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# IP PERSPECTIVES

INTELLECTUAL PROPERTY AND TECHNOLOGY LAW NEWSLETTER

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## CIPO issues new biotechnology examination guidelines

### The Canadian *Manual of Patent Office Practice* has been updated to include a revised chapter on biotechnology.

In January 2009, the Canadian Intellectual Property Office ("CIPO") updated its *Manual of Patent Office Practice* ("MOPOP") to include a revised version of chapter 17, which concerns biotechnology. This marks the first time the chapter has been amended since its initial release in 1998. Whereas the previous chapter 17 dealt merely with procedural aspects of patenting biotechnological inventions, such as deposits of biological material and nucleotide and amino acid sequence listings, the revised chapter is considerably expanded to cover substantive issues, including patentable subject matter, utility, sufficiency and novelty as they relate to biotechnology. In particular, chapter 17 now addresses a variety of subjects peculiar to biotechnology, such as the patentability of higher and lower life forms, methods of medical treatment and polyclonal and monoclonal antibodies. The new chapter 17 also provides numerous exemplary patent claims intended to clarify CIPO practice.

Summarizing the law as it relates to patenting biotechnology is a major undertaking, and CIPO is to be commended for its efforts in establishing publicly available examination guidelines in this area. Regardless of whether there is general agreement as to the correctness of CIPO's position on the topics covered, chapter 17 is a useful tool, as it provides patent applicants in Canada with an improved degree of certainty as to the examination process in this rapidly developing field in which the law remains in flux in many areas. Some of the more contentious topics addressed in chapter 17 are discussed below.

**Higher life forms.** CIPO's position respecting the patentability of higher versus lower life forms reflects its earlier policy statement in a 2006 notice titled "Office Practice Regarding Fertilized Eggs, Stem Cells, Organs and Tissues" (*Canadian Patent Office Record*, Vol. 134, No. 25, June 20, 2006). Generally, CIPO considers the distinction between patentable lower life forms and unpatentable higher life forms to be whether the life form is unicellular (lower) or multicellular (higher). Higher life forms include animals, plants, seeds,

mushrooms, fertilized eggs and totipotent stem cells. CIPO also considers organs and tissues to be non-statutory subject matter. Lower life forms acknowledged by CIPO to be patentable include microscopic algae, unicellular fungi (including moulds and yeasts), bacteria, protozoa, viruses, transformed cell lines, hybridomas and embryonic, pluripotent and multipotent stem cells.

CIPO explains that animals "at any stage of development" are not statutory subject matter for patents and consequently that fertilized eggs and totipotent stem cells (which CIPO defines as those that have the inherent ability to develop into animals) are included in the higher life form proscription (MOPOP, section 17.02.01*a*). Conversely, embryonic, multipotent and pluripotent stem cells, which do not have the inherent ability to develop into an animal, are considered by CIPO to be lower life forms. The language used by CIPO to define this exclusion echoes Article 5 of the *European Biotechnology Directive* and Rule 29 of the *Implementing Regulations to the Convention on the Grant of European Patents*, which proscribe patenting of the human body "at the various stages of its formation and development," including germ cells. There are, however, no analogous provisions in the Canadian *Patent Act* or *Rules*.

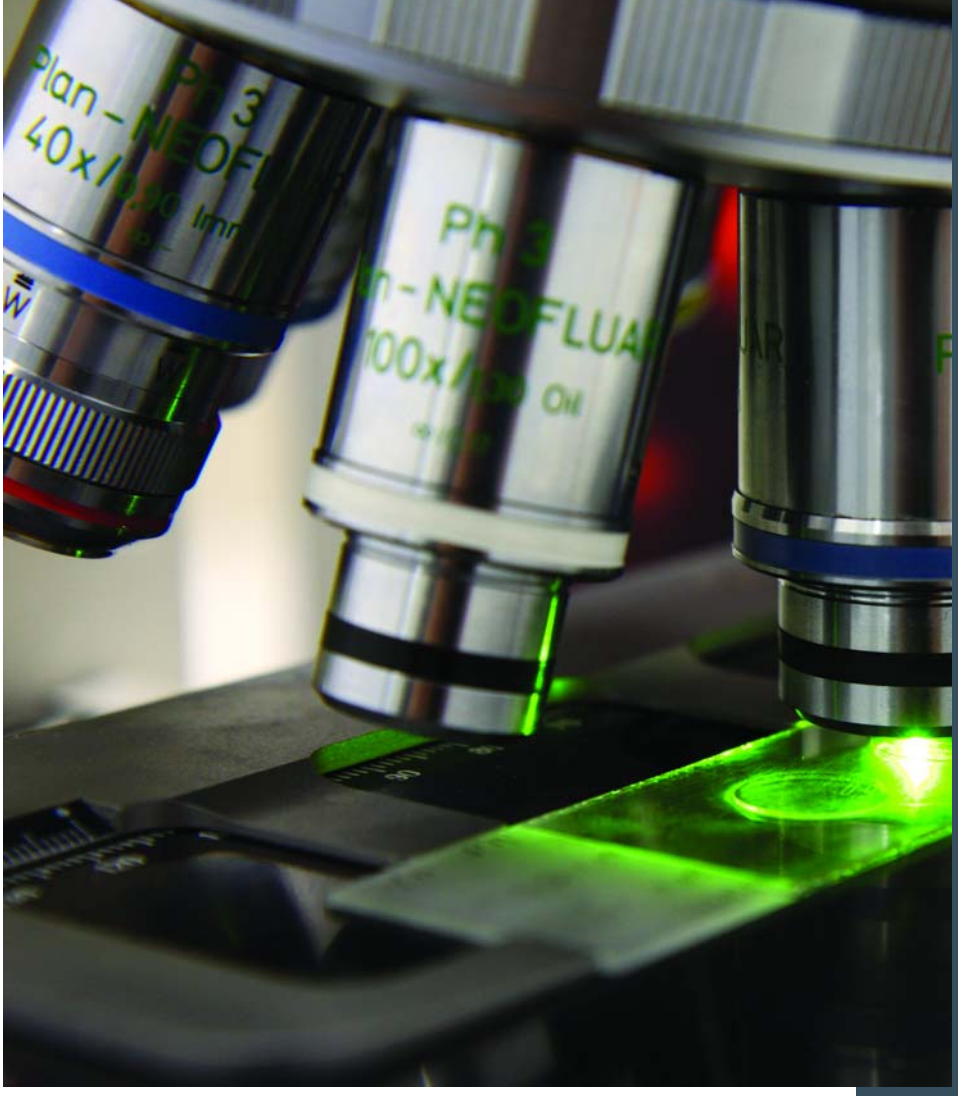
As authority for its position, CIPO cites the Supreme Court of Canada decision in *Harvard College v. Canada (Commissioner of Patents)*, 2002 SCC 76, holding that a transgenic mammal is not a patentable "composition of matter." However, both the majority and the dissent in *Harvard College* commented in *obiter dicta* that a fertilized, genetically modified egg should indeed be patentable. The Supreme Court reiterated this view in *Monsanto Canada Inc. v. Schmeiser*, 2004 SCC 34, holding that a plant cell *per se* is eligible for patent protection. Moreover, in *Schmeiser*, the Court emphasized its view in *Harvard College* that a fertilized egg was patentable **irrespective** of its subsequent development into a mouse. Indeed, the patented plant cells in the *Schmeiser* case were without doubt totipotent, as the patent specification clearly demonstrates the regeneration of whole plants from such cells. The reasoning behind a totipotent plant cell being patentable but not a totipotent mammalian cell (assuming both plants and mammals are "higher life forms") is not explained in chapter 17. It is therefore difficult to reconcile the position of CIPO regarding the patentability of stem cells and fertilized eggs with the views expressed by Canada's highest court. Certainly, if the intent is to mirror the European prohibition, the necessary express exceptions to patentability are not present in the *Patent Act* or *Patent Rules* and the basis for such a prohibition does not appear to be found in the *Harvard College* decision.

