l'innovation) soutenue financièrement par le gouvernement canadien.

Les experts ont formulé vingt recommandations, adressées aux gouvernements, aux offices des brevets, ainsi qu'aux secteurs privés et universitaires et aux médias.

Aux gouvernements, il est demandé de s'intéresser autant "à l'environnement dans lequel se développe l'innovation - notamment à la réglementation des effets de la biotechnologie sur la santé et l'environnement, à l'indépendance du système judiciaire, aux laboratoires - qu'à la propriété intellectuelle".

Aux pays dotés d'un système public de santé, il est demandé de "travailler avec l'industrie, les organismes de financement et les universités pour développer un partenariat public/privé gérant les données liées à la santé afin de stimuler les collaborations et l'innovation".

"Les agences gouvernementales de financement devraient cibler le développement de nouveaux modèles d'affaires viables et leur implantation, spécialement dans les pays à revenus faibles et moyens".

Les experts demandent en outre aux bureaux de brevets de "mettre en place des sections politiques pour étudier les moyens de rendre disponibles un plus grand nombre de données, aider à évaluer l'environnement des brevets et diffuser des informations sur le système de brevets".

Le secteur privé quant à lui est appelé à "faire preuve de transparence quant aux brevets qu'il détient et quant aux pays dans lesquels ces brevets sont en vigueur. Les universités devraient "établir des principes clairs sur l'utilisation et la diffusion de leur propriété intellectuelle, visant notamment à en élargir l'accès. Ces principes devraient également requérir l'utilisation de contrats de licence facilitant la recherche et le développement de produits dont ont besoin les pays en développement", soulignent les experts.



Agence France Presse - Portuguese

<http://afp.google.com/article/ALeqM5gT6sLO6QWCfLEyDdNTxIldJHotmg>

Especialistas pedem a abertura de uma 'nova era do direito autoral'

1 hora, 26 minutos atrás

NOVA YORK (AFP) - Especialistas internacionais reunidos nesta terça-feira em Montreal, no Canadá, abordaram a necessidade de uma "nova era do direito autoral", considerando o regime atual de patentes um entrave ao desenvolvimento da inovação e da difusão de novos produtos, especialmente no campo da saúde.

"A conclusão principal é que as pessoas que tomam decisões políticas e os dirigentes das empresas devem dar lugar a uma nova era de propriedade intelectual para estimular a inovação e ampliar o acesso às descobertas", fundamentalmente nos países em desenvolvimento, indicou o Grupo Internacional de especialistas em biotecnologia e propriedade intelectual.

"As atividades mais inovadoras acontecem quando todos, pesquisadores, empresas, governos, ONGs, trabalham juntos para garantir que as novas idéias sejam transmitidas ao público, sejam registradas de forma apropriada e difundidas com eficácia para quem precisa delas", destacou o grupo, presidido por Richard Gold, da Universidade McGill de Montreal, na qual estavam presentes mais 15 universitários, a maioria do Canadá, sob a égide da organização TIP (Sócios na inovação) respaldada financeiramente pelo governo canadense.

Os especialistas formularam 20 recomendações, dirigidas aos governos, escritórios de patentes, aos setores privados, aos universitários e à mídia.

Aos governos, pediram que se interessem tanto pelo ambiente no qual são desenvolvidas as inovações, principalmente a regulamentação dos efeitos da biotecnologia sobre a saúde, o meio ambiente, a independência do sistema judiciário, os laboratórios, quanto pela propriedade intelectual".

Eles pediram ainda que os governos trabalhem junto à indústria, os organismos de financiamento e às universidades para desenvolver uma associação público-privada que administre os dados ligados à saúde para estimular as colaborações e a inovação.

Os especialistas disseram que as agências governamentais de financiamento devem apontar para o desenvolvimento de novos modelos de negócios viáveis e sua implementação, especialmente nos países com baixas e médias rendas.



Agence France Presse - Spanish

Martes, 9 de Septiembre de 2008, 10:08hs

Fuente: AFP
EEUU-patentes

Un grupo de expertos llama a una "nueva era de la propiedad intelectual"

Un grupo de expertos internacionales llamó el martes a una "nueva era de propiedad intelectual" estimando que el régimen actual de patentes es un freno al desarrollo de la innovación y la difusión de nuevos productos, especialmente en el terreno de la salud.

