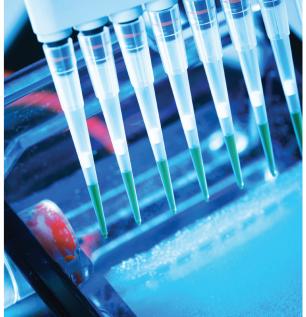


# LIFESIGNS - LIFE SCIENCES LEGAL TRENDS IN CANADA







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### MESSAGE FROM BLG



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Ottawa 613.787.3583 pfortin@blg.com Borden Ladner Gervais LLP (BLG), as Canada's leading life science practice, is engaged in all facets of the commercialization of life science technologies in Canada. Our national platform ensures that we have a vital stake in the future of life sciences in all parts of the country.

What distinguishes BLG's practice from a number of other Canadian law firms is the highly integrated nature of our practice. Our IP patent agents and lawyers work closely with regulatory, venture capital, public markets, employment and competition lawyers for clients that span the boundaries of the sector, from benchtop to board room. In recent years our IP litigators have been at the forefront of efforts to protect the crucial value of the intellectual property assets of our larger pharmaceutical clients. Our private equity/venture capital and public markets colleagues have established a reputation for practical, pragmatic and cost effective capital markets advice. Our extensive national health institutions practice ensures that we are at the table when Canada's leading research institutes are involved in licensing out promising technologies with commercial value.

After a number down years, the Canadian life science sector is continuing to strengthen and BLG's practice over the past year has grown significantly. A new government in Ottawa and the continuing commitment of provincial governments' right across the country means that the prospects for the sector in Canada have never been better — from human health to the environment to our food supply. Substantial sources of capital are once again flowing into the sector in Montreal, Toronto-Waterloo and Vancouver. In each region of Canada, BLG is working with investors and entrepreneurs to advance the commercialization of life sciences technology.

Access to capital continues to be a top issue for early stage companies. This fall, BLG, in partnership with leading firms in Canada and abroad, will launch a Global Access to Capital Program. This Program will bring to our clients and friends an enhanced network of our global contacts for their benefit. It is time for our firm to make a meaningful contribution to the access to capital issue and we look forward to working with all of on this important endeavour.

Finally, our LifeSigns publication is now a major part of our sector communications strategy. We hope that you find many of the articles to be of interest. If there are any topics covered on which you would like additional information please reach out directly to the authors or contact the undersigned. We are at your service.





Russell Williams President of Innovative Medicines Canada



#### INNOVATIVE MEDICINES CANADA

Innovative Medicines Canada represents Canada's innovative pharmaceutical industry. We advocate for our members who discover, develop, and deliver innovative medicines and vaccines. From start-ups to established global organizations, our 50 members companies are revolutionizing healthcare through the discovery and development of new medicines and vaccines.

Guided by a strict Code of Ethical Practices and a commitment to ethics and integrity - from the moment we invest in the research and development of a new molecule, all the way through clinical testing and post-marketing - we work in partnership across Canada with patients, governments, research organizations and healthcare professionals to advance the field and enhance the wellbeing of Canadians.

Innovative medicines and vaccines allow Canadians to live longer, healthier lives. Not only do innovative medicines and vaccines help prevent and often cure diseases, they also make substantial contributions to the healthcare system. New therapies help Canadians avoid costly hospital stays, invasive surgical procedures, and what can sometimes be a lifetime of chronic illness. Our companies are a critical part of the Canadian economy. Canada's life sciences sector supports over 31,000 high-quality jobs and contributes almost \$4-billion to our economy. With the right regulatory, financing and intellectual property policies, Canada can encourage growth in life sciences research and development.

Innovation is the gateway to a solid future for Canada's knowledge-based economy. We have what it takes to become an international economic powerhouse. Canadians can be proud of their researchers, scientists, infrastructure and patient communities. This is something Innovative Medicines Canada is showcasing for the world's pharmaceutical community as part of BIO 2016. Innovative Canada Members currently invest over \$750M each year in clinical trials in Canada and we work hard with our partners to make Canada a leading destination for clinical trials research. For example, as a partner of the Canadian Clinical Trails Coordinating Centre (CCTCC), we work to coordinate and implement operational efficiencies in clinical trials across Canada to better compete globally in the areas of speed, quality, and cost. We are proud of this unique commitment between industry, government and academia that sets us apart on the global stage.

At the foundation of a knowledge-based economy is the value of new ideas. New ideas turn into new inventions. New inventions can give Canada an edge to compete on a global scale. This is no different for the innovative pharmaceutical sector. All it takes is one idea to spark a new life-saving discovery. And like in other industries, ideas in the pharmaceutical sector not only have to be protected, they should also be rewarded.

To compete on this global scale, Canada needs to have laws and regulations that put us on par with other similar advanced economies in order for us to attract and develop these bright ideas at home.

One important example is the Comprehensive Economic and Trade Agreement (CETA) recently finalized between Canada and the European Union (EU). If implemented properly, CETA will help to bring Canada's intellectual property standards in line with those of the EU and will allow us to be better equipped to compete for global investments into the life sciences sector, not to mention the whole innovation economy. We support Canada and the EU in their goal to have the Agreement signed in 2016 and enter into force in 2017. Finalizing CETA will unlock access to the world's largest common market of 550 million consumers and spur annual economic activity of \$12-billion.

We believe in ensuring that Canadians have access to the innovative treatments they need and that our activities are a fundamental part of safeguarding our healthcare system for future generations. Our work allows our members to focus on what matters: delivering better healthcare solutions to Canadians.



Andrew Casey President and CEO



#### **BIOTECANADA**

#### Canada's Biotechnology Industry is Ready to Take Centre Stage

In January, Prime Minister Trudeau was asked about Canada's economic prospects in the face of an economic headwind in the form of a sagging Canadian dollar and struggling energy sector. The Prime Minister correctly noted Canada's economic strength lies not in one or two industries but in its economic diversity which includes being home to great science and innovation which has supported the establishment of a globally recognized biotechnology sector. The Minister of Innovation, Science and Economic Development, Navdeep Bains, further underscored the Prime Minister's views when he spoke to the importance of establishing Canada as an innovation-based economy. This represents an important recognition of the biotechnology sector as not only a stand-alone economic engine but also one that can act as the catalyst for Canada's economic competitiveness in a broader sense.

The views of the Prime Minister and Minister of Innovation are grounded in Canada's long and successful history in the development of modern biotechnology. Indeed, as a result of past success and innovation, Canada is now home to a thriving biotech ecosystem consisting of clusters in every province which bring together world-class universities and research institutes, biotech entrepreneurs, large multinational players, and a highly educated workforce. To illustrate, Canadian biotech companies are presently working on remarkable innovations such as: cancer treatments using shrew saliva and mosquitos; using tobacco leaves to change vaccine manufacturing methods; and, fuelling jets with oils derived from mustard seed. All told, the Canadian biotech ecosystem is an economic strength that positions Canada well to successfully deliver innovation to a world looking for solutions.

The world's population is predicted to grow to over nine billion people by 2050. This exponential growth brings with it enormous challenges as nine billion people will require new medicines, food, energy, and material goods. Moreover, as populations and economies grow, it is imperative that society develop more efficient and less impactful ways for humans to live on this planet. Within the social imperative of addressing this daunting global challenge lies the enormous economic opportunity for the innovative solutions biotechnology delivers. With its history and culture of innovation, Canada's biotech industry can play a central role in addressing these global challenges directly while also helping key domestic cornerstone industries such as forestry, mining, energy, and agriculture to transform and maintain their competitiveness in the global bio-economy.

Importantly, in achieving the government's stated objective of making Canada a "nation of innovation", the Innovation Minister has recognized the important strategic role Government must play to "cultivate a culture of innovation and entrepreneurship by providing the necessary conditions to enable a thriving innovation ecosystem across Canada". While Canada will undoubtedly continue to be home to game-changing innovation and scientific discovery, by establishing the right 'hosting conditions', government policy can greatly enhance the industry's ability to attract the talent and investment needed to successfully commercialize innovation in Canada.

At its very core, biotechnology is built on a transformative idea and its supporting science. Unlike many other industries with either large infrastructure or immovable assets, the 'idea' at the core of biotech is exceedingly mobile. In this context, Canada must take the steps necessary to establish itself as a jurisdiction that is supportive of investment and commercialization. By retaining the innovation, Canada will benefit greatly from the significant economic, health and social benefits associated with the commercialization process.

Recognizing the central role public policy plays, the federal government has begun the process of developing a National Innovation Agenda to support innovation and attract investment. Other nations recognize the importance of a competitive biotechnology sector to their domestic economies and many have moved to put in place national blueprints or strategic plans to support their biotech industries. And as the BIO trade show floor clearly demonstrates, other nations are also vigorously trying to attract biotech companies and investors to their jurisdictions. By developing an Innovation Agenda, Canada is keeping pace with competing nations and ensuring the Canadian biotechnology industry is well positioned to build on its natural strengths to become a global leader and support Canada's economic competitiveness more broadly.



Scott Moffit Managing Director, BioNova



#### **BIONOVA**

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

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

A recent survey has provided a snapshot of the industry:

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

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



Jason Field, Ph.D. Chief Executive Officer



#### LIFE SCIENCES ONTARIO

#### Our next big challenge: Channeling the successes of Ontario's Life Sciences Sector

In our sector, we talk a lot about encouraging innovation. Of course, it's important to focus on forward momentum — on how we can do things smarter, faster, more efficiently. However, to secure our success on a global scale, we must also spend equal time and effort telling the world about what we're doing right — and in many cases, first, and better, than any other jurisdiction in North America.

Ontario is a province of innovators, though I'm not sure we always see ourselves that way. We're among the top clusters in North America — one of the three most significant life science jurisdictions by number of establishments, and among the top ten by number of workers. This should be no surprise for a sector that contributes \$21.6 billion annually to Ontario's GDP.

Our job market has proven resilient, as well; our life sciences workers earn 26.5% more than the provincial average, and benefit from a job market that has grown 25.1% since 2001, compared to a provincial average of 15.9%.

I firmly believe that part of the reason we've had difficulty measuring and promoting our success is that our sector has traditionally had little in the way of benchmarking. With this in mind, last year Life Sciences Ontario undertook an industry-first study – our 2015 Life Sciences Sector Report – which helped quantify Ontario's achievements and verify that our province is a force to be reckoned with when it comes to innovation in biotech, pharmaceuticals, medical technologies, and the agri-food industry.

But, the question remains: do we see ourselves as world leaders in innovation? And, if so, are we willing to get loud about our successes? If we want others to recognize our potential and invest in our innovations, we must collectively raise our voices.

For instance, did you know that Ottawa company eSight has developed mind-blowing digital eyewear that allows the legally blind to see? That Synaptive Medical's "neural GPS" is helping surgeons reduce risk and better navigate the brain in 3D — and this technology is now in use in hospitals as far away as Pakistan? How about the Guelph biotech company, PlantForm, using tobacco plants to produce low-cost treatments for cancer and HIV/AIDS?

These are only three examples of world-class innovations happening in Ontario's life sciences sector as we speak. There are many more.

These are the superheroes of our sector — the companies and organizations creating the technologies that will secure our health and economic prosperity for generations to come — both within Canada and on a global scale. Who are they? What are their stories?

We must tell them – and tell them again – until Canada is known for its research, biotechnology, and medical innovation as much as it is known for hockey, polar bears, and the northern lights.

If you're an Ontario innovator, we want you to stand up and be counted; we will help amplify your voice. Tweet us with the hashtag #OntarioInnovation, join us at our international networking event, and make yourself at home in the Ontario Pavilion.

Prime Minister Justin Trudeau recently stated that Canada is widely recognized for its resources, but we should be also known for our resourcefulness. This is what innovation means. We already have the makings of a world-class life sciences sector; now we must tell that story writ large. This is the crucial piece that will drive not only international recognition, but also help fuel needed policy change within our sector. The opportunity is exponential and the time is now.



Paul V. Drohan President & CEO, LifeSciences BC



#### LIFE SCIENCES BC

#### Life Sciences in British Columbia, Accelerating with Vitality

British Columbia's life sciences industry is a significant economic contributor enjoying a growth phase. Over 300 companies from biotechnology, pharmaceuticals, diagnostics, medical devices, medical technologies and digital health call British Columbia home. With 177,000 employees and \$14.4B in direct GDP contribution, the life sciences industry is embedded in the larger life sciences ecosystem in the province, which brings together academia, health institutions, hospitals, government and industry. Each play a vital role in the commercialisation of innovation.

Our industry relies on academia for the discovery and development that our entrepreneurs use to fuel innovation. In turn, the rapid identification of commercial potential leads to an environment in which pre-clinical and clinical research can be performed within our health institutions and hospitals.

Government provides meaningful support for early stage companies as well as the infrastructure relied upon to research and develop innovation. To create a life science company, we need both entrepreneurs and a robust life sciences ecosystem, to help grow and mature commercial innovations.

