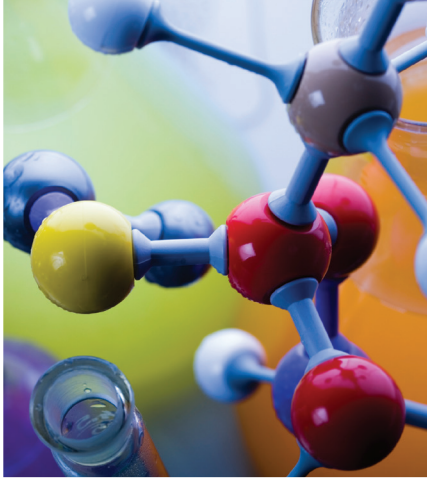
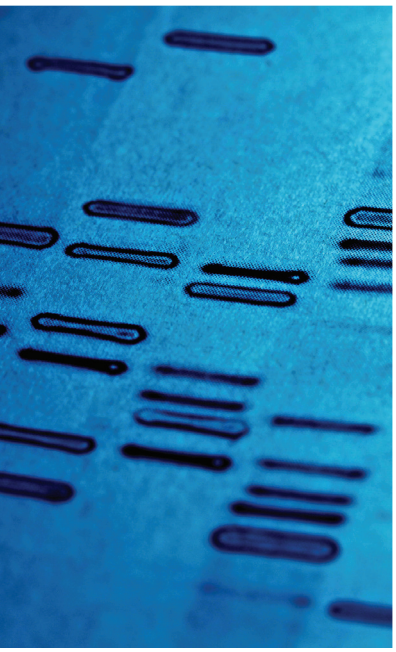
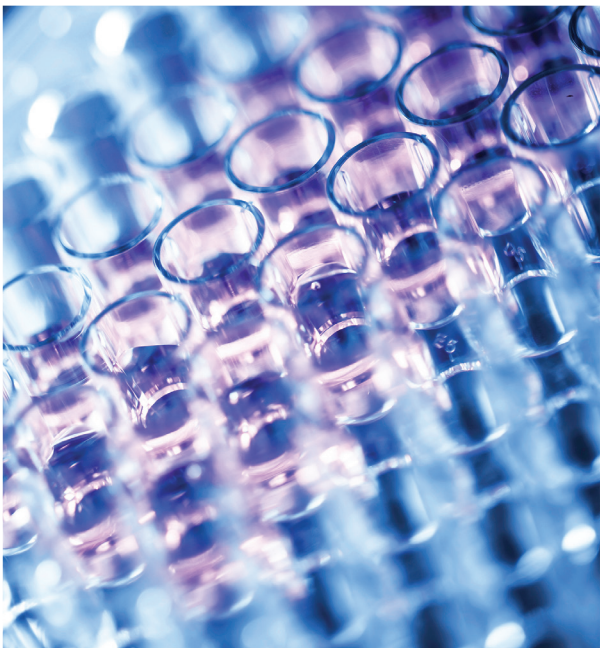
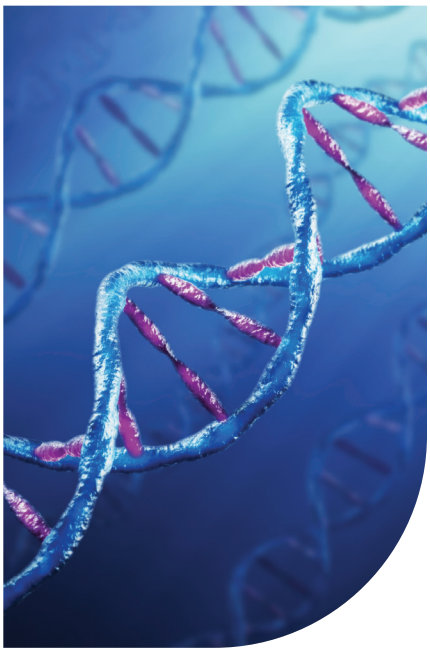




LIFE**SIGNS** • LIFE SCIENCES
LEGAL TRENDS IN CANADA

EDITION
2015-2016

Borden Ladner Gervais

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MESSAGE FROM CANADA'S NATIONAL ASSOCIATIONS

Russell Williams
President of Canada's Research-Based Pharmaceutical Companies

RX&D

Rx&D is the national association representing Canada's innovative pharmaceutical industry. We exist to help create the environment that allows our members to discover, develop, and deliver innovative medicines and vaccines. Our membership is comprised of more than 50 companies, from established companies to fledgling start-ups, who are innovating and revolutionizing healthcare through the discovery and development of new medicines and vaccines.

Our companies work with partners across the life sciences sector to make Canada the ideal destination for pharmaceutical research and development investments. These investments translate to clinical trials in Canada, which translate to Canadians benefiting from cutting edge research. Some anticipated changes within our environment have been received positively, while others are creating challenges for Canada's ability to remain attractive for global investment.

While the Government of Canada has agreed to important IP improvements as part of the Comprehensive Economic and Trade Agreement, these measures have not yet been implemented. We encourage our Government and the European Union to finalize this crucial agreement as soon as possible.

In addition, innovators in Canada continue to be negatively impacted by a heightened patent utility standard created by judicial decisions, which have also created uncertainty given their contradictory rulings. The restoration of equity and predictability in the interpretation of this fundamental patent requirement is vital for our industry.

Rx&D has supported the Government of Canada's efforts to enhance and promote safety. However, new powers with respect to the disclosure of confidential business information that came into force recently are concerning, because they are inconsistent with the equivalent powers in other laws and also with Canada's trade treaty obligations.

While a new orphan drug regulatory regime in Canada has long been anticipated, a regime has not yet been released as of the date of writing. Moving forward with such measures will increase patient access to medicines to address rare diseases, as well as stimulate further innovation.

Finally, access to innovative medicines remains an ongoing challenge in Canada. Lengthy and duplicative evaluation and approval processes restrict or delay access to new treatments. We need to work with our governments and other stakeholders to increase patient access to innovative medicines while addressing the cost and predictability concerns within our healthcare system.

We believe that ensuring Canadians have access to the innovative treatments they need, when they need them is a fundamental part of ensuring healthcare system sustainability for generations to come. We are proud of the work we do in partnership with governments, healthcare professionals, patients and the life sciences sector, and we share an important goal: Canadians living longer and healthier lives.

Andrew Casey

President and CEO

BIOTECanada

BIOTECANADA

Global changes in human health, the environment and food security are dictating the need for nations to embrace the opportunity of turning 21st century knowledge into solutions for 21st century pressures. Biotechnology has already played an integral role in human and planetary development for centuries. Looking forward, with global population closing in on nine billion, the long-term health of the planet and its inhabitants will depend on civilization's ability to develop and harness biotech innovation to change the way we live, manufacture, grow, feed, and heal.

Canada has a long history of successfully leading the development of modern biotechnology. It is a proud history that includes the discovery of insulin in 1922, the isolation of DNA by a Canadian scientist in 1943, the licensing of the first polio vaccine in 1955, the development of an early form of canola in 1974, the first Canadian biotechnology company founded in 1981, winners of the Nobel Prize in 1986 and in 1996, the first country in the world to grow commercial biotech crops in 1995, through to the world's first biofuel jet test in 2012, the recent contribution to development of a vaccine for Ebola, and dozens of other milestones along the way. All told, Canada has made its mark as a significant leader in the global ecosystem feeding biotechnology discovery and development.

This history of leadership has enabled current day Canadian scientists, researchers, and entrepreneurs, to bring forward biotechnology products improving the health, environment, economy and quality of life for the world. The result is a set of diverse and vibrant biotech clusters in virtually every province which bring together academia, entrepreneurs and multinational corporate entities to lead the development and commercialization of innovation. Without a doubt, Canada is well-positioned to benefit economically from leading the development of biotech solutions for the social imperative of addressing the global challenges caused by population growth and a changed and changing environment.

In addition to its historical strengths, recent developments are cause for increased bullishness around the Canadian biotech community. Over the past year, Canadian-based VCs – CTI Life Sciences, Versant and Teralys- closed funds bringing nearly one billion new life sciences investment dollars into play in this country. In addition to these new investment dollars, there have been several important company achievements and milestones announced over recent months including: Sarnia's BioAmber signing a supply deal with Bayer MaterialScience; Vancouver's Zymeworks inking a deal with global biotech heavyweight, Celgene; Versant Ventures, Celgene and Toronto's Northern Biologics entering into a commercial agreement; and, other multinational pharma significantly increasing their Canadian investments through partnerships in NeoMed, CQDM, CDRD and the Structural Genomics Consortium. New investments, partnerships and company success are moving the industry from simply great ideas to commercial reality.

But as a car's side view mirrors ominously remind its driver, objects are closer than they appear. In the case of biotech, those objects are other countries looking to displace Canada as a destination for biotech investment, innovation and commercial development. A scan of the BIO trade show floor serves as a strong and visual reminder that other nations are all too aware of the economic benefits of developing domestic biotech industries in support of a world inhabited by nine billion people. Nations, regions and municipalities are all putting out their nicest welcome mats to attract investors and the biotech industry alike. So with other nations not far behind, Canada must continually look to hone its competitive position as both a place to invest and develop biotech. Ultimately, if we are unable to continue to attract investment then the innovation and its associated economic benefits will move to where the investment is.

