



LifeSigns

Life Sciences Legal Trends in Canada

2019-2020 Edition

BLG
Borden Ladner Gervais

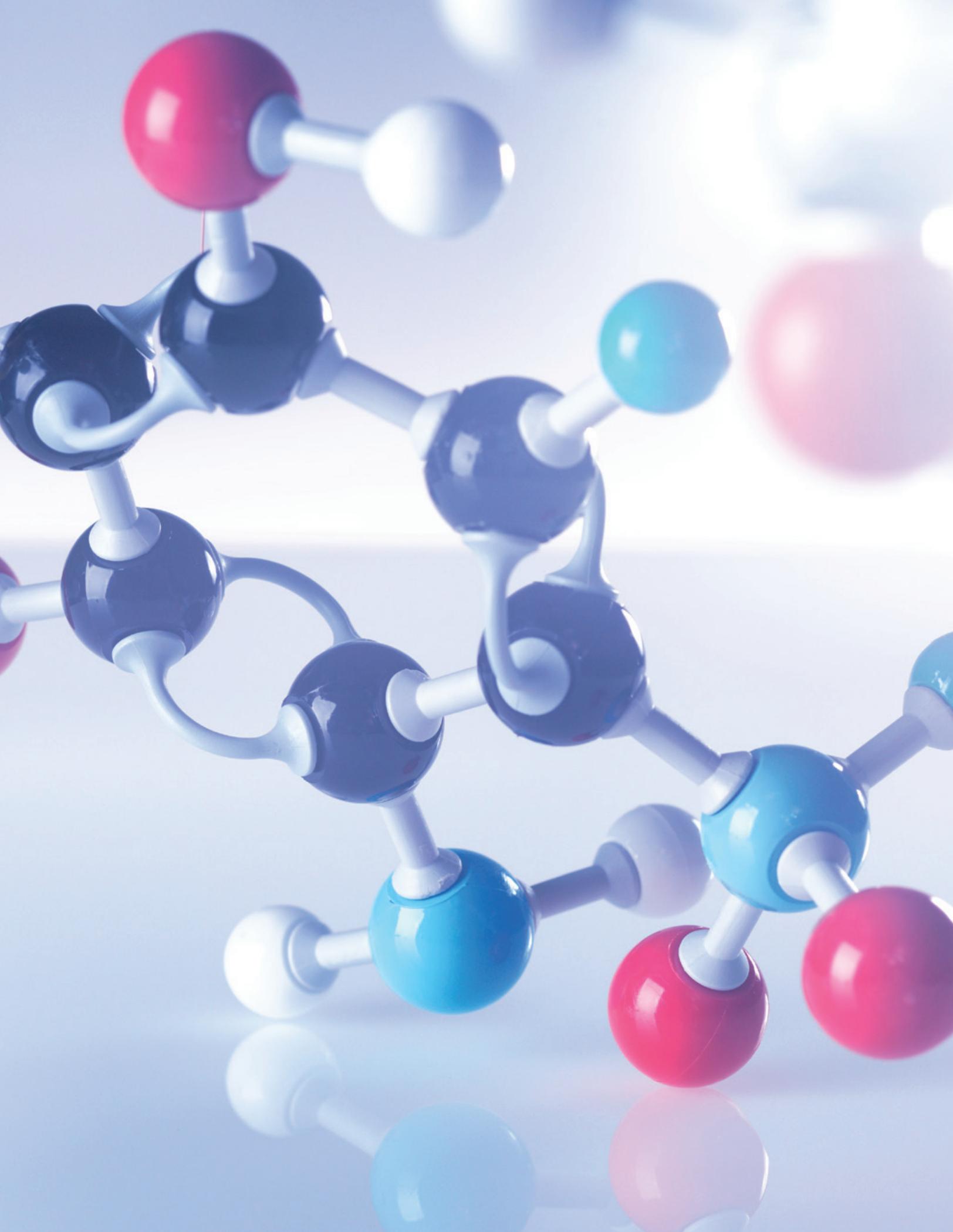


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Message from BLG



Welcome to our 6th 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, digital health, and modernization of food regulations in Canada, as well as updates in Canadian patent law including: filing requirements, patent term restoration, enforcement, and changes in industrial design practice.

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. With the implementation of patent term restoration and changes in patent, trademark and industrial design practices, Canada’s IP protection has been strengthened. The continuing commitment of Canada’s federal government and provincial and territorial governments means that the outlook for the life sciences sector in Canada from human health to the environment to our food supply is optimistic in the coming year.

We hope 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 one of us. We are at your service. ■



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Message from Canada's Leading Life Science Associations



Innovative Medicines Canada

Growing Canada's Biopharmaceutical Industry

From the discovery of insulin and radiation therapy, to the development of HIV antiretroviral drug 3TC, Canadians have always been at the forefront of medical innovation.

Last year, the federal government's Health/Biosciences Economic Strategy Table (HBEST) set an audacious goal: to double the size of Canada's health and biosciences sector and become a top-three global hub by 2025.

As a major driver of innovation in Canada, the innovative pharmaceutical industry has an important role to play in making the HBEST vision a reality. We are a natural partner for the government's plan to strengthen Canada's record on innovation and to foster health research and development right here at home. But heavy regulations create uncertainty and diverts attention away from core corporate objectives. Our industry needs agile regulations that are predictable, efficient and support patient safety to allow us to build on our sector's already strong position as the third largest funder of R&D in Canada.

The growth potential of our sector is immense: the biopharmaceutical industry is the single largest investor in business R&D in the world – investing \$1.4-trillion globally since 2006 and expected to invest another trillion dollars by 2022.

Members of Innovative Medicines Canada invest more than \$1.2-billion annually in R&D, according to a 2017 EY report, in finding new ways of treating and curing illnesses and diseases. There are more than 500 new therapies currently in development in Canada, including cancer treatments, infectious diseases and vaccines. These medicines have the potential to help Canadians and people all over the world live longer and healthier lives.

Our investment in R&D is pan-Canadian, diverse and cutting-edge.

It ranges from:

- 4,500 clinical trials involving 24,000 Canadians from coast to coast.
- World class vaccine manufacturing facilities.
- Funding for Canada Research Chairs, several research institutes and academics.
- Investments in revolutionary stem cell therapies and precision medicines.

Around the world, the life sciences sector is changing how it funds research and the development of new treatments. The old model of scientists working towards a single "blockbuster" discovery has given way to new models for external financing and research partnerships.

Canada's pharmaceutical industry has transformed itself to respond to the new realities of flexible collaborative research partnerships with academic/clinical research institutes, commercialization centres and virtual research centres, and expanding the capacity to conduct R&D work in Canada.

We are eager to work with all governments and stakeholders in the life sciences sector to create the structural and cultural conditions needed to improve Canada's ability to attract global investments. Together, we can build a better, more innovative and sustainable healthcare system for the future. ■



Pamela C. Fralick
President, Innovative
Medicines Canada



BIOTECCanada

Canada has long been able to boast of a robust pan-Canadian ecosystem consisting of a network of strong biotechnology clusters in every province built on a strong foundation of globally recognized science and research expertise.

Each cluster is a unique combination of early stage companies, entrepreneurs, research institutes, scientists, universities, hospitals and multinational pharmaceutical companies. These clusters have supported the creation of hundreds of early stage biotechnology companies across the country all of which are striving to develop and deliver innovative solutions for the health challenges associated with global population growth and environmental change. Importantly, after a long and challenging period of early stage development, several early stage biotech companies are now poised to become commercial Canadian companies. With the recently announced Clementia-Ipsen (\$1B+) and Triphase-Celgene (\$1B) deals, Canada has served notice that it is not only home to great science and research but also the entrepreneurship to commercialize its innovations.

With some significant momentum now propelling the industry, following through with the federal government's Health and Biosciences Economic Strategy Table (HBEST) report is an important objective for BIOTECCanada over the months ahead. Importantly, the HBEST identified a number of key objectives for government and industry to work towards, namely: double the number of early stage companies from 900 to 1800; double the number of 'high value' companies from 40 to 80; and, scale up a number of those companies to become globally commercial anchor companies. Clearly these are audacious stretch targets for the sector. But if the goal is to ultimately establish one or more foundational companies in Canada then audacity is required. An important first step towards establishing a foundational company will be to grow the pool of early stage companies. It is a rather simple formula: increasing the number of early stage companies greatly improves the odds that that one or more will ultimately become commercial entities. But importantly, by growing the number of early stage companies, Canada's competitive position as a destination for both talent and investment will correspondingly be enhanced.

Canadian federal and provincial innovation strategies have all identified life sciences/health as a priority sector. Importantly, the various innovation strategies identify a key goal of developing Canadian innovation into globally competitive, Canadian-based commercial companies. A critical component to achieving this objective will be a healthy biotech ecosystem which depends heavily on the active support and engagement of the multinational pharma and biotech companies as partners, investors and adopters for early stage pre-commercial biotech companies and their innovations. It is important to note that most of the Canadian companies that have seen significant growth over recent years have one or more multinational pharma as an investor and/or partner.



Andrew Casey
President and CEO
BIOTECCanada



After many years of early stage development, several Canadian biotech stars are now poised to take the next step to becoming commercial Canadian anchor companies. Importantly, a follow-on wave of next-generation companies is not far behind. And with a strong biotech investment market both in

Canada and abroad, the future looks promising. But if Canada hopes to see these companies succeed and others follow suit, then it is imperative that public policy impacting the industry be developed with an understanding of the complex and interconnected relationships within the entire ecosystem. ■



Life Sciences Ontario

Fostering a more prosperous Ontario

The Life Sciences community in Ontario has never before been as unified as it has been in recent years, whether it be voicing our collective concerns regarding the proposed changes to pricing reform, or aligning key messages across organizations for a coordinated life sciences strategy, irrespective of the challenges, we are working to protect the interest of all Ontarians and Canadians alike. Now, with the progressive conservatives at the helm at Queen’s Park, we are working with the new Provincial government to assess the current needs and challenges in the province and shift the gear towards high value sectors of greater potential.