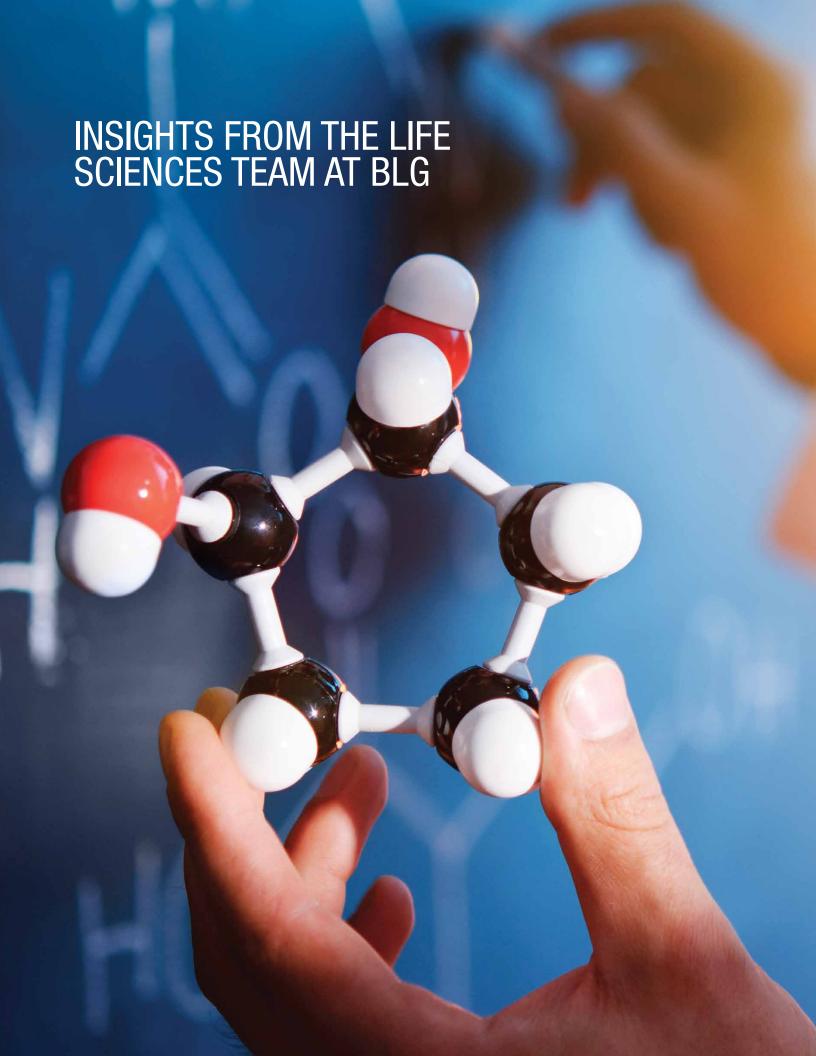
In British Columbia, we have the ingredients to successfully and frequently, commercialise innovation. We are home to one of the most entrepreneur-rich regions in North America. Developing companies is one of our strengths, and B.C. has more young companies with ten or more employees than anywhere else in Canada. We are also supported by one of the most active angel investor communities in Canada, in part due to the thoughtfully-conceived EBC (Eligible Business Corporation) and VCC (Venture Capital Corporation) programmes of our province. Our strategic advisor community has helped craft unique and value-creating deals. We have the experience and success of accessing public markets, with no less than six British Columbian companies having IPOs (Initial Public Offerings) during the past 24 months, with five of the six, now listed on NASDAQ. We have our governments, both provincial and federal, who have renewed their support of this knowledge-based economy, (e.g. BC Tech Fund and the latest 2016 Federal Budget), that will fuel commercial development and advance our innovation to benefit the economy, and most importantly, patients.

To continue our success, what is it that we need?

- 1) We need synchronisation of our efforts within the province to a greater degree and coalesce collective energies around clear priorities for the life sciences sector;
- 2) we need to continue to support the best and the brightest research translation to commercialisation;
- 3) we need to constantly attract capital to fund the development of companies in one of the most capital intensive industries;
- 4) we need to continually attract global talent to develop our community and grow our company's knowledge and skill base; and,
- 5) we need to expedite access to innovation within the healthcare system so that those who need it most, namely British Columbian patients, can benefit first.

LifeSciences BC's commitment is to continue to play a central role in achieving this success. We will continue to catalyse locally, while connecting our community globally. This work is only possible with the support of our Sponsors and Members; for this, we would like to say thank you.

Our collective success is, and will continue to be, rooted in our past. When future entrepreneurs of British Columbia's life sciences companies look back on what we achieve in the next five years, they will hopefully be proud of the care and energy used to prioritise the development of our life science ecosystem. Our ability to work collaboratively will establish the foundation of our future bio-economy, delivering not only economic value for the province, but better health for all British Columbians.



#### INTELLECTUAL PROPERTY



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#### INTELLECTUAL PROPERTY | PATENTS

# THE FEDERAL COURT DOES THE HOKEY POKEY WITH THE DISCLOSURE REQUIREMENT IN THE SOUND PREDICTION OF UTILITY

The doctrine of "sound prediction" was ushered into Canadian law as a means to protect useful inventions. A review of the case law, however, reveals that it has evolved into the impetus for a sharp distinction between demonstrated and soundly predicted utility. As a result, uncertainty has arisen with respect to what the patentee must disclose to the public where utility is predicted.

The Supreme Court of Canada's (SCC) decision in *Apotex v Wellcome Foundation*<sup>1</sup> (*AZT*) marked the first step towards an elevated substantive requirement for the disclosure of a sound prediction of utility. In *AZT*, the SCC established a three-part test for sound prediction:

- 1. There must be a factual basis for the prediction;
- 2. There must be a sound line of reasoning; and
- 3. There must be proper disclosure.

The jurisprudence in both the Federal Court (FC) and Federal Court of Appeal (FCA) demonstrates that the courts continue to struggle with the application of the third step relating to proper disclosure. On one extreme, courts have interpreted this element as requiring disclosure of the factual basis and sound line of reasoning for the predicted utility in the patent itself.<sup>2</sup>The "heightened" disclosure has resulted in several pharmaceutical patents being held invalid for lack of utility.<sup>3</sup> Other cases have found that this enhanced requirement for disclosure exists only in respect of patents claiming the new use of known compound.<sup>4</sup>

Importantly, there is no statutory basis requiring that predicted utility be disclosed within the patent and many question whether a utility disclosure requirement exists at all. While a valid patent requires public disclosure of its invention, the enhanced disclosure requirement to establish a sound prediction utility undermines the purpose of the patent system and violates Canada's treaty obligations. In particular, the disclosure requirement for sound prediction goes beyond the substantive requirements of both Article 29.1 of TRIPS and Article 27 of the *Patent Cooperation Treaty* (PCT), which provisions determine what is necessary to be disclosed in a Canadian Patent.<sup>5</sup>

#### **Recent Developments**

The unsettled law concerning the disclosure requirement continues to plague the FC and FCA in sound prediction cases.

<sup>&</sup>lt;sup>1</sup> 2002 SCC 77

<sup>&</sup>lt;sup>2</sup> See for example, Eli Lilly v Apotex, 2009 FCA 97 at paras 12-15; Eli Lilly v Novopharm, 2010 FCA 197 at para 83; Apotex Inc v Pfizer Canada Inc, 2011 FCA 236 paras 42-44 & 51-52; Eli Lilly Canada Inc v Hospira Healthcare Corp, 2016 FC 47; Allergan Inc v Apotex Inc, 2016 FC 344

<sup>&</sup>lt;sup>3</sup> See for example, Eli Lilly & Co v Teva Canada Limited, 2011 FCA 220; Sanofi-Aventis Canada Inc v Apotex Inc, 2011 FCA 300; Ratiopharm Inc v Pfizer Ltd, 2009 FC 711; Eli Lilly Canada Inc v Novopharm Limited, 2011 FC 1288

<sup>&</sup>lt;sup>4</sup> See for example, Sanofi-Aventis v Apotex, 2013 FCA 186 at 134; Astrazeneca Canada Inc v Apotex Inc, 2014 FC 638, aff'd 2015 FCA 158; Gilead Science Inc v Idenix Pharmaceuticals Inc, 2015 FC 1156.

<sup>&</sup>lt;sup>5</sup> Agreement on Trade-Related Aspects of Intellectual Property Rights, 15 April 1994, 1869 UNTS 299, art 29.1; Patent Cooperation Treaty, 19 June 1970, 28 UST 7647 as amended, art 27.







# THE FEDERAL COURT DOES THE HOKEY POKEY WITH THE DISCLOSURE REQUIREMENT IN THE SOUND PREDICTION OF UTILITY | CONT'D

Recently, it appears that the lower court has attempted to reconcile the disclosure requirement for predicted utility with previous case law and the fact that utility and disclosure are treated separately under the *Patent Act*.

In Astrazeneca Canada Inc v Apotex Inc (Nexium FC)<sup>6</sup>, Justice Rennie considered the issue of proper disclosure in the context of sound prediction. Justice Rennie concluded that there is no heightened disclosure requirement of utility in all sound prediction cases. Rather, the disclosure requirement "is limited to the context of 'new use' patents, assuming such a utility disclosure requirement exists at all." Justice Rennie relied on the SCC's comments in AZT, together with the SCC's orbiter comments from *Teva Canada Ltd v Pfizer Canada Inc*<sup>7</sup>, as the basis for his conclusion. Justice Rennie also noted that his interpretation of AZT was supported in Justice Gauthier's concurring remarks in the Federal Court of Appeal's decision in Sanofi-Aventis v Apotex (Plavix FCA).8

While not a complete resurrection of the original doctrine, Justice Rennie's view that enhanced disclosure applies only to "new use" patents represents a step in the right direction. On appeal, the FCA upheld the decision, but did not address Justice's Rennie's finding concerning the disclosure requirement with sound prediction utility.

More recently, Justice Rennie's conclusion was adopted in *Gilead Science Inc v Idenix Pharmaceuticals Inc*<sup>9</sup>, where Justice Annis held that there was no utility disclosure requirement in respect of Idenix's patent that related to a sound prediction of utility for a new composition.

Unfortunately, there have been two FC decisions in 2016 that have specifically rejected Justice Rennie's reasoning and reverted back to the elevated standard for disclosure. In *Eli Lilly Canada Inc v Hospira Healthcare Corp*<sup>10</sup>, Justice Barnes reaffirmed the disclosure requirement for sound prediction in all cases. Justice Zinn echoed this view in *Allergan Inc v Apotex Inc*<sup>11</sup>. In particular, Justice Zinn noted that in the absence of clear direction from the FCA or SCC, the factual basis and the sound line of reasoning, apart from matters of common general knowledge, must be included in the patent.

It is evident from these cases that the FC remains divided on the issue of proper disclosure in the context of sound prediction.

In March 2016, the SCC granted leave to appeal in the *Nexium* case. Hopefully, the SCC will address the issue of proper disclosure and provide some much needed guidance to restore the doctrine of sound prediction back to its original form.

<sup>6 2014</sup> FC 638, aff'd 2015 FCA 158

<sup>&</sup>lt;sup>7</sup> 2012 SCC 60

<sup>8 2013</sup> FCA 186

<sup>&</sup>lt;sup>9</sup> 2015 FC 1156

<sup>10 2016</sup> FC 47

<sup>11 2016</sup> FC 344



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#### SETTLEMENT OF GENE PATENT CHALLENGE IN CANADA

At the beginning of 2016, Canadians were looking forward with great anticipation to a Federal Court challenge launched by The Children's Hospital of Eastern Ontario (CHEO) against a suite of five patents pertaining to methods of genetic testing. However, in March of 2016, the challenge settled with the negotiation of a royalty-free license agreement between CHEO and the patentee: Transgenomic, Inc. of Omaha Nebraska.

The subject patents claim methods for identifying genetic mutations associated with Long QT Syndrome, a disorder of the heart's electrical activity. CHEO wishes to offer whole genome testing for Ontario children on a not-for-profit basis and wants to include analysis for all validated mutations, including those associated with Long QT syndrome. As the subject patents seemed to present a barrier, the challenge by CHEO sought to invalidate the patents or certain patent claims on a number of grounds including the ineligibility of gene-related subject matter for patenting.

In a press release dated March 9, 2016, CHEO announced the settlement stating that these patents "will no longer stand in the way of diagnosing a life threatening disease". The agreement between CHEO and Transgenomic Inc., as well as a template agreement that Transgenomic Inc. now offers to other Canadian not-for-profit entities wishing to conduct Long QT testing, can be found on the CHEO website (www.cheo.on.ca). The agreement is reminiscent of the non-exclusive licensing model established in the late 1980's and early 1990's for gene-related patents directed to CFTR mutations in cystic fibrosis, which permitted genetic testing to be widely accessible to patients by offering reasonable licensing terms to those wishing to conduct laboratory-developed tests. See: Minear et al., Cystic Fibrosis Patents: A Case Study of Successful Licensing. LES Nouv. 2013 Mar 1:21-30.

The CHEO press release states: "While CHEO and Transgenomic were originally going to look to the courts for a resolution on this important health care issue, they were both committed to finding a solution to the issue without the expense and delay of a prolonged court case." While gene-related subject matter is not excluded from patentability under Canadian law, a Court challenge to gene-related patents would have presented an opportunity to either affirm the status quo or to define gene-related subject matter as falling outside of the definition of invention. Absent a Court challenge, there is no change to the law regarding patent eligibility of gene-related subject matter in Canada.

It is worth noting that while gene-related subject matter is not excluded from patent eligibility, the Canadian Patent Office released guidelines in 2015 for examination of diagnostic methods. These guidelines currently impede proper examination of diagnostic inventions. In practical terms, this means that gene-related subject matter presented in diagnostic method claims will be blocked from patentability at the examination level for the foreseeable future, until the examination guidelines can be challenged in court. Had the Court challenge to the Long QT patents proceeded, it may have affirmed the patent-eligibility of diagnostic method claims, whether gene-related or not.

Bringing a gene-related diagnostic technology to market extends well beyond the initial research and discovery stage, requiring years of commercialization efforts. A Court decision to invalidate gene-related patent claims would have







#### SETTLEMENT OF GENE PATENT CHALLENGE IN CANADA | CONT'D

called into question the value of the ongoing commercialization efforts taken by publically funded research institutions across the country, typically built on a foundation of patent protection. Would a chill in private investment have been the ultimate result?