With this in mind, ensuring Canada remains globally competitive must continue to be an objective for industry and governments alike. Importantly, Canada has in place many of the components necessary for global competitiveness and success in biotechnology, namely a thriving biotech ecosystem consisting of: world-class universities, science and research institutes; biotech entrepreneurs and scientists; large multinational players; and, a highly educated workforce. Leveraging past success and this ecosystem will be key to the industry's future. In order to leverage these existing strengths, Canada needs to ensure its regulatory and policy environment allow for the industry's growth and support its efforts to attract investment. Ultimately, with the right domestic hosting conditions in place to support innovation and attract investment, Canada is well-positioned to be a global leader in the global bio-economy and develop its share of heavyweights.


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MESSAGE FROM CANADA'S REGIONAL ASSOCIATIONS

Scott
Moffit
Managing Director, BioNova

BIONOVA

The life sciences sector in Nova Scotia has been experiencing considerable growth and success over the past few years. Nova Scotians have combined ingenuity, business acumen and hard work in a harsh economic environment to create opportunities, most often based on the province's natural resources – minerals, the ocean, the forest and the land. The sector is also competitive in a global market space with more than 590 commercial products from Nova Scotia being sold in 80 countries around the world, worth nearly $300 million.

The innovation that serves the industry has spun out of world-class research facilities, a well-trained workforce and support services ranging from incubation to technical assistance to funding programs. This strong foundation of support provides key life science sectors in the fields of pharmaceuticals and vaccines, medical technologies, natural health products, bioproducts and digital health with significant growth opportunity. With these established contributors the sector has been well positioned for long term success.

A recent survey has provided a snapshot of the industry:

- More than 1100 full-time jobs paying on average $20K more than the provincial average salary
- A solid foundation with a $75 million life sciences incubator and research centre
- 185+ products in the pipeline, supported by more than $78 million in committed R&D
- More than 90% of products are sold outside of the province

BioNova leads and supports the development of life science organizations in Nova Scotia and Atlantic Canada as they build a successful, self-sustaining industry based on a foundation of competitive advantage. BioNova promotes the industry and its successes by building relationships both inside and outside Atlantic Canada and creating networking and educational opportunities.

Jason
Field, Ph.D.
Chief Executive Officer

LIFE SCIENCES ONTARIO – LSO

Many people within the life sciences sector interested in doing business in Ontario have wondered about how Ontario's Life Sciences sector performs relative to other North American jurisdictions, or just how important it is to the province's economic health.

Until February 2015, there was no clear answer to that wonder. But we knew the questions were out there because we heard them from our members, government and other partners time and again.

The deficit of evidence-based economic impact data and North American benchmarking is precisely why Life Sciences Ontario researched, wrote and published the **2015 Life Sciences Ontario Sector Report** using comparable metrics to the internationally-known and highly regarded Battelle/BIO reports.

Released in February 2015, the report provides the well-defined data that clearly measure and report on the sector's benchmarking and its economic contributions.

We can now firmly quantify that the life sciences sector makes a significant contribution to Ontario's economy. The 5,600 life sciences establishments employ over 83,000 highly-skilled workers in Ontario. The sector generates approximately $40 billion in annual revenues, which translates to approximately $38.5 billion in total contributions to Ontario's Gross Domestic Product (GPD). That easily ranks Ontario's sector among North America's must successful clusters – it's in the top 10 by employment and the top three by establishments.

This data is good news for the deep field of life sciences talent, provided they're well established in their careers. The sector's job growth outpaced the provincial average by nearly 10 per cent between 2001 and 2013, showing resilience during the 2008 economic downturn. On average, wages in the Life Sciences sector are also 26.5 per cent higher than those of the provincial average. The flip side is that it's a challenging sector to enter. Recent science graduates face an unemployment rate of 18.9 per cent. This is a substantial challenge since Ontario produced 9,813 postsecondary graduates from physical, life sciences, and technologies programs in 2011, accounting for 49 per cent of the national total.

Part of the challenge is that Ontario's life sciences companies skew to the smaller end of the scale. Of all Ontario's life sciences companies, 63 per cent have less than 10 employees and only four per cent have more than 100. On the whole, over 80 per cent of these companies are in the Medical Device and Equipment or the Research, Testing and Medical Laboratories segments with the remainder in Drugs and Pharmaceuticals and Agricultural Feedstock and Chemicals. These numbers speak to Ontario's commitment to commercialization and many policy initiatives that support translating our cutting-edge life sciences research into innovative technology companies. However, the next step is to grow many of these innovative start-ups into globally competitive firms, which will be the focus of LSO's near-future advocacy work.

To help our companies grow and thrive, Ontario's access to capital resources for life sciences needs substantial attention. Since 2001, Ontario's share of Canadian venture capital has declined approximately 20 per cent. In 2014, the Life Sciences sector was the segment to receive the least investment on the TSX/TSXV while the NASDAQ Biotechnology Index outpaced the NASDAQ Composite Index by nearly 3:1 over the past three years. For additional context about the enormity of this missed opportunity, two U.S. Life Sciences companies, Gilead and Amgen, have a combined market cap of $268.6 billion (USD) (as of Q1-2015) that is more than the approximately 1,500 companies combined that make up the entire Canadian mining sector (market cap of $265.7 billion CND as of Jan. 2015) listed on the TSX/TSXV.

In the past, making these kinds of accurate comparisons was virtually impossible due to inconsistencies in both data and methodologies. LSO saw a role in researching and publishing a report that would substantially quantify and articulate the sector's impact while establishing a data baseline to help inform policy divisions, a crucial milestone in helping Ontario's life sciences sector reach its full economic and social potential.

Life Sciences Ontario (LSO), a member-driven organization, is the voice for Ontario's life sciences sector and represents and promotes the province's vibrant and diverse life sciences sector. LSO collaborates with governments, academia, industry and other life science organizations in Ontario and across Canada to promote and encourage commercial success across the sector and its diverse subsectors.

> “We can now firmly quantify that the life sciences sector makes a significant contribution to Ontario’s economy.”
>
> Jason Field, Ph.D.

Paul V.
Drohan
President & CEO,
LifeSciences BC

LIFE SCIENCES BC

In British Columbia where our active life sciences community continues to make advances through collaboration while creating value across the province, we need to reach further, beyond our provincial and national boarders, if we really and truly are committed to growing our life sciences community. Life sciences Research & Development and industrial pursuits are part of the global enterprise and the B.C. life sciences community cannot succeed in isolation; our community must be globally focused and engage with willing and able partners around the world.

"….the clustering of resources and industries in specific locations can provide conducive – and, in some cases, essential – context for success. Cities, like universities, exist to bring people together so that they collaborate with each other and make advances that would not be possible in isolation."

2014 Science &Innovation Strategy, UK Department for Business & Innovation Skills

The United States has been a welcoming jurisdiction with significant human and capital resources for our companies. Our collaborations with our American neighbours have provided value and growth to our community and this is expected to continue. Our proximity to Asia represents a significant opportunity to access both new capital and growth oriented markets. With the Canada-Hong Kong Tax Treaty and the recent Canada-South Korea Free Trade Agreement, our companies have good reason to look to Asia and vice-a-versa. Finally, with the pending CETA (Comprehensive Economic Trade Agreement) free trade, the 17 trillion Euro market will be accessible. It is for this reason that LifeSciences BC organised a "Mini-Mission to the UK" to explore the possibilities for our companies to use the United Kingdom as their European base. The reception from the life sciences community in London and Cambridge was one of great interest and enthusiasm.

Here at home, our community continues to grow with "Rising tides lifting all boats", and in the case of BC biotechnology and medical technology, 2014 was certainly a lift for the industry. Value creation in the BC Life Sciences community had much to celebrate with two IPOs; Aquinox ($53.1 M) and Xenon ($41.4 M), both listing on NASDAQ. Each of these public offerings was the result of years of research & development, passion for patient care, a commitment to success and community support. In addition, there was significant public market capital and private capital invested in B.C. life science companies including; Tekmira ($14.5M), Aurinia ($52 M), Cardiome ($30M), Neovasc ($25.2M) and Zymeworks ($19M). There were also a large number of significant partnership/agreements established and continued, including Zymeworks & Lilly, MedGenesis & Pfizer, PHEMI & Merck, Xenon & Genentech/Roche, Augurex & LifeLabs, to name just a few. New companies were formed with CDRD/CVI spinning out Kairos and Sitka. The Centre for Drug Research and Development continues to establish itself in the innovation space by establishing collaborations with innovation institutes and large pharma including; Pfizer, GSK, J&J and Roche. Genome British Columbia's leading edge genomics development continues to advance personalised and precision medicine in B.C.

Whether it is the excellent basic research leading to translation, with the work carried out at the University of British Columbia, Simon Fraser University, University of Victoria and the British Columbia Institute of Technology; the pre-clinical work that gives way to clinical research, with 797 open/active clinical trials (21% of all active/open trials in Canada) in B.C., work within Vancouver Coastal Health Institute, Providence Health Research Institute, Prostate Centre, PROOF, Centre for Heart Lung Innovation, CoE HIV/AIDS, UBC's Life Sciences Institute, and the Brain Institute; the energetic entrepreneurs that start and grow companies with the support of advisors, institutions and corporations it is clear, our B.C. community's reliance on collaboration results in solid and lasting value for not only the life science sector but supports the over all health of the B.C. economy.

To continue growing value, LifeSciences BC will maintain the focus on three key priority areas; 1) access to capital, 2) access to health data and 3) and access to research & development. Through the development of policies and activities toward achieving these goals, we will grow our collaboration, our value and our community in British Columbia.