"La conclusión principal es que quienes toman las decisiones políticas y los dirigentes de empresa deben dar lugar a una nueva era de propiedad intelectual para estimular la innovación y ampliar el acceso a los descubrimientos", fundamentalmente en los países en desarrollo, indicó el Grupo Internacional de expertos en biotecnología, innovación y propiedad intelectual.

"Las actividades más innovadoras tienen lugar cuando todos, investigadores, empresas, gobiernos, ONG, trabajan juntos para asegurarse que las nuevas ideas sean transmitidas al público, enmarcadas de forma apropiada y difundidas eficazmente a quienes las necesitan", precisó el grupo presidido por Richard Gold, de la Universidad McGill de Montreal, en el cual participaron otros 15 universitarios, la mayoría provenientes de Canadá, bajo la égida de la organización TIP (Socios en la innovación) respaldada financieramente por el gobierno canadiense.

Los expertos formularon 20 recomendaciones, dirigidas a los gobiernos, oficinas de patentes y los sectores privados, universitarios y de los medios.

A los gobiernos pidieron interesarse tanto en "el entorno en el cual se desarrolla la innovación - fundamentalmente la reglamentación de los efectos de la biotecnología sobre la salud y el medio ambiente, la independencia del sistema judicial, los laboratorios- como en la propiedad intelectual".

A los países dotados de un sistema público de salud les pidieron "trabajar con la industria, los organismos de financiamiento y las universidades para desarrollar una asociación público-privada que administre los datos vinculados a la salud para estimular las colaboraciones y la innovación".

Añadieron que las agencias gubernamentales de financiamiento deberían apuntar al desarrollo de nuevos modelos de negocios viables y su implantación, especialmente en los países con ingresos bajos y medianos.

chr/fga/aic/ja



Asian News International

Research reveals biotech patent system breakdown

Posted: 9/10/2008 1:18:00 PM IST

Washington, Sept 10 (ANI): After conducting case studies in India, Brazil, Canada, Kenya the United States, the European Union, Japan and Australia, experts have said that the world's biotechnology patent system is broken.

The study by an international coalition of experts has claimed that the crisis in biotechnology has led not only to economic problems but to endemic mistrust among its various actors that is stopping lifesaving technologies from reaching the people who need them most in developed and developing countries.

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. 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, said Richard Gold, professor of intellectual property at McGill University and chair of the International Expert Group that produced the report.

In the report, namely 'Toward a New Era of Intellectual Property: From Confrontation to Negotiation', the authors have made a number of concrete recommendations pointing to governments, the private sector and universities as crucial players.

They have called for better management of scientific knowledge and new ways to measure whether technology transfers are working.

The seven years study, according to Gold is based 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 many developed and developing countries like India.

The researchers have highlighted an increasingly dysfunctional industry that relies on a business model based on outdated conceptions of IP.

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. Look at the way that change has swept through the IT world and brought benefits to millions, said Gold.

They said that apart from various innovations, biotechnology brings with it a host of problems. The report finds that a fixation on patents and privately-controlled research has frequently given rise to controversy and roadblocks to innovation.

Based on a study of measures of success, stem cell researchers have suggested that those who patent the most, collaborate the least,.

The Expert Group has said 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.

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.

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 paediatric 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, said Gold.

He added: 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 behaviours 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. (ANI)

IP laws creating 'bare medicine chest'

By ABC Science Online's Dani Cooper

Posted Wed Sep 10, 2008 2:00pm AEST

Updated Wed Sep 10, 2008 2:18pm AEST

The report recommends governments encourage private-public collaborations to conduct early-stage research to allow sharing of risk. (www.sxc.hu: Rodolfo Clix)



The world's intellectual property (IP) system is broken and the benefits of biotechnology are being blocked by patent laws, according to the authors of a seven-year study.

The Canadian-led study outlines ways to improve the system and help deliver lifesaving technologies to "the people who need it most".

It comes ahead of the close of public submissions next week into a review of Australian patent laws and what matters should be patentable.

The report, by the International Expert Group on Biotechnology, Innovation and Intellectual Property, finds a fixation on patents and privately controlled research has led to controversy and roadblocks to innovation.

It highlights the increasingly "bare medicine chest" of the pharmaceutical industry and the failure to deliver life-saving medications to the developing world as two of the areas of critical concern.

"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," Group chair Professor Richard Gold, of Canada's McGill University, said.

The report also found that stem cell researchers who patent the most collaborate the least.

Among the report's recommendations is a call for governments to encourage private-public collaborations to conduct early-stage research to allow sharing of risk.

