



**BLG**  
Borden Ladner Gervais

# LifeSigns

Life Sciences Legal Trends in Canada

2018-2019 Edition



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# Message from BLG



Welcome to our 5<sup>th</sup> Annual edition of LifeSigns – Canada’s leading report on life sciences legal trends in Canada. This year’s report covers notable trends including information on the cannabis sector as well as updates in the areas of intellectual property, regulatory affairs, privacy and cybersecurity, corporate commercial and capital markets.

Borden Ladner Gervais LLP (BLG) is Canada’s largest independent law firm and our Life Sciences group is actively engaged in all facets of the commercialization of life science 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. Our professionals are actively engaged in the sector, and regularly counsel clients both domestic and foreign on how best to take advantage of scientific breakthroughs and business opportunities in Canada and abroad. The highly integrated nature of our practice is what distinguishes BLG from a number of other Canadian law firms. 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 intellectual property 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 boardroom. 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.

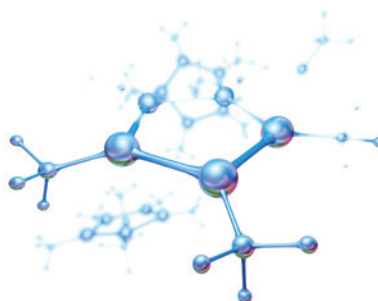
In an ever-changing global political landscape, Canada remains uniquely positioned with a federal government that remains committed to pro-trade and pro-immigration policies. Canada now has access to the 600 million people in the European Union market thanks to the implementation of the CETA trade initiative. With the implementation of patent term restoration and the Supreme Court’s abolition of the ‘promise doctrine’, Canada’s IP protection has been strengthened. The continuing commitment of Canada’s federal government and provincial and territorial governments means that the prospects for the life sciences sector in Canada from human health to the environment to our food supply are optimistic in the coming year.

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

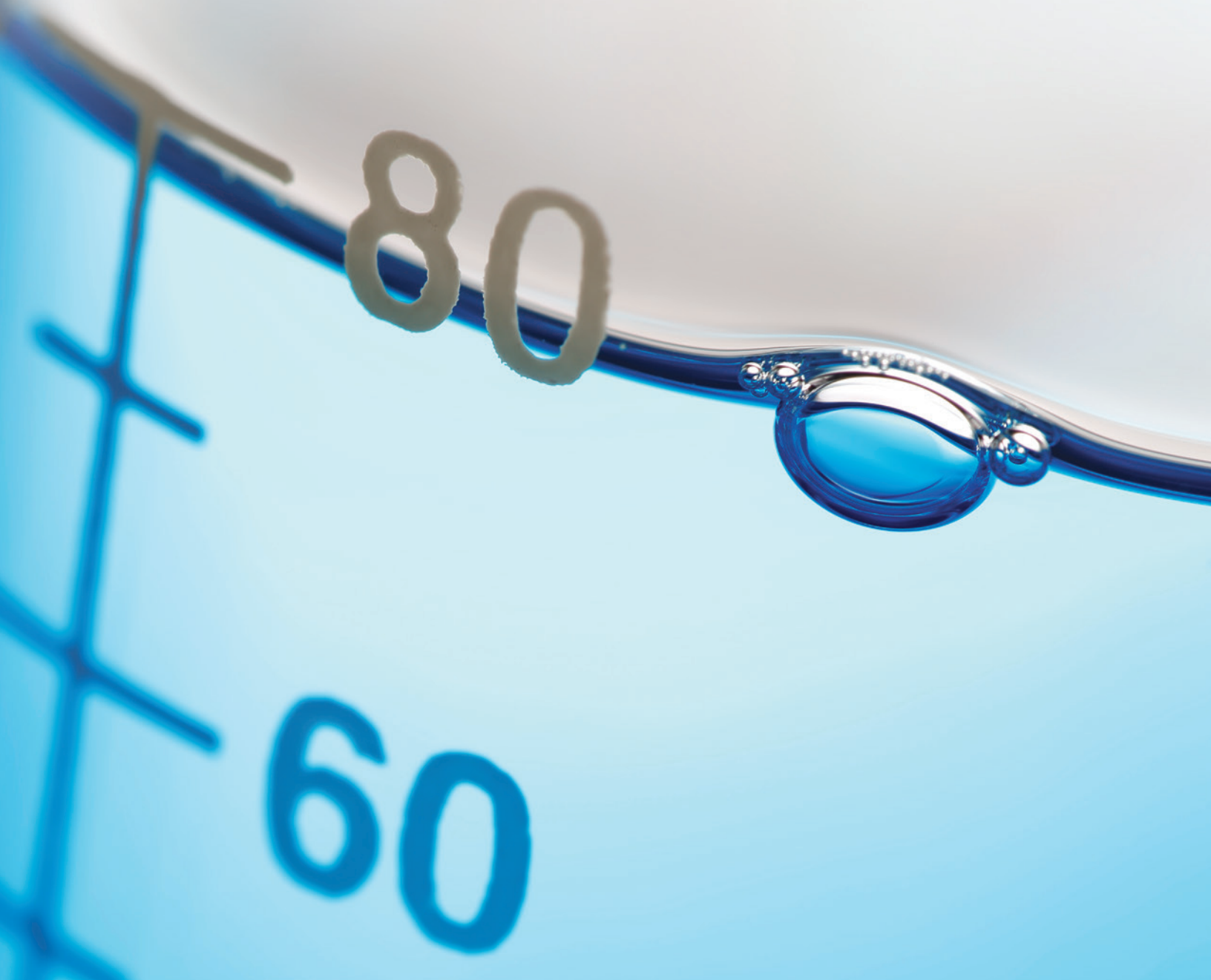


**Kira Pejemsky**

Director, Business  
Development Practice Group  
Ottawa  
613.787.3598  
kpejemsky@blg.com



# Message from Canada's Leading Life Science Associations



## Ensuring Canada's Status for Health Care Innovation and Investment

Canada has been the home to critical discoveries in diabetes, heart disease, HIV/AIDS, Alzheimer's, and many other conditions, improving or saving the lives of countless Canadians and people across the world. Today, from coast to coast, world-class research continues with the application of stem-cell technology, personalized medicine techniques, big data and artificial intelligence, all contributing to new possibilities.

Canada's life sciences industry was not created overnight nor was it created by accident. Our research talent and infrastructure, our proximity to the U.S., our cultural diversity and our mix of urban and rural environments make Canada one of the best places in the world to conduct medical research. Most importantly, the innovators behind medical breakthroughs are disciplined, committed and passionate in their pursuit of lifesaving new medicines. They can be found in universities, research facilities and companies, large and small, working tirelessly to help cure the incurable.

There are few sectors that contribute to both the health of its citizens and the wealth of its economy, and the life sciences sector is one of them. According to a recent analysis conducted by EY, Innovative Medicines Canada members in 2016 alone generated \$19 billion in economic activity, invested \$1.2 billion into R&D (9.97% of revenues) to stimulate innovation and supported 30,000 high value jobs. Compared to other economic sectors, the life sciences sector ranks third in terms of combined total R&D spending in Canada, behind only the aerospace and software and computer services sectors.

A globally competitive Canadian pharmaceutical research and innovation ecosystem includes universities, research centres and companies focused on outcomes that matter to patients, the health system and the economy. The more individual companies and the industry invest, innovate and create jobs and generates economic activity, the greater their return in the form of better health and healthcare for Canadians.

Collaboration and partnerships will continue to be the foundation of our industry's success in Canada. Working with policy makers, patients, health professionals and researchers, the innovative medicines industry can meaningfully contribute to delivering the best and most advanced healthcare to Canadians, while also ensuring continued investment and innovation.

Our priority is to give Canadians access to the best possible therapies while also helping to foster a quality, sustainable and affordable healthcare system for generations to come. If we get it right, we can help fuel research and innovation, create thousands of quality jobs and become a key engine of Canada's knowledge-based economy.

The possibilities are endless. Now is the time for all of us to double-down on our commitment to our shared goals for Canada and Canadians, now and for generations to come.



**Pamela C. Fralick**

President, Innovative  
Medicines Canada



## BIOTECCanada

The Canadian biotechnology ecosystem is one of Canada's truly great success stories. Stretching from coast-to-coast, the ecosystem has as its foundation a network of clusters located in every province. Each cluster is comprised of early stage companies, research institutes, hospitals, entrepreneurs, investors and post-secondary institutions and buttressed by Canada's capacity for strong science and research. Within each province, the clusters tend to have a particular focus relating to one of health, industrial, agricultural, or environmental biotech spaces. And in a world dealing with a population explosion and its corresponding environmental and health challenges, the innovation being developed in these clusters across the country represents an enormous economic opportunity for the sector and Canada more broadly.

With its history of developing successful companies from early stage science and research, the ecosystem has proven to be a great strength for Canada. However, the ecosystem's hubs and diverse but interconnected components within those hubs presents a challenge for policymakers tasked with both supporting and regulating the sector. From a simple regulatory perspective alone, the complexity of biotechnology innovation requires that policy departments federally and provincially ensure they are coordinated in their policy development and regulatory oversight approach. Ultimately, if policy is developed in a vacuum and with an eye only on one part of the ecosystem it can have significant detrimental, albeit unintended, consequences for one or more other parts of the ecosystem.

The interconnected nature of the industry requires government policy and oversight be equally connected if it is to be effective and competitive. Federally, departments such as Health Canada must work with other federal departments and regulatory bodies to coordinate regulatory oversight responsibilities for all parts of the industry. Whether it be approving non-browning apples, genetically modified seeds for fuel or novel medicines and therapeutics, all require a coordinated and strategic approach to the public policy overseeing their development and commercialization. This is not a call for a less stringent or lax regulatory oversight. Indeed, Canada's regulatory oversight of industry is often a competitive advantage in the global marketplace. Rather, it is a call for a more coordinated and connected public policy approach. Failing to be coordinated can render non-competitive the companies and the sector more broadly. However, on the flip side, a coordinated and strategic approach can provide a significant competitive advantage for Canada in the global marketplace looking for biotechnology solutions.

For the Canadian biotech industry the past twelve months have been very positive as evidenced by the commercial success and significant growth of individual companies across the country. Indeed, BIOTECCanada's membership numbers have increased and companies within the membership have grown in size as they get closer to commercial success. In addition, recent government initiatives such as the federal budget's commitment to invest nearly a billion dollars in science and research will further enhance Canada's ability to discover and innovate. This growth and a positive investment climate have been very positive signs for the industry. Maintaining this momentum will be absolutely critical over the period ahead. But to leverage investments and scale them to create globally competitive companies requires efficiency and coordination at all levels, not the least of which is within our public policy environment. If the horizon is defined in months rather than years or decades then short term thinking becomes the dominant mode in government and industry alike. By setting longer term horizons supported by a holistic public policy approach then more ambitious outcomes can become the objective. Canada must look to leverage past success and become home to globally competitive 'anchor' companies. Getting there requires Canadian governments and industry alike adopt a far more holistic approach to public policy, regulatory oversight, investment and business planning. Other jurisdictions have done so and enjoyed great success. Importantly, with a more holistic and longer term public policy approach, Canada can build on its past success and history to leap ahead of its global competition.



**Andrew Casey**  
President and CEO





## Coordinating Innovation: How Ontario Can Capitalize on its Life Sciences Momentum

By the time BIO 2018 wraps up, Ontario will have just completed a provincial election, setting the stage for crucial policy action that will unfurl over the next four years.

While the province's life sciences sector has continued to attract attention and investment both at home and internationally, now is a pertinent time to pause and reflect on our strategy for long-term growth.

The evidence of our momentum is everywhere: Canadian companies – two based in Ontario – were flagged among the Top 20 Life Sciences Companies to Watch in 2018. PwC's MoneyTree report headlined health tech as a sector primed for growth in 2018. The roster of Canadian companies at JP Morgan in January was nothing short of stellar. This spring, the Government of Ontario announced a \$50 million dedicated life sciences venture fund. And, global pharmaceutical giant Sanofi recently invested \$500 million toward a Canadian vaccine facility to be based in North York, Ontario.

Clearly, our industry is thriving despite the hurdles it has faced as of late. These include challenges to drug pricing and IP policy, and a striking lack of federal programs for life sciences in favour of other sectors – namely oil and gas, aerospace, and IT. However, the biggest challenge to our continued growth will be the lack of a coordinated life sciences strategy.

The Federal government is developing its own approach to such a strategy through its Health and Biosciences Economic Strategy Table. But Ontario is still among the only major life sciences jurisdictions in North America without such a plan in place; our challenge will now be to craft a comprehensive, aligned roadmap that will clearly lay out our objectives and the steps needed to reach these milestones.

To this end, Life Sciences Ontario released its Blueprint for a Coordinated Ontario Life Sciences Strategy in December 2017. It lays out a comprehensive plan and recommendations to accelerate the success of life sciences, with specific action around access to capital, talent growth, support for innovation, and promotion of our sector. The document is endorsed by leading provincial and national life sciences, health, and economic organizations.

In the wake of a provincial election, the time is now to come together around these issues, which are truly non-partisan.

This is why a pan-government life sciences strategy is so important. Canadian innovation is poised for its break-out season. But to capitalize on this momentum, we must collaborate around a coordinated strategy. This is how we will create a healthier and wealthier Canada, and bring our outstanding innovations to the world.



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




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\* 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.

## People, Innovation and Impact

We often hear about the recruitment challenges biotech employers face with limited access to capital and talent. While these barriers still exist, companies are indeed hiring, especially with the help of wage subsidies, and innovation is happening as a result!

The impact is real and can be seen across the country. Like in the case of the STEM (Science, Technology, Engineering and Math) graduates reducing waste and improving the bottom line at Applied Biological Materials in Vancouver, British Columbia. And the business graduate propelling Bioenterprise's digital marketing in Guelph, Ontario. And the recent graduate who acts as a mentor to other new hires and is a leader in solving problems at ERA Environmental Management in Montreal, Quebec. Or the young scientist who has brought a community of volunteers together resulting in more robust credible data of water samples for the Lake Winnipeg Foundation in Manitoba. These stories are truly inspiring and are catalysts for their biotech careers and Canadian innovation.

Since 1997, BioTalent Canada has been dedicated to facilitating employment in the bio-economy by working with employers, associations, academic institutions, governments and job seekers. This year alone, BioTalent Canada has helped place over 400 students, new graduates, newcomers and Canadians with disabilities with over 100 biotech employers and more new hires are happening daily. Over 250 subsidized co-op placements were created last year by our new Student Work-Integrated Learning Program (SWILP), and 750 more will be created over the next three years. Programs like these inject millions of dollars into the industry, and with good return on investment: these new jobs potentiate industry innovation, propelling biotechnology to become a major job manufacturer. This will be even more true with the imminent creation of innovative superclusters, several driven by bioscience.

For success to continue, creating opportunities for those who are dedicated and passionate about innovation is critical and takes commitment – and you can see Canada has it! **Mapping potential – Profiles of Canada's biotech frontiers**, our 2018 labour market report, showcases the programs, initiatives, organizations and people driving the industry forward so Canada's bio-economy can reach its full potential.

It is easy to be proud of the advancement of such a great Canadian industry.



**Rob Henderson**  
President and CEO



## The PEI Bioscience Cluster: Commercializing Next Generation Innovation

Built up over the last decade, the bioscience sector in Prince Edward Island embodies the success of the industry-led Cluster model.

Intensely focused on pursuing strong R&D, developing innovative market-driven solutions, and driving commercialization through a culture of collaboration, PEI has proved to be a pioneer in Canada of what has become known as the “grow your own” model of bioscience economic development,

Coordinated by the industry-led PEI BioAlliance, collaboration between all stakeholders plays a central role in how PEI acts as a “living laboratory”: integrating concurrent research and innovation processes with a public-private-people partnership designed to help innovative startups commercialize potentially transformative technologies through a highly connected and integrated business ecosystem.