INSIGHTS FROM THE LIFE SCIENCES TEAM AT BLG

PATENTS

MEDICAL TREATMENT VS. MEDICAL USE: THE SHIFTING GROUND OF PATENTABLE SUBJECT MATTER IN CANADA

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In Canada, methods of medical treatment are not considered to be patentable due to a long-standing, court-created exclusion established under an old compulsory licensing regime (*Tennessee Eastman Co. et al. v Commissioner of Patents*, (1972), 8 C.P.R. (2d) 202 (S.C.C.)). The exclusion has persisted in Canadian law, despite the regime no longer being in force. Separately, the Supreme Court has considered and upheld medical 'use' claims (*Apotex Inc. v. Wellcome Foundation Ltd.,* (2002), 21 C.P.R. (4th) 499 (S.C.C.)). The tension between these two precedents can be a significant source of confusion for applicants and foreign practitioners with applications in Canada.

More recently, decisions of the Federal Court have expanded the exclusion, striking down 'use' claims in instances when the claimed invention was deemed to inhibit or require the professional skill or judgement of a physician (e.g., *Axcan Pharma Inc. v Pharmascience Inc. et al.*, 2006 FC 527; *Janssen Inc. v. Mylan Pharmaceutical ULC et al.*, 2010 FC 1123; *Bayer Inc. v. Cobalt Pharmaceutical* et al., 2013 FC 1061). Claims limited by dosage range, for example, have been invalidated on this basis when the Court found that a physician's skill would be required to select an appropriate dose from within the range.

Prospective patentees accordingly face a somewhat paradoxical situation in Canada: broad 'use' claims are generally permissible from the perspective of statutory subject matter, while narrower claims limited in particular ways can be problematic.

Against this backdrop, the Canadian Patent Office issued a Practice Notice to its examiners in 2014 with guidelines on the examination of medical 'use' claims. Under these guidelines, claims limited by 'what' to use were generally permissible, while those limited by features perceived to require 'how' or 'when' determinations were generally impermissible.

The Practice Notice and its attendant examples were revised in March 2015. The reason for the update is a 2014 decision of the Federal Court, which criticized an earlier decision of the Commissioner of Patents for over-reliance on policy considerations (*AbbVie Biotechnology Ltd. v. The Attorney General of Canada,* 2014 FC 1251 at [120]-[125]). The most notable changes in the new Practice Notice are a softening of its language, and stark reversal of two previous policies concerning new sites of administration and patient populations.

Whereas the previous Notice indicated that a 'use' claim limited by a 'how' element "will lead to the conclusion that the claimed 'use' encompasses a method of medical treatment", the revised Practice Notice inserts a passage before this to indicate that "it must be determined whether the essential element prevents, interferes with or requires the professional skill of a physician" (emphasis added in both instances). The intention, it seems, is greater deference to an Examiner's determination based on the facts at hand.

Pertinent examples from the revised Practice Notice are summarized below.

Uses of new compounds and new uses of known compounds

Claims to 'uses' of both new and known compounds remain statutory under the revised Notice when the invention rests in the new compound or the new 'use', respectively. Dosage range features do not make claims non-statutory in these circumstances if they are deemed "unnecessary limitations to the scope of the monopoly" (it is unclear, however, how such "unnecessary limitations" would be subsequently interpreted in the courts).

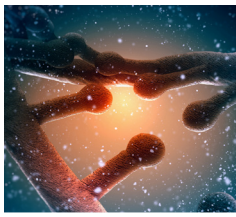
New fixed dosage form of a known drug for a known use

'Use' claims reciting fixed dosage units are judged to be directed to specific products, and remain statutory.

New dosage range of a known drug for a known use

'Use' claims reciting dosage ranges remain non-statutory, when the invention resides in the dosage range. The example indicates that "the dosage range… requires the skill and judgment of a physician to make a determination as to the dose the patient receives". Features such as "13 to 15 mg/kg/day" and "14 mg/kg/day" are considered to be equally problematic, because the physician has to make a determination in each case.

MEDICAL TREATMENT VS. MEDICAL USE: THE SHIFTING GROUND OF PATENTABLE SUBJECT MATTER IN CANADA | *CONT'D*



New dosage regimen of a known drug for a known use

'Use' claims including dosage regimens with fixed time points and fixed amounts remain statutory, though a new cautionary note indicates that such claims would not be statutory if "it is determined that the schedule claimed is a titration", which "always requires monitoring by a professional". Likewise, a new example involving a time range of "3-5 weeks" is deemed to be non-statutory due to the requirement for a physician's judgement.

New physical formulation of a known drug for a known use (new area of administration)

The revised Practice Notice *reverses* previous examination policy on use claims for inventions involving sites of administration. The two examples involve an orally administrable pharmaceutical composition (the same drug was used previously to treat the same condition), and a 'use' of an existing patch on a new site on the body (the upper leg instead of on the arm). Both are considered to be patentable subject matter.

Known compound, for a specific group of patients

The Practice Notice also *reverses* earlier examination practice for 'uses' of known compounds in a specific group of patients: a key area for personalized medicine. Application of a known drug to either an entirely new patient group or a patient sub-population (e.g. bearing a specific mutation) is deemed to be statutory. However, a new cautionary note indicates that the latter would be considered anticipated, and would also not qualify as a selection.

While the deference to the determination of an examiner afforded by the revised Practice Notice is a positive development, the foray into anticipation in the example concerning patient subpopulations is a puzzling development. No precedent is referenced to support the example, and the resolution of a previously homogenous patient group into new sub-groups (with attendant inventive advantages) is conceptually similar to the resolution of an existing drug based on racemic mixture. Claims to purified enantiomers with special advantages have been upheld as a selection on more than one occasion by the courts (e.g., *Sanofi-Synthelabo v. Apotex*, 2008 SCC 61; *Sanofi-Aventis v. Apotex*, 2013 FCA 186), and this may provide a basis for applicants to argue against application of the revised Practice Notice where 'use' claims involving personalized medicine are concerned.

CORPORATE

BLG LAUNCHES CATALYST PROGRAM TO SUPPORT LIFE SCIENCE START-UPS

Originally Published in: BLG News & Publications

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In recent years, early stage life science ventures have faced serious challenges raising financing. In the *Life Science Ontario Sector Report 2015*, Ontario's life science stakeholders identified access to capital as the key barrier to growth. Borden Ladner Gervais LLP (BLG) understands that obtaining financing is a substantial hurdle and is committed to help life science start-ups reduce this burden by offering early stage companies legal support to protect their intellectual property and to structure their corporate operations through the launch of the BLG Catalyst Program.

The BLG Catalyst Program is designed to offset legal fees by providing access to a multi-disciplinary team of tech-savvy lawyers, patent and trademark agents specializing in intellectual property protection, corporate, labour & employment law. For companies who have attracted eligible government funding, BLG's Catalyst Program will match every dollar that those companies spend on legal services with BLG, up to $10,000 per company. This matching will be provided in the form of additional legal services.

As part of the BLG Catalyst Program, BLG will offer ongoing training sessions and consultation to any startups that choose to participate in the program.

The program gives start-ups access to an experienced team of legal professionals who will provide both strategic and tactical advice to companies at a critical phase in their development.

BLG has a long history of supporting the life sciences community in Canada and this new initiative further emphasizes its commitment to help build and maintain a thriving life sciences community in Canada. For example, BLG lawyers were instrumental in creating or supporting Life Sciences Ontario, BioFinance Canada and the Sanofi BioGENEius Challenge.

In the commercial life sciences sector, Ottawa-based start-up Impakt Protective Inc., a leading developer of sports sensor and software systems, and successful participant on the CBC television show Dragons' Den, has leveraged BLG's services in intellectual property protection. "Without the steadfast direction of BLG, we would not have such strong intellectual property protection in place, which protects both the founders and our shareholders," said Danny Crossman, CEO of Impakt Protective. "The lawyers and professionals at BLG helped us avoid several potential costly mistakes along the way, and guided us in creating a solid foundation for our business."

REGULATORY TRENDS – CANADA

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

In Canada, the sale and marketing of pharmaceuticals, biologics, medical devices and other healthcare products are regulated under the *Food & Drugs Act* and regulations. Since the creation of this legislation in the 1950's, it has remained virtually unchanged. However, as of November 2014, things changed.

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

In November 2014, an *Act to Amend the Food and Drugs Act*, also known as *Protecting Canadians from Unsafe Drugs Act* or *Vanessa's Law*, came into force. The Act takes a 'product life-cycle' approach to the regulation of health products. What this means is that a health product's risks and benefits will not only be assessed before the product enters the Canadian market but also continually after it has entered the market. Health products subject to such assessments will be prescription and over-the-counter drugs, radiopharmaceuticals, vaccines and other biologics, gene and cell therapies, and medical devices, but not natural health products.

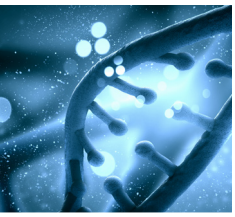
The major changes include:

- Requiring health care institutions to report serious adverse drug reactions and medical device incidents to Health Canada
- Allowing Health Canada to pursue faster regulatory action when a serious health risk is identified, including ordering a product recall or a change to the product's label to prevent injury to health
- Giving Health Canada greater powers to demand and obtain information in the person's control if Health Canada believes that the health product may present a serious risk of injury to human health
- Allowing Health Canada to disclose confidential business information about a health product without notifying, or obtaining the consent of, the person to whose business or affairs the information relates if Health Canada believes that the health product may present a serious risk of injury to human health
- Promoting greater confidence in the oversight of health products by encouraging transparency and openness in Health Canada's communication of risk-related information to the public
- Imposing stiffer fines and penalties to reflect the seriousness of the violation – up to a maximum of $5,000,000 and/or 2 years' imprisonment, and additional officer, director and agent liability should such individuals direct, authorize, assent to, acquiesce or participate in an offence committed by the corporation

II. Risk Management Plans

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

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



REGULATORY TRENDS – CANADA | *CONT'D*

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

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

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

III. Orphan Drugs Regulations – Coming

A rare disease is a life-threatening, seriously debilitating, or serious and chronic condition that affects a small number of people. Over 7,000 rare diseases have been identified worldwide, and about 80% of them have a genetic origin, and the remainder 20% from viral or bacterial infection or other environment causes.