It also suggests universities should change their measures of success of transfer of technology based on social returns rather than on the number of patents held.

Failing to deliver

Associate Professor Dianne Nicol, a biotechnology and intellectual property expert within the University of Tasmania's School of Law, who was one of the international experts consulted for the report, says its recommendations are "sensible".

"It doesn't say we've got to completely change the IP system, it says we've got to make it work better," she said.

"The main failing [at the moment] is that you can just use intellectual property laws as a barrier to prevent other people from accessing your knowledge, rather than using IP to utilise knowledge for the benefit of society as a whole."

Associate Professor Nicol says despite its promise, the field of biotechnology has failed to yield significant breakthroughs.

"The lack of sharing of knowledge is problematic in this area," she said.

The report highlights an ongoing issue in Australia over patenting of the BRCA1 and BRCA2 genes that are markers for hereditary breast cancer.

Owner of the gene patents, United States company Myriad Genetics, has been embroiled in controversy in Canada and throughout Europe over demands diagnostic testing for the genes could only be carried out by its laboratories.

Melbourne-based company Genetic Technologies has an exclusive license to use Myriad Genetics's patents to perform diagnostic testing for the genes in Australia and New Zealand.

After saying in 2002 that it would not stop other government-funded services from performing the test, Genetic Technologies announced in July it would enforce its exclusive rights over the two genes.

"Effectively the intellectual property system does give those sort of rights," Associate Professor Nicol said.

"The question then is how are those sort of rights utilised."

'Gravy train' myth

Associate Professor Nicol says the idea that patents can protect profits from new discoveries is largely a myth.

"When you look at the returns research institutions are getting they are pretty minimal," she said.

"It's not the gravy train many people were expecting."

She says unless the system is overhauled, the promises of genome and biotechnology will not be realised.

The Australian Government's Advisory Council on Intellectual Property is currently accepting submissions as part of its review on patentable subject matter, which closes on 19 September.

Among the questions raised by the paper are what matters should be patentable, whether limits on patentable matter can be justified on ethical grounds and whether current legislation is appropriate.

<http://www.abc.net.au/news/stories/2008/09/10/2360875.htm?section=world>

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Sistema de patente tem falhas

Pesquisa mostra como gargalos atrasam inovação

Giovana Girardi

O sistema de propriedade intelectual está falido. Do jeito como é feito, está atravancando o processo de inovação e o que existe em novas tecnologias não alcança quem mais precisa. Essa é a conclusão de um trabalho divulgado anteontem em Ottawa, Canadá, por uma equipe internacional de cientistas que inclui uma brasileira.

Após acompanhar por sete anos processos de negociações em várias partes do mundo, os pesquisadores concluíram que o sistema que congrega marcas e patentes, direitos autorais, direitos das comunidades tradicionais, entre outros pontos, tornou os procedimentos tão rígidos e gerou tamanha falta de confiança entre os diversos atores do processo que acabou ficando insustentável.

“Nós vemos cada vez menos produtos da indústria farmacêutica que realmente trazem alguma inovação. O potencial biotecnológico não se reverte em novos tratamentos para doenças ou em soluções para o combate à fome. Tanto nos países em desenvolvimento como nos desenvolvidos”, afirma Richard Gold, professor da Universidade McGill e coordenador do Grupo Internacional de Especialistas em Biotecnologia, Inovação e Propriedade Intelectual, que realizou o estudo.

“É um mecanismo que deveria promover o acesso ao conhecimento, a novas informações e a medicamentos, por exemplo, mas não é o que vemos acontecer. Ele falhou e precisa ser revisado”, complementa Maristela Basso, da Faculdade de Direito da Universidade de São Paulo (USP). Ela explica que, no Brasil,

um dos maiores dilemas é em relação às comunidades tradicionais. O sistema de proteção do conhecimento desses povos não leva em conta, por exemplo, que eles são muito diferentes entre si e em relação aos outros.

“São indígenas, quilombolas, ribeirinhos, caiçaras. Temos o conhecimento de um grupo, o que está difundido por vários grupos e outro que é tão espalhado que acabou caindo em domínio público. Isso tudo tem de ser considerado tanto na hora de definir e acessar essas informações quanto na hora de repartir eventuais benefícios.”

