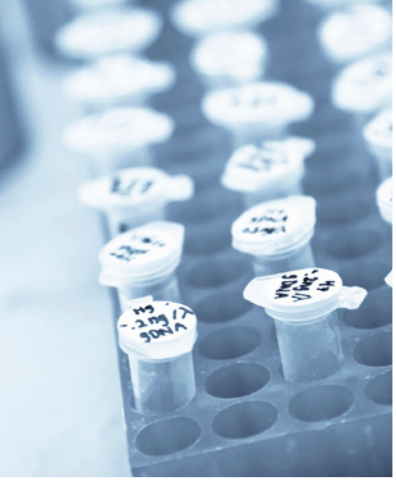

LIFESIGNS • LIFE SCIENCES
LEGAL TRENDS IN CANADA



EDITION
2014-2015

Borden Ladner Gervais

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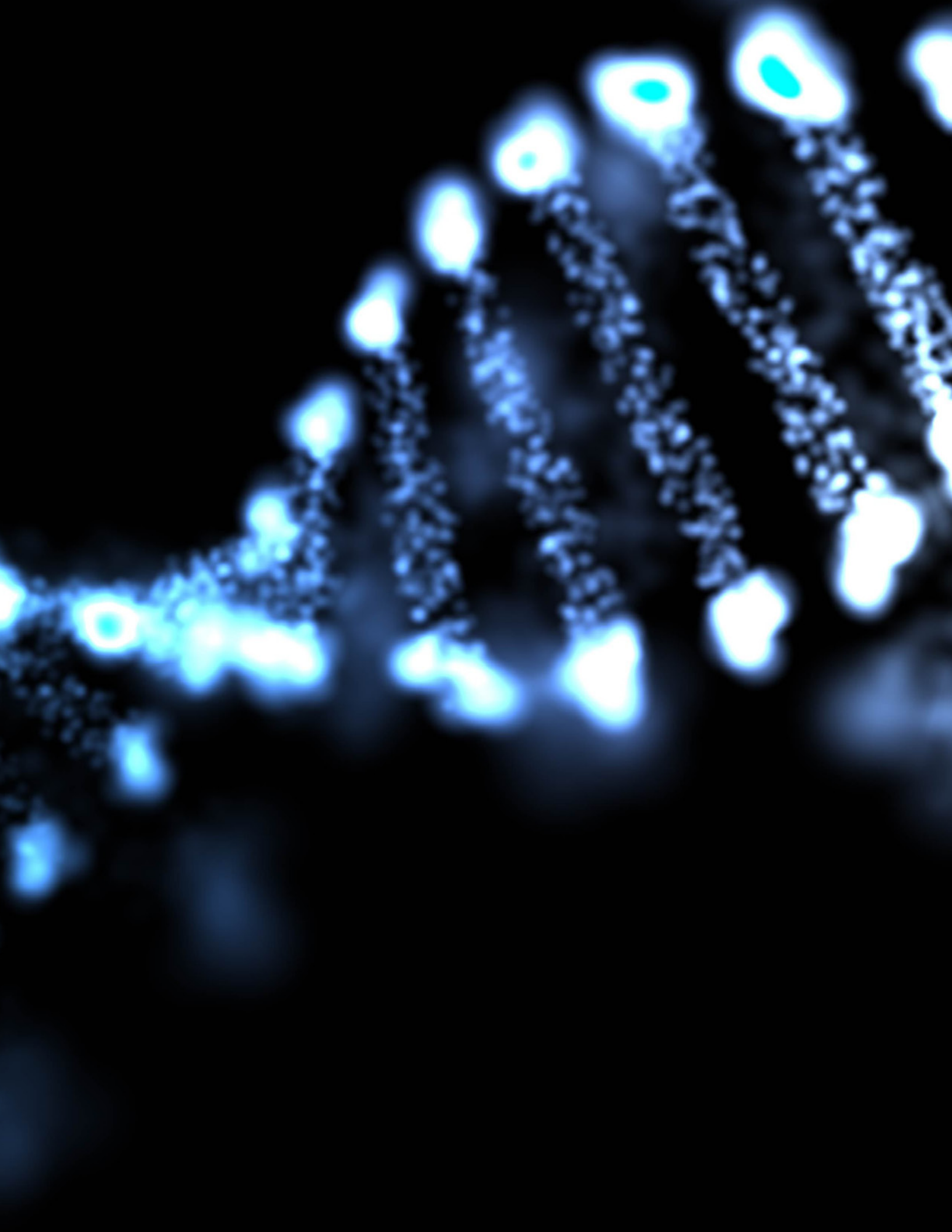
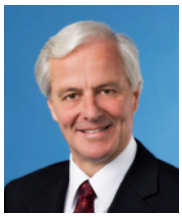


MESSAGE FROM CANADA'S NATIONAL ASSOCIATIONS



Russell Williams

President of Canada's Research-Based Pharmaceutical Companies

MAKING CANADA BETTER
R&D 100
POUR UN CANADA MEILLEUR

CANADA'S RESEARCH-BASED PHARMACEUTICAL COMPANIES RX&D

The Comprehensive Economic and Trade Agreement (CETA) between Canada and the European Union (EU)

A significant step forward for Canadian life sciences research and development (R&D) occurred last fall when an Agreement in Principle was announced with respect to the most important free trade agreement for Canada since the NAFTA with the United States and Mexico.

The Comprehensive Economic and Trade Agreement (CETA) between Canada and the European Union (EU) is an ambitious 21st century agreement, covering much more than the traditional exchange of goods and services. As part of the CETA, Canada agreed to improvements to its intellectual property (IP) regime that, once implemented, should help Canada become more competitive on the global market.

This agreement presents an opportunity to protect life sciences R&D in Canada, which builds on over a century of ground-breaking Canadian discovery and innovation, and comes with significant health and economic benefits (see www.canadapharma.org/100).

Stronger IP encourages innovation. Canada's previous efforts to strengthen IP resulted in a significant increase in private sector R&D investment through the 1990s and early 2000s. However, without consistent efforts to maintain Canada's competitive edge, our competitors have left us behind. It is now increasingly challenging to secure Canada's share of the more than $110 billion that pharmaceutical companies invest worldwide in life sciences R&D annually.

Other life sciences IP issues remain. For example, the creation of an elevated utility standard has harmed a number of innovators operating in Canada by invalidating patents that have been upheld elsewhere in the world. Given the other issues, the proper implementation of the CETA IP provisions becomes even more important, sending a positive signal to international investors looking for a stable, predictable environment in which to conduct R&D that will save and improve lives.

Patents and IP protection may sometimes seem remote from patient care. Ultimately, new medicines and vaccines deliver tremendous value to individuals, communities and society overall. They offer hope and healing in ways that previous generations never thought possible – the same will be true for generations to come. Every medical innovation begins with the belief that if we work hard enough, we can advance the science and change lives for the better. Canada has a proud heritage of research and discovery, and needs to implement the necessary policy measures to ensure that it remains a world class location for life sciences innovation.

Andrew
Casey
President and CEO

BIOTECanada

BIOTECANADA

Canada Update

The world's population is rapidly moving towards the nine billion mark. This exponential growth brings with it enormous challenges as nine billion people will require new medicines, food, energy, and material goods. In addition, the population growth and its corresponding economic surge will require economies around the world to find more efficient and less environmentally impactful methods to deliver health care, grow food and manufacture goods. Within the social imperative of addressing this global challenge lies the enormous economic opportunity for the innovative solutions biotechnology provides.

Importantly, Canada has in place many of the components necessary for global competitiveness and success in biotechnology. Indeed, Canada is home to a national biotech ecosystem including numerous regional clusters which bring together over five hundred biotech SME's, world-class universities and research institutes, large multinational pharmaceutical companies and a highly educated workforce. All told, the national biotech ecosystem is an economic strength that positions Canada well to compete in the emerging global bio-economy.

Yet, while Canada has a significant opportunity before it in providing solutions for the global challenges of population growth, other nations are also acutely aware of this opportunity and are quickly moving to develop and support their respective innovation industries by developing and implementing policy frameworks supportive of both innovation and investment. If Canada is to compete globally and reap the benefits of a robust biotech innovation industry then it must keep pace with other jurisdictions and attract investment- the fundamental fuel of biotech research and development.

Investment is a fickle world tourist; it will travel the world and stay where it feels it is most welcome and secure. To attract investment, the 'hosting conditions' for industry and investors must be as globally competitive as possible. In some ways, Canada is doing very well in this regard. Importantly, Canada's regulatory system for new medicines and other biotech innovations is efficient and effective. However, when it comes to its treatment of intellectual property, recent court decisions on patent utility and usefulness are leaving Canada's IP regime out-of-step with those of other nations.

This is not a trivial development. Highly mobile ideas are the heart of Canada's biotech industry. If Canada cannot attract investment capital then these good ideas and their corresponding economic benefits will simply go to where the investment is. Ultimately, a supportive intellectual property regime is essential if Canada is to fully realize the economic and social potential of its biotech industry. In this context, this is one area where Canada must urgently take steps to become more globally competitive.

Gabriela Prada

Director of Health Innovation, Policy and Evaluation | The Conference Board of Canada

CONFERENCE BOARD OF CANADA

Policy-makers increasingly recognize that greater innovation within health care systems is the key to meeting sustainability challenges. And although studies have demonstrated that public procurement triggers more innovation than do state subsidies for research and development, the majority of governments are not using public procurement as a strategic lever for innovation.

The opportunity behind the argument to use procurement strategically is simple: the billions of public dollars that are spent by governments each year on products and services can be used to provide incentives to the market to solve health challenges and improve health care outcomes. In other words, procurement can provide incentives to *pull* innovation into the health sector, which is a different strategy from the traditional government approach of drafting policies that aim to *push* innovation into the health sector.

The procurement proposal has been slow to penetrate the health care sector. This may well be due to the fact that the introduction of new products and processes into health systems has traditionally been perceived as a cost driver, which, paradoxically, has prevented the adoption of innovations that can enhance health system performance and decrease overall costs. This has been a big barrier for the adoption of many innovations and has limited the value they can bring to the health care system – and to societies as a whole. However, given that procurement and adoption are so closely linked, the way in which innovation is procured can prove decisive in turning a burden into a substantial advantage.

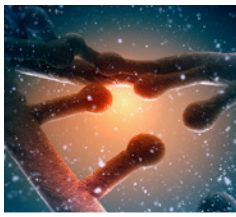
There are three categories of policy action to use procurement as an innovation lever.

The first is public procurement of R&D (or pre-commercial procurement). This can be used when there is a perceived need but no commercially available solution. Procurement becomes an R&D service contract with a multi-stage process. This approach is close to the U.S. Defense Advanced Research Projects Agency (DARPA) approach, which is credited with having driven a long list of major innovations in computer science and technology that have transformed our lives, including the Internet. In 2003, the U.S. government successfully used pre-commercial procurement to develop a new vaccine against smallpox, the dangerous and highly infectious disease that can't be cured but can be prevented through vaccination.

