

LIFESIGNS • LIFE SCIENCES LEGAL TRENDS IN CANADA



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BLG
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Table of Contents

1 Message from BLG

2 Message from Canada's Leading Life Science Associations

- | | |
|---------------------------------|--------------------------------------|
| 3 Innovative Medicines Canada | 6 Life Sciences Ontario |
| 4 BIOTECanada | 8 Life Sciences BC |
| 5 BioNova | 9 Prince Edward Island BioAlliance |

10 Insights from the Life Sciences Team at BLG

11 | Intellectual Property

- 11 | Obviousness-Type Double Patenting is not Assessed at the Publication Date of the Second Patent
- 12 | Getting Diagnostic Inventions Back on Canada's Innovation Agenda
- 14 | What CETA Means for Innovators with Canadian Patents
- 15 | Intervening Rights to be Introduced to *Patent Act* to Mitigate Potential Impact of Amendments Required by the Patent Law Treaty
- 17 | The Uphill Battle to Acquire Trademark Protection for Pharmaceuticals
- 18 | Canada Enacts New Statutory Provisions Giving Class Privilege to Patent and Trademark Agents
- 19 | Commissioner's Decision 1398 and its Favourable Impact on Antibody Patent Applications in Canada
- 20 | Intellectual Property Crosses Borders more easily than Cannabis

22 | Regulatory

- 22 | Cannabis Oil – Canadian Edibles without Food
- 24 | PMPRB Reform and Implications for Life Sciences Industry
- 26 | *Competition Act* and *Investment Canada Act* Thresholds for 2017

28 | Cybersecurity & Data Protection

- 28 | Cybersecurity and Data Protection
- 29 | Cyber Risk Management Guidance for Corporate Directors

32 | Securities and Capital Markets

- 32 | Good Tactics or Bad Faith: The Divisive Issue of Sandbagging in M&A
- 35 | BLG Poised for Mergers and Acquisitions in 2017
- 36 | British Columbia as a Life Sciences Investment Hub
- 37 | About BLG's Life Sciences Group
- 38 | Key Contacts

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Message from BLG





**Jeffrey S.
Graham**

Partner, Lawyer | Corporate
Commercial Group |
BLG National Life Sciences
Group Leader

Toronto
416.367.6174
jgraham@blg.com



**Paul Y.
Fortin**

Intellectual Property
Practice Group Business
Development Leader

Ottawa
613.787.3583
pfortin@blg.com

Welcome to our 4th Annual edition of Life Signs – Canada’s leading report on life sciences legal trends in Canada. Our report covers notable trends in the areas intellectual property, regulatory affairs, privacy and cybersecurity, and capital markets.

As Canada’s largest independent law firm, Borden Ladner Gervais LLP (BLG) and our Life Sciences practice group are engaged in all facets of the commercialization of life sciences technologies in Canada. Our national and multi-disciplinary platform ensures that we have a vital stake in the future of life sciences in all parts of the country. BLG’s Life Sciences group regularly counsels clients both domestic and foreign on how best to take advantage of scientific breakthroughs and business opportunities in Canada and abroad.

What distinguishes BLG’s practice from a number of other Canadian law firms is the highly integrated nature of our practice. Our corporate professionals have participated in numerous public offerings (including initial public offerings), venture capital investments, mergers and acquisitions, leveraged buyouts, technology transfer transactions, university spin-outs and initial financing transactions. We have structured complex licensing, distribution, development and manufacturing agreements to allow our clients to meet their current and future business needs.

Our IP patent agents and lawyers work closely with regulatory, venture capital, public markets, employment and competition lawyers, and for clients that span the boundaries of the sector from bench top to board room. In recent years, our IP litigators have been at the forefront of efforts to protect the crucial value of the intellectual property assets of our larger pharmaceutical clients.

We are proud to serve the Canadian life sciences sector and to work with some of the most innovative and highly skilled entrepreneurs and scientists in the world. In an ever-changing global political landscape, Canada is uniquely positioned with a federal government that remains committed to pro-trade and pro-immigration policies. And soon, Canada will have access to the 600 million people in the European Union market thanks to the implementation of the CETA trade initiative. Canada’s government in Ottawa and the continuing commitment of provincial governments’ right across the country means that the prospects for the life sciences sector in Canada have never been better – from human health to the environment to our food supply.

We hope that you find these articles to be of interest. If there are any topics covered on which you would like additional information, please reach out directly to the authors or contact the undersigned. We are at your service.

Message from Canada's Leading Life Science Associations





**Pamela C.
Fralick**

President of Innovative
Medicines Canada



Innovative Medicines Canada

Access to prescription medicines continues to dominate the headlines as governments in Canada and around the world look to sustain their health systems while maintaining a high quality of care.

Canadian Federal Health Minister Jane Philpott recently announced consultations for regulatory changes that would “lower drug prices,” while looking to improve drug review processes “so Canadians can get faster access to new worthwhile treatment.”

At the same time, Canada’s federal government is also looking to foster greater innovation to build a sustainable and prosperous economy. Minister of Innovation, Science and Economic Development, Navdeep Bains recently announced a supercluster initiative to jumpstart innovation in several targeted high growth sectors, including health/biosciences. There are few sectors in Canada that are contributors to both the health of its citizens and wealth of the economy, and the life sciences sector is one of them. Innovative Medicines Canada members alone support over 30 thousand jobs and directly invest over a billion dollars a year into the economy.

The question now is how to create affordability and accessibility while continuing to build a thriving life sciences industry? The solutions may be complex, but the way forward is simple – collaboration.

Patients, healthcare providers, governments, and industry alike all play pivotal roles in our health system, and likewise we share the same objective of equitable and affordable access of medicines for all Canadians. Achieving this objective requires new approaches and innovative thinking. The innovative pharmaceutical industry believes a pan-Canadian framework can address our healthcare concerns while driving growth in the sector.

Framework agreements are not unusual; many European countries such as Belgium have already taken this approach. Belgium’s ‘Pact for the future’ is predicated on the notion that a vibrant innovative pharmaceutical industry is in the best interest of both patients and the economy. In the words of the country’s health minister, Belgium “cannot remain complacent” if it wants to continue to be a global hub for pharma innovation and ensure its citizens continue to lead the world in early access to innovative medicines.

The Pact balances the need for a predictable investment environment for industry with lower prices for patients, and has four core pillars – enhanced system efficiency, support for innovation, a strengthened ethical framework, and a multi-year budgetary framework that provides price stability for government and industry alike.

These pillars are supported through increased use of risk-sharing agreements, a focus on data collection and real-world evidence and enhanced cooperation with regulators.

This is just one example, but it illustrates what a made-in-Canada solution could look like. We are well suited to make it a reality: Canada has some of the best scientists and science in the world and the capacity to harness these strengths to build a stronger healthcare system.

Our Health Minister has said that “improving the affordability and accessibility of prescription drugs is a shared priority,” and we couldn’t agree more. The innovative pharmaceutical industry is ready to bring solutions to the table and work with all health system partners to advance our healthcare system for generations to come.



**Andrew
Casey**
President and CEO



BIOTECCanada

Canada's Biotechnology Ecosystem – Home to Great Science, Scientists and Research!

Very much like an intricate clock, the biotechnology ecosystem in Canada is a complex mix of interconnected cogs and wheels. And like a timepiece, it will not function properly if one of those pieces is missing a gear or removed altogether.

Historically, Canada has played an important leadership role in the development of key health, industrial, agricultural and environmental biotech innovations which have greatly improved the way we live, grow and manufacture. As a result, Canada is a globally recognized biotech innovation leader that is home to great science, scientists, researchers and an impressive array of early stage biotech companies in all sectors. Correspondingly, Canada benefits from a vibrant and diverse biotech ecosystem that stretches from coast-to-coast and is grounded by key clusters within each province. In addition to early stage companies, these clusters include universities, hospitals, research institutes, incubators, investors, entrepreneurs and multinational pharma and biotech companies.

Importantly, when it comes to health innovation, the shifting business model of large multinational pharmaceutical and biotech companies has them playing an increasingly central role as investor and/or partner in advancing innovation from the lab bench to commercial reality. While this is a global phenomenon, Canada's historical relationship with multi-national companies is now helping to jump-start the country's biotech innovation shift. The old model of a company doing all of its R&D in-house has evolved into a new model founded on partnership and licencing. JLABS in Toronto, the only JLABS outside of the United States, stands as a shining example of this new business model which arguably will provide more significant and valuable benefits to the ecosystem than the old in-house model could have ever provided.

The promise of this new comprehensive ecosystem is now beginning to bear fruit as Canadian companies that were fledgling start-ups a few short years ago begin to show signs of significant progress and promise. Rising stars Aquinox, Zymeworks, Innovative Targeting Solutions, Clementia, Northern Biologics are but some of the companies that serve as great examples of Canadian innovation rising to the surface of the Canadian biotech ecosystem and are now moving forward in partnership with the large multinational pharmaceutical companies.

With this as a backdrop, the federal government has begun the process of implementing its Innovation Agenda. The recent federal budget announced the government will be directing \$950M towards the establishment and support of 3-5 sector 'superclusters', with life sciences/health, clean tech and agri-food being identified as priority areas for a supercluster. While the government has not yet provided specific terms and conditions for the clusters, it is known that they are expected to be industry led and must bring together universities, research institutes, investors and SME's. The superclusters must also have at their foundation large corporate players. Clearly, these early criteria are very much aligned with the established components of Canada's diverse biotech ecosystem.

While there is significant work ahead, the federal commitment to developing a life sciences supercluster that will engage all parts of the ecosystem and be supported by the \$400M Venture Capital Catalyst Initiative strongly positions Canada's biotech industry for growth and global competitiveness. It is now incumbent for industry to lead the move from aspiration to implementation. If we get it right, a world under stress from population growth and environmental change awaits our solutions.



**Scott
Moffit**

Managing Director, BioNova



BioNova

The life sciences industry in Nova Scotia has been experiencing considerable growth and success over the past few years. Generating nearly \$300 million in revenues and exporting up to 90% of products, the sector is poised as a growth facilitator for the region's future economic and social prosperity.

Nova Scotia's proximity to the ocean has led to specialization in marine-derived bioproducts and natural health products, including being the global leader in omega-3 supplements. We are also home to emerging medical technologies, including diagnostic devices and advanced diagnostic imaging capability. With a strong and flourishing industry built upon key areas in the fields of pharmaceuticals and vaccines, medical technologies, natural health products, bioproducts and digital health, the province has seen a significant increase in innovation and potential coming from its companies.

With a supportive funding ecosystem and a growing amount of research facilities, Nova Scotia's life sciences industry is becoming a pillar of the new economy.

A recent survey has provided a snapshot of the industry:

- More than 1100 full-time jobs paying on average \$20K more than the provincial average salary
- A solid foundation with a \$75 million life sciences incubator and research centre
- 185+ products in the pipeline, supported by more than \$78 million in committed R&D

Under the leadership of BioNova, Nova Scotia's industry association and sector development organization, companies in the province can build a successful, self-sustaining industry. BioNova catalyzes value creation as a responsive knowledge hub for its members and stakeholders, offering competitive programs, educational opportunities and fostering relationships both inside and outside Atlantic Canada.



**Jason
Field, Ph.D.**
Chief Executive Officer



Life Sciences Ontario

Winning the innovation race: Is Ontario life sciences headed for a breakthrough?

Take a look at the news as of late and you'll see a pattern emerging: Ontario life sciences companies are gaining major ground. It begs the question: Is our sector on the verge of breaking out?

The positive evidence is compelling. In August of last year, Damian Lamb, Managing Director of Toronto-based Genesys Capital, noted intensifying investment in life sciences companies. Soon after, Sunovion Pharmaceuticals announced it was acquiring Toronto-based Cynapsus Therapeutics **to the tune of \$624 million**.

By December, Bayer AG and Versant Ventures had inked a **US \$225 million investment** to establish a Toronto-based stem cell research company – BlueRock Therapeutics – one of the largest-ever series A financings of a biotech company to date.

According to Bayer, the investment was made due to innovation and infrastructure in Toronto, particularly stemming from the MaRS hub, and the region's emerging profile for excellence in science.

Hot on the heels of the BlueRock announcement came a number of key wins for Ontario companies: Toronto-based Synaptive Medical inked a **key growth equity deal** with General Atlantic. Ottawa's Turnstone Biologics secured **\$41.4 million in financing** led by OrbiMed, with participation from existing investors including FACIT and Versant Ventures. And Waterloo-based Intellijoint Surgical announced an \$11 million Series A, with financing led by private investors from the Waterloo-Toronto corridor.

Synaptive's President and Co-Founder, Cameron Piron, called these wins "indicative of the promise of Ontario's medical device and technology sector, and promising for life sciences across the province as a whole." These are just a handful of examples among the many Ontario-based companies turning heads and attracting foreign and domestic investment dollars to match.

Also in 2016, Johnson & Johnson chose Toronto for its first JLABS outside the US, joining the ranks of JLABS outposts in major life sciences hot spots like Boston, San Francisco, and New York.

Why Toronto? Simply put, our ecosystem is uniquely conducive to innovation.

"Here, you have the possibility of that whole spectrum of the healthcare system that doesn't exist anywhere else in a square block like this," JLABS' Melinda Richter told the Financial Post.

At its one-year anniversary celebration this past week, the 40,000 square foot incubator announced it now hosts an impressive 40+ high-potential life sciences companies across a range of sectors, including pharmaceuticals, medical devices, and consumer health solutions.

So why all the buzz for Ontario? Looking at the stats, it's easy to see why we're winning.

Data from Life Sciences Ontario's **2015 Sector Report** indicates Ontario ranks among the Top 3 North American jurisdictions by number of life sciences establishments and the among the Top 10 by employment. Conservative estimates put the industry's annual revenues at \$40.5B, which directly contributes \$21.6B to Ontario's GDP.

Six of Ontario's universities have associated medical schools, including the University of Toronto, one of North America's largest medical faculties. Our 44 universities and colleges produce more than 40,000 skilled graduates in science, technology, engineering and mathematics (STEM) each year. Between 2001 and 2013, the sector's job growth outpaced the provincial average by nearly 10 per cent and demonstrated resilience during the 2008 economic downturn.

