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Company Life Cycle Progression Requires an Evolving Legal Services Partnership

by Konrad A. Sechley, PhD and Rhowan Sivel

Each stage of the life cycle of a company or a product presents challenges that demand the expertise and resources of a strong legal partner. Be it putting your intellectual property portfolio in order, assessing financing strategies to market your products, or defending your IP rights, legal issues play a large role in the success of Canada's life sciences and pharma companies.

In the sixth edition of *Current Issues*, members of our life sciences team look at legal trends in Canada and around the world at various stages of the life cycle, from start-up through to maturity. Many of the challenges that arise are not local. Developments in Europe or the U.S. may impact business strategies for companies in Canada. That's why we've included a number of comparison pieces to help clients determine which filing strategies work best for them or which markets they should target. We're also pleased to include a contribution from our Moscow office, which celebrated its 20th anniversary in Russia last year.

In a recent exercise, we mapped out 40 unique potential legal "events" in a company's life cycle. An organization's needs at different stages of the life cycle will depend on its stage of development, overall business strategy and market conditions. External factors play a large role: the economy impacts financing strategies, and recent court decisions will impact litigation strategies. Gowlings is able to provide legal support at each stage of the life cycle to help you succeed.

It is for these reasons we continue to be an important partner in the development and success of your business. We hope you find the articles in this year's *Current Issues* helpful, relevant and timely as your company moves through its life cycle, and we invite you to contact any member of our team with questions.



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The Impacts of the Amazon.com Decisions on Medical Use Claims in Canada

by Scott E. Foster and Konrad A. Sechley, PhD

Methods of medical treatment and surgery are not statutory subject matter in Canada. Medical use claims, however, (similar to the "Swiss-type" claims of Europe) are permitted as long as they do not equate to medical or surgical methods (which involve the professional skill of a medical practitioner) and that they satisfy all the other statutory requirements (novel, inventive, useful and sufficiently disclosed).

This has been the position in Canada following the decision of the Supreme Court of Canada in the *Tennessee Eastman* (1972) case and its subsequent decisions in *Shell Oil* (1982) and *Apotex v Wellcome Foundation* (2002).

However, in a recent series of decisions involving Amazon.com's "one-click" patent, the approach to determine what constitutes statutory subject matter has been reconsidered. Although the subject matter of the *Amazon.com* cases was primarily directed at the patent eligibility of business methods and computer implemented inventions, the decisions have had an impact on the way the Canadian Intellectual Property Office (CIPO) purports to determine the validity of medical use claims in Canada.

In the *Amazon.com* cases, CIPO applied a test for assessing patent eligibility by determining the "actual contribution" which was independent of the construction of the patent claims. CIPO's approach was to identify what the inventor claimed to have invented, the "actual contribution" and to determine whether it falls within the statutory definition of "invention." If the actual contribution was considered to lie in non-statutory subject matter, the claim would be rejected. Amazon.com objected to this method of assessment, alleging that it was contrary to long-standing case law

of the Supreme Court of Canada which requires, when assessing the validity of a claim, that the claim as a whole be purposively construed.

When the *Amazon.com* case was heard in the Federal Court of Canada, the judge confirmed that the proper analysis was one of purposive construction, and that the whole claim must be interpreted and assessed for patent eligibility. A parsing of the claim into different elements was not legally valid. However, even after the Federal Court rejected CIPO's "actual contribution" approach, objections to medical use claims that involved a determination of the "actual contribution" were made by examiners.

The objections raised depended on the subject matter of the specific medical use claims at issue, but they usually followed a similar argument. Although a claim may be written in an acceptable format (i.e., a claim to a medical use, not a method of medical treatment) if on considering its inventive concept, the examiner found that the actual contribution to the art required an element of professional skill (such as targeting the use to a pre-identified patient population, e.g., a diabetic) then that claim was patent ineligible as a method of medical treatment.

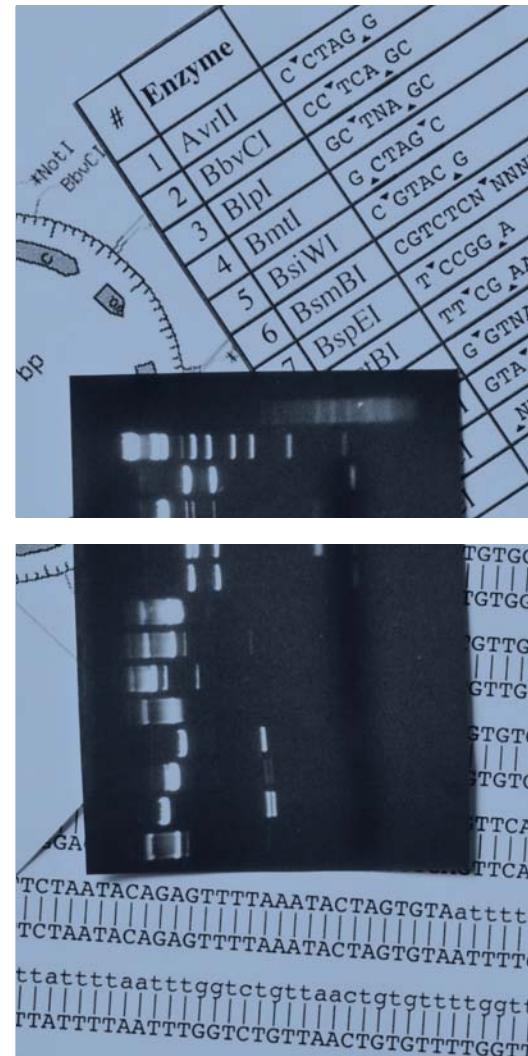
CIPO appealed the Federal Court decision. In November 2011, the Federal Court of Appeal held that the judge was correct. The assessment of validity was to be based on a purposive construction of the whole claim. However, even after the Federal Court of Appeal had confirmed that "in determining subject matter solely on the basis of inventive concept, [CIPO] adopted an analysis that is incorrect in law," objections by examiners to medical use claims based on the "actual contribution" analysis were still issued.

Given these court decisions, it was anticipated that CIPO would modify its approach. In April 2012, CIPO issued three draft practice notices for public consultation, one of which, *Office Practice Respecting Claims to Diagnostic Methods and Medical Uses*, describes CIPO's approach to examining patent applications containing claims to diagnostic methods and medical uses.

In the draft notice, CIPO appears to be returning to its rejected approach for evaluating patent eligibility, but re-stating it as a search for "inventive concept." The new proposed approach appears to be substantially similar in concept to the "actual contribution" analysis described earlier. However, the authors of this article agree with the part of the proposed notice that directs examiners to object to use claims that define "when" or "how" a medicament is to be delivered (as this requires professional skill); whereas use claims that define "what" medicament is to be used may be acceptable.

If CIPO continues to parse use claims using an "inventive concept" approach rather than purposive construction, then it is likely that further court decisions objecting to CIPO's approach will be required to address the issue. For now, patentees will have to be prepared to deal with objections reminiscent of the "actual contribution" approach.

In a recent series of decisions involving Amazon.com's "one-click" patent, the approach to determine what constitutes statutory subject matter has been reconsidered.





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Business Method Patent Protection for Life Science Products

by John Norman, PhD, Xiang Lu, PhD, and Sumiko Mori

The recent *Amazon.ca* decision of the Federal Court of Appeal in 2011 reverses the Commissioner of Patent's long-held belief that business method patents are unpatentable subject matter. The implications of this decision for life sciences companies are far-reaching. As noted by Foster and Sechley earlier in this publication, the *Amazon.ca* decision has implications to medical use claims. Additionally, as a result of the *Amazon.ca* decision, life sciences companies should now consider taking advantage of business method patent protection generally associated with technologies relating to telecommunications, computer devices, software and e-commerce.

However, with advances in computer technology, an increasing number of life science companies are incorporating sophisticated hardware and software into their diagnostic, therapeutic or surgical products. In order to maximize revenues, it is critical that life science companies understand the issues relating to patenting software and business method technologies in Canada. The area of personalized medicine is particularly ripe for advances in software and hardware driven products that can be tailored to develop patient-specific treatments.

The guiding case on business method patents is a 2011 decision of the Federal Court of Appeal in *Amazon.com Inc. v. Commissioner of Patents* (2011 FCA 328). In 1998, Amazon applied to patent its "one-click" technology. The application relates to a method of simplifying the online ordering process. The "one-click" invention allows the user to subsequently purchase items with a single mouse click without repeatedly entering security and payment information. The Canadian Commissioner of Patents refused the application on the basis that a claim to a business method is unpatentable in Canada. The Federal Court and Federal Court of Appeal disagreed, finding that there is no prohibition on business method claims under Canadian law *per se*.

Specifically, the Federal Court of Appeal found that a business method can qualify as an "art" under s. 2 of the *Patent Act* if it satisfies the following three-part test:

- i) It must not be a disembodied idea but have a method of practical application;
- ii) It must be a new and inventive method of applying skill and knowledge; and
- iii) It must have a commercially useful result.

The Court of Appeal further held that the rationale for each of these conditions is grounded in the *Patent Act*, in that they reflect the statutory requirements of novelty, utility, non-obviousness, and the prohibition on the granting of a patent for a mere scientific principle or abstract theorem. As a result, the Court of Appeal ordered the Commissioner to reexamine the application to determine whether the claims of the "one-click" application met the three-part test. Subsequently, the Commissioner granted Amazon's "one-click" patent.

The Court of Appeal also reiterated that, when construing the claims of a patent, one cannot simply look at "what has been invented" and ignore the invention as a whole. Claims are to be interpreted in a purposive manner as set out by the Supreme Court of Canada in *Free World Trust v. Électro Santé Inc.*, (2000) 2 S.C.R. 1024.

Finally, the Court of Appeal provided additional guidance that is helpful to life science companies. The definition of invention under s. 2 of the *Patent Act* is broad and encompasses "unforeseen and unanticipated technology." The *Patent Act* is not static. It must be applied in a manner that permits advances in technology to permit inventors to move from the industrial age to the electronic age. Technology is in a constant state of flux. Any attempt to define it would serve to defeat the flexibility which is so crucial to the purpose of the *Patent Act*.

The *Amazon.ca* decision has clearly had an impact on the availability of patent protection for technologies related to telecommunications, computer devices, software and e-commerce. By extension, patent protection is now available for innovations in software and business methods in the life sciences industry.



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document. One filing strategy particularly favoured by life sciences companies where experimental data may take some time to generate, is to file a series of priority documents that track the development of an invention. This practice will continue to be an important strategy after March 16, 2013.

Change	Impact	Strategy
The challenge of being "the first to the Patent Office" arises in the U.S.	Continued importance of developing creative filing strategies to ensure early filing dates	File a series of priority documents to provide: (i) flexibility with respect to timing for filing the final Patent Cooperation Treaty (PCT) application or regular national application; and (ii) the option to claim priority to multiple applications with different levels of support

The U.S. Shift to First-to-File: What it Means for Your Patent Strategy

by Emma Macfarlane, PhD and Lisa Sim

In the fall of 2011, a controversial change to the U.S. patent system was introduced. The *Leahy-Smith America Invents Act* (AIA) moves the U.S. from a first-to-invent to a first-to-file system. This shift, effective March 16, 2013, aligns the U.S. with the patent systems of other major jurisdictions. While by necessity, global patent filing strategies have incorporated practices based on first-to-file principles, subtle distinctions in the U.S. first-to-file system emphasize the importance of certain of these practices and highlight others that may require adjustment.

This article itemizes some of the key patent practices impacted by the changes with explanations of what they mean to inventors and companies in developing their patent strategies.

1. File Multiple Priority Documents

Under a first-to-file system, creative patent strategies are required to address the tension between the need to be "the first to the Patent Office" and the need for a comprehensively supported priority

2. File Early to Establish an Effective Filing Date

Revisions to the U.S. novelty and obviousness provisions (35 USC § 102 and 103, respectively) under the AIA greatly expand the pool of citable prior art, underscoring the importance of early-filing strategies.

Changes	Impacts	Strategy
Any U.S. application with an earlier “effective filing date,” <i>regardless of whether the priority claim is based on a U.S. or foreign application</i> and irrespective of its publication date, qualifies as prior art	Citable prior art will be expanded to include all U.S. applications with an earlier priority date Broad applicability of such applications to <i>both</i> novelty and obviousness	File early to minimize the available body of prior art
Any prior public use or sale of an invention <i>anywhere in the world</i> qualifies as prior art	The current distinction between activities conducted in the U.S. and elsewhere in the world is eliminated	

3. Review Assignment Practice

The expansion of the pool of prior art under new § 102 and 103 is mitigated to some extent by defined exceptions that emphasize the importance of considering assignment issues early in the patent process.

Change	Impact	Strategy
An earlier filed patent application is not citable art against a later application if both applications were commonly owned <i>as of the effective filing date</i> (i.e., priority date) of the later application	Assignments need to be in place at the time a priority application is filed	Acquire assignments early in the patent process and preferably at the time a priority application is filed

4. Revisit Where to File Priority Documents

Under the current U.S. Code, filing a U.S. provisional application as a priority document is commonly used to establish the date on which an application will qualify as prior art in the U.S., as well as the date from which the U.S. one-year “grace period” is calculated. The changes brought in by the AIA will lessen the importance of filing priority documents in the U.S.

Change	Impact	Strategy
Foreign and U.S. priority claims will be treated as equal for establishing the date on which application becomes prior art and for calculating the one-year grace period	Filing a U.S. provisional application as a priority document will be less important	After March 16, 2013, consider whether filing priority documents in other jurisdictions, for example a home country, may be advantageous

Conclusion

While the AIA appears to bring the U.S. patent system in line with other jurisdictions, certain aspects of the amendments create divergence. The months leading up to the implementation of the first-to-file provisions offer a unique window of opportunity to review current filing strategies to ensure that the upcoming U.S. changes are leveraged advantageously. As part of this review, existing technology portfolios should be assessed to identify and file applications for any inventions that may benefit from prosecution under a first-to-invent system. Such an opportunity exists so long as all subject matter claimed has an effective filing date prior to March 16, 2013.



The *Prometheus* Decision: What is the Future for the Protection of Advances in Personalized Medicine?

by Hélène D'Iorio

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The recent *Prometheus* decision rendered by the U.S. Supreme Court (U.S., No. 10-1150) is perceived by many as a blow, if not a death knell, for the protection of advances in personalized medicine.

In a unanimous ruling, the U.S. Supreme Court held that method claims of two patents directed to optimizing the dose of a specific drug for treating an autoimmune disease are not patentable because they merely recite laws of nature.