**Methods of medical treatment.** There is no prohibition against patenting methods of medical treatment in the Canadian *Patent Act* or *Patent Rules*. However, methods of treatment are typically considered unpatentable in view of the 1972 decision of the Supreme Court of Canada in *Tennessee Eastman Co. v. Canada (Commissioner of Patents)*, [1974] S.C.R. 111. In that case, the Supreme Court held that a method of using certain adhesives to close surgical incisions was unpatentable. The Court held that the otherwise broad scope of the definition of "invention" was circumscribed by section 41 of the *Patent Act*, which required claims directed to foods or medicines to include process-of-manufacture limitations. Permitting a claim to a method of using the adhesive *per se* would have circumvented the requirement in section 41 that the adhesive be claimed by reference to the method for making it. However, section 41 has since been repealed, and few subsequent Canadian court decisions have explored in any depth whether any basis still exists under the current *Patent Act* to exclude methods of medical treatment from patentability. One possible approach is to exclude methods of medical treatment on the ground that they are directed to professional skills rather than to trade, industry or commerce (see, e.g., *Shell Oil Co. v. Canada (Commissioner of Patents)*, [1982] 2 S.C.R. 536 at para. 41). However, the scope of the so-called "professional skills" exclusion is not settled, and recent Patent

Appeal Board decisions have confined this exclusion to methods that are not reproducible because they rely upon human intuition or judgment for their success (see, e.g., *Re Diamonds.net LLC Patent Application No. 2,298,467* (2006), 55 C.P.R. (4th) 328 (P.A.B.)). Presumably, therefore, if the professional skills exclusion is the only remaining basis in Canadian law for excluding methods of medical treatment from patentability, then relatively simple, reproducible methods should not be excluded.

It appears from revised chapter 17 (section 17.02.03) that any method claim that involves at least one "step of surgery" will be rejected, regardless of the ultimate purpose of the method (e.g., an otherwise patentable diagnostic method), as will any method claim that gives a therapeutic benefit, regardless of whether a surgical step is recited. Indeed, in many instances, the issue is largely academic, as claims that recite the use of a compound for treatment of a disease are permitted, provided the use claim does not positively recite any method steps. Examples of steps that CIPO considers to be surgical are provided, and it appears that certain basic procedures, such as injections or the removal of body fluids by needle or cannula, are not considered to be surgical steps *per se*. However, the examples of unpatentable "medical treatment" reflect the difficulty in articulating the underlying legal basis for this exception from patentability under current Canadian patent law. Chapter 17 explains that claims to methods for curing or preventing pathological conditions or physical abnormalities are prohibited, but claims to methods for treating non-pathological natural conditions such as aging, baldness, pregnancy and wrinkles are permitted, as are cosmetic and diagnostic methods. It is unclear why this distinction would be drawn, as both types of claims seem equally related to trade, industry or commerce (assuming that is the test). This is an area of law that might benefit from clarification by Canadian courts.

**Utility and sufficiency.** Another addition to chapter 17 concerns the requirement of utility of the claimed invention. Utility is already the subject of chapter 12 of the MOPOP, but certain topics receive special attention in revised chapter 17. Notably, CIPO takes the position that a patent application disclosing and claiming novel and inventive compound X (i.e., a claim to the compound *per se*) does not comply with the requirements for sufficiency of disclosure in section 27(3) of the *Patent Act* if the specification states that the compound can be used to treat disorders Y, A, B and C,




but the description only contains data supporting treatment of disease Y and no data or other basis for concluding that compound X would also be useful for treating disorders A, B and C. It appears that the objection is not to the claim (indeed, novel compound X is useful for treating disease Y and thus possesses utility) but rather is to the specification for failing to substantiate the additional promised utilities (MOPOP, section 17.03). This is a novel approach to examination by CIPO, which to date has always focussed on examination of the **claimed** invention. It is not clear how such an objection is to be overcome if the Examiner cannot be persuaded through argument. Must the applicant redact the specification to remove reference to additional, unproven utilities, even if the claim is in acceptable form? No specific citation of court authority endorsing this new approach is provided.

CIPO has also articulated a new utility requirement for priority claims: it now considers a priority claim to be effective only if the priority document satisfies the requirement of disclosing a "sound prediction" of the utility of the claimed invention (MOPOP, section 17.03.03). The requirement for a Canadian patent application to provide a sound

prediction of utility is well-established, but no authority has been cited for extending this requirement to priority documents.

**Correction of sequencing errors.** It has historically been very difficult to correct nucleotide or amino acid sequence listings in Canadian patent applications, even if re-sequencing of a sample of biological materials would provide the correct sequence. This difficulty will persist under amended chapter 17, which indicates that if the correct sequence may only be determined by re-sequencing a sample, the correction will constitute impermissible addition of new matter (MOPOP, section 17.04.01*e*).