An 'orphan drug' regulatory framework is currently under development in Canada. Health Canada will allow greater flexibility in the design of clinical trials and in the evaluation of the results given the smaller patient population, while placing greater emphasis on post-market activities. A 'product life-cycle' approach will be taken to assess the ongoing risks and benefits of an orphan drug. Patient input throughout the product's life-cycle will be taken into consideration by Health Canada as part of the assessment at the time of (i) designation as an orphan drug, (ii) market authorization application review and (iii) reassessment stages.

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

POSSIBLE CONSIDERATION OF FILE WRAPPERS IN CANADA

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Recent Federal Court decisions suggest that the prosecution history of Canadian patents may not be completely irrelevant. The Supreme Court of Canada in *Free World Trust v. Electro Sante Inc.* in 2000 wrote that the use of file wrapper estoppel was emphatically rejected in *Lovell Manuafacturing Co. v. Beatty Bros. Ltd.* and has been generally excluded over the years for the purpose of construing the claims.[1] The prosecution history of a patent is inadmissible for the purpose of construing the patent claims, the reason being that extrinsic evidence is not permissible for the purposes of construction.[2] The prosecution history constitutes extrinsic evidence:

> In my view, those references to the inventor's intention refer to an objective manifestation of that intent in the patent claims, as interpreted by the person skilled in the art, and do not contemplate evidence such as statements or admissions made in the course of patent prosecution. To allow such extrinsic evidence for the purpose of defining the monopoly would undermine the public note function of the claims, and increase uncertainty as well as fuelling the already overheated engines of patent litigation. The current emphasis on purposive construction, which keeps the focus on the language of the claims, seems also to be inconsistent with opening the pandora's box of file wrapper estoppel. If significant representations are made to the Patent Office touching the scope of the claims, the Patent Office should insist where necessary on an amendment to the claims to reflect the representation.[3]

The Court has noted that the reason for refusing extrinsic evidence is that such evidence would render patent construction even more difficult than it already is.[4]

However, in a 2013 decision in a patent infringement case, the Court was considering an argument relating to the essential nature of a claim element. During prosecution of the patent, claims were rejected in the face of prior art, and elements were added to the claims in order to overcome the rejection. The argument was made that there was no clearer indication that the element was essential than this addition to overcome the rejection.[5] The Court found as follows:

> While statements or admissions made in the course of patent prosecution shall not be used for the purpose of interpreting a claim, this is not what the Court is called upon to do in the case at bar. A change in the wording of a claim as a result of an objection from the Patent Office is an objective fact from which an inference may be drawn, and is not the same as representations made to the Patent Office. A purposive construction should obviously focus on the wording of a claim, obviously, but this is a far cry from saying that nothing else should be considered.[6]

The reasoning applied in *Distrimedic* was recently relied upon in the context of considering essential elements of a claim.[7]

It should be remembered that the Court has held in the past in a decision that was cited by the Supreme Court of Canada in *Free World* that information in file wrappers "may be relevant for some purposes on some occasions".[8] It remains to be seen for what purposes and on which occasions, if any, Canadian Courts will find file wrappers to be relevant. In any event, it may be prudent to expect to see more arguments relating to file wrappers in the future as parties and the Court continue to explore their possible use in litigation.

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1 *Free World Trust v. Electro Sante Inc.*, [2000] 2 S.C.R. 1024 at 1060-1061 [hereinafter *Free World*].

2 *Free World, ibid.* See also *Merck & Co. Inc. v. Apotex Inc.* (2006), 53 C.P.R. (4th) 1 at para. 119 (F.C.); varied on different grounds, 2006 FCA 323; leave to appeal to SCC refused, [2006] S.C.C.A. No. 507 [hereinfter *Merck*].

3 *Free World Trust, ibid.*

4 *Merck, supra* note 2.

5 *Distrimedic Inc. v. Dispill Inc. et al.*, 2013 FC 1043 at para. 207 [hereinafter *Distrimedic*].

6 *Distrimedic* at para. 210.

7 *Eli Lilly Canada Inc. v. Mylan Pharmaceuticals ULC*, 2015 FC 125 at para. 154.

8 *Foseco Trading Ag v. Canadian Ferro Hot Metal Specialties Ltd.* (1991), 36 C.P.R. (3d) 35 at 47 (F.C.T.D.), cited in *Free World* at para. 67.

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CORPORATE / LABOUR & EMPLOYMENT

HOW TO BEST PROTECT YOUR BUSINESS FROM DEPARTING EMPLOYEES

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Life science companies must seek to minimize the potential harm that can be inflicted by former employees after they leave employment. If an employee is currently working with your company or departing (either on good or bad terms), your company may have exposure to a number of risks, including the risk that they may set up a competitor or steal your employees, clients, property or confidential information. There are a number of contractual options which can be put in place to assist in protecting your business and minimizing this exposure.

(i) Restrictive Covenants

A business can use restrictive covenants to protect its interests by prohibiting former employees from either competing or soliciting (customers or employees) for a defined period of time. However, as between the parties, restrictive covenants are presumptively unenforceable unless it can be shown that they are reasonable. Therefore, it is important that any restrictive covenants are drafted with care. To be enforceable, a restrictive covenant in an employment contract must be reasonable in terms of: (i) geographical scope; (ii) duration; and (iii) subject matter. In contrast, in the commercial context, where the parties are negotiating on more equal terms, restrictive covenants are enforceable unless they are unreasonable.

Recently, businesses have sought creative ways of drafting restrictive covenants to protect their interests in order to overcome their presumptive unenforceability. In the recent case of *Rhebergen v Creston Veterinary Clinic Ltd*, the British Columbia Court of Appeal considered an "unconventional" restrictive covenant that did not restrict the former employee from competing outright, but imposed a financial "penalty" on the employee if she did. The Court of Appeal determined that the covenant was reasonable as it was not ambiguous and was not a penalty because it was a genuine pre-estimate of losses. This case indicates that courts may be more willing to enforce clauses that impose financial penalties on competing rather than barring it outright, provided some thought has been put into the amount of the "penalty".

(ii) Return of Property Clauses

Another way to protect your business interests is to contractually stipulate that an employee has a duty to return the business's property upon the termination of employment. While fairly obvious, including a provision in an employment agreement will make enforceability easier and can be tailored to the particular type of property. If your former employee refuses to return a laptop, for example, which contains important software or confidential information, it will be imperative to show that he or she is acting in breach of contract in doing so.

(iii) Confidentiality Clauses

In the course of their work, employees often learn or have access to confidential information about their employers' businesses. Non-disclosure or confidentiality clauses can define the rights and remedies of your business if an employee discloses confidential information – such as client information, trade secrets, or other intellectual property – to outsiders.

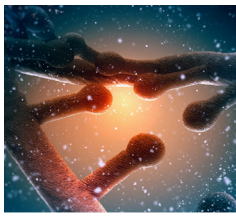
HOW TO BEST PROTECT YOUR BUSINESS FROM DEPARTING EMPLOYEES | *CONT'D*

One way life science companies can protect their confidential information is by including confidentiality obligations in their offers of employment. For example, in the recent British Columbia case of *Phoenix Restorations Ltd v Drisdelle*, Phoenix sought an interlocutory injunction to restrain two former employees from using confidential information, including lists of suppliers, estimates for customers, marketing presentations and email communications with specific customers. The Court, in reviewing the confidentiality provisions in Phoenix's offer of employment, noted that at an interlocutory stage restrictive covenants need to be more rigorously tested and scrutinized as compared to confidentiality clauses. Further, the Court noted that irreparable harm would result from confidential documents being released. This case highlights the effectiveness of well drafted confidentiality clauses in protecting confidential information.

To be enforceable, confidentiality clauses must be explicitly drafted to include any information that is particularly important to your business. This will vary from business to business, and all types of proprietary and confidential information should be considered for inclusion. If an employee ever uses or discloses such defined information inappropriately, courts generally will be prepared to uphold and enforce confidentiality clauses, and may award compensation and other remedies to the employer such as an injunction prohibiting the employee from using or disclosing the information to third parties.

Conclusion

Well-drafted employment contracts will maximize the likelihood of enforceability in the event a departing employee engages in unfair competition. Contracts should be drafted to specifically address the needs of your business and regularly updated in order to minimize potential harm to your business.



LITIGATION

CANADA RECEIVES UPDATED GUIDANCE FROM THE COMPETITION BUREAU ON PATENT LITIGATION SETTLEMENTS

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The Competition Bureau has released updated Intellectual Property Enforcement Guidelines (IPEGs), as well as a white paper on patent litigation settlement agreements.

A. New Intellectual Property Enforcement Guidelines (IPEGs) for Canada

In last year's Life Signs Legal Trends we reported on how Canada's Competition Bureau was updating their Intellectual Property Enforcement Guidelines (IPEGs) for the first time since 2000.[1] A draft was released on April 2, 2014, and on September 18, 2014 the final version was released.[2]

Interested parties were asked to comment on the draft IPEGs, and to indicate if there were other competition/IP issues that they believe the Bureau should address. As a result of the submissions, there were "clarifications on the circumstances when the non-use of an IP right could create a competition issue and the Bureau's enforcement approach to patent pooling arrangements, a particular type of business agreement among firms."