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Chief Executive Officer
Life Sciences Ontario

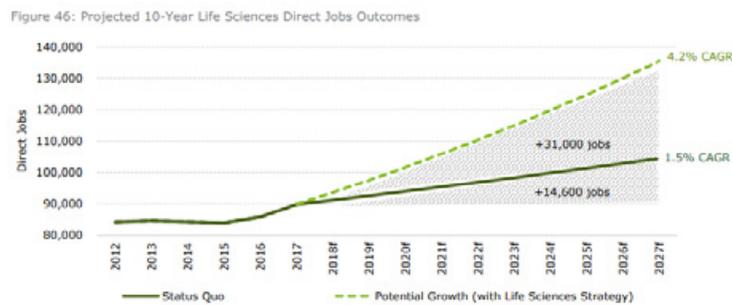


Needless to say, the Life Sciences sector in Ontario is a significant sector, with over \$8.8 billion in government revenue contributions, over 6,140 establishments, employing nearly 90,000 and generating approximately \$60 billion in revenue. If the sector were enabled by a coordinated sector strategy, the potential for growth is exponential: nearly 100,000 incremental new jobs over the next decade. [Accelerating Prosperity: The Life Sciences Sector in Ontario](#), a report by Deloitte, analyzes the challenges faced by the sector, but more importantly, shows the considerable growth potential of the economy if the sector was supported to grow at a rate comparable to other advanced jurisdictions.

With a Federal election fast approaching, our priority will be to continue to have meaningful dialogue with all levels of governments and advocate for better public policy alignment to support a competitive environment for the life sciences ecosystem. ■

Potential outcomes that could be realized with a coordinated life sciences strategy

The graph below projects potential employment outcomes using Ontario’s historical ten-year life sciences job growth rate (status quo) against a potential similar ten-year employment growth rates experienced in Massachusetts following the LSI.



Source: Status quo employment growth data obtained from Statistics Canada Tables 14-10-0202-01 & 14-10-0023-01 – See Appendix B for detailed methodology; Potential growth data obtained from 2008, 2012 and 2018 editions of Batelle’s biannual biotechnology jobs reports

BioTalent Canada

Transforming the bio-economy's talent innovation

The Canadian bio-economy has had a transformative year. With the launch of Canada's five innovation superclusters, and the release of the Government of Canada's Health/Biosciences Economic Strategy Table (HBEST) report, talent and skills have been put at the forefront of Canadian innovation.

As the industry grows, BioTalent Canada continues to foster relationships with employers, associations, academic institutions, governments and job seekers to address and alleviate the two key challenges still facing industry leaders – access to capital and access to talent – with encouraging results.

From British Columbia's Saltworks Technologies, which was able to "hire good people faster and increase their ability to compete in a global industry," or, Sarnia's Origin Materials, whose new grad hires through BioTalent Canada's wage subsidies "surpassed their expectations," the industry is experiencing first-hand how talent innovation can drive business.

New graduates like the young scientist at Mirexus Technologies who was recently promoted to Director of Strategic Development and "wouldn't be where he is without BioTalent Canada's Science Horizons program," or the young scientist whose achievements not only earned her BioTalent Canada's Catalyst Award but also a promotion to Program Manager at the Lake Winnipeg Foundation, these young minds have benefitted from wage subsidies and have gained valuable experience to push the boundaries of Canadian innovation.

The bio-economy is now crossing over directly to emerging industries such as: Digital health and artificial intelligence, Medical Cannabis production, and bioremediation. As we begin to transform the definition of the bio-economy, the need to develop and encourage young talent in STEM fields is even more crucial if Canada wants to evolve into a world leader.

Since 2018, BioTalent Canada has successfully coordinated 520 career placements, many of them falling within these new sectors, through the Student Work Placement Program. Experiential learning through initiatives like this is propelling the industry into the future and creating career-ready innovators right out of graduation.

As an organization that focuses on identifying the future skills required and the talent development for the bio-economy, it is exciting to play a pivotal role in the bio-economy's talent innovation and to look forward to seeing the industry flourish on a global stage. ■



Rob Henderson
President and CEO,
BioTalent Canada



Insights from the Life Sciences Team at BLG



Significant Changes are on the Horizon for Canadian Patent Prosecution

On December 16, 2014, Bill C-43 received Royal Assent. The legislation included long-awaited amendments to Canada's *Patent Act* to implement obligations under the Patent Law Treaty (PLT). Many of the practical details of how these changes were to be implemented were left to the then-unwritten changes to the Patent Rules.

Draft changes to the Patent Rules (the new rules) to implement the PLT were circulated for consultation in 2017, and a revised rule package was published in *Canada Gazette, Part 1* in late 2018. At the time of writing, the new rules have not yet been finalized and published in the *Canada Gazette, Part 2* – the latter being a procedural requirement for coming into force. However, unofficial indications are that any further changes will be minor ones, with implementation projected to occur in the autumn of 2019.

Almost five years on from Bill C-43, we now have a much better understanding of the details of its practical impacts, including significant changes to some of the best-known aspects of the Canadian patent system. This article provides an overview of some of the most significant changes, with a focus on examination before the Canadian Intellectual Property Office (CIPO) and maintenance. An overview of changes to filing requirements is provided separately in our article, "Upcoming Changes to Filing Requirements for Canadian Patent Applications: The Good, The Bad, and The Complicated" (Marsman & Zielinski) on page 12 of this publication.

The period of deferred examination will be shorter. Currently, examination may be requested in Canada up to five years from the international filing date. Although it was initially proposed to shorten this period more significantly, the new deadline will be four years from the international filing date.¹

Office Action response and Final Fee deadlines will be shortening. The deadlines for responding to an Office Action and paying a Final Fee will shorten from six months to four months.² Office Action response deadlines will be extendible by up to two months from the original deadline if the request is submitted with the required extension fee before expiry of the original deadline, and if the Commissioner considers that the circumstances justify the extension.^{3,4}

It will be necessary to identify and explain amendments. The new rules stipulate that amendments to the specification or drawings must be submitted on replacement pages, which must be accompanied by a statement that explains the purpose of the amendment and identifies the differences between the new page and the replaced page.⁵

There will be no abandonment without notice. A key element of the changes under the PLT is to ensure that abandonment does not occur without prior notice. In this respect, Canada will move closer to other jurisdictions in which corrective action can be undertaken within a late fee period prior to abandonment taking effect.

Different types of deadlines will be handled under different notification, late fee, and reinstatement regimes – some of the latter involving a "due care" standard. The new rules have different impacts for deadlines calculated from the filing date and deadlines triggered by requisitions (e.g., Office Actions).



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Deadlines triggered by requisitions are already signalled by the issuance of a requisition notice, and their handling under the new rules is largely unchanged.

Missed deadlines determined by the filing date will now be signalled by a notice, which will set the end date for a period of time during which corrective action can be taken with payment of a late fee. After that, an application will be considered abandoned and a reinstatement period will ensue. Some of these reinstatement periods will carry a “due care” standard, requiring reasons for the abandonment to be submitted for the Commissioner’s consideration. CIPO has yet to provide guidance for “due care” requirements.

Missed deadlines of different types will trigger different timelines and requirements for corrective action. For example, a missed examination request deadline that extends beyond the late fee period may (depending on the timing of the notice) trigger a brief period during which reinstatement is available as of right. A “due care” reinstatement period will then apply. However, missed maintenance fee deadlines will not be amenable to reinstatement as of right after the late fee period. A “due care” standard will always apply, and the reinstatement period will be differently calculated for applications and issued patents.

Reinstatement will still be available as of right within one year of a missed Office Action response deadline.

Although the 2017 draft had indicated an end to reinstatement as of right for missed Office Action response deadlines, this important element of Canadian examination has been maintained in the latest rule package.

Key late fee and reinstatement periods under the new rules are summarized in the table below:

Deadline Type	Late Fee Period	Reinstatement as of Right	Due Care Reinstatement
Maintenance Fee (application)	Up to the later of 2 months from the notice and 6 months from the original deadline ⁶	n/a	Up to 12 months from the end of the late fee period ⁷
Examination Request	Up to 2 months from the notice ⁸	Up to 6 months from the original deadline ⁹	Up to 12 months from the end of the late fee period ¹⁰
Examiner Requisitions (e.g., Office Action response deadlines)	n/a	Up to 12 months from the original deadline ¹¹	n/a ¹²
Final Fee	n/a	Up to 12 months from the original deadline ¹³	n/a ¹⁴

Third party rights may arise after a missed deadline. The new rules also establish periods during which intervening third party rights may arise following a missed deadline. These periods generally do not align late fee or reinstatement periods, and are explained in detail in the article “Third Party Rights Coming to Canada to Join New Prior User Rights” (Zielinski & Howard) on page 15 of this publication. Applicants can therefore expect docketing procedures to become much more complex once the new rules come into force.