Ela acredita que a situação acaba favorecendo a biopirataria e a falta de confiança entre as partes. Então, sem pesquisa, o País fica, também, sem inovação. ●

Science and Development Network

News, views and information about science, technology and the developing world

[Home > News](#)**NEWS****Intellectual property 'needs revamp' for developing nations**

Brett Cherry

16 September 2008 | EN | 中文

New intellectual property (IP) strategies must be adopted if developing countries are to benefit from innovations in biotechnology, says a group of international experts.

The IP system for biotechnology lags behind other industries in making its products and research more accessible, according to an expert group from The Innovation Partnership (TIP), a non-profit organisation funded by the Canadian government and organised through McGill University, Canada.

Richard Gold, president of TIP and chair of the expert group, says biotech companies and governments worldwide will have to let go of their "old IP approach" if they are to use their research to address disease and hunger in developing countries.

The study finds that companies fear developing countries do not respect IP laws, while developing countries worry that the developed world is expanding its IP rights without regard for their needs.

"There is certainly this view that the patent system being imposed on low- and middle-income countries is basically a transfer of rent from developing countries to high-income countries with very little return," says Gold.

"We have internationalised high-income country IP laws and imposed them on lower- and middle-income countries for whom the system we have developed for ourselves may not work."

In order to bridge this mistrust, the study recommends 'patent pools' — consortiums of biotech companies, nongovernmental organisations, manufacturers and national governments that share patents — to deliver medicines, foods and other products to people in developing countries.

For example, UNITAID — an international drug purchase facility — operates a patent pool to formulate medicines specifically for developing countries to manufacture and distribute at a low price.

The authors say patent pools would licence production, of a drug for instance, out to manufacturers who would be overseen by an independent technology assessment organisation to ensure standards of new biotech products from developing countries.



The US patent seal. But Western patent systems may not work for the developing world.
US Patent and Trademark Office

2008-09-17

Intellectual property 'needs revamp' fo...

And new IP strategies like patent pools could also assist technological development in the developing world, says Gold. "There is a lot of technology being developed in low- and middle-income countries, but they don't have access to the financing and business models to bring that technology forward."

To make medicines more accessible, the authors recommend pharmaceutical companies make substantial investments in public-private partnerships that will make the knowledge behind those medicines available in the public domain so countries can develop their own.

The report also recommends collaboration between universities from high- and low-income countries, especially developing postgraduate programmes enabling students from developing countries to focus on research in their home countries.

"This has the benefit of allowing these researchers to focus on problems at home without abandoning them, but also teach their community and build up an infrastructure in those countries so they can stay at home and continue to address the problem," Gold told SciDev.Net.

[Link to full report](#)

<http://www.scidev.net/en/news/intellectual-property-needs-revamp-for-developing-.html>

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Research says copyright system has collapsed

Written by Steve Mbogo



Pills. The global intellectual property system has collapsed

September 11, 2008: Days after Kenya's traditional medicine men admitted keeping medicinal inventions to themselves for fear of losing ownership to researchers, a new research says the global intellectual property system has collapsed.

The new report, partly based on research conducted in Kenya, says that the collapse is stopping life-saving technology from reaching people who need it most.

"No matter where we looked, lack of trust played a vital role in blocking (intellectual property) negotiations that could have benefited both sides, as well as the larger public," said Richard Gold of McGill University and the International Expert Group that produced the new study.

"We found similar 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."

The authors base their findings on revelations that came out of discussions with policy-makers, industry representatives, scientists and academics from around the world and outcomes of a series of case studies involving Brazil, Canada, Kenya among other countries.

http://www.bdafrica.com/index.php?option=com_content&task=view&id=9961&Itemid=5813

Study: Biotech patent system broken

September 10, 2008

By Maureen Martino

Researchers at Canada's McGill University studied patent systems from around the world and have found that, regardless of the country, the world's patent system is in serious trouble. "We found the same stumbling blocks in the traditional communities of Brazil as we did in the boardroom of a corporation," said Richard Gold, 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 study authors call the biotech patent system "outdated," and contrast it with the far more successful IT patenting system.

The problems, they say, is that fixation on patents and privately-controlled research has hampered innovation. Those that hold the the most patents are the least likely to collaborate, and the current system breeds mistrust among companies and researchers. "We need an IP system that will support collaborations...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," observed Gold.

The study, which can be viewed [here](#), included recommendations for governments, industry leaders, researchers and universities.

- see the [patent study release](#)

<http://www.fiercebiotech.com/story/study-biotech-patent-system-broken/2008-09-10>

From Monitor Online

Intellectual property can work for developing nations

Posted in: **Business & Technology**

By Brett Cherry

Sep 21, 2008 - 12:02:37 AM

New intellectual property (IP) strategies must be adopted if developing countries are to benefit from innovations in biotechnology, says a group of international experts.

