

THE HILL TIMES POLICY BRIEFING

BIOTECHNOLOGY

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BIOTECHNOLOGY POLICY BRIEFING: CAPITAL INVESTMENT



Biotechnology and government: Industry Minister Christian Paradis is the lead minister on biotechnology, but it also falls under others, including Science Minister Gary Goodyear, Environment Minister Peter Kent, Health Minister Leona Aglukkaq, and Agriculture Minister Gerry Ritz, among Cabinet ministers as well.

Private investment in Canada's biotech sector hits a 10-year low

Analysts say its time for industry and government to come up with creative solutions to attract venture capital and experienced execs.

By CHRIS PLEKASH

Canada's biotechnology sector is hard up for capital, and insiders are calling on the government and the industry to get creative when it comes to attracting investment.

According to an industry assessment published by Ernst & Young earlier this summer, private investment in Canada's biotechnology sector hit a 10-year low in 2010. The report estimates that the industry raised \$482-million in funding in 2010, down from \$733-million in 2009—a decline of more than 30 per cent. The auditor also found that the industry has not produced an initial public offering since 2007.

The news is troubling for Canada's bio-economy, which industry association BIOTECANADA estimates is worth more than \$80-billion, encompassing everything from biofuels to biopharmaceuticals. Because of the time and capital required to fund many biotech ventures, small and medium enterprises are high-risk investments. The association estimates that it takes \$1.5-billion over 10 years for a bioproduct to move from research and development, through clinical trials and regulatory approvals, before ultimately reaching market.

Paul Karamanoukian, Ernst & Young's expert on the Canadian life sciences industry, acknowledged that the worldwide economic downturn has been a major reason for the decline of available capital, but he also identified a number of domestic factors that have compounded the problem, including the sector's low profile within Canada and a lack of "serial entrepreneurs" willing to pursue repeat successes within the high-risk industry.

A recent industry survey by Pricewaterhouse Coopers and BIOTECANADA found that respondents were seeking more than \$1-billion in capital. Although the industry has struggled to raise capital in recent years, it's not from a lack of effort on the part of policy makers, said Jeffrey Graham, who specializes in biotech and pharmaceutical law with Borden Ladner Gervais LLP. "Federal and provincial governments across the country have all worked diligently to try to promote the growth and development of biotech economies in their respective jurisdictions," Mr. Graham said. "They haven't been able to solve the funding problem, particularly for early stage technologies."

Since announcing its Science & Technology Strategy in 2007,

the federal government has taken steps to encourage private investment in scientific research within Canada, but immediate benefits to the biotechnology sector have been limited. As part of the strategy, which set out to provide science and technology companies with an "entrepreneurial advantage" in the global economy, the government reformed the tax code to open innovative industries to venture capital from the United States.

One measure was the elimination of certain stipulations of section 116 of the Income Tax Act, which requires non-residents to pay tax on investments in Canada. Under the reformed section, foreign investors are no longer required to pay tax on investments that do not derive their value from immovable property.

The federal government's Scientific Research and Experimental Development (SR&ED) tax credit program also provides support for biotech and other scientific sectors involved in experimental development, basic and applied research, and technological support. Established in 1985, the SR&ED program provides a 35 per cent investment tax credit on the first \$3-million of qualified expenditures, and 20 per cent on all further expenditures.

According to the government's 2009 Science & Technology Strategy Progress Report, Canadian companies received \$4-billion in SR&ED tax credits in 2008. However, biotech is only one of many sectors competing for private investment, and continues to be disadvantaged by the time and money required for reaching market.

BIOTECANADA estimates that 90 per cent of Canada's biotech industry is made up of companies who have yet to commercialize a product, and is advocating that the program be reformed to increase the refundable expenditure limit from \$3-million to \$10-million.

Last year Conservative MP Gary Goodyear (Cambridge-North Dumfries, Ont.), minister of state for science and technology, announced a Research and Development Review Expert Panel to assess the efficacy of federal R&D funding in Canada. The panel, whose members are drawn from academia, government, and the private sector, is chaired by OpenText Executive Chairman and Chief Strategy Officer Tom Jenkins, and is expected to report to Mr. Goodyear later this fall. In addition to reviewing the SR&ED tax credit, the panel will also report on federal grant programs administered by specific departments and agencies.

The industry is now hoping that the government will extend the flow-through shares system enjoyed by mining, oil and gas,

and energy investors to the biotech sector. BIOTECANADA introduced a white paper proposing a similar system for the biotech industry late last year. Flow-through shares enable investors to deduct a share of a company's exploration and development costs from their taxes. A similar regime for biotech investment would allow investors to write off a share of a company's research and development costs.

While Mr. Karamanoukian concedes that the federal government has a role in making Canada's biotech industry appealing to investors, he also says that the industry must adapt to the current scarcity in investment. "They have to go hand-in-hand. People have the perception that science is a black hole, you just keep dumping money into it. But there's a way to make biotech more efficient," said Mr. Karamanoukian, stressing the need for more experienced executive management in Canada's biotech sector. "Businesses have to adjust to today's realities, and the government needs to come in and create a landscape that's harmonized and fair, and can compete against Europe, the U.S., and Asia."