It will be possible to request withdrawal of a Notice of Allowance. When it is desired to reopen examination after receiving a Notice of Allowance, e.g. to amend an application in a substantive way, it will no longer be necessary to wait for the Final Fee deadline to elapse. Instead, applicants will be able to request withdrawal of the Notice of Allowance by payment of a modest fee, to permit the application to undergo further examination.¹⁵ This may serve to remedy delays currently experienced when an applicant desires to have additional claims considered for the purposes of receiving a unity objection in order to gain immunity from double patenting for the additional claims if they are filed in a divisional application. ■

1. Proposed Patent Rule 81(1)(a), Canada Gazette Part 1, Vol. 152, No. 48.
2. Proposed Patent Rule 86(1)-(6), (8), (10), and (12), and 132(1), Canada Gazette Part 1, Vol. 152, No. 48.
3. Proposed Patent Rules 3(1) and 132(2), and Item 1 of Schedule 2, Canada Gazette Part 1, Vol. 152, No. 48.
4. Procedures and requirements for requesting extensions are yet to be published.
5. Proposed Patent Rule 102, Canada Gazette Part 1, Vol. 152, No. 48.
6. *Patent Act* section 27.1(2) and (3).
7. Proposed Patent Rule 73(3), Canada Gazette Part 1, Vol. 152, No. 48.
8. *Patent Act* sections 35(3) and 73(1)(d).
9. *Patent Act* section 73(3) and proposed Patent Rule 136(1)(b), Canada Gazette Part 1, Vol. 152, No. 48.
10. *Patent Act* section 73(3) and Patent Rule 134(1).
11. *Patent Act* section s73(1)(a) and Patent Rule 134(1)
12. Proposed Patent Rule 136(1)(a), Canada Gazette Part 1, Vol. 152, No. 48.
13. Proposed Patent Rules 133(e) and 136(1)(1), Canada Gazette Part 1, Vol. 152, No. 48.
14. *supra*, note 12.
15. Proposed Patent Rule 86(17), Canada Gazette Part 1, Vol. 152, No. 48.



The Good, The Bad, and The Complicated:

Upcoming Changes to Filing Requirements for Canadian Patent Applications

Changes to the Canadian *Patent Rules* mandated by Bill-C43 (the new rules), are expected to be implemented in late 2019. As of this writing, the exact date of implementation and the precise wording of the new rules are yet to be announced. Certain amendments to the *Patent Act* supported by the new rules are also expected to come into force. The new rules align Canadian patent practice with our international obligations under the Patent Law Treaty.

This article provides highlights of the upcoming changes that impact patent filing or national phase entry. Further information regarding Bill C-43 and its implications for patent prosecution and maintenance are discussed in our article, “Significant Changes Are on the Horizon for Canadian Patent Prosecution” (Boocock & Marsman) on page 9 of this publication.

While the new rules will permit greater flexibility at filing, relatively short and notice-dependent deadlines will be set to remedy most filing deficiencies. A complex aftermath is envisioned for patent filings with multiple deficiencies. Unpredictable timing for the receipt of notices with short response periods of two or three months means that applicants and agents alike must respond to notices swiftly to avoid last-minute urgency and potential loss of rights. The timing with which a notice can be expected to arrive will depend on the preparedness and efficiency of the systems in place at the Canadian Intellectual Property Office (CIPO).

Late PCT National Phase Entry at 42 months is no longer available as of right

One popular feature of filing in Canada will be lost under the new rules: strategic use of late national phase entry. Canada will continue to observe a 30-month deadline for national phase entry, but late entry up to 42 months from the earliest (priority) filing date of a PCT application (currently permitted as a matter of right) will require a statement indicating that the failure to meet the 30-month deadline was “unintentional”.¹ Prudent applicants that diligently track the 30-month national phase entry deadline will no longer be able to depend on the 42-month late entry as part of an *intentional* cost deferral strategy. Transitional rules will permit PCT applications filed before the new rules come into force to access 42-month late entry as a matter of right, whether intentional or not.²

Restoration of a missed priority claim is possible outside of the 12-month priority period

Two extra months of restored priority will be available, whether an application is a PCT national phase entry or a direct Canadian filing, if the application was filed after the 12-month priority period of an earlier-filed application, and provided that failure to file within the 12-month priority period was unintentional (*i.e.*, if the filing date is within 14 months of the earlier-filed priority application).³ The time periods in which to request restoration of priority are short: within one month of PCT national phase entry⁴ or within two months of the filing date of a non-PCT application.⁵



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Filing date can be established without an English or French language application

The new rules will relax the requirement for an application to be entirely in English or French at filing, in order to permit applicants to secure a Canadian filing date with a specification in another language.⁶ The specification must be later replaced by an English or French translation,⁷ once requisitioned by a notice bearing a two-month deadline.⁸ Notably, the submission of an inaccurate translation containing new matter can result in other problems, such as a loss of the earlier filing date in favour of the later date on which the translation was submitted.⁹ No such rule change applies to PCT national phase applications, which still require an English or French translation at national phase entry.

Filing date can be established without a filing fee

When filing an application directly in Canada the filing fee can be paid later, with the filing date still being secured, provided the fee is paid within a three-month late fee period set by a requisition.¹⁰ If the filing fee is not paid together with a late fee within the deadline set by the notice, the application is deemed irrevocably withdrawn without opportunity for reinstatement.¹¹ This does not apply to PCT national phase applications, which require fee payment at national phase entry (with certain exceptions if a bona fide attempt to pay was unsuccessful).¹²

Filing-by-reference can establish a filing date without submitting a specification

Establishing a filing date by making reference to a previously filed application that was filed in Canada or elsewhere (such as a priority application) is permitted. The previously filed application must be adequately identified, and a copy must be provided (or access granted to the document via an accepted digital library) within a two-month time period.¹³

Information left out of a newly filed application can be adopted from a priority document

If information is not present in an application at filing, but is contained in the priority document, this information can be added if action is taken within a time period that may range from two to six months from the filing date.¹⁴

Certified copies or access to priority applications will be required

This is a new requirement. For direct filings in Canada, the deadline to provide a certified copy of a priority document or official access to a digital library containing such a document will be four months from filing or 16 months from priority, or two months following receipt of a notice, with a possible two-month extension available. For PCT national phase applications, the requirement can be averted if the priority document is submitted during the international phase,¹⁵ but – importantly – may be due at national phase entry.¹⁶ Hopefully, digital library access (permitted in lieu of a certified copy)¹⁷ will become the standard of most Patent Offices of the world.

Appointing a patent agent is not required for filing

Canadian patent agents are typically involved in filing and national phase entry processes, but the new rules permit agent appointment after an application is filed, and specify the conditions under which a patent agent is to be appointed or revoked.¹⁸

Sequence Listings will not be a completion requirements

Currently considered a completion requirement, under the new rules, sequence listings will still be requisitioned within three months if absent from an application, but no completion fee will be due.¹⁹

Sequence Listings will not be considered in the excess page count

Although unrelated to filing requirements, it bears noting here that the sequence listing will be expressly excluded from the page count for the purposes of calculating the Final Fee.²⁰ This change will provide welcome reprieve from surprisingly high fee calculations for applications in the life sciences containing lengthy sequence listings. ■

1. Proposed Patent Rule 155(3), Canada Gazette Part 1, Vol. 152, No. 48.
2. Proposed Patent Rule 209, Canada Gazette Part 1, Vol. 152, No. 48.
3. *Patent Act* section 28.4(6).
4. Proposed Patent Rule 77(1)(b), Canada Gazette Part 1, Vol. 152, No. 48.
5. Proposed Patent Rule 77(1)(a), Canada Gazette Part 1, Vol. 152, No. 48.
6. Proposed Patent Rule 71(d), Canada Gazette Part 1, Vol. 152, No. 48.
7. Proposed Patent Rule 46, Canada Gazette Part 1, Vol. 152, No. 48.
8. Proposed Patent Rule 15(4), Canada Gazette Part 1, Vol. 152, No. 48.
9. *Patent Act* sections 28(1), 28.01(1), and 28.01(2).
10. Proposed Patent Rule 66(1), Canada Gazette Part 1, Vol. 152, No. 48.
11. Proposed Patent Rule 66(2), Canada Gazette Part 1, Vol. 152, No. 48.
12. Proposed Patent Rule 155(4), Canada Gazette Part 1, Vol. 152, No. 48.
13. *Patent Act* section 27.01 and Proposed Patent Rule 67, Canada Gazette Part 1, Vol. 152, No. 48.
14. *Patent Act* section 28.01 and Proposed Patent Rule 72, Canada Gazette Part 1, Vol. 152, No. 48.
15. Proposed Patent Rule 157(1)(b), Canada Gazette Part 1, Vol. 152, No. 48.
16. Proposed Patent Rule 74(2)(c), Canada Gazette Part 1, Vol. 152, No. 48.
17. Proposed Patent Rule 74(1)(b), Canada Gazette Part 1, Vol. 152, No. 48.
18. Proposed Patent Rules 27-32, Canada Gazette Part 1, Vol. 152, No. 48.
19. Proposed Patent Rules 58 and 65, Canada Gazette Part 1, Vol. 152, No. 48.
20. Proposed Patent Rules Schedule 2, Item 13(b), Canada Gazette Part 1, Vol. 152, No. 48.



Third Party Rights Coming to Canada to Join New Prior User Rights

Patent practice in Canada is changing¹ as the government aims to ratify its commitment to the Patent Law Treaty. As part of these changes, amendments to the *Patent Act* and upcoming Patent Rules, expected to come into force this year, introduce to the Canadian patent system the concept of third party rights. This appears to permit otherwise would-be infringers to continue to infringe a valid, issued patent with impunity. Below we discuss how the Canadian Intellectual Property Office (CIPO) describes third party rights, when they arise, and how they may continue even when the patent is in force. Patent owners should be vigilant to ensure the window for third party patent rights never opens.