Continued updates will be forthcoming to address issues such as: patent litigation settlement agreements, the conduct of patent assertion entities, and activity related to standard essential patents.

B. White Paper on Patent Litigation Settlement Agreements

The Competition Bureau on September 23, 2014 also released a white paper on *Patent Litigation Settlement Agreements*.[3] This was accompanied by remarks from the Commissioner of Competition.[4] The Bureau noted that there are differences between the regulatory regimes found within Canada and the United States. This includes:

1. **The lack of a notification system in Canada:** The Bureau does not have a system to be made aware of settlements between brands and generics. This contrasts with the United States where all potential pay-for-delay settlements are reported to the antitrust agencies.
2. **The absence in Canada of a 180-day period of exclusivity for the first generic to challenge a brand's patent:** The first generic challenger in the United States is rewarded with a 180-day exclusivity period. This is thought to facilitate pay-for-delay settlements because any delay would ultimately affect all generic challengers.
3. **Particularities to the Canadian PM(NOC) Regulation prohibition proceedings:** Canadian prohibition proceedings do not determine whether the patent is valid or infringed, rather they are summary proceedings designed to determine whether the generic's allegation is justified. The ability to sue for infringement after the generic has entered the market imposes risk on the generic, and the possibility of section 8 damages imposes risk on the innovator.

However, the Bureau does not believe that these differences diminish the role of competition analysis in reviewing potentially anticompetitive settlements, nor do they call for a less vigorous enforcement approach in Canada.

The Bureau noted that in the US and EU, settlements involving a compromise on the generic's entry date tend to reflect the odds of the parties' success in litigation. The more likely that the patent is to be found valid and infringed, the later in the patent term that the generic entry can be expected. In the United States, pure entry-date agreements do not violate antitrust laws because it generally reflects a compromise of litigation expectations. However, payments to the generic may run contrary to US antitrust laws.

The Commissioner of Competition has stated that the Bureau will take the position that the *Competition Act* applies even in cases where the settlement allows for generic entry prior to the patent expiry. The Bureau will not "operate from the assumption that a patent is valid and infringed."

In general, Canada has lower brand prices and higher generic prices compared to the United States. This lower gap may reduce the incentive for pay-for-delay settlements, but the Bureau does not feel it eliminates

[1] http://www.competitionbureau.gc.ca/eic/site/cb-bc.nsf/eng/01286.html

[2] http://www.competitionbureau.gc.ca/eic/site/cb-bc.nsf/eng/03808.html

[3] http://www.competitionbureau.gc.ca/eic/site/cb-bc.nsf/eng/03816.html

[4] http://www.competitionbureau.gc.ca/eic/site/cb-bc.nsf/eng/03817.html

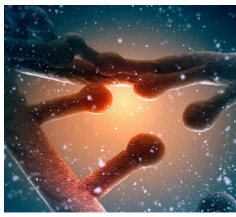
CANADA RECEIVES UPDATED GUIDANCE FROM THE COMPETITION BUREAU ON PATENT LITIGATION SETTLEMENTS | *CONT'D*

it. Guidance from the Bureau indicates that if a brand pays more than the generic could have obtained from the *PM(NOC) Regulation* proceeding, that is less likely to be justified. On the other hand, it might not attract scrutiny if the payment falls within the realm of what can be expected in litigation where the brand faces section 8 damages liability.

The Bureau will look to apply criminal or civil liabilities depending on the conduct. For example, a settlement with respect to markets or products that are not the focus of the patent litigation, or fixing a generic entry date later than the term of the patent, may attract criminal sanctions. Other settlements will be subject to the discretion of the Bureau, taking into consideration the type and value of consideration flowing from the brand to the generic for an agreed upon generic entry date; the amount of time until generic entry; and any other available evidence.

Conclusion

The release of the updated IPEGs and white paper shows the recent interest the Competition Bureau has shown in the pharmaceutical sector. While Canada's approach to patent litigation settlement agreements has not been finalized, mandatory reporting of settlement agreements may be forthcoming.



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CORPORATE

SIGNIFICANT CHANGES TO CANADA'S EXEMPT MARKET FOR LIFE SCIENCE COMPANIES

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Life Science companies in Canada are very interested in securities law related to access of capital from the exempt market (eg. accredited investors). As part of its ongoing review of the exempt market in Canada, the Canadian Securities Administration ("CSA") recently finalized and released important amendments to National Instrument 45-106 Prospectus and Registration Exemptions (to be retitled National Instrument 45-106 Prospectus Exemptions) as well as the Companion Policy to NI 45-106 (NI 45-106 and CP45-106) and other related instruments. This regulatory development will have a significant impact on life science issuers, registrants and investors alike. Some of the most popular prospectus exemptions in NI 45-106 are being overhauled and new prospectus exemptions introduced, including a version of the friends, family and business associates exemption in Ontario and a new exemption aimed at asset-backed commercial paper. These changes, which came into force on May 5, 2015, will have implications for life science issuers' subscription agreements, offering memoranda and compliance practices, among other things, while dealers and other registrants will need to understand the implications of the amendments on their ability to make recommendations to clients about exempt market securities.

The amendments are the result of the CSA's review of the exempt market in Canada and, in particular, whether the prospectus exemptions that were available in NI 45-106 remained relevant in light of economic developments and the perceived need for more protections for retail investors.

Overview of Key Changes

1. Accredited investor exemption (AI Exemption)

- Ontario joins the rest of the country in permitting fully managed accounts to purchase investment fund securities under the managed account category of the AI Exemption, without regard to the nature of the underlying account holder
- The definition of accredited investor is being expanded to add a new higher-wealth category of individual accredited investor with net financial assets of more than $5 million (this is the same category of individual who qualifies as a "permitted client" for other purposes)
- Certain family trusts will now qualify as accredited investors
- Individual accredited investors with net financial assets of less than $5 million will be required to complete and sign a risk acknowledgement form before or at the same time of a purchase of securities under this exemption

2. Minimum amount investment exemption (MA Exemption)

- The MA exemption is no longer available to individual investors

3. Friends, family and business associates exemption (Ontario) (FFBA Ontario Exemption)

- A version of the friends, family and business associates exemption which is largely harmonized with the exemptions available in other jurisdictions in Canada, will now be available for use in Ontario
- The FFBA Ontario Exemption is not available for use by investment fund issuers and, like the version of this exemption in Saskatchewan, will require the investor, the individual at the issuer with whom the investor has a relationship, and the issuer to complete and sign a risk acknowledgement form

SIGNIFICANT CHANGES TO CANADA'S EXEMPT MARKET FOR LIFE SCIENCE COMPANIES | *CONT'D*

Originally Published in: BLG News & Publications

- The founder, control person and family exemption currently in NI 45-106 and available to Ontario market participants, including investment funds and their founders and control persons, as well as their families, will be repealed

4. Short-term debt exemption (Short-term Debt Exemption)

- The credit ratings required to distribute short-term debt, which is primarily commercial paper, under the Short-term Debt Exemption have been modified

5. Short-term securitized products exemption (Securitized Products Exemption)

- A new exemption has been introduced to allow for the prospectus-exempt distribution of short-term securitized products that meet certain conditions

The Implications of the New Amendments

NI 45-106 has particular impact on issuers – including investment fund issuers and investment fund managers. Not only are the exemptions changing, but the CSA's expectations on issuers' compliance with the prospectus exemptions have significantly increased, as illustrated by the additional detailed commentary provided by the CSA in CP45-106.

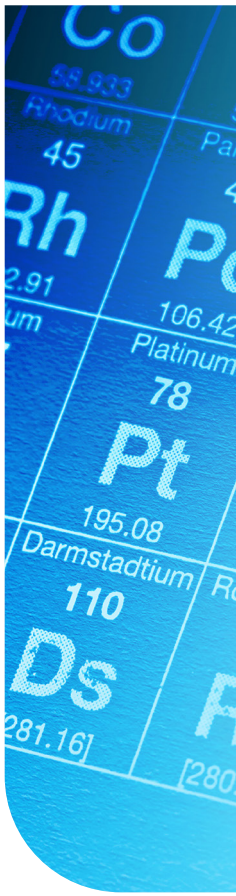
Update Subscription Agreements – As subscription agreements generally include references to the AI Exemption or MA Exemption, issuers should review and update these agreements to ensure that the new requirements are met, for example, by including a risk acknowledgement form for individual accredited investors, who don't meet the new net financial assets test noted above and to ensure that compliance with the new requirements is appropriately documented.

Update Offering Memoranda (OM) – If an OM is provided in connection with a prospectus exempt trade, the OM should be reviewed to ensure that the terms of the AI Exemption and MA Exemption, and the subscription instructions, reflect the updated rules. If an OM has been prepared to meet the "OM exemption" requirements set out in section 2.9 of NI 45-106 (the OM exemption is available in certain provinces, most notably British Columbia and is not affected by the amendments) the OM needs to be updated to include updated audited annual financial statements no later than 120 days after the financial year end of the issuer (that is, by April 30 for an issuer with a December 31 year-end). Issuers and fund managers who are in the process of updating their OM to include updated financial statements should also review the OM to ensure that the terms of the prospectus exemptions are correctly described.

Update Compliance Policies and Procedures – Issuers (and their managers in the case of investment fund issuers) should review, update and/or prepare compliance policies and procedures to reflect the amended rules and increased guidance in NI 45-106.

Registrants, particularly exempt market dealers, will need to ensure that dealing representatives, as well as executive and compliance staff understand the nature of the changed prospectus exemptions that issuers can use to issue securities to their clients, as well as the enhanced record-keeping and "know your client" expectations that these amendments will have on their dealings with clients.