Taking advantage of key local strengths, the growth in the PEI Bioscience Cluster is the story of helping entrepreneurs and innovators start and grow their ventures. Some have famously evolved, mainly through acquisition, to become multi-national leaders in the Atlantic and Canadian bioscience ecosystem, including: BioVectra, Sekisui and Elanco.

Today, the PEI Bioscience Cluster is comprised of 54 companies, eight research institutions, and several federal and provincial government partners. The Cluster currently employs 1,600 highly skilled individuals. Private sector revenues exceed \$240 million/annum, and annual R&D expenditures are more than \$70 million.

The focus of the companies that make up the PEI Bioscience Cluster is largely centered around the research, development and commercialization of natural product chemistry and bioactive-based products for human, animal and fish health and nutrition. Revenue sources include cosmetic ingredients, natural health products, feed additives, vaccines, diagnostics, and pharmaceuticals.

Many of the companies that make up the PEI Cluster are early-stage pre-commercial ventures. This is something that we are proud of. Already accounting for 45% of all new job creation across our sector, these ventures are being nurtured in a supportive startup culture which provides them with access to best-in-class mentorship, regulatory expertise, bio entrepreneurship education, skilled human resources through HR support services, shared infrastructure and supportive public policy. The BioAlliance emphasizes the importance of developing strong business plans and business models that are attractive to providers of private capital.

These are the companies pioneering cutting edge innovations across the biotechnology spectrum. This includes “green” bio (natural products from plant cells and various botanical sources); “red” bio (API and vaccine manufacturing for human, animal, and fish health); and “blue” bio (novel and sustainable biochemistry from genetic resources including fungi, bacteria, and other microorganisms found in marine habitats). These are the startups that are defining a future based on the interplay between software, hardware, materials, biologic systems, the cloud, artificial intelligence, augmented reality and data.

The Cluster’s history of success nurturing startup and early-stage bioscience ventures led to the formation in PEI in 2014 of a national virtual incubator, known as Emergence.

Structured around providing value-adding services to high-potential startup and scale-up ventures, wherever they are located in Canada, and providing a “soft landing” for international bioscience ventures seeking to start-up or establish themselves in, or expand into, Canada, Emergence today boasts a portfolio of clients that stretches from Vancouver, British Columbia to St. John’s, Newfoundland – and around the world!



**Martin J. Yuill**

Director, Incubation Services



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The impact of this virtual incubator model has been striking. Over the last year, several PEI companies have experienced unprecedented exits, acquisitions and investment. Not insignificantly, all have been clients of the Emergence incubator program, having taken advantage of the program's core service pillars. Many have attracted investment from large global corporations. One direct outcome: Croda's recent acquisition of Nautilus Biosciences has resulted in the creation of a Croda "Centre of Innovation for Marine Biotechnology" on the campus of the University of Prince Edward Island in Charlottetown.

In many ways, though, this is just the beginning: having established a solid Cluster-centered foundation for bioscience sector growth, momentum is strong.

The maturing of the current cohort of early-stage bioscience companies, strongly-positioned to raise smart capital and grow their scientific, regulatory, technical and management teams; together with the high level of attractiveness that the PEI ecosystem is demonstrating to global companies operating at the cutting edge of scientific endeavor, are set to coalesce to create the perfect conditions for our companies to take advantage of the new global market opportunities of the future.





## LifeSciences British Columbia

This year LifeSciences BC hit a historic milestone as we recognize the 20th anniversary of the Annual LifeSciences BC Awards and its ensuing success not only here in B.C., but across the country and around the world. As we reflect on how far we have come as a young ecosystem over the last 20 years, it is evident to see how much the life sciences sector in B.C. has grown. Our strong progress has stemmed from consistent capital investment and strategic partnerships that have helped many of our B.C. companies. We are also extremely fortunate to have excellent academic and research institutions supporting key collaborations that generate great science and medical technology. We have a wealth of both private sector and government-supported organizations reinforcing company creation and expansion. B.C. is one of the most entrepreneur-rich jurisdictions in North America, with a pipeline of world-class scientists generating big ideas, important medical solutions and valuable research. These key ingredients create a B.C. life sciences sector that is not only a significant contributor to the economy, but also plays a valuable role in bettering health and patient-care outcomes for all Canadians.

This February, the government of Canada announced that the B.C. led Digital Super Cluster was one of five winning bids from across the country. The Digital Technology Supercluster Consortium is a cross-industry initiative dedicated to ensuring B.C. and Canada are innovative and world-class leaders in the digital economy. LifeSciences British Columbia was involved as a founding member in the super cluster discussions with an objective to promote the use of advanced data collection, analytics and visualization to produce innovations in the field of precision medicine. The single payer medical system, globally recognized scientists and clinicians, a growing cluster of companies and our repository of health data are resources that can be leveraged for B.C. to become a leader in precision medicine. During this supercluster undertaking, key industry leaders working collaboratively, recognized that the challenges facing our companies as they grow, are similar, regardless of sector. The extended networks, new relationships and collaborations that have resulted from this initiative, will benefit the entire innovation ecosystem well into the future and reach far beyond our borders.

Our entire community will play an essential role in accelerating the success of our sector by:

1. Optimizing and aligning the life sciences ecosystem to support the translation of our world-class science into new innovations and commercial products. This includes strengthening the network and connection of key players in the ecosystem within B.C., Canada and the world. Alone we may attract some attention but aligning our efforts with the pan Canadian life sciences industry and strengthening our ties with the Cascadia corridor, can take the B.C. life sciences sector to the next level.
2. Assisting our companies in accessing smart capital by introducing and promoting B.C. companies to investors and strategic partners from around the world.
3. By continuing to train, retain and develop our local talent, as well as attracting talent from around the world. It's all about the people and it is all about strengthening our life science ecosystem to ensure we continue to support the fundamentals of company creation and growth. This is critical.

To meet the next year with a vision that matches our past and fuels our future we believe “**A strong ecosystem accelerates success.**” This will be our theme for the year ahead. British Columbia has cultivated a vibrant and diverse Life Sciences community that positions us to not only succeed here on our own soil, but globally!



**Dr. Lesley Esford**  
President & CEO



# Insights from the Life Sciences Team at BLG



## I INTELLECTUAL PROPERTY

Intellectual Property | Patents

### Beware the Election You Didn't Make:

#### An Update on Unity Objections, Elections, Divisionals, and Double Patenting Considerations During Canadian Examination

Canada has unique local law with respect to double patenting. Like the U.S., there is an obviousness standard for double patenting, but unlike the U.S. terminal disclaimers are unavailable. The Supreme Court of Canada has, however, affirmed that a divisional forced by the Canadian Intellectual Property Office (CIPO) during examination is safeguarded against double patenting challenges.<sup>1</sup>

Historically, Canada's jurisdictional quirks have been balanced by flexible examination practices that have allowed applicants to achieve a "forced" division in alignment with patenting aims. However, recent observed changes to examination practices following unity objections mean that applicants must now exercise caution (1) to avoid being boxed in to subject matter that was not intended as an election, and (2) to maintain the ability to pursue divisional applications for other subject matter of interest without risk of double patenting.

When a unity objection is raised during Canadian examination, applicants have the option of electing one subject matter group or of requesting reconsideration of the objection, with arguments and/or claim amendments. The latter options are useful when the unity objection is premature, or when an applicant has claims of a different scope that it wishes to present for consideration.

The *Patent Act*<sup>2</sup> (the Act) sets out basic divisional practice in subsection 36(2):

*Where an application (the "original application") describes and claims more than one invention, the applicant may limit the claims to one invention only, and any other invention disclosed may be made the subject of a divisional application, if the divisional application is filed before the issue of a patent on the original application.*

The recent changes appear to have a basis in CIPO's Examiners' Bulletin No. 2017-P4-B<sup>3</sup>, which endorses a more restrictive approach than is apparent from the language of the Act. The bulletin states that examiners must use standard wording to acknowledge elections:

*When examining claims to elected subject-matter, where the application is not in a state to be approved for allowance, the examiner must include [standard wording paragraphs] in their report. This [standard wording] indicates that the applicant cannot "switch groups" (amend the claims to be directed to the non-elected subject-matter) during prosecution of the particular application.*

The inability to switch groups post-election may not seem surprising, but this was accepted by at least some Canadian examiners in the not so distant past.

The bulletin also states that there may be a so-called "implicit election" even if no election is acknowledged by an applicant:

*An election is considered to have occurred when the applicant limits the claims to fewer inventions than were defined in the claims set containing the section 36 defect as identified by examiners in a previous report. An election may be apparent from an explicit statement in the response (e.g. "In response to the section 36 defect identified by the examiner, the applicant elects Group A – claim 1-x), or it may be implicit and determined by the manner in which the claims were amended (e.g. certain claims have been deleted or modified, leaving only the claims corresponding to Group A or a set of claims which do not lack unity despite not conforming exactly to one of the groups of the original unity defect).*



**Graeme Boocock, Ph.D.**

Patent Agent  
Intellectual Property Group  
Ottawa  
613.369.4775  
gboocock@blg.com

While some of these details are included in CIPO's Manual of Patent Office Practice (MOPOP), there is no direct indication in MOPOP, as there is here, that a subject matter group different from the groups identified in unity objection could be deemed elected. The text of the bulletin appears to indicate that this could occur whenever the claims are amended or the number of inventions reduced.

Once an election – explicit or implicit – has been acknowledged by an examiner, the claims may not be amended to include subject matter that is outside the scope of that election. If this occurs, the bulletin states that examination should be halted until the offending subject matter is removed:

*Where the examiner has used this [standard wording], and the applicant subsequently amends the claims to be directed to non-elected subject-matter (i.e. the applicant switches groups), the applicant is considered to be non-compliant with subsection 36(2) of the Patent Act. The examiner must identify the unity defect in a report... and defer substantive examination on the non-elected subject matter until the unity defect is overcome.*

Overall, it is the combination of an implicit election – the characterization of which is left to the discretion of an examiner – with the inability to add subject matter beyond the election that could prove problematic for applicants.

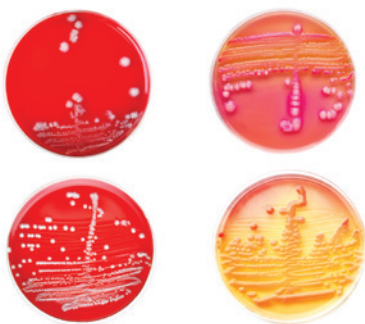
In view of local law in double patenting, the possibility of having unity reconsidered for a revised claim set has long been an important

feature of Canadian examination. Now, an applicant could now find itself inadvertently limited in later examination by an earlier implicit election that it did not intend to make. Subsequent amendments to broaden claims or to add subject matter never before considered could bring examination to a standstill.

Yet pursuing this additional subject matter in divisional application would not be without risk; the question of whether the SCC's double patenting protection extends to divisional applications forced merely for being outside the scope of an examiner-defined implicit election is untested.

In view of this, applicants should be explicit with CIPO whenever an election is not intended after a unity objection. Unless an applicant is happy to restrict its desired Canadian patent protection to the subject matter groups defined in an initial unity objection, it would be best to present all amended claims of interest together for reconsideration after such an objection in order to avoid an implicit election. This is particularly important when the amended claims include a change in scope that could render the initial unity objection inapplicable.

1. *Consolboard Inc v Macmillan Bloedel (Saskatchewan) Ltd* (1981) 56 CPR (2d) 145 (SCC) at p169.
2. R.S.C., 1985, c. P-4
3. [https://ipflyonthewall.files.wordpress.com/2018/01/a-2017-01180\\_0001.pdf#page=11](https://ipflyonthewall.files.wordpress.com/2018/01/a-2017-01180_0001.pdf#page=11)





## The Promise Doctrine: Patent Challengers Attempt to Broaden Beyond Utility

In 2017, the Supreme Court of Canada (SCC) addressed the “Promise Doctrine” that developed in Canada through case law in respect of the utility requirement in section 2 of the Canadian Patent Act. In a patent infringement/impeachment action involving the drug NEXIUM esomeprazole, the Federal Court and the Court of Appeal found the patent at issue to be invalid on the basis that one of the two “promises” of the patent was not demonstrated nor soundly predicted.<sup>1</sup> The SCC considered whether the Promise Doctrine is the correct approach for the requirement in section 2 of the Patent Act that an invention be useful, and concluded that it is not.<sup>2</sup>

The SCC summarized the Promise Doctrine in the following way: “The Promise Doctrine, as developed by the Federal Courts’ jurisprudence, holds that if a patentee’s patent application promises a specific utility, *only if* that promise is fulfilled, can the invention have the requisite utility – ‘the promise of the patent is the yardstick against which utility is measured’”.<sup>3</sup> The SCC concluded that the Promise Doctrine is not consistent with the words and scheme of the *Patent Act* and is “excessively onerous in two ways: (1) it determines the standard of utility that is required of a patent by reference to the promises expressed in the patent; and (2) where there are multiple expressed promises of utility, it requires that all be fulfilled for a patent to be valid.”<sup>4</sup> The SCC held that a single use makes the subject matter of the patent useful.<sup>5</sup>

The SCC provided the analysis to be used by the Court in addressing an allegation relating to utility: “First, courts must identify the subject matter of the invention as claimed in the patent. Second, courts must ask whether that subject matter is useful – is it capable of a practical purpose (i.e. an actual result)?”<sup>6</sup> Further, a scintilla of utility is sufficient as is a single use related to the nature of the subject matter.<sup>7</sup> As a result, it appears that the analysis of utility has received much needed clarity.

However, the SCC made additional comments to respond to the argument that the Promise Doctrine ensures patentees do not overpromise in patent applications. The SCC acknowledged that overpromising is a mischief.<sup>8</sup> In particular, the SCC stated the following:

The scheme of the Act treats the mischief of overpromising in multiple ways. There are consequences for failing to properly disclose an invention by claiming, for instance, that you have invented more than you have. A disclosure which is not correct and full, or states an unsubstantiated use or operation of the invention, may be found to fail to fulfill the requirements of s. 27(3). An overly broad claim may be declared invalid; however, under the operation of s. 58 of the *Patent Act*, remaining valid claims can be given effect. As well, this mischief may result in a patent being void under s. 53 of the Act, where overpromising in a specification amounts to an omission or addition that is “willfully made for the purpose of misleading”.<sup>9</sup>

These statements by the SCC have resulted in allegations that the patentee has “overpromised” in violation of section 27(3) of the *Patent Act*, as well as allegations of overbreadth.<sup>10</sup> The Court has noted that these allegations of “overpromising” are similar to the arguments that were made in respect of utility, which are no longer accepted.<sup>11</sup> The Court has further noted that there does not appear to be a rationale for the SCC rejecting the Promise Doctrine



**Chantal Saunders**

Partner, Lawyer  
Patent Agent | Intellectual  
Property Group  
Ottawa  
613.369.4783  
csaunders@blg.com

as part of the utility analysis but then requiring this doctrine to be considered in an analysis pursuant to section 27(3), particularly in the absence of clear language in this regard.<sup>12</sup> Proceeding in this way would also seem to be overruling itself in respect of its findings of the disclosure requirements set out in section 27(3) in *Teva Canada Ltd v Pfizer Canada Inc.*, a case that specifically addressed this section.<sup>13</sup>

The Court has concluded that the analysis under section 27(3) was not changed in the SCC *AstraZeneca* decision.<sup>14</sup>

It seems likely that parties will continue to try to find new arguments based on language used by the SCC in *AstraZeneca*, and the Courts will continue to be called upon to consider what was intended by the SCC.

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1. *AstraZeneca Canada Inc v Apotex Inc*, 2017 SCC 36 [AstraZeneca].

2. *Ibid*, at para 23-24.

3. *Ibid*, at para 28.

4. *Ibid*, at para 37.

5. *Ibid*, at para 48-49.

6. *Ibid*, at para 54.