The Court held that the claims did not do “significantly more” than describe the laws of nature, and accordingly, were not patentable. The steps in the claimed methods (apart from the natural laws themselves) were found to involve “well-understood, routine, conventional activity previously engaged in by researchers in the field.” The Court expressed the view that upholding the patents at issue would “risk disproportionately tying up the use of the underlying natural laws, inhibiting their use in the making of further discoveries.”

Unfortunately, the situation in Canada is not very different. In recent years, claims directed to dosage regimens (expressed, for example, as plasma concentrations in a patient) have been rejected as falling outside the definition of

“invention” because they are directed to a method of medical treatment that requires professional skill. It is to be noted that method of medical treatment claims are not patentable subject matter in Canada because they are essentially non-economic and unrelated to trade, industry or commerce; in other words, not directed to a vendable product (unlike use claims, which are patentable).

The situation in Canada is somewhat anomalous because claims directed to a dosage regimen have been upheld by the Supreme Court of Canada, while in more recent decisions, the same type of claims have been struck down.

In *Apotex v. Wellcome Trust et al.* 2002 S.C.C. 77, 21 CPR (4th) 499 (pertaining to the AZT Patent), the validity of the following claim was upheld:

Claim 27: A formulation according to claim 21 or 26, wherein said 3'-azido-3'-deoxythymidine is present in an amount effective to achieve a peak plasma concentration on administration of from about 1 to about 75 µm.

The Trial Division of the Federal Court of Canada upheld the validity of the claim on the ground “the patent deals with an economic area related to trade, commerce or industry. Indeed, the

patent claims protection for drug formulations which are of considerable economic as well as medical value." The decision of the Federal Court, in respect of the question of methods of medical treatment, was upheld by the Federal Court of Appeal (10 CPR (4th) 65). That decision, in turn, was appealed to the Supreme Court of Canada. On appeal, the Supreme Court specifically addressed the question of whether any of the claims of the AZT Patent were directed to a method of medical treatment. The Supreme Court stated, "The AZT patent does not seek to 'fence in' an area of medical treatment. It seeks the exclusive right to provide AZT as a commercial offering. How and when, if at all, AZT is employed is left to the professional skill and judgment of the medical profession."

Yet in subsequent decisions, commencing with the *Axcan* decision (2006 FC 527), the Courts rejected claims directed a dosage regimen. In *Axcan*, the claim at issue read:

Pharmaceutical composition for the treatment of primary biliary cirrhosis, characterized in that it includes ursodeoxycholic acid as a vehicle and if necessary pharmaceutical excipients, the said composition being processed in a form allowing for the said treatment of primary biliary cirrhosis based on a dosage of 13 to 15 mg/kg/day.

In distinguishing the *AZT* decision, the Court held, "The invention here is quite different. It is up to the physician based on his or her knowledge of the patient's rate of metabolism and other factors to determine the appropriate daily dosage. I cannot, for a moment, contemplate that *Axcan* can claim exclusive property in the dosage and sue a physician for prescribing . . . at a dosage less than 13 mg/kg/day or greater than 15mg/kg/day." The Court goes on to conclude, "There is a distinction between the dosage in a capsule and a dosage range based on the patient's weight. As I read the claim, the emphasis is on the dosage range and a dosage range is not a vendable product."

The Canadian Intellectual Property Office has also been rejecting claims directed to a dosage regimen on the basis of the *Axcan* decision.

In conclusion, a comparison of the U.S. and the Canadian jurisprudence can be summed up as follows: Different grounds of rejection but the same result.

The Canadian Intellectual Property Office has been rejecting claims on the basis of the *Axcan* decision.





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Don't Delay: Global Considerations for Patent Assignments

by Gloria Hsi, PhD and Lisa Sim

The ability to rely on ownership of an invention is critical to a business seeking full enjoyment of the rights available to it in the invention. While assignment agreements drew little attention in the past, recent decisions in multiple jurisdictions confirm the importance of considering assignment agreements early in the patent process and throughout the life cycle of a business' global patent strategy. These decisions raise key considerations for securing ownership and avoiding surprises.

Review and Confirm Assignments

The realities of business make it prudent practice to acquire assignments of inventions before the invention even exists. For example, businesses commonly require their employees and contractors to execute employment agreements including assignment provisions that purport to assign ownership of all future inventions and related rights to the business.

In Canada, two recent decisions considered this issue: *Verdellen v. Monaghan Mushrooms Ltd.*, 2011 ONSC 5820; and *Century 21 Canada Ltd. Partnership v. Rogers Communications Inc.* [2011] B.C.J. No. 1679. These cases applied basic property law principles in restating that assignment agreements cannot effectively assign legal ownership to intellectual property, such as an invention, if the invention does not yet exist. Rather, an assignment to a future invention is merely a promise to assign, requiring additional acts to complete the assignment once the invention is created.

It then becomes critical to ensure that inventor-employees are obligated to, and do in fact, execute further agreements to confirm the business' ownership to a future invention once it is made.

Regularly revisiting ownership status of an invention is also good practice. An opportune time for reviewing ownership status and confirming assignments is early in the patent process, such as at the time of filing.

Have Rights Actually Been Assigned?

In contrast to Canadian practice, U.S. law establishes that no further action is necessarily required to convert legal title to a future invention once the invention comes into being (*Filmtec Corp. v. Allied-Signal, Inc.*, 939 F. 2d. 1568 (Fed. Cir. 1991)). In this context, recent U.S. decisions distinguish a present assignment of a future interest from a mere promise to assign (*C. R. Daniels, Inc. v. Naztec Int'l Group, LLC*, 1:11-cv-01624 (D. Md. Apr. 13, 2012); *Board of Trustees of Leland Stanford Junior University v. Roche Molecular Systems, Inc.*, 131 S. Ct. 2188 (2011)). In these decisions, the use of language such as “does hereby assign” or “does assign” was considered to effect a present assignment of a future interest, whereas language such as “agree to assign” was considered to transfer a mere promise to assign rights in the future. The impact of this distinction can be severe since, unlike a present assignment of a future interest, a promise to assign results in no transfer of title until the assignment is confirmed.

It is, therefore, important to consider the language of the assignment to confirm that interest has actually been assigned and not just promised.

Assign Priority Rights Before Filing

A valid priority date can be critical to patentability in that it limits the state of the art that is considered when assessing novelty and inventive step requirements. Assignment of the right to claim priority can, therefore, have a crucial affect on patentability, as recently demonstrated in decisions by the European Patent Office (EPO) Boards of Appeal (T0062/05) and national courts of the contracting states to the European Patent Convention (*Edwards Lifesciences AG v. Cook Biotech Incorporated* [2009] ENHC 1304 (Pat)). These decisions emphasize stringent requirements for transferring priority rights. Specifically, the decisions confirm that priority can be claimed only by the identical applicant of the earlier application, and that the right to claim priority is only transferable so long as it is transferred by way of assignment or the operation of law, before the filing of the later application.

The potentially serious consequences of an invalid transfer of a priority claim highlight the importance of considering assignments early in the patent process, and preferably before relying on a priority claim.

Recent developments in assignment practice worldwide confirm the increasing importance of considering assignment issues early in the life cycle of a business' global patent strategy to ensure that ownership of the invention and its related rights is secured.



. . . recent decisions confirm the importance of considering assignment agreements early and throughout the life cycle of a business' global patent strategy.



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Opposing Patent Rights Before the Canadian, European, and U.S. Patent Offices

by Sonia M. Ziesche and Sean Alexander

Third parties frequently wish to challenge the validity of problematic patents or patent applications to secure freedom to operate, avoid potential infringement suits, or simply as a tactic in business negotiations. While it may be necessary to resort to court proceedings it is usually simpler and less costly to contest a patent at the appropriate patent office.

Standards for patentability, state of the art, and the legal basis for opposing patents can differ from country to country, so it is important to develop a cohesive approach to maximize chances of success. In this article, we review the ways patent rights may be challenged in Canada, Europe and the U.S.

Challenging Patent Rights in Canada

There are a number of ways to contest patent rights before the Canadian Patent Office. Before grant, a third party may file published prior art documents accompanied by an explanation of why the art is pertinent under section 34.1 of the *Patent Act*. In addition, they may file a protest pursuant to section 10 of the *Patent Rules*. A protest may extend beyond the mere submission of prior art and can include submissions questioning patentability on a variety of grounds.

Post grant, a request for re-examination under section 48.1 of the *Patent Act* may be filed, citing published prior art.

These procedures are *ex parte* and the third party is not permitted to communicate directly with the Examiner or Re-examination Board. Indeed the third party is not even informed of any actions taken as a result of their intervention. Consequently, these provisions are rarely used and it is more common for an interested party to attempt to impeach a patent under section 60 of the *Patent Act* or to make a counterclaim for invalidity when sued for infringement.

The European Perspective

Within nine months of the date of grant, a European patent may be opposed under Article 99 of the *European Patent Convention* (EPC). The grounds on which a patent may be opposed are laid out in Article 100 EPC and include lack of patentable subject matter, failure to sufficiently disclose the invention, and that the patent extends beyond that which was originally filed. Opposition proceedings are *inter partes* and any party may request an oral hearing by the Opposition Board. Frequently a decision is rendered at the conclusion of the oral hearing. On request, a decision of an Opposition Board may be subject to review by a Board of Appeal.

In addition to post-grant opposition, Article 115 EPC provides basis for a third party to make observations to the European Patent Office concerning the patentability of a patent or patent application. As in Canada, submitting observations does not make one a party to proceedings and consequently the process is less frequently utilized than opposition proceedings.

Patent Challenges in the U.S.

The *Leahy-Smith America Invents Act* proposes to expand the provisions on pre-grant third-party observations by encouraging third-party submissions of relevant documents to the U.S. Patent Office prior to issuance of a patent application filed on or after September 16, 2012. The prior art may now be accompanied by concise statements explaining each document, thus making the observations significantly more powerful than the current provisions. However, the opportunity for filing such observations is relatively curtailed in that observations may only be made prior to the notice of allowance and within six months of publication or the issuance of the first rejection.

The *America Invents Act* will also provide two new options for challenging the validity of a U.S. patent – post-grant and *inter partes* review (for more on the *America Invents Act*, see page 10).

Under the new post-grant review process, granted U.S. patents that have an effective filling date of March 16, 2013 or later may be challenged within nine months of grant or issuance of a re-issued patent.

A third party may request cancellation of one or more claims alleging invalidity based on any ground, with the exception of failure to comply with “best mode.” Prior art is not limited to printed publications, and may include evidence of sales or public use, etc. Post-grant review may also be granted if the petition raises a new or unsettled legal question important to the patent system. After the Patent Trial and Appeal Board renders its final decision, the petitioner is estopped from asserting invalidity of any claim in the patent on any ground that the petitioner actually raised, or could reasonably have been expected to raise, before the board.

Inter partes review, which replaces the current “*inter partes* reexamination” proceeding, is intended to be a relatively quick proceeding for challenging a U.S. patent’s validity in the Patent Office on the grounds of double patenting, anticipation, or obviousness on the basis of printed publications or patents. The new *inter partes* review procedure commences September 16, 2012.

In view of the variety of options available, and the differences in national laws, it is advisable to seek expert help when opposing a patent. In addition, patent owners should place a premium on high-quality prosecution so as to minimize the grounds available to a potential opponent.



Patent Practice in the Russian and Eurasian Patent Offices

by David Aylen

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Businesses operate globally, sell products internationally and reach consumers in every time zone. Intellectual property portfolio management decisions, however, are very much based on jurisdiction. Gowlings has operated in Russia and the CIS for over 20 years, working with clients to determine the intellectual property strategies that work best for them. The following article outlines considerations for filing in this part of the world.

In the Russian Federation, CIS member states and in the Ukraine, a patent may be obtained directly under a country's national laws. For example, a Russian patent is granted by ROSPATENT. For some countries, including Russia, the alternative is to seek patent protection through the Eurasian Patent Office (EAPO) for coverage in all of its member states: Russia, Kazakhstan, Belarus, Azerbaijan, Armenia, Kyrgyzstan, Moldova, Tajikistan and Turkmenistan. Ukraine, Georgia and Uzbekistan are not part of the EAPO.

The overwhelming majority of applications are direct-filed in Russia, in Ukraine, Kazakhstan and Belarus. For example, in 2010 new applications filed were as follows:

Applications 2010	
Russia	42,500
Ukraine	5,312
Belarus	1,933
Kazakhstan	1,700
Eurasia	3,329

Whether it is a direct-filed application in Russia, Ukraine, in a CIS country or a national phase entry filing through the Patent Cooperation Treaty (PCT), or an EAPO-filed application, an issued patent has a term of 20 years from its filing date. In Russia, patents are granted by ROSPATENT for inventions, utility models and industrial designs but only patents for inventions may be obtained via PCT and EAPO filings.

Under the EAPO regime, a successful applicant receives the grant of a Eurasian patent, which is valid in all contracting states. Issued Eurasian patents accord rights that are effectively equivalent in scope to individual patents that would otherwise be granted on a national level in each contracting state.

Prosecution: Determining the Right Strategy

The following chart illustrates the key components of filing under the three main methods.

RUSSIA Direct	RUSSIA PCT	EURASIA
<p>Request for grant (full name and address of applicant and inventor)</p> <p>Specification, etc. (1 copy of the abstract, specification, drawings if any, and claims on A4 paper)</p> <p>Certified copy of priority application within 16 months of claimed convention priority date</p> <p>Translation of the full specification into Russian within 2 months</p> <p>No POA unless requested</p> <p>Assignment when available and if needed</p> <p>(Electronic filing available)</p>	<p>Request for NPE 31-month time limit</p> <p>Translation up to 4 months after filing</p> <p>No POA unless requested (Electronic filing available)</p>	<p>Available via PCT</p> <p>Request for grant (full name and address of applicant and inventor)</p> <p>Specification, etc. (1 copy of the abstract, specification, drawings if any, and claims on A4 paper)</p> <p>Translation must be filed within 2 months or by 31st of the month if via PCT</p> <p>POA at time of filing</p>

When filing a Eurasian application, all contracting states are automatically designated. It means an applicant is not able, at this stage, to seek patent protection in only some of the contracting states. The first opportunity to narrow down the territories is at the time of grant when the first annuities are due to be paid. If the annuity for a certain country is not paid, the patent is abandoned in that country.