Seeking commercialization funding is difficult at the best of times for even the most accomplished of institutional researchers. With the chronic reduction of public funds available for research, institutional researchers often turn to industry partners and investors to help commercialize their products or tests. Without a proprietary position, an investor has little basis to believe that the investment needed for development, validation, and approval of a gene-related technology can be recouped. The choice of whether to offer a patented technology on reasonable terms, such as royalty-free not-for-profit access, resides with the patent holder. Without any patent position, the choice is unlikely to arise for new gene-related technologies: the investment needed to bring such technologies from proof-of-concept to regulatory approval is unlikely to come knocking.



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# "FAIR EXPECTATION OF SUCCESS" IS NOT THE OBVIOUSNESS STANDARD IN CANADA – FCA CONFIRMS

In 2008, the Supreme Court of Canada (SCC) released its decision in *Apotex v. Sanofi*, setting out a series of steps to consider when assessing obviousness in a patent validity challenge. The test was enumerated as follows:

- (1) (a) Identify the notional "person skilled in the art";
  - (b) Identify the relevant common general knowledge of that person;
- (2) Identify the inventive concept of the claim in question or if that cannot readily be done, construe it;
- (3) Identify what, if any, differences exist between the matter cited as forming part of the "state of the art" and the inventive concept of the claim or the claim as construed:
- (4) Viewed without any knowledge of the alleged invention as claimed, do those differences constitute steps which would have been obvious to the person skilled in the art or do they require any degree of invention?<sup>2</sup>

At the fourth step, the SCC held that the issue of whether something is "obvious to try" may arise. The SCC set out three further factors for consideration at this stage of the inquiry:

- 1. Is it more or less self-evident that what is being tried ought to work? Are there a finite number of identified predictable solutions known to persons skilled in the art?
- 2. What is the extent, nature and amount of effort required to achieve the invention? Are routine trials carried out or is the experimentation prolonged and arduous, such that the trials would not be considered routine?
- 3. Is there a motive provided in the prior art to find the solution the patent addresses?<sup>3</sup>

Importantly, the SCC considered the United States and United Kingdom jurisprudence on obviousness at that time, and adopted this test, rather than the tests that may be easier to meet. Furthermore, the Court held that "the "obvious to try" test will work

only where it is very plain or, to use the words of Jacob L.J., more or less self-evident that what is being tested ought to work." The mere possibility that something may turn up was held not to be enough to render an invention obvious. 5

Despite this clear language, the Federal Court, in a series of decisions, appeared to accept arguments from generic companies that the "obvious to try" test was met if there was a "fair expectation of success" in any solution tried in response to a problem. This lower standard was cited to a Federal Court of Appeal (FCA) case interpreting *Apotex.*<sup>6</sup> However, a thorough reading of that case shows that the FCA did not lower the standard for obviousness at all. In fact, the FCA was referring only to the motivation factor of the "obvious to try" analysis.

Due to the inability of many patentees to appeal judgments against them in NOC proceedings in Canada, this lower obviousness standard was becoming pervasive. As a result, the standard for patents to be invalidated due to obviousness allegations was being lowered.

However, recently, the FCA was able to hear a patentee's appeal on this issue. Despite ruling against the patentee overall, the FCA took the time to restate that the SCC's statement did, indeed, govern the obviousness analysis:

First, Eli Lilly asserts that the Judge erred in law in his obviousness analysis by applying an incorrect test for obviousness when he wrote, at paragraph 150 of his reasons, that the "test, rather, is whether the skilled person had good reason to pursue predictable solutions or solutions that provide a 'fair expectation of success'". We agree that the correct test, and the test that ought to be applied by the Federal Court. is that articulated by the Supreme Court of Canada in Apotex Inc. ...: "For a finding that an invention was 'obvious to try', there must be evidence to convince a judge on a balance of probabilities that it was more or less self-evident to try to obtain the invention. Mere possibility that something might turn up is not enough."7 [emphasis added; citations omitted]

This confirmation that the standard for invalidity due to obviousness has not been lowered should be welcome to patentees.

<sup>&</sup>lt;sup>1</sup> Apotex Inc. v. Sanofi-Synthlabo Canada Inc., [2008] 3 S.C.R. 265 [hereinafter Apotex].

<sup>&</sup>lt;sup>2</sup> Apotex, at para. 67.

<sup>&</sup>lt;sup>3</sup> Apotex, at para. 69.

<sup>&</sup>lt;sup>4</sup> Apotex, at para. 65.

<sup>&</sup>lt;sup>5</sup> Apotex, at para. 66.

<sup>&</sup>lt;sup>6</sup> Apotex Inc. v. Pfizer Canada Inc., 2009 FCA 8 at para. 44

<sup>&</sup>lt;sup>7</sup> Eli Lilly Canada Inc. v. Mylan Pharmaceuticals ULC, 2015 FCA 286 at para. 4.



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#### INTELLECTUAL PROPERTY | CORPORATE

#### QUESTIONABLE POLICY: NEW CANADIAN IP ENFORCEMENT GUIDELINES MISS THE MARK ON PHARMA

On March 31, 2016, the Canadian Competition Bureau released a long-awaited substantive update of its *Intellectual Property Enforcement Guidelines* (the "IPEGs") (see here).

The IPEGs (first issued in September 2000) describe the Bureau's approach to the interface between competition law and intellectual property rights, and its enforcement approach to conduct involving the exercise of IP rights. The newly published updated IPEGs (the "New IPEGs") set out the Bureau's enforcement approach in respect of, among other things, the settlement of patent litigation proceedings in the pharmaceutical industry and so-called "product switching" strategies by innovator pharmaceutical companies.

#### **Pharmaceutical Patent Litigation Settlements**

As reflected in the New IPEGs, the Bureau's enforcement approach to patent litigation settlements may be summarized as follows:

- i. There are two antitrust safe harbors. The first is for entry split settlements, defined as "a settlement [that] does not involve the [innovator] firm providing any consideration to the generic firm other than allowing the generic to enter the market on or before patent expiry". The second is for settlements providing for entry by the generic firm on or before patent expiry plus a payment within the reasonable estimate of the sum of (a) the fair market value of any goods or services provided by the generic firm to the innovator manufacturer, (b) the magnitude of the innovator company's section 8 damages exposure under the *Patented Medicines Notice of Compliance* ("PMNOC") regulations the Canadian equivalent of the US Hatch-Waxman Act and (c) the innovator company's expected remaining litigation costs absent settlement.
- ii. Settlements involving compensation (a "payment") to a generic firm may attract scrutiny under the *Competition Act* (the "Act"). Civil review under the civil agreements provision in section 90.1 is the default. Subject to the second safe harbor noted above, settlements including a payment to the generic firm pursuant to which the generic firm enters the market on or before patent expiry may be reviewed under section 90.1 of the Act, or "possibly" under the abuse of dominant position provision in section 79. The Bureau's concern here is with payments from innovators to generic firms that could have the effect of delaying generic entry and competition; and
- iii. The scope for criminal review is restricted. The Bureau will not review a settlement under the criminal conspiracy provision in section 45 of the Act unless (a) the settlement extends beyond the exclusionary potential of the patent by (i) delaying generic entry past the date of patent expiry or (ii) restricting competition for products unrelated to the patent subject to the PMNOC proceeding, or (b) the settlement is a "sham". A "sham" is defined as a settlement "where the parties recognize that the patent is invalid and/or not infringed and use a purported settlement of the PMNOC proceedings to engage in conduct contrary to [the criminal conspiracy provision in] Section 45 as opposed to addressing patent protected rights. That is, the PMNOC regulations and the settlement are used as a disguise for an otherwise naked conspiracy".

# QUESTIONABLE POLICY: NEW CANADIAN IP ENFORCEMENT GUIDELINES MISS THE MARK ON PHARMA | CONT'D

#### "Product switching"

With respect to so-called "product switching" strategies by innovator companies, the New IPEGs draw a distinction between "hard switches" (*i.e.*, withdrawing from the market an older, less effective product for which the underlying patent(s) will soon expire in order to switch demand to a new or improved product which enjoys on-going patent protection), on the one hand, and "soft switches" (*i.e.*, where the innovator firm continues to sell the older product but stops promoting it to physicians), on the other hand.

The new guidelines indicate that "hard switches" will likely be examined by the Bureau under the abuse of dominance provision in section 79 of the Act. According to the Bureau, if the conduct of the innovator company "could be for the purpose of forcing the replacement of sales of [the older product] with those of [a new product] to exclude or impede" entry of the generic version of the older product, the Bureau would view the withdrawal of the older product as falling outside the statutory exception in section 79(5) of the Act which immunizes from review under section 79 any "act engaged in pursuant only to the exercise of any right" under a federal IP statute, including the Patent Act. As for "soft switches", the New IPEGs state these will not "likely" raise an issue under the Act, provided that the innovator firm does "anticompetitively undermine the prescription base" of the older product through, for example, the making of false or misleading statements regarding that product.

#### Comment

The Bureau's intended approach to patent litigation settlements and "product switching" miss the mark in several important respects, including the following.

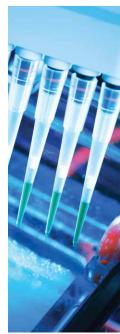
First, criminal review of patent litigation settlement agreements is clearly inappropriate. The criminal conspiracy provision in section 45 of the Act was never intended to be used to prosecute parties to settlements of contested, costly and highly-complex patent litigation. Further, the Bureau's intended use of section 45, even in the limited circumstances contemplated in the New IPEGs, constitutes an unjustified divergence from the approaches

in both the US and the EU, where settlements of complex contested patent litigation are subject to civil antitrust review only. The divergence created by the new Canadian IP guidelines cannot be explained or justified with reference to any legal, regulatory or other differences between Canada and the US or the EU.

Second, notwithstanding that section 79 is by its express terms concerned with acts that have as their purpose an intended negative effect on a competitor that is predatory, exclusionary or disciplinary (that have had, are having or are likely to have the effect of substantially lessening or preventing competition in a market) and therefore cannot properly be applied to consensual settlements of patent litigation proceedings, the Bureau has refused requests from various stakeholders to remove from the New IPEGs reference to the possibility that patent ligation settlements could be challenged under the abuse of dominance provision in section 79 of the Act. Compounding the problem, the New IPEGs contain no meaningful guidance as to the circumstances in which the Bureau might proceed under section 79. Given the dramatically different consequences of a review under the civil agreements provision in section 90.1 versus the abuse provision in section 79 (i.e., prohibition order only vs. multi-million dollar fines), the Bureau's failure to provide the requested guidance is unfortunate.

With respect to so-called "product switching", the Bureau's position that "hard switches" are reviewable under the abuse of dominance provision in section 79 because "BRAND's conduct [in withdrawing the older product before the generic version was able to enter the market and take advantage of provincial automatic substitution laws] could be for the purpose of excluding entry by GENERIC" is inconsistent with, among other things, the *Patent Act*, the IPEGs as they existed before April 2014 and the relevant Canadian case law.

In this last regard, for example, the Competition Tribunal confirmed almost 20 years ago in *Director of Investigation and Research v Tele-Direct (Publications) Inc and Tele-Direct (Services) Inc*,<sup>2</sup> that an alleged exclusionary effect or exclusionary intent on the part of an IP owner is insufficient to transform the mere exercise of statutory rights under the IP statutes into something more, thereby depriving the IP owner of the protection of section 79(5). In its decision in *Tele-Direct*, the Tribunal rejected the Director's argument that "subsection 79(5) does not preclude a finding that 'abuses' of intellectual property rights are anti-





<sup>&</sup>lt;sup>2</sup> (1997), 73 CPR (3d) 1 (Comp Trib).







# QUESTIONABLE POLICY: NEW CANADIAN IP ENFORCEMENT GUIDELINES MISS THE MARK ON PHARMA | CONT'D

competitive acts", and his position that Tele-Direct's alleged "exclusionary intent in respect of their trademarks" and practice of selective licensing constituted an abuse of its trade-mark rights reviewable under section 79 of the Act. In explaining this conclusion, the Tribunal stated (in relevant part):

"... in the Tribunal's view, something more than the mere exercise of statutory rights, even if exclusionary in effect, must be present before there can be a finding of misuse of a trade-mark. Subsections 79(5) explicitly recognizes this.

The respondents' refusal to license their trademark falls squarely within their prerogative. Inherent in the very nature of the right to license a trade-mark is the right for the owner of the trade-mark to determine whether or not, and to whom, to grant a licence; selectivity in licensing is fundamental to the rationale behind protecting trade-marks....

While the evidence suggests that Tele-Direct is motivated, at least in part, by competition in its decision to refuse to license its trade-marks, that fact is that the *Trade-marks Act* allows trademarks owners to decide to whom they will license their trade-marks. The respondents' motivation for their decision to refuse to license a competitor becomes irrelevant as the *Trade-marks Act* does not prescribe any limit to the exercise of that right.

... Although the respondents may have been zealous in protecting their trade-marks, both in refusing to license and in threatening litigation for infringement, the irrefutable fact is that the respondents have been, through the provisions of the *Trade-marks Act*, accorded the right to refuse to license their trade-marks, even selectively. The exercise of this right is protected from being an anti-competitive act by subsection 79(5) of the Act". 3 [underlining added]

In the same way, product switching and other product innovation or improvement strategies (even if allegedly exclusionary in effect or intent) constitute

the legitimate exercise of an innovator company's rights as a patent holder under the Patent Act, through the valid use (in obtaining a patent for an innovation or improvement, and using that invention in a new or improved product)4 and non-use (in, among other things, discontinuing the supply of an older product) of IP, and therefore falls squarely within the statutory exception in section 79(5) of the Act. The Patent *Act* provides a comprehensive regulatory framework for determining whether a product improvement is sufficient for patent protection. Section 32 of the Patent Act expressly provides that a person who has invented an improvement on any patented invention may obtain a patent for the improvement. To qualify for patent protection, an improvement must be new and useful, and must be an invention in its own right (not an obvious equivalent of the original invention). With respect to the non-use of IP, subject to section 65 of the *Patent Act* (abuse of rights under patents), the rights conferred by a patent include a right of nonuse; there is no obligation under the Canadian patent system for a patentee to use or work an invention.