The second category is innovation procurement. This involves specifying a requirement that cannot be met by an off-the-shelf solution or product but that can be developed within a reasonable period of time. This approach stimulates stakeholders, including vendors, to integrate and re-design existing solutions to create a new one that is customized to the specified needs. This approach was used with success in 2009 in the United Kingdom when, as part of a campaign to fight hospital-acquired infections, Kinneir Dufort and Bristol Maid developed their *easy clean hospital bedside cabinet*. This cabinet is superior to previous ones, is cost neutral, offers improved storage and a 40 per cent reduction in weight, and is faster and easier to clean (thereby supporting a more efficient patient flow between hospital units).

CONFERENCE BOARD OF CANADA | *CONT'D*

Finally, procurement approaches can also be used to support the uptake of innovations that already exist but are not widely adopted, driving a need to install a system management program to speed up adoption and diffusion. There are various strategies that are being tested, ranging from procuring for solutions to negotiated requests for proposals and risk sharing agreements (all of which we explored in our latest report *Innovation Procurement for Medical Devices: Driving Health System Improvement*). These strategies represent a paradigm shift in procurement practices, which have typically focused on cost control, to an emphasis on greater value for money. Because of the change they involve and the limited experience determining and assessing value, these approaches are complex and require a high degree of sophistication in the management of the process and a redesign of the procurement team. However, a few world cases are already demonstrating that they can bring significant value to health and health care systems and to societies at large. The Conference Board of Canada is organizing the Second International Roundtable for Innovation Procurement in June 2014 in Barcelona, Spain, to facilitate dialogue among tendering officials with experience in these approaches. The goal is to capture their practices and know-how and support knowledge sharing. Stay tuned for more details.



INSIGHTS FROM THE LIFE SCIENCES TEAM AT BLG

“It is in our genes to contribute our time and energy to helping to promote Canada’s life science sector, both domestically and abroad.”

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CANADA'S LIFE SCIENCES INDUSTRY AND BLG

The Canadian life sciences sector is an important contributor to Canada's innovation economy. The sector is incredibly diverse in Canada. It includes small and medium-sized companies developing diagnostics, biopharmaceuticals, pharmaceuticals and medical devices, as well as global companies with research, development and manufacturing operations in Canada, serving both domestic and international markets. There are also contract service providers that provide industry support for research and development, clinical trials and manufacturing to researchers and companies in Canada as well as around the globe.

In the industrial sector, companies developing bio-materials for industrial and consumer applications, and environmental companies deploying bio-remediation technologies offer new solutions for oil spill cleanup, and safe municipal sewage and water cleanup options. Other industrial companies are taking biomass materials and transforming them into new energy sources and value added products. In the agricultural sector, life science technologies are having a positive on yield, quality and pest resistance.

At the same time, Canada's world-class health research institutions and research networks are integral partners in research and knowledge translation to support each of the commercial applications noted above.

Our firm, Borden Ladner Gervais LLP (BLG), is active in all aspects of life science commercialization in Canada. BLG has tremendous bench-strength in Intellectual property, both the prosecution of new inventions and the protection of patents and other forms of intellectual property in the face of challenges from third parties. For many years, BLG has helped emerging companies to raise capital, establish business entities and address the myriad of issues on which practical and strategic legal advice is essential. At the same time, the firm acts for many domestic and international life science companies with products in sale helping them navigate the complex legal regulatory environment in Canada that they face.

The diversity of BLG's practice has provided us with a "life cycle" view of the sector and has helped our Life Science Group become one of Canada's most respected full service life science law firms.

It is in our genes to contribute our time and energy to helping to promote Canada's life science sector, both domestically and abroad. We realize that it is our responsibility to contribute to local, regional and national life science industry associations as sponsors and as volunteers on committees and task forces. We realize that for Canada to enhance its position in the highly competitive world of life science commercialization we must find ways to partner with the sector whenever we can.

This publication, LifeSigns Trend Report, is the most recent effort on our part to share with our clients and friends insights into some of the issues that we address in our efforts to advise the sector. We hope that you will find this publication of value and that you will share it with your colleagues. We also hope that you will provide us with your feedback so that we can make future editions of even greater value to you.

PATENTS

FUNDING INTELLECTUAL PROPERTY AND ACADEMIC-INDUSTRY COLLABORATION THROUGH CIHR COMMERCIALIZATION GRANTS

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The Proof of Principle POP grant program administered through the Canadian Institutes of Health Research (CIHR) has been in place since 2001. It provides a unique source of funding not only to academic researchers, but also to companies collaborating with academic researchers through matching partnered grants.

Academic researchers with commercially relevant projects should investigate funding opportunities offered by this program. Further, companies with links to academia stand to benefit from this funding program because of the opportunity for academic researchers to receive funds to match the support of a committed industry partners, which can effectively double the money available to a project. POP award recipients will certainly be the investigators to watch for their future commercialization and industry collaboration efforts.

POP offers two different phases of opportunity for commercializing academic research. Phase I provides up to $160,000 to academic investigators with projects of potential commercial application, if the intellectual property is not yet licensed outside of the originating university. Phase II provides up to $300,000 to academic investigators to match the funds committed by a commercial partner.

Designed to advance discoveries towards commercialization, the POP program encourages protection of intellectual property, and in so doing, helps to bring academic innovations into commercial application for technologies that can improve health outcomes for Canadians. In order to qualify for funding, a project must be demonstrate market and opportunity and will ideally be at a stage where the funding award can tip the balance to permit critical experiments to be done to establish the proof of principle for an invention or inventive concept, potentially allowing a patent application to be filed.

The POP grant program requires an applicant to work with the institution's technology transfer office to assemble a commercialization plan, complete with an overview of the intellectual property position of the proposed work. The requested budget for the application can include up to 20% for eligible commercialization activities. Up to $15,000 can be attributed to patent costs, which will go a long way to offset the costs of drafting and filing a patent application within the 1-year term of the award. Consulting fees, market studies, communication and networking costs, and trips to visit collaborators are eligible expenses

The POP review committee includes academic and industry specialists, as well as intellectual property and commercialization specialists. The combined expertise of the POP review committee is unique in Canada, and reviewers provide beneficial feedback to unsuccessful applicants that often results in successful re-application in a subsequent round.

In the published decisions pertaining to the Fall 2013 PoP grants, fourteen Phase I applications were funded across 11 different Canadian institutions. Three Phase II applications were funded, representing three different institutions, with AmorChem (Montreal), DeCell Technologies Inc. (Halifax), and Aquila Diagnostics Systems Inc. (Edmonton) as the funding partners.

The PoP program will continue in its current format for two rounds in the 2014/2015 competition, but watch for changes in Fall of 2015, consistent with CIHR's reforms of funding programs and the peer review process.

Dr. Kathleen Marsman is the current Chair of the CIHR Proof of Principle grant review committee, and is a patent agent in the Ottawa Office of Borden Ladner Gervais LLP.

FEDERAL COURT OF CANADA UPHOLDS BIOLOGICS PATENT CLAIMS TO USES OF FUNCTIONALLY-LIMITED ANTIBODIES

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Prospective patentees in the antibody arts in Canada have long faced objections to claims that cover antibodies different from those exemplified in their applications. This typically includes non-exemplified antibodies defined in term of percent identity to a reference sequence, and those having conservative sequence modifications based thereon. Patent examiners at the Canadian Intellectual Property Office (CIPO) usually allege that undue experimental burden would befall a skilled person wishing to make candidate mutants and determine which ones are functional. To sustain such objections, examiners usually point to decisions of the Commissioner of Patents dealing with antibody applications from the late 1980s to early 1990s.

In a decision marking the first time that antibody technology has been extensively scrutinized by a Canadian court, the Federal Court of Canada upheld claims covering uses of a human anti-IL12 antibody for treating psoriasis in its recent decision in *AbbVie Corporation v. Janssen Inc.*, 2014 FC 55.

AbbVie, the patent owner, had unexpectedly discovered that psoriasis resolved in a patient who inadvertently received a human anti-IL12 antibody, termed J695 (briakinumab), made using phage display technology. The "use" claims asserted by Abbvie were not, however, limited by specific epitope, antibody sequence, or method of production, though the claims did specify minimum affinity and potency values.

Janssen makes and markets a human anti-IL12 antibody for treating psoriasis under the name STELARA™ (ustekinumab). This antibody was not developed by phage display, but rather in mice having a reconstituted human immune system. In fact, the STELARA™ product shares only incidental sequence identity with J695 (about 50%), and also binds to a completely different epitope on IL-12.

The patent claims were counter-attacked by Janssen on the grounds of obviousness, over-broad or "covetous" claiming, and ambiguity. The Court upheld the claims, finding them to be both valid and infringed by Janssen.

In his analysis of obviousness, the trial judge provided a helpful and lengthy list of technologies from expert testimony that he accepted as forming the state of the art as of March 1999. These include methods of CDR recovery, modification, mutagenesis, and grafting, as well as activity testing and methods of making human antibodies by either phage display or using immune-reconstituted mice. These are many of the technologies that have, to date, been deemed "non-routine" by patent examiners in applications filed well after 1999.

The inventive concept of the claims in issue was found to be that psoriasis may be treated by the use of human antibodies that bind to human IL-12, which antibodies have an affinity of at least the claimed amount and a potency of at least the claimed amount. Before this discovery there was only hope that binding IL-12 would treat disease, but this was an example where a patient had successfully been treated. The Court noted the distinction between the approaches to obviousness, where an invention that is "worth a try" may not be "more or less self-evident". In this case, the invention was not self-evident having regard to the prior art, and thus it was not obvious. The Court also found that the claims were not unduly broad.

The attack on ambiguity focused on claim features pertaining to minimum affinity and potency variables. Patent applicants may recognize that such features often fall afoul of CIPO examining practice, with examiners alleging that such features are objectionable for "encompassing antibodies with spectacularly high affinities". The trial judge found nothing ambiguous about these limitations, stating that they simply conveyed minimum standards. The trial judge indicated that the question of whether an antibody with vastly higher affinity or potency would be considered a patentable improvement was one best left for another day.

A decision like *Abbvie v. Janssen* has been long awaited in the field of biologics. Although now under appeal, the decision should nonetheless encourage applicants to argue against antibody claim objections in which an examiner states that departure from a specific set of CDR sequences would result in a lack of utility, or that putting a claimed invention into practice would require impermissible inventive work.

PATENTS

SUPPORT FOR CLAIMS: AN ONGOING ISSUE IN CANADA

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Canadian examiners' objections to claims in which the examiner argues that there is not full support for the claims in the description, employing Rule 84, have become increasingly common, especially in the biotechnology field. This objection is often made in conjunction with a lack of sound prediction objection and a scope of claim objection , i.e. the scope of the claims goes beyond what can be soundly predicted from a fair reading of the description, are excessively broad and are not adequately supported by the description. All three objections can often be overcome with a single amendment or argument.