Subject Matter, Novelty and Patentability: Russia

To be patentable, the subject matter of an invention (Article 1350) must be a technical solution in any area related to a product or a means. A product includes a structure, substance, microorganism strain, or culture of cells of plants or animals. A means is a process of conducting actions on a material object with help of material means.

An invention is patentable (Article 1350(1)) if it is new, has an inventive level and is industrially applicable, i.e., if it is novel, unobvious and useful.

“New” means that it is not known from the level of technology (Article 1350(2)). The level of technology includes any information that became generally accessible in the world before the priority date of the invention. It also includes previously filed applications in Russia with an earlier priority date that are subsequently published within 18 months under Article 1385(2).

“Inventive level” means that, for a specialist, it does not obviously follow from the level of technology (Article 1350(2)).

“Industrially applicable” means that it can be used in industry, agriculture, health care, or other branches of the economy, or the social sphere (Article 1350(4))

There is an “absolute novelty” requirement with a six-month grace period associated with the prior disclosure of the invention by the inventor, so long as the actual filing date of the application in ROSPATENT, and not the priority date, is no more than six months from the date of that disclosure by the inventor (Article 1350(3)).



Subject Matter, Novelty and Patentability: In the EAPO

While the procedural and substantive requirements for applications filed in the EAPO strongly resemble those for applications filed directly in Russia, they are not, in literal terms, the same.

There is no definition or list of criteria for eligible subject matter. The Patent Regulations of the Eurasian Patent Convention (EPC) stipulate a Eurasian patent shall be granted for any invention that is novel, involves an inventive step and is industrially applicable (Rule 3(1)).

“Novel” means that it is not anticipated by prior art. Items of prior art may only be taken into account separately for the purpose of determining novelty.

“Prior art” is any kind of information made available in the world before the date of filing of the Eurasian application or, where priority is claimed, before the priority date of the application. It can also include a co-pending application having an earlier filing/priority date if that application is subsequently published.

“Inventive step” means that it is not obvious to a person skilled in the art.

“Industrially applicable” means that it can be used in industry, agriculture, public health or other fields of human activity.

There is an “absolute novelty” requirement with a six-month grace period as there is in Russia. However the six-month grace period is defined as: information relating to the subject matter of the invention that has been made available to the public not earlier than during the six months preceding the filing date of, or the priority date claimed for, the Eurasian application, by the inventor or applicant or by any person having obtained the information directly or indirectly from them (Rule 3(2)).

Examination

A few other differences to note include examination and office actions. In Russia, examination may be deferred for up to three years, but in the EAPO, examination must be requested at the time of filing. With regards to office actions in Russia, a response to an office action is typically due within two months from the date of receipt, which is deemed to be no longer than four months from the date of issuance. One 10-month extension is possible. In the EAPO, a response is typically due within four months of issuance. Extensions of time of any length are possible.

The Eurasian Patent Office provides an easy, quick and cost effective means of obtaining patents in Russia and the CIS member states. It is a logical choice when a decision has been made to protect an invention in multiple countries forming part of the CIS. The EAPO provides a particularly advantageous means of sidestepping the patent offices of the smaller CIS countries where there is little transparency and great uncertainty with respect to practice and procedure. EAPO practice and procedure is relatively predictable, permissive and user-friendly.

On the other hand, in cases where Russia and Ukraine are the primary countries of interest, direct filing in those countries is the preferred route. Ukraine is not part of the EAPO. Moreover, in the context of a contentious invalidity challenge, it is thought the issued claims of a Russian patent are likely more robust than those of an EAPO patent.

Resources

The websites for Russia, Ukraine and others, as well as for the EAPO provide quite comprehensive information as to the process, background and relevant databases (subscription sometimes required).

Russia

Official site: www.rupto.ru

Search site: www.fips.ru

Eurasia

Official site: www.eapo.org/eng/ea/

Search site: www.eapatis.com/ensearch/

Ukraine

Official site: www.s dip.gov.ua

Search site: www.ukrpatent.org

Kazakhstan

Official site: www.kazpatent.kz

Belarus

Official site: www.belgospatent.org.by



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Eric practises taxation, finance and banking law. He also worked as a financial auditor and as a risk management and accounting policy implementation specialist for several years in the financial services industry in the United States, Canada and Singapore.

Research and Development: Continued Support in Canada

by Carole Chouinard, Robert D. Ford and Eric Koh

Canada's Scientific Research and Experimental Development (SR&ED) Program continues to be one of the most generous programs of its kind in the world. The tax incentives are delivered through the *Income Tax Act* (ITA) and administered by the Canada Revenue Agency (CRA). Unlike the comparable U.S. program, Canada's SR&ED program is legislated, i.e., it is not subject to annual budgetary limitations.

The Canadian Federal Budget 2012 (Budget 2012) contains important changes to the SR&ED program which are modeled on the recommendations of an expert panel and widely published in the report, *Innovation Canada: A Call to Action* (the Jenkins Report). Generally, despite certain changes introduced by Budget 2012, the SR&ED program continues to offer opportunities and benefits to the life sciences industry in Canada.

Relative to the fundamental changes and reductions recommended in the Jenkins Report, changes to the SR&ED program proposed by Budget 2012 are incremental rather than revolutionary. Budget 2012 recognizes the importance of the SR&ED program by maintaining the existing framework.

The general investment tax credit rate applicable to SR&ED qualified expenditures will be reduced to 15 per cent from 20 per cent after 2013. However, the negative impact of this reduction to life sciences companies will be limited, as the enhanced rate of 35 per cent will continue to be available to Canadian-controlled private corporations (CCPCs) as defined in the ITA.

The remaining amendments to the SR&ED program will impact all companies. In 2014, SR&ED capital expenditures will no longer be eligible for SR&ED deductions and investment tax credits. It is likely that such expenditures will now be capitalized and amortized over the

life of the capital property. Additionally, the amount of an arm's-length contract payment eligible for SR&ED tax credits for the payer will exclude any amount paid in respect of a capital expenditure incurred by the performer of the contract.

Furthermore, the 65 per cent prescribed rate to be applied to the simplified proxy SR&ED overhead expenditures will be reduced to 60 per cent for 2013 and to 55 per cent thereafter. Finally, beginning in 2013, the expenditure base for tax credits will exclude the profit element of arm's-length SR&ED contracts, such that only 80 per cent of the contract costs will be eligible for tax credits. This is unfortunate as it unnecessarily penalizes cost-efficient life sciences companies that outsource to reduce costs.

Undeniably, the overall reductions to the SR&ED program will reduce its benefits to life sciences companies. These reductions are expected to save the government approximately \$1.3 billion over the next five years. Government is directing these savings towards increased expenditures in other programs which will mitigate negative impacts and may indeed prove to be a net benefit to life sciences companies located in Canada.

Early-stage funding is crucial for life sciences companies that are heavily dependent on cash to fund their R&D activities. However, capital markets continue to be hobbled by economic uncertainty, and venture capital financing remains anemic in Canada. Therefore, Canadian innovation companies, particularly in the life sciences industry, are often unable to access adequate funding to develop into full commercial enterprises. Budget 2012 acknowledges this problem and includes \$500 million over five years to stimulate and support venture capital activities in Canada. Furthermore, \$95 million will be



provided over the next three years, and \$40 million annually thereafter, to make the Canadian Innovation Commercialization Program permanent.

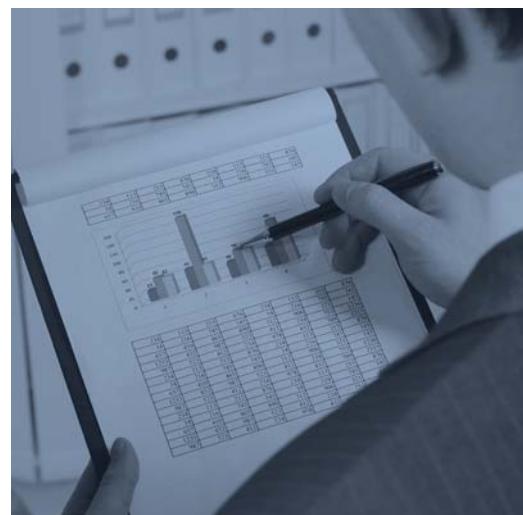
In addition, the National Research Council's (NRC's) Industrial Research Assistance Program, which is currently underfunded, will receive an additional \$110 million per year. NRC will also create a concierge service to assist small and medium-sized businesses. Private and public sector research collaboration will be enhanced through additional funding for new and existing programs. There is also additional funding to support R&D in universities and other institutions.

Budget 2012 also introduces measures to inject more predictability into the SR&ED program which should reduce compliance costs. These measures include a CRA pilot project to determine the feasibility of a formal pre-approval process, enhancing CRA's self-assessment eligibility tool and collaboration between CRA and industry representatives, and improving the Notice of Objection process to allow for a second review of scientific eligibility determinations.

There are indications that Budget 2012 is only the initial step of a comprehensive overhaul of the manner in which innovation and R&D is publicly financed in Canada. The government has stated that there will be additional changes and initiatives in response to the recommendations in the Jenkins Report.



The SR&ED program continues to offer opportunities and benefits to the life sciences industry in Canada.





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When Life Sciences Meet Technology

by Benoit Yelle

Whereas at one time, inventions could be characterized as falling squarely within one field, inventions may now cross the boundaries of numerous fields. This trend is also observed in litigation. A 2012 decision of the Federal Court of Canada confirms the boundaries between fields of art have indeed blurred.

In *Eurocopter v. Bell Helicopter Textron Canada Limitée*, 2012 FC 113, the defendant was successful in invalidating claims directed to a helicopter landing gear based on a lack of sound prediction defence.

While the lack of sound prediction defence is common in proceedings involving inventions in the pharmaceutical field, it was not previously considered as an effective strategy in the case of a mechanical invention such as helicopter landing gear.

The Federal Court concluded that “an explicit promise to reduce drawbacks of prior art ‘significantly’” had been made. The drawbacks were identified as:

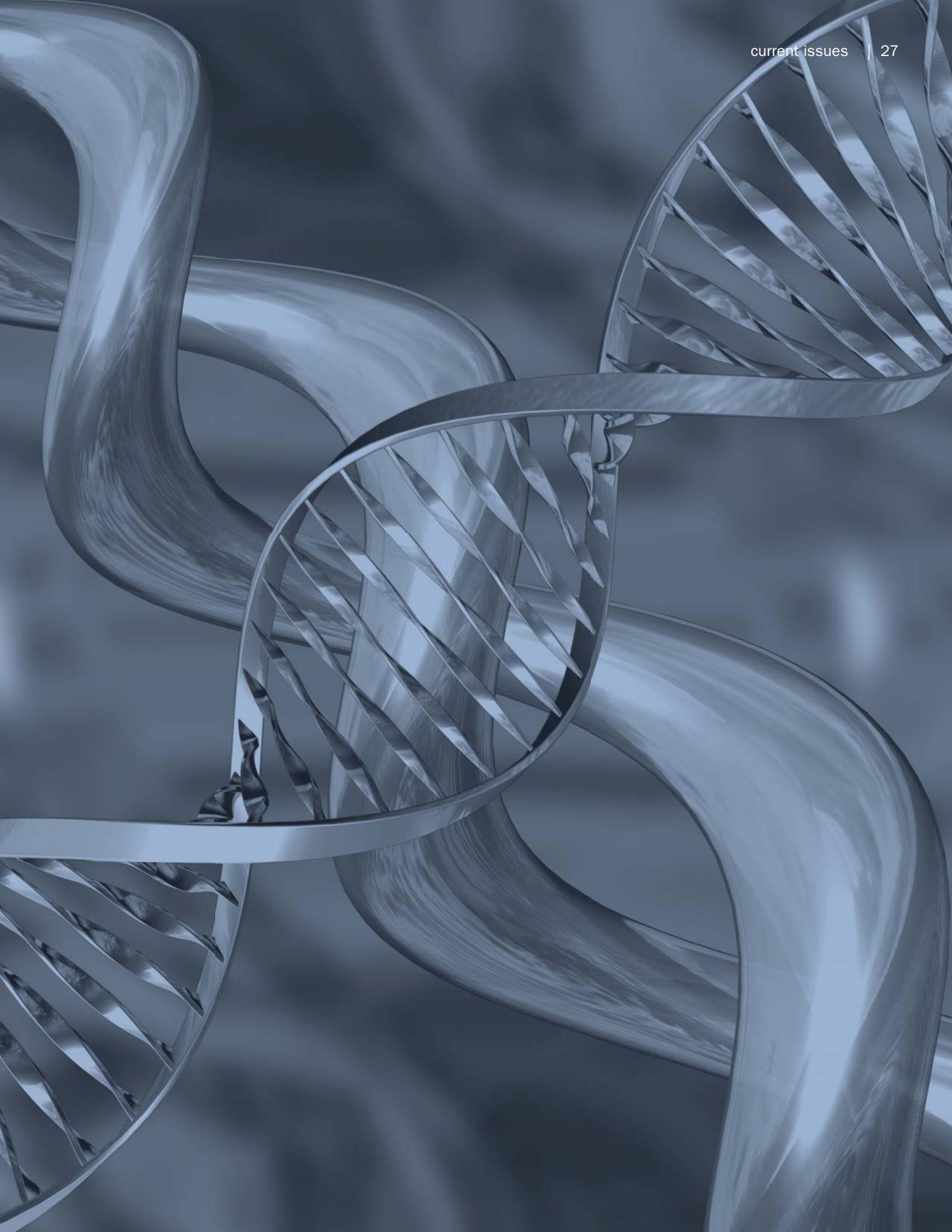
- Elevated acceleration factors upon landing (load factors);
- Difficult frequency adaptation with respect to ground resonance; and
- High landing gear weight.

The Court concluded that this “is the promised utility of the disclosed invention.”

The Court held that the patentee had failed to provide enough evidence to establish the claims at issue had a demonstrated utility, or that they were based on a sound prediction.

As a result, a number of claims were invalidated because, based on the promised utility, there was no demonstrated utility or otherwise sound prediction of utility in the description.

While the decision is currently under appeal, the take-home lesson for now is that inventions in the mechanical or IT fields are not immune from attacks on their validity based on grounds such as sound prediction. Accordingly, care must be taken in drafting patent applications to ensure that statements that could be construed as being directed to the promised utility of the invention are kept to a minimum, and that the bar of promised utility is set as low as possible.