The IP system for biotechnology lags behind other industries in making its products and research more accessible, according to an expert group from The Innovation Partnership (TIP), a non-profit organisation funded by the Canadian government and organised through McGill University, Canada.

Richard Gold, president of TIP and chair of the expert group, says biotech companies and governments worldwide will have to let go of their "old IP approach" if they are to

use their research to address disease and hunger in developing countries.

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And new IP strategies like patent pools could also assist technological development in the developing world, says Gold. “There is a lot of technology being developed in low- and middle-income countries, but they don’t have access to the financing and business models to bring that technology forward.”

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‘Old IP’ System Stifles Biotech Innovation, Hinders Third-World Rx Access, Report Says

[September 10, 2008]

*Richard Gold
Associate Professor,
Center for Intellectual Property Policy
McGill University*

NAME: Richard Gold

POSITION: Associate professor of innovation and intellectual property and director, Centre for Intellectual Property Policy, McGill University; president, The Innovation Partnership

BACKGROUND: Research associate, Health Law Institute, University of Alberta; fellow, Einstein Institute for Science, Health & the Courts; assistant professor, University of Western Ontario; associate, Torys LLP; clerk, Supreme Court of Canada; clerk, Ontario Court of Appeal

The world’s intellectual property system is broken, stifles innovation, and prevents life-saving technologies from reaching patients in developed and developing countries, according to a report released this week by an international IP coalition.

The report, entitled “Toward a New Era of Intellectual Property: From Confrontation to Negotiation,” was funded by the Social Sciences and Humanities Research Council of Canada, and is the result of seven years of work by McGill University professor Richard Gold and a group of experts in law, ethics, and economics called the International Expert Group on Biotechnology, Innovation, and IP.

In the report, the authors present findings from discussions with international policy makers, industry representatives, scientists, and academics, as well as from several biotech IP case studies from around the world.

According to the report, biotech policy makers, business leaders, and academics rely too heavily on an “old IP” system that encourages as much patenting as possible and is counterproductive to innovation and hinders developing nations from accessing potentially life-saving technologies.

Instead, the authors assert that biotech players need to adopt a “new IP” strategy that focuses on cooperation and collaboration at all levels; and they make several recommendations to government, industry, and university officials to help implement such a strategy.

Among these recommendations are for universities to develop clear IP-licensing principles to promote greater access to biotechnology innovations and to develop better measures of tech-transfer success based on social returns; for industry to participate in more public-private partnerships and to be transparent about their patent holdings; and for governments to take a more active role in encouraging and mediating public-private partnerships and to collect standardized patent-related information, including licensing data.

The full report, released at a press event this week in Ottawa, can be found on the website of The Innovation Partnership, a non-profit that will focus on addressing many of the issues raised by the research. Comprehensive data supporting the group's report will be released on Oct. 14 at a press event in Washington, D.C.

This week, McGill's Gold gave a snapshot of the report's findings – particularly their implications for university biotech transfer – in an interview with BTW.

What was the impetus for this study and report? Who were the major players involved in its creation?

It started in 2001. There was a small group of experts to start with. We recognized several trends: the increased debate about technology transfer and the role of the university in tech transfer; the debate about research exceptions, particularly in the US, but not exclusively; and debates over access to medicines – so the [World Trade Organization Ministerial Conference of 1999] in Seattle had just happened, followed by the Doha Declaration [on the TRIPS Agreement and Public Health] in 2001. Following this there was ... greater questioning of tech transfer, and questioning of the Bayh-Dole Act and its effectiveness in the US and other countries.

These were all trends that we were seeing all pushing toward the question: What is the role of technology transfer and innovation in biotechnology? There were also early signs that the pharmaceutical industry was seeing a declining level of innovation. There was already talk about their big blockbuster patents coming to the end, and how they would refill the medicine cabinet.

As these developments occurred we added depth to the team, and were funded by the Canadian government to look into these questions. Canada, after the US, is probably number two in biotech, at least per capita. The Canadian government has put a lot of investment – both at the national and provincial levels – in biotechnology, health, and agriculture. Also, [in 2003] Canada was the first country to [waive two licensing provisions of the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights], and [established] the Access to Medicines Regime, so these questions were quite important to the country. As time went by our research questions became more refined, and as developments happened, the research took its present shape.