The Canadian Parliament could have sought to restrict or regulate the exercise of IP rights in connection with the introduction of new or improved patented medicines, but perhaps understanding the adverse effects this could have had on innovation and competition, it did not. A great deal of pharmaceutical R&D is incremental and incremental innovation has been the key to many major advances in the treatment and prevention of disease. Product switching encourages incremental innovation and the early introduction of improved products. The Bureau's enforcement approach in respect of "hard switches" therefore risks chilling investments in innovation and undermining vigorous, welfare-enhancing competition. Further, as a matter of competition law policy, the proposition underlying the Bureau approach to "hard switches", namely that Canadian competition law should impose a legal obligation on innovator drug manufacturers, enforced through potential multi-million dollar fines, to continue selling an old product in order to facilitate entry by generics by the most efficient means available, is startling, to say the least.

<sup>&</sup>lt;sup>3</sup> Tele-Direct, supra at 29, 31-33.

<sup>&</sup>lt;sup>4</sup> After patenting the original medication, an innovator company may obtain new patents for improvements or innovations on the original medicine, such as new dosages, strengths, formulations, delivery methods or new uses for the drug. For example, patients may find improved dosing – such as once a day dosing instead of multiple times a day dosing – more convenient and doctors may prefer it for improved patient compliance (as patients are more likely to take the proper dose of the drug). Similarly, improvements in a drug's formulation or delivery method, such as a drug for schizophrenia that dissolves in the patient's mouth, rather than having to be swallowed, or one that has a stable colour over time, in contrast to an older version of the same drug that did not have a consistent colour over time and was unsettling to the patient, may be preferable from both the patient's and his or her doctor's perspective.



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# CANADIAN PATENT OFFICE MISSES THE MARK ON DIAGNOSTICS

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Accurate diagnosis of disease, early detection of disease, and personalized medicine stand to introduce much-needed efficiencies in the health care systems in Canada.

Personalized medicine holds the possibility of an individualized approach to the treatment of disease based on the unique (often genetic) parameters of a patient and/or the subtype of the disease afflicting the patient. The appropriate drug(s), dose, timing of dosing, etc. for a given disease, or subtyped of the disease, may be determined, thereby providing the option of tailoring of treatment. This is in contrast to, for example, those treatments which are provided to a population of patients, but only a subset of which may benefit from treatment. Ideally, personalized medicine technologies will maximize the likelihood of successful treatment of a unique patient.

The demand for new discoveries and inventive approaches in personalized medicine is great. The risk involved in the development of personalized medicine technologies may be worth the rewards of success. However, one of the incentives to invent new diagnostic approaches is under threat in Canada and elsewhere: the option of seeking patent protection to maintain a proprietary position during development may no longer be an option.

Canadian patent examination guidelines for diagnostic inventions were release in June of 2015, entitled: "Patent Notice: Examination Practice Respecting Medical Diagnostic Methods — PN 2015-02". This Notice is an open letter to Canadian Examiners, outlining the way in which they are to approach examination of diagnostic-related inventions. For 3 years prior to the release of this Notice, the examination of patent applications for diagnostic inventions had ground to a halt at the Canadian Patent Office. Patent Agents noticed this lack of examination activity in the diagnostic area and we made inquiries and launch complaints at the Patent office, out of concern for the prejudice to Applicants for these delays in the Examinations of patent applications by the Patent Office.

The patent term is 20-years from filing regardless of the date of issuance. This term was ticking away for all pending diagnostic applications while the Patent Office carried out internal deliberations about what should be patent-eligible subject matter. Unlike the United States, Canada offers no patent term adjustment for delays in Examination attributable to the Patent office.

It was soon revealed that the Patent Office was trying to interpret a Federal Court of Appeal decision regarding computer-implemented inventions (Canada (Attorney General) v Amazon.com Inc, 2011 FCA 328 [Amazon]) for implications relevant to diagnostic methods. Until the interpretation by the Patent Office could be entrenched in a Notice, Examination of diagnostic inventions would not occur based on current practice. Although the Amazon decision had a favorable result to the patentee, it did not adequately counter statements made in the lower court decision regarding patent eligibility of personalized medicine method claims per se. It is widely believed among Patent Agents in Canada that the analysis offered in the Practice Notice regarding diagnostic inventions is flawed.

Ultimately, the Patent Office decided it was time for a change in the examination of diagnostic invention. The uncertainty provided by the Notice places a chill on the patentability of diagnostic methods in Canada, even for useful inventions that would permit early detection, personalized treatment, or identification of susceptible individuals for disease prevention.





# CANADIAN PATENT OFFICE MISSES THE MARK ON DIAGNOSTICS | CONT'D

The Notice teaches a problem: solution approach (or "contribution analysis"), in place of the standard of purposive construction, which it purports to employ. Under the Notice, Examiners are now advised to assess a claim based on its essential elements. Under this approach, Examiners may ignore features they deem not to be critical to the solution offered by the invention, and if merely left with data acquisition and data analysis steps, the claim can be deemed "disembodied" and thus ineligible for patent protection. Inventions pertaining to diagnosis typically require that a sample be acquired from a patient and be tested for one or more parameters of interest (data acquisition) and subsequently that the level or presence of the parameters detected in the sample be compared with a level indicative of the condition to be diagnosed (data analysis). We are finding that diagnostic claims which represent true advances in the field, which are novel and inventive absent any "prior art" objection, are now rejected as ineligible subject matter on the basis of this examination approach.

Recent high profile situations have come to light in which diagnostic tests are considered unaffordable. It is possible that the Patent Notice was formulated in a manner that reflects a direction in public policy, more than an objective interpretation of intellectual property laws. It is not an uncommon sentiment that inventions relating to a new biomarker, a genetic variant, or a biological correlation indicative of a health condition should made freely available to the public, regardless of the effort expended in arriving at the invention.

Canada has leading researchers active in the field personalized medicine technologies. However the research efforts leading to these inventions, and taking them through the validation process is a lengthy and expensive path. Rarely is the expense borne entirely by public funding. The private sector involvement in commercial aspects of testing and developing diagnostic assays and kits is inevitable. Would industry concede to doing such testing if there was no option for a proprietary position for the 20-year patent term, when it is available to all other categories of invention? Are diagnostics simply too important to be patented? Has the Patent Office permitted the popular public outcry for unrestricted access to diagnostics to influence its Examination guidelines?

The approach of the Canadian Patent Office to patenting diagnostic inventions is not consistent with other countries. In the European Patent Office, there is no subject matter restriction that would exclude diagnostics from patent eligibility, claimed as either kits or methods. While there is a similar trend in the United States Patent Office away from granting patents for diagnostic-related inventions, in practice diagnostic kit and method claims are still eligible subject matter, provided adequate tangible details of a test to be conducted are recited in the claims. Patent decisions in the U.S. courts have refined the subject matter restrictions pertaining to diagnostic inventions, but importantly, these have not resulted in a ban on an entire subject matter classification. The 2012 US Supreme Court decision in the case of Mayo Collaborative Servs. v. Prometheus Labs., Inc. deemed a method pertaining to personalized medicine to be patent-ineligible. Further, the US Supreme Court ruled certain claims pertaining to genetic markers of breast cancer susceptibility to be ineligible for patenting, in the controversial 2013 case of Association for Molecular Pathology v. Myriad Genetics. Nevertheless, including tangible components in such claims can render diagnostic claims patent eligible, in the view of the U.S. Examiners. In Canada, the addition of similar tangible components, according to the position of the Practice Notice, may have no impact, as the Examiner may rule out such components as "inessential elements", unless the tangible component is entirely novel in itself. This approach would put Canada at odds and out of step with other jurisdictions.

Personalized medicine technologies have the potential to transform health care, by specifically identifying and targeting treatments to those patients that will benefit most. We are in the early days of the implementation of the "Patent Notice: Examination Practice Respecting Medical Diagnostic Methods" of the Canadian Patent Office, and are only now starting to Respond to the Examiner's recent objections under this Practice Notice. It remains to be seen how personalized medicine technologies will fare in the Canadian Patent Office. We expect that there will be an evolution in what the Patent Office considers patent eligible as experience is gained in implementing the Practice Notice, and from the Responses submitted by the Applicants through their Patent Agents.



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# RESPONDING TO A DIFFICULT DIAGNOSIS: STRATEGIES FOR ADDRESSING OBJECTIONS BASED ON NEW CANADIAN EXAMINATION GUIDELINES FOR MEDICAL DIAGNOSTIC METHODS

It bears repeating that the recent Practice Notice<sup>1</sup> issued by the Canadian Intellectual Property Office (CIPO) on the subject of medical diagnostic methods is contrary to Canadian jurisprudence. Based on CIPO policy of tenuous legal basis (to put it mildly), the situation for diagnostic-related applications in Canada is markedly different from the court-created state of affairs in the U.S. However, past experience with other CIPO examining policies suggests that legal argument alone is unlikely to be successful in overcoming Practice Notice-based objections at the examining level, until CIPO is corrected by the courts. Best practices for addressing subject matter objections based on PN2015-02 are difficult to discern at this early stage, and there is certainly no obvious one-size-fits-all claim format, for example, that would circumvent current issues. This article aims to outline a few possible courses of action.

In its practicalities, there are similarities in how diagnostic claims are treated in both jurisdictions. What has been deemed "conventional" or the "particular technical environment" in precedential U.S. decisions has some correspondence to what Canadian examiners now call "common general knowledge (CGK) features" and subtract away during the assessment of subject matter eligibility.

Applicants wishing to take a pragmatic approach may wish to consider attempting to work within the confines of PN2015-02, legally unsound as it may be. To this end, receptive examiners may be open to reframing the problem and solution that underpins the analysis of the claims. It may be possible to explain to such an examiner that a diagnostic invention also addresses a data acquisition problem, and hence includes essential data acquisition features.

Since the PN2015-02 indicates that common general knowledge is to be considered in establishing essentiality, it may be possible to explain to an examiner that a body of literature pertaining to a particular analyte (and methods for its detection) was not common general knowledge that a skilled person studying a particular disease

could be expected to possess or pursue, if no link between the two had ever been made before. After all, the Supreme Court has indicated that a skilled person is only expected to be "reasonably diligent in keeping up with advances in the field to which the patent relate[s]".2 Information drawn from a seemingly irrelevant field is arguably not the sort of common general knowledge the skilled person would possess, and only becomes relevant with the benefit of hindsight.

The nature of what constitutes a "new analyte" is not defined PN2015-02, and may also provide some leeway to negotiate with receptive examiners. If the detection steps involve a new mutation, fragment, isoform, degradation product, or post-translational modification, these would seem to qualify as a "new analyte" on a plain reading of the term. Applicants may also be able to assert that a combination of known analytes — perhaps even a combination of known variants therein — effectively constitutes a "new analyte".

It may also be helpful to reassure an examiner that an applicant is not seeking to monopolize a mere correlation. To this end, broad steps of "determining" could be refined to state something more explicitly physical, e.g., to define reagents or to specify binding and/or reacting steps. That said, the rather slapdash treatment of technically limited dependent claims to date raises questions of if and how added features of this sort will be assessed under the Practice Notice.

The author has seen some diagnostic-type method claims culminating in a step of "selecting a treatment" allowed in a small number of applications, though it is unclear at the present time if this represents a trend. This could be a viable course of action for some applications, for example with companion diagnostics resulting from diagnostic/drug co-development.

Finally, some applicants may wish to take advantage of abandonment and reinstatement provisions to defer examination in the hope that CIPO will be forced to correct its policies in the meantime. Reinstatement is available as of right in Canada at the time of writing, upon payment of the required government fee. The reinstatement period effectively extends Office Action deadlines one year beyond the initial deadline.

<sup>&</sup>lt;sup>1</sup> CIPO, "Examination Practice Respecting Medical Diagnostic Methods", Practice Notice 2015-02 (Ottawa: Industry Canada, 29 June 2015) [PN2015-02].

<sup>&</sup>lt;sup>2</sup> Whirlpool Corporation v Camco Inc, 2000 SCC 67 at para 74.