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Repairing Medical Devices in Canada and Europe: Permissible Repair or Infringement?

by Hélène D'Iorio and Tuba Yamac, PhD

The procurement and replacement of medical devices can be prohibitively expensive and as a result, hospitals, health clinics and laboratories are increasingly opting to repair or recondition existing equipment, or to purchase used and repaired or reconditioned equipment. Repairing is generally understood to mean fixing something that is broken. However, reconditioning can go beyond a simple repair and involve re-wiring, replacing worn parts, upgrading parts, or even taking apart and rebuilding an entire device with new or replacement parts.

Despite the cost savings and environmental benefits of recycling, the reconditioning of single- and multiple-use devices raises concerns of safety, traceability, regulation and liability. In the case of patented medical devices, there is a risk of patent infringement by the parties performing the reconditioning (the reconditioners), by the purchasers of the reconditioned device, and possibly by the suppliers of the parts making up the reconditioned device.

The Canadian Perspective

A Canadian patent gives the patent owner a right to stop others from making, constructing, using and selling the patented product in Canada. The common law doctrine of exhaustion of rights provides the purchaser an implied right to use, repair and resell that patented product. Repair that prolongs the life and utility of the product is permissible. Procuring entirely new parts can also be considered permissible where a “new” product is not manufactured. Work going beyond repair, such as the reconditioning of a medical device that results in a remanufacture of the patented product, is considered to infringe the patent. It should also be noted that adapting a patented device may place it under the

claims of another patent. Also, reconditioning a device outside of Canada may not escape infringement once the device is imported into Canada.

The reconditioner as well as the purchaser of the reconditioned product, such as the hospital or clinic, may be liable for direct infringement as direct infringers. The supplier of parts may also be liable for indirect (contributory) infringement if:

- It sells a component of the patented product that results in direct infringement;
- It induces or exercises influence over the direct infringer such that the infringement would not have taken place without that influence, and;
- It knowingly exercised this influence.

The European Perspective

In Europe, infringement of European patents is considered by the national courts of each member state. They tend to have differing approaches, particularly on the topic of permissible repair versus impermissible reconstruction, and may come to different findings of infringement based on the same claims of a European patent. A centrally enforceable EU patent which would remove the divergent approaches is currently under discussion.

For example, the U.K. currently takes a narrow approach to what constitutes permissible repair compared to the German courts. In a recent case, *Schütz (UK) Ltd v. Werit (UK) Ltd* [2011] EWCA Civ 303, the U.K. Court of Appeal ruled that where a component forms part of the patented product as defined in the claims, its replacement in general constitutes a prohibited re-making of the product independent of its contribution to the technical effect achieved by the invention.

In contrast, the German courts have a balance-of-interest outlook and will consider what is the essential element of the claimed invention during infringement proceedings. Repair or replacement of the essential claimed element would be found to infringe the claim, whereas repair or replacement of an inessential claimed element is considered permissible. This means in the U.K., patent holders appear to have stronger rights of control over the repair and reconditioning of patented products.

In Canada as in Europe, there exists a line, albeit blurry at times, between repair and infringement. Crossing it could prove to be a very expensive proposition, so reconditioners, owners and purchasers of reconditioned devices and suppliers of parts, beware!



The reconditioning of single- or multiple-use devices raises concerns of safety, traceability, regulation and liability.





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When Two is Better than One: Synergistic Combination Patents

by Emmanuel Manolakis and Lee A. Johnson, PhD

As the Supreme Court acknowledged in the 1979 decision in *Monsanto v. Commissioner of Patents*, citing with approval an earlier decision of the Chancery Division:

In the drug field in particular research is very expensive and the number of “winners” found is only a minute proportion of those synthesized and tested. Once a winner is found, however, it is very common also to find that bodies more or less closely related to it have the same or even greater activity . . . Unless, therefore, the original inventor . . . can properly be given reasonably broad cover, it is likely that soon after others hear of his success similar bodies will be made by others . . . [and] any reward he may obtain for his invention and research is likely to be of little value.

In other words, in life sciences research, the mythical “eureka” moment often occurs only after an enormous investment of effort and expense. Once it does, absent strong patent protection, copycats looking to capitalize on the gains of others are likely to follow.

As with any pharmaceutical invention, the discovery of a pharmaceutical combination that displays a synergistic effect (defined in the 2009 Federal Court *Lundbeck* decision as one in which the use of two or more compounds in a combination therapy generates a result that is greater than the sum of its parts) will often be surprising, and arise after extensive investigation. Therefore, the inventor should consider seeking patent protection not only for the “winning” synergistic combination, but also for other combinations for which a similar synergistic effect may be predicted. For example, if compounds A and B are shown to have a synergistic effect when administered together, and compounds B and C share a common characteristic, the inventor may wish to seek patent protection over the combination of both A + B and A + C. In Canada, such protection may be obtained under the doctrine of sound prediction, provided certain criteria are met by the

patent application, and by the prediction itself.

Under the doctrine of sound prediction, a patent must set out (i) a factual basis for the prediction; (ii) an articulable and “sound” line of reasoning leading from the factual basis to the prediction; and (iii) proper disclosure. While case law does not clearly define what constitutes a sound prediction, the following factors have been considered:

- Claims must be fairly based on the disclosure;
- It must be *prima facie* reasonable that the patentee has a claim;
- Prediction cannot mean a certainty; and
- The desired result must be inferable from the factual basis.

For a synergistic combination patent, factual basis may be provided by the observed synergistic effect. Support is a matter of fact rather than degree. In the 1982 *Re Lilly Industries* decision, the Patent Appeal Board held that disclosure data exemplifying the synergistic effects was not explicitly required. In that case, the factual basis was limited to a statement that, “. . . it has been surprisingly found that the combinations of the invention are particularly effective . . .”. It should be noted that such an Appeal Board decision, while persuasive, would not be binding on any court, and it is generally advisable that a patent applicant disclose at least some data, if available, demonstrating the observed synergistic effect.

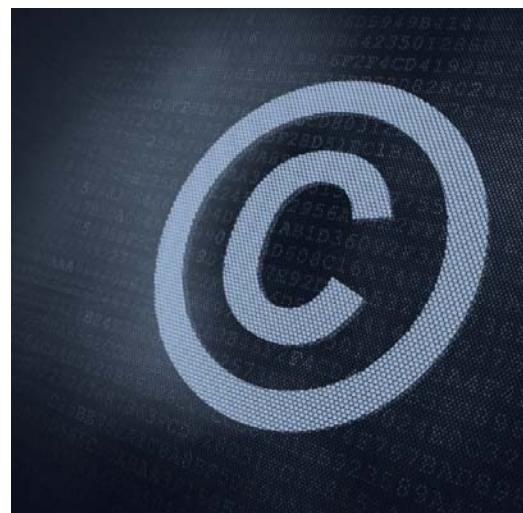
For the “sound” line of reasoning, the disclosure may describe common characteristics between the tested combination and the other claimed combinations, e.g., common chemical structures, functions, or modes of action. A theoretical explanation as to the cause of the synergistic effect, and why it may be reasonably expected in respect of the other, untested, claimed combinations, may also be advisable.

Over the course of prosecution (or litigation), it may be advantageous for an inventor or another expert in the field of the invention to provide evidence about what was commonly known in the art at the filing date. Returning to our hypothetical scenario, having discovered the (tested and disclosed) synergistic combination of A and B, the patentee also claimed the (untested) combination of A and C. Add to this scenario the assumption that it was known, at the date of filing of the patent application, that B and C share a common characteristic (e.g., three-dimensional shape). Further assume that knowledge of this common characteristic would have led a skilled person to predict, based on the test results for A + B, that A + C would also be synergistically effective. In this case, information about commonly shared knowledge may be useful in justifying the “soundness” of the prediction. Such information may aid in persuading the Patent Office (or a court) the claims to A + C are valid.

A surprisingly synergistic combination may constitute a valuable invention worthy of patent protection. To ensure that, following the “eureka” moment of its discovery, the inventor is rewarded with the broadest scope of patent protection possible, careful consideration of Canadian patent law particularities and practice should be taken in preparing the patent application, and carrying it through examination before the Patent Office.



... the discovery of a pharmaceutical combination that displays a synergistic effect will often be surprising and arise after extensive investigation.





Leveraging and Licensing IP Assets to Grow Your Bottom Line

by Grant W. Lynds

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Focused on IP litigation, including pharmaceutical patent litigation, Grant's practice also extends to patent preparation and prosecution, primarily in the mechanical arts, patent licensing, opinions, and portfolio management.

Companies strive to increase the value of their assets and the revenue earned from those assets. These assets may include intellectual property, but companies often struggle with identifying an appropriate value for IP assets. The mission to derive more revenue from IP assets is a step in the right direction to maximize their revenue-earning potential, and doing so may drive boards of directors to consider IP assets as an integral part of their long-term investment decisions.

First, companies must take stock of their IP assets by conducting an IP audit or assessment. This type of audit frequently entails interviewing and canvassing the appropriate managers within the company to identify all of the patents, registered and unregistered trade-marks, trade secrets, know-how, copyrights and industrial designs.

The next step should be to consider all IP assets that could be protected. This is a time-sensitive task that should be addressed immediately if it is not part of the company's ongoing operations. For example, if there are inventions that could be the subject of patent protection, one needs to identify those inventions in view of any public disclosures to ensure they can be protected. By the nature of the patent prosecution process, it

takes time to obtain a portfolio of issued patents, which may then be exploited. The investment in a patent portfolio also requires the non-monetary commitment of technical time from inventors. This time investment needs to be understood by all of management to ensure a shared commitment to the process and recognition that exploitation revenue may not come quickly.

In carrying out this step it is important to think about IP in its broadest sense when reviewing the company's operations, instead of focusing on the two types most frequently encountered, patents and trade-marks. Even if there has been a public disclosure of an invention or if there is non-patentable subject matter, thus barring one from obtaining patent protection, one should take a broad view to determine whether there is technical know-how that could be packaged as a licensing opportunity.

Another consideration is whether the value of the IP assets is to be realized by excluding competitors from the relevant market or by generating revenues from licensees. If the goal of asserting a patent portfolio is to protect the market by excluding infringers, this is best understood at the outset, since it will impact the strategy for asserting or litigating that portfolio. That strategy

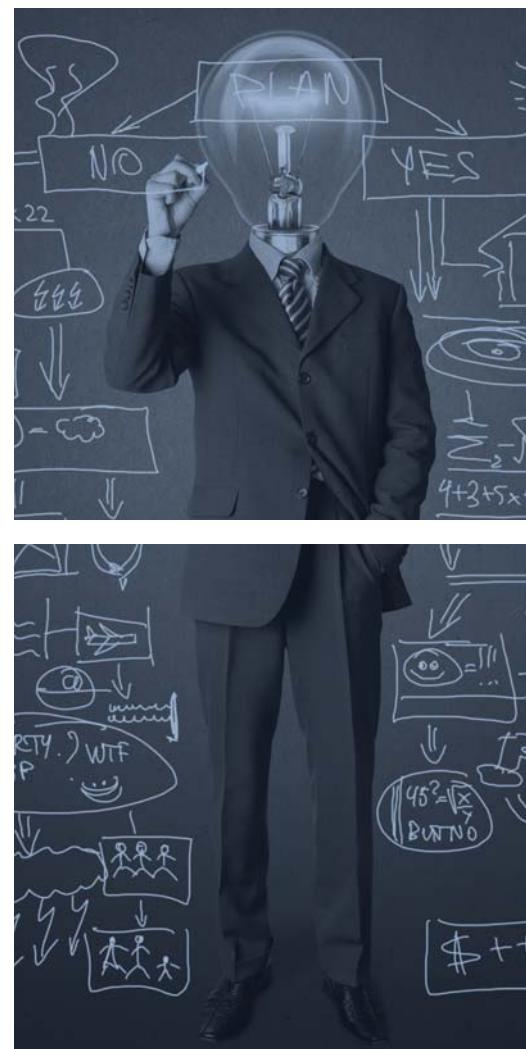
may be different if, instead, the goal is to develop and grow a base of royalty-paying licensees.

Patent portfolios may never be exploited in the sense of earning revenue from licensing or litigation. However, they may still have value in defending against a patent assertion by others. When a company receives assertion letters or is named as a defendant in an infringement action, one of the first steps should be to map the company's own IP assets against the products and services of the asserter. The difficulty of recognizing the defensive value of your own portfolio is to develop an estimate of its value.

If one assumes the patent holder litigates its IP against your company and is successful, a worst case scenario is that your accused products or services are forced off the market due to an injunction. One may therefore estimate the present-day value of that lost revenue stream. However, if your company has an IP portfolio that can be cross-licensed or enforced by way of a counterclaim against that patent holder, and if you are able to remain on the market – in whole or in part – your IP portfolio has a defensive value. This value may be measured against your revenue stream that could have been lost if you did not have any IP to counter the attack from the patent holder.

IP assets are valuable, but the challenge in leveraging their value is to ensure they are identified and developed so their full value may be exploited. There is a great deal of education associated with IP assets but their true value is often only recognized when they are viewed unconventionally.

IP assets are valuable, but the challenge in leveraging their value is to ensure they are identified and developed so their full value may be exploited.





Use of IP Audits to Optimize Patent Life Cycle Management

by Dan Polonenko, PhD

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The process of securing allowances of patents usually takes three, four or even five years from the priority filing date, depending on subject matter and the jurisdictions of patent prosecution. A great deal can change in a patent applicant's circumstances over these extended time periods. Patent applications with great potential value at the time of filing, may lose their corporate and/or commercial relevance over time. For the purposes of this article, patent life cycle management will be considered from the perspectives of institutions, start-up companies, and large corporations.

Most patent applications filed by institutions and start-up companies are exploitative, i.e., intended to capture and protect commercial monopolies for an invention's compositions and/or use and/or related methods. Institutional goals in filing patent applications include attracting licensing interests from commercial entities, or securing assets that can be spun-out into a company. Start-up and early-stage companies file patent applications that can be used as collateral for securing capital investments and/or research funding; and/or to provide for exit strategies which may include one or more of joint venture agreements and mergers or acquisitions by larger, better-funded companies. Large corporations tend to file patent applications for defensive

reasons as well as exploitative considerations, securing freedom-to-operate and ensuring commercially valuable IP for cross-licensing in cases where they might not have freedom-to-operate.