The research group was the International Expert Group on Biotechnology, Innovation, and Intellectual Property, right? What was the role of the non-profit The Innovation Partnership in this?

It was an outcome, actually, perhaps a surprising one. When we started this work, we had few preconceptions about where our research would lead. But in several instances in different areas, we noticed there was a missing actor. That actor was kind of this 'trust builder,' as we describe it in the report. That trust builder needed to bring together the actors to allow collaborations to happen. And governments who normally one would think would fill that role hadn't been. We recognized that since trust was so critical to the development of these collaborations and essential to the future of biotechnology that someone had to play that role. We didn't see many actors out there, although there were a few.

But we felt it was important that we create one, as well, as an outcome of our research, for a couple of reasons. One is that we had already developed the network in doing our research. The research was done in collaboration with industry, NGOs, and so on. We already had developed a certain level of trust, had a network, and had developed and developing nations involved with the project, so we were well-positioned to do it. We're not the only ones – there are other groups that play this role, but we thought there was still a need.

One of the key findings in your report is the idea that academic researchers who are more likely to seek patents are less likely to collaborate with other researchers on a scientific level. Can you discuss this in a bit more detail? Do you have data backing this up?

Yes, the actual article that will be described in this will be put through a peer-review process. This is more of a preliminary finding, and the final report will come out after it has gone through the peer-review process. I'm fairly confident in the result, but it will come out in a purer form later with all the caveats that scientific literature would have.

In the past we've been able to measure fairly simple things about tech transfer, like its effect on publishing [of research]. But the big question is: If we are right – and I think the evidence supports that we are – that collaborations are key, then what is the effect of patents on this?

We've been getting at this backwards, in the ways we can, by using published literature – looking at the anti-commons problem, delays in publication, and so on. But so far we haven't been able to tackle the link between patenting and commercialization behavior, and the effectiveness and desire of PIs to get involved with collaborations. If patenting runs counter to it, that's something we ought to know. That wouldn't mean that patenting is bad; it just means that you have to either have counter-balancing forces, or be more careful at the university level about when you would encourage and allow patenting.

Essentially we studied a research consortium of stem cells in Canada, but who were internationally linked. The idea was to isolate for each of those actors how much they published and who they published with. We used publication with someone else as a proxy for collaboration. And then we looked at how much they patented. There was a lot of work just getting the data and clarifying the millions of relationships, but through those analyses you can then do regression analyses and so forth, and I'm not [the] statistician on the research team – but essentially we found that there was this oppositional effect of those who patented more tended to collaborate less. Of course there are some caveats that need to be put on it, but that was the bottom-line finding.

It's interesting that you used stem cells, since that area has been a lightning rod for IP controversy around the world. Do you think this finding may have been influenced by the fact that the commercial promise of stem cells is so great? Do you think your findings would have been the same if you used as a basis for this research question a vaccine for a disease that primarily affects developing nations, for example?

This is one of the things that we raise in the study – an absence of good empirical evidence. I think it always dangerous to extrapolate too far from one case study. Yes, I am able to say this with confidence about Canadian stem cell researchers, and I'm pretty confident about worldwide researchers because the links were international. And I think it's probably true for other fairly early-stage technologies in biomedicine – for instance, epigenetics, nanobiotechnology.

As you move to technologies that are used primarily in the developing world, there are fewer commercial opportunities, so the behaviors would likely be different. The policies at the universities become different, the funders become different. How significant these differences are – I don't know. You would have to run the same type of procedure on that. The advantage of what we've done is that we've disclosed a lot of how we've done it, so hopefully it will be easier for people to replicate it in stem cells and apply it to other fields, and only then will we find whether this conclusion is a general conclusion about biotech, about university research, or only about those technologies that seem to have a greater commercial value.

The report makes recommendations to academia, industry, and government, and the common theme is collaboration. Each of these groups has different motives when it comes to biotechnology research and commercialization, though.

They all have different motivations, and sometimes we look at one view and don't look at the other. So we tried to bring a global view here, and an understanding that different actors come to biotech research and development for different reasons.

At the same time, we identified the common interest, and that is collaboration. It is important to understand that industry gets involved with collaborations because in the end it has to meet [its] bottom line. As they're facing declining levels of innovation, they need to find ways to fill up the medicine cabinet. And a lot of the new technologies, like epigenetics or stem cells, are exceedingly high risk. It's difficult for

one company to take on that risk themselves, so they are going to be forced into collaborations to spread that risk, both financially and technologically. They're pushed to collaborate because really, if they are going to take advantage of biotech, yes they can buy biotech companies like they are doing now, but at a certain point that strategy is not going to work.