Review Agreements with Selling Dealers – If an issuer wishes to rely on a selling dealer to help document the availability of a prospectus exemption (for example, that the investor meets one of the financial tests set out in the definition of "accredited investor"), that may need to be better reflected in the subscription agreement and/or a dealer agreement. This is particularly relevant given the CSA's enhanced guidance on their expectations in this area in CP45-106.



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PATENTS

QUICK TIPS ON CANADIAN PATENT PRACTICE

Double Patenting and Selection Patents

Double Patenting

Canada has strict double patenting laws. The claims of two (or more) patents must be "patentably distinct" (i.e. novel *and* inventive) in view of one another. Canadian Examiners may not be aware of related applications during prosecution. It is therefore important to deal with related cases proactively, preferably before any patent issues. Terminal disclaimer is not available as a remedy and claims cannot be amended after issuance to deal with double patenting issues. Double patenting is a common ground of invalidity during litigation.

Divisional Applications

Applicant-directed ("voluntary") divisional applications are not advised in Canada due to our laws on double patenting. It is important to ensure that the claims of a single application cover all aspects/scopes of the invention to be protected. There are no excess claim fees in Canada and multiple-claim dependencies are permitted. A divisional application filed in response to a Canadian unity of invention objection is protected from a future double patenting challenge.

Selection Patents

Selection patents are permitted in Canada if the selection possesses an unexpected advantage (or lack of disadvantage) and *that advantage is disclosed in the patent specification*. Comparative data can be helpful. Extrinsic evidence cannot be relied upon to demonstrate a proper selection.

Expedited Examination

Patent Prosecution Highway

The Patent Prosecution Highway (PPH) provides a means to accelerate prosecution by conforming the Canadian claims to those allowed or granted in a foreign jurisdiction with which Canada has a PPH agreement. Claims of multiple cases from one Jurisdiction may be combined. Currently, there is no government fee for making a request under PPH.

Due to Canada's laws on double patenting, it is important to ensure that the claims pursued under PPH cover all aspects/scopes of the invention to be protected since voluntary divisionals are not advised. It is common for Applicants to base the PPH request on a limited claim set granted in another jurisdiction. In such cases, Applicant may be surrendering scope of protection that could have otherwise been pursued in Canada.

Special Order

An alternate mechanism for expedited examination, that is more flexible than the PPH, is Special Order examination. Special Order is requested by stating that failure to advance the application is likely to prejudice the Applicant's rights; the official government fee is $500.00. Under Special Order, the claims in Canada are not necessarily limited by conforming to allowed claims in a foreign jurisdiction.

QUICK TIPS ON CANADIAN PATENT PRACTICE | *CONT'D*

Green Technology Applications

A further mechanism for expedited examination relates to Green Technology Applications. If the application relates to "technology the commercialization of which would help to resolve or mitigate environmental impacts or to conserve the natural environment and resources", the government fee is waived.

Regulatory Considerations

Notice of Compliance (NOC)

If the application relates to a medicinal product for which regulatory approval in Canada has been (or may be) sought, the resulting patent may be eligible for listing on the Patent Register, which has significant benefit to innovators. To be eligible for listing, the patent must have a claim explicitly directed to the medicinal ingredient, use, dosage form or formulation for which approval is ultimately granted.

Patented Medicines Price Review Board (PMPRB)

The Patented Medicines Price Review Board (PMPRB) regulates the prices of patented medicines in Canada. If a patent relates in any way (i.e. "by the merest slender thread") to a commercial drug product in Canada, then the resulting patent must be reported to the Patented Medicines Price Review Board (PMPRB). This is the case even if the claims recite an unapproved medical indication, a process or polymorph not currently in use, or the patent cannot otherwise be listed on the Patent Register. Should the PMPRB determine that the issued patent relates to a commercial product, the PMPRB will have jurisdiction to determine the maximum price of such commercial product until the patent expires or permanently lapses, even if other patents covering such products per se have expired. Moreover, such jurisdiction will be retroactive to the date of publication of the application and could thus potentially effect sales from previous years. These issues should be considered before paying the final fee.

Inoperable Embodiments

In Canada, if a claim is found to encompass an inoperable embodiment, the entire claim is invalid. Claims of intermediate and narrow scope are therefore valuable from an enforcement perspective.

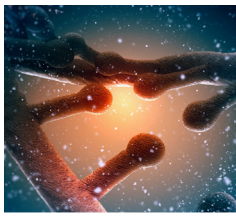
Claims may be amended any time during prosecution. There are no claim fees in Canada, and multiple-claim dependencies are permitted.

Patent Eligible Subject Matter

Methods of medical treatment (e.g., Method of treating condition X by administering Y) are not patentable in Canada. However, such claims may be rewritten in to corresponding "Use-Type", "Swiss Style" and "compound/composition for use", type formats, which are not directed to methods of medical treatment and are permissible in the Canadian Patent Office.

Method of diagnosis claims should be permitted if no "treatment" steps are claimed. However, these cases appear to have been set aside in the Patent Office pending the issuance of a practice notice.

Higher life forms are not patentable. Claims to genes, cells, methods of making or using the higher life forms are currently patentable.



CORPORATE

IMPORTANT NEW PRINCIPLES IN CONTRACTUAL NEGOTIATIONS

Originally Published in: BLG News & Publications

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In November 2014, the Supreme Court of Canada ("SCC" or the "Court"), in the case of *Bhasin v Hrynew,* recognized a new duty for contracting parties: the "honest performance" of contractual obligations. Pursuant to this new duty, "parties must not lie or otherwise knowingly mislead each other about matters directly linked to the performance of a contract". The Court does not see this as imposing a positive duty of disclosure: it distinguishes between "active dishonesty", which is not permitted, and failure to disclose a material fact, which appears to be.

The SCC also recognized for the first time in Canadian common law that there is a "general organizing principle" of good faith contractual performance. Pursuant to this principle, "parties generally must perform their contractual duties honestly and reasonably and not capriciously or arbitrarily".

The Court's view is that the principle of good faith contractual performance is grounded in the reasonable expectations of commercial parties, whom the Court finds "expect a basic level of honesty and good faith in contractual dealings", despite remaining at arm's length. The Court was careful to note that this principle must be applied in a manner that is consistent with the common law of contracts, including the freedom of parties to act in their own self-interest.

As an "organizing principle", good faith contractual performance is not a free-standing legal rule, but rather a standard that will inform more specific legal doctrines – such as, for example, the new duty of honest performance.

The new duty of honest performance applies to all contracts. While parties to a contract cannot contract out of "honest performance", the Court allows that the content of the duty and standards for satisfying it may be defined in an agreement, as long as the parties respect the duty's "minimum core requirements".

This decision will have far-reaching implications for parties to Canadian contracts. Parties will need to consider whether they are discharging the new duty of "honest performance" when performing a contract. If a given course of action may be construed as actively dishonest or misleading, businesses should avoid pursuing it unless prepared to accept the risk of litigation. We expect that the decision will lead to new litigation alleging breach of the duty of "honest performance".

While the decision was an attempt to provide some certainty and predictability in an area which has to date been inconsistent and unclear in Canada (outside of Quebec), the decision leaves a number of questions open: How will the new duty of honest performance be measured? What are its "minimum core requirements"? Is it a free-standing cause of action? How will damages be assessed? Will other new duties be recognized under the newly-recognized organizing principle of good faith performance?

Another open question is how the decision will be applied to pre-contractual dealings, such as negotiations. It may be that a duty of honesty in contractual negotiations would be imposed in circumstances where parties are bound by an existing agreement. It is important to reiterate that the new duty of honest performance does not impose a positive duty of disclosure, which presumably would include parties' negotiating positions. The decision is clear however that "active dishonesty" would not be permitted if the duty of honesty were to be imposed in the context of contractual negotiations.

GENERIC WINDFALL IN SECTION 8 DAMAGES CLAIMS UPHELD BY THE SUPREME COURT OF CANADA

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Canada has had, since 1993, a system linking generic drug approval to preliminary clearance of certain patent hurdles. Proceedings brought pursuant to this system are generally referred to as "NOC Proceedings". In return for this linkage system, the Canadian Government enacted a provision in the *Patented Medicines (Notice of Compliance) Regulations* (the *NOC Regulations*), whereby the innovator can be held liable in damages to any generic company it kept off the market while a proceeding determining whether the generic had preliminarily cleared those patent hurdles was pending. As this provision is found in section 8 of the *Regulations*, these proceedings are commonly known as "Section 8 Proceedings".

The damages under this provision have been likened to damages owed if an interlocutory injunction is granted but the case is not proven. However, a "hypothetical world" must be created by the Court to try to recreate the scenario that would have occured if a generic company, who was successful in a NOC Proceeding, had entered the market at an earlier time. As a result of the legal uncertainty surrounding the conditions of this hypothetical world, recent Court decisions have resulted in a windfall to generic companies when these damages are calculated in the face of multiple NOC Proceedings against multiple different generic companies.

In 2014, the Federal Court of Appeal heard two appeals relating to section 8 damages claims.[1] Both were split decisions. The drug at issue was ramipril. The main dispute between the members of the Court centered around how to determine the date that potential competitors would enter the market in the hypothetical world. This date, as it related to generic companies other than the claimant, would impact the quantum of damages owed to the claimant, as the hypothetical date of market entry for these other generic companies determines the size of the hypothetical market captured by the claimant.