Formal IP audits are usually conducted as a result of a triggering event. For institutions, a typical triggering event might be an expression of interest from a company seeking licensing-in of one or more patent applications. Licensing candidates typically conduct IP audits to assess the scope and quality of protection provided by filed patent applications, and to identify related commercial opportunities. For start-ups and small companies, IP audits are requisite components of the due diligence conducted by potential investors or business partners. For a large corporation, an IP audit trigger may relate to a licensing-in opportunity or to an IP portfolio acquisition opportunity. A large corporation would be responsible for conducting or managing an IP audit of a third party's IP portfolio or an individual patent family. In cases where a large corporation is the target of a merger or acquisition, or alternatively, is seeking significant financing, its IP portfolio will be scrutinized by one or more third parties. In all of these cases, IP audits can be hectic and chaotic. They are often complicated by paucities of essential documents and records, the result of poor practices

in documentation and document storage over the time the IP was developed and protection sought by patent filings and prosecution.

A good business management practice for patent applicants, regardless of whether they are institutions, start-up or small companies, or large corporations, is to conduct and summarize internal IP audits on a regular basis, e.g., annually. Internal IP audits should have at least four categories of “checklist” questions, including: (i) administrative, (ii) prosecution status, (iii) assessment of commercial opportunity and potential value, and (iv) commercialization status. Internal IP audit summaries should be kept as hard copies in “IP Due Diligence” binders and also as electronic files in secure directories. This approach provides management with the means to track and confirm that key administrative documents such as invention disclosures, assignments, disclosure agreements, material transfer agreements and licenses have been properly executed, recorded, stored and catalogued. Regular internal audits also help ensure that time-critical events such as patent filing deadlines, patent office response deadlines and fee payment deadlines are addressed in a timely manner, and that pending and issued patents are in good standing in all jurisdictions in which they have been filed.

For both institutions and corporate entities, regularly scheduled internal IP audits to update: (i) the target market relevance and conditions with respect to the IP’s potential value, and (ii) progress made toward commercialization; will facilitate favourable third-party IP due diligence reviews. Furthermore, information generated by these audits will facilitate management’s decision-making on commercialization strategies, licensing strategies, and early identification of new opportunities to develop or acquire, or alternatively, divest selected components of IP portfolios.

Regular internal IP audits help ensure that . . . pending and issued patents are in good standing.





Brand Names: Unpredictability in Regulatory Approval Hinders Life Cycle Plans

by Jane B. H. Steinberg

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With over 30 years of experience in contentious and non-contentious IP matters, Jane specializes in matters relating to trade-marks and domain names, including litigation, prosecution and mediation.

Brand names can play a key part of the management of a product over its life cycle. Unlike patents, trade-marks can enjoy an unlimited life and are therefore valuable assets to pharmaceutical companies. A unique brand, consistently used and promoted, generates goodwill and brand loyalty, hence solidifying market position. However, the road to a unique and globally acceptable brand name is not easily travelled, and pharmaceutical companies continue to face uncertainty in their efforts to clear brand names for use in key markets.

Obtaining approval of a proposed brand name as a trade-mark at the Canadian Trade-marks Office (TMO) can be challenging as the pharmaceutical field is very crowded. However, securing TMO approval is only part of the work required. Health Canada also reviews the acceptability of proposed brand names as part of the marketing approval process, and a rejection from Health Canada trumps the trade-mark registration process. With health regulatory refusal of brand names at a rate approaching 40 to 50 per cent in Canada, the United States and Europe, it is clear that predictability is the loser in the equation. As owners appeal for greater certainty in the brand search game, Health Canada has promised a consultation process that will involve

the brand name approval process as well as labelling issues. An industry meeting scheduled for early March was postponed to an as yet unspecified date, although we are told that it should be held reasonably early in Health Canada's fiscal year, which began on April 1. Until then, the pharmaceutical industry in Canada must continue to operate under a Health Canada Guidance dated January 1, 2006 as well as a Fact Sheet dated November 9, 2009.

Over the past decade, health regulatory authorities, including Health Canada, have become increasingly focused on the review of proposed brand names from a safety perspective, the goal being to avoid approving a brand name that might contribute to a medication error. This heightened focus triggered look-alike and sound-alike (LA/SA) trade-mark scrutiny, much of which revolved around the United States Food & Drug Administration's use of a computer analysis intended to identify trade-marks with phonological or orthographic similarities (POCA).

While Health Canada does not yet use the POCA analysis, it has indicated its intention to do so, and is in the process of implementing the POCA application, presumably to do things such as

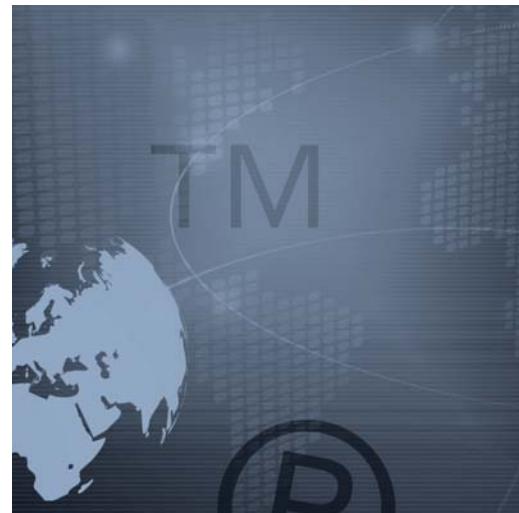
incorporate the Canadian database of drugs on the market and create a French version of the application.

The upcoming Health Canada consultation is eagerly awaited as the industry searches for clarity in the process. In the meantime, Gowlings has modified its pharmaceutical searches to include a POCA analysis as well as a review of trade-marks on the TMO Register. We are applying the specific algorithm used by the U.S. Food & Drug Administration to pharma brand names in use in Canada. This is part of our effort to predict LA/SA issues with greater certainty in the event that Health Canada does, in fact, implement the POCA analysis. It is hoped that this analysis will help to forecast what may be on Health Canada's radar during the approval process.

In the meantime, companies should continue to observe the January 1, 2006 Guidance. To reduce the likelihood of medication errors, the Guidance discourages naming practices that result in similarities in brand names or brand names that are similar to generic names. It also discourages the use of product line extensions (e.g., a modifying prefix or suffix). A company should submit to Health Canada a risk assessment and evaluation of its proposed trade-mark, supported by studies, data and analyses. A risk assessment can include searches for similar proprietary and non-proprietary names, computer analyses, prescription testing studies and a review of medication error literature.

Health Canada's Fact Sheet of November 9, 2009 advises manufacturers to reduce the incidence of offending names through research and by choosing brand names that are distinctive and easily written and pronounced. To be acceptable, a brand name must not be liable to cause confusion in print, handwriting or speech with the brand name of another medicine.

Stay tuned for further news on the Health Canada consultation!



Pharmaceutical companies continue to face uncertainty in their efforts to clear brand names for use in key markets.





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Procedures Available for Amending the Claims of Issued Canadian Patents

by Ian J. Colton and Connie Too

Much can happen after a patent is issued. Laws change, industrial processes improve, competitors emerge, and new products and features are in demand. Consequently, a patent portfolio should be periodically assessed to ensure it fully protects the exclusivity of an invention and provides a competitive advantage to the patentee as the market landscape evolves. The assessment should be made against marketed products and production processes – the patentee's as well as competitors' – to ensure the portfolio remains relevant and robust.

Following such an assessment, certain key patents in the portfolio may be identified as problematic or inadequate and amendments to them may be required.

A patentee's ability to amend an issued patent in Canada is limited. Nevertheless, there are four avenues available:

1. Correcting clerical errors;
2. Disclaimer;
3. Reissue; and
4. Re-examination.

Availability and Limitations

Errors in a specification that arose from the process of writing, transcribing or reproducing text may be corrected at any time during the term of a patent. Significant amendments may be made if a clerical error is established. However, correction is discretionary, and may be refused by the Commissioner of Patents if contrary to public interest. Thus, replacement of whole claims, corrections of translation errors or priority claims, or amendments to broaden the scope of a claim are unlikely to be allowed.

A disclaimer can be used to disclaim claims or parts thereof, thereby enabling the patentee to reduce claim scope. Claimed subject matter can be disclaimed if it was originally included by mistake, accident or inadvertence and without any wilful intent to defraud or mislead the public. Disclaimers may be made at any time over the term of the patent and are typically used to exclude specific features in a claim that are anticipated by prior art or are inoperative.

Disclaimers are not reviewed by the Patent Office and cannot be refused. As a result, care should be exercised when preparing disclaimers to ensure that claim scope is not inadvertently broadened. Otherwise, the resulting claims may be held invalid during a future impeachment proceeding.

A defective or inoperative patent may be corrected by reissue if requested within four years of its date of issue. The defect must be by reason of insufficient description or specification, or a patentee claiming more or less than they had the right to claim. The error resulting in the defective patent must have arisen from inadvertence, accident or mistake and without any fraudulent or deceptive intention. Errors of omission, miscommunication, misunderstanding of foreign practice or misappreciation of information may be addressed, provided the subject matter was intended to be protected in the original patent.

Reissue facilitates amendments that redefine the originally-claimed invention by, for example, broadening or narrowing the scope of issued independent claims or adding new narrower claims, and allows amendments to the patent description to add subject matter that is common knowledge. However, amendments to add new matter, to reintroduce claims cancelled during prosecution, or to take advantage of a new law or jurisprudence are not permitted. If a request for reissue is accepted, an amended patent specification is subject to further examination.

Re-examination provides a means to amend patent claims whose patentability is in doubt in view of prior art. Newly discovered prior art or art that was misappreciated during examination may be raised. Where a substantial new question of patentability is raised, a re-examination board considers the patent claims in view of supplied prior art. A patentee can propose non-broadening amendments to the patent claims. Following re-examination, the board may cancel non patentable claims, confirm claims, or incorporate amended claims. The board's decision is subject to appeal by the patentee. Interestingly, re-examination may also be used by a third party to summarily challenge the patentability of issued claims on the basis of prior art.

There are different procedures, requirements and limitations associated with each of the above avenues and varying degrees of amendment are possible. Careful consideration must be undertaken in order to select the appropriate route and to navigate through it successfully.



**Re-examination
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of prior art.**





Utility and Disclosure: Divergent Results in Canada and the United States

by Patrick Stewart Smith

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Patrick practises in the area of IP with particular emphasis on patents and trade-marks. He has appeared as counsel in more than 100 reported decisions relating to patents, trade-marks and copyright in the Ontario Court, Federal Court and Supreme Court of Canada.

Two recent patent decisions in the United States and Canada highlight the differences in the application of utility and disclosure even though the relevant statutory sections are the same. The patents at issue claim the use of atomoxetine hydrochloride for use in the treatment of ADHD. The U.S. patent was found to be valid even though the results of a clinical trial were received after the U.S. application was filed. The positive results were received before the Canadian patent application was filed, yet the Canadian patent was invalidated on a utility attack.

ADHD is a chronic and inheritable neurobiological disorder characterized by an inappropriate level of inattention, hyperactivity and impulsiveness. The disorder impacts 3 to 5 per cent of school-age children, most of whom carry symptoms into adulthood. It can result in the significant impairment of school, family, and social relationships. There is no cure for ADHD, but symptoms may be ameliorated by medication. Stimulants are controlled substances and are not effective for all patients. Tricyclic antidepressants (TCAs) were also used but concerns were raised when desipramine was implicated in the sudden death of some children.

Eli Lilly's Strattera atomoxetine hydrochloride was the first non-stimulant ADHD drug approved

by the FDA and Health Canada. Atomoxetine was synthesized around 1980 and tested extensively in the treatment of depression. The results of the clinical trials lead to the abandonment of atomoxetine for use in depression but did show that atomoxetine was well-tolerated by patients.

Lilly scientists conceived that atomoxetine may be effective in the treatment of ADHD and so they approached leading ADHD researchers at the Massachusetts General Hospital (MGH), the teaching hospital associated with Harvard University, to conduct a clinical trial. Lilly funded an ADHD study, provided atomoxetine and placebo and allowed MGH access to Lilly's confidential FDA filings for the purpose of running the study. The overall response rate for atomoxetine was clinically and statistically higher than placebo. The relative timing of the study is as follows: (1) FDA approval for the study; (2) U.S. patent application filed; (3) positive results received by Lilly and published at the world's largest meeting of ADHD practitioners; and (4) Canadian patent application filed.

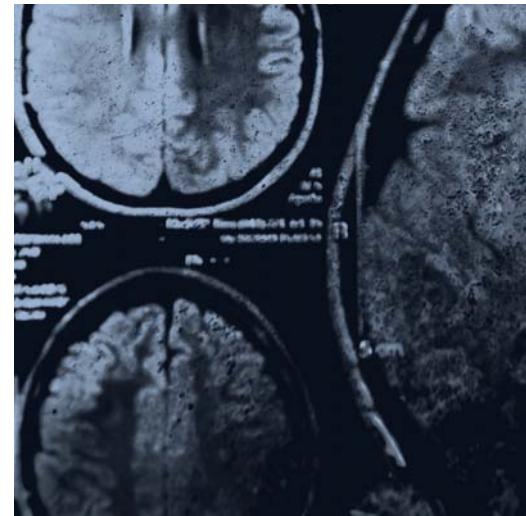
The disclosure and claims of the U.S. and Canadian patents are virtually the same. The patents disclose that atomoxetine is effective in all forms of ADHD in children, adolescents and adults. The improved safety profile of atomoxetine

is disclosed and recommended dosing is provided. In both jurisdictions, the central invalidity argument related to the fact that the results of the MGH study were not provided in the patent disclosures.

The U.S. Court of Appeals for the Federal Circuit (*Eli Lilly and Co. v. Actavis Elizabeth LLC et al.*, Appeal No. 2010-1500 (Fed. Cir. July 29, 2011)) overturned the trial decision, which found the patent invalid for “lack of enablement/utility.” The Court of Appeal reasoned the invention had utility and the specification met the objective disclosure test required by the statute. On the other hand, the Canadian Federal Court and Federal Court of Appeal held the patent invalid for want of disclosure of sound prediction (*Novopharm v. Eli Lilly and Co.*, 2010 FC 915, 87 C.P.R. (4th) 301, upheld 2011 FCA 220, 94 C.P.R. (4th) 95). Under current Canadian law, a utility analysis is measured by reference to the “promise of a patent.” The trial judge said that the patent implicitly promised long-term usefulness. Because long-term testing had not been done at the time of filing, the patent was based upon sound prediction, which requires enhanced disclosure of the factual basis and a sound line of reasoning for the prediction. As such, the results of the MGH study were required to be disclosed.

There is nothing in the Canadian Patent Act that requires this “enhanced disclosure” for inventions based upon sound prediction. If a patent discloses a new, non-obvious and useful invention and provides sufficient information to allow a person of skill to make and use an invention, there should be sufficient consideration for the grant of a patent. Increasing utility standards by reference to a promise of the patent discourages applicants from discussing the attributes of their inventions for fear of being held to a higher utility standard. It is hoped that future cases will clarify this law.