Jeffrey Graham concurred that creative investment solutions are essential to the future success of Canada's biotech sector. "If we really want to create an industry here that's going to have world class presence and sustainability, we've got to think outside the box, we've got to get creative," said Mr. Graham. "We've got to be prepared to really help Canadian companies by successful both in commercializing technologies in Canada and then in going out and exploring international markets."

One recent success story for Canada's biotech sector is Zymeworks Inc., a Vancouver based company that last week announced a research agreement with pharmaceutical giant Merck. The deal is potentially worth \$187-million and will enable Merck to commercialize antibodies produced through Zymeworks' Azymetric antibody platform.

Zymeworks' CEO Ali Tehrani noted that Canada's biotech industry needs to attract experienced executives if it's going to tap into much needed foreign venture capital. Mr. Tehrani pointed to European programs for recruiting foreign business leaders as a model Canada needs to adopt. Countries such as Denmark provide foreign executives with three years of low income tax rates in an effort to attract experienced corporate managers.

"When you think about it, it's not a big deal," observed Mr. Tehrani. "Even if the salary is \$500,000, is the money they keep going to destroy the government's budget? It wouldn't—what they would do in turn is open the door for investments to come to their respective companies, which creates more jobs and the cycle keeps going."

Recruiting experienced senior level executives is a prerequisite to recruiting capital, added Mr. Tehrani. "Canadian companies need money. If the money's not in Canada, you've got to go to the U.S. What do the U.S. guys look for? They look for senior executives with a lot of experience that they recognize and feel comfortable investing in."

cplekash@hilltimes.com
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Photographs by Jake Wright, The Hill Times

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National Biotechnology Week

Semaine Nationale des Biotechnologies



bi-o-tech-nol-o-gy [bahy-oh-teck-nol-uh-jee]:

noun - the use of living organisms, or processes including cells, bacteria, yeast, and enzymes to make new products or improve manufacturing.

Examples include:

- pest resistant crops
- vaccines
- detergents
- medicines
- bio-fuels
- chemicals

bi-o-tech-nol-o-gie [bahy-oh-teck-nol-uh-jee] :

nom - l'utilisation d'organismes vivants, ou de procédés incluant les cellules, les bactéries, les levures et les enzymes pour fabriquer de nouveaux produits ou améliorer la production.

Les exemples incluent:

- les cultures résistantes aux parasites
- les vaccins
- les détergents
- les médicaments
- les bio-carburants
- les produits chimiques

What is Canada's biotechnology industry? Qu'est ce que l'industrie de biotechnologie au Canada ?

♦A: Saving lives with the creation of new vaccines
Sauver des vies grâce à la création de nouveaux vaccins

♦B: Feeding populations with improved crops which increase yields
Nourrir les populations avec des cultures améliorées qui augmentent les rendements

♦C: Greening our economy by turning Canada's biomass into products
Rendre écologique notre économie en transformant la biomasse du Canada en produits

♦D: All of the above
Toutes les réponses

Answer - D
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BIOTECANADA

BIOTECHNOLOGY POLICY BRIEFING: POLITICAL LEADERSHIP

Feds urged to show stronger leadership on biotech

Industry insiders say the government needs senior leadership when it comes to science and technology.

By CHRIS PLECASH

It's been four years since the government introduced its Science and Technology Strategy, and industry insiders say it's time for the federal government to show renewed leadership in making Canada a world leader in biotechnology.

Soon after forming government in 2006, the Conservatives scrapped the Canadian Biotechnology Advisory Committee, which advised the government and informed the public on the biotechnology industry. The committee was replaced by the Science, Technology, and Innovation Council, an arm's length committee that provides confidential advice to the government and issues public reports on science and technology in Canada on a two-year basis.

Similarly, the Canadian Biotechnology Strategy, which sought to capitalize on the economic, health, and environmental benefits of Canada's biotechnology sector, was replaced by the more general Science and Technology Strategy in 2007.

"What I'm hearing now is that

biotechnology is stagnant, and it shouldn't be," said Liberal MP and science and technology critic Ted Hsu (Kingston and The Islands, Ont.), who holds a PhD in physics and worked to support sustainable energy initiatives prior to his election earlier this year. "A lot of decisions get made at the PMO level, not the ministerial level. If Canada wants to focus on science and technology, the expertise needs to be in the PMO, so that there's direct expert input when it comes to the sector, particularly biotechnology."

Industry association BIOTE-Canada reports that Canada's biotech sector, which encompasses industrial, agricultural, and medicinal applications of modified organisms, is an \$87-billion industry—seven per cent of Canada's GDP.

"Do we want to be good enough and survive, or do we want to lead," asked Ali Tehrani, CEO of Vancouver based biotech researcher Zymeworks. "If we just want to survive, then we're doing that, no problem. If we want to lead, we have to be innovative, and being innovative means thinking creatively, looking at other formulas, not what worked 20 years ago."