There appear to be two basic but related grounds for a lack of support for the claims objection. The first relates to general scope of support issues in which the examiner usually argues that the scope of the claims goes beyond what is reasonable in view of the description. Sometimes the examiner will specify the point of contention, for example, by requesting that the claims recite specific proportions of compounds in a composition in order to achieve the utility required. Sometimes the examiner will require the utility be defined with greater specificity, for example, diagnosis of breast cancer rather than cancer generally. The second is an objection that is based on claiming by "desired result" rather than the combination necessary to achieve the result. This second objection can commonly be an issue in the antibody arts in which the antibody is defined by way of its activity rather than by way of its structure.

Assuming that the applicant disagrees wholly or partly with the examiner and does not wish to narrow the claims, then the first type of objection based on scope of support can often be argued by showing the state-of-the-art at the claim date by way of scientific or technical references. Another related approach which appears to have had some success is to show the state of mind of the inventor at the claim date. This can be done by way of dated laboratory notebooks. This itself is an interesting development as many of us were, perhaps naïvely, of the view that this sort of evidence was only needed in conflict procedures which disappeared with the amendments made to the *Patent Act* in 1989 (similar to but simpler than US interference proceedings).

With respect to the second type of objection, claiming by "desired result", this objection is most often overcome by including further details of the combination or means necessary to achieve the result in the claim or claims at issue. In the antibody arts, however, if the antibody is the focus of the claim then it is becoming increasingly common for the examiner to require structural details. Again, in the antibody arts, if the antibody is not central to the claimed invention but plays a part in it, such as use in a chemical isolation or purification step, then, sometimes an applicant can successfully argue that the language in the claims suffices.

As mentioned, such a lack of support objection is often made in conjunction with lack of sound prediction and claim scope objections and often all the objections can be dealt with together, a single amendment or argument addressing all of the objections, a point to consider when encountering such objections.

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WHY DO BUSINESS IN CANADA?

Companies seeking to do business in North America should consider the many benefits of doing business in Canada. Canada has a stable economy, a highly-skilled work force, diverse manufacturing capabilities, and a sophisticated and cost-effective patent regime. Canada is viewed as a gateway to the United States and is frequently used as a test market before entering the larger North American marketplace. Outlined below are some of the reasons companies should consider doing business in Canada.

10 Reasons to Consider Entering the Canadian Market

1. According to a detailed study of international business costs in 11 countries in North America, Europe and Asia-Pacific, conducted by KMPG, Canada's business costs were second-lowest.
2. Canada is the best country for business in the G-20 according to Forbes Magazine's November 2012 study. It remains a welcoming and profitable place for international business and foreign direct investment.
3. For the fifth consecutive year, the World Economic Forum rates Canada's banking system as the world's soundest.
4. Canada has the most highly-educated population in the OECD and attracts the best and brightest from around the globe.
5. International companies recognize Canadian leadership in industries such as fiber optics, aerospace and biopharmaceuticals. The country is also a world leader in fields such as medical devices, digital gaming, and agri-food.
6. Canada is strategically located in the crossroads between the North American marketplace and the booming economies of Asia.
7. Canada offers businesses favourable R&D tax credits and incentives, effective intellectual-property protection and enforcement, open competition in domestic market in the deployment of digital information and communications technologies and platforms, transparent government-procurement practices, and openness to high-skill immigration.
8. Canada offers ease of cross-border trade with lucrative markets. Canada is a signatory to the North American Free Trade Agreement (NAFTA) – a tri-lateral agreement between Canada, the U.S. and Mexico. Canada recently joined The Comprehensive Economic and Trade Agreement (CETA) with the European Union.
9. According to The World Bank's Doing Business report, Canada has one of the simplest business start-up processes in the world. Opening your business requires a single procedure and takes around five days – one of the quickest turnarounds among nations analyzed in the report.
10. Canada ranks third in the world for quality of life, according to The Organization for Economic Cooperation and Development.

WHY DO BUSINESS IN CANADA? | *CONT'D*

10 Reasons to Seek Patent Protection in Canada

1. Canadian patents not only protect your market share in Canada, they also protect against competing products being imported into Canada or being made in Canada and exported to foreign markets, such as the neighbouring USA.
2. Canada has a sophisticated and cost-effective patent system. Government fees are fairly low, there are no claim fees, and multiply-dependent claims are permitted.
3. Canada has a "first to file" patent system and a convenient one-year grace period for inventor-derived disclosures. A patent must be filed in Canada within one year of the disclosure.
4. An international PCT application may enter national phase in Canada up to 42 months from the priority date (standard is 30 months), providing additional time to make business decisions while deferring costs.
5. Examination may be deferred up to five years from the filing date. This provides an opportunity to assess prosecution in other jurisdictions before making decisions regarding Canada. Conforming the claims to those granted in another jurisdiction may expedite prosecution in Canada.
6. Examination may be expedited by requesting Special Order or using the Patent Prosecution Highway (PPH). Expedited examination is also available for cleantech applications.
7. Patent prosecution in Canada is fairly flexible. Claims may be amended at any time during prosecution and strict verbatim support for amendments is not required, as long as the subject matter is reasonably inferable from the specification as filed.
8. Examination continues to progress as long as new arguments and amendments are being put forward. Final Actions are rarely issued and examiner interviews are permitted.
9. Canada has adopted the "Saccharin doctrine" which provides added protection for patented processes. An imported product can infringe a Canadian process patent even if the process was performed outside Canada.
10. Additional protections for drug patents are provided under the Patented Medicines (Notice of Compliance) Regulations (akin to the Hatch-Waxman system in the USA) and data protection is available for innovative drugs.

For additional information on doing business in Canada, please feel free to contact the authors or visit **blgbooks.com** for access to free publications.

CRUISING THE PATENT PROSECUTION HIGHWAY IN CANADA

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The Patent Prosecution Highway (PPH) is a program through which examination of a Canadian patent application may be accelerated by aligning the Canadian patent claims with those issued or allowed in a foreign counterpart application.

As of January 2014, the Canadian Intellectual Property Office (CIPO) is part of the Global PPH (GPPH) pilot program. The patent offices from the following countries are also involved in the GPPH: Australia, Denmark, Finland, Hungary, Iceland, Israel, Japan, Korea, Nordic Patent Office, Norway, Portugal, Russia, Spain, Sweden, United Kingdom, and the United States of America.

Canada also has PPH agreements with China, Germany, and Mexico. The program can also be accessed based on claims deemed to be allowable in an international search report (ISR) issued in Canada or the United States.

Using the PPH

There are no government fees for using the PPH program. A Canadian application is eligible if:

1. the claims are "sufficiently similar" to those allowed or issued in the foreign counterpart;
2. the application is open to public inspection;
3. examination is requested but no Office Action has issued; and
4. the application has never been abandoned.

An amendment may be filed to align the Canadian claims with those of the foreign counterpart. There are no claim fees in Canada and claims from multiple foreign counterparts may be combined.

Once accepted into the PPH program, CIPO will issue an Office Action (or Notice of Allowance) within three months. The Applicant will then have three months to respond. Delays can result in the application being expelled from the program.

Benefits of the PPH

The PPH provides a means to accelerate prosecution in Canada and other PPH jurisdictions without fee, thereby reducing portfolio management time and costs. Use of the PPH can also provide consistency in scope of protection across multiple jurisdictions.

Drawbacks of the PPH

By limiting the claims to those of a foreign counterpart, an Applicant may be giving up scope that could have otherwise been pursued in Canada.

Whereas some jurisdictions have a flexible divisional practice, permitting an Applicant to pursue additional claims in a later application, Canada does not. Divisional applications are vulnerable to double patenting challenges in Canada, unless they are filed in response to a unity of invention objection, and terminal disclaimer is not a remedy. Therefore, it is advised to pursue all potential claims in a single application in Canada.

Alternatives to the PPH

Examination may be accelerated in Canada by two alternative routes:

1. Special Order may be requested by paying a government fee and indicating that failure to accelerate prosecution may prejudice the Applicant's rights. No reasoning or evidence is required.
2. Green Technology applications are eligible for accelerated examination if the application relates to a technology that, if commercialized, would help resolve or mitigate environmental impacts or conserve the natural environment and resources. There is no government fee for this program.

An Applicant is not limited by the scope of claims granted in a foreign jurisdiction when using these alternative routes.

Using the PPH in Reverse

An Applicant may consider accelerating prosecution in Canada via one of the routes listed above and then entering the PPH in another jurisdiction based on the allowed Canadian claims.

Conclusions

The PPH is an effective means to accelerate patent prosecution but may not always be the best route for Canada due to our laws on double patenting. In some cases, better protection can be obtained by accelerating examination via an alternative route. A patent agent can help you navigate this highway.

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PATENTS

TOO MUCH INFORMATION? OR NOT ENOUGH? WALKING THE TIGHTROPE OF SUFFICIENCY OF DISCLOSURE

In November 2012, the Supreme Court of Canada unanimously voided[1] Pfizer's patent for Viagra[2], to the consternation of the pharmaceutical industry. Much of the commentary at the time revolved around the Court's finding that sildenafil (marketed as Viagra™) was the *only* compound that was effective as claimed, out of an enormous number of possibilities. As such, the Court held that proper disclosure is a crucial element of the bargain between a patentee and the public and that Pfizer had failed to uphold its end of the bargain.

But was this indeed the case? Could the outcome have been different? And where does this leave prospective patentees in Canada now?

By way of background, Pfizer's patent for Viagra™ disclosed a new use for a class of compounds for the treatment of erectile dysfunction. The broadest claim, claim 1, was directed to the use of a compound of formula (I), which was calculated to encompass roughly 260 quintillion possible compounds. Subsequent claims cascaded down to successively smaller ranges, with claims 6 and 7 each reciting a single compound, one of which was sildenafil (claim 7).

Based on evidence presented at the hearing[3], the Court characterized the invention as the use of sildenafil for treating erectile dysfunction, because Pfizer's tests indicated that *only* sildenafil was effective in treating erectile dysfunction while none of the other compounds had been shown to be effective in doing so. Given this characterization, the Court found that the invention was insufficiently disclosed, rendering the skilled reader unable to practice the invention.

The Court however recognized the practice of drafting cascading claims, noting that the useful claim will usually be the one at the end concerning an individual compound. The Court's decision therefore appears to hinge on the finding that *two* individual compounds were claimed, and only *one* was effective, thus obscuring the true invention and denying the public its right to proper disclosure. This begs the question of whether the outcome would have been different if only one individual compound, sildenafil, had been claimed.

Alternatively, the decision suggests that the invention would have been properly disclosed if *both* individually-claimed compounds had been effective in treating erectile dysfunction. Subsequent courts seem to have adopted this

[1] The Supreme Court revised its earlier order on June 4, 2013, removing the statements indicating that the patent is invalid and void, and stating that Teva had established that its allegations, that the patent is not valid, were justified under the relevant statutory regulations.