Chapter 17 does not explain whether a different standard will apply if the sample was deposited under the *Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Protection*. Section 38.1 of the *Patent Act* provides that such a deposit forms part of the specification, so it is arguable that a re-sequencing of a sample from such a deposit should not constitute new matter. Canadian courts have not considered this issue. The United States Patent and Trademark Office ("USPTO") permits reliance on the deposit for this purpose (*Manual of Patent Examining Procedure* ("MPEP") §2163).

**Working examples.** The revised chapter 17 also emphasizes the desirability of working examples in the patent specification. While CIPO correctly notes that there is no absolute requirement under section 27(3) of the *Patent Act* for an application to include examples, it states that exemplary support may be required in some cases to fulfill the "what is your invention" aspect of proper disclosure (MOPOP, section 17.04.03). In support of such a requirement, CIPO cites section 80(1)(f) of the *Patent Rules*, which provides that the description shall "set forth at least one mode contemplated by the inventor for carrying out the invention in terms of examples, where appropriate, and with reference to the drawings, if any...." Reliance on this section of the *Rules* is a new approach. The purpose of this provision — found in a section of the *Patent Rules* setting out the formal requirements for the description and also requiring a title of the invention, background section and so on — is not clear, and Canadian courts do not appear to have ever considered this provision in assessing sufficiency of description in a patent specification.

**Monoclonal antibodies.** Revised chapter 17 includes a section on "special topics," which presently contains only a discussion of claims to antibodies (MOPOP, section 17.08). Based on the Commissioner's decision in *Re Institut Pasteur Application* (1995), 76 C.P.R. (3d) 206 (P.A.B.), CIPO's practice has been to permit a claim to an antibody in an application disclosing a novel antigen but to allow a claim directed to a monoclonal antibody only if the specification includes at least one working example demonstrating the preparation of a monoclonal antibody. In *Institut Pasteur*, the Commissioner held that in the mid-1980s, the basic Köhler and Milstein hybridoma technique for producing monoclonal antibodies was sufficiently uncertain that a mere reference in a patent application to use of "traditional techniques" was not enabling.

The amended chapter 17 now acknowledges that the general procedures for making monoclonal antibodies are sufficiently well-known in the art that a detailed explanation of such procedures is not normally required to provide an enabling description of the invention. Nevertheless, CIPO indicates that whether a monoclonal antibody has been made remains relevant to whether the antibody has been described in sufficient detail.

In a significant departure from past practice, CIPO now indicates that a working example is


not absolutely essential. However, if a working example is not provided, revised chapter 17 explains that the specification must include a structural description of the particular epitope on the antigen to which the monoclonal antibody specifically binds to sufficiently describe the monoclonal antibody. The basis for this conclusion is unclear, as no Canadian court decision has ever established such a requirement for claims to monoclonal antibodies. In contrast, the USPTO takes the view that disclosure of an antigen fully characterized by its structure, formula, chemical name, physical properties or deposit in a public depository provides an adequate written description of an antibody claimed by its binding affinity to that antigen — i.e., there is no need to characterize a particular epitope, binding pocket or the like (MPEP §2163, citing *Noelle v. Lederman*, 355 F.3d 1343, 1349 (Fed. Cir. 2004)).

From a scientific standpoint, the description of a monoclonal antibody specific to a particular antigen would not appear to require identification of the particular epitope to which the monoclonal antibody binds. If there are two or more epitopes, then the monoclonal antibody binds to one of them. This also appears to be irrelevant to making monoclonal antibodies. Presuming various antibody-producing B lymphocytes can be successfully fused with myeloma cells to produce hybridomas, serial dilution to obtain one cell per well provides monoclonal antibodies, all of the same binding specificity. The specific epitope to which such monoclonal antibodies bind would often not be known but could be determined if needed. Further, if the claim does not recite binding specificity to a particular epitope, it is unclear why the description would have to describe the particular epitope.

Provided it is possible to immortalize a B lymphocyte that produces antibodies to a particular antigen (which revised chapter 17 concedes is generally a routine matter), then it is readily possible to produce monoclonal antibodies specific to the antigen. It is not necessary to know what epitope the antibody has been raised against, nor to describe this, unless the claims are directed to an antibody specific to a particular epitope. The claimed property of being monoclonal relates to the antibodies all being derived from a single immortalized B lymphocyte (i.e., a hybridoma) and thus inherently having the same specificity, not that the B lymphocyte produces an antibody reactive with a pre-selected epitope of the antigen.

The new examination policy concerning monoclonal antibodies also appears to be internally inconsistent. It is unclear why the requirement for a structural description of a particular epitope to which a monoclonal antibody binds would be viewed as interchangeable with the alternative requirement of a statement that at least one monoclonal antibody was made. The latter description would not identify the epitope to which the antibody binds but would only demonstrate that the specification is enabling, and the MOPOP now acknowledges that methods for making monoclonal antibodies are routine. Further, the description of a single monoclonal antibody (even by structure) specific to one epitope would not describe antibodies that are specific to other epitopes on the antigen. It is unclear why the making of a single monoclonal antibody would provide a description sufficient to support a claim to a monoclonal antibody specific to an antigen but not limited to a particular epitope.

**Conclusion.** The field of biotechnology has evolved greatly since the inaugural version of chapter 17 was released. This updated and expanded version of chapter 17 may be welcomed by inventors and patent practitioners as an attempt by CIPO to address some of the unique challenges posed by biotechnological inventions.

David E. Schwartz and Brandon Reinhart, Ottawa

# Grace period disclosure by patent applicant cannot be transformed into prior art by a third party application

## This decision is believed to be the first to consider the applicability of the one-year grace period to co-pending applications where the earlier application describes a product disclosed to the public by the applicant of the later-filed application before either application was filed.

The Federal Court of Canada recently awarded a significant victory to the plaintiff in *Uview Ultraviolet Systems Inc. v. Brasscorp Ltd.*, 2009 FC 58, a patent infringement action. Uview was represented in this matter by Brian P. Isaac of Smart & Biggar's Toronto office and Kevin K. Graham of our Ottawa office.