7. *Ibid*, at para 55.

8. *Ibid*, at para 45.

9. *Ibid* at para 46.

10. For example, see *Pfizer Canada Inc. v. Apotex Inc.* 2017 FC 774 (Pfizer).

11. *Pfizer, ibid*, at para 359-360.

12. *Pfizer, ibid*, at para 363. See also *Hospira Healthcare Corporation v. Kennedy Trust for Rheumatology Research*, 2018 FC 259 at para 258.

13. *Pfizer, ibid*, at para 364; *Teva Canada Ltd v Pfizer Canada Inc*, [2012] 3 SCR 625.

14. *Pfizer, ibid*, at para 365.



## Patent Term Restoration in Canada – Are the Requirements Reasonable?

On September 21, 2017, part of the Comprehensive Economic and Trade Agreement (CETA) between Canada and the European Union (EU), relating to patent term restoration, became law in Canada. This meant, for the first time, it was possible for time to be restored to a patent relating to a medicine to make up for the time that medicine spent going through the approval process before it could be marketed. If certain conditions were met, then up to two years could be added to the exclusivity period granted by an issued patent relating to a medicinal ingredient.

When the *Patent Act* provisions and *Certificate of Supplementary Protection Regulations* (CSP Regulations) were announced, one of the stated purposes was to “incentivize the early introduction of innovative drugs into the Canadian market”.<sup>1</sup> This incentive was accomplished by requiring innovators to file their New Drug Submission (NDS) within 12 months of having filed a similar submission in the EU or any country that is a member of the EU, the United States, Australia, Switzerland or Japan.<sup>2</sup> An exception is provided, permitting the filing of applications within 24 months of the foreign submission, if the application is filed within the first year of operation of the CSP Regulations.

Many worried that these requirements would effectively render the CSP Regulations useless. However, 8 months into their operation, 14 applications for CSPs have been made, 13 for human products and 1 for a veterinary product.<sup>3</sup> In addition, 4 CSPs have been issued. This could be seen as a higher number than expected given the worries stated about the timing requirements. However, it is unclear how many companies took advantage of the exception noted, allowing a longer filing period for Canada in the first year of the CSP Regulations. It will be interesting to monitor if this rate continues. Furthermore, it will be of great interest to see how this number compares to the overall number of NDSs filed in Canada during the same period. Hopefully Health Canada includes these numbers in their yearly statistics.

The requirements for a CSP application also confirm that the NDS needs to be complete. A placeholder cannot be filed while a company waits to ensure that their initial equivalent submission in another jurisdiction is sufficient. As a result, in order to be eligible to file for a CSP, companies need to be in a position to manage multiple drug submissions in multiple jurisdictions at the same time as it is unlikely that the first submission will have been approved prior to the requirement to file in Canada.

Reviewing the Register of CSPs and Application, those listed all appear to be made by larger pharmaceutical companies with a multinational presence. Such companies likely have the necessary resources to manage the multiple jurisdictions necessary. As time progresses, it will also be interesting to monitor whether this dynamic changes and whether the smaller companies will also be able to use this valuable marketing advantage.

We are in the early stages of the operation of this system. The CETA allows for the requirement that the Canadian NDS be filed within a “reasonable period”. A number of factors play into whether the period prescribed by the CSP Regulations actually is reasonable. Only time will tell.



**Beverley Moore**

Partner, Lawyer  
Trademark Agent Intellectual  
Property Group  
Ottawa  
613.369.4784  
bmoore@blg.com



**Chantal Saunders**

Partner, Lawyer  
Patent Agent | Intellectual  
Property Group  
Ottawa  
613.369.4783  
csaunders@blg.com



**Carina De Pellegrin**

Counsel, Lawyer  
Intellectual Property Group  
Ottawa  
613.787.3725  
cdpellegrin@blg.com

1. *Certificate of Supplementary Protection Regulations* – Regulatory Impact Analysis Statement: <http://gazette.gc.ca/rp-pr/p1/2017/2017-07-15/html/reg16-eng.html>.

2. *Certificate of Supplementary Protection Regulations*, s. 6; *Patent Act*, s. 106.

3. Register of Certificates of Supplementary Protection and Applications: <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/register-certificates.html>.

## Defensive Publication as an Intellectual Property Strategy

Not long ago, searching prior art patent literature was a paper pursuit, conducted in a public search room in a Government building. Appropriate invention classifications would be identified, and folios of patents in these classifications were wheeled in on trolleys for the searcher's review. It would have seemed preposterous to think that such documents could be searched in mere seconds, from the comfort of one's own desk with a few keywords and the push of a button. How things change.

The ease with which documents can now be searched by keyword queries in the patent literature and the scientific literature, has made prior art searching more accessible, albeit *effective* searching remains an art. Increased accessibility permits would-be applicants to more easily make patentability determinations before engaging the patent system. Patent Examiners have tools that permit expedient novelty and inventive step searches. Corporations can undertake patent landscape and freedom-to-operate searching, before launching a product.

Not all innovations are amenable to patenting. A published application provides no assurance that a patent will issue. When it becomes clear that obtaining a patent is undesirable or untenable, it may be too late to keep the patent application out of the public realm. However, if there is still time to decide, then the pros and cons of defensive publications can be carefully assessed versus other options such as trade secret protection. A published application, whether issued to patent or not, is nevertheless searchable (and readily findable) and provides advantages to an intellectual property strategy. Published information is citable against similar (but later-filed) patent applications. A published, but abandoned, application may advantageously establish that the originating lab or inventors are leaders in the field, and can attract collaborators, while simultaneously signaling that the information is free to use.

### Abandonment and Lapse as a Defensive Publication Strategy

In Canada, abandoned patent applications irretrievably lapse if a 1-year period passes without reinstatement. Other jurisdictions have different rules, such as the U.S., where an applicant has 6-months to reply to an Office Action before abandonment occurs. Non-payment of fees offers a route to abandonment in most countries. Abandoned and lapsed patent applications that have already been published remain published and accessible to the public, although no residual proprietary rights remain. Canadian patent applications are currently searchable by keyword only in title, abstract and claim fields (not in the description), although the international (PCT) application from which most Canadian applications are derived may be searchable in all text fields, similar to published U.S. applications.

### Confidentiality Period, and the Published Application as Defensive Publications

There is an 18-month confidentiality period for pending applications, extending from the earliest filing date. The confidentiality period can be waived by requesting early publication. 18-months is now an international standard. The published claims of an application serve as a general indication of what may be pursued to patent. However, what is not claimed in the issued patent can be considered disclaimed. Claim scope conceded during prosecution is considered to be in the public realm.

On a historical note: Canadian patent applications filed prior to October 1, 1989 did not become published. Only issued patent were published. The confidentiality enjoyed during the pendency of an application allowed inventors to develop an invention in secret, sometimes over a lengthy period of many years. An invention could remain entirely secret if a patent never issued. Other jurisdictions also held applications in secret until issuance.



**Kathleen Marsman, Ph.D.**

Patent Agent  
Intellectual Property Group  
Ottawa  
613.787.3572  
kmarsman@blg.com



One difficulty associated with unpublished applications was that “submarine” patents could surface after examination delays, to surprise an unsuspecting public that had already embraced the technology without knowing a patent would block or control its use.

### U.S. Defensive Publication and Statutory Invention Registration

In the 1960s, the United States instituted the Defensive Publication program permitting publication of patent applications for applicants who decided not to pursue a patent. Such documents constituted prior art, and could be cited to prevent others from obtaining a patent. Defensive Publications were designated a serial number beginning with “T”, and are still searchable on the USPTO website. Later, a similar route was available in the U.S. under the Statutory Invention Registration program, in which such published applications were designated a serial number preceded by the letter “H”. Eventually, the current standard of publication after 18-months of confidentiality negated any benefit of such publications.

### Dedication of Patents to the Public

While not intended as a defensive publication strategy, Canada offers a formal way to dedicate patents to the public. This practice pre-dates the introduction of maintenance fees that required patentees to re-affirm their commitment to a proprietary position on an annual basis. At the time, public dedication was one of the few ways for patentees to rid themselves of unwanted patents. Until 1995, the majority of public dedications of Canadian patents were made in the interests of permitting patented drugs to avoid price review. Dedication to the public no longer permits avoidance of patented medicine price review, but there is another advantage: averting invalidation in a double patenting challenge (*Sandoz v Abbott*, 2010 FCA 168). The opportunity to abandon an issued patent by missing a maintenance fee comes but once a year and is followed by a 1-year reinstatement period. By contrast, a public dedication is effective as of the declared date. Patents dedicated to the public remain published, and thus remain citable as prior art.

### Peer Reviewed Literature

Articles published in peer reviewed journals serve as defensive publications. However, the peer review process takes time, and comes without assurance of acceptance into the selected journal. Once accepted, the article may still wait in a queue for publication. Peer review demands a high standard for the data and written content of the article. Speed of publication may be important when making a defensive publication to keep competitors from filing or publishing first, in which case the peer review process may not proceed quickly enough. It is the earliest date of publication, not the date of submission, review, or acceptance, that becomes the pertinent date for citable prior art.

### Open Data

Defensive publication of data to an open source websites may permit the data to be accessed, used, and shared by all, such as with genomic data. Open data, as a philosophy, commits information to the public domain but may not guarantee that innovations made through accessing such open data will also be free for the public to use. To serve effectively as citable prior art, contributions to open data sites should be attributed to an author and should show a date of contribution/publication. Contributors and users of open data should be aware of any restrictions placed on them.

### Defensive Publication Websites

Defensive publication websites with the stated purpose of providing a space for disclosures to published quickly without review, with ongoing public access, may serve as prior art repositories. Some sites purport to be frequented by patent examiners. Contributors to such sites should conduct due diligence to ensure that the site meets their goals for the defensive publication.

### Conclusion

For innovators in the life sciences, a defensive publication permits others to build upon the information while establishing one's own date of contribution. However, what the public sees cannot be un-seen. Taking the defensive publication route is a commitment to public access, and concedes a future proprietary position.



## Canada's Diagnostic Examination Practice Faces Scrutiny

The Canadian Intellectual Property Office (CIPO) introduced examination guidelines for assessing diagnostic and personalized medicine inventions in 2015 in the form of Practice Notice PN 2015-02. This past year saw its contents incorporated into CIPO's Manual of Patent Office Practice (MOPOP). Collectively, the guidelines direct examiners to categorize such inventions as addressing one of only two possible problems, either a "data acquisition problem" or a "data analysis problem", and to thereafter consider only the subset of claim features that address the selected problem.

Under these guidelines, inventions stemming from the discovery that a measurable parameter is surprisingly instructive in the diagnosis of an illness are no longer considered patentable subject matter by CIPO, unless the measurable parameter is an analyte that in itself is a new and inventive composition of matter, or unless the analysis involves a new and inventive machine or assay. Few diagnostic inventions are accompanied by a corresponding composition of matter invention, much less a machine. The effect of these guidelines has been a rejection of claims to diagnostic inventions that were previously considered patentable subject matter in Canada. The change in examination policy is not based upon any change in law.

The change was introduced after a three-year delay in examination was starting to be noticed by inventors, applicants, and their patent agents, as diagnostic examination had quietly ceased in about 2012. The delay, it was later learned, was in anticipation of the development of a new, more restrictive policy for diagnostic inventions. Once examination commenced in late 2015, applicants and their patent agents argued against the unexpected policy development, in hopes that patents could still issue in this field. However, face with intransigent objections, many ultimately opted to abandon their Canadian applications.

Outside of the patent profession, others have started to take notice.

- Richard Owens, a senior Munk fellow at the Macdonald-Laurier Institute, published an article on December 13, 2017, in the Financial Post entitled *The disturbing problem at Canada's Patent Office: It's suddenly denying medical-test patents*. The article exposes the inconsistency nature of CIPO's policy with Supreme Court jurisprudence on claims construction and subject matter eligibility, and the potential detrimental impacts on healthcare innovation for Canadians.
- Norman Siebrasse, a Law Professor at University of New Brunswick, wrote on this topic in his blog post on January 8, 2018 entitled *Diagnostic Methods at CIPO*. Professor Siebrasse argues that CIPO's practice is to vary the meaning ascribed to claims depending on an assessment of the inventive concept (effectively the inventors' contribution) in a manner contrary to jurisprudence. Professor Siebrasse calls on CIPO to rescind its policy.
- Gloria Galloway, Parliamentary Reporter for The Globe and Mail, published an article entitled *Diagnostic Patents Denied to Researchers who Link Known Body Chemicals to Disease* on April 25, 2018. Although the office of the Minister of Innovation, Science and Economic Development (the ministry responsible for CIPO) informed Ms. Galloway that CIPO's policies were drafted in accordance with court decisions, Ms. Galloway points out that others disagree, including CIPO's own Biotechnology Division Section Head, who was himself strongly opposed to the policy.

The Intellectual Property Institute (IPIC) of Canada, under the guidance of IPIC President (patent agent and lawyer) Grant Lynds, announced on April 6, 2018 that IPIC and CIPO have agreed to initiate a working group of CIPO staff and IPIC members to further study the issues around medical diagnostic patent claims. Securing this commitment, after facing such public scrutiny for the policy, is a step in the right direction. However, a change in policy may not come quickly enough for patent applicants who have patiently waited for a fair examination in Canada since at least 2012.



**Graeme Boocock, Ph.D.**

Patent Agent  
Intellectual Property Group  
Ottawa  
613.369.4775  
gboocock@blg.com



**Kathleen Marsman, Ph.D.**

Patent Agent  
Intellectual Property Group  
Ottawa  
613.787.3572  
kmarsman@blg.com



**Mark Vickers, Ph.D.**

Partner, Patent Agent  
Intellectual Property Group  
Ottawa | 613.787.3575  
Toronto | 416.350.2669  
mvickers@blg.com

## New Canadian Court Proceedings for Patented Medicines in Canada

### Recent Amendments to the *Patented Medicines (Notice of Compliance) Regulations*

Several cases have now been started in the Federal Court of Canada under Canada's amended *Patented Medicines (Notice of Compliance) Regulations* (the Regulations). These Regulations link the regulatory approval of companies who directly or indirectly reference a patentee's New Drug Submission (NDS) with the clearance of certain patent hurdles in Federal Court.

The amendments to the Regulations are substantial and have changed the way the rights of these parties will be adjudicated in cases where the patentee has filed a patent list.

The amended Regulations outline how proceedings are commenced and will unroll under the new scheme. The amendments were triggered by the *Comprehensive Economic and Trade Agreement* (CETA) between Canada and the European Union; and in particular the requirement that linkage proceedings such as these provide equivalent and effective rights of appeal to all parties. As a result of this requirement, the Canadian government chose to change the entire scheme of the linkage proceedings.

While the proceedings are still triggered by the "second person" sending a Notice of Allegation (NOA) to the "first person" alleging non-infringement and/or invalidity of any listed patents, a "first person" or patentee may begin an action for a declaration of infringement within 45 days. This is the most significant change, as these actions involve discovery and live witnesses at trial. Previously, the proceedings brought pursuant to the Regulations were applications based on a written record of affidavits and cross-examination transcripts of fact and expert witnesses and were heard at a short hearing where the lawyers argued the case.

These actions are now, also, full, *in rem* determinations of infringement and validity. If a patent is listed on the patent register, and a NOA is sent, then this action could be the only chance an innovator has to defend the patent. Dual litigation (NOC application then patent infringement action) is a thing of the past.

In addition, once an NOA is sent, all issues relating to the patent can be raised, not just those relating to the claims that were eligible for listing.

In order to expedite the process, the second person must now send, with the NOA, electronic copies of the prior art listed in the Notice of Allegation, as well as any relevant portions of its Abbreviated New Drug Submission (ANDS). If requested, the innovator needs to produce contact information for the inventors as well as copies of laboratory notebooks and reports that are relevant to determining whether certain properties of the invention were established as of the filing date of the patent at issue either when the Statement of Claim is served, or shortly thereafter.