Life Sciences Ontario | *Cont'd*

Mark Lievonen, former president of Sanofi Pasteur Limited, perfectly summed up Ontario's unique value-add:

"There is a growing life sciences cluster here, in Ontario, and it's developing rapidly. I like to refer to it as an ecosystem. There are large companies like ourselves, universities and research institutions, skilled labour, small companies – all of this coming together."

It's clear our sector has the research, innovations, talent, and ecosystem to become a key driver of our knowledge economy. It's already in motion. We're gaining speed. To win the final leg of this race, we now need a strategy that will take us past the finish line. This includes an infusion of policy that supports our sector and incentivizes investment, and a government willing to enact it.

*Dr. Jason Field is President and CEO of **Life Sciences Ontario**, a not-for-profit, member-funded organization dedicated to advancing the success of Ontario's life sciences sector.*



Dr. Lesley Esford

President,
LifeSciences BC



Life Sciences BC

LifeSciences BC 2017 – Translating Insights into Action

VANCOUVER, British Columbia, May 2017 – British Columbia’s life sciences sector has become the fastest growing cluster in Canada, surpassing all other jurisdictions with several IPOs and \$2.4B in investment capital. Our life sciences community is feeling the success brought by of years of effort and in depth discovery.

This year at LifeSciences BC we are focusing on “*Translating Insights into Action*”, further strengthening our life science ecosystem while ensuring that we continue to support the fundamentals of company creation and growth.

We have many strengths in B.C., including generating great science. Optimizing and aligning the life sciences sector to support translation of our world-class science into new innovations and commercial products will be key. Our challenge is to ensure that we have the resources, capital and talent to achieve our goals. We are diligently coordinating the efforts of our entire ecosystem to ensure we are not only speaking to the innovators, but government, VC’s, to private payers, and academia. It is a vigorous conversation.

The various players - academic institutions, government, industry associations, accelerators, incubators and industry - need to recognize (and support) the role each play in our ecosystem in order to fortify the connections between them. Each performs an essential role in the effort to facilitate lasting growth – none will be as effective in isolation, *A Rising Tide Lifts All Boats*.

The B.C. cluster is built on a strong foundation of first class health research generated by government agencies, universities, teaching hospitals and technical colleges, as well as a strong start up community. Innovation can be supported by technology platforms such as genomics, AI, applied materials, and VR/AR health technologies.

Our life science ecosystem is defined as early maturing, with a large number of small companies with under 30 employees. There is an opportunity to strengthen the ecosystem to support the continued generation of great science, company creation with a focus on company growth; Translating Insights into Action.

We have many of the ingredients to foster innovation in B.C. and we are moving in the right direction. We need to continue to generate great science and the related discovery and development will continue to advance new start-ups. Recognizing the need to do a better job of scaling up those small companies, and supporting their progress and growth, as a community we will commit to;

1. Strengthening the network and connection of key players in the ecosystem within B.C., Canada and the world.
2. Assisting our SMEs in accessing smart capital – introducing and promoting B.C. companies to investors from around the world.
3. Finding ways to support adoption and procurement of innovation at all levels of the public and private sector.

If we can do this, we will have secured our place in Canada and around the world, while being a beacon of inclusion, resourcefulness, talent and opportunity for all.



Rory Francis
Executive Director



Prince Edward Island BioAlliance

Russian Dolls – Alignment, Focus, and Fit Equals Results

We've all seen Russian dolls, colourfully painted, finely crafted to fit one inside the other in a way that doesn't reveal the unique aspects of each component until they are taken apart. The outer shells protect the inner components and determine their shape.

Economic Clusters across Canada and internationally are highly networked sets of relationships where, in the best examples, a shared vision for the future prosperity of the Cluster is a unifying force that aligns the efforts of the business, academic, and government partners.

So what do Economic Clusters and Russian dolls have in common? No, this is not a Donald Trump joke. It's an analogy that we find useful in explaining some key elements of the successful growth and development of the Prince Edward Island Bioscience Cluster, and how we're influencing the national biotech ecosystem in Canada.

The Prince Edward Island BioAlliance is the private sector-led partnership of businesses, research and academic institutions, and government agencies enabling the growth of the province's bioscience sector. Those enablers include our S&T platform, human resources, access to capital, infrastructure, public policy, and technology assessment capabilities.

Our companies' focus is the research, development and commercialization of bioactive-based products for human, animal, and fish health and nutrition. The Cluster includes 50 bioscience companies, eight research institutions, and federal and provincial government partners. Private sector revenues exceed \$200 million, and annual R&D expenditures are more than \$70 million. Revenue sources include cosmetic ingredients, natural health products, feed additives, vaccines, diagnostics, and pharmaceuticals. If we accept that the outer 'doll' is the Canadian bioscience business ecosystem, then the PEI Cluster is the next layer inside.

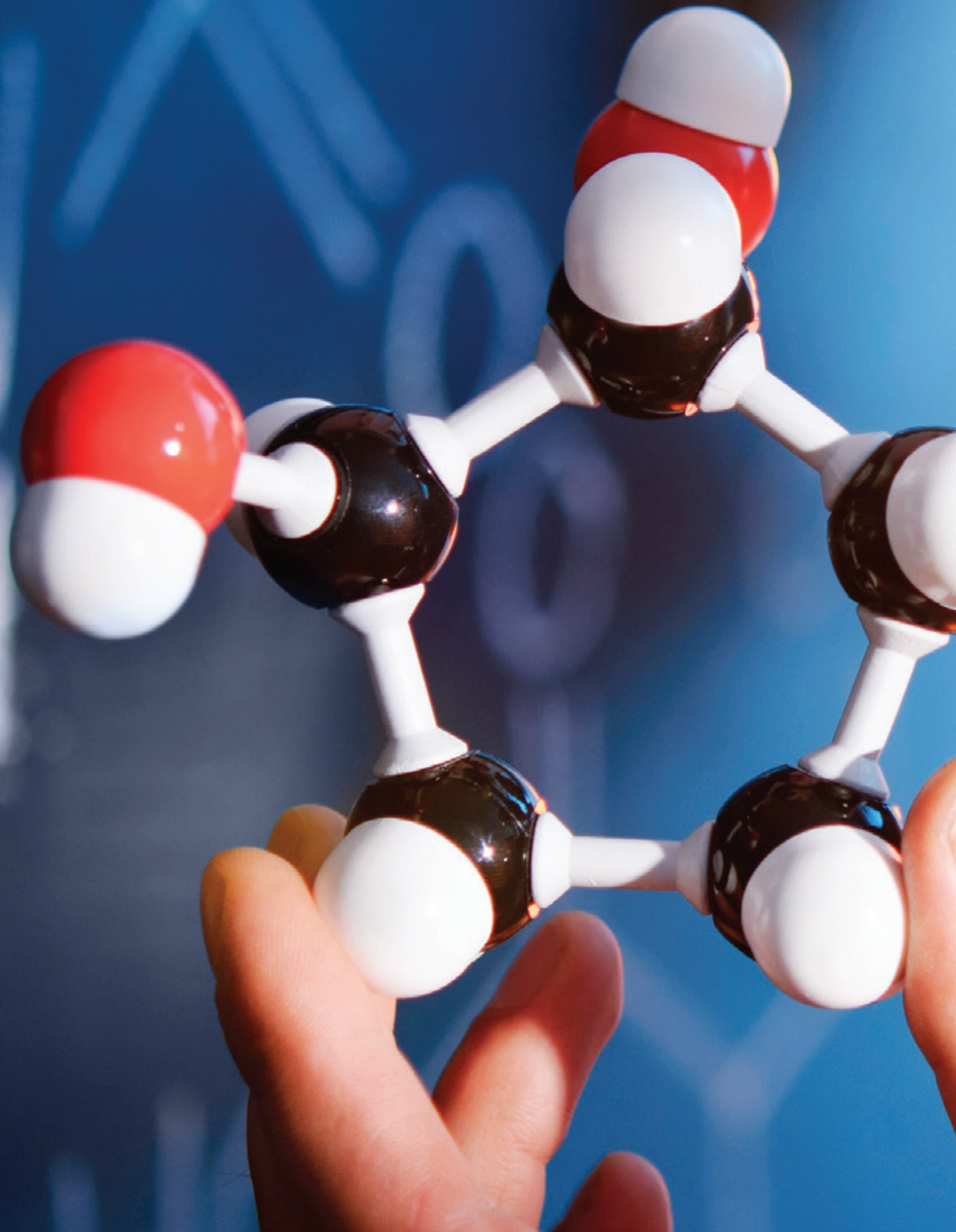
The BioAlliance is the home of Emergence, a Canadian Accelerator and Incubator Program (CAIP) virtual incubator entirely dedicated to helping bioscience-based businesses achieve commercialization success. Providing services including product development, IP strategy, market assessment, regulatory strategy, and capital formation, Emergence is currently incubating 48 early stage companies from the Atlantic region, across Canada and from international locations desirous of a North American entry point. Emergence is the next Russian doll, all the more successful because external factors that enable a successful incubator can be influenced by the Cluster strategy.

Inside the Emergence incubator lives the Critical Path Mentorship Program, an MIT Venture Mentorship model program that provides essential one-on-one and team mentoring to bio-entrepreneurs and bioscience start-ups. The program brings the experience of outstanding mentors from the local Cluster, other parts of Canada, and the US, to bear on the challenges of client companies. The mentorship initiative has magnified impact because it does not stand alone – it is supported and complemented by other elements of the Incubator ecosystem.

But is this success scalable? Besides the national reach of Emergence, our Cluster partners were also founders of Natural Products Canada, North America's first business accelerator dedicated to commercialization of products and technologies based on natural product chemistry, funded through the CECR Program. More recently, we established the Canadian Centre for Cannabis Research, bringing a local and national scientific partnership around the development and commercialization of cannabis-derived health products.

Fit and alignment- these are reinforcing aspects of the Russian Dolls that constitute the key elements of the PEI Cluster. We're on track to ensuring that the PEI Cluster's impact is felt across the Canadian biotech ecosystem.

Insights from the Life Sciences Team at BLG



Intellectual Property

Intellectual Property | Patents



**Chantal
Saunders**

Partner, Lawyer,
Patent Agent | Intellectual
Property Group

Ottawa
613.369.4783
csaunders@blg.com

Obviousness-Type Double Patenting is not Assessed at the Publication Date of the Second Patent

Although we may not know the correct date, or indeed if there is any date, for assessing obviousness-type double patenting, as a result of various decisions involving a patent relating to the use of tadalafil to treat erectile dysfunction, we do know that the publication date of the second patent is not the correct date.

The Federal Courts recently considered double patenting allegations against Eli Lilly's patent in separate NOC Proceedings against two generic companies, Mylan and Apotex. In the first decision¹ to address the issue of the proper date to assess obviousness-type double patenting, the Court found that the proper date is the priority/claim date of the first patent.² The Court made this finding because it considered that the question is "whether the invention claimed in the second patent could or should have been included in the first patent." This assessment follows from a recognition that double patenting is intended to address an improper extension of the monopoly.³ In this case, there was no obviousness-type double patenting on this analysis. The Court determined that the relevant date was not the priority/claim date of the second patent because the obviousness-type double patenting analysis would become simply an obviousness analysis, which would circumvent the timing requirements of section 28.3 of the *Patent Act*.⁴ The Court found that if this were the correct date, there was still no obviousness-type double patenting on the facts of the case. The Court also found that the decision of the Supreme Court of Canada (SCC) in *Whirlpool Corp v Camco Inc*⁵ did not address the issue of the proper date.⁶

In the second decision,⁷ the Court declined to make a "firm determination" on the proper date on the basis that the date was moot on the facts of the case.⁸ The Court did note that there was a sound argument for the use of the priority/claim date of the second patent but agreed with the Court in the

Mylan proceeding that neither the Canadian filing date nor the publication date of the second patent was the correct date.⁹

Mylan appealed the first decision and the appeal focused on whether *Whirlpool* determined the publication date of the second patent to be the correct date. The Court of Appeal rejected this argument, finding that the publication date of the second patent could not be the correct date for a number of reasons.¹⁰ The Court of Appeal then declined to determine the appropriate date on the basis that the second patent was patentably distinct over the first patent assessed at the priority/claim date of either the first or second patent.¹¹

Apotex also appealed the second decision and argued that the Mylan Court of Appeal did not follow the decision in *Whirlpool*. The Court of Appeal did not agree, finding that the decision in *Whirlpool* did not decide that the date at which the comparison is to be done is the date of publication of the second patent.¹² Further, the Court of Appeal stated:

Perhaps, the Court, having construed the claims of each of the patents with the assistance of the persons skilled in the art, simply compares the claims and decides whether the later claims are patentably distinct from the earlier claims on the basis of the insights which it has gained in the course of the construction of the patents.¹³

Apotex's leave to appeal to the SCC was denied.¹⁴

Thus, the issue of whether there is a date for assessing obviousness-type double patenting and if so, what this date should be (other than the publication date of the second patent), remains open. Perhaps the reason that there is this open question lies in the fact that there is no statutory basis for double patenting and therefore no guidance provided by the *Patent Act*.

¹ *Eli Lilly Canada Inc v Mylan Pharmaceuticals ULC*, 2015 FC 17 [Mylan proceeding].

² *Ibid* at para 133.

³ *Ibid*.

⁴ *Ibid* at para 134.

⁵ *Whirlpool Corp v Camco Inc*, 2000 SCC 67 [*Whirlpool*].

⁶ *Ibid* at para 133.

⁷ *Eli Lilly Canada Inc v Apotex Inc*, 2015 FC 875.

⁸ *Ibid* at para 135.

⁹ *Ibid* at para 128.

¹⁰ *Mylan Pharmaceuticals ULC v Eli Lilly Canada Inc*, 2016 FCA 119 at para 51.

¹¹ *Ibid* at para 52-53.

¹² *Apotex Inc v Eli Lilly Canada Inc*, 2016 FCA at para 39.

¹³ *Ibid* at para 40.

¹⁴ *Apotex Inc v Eli Lilly Canada Inc*, leave to appeal to SCC refused, 37368 (27 April 2017), [2016] SCCA No 571



**Kathleen
Marsman, Ph.D.**

Patent Agent
Intellectual Property Group

Ottawa
613.787.3572
kmarsman@blg.com

Getting Diagnostic Inventions Back on Canada's Innovation Agenda

Did you hear the one about the researcher who walks into her university's technology transfer office and says:

"With my federally-funded operating grant, I have invented a way to identify chemotherapy responders based on clinical biomarkers. Can you help me apply for a patent?"