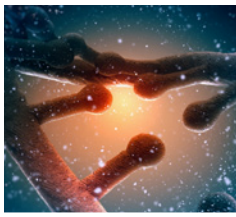
[2] *Teva Canada Ltd. v. Pfizer Canada Inc.,* 2012 SCC 60

[3] *Pfizer Canada Inc. v. Novopharm Ltd.,* 2009 FC 638

TOO MUCH INFORMATION? OR NOT ENOUGH? WALKING THE TIGHTROPE OF SUFFICIENCY OF DISCLOSURE | *CONT'D*

interpretation. For example, a patent that disclosed a class of compounds for treating inflammation, and contained cascading claims ending in three individually-claimed compounds, was upheld on the basis that the skilled reader was not misled by there being a number of compounds that appeared to be interesting, because all individually-claimed compounds worked[4]. Similarly, a patent that included a group of six individually-claimed compounds for treating tumors through selective inhibitory activity was upheld on the basis that all six compounds exhibited selective inhibition and there was no attempt to hide the best inhibitor candidate[5].

Pfizer might therefore have prevailed if sildenafil had been the only individual compound claimed, or if it could have been determined that the compound of claim 6 also worked as claimed[6], had not the specification stated that "certain especially preferred compounds" were tested and "*one*" of these compounds was effective. The Court interpreted these statements as requiring further research to determine which of the two individually-claimed compounds was useful, taking a dim view of what it considered to be Pfizer's attempts to "game" the system. Prospective patentees would be well served to take these decisions into consideration when pursuing patent protection in Canada.



[4] *Pfizer Canada Inc. v. Apotex Inc.,* 2014 FC 314

[5] *Teva Canada Ltd. v. Novartis AG*, 2013 FC 141

[6] This appears to have been the case since, shortly after the decision on Viagra™, Pfizer adduced evidence that the compound of claim 6 was in fact tested before the Canadian filing date and found to be useful for treating erectile dysfunction (*Pfizer Ireland Pharmaceuticals v. Apotex Inc.,* 2014 FCA 13)

LITIGATION

SECTION 8 DAMAGES UNDER THE PM(NOC) REGULATIONS: WINDFALL FOR THE GENERICS

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Canada has a system, similar to the Hatch-Waxman proceedings in the United States, for linking generic drug approval to preliminary clearance of patent hurdles. These proceedings are colloquially known as NOC Proceedings, and are brought pursuant to the *Patented Medicines (Notice of Compliance) Regulations* (the *Regulations*). There are a few main differences between the systems: 1) The proceedings are not full actions, and thus have no discovery; 2) the findings made are not *in rem* determinations of infringement and/or validity, and are not binding on any subsequent action to determine infringement or validity of the patent; 3) the innovator has no right of appeal if the generic company is successful and obtains its market approval; and 4) the innovator can be liable to any generic company it kept off the market, for damages suffered by that company while the proceeding was pending.

It is this last difference, where there has been a recent fundamental shift in the law. Until recently, the Federal Courts in Canada had made a number of findings that prevented generic companies from gaining a windfall through the operation of the regulations that govern these proceedings. Generic companies had been limited to their damages, rather than being able to claim the profits of the innovators. The time period was limited to that in the regulations, and there was no ability for the generic companies to claim twice for the ramp-up period. Damages were owed, but they were based on the damages suffered by the generic company while it was being kept off the market. This approach is in keeping with the purpose of the *Regulations*.

However, two recent decisions from the Federal Court of Appeal have changed that.[1] These decisions relate to the drug ramipril. NOC Proceedings were brought against a number of generic companies, and ultimately, the majority were unsuccessful. Thus, Sanofi brought patent infringement proceedings against both Apotex and Teva when they came to market. Counterclaims of invalidity and for damages pursuant to section 8 of the *Regulations* were brought. The patent was held to be invalid, and Sanofi was held to be liable for damages to both Apotex and Teva, pursuant to s. 8.

The quantum of damages owed to each generic company was previously thought to be determined by how much of the generic market each company would take up. However, in previous cases, there had only been one generic company claiming s. 8 damages; thus, determining the size of the hypothetical generic market in the NOC world had been relatively simple. Arguments were mostly about the timing and extent of market penetration. Nevertheless, this was generally governed by what had happened in the real world. However, in the ramipril cases, two generic companies had brought suits for damages. The innovator argued that the overall market in the hypothetical NOC world should be the same hypothetical NOC as between the two companies, with the dispute being over how much to pay to each from within that overall market. The Federal Court of Appeal disagreed.

The Court held that each claim for s. 8 damages must be determined on its own merits based on the evidence presented. Furthermore, it held that the behavior of competing generic drug manufacturers must be determined on the basis that the *Regulations* exist. As a result, the hypothetical world constructed for each generic market is not the same. This can result in a potential windfall for each generic company as it is possible for each generic company to prove to the Court that in the hypothetical NOC world it would have obtained a share of the market bigger than it holds in reality.

It is thus possible for the innovator to be forced to pay damages that exceed the real world market share of a generic company. Depending upon how many generic companies claim damages, it is possible that the total payout made by an innovator could be several multiples of real world damages of any one generic company. As a result, innovators now need to consider this new reality when determining whether to bring a proceeding pursuant to the *Regulations.*

[1] *Apotex v. Sanofi-Aventis*, 2014 FCA 68 and

SOUND PREDICTION AND THE PROMISE OF UTILITY – THE SWINGING PENDULUM

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In recent years, there has been much discussion regarding patents for blockbuster drugs being invalidated in Canada for lacking utility. In Canada, the invention claimed in the patent must be useful. However, the utility does not have to be demonstrated at the time of filing. Patentees are permitted to rely on a sound prediction of utility.

In deciding an invalidity challenge involving the utility of the patent, Canadian Courts first construe the "promise of utility" from the patent. The Courts then consider whether that promise has been demonstrated as of the filing date of the patent, or whether the patentee must rely on a sound prediction of utility in fulfilling the promise. If the promised utility is demonstrated as of filing, the inutility challenge fails. The Courts generally accept that proof of that utility need not be in the patent.

However, if the patentee needs to rely on the sound prediction of utility, the Court moves on to a further test: 1) identify the factual basis for the prediction; 2) determine whether there is a sound line of reasoning from the prediction to the promise of utility; and 3) decide whether the factual basis and the line of reasoning are properly disclosed in the patent specification. Without disclosure of the factual basis and sound line of reasoning, the inventor is seen to be giving nothing to the public in exchange for the monopoly.

The idea of sound prediction was originally incorporated into Canadian law as a patent-friendly policy, as it allowed protection of useful inventions without the need to make and test every compound covered by a patent. However, in practice, the lower courts have used this doctrine to invalidate many pharmaceutical patents. The current heightened standard for utility has no statutory basis and contravenes Canada's treaty obligations and international norms.

The construction of the "promise" is often the key to the utility discussion, as it will determine the level of utility the patentee will have to meet in order to maintain the patent's validity. Where there is no explicit promise provided in the specification, the courts have agreed that only a "mere scintilla" of utility is required.

In many past pharmaceutical cases where the Court has construed an explicit promise from the patent, the threshold of utility required will generally only be satisfied if the patent contains longer term proof of utility within the patent. The promise in some of these earlier cases has been held to be, for example, treatment of a chronic disease in humans; long term treatment of a disease in humans; all of the stated advantages in the patent; and a reduction in side effects. With these types of promises, even clinical data in the patent was often held not to be sufficient to help meet the sound prediction test.

More recently, the Courts have started to recognize that the "promise" is different from the objects, advantages and mere statements of a practical purpose, which are also found in a patent. Furthermore, the Court has allowed different claims to have different promises. In particular, compound claims, process claims, use claims, and claims to medicaments containing compounds all have been held to have different promises when considering inutility allegations. Finally, there may be recognition from the Court that the disclosure element of this test can be met by taking into account the common general knowledge of the person skilled in the art. The Supreme Court will be hearing a case focused on this issue in November 2014. That decision will be anxiously awaited by patentees and challengers alike.

Thus, in the meantime, it appears that the pendulum may be swinging back towards centre when it comes to patentees trying to uphold their patents in Canada. While the "promise" doctrine and the enhanced disclosure requirements (which the courts have now suggested may not be so stringent) are still unique to Canada, an invalidity challenge based on inutility may not be the "crushing hammer" that it used to be. Patents covering drugs are being upheld in the face of such challenges, when the "promise" is construed reasonably, and the patentee has made appropriate disclosures.

LITIGATION

GUIDANCE REQUIRED FOR JUDGE-MADE CONCEPT OF DOUBLE PATENTING

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Despite statements by the Supreme Court of Canada[1] ("SCC") that patent law is entirely statutory, it has been recognized by the SCC and other levels of the Federal Court that double patenting is judge-made law. The SCC in fact refers to the decision in *Whirlpool Corp. v. Camco Inc*[2]., and not a section of the *Patent Act*, as support for the concept that there may only be one patent covering an invention.

Section 36(1) of the *Patent Act* is often cited as support for the concept of double patenting but this section states only that:

> a patent shall be granted for one invention only but in an action or other proceeding a patent shall not be deemed to be invalid by reason only that it has been granted for more than one invention.[3]

This section discusses "a" or one patent, not the two patents required for an assessment of double patenting and appears instead to be addressing the opposite problem to double patenting, namely multiple inventions claimed in one patent. This interpretation accords with the consideration of section 36(1) in the Manual of Patent Office Practice ("MOPOP") in Chapter 14[4], the section relating to unity of invention. This interpretation also accords with the remainder of section 36 that addresses procedurally how to limit claims in an application that describes more than one invention.

Section 36 does not address the procedure to follow if more than one patent claims the same invention, providing further support that this section was not intended to address this situation.

As a result of being judge-made, the law has evolved in a fractional manner, with each decision addressing only the issues before the Court in a given case. Accordingly, many questions remain. Further problems arise as a result of case law that developed in the context of patents filed and issued pursuant to the "old" *Patent Act*[5], wherein the term of the patent commenced at the date of issuance of the patent and continued for 17 years. Thus, situations could and did arise in which earlier filed patents issued after later filed patents and thus expired after the later filed patents. The applicability of such case law, particularly in light of the broad language used by the Court in discussing the "earlier" and "later" patents, is unclear.

The Court and practitioners alike require guidance with respect to this concept in order to properly advise clients, consider whether an allegation of double patenting is warranted in litigation, and make a proper determination on the merits of any case. Much as the concept of obviousness began in common law, and was ultimately included as section 28.2 of the Patent *Act*[6], if the concept of double patenting continues to exist in Canadian patent law, legislative consideration may be necessary.

[1] *Apotex Inc. v. Sanofi-Synthelabo Canada Inc.* 2008 SCC 61 at para. 12

[2] Ibid. at para. 95, citing *Whirlpool Corp. v. Camco Inc.*, 2000 SCC 67 at para. 63.