Mr. Tehrani said his concern isn't so much for Zymeworks; the privately-owned company announced a lucrative deal with multi-national pharmaceutical company Merck early this summer. Rather, he's one of many industry insiders urging



Photographs by Jake Wright, The Hill Times

Science files: Gary Goodyear and Industry Minister Christian Paradis.

the federal government to show more leadership in promoting Canada's biotech sector.

Jeffrey Graham, who specializes in biotech legal issues for Borden Ladner Gervais LLP, acknowledged that federal and provincial governments have made coordinated efforts to streamline regulation, attract investment, and encourage cross-sector collaboration, but he added that there needed to be a senior level federal Cabinet position when it comes to science and technology.

"What we need to do, and this is a view many in the sector would share, would be to elevate that responsibility and include it at the senior level of Cabinet," said Mr. Graham, citing Israel as an example of a country with a minister accountable on matters sci-

ence policy and expenditures. "[It] would be in the best interests of the sector, and frankly in the best interests of government, from a policy coordination standpoint."

"We've always been coupled with other industries... It would be nice to see a deputy minister, someone with a dedicated voice," said Mr. Tehrani, who seconded the need for senior level ministers responsible for science and technology policy, both federally and provincially.

"I think everyone in the federal government gets it. Everybody says 'biotech is cool, we gotta be there,' but I think they see it as a nice to have, not a need to have," Mr. Tehrani added, praising former Industry Minister Tony Clement (Parry Sound-Muskoka, Ont.) for recognizing the role of the bioeconomy in creating jobs in Canada.

Mr. Clement held the portfolio from 2008 until he was replaced by Industry Minister Christian Paradis (Mégantic-L'Érable, Que.) soon after the 2011 election. Assisting Mr. Paradis on biotechnology policy issues is Gary Goodyear (Cambridge-Dumfries, Ont.), who has served as minister of state for science and technology since 2008. Earlier this summer Mr. Goodyear attended the BIO International Convention in Washington, D.C., which brought together biotechnology and pharmaceutical stakeholders from all over the world.

"Our government is committed to making sure that Canada remains a world leader in biotechnology research because of the benefits it provides for Canadians in terms of jobs and improved quality of life," Mr. Goodyear declared in a press release following the conference, adding that he looked forward to "helping our life sciences industry become even more globally competitive."

Despite Mr. Goodyear's participation in the recent conference, it's unclear who has ministerial responsibility when it comes to Canada's biotechnology sector. When *The Hill Times* requested an interview on life sciences policy, staff for Mr. Paradis stated that biotechnology was Mr. Goodyear's portfolio, while staff for Mr. Goodyear referred the matter back to Mr. Paradis' office.

cplecash@hilltimes.com
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Do you believe

that Canada can be a world leader in generating jobs and investment in life sciences and the knowledge economy?

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Canada is currently negotiating a comprehensive trade agreement with the

European Union (EU) that would put us in the unique position of being the only country in the world to have favoured trading status with both the Europeans and the U.S.

An internationally competitive intellectual protection regime for Canada is part of the discussions. A deal with the EU will preserve and create jobs in life sciences and provide a \$12 billion boost to the Canadian economy while increasing our bilateral trade by 20 %.*

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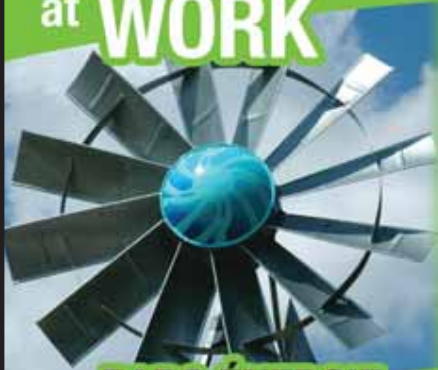


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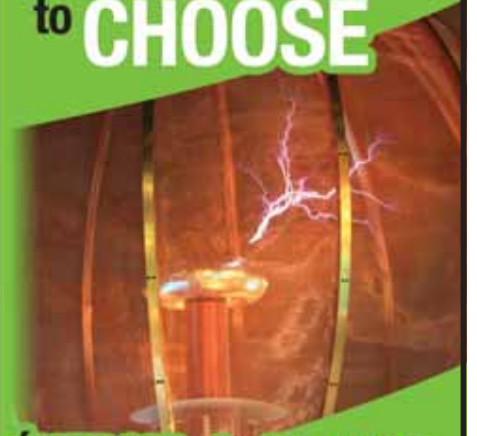
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BIOTECHNOLOGY POLICY BRIEFING: PARTNERSHIPS

Ontario, Quebec bring trade cooperation to shared life sciences industry

Inter-provincial Life Sciences Corridor seeks to brand one of the world's largest biotech clusters.

By CHRIS PLEKASH

Ontario and Quebec are looking to raise the international profile of their combined life sciences industries, but their plan's success will be measured by its ability to spur investment.

Earlier this summer, the provinces announced the Québec-Ontario Life Sciences Corridor on the eve of the Biotechnology Industry Organization's international convention in Washington D.C., which was attended by representatives from 65 countries and the world's 10 leading pharmaceutical companies, including Pfizer, Novartis, and Bayer.