"Good for you!" responds the technology transfer officer, *"But I'm sorry... we can't help you. There's no path to protecting your invention (which the patent office considers a mere correlation) and so it's doubtful we can commercialize. Best of luck to you."*

That's it. That's the punch line. The reader will be forgiven for not finding humour in this situation, and indeed this author wishes it was a joke.

Since the release of examination guidelines in 2015 entitled: Patent Notice: Examination Practice Respecting Medical Diagnostic Methods (PN 2015-02), the Canadian Intellectual Property Office (CIPO) has rejected nearly all claims in the *category* of invention entitled "Diagnostic Methods".

International Patent Classification (IPC) categories were established with the 1971 Strasbourg Agreement 1971, in which the vast majority of countries of the world agreed upon a hierarchical system for the classification of inventions. National classification systems were used prior to 1971, and are still in use. Suffice it to say that nested within Class A entitled "Human Necessities" resides the classification A61B "Diagnosis; Surgery; Identification", under which numerous sub-classification reside, many of which relate to methods and processes for diagnosis of disease. Up until 2012, inventions relating to diagnostic methods were considered patentable, and the Examiners working in this classification were permitted to do their job. In 2012, examination of diagnostic patent applications quietly ceased, awaiting the new examination guidelines. Once released in 2015, it became apparent that a change in policy, not necessitated by a change in Canadian law or jurisprudence, would prevent

diagnostic methods being considered "inventions" unless rather arbitrary distinctions could be made: that the analyte measured was previously unknown, or that the acquisition (method of analyte measurement) of the data was the nature of the invention. Put another way: the diagnostic invention had to involve a new compound or a new method of measurement.

Now that PN 2015-02 is in place, it seems that the new role of the Canadian Patent Examiner in the diagnostic classifications is to school inventors and their agents as to the true nature of their advances being "mere correlations". Examiners are required to use an embarrassment of stock phrases that advise applicants that their solution to what they viewed as a diagnostic problem was quite misled. Examiners must advise Applicants that their real problem fell into one of two pre-defined categories: either it was a *data acquisition* problem, or *data analysis* problem, despite the Applicants' protestations that they believed there was a diagnostic problem to be solved. Examiners proceed to argue that diagnostic methods, and corresponding kits, which yield potentially life-saving solutions to an aging population and an over-budget health care system, have no essential elements, and are mere correlations. Examiners are required to reject these patent claims, on the ground that such diagnostic methods are not what was envisioned by the definition of invention provided in Section 2 of the *Patent Act*. Canadian patent practitioners disagree with this position, and are in discussions with the Patent Office about this misguided practice. No Patent Appeal Board or court challenge has yet occurred.

Through anonymously published documents obtained in requests under the *Access to Information Act*, the origins of this examination policy are revealed as a predominantly a philosophical viewpoint implemented by senior officials, despite clear internal opposition. Perhaps some view life-saving technologies as *too important* to give any one party a proprietary position. However, one might be given to wonder whether the Patent Office truly believes the underlying sentiments behind the stock examination paragraphs: that diagnostic inventions are mere truths stumbled upon coincidentally by a lucky clinician who now seeks to control this truth, and to hold it back from the public.

Getting Diagnostic Inventions Back on Canada's Innovation Agenda | *Cont'd*

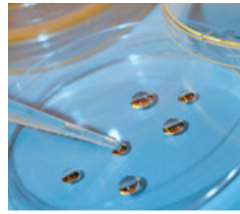
The truth is: to deny a diagnostic invention a proprietary position is to hold it back from the public. The vast majority of Canadian diagnostic inventions are made in a clinical or institutional setting. Not only would the hospital or institution be publically funded, but the research funding used to conduct the work was probably a government-funded grant. The Canadian Institutes for Health Research (CIHR), which is the Canadian government equivalent to NIH in the U.S., invests about \$1 billion per year in health research. The mandate stated in the *CIHR Act* is to “excel, according to internationally accepted standards of scientific excellence, in the creation of new knowledge and its translation into improved health for Canadians, more effective health services and products and a strengthened Canadian health care system.” With such a mandate and budget, it is a fair assumption that some of this money will be spent finding new diagnostic methods.

Research and discovery of diagnostic methods is not enough to permit access to the public. Another agency in Canada is responsible for upholding safety, efficacy, and quality standards of such developments: Health Canada. Once a diagnostic method is discovered, the regulatory route for adoption of this method is a stringent one, and rightly so. *In vitro* diagnostic kits are regulated by Health Canada as Category 4 (non-invasive) Medical Devices. The fulsome requirements of a regulatory submission cannot be borne by a research grant. Typically, investment and private money supports the rigorous testing and development required for the necessary regulatory route. A medicinal chemist could not be

considered responsible for the cost of bringing a drug candidate through clinical trials. A proprietary position for a drug is prerequisite to any investment in clinical development. With diagnostic methods being a way of making decisions as to who should receive a treatment, such as a drug, regulatory requirements should be comparably stringent for diagnostics as for drugs. Why should one classification of invention be permitted a proprietary position, while the other is denied?

Without a proprietary position, investors will not invest in diagnostic method development. Absent the option to patent, there is little else that can be pursued as a proprietary position. Being denied a patent, the inventors of diagnostic methods will see their (taxpayer funded) developments published, and perhaps some adoption as laboratory developed test, but commercial production to permit widespread adoption and the economy of scale for the Canadian public to access will remain elusive.

In the 2017 Canadian Federal budget, innovation features prominently on the agenda. However, diagnostics will be left behind. The disconnect between the government funding agencies that fund research (CIHR and others), permit protection of inventions (CIPO), and regulate commercial adaptation by the public (Health Canada) are working at cross-purposes. The critical link of intellectual property protection that necessarily resides between making a diagnostic invention, and permitting the public access to the resulting diagnostic product is currently severed. Until rectified, tax-payer funded diagnostic developments will continue to fall on the cutting room floor.





Beverley Moore

Partner, Lawyer,
Trademark Agent
Intellectual Property Group

Ottawa
613.369.4784
bmoore@blg.com

In October 2016, Canada signed the Comprehensive Economic and Trade Agreement (CETA) with Europe. The next day, Canada started implementing the CETA. As a result, Canada will soon have a form of patent term restoration.¹ Up to two years of additional protection can be granted to make up for the time a drug has spent obtaining regulatory approval.

The CETA implementation bill, C-30 is an omnibus bill entitled: An Act to implement the Comprehensive Economic and Trade Agreement between Canada and the European Union and its Member States and to provide for certain other measures. It is meant to address all Federal statutes that require amending pursuant to the CETA.

As part of its amendments to the Canadian *Patent Act*, Bill C-30 provides the skeleton of Canada's new, *sui generis*, patent term restoration; in the form of a Certificate of Supplementary Protection (CSP). The Bill leaves a number of considerations to be detailed in regulations expected after the Bill receives Royal Assent. However, the basic framework is present. The Bill also provides that during the CSP's term, "the same rights, privileges and liberties that are granted by the patent" are granted to the certificate's holder and their legal representatives, with respect to the making, constructing, using, and selling of any drug that contains the medicinal ingredients set out in the certificate.

The *Patent Act* will now contain a definition of the word "drug": "a substance or mixture of substances manufactured, sold or represented for use in the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings or animals; or restoring, correcting or modifying organic functions in human beings or animals." This definition is expected to figure in the CSP regulations. However, it will also have implications with respect to the Patented Medicines Prices Review Board and its jurisdiction, as the *Patent Act* has not previously contained such a definition.

On payment of the prescribed fee, a patentee may apply to the Canadian Minister of Health for supplementary protection if all of the following conditions are met:

- a. The patent is not void and meets prescribed requirements;
- b. The patent was filed on or after October 1, 1989;
- c. The patent pertains in the prescribed manner to a medicinal ingredient or combination in a drug for which an authorization for sale of the prescribed kind was issued on or after the day on which this section comes into force;
- d. The authorization for sale is the first for the medicinal ingredient or combination;
- e. No other CSP has been issued for the medicinal ingredient or combination; and
- f. If an application for marketing approval equivalent to the authorization for sale has been filed in a prescribed country with respect to the medicinal ingredient or combination, then the authorization for sale in Canada has been filed within a prescribed period, beginning on the day on which the first such application was submitted in another country.

These provisions essentially provide that there can be a single CSP for a patent in relation to a medicinal ingredient, and that the provisions will not be retroactive. A person will only be able to apply for a CSP for a drug that is approved after this Bill is proclaimed into force. Furthermore, there will be restrictions to ensure that drugs are filed quickly in Canada, for the benefit of Canadians. Each of these "prescribed" periods and requirements will be the subject of regulations that are still to come, as will the timing of the application and certain of its prescribed contents.

The Bill provides, in accordance with the exception also present in the CETA, that it will not be an infringement to make, construct, use or sell the medicinal ingredient or combination for the purposes of export.

The CSP's term will be calculated by "subtracting five years from the period beginning on the filing date of the application for the patent and ending on the day on which the authorization for sale set out in the certificate is issued" – for a maximum of two years.

This is the first time Canada has had such a mechanism available to innovators. It will be interesting to see how the details are implemented, and then enforced, in order to give effect to the CETA.

¹ As of the date this article was drafted, the Bill was not in force, and the necessary Regulations had not yet been promulgated. By publication, this may have changed.



**Jillian
Brenner**

Associate, Lawyer,
Intellectual Property Group

Ottawa
613.237.0234
jbrenner@blg.com

Intervening Rights to be Introduced to *Patent Act* to Mitigate Potential Impact of Amendments Required by the Patent Law Treaty

In its current state, the *Patent Act* does not provide for third party intervening rights where a patent application has been abandoned and later reinstated. Rather, a patentee is entitled to reasonable compensation for infringements occurring once the application for the patent becomes open to public inspection, as provided in section 55(2) of the *Act*.¹

On December 16, 2016, Bill C-43, referred to as the *Economic Action Plan 2014 Act, No.2* received royal assent. The Bill seeks to, among other things, introduce amendments to the *Patent Act* and *Industrial Design Act* in order to integrate two international treaties: the *Geneva Act* (1999) of the *Hague Agreement Concerning the International Registration of Industrial Designs* and the *Patent Law Treaty*.²

The amendments to the *Patent Act* allow Canada to ratify the *Patent Law Treaty*, to which Canada was a signatory in 2001. Ratification of the Patent Law Treaty requires various procedural changes to Canadian patent practice, including changes regarding filing date requirements, claiming date priority, assignments and representations.³

While the *Patent Law Treaty* does not seek to harmonize substantive patent law, Bill C-43 also introduced a new provision concerning third party intervening rights. The Canadian Intellectual Property Office's (CIPO) rationale for including this new provision is to discourage abuse of the patent system and protect third parties from potential uncertainty arising from the procedural changes to the patent system.⁴ CIPO provided examples wherein the provisions added to ratify the *Patent Law Treaty* may contribute to longer periods of market uncertainty for third parties by:

- making it harder to determine when an application is irrevocably abandoned where one or several maintenance fee payments were missed; and

- eliminating the possibility of having patents invalidated because of administrative lapses.⁵

In an attempt to mitigate the potential impact of these new provisions, Parliament has included new section 55.11, which will allow for intervening rights where a patent application is abandoned and reinstated or an expired patent is revived.⁶ Specifically,

- Subsection 55.11(2) provides that no action for infringement of a patent lies against an infringer if that act is committed in good faith by the person during a prescribed period established by regulation.
- Subsection 55.11(3) provides that no action for infringement of a patent lies against a person, in good faith, committed an act that would otherwise constitute an infringement of a patent or made serious and effective preparations to commit that act outside of the prescribed period in set conditions.
- Finally, subsection 55.11(4) transfers the intervening rights to persons who later acquire the patented invention, directly or indirectly, from the persons identified under subsection (2) or (3).⁷

There is nothing in this section suggesting that intervening rights will be applied retroactively.

The new protection arising from this provision has caused some concern in the intellectual property community. Importantly, the protection afforded by these intervening rights exists as a defence to infringement, and would not prevent a patentee from bringing an action for infringement. As a result, there is some uncertainty for potential infringers wanting to ensure that their acts will be protected completely, prior to any investment of resources. Moreover, the Intellectual Property Institute of Canada has commented that the provision contains terms that are uncertain and may ultimately require judicial interpretation. For example, what is required for an act to be "committed in good faith", and what is required to establish that the person "made serious and effective preparations to commit that act"?⁸

¹ *Patent Act*, RSC, 1985, c P-4, s 55(2).

² Bill C-43, *A second Act to implement certain provisions of the budget tabled in Parliament on February 11, 2014 and other measures*, 2nd Sess, 41st Parl, 2014 [Bill C-43].

³ CIPO, "Amendments to the Patent Act: Questions and Answers", online: <http://www.ic.gc.ca/eic/site/cipointernet-internetopic.nsf/eng/wr03892.html> [CIPO Questions and Answers]

⁴ *CIPO Questions and Answers*, *ibid*.

⁵ *CIPO Questions and Answers*, *ibid*.

⁶ *CIPO Questions and Answers*, *ibid*.

⁷ *Bill C-43*, *supra* note 2, cl 136.

⁸ *IPIC, Proposed Amendments to the Patent Act and to the Industrial Design Act per Part 4, Clauses 102 to 142 of Bill C-43 (Economic Action Plan 2014 Act, No. 2) (14 November 2014)*, online: https://www.ipic.ca/download_submission.php?file=154.

Intervening Rights to be Introduced to *Patent Act* to Mitigate Potential Impact of Amendments Required by the Patent Law Treaty | *Cont'd*

Furthermore, the relevant period set out in this new provision is yet to be established. Presumably, the period of time will be from when the application is abandoned to the time in which the application is reinstated, however, the new Rules have not been completed. The United States appear to have a similar provision under 35 U.S.C. § 41(c)(2), setting the relevant period after the 6-month grace period but prior to the acceptance of a maintenance fee.⁹

The new provision on third party intervening rights has yet to come into force. The date is to be specified by the Governor in Council and will likely occur after corresponding amendments to the Patent Rules have been developed. While some suggested that these Rules would be completed in late 2015, or early 2016, they have yet to be released.