The case involved two patents: Canadian Patents Nos. 2,235,673 ("'673 patent") and 2,224,024 ("'024 patent"), both related to the injection of ultraviolet (leak detection) dyes and conditioning oil into air conditioning systems in automobiles. The defendant counterclaimed to invalidate both patents and for damages against Uview, alleging that Uview made false and misleading statements contrary to section 7(a) of the *Trade-marks Act*.

In the result, the Court held that all claims of the patents asserted in the action were valid and infringed and awarded a permanent injunction as well as damages. The defendant's counterclaim was also dismissed.

A significant aspect of the decision is the Court's interpretation of section 28.2 of the *Patent Act*, which provides a one-year grace period for filing a patent application after public disclosure of an invention. Sections 28.2(c) and (d) of the *Patent Act* provide that a co-pending application filed by another party is citable as prior art against an application if the co-pending application has an earlier claim date (i.e., filing date or priority date).

Uview released the commercial embodiment of the inventions claimed in the patents, its SPOTGUN product, approximately 10 months before the claim date of the '024 patent. In the interim, the defendant filed a patent application that had an earlier claim date than the '024 patent. However, the defendant's application expressly acknowledged Uview's SPOTGUN product as prior art. The defendant also admitted that it was aware of the plaintiff's SPOTGUN product when it designed the product described in its patent application.

The Court concluded that the defendant's patent application was not citable as prior art

against the '024 patent. Justice O'Keefe held that "it would not make any sense to allow the subject matter of a claim to be disclosed in the period of one year prior to the filing date and still be patentable if someone else could use the disclosed subject matter as prior art to defeat the Applicant's application for a patent." Justice O'Keefe found that this was all the more true when the co-pending application acknowledges that the commercial embodiment covered by the patent is prior art.

The defendant also asserted that the '673 patent was invalid pursuant to section 53 of the *Patent Act* as a result of an alleged untrue allegation in the petition regarding ownership of the invention and due to alleged wilful omission of drawings. The Court, noting that an alleged untrue allegation or omission must be both material and "wilfully made for the purposes of misleading" for a patent to be invalid pursuant to section 53, held that the asserted defences did not provide any basis to invalidate the '673 patent.

Another defence asserted by the defendant was that certain impugned products did not infringe as they were obtained from a licensee of Uview. Specifically, the defendant entered into a supply agreement with Uview's licensee in the midst of the litigation. The defendant

directed its suppliers to supply the same product that they previously supplied to the defendant to Uview's licensee, who provided minimal assembly services and ultraviolet dye with the same formulation previously used by the defendant. The products were then shipped to and sold by the defendant. Justice O'Keefe, noting that it was necessary to interpret the licence agreement in order to determine whether a defence flowed from it, found that the agreement only granted a licence for the licensee to make, use or sell its own product, not products of third parties. Accordingly, the alleged licence defence was rejected.

In addition to the defences discussed, the defendant denied infringement and asserted a litany of validity attacks against both patents, including anticipation, obviousness, claim overbreadth, lack of utility, lack of good faith prosecution, claim ambiguity and double-patenting, all of which were rejected by the Court.

As noted above, the defendant's counterclaim in respect of false and misleading statements under section 7(a) of the *Trade-marks Act* was dismissed. Justice O'Keefe succinctly dealt with the counterclaim, noting that damage was an essential element of the cause of action under section 7(a) of the *Trade-marks Act* and that the defendant had not proven any resulting damage. Citing the 2007 decision of the Federal Court of Appeal in *BMW Canada Inc. v. Nissan Canada Inc.*, 2007 FCA 255 at paras. 30-37, he dismissed the counterclaim, despite a bifurcation Order making the extent of damages or profits the subject of a reference after trial on the issue of liability.

The decision is currently under appeal.

Brian P. Isaac and Joseph J. Fraresso, Toronto

# Federal Court of Appeal finds VIAGRA worth a try but not obvious

## The new "obvious to try" standard requires a "self-evident" expectation of success.

The "obvious to try" test in Canada is different from the "worth a try" test applied in a parallel U.K. proceeding, according to a recent decision of the Federal Court of Appeal pertaining to Pfizer's Canadian patent for VIAGRA.

*Apotex Inc. v. Pfizer Canada Inc.*, 2009 FCA 8 ("*Apotex*"), involved an appeal from a lower Court decision that had upheld the validity of Pfizer's Canadian Patent No. 2,163,446, which disclosed and claimed the use of sildenafil or its salts for the treatment of erectile dysfunction ("ED"). The cited prior art included scientific journal articles containing speculative suggestions that PDE inhibitors could be developed to treat ED, as well as a prior patent disclosing sildenafil as a PDE inhibitor for the treatment of cardiovascular disorders. At first instance, the Court had concluded that the most that could have been said at the priority date was that the claimed invention was "worth a try", which was insufficient to render it obvious. In reaching this finding, the Court had applied the test for obviousness set forth in *Beloit Canada Ltd. v. Valmet OY* (1986), 8 C.P.R. (3d) 289 (F.C.A.) ("*Beloit*"), according to which a claimed invention is obvious only if the state of the art and common general

knowledge would have led an unimaginative skilled technician directly and without difficulty to the claimed invention.

The *Beloit* judgment was the leading authority on obviousness in Canada for more than two decades prior to November 2008. Both before and after *Beloit*, Canadian courts had consistently rejected the U.K. "worth a try" test for obviousness in Canada.

On appeal, however, the appellant argued that the law of obviousness had changed in this respect as a result of the November 6, 2008, judgment of the Supreme Court of Canada in *Apotex Inc. v. Sanofi-Synthelabo Canada Inc.*, 2008 SCC 61 ("*Sanofi*", reported in the Autumn 2008 issue of *IP Perspectives*). In *Sanofi*, the Supreme Court declined to apply the *Beloit* test and instead applied a more general factual framework, focusing on whether the differences between the claimed invention and the state of the art would have been obvious.

Moreover, the Supreme Court held in *Sanofi* that an "obvious to try" inquiry may be appropriate in "areas of endeavour where advances are often won by experimentation" and identified a number of non-exhaustive considerations to aid in the "obvious to try" inquiry:

1. Is it more or less self-evident that what is being tried ought to work? Are there a finite number of identified predictable solutions known to persons skilled in the art?
2. What are the extent, nature and amount of effort required to achieve the invention? Are routine trials carried out or is the experimentation prolonged and arduous, such that the trials would not be considered routine?
3. Is there a motive provided in the prior art to find the solution the patent addresses?
4. Another important factor may arise from considering the actual course of conduct that culminated in the creation of the invention.