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#### INTELLECTUAL PROPERTY | PATENTS

#### WHETHER TO BLIND YOUR EXPERTS: THE ANSWER IS UNCLEAR

The Federal Court has recently focused on the propriety of the information provided to experts prior to the experts forming their opinions in patent cases. There were several cases that appeared to suggest what the Court considered to be the proper approach. In *Teva Canada Innovation v. Apotex Inc.*, <sup>1</sup> Justice Gleason preferred the evidence from Apotex's experts for a number of reasons, including the blinding of its experts:

I agree that the manner in which the experts were retained and instructed in this case provides a reason to prefer the evidence of the Apotex experts over that of the Teva experts. Because they did not know what alcohol Apotex had used in its Products when they conducted their construction exercise, their interpretation was undertaken in accordance with the direction from the Supreme Court of Canada, requiring that the construction exercise be uninfluenced by concerns over infringement or invalidity. The Teva experts, on the other hand, conducted their construction of the terms with a view to the potentially infringing substance.<sup>2</sup>

Further, the Court stated: "I disagree with Teva that all that counsel did when it provided its experts with extracts from the Apotex ANDS and NOA at the outset was to alert them to the issues that were relevant and thus to focus their analyses on "where the shoe pinches"." <sup>3</sup>

The Court in *AstraZeneca Canada v. Apotex Inc.* also preferred the evidence of Apoex's experts because the experts were blinded.<sup>4</sup>

However, in *Eli Lilly Canada Inc. v. Apotex Inc.*, Apotex tried to rely on Justice Gleason's decision in *Teva Innovation*. Justice Gleason refused to prefer the evidence of Apotex's experts on the basis that they were blinded: "In *Teva* and *AstraZeneca*, the approach taken was found to undercut the experts'

credibility as it led to an improper results-oriented opinion. Neither case can be read for the position that Apotex sought to advance here, namely, that in any case where one party blinds its experts but the other does not, the former's evidene is to be preferred. Rather, these two decisions must be limited to the facts that arose in these cases."  $^{5}\,$ 

Similarly, in *Shire Canada Inc. v. Apotex Inc.*, <sup>6</sup> a decision issued on April 7, 2016, Apotex argued that its expert witnesses should be preferred because Apotex blinded its experts. For example, its experts did not see the Notice of Allegation nor were they told of Apotex's legal position. Apotex argued that, because claim construction must be completed before infringement or validity is considered, providing information about the allegedly infringing product or relevant prior art could lead to the expert's analysis becoming a results-oriented one. The Court concluded that this is not a legal principle that must be applied in all cases and there may be no reason for concern regarding blinding depending on the opinion. The Court also noted that there are circumstances in which blinding may not necessarily lead to more reliable evidence. The Court did not consider the blinding of the experts by Apotex in this case to be conclusive.<sup>7</sup>

In comparison, in a decision released April 1, 2016, the Court preferred the evidence of Apotex's expert because of the expert's expertise but also because her opinion was "offered with no possible influence". <sup>8</sup> The Court in particular noted that Allergan's expert had discussed the patent and the NOA with counsel for Allergan whereas Apotex's expert provided an opinion on the common general knowledge and the prior art without knowledge of the patent in issue or the position of the parties. <sup>9</sup>

At the moment, it is difficult to determine the best way to approach elicting expert evidence but these decisions should certainly be taken into consideration at the time of contacting experts.

<sup>&</sup>lt;sup>1</sup> Teva Canada Innovation v. Apotex, 2014 FC 1070 at para. 94-97 [hereinafter Teva Innovation].

<sup>&</sup>lt;sup>2</sup> *Ibid.* at para. 94.

<sup>&</sup>lt;sup>3</sup> *Ibid.* at para. 96.

<sup>&</sup>lt;sup>4</sup> AstraZeneca Canada v. Apotex Inc., 2014 FC 638 at para, 321-324.

<sup>&</sup>lt;sup>5</sup> Eli Lilly Canada Inc. v. Apotex Inc., 2015 FC 875 at para. 166.

<sup>&</sup>lt;sup>6</sup> Shire Canada Inc. v. Apotex Inc., 2016 FC 382.

<sup>&</sup>lt;sup>7</sup> *Ibid.* at para. 42-47.

<sup>&</sup>lt;sup>8</sup> Allergan Inc. v. Apotex Inc., 2016 FC 344 at para. 16.

<sup>9</sup> Ibid. at para. 13-16.



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### THE NON-INFRINGING ALTERNATIVE DEFENCE WHEN ASSESSING DAMAGES COMES TO CANADA

Patent infringers in Canada may have a new argument in their arsenal against an assessment of damages: the non-infringing alternative.

Historically, Canada has rejected the notion that a non-infringing alternative is relevant to an assessment of damages for patent infringement. This history was described by the Federal Court in *Merck & Co., Inc. v. Apotex Inc.*, as originating from the UK House of Lords decision in *The United Horse Shoe and Nail Company, Limited v Stewart and Company*. The Court found that one did not consider whether an infringer could have sold an existing non-infringing alternative, or could have developed a new non-infringing process, or could have avoided infringement altogether by obtaining a licence, because it is completely irrelevant to the question of damages.

In considering the policy arguments that were set forth, the Judge responded with her own policy reasons for rejecting the legal relevance of noninfringing alternatives, including:

- a patentee would be inadequately compensated;
- the non-infringing alternative was already taken into account because the patentee could not claim lost profits in respect of sales lost to non-infringing products;
- iii) acknowledging the relevance of noninfringing alternatives would create an incentive to infringe; and
- iv) acknowledging the relevance of noninfringing alternatives would be inconsistent with Canada's repeal of the compulsory licensing regime and Canada's international obligations (specifically article 1709(10) of the North American Free Trade Agreement and article 31 of the Agreement on Trade-Related Aspects of Intellectual Property Rights).

This was reversed by the Federal Court of Appeal.<sup>3</sup> It was stated that a non-infringing alternative is legally relevant.

The purpose of the *Patent Act* was described as seeking to advance research and development, and to encourage broader economic activity. This was established by balancing "the benefit conferred on the public through the disclosure of a new and useful invention, and the benefit conferred on the inventor through the grant of a monopoly. Thus, in the event of infringement, under-compensation of an inventor discourages research and development, and the disclosure of useful inventions. Equally, over-compensation of an inventor chills potential competition to the extent that a potential infringer is uncertain about the scope and validity of a patent. The balance at the heart of the *Act* requires perfect compensation."<sup>4</sup>

In deciding this balance, the Court found that where a defendant can make and sell a non-infringing alternative, the patent does not confer a complete monopoly on the patent holder. Instead, the patent confers a share of market power upon the patentee.

Perfect compensation was said to require consideration of:

- i) what, if any, non-infringing product the defendant or any other competitors could and would have sold "but for" the infringement; and,
- ii) the extent lawful competition would have reduced the patentee's sales.

The policy arguments sustained by the Judge were dismissed on appeal, with the Panel stating that the first and second policy reasons were addressed by perfectly compensating the patentee. The third policy reason regarding creating an incentive to infringe was said to be balanced by the availability of other remedies at law, such as elevated costs, injunctive relief for the remaining duration of the patent, an accounting of the infringer's profits, and punitive damages. The fourth and final policy reason was disregarded because reasonable royalty damages are only equivalent to the granting of a compulsory licence if there is no non-infringing alternative. Thus, the Court of Appeal has held that the non-infringing alternative is legally relevant to the assessment of damages.

<sup>&</sup>lt;sup>1</sup> Merck & Co., Inc. v. Apotex Inc., 2013 FC 751

<sup>&</sup>lt;sup>2</sup> (1888), 5 RPC 260, 13 App Cas 401 (HL)

<sup>&</sup>lt;sup>3</sup> Apotex Inc. v. Merck & Co., Inc., 2015 FCA 171

<sup>4</sup> Ibid at para 42.







# THE NON-INFRINGING ALTERNATIVE DEFENCE WHEN ASSESSING DAMAGES COMES TO CANADA | CONT'D

Moving on from the legal question, the Court of Appeal stated that at least the following questions of fact will need to be considered by the Court:

- i) Is the alleged non-infringing alternative a true substitute and thus a real alternative?
- ii) Is the alleged non-infringing alternative a true alternative in the sense of being economically viable?
- iii) At the time of infringement, does the infringer have a sufficient supply of the non-infringing alternative to replace the non-infringing sales? Another way of framing this inquiry is <u>could</u> the infringer have sold the non-infringing alternative?
- iv) <u>Would</u> the infringer actually have sold the non-infringing alternative?

On the facts of this case, Apotex failed to meet its burden that, notwithstanding its manufacturing capacity, it could and would have sold a non-infringing product. The Panel found that the alleged alternative must have been actually available to replace the infringing sales as they were made.

Furthermore, Apotex did not point to evidence that demonstrated the profits that it would have made through the non-infringing alternative would have been greater than value lost in any of the identified scenarios.

On April 14, 2016 Canada's Supreme Court dismissed Apotex's leave to appeal on this issue. We cannot yet be certain as to how the non-infringing alternative will be applied in Canada, but at least one other decision rejecting the non-infringing alternative defence is currently under appeal and may perhaps provide further insight for the future.

<sup>&</sup>lt;sup>5</sup> Apotex Inc. v. Merck & Co. Inc., 2015 FCA 171, leave to appeal to S.C.C. refused, 36655 (April 14, 2016)

<sup>&</sup>lt;sup>6</sup> ADIR v. Apotex Inc., 2015 FC 721, appeal in A-315-15



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#### INTELLECTUAL PROPERTY | PATENTS

#### BC COURT OF APPEAL OVERTURNS CLASS CERTIFICATION IN PATENTS CASE, FINDING PATENT REGIME TO BE COMPLETE CODE IN RESPECT OF REMEDIES

In *Low v. Pfizer Canada Inc.*, a unanimous decision of the Court of Appeal for British Columbia restricted the ability of consumers to make claims based on alleged unlawful acts under the *Patent Act*, R.S.C. 1985, c. P-4, and associated regulations. In so doing, the Court of Appeal reversed the certification of the *Low* class proceeding by the trial court and dismissed the action.

This result continues the development of a line of authority that will be important to inventors and manufacturers using the patent system, as any remedies in respect of invalid patents will be limited to those set out in the statutes and regulations. No rights at common law are available to consumers in respect of breach of the *Patent Act*.

#### **Patent Regulatory Regime in Canada**

Patent rights are a creature of statute; there is no right to patents at common law. The patent system provides to the inventor the benefit of a monopoly on a new invention for a limited time period. In exchange, information must be disclosed regarding the product, such that a reasonably informed artisan can create the item in question and make it publicly available at the expiry of the monopoly.

The validity of patents may be challenged through special proceedings. If the patent is successfully challenged by a generic manufacturer and the patent is found to be invalid, the generic manufacturer will then obtain rights under the patent system to market their drug. The generic manufacturer is also provided with a right to claim compensation from the unsuccessful manufacturer for loss suffered by reason of delayed market entry.

There is no remedy in the patent system available to consumers for conduct alleged to have breached the *Patent Act* or the regulations.

#### Background of the Low Case

Pfizer obtained a patent for its drug Viagra. The active ingredient is sildenafil citrate. After obtaining the patent for the use of sildenafil citrate, as well as "about 260 quintillion" other compounds, in the treatment of erectile dysfunction, Pfizer had a monopoly on the sale of sildenafil in Canada and prevented generic manufacturers from introducing a generic version until the patent expired or was invalidated.

Generic manufacturers challenged the patent and proceedings were commenced in respect of the patent. Ultimately, the Supreme Court of Canada determined in 2012 that Pfizer's patent was invalid, and generic drug manufacturers then entered the market, selling generic versions of Viagra at lower prices.

The plaintiff Low commenced a claim, alleging that Pfizer had unlawfully abused the patent system to obtain a monopoly over sildenafil citrate, and as a result, overcharged the purchasers of Viagra. Low alleged that the difference between the revenue Pfizer collected by charging the actual price of Viagra, and the revenue it would have collected in the presence of generic competition represents "ill-gotten gains". Low framed his claim under the tort of unlawful interference with economic relations and in unjust enrichment. Low sought to certify his action as a class action in the Supreme Court of British Columba

#### **Supreme Court of British Columbia Certifies Claim**

In 2014, the certification judge found that Low's claim disclosed valid causes of action (2014 BCSC 1469).







# BC COURT OF APPEAL OVERTURNS CLASS CERTIFICATION IN PATENTS CASE, FINDING PATENT REGIME TO BE COMPLETE CODE IN RESPECT OF REMEDIES | CONT'D

Pfizer argued that the patent system, which included several statutes and regulations, completely governed the marketing of patented drugs and included within it all rights and remedies. In the absence of a cause of action for individual consumers, Pfizer argued Low's claim could not succeed.

The certification judge reviewed the recent consumer remedy class action law in British Columbia, focusing on *Koubi v. Mazda Canada Inc.*, 2012 BCCA 310, *Wakelam v. Wyeth Consumer Healthcare/Wyeth Soins de santé Inc.*, 2014 BCCA 36, and *Macaraeg v. E Care Contact Centres Ltd.*, 2008 BCCA 182. The certification judge held that these cases stood for the proposition that statutory remedies available to the plaintiffs replaced and excluded remedies the plaintiffs might otherwise have at common law. On this basis, he distinguished them from the statutes governing the patent system, which were silent as to consumer remedies.

The certification judge held that because Parliament created no right of action for consumers arising directly out of a breach of the *Patent Act*, there was no bar to an action by consumers if the conduct in breach of statute was also relevant to a cause of action. Finding that the *Patent Act* was not a complete bar to a consumer remedy, the chambers judge then analyzed the alleged tort of unlawful interference with economic relations. He concluded that if a generic manufacturer could obtain compensation as a result of an invalid patent, that could satisfy the "unlawful means" element of the tort. He concluded that the unlawful interference with economic relations claim was not bound to fail.

The certification judge also considered whether the claim in unjust enrichment was bound to fail. On this point, the analysis turned on whether Pfizer could establish that any enrichment it may have received was due to a juristic reason. Pfizer argued that it had marketed Viagra pursuant to statutory rights. The court held while activity pursuant to statutory rights may be a juristic reason, that is not always the case. Accordingly, it was not certain that the cause of action was bound to fail for this juristic reason. The court went on to hold that contracts between direct purchasers and Pfizer for the sale and purchase of the drug were not illegal or void

for mutual mistake. There were no pleaded facts suggesting that the price was a fundamental fact on which the contracts were based, or that the plaintiff or other class members would have refused to pay had they known of the patent's possible invalidity. Despite these findings, he concluded that the claim in unjust enrichment was not bound to fail.

#### Court of Appeal Reverses Certification, Finding That the Patent System is a Complete Code

Pfizer argued on appeal that because Low's claims are entirely derived from the *Patent Act*, Low must look to the statute for a remedy, which does not exist. Low submitted that his claim is based in the common law, and the complete code argument does not apply.

Low did concede that the patent statutory regime is a complete code as regards the relationship between generic and brand name manufacturers. Low argued, however, that because the Patent-related statutes and regulations are silent as to consumer rights and remedies for breach of the *Patent Act*, it cannot be a complete code. The proper question to ask, he submitted, was whether the legislature intend to "oust" consumer rights of action, not whether it intended to create them.