The stay of issuance of regulatory approval to the second person was not extended past the 24 months allowed under the much simpler previous process. Actions under the amended Regulations are fully case managed from the start to hopefully allow for an expedited schedule and a decision within 24 months. The Federal Court has indicated that trials will be scheduled for 20.5 months from the start of the proceeding and last no longer than two weeks.

In addition, and as a result of the expedited schedule, there are many procedural differences between these proceedings and the way a patent infringement action usually progresses through the Federal Court. These differences could also affect the rights of the parties. For instance, there are new provisions in the Regulations dealing with confidentiality of documents and provisions for evidence in chief to be led by way of affidavit.

As these actions are commenced in response to the second person's NOA and not their actual market entry, they are likely to occur at an earlier point in time relative to other jurisdictions and will unfold on a rigorous timeline. Therefore, pharmaceutical companies will be required to seriously review and consider their strategies going forward, in view of the new Canadian scheme.



**Carina De Pellegrin**

Counsel, Lawyer  
Intellectual Property Group  
Ottawa  
613.787.3725  
cdepellegrin@blg.com



**Beverley Moore**

Partner, Lawyer  
Trademark Agent Intellectual  
Property Group  
Ottawa  
613.369.4784  
bmoore@blg.com



**Chantal Saunders**

Partner, Lawyer  
Patent Agent | Intellectual  
Property Group  
Ottawa  
613.369.4783  
csaunders@blg.com

## NOC Regulations: The Intersection of Section 8 Damages and Infringement

The Federal Courts have finally settled the issue of whether a second person can claim damages pursuant to s. 8 of the *Patented Medicines (Notice of Compliance) Regulations* (the *NOC Regulations*) when they infringe one of the first person's patents.

In the continuing saga of AstraZeneca and Apotex with omeprazole, Apotex was found to infringe one of AstraZeneca's formulation patents relating to omeprazole.<sup>1</sup> The Court had also, previously, found that Apotex was entitled to s. 8 damages for being kept off the market in unsuccessful NOC Proceedings.<sup>2</sup> The references for both proceedings were combined and the Court considered both damages claims together.<sup>3</sup>

Apotex argued that its entitlement to damages as a result of the section 8 case should be set off against AstraZeneca's entitlement to damages in the infringement case. AstraZeneca argued that Apotex had not suffered any financial loss, but rather only a lost opportunity to infringe its patent.

In considering the arguments, the Court held that its discretion under section 8(5) must consider all of the circumstances bearing on the claim. The Court held that it was "left with a situation where, in order to recover its 'losses' from being barred from selling Apo-Omeprazole ... Apotex necessarily had to infringe AstraZeneca's 693 Patent." Thus, if Apotex had entered the market during the section 8 period, it would have been required to disgorge its profits to AstraZeneca as a result of the finding in the infringement case. As a result, the Court held that Apotex was not entitled to recover any damages under section 8, as it had suffered no loss.

In a second case between Apotex and AstraZeneca, this time with respect to the esomeprazole drug, a similar finding was made.<sup>4</sup> The patent at issue had been found valid by the Supreme Court, after the section 8 trial, but before the ruling. Apotex did not dispute infringement during the trial but sought to reopen evidence following the SCC's ruling. As a result, this decision contains a number of rulings on ancillary matters, however, the Court concluded that the parties should not be given an opportunity to introduce new evidence, and ruled on the section 8 analysis.

Apotex argued that infringement was not relevant to the loss contemplated by section 8, and may only be relevant to assessing the amount of compensation pursuant to section 8(5), while AstraZeneca argued that all section 8 liability is offset by the infringement. The court cited its decision referenced above, and held that considering the analysis under s. 8(5) was the correct approach. However, the Court then held that to determine compensation, one must look to what would have happened in the but-for world.

The Court held that it was more likely than not that Apotex would have launched its Apo-Esomeprazole product and that that product would have infringed the 653 Patent. Furthermore, on a balance of probabilities, AstraZeneca would have enforced its patent rights against Apotex in the but-for world, as it did in the real world. The Court made a number of conclusions about court proceedings that mirrored the real world happenings and concluded that any sales of Apo-Esomeprazole that Apotex would have been able to make during the section 8 period would have been held to infringe the '653 Patent. Thus, Apotex was claiming compensation for being prevented from infringing AstraZeneca's valid patent. The Court held that any Apotex loss was fully offset by its infringement.

Both of these cases were appealed, however the omeprazole case was discontinued. The esomeprazole appeal is still pending.

These pronouncements come as the *NOC Regulations* have been amended to provide that there can no longer be a separate infringement proceeding following the NOC application. However, the doctrine should remain applicable to those patents that were not eligible for listing on the Patent Register.



**Beverley Moore**

Partner, Lawyer  
Trademark Agent Intellectual  
Property Group  
Ottawa  
613.369.4784  
bmoore@blg.com

1. *AstraZeneca v. Apotex*, 2015 FC 322, aff'd 2017 FCA 9.
2. *Apotex v. AstraZeneca*, 2012 FC 559, aff'd 2013 FCA 77.
3. *AstraZeneca v. Apotex*, 2017 FC 726, appeal discontinued.
4. *Apotex v. AstraZeneca*, 2018 FC 181, currently under appeal.



## Cannabis – An Industry Based on an Ingredient

As in a companion article earlier this in this publication, Canada is jumping into the deep end of the international law pool with its move away from prohibition and toward regulation of cannabis. This change in course is expected to more effectively curb cannabis use by children and remove a source of revenue held exclusively by criminals. It will also open an enormous new adult use market alongside the already robust medical market for Canada's growing cannabis industry. This industry is about to become much more visible and far larger.

For context, Canada has regulated production of medical cannabis in a commercial and competitive system since 2013 under the federal *Access to Cannabis for Medical Purposes Regulations* (the ACMPR)<sup>1</sup> and its predecessor regulations, the *Marihuana for Medical Purposes Regulations* (the MMPR).<sup>2</sup> As of May 16, 2018, there were 104 entities licensed to cultivate cannabis plants, sell cannabis products, or both, in commercial medical channels regulated by the ACMPR.<sup>3</sup> As of December 31, 2017, there were 269,502 Canadians purchasing medical cannabis products from these licensed producers.<sup>4</sup> Soon Bill C-45: *An Act respecting cannabis and to amend the Controlled Drugs and Substances Act, the Criminal Code and other Acts* (the *Cannabis Act*)<sup>5</sup> will remove cannabis from Schedule II of the *Controlled Drugs and Substances Act*,<sup>6</sup> (the CDSA). With that change, cannabis will be regulated by default in Canada rather than prohibited. Three important outcomes are that cannabis will be available for unqualified adult use in addition to medical use, it will be saleable in storefronts and products will diversify. We focus on product diversification in this article. Some may think of "cannabis" as being primarily dried *Cannabis sativa* flowers. The reality is that those flowers are increasingly a source of ingredients rather than a destination product in their own right.

What will product diversification look like in Canada? I have worked with this industry as legal counsel every day for over two years. I see a beta version of Canada's cannabis future when I travel to Colorado, California, Nevada or other adult-use states, where slack regulations allow experimentation, offer a low barrier to entry and foster intense competition. In many ways, the various U.S. state markets are the opposite of Canada's heavily regulated market with its limited access to new varieties of *C. sativa*, relentless quality control, exclusively mail order delivery, and only two product categories – dried flower and cannabis oil.

While U.S. federal illegality greatly complicates any interface between the Canadian cannabis industry and the separate state industries, intellectual property can cross borders (as discussed in one of the 2017 LifeSigns articles<sup>7</sup>). A key point in the regulatory timeline for cross-border licensing opportunities will be when saleable classes of ready-to-use cannabis under the *Cannabis Act* are expanded. Some product diversification to add dosage forms of dried cannabis (pre-rolls and vaporization pods are the likely dosage forms) is expected with the onset of the *Cannabis Act*. This will be significant, but this article is primarily focused on new classes of cannabis, which are generally expected to expand in late 2019 to include concentrates and edibles.

In the Canadian medical market, dried flower is gradually losing market share to cannabis oil. As described in detail in one of the 2017 LifeSigns articles<sup>8</sup>, "cannabis oil" in Canada is for eating, not for vaping – think of it as edibles without food. Cannabis is purchased in a dropper bottle, capsules or a mouth spray. Cannabis oil offers consistent dosing and removes the need to vaporize or smoke cannabis. Cannabis oil is also a higher-margin class of cannabis, making it more attractive to licensed producers. Both the consistency of dosing and the margins are further increased when cannabis oil is encapsulated in gencaps or softgels. Similarly to cannabis oil in Canada, edibles and concentrates in Colorado and other more mature state markets are likewise taking market share



**David Wood, Ph. D.**

Lawyer, Patent Agent  
Intellectual Property Group  
Calgary  
403.232.9742  
dwood@blg.com

from dried flower, and offering industry participants higher margins. Products developed under loosely-regulated state markets are very likely to have more consistent production standards under Canadian federal regulations than state regulations. The result will be greater consistency in user experience, whether adult use or medical.

With classes of cannabis to choose from including dried cannabis (intact flower, milled, decarboxylated, pre-rolled, in pods), cannabis oil (in a dropper bottle, in capsules), concentrates (whether in cartridges or in a container), and edibles (which include beverages), there will be many ways to define a cannabis product in the cannabis industry under the *Cannabis Act*. Further increasing options is the fact that not all cannabis products are focused on psychoactivity. Some cannabis products sold under the ACMPR include significant amounts of cannabidiol (CBD) and lower amounts of delta-9-tetrahydrocannabinol (THC), and are not realistically psychoactive. Higher CBD products will open new demographics in adult use markets with people looking to steer their experience, without a medical motivation and yet not focused on strong psychoactive effects associated with THC. In addition, beyond CBD and THC, there are many other phytocannabinoids, terpenoids, phenylpropanoids and other chemicals that in combination determine the subjective qualities of the psychoactive effects of cannabis. This ingredient is extremely variable.

Another source of both complexity and options for defining a niche is our soon-to-be split industry. In Canada, cannabis will be unique among all substances in that it will be made available for medical use outside the prescription drug system,<sup>9</sup> but also purchased by adults for reasons of their own choosing. There is no other product with that split market, or any comparable split market, in Canada. There is also no other clear example of a product that can be eaten, drank, smoked, vaporized, used topically or used transmucosally, and is variably psychoactive.

With so many classes and dosage forms of cannabis, and multiple varieties of *C. sativa* to cultivate for ingredients, the user experience and the brand associated with a cannabis product can be well-defined by the product itself – happily in the face of extremely restrictive labeling requirements. In addition, the concept that stores fulfilling a social role similar to that of a liquor store will also be free to sell products with little or no psychoactivity will itself present new avenues to brand a retail business according to the particular cannabis products that it chooses to stock.

Adjacent to the products themselves is their manufacture. Technology is constantly improving how we cultivate, dry, cure, roll, extract, formulate, encapsulate, package, and label cannabis to prepare destination products, in addition to the varieties of *C. sativa* cultivated for the inputs. The efforts of nurseries, cultivators, and processors each contribute to defining a product and the experience associated with it. Further potential for disruption is found in production of CBD, THC or other phytocannabinoids in yeast and other microorganisms.

In an industry that is based on an ingredient, any technology that contributes to or facilitates maintaining quality and compliance while increasing efficiency will select the winners. As the products diversify, as our understanding of the molecular basis for the medical benefits and psychoactive properties of cannabis improves, and as the techniques used to manufacture the products evolve, we will see an industry grow and a new fixture of the Canadian economy settle into place over about the next five years. The economic opportunities are significant, as is the possibility for positive social change that a responsibly-regulated industry can provide by competing with the illicit market and increasing access to education about cannabis.

1. SOR/2016-230
2. SOR/2013-119
3. <https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-use-marijuana/licensed-producers/authorized-licensed-producers-medical-purposes.html>
4. <https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-use-marijuana/licensed-producers/market-data.html>
5. Eliz. II: 64-65-66
6. SC 1996, c 19
7. LifeSigns 2017-2018 Edition
8. “Cannabis Oil – Canadian Edibles without Food”, LifeSigns 2017-2018 Edition
9. Cannabis is not prescribed in Canada. A physician writes a medical document for their patient, and the medical document is sent to a licensed producer, making the physician’s patient a client of that licensed producer and allowing them to purchase cannabis directly from the licensed producer by mail delivery. Mail delivery was required for an exclusively federal system that avoided any discussion with the provinces on implementation when the MMPR was first set up.



## Breaking the Rules to Fix a Broken System: Canada's Thoughtful Breach of the Single Convention

Canada, alongside 185 other nations, is party to the *Single Convention on Narcotic Drugs* (the "Single Convention"),<sup>1</sup> one of three United Nations Conventions focused on narcotic drugs (collectively, the UN Conventions).<sup>2</sup> The UN Conventions mandate prohibition as an approach to preventing and combatting social and economic harms resulting from drug abuse and addiction, and to curtail illicit activity related to narcotic drugs. Bill C-45: *An Act respecting cannabis and to amend the Controlled Drugs and Substances Act, the Criminal Code and other Acts* (the *Cannabis Act*)<sup>3</sup> will remove cannabis from Schedule II of the *Controlled Drugs and Substances Act*,<sup>4</sup> (the CDSA), with the result that cannabis will be regulated by default in Canada rather than prohibited, and will be available for unqualified adult use in addition to medical use.



**David Wood, Ph. D.**  
Lawyer, Patent Agent  
Intellectual Property Group  
Calgary  
403.232.9742  
dwood@blg.com

Not surprisingly, there is some tension between Canada's decision to regulate adult use cannabis and our obligations under the UN Conventions. To avoid euphemism, by regulating adult use cannabis, Canada is breaching the Single Convention. However, we do not do so thoughtlessly. The goals of the *Cannabis Act* are very much aligned with those of the UN Conventions. The primary objectives of the *Cannabis Act* are to protect children from exposure to cannabis and to remove a source of revenue from criminals. The *Cannabis Act* reflects an expectation in Canada that these goals are better served by regulation than by prohibition, and in view of the facts, this is a rational perspective. While Canada's approach breaches the Single Convention, we are doing so for reasons entirely consistent with serving the interests of the UN Conventions. If an unintended outcome of this sea change in policy is that a new fixture of the economy provides an additional basis for growth to Canada, so much the better.

The goals of the UN Conventions are laudable and deserve effective execution. As a mechanism to achieve the goals, the Single Convention requires that lawful use of narcotic drugs be restricted to medical or scientific use, and that illicit use of narcotic drugs be prohibited in each party to the Single Convention, with deprivation of liberty being a consequence for possession or trafficking in narcotic drugs. Canada has laws to this effect in the CDSA.

Prohibition may at first blush seem like a logical approach to meeting the goals of the UN Conventions. Unfortunately, prohibition has failed in Canada. Illicit cannabis is commonly used, accessible by minors, and grown with unsafe pesticides and practices. Criminals enjoy a monopoly on the profits of trafficking. Cannabis was prohibited in Canada in 1923, before the United Nations existed, let alone the UN Conventions. After over ninety years of cannabis prohibition, use in Canada is increasing or remaining stable.<sup>5</sup> The Single Convention urges us to appreciate the dangers of drug abuse and require parties to fight back with prohibition. Yet in the face of prohibition, criminals become rich and young people have easy access. This outcome defeats a key purpose of prohibition – to mitigate social and economic harms, and curtail illicit activity.