With respect to the first of these considerations, the Supreme Court emphasized that "the 'obvious to try' test will work only where it is very plain or ... self-evident that what is being tested ought to work."

Apotex argued that the *Sanofi* decision fundamentally changed the law of obviousness in Canada by incorporating the U.K. "worth a try" test and that the Federal Court Judge had erred in failing to apply this test. Apotex also argued that the U.K. Court of Appeal decision in *Lilly Icos Ltd. v. Pfizer Ltd.*, [2002] EWCA Civ 1 ("*Lilly Icos*"), which invalidated Pfizer's U.K. VIAGRA patent for obviousness, should be used as a blueprint for the application of the "worth a try" test in Canada.

In rejecting these submissions, the Federal Court of Appeal observed that "obvious to try" as explained by the Supreme Court in *Sanofi* is not synonymous with "worth a try":

> "The test recognized is 'obvious to try' where the word 'obvious' means 'very plain.' According to this test, an invention is not made obvious [merely] because the prior art would have alerted the person skilled in the art to the possibility that something might be worth trying. The invention must be more or less self-evident."

The Federal Court of Appeal rejected the contrary decision of the U.K. Court of Appeal in *Lilly Icos* on the ground that it had been reached on the basis of a broader test for obviousness than that adopted by the Supreme Court in *Sanofi*. The Court commented that the test applied by the U.K. Court of Appeal appears to be met if the prior art indicates that something may work and there is sufficient motivation to make this avenue worthwhile to pursue, even if the claimed invention was not "more or less self-evident." The Court characterized this approach as being based on the mere possibility that something may work and held that this approach had been rejected by the Supreme Court in *Sanofi*. The Court held that

the Canadian "obvious to try" test requires that it must be "self-evident" that something will work, rather than just possible that something may work.

The Federal Court of Appeal noted the U.K. court's apparent view in *Lilly Icos* that where the motivation to achieve a result is very high, the degree of expected success becomes a minor matter. While the Court agreed that a high degree of motivation may compel the skilled person to pursue experimentation even if the chances of success are not particularly high, the Court emphasized that:

> "[T]he degree of motivation cannot transform a possible solution into an obvious one. Motivation is relevant in determining whether the skilled person has good reason to pursue 'predictable' solutions or solutions that provide 'a fair expectation of success' ..."

In other words, no degree of motivation will satisfy the separate requirement that it must be "more or less self-evident that what is being tried ought to work." The Court of Appeal appears to have compared this requirement with a "fair expectation of success" or a "predictable solution," citing recent judgments of the House of Lords (in *Angiotech Pharmaceuticals Inc. v. Conor Medsystems Inc.*, [2008] UKHL 49 ("*Angiotech*") at para. 42) and the United States Supreme Court (in *KSR International Co. v. Teleflex Inc.*, 127 S.Ct. 1727 (2007) at 1742). Interestingly, in *Angiotech*, the House of Lords reversed a finding of obviousness that had been based on the "obvious to try" test on the ground that a fair expectation of success had not been established; thus, it is possible that U.K. law may be moving away from the approach taken in *Lilly Icos* and closer to the Canadian position. However, it is clear from *Angiotech* that the degree of the expectation of success required to constitute a "fair" expectation in the U.K. is a question of fact that depends in part upon the degree of motivation, whereas the expectation of success and the degree of motivation are independent considerations under Canadian law.

From the *Apotex* and *Sanofi* decisions, it appears that the introduction of an "obvious to try" inquiry into Canadian law has not significantly raised the threshold degree of inventiveness or non-obviousness required to support a patent. It is clear from these decisions that a claimed invention will not be held obvious merely because it was worth a try, unless it would have been self-evident that what was being tested ought to work. These decisions leave open the question as to when an "obvious to try" inquiry is or is not appropriate. This inquiry has thus far been applied only to the pharmaceutical industry, but the reference in *Sanofi* to "areas of endeavour where advances are often won by experimentation" is literally broad enough to encompass many other industries. The full impact of *Sanofi* remains to be seen in future cases.

Kathy Rzeszutek and Stephen J. Ferance, Vancouver

## Cape Breton distiller wins back the right to use GLEN for whisky

In the June 2008 edition of *IP Perspectives*, it was reported that the Federal Court had decided that a whisky made in the style of Scotch whisky cannot use the word GLEN in its name if it is not distilled in Scotland.

The Federal Court of Appeal disagrees.

In a unanimous decision delivered on January 22, 2009, the Federal Court of Appeal held that Cape Breton distiller Glenora Distillers International Ltd. is entitled to register the trade-mark GLEN BRETON for use in association with its single-malt whisky (*Glenora Distillers International Ltd. v. The Scotch Whisky Association*, 2009 FCA 16).

In its opposition, the Scotch Whisky Association contended that the word GLEN had become recognized as designating whisky from Scotland (i.e., Scotch whisky) and was therefore a prohibited mark, and that the use of GLEN BRETON in association with a whisky distilled in Canada was likely to mislead. The Association relied on the use of GLEN-prefixed marks in association with well-known Scotches such as GLENLIVET, GLENMORANGIE and GLENFIDDICH.

The Opposition Board disagreed and allowed the application. As reported previously, the Association successfully appealed the decision of the Opposition Board to the Federal Court, which concluded that the word GLEN had become recognized in Canada as designating Scotch whisky and was therefore a prohibited mark, and directed that the application be refused.

The Federal Court of Appeal has now reversed that decision, holding that the Court below made an error in failing to consider whether GLEN — having only previously been used as a component of various trade-marks — was in itself a trade-mark designating Scotch whisky. While the word GLEN has been used as a prefix for many trade-marks associated with Scotch

whisky, the Federal Court of Appeal noted that it had never been used as a trade-mark standing alone in association with whisky or otherwise. The Court therefore held that the word GLEN had not been shown to be a mark designating Scotch whisky and that it was not prohibited.

Unless leave to appeal to the Supreme Court of Canada is sought and allowed, this decision marks the end of Glenora's long battle to register the trade-mark, which began in November 2000 when it filed its application with the Canadian Trade-marks Office.