The Court of Appeal did not agree that silence in the legislation must be taken as an indication that a right to civil action should be inferred. The Court of Appeal relied on the decision in *R. v. Saskatchewan Wheat Pool*, [1983] 1 S.C.R. 205, which is authority for the proposition that there is no common law tort of breach of statute. The Court of Appeal held that Low's claim is fundamentally a claim for breach of statute as his right to recovery is said to arise out of "abuse of the Patent system".

The Court of Appeal concluded that the Patent system is a complete code and forecloses parallel civil actions by consumers rooted in breach of the *Patent Act.* Importantly, patent rights are a construct of statute and, as such, patent rights do not exist at common law. The Court held that in circumstances such as these, where Parliament has comprehensively legislated a particular area of the law, the reasonable inference is that it did not intend to extend rights of recovery beyond those embodied in the regime. The Court held that this is a complete bar to Low's claim.

# BC COURT OF APPEAL OVERTURNS CLASS CERTIFICATION IN PATENTS CASE, FINDING PATENT REGIME TO BE COMPLETE CODE IN RESPECT OF REMEDIES | CONT'D

The Court of Appeal then continued, in the alternative, to consider whether the certification judge was correct in his analysis of the causes of action. It found that he was not, specifically erring in his analysis of "unlawful means" and "juristic reason". First, the certification judge should have considered whether there was actionable conduct to support the tort claim. The Court of Appeal found that there was no actionable claim outside the statutory regime, so the parasitic claim in tort could not succeed. Second, the Court held that the contracts between Pfizer and the direct consumers were juristic reasons that barred the claim in unjust enrichment. The claim, therefore, had no prospect of success, notwithstanding any uncertainty concerning whether the Patent system provides a juristic reason.

The Court of Appeal reaffirmed its earlier decisions in *Koubi* and *Wakelam*, and held that *Wakelam*, in particular, stands as authority that complete statutory codes exclude equitable claims in unjust enrichment.

#### **Impact on Inventors and Manufacturers**

Critically, the Court of Appeal decision restricts the ability of plaintiffs to bring equitable and tort claims based on breach of the *Patent Act*. This decision, along with the Court of Appeal's decisions in *Koubi* and *Wakelam*, is of significance to any manufacturer who may face claims from direct consumers. Expect statutory regimes to be more carefully scrutinized on a summary basis without the need of a full trial.









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#### INTELLECTUAL PROPERTY | PATENTS

#### SELECTED PHARMA AND BIOTECH IMPLICATIONS OF CETA AND TPP

Recently, Canada has concluded negotiations on two international treaties whose terms will have an effect on patent rights for patentees in Canada.

The Comprehensive Economic and Trade
Agreement (CETA) was negotiated between Canada
and the European Union. It covers the broad trade
relationship Canada has with Europe. Canada's
Minister of International Trade released a joint
statement with the European Commissioner for
Trade, indicating that they expect CETA to be
signed in 2016 and enter into force in 2017.1

The Trans-Pacific Partnership (TPP) was negotiated between Australia, Brunei Darussalam, Chile, Japan, Malaysia, Mexico, New Zealand, Peru, Singapore, the United States, Viet Nam and Canada. Canada's Minister of International Trade has released a statement indicating that it is still too soon to endorse the TPP, but also too soon to close the door. Canada has signed the agreement. However, the Minister maintains that the text will be tabled in Parliament for debate before any final decision is made.<sup>2</sup>

#### **CETA**

CETA will change how pharmaceutical patents are dealt with in two major respects. First, a "sui generis" protection is being provided. Essentially, patent term restoration can be granted to a single, specific type of patent for a new pharmaceutical product. This restoration is to address delays faced in obtaining marketing approval. The agreement states that this will be for a maximum of 2-5 years. However, the Canadian government has indicated that 2 years will be the maximum period in Canada. Furthermore, there will be exceptions granted for generic pharmaceuticals that are exported. This restoration period will only apply to new marketing authorizations granted after it comes into force.

The second item arising from CETA is that the government is to ensure that all parties to a patent linkage system will have an equal and effective right of appeal. This specifically applies to innovators who use the *Patented Medicines* (Notice of Compliance) Regulations. Currently, if

an innovator is unsuccessful in the proceeding brought pursuant to those *Regulations*, that innovator loses any right of appeal as soon as the generic company is granted its marketing authorization for a product at issue. The generic company always has a right of appeal. This marketing authorization grant can, and does often, occur shortly after the innovator loses the proceeding. However, the Canadian Government, during the CETA negotiations, promised the Canadian Generic Pharmaceutical Association that it will also address what it termed "excessive and duplicative litigation by ending the practice of dual litigation." Currently, for a number of reasons, including the lack of a right of appeal for innovators under the *Regulations*, the losing party in a case brought pursuant to the Regulations can sue for either patent infringement or to impeach the validity of the patent. This is the dual litigation the Government has promised to end. Thus, the "Right of Appeal" provision in CETA may become meaningless.

#### **TPP**

The TPP does not appear to add any new provisions specifically directed at implementing changes to the pharma and biotech industry. It contains a number of provisions with which Canada is already compliant. Furthermore, it reiterates the patent term restoration found in CETA. Of most interest, however, is the additional type of patent term restoration found within the text; this one for delays in the patent office.

In particular, the TPP indicates that if there are unreasonable delays in the issuance of patents, a means to adjust the term of the patent to compensate for that delay shall be provided to the patent owner. Unreasonable delay is defined as more than five years from the filing date or more than three years from the request for examination of the patent. However, there is an exception provided for periods of time that are not directly attributable to the granting authority and for periods of time that are attributable to the patent applicant.

The Canadian Government has not provided any indication of how long this restoration period will be. Furthermore, it has not indicated how the exceptions will be codified. However, this does give some hope to patentees who have seen their applications mired in policy changes at the office.

<sup>&</sup>lt;sup>1</sup> Joint statement by European Commissioner for Trade and Canada's Minister of International Trade on Canada-EU trade agreement, February 29, 2016, <a href="http://news.gc.ca/web/article-en.do?mthd=index&crtr.page=1&nid=1036759">http://news.gc.ca/web/article-en.do?mthd=index&crtr.page=1&nid=1036759</a> last accessed April 28, 2016.

Open Letter to Canadians on the Trans-Pacific Partnership from the Honourable Chrystia Freeland, Minister of International Trade, January 25, 2016, <a href="http://www.international.gc.ca/trade-agreements-accords-commerciaux/agr-acc/tpp-ptp/open\_letter-lettre\_ouverte.aspx?lang=eng">http://www.international.gc.ca/trade-agreements-accords-commerciaux/agr-acc/tpp-ptp/open\_letter-lettre\_ouverte.aspx?lang=eng</a> last accessed April 28, 2016.

Canadian Generic Pharmaceutial Association Statement Regarding Agreement in Principle in CETA Negotiations, October 18, 2013, <a href="http://www.canadiangenerics.ca/en/news/docs/10.18.13\_CGPA\_Statement\_re\_CETA\_FINAL.pdf">http://www.canadiangenerics.ca/en/news/docs/10.18.13\_CGPA\_Statement\_re\_CETA\_FINAL.pdf</a> last accessed April 28, 2016.

#### REGULATORY



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#### REGULATORY | CORPORATE

#### GENETIC DISCRIMINATION AND CANADIAN LAW

A number of national governments — for example, in the United States, Australia and a number of European countries — have taken legislative action to address genetic discrimination. While Canadian human rights laws, insurance laws and privacy laws do contain provisions that seek to minimize unjustifiable discrimination and prevent improper access to or use of personal information, at present no laws in Canada provide specific protection against genetic discrimination. However, in light of recent events, it appears likely that Canada will in fact join the nations that have enacted legislative action to address genetic discrimination.

#### **Background**

Genetic testing, which involves the analysis of a person's chromosomes, genes, or gene products (proteins) to identify the presence of specific traits, can have many benefits. It allows people to learn about their parentage and ancestral origins and is helping scientists to map prehistorical routes of human migration. It can be used to diagnose genetic conditions (diagnostic testing) or to identify a predisposition to a genetic disease (predictive testing). This information can help people initiate appropriate treatment early and adopt lifestyles that will minimize the possible harm of a genetic condition. It can guide the selection of pharmacologic therapies and can identify patients who are candidates for gene therapy, which uses various techniques to replace, correct, suppress, or eliminate a mutated gene.

The possibility of improving outcomes and costeffectiveness by tailoring therapy to a patient's
genetic profile has prompted government funding
in the emerging field of "personalized medicine".

Although, at present, relatively few tests for genetic
conditions are widely recognized as reliable, and
while a positive test result does not necessarily
predict the onset or severity of an illness, it
is expected that genetic testing will continue
to open up new areas of medical knowledge
and new options for treatment. New tests are
being developed at a rapid pace and these will
increasingly become available.

At the same time, genetic information can, however, also be used to discriminate against someone. For example, a genetic test could reveal that a person who is otherwise in good health has a higher risk of one day requiring advanced

health care or being unable to work because of an inherited condition. This information could affect how decisions are made in such matters as insurance and employment. If an applicant for insurance has a higher risk for a certain disease, then that applicant presents a higher risk to the insurer of having to make payments for health coverage or life insurance. This may affect the terms of any policy offered to the applicant. Similarly, an employer may be less willing to hire a job applicant who is genetically at high risk of developing an illness or genetic condition.

Although the long-term ethical and legal consequences of genetic testing for employment matters, insurance contracts, and preventive medicine and treatment are not yet fully known, cases of alleged genetic discrimination have been emerging in different parts of the world, prompting calls from concerned citizens for government action.

#### **Proposed Canadian Response**

In the lead up to the recent Canadian Federal election, the Government of Canada introduced the "Protection Against Genetic Discrimination Act". However, the Bill died when the House of Commons was dissolved last June.

Earlier this year, a Bill was passed in the Senate of Canada entitled "An Act to prohibit and prevent genetic discrimination" (the "Senate Bill"). Most recently the Senate Bill was introduced in the Canadian House of Commons. Whether the Senate Bill ultimately receives Royal Assent in its current form or in a modified form, it seems quite likely that legislation will be enacted in Canada that prohibits genetic discrimination.

The Senate Bill proposes criminal sanctions for actions such as when one person requires another to undergo a genetic test or disclose the results of one as a condition of (a) providing goods or services to that individual; (b) entering into or continuing a contract or agreement with that individual; or (c) offering or continuing specific terms or conditions in a contract or agreement with that individual. The rationale for the use of the criminal law power is to attempt to bolster this federal effort to extend the protection beyond the ambit of traditional federal authority.

In addition, the Bill proposes amendments to several statutes of the Government of Canada – the *Canadian Human Rights Act*, the *Privacy Act*, the *Personal Information Protection and Electronic Documents Act* and the Canadian Labour Code.



#### GENETIC DISCRIMINATION AND CANADIAN LAW | CONT'D



goods, services, facilities and accommodation. The proposed amendment to the *Privacy Act* and the Personal Information Protection and Electronic Documents Act would specify that information resulting from genetic testing is among the types of personal information protected by these Acts. The *Privacy Act* protects personal information collected, used and disclosed by federal government institutions listed in the Act, as well as any parent Crown corporation and any wholly owned subsidiary within the meaning of the *Financial* Administration Act. The Personal Information Protection and Electronic Documents Act protects personal information that is collected, used and disclosed by private sector organizations in the course of commercial activities. It also protects information on employees who work for a federally regulated business.

The proposed amendment to the Canadian Human

Rights Act would deem discrimination on the basis

of a predisposition to a disability, as inferred from

ground of disability. This Act applies to the federal

government and First Nations governments, as well

as to federally regulated businesses and industries,

such as banks and telecommunications companies,

in matters of employment and the provision of

genetic test results, to be discrimination on the

The proposed amendments to the Canada Labour Code would protect employees from being required to undergo or disclose the results of genetic tests and provide employees with other protections related to genetic testing and test results.

#### **Observations**

Various organizations, legal experts and other commentators have argued in favour of the need to pass legislation in Canada to explicitly address genetic discrimination. At the same time, the insurance industry has noted that insurance contracts are generally governed by provincial laws.

Although provincial human rights codes may already provide some protection for individuals from genetic discrimination, they also include some exceptions that may allow automobile, life, accident or sickness or disability insurance providers to make distinctions based on an applicant's age, sex, marital status, family status, or physical or mental disability. A discriminatory practice in insurance may be justified on reasonable and bona fide grounds — in other words, if it is based on accepted and sound insurance practices and if no practical non-discriminatory alternative exists.

The current position of the Canadian insurance industry is that, while companies will not require genetic testing of applicants for insurance, they will ask whether the applicant has been genetically tested in the past, and they will require disclosure of those test results where they exist. This position is generally justified on the basis that there exists a good faith obligation under most provincial laws for an insurance applicant to disclose to the insurance company all information that might have a bearing on the company's assessment of risk. The insurance industry has expressed concern that insured persons who learn, after taking a genetic test, that they are at high risk for a genetic disease could knowingly take out policies for large amounts of additional coverage without insurers being aware of any increased risk. Disclosing the results of genetic testing would therefore help ensure that both parties negotiating an insurance contract would have the same knowledge about the health risks of the applicant.

While the position of the insurance sector seems quite reasonable, it is likely that the greater public interest in ensuring Canadians have access to medical advances in genetic testing without the fear of negative consequences or repercussions on them and their families' means that a better defined Canadian legislative framework is essential. This is an issue that will be a subject for further public debate and consideration in the coming months.





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#### REGULATORY | LITIGATION

#### **CASL - YEAR IN REVIEW**

Canada's anti-spam law (commonly known as "CASL") creates for life science companies, a comprehensive regime of offences, enforcement mechanisms and potentially severe penalties designed to prohibit unsolicited or misleading commercial electronic messages, the unauthorized commercial installation and use of computer programs on another person's computer system and other forms of online fraud.