[3] *Patent Act*, R.S.C. 1985, c. P-4, as am., s. 36(1).

[4] Canadian Intellectual Property Office, "Manual of Patent Office Practice" (December 2013) at Ch. 14, online: http://www.cipo.ic.gc.ca/eic/site/cipointernet-internetopic.nsf/vwapj/rpbb-mopop-eng.pdf/$file/rpbb-mopop-eng.pdf.

[5] *Patent Act*, R.S.C. 1985, c. P-4, as am., s. 46.

[6] *Patent Act*, R.S.C. 1985, c. P-4, as am., s. 28.2.

"I SHOULDN'T COPY, RIGHT?" WHY PHARMACEUTICAL COMPANIES SHOULD CARE ABOUT COPYRIGHT

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The Product Monograph

In the pharmaceutical industry, the issue of copyright can arise in the context of product monographs. Once approved by Health Canada, product monographs are publicly available documents and contain the information for safe and effective use of a drug. It is drafted and redrafted as Health Canada and the drug manufacturer discuss the product and exchange information. A final approved product monograph may not include all of the information exchanged between the parties, but is the result of discussions and compromise between them. It is published as part of the Notice of Compliance ("NOC") issued by Health Canada and without it, the drug product cannot be sold.

A claim in copyright infringement for substantial reproduction of a product monograph remains an available avenue for an innovator seeking to enforce its intellectual property in Canada. After all, it can be argued that a product monograph is a "literary work" within the meaning of the *Copyright Act*. The most recent (and possibly first) attempt by an innovator to initiate an action for infringement of copyright in a product monograph unfortunately provided no clarity on this issue. AstraZeneca started the infringement action and Apotex responded by seeking to expunge the copyright registrations held by AstraZeneca. However, the infringement action was discontinued. The issue has been raised as part of other actions, for example, as part of motions for interlocutory injunctions.[1] Canadian Courts have not yet decided the issue, but have indicated that the arguments (for either view) are "arguable" at least. The Court has hinted that it would require detailed evidence concerning the 'degree of direction and control' exercised by or under Her Majesty, since section 12 of the *Copyright Act* provides that any work prepared under the direction and control of Her Majesty (or "any government department") belongs to Her Majesty.

So while the outcome remains far from settled, it is easy to understand the dilemma that would ultimately test the Court: weighing public disclosure and access to pharmaceutical information on one hand, and the rights of authors, which encourages the creation of works, on the other. Making pharmaceutical information available to the public (physicians, pharmacists, and patients) is a major objective to be achieved by the product monograph. The Court has signaled that there exists a challenge in attempting to balance public policy with the rights afforded by copyright law. While an incredible amount of work is put into the innovator company's monograph, the Court has said it can be difficult for a generic to produce its version of a monograph that does not substantially reproduce the standard information found in the innovator's (i.e.information as to the action of the drug, its indications of clinical use, precautions to be taken, dosage and administration, etc.). Therefore, the challenge facing the generic manufacturer, from the Court's point of view, is for it to produce a monograph which will be approved, and contain much of the essential information found in the innovator's monograph, but to obtain it from independent and public sources and thus avoid infringement.[2] This seems unlikely, so it remains to be seen how the Court will ultimately side in this seemingly unstable intersection of copyright and patent law.

Working with Copyright-Protected Publications

It is also important to consider the effect of working with or sharing copyright-protected publications. For example, while collaboration and knowledge-sharing are vital to those in the pharmaceutical industry, it is important for employees to read and be aware of the Terms and Conditions of a content-provider's website to determine if "sharing" of content (without permission) is prohibited. While "sharing" may be expressly prohibited, it could nevertheless be excepted from copyright infringement if it is a "fair dealing" pursuant to section 29 of the *Copyright Act* (i.e. if for "research", "private study" or "education" purposes). So while the act of sharing may ultimately qualify as an exception to "copyright infringement" in Canada, it may still be a breach of the company's Terms and Conditions.

It is therefore incumbent on companies to ensure that they have the appropriate licenses to cover the types of uses they require. Corporate responsibility and adherence to copyright law is vital in this regard, since information sharing is key to growth in the pharmaceutical field.

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[1] See *Pfizer Canada Inc. v. Canada (Attorney General)* (1986), 10 C.P.R. (3d) 268 (F.C.T.D.); *Proctor & Gamble Pharmaceuticals Canada Inc. v. Novopharm Ltd.* (1996), 68 C.P.R. (3d) 461 (F.C.T.D.) at para. 33; *Upjohn Co. v. Apotex Inc.* (1993), 51 C.P.R. (3d) 292 at para. 19 (F.C.T.D.).

[2] See *Smith, Kline & French Canada Ltd. v. Frank W. Horner Inc.* (1982), 68 C.P.R. (2d) 42 (F.C.T.D.).

LITIGATION

POTENTIAL NEW IP ENFORCEMENT GUIDELINES FROM THE COMPETITION BUREAU

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Canada's Competition Bureau is in the process of updating their Intellectual Property Enforcement Guidelines (IPEGs) for the first time since 2000. On April 2, 2014, the Competition Bureau released a draft update[1] of its IPEGs for public review.

In general, the IPEGs state that a firm must engage in anti-competitive conduct that creates, enhances or maintains market power to violate the *Competition Act*. The circumstances in which the Bureau may apply the *Competition Act* to conduct involving IP or IP rights fall into two broad categories: 1) those involving something more than the mere exercise of the IP right, and 2) those involving the mere exercise of the IP right and nothing else.

The Competition Bureau recognizes that the unilateral exercise of the IP right to exclude does not violate the general provisions of the *Competition Act* no matter to what degree competition is affected. To hold otherwise could effectively nullify IP rights, impair or remove the economic, cultural, social and educational benefits created by them and be inconsistent with the Bureau's underlying view that IP and competition law are generally complementary.

However, the Attorney General of Canada may initiate a proceeding pursuant to section 32 of the *Competition Act*, even if the action under investigation involved the mere exercise of an IP right. Section 32 is a under the special remedies part of the *Competition Act*, and requires proof of undue restraint of trade or lessened competition. The Competition Bureau expects that such an enforcement action would be required only in certain narrowly defined circumstances, by using a two-part analysis:

> In the first step, the Competition Bureau establishes that i) the holder of the IP is dominant in the relevant market and ii) the IP is an essential input or resource for firms participating in the relevant market.
>
> In the second step, the Competition Bureau establishes that invoking a special remedy against the IP right holder would not adversely alter the incentives to invest in research and development in the economy. This step is satisfied if the refusal to license the IP is stifling further innovation.

If all of the above factors are present, then the Competition Bureau would conclude that incentives to invest in research and development have been harmed by the refusal and a special remedy would help realign these incentives with the public interest in greater competition. Nonetheless, the Competition Bureau recognizes that all three factors would be satisfied only in very rare circumstances.

The draft IPEGs were released on the same day as a new Memorandum of Understanding (MOU) between the Competition Bureau and the Intellectual Property Office.[2] This MOU provides that where possible and subject to their respective confidentiality obligations, the two groups will:

1. consult with each other on enforcement guidelines or policy documents that may have a bearing on the other Participant's mandate;
2. examine the potential referral of competition concerns from CIPO to the Bureau that arise from IP rights;
3. participate in knowledge transfer sessions to increase expertise in areas of mutual interest;
4. participate in collaborative discussions relating to IP issues and their impact on competition as well as on Canadian intellectual property and competition laws;
5. share information related to best practices and lessons learned on dealing with marketplace agency counterparts in different jurisdictions;
6. share information on best practices pertaining to respective enforcement and IP activities, training, information technology and accommodation;
7. develop an employee exchange program, where the Participants will host an employee from the other for a period of 6 to 12 months;
8. cooperate on the organization of a joint workshop on the role of competition policy and intellectual property rights; and,
9. meet annually (or semi-annually, if necessary) at the senior management level to discuss the items enumerated above and to explore further opportunities for cooperation and collaboration.

The Competition Bureau did provide time for further input as a part of the public review process, and so we will have to wait and see the final IPEGs to determine if this review process yields any significant changes that would impact life science companies working in Canada.

[1] http://www.competitionbureau.gc.ca/eic/site/cb-bc.nsf/eng/03715.html
[2] http://www.competitionbureau.gc.ca/eic/site/cb-bc.nsf/eng/03709.html

REGULATORY TRENDS – CANADA

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I. Canada's Food & Drugs Act – Major Changes Proposed

In Canada, the sale and marketing of pharmaceuticals, biologics, medical devices and other healthcare products are regulated under the *Food & Drugs Act* and regulations. Since the creation of this legislation in the 1950's, it has remained virtually unchanged. However, things are about to change.

Due to increased publicity and litigation over Health Canada's failure to warn the public about the dangers of certain drugs, particularly when the same dangers were raised by the World Health Organization and foreign regulatory authorities a few years earlier, concerns over insufficient detection and management of potential safety issues caused legislators to re-examine the current legislation for the purpose of strengthening Health Canada's regulatory powers.

Bill C-17, also known as the *Protecting Canadians from Unsafe Drugs Act or Vanessa's Law*, was formed. Bill C-17 proposes taking a 'product life-cycle' approach to the regulation of health products. What this means is that a health product's risks and benefits will not only be assessed before the product enters the Canadian market but also continually after it has entered the market. Health products subject to such assessments will be prescription and over-the-counter drugs, radiopharmaceuticals, vaccines and other biologics, gene and cell therapies, and medical devices, but not natural health products. Another major change is to give Health Canada the ability to order a recall of an unsafe drug, because under the current legislation, drug recalls are undertaken voluntarily by manufacturers and distributors.

Other proposed major changes include:

- Stronger requirements for adverse reaction reporting (including requiring health care institutions to report serious adverse drug reactions and medical device incidents to Health Canada)
- Giving Health Canada greater powers to demand and obtain safety information
- Allowing Health Canada to pursue faster regulatory action when a serious health risk is identified, including the right to order a product recall or a change to the product's label to make new safety information available
- Imposing stiffer fines and penalties to reflect the seriousness of the violation – up to a maximum of $5,000,000 and/or 2 years' imprisonment (from the current $5,000 fine and/or 3 years' imprisonment)

II. Risk Management Plans – Proposed Requirements

In keeping with adopting a 'product life-cycle' approach to assessing the risks and benefits of a health product, Health Canada requires sponsors/market authorization holders to provide risk management plans. A risk management plan is a dynamic, stand-alone document that is to be updated throughout a product's life cycle and contains descriptions of pharmacovigilance activities and interventions designed to identify, characterize, prevent or minimize risks related to medicinal products, as well as an assessment of the effectiveness of those interventions.