Geneviève M. Prévost, Toronto

## Implications of inaccurate Declaration of Use examined by Federal Court

The implications that flow from filing an inaccurate Declaration of Use were recently examined by the Federal Court in *Parfums de Coeur, Ltd. v. Christopher Asta,* 2009 FC 21. This decision is of significant interest to anyone familiar with the severe consequences of filing an inaccurate statement of use in the U.S.

In Canada, if a trade-mark application is based on proposed use (also known as an intent-to-use application in the U.S. and elsewhere), the application will not proceed to registration until a Declaration of Use is executed and filed. The Declaration of Use is an unsworn document indicating that the trade-mark has been used in Canada in association with the wares and services listed in the Declaration. A registration will then issue for those wares and services.

This case involved an application by a challenging party to expunge a Canadian trade-mark registration based on the allegation that the Declaration of Use was not accurate.

Specifically, the Declaration of Use included a long list of wares. An issued registration incorporated all the wares set out in the Declaration of Use. However, it was later established that the trade-mark had only been used in Canada in association with two of the 44 wares listed in the Declaration of Use.

Prior to the commencement of the expungement proceeding, the challenging party advised the registrant of its intention to initiate such a proceeding. At that point, the registrant amended its registration to delete all of the wares except the two for which there was use prior to execution of the Declaration of Use.

The registrant testified that it believed it was acceptable to execute the Declaration of Use so long as there had been use in association

with some of the wares in the Declaration. Accordingly, the Court decided that the error by the registrant was either innocent or negligent but not fraudulent.

The Court noted that if this case had been decided under U.S. law, the registration would either have been expunged in its entirety or, if the error related to only certain classes, the entirety of those classes would be removed from the registration. The challenging party argued in part that Canadian law should be consistent with decisions in the U.S. on this issue.

The Federal Court disagreed, emphasizing that the law in Canada is different from the law in the U.S. The Court held that in general, unless the error was an intentional misstatement, the error is unlikely to result in an invalid registration.

It is particularly noteworthy that the Court emphasized the registrant's amendment of the registration (to delete the wares that should never have appeared in the Declaration of Use) prior to the commencement of the expungement proceeding. While the Judge did not explain what would have happened if the registration had not been voluntarily amended prior to the initiation of the expungement proceeding, these comments leave open the possibility that the result may have been different.

Given that some uncertainty remains in Canada on this issue, all applicants are strongly advised to ensure that there has been use in Canada in respect of all wares and services listed in a Declaration of Use before it is executed and filed with the Trade-marks Office.

Philip Lapin, **Ottawa**

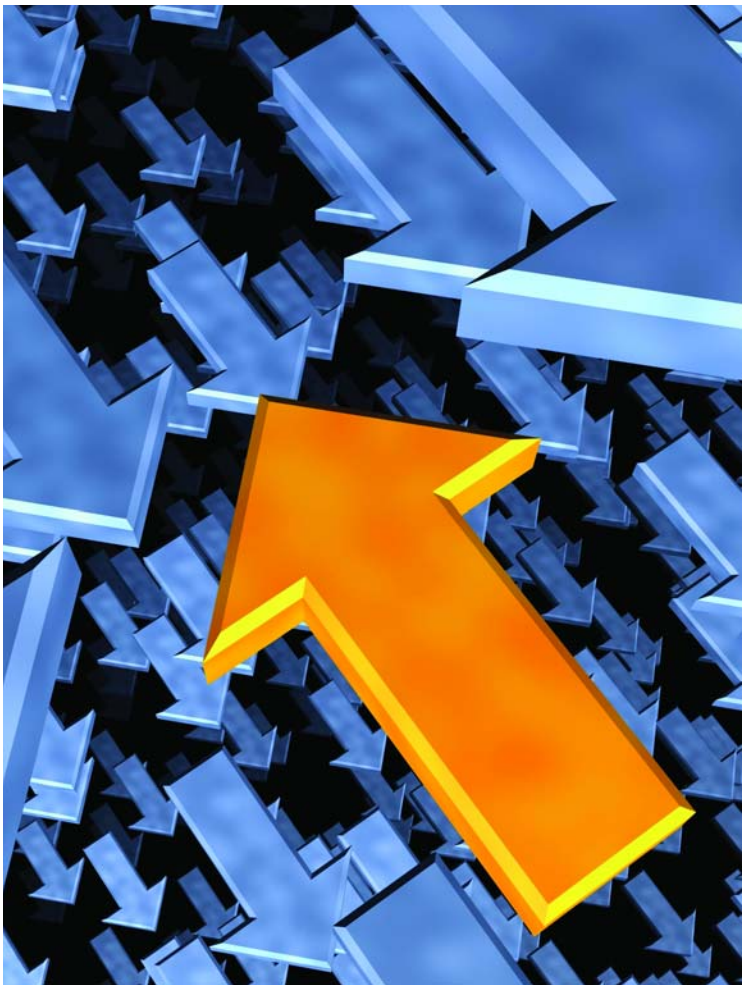
## New practice for Canadian trade-mark oppositions

The Canadian Trade-mark Opposition Board recently published a new Practice Notice that will come into force on March 31, 2009, which will significantly modify the granting of extensions of time in trade-mark oppositions.

Prior to 2007, the Opposition Board was generally agreeable to granting numerous, long extensions of time at each stage of an opposition. That practice was significantly curtailed in 2007.

The new Practice Notice has reinforced some of the changes that were introduced in 2007 and has also introduced a number of other important changes.

Specifically, the Opposition Board has introduced what it calls benchmark extensions. At each stage of an opposition, the Opposition Board is prepared to grant each party a single benchmark extension. In the pleading stage, such extensions are available without the consent of the other party. However, for benchmark extensions beyond the pleading stage, the consent of the other party is required.



While the Opposition Board has discretion to grant extensions beyond the benchmark extensions, such additional extensions of time will only be granted if exceptional circumstances are established.

Borrowing from opposition practice in the United Kingdom, the new Practice Notice introduces the concept of cooling-off periods. Each party may obtain a single nine-month cooling-off period prior to the filing of its evidence, provided that settlement discussions are ongoing and that the other party consents.

In addition to the extensions noted above, a single further extension of time will be available to enable parties to finalize a settlement.

The stringent language of the new Practice Notice suggests that the Opposition Board will be very reluctant to grant extensions of time beyond the specified benchmarks and cooling-off periods. Accordingly, unlike opposition practice prior to 2007, it is important for the parties to treat deadlines seriously, since it is entirely possible that the Opposition Board will refuse extension requests beyond those specifically contemplated in the Practice Notice.