During 2015, government agencies responsible for the enforcement of CASL issued important guidance for the interpretation of CASL and took significant first steps to enforce CASL against Canadian businesses. The guidance and enforcement actions are instructive for organizations that wish to comply with CASL's rules for the sending of commercial electronic messages and the installation of computer programs.

#### **CASL's CEM Rules**

For most organizations, the key parts of CASL are the rules for commercial electronic messages ("CEMs"). Subject to limited exceptions, CASL creates an opt-in regime that prohibits the sending of a CEM unless the recipient has given informed consent (express or implied in limited circumstances) to receive the CEM and the CEM complies with prescribed formalities (including an effective and promptly implemented unsubscribe mechanism) and is not misleading.

CASL also prohibits, subject to limited exceptions, the commercial installation and use of a computer program on another person's computer system without the express consent of the owner or authorized user of the computer system. The computer program rules apply to almost any computer program (not just malware, spyware or other harmful programs) installed on almost any computing device (including mobile phones) as part of a commercial activity (regardless of expectation of profit).

CASL violations can result in potentially severe administrative monetary penalties (up to \$10 million per violation for organizations and \$1 million per violation for individuals), and civil liability through a private right of action (commencing July 1, 2017). The Canadian Radio-television and Telecommunications Commission ("CRTC"), the Competition Bureau and the Office of the Privacy Commissioner of Canada have enforcement responsibility under CASL, and have various enforcement tools for that purpose (e.g. preservation demands, production notices and warrants).

#### Guidance

CRTC and the Privacy Commissioner of Canada published in 2015 the following quidance documents:

- Canada's Anti-Spam Legislation Requirements for Installing Computer Programs, which explains CASL's rules for the installation of computer programs and CRTC's views regarding an important exception for "self-installed software".
- From Canada's Anti-Spam Legislation (CASL) Guidance on Implied Consent, which explains CASL's rules for consent and provide helpful guidance for CASL compliance.
- Anti-spam law's changes to Canadian federal privacy law: A guide for businesses doing e-marketing, which explains Canadian privacy law requirements for the use of personal information (including email addresses) to send CEMs.







#### CASL – YEAR IN REVIEW | CONT'D

#### **Enforcement Action**

CRTC and the Competition Bureau announced the following CASL enforcement actions in 2015:

- CEMs Sent without Consent or Unsubscribe Mechanism: CRTC issued the first Notice of Violation under CASL to Compu-Finder. The Notice imposed a \$1.1 million administrative monetary penalty for "flagrantly" violating CASL by sending CEMs without the recipients' consent and with an ineffective unsubscribe mechanism.
- CEMs with Deficient Unsubscribe
   Mechanism: The online dating service
   PlentyofFish Media entered into an undertaking
   (settlement), including payment of a \$48,000
   administrative monetary penalty, with CRTC
   for the alleged sending of CEMs with an
   unsubscribe mechanism that was not clearly
   and prominently set out and could not be
   readily performed.
- CEMs with Deficient Unsubscribe
   Mechanism and Without Required Content:
   The national media company Rogers Media
   Inc. entered into an undertaking (settlement), including payment of a \$200,000 administrative monetary penalty, with CRTC for the alleged sending of CEMs with an unsubscribe mechanism that did not function properly or could not be readily performed or with required content that was not valid for the required minimum 60 days. In addition, Rogers Media allegedly failed to honour some unsubscribe requests within 10 business days.

- CEMs Sent without Consent or Required Content: The regional airline Porter Airlines entered into an undertaking (settlement), including payment of a \$150,000 administrative monetary penalty, with CRTC for the alleged sending of CEMs without proof of consent and the alleged sending of CEMs that did not contain required information or have a required unsubscribe mechanism.
- Misleading CEMs: The Competition Bureau commenced against two car rental companies, Aviscar and Budgetcar, proceedings seeking remedies (including \$30 million in administrative monetary penalties and refunds to consumers) for alleged deceptive marketing practices (including sending false or misleading emails) regarding vehicle rental prices.
- Malware: CRTC announced its first ever CASL warrant to take down a Win32/Dorkbot commandand-control server located in Toronto, Canada as part of a coordinated international effort.



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#### REGULATORY | CORPORATE / LABOUR & EMPLOYMENT

#### **WORKERS MAY BE ENTITLED TO NOTICE ON** TERMINATION DESPITE BEING CLASSIFIED AS INDEPENDENT CONTRACTORS

There are many advantages for a life science company hiring a worker as an "independent contractor" instead of an "employee". From a business point of view, for example, a business hiring an independent contractor does not have to withhold or remit employment insurance, pension plan and tax payroll deductions to the Canada Revenue Agency and there may be savings on the business' Workers' Compensation premiums. In addition, businesses may use "independent contractors" so that they can terminate the worker without having to provide notice of termination. However, despite being classified as an "independent contractor", courts are increasingly examining the relationship between the employer and the worker to determine whether the worker is an independent contractor, an employee or a dependent contractor.

The concept of a 'dependent contractor' was recognized previously by the Ontario Court of Appeal in McKee v Reid's Heritage Homes Ltd. In that case the Court of Appeal found that employment relationships exist on a continuum; with the employer/employee relationship, at one end of the continuum, and independent contractors at the other end. Between those two points, lies a third intermediate category of relationship, now termed dependent contractors. Like independent contractors, workers falling into this third intermediate category usually have their own businesses and they do not have the traditional hallmarks of employment, such as health benefits or vacation entitlements, however, workers in this third intermediate category may be entitled to notice on termination. One of the key principles the courts look at in determining whether the worker is a dependent contractor is the exclusivity of the relationship between the parties.

Recently, in Keenan v. Canac Kitchens Ltd., the Ontario Court of Appeal heard an appeal from Canac Kitchens who had terminated two independent contractors without notice. The Keenans were independent contractors who had signed independent contractor agreements that provided that they were to devote "fulltime and attention" to Canac Kitchens. The Keenans worked almost exclusively for Canac Kitchens until 2009, when they were told that Canac Kitchens was shutting down. Canac Kitchens gave the Keenans nothing on termination - no notice, no pay in lieu of notice, and none of the usual statutory entitlements. After Canac Kitchens ended the relationship in March 2009, the Keenans brought an action against Canac Kitchens. At trial, the trial judge looked at the following principles in determining whether the Keenans were dependent contractors:

- 1. Whether or not the worker is limited exclusively to the service of the principal;
- 2. Whether or not the worker is subject to the control of the principal not only as to the product sold, but also as to when, where, and how it is sold;
- 3. Whether or not the worker has an investment or interest in what are characterized as the tools relating to his service;
- 4. Whether or not the worker has undertaken any risks in the business sense, or, alternatively, has any expectation of profit associated with the delivery of his service as distinct from a fixed commission; and
- 5. Whether or not the activity of the agent is part of the business organization of the principal for which he works.







#### REGULATORY | CORPORATE / LABOUR & EMPLOYMENT

## WORKERS MAY BE ENTITLED TO NOTICE ON TERMINATION DESPITE BEING CLASSIFIED AS INDEPENDENT CONTRACTORS | CONT'D

The trial judge found that all five of those now well-known principles favoured a finding that the Keenans were dependent contractors and they were entitled to reasonable notice on termination. The trial judge awarded the Keenans damages of 26 months' notice.

On appeal, after examining the history of the relationship between the Keenans and Canac Kitchens, the Court of Appeal upheld the lower court's finding of exclusivity on the basis that the Keenans were economically dependent on Canac Kitchens for over 30 years and the substantial majority of the work performed by the Keenans was performed for Canac Kitchens. In addition, the Court of Appeal upheld the lower court decision finding the notice period of 26 months was reasonable based on the Keenans' age, length of service, and their positions even though such notice is generally only awarded in exceptional circumstances.

Courts are increasingly examining the relationship between the employer and the worker to determine whether the worker is an independent contractor, an employee or a dependent contractor. This decision makes it clear that merely calling someone an independent contractor (even if that term is used in a written agreement) or merely having a separate corporation through which the person is paid does not mean that the person will be treated as an independent contractor in court. Courts and tribunals will conduct their own assessment as to whether a worker is an employee, an independent contractor or a dependent contractor. If the worker is determined to be a dependent contractor, the worker may be entitled to reasonable notice or pay in lieu thereof similar to that of an employee.



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#### CYBER RISK MANAGEMENT - INSIDER RISK

The enemy is within the gates; it is with our own luxury, our own folly, our own criminality that we have to contend. — Marcus Tullius Cicero

People are a major security risk. Most cybersecurity incidents originate from, or are facilitated by, a current or former insider of the victim organization. Life sciences companies and other organizations that handle commercially sensitive or regulated data (e. personal health information) are particularly susceptible to insider risk.

To manage insider risk, an organization should use a multi-disciplinary program and implement administrative, technological and physical security policies and practices to protect the IT systems and data of the organization and its relevant business partners. Legal advice is essential to address the legal challenges presented by insider risk management.

#### What is Insider Risk?

Studies consistently confirm that a majority of cybersecurity incidents originate from, or are facilitated by, the victim organization's current or former insiders (e.g. executives/managers, employees and contract workers, whether permanent or temporary, full time or part time, and similar individuals working for business partners) acting maliciously or inadvertently. IBM's 2015 Cyber Security Intelligence Index reported that 55 percent of all cybersecurity incidents were carried out by insiders.

Insiders present significant cyber risk because they have privileged access to the organization's information technology (IT) systems (i.e. no need to circumvent perimeter-based security), special knowledge of the organization's valuable data and security practices and a greater window of opportunity for misconduct. Those circumstances often enable insiders to engage in misconduct that is harder to detect and remedy, and results in more harm, than external attacks.

Insiders can intentionally cause cybersecurity incidents for a broad range of reasons (e.g. financial gain, anger/revenge, recognition/power, adventure/ thrill, love/jealously, curiosity, extortion/blackmail and ideology). Insiders can also cause or facilitate cybersecurity incidents as a result of carelessness or error (e.g. easy-to-guess or stored-in-plain-sight passwords, lost devices, erroneous disclosure of sensitive information or

inadvertent activation of malicious email attachments) or manipulation (e.g. through fraud/deception or coercion) by other insiders or outsiders.

Regardless of whether an insider's acts are malicious or inadvertent, the results can be the same — potentially devastating losses and liabilities to the organization (e.g. direct financial losses caused by theft, fraud or business disruption; investigation, mitigation, remediation and litigation costs; loss to stakeholder value; harm to reputation and relationships with consumers, commercial customers and business partners; disclosure of confidential information; loss of competitive advantage; civil liabilities and regulatory penalties) and potentially significant liabilities on the part of the organization's directors and executives.

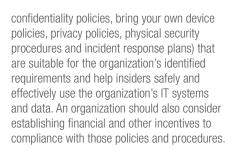
#### **Managing Insider Risk**

Insider risk management is more than an IT problem. An effective insider risk management program requires a risk-based, multi-functional approach by an organization's various departments and disciplines (e.g. senior management, human resources, procurement, risk management, IT, physical security and legal) to deter, prevent, detect and respond to cybersecurity incidents caused by insiders. Insider risk management requires an organization to carefully select, educate, train and disengage insiders, establish policies, procedures and systems for use of the organization's IT systems and data and monitor and verify compliance. Following is a summary of some fundamental components of an insider risk management program.

- Engagement: An organization should exercise appropriate, lawful due diligence (e.g. background/security checks, screening and interviews) when hiring/engaging insiders. An organization should require an insider to contractually agree to comply with the organization's relevant policies and procedures, many of which should apply both during and after the term of employment/engagement, and give legally valid consent to the organization's monitoring/enforcement programs.
- Policies/Procedures: An organization should conduct periodic threat risk assessments to identify and prioritize its cyber risk requirements. The organization should then establish and implement documented, clear and simple policies and procedures for use of the organization's IT systems and data (e.g. data security and

#### REGULATORY | CORPORATE

#### CYBER RISK MANAGEMENT - INSIDER RISK | CONT'D



- Education/Training: An organization should educate and train its insiders, during onboarding and on a continuous basis afterwards (including through periodic reminders and refresher training), so that insiders understand the organization's cyber risk management policies and procedures and are able to safely use business and personal IT systems and services (e.g. websites, email, instant messaging and social media), take appropriate precautions at work, at home and while travelling to protect themselves and the organization against cyber risks, and identify, understand, resist and respond to cyber threats (e.g. phishing, fraudulent emails, social engineering scams and recruiters) and data security incidents.
- Security: An organization should implement appropriate administrative practices and physical and technological systems (e.g. IT system and data access controls based on data classification and least privilege access, user and device authentication and physical security measures) to secure and limit privileged access to the organization's IT systems and data, and to detect and prevent unauthorized access to those systems and data. An organization should strive to achieve a reasonable and lawful balance between enablement and control.
- Monitoring/Verification/Enforcement: An organization should lawfully monitor (including by using appropriate technologies) and routinely test for compliance with the organization's cyber risk management policies and procedures by all insiders (including senior executives/management), and reasonably enforce those policies and procedures in a manner consistent with applicable law. An organization should consider enhanced monitoring during high-risk periods (e.g. first and last months of an insider's employment/engagement). Insiders should be encouraged to be vigilant and promptly report

- suspect behaviour by other persons and all actual and reasonably suspected cyber risk incidents involving themselves or other persons.
- Disengagement: An organization should follow appropriate, lawful procedures when disengaging an insider, including cancelling passwords, terminating access to the organization's IT systems and data, retrieving the organization's assets (e.g. computing and storage devices and physical security access devices), deleting the organization's data from the individual's personal computing devices, conducting exit interviews and providing reminders of ongoing legal obligations, and reviewing recent (e.g. past 90 days) IT system and data use for unusual behaviour.
- Incident Response Plan: An organization should have a comprehensive, practiced and tested incident response plan that includes procedures for dealing with insiders who are suspected of having caused or contributed to a cyber security incident.