The innovator argued that the overall market in the hypothetical world should be the same as it is in the real world, and that the dispute should be over how much of that market should be apportioned to each different generic claimant. However, the majority of the Court disagreed, holding that in each separate claim for section 8 damages, the evidence presented should determine the claim. Furthermore, while calculation of damages requires that the *NOC Regulations* be suspended for the purposes of the generic claimant, the Court of Appeal held that the *NOC Regulations* are not suspended for the purposes of considering when any other generic company may have hypothetically entered the market.

Thus, when multiple generic companies claim section 8 damages, the size of the generic market can be determined for each of them independently, and without any real-world knowledge of when each company actually entered the market after the conclusion of their respective NOC Proceedings. As a result, the quantum of damages required to be paid out by the innovator in such situations could be larger than the actual generic market. Since that money is being paid to the generic claimants, they would necessarily be obtaining a windfall in that the sum awarded that will be greater than what they earned in the same real-world time period. This is contrary to the purpose of damages, which are meant to compensate for loss, not provide a windfall.

In the Apotex case, the Supreme Court of Canada granted Sanofi-Aventis leave to appeal. This gave innovators hope that the Supreme Court would sort out the jurisprudence and overturn the generic windfall that had been granted by these decisions. However, on April 21, 2015, the Supreme Court heard the case, and dismissed Sanofi-Aventis' appeal from the bench.[2] No substantive reasons were issued; merely a statement that the appeal was dismissed substantially for the reasons of the majority of the Court of Appeal. It was a unanimous decision.

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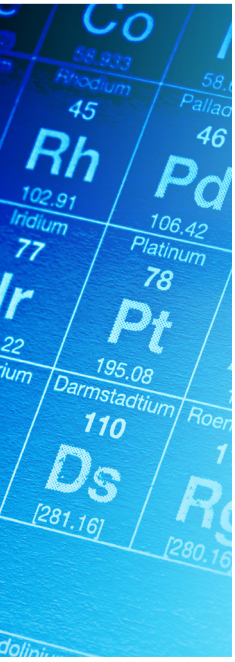
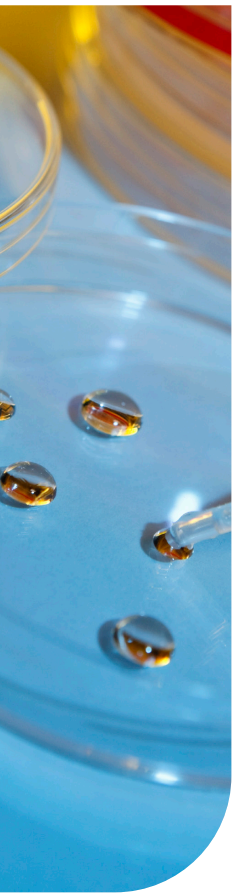
[1] *Apotex Inc. v. Sanofi-Aventis*, 2014 FCA 68; *Teva Canada Limited v. Sanofi-Aventis*, 2014 FCA 67.

[2] *Sanofi-Aventis v. Apotex*, Case No. 35886, dated April 21, 2015.

[3] *Sanofi-Aventis v. Novopharm*, 2009 FC 1285.





LITIGATION

GENERIC WINDFALL IN SECTION 8 DAMAGES CLAIMS UPHELD BY THE SUPREME COURT OF CANADA | *CONT'D*

Since the Federal Court in these cases had earlier dismissed a motion to consolidate or hear the section 8 claims from different Since the Court in these cases had earlier dismissed a motion to consolidate or hear the section 8 claims from different generic companies together, holding only that they should be heard consecutively by the same judge,[3] it remains to be seen if the decisions of the Court of Appeal and the Supreme Court will affect the outcome of further such motions. This result is also particularly concerning given that an innovator seldom has a right of appeal in NOC Proceedings, and furthermore, there is a rise of jurisprudence holding that it is an abuse of process for an innovator to maintain a proceeding against a second generic company once an allegation that the patent at issue is invalid has been found justified. Without any right to appeal, or have individual cases determined, it seems unfair to then further require the innovator to pay out more than it would have otherwise lost had it not started NOC Proceedings in the first place.

[3] Sanofi-Aventis v. Novopharm, 2009 FC 1285.

SIGNIFICANT CHANGES TO CANADIAN PATENT PRACTICE ON THE HORIZON

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Over the past year, Canada has implemented amendments to its IP laws to comply with a number of international treaties. On December 16, 2014, amendments to the Canadian *Patent Act* received Royal Assent. The amendments aim to fulfill Canada's obligations under the *Patent Law Treaty*, and to align aspects of the Canadian system with other countries. Some of the changes will, no doubt, seem familiar to non-Canadian practitioners, but nonetheless represent a significant watershed for Canadian practice. The date on which these amendments and related regulations will be in effect is not currently known, and much uncertainty remains until draft regulations are published.

The amendments do not include those to address Canada's obligations under the Canada Europe Trade Agreement (CETA), in respect of which further amendments are likely to be introduced later in 2015.

Simplified Administrative Procedures

One object of the amendment is to simplify filing procedures. It will be possible, for instance, to obtain a filing date in Canada without a fee and without a translation into English or French. If part of a description or drawing is omitted at filing, an applicant will be able to subsequently include it even if it adds new matter (a later filing date may then apply). Incorporation-by-reference of a previously-filed application will be permitted, and restoration of priority will be available in Canada up to 14 months from the priority date, provided that the failure to file within the initial 12-month period was "unintentional" and provided that any yet-to-be determined "prescribed conditions" are met. The one-year grace period for inventor-derived disclosures will be extended to cover applications with restored priority.

In the spirit of simplified administrative procedures, the amendments also specify that a patent will not be declared invalid by reason only that the application on the basis of which the patent was granted was not maintained in effect. This amendment is likely in response to recent Court decisions on this issue.

Reinstatement

The regulations will have particular impact in one area, namely reinstatement, which will only be possible if an applicant can show that the failure to take action that led to the abandonment occurred despite "due care" being taken. Under the revised *Act*, the Commissioner of Patents may create rules to determine the standard and when it applies. To date, reinstatement has been available as of right in Canada within one year of a missed deadline, and applicants often use the abandonment period to obtain additional time to take action. Reinstatement is also currently the only way for applicants to add claims and restart prosecution after allowance: an important mechanism in view of peculiar local laws for double patenting. The coming regulations will determine whether the amendments to the *Patent Act* will spell the end of flexible abandonment and reinstatement practice, and could have significant ramifications for how potential double patenting situations are addressed.

SIGNIFICANT CHANGES TO CANADIAN PATENT PRACTICE ON THE HORIZON | *CONT'D*

Infringement and Intervening Rights

The amendments also provide clarification on the issues of infringement and third party intervening rights. For example, there will be no pre-grant infringement until the specification is published in English or French. Furthermore, during an abandonment period when the "due care" standard for reinstatement applies, third parties will be protected from "good faith" acts that would otherwise have constituted infringement.

Timing and Details of Coming into Force

The Commissioner of Patents is granted broad new rule-making authority under the amendments, and, at the time of writing, draft regulations have not yet been published. Accordingly, it is not yet known precisely how and when these amendments will be implemented. The Patent Office has indicated that draft regulations should be published for consultation by late 2016, and it seems likely that both the amendments and the regulations will come into force by early 2017.

Privilege

Further amendments to the *Patent Act* are currently pending before Parliament. These amendments include long-sought provisions providing privilege for communications between registered patent agents and their clients for matters relating to the protection of an invention. This agent privilege will bring Canada into line with privilege existing in other countries.

CHANGES IN CANADIAN INSTITUTES OF HEALTH RESEARCH FUNDING: WHAT WILL BECOME OF CIHR PROOF OF PRINCIPLE COMMERCIALIZATION GRANTS?

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As all Canadian health researchers are undoubtedly aware, CIHR is in the throes of reforming the investigator-driven grants program. Major changes are afoot. Gone are the days of investigators gathering from across Canada to cloister themselves together in Ottawa hotel meeting rooms, fueled by mediocre coffee and chicken-wrap sandwiches, pondering the merits of the grant applications of their peers. The new grant review process is primarily electronic, drawing from a pool of reviewers within the newly formed College of Reviewers. Nostalgia for the past and the intangible benefit of these face-to-face gatherings cannot rival the undeniable efficiencies promised by the new scheme.

The previous Open Funding opportunities (primarily operating grants) will be phased out entirely. CIHR operating grants as well as most other themed CIHR grants will be replaced by two new funding schemes: a *Foundation Scheme* and a *Project Scheme*. Available money for grants will not be reserved or apportioned to specific technologies within a technologically distinct peer review committee (such as biomedical engineering, cardiovascular, endocrinology, etc), as had previously been the case for review of operating grants applications.

Foundation Scheme grants will fund individual investigators, for a period ranging from 5 to 7 years, with an annual dollar value of $50,000 to $1.5 million. The grants are awarded on the basis of an individual's track record, while taking that person's proposed research into consideration.

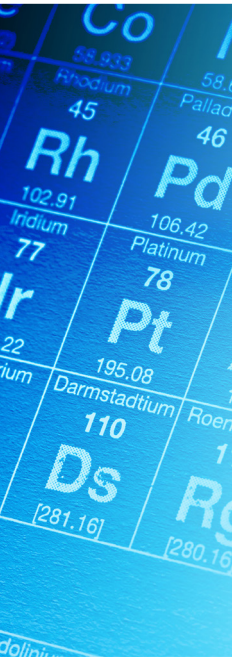
Project Scheme grants will fund projects based on the calibre of the proposed idea. The merits of the proposed work, and to some extent the calibre of the individual or team proposing to conduct the work, is evaluated. Project Scheme grants can be proposed for a 1 to 5 year period, with an ask ranging from $50,000 to $750,000.