The complete text of the Practice Notice is available at: http://www.cipo.ic.gc.ca/eic/site/cipointernet-internetopic.nsf/eng/wr01558.html.

Philip Lapin, **Ottawa**

## New summary trial mechanism proposed for Federal Court

The procedures for obtaining summary judgment under the *Federal Court Rules* ("*Rules*") could change if proposed amendments, published on January 24, 2009, are adopted. The amendments are intended to allow for the efficient disposition of actions, in whole or in part, where a trial to hear a full range of evidence is unnecessary.

The scope of summary judgment in the Federal Court has narrowed significantly in recent years due to the Federal Court of Appeal's finding that summary judgment is unavailable where there is a genuine issue to be tried. As a result, whenever there was conflicting evidence, the Court found a genuine issue and denied summary judgment.

The proposed amendments address the concern of the Federal Court of Appeal by explicitly adding a summary trial mechanism to the *Rules*. After a defence has been filed and prior to a trial date being set, any party may bring a motion for either summary judgment or summary trial. If a party moves for summary judgment and a genuine issue for trial is found on one or more issues, the Court may convert the motion to a summary trial on those issues or send the case to trial.

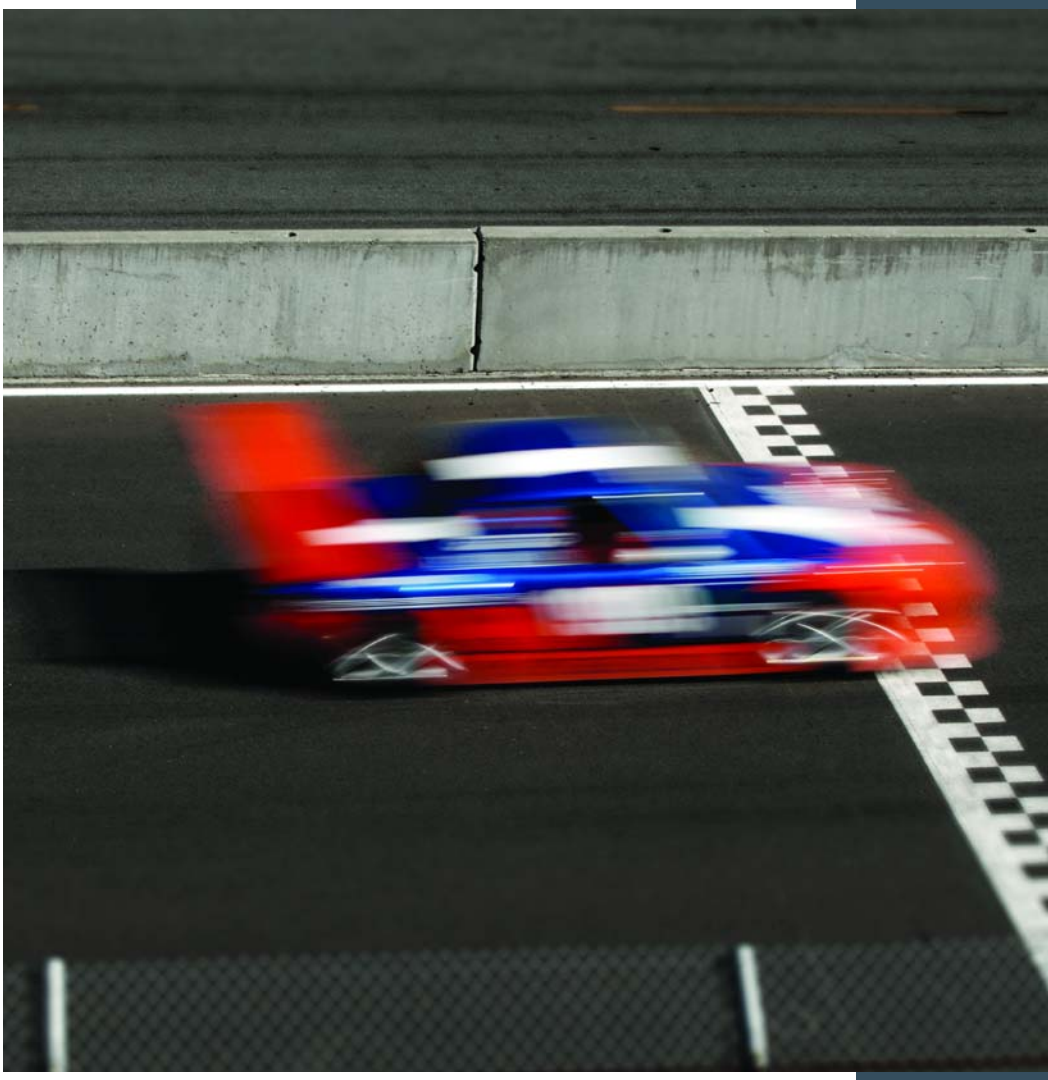
The proposed summary trial rules provide that if the Court is satisfied that there is sufficient evidence for adjudication — regardless of the amounts involved, the complexities of the issues and the existence of conflicting evidence — the Court may grant judgment either generally or on an issue, unless the Court is of the opinion that it would be unjust to decide the issues on the motion outside of trial.

The standard of proof on summary trial is the same as at a trial. Admissible evidence for both parties consists of affidavits (which cannot be based on information and belief), admissions received pursuant to a request to admit, expert affidavits or statements and discovery evidence. Additionally, the Court may require a deponent or expert to attend for cross-examination. The Court may draw an adverse inference if a party fails to cross-examine or file responding or rebuttal evidence.

While a motion for summary trial can be brought in any case, the Court may dismiss the motion if the case would not be suitable for summary trial or if the summary trial would not assist in the efficient resolution of the action. It can be expected that summary trial will be particularly advantageous in very strong cases or in cases with limited evidentiary records. The summary trial mechanism is unlikely to be effective in situations where it is not possible to put all the necessary evidence before the Court without live testimony, such as where a key witness can only be made to testify by subpoena.

The new rules should come into effect within the next year. The introduction of these rules is intended to streamline the litigation process to quickly resolve appropriate cases through the summary trial mechanism, which will in turn make more time available for cases requiring a full trial. This should make the Federal Court of Canada a more attractive venue for efficient and timely litigation.