⁹ 35 USC § 41(c)(2)



**Jamie
Mills**

Partner, Lawyer
Patent Agent | Intellectual
Property Group

Ottawa
613.369.4782
jmills@blg.com

The Uphill Battle to Acquire Trademark Protection for Pharmaceuticals

Acquiring and enforcing trademark protection for pharmaceutical dosage forms, such as tablets or capsules, can be considered an uphill battle in Canada. There are few circumstances where the colour and shape of a pharmaceutical dosage form is deemed registerable because the Trademarks Opposition Board and the Courts have repeatedly held that such trademarks are not inherently distinctive.

The test for trademark distinctiveness requires that:

1. a mark is associated with a ware;
2. the “owner” uses the association between the mark and his or her product; and
3. the association enables the owner of the mark to distinguish his or her wares from that of others.¹

When arguing that a trademark is distinctive, one usually needs to show only that a consumer identifies the trademark to a significant degree with a source. However, in the context of pharmaceuticals, fulfilling this test requires the applicant to show that physicians, pharmacists or patients associate the dosage form, absent all its markings, with a single source. Given that there are often other products on the market which are similar in colour and/or shape to the applicant’s products, pharmaceutical companies seeking trademark registration of their dosage forms routinely fail in this analysis.

This was demonstrated in 2015 in *Pfizer v Canadian Generic Pharmaceutical Association*² (*Pfizer*) when the Federal Court decided that Pfizer’s blue, diamond-shaped VIAGRA® tablet was not distinctive enough to acquire trademark protection. In *Pfizer*, despite evidence that some patients used the term “little blue pill,” the Federal Court found that patients did not associate the Viagra® pill with a single source to any significant degree. Therefore, the shape and colour of the tablets could not be registered as a trademark. This decision demonstrates the difficulty that pharmaceutical companies face when acquiring trademark protection for these types of products.

If a pharmaceutical company acquires protection for its dosage forms, then the question arises whether it can enforce this protection through infringement proceedings. Actions brought under sections 19 or 20 of the *Trademarks Act* essentially require a plaintiff to demonstrate that an ordinary consumer in a hurry would likely confuse the infringing mark with the registered mark. In this context “confusion” means that the consumer believes both products are being sold from the same source. In order to determine a likelihood of confusion, the Courts apply an analysis that takes into consideration whether the marks look the same, sound the same or are sold in respect of the same wares. Therefore, if two dosage forms are the same shape, the same colour and are associated with similar wares, a Court likely will find confusion.

However, when considering pharmaceuticals, the Court has seemingly applied a different standard of confusion in its infringement analysis. It assumes that doctors and pharmacists will not act in a hurry. Although there have not been any recent infringement actions regarding dosage forms, the Court considered confusion in the context of pharmaceuticals in *Ratiopharm Inc. v Laboratories Riva Inc.*³ In this case Ratiopharm sold a codeine-based cough syrup under the registered trademark CALMYLIN and Riva sold a similar codeine-based product by the name DAMYLIN. The Court decided that patient confusion was not at issue because the products were sold behind the counter and patients were not selecting the products off the shelf. When determining whether doctors and pharmacists might confuse the two marks, the Court held that these were professionals who, unlike regular consumers, would not act in a hurried manner. When considering the diligence that pharmacists and physicians use in prescribing and distributing pharmaceutical products, the Court concluded that there was not a likelihood of confusion between the two trademarks in the mind of the average patient, physician or pharmacist.

In conclusion, pharmaceutical companies need to be aware of the difference in standards relating to enforcement of pharmaceutical trademarks as compared to trademarks relating to other types of products in Canada.

¹ *Phillip Morris Inc. v Imperial Tobacco Ltd.* (1985), 7 CPR (3d) 254 at p 270.

² 2015 FC 493.

³ 2006 FC 889.



Adrian J. Howard

Lawyer and Trademark Agent | Intellectual Property Group

Ottawa
613.787.3557
ajhoward@blg.com

Canada Enacts New Statutory Provisions Giving Class Privilege to Patent and Trademark Agents

Canada has enacted legislation granting privilege to certain communications made between patent and trademark agents and their clients.

Historically, Canadian jurisprudence has held that neither profession was entitled to any professional legal privilege. Agent privilege did not even apply in Canadian litigation even when the communication was originally made in a country where agent privilege did apply.

The courts previously noted that it would take an Act of Parliament to create a new class of privilege for agents, and we now have that class privilege as a result of the passage of Bill C-59.¹ This bill made changes to the Canadian *Patent Act* and the *Trademarks Act*.

Section 16.1 of the *Patent Act*

The *Patent Act* now provides that a privilege akin to solicitor-client privilege applies to communications that were:

- Between the patent agent and their client (or individuals acting on their behalf);
- intended to be confidential; and
- were made for the purpose of seeking or giving advice with respect to any matter relating to the protection of an invention.

One should note that legislation does not restrict the communication to an invention belonging to the client, or whether it belongs to someone else. Presumably, this new privilege will protect communications relating to the validity and/or infringement of a third party's patent. It will be up to the Canadian courts to determine the actual scope of the new provision.

Section 51.13 of the *Trademarks Act*

The enactment for trademark agents is drafted essentially the same as it is for patent agents, but it will protect communications that are made for the purpose of seeking or giving advice with respect to any matter relating to the protection of a trademark, geographical indication or mark referred to in paragraph 9(1)(e), (i), (i.1), (i.3), (n) or (n.1).

Again, the meaning of “any matter” is not defined and will likely be an issue for the Canadian courts to determine. Also, trademark agents should note that the privilege does not apply to communications relating to all of the prohibited marks described in subsection 9(1) of the *Trademarks Act*.

Foreign communications: The changes to the *Patent Act* and the *Trademarks Act* also reverse the jurisprudence regarding foreign patent agent communications. An individual who is authorized as an agent in another country and who can claim patent agent privilege will now be protected by privilege in Canada.

Exceptions: This new class privilege will also be subject to the same exceptions as solicitor-client privilege.

Timing: The changes to the *Patent Act* and *Trademarks Act* came into force on June 24, 2016 and apply to all communications that are made after that date. Privilege also applies to communications that were made before that date if the communications were still confidential as of that day. However, the privilege would not apply in respect of a court proceeding that had commenced before that date.

Lawyers who are also agents

One further benefit from this new legislation will aid those individuals who are both lawyers and patent or trademark agents. Previously, if a lawyer/agent was subpoenaed in litigation, the Canadian courts would have looked to whether a prior client communication was privileged by determining what role the lawyer/agent was playing. If the communication was made by the individual in their role as a lawyer, then it would be privileged. If the communication was made by the individual in their role as a patent or trademark agent, then it would not be privileged. The difficulty for the lawyer/agent was that you would only know for sure whether the communication was privileged after the trial judge made their ruling.

These changes to the law hopefully will give joint lawyer/agents more comfort that their communications will be protected by privilege. This change to Canadian law was a welcome one, and we shall have to wait and see how the Canadian courts interpret this new legislation.

¹ An Act to implement certain provisions of the budget tabled in Parliament on April 21, 2015 and other measures, <http://www.parl.ca/LEGISInfo/BillDetails.aspx?billId=7959017&Language=e&Mode=1>



**Graeme
Boocock, Ph.D.**

Patent Agent | Intellectual
Property Group

Ottawa
613.369.4775
gboocock@blg.com

Commissioner's Decision 1398 and its Favourable Impact on Antibody Patent Applications in Canada

May 2016 saw the publication of **Commissioner's Decision 1398** (CD1398), which clarified sufficiency requirements for humanized antibody claims in Canada. Previously, such claims had been uniformly rejected unless (i) CDR sequences for a monoclonal antibody were disclosed, or (ii) a humanized antibody had been exemplified in the application. Examiners at the Canadian Intellectual Property Office (CIPO) typically raised support and/or enablement objections, stating that undue experimental burden would be required to make and test a humanized antibody starting with an epitope or with an unsequenced monoclonal. This practice was based on a stringent adherence to an earlier Commissioner's Decision (**CD1296**), itself concerning an application with a relatively early filing date in 1990.

Recognizing an "evolution" of the common general knowledge since 1990, the Patent Appeal Board (PAB) found in CD1398 that the production of humanized antibodies had become routine as of the 2002 filing date for the subject application. Accordingly, it found that humanized antibodies could be claimed at that date by reference to a well-defined epitope, under the same rationale permitting monoclonal antibodies to be claimed in similar circumstances.

In January 2017, Chapter 17 of CIPO's Manual of Patent Office Practice (MOPOP) was updated to provide specific guidance on the subjects of chimeric, humanized, and fully human antibodies. **MOPOP Section 17.03.03** on chimeric and humanized antibodies reads in part:

Although core steps for preparing humanized and chimeric antibodies are now well established in the state of the art, the examiner must carefully consider, on a case-by-case basis, whether the skilled person, in view of their common general knowledge in the relevant art and the teachings of the specification, was enabled to prepare a humanized or chimeric antibody specific for the target antigen without having to undertake undue experimentation or display inventive ingenuity at the filing date.

Thus, [statutory enablement requirements] may be satisfied in cases where, at the filing date, a person skilled in the art, in view of their common general knowledge and having

only the specification and a fully characterized target antigen would not have to undertake undue experimentation or display inventive ingenuity to produce a generic humanized or chimeric monoclonal antibody specific to the target antigen.

Similar guidance is provided for fully human antibodies. Welcome in this revised text is mention of a "case-by-case" approach, and emphasis on consideration of the filing date of the application: factors that had not played a strong role in earlier examining practices.

The year post-CD1398 has seen a commensurate relaxation in enablement requirements across the board for antibodies, in alignment with changes in the state of the art. Claims to non-exemplified humanized antibodies are no longer uniformly rejected for lack of enablement when only an epitope is disclosed. This approach has also been extended beyond the scope of the subject matter considered in CD1398. Claims to antibodies defined by competitive binding to a reference antibody have been allowed, along with claims to antibodies defined by discontinuous or conformational epitopes: both areas of notable difficulty prior to CD1398. For now, claims encompassing modifications in CDR sequences remain problematic unless modifications have been exemplified.

If there has been a downside to all this, it has been that the bar for obviousness has been lowered along with the bar for enablement. Applicants previously facing intransigent enablement objections to their humanized antibody claims may now see the rationale of previous objections turned completely on its head, with obviousness objections ensuing under some circumstances. This is an unfortunate byproduct of the highly punctuated manner in which the sufficiency requirements for antibody sub-types have been reviewed and clarified in only a small number of Commissioner's Decisions over a long period of time.

Fortunately, CD1398 and the parallel revisions to MOPOP seem to signal an end to a one-size-fits-all approach to antibody technologies. Examiners are now expressly instructed to consider the relevant facts of an application, and the state of the art at the relevant time. This raises the hope that applications in these technological areas will face a fair and responsive examination for enablement and support requirements in Canada from now on.



**David
Wood, Ph. D.**

Lawyer and Patent
Agent | Intellectual
Property Group

Calgary
403.232.9742
dwood@blg.com



**Mark
Vickers, Ph.D.**

Partner | Patent Agent
Intellectual Property Group

Ottawa | 613.787.3575
Toronto | 416.350.2669
mvickers@blg.com

Intellectual Property Crosses Borders more easily than Cannabis

Canada's federally legal medical cannabis industry grows stronger in domestic and international presence by the day. As of March 31, 2017, there were 167,754 Canadians registered as clients of the 42 licensed producers operating under the federal *Access to Cannabis for Medical Purposes Regulations* (the "ACMPR"). Licensed producers, numbering 48 as of June 15, 2017, provide for quality-controlled legal cannabis by mail delivery across Canada.¹ Federally-regulated medical cannabis programs are also emerging or operating in Argentina, Australia, Chile, Colombia, Czech Republic, Germany, Israel, Italy and other jurisdictions. As of April 21, 2017, 29 American states, the District of Columbia, Guam, and Puerto Rico have passed or enacted legislation for medical use of cannabis, which remains federally prohibited.² These 29 states include over 60% of the population of the United States.

Beyond medical use, the Government of Canada has committed to implementing legal sale of cannabis for unqualified adult use throughout Canada by July 1, 2018. Bill C-45, entitled *An Act respecting cannabis and to amend the Controlled Drugs and Substances Act, the Criminal Code and other Acts* (the "**Cannabis Act**"), was published on April 13, 2017. If passed as drafted, Bill C-45 will remove cannabis from schedule II of the *Controlled Drugs and Substances Act* (the "CDSA"). The *Cannabis Act* regulates cannabis both as a substance and as any species of plant within the genus *Cannabis*. Production and use of cannabis for medical and other applications, and production and use of industrial hemp will each be regulated under the *Cannabis Act*. The *Cannabis Act* maintains criminal penalties for sale to minors, personal production beyond defined limits, and commercial activity involving illicit cannabis.

Eight American states, the District of Columbia and Uruguay have passed or enacted legislation for unqualified adult use of cannabis. Canada will be the first G20 nation to federally regulate both medical and unqualified adult use of cannabis under one framework. Canada's functional and expanding medical cannabis industry combined with federal regulation of unqualified adult use positions Canada as a leader in this emerging industry that uniquely bridges medical and other markets.

International treaty obligations confine import and export of cannabis to medical or scientific contexts, and the cost of importing and exporting cannabis is often prohibitive due to permitting and security requirements. Licensing has and will continue to allow entities to leverage intellectual property outside of their home jurisdictions, including in separate American states, where interstate commerce is blocked by federal illegality. The intellectual property may cover products, production methods, packaging, branding, business methods or any aspect of the supply chain. The licensed intellectual property would likely primarily include one or more of trade secrets, patents, plant breeder's rights, or trademarks.

Traditionally, cannabis products follow a supply chain that includes many steps: planting seeds to grow mother plants, cutting and transporting clones, planting and growing clones, harvesting flowers, processing the harvest, and

¹ www.canada.ca/en/health-canada/services/drugs-health-products/medical-use-marijuana/licensed-producers/authorized-licensed-producers-medical-purposes.html, accessed June 15, 2017; www.canada.ca/en/health-canada/services/drugs-health-products/medical-use-marijuana/licensed-producers/market-data.html, accessed June 15, 2017.

² www.ncsl.org/research/health/state-medical-marijuana-laws.aspx, accessed June 15, 2017 (the information is current to April 21, 2017).