When third party rights may arise. The amended *Patent Act*² appears to provide a safe-harbour for a person who, in good faith, commits an act that would otherwise constitute patent infringement, if the act was committed during a period of time as outlined below, as defined by the draft regulations.³

Starting period	Condition	Ending period
Six months after non-payment of a maintenance fee on a pending application	If the Commissioner sent a notice to the applicant and the application is deemed to be abandoned	The earlier of reinstatement or grant, and the demonstration that due care was taken ⁴
	If the application is not deemed to be abandoned	The earlier of the payment of all required fees or grant
Six months after non-payment of a maintenance fee for a granted patent	If the Commissioner sent a notice to the applicant and the patent is deemed to have expired	The date on which all required fees are paid, and the demonstration that due care was taken ⁵
	If the patent is not deemed to be expired	The date on which all required fees are paid



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Starting period	Condition	Ending period
Six months after the end of the prescribed time to request examination	If the application was deemed to be abandoned	The earlier of reinstatement or grant, and the demonstration that due care was taken ⁴
	If the application was not deemed to be abandoned	The earlier of the request being made and payment of all required fees, or grant
12 months after the application was deemed to be abandoned for any other reason, and the conditions for reinstatement were not met		Grant, and the demonstration that due care was taken ⁴

The third party can continue the otherwise-infringing act. The amendments state if a person, in good faith, committed an act of infringement during the safe harbour period, or made serious and effective preparations to do so, the person may continue to commit the act even after the patent is reinstated – including after grant.⁶

Third party rights can be transferred. If the would-be infringing acts or preparations were carried out in the course of a business, the third party rights of that business may be transferred such that the transferee is protected from infringement. The transferor would thus relinquish their third party rights.⁷

Divisional applications are also vulnerable. Third party rights for acts committed when an application is in a safe-harbour period also seem to apply to any divisional application thereof. This applies to acts committed during the safe-harbour period for the parent application, but excludes acts committed after the divisional application was presented.⁸

Patent strategy should be devised with third party rights in mind. Currently, the only penalty for allowing an application to go abandoned, and waiting until the end of the one-year period for reinstatement, is payment of a modest late fee. Applicants should beware, as the new penalty could be much steeper – the risk of losing exclusive rights to their patent.

CIPO explains⁹ that in its view, these changes to the *Patent Act* and Patent Rules are intended to be a balancing act. While applicants will have new safety nets, including longer reinstatement periods after missing

certain deadlines, this correspondingly increases periods of uncertainty for parties who may be interested in using the invention. Therefore, CIPO rationalizes that third party rights have been introduced in an attempt to be fair to the would-be infringer, and deter applicants and patentees from exploiting said safety nets.

Changes to prior use rights¹⁰ have already become law in Canada. Similar rights have already been given to a person who committed, or made serious and effective preparations to commit, would-be infringing acts before the claim date of a patent. Before these amendments came to force in December 2018, a third party was limited to using or selling only the article(s) they constructed, purchased, or acquired prior to the claim date. Now, as with third party rights, it appears that they may continue to commit the otherwise-infringing acts, including manufacture, as long as the applicant was not the source of knowledge of the subject-matter. These prior use rights are also transferable.

Transitional provisions¹¹ indicate that the third party safe harbours will begin after the coming into force of the Patent Rules, which is expected this fall. It remains to be seen how third party and prior use rights will be interpreted by the courts, including the requirements for “good faith”, “due care”, and making “serious and effective preparations”. Until that time, the best advice for patent owners is to do everything possible to avoid opening the window for third party rights, and to hope no prior users are out there. ■

1. See also: "Significant Changes Are on the Horizon for Canadian Patent Prosecution" (Boocock & Marsman) on page 9 of this publication and "The Good, The Bad, and The Complicated: Upcoming Changes to Filing Requirements for Canadian Patent Applications" (Marsman & Zielinski) on page 12 of this publication.
2. *Patent Act* section 55.11
3. Proposed Patent Rule 129. Canada Gazette, Part 1, Vol. 152, No. 48
4. *Patent Act* subsection 73(3)
5. *Patent Act* subsection 46(5)
6. *Patent Act* subsection 55.11(3)
7. *Patent Act* subsections 55.11(4)-(10)
8. Proposed Patent Rule 129(d). Canada Gazette, Part 1, Vol. 152, No. 48
9. <https://www.ic.gc.ca/eic/site/cipointernet-internetopic.nsf/eng/wr04279.html>
10. *Patent Act* section 56
11. Proposed Patent Rule 231. Canada Gazette, Part 1, Vol. 152, No. 48



Consideration of the Obviousness Framework by the Federal Courts

In 2008, the Supreme Court of Canada (the SCC) released its decision in *Apotex Inc v. Sanofi-Synthelabo Canada Inc*,¹ relating to, *inter alia*, obviousness. The SCC, after considering two U.K. decisions, namely *Windsurfing International Inc v. Tabur Marine (Great Britain) Ltd*² and *Pozzoli SPA v. BDMO SA*,³ provided a framework for considering an allegation of obviousness, which has since been applied.

In 2017, almost ten years after the introduction of this framework, the Federal Court of Appeal (FCA) released two decisions in which the FCA appears to be analyzing the framework itself, with the FCA stating in one decision: “[I]t is true that the *Windsurfing/Pozzoli* framework does provide structure but it is not obvious that it has been useful.”⁴

The first 2017 decision, *Bristol-Myers Squibb Canada Co v. Teva Canada Limited*, 2017 FCA 76 (*BMS*), released in January, related to the medicine atazanavir. After reviewing the U.K. decisions and the *Sanofi* framework, the FCA noted that the SCC was cautious about substituting one rigid rule for another, and favoured “an expansive and flexible approach that would include ‘any secondary considerations that [will] prove instructive’”.⁵

The FCA also addressed the test itself, noting that “the obviousness analysis asks whether the distance between two points in the development of the art can be bridged by the Skilled Person using only the common general knowledge available to such a person”.⁶ The first point is the prior art as of the relevant date. The second point was termed the “inventive concept” in the *Sanofi* framework, but the FCA noted this has been referred to as “the solution taught by the patent”, “what is claimed” or “the invention” in previous jurisprudence.⁷ The FCA, considering whether the “inventive concept” was intended to redefine the second point, concluded that the SCC would not have changed the definition of obviousness by implication.⁸

The FCA concluded that the Court had erred in its determination of the inventive concept and if it had been properly determined, the Court would have found no differences between the prior art and the inventive concept or the solution taught by the patent. Accordingly, there would have been no need to apply the “obvious to try” test set out in *Sanofi*.

In *Ciba Speciality Chemicals Water Treatments Limited v. SNF Inc*, 2017 FCA 225 (*Ciba*) issued in March 2017, the FCA again considered the issue of obviousness. The FCA wrote the following:

There may be cases in which the inventive concept can be grasped without difficulty but it appears to me that because “inventive concept” remains undefined, the search for it has brought considerable confusion into the law of obviousness. That uncertainty can be reduced by simply avoiding the inventive concept altogether and pursuing the alternate course of construing the claim. Until such time as the Supreme Court is able to develop a workable definition of the inventive concept, that appears to me to be a more useful use of the parties’ and the Federal Court’s time than arguing about a distraction or engaging in an unnecessary satellite debate.⁹



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The result of these two FCA decisions is that it appears to be unclear to the lower courts how to determine the second point in the obviousness analysis – whether to identify an inventive concept, or construe the claims. Indeed, different decisions have considered the issue differently, sometimes finding that it is possible to determine the inventive concept and sometimes using the claims as construed.¹⁰ It should be noted that claims are construed as of the publication date of the patent application. Obviousness, however, is to be assessed as of the claim date, which in most cases will be earlier than the publication date. As such, using the claims as construed for the purposes of assessing obviousness could result in the indirect consideration of ineligible art.

It remains to be seen whether the SCC will consider it necessary to address the issue of obviousness in light of these, and subsequent, decisions. Leave to appeal was denied by the SCC in *Ciba*, which

suggests that the SCC may consider its *Sanofi* decision to be sufficiently clear, notwithstanding a clear request by the FCA to develop a definition. ■

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1. *Apotex Inc v. Sanofi-Synthelabo Canada Inc*, 2008 SCC 61.
 2. *Windsurfing International Inc v. Tabur Marine (Great Britain) Ltd*, [1985] RPC 59 (CA).
 3. *Pozzoli SPA v. BDMO SA*, [2007] EWCA Civ 588.
 4. *BMS*, at para 59 and 61.
 5. *BMS*, at para 60.
 6. *BMS*, at para 65.
 7. *BMS*, at para 65.
 8. *BMS*, at para 67-68.
 9. *Ciba*, at para 77.
 10. *Georgetown Rail Equipment Company v. Rail Radar Inc*, 2018 FC 70; *Hospira Healthcare Corporation v. The Kennedy Trust for Rheumatology Research*, 2018 FC 259.



Revised Canadian Intellectual Property Enforcement Guidelines: Worth a Closer Look

On March 13, 2019, the Canadian Competition Bureau issued revised Intellectual Property Enforcement Guidelines (the IPEGs). The IPEGs, first issued in September 2000, describe the Bureau's approach to the interface between competition law and intellectual property rights, and its enforcement approach to conduct involving the exercise of IP rights, including in respect of pharmaceutical patent litigation settlements and so-called "product switching" strategies by innovator pharmaceutical companies.

The revisions are the product of what the Bureau has indicated will be its final yearly review of the IPEGs. When it first made substantive updates to the IPEGs in March of 2016¹, the Bureau had promised to review the IPEGs annually going forward. In the revised IPEGs, however, the Bureau gives the more modest undertaking to review the guidelines "as needed".

As the Bureau stated in November 2018 when it published a draft version of the revised IPEGs for public consultation, "[t]he updates are modest and will not substantially change the Bureau's approach in enforcing the *Competition Act* with respect to matters involving intellectual property". That being said, certain of those updates are worthy of note and attention by life sciences companies and firms in other patent-intensive industries.