Ontario Research and Innovation Minister Glen Murray and his Québec counterpart Clément Gignac were among the members of the conference's Canadian delegation, which was led by Conservative MP Gary Goodyear (Cambridge-North Dumfries, Ont.), minister of state for science and technology.

The initiative is part of the Ontario-Quebec Trade Cooperation Agreement, which seeks to encourage innovation and investment throughout the two provinces by removing trade barriers and harmonizing regulations on industry, energy, and business. The provinces are hoping to capitalize on a shared skilled workforce, a solid research base, and a proven record of life sciences innovation.

Ontario and Quebec, which make up more than half of Canada's population and 60 per cent of the country's GDP, contain 490 post-secondary programs in life sciences and boast one of the most educated workforces in the world. The region also hosts more than 1,000 life sciences companies employing more than 66,000 people, and is the largest centre for venture capital in Canada.

The region already accounts for 77 per cent of total biotechnology revenues in Canada and has produced breakthroughs in stem cell research, genetics, and anti-retroviral pharmaceuticals. Now

the provinces are hoping that their concerted effort will attract venture capital from abroad.

In a statement following the announcement, Minister Murray praised the agreement's potential to ensure that "more investment, jobs and ground-breaking healthcare discoveries are made in the Ontario-Québec corridor."

Both provinces have already recognized the value of biotechnology and the wider life sciences field to their respective economies. The Québec government plans to invest more than \$120-million over the next three years into its internationally-renowned biopharmaceutical industry, while Ontario is investing \$161-million through its Life Sciences Commercialization Strategy, which will support biotech startups, facilitate clinical trials, and support research and development in healthcare technology.

While the facts on the provinces' combined industries are impressive, the announcement simply puts a name to something that was already in place. The success of the newly branded Life Sciences Corridor will depend on the long-term benefits to the industry.

Among their first steps, the provinces will attempt to establish an efficient framework for the coordinating activities within the corridor. Under this effort, the two governments will need to further harmonize trade rules, compile an inventory of their shared industry stakeholders, and try to find new solutions to the shortage of funding faced by many small and medium sized biotech and life science companies.

The corridor strategy exemplifies the sort of creative collaboration and long-term vision that Ernst & Young's Paul Karamanoukian said has been lacking in Canada's biotech industry. Mr. Karamanoukian, who serves as an expert on the life sciences industry for the auditing agency, said that finance and marketing are as important as science when it comes to the future competitiveness of the biotech sector in Canada.

"The system needs to be geared towards a common goal," said Mr. Karamanoukian, who emphasized the need for provincial and federal governments to reform regulations and come with creative investment incentives for the biotech industry.

"This is a roadmap for how to achieve these goals," observed Dr. Michael Rudnicki, senior director of stem cell research and regenerative medicine at the Ottawa Hospital Research Institute's Sprott Centre. The Centre's stem cell research is contributing to the development of therapies for a range of injuries and illnesses, including heart disease, multiple sclerosis, diabetes, and brain and spinal cord damage.

Like many stakeholders in the life sciences, Dr. Rudnicki said he welcomes government efforts to develop the industry in Canada, but the measure of such an initiative's success is in its ability to attract the capital necessary to fund further research and development.

"Without private sector investment, all of this is moot," Dr. Rudnicki noted. "This overall initiative to raise the profile of the industry through the creation of a corridor will potentially stimulate investment from other countries."

Zymeworks CEO Ali Tehrani praised the initiative as a step towards ending inter-provincial competition when it comes to Canada's life sciences clusters. Although Zymeworks is a Vancouver-based biotech company, Dr. Tehrani said that Ontario and Québec's cooperation is good for Canada's entire industry.

"One of my frustrations is that we've been competing as provinces for a long time, rather than competing internationally," Dr. Tehrani told *The Hill Times*. "By creating this corridor, this is the first step in eliminating those lines and actually working together to help Canada."

cpkash@hilltimes.com
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BIOTECHNOLOGY POLICY BRIEFING: CAPITAL INVESTMENT

Government recently squandered opportunity to take giant leap forward in battle against AIDS

The current federal government boasts of being a 'strong stable majority' government, but its record on stable policies to nurture growth in important economic sectors, such as biotechnology, has not been good.



BY LIBERAL MP TED HSU

The development of biotechnology products requires substantial capital investment on timescales of up to a decade. This means that investors in the sector seek stable business conditions and long-term, predictable government policy. The current federal government boasts of being a "strong stable majority" government, but its record on stable policies to nurture growth in important economic sectors, such as biotechnology, has not

been good. The biotechnology sector has the potential to create high-skilled jobs and economic growth across the country and can also help improve our healthcare system.

Knowing how to get new products from the laboratory to market, which is important to the success of bio-technology, is an ability whose diffusion throughout our economy will be crucial to the innovative, ever more productive, 21st century economy that Canada should and must aspire to.

Federal government policy to support the biotechnology sector in Canada must be based on a long-term plan, and provide the stability that investors and other stakeholders in R&D need. Policy implementation has to be

thought out before announcements are made.