Intellectual Property Crosses Borders more easily than Cannabis | *Cont'd*

preparing cannabis products for sale. In addition to intellectual property monopolizing the seeds themselves, each of these steps can be optimized, and the details of any such optimizations may in some cases be kept as trade secrets or patented. Preparing cannabis products for sale could be as simple as drying, curing, and packaging trimmed flowers. However, an expanding portion of the total Canadian market is for “cannabis oil”, a defined term in the ACMPR that essentially means edibles without food or topicals without cream. Another article in this bulletin describes cannabis oil in more detail. Preparing cannabis oil requires extraction from plant matter and formulating the extract into cannabis oil, additional steps that can also be optimized and in some cases protected.

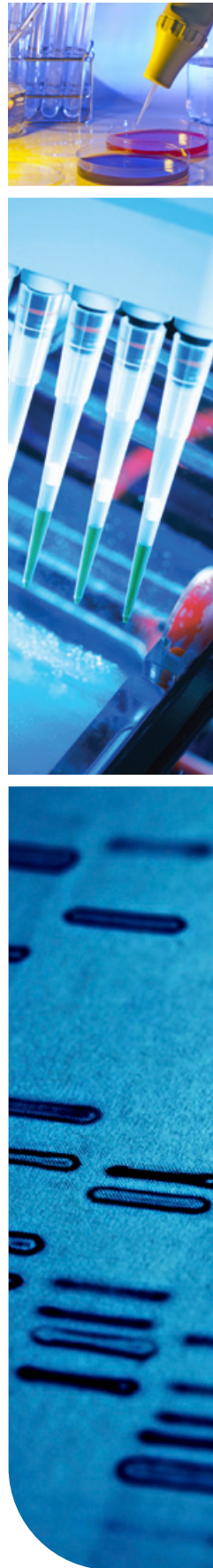
American state markets tend to offer product diversity far beyond the dried flower and cannabis oil available in Canada. Such products, including infused foods (edibles), infused beverages, topicals, vaporizable concentrates, tinctures, transdermal patches, transmucosal lozenges, and many others, gain market share from dried flower each year. Each of these products requires additional production steps and in some cases delivery devices integral to the product, all of which may be improved upon. The *Cannabis Act* defines “cannabis” broadly enough to include any of these products, if and when they are regulated for sale in Canada. Failing to regulate these popular products for sale would leave an obvious need for the illicit market to meet and compromise one of Bill C-45’s primary goals – undermining the market for illicit cannabis. Refocusing on the upstream end of the industry, phytocannabinoids biosynthesized in yeast or otherwise produced without growing cannabis plants would also be within the definition of “cannabis” in the *Cannabis Act*. Yeast-based production is an emerging subset of the industry that clearly has potential for leveraging patents and trade secrets.

Sale of cannabis from dispensaries is outside of the ACMPR and contravenes the CDSA. As such, all Canadian cannabis dispensaries are currently subject to closure and seizure of assets,

although enforcement is inconsistently applied in some municipalities. The provinces will be empowered by the *Cannabis Act* to regulate storefront sale of cannabis in Canada. Storefront sale will present a significant economic opportunity, particularly in those provinces that choose to allow sale of cannabis through privately owned and operated businesses. Storefronts operating under federal and provincial law will also allow national retail brands to be established in Canada, including by expansion from Colorado and other better-developed state markets. Federal legality will bring uncomplicated registration of trademarks for retail sale services and make true franchising possible – particularly with licensed producers continuing as the starting point of the supply chain. Branding and advertising guidelines in Canada are expected to be strict based on Bill C-45. The details will be in future regulations under the *Cannabis Act*. As a result, developing a culture of compliance in Canada may result in branding that meets standards in other jurisdictions with conservative advertising regulations.

In addition to allowing expansion to new markets, intellectual property licensing may, depending on the circumstances, result in collaborations that allow access to local genetics, product diversity regulations, advertising regulations, the absence of patents or other exclusionary intellectual property rights, or other jurisdiction-specific advantages.

Absent a reversal in political trends, rapid growth in commercial activity and market size for cannabis is likely within Canada and globally at least over the next five years as the industry matures and social acceptance of both medical and unqualified adult use of cannabis increases. The resulting competition and diversity in applications for cannabis, in medical and other contexts, will drive optimization and innovation at all levels of the supply chain. With unqualified adult use alongside medical use, greater product diversity, and storefront sale of cannabis in Canada, the Canadian cannabis industry will diversify, providing more ways to participate. The cannabis industry is technology-intensive and based on a heavily and uniquely regulated commodity. Intellectual property is a significant asset to industry participants and licensing presents a logical cross-border expansion strategy, particularly since crossing a border with cannabis is currently either cost-prohibitive or impossible.





**David
Wood, Ph. D.**

Lawyer and Patent
Agent | Intellectual
Property Group

Calgary
403.232.9742
dwood@blg.com

Cannabis Oil – Canadian Edibles without Food

Canada's federally legal medical cannabis program under the Access to Cannabis for Medical Purposes Regulations (the "ACMPR") provides cannabis to patients in two ready-to-use forms: dried cannabis flowers¹ and cannabis oil.² Cannabis oil is distinct from dried cannabis flowers in that it is swallowed, absorbed transmucosally, or applied topically – cannabis oil cannot be smoked or vaporized. This distinction and its benefits are likely to increase acceptance of cannabis as a therapy by physicians and patients in Canada.

For a brief regulatory context, the federal ACMPR provide an exception to the current prohibition on cannabis affected by the *Controlled Drugs and Substances Act* (the "CDSA"). Canadians who participate in the program may become clients of one or more licensed producers (an "LP" or "LPs") and purchase quality-controlled medical cannabis for mail delivery. The Canadian cannabis industry will soon expand beyond the medical market to include an unqualified adult use market. Both the medical and unqualified adult use cannabis markets will be regulated by legislation first published in Bill C-45, entitled *An Act respecting cannabis and to amend the Controlled Drugs and Substances Act, the Criminal Code and other Acts* (the "*Cannabis Act*").

As of May 31, 2017, Health Canada has issued 22 licenses for production and/or sale of cannabis oil and 48 licenses for production and/or sale of dried cannabis flower.³ Many would consider dried cannabis flower to be the default medical cannabis product. However, the popularity of cannabis oil continues to increase in the Canadian medical cannabis market, following a similar trend to the retail-driven American state markets for infused foods, beverages, lozenges, topicals, tinctures, and similar products in both medical and adult-use cannabis markets.

The term "cannabis oil" may bring a variety of products to mind. In Canada, cannabis oil commonly means either (a) edibles with no food matrix or (b) topicals with no ingredients other than the oil used to reformulate cannabis extract into cannabis oil. Requirements in the ACMPR

exclude cannabis oil suitable for smoking or vaporizing. The ACMPR also exclude infused food or beverage products, and topical products that include creams, moisturizers, vitamins, or other additional ingredients. Bill C-45 does not introduce any new product categories, but the *Cannabis Act* is drafted with a schedule including dried cannabis and cannabis oil. This schedule may be expanded to include vaporizable concentrates, infused solids, infused non-solids, and other products, which clients of LPs are free to make for themselves (provided no organic solvents are used), but which cannot be purchased from LPs. Each of these product categories is popular both in regulated American state markets and in the Canadian illicit cannabis market. Failing to regulate these popular products for sale would leave an obvious need for the illicit market to meet and compromise one of Bill C-45's primary goals – undermining the market for illicit cannabis. As a result, there is a widespread expectation within the industry that these products will be regulated for sale at some point after the *Cannabis Act* comes into effect.

The ACMPR require that cannabis oil be liquid at room temperature and limit the combined concentration of delta-9-tetrahydrocannabinol ("THC") and delta-9-tetrahydrocannabinolic acid ("THCA") in the cannabis oil. The combined concentration of THC and THCA must be no greater than of 30 mg/ml of THC, including THC that would result from complete decarboxylation of all THCA in the cannabis oil ("Total THC"). Cannabis oil in a capsule or similar dosage form is restricted to a maximum of 10 mg Total THC per dosage unit. The ACMPR do not limit the amount of cannabidiol ("CBD") or cannabidiolic acid ("CBDA") in cannabis oil by volume or by dosage unit.

Packaging for cannabis oil must indicate the Total THC concentration, and the analogous number for CBD and CBDA. Other phytocannabinoids, terpenoids, phenylpropanoids or other compounds extracted from *Cannabis sativa* plant matter during preparation of cannabis oil are unrestricted in maximum concentration and have no labelling requirements. Notwithstanding the lack of labelling requirements, some LPs summarize other phytocannabinoids and terpenoids in cannabis oil or dried cannabis flower.

1 Dried cannabis flowers are referred to as "dried marihuana" in the ACMPR. The term is replaced with the more appropriate "dried cannabis" in the draft *Cannabis Act*, published for first reading on April 13, 2017 as Bill C-45.

2 Some LPs also sell seeds and clones for personal medical production. The ACMPR also allow for sale of fresh cannabis flowers, which are not currently offered for sale by any LP.

3 www.canada.ca/en/health-canada/services/drugs-health-products/medical-use-marijuana/licensed-producers/authorized-licensed-producers-medical-purposes.html, accessed June 15, 2017.

Cannabis Oil – Canadian Edibles without Food | *Cont'd*

No additives may be included in cannabis oil other than those necessary to maintain the product's quality and stability. While the draft *Cannabis Act* as published in Bill C-45 does not introduce new products, the *Cannabis Act* provides that neither dried cannabis nor cannabis oil can include any of nicotine, caffeine, or ethyl alcohol. Bill C-45 provides a draft act and does not regulate cannabis oil at the level of detail as the ACMPR, which are regulations. However, specific exclusions suggests that products with a greater number of ingredients, or an expansion of the definition of "cannabis oil", may be possible under the *Cannabis Act* in one or both of the medical and adult use markets. Any such products would likely be added to a schedule in the *Cannabis Act*, making regulation of such products for production and sale in Canada possible, with details likely following in associated regulations.

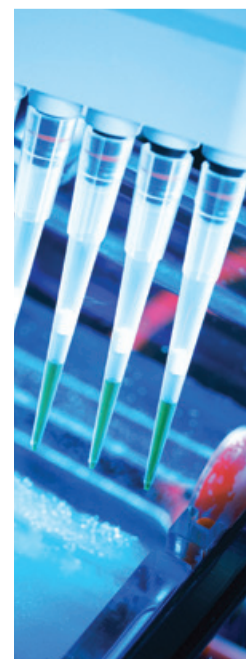
LPs typically use food grade oils, such as olive oil, grapeseed oil, coconut oil, or other medium chain triglyceride oils, to reformulate cannabis extract into cannabis oil. Extraction may be carried out using CO₂, ethanol, water, food oil, or other approaches that do not require use of butane or similar organic solvents. Cannabis oil is often sold in blends high in THC, high in CBD, or balanced between these two phytocannabinoids. Some LPs categorize cannabis oil by strain name or as sativa, indica, or hybrid, according to the *C. sativa* variety or varieties from which the cannabis oil was prepared. As the industry matures, approaches to formulation, manufacturing, and labelling may become more standardized as between LPs. Divergence of product lines among and within LPs based on a standardized framework may follow as LPs distinguish and brand themselves with unique and in some cases proprietary cannabis oil products (as seen in the various state markets in the United States).

Consistent dosage is simplified with cannabis oil compared with dried cannabis flowers. The 30 mg/ml maximum Total THC concentration limit provides for reasonable dose control with a dropper (all the more so with some LPs that sell cannabis oil at about 20 mg/ml or 10 mg/ml Total THC). Capsules with no more than 10 mg Total THC also simplify consistent and conservative dosing. Since no smoking or vaporizing is necessary, the cannabis oil may be taken discretely and indoors. The manner in which cannabis oil is used may facilitate acceptance of cannabis oil as a treatment option by physicians and patients unfamiliar with cannabis, compared with dried cannabis flower.

This is particularly true where the label, container and other branding is clean, professional, and similar in feel to pharmaceutical products. Such presentation is closer to most physicians' and patients' comfort zone since cannabis oil presents more like a pharmaceutical, compared with dried cannabis flower, both in appearance and in terms of administration.

Cannabis oil, particularly with the correct branding and when supplied in capsules, may resemble a pharmaceutical drug, but is uniquely regulated under the ACMPR in Canada. Sale of cannabis oil as a drug *per se* would, as with any substance, require compliance with the *Food and Drug Regulations* ("FDR"). As with all cannabis purchased by Canadians in the ACMPR, cannabis oil is not indicated for any particular medical condition and has not been authorized for sale as a drug by Health Canada under the FDR. Cannabis oil is exempted from application of the FDR by the *Cannabis Exemption (Food and Drugs Act) Regulations*, which are issued under the *Food and Drugs Act*. The ACMPR regulate production, processing, and labelling of cannabis oil to ensure quality, safety, and clarity. The ACMPR requirements are unique and specific to cannabis oil, and distinct from corresponding requirements for drugs generally in the FDR.

Cannabis oil offers advantages over dried cannabis flowers. No smoking, vaporizing, or decarboxylation for edible use is necessary. Consistency in dosing is simplified and cannabis oil can be taken discretely. Cannabis oil also provides a step toward greater standardization of cannabis products. In addition to greater consistency, convenience and a more comfortable transition from better known pharmaceutical solutions compared with dried cannabis flowers, cannabis oil offers a product that LPs may find more attractive from a business perspective. Significant value to the LP's clients may be added by preparing cannabis oil, which may translate into a stronger profit margin than with dried cannabis flowers. As discussed in another article about the Canadian cannabis industry in this bulletin, patents, trade secrets, or both may be leveraged where appropriate to protect specific formulations, dosage forms, and methods for manufacturing or encapsulating cannabis oil. Intellectual property may also protect packaging and devices for facilitating dosing of cannabis oil. With an industry based on dried cannabis flowers as the departure point, cannabis oil offers greater convenience and consistency in dosing, and avoids the health, convenience and social drawbacks associated with smoking or vaporizing. Cannabis oil, particularly in capsules, also points the way forward to greater standardization of cannabis for medical and other uses.





Jeffrey S. Graham

Partner, Lawyer | Corporate
Commercial Group |
BLG National Life Sciences
Group Leader

Toronto
416.367.6174
jgraham@blg.com

PMPRB Reform and Implications for Life Sciences Industry

In June 2016, as a first step to framework modernization, the Patented Medicine Prices Review Board (PMPRB) announced that it is undertaking major consultations regarding possible reform of its Compendium of Policies, Guidelines and Procedures, commonly referred to as “the Guidelines.” The PMPRB’s legal authority is derived from the Patent Act (“Act”) and the Patented Medicines Regulations (“Regulations”). The Guidelines represents non-binding interpretive guidance and direction from the Board to patentees and Board Staff on how to comply with the Act and the Regulations.