In recognizing that risk management planning has become a global activity, Health Canada has indicated that it will accept the EU format that adheres to the "*Notice Regarding Implementation of Risk Management Planning including the adoption of International Conference on Harmonisation (ICH) Guidance Pharmacovigilance Planning – ICH Topic E2E*". Health Canada will also accept the U.S. *Risk Evaluation and Mitigation Strategies* (REMS) as long as the essential risk minimization elements outlined in the EU format are covered. Even though the use of an EU and a US format is acceptable, Health Canada has indicated that where special considerations exist with respect to medical practice or populations in Canada, the sponsor/market authorization holder must address the special Canadian context in its risk management

REGULATORY TRENDS – CANADA | *CONT'D*

plan. A risk management plan should include all available post-market data (if marketed in Canada or elsewhere) in the form of an annual summary report or a periodic safety update report. The plan should also provide a rationale in situations where additional pharmacovigilance (e.g. a drug utilization study, registry) or risk minimization activities (e.g. contraindication, restricted distribution) are proposed or implemented outside of Canada even if it is not proposed or implemented in Canada.

A risk management plan is required to be submitted for a drug, biologic or radiopharmaceutical that is intended for human use, in the following circumstances:

- as part of a new drug submission
- when a serious safety issue has been identified
- when a previously acceptable risk management plan has undergone significant changes
- significant change in what is known about the risks and benefits or in the frequency or severity of a known risk or the identification of a previously unknown risk

III. Orphan Drugs

With over 7,000 rare diseases identified in Canada, an 'orphan drug' regulatory framework is currently under development in Canada. A 'product life-cycle' approach will also be taken to assess the risks and benefits of an orphan drug both before and after market entry into Canada.

Applicants seeking 'orphan drug' designations for their drugs must demonstrate all of the following:

- prevalence of the disease in Canada is less than 5 in 10,000
- the severity of the disease
- the medical plausibility of the drug
- a lack of existing therapy or potential for significant improvement

Adherence to a risk management plan, a pharmacovigilance plan, a commitment to carry out confirmatory studies, and the implementation of quality controls will be conditions that must be satisfied in order to obtain and maintain market authorization for the orphan drug in Canada.

THE PMPRB – CANADA'S PATENTED MEDICINES PRICING CONTROLS

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Canada has a regulatory regime that can affect the pricing of both small molecule and biologic medicines. The Patented Medicine Prices Review Board (PMPRB) was put in place to protect consumers from excessive medicine prices. Patentees must be aware of the reporting and other requirements of this regime in order to avoid potentially significant financial penalties.

The PMPRB is an independent, quasi-judicial body established under the *Patent Act*. Its role is to ensure that prices charged for patented medicines sold in Canada are not excessive.

Patentees of an invention pertaining to a medicine are obliged by law to report all such medicines sold in Canada to the PMPRB. This obligation has been interpreted very broadly. If a patent is connected to a medicine by the "merest slender thread", it must be reported. In addition, the "patentee" is defined broadly to include any person who has the benefit of a patent. The Supreme Court of Canada has interpreted this jurisdiction broadly. Thus, in the past, this has included licensees (both exclusive and non-exclusive) and assignees. However, two recent lower court decisions have been less expansive, particularly in respect of the PMPRB's jurisdiction in respect of licensees, as the prices of an authorized generic drug and of the drug of a company related to the patentee were held not to be within the jurisdiction of the PMPRB.

In particular, in addition to the patents that directly relate to a medicine, such as patents covering the compound, its use, its dosage forms and its formulations, all patents relating to any process, intermediate, use, or formulation of the medicine must be reported to the PMPRB. This report must be made regardless of whether the patent is being used by the patentee. Courts have found that even if the process is not one that can be used commercially, it must be reported to the PMPRB. The PMPRB is of the view that any patent relating to a medicine in Canada can exclude others, and thus can be used to increase the price. A patentee may not avoid reporting a patent to the PMPRB by not listing it on the Patent Register (the Patent Register is the Canadian equivalent to the United States' Orange Book).

The PMPRB sets the maximum price at which a medicine can be sold in any market in Canada. In setting this price, the PMPRB considers a number of factors, including the price of the drug in other markets; the price of other drugs in its therapeutic class in both Canada and other markets; and the consumer price index. In addition, if this information is not sufficient, the Board can also consider the cost of making and marketing the medicine. These factors result in a highly technical and fact-specific analysis. In determining the maximum price of a medicine in Canada, patentees can make representations to the Board about the relevant factors that should be considered.

REGULATORY

THE PMPRB – CANADA'S PATENTED MEDICINES PRICING CONTROLS | *CONT'D*

The PMPRB has jurisdiction over the price of a medicine sold in Canada as long as there is a patent relating to it. This includes medicines sold under the Special Access Program. Furthermore, once a patent issues, the PMPRB will take jurisdiction over the price of that medicine from the laid open date of the patent. This can bring a medicine not previously subject to the PMRPB's jurisdiction under its jurisdiction, or can bring a medicine back under the PMPRB's jurisdiction if a new patent issues after all other patents have expired. It is thus critical for companies to consider PMPRB issues when deciding whether or not to issue a patent in Canada pertaining to a medicine sold in Canada.

If the PMPRB finds that the price at which the medicine was sold in Canada is excessive, then it can order the patentee to reduce the price of the medicine, and can also order a repayment of the excessive pricing. If the PMRPB finds there has been a policy of selling at an excessive price, it can order a patentee to offset up to twice the excessive revenues found to have been earned.

The initial reporting timelines for the PMPRB are tight. A patentee is required to notify the PMPRB as soon as practicable of its intention to sell a patented drug product in Canada, and the date on which it intends to offer the product for sale. In addition, a patentee must report a medicine subject to the PMPRB's jurisdiction within 7 days after the first Notice of Compliance is issued, or 7 days after the medicine is first offered for sale in Canada (whichever is earlier). Where a medicine is sold in Canada before a patent is issued, a report must be made upon issuance.

It is thus extremely important that patentees are aware of the the full extent of their patent portfolios relating to their products, and are vigilant in monitoring patent issuance in Canada.

HUMAN RIGHTS IN THE EMPLOYMENT CONTEXT

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Human Rights Legislation

In Canada the respect of human rights in employment is legislated in all jurisdictions. This legislation is quasi-constitutional and remedial in nature and applies to all employers to ensure that the individual human rights of workers, which have been identified as being of vital importance, are respected.

As it relates to employment relationships, human rights legislation gives employees and potential employees statutory protection from discrimination on a number of core grounds, being race, colour, age, gender and disability. Creed and religion are also recognized prohibited grounds of discrimination in all jurisdictions.

The federal and provincial legislative schemes typically establish complaint based systems under which statutorily created human rights tribunals have the jurisdiction to deal with complaints of discrimination in employment and other contexts. Courts of law have also become increasingly open to the consideration of common law claims that feature a human rights component such as constructive dismissal claims. In the unionized context, grievance arbitrators typically interpret and apply human rights legislation.

Human rights tribunals have the authority to order a wide variety of remedies such as orders to cease contravention of the legislation; monetary awards for injury to the dignity, feelings and self-respect of claimants; compensatory awards for financial losses, most typically lost wages; and the recovery of expenses such as job search expenses or hearing attendance related costs. In some jurisdictions, legal costs can also be awarded where a party to the proceeding has engaged in improper conduct or brought a trivial, frivolous or vexatious complaint. Reinstatement is also an available remedy and although not often ordered, typically because a large number of complaints are settled before the hearing stage, in a 2013 Ontario case where an employee who had been absent from the workplace for almost 10 years, the tribunal thought it appropriate to order reinstatement together with full compensation for lost wages over the employee's entire period of absence.

Employers' Obligations in the Employment Context

Human rights legislation in the employment context fulfills a dual purpose: (1) to ensure that individuals are not precluded from employment for a discriminatory reason, which means that employers' hiring practices can be challenged as discriminatory; and (2) to ensure that during employment, employees are free from direct discrimination, as well as indirect discrimination which can occur when an employer unwittingly adopts policies that have a discriminatory effect on a particular group of individuals.

Additionally, human rights legislation imposes a positive duty on employers to accommodate employees with respect to an identified ground of discrimination, in recognition that there may be different ways for an employee to perform the job while still accomplishing the employer's legitimate work-related objectives.

Generally speaking, employers are required to meet their accommodation obligation up to the point of undue hardship. Typical factors used to consider whether undue hardship has been reached are the cost involved, outside sources of funding and health and safety requirements.

The case law dealing with employment based human rights which has helped to flesh out the scope of an employer's duty to accommodate has typically been centered on cases involving discrimination on the grounds of race, religion or disability, the latter typically focusing on physical impairments relating to recognized illnesses. More recently however, less common grounds of discrimination, namely age, family status and mental illness, have been at the forefront of human rights decisions, and are representative of an emerging legal trend. These developments are not surprising given that Canada's workforce is aging and employees are increasingly working beyond the traditional age of retirement. There is also an increased awareness and understanding of mental health in our society and the fact that it can manifest itself in the work environment.

HUMAN RIGHTS IN THE EMPLOYMENT CONTEXT | *CONT'D*

Age and Hiring Practices

In a case involving a 60 year old former lawyer who applied for a position as a legal writer, the Ontario Human Rights Tribunal determined that a decision by the employer not to select him for an interview was a violation of the candidate's right to be free from discrimination on the basis of age. The Tribunal concluded that the employer's statement to the candidate that it was moving towards more junior candidates with less experience and lesser salary expectations was the reflection of a stereotypical assumption and on that basis awarded damages to the unsuccessful candidate for injury to his dignity, feelings and self-respect.

Family Status

In another recent arbitral award dealing with the grievance of a single mother who worked rotating night and day shifts, an arbitrator concluded that the employer's rule requiring employees to work a combination of day and night shifts had the effect of imposing a burden on the grievor due to her childcare responsibilities that was not imposed on other employees who did not share her family status. As a result, the arbitrator ordered that the grievor be accommodated by working day shifts exclusively.

In another family status case dealing with shift work, the Federal Court of Canada confirmed that an employment rule which interferes with an employee's ability to fulfil her substantial parental obligations in any realistic way is discriminatory.

Fleshing Out the Duty to Accommodate

The cases referred to above, as well as a number of recent decisions relating to the duty to accommodate mental illness, establish that once an employer is made aware of the employee's problem (i.e. mental illness, family obligations) the employer has a duty to investigate and consider accommodation on an informed basis, using a contextual approach and an individualized analysis. This in turn signifies that the employer and the employee must engage in meaningful discussions regarding accommodation on the basis of appropriate information.

These cases and future ones will continue to help flesh out and shape the statutory duty to accommodate which employers have under the Canadian legal system.

THE NEW DIRECTION OF VENTURE CAPITAL FINANCING IN THE LIFE SCIENCES

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Recently, life science companies have faced serious challenges raising financing. While overall venture capital financing in Canada is on the rise compared to past years (though still nowhere near the amounts seen in the early 2000s), life science start-ups are not experiencing the same increase. According to the Industry Canada "Venture Capital Monitor", investment in life sciences companies totalled $40 million during the third quarter of 2013, a decrease of about 56% compared to the same period in 2012.