The Single Convention groups all use of narcotic drugs into two categories: (a) medical/scientific use and (b) illicit use. Faced with the failure of prohibition, Canada has changed its approach to fighting abuse of cannabis by introducing a third type of cannabis use to the discussion, which is neither medical nor illicit. The third category is "regulated". Regulated adult use cannabis will soon be available across the country with nationally applicable good production practices. Canada has a strong jumping off point to take this unprecedented step for a 21<sup>st</sup> century member of the G20. Licensed producers have been providing commercially-produced regulated cannabis to Canada's medical cannabis market since 2013. As of May 16, 2018, there were 104 entities licensed to cultivate cannabis plants, sell cannabis products, or both.<sup>6</sup> As of December 31, 2017, there were 269,502 Canadians legally purchasing medical cannabis products from these licensed producers.<sup>7</sup> As further production capacity comes online, the regulated adult use market will remove market share from the illicit market.

The *Cannabis Act* will change our relationship with cannabis. Regulation, education and elimination of the mystery are likely to curb abuse of cannabis. Cannabis should be mundane – its illegality gives it far too much power as a mysterious and ill-defined bogeyman. If the goal is truly to mitigate abuse of narcotic drugs, we can do that by educating the public rather than by threats and coercion – education has met with success in Canada to curb tobacco use, alcohol abuse generally and drunk driving specifically. Once Bill C-45 passes, those who are interested in using cannabis, and who do not have medical access, can simply purchase it without breaking the law. We are breaching the treaty, but the path Canada has chosen is very likely to outperform prohibition in terms of making Canada a better place to live and effectively addressing the social and economic challenges of cannabis.

An important outcome of Canada's policy change, particularly for a business law publication, is that the goals of the *Cannabis Act* are met when a robust, vibrant and engaging regulated cannabis industry pulls business away from criminals compellingly. Product diversity, appealing branding, high-potency products, and attractive storefronts are all available to the illicit market. For the regulated market to undermine the illicit market, it must outcompete the illicit market. The regulated market must be responsibly and tastefully executed, but it cannot be invisible, inaccessible or disappointing. To the extent that someone is interested in eliminating the illicit market, they are

correspondingly interested in allowing the regulated market the freedom it needs to outcompete the illicit market. A second article in this year's Life Signs explores the opportunity presented by addition of a regulated adult use market to the Canadian cannabis industry alongside the medical cannabis market.

1. *Single Convention on Narcotic Drugs*, 30 March 1961 (as amended by the 1972 Protocol), 976 UNTS 14152 (entered into force 13 December 1964); membership status is available at <https://treaties.un.org/>
2. Canada is also party to the *Convention on Psychotropic Substances*, 21 February 1971, 1019 UNTS 14956 (entered into force 8 August 1975), which has 186 parties, and the *United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances*, 20 December 1988, 1582 UNTS 27627 (entered into force 11 November 1990), which has 190 parties and 87 signatories; membership status is available at <https://treaties.un.org/>
3. *Eliz. II*: 64-65-66
4. *SC* 1996, c 19
5. <https://www.canada.ca/en/health-canada/services/canadian-tobacco-alcohol-drugs-survey/2015-summary.html>
6. <https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-use-marijuana/licensed-producers/authorized-licensed-producers-medical-purposes.html>
7. <https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-use-marijuana/licensed-producers/market-data.html>



## I REGULATORY

Medical Products | Regulatory

# Overview of Canadian Health Regulation and Recent Developments

The regulatory landscape for pharmaceuticals and medical devices in Canada continues to evolve. Following a general overview of the regulatory environment, set forth below is a brief summary of some key recent developments.

### Overview of Regulation

The Food and Drugs Act (FDA) applies to all medical products (that is, drugs, medical devices and natural health products) sold in Canada, whether manufactured in Canada or imported. The FDA and the Food and Drug Regulations (FDA Regulations) seek to ensure the safety of medical products in Canada by governing their manufacture, sale and advertisement.

As regards medical products, the FDA and the FDA Regulations are administered by the Health Products and Food Branch (HPFB) of Health Canada. In turn, HPFB is divided into directorates. The Therapeutic Products Directorate (TPD) has broad authority over pharmaceuticals and medical devices. The Biologics and Genetic Therapies Directorate (BGTD) is responsible for biologics and radiopharmaceuticals. The Natural and Non-Prescription Health Products Directorate (NNHPD) is responsible for the review and approval of non-prescription and disinfectant drugs, as well as natural health products.

The Marketed Health Products Directorate (MHPD) monitors the safety, effectiveness and quality of marketed medical products in Canada, including: prescription and non-prescription medications, biologics, vaccines and natural health products. The MHPD is also responsible for the post-marketing monitoring, surveillance, adverse event assessment and communication for marketed health products, including pharmaceuticals, radiopharmaceuticals, biologics and medical devices.

The HPFB is responsible for the enforcement of the FDA and the FDA Regulations. The Office of Patented Medicines and Liaison is responsible for the administration of the Patented Medicines (Notice of Compliance) Regulations (NOC Regulations), maintenance of the Canadian Patent Register and determination of the innovative drug status under the data protection provisions of the FDA Regulations.

The Canadian Intellectual Property Office is responsible for the administration and processing of intellectual property rights in Canada, including those related to medical products.

The provincial governments have jurisdiction over, and are responsible for, the funding of all healthcare services. For pharmaceutical coverage, each provincial drug plan sets specific price and other cost-containment guidelines. The impact of the various regulations at each level of government has resulted in a uniquely Canadian landscape that is sometimes difficult to rationalise on efficiency grounds.

After Health Canada has approved a drug to be sold in Canada, but before these drugs are funded under most public drug plans, a manufacturer must apply to the Canadian Agency for Drugs and Technologies in Health (CADTH) to have its drug reviewed through the Common Drug Review (CDR). CADTH is an independent, not-for-profit national body funded by Canada's federal, provincial and territorial governments. Healthcare decision-makers in Canada are provided by CADTH with credible, impartial advice and evidence-based information about the effectiveness and efficiency of drugs and other health technologies. The CDR recommends which new non-cancer drugs can be covered under publicly funded drug benefit plans in Canada. All federal, provincial and territory governments take part in this review except the province of Québec.



**Jeffrey Graham**

Partner, Lawyer  
Corporate Commercial Group  
BLG National Life Sciences  
Group Leader  
Toronto  
416.367.6174  
jgraham@blg.com



**Pamela Odina**

Associate  
Toronto  
416.367.6518  
podina@blg.com



The pan-Canadian Oncology Drug Review assesses cancer drugs and recommends the drugs that Ontario and other provinces and territories in Canada (except Québec) should fund under their public drug programmes. Québec has a National Institute for Excellence in Health and Social Services, modelled on the British National Institute for Health and Care Excellence, which evaluates the clinical benefits and costs of medical technologies, drugs and interventions, and develops recommendations and clinical guidelines for the Québec Ministry of Health.

Following the completion of the review process described above, the pan-Canadian Pharmaceutical Alliance brings provinces, territories, and federal drug plans together to negotiate prices for publicly covered drugs. In addition, the Patented Medicines Prices Review Board (PMPRB) has responsibility for ensuring that the prices of patented medicines sold in Canada are not excessive and reporting on pharmaceutical trends.

### Changing Landscape

Below is a brief summary of four major updates: proposed amendments to the *Patented Medicines Regulations* and new PMPRB Guidelines, a new National Advisory Council on Pharmacare, Health Canada's consultations on its regulatory review of drugs and devices, and operational changes to CADTH's biosimilar review process.

#### Proposed Changes to PMPRB Guidelines

In December 2017, the Department of Health proposed amendments to *Patented Medicines Regulations*. The proposal includes the addition of three new price regulatory factors to be used by the PMPRB to assess whether the price of a patented medicine is excessive; an updated list of countries that the PMPRB may use to compare prices; and new reporting requirements, including the reduction of reporting obligations for patented veterinary, over-the-counter and generic medicines. In anticipation of the amendments entering into force, the PMPRB has published a Scoping Paper. It provides a high-level overview of how the Board might operationalize the proposed Regulations through a set of non-binding guidelines as outlined in Sec. 96 of the *Patent Act*. PMPRB is undertaking consultations regarding this possible reform of its Compendium of Policies, Guidelines and Procedures, commonly referred to as "the Guidelines." The amended Regulations and updated Guidelines are expected to come into force by January 2019.

#### Development of National Pharmacare Program

In February 2018, the Federal Government announced a new Advisory Council on the Implementation of National Pharmacare as part of Budget 2018. Former Ontario Health Minister, Dr. Eric Hoskins, was appointed as Chair of the Council. Dr. Hoskins is a long-time

advocate for pharmacare and recently implemented the OHIP+ program. The Advisory Council's mandate is to conduct an economic and social assessment of domestic and international models and recommend viable options on how to implement pharmacare to improve the accessibility and affordability of prescription medications. It will consult with relevant experts, as well as national, provincial, territorial and Indigenous leaders.

More recently, the Standing Committee on Health presented its report, *Pharmacare Now: Prescription Medicine Coverage for All Canadians*. The report lays out a framework for a single payer, publicly funded prescription drug coverage program in Canada. Federal Health Minister Ginette Petitpas Taylor confirmed that the Committee's recommendations will be considered by the Advisory Council, which is expected to submit its report to the federal Minister of Health and Minister of Finance by spring of 2019.

#### Health Canada's Regulatory Review of Drugs and Devices

Health Canada launched consultations on improving its regulatory review of drugs and devices (R2D2) in September 2017. The purpose of the R2D2 initiative is to improve the current regulatory system by making it more efficient, supporting timely access to therapeutic products, and building better linkages within the entire health care system. Health Canada intends to implement a plan by 2021. In the coming months, Health Canada has indicated that it will be consulting on digital health technologies, Health Canada's eLearning course on Premarket Medical Device Regulation, software subject to Canada's Medical Devices Regulations, needs of the health care system to support drug review prioritization decisions, renewal of the Special Access, sale of a drug for emergency preparedness response and medical device cybersecurity.



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### Amendments to CADTH's Biosimilar Review Process

CADTH has recently revised its biosimilar review process for its CDR and pCODR. The streamlined process is intended to reduce duplication, optimize resources, and establish a unified approach to evidence review for all participating jurisdictions to benefit patients, clinicians, and governments. New biosimilar submissions filed with CADTH will now have a shorter timeline, fewer submission requirements, and an abbreviated biosimilar summary dossier template. The resubmission criteria for the pCODR process now

requires a submitter to file a completed *pCODR Resubmission Eligibility Form* and provide copies of one or more new studies that would address the specific issues identified in a recommendation. This expands on the revisions previously implemented by CADTH to the resubmission eligibility criteria for the CDR process. In addition, the pCODR process has been amended with new checkpoint response timelines and updated pCODR templates to be used for new submissions. Finally, a new fee structure now applies to both the CDR and pCODR programs.



## The Importance of Strategic Outsourcing to Life Science Companies\*

One of the most important disciplines for an early stage or emerging life science company is the ability to successfully execute strategies to outsource key functions within the organization to third parties.

It is well recognized that advances in genomics, combinatorial chemistry, high-throughput screening (HTS), among other things, have all contributed to an explosion in the number of new promising biological targets and lead molecules. However, early stage or emerging life science companies rarely have either the funding or the expertise to fully embrace the new technologies' potential. Thus, companies often choose to outsource their research programs to specialized CROs or academic centers capable of providing a state-of-the-art expertise in certain areas.

In addition, in order to increase the success rate of drug discovery programs, life science companies are often seeking to accelerate every stage of early drug discovery process, starting from target identification and validation, and all the way towards a preclinical drug candidate. In many cases, it is less expensive and more efficient to outsource those challenges to external organizations, than it is to create in-house infrastructure and hire the necessary research staff.

There are a number of principles of outsourcing that are often cited in the literature and applied in practice. Some of the most important principles are briefly summarized below:

First, it is key to select the right partner. It is important to ask questions about a partner's background, track record and experience. A partner who lacks the expertise required to achieve the desired result or who fails to deliver on time can result in a costly operation. The right partner should also have experience in the entire development process to foresee and prevent any issues from arising. Part of the due diligence process should be a careful review of the experience of the partner with similar projects in the past. Checking with current and past clients of the prospective partner is good business practice.

Second, companies that successfully outsource have a clear objective in mind that is understood by both the key internal parties who will be responsible for managing the relationship with the outsourced partner and the key representatives of the partner.

Third, in addition to the partner's background, track record and experience, another key for success is that the culture of the company and its partner be compatible. Alignment is key. Often this issue of cultural alignment will become apparent during the negotiation phase of the relationship. If the representatives of the prospective partner appear to make the process unduly difficult, this may be an indication that there is a reasonable prospect that post agreement, those responsible for delivering the project will also be difficult. Getting to "yes" in the course of a contract negotiations can sometimes be very time consuming and complex. However, one expects that a prospective partner will be willing to make reasonable concessions to gain the mandate and if that is not apparent from the early stage of contractual negotiations, this fact can be an indication that the post contract relationship may be less cooperative than optimal.

Fourth, it is important that those within the company responsible for the outsourcing have the relevant experience to manage the partner effectively. Experience matters and either the company has someone who has the experience necessary to oversee the project successfully or it should consider hiring a project manager with the relevant skills. By making this investment, companies can shorten the learning curve, avoid costly mistakes and more quickly become effective partners.



**Jeffrey Graham**

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

Toronto  
416.367.6174  
jgraham@blg.com

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Firth, service-level commitments are extremely important and should be reviewed and improved over the life of the relationship with the partner. Ultimately, customer satisfaction depends on the effectiveness of relationship between those in the company responsible for the oversight of the outsourcing relationship and the counterparts at the partner. The more effective the relationship, the more likely the success of the outsourcing.

Finally, it is important to recognize that outsourcing can also present serious risks to a company. For example, the intellectual property of a company, including business plans, trade secrets and other proprietary knowledge need to be carefully secured and outsourcing of key functions, can potentially put at risk the company's strategy to protect its intellectual property. A carefully negotiated agreement will ensure that improvements to existing inventions or new inventions that are directly related to the outsourced work are owned or controlled by the company.

Increasingly, cybersecurity has emerged as a critical issue in every sector of the economy. A company considering the outsourcing of an important function or project must insist that a prospective partner have an information security risk management strategy that complies with best practice.

All in all, the success of the life science industry, especially the impressive success of many early stage and emerging companies, is closely connected to the many successful outsourcing arrangements that have been undertaken. There is no reason to doubt that there will be any fewer successful outsourcing arrangements within the life science sector in the future.



## Competition Act and Investment Canada Act Thresholds for 2018

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 February 10, 2018, the Federal Government published the increases for the pre-merger notification "transaction-size" threshold under the *Competition Act*, and the pre-merger review threshold under the *Investment Canada Act* for acquisitions involving Canadian businesses, including life science businesses, by state-owned enterprises controlled in World Trade Organization (WTO) member states.

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

The pre-merger notification "transaction-size" threshold for 2018 has increased to **C\$92 million**, from the 2017 threshold of C\$88 million. A proposed transaction generally requires notification to the Competition Bureau under the *Competition Act* where both of the following thresholds are exceeded:

1. **Party-size threshold:** The parties to the transaction, together with their affiliates, collectively have assets in Canada, or gross annual revenues from sales from or into Canada, that exceed C\$400 million (this threshold remains unchanged from year to year); and,
2. **Transaction-size threshold:** The size of the specific transaction will exceed C\$92 million. In the case of asset or share transactions, this would mean that either the value of the assets in Canada of the target, or the annual gross revenues from sales in or from Canada generated from those assets, exceed C\$92 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 per cent of the total outstanding voting shares of a public corporation, or above 35 per cent in the case of a private corporation. If the entity acquiring the shares already owns shares in excess of 20 or 35 per cent (depending on the type of transaction), the transaction would have to result in the entity owning more than 50 per cent 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), will remain at **C\$1 billion**. This increase came into effect on June 22, 2017.

As also discussed in our bulletin on September 21, 2017, this threshold was increased to **C\$1.5 billion** in enterprise value for non-state owned enterprise investors from any Comprehensive Economic and Trade Agreement (CETA) country or other bilateral free trade agreement partner country (now defined in the *Investment Canada Act* as a "**Trade Agreement Investor**"). Other Trade Agreement Investors include European Union countries, Chile, Colombia, Honduras, Mexico, Panama, Peru, South Korea, and the United States.