The Act

The Act as a whole falls under the jurisdiction of the Minister of Industry, with the exception of sections 79 to 103 pertaining to the PMPRB, which are the responsibility of the Minister of Health. These sections of the Act require that the PMPRB take remedial action when, following a public hearing, it finds that the manufacturer of a patented medicine is charging an excessive price. Subsection 85(1) of the Act identifies factors (“the section 85(1) factors”) that the PMPRB must take into consideration when evaluating whether a price is excessive. These are: the prices at which the same medicine has been sold in the relevant market; the prices at which other medicines in the same therapeutic class have been sold in the relevant market; the prices at which the medicine and other medicines in the same therapeutic class have been sold in countries other than Canada; changes in the Consumer Price Index (“CPI”); and other factors as may be specified in any regulation made for the purpose of this subsection.

If after considering the above factors in a hearing, a panel of Board members is unable to determine if a price is excessive, subsection 85(2) of the Act provides that it may consider the costs of making and marketing the medicine, as well as other factors which can be specified by regulations under that subsection, or that the Board members consider relevant in the circumstances.

The Regulations

The Regulations specify the information and documents that patentees must provide the PMPRB for it to carry out its regulatory mandate effectively.

They include requirements relating to the prices of all patented medicines sold in Canada and prices in foreign countries where they are also sold. The Regulations also specify which countries Canada looks to in comparing its prices. Currently these are the seven countries of the PMPRB⁷, which, as mentioned, were selected on the basis of their level of pharmaceutical R&D.

Although section 85 of the Act allows for further excessive pricing factors to be prescribed in the Regulations or considered by Board members in a hearing context, no such guidance has been forthcoming to date. Under section 101 of the Act, only the Governor in Council has authority to make and amend the Regulations, subject to the recommendation of the Minister of Health on certain key matters. However, the Minister can only make such a recommendation after having consulted with provincial Ministers of Health, representatives of the pharmaceutical industry and other relevant stakeholders.

The Guidelines

Section 85 of the Act contemplates intervention only where a patented drug price is considered “excessive”, which is determined based on a set of broadly expressed factors. Given the open-ended nature of the exercise contemplated under the legislation, many of the core administrative concepts which give effect to the PMPRB’s consumer protection mandate have been developed through the Guidelines, which the Board is authorized to make under subsection 96(4) of the Act, subject to consulting first with relevant stakeholders

In its response to the PMPRB Discussion Paper entitled PMPRB Guideline Modernization, a number of well-informed voices have filed comments. For example, the Canadian Life and Health Insurance Association has suggested the PMPRB stop targeting its prices so they fall in line with seven other countries: France, Germany, Italy, Sweden, Switzerland, the United Kingdom and the United States. Rather, the CLHIA has recommended that PMPRB should increase its use of market-based approaches to strive for the lowest possible price for Canadians and International price referencing should only be one input into what a non-excessive price should be.

PMPRB Reform and Implications for Life Sciences Industry | *Cont'd*

The pan-Canadian Pharmaceutical Alliance wrote in its response that the term “excessive” shouldn’t only be defined by dollar amounts but should consider socio-economic factors, affordability in relation to gross domestic product and market dynamics. It also argues that costing more than its competitors shouldn’t mean a drug is necessarily excessive.

BioteCanada, in its submission, argues that the mandate of the PMPRB should reflect realities noting that in recent years governments have developed mechanisms including CADTH, INESSS, cCPA and product listing agreements to provide greater certainty for drugs in the healthcare market and that these organizations and efforts have had an impact as Canadian drug prices have tracked below international medium prices.

In its response, Innovative Medicines Canada suggests that PMPRB isn’t the right agency to decide on the affordability of medicine in Canada, since it’s not accountable for spending

decisions, doesn’t pay for medicines and doesn’t have clarity into drug and health budgets. It also argues innovative medicines are often viewed as a commodity, rather than an investment. It indicates that while recognizing fiscal constraints, Canadians should collectively aspire to more ambitious goals. Further Innovate Medicines Canada believes that Canadians should aspire to create a marketplace that encourages market entry of novel medicines. In its view, this approach will benefit both payers and patients. Payers will benefit from greater levels of competition, and patients will benefit from having more options available to them and their health care practitioners.

Path forward

The consultations are continuing. The PMPRB has indicated that it proposes to invite stakeholders to appear before the Board and make representations in support of their written submissions. Once this process is completed there will be publication of proposed changes to Guidelines for comment through a notice and comment process.





Denes A. Rothschild

Senior Associate
Competition and Foreign
Investment Review

Toronto
416.367.6350
drothschild@blg.com



Devin Persaud

Associate | Corporate
Commercial Group

Toronto
416.367.6298
dpersaud@blg.com

Competition Act and Investment Canada Act Thresholds for 2017

Certain merger notification thresholds under Canada's *Competition Act* and the foreign investment review thresholds under the *Investment Canada Act* are updated on a yearly basis. On March 3, 2017, the Competition Bureau announced that the pre-merger notification "transaction-size" threshold under the *Competition Act* had increased. The Federal Government has also announced that the pre-merger review threshold under the *Investment Canada Act* for acquisitions involving Canadian businesses by WTO ("World Trade Organization") members will also increase.

New Pre-Merger Notification "Transaction-size" Threshold under the Competition Act

The Competition Bureau announced that the pre-merger notification "transaction-size" threshold for 2017 has increased to **CAD \$88 million**, from the 2016 threshold of CAD \$87 million. This increase took effect on March 4, 2017. A proposed transaction generally requires notification to the Competition Bureau under the *Competition Act* where both of the following thresholds are exceeded:

- 1. Size-of-the-parties threshold:** The parties to the transaction, together with their affiliates, collectively have assets in Canada, or gross annual revenues from sales in, from or into Canada, that exceed CAD \$400 million; and,
- 2. Transaction-size threshold:** The size of the specific transaction will exceed CAD \$88 million. In the case of asset transactions, this would mean that either the value of the assets in Canada, or the annual gross revenues from sales in or from Canada generated from those assets, exceed CAD \$88 million. In the case of an acquisition of voting shares, this would mean that either the value of the assets of the corporation in Canada (and its affiliates), or the annual gross revenues from its sales in or from Canada generated from those assets, exceed CAD \$88 million. Additionally, in order for pre-merger notification to be triggered with respect to voting share transactions, the percentage of voting shares held by the entity acquiring the shares would have to rise as a result of the transaction above 20 percent of the total outstanding voting shares of a public corporation, or above 35 percent in the case of a private corporation. If the entity acquiring the shares already owned shares in excess of 20 or 35 percent (depending on the type of transaction, the transaction would have to result in the entity owning more than 50 percent of the total outstanding voting shares of the corporation acquired.

Pre-Merger Review Thresholds for Direct Investments under the Investment Canada Act

The threshold for pre-merger reviews for direct investments involving Canadian (non-cultural) businesses by WTO members (non state-owned) is expected to increase to **CAD \$1 billion** in enterprise value on April 24, 2017. This threshold was originally scheduled to increase to CAD \$800 million in 2017, and to CAD \$1 billion in 2019. However, in its 2016 Fall Economic Statement the Federal Government announced that "to ensure that Canada's legislative framework supports investments that can create jobs and opportunities for middle class Canadians, the threshold for review under the *Investment Canada Act* will be raised to \$1 billion, two years sooner than planned".

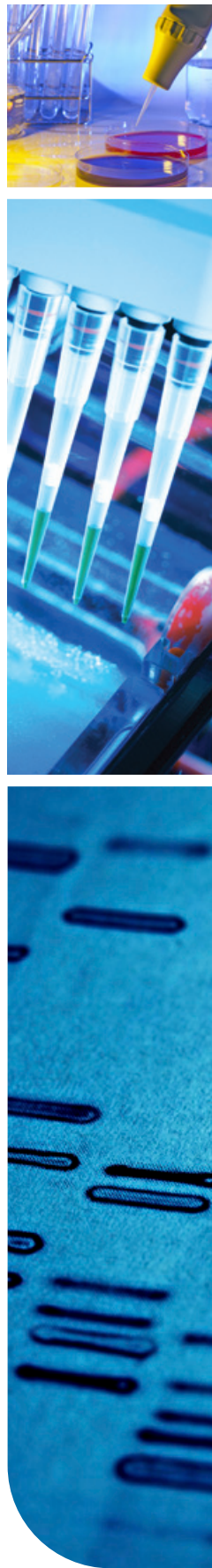
Competition Act and Investment Canada Act Thresholds for 2017 | *Cont'd*

The Investment Review Division of the Department of Innovation, Science and Economic Development also announced that the threshold for pre-merger reviews for direct investments involving Canadian (non-cultural) businesses by state-owned enterprises which are WTO members will increase to **CAD \$379 million** from CAD \$375 million in 2016. This threshold is based on the “book value” of the Canadian business’ assets.

The existing (book value) threshold of **CAD \$5 million** will continue to apply to transactions that relate to cultural businesses¹ or where none of the parties are from a country that is a WTO member. If these thresholds are not exceeded, the acquisition of control of a Canadian business by a non-Canadian entity is only subject to a post-closing reporting obligation (notification).

¹ A “cultural business” is defined by the Investment Canada Act as a business that carries on any of the following activities:

- (a) the publication, distribution or sale of books, magazines, periodicals or newspapers in print or machine readable form, other than the sole activity of printing or typesetting;
- (b) the production, distribution, sale or exhibition of film or video recordings;
- (c) the production, distribution, sale or exhibition of audio or video music recordings;
- (d) the publication, distribution or sale of music in print or machine readable form; or
- (e) radio communication in which the transmissions are intended for direct reception by the general public, any radio, television and cable television broadcasting undertakings and any satellite programming and broadcast network services.





Éloïse Gratton

Partner | National Co-Leader
of the Privacy and Data
Protection Practice Group

Montréal | Toronto
514.954.3106 | 416.367.6225
egratton@blg.com

Cybersecurity and Data Protection

The *Annual Privacy Governance Report 2016*¹ recently published by Ernst & Young and the International Association of Privacy Professionals states that privacy is now a board-level issue for 73 per cent of all organizations. Specifically, 14 per cent of Canadian privacy professionals are reaching the C-Suite and more than 50 per cent of privacy leaders are within two rungs of the CEO position.

Upon security breaches taking place, privacy commissioners will often take the opportunity to provide guidance as to what types of measures are adequate under applicable data protection laws. In recent months, many regulators have provided guidance on the development and implementation of adequate cybersecurity measures and protocols. Businesses therefore have to stay up to date on the data privacy and security legal guidance which is quickly evolving. With the new *Personal Information Protection and Electronic Documents Act* (PIPEDA) breach notification and recordkeeping requirements coming into force in the near future, providing that it will be a criminal offence for an organization to knowingly fail to report breaches, punishable by significant fines, many businesses are preparing by investing in breach incident management response plans, adopting relevant breach response and recordkeeping policies, and training their staff on how to report and adequately respond to security breaches.

Following the Ashley Madison security breach, which exposed the personal information of some 32 million users of the online dating website, the Office of the Privacy Commissioner of Canada released an important report which raised a number of key elements and recommendations

for all organizations subject to the federal PIPEDA. The report sheds light on several issues, such as the need to implement safeguards supported by an adequate information security governance framework; the risks associated with charging a fee for the deletion of user profile information; the issues pertaining to the long-term retention of information contained in inactive or deactivated customer profiles; the importance of email verification (when collecting email addresses); and the impact of false or misleading security seals or icons.

In last year's report, we discussed the growing trend towards privacy class actions being filed following a security breach or a business practice breaching applicable data protection laws. We note that there are currently 33 privacy breach class actions pending in Canada. While cases like Ashley Madison get most of the attention, there are more internal privacy breach cases than external ones: 79 per cent of pending privacy breach class actions are employee-generated. In 2016, settlements were reached in two privacy class actions cases, which may provide incentive for additional claims being filed in the future, if they are not being litigated.

New technologies are also presenting additional privacy and data security challenges. Wearable technologies and related apps and services, which can use sensors to collect environmental, behavioural, and social data from consumers or employees are gaining in popularity. With the Internet of Things, seemingly mundane everyday devices are fitted with microchips, sensors, and wireless communication capabilities. These recent innovations may trigger additional privacy and data security challenges that have to be considered when a business is assessing its legal risk exposure.

¹ https://iapp.org/media/pdf/resource_center/IAPP%202016%20GOVERNANCE%20SURVEY-FINAL3.pdf



**Bradley
Freedman**

Partner | National Leader
of Cybersecurity Law Group,
Vancouver Regional Leader of
our Technology Law Group

Vancouver
604.640.4129
bfreedman@blg.com

Cyber Risk Management Guidance for Corporate Directors

Cyber risk management is an increasingly important challenge for organizations of all kinds and sizes. Corporate directors have a legal responsibility to ensure that their corporations have appropriate cyber risk management policies and practices and are prepared to respond effectively to cyber incidents. Corporate directors can obtain helpful guidance from regulators, industry associations and other organizations.

Cyber Risks

Cyber risks are the risks of damage, loss and liability (e.g. business disruption, financial loss, loss to stakeholder value, reputational harm, trade secret disclosure and other competitive harm, legal non-compliance liability and civil liability to customers, business partners and other persons) to an organization resulting from a failure or breach of the information technology systems used by or on behalf of the organization, including incidents resulting in unauthorized access, use or disclosure of regulated, protected or sensitive data. Cyber risks can result from internal sources (e.g. employees, contractors, service providers and suppliers) or external sources (e.g. nation-states, terrorists, hacktivists, competitors and acts of nature).

Cyber risks appear to be increasing in frequency, intensity and harmful consequences as a result of various circumstances, including increasing sophistication and complexity of cyber-attacks, increasing use of information technology (e.g. increased access points and use of third-party services and infrastructure) and data (e.g. customer personal information, payment information and Big Data), increasing regulation (e.g. regulated personal/financial information and security breach reporting obligations) and increasing legal liability (e.g. privacy breach liability). Commentators have said that there are only two kinds of organizations – those that have been hacked and know it, and those that have been hacked and don't know it yet.