Pharmaceutical and biotech companies face unique challenges in their pursuit of funding. Life science projects are considered high-risk with historically low returns on investments. Longer development timelines, including lengthy clinical trials for drugs, means investors have to wait much longer to realize returns. The result is that access to capital remains a challenge for life sciences projects. As PwC's "Canadian Life Sciences Industry Forecast 2013" suggests, Canadian organizations will be looking more and more to partnerships and licensing strategies to fill this funding gap, with the need for capital now exceeding $1 billion to achieve further growth.

As pharmaceutical companies face impending expiration of patents for successful drugs, which creates a need for new drugs to bring to market, many are re-strategizing. Rather than focus on in-house research and development, many pharmaceutical companies are looking to farm out the risk of drug development by partnering with, or investing in, early-stage life sciences companies.

Life science companies have also been looking for other ways to attract investment capital, namely by working with research centres that connect innovative and promising academic research with the commercialization capabilities of the private sector.

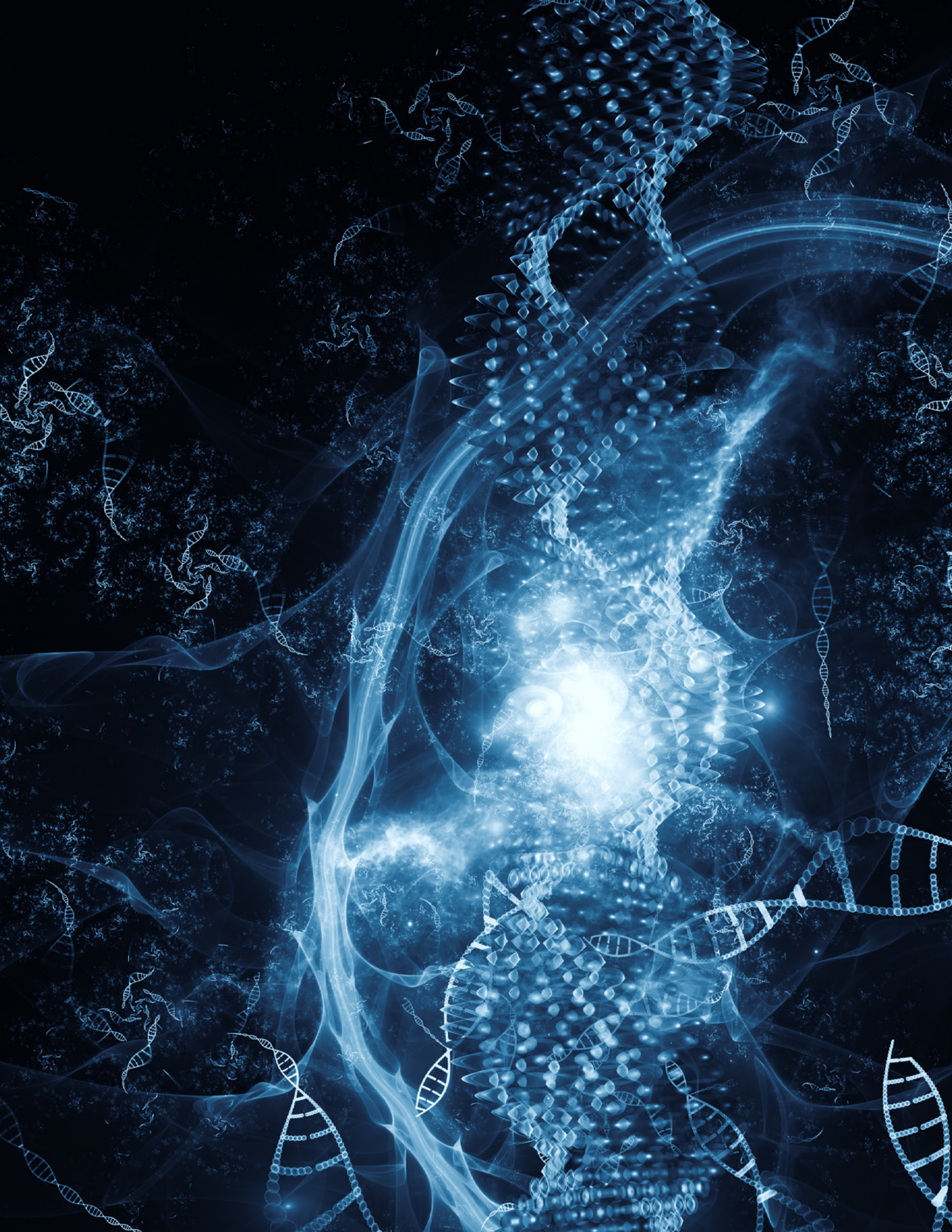
The NEOMED Institute, a biopharma non-profit research centre launched in Québec in November 2012 is the result of collaboration between AstraZeneca Canada, Pfizer Canada and the Québec Government. According to the institute's website, its primary aim is to help "translate early stage innovations into solid partnership opportunities." Its founders made a commitment to invest $100 million over a five year period.

In 2013, MaRS Innovation and Pfizer also joined forces to identify investment opportunities, within its member institutions and affiliated teaching hospitals, emerging from promising scientific research discoveries and advance early-stage technologies in the therapeutics and diagnostics fields of human health.

Finally, the University of British Columbia "Centre for Drug Research and Development" (CDRD) provides resources to assist researchers to advance early-stage drug candidates and bridge the commercialization gap that often exists.

The Canadian government has also recently taken action after a report it commissioned revealed that companies were struggling to find additional funding beyond an initial financing of a few million dollars. In 2013, the Canadian government launched the Venture Capital Action Plan ("VCAP"), which includes an allocation of $400 million in venture capital support, by establishing new funds while also recapitalizing larger funds. Further to this commitment, in September 2013, the government announced its intent to make a total of $50 million in commitments to four existing venture capital funds – two of which focus on life sciences.

Though times have been tough in terms of raising capital for early stage life science ventures, new programs and strategies can help to ensure that Canada remains a strong presence on the global stage.



MESSAGES FROM REGIONAL ASSOCIATIONS

Rory
Francis
Executive Director

PEI BIOALLIANCE

While its tag line may be 'Next Generation Prosperity', a recent economic analysis of the Prince Edward Island Bioscience Cluster suggests that this economic sector is already having a profound impact on the province's economy.

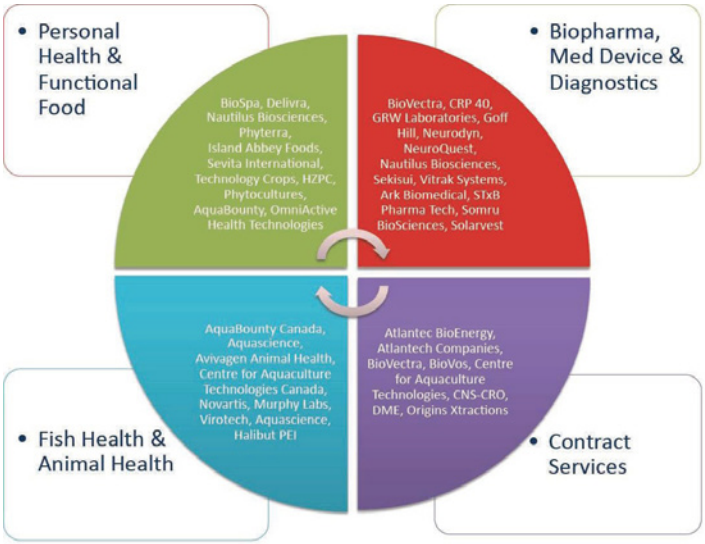
The Prince Edward Island Bioscience Cluster has shown remarkable growth over the past decade. This unique partnership of businesses, research, academic institutions, and government now includes 40 companies with sales growth averaging 33% per year over the past three years. Follow on private financing has increased over 40 per cent during this time period, reaching $22 million in 2012.

The Prince Edward Island's bioscience sector now rivals the banking sector and the accommodations and food services industry in terms of contribution to the province's GDP, at 2.7%. On a per capita basis, Prince Edward Island now places second or third in the country in pharmaceutical manufacturing and organic chemistry manufacturing respectively. With products ranging from cosmetic ingredients, to natural health products, animal and fish health products and pharmaceutical ingredients, export sales have been growing rapidly.

Rory Francis, Executive Director of the Prince Edward Island BioAlliance, says that establishing an effective innovation ecosystem focused on building successful bioscience companies has been a team effort. "We all know the recipe: intellectual property, entrepreneurs, capital, human resources, public policy, infrastructure, markets. But that doesn't mean you can bake the cake. It's taken the alignment of partners' efforts over several years to create a great platform for bioscience here in Prince Edward Island."

The PEI Bioscience Cluster is attracting new companies, capital, and skilled talent to the province. "Access to strategic science and technology, commercialization support and the right kind of capital at the right time" says Francis. "These are key advantages for the companies locating here, whether at the incubation or growth stages."

Can governments and private sector both get the return on investment they are looking for in the bio sector? The BioAlliance thinks they have the answer.



Marli
MacNeil
Chief Executive Officer

BIONOVA

For centuries, Nova Scotians have combined ingenuity, business acumen and hard work in a harsh environment to create opportunities, most often based on the province's natural resources – minerals, the ocean, the forest, the land. Today, new generations of Nova Scotians, joined by talented men and women from all over the world, are using those same skills – innovation, entrepreneurship and perseverance – to grow a life sciences industry.

The innovation that serves as the cornerstone for the industry has spun out of research-oriented universities, a medical school, leading healthcare facilities for children and adults and the minds of business people. Supported by government incentives for research and commercialization, this innovation has been taken on by entrepreneurs and successful companies have been built in the areas of medical technology, vaccine and drug discovery, digital health, nutraceuticals and natural health products, and agricultural bioproducts.

Among Nova Scotia's life sciences success stories are the world's leading manufacturer of fish-derived omega-3 products, the largest manufacturer of seaweed-based specialty products in the world, a unique healthcare/IT convergence to provide patient access to therapies and a number of medtech companies with significant international sales and profits. In addition, several companies working in anti-infectives and immunotherapy are being tracked globally, so excitement keeps building for the future.

A recent survey provided a snapshot of the industry:

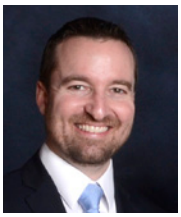
- 50 companies, with more than half already selling into the global marketplace;
- Annual export sales of $300 million;
- Direct employment for 1100;
- A healthy pipeline with more than $78 million committed to new product development through R&D in 2014;
- A vibrant and supported start-up environment.

Research and technology platforms that will influence future growth include:

- Marine biotech research for natural health product and bioproducts;
- Neuroscience research for to both therapeutics and devices;
- Biomedical engineering for medical technology products;
- Imaging expertise providing research services and a commercialization stream of new products and procedures.