A university is pushed to collaboration for a very different reason, which is that they want to serve the public, and they want to keep their researchers involved in the most cutting-edge research. More and more evidence is suggesting that if universities – especially in more technologically focused fields – work by themselves, they're not going to get that. They need industrial partners. But they need to do it on the right terms ... and to understand what their motivation going in is.

Government is interested for different reasons. They're looking at social and economic development, though it will depend if you are a rich or poor country. If you are a rich country, and you have a good biotech sector, you want to maintain it; you want it to provide income; and to a certain extent, you also want it to provide needed products and services in your country, especially countries that have a public health care system – they pay for that service. If you're a developing country, you just want access.

No matter who you are, you need to be involved in collaborations. But everybody needs to know why they're involved and to understand why everybody else is involved, and I think that's the part that has been missing. Sometimes we just look at universities and we ignore why industry is involved and to what extent. Some people might say, 'This is publicly financed research, and therefore there should be no patents and anybody should be able to use it.' But that doesn't take into account how you are going to get industry to be actively involved. And sometimes industry doesn't recognize enough why universities are involved and what's in it for them. Part of our goal here is to explain that each one of them has a reason to collaborate, but they need to talk.

One specific recommendation in the report is for universities to develop clear principles for using and disseminating IP to ensure greater access. Many universities like the University of British Columbia (BTW, 6/4/2008), the University of California-Berkeley, and those involved with the Nine Points document (BTW, 3/19/2007) have begun to do this. Is this enough?

No. We were very pleased to see the Nine Points document, and that's a step in the right direction. But that's only the beginning. That's not setting up a really collaborative research platform. It's fine to have a university or a couple of universities involved with a couple of companies. But we're looking at larger partnerships where data is shared more. There are fewer of those, and they will have different flavors depending on where they are in the research cycle.

If you're looking at more fundamental research, like the Structural Genomics Consortium – that's a very large platform, with funding from multiple sources, including an important investment from industry, which I think is critical. I don't think a lot of public-private partnerships have relatively little investment by industry. And as they are moving into an epigenetics program, where the molecules that are developed will be completely in the public domain and no one will be allowed to patent or commercialize them in order to develop the basic knowledge of how epigenetics work and what its effects in humans are, you're going to have early-stage partnerships that need to be much more broadly based than they are now. What are those open platforms that are able to attract industry and universities? There is a start, but we haven't gone far enough. We need greater investment in these platforms, and I think that's where the government comes in, because I think the government needs to provide greater incentives for people to create those platforms – either through funding of those models, or as a participant, as the Structural Genomics Consortium has.

The Nine Points document is good, and UC-Berkeley's policies are moving in the right direction, and that's only in the US. In Canada, it's true that UBC has adopted global access principles, but that's more about humanitarian clauses and starting to think about measuring social outcomes of innovation. It's an important first step, and I congratulate them, but it's a far cry from where we need to be in terms of really designing these consortia. I've been talking to biotech industry leaders in Montreal, for instance, and saying, 'You actually should be sharing your information much more widely within the Montreal

community, and find the legal structures so that one company can learn from another – otherwise you're not going to be able to take these little atoms of knowledge and consolidate them into something new.'

That's thinking they haven't been involved with, and neither have Canada's universities, unfortunately, for the most part. We're about 10 years behind the US. And when you move outside the US, it's even farther behind. Europe is behind Canada in this regard, and then when you start looking at Africa or Asia, we're still trying to export Bayh-Dole. There is a lot of debate about how good Bayh-Dole is for the US, and clearly the jury is still out on it, but clearly it is not good for other countries. It was meant to respond to a particular structure that existed in the US where, in order for a university to get permission to transfer knowledge, they had to go through a huge bureaucracy. That doesn't exist in other places. The funding mechanisms for universities – large private universities like Harvard and Stanford that do tons of research and public good don't exist in most countries.

So Bayh-Dole doesn't export well, yet people are still implementing it. We did a course last year in Kenya, for example, and we told them to think about tech transfer as a way to disseminate their knowledge and not to make money, but they kept coming back to, 'How do we make money?' And they're not going to. There is a lot of learning that needs to be done about what tech transfer is about and what it is not. It's not about making money, it's about fulfilling the mission of the institution to create knowledge and disseminate it.