The disclosure and claims of the U.S. and Canadian patents are virtually the same.





Essentials of a Canadian Patent Strategy

by Jay Zakaïb

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Although Jay is also a licensed patent agent, the primary focus of his practice is patent litigation, mainly in the life sciences, pharmaceutical, material sciences, petrochemical and agrifood industries. He holds degrees in chemical engineering, as well as civil and common law.

Developing a solid patent strategy is key to the success of many businesses but especially for pharmaceuticals and biologics. This article provides a brief overview of some key elements of a successful strategy with many of the areas discussed in greater detail in subsequent articles.

Data Protection and Patent Protection

Innovators can protect data that supports regulatory approval for innovative compounds. Regardless of patent rights, this protection applies for a maximum of eight years and six months from the time of issuance of the first Notice of Compliance (NOC) for a new medicinal ingredient (six years of data package exclusivity, two years of market exclusivity, and potentially a six-month pediatric extension).

However, the patent portfolio of a drug product remains the first line of defence to recoup research and development investment. The innovator must align its regulatory submissions with its patent portfolio since data protection is limited for certain drug products. For example, therapeutic combinations may have little or no data protection where the medicinal ingredients were previously approved by NOC. The Minister may deny innovative drug status to a product at any time. Consequently, patent enforcement

remains essential for rights holders and the PM(NOC) Regulations (linkage) remain the best vehicle for protecting the innovator's market.

The Timing Requirement

Patents in respect of a drug must be submitted for listing upon filing of the related New Drug Submission (NDS) or a supplement to the NDS. If the patent is still pending at regulatory filing, the patent list must be filed within 30 days of issuance of the patent in respect of all submissions to which it pertains.

Moreover, the patent must have a Canadian filing date that precedes the filing date of the NDS or of the supplement to the NDS to which it relates. These timing requirements serve the sole purpose of limiting the opportunity for listing and enforcing innovator patents. No extensions of time are granted for meeting filing requirements.

The Relevance Requirement

Prior to 2006, a patent was relevant and could be listed in respect of a drug if the patent claims could cover a competing product. In 2006, the Minister changed the law to require specificity of the patent claims to cover the innovator's product, based upon the submissions filed.

Recent jurisprudence of the Federal Court suggests an additional requirement not

addressed in the Patent Act or in the Patented Medicines (Notice of Compliance) Regulations. Arguably the claims of the patent must not only cover the innovator's product, but also specifically recite the subject matter for which a Notice of Compliance was granted in the claim. This undue narrowing of patents that may be listed restricts the innovator's ability to maintain market exclusivity by virtue of its patent portfolio. To improve the likelihood for listing, the innovator should, where practicable, include language in the patent specification that specifically (or narrowly) recites the commercial product and/or its commercial use.

Claims relating to processes of manufacture, key intermediates or metabolites remain ineligible for listing. Where an innovator uses a claimed invention to manufacture its product, the generic infringes those claims when comparing its product to the innovator's. However, linkage currently provides no relief for this patent infringement.

Getting Frozen

The linkage regulations provide that a generic entrant may freeze the Patent Register before the innovator is able to list all of its patents, ensuring that delays in listing a patent prejudice the innovator. The Patent Register is frozen by filing an abbreviated New Drug Submission, such that the generic need not address any subsequently listed patents. Consequently, enforcing patents requires rapid and diligent prosecution to secure listing as early as possible.

Based on current jurisprudence, filing a patent list prior to the generic filing of an Abbreviated New Drug Submission (ANDS) is not sufficient to prevent the patent freeze. The Minister requires the innovator to have obtained an actual listing of the patent on the Patent Register prior to a generic filing of its ANDS. The Court does not currently recognize the filing date of the patent list, only the date of listing. Unless the innovator's product has data package exclusivity, a generic ANDS may be filed at any time, triggering the patent freeze.

Key Considerations

Once a NOC for an innovative product has been received, essentially all related patents should be issued, and patent lists filed and listed, especially where there is no data package exclusivity, or where data protection is about to lapse.

Since interlocutory injunctions are unavailable in patent infringement actions in the pharmaceutical industry, innovators must understand that failure to engage linkage allows generics to cannibalize an innovator's market share upon issuance of a NOC for a competing product. Linkage provides a warning of oncoming generic early working of a product, and remains the best means of protecting that market.



Filing a patent list prior to the generic filing of an Abbreviated New Drug Submission is not sufficient to prevent the patent freeze.



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Data Protection: Early Days

by Jane Clark and Adrienne Blanchard

Canada amended its Data Protection Regulations in 2006, aiming to provide protection for “innovative drugs.” This was Canada’s second attempt to implement its 1994 NAFTA and TRIPS treaty obligations that require signatory member countries to protect data that is originated from considerable effort and required to be submitted for government approval. The current term of protection is eight years counting from the innovative drug’s date of approval (notice of compliance) preventing others from making a direct or indirect comparison from receiving approval until expiry of that term. In addition, a pediatric six-month extension is available if certain criteria are met.

Under the Canadian system, a register of innovative drugs is maintained, listing all drugs that have been found by Health Canada to be eligible for protection. Protection is typically requested by the innovator during the regulatory submission process. Once found to be eligible, a product may lose protection if it is not marketed in Canada.

The Regulations have now survived a challenge to their validity. In December, 2010, a Federal Court of Appeal judgment upheld their validity (2010 FCA 334) with leave to appeal to the Supreme Court of Canada denied in July, 2011. In that case, the Regulations were found to be a valid exercise of power since their purpose was to encourage the development of new drugs which, *inter alia* constituted a valid public and safety purpose; and, further, they were aimed at ensuring that Canadians have reasonable access at reasonable prices, to new, safe and effective drugs rather than balancing commercial interests between innovators and generics.

While the Regulations have now been found constitutionally valid, there has since been a handful of cases under this new regime dealing with interpretation, aimed at determining the scope of “innovative drugs” covered by the Regulations, as well as status issues with respect to the innovative drug register.

“Innovative drug” is defined as a drug that contains a medicinal ingredient not previously approved in a drug by the Minister and that is not a variation of a previously approved medicinal ingredient such as a salt, ester, enantiomer, solvate or a polymorph. As such, a drug is excluded from protection if it is previously approved or is a variation of a previously approved drug.

Two cases have dealt with the first exclusion, the “previously approved” exclusion, and have come to seemingly different results. In *Epicept* (2010 FC 956), data protection for CEPLENE was denied on the basis that while it was a “new drug,” the medicinal ingredient was previously approved notwithstanding that the previous approvals were by DIN (Division 1), as homeopathic/over-the-counter drugs and not by NOC (Division 8), which applies to prescription drugs. An appeal was dismissed as moot since Epicept had withdrawn its underlying new drug submission. On the other hand, in *Celgene* (2012 FC 154, at paras 42-46), data protection for thalidomide was granted on the basis that it was a new drug. Since thalidomide was determined to be unsafe in 1962, the previous approval was withdrawn and the Court found that it did not operate to exclude thalidomide from data protection. An appeal on this case is pending. In yet another case, affirmed on appeal, a generic company sought to remove the data protection listing for ELOXATIN (2011 FC 507; 2012 FCA 106). Sales in Canada from another jurisdiction authorized under the Special Access Programme did not render ELOXATIN “previously approved.”

In the *Takeda* case (2011 FC 1444), the Court considered the second exclusion from protection for “variations” and in particular, interpreted the group of five examples within the phrase “not a variation of a previously approved medicinal ingredient such as a salt, ester, enantiomer, solvate or polymorph.” The Court denied protection to the enantiomer DEXILANT as a matter of law. Falling within one of the enumerated examples of variations was treated an automatic bar to data protection regardless of the nature and extent of the data necessary to be submitted to obtain approval. An appeal on this case is also pending.

In the *ELOXATIN* case, a further issue was the generic company’s standing to challenge a product, listed on the Innovative Drug Register. The Court found that a generic company may be given standing to make submissions. The Court distinguished an earlier case which denied standing to the association of generic pharmaceutical manufacturers to challenge a listing by GlaxoSmithKline (2011 FC 465).

As such, while they have survived a validity challenge, it is still early days in considering the scope of the Regulations, eligibility criteria and what constitutes an “innovative drug.”

One other ongoing development to be aware of is that, while Canada offers comparatively less protection than Europe and the U.S., international treaty negotiations are currently underway between Canada and the EU that implicate data protection. Depending on whether a final agreement is negotiated, it is possible that there may be changes to the scope and term of protection available for innovative drugs in Canada.



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Data Protection: A Viable Alternative to Patent Protection?

by Isabel J. Raasch and Jennifer L. Wilkie

While the Data Protection Regulations appear to provide a more “dependable” period of exclusivity than patents, in that they circumvent the complex and somewhat unpredictable legal battles surrounding patent enforcement, this is not necessarily the case. Data protection is better seen as complementary to, rather than a replacement for, patent protection. In this regard, there are three particular areas of note when comparing patents and data protection: (1) the subject matter of the protection; (2) the susceptibility of that protection to legal challenges; and (3) the scope of the protection.

Subject Matter Being Protected

There are key differences in scope between data protection and patent protection. Data protection applies only to an “innovative drug,” one that has not previously been approved. As such, data protection related to new uses is generally not available, although there may be exceptions in rare circumstances (e.g., *Celgene* case). Moreover, data protection is not available for “variations” of previously approved medicinal ingredients (e.g., enantiomers, salts, esters, solvates and polymorphs) as confirmed by the decision of the Federal Court in *Takeda v. Canada* and by the Minister’s decision involving fluticasone furoate in *CGPA v. Canada*. Data protection does not extend to combinations of old compounds, methods or processes. In contrast, patents can protect inventions related, not only to new compounds, but also new uses and variations thereof, combinations of old compounds and methods or processes for their manufacture.

As such, patents offer a more multifaceted approach for protecting investments in a drug products, recognizing that there is often more than one aspect of a drug that is inventive.

Susceptibility to Legal Challenges

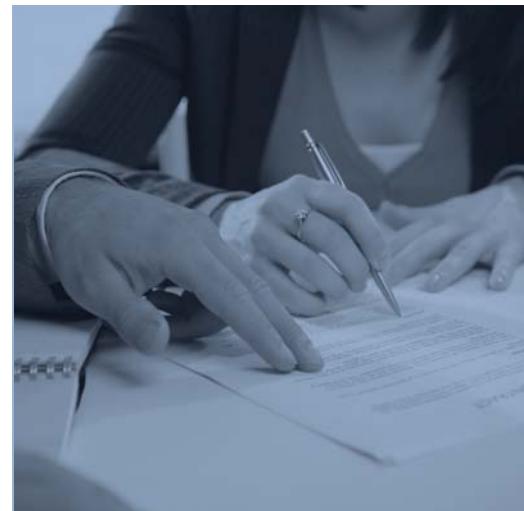
While data protection is subject to a smaller range of legal challenges than patents, it is not immune to litigation. A challenge may be brought by an innovator seeking to list a drug or by a generic company seeking to de-list it. The Federal Court of Appeal recently affirmed that: (1) a generic has standing to seek to de-list a drug where they have had a rejection of a drug submission because of the presence of a drug on the Innovative Drug Register; and (2) the Minister of Health may make a fresh decision about the listing of a drug at any time (e.g., at the request of a generic). The stakes are high in the case of challenges to data protection, especially in the absence of patents covering the product. Patents offer a second, very important layer of protection.

Scope of Protection

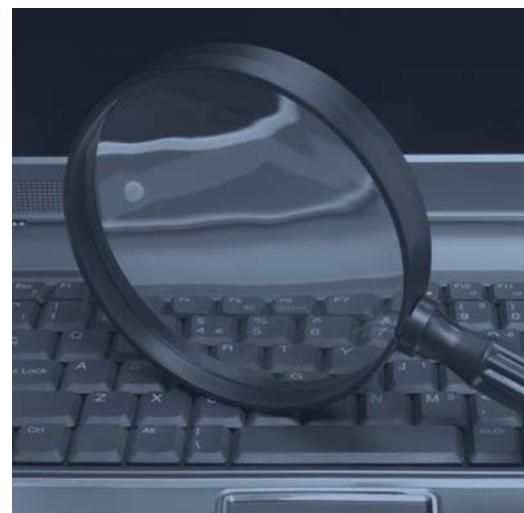
Data protection does not provide against activities that do not require regulatory submission and approval (NOC). Examples include the importation of a pharmaceutical compound (without sale in Canada), manufacture of a pharmaceutical compound, and export of a compound. The only way to protect against these activities is by asserting a patent right either under the Patented Medicines (Notice of Compliance) Regulations, if the patent is listed; or by a patent infringement action. In addition, there are often instances where key aspects of the product (e.g., formulation) are developed as the product is maturing (e.g., at the end of the data protection period) which, as such, can only be protected by patents. A further consideration is that patents may offer additional protection and value: they provide an incentive for investment in R&D, licensing opportunities and a basis of negotiation in litigation beyond what data protection offers.

Finally, it should be noted that interpretation and application of the Data Protection Regulations are in their early days and are therefore unpredictable. Indeed, five relevant decisions issued in 2011 and 2012 were all appealed (two appeals are pending) at this writing. This is not dissimilar to the early days of the Patented Medicines (Notice of Compliance) Regulations, when, 19 years ago, what began as a trickle of cases turned into an avalanche of jurisprudence now comprising hundreds of decisions including a substantial number of patent listing decisions.

In view of the above, the best strategy continues to be concurrent use of both patents and the Data Protection Regulations to ensure the greatest scope and likelihood of protection for innovators.



**Patents may offer . . .
a basis of negotiation
in litigation beyond
what data protection
offers.**





Patented Medicines (Notice of Compliance) Listing Update

by Marc Richard

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Listing a patent on the Patent Register maintained by the Minister of Health is the gateway through which an innovator gains access to the provisions of the Patented Medicines (Notice of Compliance) Regulations (PMNOC Regulations). Any person seeking to market a generic copy of a pharmaceutical product in Canada, in respect of which a patent is listed, must address the infringement and/or validity of that patent or await its expiry. There is an opportunity for the innovator to seek an order from the Federal Court prohibiting the Minister from issuing a Notice of Compliance (NOC) to the generic on the basis that allegations of non-infringement and/or invalidity are not justified. As this exercise is conducted prior to generic entry, it can prevent disruption of the marketplace. Conversely, in a patent infringement action, given the absence in Canada of effective injunctive relief, the generic entrant will often have access to the market over the course of the action. If the Minister refuses to list a patent on the Register at the time of submission for listing, the innovator is deprived of any opportunity to seek the preliminary determination under the PMNOC Regulations.