Recently, the government squandered an opportunity to take a giant leap forward in joining the battle against AIDS. In 2007, Microsoft founder and philanthropist Bill Gates joined with Prime Minister Stephen Harper to publicly announce a major new initiative in the treatment of HIV/AIDS. The Government of Canada along with the Bill and Melinda Gates Foundation pledged a total of \$139-million, of which \$88-million was to go towards the building of a facility to manufacture vaccines for clinical trials. Unfortunately, the government changed its mind, at the last minute and cancelled the construction of this new facility. This was a wasted opportunity for Canada and Canadians; such a facility would have created jobs, grown the economy, encouraged other groups to invest in Canada and increased our profile on the world stage.

The cancellation was controversial and resulted in hearings on Parliament Hill. Bureaucratic barriers, questions about the necessity of a new vaccine manufacturing

facility and politics have all been blamed, but all these explanations have been challenged. The best answer that I can find is that we'll never know why the decision was made to cancel the new HIV vaccine manufacturing facility. If that wasn't bad enough, four separate groups spent hundreds of thousands of dollars each preparing bids in the hopes of getting the contract to operate this facility. The cancellation meant a waste of time, money, and precious talent in the biotechnology sector.

The damage goes beyond this one project. Canada's reputation was affected. Investors the world over lost confidence in Canada, and are less likely to partner with the Canadian government and invest in Canadian projects since they now have reason to fear that the government may not be a stable, reliable partner.

Before the politicians proceed with publicity and a photo-op for future projects, I would suggest that they appoint a small task-force comprised of an expert from each of industry, the public service and the scientific community. This task force would be charged

with thinking through the project proposals and making sure that, from the point of view of each expert, the proposal makes sense—business sense, scientific sense—and that the government can and should follow through on a long-term commitment to see the project to the end.

The Conservative government touts its "stable majority." If it wants to help Canadian bio-technology businesses be the high-skill job creators and economic engines that they can be, the government should not only aim for long-term, stable policies, but policies that are smart and coherent, based on facts, evidence and what's best for Canada. Those are the policies that are mostly likely to continue from government to government and not be affected by changing political winds, and that is the environment that will nurture this industry and lead to the creation of permanent jobs and economic growth.

Liberal MP Ted Hsu, who represents Kingston and the Islands, is his party's science and technology critic.

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BIOTECHNOLOGY POLICY BRIEFING: BIOECONOMY

BIOTECCanada's goal: make Canada a biotech world leader by 2020

Industry association looks to feds, the central player in facilitating access to capital.

By D'ARCY MCDONELL

The biotechnology sector in Canada is on the verge of something very big, says BIOTECCanada president Peter Brenders.

"Biotech is the technology that is going to solve all the world's problems," Mr. Brenders told *The Hill Times* confidently, adding that Canada is poised to become a global leader in the industry if the right pieces fall into place.

Which pieces fall where, however, is never guaranteed, which, he said, is where BIOTECCanada comes in. The industry association, comprised of approximately 250 member companies and serving as a representative voice for the more than 550 biotechnology companies operating across Canada, has a simple mission. "We are dedicated to the sustainable commercial development of biotech in Canada."

Canada's current biotech industry, or bioeconomy as Mr. Brenders calls it, includes a range of industries and "it touches a lot," he said, "it is used in forestry, it is used to make auto parts, its bio-plastics, its fuels, its foods, etc."

According to BIOTECCanada, Canada's bioeconomy makes up for about seven per cent of the GDP, bringing in about \$86.5-billion annually.

Like most industries, biotech's prosperity is dependant on effective industry representation. In order to fulfill the organization's professed mission, Mr. Brenders said that there are three areas of focus: first, helping companies develop their businesses; second, performing an advocacy function in terms of improving operating environments; and third, taking on a public affairs capacity by promoting Canada's biotech companies both at home and abroad—what Mr. Brenders called "waving the pom-poms."

Recently, BIOTECCanada has come out with what Mr. Brenders referred to as a "big, hairy, audacious goal." He wants to see Canada become the world's biggest bio-based economy by 2020. "We're up there, we're really competitive, but it takes three things," he said. "As an association, we are working on three things," that fit into the organization's larger framework.

The first is a focus on capital. To create companies that will be able to sustain capital, they are first going to need some type of capital or equity investments, said Mr. Brenders. The focus for his organization is to help create an investment-friendly environment for biotechnology in Canada, which requires the federal government to play an important role.

A major part of that role is in implementing programs or initiatives aimed at soliciting investment in Canadian biotechnology companies. "The federal government is a central player in facilitating access to capital," said Mr. Brenders. He uses a recent example of a government initiative that dramatically increased the viability of Canada's biotech industry. Changes made to the Canada-U.S. Tax Treaty to start recognizing U.S. entities called Limited Liability Corporations, or LLCs, enabled these large venture funds to avoid the double taxation they were facing previously. As a result of this minor administrative change, biotechnology in Canada saw large increases in the number of investments in Canadian companies.