On January 23, 2018, 11 countries agreed on the core elements of a new agreement to be called the "Comprehensive and Progressive Agreement for Trans-Pacific Partnership" (CPTPP)<sup>1</sup>. The text of the CPTPP outlines that this threshold will also be **C\$1.5 billion** for investors (other than state-owned enterprises) of each signatory state (*i.e.* Australia, Brunei, Japan, Malaysia, New Zealand, Singapore, and Vietnam), once that signatory state ratifies the CPTPP in its own jurisdiction.



**Devin Persaud**

Associate  
Corporate Commercial Group  
Toronto  
416.367.6298  
dpersaud@blg.com



**Gregory McLean**

Senior Associate  
Competition/Antitrust and  
Foreign Investment Review Group  
Toronto  
416.367.6136  
gmclean@blg.com



**Denes A. Rothschild**

Partner, Lawyer  
Competition/Antitrust  
and Foreign Investment  
Review Group  
Toronto  
416.367.6350  
drothschild@blg.com



The Investment Review Division of the Department of Innovation, Science and Economic Development also published that the threshold for pre-merger reviews for direct investments involving Canadian (non-cultural) businesses by state-owned enterprises which are controlled in WTO member states will increase to **C\$398 million** from C\$379 million in 2017. This threshold is based on the “book value” of the Canadian business’ assets.

The existing book value threshold of **C\$5 million** will continue to apply to transactions that relate to cultural businesses<sup>2</sup> 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. Formerly known as the Trans-Pacific Partnership, prior to the exclusion of the United States.
2. A “cultural business” is defined by the *Investment Canada Act* as a business that carries on activities in the book, magazine, periodical or newspaper industries, film/video/TV, music, or radio broadcasting industries.



## Securities Commissions Provide Guidance on New Take-Over Bid Regime

In *Aurora Cannabis Inc. (Re)*, 2018 ONSEC 10, the Ontario Securities Commission and the Saskatchewan Financial and Consumer Affairs Authority (the Commissions) recently, and for the first time, provided guidance on the conduct of hostile take-over bids under the new Canadian regulatory regime, which came into force in early 2016. The Commissions held that, in essence, the take-over bid regime is a nearly complete code. Notably, the Commissions held that: tactical shareholder rights plans will rarely be allowed; the minimum bid period will seldom be abridged beyond the enumerated exceptions; and, the bidder's ability to purchase up to 5 per cent of shares of the target on the open market will rarely be negated.

### Background

In November 2017, *Aurora Cannabis Inc.* (Aurora) launched a hostile take-over bid for all of the issued and outstanding common shares of *CanniMed Therapeutics Inc.* (CanniMed). In the months prior to the bid, CanniMed had been in exclusive negotiations with *Newstrike Resources Ltd.* (Newstrike) related to a potential acquisition of Newstrike by CanniMed.

Two nominee directors on the CanniMed board of directors (CanniMed Board) and one of CanniMed's large institutional shareholders, Vantage Asset Management (Vantage), opposed the Newstrike transaction and insisted that CanniMed would be better to pursue a strategic sale process.

Unhappy with CanniMed's pursuit of the Newstrike transaction which was nearing an agreement between the parties, and unbeknownst to the CanniMed Board, Vantage approached Aurora to suggest it pursue a business combination with CanniMed. Aurora subsequently entered into "hard" lock-up agreements with Vantage and other CanniMed shareholders representing approximately 38 per cent of CanniMed's then issued and outstanding shares. Just days before CanniMed announced it had entered into a binding agreement with Newstrike, Aurora submitted a non-binding proposal to acquire CanniMed. After further deliberations, the CanniMed Board determined to proceed with the transaction with Newstrike and on November 17, 2017, entered into a binding agreement that provided for the purchase of all of Newstrike's common shares by CanniMed pursuant to a plan of arrangement. On November 24, 2017, Aurora commenced its hostile bid with one of the conditions being the termination of the Newstrike arrangement agreement.

In response to the bid, and on the recommendation of a special committee of independent directors of the CanniMed Board (the Special Committee), CanniMed adopted a shareholder rights plan (the Plan). The Plan precluded Aurora from acquiring any CanniMed shares (at the time it did not own any) or from entering into any additional lock-up agreements in respect of the bid.



**Philippe Tardif**

Partner, Lawyer  
Corporate Commercial Group  
Toronto  
416.367.6060  
ptardif@blg.com



**Jason Saltzman**

Partner, Lawyer  
Securities and Capital Markets Group  
Toronto  
416.367.6196  
jsaltzman@blg.com



**Mark Wheeler**

Partner, Lawyer | Securities  
and Capital Markets Group  
Toronto  
416.350.3501  
mwheeler@blg.com



**Graham Splawski**

Associate, Lawyer | Commercial  
Litigation and Arbitration Group  
Toronto,  
416.367.6206  
gsplawski@blg.com



**Ashley Thomassen**

Associate, Lawyer  
Commercial Litigation  
and Arbitration Group  
Toronto  
416.367.6509  
athomassen@blg.com

In November and December 2017, Aurora, CanniMed, and the Special Committee all brought applications to the Commissions, and the applications were heard on an urgent basis.

On December 22, 2017, following a simultaneous hearing with the FCAA (Saskatchewan) and the OSC, the Commissions issued orders denying Aurora's application to shorten the 105-day minimum deposit period; denying CanniMed's cross-application to prohibit Aurora from acquiring 5 per cent of CanniMed common shares; finding there was insufficient evidence to establish the locked-up shareholders were acting jointly or in concert with Aurora; requiring Aurora to issue amended new releases and an amended take-over bid circular to disclose certain information that could reasonably affect CanniMed shareholders' decision to accept or reject the offer; and cease trading the Plan.

### Key Points in Commissions' Guidance

The Commissions took this opportunity to make clear that the amendments to the take-over bid regime that were made in 2016 are largely meant to ensure predictability of the regime.

#### Alternative Transaction Determination

With respect to Aurora's application to shorten the minimum deposit period, the Commissions found the policy rationale for the "alternative transaction exception" did not exist in this case. Aurora's decision to include, as a condition of its bid, that the Newstrike transaction not be completed could not transform the Newstrike transaction into an "alternative transaction." Interestingly, however, by indicating that the developed strategic rationale and the history and timing of the Newstrike transaction "convinced [the Commissions] that the acquisition was not intended as a defensive tactic" against the bid, the Commissions' statement could possibly be interpreted as suggesting that if the Newstrike transaction was found to be an impermissible defensive tactic, it may have been characterized as an alternative transaction for the purposes of the exception.

#### Shareholder Rights Plan

Further, the Commissions made clear that, except in rare circumstances, tactical shareholder rights plans will not be permitted. The Commissions stated that a plan that simply reiterates the requirements of the current take-over bid regime would serve no purpose and potentially confuse investors whereas given the protections of the new take-over bid regime, there rarely would be a need to provide for any further protections. The Commissions found that the rebalancing of the take-over bid regime by mandating the 105-day deposit period, the minimum 50 per cent tender condition and the mandatory 10-day extension following satisfaction of conditions, provided sufficient protections in this case, and likely in most cases, to facilitate shareholder choice. Moreover, the Commissions found that the Plan "could not primarily be said to be giving the Board time to conduct an auction to allow time for higher bids to emerge". It appears that only in rare and unique circumstances will the Commissions permit a target of a hostile bid to keep a tactical rights plan in place.

### Lock-Up Agreements and Joint Actors

Finally, despite the Commissions' finding of fact that Aurora's bid was commenced based on material non-public information (MNPI) from Vantage, the Commissions concluded there was insufficient evidence for a finding that the locked-up shareholder were acting jointly or in concert with Aurora. Relying in part on the language in the regulation (subsection 1.9(3) of NI 62-104), the Commissions clarified that lock-up agreements are acceptable business tools and not necessarily indicative of joint actor status. The Commissions noted that the presumption that an agreement to exercise voting rights leads to a joint actor status can be rebutted, where the voting rights are tailored to be consistent with and to support otherwise permissible commitments to tender a party's securities to the bid. Further, despite ordering Aurora to amend its news releases and takeover bid circular, the Commissions found that once CanniMed announced that it had entered into the Newstrike arrangement agreement, the receipt of the MNPI was, for Aurora, cleansed by such disclosure. These findings signal that the Commissions will likely be reluctant to make a finding of joint actor status without clear and substantive evidence of coordination, such as economic sharing or transferring voting rights or entitlements.

### BLG Team

BLG represented CanniMed in all aspects of the transactions with Newstrike and Aurora, including at the hearings before the Commissions.

The BLG securities team was led by **Philippe Tardif** with support from **Jason Saltzman, Andrew Powers, Mark Wheeler, Colin Cameron-Vendrig, Rocky Swanson, and Joseph DiPonio**.

The BLG litigation team was led by **James D. G. Douglas** and **Caitlin Sainsbury** with support from **Graham Splawski** and **Ashley Thomassen**.



## Canadian Personal Information Security Breach Obligations – Preparing for Compliance

Commencing November 1, 2018, Canada's federal *Personal Information Protection and Electronic Documents Act* (PIPEDA) will require an organization that suffers a “breach of security safeguards” involving personal information under its control to keep prescribed records of the breach and, if the breach presents a “real risk of significant harm to an individual”, to promptly report the breach to the Privacy Commissioner and give notice of the breach to affected individuals and certain other organizations and government institutions. Preparing for compliance with the personal information security breach obligations may require significant effort, time and expense. Canadian organizations, including life science businesses, should now be taking steps to prepare for compliance.



**Bradley Freedman**

Partner, Lawyer  
National Leader of  
Cybersecurity Law Group,  
Vancouver Regional Leader  
of our Technology Law Group  
Vancouver  
604.640.4129  
bfreedman@blg.com

### Background

PIPEDA regulates the collection, use and disclosure of personal information in the course of commercial activities by private sector organizations in all provinces except British Columbia, Alberta and Québec (each of which has a substantially similar personal information protection law) and by all organizations that operate a “federal work, undertaking or business” (e.g. banks, telecommunications and transportation companies) or that transfer personal information across a provincial border for consideration.

PIPEDA was amended in 2015 by the *Digital Privacy Act* to add obligations for reporting, notification and record-keeping regarding certain personal information security breaches, but those obligations were not in force because regulations prescribing required details were not enacted. In March 2018, the Government of Canada issued an *Order in Council* to bring those obligations into force on November 1, 2018. The Canadian government published the required *Breach of Security Safeguards Regulations* on April 18, 2018.

### Reporting, Notification and Record-Keeping Obligations

Following is a summary of the personal information security breach reporting, notification and record-keeping obligations as set out in PIPEDA and the *Breach of Security Safeguards Regulations*.

#### Key Concepts – Breach of Security Safeguards and Real Risk of Significant Harm

The reporting, notification and record-keeping obligations invoke two key concepts: “breach of security safeguards” and “real risk of significant harm to an individual”.

PIPEDA broadly defines “breach of security safeguards” as “the loss of, unauthorized access to or disclosure of personal information resulting from a breach of an organization’s security safeguards [required by PIPEDA] or from a failure to establish those safeguards”. The required security safeguards include physical, organizational and technological measures, appropriate to the sensitivity of the personal information, to protect the personal information (regardless of the format in which it is held) against loss, theft and unauthorized access, disclosure, copying, use or modification.

PIPEDA broadly defines “significant harm” as including “bodily harm, humiliation, damage to reputation or relationships, loss of employment, business or professional opportunities, financial loss, identity theft, negative effects on the credit record and damage to or loss of property”. PIPEDA provides that the circumstances relevant to determining whether a breach of security safeguards creates a real risk of significant harm include: (a) the sensitivity of the personal information involved in the breach; (b) the probability that the personal information has been, is being or will be misused; and (c) other prescribed factors (none at this time).

### Reporting to the Commissioner

If an organization suffers a breach of security safeguards involving personal information under its control and it is reasonable to believe that the breach creates a real risk of significant harm to an individual, then the organization must report the breach to the Commissioner as soon as feasible after the organization determines that the breach has occurred. The report may be sent to the Commissioner by any secure means of communication.

The report must be in writing and must contain: (a) a description of the circumstances of the breach and, if known, the cause; (b) the day on which, or the period during which, the breach occurred or, if neither is known, the approximate period; (c) a description of the personal information that is the subject of the breach to the extent that the information is known; (d) the number of individuals affected by the breach or, if unknown, the approximate number; (e) a description of the steps that the organization has taken to reduce the risk of harm to affected individuals that could result from the breach or to mitigate that harm; (f) a description of the steps that the organization has taken or intends to take to notify affected individuals of the breach; and (g) the name and contact information of a person who can answer, on behalf of the organization, the Commissioner's questions about the breach.

An organization may submit to the Commissioner any new information the organization becomes aware of after the organization submits its breach report to the Commissioner.

### Notice to Affected Individuals

If an organization suffers a breach of security safeguards involving an individual's personal information under the organization's control and it is reasonable to believe that the breach creates a real risk of significant harm to the individual, then the organization must notify the individual of the breach as soon as feasible after the organization determines that the breach has occurred, unless giving notice is otherwise prohibited by law.

The notification must contain sufficient information to allow the affected individual to understand the significance of the breach and to take steps, if possible, to reduce the risk of harm that could result from the breach or to mitigate that harm. In addition, the notification must contain: (a) a description of the circumstances of the breach; (b) the day on which, or period during which, the breach occurred or, if neither is known, the approximate period; (c) a description of the personal information that is the subject of the breach to the extent that the information is known; (d) a description of the steps that the organization has taken to reduce the risk of harm that could result from the breach; (e) a description of the steps that affected individuals could take to reduce the risk of harm that could result from the breach or to mitigate that harm; and (f) contact information that the affected individual can use to obtain further information about the breach.

The notification must be conspicuous and must be given directly to an affected individual except in specified circumstances in which

indirect notification is required. Direct notification must be given to an affected individual in person, by telephone, mail, email or any other form of communication that a reasonable person would consider appropriate in the circumstances. Indirect notification to an affected individual must be given in the following circumstances: (a) direct notification would be likely to cause further harm to the affected individual; (b) direct notification would be likely to cause undue hardship for the organization; or (c) the organization does not have contact information for the affected individual. Indirect notification must be given by public communication or similar measure that could reasonably be expected to reach the affected individual.

### Notification to Other Organizations/Government

If an organization notifies an individual about a breach of security safeguards, then the organization must give notice of the breach to any other organization or government institution that the notifying organization believes may be able to reduce the risk of harm that could result from the breach or mitigate that harm.

### Record-Keeping Obligations

An organization must keep and maintain a record of every breach of security safeguards involving personal information under its control, even if there is no obligation to report or give notice of the breach (i.e. the breach does not create a real risk of significant harm to an individual). The record must contain any information that enables the Commissioner to verify the organization's compliance with the breach reporting and notification obligations. An organization must maintain the record of a breach for 24 months after the day on which the organization determines that the breach has occurred, and must provide the record to the Commissioner on request.

### Enforcement

The Commissioner may investigate an alleged contravention of the personal information security breach reporting, notification and record-keeping obligations either as a result of a complaint filed by an individual or on the Commissioner's own initiative, and publish a report of findings and recommendations after completing the investigation.

The Commissioner's statutory confidentiality obligations include reports and records obtained as a result of the personal information security breach reporting, notification and record-keeping obligations, but the Commissioner is permitted to "make public any information that comes to his or her knowledge" if the "Commissioner considers it in the public interest to do so". In addition, the Commissioner may also disclose to a government institution any information contained in a breach report or record of a breach "if the Commissioner has reasonable grounds to believe that the information could be useful in the investigation of a contravention of the laws of Canada or a province that has been, is being or is about to be committed".