Recently, the Minister of Health has taken a more restrictive view of which patents are “relevant” for the purposes of the PMNOC

Regulations. This change was precipitated by amendments to the PMNOC Regulations in 2006 to clarify the types of submissions which would engage an opportunity to list a patent. There was a concern that a patent might be listed for virtually any type of regulatory submission or change, leading to the listing of patents with no relevance to the product approved by the submission. To address this concern, the listing provisions were amended to require what the government termed “product specificity.” Generally, the amendments require that, where a particular medicinal ingredient, formulation, use or dosage form is approved, the patent listed in respect of the submission must contain a claim to the approved medicinal ingredient, formulation, use or dosage form.

In principle, the amendments are consistent with the purpose of the PMNOC Regulations, which is the prevention of the abuse of the “early working” exception to patent infringement. This exception permits the marketer of a generic product to use the patented invention to speed up its regulatory approval. However, recent interpretations of the “product specificity” requirement in positions taken by the Minister, and accepted to some degree by the Federal Courts, have resulted in a more restrictive application of the listing provisions.

The Minister has taken the view that it is not enough that a patent claim encompass or cover the medicinal ingredient, formulation, use or dosage form of the commercial product. The claim must also expressly “match” the approved form. The result is that even where a claim would be clearly infringed by a generic copy, the claim would not be listable unless its language precisely matches that of the submission. While such a stringent requirement is not apparent from the language of the PMNOC Regulations, and does not support the purpose of preventing abuse of early working through infringement, the Court has recently given support to this interpretation in certain contexts.

In the context of a patent where the claims listed one approved medicinal ingredient in the formulation/dosage form and the commercial product contained two medicinal ingredients, the Court held that the Minister did not err in not listing the patent, given that “precise and specific matching” is required. (*Purdue Pharma v. Canada* 2011 FCA 132; 2010 FC 738; see also *Bayer Inc. v. Canada* 2009 FC 1171). In a more recent decision under appeal at the time of this writing, the Court refused to list claims comprising three approved medicinal ingredients, where two of the three ingredients were explicitly set out in the claims, and the third was clearly encompassed within a class of compounds listed in the claims. (*Gilead Sciences Canada Inc. v. Canada* 2012 FC 2). Absent the explicit mention of the third medicinal ingredient, the Court held the patent could not be listed.

Given these developments, the best approach is to identify the attributes of the potential commercial product and the contents of the regulatory submission at an early stage and draft patent claims accordingly. This can be difficult in view of the research and development process and the effect of disclosure on patentability. Nonetheless, absent a clarification in the legislation or the jurisprudence, it is the most effective way to ensure entry through the gateway to the PMNOC Regulations.

. . . listing provisions were amended to require what the government termed “product specificity.”





Recent Pricing Issues in Canada

by Adrienne Blanchard and Jane Clark

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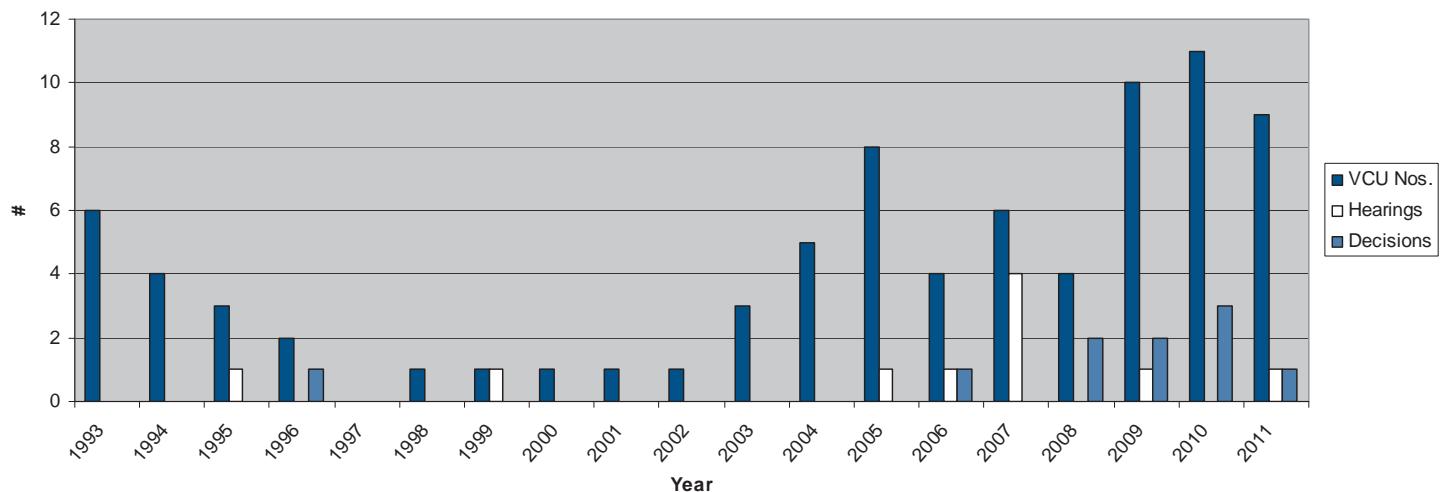
In Canada, pricing of pharmaceuticals is affected primarily in two contexts: under the federal price control scheme, and as a result of pricing on provincial formularies. In the case of the latter, provinces agree to a formulary price for medications, but negotiate agreements on volume discounts and other incentives from manufacturers in return for the listing.

Federal: The Patented Medicine Prices Review Board

In recent years, the PMPRB focused on resolving old matters with no new hearings since 2009, and no new notice of hearings issued in 2011. The trend has been that a growing number of issues are resolved by Voluntary Compliance Undertaking (VCU); effectively, a form of settlement (see Figure 1).

Two decisions were released since our update in the 2011 *Current Issues* publication: the *COPAXONE* and *ratio-SALBUTAMOL* decisions.

The *COPAXONE* decision, issued on February 23, 2012, was a redetermination of an earlier matter, which had been remitted back to the Board by the Federal Court of Canada (2009 FC 1155) and was the only matter considered by the Board in 2011. The Federal Court had determined in 2009 that in the earlier decision, the Board Panel had paid “lip service” to assessing the factors required to be assessed in any allegation of excessive pricing, but in the end had only applied the factor set out in section 85(1)(d), the CPI factor. In the redetermination decision, the Board again applied the CPI factor and found excessive pricing, although, the reasons seem to be primarily CPI-focused again, with mention that *COPAXONE* was the lowest priced medicine relative to its therapeutic comparators. An application for judicial review of that redetermination was

PMPRB (VCU's, Hearings, Decisions), Figure 1

Source: PMPRB's website. "Decisions" relate to decisions on merits only (interlocutory proceedings excluded); "Hearings" reflect first date in Notice of Hearing only.

filed in Federal Court on March 20, 2012 seeking a directed verdict that the Board Panel re-determine the matter on the basis the allegations of excessive pricing be dismissed.

In the ratio-SALBUTAMOL decision, released on May 27, 2011, the court found the price to be excessive. In doing so, it canvassed a myriad of practical and substantive issues including that ratiopharm was a patentee (even if a generic company) under the *Patent Act*. Supply agreements with an innovator were sufficient to make it a patentee; to find otherwise would allow a patentee to insert commercial entities in the distribution chain to avoid Board jurisdiction. In considering the supremacy of the Act versus the Guidelines, it found this was not a case to deviate from the Guidelines. One significant issue was the attempt by ratiopharm to reduce the Board's calculation of the average selling price (and consequently, excess revenues) by including deductions to the trade, but these were denied inclusion based upon lack of evidence. A common thread throughout the decision is the liberal interpretation of the statute: that the words cannot be interpreted strictly in accordance with commercial law principles; that the purpose of the Act was consumer protection; and, that the Board's mandate was to ensure Canadians have access to patented medicines that are reasonably priced.

Provincial: Market Access Issues

The provinces play a significant role in market access for those products covered by the provincial formularies. Many provinces are taking a closer look at health-care expenditures, and in recent years some have made efforts to address generic pricing. There have also been efforts to obtain pricing discounts and other incentives from manufacturers. Many of these changes are being effected on a policy basis, rather than through legislative change. A growing phenomenon in recent years is the prevalence of product listing agreements. Under these agreements, a province may obtain concessions from a manufacturer for the listing of a product on the provincial formulary.

In Ontario, we note a curious provision in the regulations under the *Ontario Drug Benefit Act* (O. Reg. 201/96, subsection 11(8)), brought into force in July 2011, relating to generic pricing. It permits a generic drug product to obtain a higher than otherwise permitted price on the formulary in cases where a generic manufacturer has challenged a patent. This provision has yet to be interpreted as it applies only to generic products that apply for the Ontario formulary on or after April 1, 2012. It will be interesting to see how this is applied in practice.



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Parlez-vous français? Language Requirements for Doing Business in Québec

by Giovanna Spataro and Melissa Tehrani

Advertising in the province of Québec – whether on commercial signage, in print media, on the Internet or via the tiny text on a product's packaging – adheres to a unique set of language rules of which businesses wishing to capitalize on the country's second most populous province must be mindful.

A Few Rules to Remember

The language of business, commerce and advertising in Québec is regulated by the Charter of the French Language (the Charter) and its Regulation respecting the language of business and commerce (the regulation), and enforced by the *Office québécois de la langue française* (OQLF). The Charter, which dates back to the 1970s, provides several basic French language requirements with respect to product packaging and labelling, commercial publications and advertising.

For example, the Charter requires all packaging and labelling in Québec, including text on shipping containers, to be in French, or in French and another language, provided that the French text is at least equally prominent to text in the other language. This is the “equal prominence rule” which extends to product inserts, brochures and other materials accompanying a product, i.e., instruction manuals, warranty certificates and promotional coupons printed on a product's packaging or supplied with the product at the time of purchase. Text and inscriptions on the product itself, such as product identity information or directions for use must also be in French, or comply with the equal prominence rule. Similarly, all catalogues, brochures, commercial directories and other publications of the same nature must be in French or comply with the equal prominence rule.

All commercial advertising, particularly on public signs, posters and point-of-sale materials, is subject to the Charter and therefore must be either exclusively in French or bilingual, provided the French text is “markedly predominant.” The markedly predominant concept is the object of its own regulation under the Charter and generally requires that “text in French has a much greater visual impact than the text in the other language.” For example, the markedly predominant rule dictates that French text must be at least twice as large as text in the other language, and occupy an area at least twice as large on posters and point-of-sale advertising.

Exceptions of Interest

Among certain exceptions to these rules, and perhaps the most important is the “recognized” trade-marks exception. Recognized trade-marks for which no French version has been registered need not be translated into French. However, the courts and the OQLF have differing views as to what constitutes a “recognized” trade-mark. While the OQLF holds that a mark must be registered to be “recognized,” the courts have maintained that a common law mark may be a recognized trade-mark. Text that is applied permanently to a product by means of engraving, baking, inlay, riveting or embossing need not be in French, provided the product is from outside Québec. It must be noted, however, that a recent draft regulation proposes to restrict this exclusion by excluding the following six types of appliances from its application: stoves, microwaves, refrigerators, washing machines, dryers and dishwashers. In any event, any text concerning the safety of a product must be in French.

Moreover, catalogues, brochures and similar publications may be exclusively in a language other than French if they are to be inserted in a news publication or magazine published exclusively in that other language. The regulation further sets out exceptions to the rule for commercial advertising, making English-only advertising legal on English television and radio stations and in English newspapers and magazines.

The OQLF’s New Campaign

In November 2011, the OQLF officially launched the campaign “A sign of respect of the law” (*Une marque de respect de la loi*). This highly publicized television and online initiative was developed to inform marketers of the OQLF’s position on commercial signage in Québec: English-only trade-marks designating business names on commercial signage must now be accompanied by a French generic descriptor or expression. Although the OQLF appears to acknowledge the “recognized” trade-mark exception, it considers that if such a trade-mark is used as the name of a business, it must be in French or accompanied by a generic descriptive term in French.

This new campaign may have particular consequences on a trade-mark’s legal protection. In fact, businesses endeavouring to comply with the OQLF’s new requirement are well advised to consider how compliance may affect their mark.

Although there is currently some doubt as to whether the OQLF’s interpretation of the Charter will withstand legal challenge, its current position on the language of business names is a reflection of a renewed concern over language issues in Québec, particularly in the Montréal area. This heightened sensitivity has been widely reported in the province’s media: even Montréal’s NHL team was the object of criticism after naming an anglophone as head coach! Further, the OQLF’s recent announcement that it will hire close to 70 additional personnel is evidence of increased enforcement action. Compliance with Québec’s French language requirements is no longer a purely legal issue, it is a matter of public image.



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Canadian Life Science Deals and Investments: 2011 Year Review

by Peter D. Fairey, Robert D. Ford and Michael Herman

The availability of research and development and venture capital funding is critical for Canadian life sciences companies. Without available risk capital, Canadian entrepreneurs cannot create and commercialize innovations.

The environment for raising venture capital funding has been very difficult over the last several years, but we are pleased to report some good news from 2011.

According to the Canadian Venture Capital and Private Equity Association and Thomson Reuters, total venture capital market activity in Canada grew to \$1.5 billion in 2011, up 34 per cent from the year before.

Specific to venture activity in biopharmaceuticals and other life sciences sectors, financings were up 15 per cent from 2010 at \$343 million (2010 life science venture investment was up 38 per cent from 2009).

In the United States, venture capital investment in 2011 increased to US\$28.4 billion in 3,673 deals, compared to US\$21.8 billion in 3,277 deals in 2010, an increase of 22 per cent in dollars and 4 per cent in number of deals, according to the MoneyTree™ Survey Report by PricewaterhouseCoopers LLP and the National Venture Capital Association, and based on data from Thomson Reuters. Coming off modest growth in 2010, biotechnology investing increased 22 per cent in dollars in 2011, but decreased 9 per cent in number of deals, with US\$4.7 billion invested in 446 deals.

It is interesting to note that over the past six years, overall venture capital investment in Canada and the United States has moved more or less in tandem. However, the gap between average amounts invested in Canadian companies compared to U.S. companies eroded in 2011, with Canadian companies on average raising only 37 per cent of the amount raised by their counterparts in the United States.