Mr. Brenders said there is more to be done, however, and looks to a successful government tool used in the oil and gas industry. Called "flow-through shares," which he explained as "financing tools that have turned Canada into a global powerhouse for the resource industry," adding, "we'd like to see that tool expanded into biotechnology."

Secondly, BIOTECCanada is working on

improving the biotechnology operating environment. "Once you have that money and that research," said Mr. Brenders, "the question is, can you actually bring your product to market?" He pointed to complicated, interdepartmental regulatory processes in the government. "There are many agencies in the government that simply don't talk to each other," he said, "we're trying to streamline that."

One area that he said BIOTECCanada will be actively lobbying for improvements in is the streamlining of interdepartmental work at the federal level. Using a novel food crop as an example, Mr. Brenders pointed out the numerous government departments that regulatory approvals must pass through.

"Through CFIA, through Health Canada, through Environment Canada—and the three don't actually talk to themselves. You'll be filing paperwork several times, over and over," he said. This is one of their asks, according to Mr. Brenders, "to see greater work across the departments."

Encouraging a more efficient regulatory process is a huge part of improving the oper-

ating and regulatory environment, but there is another side to it as well. He said that biotechnology in Canada is one of the heaviest regulated industries in the world, and while that is a good thing for the industry, it is only good so long as it remains science-based. "You want regulation, and you want it to be based on science," he said, "you want to be able to test and find out if something works or doesn't work, is safe or is not safe."

The third and final pillar his organization will be emphasizing in the years to come, as a means to achieve global supremacy in the biotechnology field by 2020, is a focus on the people. This means looking at how to train people, how to recruit people, and how to keep people in the industry.

By developing their strategic direction around those three areas, BIOTECCanada hopes to start making some inroads and realizing some of the changes necessary to achieve their end goal.

"We know where we want to go," Mr. Brenders said, "and we know there are steps we need to take, and tweak, to keep

us ahead of the global competition."

The onus doesn't fall entirely on the industry association, however, and that is where Mr. Brenders and his colleagues are looking to the federal government for some assistance in breaking down barriers and achieving their ambitious goal.

"We'll sit down and talk to the government, we'll put our companies up front and we'll work with them collaboratively and say, 'Here's how our regulations need to be strengthened, here's how our regulations are working,'" Mr. Brenders said.

He added that his experience with government supporting the biotechnology field has been positive.

"The government has been very cooperative in working with us as they understand in terms of what the industry needs are. It's just sometimes the execution has been delayed." Such is where he hopes increased lobbying and advocacy will pick up the slack.

dmcdonell@hilltimes.com
The Hill Times



BIOTECHNOLOGY: PRODUCING A HEALTHY, ABUNDANT FOOD SUPPLY

Scientists are developing foods that can help prevent disease and deliver other important health benefits. Thanks to biotech canola and soybean crops, consumers now have greater access to heart-healthy oils with lower levels of saturated fat. Biotech crops are also helping protect our food from harmful insects and diseases.

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- Foods with increased disease-fighting properties
- Foods with improved oil profiles
- Foods with higher levels of protein
- Fresher, longer-lasting and tastier foods

Canada's world-renowned regulatory system

Every product of biotechnology is thoroughly reviewed by Health Canada and the Canadian Food Inspection Agency to ensure that it's safe for people and the environment.



For more information on plant biotechnology, visit:
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BIOTECHNOLOGY POLICY BRIEFING: INTELLECTUAL PROPERTY



Industry stakeholders say more is required for Canadian companies to truly compete with their American and European counterparts.

Canada's current IP regime lags behind U.S., EU in protecting biotech research and development

Observers say Canada's intellectual property regime needs to extend protections on R&D data to compete globally.

By D'ARCY MCDONELL

While industry stakeholders readily acknowledge that progress has been made in the field of intellectual property (IP) law over the past 25 years, more is required for Canadian companies to truly compete with their American and European counterparts.

As Rx&D President Russell Williams wrote in a *Hill Times* column, Canadian companies' ability to garner a greater portion of the

\$100-billion in worldwide biotechnology investments will depend heavily on the strength of Canada's IP regime.

Peter Brenders, president and CEO of BIOTECCanada, explained that there are two main components within intellectual property regimes: patents and data protection. Patents are protective instruments that ensure the safeguarding of a company's product over a certain period of time, preventing other companies from capitalizing independently on a competitor's innovation. In Canada, a patent lasts 20 years.

While patents are vital to any IP regime, Mr. Brenders said they don't always provide a sufficient window of opportunity to conduct the necessary research and development while at the same time ensuring continued protection once the final product is brought to market.

Under the current system, a company in Canada "could come

up with a new product, but if you know it's not protected, it's going to be copied out of China in a heartbeat—at which point, you'll never sell it."

And while patents may protect intellectual property over a two-decade period, the fact remains that in an industry as complex as biotech the research and development phase can take several years. "Because they take so long to develop, the patent could expire by the time the product comes to market," said Mr. Brenders. "What you're developing is high risk. Things could fail, it could take 17 or 18 years to properly produce a product in biotech—then when you bring it to market, you only have protection for two years. Not a great business case."