First, the Bureau has added a reference to the Competition Tribunal's *Toronto Real Estate Board* (TREB) decision and to the Federal Court of Appeal's (FCA) decision² dismissing TREB's appeal,³ as further authority for its enforcement position that conduct representing the "mere exercise of an IP right" is not cause for concern under the general provisions of the *Competition Act* (e.g., criminal conspiracy under section 45, abuse of dominance under section 79 and agreements between competitors that prevent or lessen competition substantially under section 90.1). Conduct involving "something more" than the mere exercise of an IP right, however, may be reviewed under those provisions.



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In the TREB case, the Competition Tribunal rejected TREB's claim that it held copyright in respect of its multiple listing service (MLS) database and that certain restrictions imposed by it on the use and dissemination of MLS data were therefore protected from review under the abuse of dominance provision by the statutory exception in section 79(5) of the *Competition Act*.⁴ The Tribunal found that TREB had not established copyright in the database, but concluded that the impugned restrictions conferred advantages on TREB and certain of its members "beyond those derived from the *Copyright Act*"⁵ and were therefore something more than the mere exercise of an IP right. While the Tribunal's decision is consistent with the dichotomy between the mere exercise of an IP right and "something more", as traditionally understood and applied, the point of note and potential concern here is the Bureau's statement in the revised IPEGs that the FCA "also noted that Parliament intended to insulate intellectual property rights from allegations of anti-competitive conduct where the IP right is the sole purpose of exercise or use".⁶ In other words, the Bureau appears to interpret the FCA as holding that an alleged exclusionary or otherwise anti-competitive intent on the part of an IP owner is sufficient to transform the mere exercise of a statutory right under one of the federal IP statutes into "something more", thereby depriving the IP owner of the protection of the exception in section 79(5). Although the Bureau's position in this regard was already reflected (at least impliedly) elsewhere in the IPEGs,⁷ the Bureau's express statement regarding its interpretation of the TREB appeal decision suggests a hardening of its position on this issue.

Second, the Bureau has added a statement in the footnote to the heading to hypothetical Example 9A – which deals with a so-called "hard" product switching strategy by an innovator pharmaceutical manufacturer – that "[b]rand-name manufacturers withholding Canadian Reference Products to delay generic entry may also be conduct that poses competition concerns".⁸ In this regard, the revised footnote now also refers to the Bureau's inquiry relating to the policies or practices of certain innovator companies, which were alleged to restrict generic manufacturers' access to samples of the innovators' products contrary to the abuse of dominance provision in section 79 of the *Competition Act*. Although that inquiry was discontinued in 2018 with no finding of abuse, the position statement issued by

the Bureau following that inquiry included the following warning to pharmaceutical industry participants: "the [alleged] practices within the pharmaceutical industry that gave rise to [the] investigation are of concern to the Bureau, and may warrant further enforcement or advocacy action in the future".⁹

Third, in light of the amendments to the *Patented Medicines (Notice of Compliance) Regulations* (the PMNOC Regulations) that replaced summary determinations with full actions, the Bureau has removed "dual litigation" from its description of the "significant differences in the regulatory regimes governing pharmaceuticals in Canada relative to other jurisdictions [which] may have implications for the both the incentives of parties to reach settlements and the terms of settlements that may occur in Canada".¹⁰ While litigation under the PMNOC Regulations is now considered final and results in an *in rem* determination of patent validity and infringement, obviating the need for a second patent infringement or impeachment action by the unsuccessful party in respect of the patents at issue in a PMNOC proceeding, innovator and generic firms in Canada can still be subject to a form of dual litigation. Unlike in the United States, patents not listed on the Patent Register¹¹ cannot be joined to a PMNOC proceeding. As a result, an innovator firm is free to launch litigation in relation to these unlisted patents at any time. This includes once the PMNOC proceeding has concluded and after the patents on the Patent Register have expired. This significant difference is not expressly accounted for in the revised IPEGs.

Finally, the Bureau has further qualified its longstanding position "that, in general, IP holders arranging their affairs so as to more effectively enforce their IP rights do not raise issues under the [*Competition Act*]"¹². In footnote 58, the Bureau has added the following statement which will be of interest to owners of standard essential patents: "A transfer of IP could also create a competition issue if it is made by an owner of a standard essential patent for the purpose of avoiding a licensing commitment". As discussed in another article in this compendium, the *Patent Act* was recently amended to include a reference to standard essential patents, however, further clarity is still needed by way of regulation to understand how these provisions will be applied. ■

1. See https://blg.com/en/News-And-Publications/Publication_4466
2. See <https://www.canlii.org/en/ca/fca/doc/2017/2017fca236/2017fca236.html>
3. See *The Commissioner of Competition v. The Toronto Real Estate Board*, 2016 Comp Trib 7 [TREB CT], aff'd 2017 FCA 236 [TREB FCA].
4. That exception states that “an act engaged in pursuant only to the exercise of any right or enjoyment of any interest derived under [a federal intellectual property statute, including the *Copyright Act* and the *Patent Act*] is not an anti-competitive act”.
5. TREB CT, *supra* at para 757.
6. See para 41 of the revised IPEGs. [emphasis added] See also TREB FCA, *supra* at para 180.
7. See the Bureau’s discussion and analysis of a “hard” product switching strategy in hypothetical Example 9A at paras 131-38 of the revised IPEGs [“If the Bureau was of the view that BRAND’s conduct could be for the purpose of forcing the replacement of sales of Product A with those of Product B to exclude or impede entry by GENERIC and Generic A, the Bureau would not view the withdrawal of Product A by BRAND as a mere exercise of its patent right and thereby conduct exempt under subsection 79(5)”. This was language was added to the IPEGs in the March 2016 update. See our critique of this change in our bulletin, “Questionable Policy: New Canadian IP Enforcement Guidelines Miss the Mark on Pharma”, April 5, 2016.
8. See footnote 55 of the revised IPEGs.
9. See “Competition Bureau Statement Regarding Its Investigation into Alleged Practices of Celgene, Pfizer, Sanofi” available at <https://www.competitionbureau.gc.ca/eic/site/cb-bc.nsf/eng/04407.html>.
10. Para 160 of the revised IPEGs.
11. The listing rules are extremely strict, such that relevant and enforceable patents may not be and, in certain cases, cannot be listed on the Patent Register. For example, the timing restrictions are extremely strict and it is not uncommon for a patent listing deadline to be missed if it is not filed timely or if the patent was filed at the ‘wrong’ time (e.g., the only time a compound patent can be listed is with a new drug submission). Further, process patents as a class are ineligible for listing on the Patent Register. It is often the case that such a patent will describe and claim a method of making the medicinal ingredient that is the only economically viable method for that molecule to be made.
12. See para 156 of the revised IPEGs.



Patent Term Restoration in Canada

Canada's patent term restoration regime has been up and running for over a year and a half. As of the end of April 2019, there have been 38 applications filed, and 29 granted; seven have been refused and the remainder are pending. The regime seems to be effective for those companies that are able to file their drug submissions in Canada within a year of the first filing in other major jurisdictions.

This one-year deadline is seen as the major impediment for companies that are trying to take advantage of this regime. For many larger companies, it appears that they have been able to move resources around and change their filing strategy in order to meet this deadline, however, smaller biotechnology and pharmaceutical companies do not necessarily have the resources to dedicate to filing in multiple jurisdictions before they have approval in a major market, such as the U.S. or Europe.

The Certificate of Supplementary Protection (CSP) regime aims to restore some of the time lost to regulatory approval. Up to two years of patent term can be restored by way of CSP. The time to be restored is calculated by subtracting five years from the period beginning on the filing date of the patent application, and ending on the day on which the Notice of Compliance (NOC) or marketing approval set out in the certificate is issued. From that resulting number, up to a maximum of two years is allowed. The CSP will take effect upon expiry of the patent and will only restore patent term for the specific molecule approved in the NOC. The Minister of Health can reduce this calculated period if the holder's failure to act resulted in a period of unjustified delay in the process of obtaining the NOC.

As the regime seems to be here to stay, companies should take note of its requirements and devise a filing strategy in order to ensure that they are not prevented from taking advantage of the scheme.

There are three main requirements:

1. Eligible regulatory approval:

- NOC pursuant to Canada's *Food and Drug Regulations*;
- It must be the first NOC for that medicinal ingredient;
- It must have issued after September 21, 2017; and
- If Canada is not the first country for which an application for marketing approval for that medicinal ingredient or combination has been submitted, the application in Canada must have been filed within 12 months of the earliest foreign application for marketing approval in:
 - The European Union and any country that is a member of the EU;
 - The United States of America;
 - Australia;
 - Switzerland; and
 - Japan.



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2. Eligible medicinal ingredient:

- The following “prescribed variations” of medicinal ingredients will be considered to be the same medicinal ingredient for the purposes of determining whether the NOC is first:
 - Esters, salts, complexes, chelates, clathrates, or other non-covalent derivatives;
 - Enantiomers or mixtures of enantiomers;
 - Solvates or polymorphs;
 - *In vivo* or *in vitro* post-translational modifications; and
 - Any combination of the above variations
- There can have been no other CSP issued for the medicinal ingredient;
- A medicinal ingredient or combination, however, will not be considered the same if they are approved for human and for veterinary uses.

3. Eligible patent:

- Must be in force and not expired or void;
- Must have been filed after October 1, 1989;
- Must pertain to a medicinal ingredient or combination of medicinal ingredients in a drug for which the NOC was issued, and contain a claim for:
 - The medicinal ingredient or combination;
 - The medicinal ingredient or combination as obtained by a specified process; or
 - The use of the medicinal ingredient or combination.