Some of the recent and more notable reported Canadian life sciences venture deals are listed on the following page.



... over the past six years, overall venture capital investment in Canada and the United States has moved more or less in tandem.



RECENT, NOTABLE CANADIAN LIFE SCIENCES VENTURE INVESTMENTS

Name	Sector	Province	\$Announced (Thousands)	Date
Advitech Inc.	Industrial Biotechnology	AB	3520	3/30/11
Affinium Pharmaceuticals	Drug Discovery	ON	15000	8/29/11
Allylix	Other Biopharmaceuticals	CA	382	10/1/11
Ambit Biosciences Corporation	Other Biopharmaceuticals	CA	30000	6/10/11
Aquinox Pharmaceuticals Inc.	Diagnostics/Therapeutics	BC	25000	1/31/11
Asmacure, Inc.	Drug Discovery	QC	N/A	5/6/11
Axela Inc.	Diagnostic Equipment (not Imaging)	ON	N/A	1/7/11
Biopharmacopae Design International, Inc.	Diagnostics/Therapeutics	QC	2000	2/21/11
Circle Cardiovascular Imaging Inc.	Medical Imaging Equipment	AB	3900	7/12/11
DVS Sciences Inc.	Medical Lab Instruments	CA	14600	7/14/11
Enobia Pharma Inc.	Drug Discovery	QC	40000	8/8/11
Functional Neuromodulation, Ltd.	Diagnostics/Therapeutics	ON	10400	10/17/11
GenoLogics Life Sciences Software Inc.	Bioinformatics/Genomics	BC	8000	10/20/11
Glcare Pharma	Drug Discovery	QC	7000	7/21/11
Golden Health Care Inc.	Healthcare Facilities (in-patient)	SK	5000	4/15/11
Indel Therapeutics Inc.	Drug Discovery	BC	1400	5/2/11
Interface Biologics Inc.	Implantable Medical Devices	ON	7000	1/10/11
Jennerex Biotherapeutics Inc.	Drug Discovery	ON	N/A	8/18/11
MedRunner Health Solutions Inc.	Enterprise Systems	NB	400	12/13/11
Milestone Pharmaceuticals Inc.	Drug Discovery	QC	13000	6/13/11
Monteris Medical Inc.	Surgical Devices	MB	8600	7/7/11
MSI Methylation Sciences Inc.	Drug Discovery	BC	19000	9/29/11
Newtopia Inc.	Other Biopharmaceuticals	ON	N/A	2/3/11
NuChem Therapeutics Inc.	Contract Research	QC	N/A	12/5/11
Origin BioMed Inc.	Pharmaceuticals	NS	2000	9/1/11
Phenomenome Discoveries Inc.	Drug Discovery	SK	710	8/31/11
Portola Pharmaceuticals	Drug Discovery	CA	89000	11/21/11
Prevtec Microbia Inc.	Agricultural/Animal Biotechnology	QC	4000	10/12/11
Profound Medical Inc.	Medical Imaging Equipment	ON	9400	2/17/11
Radient Technologies Inc.	Agricultural/Animal Biotechnology	ON	1750	12/21/11
ResVerlogix	Drug Discovery	AB	24250	11/29/11
Tekmira Pharmaceuticals Corporation	Pharmaceuticals	BC	1605	6/16/11
Trillium Therapeutics Inc.	Drug Discovery	ON	1000	6/29/11
Vigil Health Solutions Inc.	Enterprise Systems	BC	520	6/1/11
Warnex Inc.	Medical/Lab Services	QC	700	12/31/11
Xceed Molecular Inc.	Other Biopharmaceuticals	ON	N/A	1/7/11
Zelos Therapeutics Inc.	Drug Discovery	ON	N/A	2/1/11
Zymeworks, Inc.	Diagnostics/Therapeutics	BC	8100	9/22/11
Zymeworks, Inc.	Diagnostics/Therapeutics	BC	N/A	2/1/11

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While venture capital investment increased significantly in 2011, venture capital fundraising did not fare as well. New commitments to venture capital funds were almost unchanged between 2010 and 2011 at \$1 billion. In contrast, fundraising in the United States increased by almost 32 per cent to more than US\$18 billion.

As a partial response to relatively weak fundraising activity over the past few years, the federal government's recently released 2012 budget commits \$500 million over five years to stimulate and support venture capital activities in Canada. Although short on details, the government's commitment recognizes the importance of the venture capital industry to the growth of Canada's innovation economy.

By its nature the venture capital model is dependent on successful exit transactions. Venture returns crystallize only when a company makes a public offering or when it is acquired. Successful venture-backed life science IPO and M&A exits are critical to attracting additional capital to Canadian early stage life sciences companies.

M&A activity in the pharmaceutical and biotechnology sectors outside Canada continued to be robust. In Canada however, there were only a handful of notable deals in the past year, including Alexion Pharmaceuticals Inc. US\$1.1 billion purchase of Enobia Pharma Corp and Cephalon's (NASDAQ: CEPH) \$525M acquisition of biotech Gemin X (followed in November 2011 by the acquisition of Cephalon by Teva Pharmaceutical Industries Ltd. (NASDAQ: TEVA)). In addition to the larger biotech deals, there were also some significant strategic add-on medical device acquisitions involving Canadian targets, such as OraSure Technologies' (Nasdaq: OSUR) acquisition of Ottawa-based DNA Genotek Inc. for \$50 million in cash.

These deals represent the latest Canadian biotech buyouts by international pharma companies at a time when biotech IPOs are few and far between (there were zero Canadian life sciences IPOs in 2011). Overall, however, Canadian life sciences companies have been far less involved in M&A activity than their counterparts in the U.S. and other international markets.

In our view, conditions remain conducive to continued life sciences M&A activity in 2012. Pressures on biomedical companies of all sizes to reduce the costs and risks of product development have been and will continue to be a catalyst for mergers and acquisitions activity. Further, major pharmaceutical firms continue to look to fill their product pipelines through the acquisition or licensing of biotech assets. The year 2012 will continue to see large pharmaceutical and device companies search out attractive add-on acquisition targets in Canada and elsewhere to help them address their strategic and competitive challenges.

As one of Canada's largest law firms, Gowling has been privileged to act as legal counsel in a number of important biotechnology and life science funding and M&A transactions.



. . . conditions remain conducive to continued life sciences M&A activity in 2012.



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Balancing Interests in Drug Submissions to Health Canada: Confidentiality versus Disclosure

by Christopher C. Van Barr and Tushar Tangri

When an innovator pharmaceutical company files a New Drug Submission (NDS) or a Supplementary New Drug Submission (SNDS) with Health Canada, it may be forgiven for thinking that its submission will be held in confidence. Innovator submissions typically contain valuable and commercially sensitive information, such as manufacturing processes, and competitors may request disclosure of the submission pursuant to the Access to Information Act (the Act). This article explores recent law that describes what may happen after such a request is made.

The general rule under the Act is that the government must disclose information, such as information in a submission, to the requesting party. However, there are exemptions that protect confidential information submitted by a party. These exemptions are found under section 20(1) of the Act. Recently, the Supreme Court of Canada (SCC), in *Merck Frosst Canada Ltd. v. Canada (Health)*, 2012 SCC 3, ruled on the scope of the exemptions under the Act.

In *Merck*, one of Merck's competitors made a request under the Act for disclosure of Merck's NDS and SNDS relating to the drug Singulair®. Health Canada refused to disclose some documents while disclosing others without providing notice to Merck, and requested that Merck make submissions as to why the remaining set of documents should not be disclosed to the requesting party. Merck took the position that none of the documents, including those already provided to their competitor, should be disclosed, as they are exempted under the Act. This led Merck to bring a judicial review of Health Canada's decision, which Merck eventually appealed up to the SCC.

The SCC first considered the circumstances under which notice of an intention to disclose information must be provided to the party that submitted the information. In this regard, the SCC interpreted section 27 of the Act, and held that the government may disclose information without providing notice only in *clear cases* where, after reviewing all of the evidence, it concludes that there is *no reason* to believe that the information to be disclosed falls under one of the section 20 exemptions. Such a high threshold should help to ensure that, as a standard practice, confidential information is not disclosed without providing notice to the originator of that information.

The SCC then dealt with the exemptions under section 20(1) of the Act which outline the types of information that cannot be disclosed to a requesting party. Exempted information falls into one of three categories:

1. Trade secrets;
2. Financial, commercial, scientific or technical information that is confidential; and
3. Information, the disclosure of which, could reasonably be expected to result in material financial loss or gain, or prejudice the competitive position of the information provider.

After notice of intended disclosure is provided, the originator of the information must, if it seeks to prevent disclosure, prove on a balance of probabilities that the information falls into one of the above categories. The SCC in *Merck* provided the following guidelines concerning these categories.

1. Trade Secrets

The SCC's interpretation of the scope of the first category, namely trade secrets, is broader than that of the lower appellate court, essentially holding that in the context of the Act, a trade secret is a plan or process, tool, mechanism or compound which is intended to remain confidential by the party disclosing this information.

2. Confidential Financial, Commercial, Scientific or Technical Information

With respect to the second exemption category, the SCC held that it does not encompass the formatting and structure of any information or submission provided to Health Canada. Furthermore, where the submission relies on publicly available materials, such as scientific articles and studies in the public domain, then such materials are not exempted from disclosure since they are not confidential. Having said this, the SCC left the door open to situations where it is not the existence of public studies and articles that is argued as being confidential, but rather the *reliance on or evaluation* of these studies and articles by an innovator that is confidential. Such a determination will depend entirely on the facts of a particular case.

3. Material Financial Loss or Gain or Prejudice to Competitive Position

Finally, with respect to the third exemption, the SCC held that the party seeking to prevent disclosure of this category by Health Canada must establish a "reasonable expectation of probable harm." As a result, the possibility of harm is not sufficient to invoke this exemption. However, the SCC also noted that a party need not show on a balance of probabilities that harm *will* in fact occur as a result of disclosure. The appropriate standard is somewhere in between, and each case will turn on the evidence presented.

In summary, the SCC expanded the circumstances under which notice of intended disclosure must be given, and also clarified how the Act's exemptions will apply to commercially sensitive information. However, it should not be forgotten that the SCC dismissed Merck's appeal and did not overturn the Minister's unilateral decision to disclose Merck's information. Innovators will need to be wary about what they disclose to the Minister and, perhaps more importantly, how they respond to any notice of intended disclosure provided by the Minister.



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Profiting in the Provinces? Evolving Strategies of Generic Pharmaceutical Damages Claims

by Christopher C. Van Barr and Kiernan A. Murphy

Generic pharmaceutical companies operating in Canada have, in recent years, developed new strategies to claim increased statutory damages.

Section 8 of the Patented Medicines (Notice of Compliance) Regulations (the Regulations) provides that a generic shall be entitled to any loss suffered if a prohibition application against it is withdrawn, discontinued, or dismissed. Generics have focused on the phrase “any loss suffered” in an attempt to expand the scope of their claims.

A first and primary generic strategy to increase claimed losses, as employed in *Merck v. Apotex* (2009 FCA 187), is to seek disgorgement of innovator profits pursuant to section 8. However, in this case, the Federal Court of Appeal held that the Regulations limit generics to claiming only their own lost profits.

A second generic strategy employed in *Merck* was to seek damages beyond the statutorily prescribed period by seeking its lost future profits. The FCA, overturning the trial judge on this point, rejected this claim and limited damages to losses suffered, as opposed to caused, during the statutory period. The Court recently confirmed this in *Teva v. Sanofi-Aventis* (2011 FCA 149).

A third generic strategy sought to revisit the issue of innovator profits through a different juridical mechanism by adding a claim for unjust enrichment. However, in *Apotex v. Servier* (2009 FC 319) the Federal Court found that a claim for unjust enrichment framed in the same terms as the damages claim was improper. Furthermore, in *Eli Lilly v. Apotex* (2009 FC 693), the Court subsequently held that it lacked jurisdiction to hear equitable causes of action such as unjust enrichment, and that the Federal Courts Act does not confer jurisdiction where the conduct of a party, not a patent, is at issue. Likewise, in *Apotex v. Nycomed* (T-1786-08, April 18, 2011, unreported) the Federal

Court found that the generic could not claim for unjust enrichment independent of section 8 of the Regulations.

These decisions culminated in the recent decision of the Federal Court of Appeal in *Apotex v. Nycomed* (2011 FCA 358). Here, the Court rejected claims for disgorgement of an innovator's profits for wrongful invocation of the Regulations, holding that Parliament had excluded such claims from the scope of section 8, and that the Federal Court had no jurisdiction to provide equitable relief in relation to such claims. Moreover, the Court specifically added that generics are not entitled to innovator profits simply because the prohibition applications which innovators initiated were ultimately dismissed as contemplated by section 8 of the Regulations.

While the federal courts have spoken definitively on the issue of innovator profits, that is not the end of the story. Generic manufacturers are now bringing unjust enrichment claims to the provincial courts. The recent decisions in *Apotex v. Abbott* (2010 ONSC 6909, leave to appeal refused 2011 ONSC 3988) were the first in these courts to consider this issue. Apotex had claimed damages pursuant to section 8 of the Regulations in the Federal Court. However, given unhelpful Federal Court jurisprudence, it discontinued the action there and commenced a virtually identical action in the Ontario Superior Court of Justice, adding a claim for unjust enrichment. The apparent goal was to claim innovator profits in a more favourable jurisdiction. Abbott brought a motion to strike the claim. The motions judge dismissed the motion, holding that it was not plain and obvious that the Regulations are a complete code ousting common law causes of action or remedies. The motions judge also held that the Regulations were not a "disposition of law" constituting a juristic reason for the innovators' enrichment because innovators were not "required by law" to invoke the Regulations.

The motions judge therefore held that it was not plain and obvious that the claim for unjust enrichment would fail. Subsequent motions for leave to appeal, attacking among other things, the fact that a disposition of law need not be "required by law," were dismissed.

These recent decisions have not decided that claims for unjust enrichment in cases for generic damages are proper; they have merely delayed deciding the issue. Furthermore, the Ontario cases were decided prior to the Federal Court of Appeal's most recent decision.

In any event, perhaps as a result of this temporary success, Apotex has, in *Apotex v. Eli Lilly* (CV-11-420115), also discontinued its claim for generic damages in the Federal Court and commenced a similar action in the Ontario Superior Court of Justice. In this case Apotex claims not only for unjust enrichment, but also treble damages and double costs pursuant to old English statutes, as well as damages or profits pursuant to section 53.2 of the *Trade-marks Act*.

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