Mr. Brenders said he advocates reforming data protection laws. Similar to the notion of patent protection, data protection ensures that no other firm can utilize the research conducted by a company

for a pre-determined period of time. In Canada, that period is eight years. For example, a company may bring a final product to market, but because of earlier research and development challenges, that product only remains patent-protected for a further two or three years. When the patent expires, data protection seeks to extend the competitive viability of the product.

Data protection is thus not protecting the product itself, but instead protects the data compiled through the research and development of a bioproduct. This means that an outside company cannot simply steal another company's research and development data so as to produce an identical product to be released immediately after the initial patent expires.

The biotech industry now says Canada needs to increase the length of time provided under data protection legislation. Passed

in 2006 as regulatory amendments to the Patented Medicines (notice of compliance) Regulations ("PM(NOC)Regulations"), the Canadian government initiated the eight year protective regime. But industry stakeholders are now calling for an extension of that regulation in order to compete with international standards. In the European Union, governments provide data protection for 10 years. In the U.S., for 12.

Mr. Brenders said that these differences cause an imbalance in international biotech regulations that has the potential to put Canadian innovators at a disadvantage. "I think Canada just needs to be on a level playing field," he said, adding that data protection is the number one issue that his member clients identify as an area in need of improvement.

Mr. Williams further reiterated the importance of reviewing Canada's regulatory regime, pointing to the successes that followed in the 25-year wake of Canada establishing regulatory mechanisms. "The fact is that improvements in IP over the last 25 years have spurred an 800 per cent increase in pharmaceutical research and development investment in Canada," he wrote.

Mr. Williams further argued that the upgrading of Canada's biotechnology regulatory regime could act as a boon to ongoing negotiations between the governments of the EU and Canada, who are looking to establish a comprehensive economic and trade agreement (CETA). He said that instead of fearing a trade agreement with the EU, we should instead appreciate the potential for substantial benefits to Canadian industry by aligning with Europe, home to a 500 million-strong consumer market.

Mr. Williams said he anticipates that an economic arrangement with the EU will be reached sometime in 2012. He said that it is important to "seize this opportunity" to calibrate our own IP regime so as to "improve the quality of life of all Canadians."

A 2011 public opinion poll conducted by Nanos Research found a strong base of support for upgrading the country's IP regime amongst Canadians, with eight out of 10 respondents claiming support for updated regulatory controls to at least match those of the EU and the U.S.

Mr. Brenders acknowledged that eight years of data protection is better than none, saying it's "better than a kick in the pants—but we would like to see it on par" with competitors in other parts of the world—particularly those competing directly with Canadian firms.

Intellectual property protection is of critical importance to the maintenance of an economy based on innovation, but it's especially vital to industries and companies requiring such extensive research and development, such as biotech. "Without IP, there is no industry," Mr. Brenders said, elaborating, "you always need some kind of IP—it's what our capitalist system is built on."

Industry associations and other stakeholders are planning on lobbying government for the desired changes during the upcoming 'Biotech Week,' planned for Sept. 16-23.

dmdonell@hilltimes.com
The Hill Times

BIOTECHNOLOGY POLICY BRIEFING: OVERVIEW

'Everyone wants what Canada has,' says leading biotechnology industry association

A 2011 report by BIOTECCanada says the current Canadian bioeconomy, valued at \$86.5-billion in 2010, represents seven per cent of national GDP.

By D'ARCY MCDONELL

Canada's leading biotechnology industry association says it's boosting the country's potential to capitalize on abundant natural opportunities, and strong research and development capabilities within our borders.

President and CEO of BIOTECCanada, Peter Brenders, praised biotech as the "technology that is going to solve all our problems," noting that "it enables so much," in industries from fuels to forestry, foods to vaccinations. And as high as confidence runs in the technology as a whole, it runs just as high for Canada's potential to benefit in a big way.

A 2011 report by BIOTECCanada states the current Canadian bioeconomy—a term used to describe an aggregate view of the various biotech sectors' contributions to the national economy—valued at \$86.5-billion in 2010, representing seven per cent of the national GDP.

Initially surpassing the automotive and aerospace industries in 2007, Canada's bioeconomy continues to exceed them in size today.

Employment in Canada's bioeconomy surpassed 3.2-million people in 2010, with the majority located in Ontario (485,000), Quebec (350,000), British Columbia (120,000) and Alberta (110,000).

The bioeconomy in Canada is commonly split into three sub-groups: health, medicine, and pharmaceutical manufacturing; agriculture and food bio-processing; and organic chemical manufacturing.

The health, medicine and pharmaceutical manufacturing sector represents approximately \$54.5-billion annually, equal to 64.4 per cent of the bioeconomy's contributions to overall GDP, according to the same report.

Companies operating in these fields are concerned primarily with developing biotechnologies at research institutions and manufacturing pharmaceuticals.

Where biotechnology is concerned, Mr. Brenders highlighted advances being made in the health and medicine field, speaking to "tremendous vaccines and great advances in technologies treating diseases that we could never do in the past."