#### **Risks Presented by Business Partners**

An organization's relationships with business partners (e.g. subcontractors, suppliers, service providers and collaborators) can exponentially increase the number of insiders and significantly change the nature and magnitude of insider risk. Organizations often provide business partners with access to, or possession or use of, the organization's IT systems or data. As a result, business partner relationships pose an inherent risk of additional insider threats to the organization's IT systems and data.

For those reasons, an organization's insider risk management program should include relationships with all of the organization's business partners, and should address risks presented by business partner personnel who have access to or use of the organization's data or internal or external IT systems. In other words, for the purposes of insider risk management: (1) an organization's insiders should be considered to include all individuals, employed or engaged by the organization's business partners, who have direct or indirect access to, or use or custody of, the organization's IT systems or data; and (2) an organization's IT systems should be considered to include all external IT systems that are owned or operated for the organization by a business partner (e.g. a cloud service provider or other provider of outsourced services, such as payroll and benefits service providers) or used by a business partner to provide services to the organization.







#### CYBER RISK MANAGEMENT - INSIDER RISK | CONT'D

Insider risk management practices that an organization follows regarding its own personnel and internal IT systems and data should be extended to the organization's

Managing insider risk presents various legal challenges, including ensuring that risk management practices are legally effective and comply with applicable law. For example:

- Performing background checks and screening of individuals during the hiring or engagement process implicates compliance with labour/ employment and human rights laws.
- Designing and implementing IT system and data use policies and procedures implicates compliance with privacy/personal information protection laws and labour/employment laws, including rules regarding changes to terms of employment that can constitute constructive dismissal.
- Monitoring IT system use and other work related activities implicates compliance with privacy/personal information protection laws and labour/ employment laws.

 Testing incident response plans and responding to cybersecurity incidents implicates compliance with privacy/personal information protection laws, labour/employment laws and laws regarding evidence and legal privilege.

Timely legal advice can assist an organization to effectively address generally applicable legal requirements and ensure compliance with laws specific to the organization or its activities. The involvement of lawyers in specific risk management activities (e.g. incident response plan testing and responding to cybersecurity incidents) might be necessary to enable the organization to effectively assert legal privilege over sensitive communications for the purpose of seeking legal advice or preparing for litigation.









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#### REGULATORY | CORPORATE

#### **OUTSOURCING, PROCUREMENT AND CYBERSECURITY**

Cybersecurity is rarely a core business — but it is a requirement of doing business for all companies, including life science companies. Organizations seeking to establish and maintain systems that are secure against cyberattack must enlist the skills and knowledge of third-party providers. With any IT contract, it is necessary to ensure that expectations and deliverables are specifically defined, that appropriate representations and warranties are given, and that costs and penalties are properly scaled. This is particularly true in the area of cybersecurity, with its plethora of suppliers and technologies, and where the failure of a system or service can have catastrophic consequences.

Outsourcing and procurement issues extend far beyond the purchasing of cybersecurity systems. Indeed, most cybersecurity procurement issues arise in the acquisition of services from vendors. These would include, by way of example only, payroll services, expense services, healthcare services, data storage services (including, not incidentally, cloud services). In an age when doing business requires the extensive sharing of information, organizations need to know that the systems of their suppliers and co-contractors are secure. Equally, they need to be confident in assuring customers, clients, and co-contractors that their own systems are secure.

In best of class systems, this assurance is contractual, with a varying mix of specific terms and conditions. The topics to which those terms and conditions would be addressed are at least those set out below. These are particularly applicable where the Vendor is being provided with or has access to private or confidential information. In those cases, suppliers are often required to:

- implement and maintain commercially reasonable physical and cybersecurity safeguards and security mechanisms;
- distinguish, where necessary, between the treatment of confidential and private information;
- warrant that they complies with all applicable laws of all applicable jurisdictions
- take steps to prevent unauthorized access to data;

- maintain written policies and procedures defining and limiting access;
- verify that security procedures operate effectively;
- maintain systems which adhere to or comply with accepted "standards" or protocols such as such as NIST, ISO, COBIT and PCI DSS;
- maintain disaster recovery and business continuity plans;
- maintain personnel training or certification systems;
- notify in the case of the breach, with specific information, including impact assessments and corrective action; and
- indemnify and defend where required.

In addition to ensuring that contractual relationships with suppliers address suppliers' cybersecurity obligations, businesses must also ensure that their suppliers are in fact meeting their obligations under those contracts. Conversely, businesses need not only understand their own security obligations to clients and co-contractors, they also need to ensure their internal policies and programs meet the standards defined in those contracts. Audits of the relevant contracts and compliance with their terms are high priorities in every best of class cybersecurity plan. Audit rights, or the right to require third-party review now frequently appear as terms or conditions in supplier contracts.

National governments, particularly in the United States and the United Kingdom, have been leaders in the development and application of procurement policies meant to maximize the security of information and communications systems. As many life science companies handle especially sensitive and valuable information, they need to understand these policies.

The government of the United Kingdom has developed a preferred organizational standard for cybersecurity, a form of certification it calls "Cyber Essentials". This standard is intended to provide a clear statement of the basic controls all organizations should implement to mitigate risk from common Internet-based threats. It also offers a mechanism for organizations to demonstrate to customers, investors, insurers and others that they have taken essential precautions.

#### OUTSOURCING, PROCUREMENT AND CYBERSECURITY | CONT'D

In the United States, the Department of Defence (DoD) requires that contracts of supply incorporate specific cybersecurity clauses, while the Department of Homeland Security has proposed procurement language for control systems. In June 2014, the General Services Administration (GSA) and the DoD announced an initiative to develop and implement "a repeatable, scalable process for addressing cyber-risk in federal acquisitions based on the risk inherent in the product or service being purchased". The process is intended to include baseline cybersecurity requirements as a condition of contract award, cybersecurity acquisition training, and common cybersecurity definitions. In

December 2014, the U.S. Defence Information Agency released a draft of its Cloud Computing Security Guide, setting out the requirements with which providers seeking to win contracts would need to comply.

The lesson in all of this is simple and straightforward - not only must organizations ensure that their suppliers are cybersecure, they must be able to provide the same assurance to their own customers. Competitiveness depends on it.







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#### CAPITAL MARKETS | CORPORATE

## CANADIAN PUBLIC CAPITAL MARKETS – PUNCHING ABOVE THEIR WEIGHT IN THE LIFE SCIENCES SECTOR

#### Introduction

In recent years, the Canadian market has evolved into a leading platform for the financing and listing of innovation companies on Canadian stock exchanges. A major driver behind this growth has been Canadian investors' appetite for investing in early stage and growth oriented public companies. Canada is emerging as a hub - or you might even say a network of hubs in Toronto, Vancouver and Montreal - for the innovation sectors. Increasingly Canadian companies are choosing to stay in Canada and invite investors from Silicon Valley, Boston and other high profile tech markets to participate in private round financings, initial public offerings (IPOs) and follow on offerings here in Canada.

### What Do the Market Figures Tell Us About Innovation Companies Listed in Canada?

While enjoying a formidable combined market capitalization of over \$2.3 trillion, the TSX and TSX Venture Exchange (TSX-V), the exchange for public venture companies (in combination referred to as TMX) is indeed more than the world's leading mining, energy and resources market. TMX boasts a vast market for mining and energy companies, with a combined market cap of \$412 billion, and includes some of the world's iconic mining and oil and gas enterprises. But these figures hardly tell another amazing story of how the Canadian market has evolved to become a significant ecosystem for hundreds of innovation companies in Life Sciences, Clean Tech and Renewables, Technology and Communications and Media, with a combined market cap of \$351 billion.

During 2014 and 2015, 69 new technology and innovation companies went public on the TSX and TSX-V, more than any other industry sector and they raised over \$17 billion in equity during the same period.

For investors, there are currently over 420 technology and innovation companies listed on the TSX and TSX-V, offering the opportunity for diversification and to participate in numerous fast-growing businesses—many with global operations.

During the period from 2009 to 2015, TSX and TSX-V listed issuers in the innovation sector completed 178 IPOs and new listings, raised \$34 billion and experienced a \$128 billion increase in market value.

The exciting data point within this is that Life Sciences companies listed on the TMX have a combined market cap of over \$80 billion. While the vast majority (92%) of these companies are pharma businesses, they also include biotech, healthcare facilities, healthcare services and healthcare technology.

#### What the TMX Has to Offer

The TMX is the fourth largest exchange in the world measured by the amount of capital raised by its issuers. It only trails New York, NASDAQ and Hong Kong. So far in 2016, TMX's shares have outpaced all but two of its 26 peers in the Bloomberg world exchanges index.

The TMX is home to more than 127 Life Sciences companies and in 2015, life sciences companies on the TSX and the TSX-V raised \$6.5 billion of capital which includes the \$1.8 billion financing of Valeant Pharmaceuticals

# CANADIAN PUBLIC CAPITAL MARKETS – PUNCHING ABOVE THEIR WEIGHT IN THE LIFE SCIENCES SECTOR | CONT'D

International Inc. TMX-listed life sciences companies had good investment coverage with approximately 80% of them enjoying analyst reporting. This in turn contributed to better informed investors and traders who were behind the \$5.3 billion worth of life sciences companies' shares that were traded on the TMX last year.

### The Bought Deal – A Uniquely Canadian Concept

And speaking about innovation, Canada's regulatory regime allows public companies to raise capital through the unique "bought deal" offering in which an investment bank commits to buy the shares of a company and resells them into the market, thereby providing the company with a guarantee of sorts that its financing will be successful. This flexible mechanism is routinely used by issuers to fund growth, as well as by significant shareholders to obtain liquidity, but it is a "made and used in Canada only" mechanism and has not (at least not, yet) been adopted in the U.S.

#### Canada-U.S. Financing Flexibility

Also of note is that securities regulators have an accommodation in place for Canadian public companies looking to raise capital from U.S. based investors. Generally, if a company has been public in Canada for at least a year and has a public float of more than US\$75 million, it may take advantage of the multijurisdictional disclosure system (MJDS). The MJDS permits a company to raise capital in the U.S. with minimal U.S. regulatory and consequential timing risks. Note, however, that a "Southbound MJDS" company must still qualify as a foreign private issuer under US law at the time it files for its offering in the U.S. and annually thereafter.

A Canadian issuer not currently contemplating a U.S. financing may nevertheless also list on a U.S. exchange. In addition to broadening the investor base, a U.S. listing may provide competitive

advantages: in a U.S. acquisition, shares may be offered as consideration to shareholders of the target company. Southbound MJDS companies do not face significant additional reporting obligations as a result of a U.S. listing.

#### Recent examples of Successful Life Sciences Companies Raising Money through Public Offerings

- Titan Medical Inc., a leading developer of a patented surgical robotic system for use in minimally invasive surgery, went public through the TSX-V's highly successful Capital Pool Company (CPC) program in 2008 before the company had developed a functional prototype of its device. The company has, since then, raised over \$100 million through a number of public and private offerings for the development of its SPORT surgical system, and it is now listed on the TSX. The SPORT was recently demonstrated at a leading healthcare conference in Boston.
- Cynapsus is a specialty, pharmaceutical company developing and preparing to commercialize a Phase 3, fast-acting, easy-to-use, sublingual thin film for the on-demand management of debilitating "off" episodes associated with chronic, progressive neurodegenerative diseases characterized by motor symptoms. Cynapsus originally went public on the TMX through the CPC program and it has raised approximately \$150 million through private placements and public offerings over the past 12 years, including US\$72.5 million raised through its public offering in the U.S. in 2015. Cynapsus is an excellent example of how a Canadian company may go public and raise substantial capital in the Canadian market and then when it reaches a size and stage of its technology that U.S. investors demand, complete a "re-IPO" in the U.S. with a concurrent co-listing on the NASDAQ, while remaining a Canadian corporation and maintaining its listing on the TSX.

Having regard to the compelling market statistics, Canadian life sciences companies are well advised to explore the advantages of a public listing in Canada.













# ABOUT BLG'S LIFE SCIENCES GROUP

#### A LEADING CANADIAN LIFE SCIENCES PRACTICE

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

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

#### **WORKING IN ALL FACETS OF LIFE SCIENCES**

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

- Class Actions
- Dispute Resolution

#### **ADVISING ON**

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

- Intellectual property portfolios and management, including advising on Health Canada Patent Register
- Competitors' intellectual property
- Freedom to operate, validity and infringement analysis and opinions
- Litigation support, including IP, product liability, administrative proceedings, contract and licensing disputes, etc.
- The application of the NOC Regulations and data protection system to subsequent entry biologicals

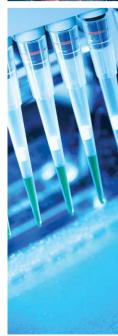
#### **INTEGRATED BUSINESS LEGAL SERVICES**

Clients can expect to find a team of professionals at BLG that is entrepreneurial and business minded. We have extensive experience assisting clients in structuring and documenting standard and unique business structures, including mergers, divestitures, acquisitions, joint ventures, licenses and partnerships. Our Competition, Advertising, Government Relations, Labour and Employment and Tax Groups also regularly serve clients of the Life Sciences Group. With such a cross-disciplinary practice, you can look to BLG to act as your trusted and well-connected advisor.

#### FOOD AND DRUG REGULATORY ADVICE

At BLG, we are among the leaders in the food and drug regulatory community in Canada, and assist clients in navigating through the highly complex environment of federal and provincial regulations. We provide strategic advice under the Food and Drug Regulations as well as the *Patented Medicines (Notice of Compliance) Regulations*, and consult on drug reimbursement strategies for dealing with provincial formularies and the Patented Medicine Prices Review Board. We also assist clients in all aspects of the legislative process, including helping clients conceive and implement effective advocacy strategies to achieve their public policy objectives, including changes to statutes and regulations.







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