The holder of the CSP will have the same rights and privileges as a patentee with respect to making, constructing, using, and selling any drug referenced in the CSP, however, it will not be considered an infringement of the CSP if the medicinal ingredient or combination is made, constructed, used or sold for export. ■



Changes to Canada's Industrial Design Regime – Streamlining & Harmonizing the Process

Canada's *Industrial Design Act* (IDA) and Industrial Design Rules (IDR) were amended for greater harmonization and to streamline the process. The Industrial Design Office Practice Manual (IDOP) was updated to reflect these changes. These changes took effect on November 5, 2018. The following provides some of the highlights. Unless otherwise stated, these changes apply only to applications filed on or after November 5, 2018.



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- **Party to the Hague System:** Applicants now have the option of obtaining a Canadian Industrial design by designating Canada in an international design application filed under the Hague Agreement. Applicants can now apply for an industrial design in multiple countries using a single application. Once the application is recorded in the International Register, the Canadian Industrial Design Office will require that the application also meets Canadian requirements before registering it in Canada (40 to 52 IDR).
- **Laid Open Date:** Applications will now be made available to the public at registration or 30 months from the earliest priority date, whichever comes first (this does not apply to Hague applications, which is made public in accordance with the Hague Agreement). (8.3 IDA; 32(1) and 46(1) IDR).
- **Grace Period:** The grace period for self-disclosures, made in Canada or elsewhere, now starts one year before the priority date. Furthermore, an earlier Canadian application from the same applicant will not be novelty destroying for the later application, if the later application is filed within 12 months of the first. (8.2(1)(a) IDA and 31 IDR).
- **Presentation of Application:**
 - **Photos & Line Drawings:** The finished article can now be represented using line drawings, photos, other graphic reproductions, or any combination thereof. This means that line drawings and photos can both be present in a single application (14 IDR, 8.05.04 IDOP).
 - **Images in colour accepted:** This is not new; this practice continues with the new changes and applies to all pending and new applications (8.05.06 IDOP).
 - **Images in a variety of formats:** Images can now be submitted using a variety of file formats, including PDF, JPEG, TIFF, and GIF (1.04.03 IDOP).
 - **Mandatory Content:**
 - Required: The application must include the common name of the finished article (14 IDR).
 - Optional: A brief statement of description and/or limitation may be included. However, any description cannot refer to a utilitarian function. In the absence of a limitation, the application is deemed to relate to all of the features of shape, configuration, pattern and ornament shown in the drawings; in fact, expressly stating as much is no longer permitted (17(1) to (4) IDR, 8.06.01 IDOP).
 - No longer required: A description is no longer necessary.

- **Stippled lines not required to disclaim:** Statement can be used to disclaim portions of the article, rather than using stippled lines (8.06.02.01 IDOP).
- **Environment View:** Applications no longer limited to a single environmental view (8.05.05.13 IDOP).
- **Variants now permitted:** Variants having designs that do not differ substantively, are now permitted in a single application. Such variants can include colour variants, sets of finished articles (like a fork, knife, and spoon), and other designs that do not differ substantially from one another (20(1) IDR, 8.04.01 IDOP).
- **Term of Protection:** The term of protection now ends the later of 10 years from registration and 15 years from filing (10(1)(b) IDA). For Hague applications, the term can furthermore not extend past the date of expiry of the Hague application in respect of Canada (47(2)(b)(ii) IDR).
- **Divisional Applications:** Divisional applications directed to any subject matter disclosed, even if disclaimed in the original parent application, are permitted. Divisionals can be filed up until two years from original filing date of parent. After the

two year period expires, the application can still be divided if a unity objection is raised by the examiner; such divisional may be filed up until six months from date of reply to the unity objection (20 IDA).

- **Correcting Errors in Register:** Any error in the Register can be corrected within six months of entry if the error is obvious (this does not apply to Hague applications) (3.1 IDA).
- **Weekends & Holidays:** Deadlines falling on weekends and holidays are now automatically extended to the next working day (21 IDA). This applies not only to new applications, but also to pending applications.
- **Representation:** An applicant will no longer need to appoint an agent, but can represent himself before the Industrial Design Office (12 IDR).

The changes to the Industrial Design Regime serve to harmonize our laws with those of other countries, allowing us to accede to the Hague Agreement, as well as simplifying the requirements for applicants. Changes will soon be implemented in other areas of IP, such as trademarks and patents, to similarly allow greater harmonization. ■



Cannabis Ship This? The Canadian Cannabis Import and Export Regime under the *Cannabis Act*

On October 17, 2018, the sale and use of cannabis for recreational purposes was legalized in Canada. Canadian cannabis companies have grown exponentially as they evolve from supplying medical cannabis to recreational cannabis. The future growth of Canadian cannabis companies depends on international expansion and the movement of cannabis across borders to capitalize on their first mover advantage. Yet, this expansion is subject to Canadian laws, which are at odds with Canada's international obligations regarding the production, manufacture, export, import, distribution of, trade in, and use and possession of cannabis and other drugs.

Importing cannabis into Canada, or exporting cannabis from Canada, is illegal without a permit or exemption.¹ Movement of cannabis into and out of Canada is primarily controlled by three government departments under the *Customs Act*, *Cannabis Act*, *Controlled Drugs and Substances Act*, and *Food and Drugs Act*, and various other regulations and government policies. Health Canada is responsible for issuing export and import permits and ensuring compliance with Canada's international obligations, the Canadian Food Inspection Agency monitors and enforces sanitary and phytosanitary issues, and the Canada Border Services Agency controls the physical movement of cannabis at ports of entry and works with law enforcement in cases of illegal cannabis and other drugs.

The *Cannabis Act* provides a limited window to import and export cannabis.² Health Canada will only issue permits for medical or scientific purposes or for industrial hemp.³ The permit requirements are set out in the *Cannabis Regulations*, which provide that Health Canada may refuse to issue a permit if the shipment contravenes the export or import laws of the importing country or any country of transit.⁴

Canada's legalization of recreational cannabis potentially puts it offside its international obligations, complicating the ability of Canadian producers to scale up their international operations.⁵ Canada is a signatory to the Single Convention on Narcotic Drugs, 1961, as amended by the 1972 Protocol, the Convention on Psychotropic Substances, 1971, and the United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988. In a broad sense, each of these treaties recognizes the therapeutic and medical value of drugs but also the potential for abuse, and the significant social and economic harms that accompany abuse. The treaties commit Canada to limiting the production, manufacture, export, import, distribution of, trade in, and use and possession of cannabis to medical and scientific purposes. Canada's international obligations and domestic laws are now inconsistent. In response, Health Canada, which is responsible for controlling the movement of cannabis in a manner consistent with these international obligations, has attempted to navigate the issue by stating its policy focus is on domestic health and social issues around the sale and use of cannabis, and not facilitating a regime designed to service global recreational demand.



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Canadian companies are nonetheless aggressively pursuing exports of dried cannabis, cannabis oils, and genetics under exemptions for medical and scientific purposes. Canadian companies are using the Canadian export regime to jump-start cannabis production in newly acquired foreign medical companies or in international joint ventures. In 2016, only a single Canadian producer, Tilray, publically reported exporting cannabis from Canada. By the end of 2018, after legalization, several leading Canadian producers, including Canopy, Aurora, Aphria, Cronos, Hexo, and others had followed suit and were exporting cannabis to Europe, Australia, the Middle East, and Africa.

At the international level, there is some movement to re-evaluate the treatment of cannabis as a controlled drug. The Director General of the World Health Organization recently recommended to the Secretary General of the United Nations that cannabis and cannabis resin be removed from international drug control treaties and that other THC containing products be re-classified under less restrictive provisions.⁶ No vote has yet been held by the UN's Commission on Narcotic Drugs to accept or reject this recommendation.

The growing international market for cannabis, both medical and recreational, and the WHO's recent recommendations may, in time, result in a softening of the strict Canadian import and export regime administered by Health Canada. Until then, Canadian producers

must walk a fine line between global expansion and domestic and international legal compliance. That means that they must restrict their import and export activities to permitted medicinal or scientific end uses. ■

1. *Cannabis Act*, S.C. 2018, c. 16, s. 11(1) [*Cannabis Act*].
2. Prior to the *Cannabis Act*, the *Access to Cannabis for Medical Purposes Regulations*, SOR/2016-230 [*ACMPR*] (repealed as of October 17, 2018 pursuant to SOR/2018-147, s. 33) authorized the use of Cannabis for medical reasons and provided a limited window for licensed producers to import or export cannabis. Under the *Cannabis Act*, permits issued under the *ACMPR* are deemed a permit issued under the *Cannabis Act*.
3. *Cannabis Act*, s. 62(2); *Cannabis Regulations*, SOR/2019-144, s. 204 and 213.
4. Unlike the previous *ACMPR*, an exporter is not required to declare that the shipment does not contravene the laws of the country of final destination or any country of transit or transshipment. See *ACMPR*, s. 96 and 102.
5. The Government of Canada admitted that legalization of cannabis for recreational purposes violates Canada's treaty obligations. See, for example, Minister Freeland's testimony to the Senate Committee on Foreign Affairs and International Trade on May 1, 2018: "In terms of the conventions, as I said, we do recognize that we would be in contravention. I think we need to be open about that."
6. WHO, Dr. Tedors Adhanom Ghebreyesus, Director-General, letter to Mr. António Guterres, Secretary-General of the United Nations on the forty-first meeting of the WHO Expert Committee on Drug Dependence (January 24, 2019).



New Federal Beer Regulations

The federal government recently amended the *Food and Drug Regulations* as they relate to beer. These amendments remove the allergen labelling exemption; and remove the ale, stout, porter and malt liquor compositional standards, replacing them with one standard. These amendments will come into force as of December 13, 2022.



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Allergen Labelling

Beer used to be the only prepackaged food exempt from the requirement in prepackaged food that certain allergens be labelled. This exemption is repealed by the recent amendments. By December 13, 2022, beer will need to identify on its label if a food allergen, gluten, or added sulphites are present, either through a list of ingredients or a statement about the food allergen source, gluten source, or added sulphites.