After the Commissioner issues an investigation report in response to a complaint about an alleged contravention of the personal information security breach reporting, notification and record-keeping obligations, or gives notice that the investigation



has been discontinued, the individual complainant may apply to the Federal Court of Canada for an award of damages (including damages for any humiliation) and other remedies.

An organization's knowing contravention of the personal information security breach reporting, notification (to individuals, but not to organizations or government institutions) and record-keeping obligations is an offence punishable by a fine of up to C\$100,000.

## Compliance Challenges

PIPEDA's personal information security breach obligations present a number of uncertainties and compliance challenges. For example:

- **Significant Harm:** When must an organization assess whether a personal information security breach presents “a real risk of significant harm to an individual”, and how should that assessment be documented for future reference?
- **Reporting/Notification:** When will an organization be considered to have “determined” that a personal information security breach has occurred? What financial costs or other circumstances will constitute “undue hardship” to an organization to justify indirect notification? Is indirect notification always required if direct notification to any affected individual is unsuccessful (*e.g.* email or postal mail notification is undeliverable/rejected)? What “secure means of communication” may be used to deliver a report to the Commissioner?
- **Withholding/Delaying Reporting and Notification:** In what circumstances (if any) may an organization delay reporting or notification of a personal information security breach, or withhold information about a breach? For example, may an organization delay reporting or notification of a breach to avoid compromising an investigation of the breach, at the request of law enforcement, to protect commercially sensitive information or to comply with confidentiality obligations?
- **Record-keeping:** Are there any practical thresholds or exceptions to the obligation to create a record of a personal information security breach that does not present a risk of significant harm to an individual? What information should be included in a record of a breach?
- **Data Controllers/Processors:** How do the personal information security breach obligations apply to an organization that processes or stores personal information (a “data processor”) on behalf of another organization (a “data controller”), particularly if the data controller fails or refuses to comply with personal information security breach reporting and notification obligations? How should a data controller comply with its personal information security breach obligations if relevant data processors fail or refuse to cooperate?

Some of those issues might be addressed in guidance documents issued in the future by the Commissioner.

## Preparing for Compliance

Canadian organizations should now be taking steps to prepare for compliance with PIPEDA's personal information security breach obligations. Following are some suggestions:

- **Security Safeguards:** An organization should assess its security safeguards for personal information and consider whether additional or enhanced safeguards (*e.g.* robust encryption with a secured encryption key) will reduce the risk that a personal information security breach will occur or will result in significant harm to individuals.
- **Policies/Procedures – Assessment and Response:** An organization should have written policies and procedures so that each potential personal information security breach is immediately escalated to designated and properly trained personnel for investigation, assessment and response in accordance with a written incident response plan that is consistent with applicable legal requirements, regulatory guidance and relevant best practices. For more information, see BLG bulletins *Cyber Incident Response Plans – Test, Train and Exercise* and *Data Security Incident Response Plans – Some Practical Suggestions*.
- **Policies/Procedures – Record-keeping:** An organization should have written policies and procedures so that designated and properly trained personnel create and securely retain (for applicable retention periods) legally compliant records of every detected personal information security breach.
- **Policies/Procedures – Reporting, Notifications and Disclosures:** An organization should have written policies and procedures so that designated and trained personnel make and document informed decisions about reporting personal information security breaches to the Commissioner, giving notice of those breaches to affected individuals and relevant government agencies and other organizations, and making timely disclosures of those breaches to other interested persons (*e.g.* investors and business partners). Legal obligations to report, notify and disclose personal information security breaches may be imposed by statute and by common law and civil law. For more information, see BLG bulletins *Cyber-Risk Management – Data Incident Notification Obligations* and *Cyber Risk Management – Regulatory Guidance for Reporting Issuers' Continuous Disclosure of Cybersecurity Risks and Incidents*.
- **Legal Privilege:** An organization should have a legal privilege strategy that is consistent with personal information security breach reporting, notification and record-keeping obligations to help avoid inadvertent and unnecessary disclosure of privileged legal advice. For more information, see BLG bulletins *Cyber Risk Management – Legal Privilege Strategy (Part 1)*, *Cyber Risk Management – Legal Privilege Strategy (Part 2)* and *Legal Privilege for Data Security Incident Investigation Reports*.
- **Contracts with Data Processors:** An organization should ensure that its contracts with service providers contain appropriate provisions so that the organization is able to comply with personal information security breach obligations in respect of information that is processed or stored by service providers. An organization that provides data processing services should ensure that its contracts with customers address personal information security breach obligations.

## House of Commons Releases Report on Privacy Laws

Preparations for the upcoming entry into force of the European *General Data Protection Regulation* (GDPR) are underway in Canada's House of Commons. On February 28, 2018, the Standing Committee on Access to Information, Privacy and Ethics (ETHI or Committee) presented its report on the review of the *Personal Information Protection and Electronic Documents Act* (PIPEDA), entitled "*Towards Privacy by Design*" to the House of Commons.

As its name indicates, this report recommends that the review of PIPEDA by the Government of Canada be guided by the concept of "privacy by design," which is the idea that privacy considerations should be taken into account at all stages of the development of a product. Accordingly, the Committee put forward numerous suggestions aimed at reinforcing PIPEDA, with a clearly stated goal of ensuring that it will be considered adequate by the European Union (EU) in the context of the coming into force of the GDPR in May.

The ETHI made 19 recommendations to potentially update the protection of personal information framework in Canada. This bulletin will focus on the most important recommendations for organizations doing business in Canada, including life science businesses, which are as follows:

- Moving towards an opt-in consent as the default for uses of personal information for secondary purposes;
- Considering amending PIPEDA to clarify situations where personal information can be used to satisfy legitimate business interests;
- Examining the best ways to protect depersonalized data;
- Recognizing a right to erasure and a right to de-indexing, at a minimum for minors;
- Giving the Office of the Privacy Commissioner of Canada (OPC) stronger enforcement powers, including the power to make orders and impose fines for non-compliance, as well as broad audit powers, including the ability to choose which complaints to investigate.

### Meaningful Consent

The ETHI noted that consent is the cornerstone of PIPEDA. However, the OPC testified that recent innovations have added significant complexity to online interactions and have resulted in more ways to use personal information, a statement affirmed by comments from many witnesses indicating that it has become impossible for individuals to take the time needed to properly inform themselves of the conditions of use for each service and provide informed consent. The ETHI nonetheless expressed its view that consent must stay at the core of PIPEDA's privacy protection model, as it respects individuals' autonomy in deciding what to do with their personal information, although it must be enhanced by a greater reliance on express consent (also known as "opt-in consent") rather than implied consent.

### Opt-in Consent as the Default for Using Personal Information for Secondary Purposes

The ETHI heard witnesses argue that opt-in consent should be implemented as the default model, which means that users would explicitly choose to disclose their personal information. Others had reservations about the practical implications of such a system and one witness suggested making a distinction between using personal information for the purpose of providing the service requested by the users and using it for secondary purposes, such as marketing. In this last case, this witness argued that an opt-out option should be clearly and readily available to the individual. This is aligned with the view previously articulated by the OPC in *PIPEDA Case Summary #2003-203*, which states that the following criteria must be met in order for an organization to be able to rely on an opt-out consent when using personal information for secondary purposes:

- The personal information must be demonstrably non-sensitive in nature and context.



**Éloïse Gratton**

Partner, Lawyer  
National Co-Leader of the  
Privacy and Data Protection  
Practice Group  
Montréal | 514.954.3106  
Toronto | 416.367.6225  
egratton@blg.com



**François Joli-Cœur**

Senior Associate, Lawyer  
Privacy and Data  
Protection Group  
Montreal  
514.954.3144  
fjolicoeur@blg.com

- The information-sharing situation must be limited and well defined as to the nature of the personal information to be used or disclosed and the extent of the intended use or disclosure.
- The organization's purposes must be limited and well defined, stated in a reasonably clear and understandable manner, and brought to the individual's attention at the time the personal information is collected.
- The organization must establish a convenient procedure for easily, inexpensively, and immediately opting out of, or withdrawing consent to, secondary purposes and must notify the individual of the procedure at the time the personal information is collected.<sup>1</sup>

The ETHI has recommended that PIPEDA be amended to provide for opt-in consent as the default for using personal information for these secondary purposes, "with a view to implementing a default opt-in system regardless of purpose", thereby reopening the issue of the type of consent which must be obtained for using personal information for secondary purposes.

### Improving Algorithmic Transparency Privacy

The ETHI heard witnesses highlight the risk posed by algorithms processing large amount of personal information and this data being used to make potentially discriminatory decisions about individuals (for instance, in artificial intelligence applications). Articulating the view that organizations should be more transparent about the use of algorithms to process personal information, the ETHI recommended that the government consider implementing measures to improve algorithmic transparency.

### Review the Definition of "Publicly Available Information"

PIPEDA excludes from its scope certain categories of publicly available information specified by regulations. The ETHI recognized that the list specified in the current regulations is obsolete, as it refers to mediums like phone books, and that it should be technology neutral. The ETHI therefore recommended that the government review the definition of "publicly available information" and consider taking into account situations in which individuals post personal information on a public website. While it is unclear if the intent is to completely exclude this type of information from the scope of PIPEDA, this position is probably meant to ensure that the fact that this type of data that is readily available is at least considered when determining the type of protection this type of data actually warrants.

### Clarifying When Personal Information Can Be Used for "Legitimate Business Interests"

Under the European model, businesses may collect, use and disclose personal information without consent for their legitimate business interests. Some witnesses before the ETHI suggested that PIPEDA should operate in a similar manner to address situations where obtaining consent is difficult, such as for search engines results, in the context of big data and when new possibilities for use arise after the initial collection of the data. The OPC testified against this idea

on the basis that such an exception would be too broad and could therefore lead to abuse by organizations.

The ETHI, while noting concerns regarding the implementation of a new exception, recommended that the government consider amending PIPEDA to at least clarify situations where personal information can be used to satisfy legitimate business interests. We note that the inclusion of an exception in that sense in PIPEDA could potentially compensate for the more stringent opt-in consent model for secondary purposes, if secondary purposes were to be considered legitimate business interests.

### Protecting Depersonalized Data

The legal treatment of depersonalized data (usually referred to as "anonymized" or "de-identified" data) is an important issue for businesses and individuals in the era of big data and artificial intelligence, where data does not always have to identify an individual to be of value to businesses. The ETHI noted that some witnesses believed that depersonalized data should not be considered "personal information," while others were of the view that they should be exempted from the consent requirement. The OPC has recently recommended in its 2017 ["Report on Consent"](#) that Parliament examine this issue as de-identified data may provide the "flexibility needed to achieve a better balance between privacy protection and economic value of data."

The ETHI was not ready to recommend an exception to the consent requirement for depersonalized data and simply recommended that the government examine the best ways to protect such data, for instance from risks of re-identification, thus addressing a concern that was raised by the OPC in its 2017 report, when it noted that "re-identification is a real risk not only because of the availability of data sets that can be used to re-identify personal information, but also because of the lack of rigour in de-identification methods."

### Data Portability Should be Explicitly Recognized in PIPEDA

The GDPR provides individuals the right to "data portability," which is the right to receive the personal information individuals have provided to an organization, in a common and machine-readable format, so that the individual can easily transmit this data to another organization. The ETHI noted that such right means that service providers must ensure that their processes for collecting and storing personal information are compatible with that of their competitors and recommended that PIPEDA explicitly recognize this right.

### Online Reputation and Right to Be Forgotten

Last month, the OPC issued its ["Draft Position on Online Reputation,"](#) which we discussed in a [previous bulletin](#) and where it essentially stated that PIPEDA already contains protection akin to the European right to be forgotten (or "right to erasure," as it is named in the GDPR). In its new report, the ETHI covered this subject in great detail. In its opinion, the right to be forgotten refers to two concepts: the right to erasure and the right to de-indexing (or "dereferencing" or "delisting").

### Recognizing the Right to Erasure (at a Minimum for Minors)

According to the ETHI, the right to erasure is the right to have information removed from a website. It noted that PIPEDA contains very limited provisions regarding the deletion, correction or accuracy of personal information. When they have self-provided the information, individuals should be able to withdraw their consent and have their information deleted (except in certain situations, such as when there are contractual provisions to the contrary). Citing the testimony of Privacy Commissioner of Canada, Daniel Therrien, the ETHI stated that individuals should have an absolute right to have information they posted on social media removed.

According to the ETHI, when information about an individual (e.g. a photo posted on social media by a friend of the individual) has been provided to an organization by someone else, the situation is more complex. In such a situation, the ETHI indicated that the right under PIPEDA to have organizations correct inaccurate, incomplete or out-of-date information, as well as the notion that organizations may only collect, use or disclose personal information for reasonable purposes should find application. That said, according to the ETHI, these principles do not provide for a comprehensive regime and do not allow for redress in cases where factual yet potentially harmful information is posted online, such as embarrassing acts or photos, which could have serious consequences for those affected, especially minors.

The ETHI therefore concluded that while a right to erasure is not a concept that is foreign to PIPEDA, a more robust regime should be included in the statute and that as a general principle, individuals should be entitled to have their personal information removed from online sources when they end a business relationship with an organization.

The ETHI also heard witnesses discuss the risks of a right to erasure with respect to the right of freedom of expression and the public interest, and therefore expressed the view that a right to erasure would have to be carefully framed to strike an appropriate balance between freedom of expression and protection of privacy. The ETHI concluded by recommending that the government consider amending PIPEDA to include a framework for a right to erasure based on the GDPR model that would, at a minimum, include a right for young people to have information posted online either by themselves or through an organization taken down.

### Recognizing a Right to De-Indexing (at a Minimum for Minors)

Unlike the right to erasure, the right to de-indexing does not involve deleting the information in question, but rather ensuring that the results no longer appear in search engines results. The ETHI noted that Canada does not have an explicit de-indexing regime like the EU, where the right to de-indexing was established in a 2014 decision by the Court of Justice of the European Union, which found that it existed under the directive that is soon to be replaced by the GDPR.

In the OPC “[Draft Position on Online Reputation](#)” mentioned above, the OPC argued that under PIPEDA, search engines would be required to remove links in certain circumstances, but when testifying in front of the ETHI, Commissioner Therrien recognized that this position has its critics and that it would be worth clarifying PIPEDA in this respect.

The ETHI noted that the most important concern with respect to de-indexing relates to having a private organization (such as Google) receiving requests and making the decision of whether to de-index content.

Despite critics of de-indexing, the ETHI concluded that implementing a legal framework allowing individuals to request, in specified circumstances, the de-indexing of harmful personal information is a good way of protecting Canadian’s reputation and privacy. The public interest and freedom of expression would be protected by implementing a framework providing for a rigorous and transparent decision-making process. The ETHI therefore recommended that the government consider including a framework on the right to de-indexing in PIPEDA, and that the right be expressly recognized in the case of personal information posted online by minors.

### Stronger Enforcement Powers for the OPC

In its 2017 [Report on Consent](#) which we discussed in a [previous bulletin](#), the OPC asked for a change to the current ombudsman model and requested stronger enforcement powers.

The ETHI heard many witnesses on both sides of the issue, some arguing for more powers to the OPC while others favouring the *status quo*. The ETHI sided with the parties asking for stronger powers and a departure from the ombudsman model, recommending using the United Kingdom system as a model. In the end, the ETHI recommended that PIPEDA be amended to give the OPC stronger enforcement powers, such as:

- The power to make orders and impose fines for non-compliance; and
- Broad audit powers, including the ability to choose which complaints to investigate.

### Adequacy of PIPEDA Under the GDPR

Under the GDPR, organizations in the European Union are prohibited from transferring personal data to any non-member state whose laws do not adequately protect this data. The EU will therefore have to assess the adequacy of PIPEDA under the GDPR. Commissioner Therrien testified before the ETHI that the GDPR contains rights and provisions that do not appear in PIPEDA, such as the right to data portability and data erasure and the concept of privacy by design. The GDPR also contains rigorous enforcement measures, including fines which may amount to the higher of €20 million or 4 per cent of the organization’s total worldwide annual turnover for the preceding fiscal year, which is not the case for PIPEDA.