The second major sector within Canada's bioeconomy is agriculture and food bio-processing. Through agricultural activities aimed at increasing crop production and other related manufacturing operations such as breweries, wineries and distilleries, the agri-food field generates approximately \$22.6-billion per year, itself accounting for



The health, medicine, and pharmaceutical manufacturing sector represents approximately \$54.5-billion annually, equal to 64.4 per cent of the bioeconomy's contributions to overall GDP, according to a 2011 report by BIOTECCanada.

26.1 per cent of biotech's contributions to the national GDP.

"What we have to do is increase the productivity of that land," said Mr. Brenders, speaking to the "phenomenal" technology available to increase crop yields, as well as producing larger crops while using less inputs.

He noted the huge projected influxes in global populations and the associated need to produce exponentially more using the same amount of land we currently rely on.

Mr. Brenders pointed to a Kingston, Ont.-based company called Performance Plants, whose research has led to increases not only in yields but by extension, an increase in the efficiency of water usage as another scarce resource.

"They basically are reducing the water required to grow corn by two-thirds," Mr. Brenders said, adding that these new water and agricultural technologies will reduce the quantity of chemicals and fertilizers being used. "Overall," he said, that means, "we can do it a lot cheaper."

According to the Department of Foreign Affairs, the Canadian agri-food sector is a global leader, in part due to what the government calls the No. 1 ranked business environment among G7 countries.

DFAIT also stated that Canada's success in biotechnology is made possible, to an extent, thanks to lower R&D costs compared to many other OECD countries. Sitting at a rate of 0.4 per cent in Canada, the country's cost level beats out those of the United States and Japan, which sit at 1.1 per cent, and two per cent, respectively.

Mr. Brenders singled out Canadian innovators focused on improving a plant's tolerance to harsh weather, "like droughts, or heavy rain, or cold."

He said new methods of allowing plants to grow in harsh climates, is making "Africa all excited," adding that bringing this technology into global agriculture could see a "big, big growth" in the field.

The third largest sub-sector within Canada's bioeconomy is organic chemical manufacturing. Generating an approximate \$8.2-billion each year, it represents 9.5 per cent of biotech's overall economic activity. The field focuses on manufacturing, including organic acids, alcohol peroxides and ethers, among others; as well as mining and bio-processing materials such as copper.

Mr. Brenders elaborated beyond the numerical and statistical performance of Canada's bioeconomy, speaking to the wide-ranging practical uses of biotech in addressing future concerns.

Looking first at addressing future energy needs, he acknowledged alternative renewable sources, but noted that biotech has recently broken out on the sustainability scene.

"There is renewable, yes," Mr. Brenders said.

"But now we know how to convert biomass, whether it is algae, waste, etc., into ethanol, and into other types of fuels, and then right into methane gas. So you can solve energy," he explained.

And as the push for environmentally friendly practices continues to factor into future plans for economic

activities, Mr. Brenders said biotechnology can play a big role there too.

Developments in biotech can "solve the environment through remediation," he says, explaining that "we now know how to engineer microbes, how to develop enzymes that basically clean up messes, oil spills."

It is these developments that Mr. Brenders said led he and his colleagues at BIOTECCanada to believe that "everyone wants what Canada has."

This is due to natural endowments and a strong R&D footing, but is furthered by what Mr. Brenders sees as a particular area of competitive advantage for Canada: a position of relative strength and stability in the wake of the global economic downturn.

"The exciting thing for Canada is we're now coming out of the recession, and companies are already landing great deals," said Mr. Brenders.

He points to a recent \$187-billion deal involving B.C.-based Zymeworks and U.S.-based Merck, a global leader in health care. The deal will see collaboration between the two companies, together working towards the development of novel antibodies for health care purposes.

"The reality is that these companies are here now," he said.

"It's not how everybody thought of biotech as having a place somewhere in the future—we're starting to realize that those technologies are all here already, today."

According to a 2009 public opinion poll conducted by Nanos Research, the Canadian public is echoing those

same optimistic sentiments.

More than nine out of 10 Canadians, the poll showed, said they saw biotechnology as important to Canada's future economic prosperity. Over eight in 10 Canadians support research in biotech and the use of products and processes that involve biotech.

The results do, however, highlight a perceived need for more involvement by government in promoting the country's bioeconomy. The poll indicated that Canadians were more likely to believe that the Canadian government was being surpassed in its support for domestic biotech growth by both that of Japan and the United States.

And while Mr. Brenders said that government lobbying efforts will be maintained in coming months and years, particularly in the upcoming biotech week and a day on Parliament Hill where stakeholders will have the chance to speak directly with members of government, he said he remains confident the right pieces will fall into place.

"Globally, every nation in the world is getting into biotech," Mr. Brenders said, adding that Canada has been promoting a wide array of biotech's uses that are already "embedded in a host of our industries across the country."

Mr. Brenders said that when you look at the long list of uses for biotech, its "enormous footprint" in Canada can't be ignored, nor can the potential for pre-eminence in the global biotech market.

dmcdonell@hilltimes.com
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