A food allergen is currently defined as any protein from any of the following foods, or any modified protein, including any protein fraction, that is derived from any of the following foods:

- | | | |
|---|-------------------------|--------------------|
| (a) almonds, Brazil nuts,
cashews, hazelnuts,
macadamia nuts,
pecans, pine nuts,
pistachios or walnuts; | (c) sesame seeds; | (h) crustaceans; |
| (b) peanuts; | (d) wheat or triticale; | (i) shellfish; |
| | (e) eggs; | (j) fish; or |
| | (f) milk; | (k) mustard seeds. |
| | (g) soybeans; | |

A number of ingredients found in today's beers will now need to be labelled, and the source of a food allergen must also be labelled.

Compositional Standards

The definition of beer has been modified to include fermentation by yeast or a mixture of yeast and other microorganisms. This is a more inclusive definition, to take into account modern brewing.

The "ale, stout, porter or malt liquor" distinction has been removed in preference of a single definition of beer. This single definition flows through to the common names for beers with various alcoholic percentages, which must be used on any label or advertisement. The goal of these amendments is to provide for one compositional standard for all beer regardless of style.

In addition, a maximum residual sugars of four per cent has been added to the definition. Furthermore, the food additives standards were clarified to align with Health Canada's Lists of Permitted Food Additives, rather than having a separate list for beer.

Implementation

The government has set up a transitional period, giving manufacturers 2.5 years to come into compliance with the new labelling requirements. ■

Digital Health Technologies: Product Regulatory and Litigation Developments

Digital health technologies are diverse. These devices range from standalone software applications to integrated hardware systems which can utilize external platforms such as computers and smart phones. It is estimated that by 2020, there will be a total of 161 million medical devices in operation with more than half of the market share made up of wearable devices. While digital health technologies promise to positively transform the health care delivery model for patients, health-care systems and industry, these technologies also present significant liability and regulatory concerns, which are heightened depending on the level of connectivity and the data collected, stored and used by such technologies. These concerns should be on the radar of not just the manufacturers, distributors, and importers of such products but also for health-care institution adopters and health practitioners that may be recommending the use of such products to their patients.

All Eyes on Regulatory Changes

Health Canada has recognized the complexities of regulating such technologies and is looking to implement both pre-market and post-market methods of regulation to provide additional oversight. The impetus for such changes appears to be the regulator's recognition of the increased complexities of such technologies and their data collection abilities, increasing alignment with other regulators and the development of policies that support the integration of such technologies while maintaining patient safety.

On April 10, 2018, Health Canada announced expected changes to the regulator's approach to digital health technologies. The regulator announced the launching of the new Digital Health Review Division, which is poised to assist with improving access to innovative digital health technologies with a special focus on cybersecurity, artificial intelligence, mobile medical apps, telemedicine, software as medical device, medical device interoperability, and wireless medical devices.

The renewed focus on digital health technologies is not expected to displace the manufacturer's statutory obligation to "take reasonable measures to" address the risks inherent with the medical device (regardless of its class categorization) as stipulated under section 10 of the Medical Devices Regulations SOR/98-282 (the MDR):

A medical device shall be designed and manufactured to be safe, and to this end the manufacturer shall, in particular, take reasonable measures to:

- (a) identify the risks inherent in the device;*
- (b) if the risks can be eliminated, eliminate them;*
- (c) if the risks cannot be eliminated,*
 - (i) reduce the risks to the extent possible,*
 - (ii) provide for protection appropriate to those risks, including the provision of alarms, and*
 - (iii) provide, with the device, information relative to the risks that remain; and*
- (d) minimize the hazard from potential failures during the projected useful life of the device.*



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Within the context of connected medical devices and a manufacturer's obligations under section 10 of the MDR, it is arguable that cybersecurity risks and unauthorized intrusions on the data integrity of such products that cannot be eliminated would require the manufacturer to devise protective measures and inform consumers and learned intermediaries of said risks.

On December 7, 2018, Health Canada confirmed that manufacturers should consider cybersecurity vulnerabilities at the pre-market stage in its draft guidance document on Pre-Market Requirements for Medical Device Cybersecurity. Pending finalization of this guidance document following stakeholder comments (which were to be delivered by early February 2019), Health Canada is expected to call on manufacturers to: 1) incorporate cybersecurity into the risk management process for every device, 2) develop and maintain a framework for managing cybersecurity risks throughout their organizations; and 3) verify and validate cybersecurity risk measures in the design requirements and/or specifications. As the language used in the draft guidance document is permissive, it is not clear what aspects, if not all, may be set as mandatory by Health Canada.

In addition to regulatory oversight by Health Canada, digital health technology stakeholders may be subjected to additional oversight by provincial and federal regulators with respect to the manner in which the data is stored, collected and used by these devices. Depending upon the province and the data at issue, a breach may also require a mandatory notification to the provincial and federal privacy regulators. For example, in Ontario, the provincial regulator now requires a health information custodian to notify an affected individual at the first reasonable opportunity if "personal health information" in its custody or control is stolen, lost, used or disclosed without authority or following a significant breach event.

The following are some factors that can be considered in determining if a breach is "significant":

- whether the compromised personal health information is sensitive;
- involved a large volume of information and individuals; and
- whether more than one health information custodian or agent was responsible for the unauthorized disclosure.

Under the Ontario personal health information legislation, a custodian includes health-care practitioners such as doctors and nurses, but also organizations, such as public or private hospitals or care homes. A similar mandatory breach notification requirement where a

"real risk of harm to individuals exists" is also reflected in the federal privacy legislation. As of November 1, 2018, organizations subject to the *Personal Information Protection and Electronic Documents Act* (PIPEDA) will be required to notify the individuals affected, the federal privacy commissioner, and possibly other organizations and government entities for the purposes of mitigating the impact of the breach. Under the federal legislation, "significant harm" includes "bodily harm, humiliation, damage to reputation or relationships, loss of employment, business or professional opportunities, financial loss, identity theft, negative effects on the record and damage to or loss of property".

Finally, an often less-talked about regulatory compliance issue is the additional licensing and certification approvals that may be required under the *Radiocommunication Act* and related regulations. Depending on the nature of wireless connectivity inherent within the digital health technology, this set of regulatory requirements may be an additional source of regulatory concern for manufacturers, distributors, importers, and retailers of such technologies. Depending on the technology, these considerations may also apply at the research and development stage.

Beyond Regulation: Litigation Concerns

Digital health technologies can present litigation risks. In addition to inherent product liability risks associated with design, manufacturing, marketing, labelling, or promotion of the product, the cyber breach and data security vulnerabilities represent a significant source of liability depending on the connectivity and data capabilities of these types of technologies.

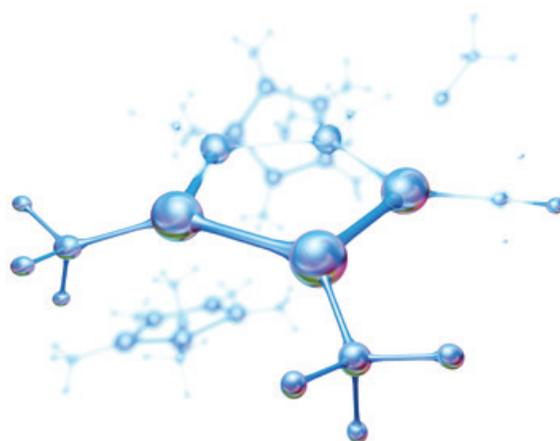
While there have not been any reported product liability decisions involving connected medical devices in Canada, the developing IoT litigation in other common law jurisdictions highlights the litigation concerns associated with connected technologies. As an illustration, in the California case of *Ross v. St Jude Medical Inc. (Ross)*, the connected medical device manufacturer resisted a proposed class action related to alleged cybersecurity failures within the defendant's connected cardiac devices. These devices came equipped with a wireless monitoring technology, allowing remote observations. While there was no evidence that the representative plaintiff was harmed by the alleged product vulnerability, the claims for damages were advanced on the basis of the possibility that a loss may occur due to the purported failures. While the action was ultimately dismissed, the July 5, 2018 decision in *Flynn v. FCA*, involving similar claims, but a different type of technology (connected vehicles),

described the product litigation risks associated with alleged cybersecurity vulnerabilities, even when there is no evidence that the plaintiffs were harmed by the alleged flaws in certain vehicles' infotainment system. In that case, the defendants prevailed against the plaintiffs by successfully dismissing on summary judgment their claims for unjust enrichment and part of their fraud claims. The plaintiffs' remaining claims of fraud and warranty claims however survived and the class action was partially certified. Despite a further appeal to U.S. Supreme Court, the defendants were unsuccessful in defeating the partial certification of claims surviving the summary judgment motion. It remains to be seen if the evolution of the Flynn case may inspire more class actions involving connected products.