In this context, the ETHI made the following recommendations:

- That the government work with its European Union counterparts to determine what would constitute adequacy status for PIPEDA in the context of the new GDPR;
- That the government determine what changes to PIPEDA, if any, will be required in order to maintain its adequacy status under the GDPR;
- That if it is determined that the changes required to maintain adequacy status are not in the Canadian interest, the government create mechanisms to allow for the seamless transfer of data between Canada and the European Union;
- That the government work with the provinces and territories to make sure that all relevant jurisdictions are aware of the requirements for adequacy status to be granted by the EU.

## Conclusion and Business Takeaways

This new report gives a preview of what the upcoming amendments to PIPEDA could look like. In some cases, these amendments may be inspired by the upcoming new European privacy protection framework, especially in light of the Commissioner Therrien's statement before the ETHI that reassessing PIPEDA's adequacy status "is a pressing issue with possible far-ranging implications for Canada's trade relationship with the EU".

Organizations doing business in Canada should therefore start to prepare for the possibility of a more stringent regime, including stricter consent rules (particularly around the use of personal information for secondary purposes); having to comply with new requirements and individuals' rights, such as the right of portability and the right to erasure; as well as ensuring that they are compliant to avoid punitive fines, in light of the fact that Canada is currently considering a potential shift from an ombudsman model to a regulator with the power to impose administrative fines. The ETHI did not take a strong stance on the issues of de-identification and processing for legitimate business interests, so perhaps the final review of PIPEDA will provide more details in these areas.

1. PIPEDA Case Summary #2003-203, "Individual raises concerns about consent clauses on credit card application form," *Office of the Privacy Commissioner of Canada*, May 2003.





## CLASS ACTION

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# The Resurrection of the Innovator Liability Theory in Emerging U.S. Case Law and the Threat of Novel Applications in Canada

### Resurrection of Innovator Liability in the U.S.

A recent decision of the Superior Court of Massachusetts in *Rafferty v. Merck & Co., Inc.*, SJC-12347, 2018 WL 1354064 (Mass.), has highlighted a concern about a growing recognition in the United States jurisprudence of the theory of innovator liability. The *Rafferty* case is one in a line of recent cases in which U.S. Courts have held that innovators of brand-name drugs can be held liable for injuries caused by generic drugs which were not manufactured by the innovator company. The theory asserted by plaintiff's counsel is that the innovator company should be held liable because it is foreseeable that its drug will be manufactured by a generic company which will use the labelling prescribed by the regulatory framework applicable to the innovator drug.

In *Rafferty*, the plaintiff alleged he suffered certain side effects from ingesting the generic equivalent of the drug Proscar®, the innovator of which was *Merck & Co. Inc.* (Merck). Congress' passing of what has become known as the Hatch-Waxman Act in 1984, allowed for approval of a generic drug without the same level of clinical testing required for approval of a brand-name drug, provided the generic drug is identical to the already-approved brand-name drug in several key respects. While the labelling of a brand-name drug requires that it be accurate and adequate, the generic drug warning label is only required to be identical to the brand-name label. Accordingly, it has been held that as Federal law pre-empts state law where it is impossible for a party to comply with both requirements, claims against generic drug manufacturers have been pre-empted where it is alleged that the generic drug manufacturer's warning labels were not adequate or allegations of a design-defect claim were made. As the plaintiff could not bring a failure to warn claim against the generic manufacturer, he sued Merck alleging that it failed to maintain the accuracy of the label. Merck sought to dismiss the claim.

Although the Court agreed with Merck that the action against it should be dismissed, nonetheless, the Court held that "a brand-name drug manufacturer that controls the contents of a label on a generic drug owes a duty to consumers of that generic drug *not to act in reckless disregard of an unreasonable risk of death or grave bodily injury*". The Court further held that the question whether a defendant owes a plaintiff a duty of reasonable care is also determined with reference to social values, customs, and appropriate social policy. Here, the Court found that Mr. Rafferty had not alleged facts sufficiently plausible to suggest a connection between Merck and the product that harmed him, where that connection must be more than merely supplying a part of the product or instructions for that type of product. The Court also recognized that the imposition of innovator liability would discourage the investments necessary to develop new and beneficial drugs. While the Court did not impose liability and remanded the case to allow the plaintiff to allege further and sufficient facts to support a claim for recklessness, the Court accepted that where a reckless disregard for safety of others was demonstrated, liability could be imposed.

With this decision, Massachusetts joins a limited number of other states (California, Virginia, Vermont, and Illinois) which have considered this theory of liability and have renewed its potential application. In May of 2017 the U.S. Court of Appeals for the Fourth District considered an appeal from the U.S. District Court of West Virginia on the issue of whether West Virginia law permitted a claim of failure to warn and negligent misrepresentation against a brand-name manufacturer when the drug ingested was produced by a generic manufacturer (*McNair v. Janssen Pharmaceuticals* 694 Fed. Appx., 115 (4th Cir. 2017)). In *McNair*, a generic version of the drug Levaquin® was prescribed to the plaintiff, who, after using the generic version, developed acute respiratory distress syndrome (ARDS). She alleged she was provided warning information prepared by Janssen which did not include a warning relating to ARDS though this was known to the company. The plaintiff argued that as Janssen had exclusive control



**Glenn Zakaib**

Partner, Lawyer  
Class Actions Group  
Toronto  
416.367.6664  
gzakaib@blg.com



**Edona Vila**

Associate, Lawyer  
Insurance & Tort Liability Group  
Toronto  
416.367.6554  
evila@blg.com

over the labelling, it should be held liable for the adverse event. In considering the theory of innovator liability, the Court noted that as early as 2008 and subsequently in 2010, courts in California and Vermont held brand-name manufacturers liable for failure to warn in relation to a generic drug<sup>1</sup>. Fortunately, on May 11, 2018, West Virginia's highest court recently considered the lower Court decision on appeal and refused to apply the theory of innovator liability (*McNair v Johnson & Johnson*, No. 17-0519, W.Va, May 11, 2018). In doing so, the Court declared that "there is no cause of action for failure to warn and negligent misrepresentation against a brand-name drug manufacturer when the drug ingested was produced by a generic drug manufacturer".

It remains to be seen if the adoption of innovator liability in the high profile Illinois trial decision in the case of *Dolin v. GlaxoSmithKline Beecham Corp.* 269 F. Supp. 3d 851 (2017 U.S. Dist.) will face a similar fate on appeal as the *McNair* case did in West Virginia. In *Dolin*, the U.S. District Court for the Northern District of Illinois reinvigorated the theory of innovator liability in a wrongful death claim against the defendant manufacturer. The claim alleged that the brand name manufacturer defendant negligently failed to include a warning in the label that its drug can be a cause of adult suicide and had asserted in its label that there was no risk of suicide beyond age 24. The suit also alleged that the defendant concealed and negligently misrepresented the adult suicide risk data. The decision is on appeal to the Seventh Circuit and a decision is expected sometime this year (Appeal No. 17-3030).

Regardless of the outcome of the appeal of the *Dolin* case in Illinois and the significant win for innovators in West Virginia, in December of 2017, California's high Court became the first state high court in this developing jurisprudence to unanimously recognize the innovator theory of liability (*T.H. v. Novartis Pharmaceuticals Corporation* 4 Cal. 5<sup>th</sup> 145). In that case, the plaintiff had sued the manufacturer

for negligence, intentional misrepresentation, concealment, and negligent misrepresentation arising from its failure to warn of the risks of the brand-name drug Brethine. In a precedent setting decision, the California Supreme Court found that brand-name drug manufacturers have a duty to use ordinary care in warning about the safety risks of their drugs regardless of whether the injured party was dispensed a brand-name or generic version of the drug. In arriving at this finding, the Court held that a brand-name manufacturer's sale of the rights to a drug does not, as a matter of law, terminate its liability for injuries foreseeably and proximately caused by deficiencies in the warning label prior to sale, thus affirming existence of a cause of action for warning label liability.

### The Status of Innovator Liability in Canada

The issue of liability of an innovator for an alleged injury caused by a generic version of the drug was first considered in 2010 by the Ontario Superior Court of Justice in the case of *Goodridge v. Pfizer Canada Inc.* (2010) 101 O.R. (3d) 202. The Court was asked on a motion to certify a class proceeding, to adjudicate on the entitlement of one of the representative plaintiffs to bring an action to hold Pfizer liable for her consumption of a generic equivalent of the anti-epileptic drug Neurontin (gabapentin). The defendants brought a cross-motion to strike out portions of the claim, including allegations of the duty of care owed to consumers of the generic version of the drug.

The Court acknowledged that to be approved by Health Canada, generic versions of a drug must have the same active ingredient as the brand-name drug. It was noted that generic versions of innovator drugs are reviewed under an abbreviated process that focusses on whether the generic is bioequivalent and as such is interchangeable with the innovator drug. The regulatory assumption is that the safety and efficacy of the innovator's drug demonstrated in the original submission and confirmed during the marketing period can be extrapolated to the generic drug.



While the Court agreed that it was reasonably foreseeable to the innovator that harm would be caused by competitors manufacturing the allegedly defective drug, the defendant innovator did not have a duty of care for being the innovator of generic gabapentin. The Court asserted that there is much more to the presence of a duty of care than whether harm was reasonably foreseeable to a defendant and there were policy reasons for concluding that there was no duty of care on the innovator to the consumers of the generic drug. In considering the issue of duty of care the Court stated:

**69.** In *Anns v. Merton London Borough Council* (1977), [1978] A.C. 728 (U.K. H.L.), the House of Lords adopted a two-step analysis to determining whether there was a duty of care between a plaintiff and a defendant: (1) Is there a sufficiently close relationship between the plaintiff and the defendant such that in the reasonable contemplation of the defendant, carelessness on its part might cause damage to the plaintiff? and, (2) Are there any considerations that ought to negative or limit: (a) the scope of the duty; (b) the class of persons to whom it is owed; or (c) the damages to which a breach of it may give rise.

**70.** As developed by the case law in Canada, if the relationship between the plaintiff and the defendant does not fall within a recognized class whose members have a duty of care to others, then whether a duty of care to another exists involves satisfying three requirements: (1) foreseeability, in the sense that the defendant ought to have contemplated that the plaintiff would be affected by the defendant's conduct; (2) sufficient proximity, in the sense that the relationship between the plaintiff and the defendant is sufficient *prima facie* to give rise to a duty of care; and (3) the absence of overriding policy considerations that would negate any *prima facie* duty established by foreseeability and proximity. Thus, whether a relationship giving rise to a duty of care exists depends on foreseeability, moderated by policy concerns [citations omitted].

While the Court was referred to U.S. case law in argument at the motion, the bulk of which favoured the defendants, the judge was of the view that the applicability of that law was problematic because some of the cases cited involved allegations of fraudulent and negligent misrepresentations for wrongful marketing activities which the judge ruled would not be applicable in this case. Additionally, the motion judge confined his analysis to Canadian authorities given the difference in approach between US and Canadian law to strict liability in negligence for product liability. The Court held that as a matter of proximity, the drug innovator defendants in their relationship with consumers of generic gabapentin did not have a relationship of manufacturer to consumer. Therefore, the relationship was found to be more remote than that between the generic manufacturer and the consumer. While arriving at this finding the judge further noted:

**92.** However, in observing that the relationship between the innovator and the consumer of a generic version of the drug is more remote than the relationship between the manufacturer and the consumer, I wish to be clear that I do not regard the manufacture of generic gabapentin to be an intervening event that would disturb any duty of care that the innovator has to the consumers of generic gabapentin. I simply observe that the consumer of generic gabapentin has a closer relationship of reliance and expectations with the manufacturer or with the learned intermediary than the consumer does with the innovator of Neurontin. The question remains whether it is just and fair to impose duties of care on this less proximate relationship. In any event, as the above authorities indicate, the raw proximity factor is less important to the duty of care analysis than the question of whether it is fair and just to impose a duty of care on the particular defendant.

[...]

**94.** Would it be fair to make the innovator of Neurontin liable for designing a drug copied by another manufacturer and harmful to its consumers? Perhaps, if the law were prepared to move to strict liability for harm, but Canadian law does not impose strict liability, and, in the case at bar, despite the Plaintiffs' characterizations and attempts to label the harm, the harm alleged to have been suffered by the consumers of generic gabapentin cannot be classified as a flaw in the design of Neurontin which would be the only basis for alleging misconduct against the innovator [*emphasis added*].

**95.** Negligence in design involves the innovator making poor choices and managing risk poorly when deciding how a product should be planned or put together. But the harm caused to the consumers of generic gabapentin is not a result of a design choice. Neurontin was not designed for any use other than as an adjunct treatment of epilepsy. Neurontin was not designed by the Defendants choosing to accept the risk of a propensity of suicidal behaviour; rather, a propensity for suicidal behaviour was a side effect to watch for and, if observed, it was a side effect to be disclosed by giving adequate warnings to the users of the drug. There is no design flaw in the case at bar because design errors presuppose design choices. The Plaintiffs submitted that Neurontin was a drug with a fatal flaw. That remains to be proven, but assuming that the submission is true, its flaw was not a design flaw. The Defendants may have designed a drug that turned out to have a defect, but that is different than choosing to design a drug with a defect that could have been avoided by more careful decisions about how to design the drug. And, in any event, the Defendants made no design choices with respect to the off label uses of Neurontin.

The judge concluded that it would be unfair to make the defendants, as innovators, liable simply for releasing an idea that is copied, as doing so would impose strict liability. This was particularly problematic in this case as the drug was being prescribed most often for off-label uses which the innovator could not control. The Court ultimately held it would not be fair or just to make the innovator liable for something that should and can only be done by others. Therefore no duty of care was found.

## Conclusion

Although the *Goodridge* case has been considered on multiple occasions for the principles relating to class certification, thus far the finding of the Court on innovator liability has not been challenged and remains the current state of the law in Ontario<sup>2</sup>. The resurrection of consideration for innovator liability in the United States and its apparent growing recognition, may lead to a reconsideration of the position of innovator liability in Canada. Certainly the Canadian Court did not preclude liability of an innovator for negligent design of an innovator drug and it remains open for the Courts in Canada to

revisit the evolving duty of care, particularly where findings of fraud, misrepresentation or concealment have been alleged.

1. *Conte v. Wyeth, Inc.*, 168 Cal. App. 4th 89, 85 Cal. Rptr. 3d 299, 320-21 (Cal. Ct. App. 2008) (holding that, under California law, the brand-name manufacturer owes a duty of care to patients who ingest the generic drug). See also: *Kellogg v. Wyeth*, 762 F. Supp. 2d 694, 708-09 (D. Vt. 2010) (concluding, under Vermont law, that brand-name manufacturers owe a duty of care to physicians who prescribe and patients who ingest the generic drug).
2. The *Goodridge* case was favorably considered and followed by Justice Belobaba on an unreported decision of a successful motion to strike of the defendant manufacturer in *Brown v Janssen* (April, 7, 2016, Toronto 06-CV-321585CP(ONSC)). Indeed, Justice Belobaba agreed in full with Justice Perell's reasoning in *Goodridge* in finding that no duty of care existed and recognizing that "no Canadian court has ever held that a brand name manufacturer owes a duty of care to users of the generic version manufactured by a competitor". Similarly, the innovator liability theory was also rejected in the civil law jurisdiction of the province of Quebec (see: *Brousseau v Laboratoires Abbott Ltée* 2016 QCCS 083).



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## 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



**Pascal de Guise**  
Montréal  
514.954.3167  
pdeguise@blg.com



**Chantal Saunders**  
Ottawa  
613.369.4783  
csaunders@blg.com





### **Calgary**

Centennial Place, East Tower  
1900, 520 – 3<sup>rd</sup> 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](mailto: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

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