Various levels of government provide support for life sciences companies. R&D tax credits, investment incentives, start-up programs and incubation facilities are available to make the transition from concept to customer a little easier. Formal and informal networks enable industry to work with academic researchers and clinicians and access is available to the contractors and suppliers needed to help young companies expand.

In 2012, the province's first major life sciences exit brought more than half a billion dollars to local and national investors. There will be more pay days like that with excellent science as the foundation, smart entrepreneurs to guide growth and solid ideas on how to meet the world's needs for health, nutrition and environmental security.



Jason
Field, Ph.D.
Chief Executive Officer

LIFE SCIENCES ONTARIO – LSO

Ontario has invested heavily in education and research and we are currently home to one of the most well educated young workforces in the world. But youth unemployment is a growing concern, particularly in areas of STEM (science, technology, engineering and mathematics) disciplines.

The life sciences industry is uniquely positioned to help address some of the biggest social challenges that governments around the globe are facing: strengthening economies through the creation of jobs in knowledge-based industries, sustainable and high quality healthcare, affordable clean energy alternatives, sustainable food sources and the need for technologies that support a clean and healthy environment. Indeed, life sciences is the key to Ontario's future prosperity.

Ontario's academic institutions have responded to these challenges by integrating innovative entrepreneurship training and business incubation programs on campuses across the province. The result has been a new generation of life science entrepreneurs with the tools and resources needed to bring innovation out of the laboratory.

Life Sciences Ontario (LSO) has also contributed to supporting young scientists and entrepreneurs. Since 2009, LSO has offered a professional mentorship program to help new science graduates build their networks, explore alternative career paths and gain advice from experienced life science professionals. To date, the program has matched over 500 mentors and protégés.

In 2011, LSO created a quarterly peer-to-peer roundtable series specifically tailored to life science entrepreneurs. The Life Sciences Ontario Entrepreneur Peer-to-Peer (P2P) program advances the economic development of the life sciences industry through collaboration and information sharing between experienced business leaders, subject matter experts and new Life Sciences entrepreneurs. Key topics discussed span pre-commercial planning/activities through to product life-cycle management.

Since 1989, LSO has delivered many opportunities for Ontario's life sciences sector to connect; including a monthly Knowledge and Networking Breakfast Forum, an annual LSO Awards Gala and an annual Fall Symposium. LSO's high-quality education and networking programs offer great value by providing members with opportunities to learn and build new connections, leading to new business partnerships and employment opportunities.

Integrating entrepreneurship education in Ontario's academic institutions is definitely a move in the right direction. However, we need to ensure that there is a receptive business environment for these emerging life sciences entrepreneurs. A business environment that provides access to risk capital, is a first adopter of innovation and has a high tolerance for the early failures that all successful entrepreneurs experience.

Life Sciences Ontario is an organization that represents all aspects of Ontario's life sciences ecosystem. Our vision is a vibrant life sciences sector in Ontario that speaks with a unified voice to create an environment that fosters collaboration, innovation and commercial success. Our commitment is to work with all stakeholders and policy makers to make this vision a reality.

LSO will work across Ontario's diverse sector to speak with a unified voice; and to recommend and promote well developed policies that address the challenges of promoting innovation, improving productivity, increasing access to capital and supporting commercialization efforts in order to realize the full potential of our world-class life sciences research and the young entrepreneurs that will bring it to the global marketplace.

ABOUT LIFE SCIENCES ONTARIO (LSO)

Life Sciences Ontario (LSO) is a member-driven organization that represents more than 150 life science companies, service providers, academic and research institutes, partner organizations, individuals and students in Ontario. Together, our members represent more than 17,000 employees, researchers and students across the provinces life sciences sector. LSO collaborates with governments, academia, industry and other life science organizations in Ontario and across Canada to promote and encourage commercial success throughout the diverse life sciences sector. We do this through advocacy, economic development, mentorship and professional development programs, educational and networking events and promotion of our industry locally, nationally and internationally. LSO is the **Voice for Life Sciences in Ontario**.

Gail
Garland
Chief Executive Officer

ONTARIO BIOSCIENCE INNOVATION ORGANIZATION – OBIO

Since its founding, the Ontario Bioscience Innovation Organization (OBIO®) has been engaged in strategy development, policy, and government relations activities to further development and commercialization of human health technology in Ontario. OBIO is recognized for its distinction in highlighting the role of industry, as well as government and public sector agencies in finding healthcare solutions and achieving common goals.

In 2009, the CEO's of Ontario's life science companies came together in response to a crisis in which companies faced immense difficulties accessing capital and biotech infrastructure eroded causing significant challenges to industry development and commercialization of Ontario's investment in research. Over 80 people in C-level positions participated in a process that launched OBIO and set the tone for the organization's approach to planning, stakeholder engagement, consultation and prioritization. OBIO's vision is to ensure a sustainable biosciences sector in Ontario that offers job creation, improved health outcomes and a more prosperous economy for the province.

During the 5 years OBIO has been operating, we have seen the fall out-from 2008, some recovery of the venture capital and Investment Banking sectors, an opening of the IPO window for biotech in the US, the introduction of Obama care and world-wide discussions on value for money in health innovations. We have seen changes in government and policy at both the provincial and federal level affecting tax credits, market access, technology procurement and dissemination and funds that invest in commercialization. The launch and renewal of programs like FedDev Ontario have directly helped Ontario bioscience companies to grow and create value. A number of government funded organizations such as HTX, EXCITE, MaRS Innovation and CCRM were established to address the commercialization gap for Ontario's science and more recently international funds and angel groups have opened offices in the province.

OBIO has played a leadership role in recognizing the alignment between provincial healthcare priorities and innovation and was first to report on how innovation is key to the health and prosperity of Ontarians and must be adopted and disseminated to have impact. In 2011, OBIO led the province-wide Ontario Bioscience Economic Strategy Team (OBEST®) to develop a strategic vision and action plan. OBEST mobilized over 300 stakeholders and set objectives for capital access, human resources, innovation adoption and export, anchoring the industry, culture, and integration. OBIO currently focuses on three, high-impact initiatives:

- **The OBIO Capital Access Advisory Program (CAAP™)** develops Ontario's earlier stage enterprises and builds their capabilities from a venture readiness perspective. Under the direction of an international steering committee of venture capital experts, companies receive highly customized direction on goal setting and coaching on strategic execution. Ten companies competed successfully for a place in the 2014 program which kicked-off in April. CAAP receives financial support from the Government of Ontario and the private sector.
- OBIO's **Innovation Adoption Initiative** is developing policy recommendations to strengthen Ontario's capacity to deliver cost-effective, outcome-focused patient care as efficiently and innovatively as practicable while catalyzing commercialization in the health innovation sectors. In 2013, OBIO built a coalition of healthcare stakeholders who prepared an economic analysis and report on technologies that have been adopted in other jurisdictions but were delayed or failed to gain access to the Ontario healthcare system. (http://obio.ca/wp-content/uploads/2013/12/Innovation-Adoption-Report-for-Distribution.pdf)The project's next step focuses on deriving and implementing a common and transparent definition of value and metrics that can be used for healthcare innovation adoption.
- OBIO's **Building Interconnectivity** Initiative is facilitating connections between industry leaders through the Executive Exchange Series (EES) and events such as Insider Insight Dinners. OBIO's non-partisan MPP Life Sciences Caucus and advocacy efforts have built understanding and connections between industry and the MOHLTC and other ministries.

The global human health bioscience sector is showing positive signs and continuing to gain momentum in 2014. Ontario needs to embrace policies and processes to become an active participant and derive commercial returns. OBIO is working with all stakeholders to move our key initiatives forward to meet this objective.

OBIO's membership is rich with leaders from the health technology and biopharmaceutical industries, academic, legal and financial institutions. Our ability to deliver is due to the tremendous commitment of our supporters, sponsors, partners and volunteers. We are grateful for the engagement of such a dedicated group of individuals.

Paul V.
Drohan
President & CEO,
LifeSciences BC

LIFE SCIENCES BC

Sometimes one wonders if the strategy is true, whether the predicted outcome will materialize.

Our members have believed for several years that the fundamental strengths of the life sciences community in British Columbia will return to prominence if we follow a deceptively simple recipe: start with truly novel, ground breaking science; add management personnel pre-seasoned by global biotech and life sciences experience; mix-in public policy that encourages innovation, entrepreneurialism, and capital risk-taking; and keep refining until you get it right.

The data are pretty clear that the banquet served up by this recipe has the potential to feed the industry for some time. Once again, our life sciences companies are striding a global stage attracting Pharma partnerships of size and potential, attracting serious capital from well-regarded sophisticated investors, and generating business outcomes that hint at longer term sustainability. We have seen public policy makers respond to our calls for measures that encourage capital risk taking – certainly no panacea among the measures offered but solid, complementary efforts nonetheless.

B.C. has many examples that validate the energy and policy: spin-outs from the Centre for Drug Research and Development; sizable initial public listings and capital raises from some of our marquee companies; clinical data from medical technologies; the emergence of new revenue focused businesses; and tangible examples of the integration of biotech, medtech, and infotech into nascent digital enterprises that will further transform our healthcare environment.

And we have seen and are grateful for resurgence among our sponsors too, surely as strong a sign as any to the economic impact and future potential of this industry.

It is tempting to say that we are benefitting from the proverbial high tide that lifts all boats. Without question, the dramatic return of public investors to biotechnology and life sciences narratives over the last 12 months has provided welcome fuel to a capital-intensive industry. Yet I would argue that the data also clearly say that this return of capital has been quite geographically focused. Focused in clusters such as B.C. with the magic combination of great public research institutions, strong national and provincial funding agencies supportive of early, novel, and challenging research, a pool of talented and battle hardened management, and a vibrant entrepreneurial spirit.

So, yes the strategy is true and the predicted outcome does seem to be materializing. However, I feel like a coach whose team has started winning when I say: do not forget why we are winning. We need to continually challenge ourselves; reinvest in the science; attract the personnel; provide returns for investors.

Some of these returns will come from our remarkable and unique strengths of integration. This integration is at both the micro and macro levels.

At the micro level a single payer health system, a provincial clinical research enterprise, anonymized manipulable patient data, all within globally recognized teaching hospitals, provides a remarkable set of investigative tools that we should continue to exploit to attract science, people, and capital to B.C.

At the macro level we are blessed with endowed research organizations, and opinion leaders, independent of public policy makers, who as leaders recognize the need to work together as a community, for the community – and better yet do so in a profoundly collaborative manner.

Given all these strengths and positive signs, we now need to focus on two basic tasks. First, keep the energy focused on our original strategy. It is working and will continue to work if we stick to it. Second, and increasingly more importantly, we need to start generating sustainable returns through sustainable businesses that will replace the historic and lamented anchors that built this industry in B.C. Through multiple sustainable businesses, with leading innovators who want to build their businesses here, and keep their businesses here, we will emerge to our rightful place alongside the two or three global clusters about which we all talk.

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