Directors' Duties – General

A corporate director's responsibility for cyber risk management derives from the well-established, generally applicable director's duty of care, which requires a director to exercise the care, skill and diligence that a reasonably prudent person would exercise in comparable circumstances. The duty of care requires a director to proactively supervise

management and make informed, properly advised decisions.

It is generally accepted that a director's duty of care requires the director to oversee management's activities regarding risk identification and risk management generally, and with particular attention to internal controls and management information systems. Directors are required to be an integral part of the risk management process and must play an active role in the foundational determinations (and periodic reviews) of the corporation's risk appetite and resulting risk tolerance. Directors are expected to ensure that management has taken reasonable steps to identify and manage risks through an appropriate risk management program, and directors should have direct oversight regarding significant risks affecting the corporation (which the directors should monitor and discuss regularly with senior management).

Canadian courts recognize that corporate directors and officers often have business expertise that courts do not have, that business decisions often involve some degree of risk and may be reasonable and defensible when they are made even though they are ultimately unsuccessful, and that it is inappropriate for courts to apply perfect hindsight to corporate directors' past decisions. Those considerations are the foundation of the "business judgment rule", whereby courts will defer to directors' reasonable business judgment provided that the directors acted independently and without conflict of interest and used an appropriate degree of prudence and diligence in reaching a business decision that falls within a range of reasonable alternatives at the time it was made.

Directors' Duties – Cyber Risk Management

Regulators, self-regulatory organizations, industry associations and other organizations have emphasized that corporate directors must be engaged and take an active role in cyber risk management activities, and must ensure that management has properly implemented appropriate policies and procedures to manage cyber risks and to effectively respond to cybersecurity incidents. For example:

- The National Association of Corporate Directors' *Director's Handbook on Cyber-Risk Oversight* (January 2017) emphasizes that effective management of cyber risks requires conscientious and comprehensive oversight by an organization's board of directors.

Cyber Risk Management Guidance for Corporate Directors | *Cont'd*

- World Economic Forum's *Advancing Cyber Resilience Principles and Tools for Boards* (January 2017) emphasizes that board-level action regarding cyber resilience is "absolutely urgent", and explains that organizational leadership has a vital role to play in securing cyber resilience.
- Canadian Securities Administrators' *CSA Staff Notice 11-332 Cyber Security* (September 2016) notes that guidance documents issued by various regulatory authorities and standard-setting bodies highlight the need for an organization to manage cyber security at an organizational level with responsibility for governance and accountability at executive and board levels.
- Mutual Fund Dealers Association of Canada's *Compliance Bulletin – Cybersecurity* (May 2016) recommends that member dealers establish a cyber risk governance and risk management framework that includes the involvement of directors and senior management.
- Investment Industry Regulatory Organization of Canada's *Cybersecurity Best Practices Guide* (December 2015) emphasizes that cybersecurity is a multi-faceted challenge that requires a sound governance framework – strong leadership, board and senior management engagement and clear accountability – for a successful cybersecurity program. "Directing the implementation of a comprehensive cybersecurity program... is incumbent upon all boards – regardless of company size".
- Global Network of Director Institutes' *Perspectives Paper – Guiding Principles for Cybersecurity Oversight* (November 2015) explains that directors and boards need to treat cybersecurity as an integrated component of enterprise-wide risk management, and that cyber risk needs to be overseen by the full board, with support from appropriate committees.
- Chartered Professional Accountants Canada's *Board Bulletin – Cybersecurity Risk – Questions for Directors to Ask* (July 2015) explains that a board of directors must be satisfied that the organization has a security program that sufficiently protects internal business systems and connections to cyberspace including transactions between employees, customers, suppliers and governments, from cyber-crime and mischief.
- Institute of Internal Auditors Research Foundation's *Cybersecurity: What the Board of Directors Needs to Ask* (August 2014) emphasizes that directors must take an active role in the organization's cybersecurity or face the possibility of potential shareholder lawsuits, and even the possibility of being removed from the board.
- Conference Board's *Director Notes – The Board's Role in Cybersecurity* (March 2014) advises that corporate boards must ensure that their companies have appropriate processes in place to manage cyber risks in the context of their business.

The views expressed by regulators, organizations and associations might not have the force of law, but they may be relied on by courts in determining the standard of reasonable care, skill and diligence required of corporate directors regarding the management of a corporation's cyber risks.

Recent Guidance for Directors

Regulators, industry associations and other organizations have issued helpful cyber risk management guidance and tools for corporate directors. Following are two recent examples.

(a) NACD *Director's Handbook on Cyber-Risk Oversight*

In January 2017, the National Association of Corporate Directors (NACD) and the Internet Security Alliance published the 2017 edition of the *NACD Director's Handbook on Cyber-Risk Oversight*. The Handbook identifies and details five key steps that directors of all kinds of organizations (e.g. public companies, private companies and non-profit organizations) should consider for cyber risk management: (1) directors need to understand and approach cybersecurity as an enterprise-wide risk management issue, not just an information technology issue; (2) directors should understand the legal implications of cyber risks as they relate to their company's specific circumstances; (3) boards should have adequate access to cybersecurity expertise, and discussions about cyber risk management should be given regular and adequate time on the board meeting agenda; (4) directors should set the expectation that management will establish an enterprise-wide cyber risk management framework with adequate staffing and budget; and (5) board-management discussions of cyber risk should

Cyber Risk Management Guidance for Corporate Directors | *Cont'd*

include identification of which risks to avoid, accept, mitigate or transfer through insurance, as well as specific plans associated with each approach.

The Handbook includes detailed *Questions for the Board to Ask Management about Cybersecurity*, a summary of cybersecurity considerations relevant to mergers and acquisitions and suggestions for cybersecurity metrics to be included in board-level briefings.

(b) World Economic Forum *Advancing Cyber Resilience Principles and Tools for Boards*

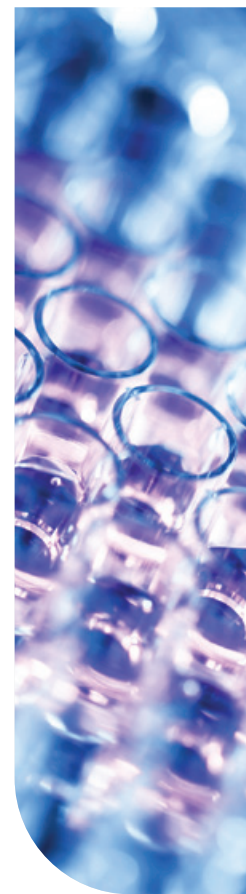
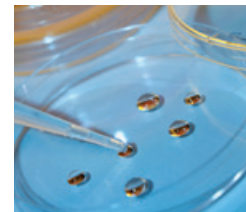
In January 2017, the World Economic Forum published a report titled *Advancing Cyber Resilience Principles and Tools for Boards* to provide a framework and set of tools for directors to use to integrate cyber risk and resilience into business strategy.

The Report includes *Board Principles for Cyber Resilience*, which is a framework of ten principles to enable directors to encourage cyber resilience: (1) responsibility for cyber resilience; (2) command of the subject; (3) accountable officer; (4) integration of cyber resilience; (5) risk appetite; (6) risk assessment and reporting; (7) resilience plans; (8) community; (9) review; and (10) effectiveness.

The Report includes a *Cyber Principle Toolkit*, which supports the ten *Board Principles* with a set of questions to foster board-management dialogue and aid the board in fulfilling its oversight obligations. The Report also includes a *Board Cyber Risk Framework* to provide a process for use by boards to understand and evaluate their organization's cyber risks and resilience strategy.

Comment

Corporate directors should take seriously their legal responsibility to take an active role in their corporations' cyber risk management activities, and ensure that corporate management has properly implemented appropriate policies and procedures to manage cyber risks and to respond effectively to cybersecurity incidents. Directors should ensure that their cyber risk management decisions are informed (based on reasonable inquiries of management) and properly advised (based on appropriate expert advice). Directors should document their cyber risk management activities, so that they will be able to effectively respond to lawsuits and regulatory inquiries and successfully establish the due diligence and other circumstances required to invoke the business judgment rule.





Paul A.D. Mingay

Partner | National Leader
of the Public M&A Group,
Mergers and Acquisitions

Toronto
416.367.6006
pmingay@blg.com



Andrew Bunston

Partner | Securities and
Capital Markets Group

Toronto
416.367.6717
abunston@blg.com



Colin Cameron-Vendrig

Associate | Securities and
Capital Markets Group

Toronto
416.367.6242
cameronvendrig@blg.com

Good Tactics or Bad Faith: The Divisive Issue of Sandbagging in M&A

Introduction

There are few issues in a private M&A transaction as potentially divisive as the treatment of “sandbagging” in the purchase agreement. “Sandbagging” occurs when the buyer has knowledge of a breach by the seller of a representation, warranty or covenant, closes the transaction despite such knowledge and then seeks indemnification from the seller post-closing for losses caused by the breach. The concept of “sandbagging” goes beyond M&A tactics and strategy and can become a debate between buyer and seller about fundamental concepts of honesty, fairness and good faith. This article will explain what sandbagging is, provide examples of “pro” and “anti” sandbagging provisions, discuss how prevalent these provisions are in the Canadian M&A market and explore how Canadian courts have dealt with the issue.

What is Sandbagging in M&A?

The purchase agreement in a private M&A transaction typically includes a range of representations, warranties and covenants that a seller makes to a buyer in regard to the company or asset being bought and sold. “Sandbagging” occurs when the buyer learns that one or more of these representations, warranties or covenants is inaccurate, does not communicate that knowledge to the seller, completes the transaction despite such knowledge and then seeks indemnification from the seller post-closing for losses arising from the inaccuracy. Purchase agreements in a private M&A transaction typically include one of the following general approaches to sandbagging: “pro-sandbagging” provisions can be included stating that sandbagging is allowable, “anti-sandbagging” provisions can be included stating that sandbagging is prohibited or the agreement can remain silent on the issue.

Given their respective interests, buyers tend to prefer pro-sandbagging provisions and sellers tend to prefer anti-sandbagging provisions. Buyers pushing for the inclusion of a pro-sandbagging clause can make a number of arguments:

- Sandbagging encourages full and accurate disclosure on the part of the seller.
- A buyer’s ability to rely on the correctness of a seller’s representations and warranties is an integral part of the bargain between the parties. In other words, a pro-sandbagging clause is simply a reflection of one of the core tenets of M&A: that responsibility for accurate disclosure lies with the seller.
- Sandbagging discourages the seller from drowning the buyer in disclosure and then claiming the buyer had knowledge of a breach in light of its access to extensive materials. Put differently, it limits a tactical approach to disclosure by the seller.

Sellers pushing for the use of an anti-sandbagging clause can likewise advance a number of arguments:

- It is simply unfair that the onus for full disclosure lies only with the seller with no reciprocal obligation on the buyer to reveal what it has learned.
- The diligence process should encourage the buyer to raise concerns and provide the seller the opportunity to address them and, if necessary, rectify deficiencies, rather than allowing the buyer to weaponize the post-closing indemnification process.

Good Tactics or Bad Faith: The Divisive Issue of Sandbagging in M&A | *Cont'd*

- It is unfair for sellers to be put through a full due diligence review by the buyer only to have the buyer withhold knowledge of a breach by the seller and then capitalize on what might have simply been an oversight.

The relative merits of these arguments can vary depending on the dynamics of the deal and the circumstances of both parties. For instance, if the buyer is a large corporation conducting diligence through a range of external advisors, the fact that one part of its team gained knowledge of an inaccuracy might not mean that this knowledge was communicated to decision makers or that the full consequence of the inaccuracy was understood. By contrast, if the seller is unsophisticated it may be that after a comprehensive diligence review the buyer has far more granular information about the business or asset than the seller, such that a prosandbagging provision would only increase the buyer's existing informational advantage.

Examples of Pro and Anti-Sandbagging Provisions¹

Pro-Sandbagging

The right to indemnification, payment, reimbursement, or other remedy based upon any such representation, warranty, covenant, or obligation will not be affected by... any investigation conducted or any Knowledge acquired at any time, whether before or after the execution and delivery of this Agreement or the Closing Date, with respect to the accuracy or inaccuracy of, or compliance with, such representation, warranty, covenant, or obligation.

Anti-Sandbagging

No party shall be liable under this Article for any Losses resulting from or relating to any inaccuracy in or breach of any representation or warranty in this Agreement if the party seeking indemnification for such Losses had Knowledge of such Breach before Closing.

The Role of “Knowledge” in Anti-Sandbagging Provisions

The core function of an anti-sandbagging provision is that it prevents a buyer from claiming under its indemnity if the buyer had knowledge of the breach forming the basis of its claim before the transaction closed. The definition of “Knowledge”, therefore, is key to the rest of the provision. A more expansive definition that captures implied or constructive knowledge casts such a large net that a buyer may find it difficult to disprove knowledge when making a claim. This becomes particularly true when the seller has made extensive disclosure or when the buyer relied on a large deal team.

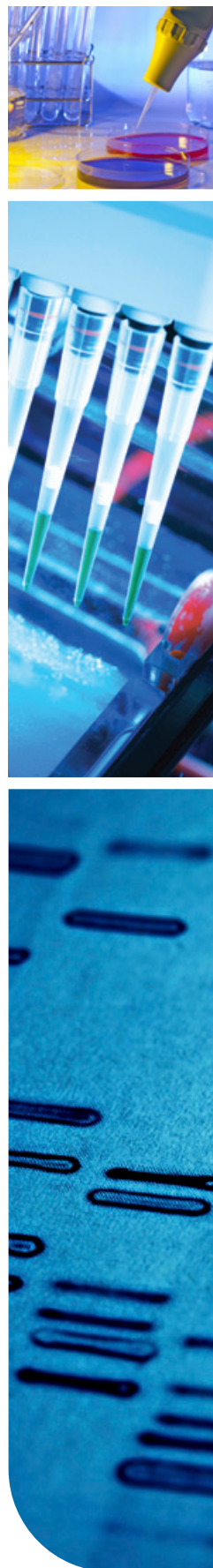
Remaining Silent on Sandbagging

Where the purchase agreement is silent on the issue, the legality of sandbagging will be determined by the law in the jurisdiction governing the purchase agreement. To that end, parties should look to what elements are required to establish breach of contract in the jurisdiction they have chosen to govern disputes under the purchase agreement. The key factor is likely to be how the selected jurisdiction treats prior knowledge of a breach and whether reliance is a necessary component of breach of contract.

What is Market?