That leads to the report's recommendation to develop new ways to measure tech-transfer success. The focus has traditionally been on number of patents, licenses executed, and licensing revenues, but groups such as the Association of University Technology Managers are trying to develop metrics that can more accurately reflect the success of tech transfer (BTW, 12/10/07 and 3/5/08). Has your group developed any ideas on how to do this?

Yes and no. Part of this lack of a link between commercialization and networking was really part of an effort to try and answer the question: 'How do we develop empirical methods to establish the effectiveness and impact of innovation?' That was the aim of the project.

We don't have the answers yet, and we're trying to respond to that. And I understand why it is so hard for universities – because we haven't invested enough in developing the statistical methods. Too few people are doing this really difficult work of figuring out how to take this data and put it in a meaningful form. It's also that we need the data to be stored in a better form. When you have different patent offices around the world with completely different systems to search the data, with different information – it's very difficult to compare US performance to European performance to Canadian performance.

We also don't have much of a window on licensing practices, because those are mostly confidential. Unless we know what is actually happening in the license, it is very difficult. We don't collect data on that; the Japanese are trying to, by the way. So part of the call is yes, we want AUTM and universities to have better measures, but at the same time we need governments to be involved in collecting better data. These two things evolve together. We need more investment in the statistics end to see if we can actually find patterns that indicate success; have better data collection to make that possible; and have the openness that I think AUTM is demonstrating. It's a little bit of a chicken and egg problem right now.

People look to the US as an example because of the success of the biotech industry here, which is probably why other countries have sought to adopt a Bayh-Dole-like structure. But do you think that Bayh-Dole is working in the US, or that this report might be perceived as an argument that it needs to be reformed?

I think we'll leave the particular law reform in the US to Americans. If you look at our research team, we've got people on both sides of the equation. The real answer is that you can't look at Bay-Dole by itself. It came in at a certain time in 1980 within a patent regime that was already being modified. It's impossible to say that Bayh-Dole was or was not responsible. Yes, there are certain small problems with the exact way it works. Does it function? It may in the US setting. If you got rid of Bayh-Dole, would all the criticisms of the Patent Act go away? Certainly not. My guess is, by just looking at the literature, that Bayh-Dole was

more the tail than the dog. There were already structural changes happening in the US that better explain what happened than Bayh-Dole itself.

But you've got Bayh-Dole; it's embedded in your legislation; it's not going away. The better question, to me, is that given that it exists, as do march-in rights and other aspects of Bayh-Dole that haven't been exercised as much, what can we do with the system we have? Does it need substantial modification? I think there are some positive aspects of some of the proposals put forth, but again, that's for Americans to decide.

In my opinion, the US has a patent system that has the most checks and balances of any system in the world. You can isolate a couple of bad points about it, but there are a whole bunch of really positive aspects of US patent law. Unfortunately, when it is exported, we tend to only export part of it. You export the part of Bayh-Dole that says universities should commercialize. But you don't spread the march-in rights, and the high patenting standards of the US.

Has your group worked to promote some of these recommendations and changes at your own academic institutions?

Yes, I'm on the IP committee for McGill, and we'll soon be having a university-wide joint meeting on IP issues. I've been talking with the tech-transfer office. We'll be talking at the Canadian equivalent of AUTM in the fall. And similarly, our colleagues at the University of Alberta and the Ottawa University have been working with their tech-transfer offices. I can't say we've had enormous success, but it's a process.

Part of the problem is that tech transfer hasn't been seen as one of the overall missions of the university. It's been seen as a very narrow technical area and therefore lumped into a separate department. The people that run those, for the most part, recognize the problems. The problem is they hit a ceiling where they can't engage the senior management of universities. You get to the vice-president level of the institution, and the interest level goes down. They don't see it as one of the essential missions of the university. What was interesting at UBC, and part of the reason they have the policy they do, is that their president decided that this was important to the university. It's rare that senior officials at universities take this on.

Look at the fight that the Universities Allied for Essential Medicines had with universities like Yale, which one would expect would be a leader in this area. I realize there are differences in mandates between public and private universities, but there is a ceiling that a lot of people involved in these issues feel exist. Part of the message of this report is that this is actually essential to the well-being of the university. This is part of making the university relevant to its community; in particular, public universities, which all Canadian universities are, should be much more cognizant about not just counting patents. For example, a company moves to Montreal because they want to work with McGill researchers. That, to me, is a much better selling point for a university seeking funding from the public purse than, 'We got 50 patents this year.'

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