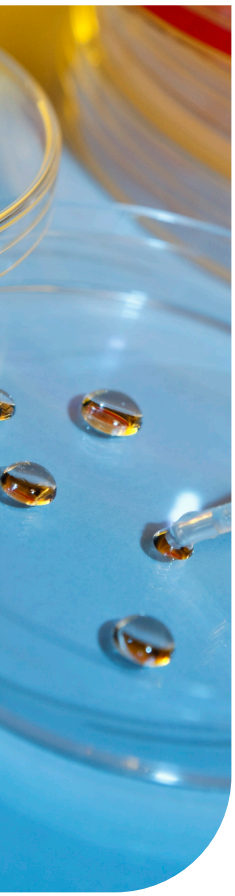
Pilot competitions for each of the Foundation Scheme and Project Scheme categories are being conducted. Electronic reviews are happening, and interactive on-line discussions are a reality. There is no turning back. Anecdotally, it seems that the enthusiastic banter of the face-to-face discussions is missing from the interactive comments posted in the pilot competitions. Admittedly, these anecdotes are based on a very small sampling of comments from pilot participants as relayed to this author. Nevertheless, it seems that the health researchers have accepted the change, and a willingness to adapt.

There is one small but notable CIHR legacy grant program that has not yet faded into the sunset of the reformation: the *Proof of Principle Commercialization Grant Program* affectionately known as "PoP", which has funded commercialization grants since 2001. The PoP program has typically run two competitions per year, and will launch the final competition in June 2015 (application deadline: September 2015). In January 2016 this program will lose its individual identity, but CIHR intends to keep a similar the funding opportunity available under the *Project Scheme* category. The applicants and reviewers who have been integrally involved with the PoP program through the years are hoping that certain aspects of this unique program will be maintained to that research-derived inventions with commercial potential can continue to be eligible for early stage funding, before a commercial partner is identified. The diverse make-up of the review committee, and the unique method for assessing commercial potential in the grant review process, are but two aspects that have distinguished PoP from most other CIHR grants to date.

In the final program launch for the legacy program of PoP grants, two different phases of grants will continue to be offered. Phase I provides up to $160,000 to academic investigators with projects of potential commercial application, if the intellectual property is not yet licensed outside of the originating university. Phase II provides up to $300,000 to academic investigators to match the funds committed by a commercial partner.

The PoP grant program has provided a niche source of funding not only to academic researchers, but also offered advantages to industrial partners collaborating with such researchers through matching partnered grants. Researchers with commercially relevant projects were able to seek funds to ascertain commercial potential, and bring inventions from a more conceptual stage to a more commercially attractive stage with funds made available through this program. Industry stood to benefit from the PoP program because academic researchers could seek matching funds to complement the





PATENTS

CHANGES IN CANADIAN INSTITUTES OF HEALTH RESEARCH FUNDING: WHAT WILL BECOME OF CIHR PROOF OF PRINCIPLE COMMERCIALIZATION GRANTS? | *CONT'D*

investment of a committed industry partner, to obtain proof of principle data to further support promising data, effectively doubling the money available to a project. PoP grant recipients have been the investigators to watch, in terms of future commercialization efforts, start-up companies, and industry collaboration efforts.

The last few legacy programs which have not been fully absorbed into the Project Scheme grants are commercialization grants and certain knowledge translation grants. "Knowledge translation" (or KT) is a term that encompasses (among other areas) *policy* for health care services and the health care system. The PoP grants have developed a tailored application processes, which cannot be replicated in the common Project Scheme application form. For Example, the PoP application asks applicants about what problematic *prior art* may have been located (known publications or patents that could deter patentability of their invention); whether the applicant believes there is *freedom-to-operate* for the proposed commercial plan (read: whether other blocking patents are known to exist); and what the commercial landscape looks like (a review of competing technologies). Savvy PoP applicants address regulatory hurdles, market entry barriers, and identify receptor companies, all in the span of the current 14-page limit application.

With the efficiencies of a common application form for all Project Scheme grant applicants, the nuances of information needed to specifically evaluate commercialization potential of a technology may be lost.

In an effort to ensure a smooth transition, CIHR has advised that a *minimum funding threshold* will be established for commercialization and KT applications (together), once these are absorbed into the Project Scheme. The dedicated community of PoP reviewers, drawn from technology transfer offices, private industry, commercialization specialists, venture capitalists, patent agents, and successful applicants, is making efforts to advise of ways in which commercialization grants can best be evaluated within the Project Scheme by appropriately identified reviewers within the College of Reviewers. PoP applicants in the legacy application process, are able to request funding for up to $32,000 in commercialization activities, including $15,000 for patenting costs. Such funds typically offset the costs of drafting and filing a patent application within the 1-year term of the award, or address ongoing costs of previously filed patent applications. There is a suggestion that such expenses (assuming specific justification) will be permitted as budget items for any application within the Project Scheme.

By bringing commercialization grants into the Project Scheme, CIHR suggests that commercialization *per se* need not be viewed as a separate and distinct activity from research. Commercialization of research is ready for *prime time*. If commercialization grants had remained limited to separate and limited budget, perhaps opportunities would be lost. If commercialization expenses become eligible to all applications asserted within the Project Scheme, perhaps more investigators will be encouraged to embrace commercialization as a natural extension of their research program. Commercialization of technologies developed with CIHR funding is an important step in improving the health of Canadians, and others world-wide. With change can come opportunity.

Dr. Kathleen Marsman is the current Chair of the CIHR Proof of Principle grant review committee, with which she has been involved since 2003. Kathleen is a patent agent in the Ottawa Office of Borden Ladner Gervais LLP.

THE TORTOISE AND THE HARE: FLEXIBLE EXAMINATION OPTIONS IN CANADA

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In Canada, examination of applications occurs only upon request and such a request can be deferred for up to five years from the filing date. Once a request for examination has been made, the application is placed in queue and is examined relative to its order in the queue. In certain situations, an Applicant may wish to expedite or streamline prosecution thereby reducing financial and human resources. There are three options for requesting expedited examination in Canada:

- the Patent Prosecution Highway program;
- Special Order, under paragraph 28.(1)(a) of the *Patent Rules*; and
- expedited examination of Green Technologies under paragraph 28.(1)(b) of the *Patent Rules*.

Patent Prosecution Highway (PPH): Now Available for European Applications

The PPH project is an initiative aimed at expediting the patent prosecution process, whereby a patent office in one country may rely on the search and examination work conducted by a participating foreign patent office indicating that a claim is allowed or allowable. This expedited process can reduce prosecution costs to both the patent applicant and the patent office.

The Canadian Intellectual Property Office (CIPO) has entered into PPH agreements with patent offices in a number of foreign countries, including the United States (US), United Kingdom, Germany, Japan, South Korea, Denmark, Finland, and Spain. In January 2015, CIPO entered into a new pilot agreement with the European Patent Office. This bilateral program is based on both nationally filed and Patent Cooperation Treaty (PCT) applications. Once the applicant has obtained allowable claims in Europe or a participating PPH country, a request for expedited examination under the PPH can be filed with CIPO, provided that the Canadian application entered the National Phase on or after January 6, 2015.

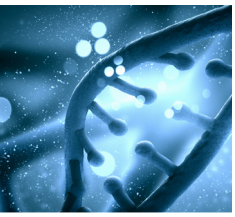
In order to enter the PPH, the Canadian claims must "sufficiently correspond" to the allowed claims, the application must be laid open to public inspection, and examination must be requested. Amendment of the claims is permitted at the time of the request and it is noted that "sufficiently correspond" is flexibly interpreted in Canada (e.g. "use' claims may be pursued in Canada on the basis of allowed "method" counterparts). Importantly, the request must be made before examination in Canada has commenced. According to statistics released by CIPO, PPH applications have a higher grant rate and receive fewer Office Actions than applications being examined in the regular stream. There are no government fees associated with entering the PPH program.

Special Order

In cases where expedited examination is desired, but examination has already commenced, it may still be possible to advance prosecution by requesting "Special Order" under paragraph 28.(1)(a) of the *Patent Rules*. In order to be accepted for Special Order status, the Applicant must pay a $500 government fee and submit a declaration that states that failure to advance the application is likely to prejudice the Applicant's rights.

The Canadian Patent Office requires that an application be examined within 2 months of receiving a request for examination under Special Order status. A response from the Applicant is required within 3 months from the date of issuance of an Examiner's report and an Examiner's report must be issued within 2 months of receiving such a response.

Under the current *Act* and *Rules*, Canada has flexible abandonment and reinstatement procedures. It should be noted that if an application that is being prosecuted under Special Order is allowed to go abandoned, it will lose its Special Order status. This is not the case with applications being prosecuted under the PPH.



PATENTS

THE TORTOISE AND THE HARE: FLEXIBLE EXAMINATION OPTIONS IN CANADA | *CONT'D*

Green Technologies

If an application relates to "a technology, the commercialization of which would help to resolve or mitigate environmental impacts or conserve the natural environment and resources" examination may be advanced under paragraph 28.(1)(b) of the *Patent Rules*, by requesting advancement and submitting a declaration. No government fee is required.

Conclusion

In Canada, there is an opportunity to defer examination up to 5 years from the filing date, which may be desirable in cases where an Applicant wishes to delay examination and, consequently, defer costs and decisions. There are several routes for expediting patent examination in Canada and for reducing worldwide prosecution costs. The route that an Applicant chooses will depend on the technology and the status of prosecution of the application in Canada and elsewhere. Borden Ladner Gervais can assist in determining an appropriate strategy for accelerating or deferring examination of a particular case in Canada.

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