The American Bar Association's *2016 Canadian Private Target Mergers & Acquisitions Deal Points Study* – a common reference point for market practice in private acquisition transactions – suggests that 31% of Canadian deals include pro-sandbagging clauses (15% in 2014 study, 24% in 2012 study and 10% in 2010 study), 15% include anti-sandbagging clauses (14% in 2014 study, 9% in 2012 study and 21% in 2010 study) and 54% are silent on the issue (71% in 2014 study, 67% in 2012 study and 69% in 2010 study). Clearly, the market is becoming more attuned to this issue and more agreements are explicitly addressing it. Having said that, the lack of a sandbagging clause one way or the other may be just as much a result of a strategic decision as the inclusion of one, as discussed below.

¹ American Bar Association, *Model Stock Purchase Agreement*, Second Edition.



Good Tactics or Bad Faith: The Divisive Issue of Sandbagging in M&A | *Cont'd*

What Have Courts Said?

The case law around sandbagging was already unsettled in Canada and has now entered a new phase of potential uncertainty in the wake of the Supreme Court of Canada's 2014 *Bhasin v Hrynew* decision.

In Canada, there has yet to be a definitive ruling on the issue of sandbagging. In *Transamerica Life Canada Inc. v ING Canada Inc.*, a seller claimed that a buyer breached an implied duty of good faith and fair dealing in so far as it closed a transaction despite having knowledge of a breach. The motion judge dismissed the pleadings but the decision was ultimately overturned at the Ontario Court of Appeal on the basis that the law was unclear and so warranted further inquiry by a trial judge.

In *Bhasin v Hrynew*, the Supreme Court recognized good faith contractual performance as a general organizing principle of Canadian common law, and that parties to a contract are under a duty to act honestly in the performance of their contractual obligations. Honest performance requires that parties "not lie or otherwise knowingly mislead each other about matters directly linked to the performance of the contract." While it is likely that the organizing principle set out in *Bhasin v Hrynew* will have implications for how Canadian courts treat sandbagging going forward, there is no Canadian case law yet to suggest what exactly the consequences will be.

Case law in the U.S. indicates that explicit pro-sandbagging and anti-sandbagging clauses are often enforceable. When an agreement is silent on sandbagging, however, the law varies between states and is generally tied to whether that state treats reliance as a necessary component of a claim for breach of contract. For example, Delaware takes a contract-based approach and does not require a buyer to show reliance on a seller representation, warranty or covenant in order to establish breach. By contrast, California does require a buyer to demonstrate that it relied on the truth of a seller representation, warranty or covenant in order to find a breach.

Conclusion

The decision to request either a pro-sandbagging or anti-sandbagging clause can be an important part of a negotiation. As noted at the outset, either clause raises issues of fairness and good faith that can result in acrimonious discussions that, in turn, can poison the buyer-seller relationship. For a buyer, the price of a pro-sandbagging clause may be to give up something else of value. A seller, on the other hand, may be content to rely on the developing law of good faith in contract as protection rather than seek an express anti-sandbagging clause. Accordingly, the decision regarding sandbagging provisions is worth some deliberate attention on the part of buyers and sellers – it is not just a legal discussion.



**Frank S.
Callaghan**

Partner | Corporate and
Capital Markets Group

Toronto
416.367.6014
fcallaghan@blg.com

BLG Poised for Mergers and Acquisitions in 2017

Despite the uncertainty created by Brexit and the results of the U.S. election, we expect Canadian merger and acquisition activity in 2017 to be busy. According to The 4 Biggest Trends in Mergers and Acquisitions for 2017 published by *Forbes* “In today’s slower-growth environment, many businesses are on the hunt for high-quality companies that will add to the bottom line, despite higher valuations” and “business owners have plenty of reasons to remain hopeful”.

BLG is poised to meet the appetite for deals in 2017. In 2016, we advised on more than 100 M&A deals with an aggregate disclosed value of over CDN\$24B. We worked with public and private Canadian and international clients in many sectors including financial services, energy, technology, mining, health, communications and retail.

Significant transactions included acting as counsel to:

- Enersource Corporation in connection with its proposed merger with Horizon Utilities Corporation and PowerStream Inc., and the acquisition by the merged entity of Hydro One Brampton Networks Inc. to form a consolidated electricity distributor with an enterprise value in excess of CDN\$3B. This consolidation is the largest amalgamation in the history of the Ontario electricity sector. When the merger is completed, the resulting entity will be the second largest distribution utility in Ontario.
- The Special Committee of Corus Entertainment in its CDN\$2.65B acquisition of Shaw Media which was challenged, unsuccessfully, by Catalyst Capital Group Inc.
- Canoe Financial and O’Leary Funds Management LP in the acquisition of the O’Leary investment funds, with portfolio assets of almost CDN\$4B, by Canoe as well as acting for Canoe on the extensive pre- and post-closing fund changes and mergers resulting from the acquisition.
- Cynapsus Therapeutics Inc. in its US\$635M acquisition by Sunovion Pharmaceuticals Inc., the largest life sciences transaction in Canada in the past 5 years.
- Dolly Varden Silver Corporation in its successful defence of a take-over bid by Hecla Mining, including the successful representation of Dolly Varden in joint hearings by the Ontario and British Columbia Securities Commissions.
- The Special Committee of the Board of Taseko Mines in its successful proxy fight with Raging River Capital.
- Stone Canyon Industries, LLC in its acquisition from Platinum Equity of BWAY Corp. for US\$2.4B.
- HollyFrontier Corp. in its proposed CDN\$1.125B acquisition of Suncor Energy Inc.’s Petro-Canada Lubricants Unit announced October 31, 2016.
- FS Group Holdings Ltd. in its acquisition of Front Street Capital and Front Street Capital’s subsequent merger with Aston Hill Financial Inc. to create a leading independent asset manager.
- Caesars Interactive Entertainment in its US\$4.4B sale of its Playtika social and mobile games business to Alpha Frontier Limited.
- The Board of Directors of Eldorado Gold in its CDN\$900M sale of assets to China National Gold.
- Sensus Canada Inc. in Xylem Inc. and Xylem Luxemburg S.A.R.L.’s CDN\$1.7B acquisition of Sensus USA Inc. and Sensus Metering Systems (Luxco 1) S.A.R.L.
- Sumitomo Corporation in its proposed EUR\$751M acquisition of Fyffes PLC announced December 9, 2016.
- Securian Financial Group in its proposed acquisition of the Affinity business of ivari announced November 1, 2016.
- The Special Committee of PWC Capital Inc. in its proposed merger with Versa Bank, its partially owned subsidiary, under the *Bank Act*.

Thank you to all of our clients and business contacts for making 2016 a successful year and we wish everyone a happy, healthy and prosperous 2017.



Stephen Robertson

Partner | Securities and Capital Markets Group and Investment Management Group

Vancouver
604.632.3473
srobertson@blg.com

British Columbia as a Life Sciences Investment Hub

British Columbia has long been known for being a source for natural resources (it isn't called Beautiful British Columbia for nothing) – but the Province is looking to change that perception by also establishing itself as a hub for technology companies and innovation. To that end, in late 2016, the government of British Columbia established a \$100 million investment fund (the BC Tech Fund) with a mandate to invest directly in technology companies based in the province.

The BC Tech Fund was established to make early-stage capital more available in British Columbia, so that tech companies can grow their businesses without having to move to more traditional Canadian tech hubs, such as Toronto or Montreal. The government of British Columbia recognized that the technology sector was a growing part of its economy – representing 7% of the province's GDP, and 4.9% of its overall workforce (which is more than the mining, oil & gas, and forestry sectors combined). That level of concentration and growth required additional investment in order to have the necessary support to succeed, and thus the BC Tech Fund was born.

The BC Tech Fund is mainly focused on Series A companies (companies with established products that are generating between \$1 million and \$3 million in annual revenue) who are either headquartered or having a significant management presence in British Columbia, or that have substantial operations or substantial number of employees based in British Columbia. It can also invest in venture capital companies that themselves focus on Series A companies. The target companies (or the focus of the venture capital firms) must be on the technology sector, and the life sciences and healthcare industry is a specified main part of that concentration. In addition to other investments it has already made, the BC Tech Fund has made a significant investment into a life science venture capital fund established by Lumira Capital Corp., a high profile Toronto based life sciences venture capital investor – who, in connection with obtaining this funding, has itself already established an office in British Columbia. The government anticipates that investing in high profile venture capital companies like Lumira would have a multiplier effect and attract more venture capital firms to British Columbia.

The BC Tech Fund is managed by Kensington Capital Partners. Kensington has a specific mandate to:

- Help create new venture capital funds in British Columbia through ecosystem-building activities.
- Help attract investment into British Columbia tech companies and British Columbia-based venture capital funds.
- Help British Columbia companies connect with strategic partners to help them grow their business.
- Help develop solutions for regional issues related to accessing venture capital.

The BC Tech Fund is in addition to the over \$90 million in assets already under management in the BC Renaissance Capital Fund, an investment fund that was established to procure additional investments in BC-based venture capital firms. That fund has already attracted over \$350 million of investment in British Columbia and led to the creation of over 1,000 jobs, and the government is hopeful that the BC Tech Fund stimulates a similar, if not enhanced, investment focus. The Renaissance Fund's managers are also highly involved in the technology community, by providing mentoring, speaking at conferences, and participating in education seminars. It is hoped that the beneficiaries of the BC Tech Fund will also be participating similarly.

The establishment of the BC Tech Fund has been met with positive responses from the technology community, many very excited at the prospect of additional capital being available as well as with the strengthened emphasis of the government on early stage technology investment. The fund's performance and returns will be carefully monitored by both the government and the public to determine the full effect on the economy in general, and the technology sector in particular.

The fund itself is just one part of a larger technology strategy initiated by the British Columbia government, a strategy that also integrates a focus on growing the technology talent pool by increasing the number of education programs and graduates annually, expanding access to markets for the technology products produced in British Columbia, and creating a centre for data-driven innovation.

Given its short term of existence, it is difficult to judge the exact impact of the BC Tech Fund to date, but there is no doubting the government's intention with creating the fund – technology companies (including life science companies) are an increasing part of the global economy, and British Columbia intends to be a strong supporter of that industry for years to come.

About BLG's Life Sciences Group

A Leading Canadian Life Sciences Practice

Borden Ladner Gervais LLP truly speaks your language. Our team includes many individuals who hold PhDs or Master's degrees in the life sciences, and bring an in-depth understanding of the science and technology on which your business is built. A number of our professionals also have relevant industry related positions, which provides us with working knowledge and a genuine comprehension of this sector – both where it has been and where it is heading. In addition, we maintain a close involvement to the life sciences community, and have partnered with leading members to create or support central organizations where members can come together, share knowledge and gain valuable insights.

- More than 70 life science lawyers and patent agents across offices in Calgary, Montréal, Ottawa, Toronto and Vancouver
- MDs, PhDs, and other advanced degrees in medicine, life sciences, and engineering
- Professionals with experience working in the industry sector

Working in all Facets of Life Sciences

- Intellectual Property Protection and Litigation
- The Patented Medicines (Notice of Compliance) Regulations
- Food and Drug Law
- Financings and Capital Markets
- Licensing, Research Collaborations and other Strategic Alliances
- Mergers, Acquisitions and Divestitures
- Federal Patented Medicine Pricing and Provincial Price Reimbursements
- Government Relations
- Advertising and Promotion
- Competition
- Labour and Employment
- Privacy
- Tax
- Product Liability
- Class Actions
- Dispute Resolution

Advising on

- Product development, promotion, wholesaling and distribution arrangements
- Manufacturing and supply agreements
- Clinical trial agreements involving all phases of clinical research
- Product (formulary) listing agreements with provincial health authorities
- Regulatory requirements of Health Canada including clinical trials, new drug submissions, Notices of Compliance and Drug Identification Numbers, packaging, labelling, advertising clearances, marketing, audits and product recalls
- Provincial pharmacy requirements including payments of rebates, incentives and professional allowances
- Federal and provincial privacy and document retention requirements including compliance reviews and drafting compliance programs
- Dealings with the Patented Medicine Prices Review Board, including interpretation of Excessive Price Guidelines, negotiations of Voluntary Compliance Undertakings and administrative proceedings before the Board
- Practice standards and ethical codes of conduct
- Private and public merger and other acquisition transactions including due diligence
- Venture capital, institutions investment and public market financing transactions, acting either on behalf of investors, agents or the investee companies
- Public policy including advice on government relations, regulatory affairs and strategic communications
- Intellectual property protection, including preparing and prosecuting patent and trademark applications, obtaining patents and trademarks, copyright protection, and preparing, prosecuting and obtaining plant breeders' rights, issues surrounding data protection and litigation under the *NOC Regulations*

Key Life Sciences Contacts



Jeffrey S. Graham
National Life Sciences Group Leader
Toronto
416.367.6174
jgraham@blg.com



Jason Howg
Calgary
403.232.9415
jhowg@blg.com



Louis Clément
Montréal
514.954.2524
lclement@blg.com



Chantal Saunders
Ottawa
613.369.4783
csaunders@blg.com



Calgary

Centennial Place, East Tower
1900, 520 – 3rd Ave S W, Calgary, AB, Canada T2P 0R3
T 403.232.9500 | F 403.266.1395

Montréal

1000 De La Gauchetière St W, Suite 900
Montréal, QC, Canada H3B 5H4
T 514.879.1212 | F 514.954.1905

Ottawa

World Exchange Plaza, 100 Queen St, Suite 1300
Ottawa, ON, Canada K1P 1J9
T 613.237.5160 | F 613.230.8842 (Legal)
F 613.787.3558 (IP) | ipinfo@blg.com (IP)

Toronto

Bay Adelaide Centre, East Tower
22 Adelaide St W, Suite 3400, Toronto, ON, Canada M5H 4E3
T 416.367.6000 | F 416.367.6749

Vancouver

1200 Waterfront Centre, 200 Burrard St, P.O. Box 48600
Vancouver, BC, Canada V7X 1T2
T 604.687.5744 | F 604.687.1415

BLG Consulting (Beijing) Limited

11A16, No. 7 Guanghua Road
Chaoyang District, Beijing, 100004, P.R. China
T 86 010.8526.1820 | F 86 010.6512.6125

For more information, please contact:

Paul Fortin

Director of International Business Development &
Life Sciences Business Development Leader
613.787.3583 | pfortin@blg.com