Final Remarks

While the foregoing discussion focuses on the inherent product-specific vulnerability risks, undoubtedly the increase in usage of other connected devices to IoT platforms and their related interconnections may pose extraneous risks to the integrity of product specific digital health technologies. Though the fast-paced developments and adoption rates of digital health technologies have already called for an update to the current Canadian medical device regulatory framework, it remains to be seen how courts will consider the liability theories associated with product liability claims of IoT technology failures. Regardless of the industry, it is likely that we all stand to witness an incredible evolution in the product liability landscape. ■

1. Business Insider Intelligence, "The Global market for IoT healthcare tech will top \$400 billion in 2022", (May 25, 2016), online: www.businessinsider.com/the-global-market-for-iot-healthcare-tech-will-top-400-billion-in-2022-2016-5
2. Health Canada, "Notice: Health Canada's Approach to Digital Health Technologies" (April 10, 2018) online: www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/activities/announcements/notice-digital-health-technologies.html
3. Health Canada, "Consultation: Pre-Market Requirements for Medical Device Cybersecurity" (December 7, 2019) online: <https://www.canada.ca/en/health-canada/services/drugs-health-products/public-involvement-consultations/medical-devices/consultation-premarket-cybersecurity-profile.html>
4. *Ibid.*
5. Ontario's *Personal Health Information Protection Act*, R.S.O. 1990, c. P. 10 which governs how identifying identifiable information about an individual interacting with a healthcare custodian ought to be protected defines "personal health information" as "information that identifies an individual or for which it is reasonably foreseeable in the circumstances that it could be utilized, either alone or with other information, to identify an individual".
6. Ontario Regulation 329/04 (in force as of October 2017).
7. *Ibid.*
8. *Radiocommunication Act*, R.S.C. 1985, c.R-2.
9. *Ross v. St Jude Medical Inc.*, No 2:16- cv- 06465 (CD Cal 2016).
10. *Flynn v. FCA US LLC*, 3:15-cv-00855 (SD Ill 2015), see page of the July 2018 decision of Justice Reagan.



Recent Amendments to the Canadian Patent Act Have Come into Force

A number of significant amendments to Canada's *Patent Act* came into force at the end of 2018. These amendments will have an impact on both obtaining and enforcing patent rights in Canada. The *Budget Implementation Act, 2018* (the Budget Act) sets out, in Division 7, Subdivision A, these various amendments to the *Patent Act*.



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1. Admissibility into Evidence of a Patent's Prosecution History

Historically, Canadian courts have repeatedly confirmed the principle that statements made during prosecution of a patent application were not relevant to the construction of that patent in later patent litigation.¹ The Budget Act changes this established principle by the addition of section 53.1(1) to the *Patent Act*. This provision will allow into evidence in any court action or proceeding involving a Canadian patent, any written communication from the applicant or patentee to the Patent Office that may rebut representations made by the patentee related to the construction of any claim of the patent, including communications made during prosecution of the patent, disclaimers, and in any request for re-examination of the patent. Such written communications relating to a patent can also be allowed into evidence in any action or proceeding respecting a Certificate of Supplementary Protection in which that patent is set out, under the new section 123.1 of the *Patent Act* added by the Budget Act. Of particular significance, the transition provisions are such that this provision applies to pending litigation and not just litigation commenced after the coming into force of the legislation.

2. Demand Letters

The Budget Act also provides in the new section 76.2, that demand or cease-and-desist letters related to the enforcement of patent rights must comply with prescribed requirements. There have been a number of cases in the Canadian courts which have sought to deal with the issue of inappropriate cease-and-desist letters, and the impact those letters might have for the sender. For example, in *Excalibre Oil Tools Ltd. v. Advantage Products Inc.*,² the sender of inappropriate cease and desist letters was found liable for damages under section 7(a) of the *Trademarks Act*, because the overtly threatening letters were ultimately found to constitute false or misleading statements tending to discredit the business, goods, or services of the patentee's competitors and caused damage to their business.

The new legislation indicates that any person who receives a written demand that does not comply with the "prescribed requirements", as well as any person who is aggrieved as a result of the receipt of such an inappropriate demand made to a third party, may bring proceedings in the Federal Court. The Court could grant damages, punitive damages, an injunction, a declaration or an award of costs in respect of the inappropriate demand.

No detail regarding the required contents of demand letters is provided in new section 76.2, and regulations will be necessary in order to set out these "prescribed requirements". New section 76.3 expressly provides the power to make such regulations including to set out what constitutes a written demand, what constitutes an aggrievement, the requirements with which a written demand must comply, the factors the Federal Court may and may

not consider in any related proceeding, as well as any circumstances where a defendant should not be found liable under the written demand provision. Consequently, it appears that additional regulations will be required before the provision will be clarified and able to work as intended. As of the date of writing, no draft of these regulations has been published.

New section 76.2 (4) also makes a corporation's officers, directors, and agents jointly and severally, or solitarily, liable with the corporation if they authorized or acquiesced in the sending of such demands, unless they can show that they exercised due diligence to ensure the written demands complied with the prescribed legal requirements.

3. Experimental Use Exception

New section 55.3(1) expressly recognizes that something that is done "for the purpose of experimentation relating to the subject matter of a patent" is not an infringement of that patent. While Canadian courts had recognized that non-commercial, experimental use of a patented invention could sometimes constitute an exception to infringement, there will now be further clarification of this exception. New section 55.3(2) provides that regulations may be made to outline the factors that a court may consider, must consider or will not be permitted to consider in determining whether an act is for the purpose of such experimentation. As of the date of writing, no draft of these regulations has been published.

4. Prior Use Exception

The *Budget Act* also amends section 56 of the *Patent Act*, further detailing when the good faith use or sale of an article or service, which later becomes patented, can be considered an exception to infringement. In particular,

the Act now provides that the infringement exemption continues after the patent issues. Furthermore, this prior use exemption can be transferred such that the transferee will become exempt if they commit an act after the transfer that the transferor could have committed under the exemption before the transfer.

5. Standard-Essential Patents

Canada has not previously had a regime that deals with standard-essential patents. New section 52.1(1), however, provides such a regime. If a patentee enters into a licensing commitment with respect to a standard-essential patent, that commitment binds any subsequent patentee or holder of a Certificate of Supplementary Protection.

Again, there are no details as to what constitutes a licensing commitment or a standard-essential patent, however, regulations may be made as to these definitions. As of the date of writing, no draft of these regulations has been published.

In conclusion, many of these recent legislative changes are significant, but will require further regulation and judicial interpretation before their effect and scope will be fully understood. If you would like to further investigate and discuss the potential impact these changes to Canada's patent law may have for your business and your patent strategy, please contact one of BLG's legal professionals. ■

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1. *Free World Trust v. Électro Santé*, 2000 SCC 66 at para 64-67.
 2. 2016 FC 1279 (under cross-appeal in A-460-16, see 2019 FCA 22).

Modernization of Food Regulations in Canada

The *Safe Food for Canadians Act* (SFCA) finally came into force on January 15, 2019, after receiving Royal Assent in November 2012. The SFCA is described as follows: “An Act respecting food commodities, including their inspection, their safety, their labelling and advertising, their import, export and interprovincial trade, the establishment of standards for them, the registration or licensing of persons who perform certain activities related to them, the establishment of standards governing establishments where those activities are performed and the registration of establishments where those activities are performed.”

Prior to the SFCA, food was regulated under different statutes and regulations at the federal level, all of which were administered and enforced by the Canadian Food Inspection Agency (CFIA). These were created and updated at different times and frequencies over several decades, and while they were effective for the most part, the Canadian government felt a need to strengthen and modernize the regulatory regime to better manage risks related to food safety, while offering players in the Canadian food industry continued opportunities in international trading markets.

The SFCA consolidated the *Fish Inspection Act*, the *Canada Agricultural Products Act*, the *Meat Inspection Act*, and the food provisions of the *Consumer Packaging and Labelling Act*. By consolidating and modernizing the food provisions in these statutes, the SFCA provides greater consistency in rules and regulations as well as strengthens the CFIA's oversight of food commodities being traded inter-provincially or internationally, to make Canada's food system safer and stronger for consumers. It is also a key step in aligning our food safety system with those of our international trading partners, including the United States. The *Food and Drugs Act* continues to exist separately, protecting consumers from any foods that are unsuitable for consumption, including those marketed exclusively within provinces.

In summary, the SFCA impacts the Canadian food regulatory regime in the following ways:

- by imposing tougher prohibitions, penalties and fines for activities that put the health and safety of Canadians at risk (e.g., in some cases, fines could be as high as \$5 million or higher at the court's discretion, and jail time is a possibility);
- by prohibiting against deceptive practices, tampering and hoaxes;
- by permitting the CFIA to develop regulations related to tracing and recalling food, and providing appropriate tools to take action on potentially unsafe food commodities;
- by instituting a more consistent inspection and enforcement regime across all food commodities, enabling inspectors to be more efficient;
- by prohibiting selling food commodities that have been recalled;
- by strengthening import controls, such as, registering or licensing importers, and prohibiting a person from selling, advertising or even having in their possession a food commodity that has been imported in contravention of the SFCA, to foster a level playing field between importers and domestic producers;



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- by providing the CFIA the authority to certify all food commodities for export; and
- by creating a review mechanism for regulated parties to seek review of certain decisions made by CFIA officials, thus providing an additional avenue of recourse for regulated parties (in addition to judicial review by the Federal Court).

The *Safe Food for Canadians Regulations* (SFCR) also came into force on January 15, 2019, although certain requirements under the SFCR are being phased in over the following 12 to 30 months. The SFCR consolidated 13 food commodity-related regulations (including, without limitation, many of the regulations enacted under the *Canada Agricultural Products Act*) and the food-related provisions of the Consumer Packaging and Labelling Regulations into a single food

regulation. The SFCR apply internationally recognized standards for food safety to food that is imported into or prepared in Canada for interprovincial trade or for export. The SFCR include requirements in respect of trade, licences, preventive control measures, traceability, commodity-specific requirements, recognition of foreign systems, ministerial exemptions, inspection legends, packaging, labelling, grades, seizure and detention as well as organic products.

As part of a multi-year, structured and comprehensive review of its regulatory frameworks, the CFIA has focused not only on modernizing its food safety regime, but also modernizing its food labelling and inspection regimes, all of which ultimately benefit Canadian consumers and the food industry. ■

About BLG's Life Sciences Group

A Leading Canadian Life Sciences Practice

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

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

Working in all Facets of Life Sciences

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

Advising on

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

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