Daniel M. Anthony, Ottawa



## Smart & Biggar/Fetherstonhaugh honoured with three awards at *Managing Intellectual Property's 2009 North America Awards*

Smart & Biggar/Fetherstonhaugh has been recognized as the 2009 Canadian Copyright Firm of the Year, the 2009 Canadian Trade Mark Contentious Firm of the Year and as having the 2009 Canadian Trade Mark Case of the Year by U.K. publication *Managing Intellectual Property* magazine (*MIP*). This is the second year in a row that Smart & Biggar/Fetherstonhaugh has been honoured in two of *MIP*'s five categories recognizing excellence in the field of Canadian intellectual property law and the first time the firm has been recognized in the category of Case of the Year. The award-winning case was *Louis Vuitton Malletier S.A. v. Pi-Chu Lin*, 2007 FC 1179, aff'd 2008 FC 45, reported in the February 2008 edition of *IP Perspectives*.

The results of the *MIP North America Awards* were based on extensive interviews with in-house IP and business leaders conducted in late 2008 and early 2009 in connection with *MIP's World IP Survey* in the U.S. and Canada. The awards were presented at the second annual *MIP North America Awards* ceremony, held on March 26, 2009, in Washington, DC.

*MIP* was founded in 1990 and is now firmly established as the leading international magazine for IP owners. Published 10 times annually and distributed globally to more than 8,000 readers, the publication covers developments affecting intellectual property from both a legal and business perspective.

# Firm receives top honours in recent survey publications

***2008 Lexpert Guide to the Leading US/ Canada Cross-border Litigation Lawyers in Canada.*** Three of our lawyers appear in the area of IP litigation — more than any other firm in Canada:
Gunars A. Gaikis
François Guay
A. David Morrow

***PLC Which Lawyer? IP Life Sciences Handbook 2008/09.*** Four of our lawyers have been selected for the areas of intellectual property and patent counselling. No other firm in Canada has more lawyers appearing in these areas.

Selected in intellectual property:
Gunars A. Gaikis
A. David Morrow

Selected in patent counselling:
Joy D. Morrow
J. Christopher Robinson

***The 2009 Lexpert/American Lawyer Guide to the Leading 500 Lawyers in Canada.*** Five of our lawyers were recognized in the areas of biotechnology, intellectual property and IP litigation. No other firm in Canada has more lawyers appearing in these areas.

Selected in biotechnology:
Joy D. Morrow

Selected in intellectual property:
François Guay
Michael D. Manson
A. David Morrow

Selected in IP litigation:
Gunars A. Gaikis
François Guay
A. David Morrow

***Chambers Global — The World's Leading Lawyers for Business.*** In the 2009 edition, Smart & Biggar/Fetherstonhaugh has been recognized as a leading firm in the area of intellectual property with seven lawyers listed in the areas of intellectual property and IP litigation.

Selected in intellectual property:
John Bochnovic
Mark K. Evans
Joy D. Morrow

Selected in IP litigation:
Mark K. Evans
Gunars A. Gaikis
Steven B. Garland
Michael D. Manson
A. David Morrow

***The Legal Media Group Guide to the World's Leading Patent Law Practitioners.*** In the 2009 edition, the firms have been recognized with seven leading patent lawyers in the guide — more than any other firm in Canada:
John Bochnovic
Gunars A. Gaikis
Steven B. Garland
François Guay
Michael D. Manson
John R. Morrissey
A. David Morrow

***The International Who's Who of Trademark Lawyers 2009.*** Three of our lawyers have been selected to appear in the guide. No other firm in Canada has more lawyers recognized in this guide:
Michael D. Manson
A. David Morrow
Keltie R. Sim

***The Best Lawyers in Canada.*** In the 2009 edition, Smart & Biggar/Fetherstonhaugh has once again been chosen as the top ranked firm in the area of biotechnology law. In total, twelve of our lawyers have been selected in the areas of biotechnology and intellectual property.

Recognized in biotechnology:
Gunars A. Gaikis
Brian G. Kingwell
Joy D. Morrow
J. Christopher Robinson
David E. Schwartz

Recognized in intellectual property:
John Bochnovic
Mark K. Evans
Gunars A. Gaikis
Steven B. Garland
François Guay
Michael D. Manson
John R. Morrissey
A. David Morrow
Joy D. Morrow
J. Christopher Robinson

***Managing Intellectual Property's 2009 World IP Survey.*** Smart & Biggar/Fetherstonhaugh has once again been ranked as a Tier One firm in all four categories relating to intellectual property: patent prosecution, patent contentious, trade mark prosecution and trade mark/copyright contentious.

# Notes

## Announcements

**Daniel S. Drapeau** has joined our Montreal office as counsel. Mr. Drapeau's practice focuses on obtaining and enforcing intellectual property rights, including patent and trade-mark litigation, anti-counterfeiting programs and obtaining rights in the fields of trade-marks, copyright and industrial designs. Mr. Drapeau was called to the Quebec Bar in 1991 and is a registered trade-mark agent. He holds a B.A. from the University of Ottawa and an LL.B./B.C.L. from McGill University.

**Steven B. Garland** has been elected Vice President of the Canadian Group of AIPPI (International Association for the Protection of Intellectual Property).

**Alistair G. Simpson** was interviewed for the Canadian Bar Association's National Magazine for their article titled "Business patent overhaul," which appeared in the January-February 2009 issue.

## Seminars and presentations

**Philip Lapin**, **Christine N. Genge** and **Kevin K. Graham** are teaching the course "Intellectual Property Law for Engineers" at the University of Ottawa during the 2009 winter term.

**Brian P. Isaac** provided an update on the topic of "Counterfeit and Grey Goods" at the Law Society of Upper Canada's 13th Annual *Intellectual Property Law: The Year in Review*, which was held in Toronto on January 15, 2009. **Steven B. Garland** provided the "Update on Patents 2009" as part of the same program when it was conducted in Ottawa on January 16, 2009.

**Karen F. MacDonald** spoke on the topic of "Counterfeiting and the Money Chase" at the monthly luncheon of the Vancouver Chapter of the Association of Certified Fraud Examiners, held in Vancouver on January 28, 2009.

**Daphne C. Lainson** hosted the Toronto chapter of the AIPLA Women in IP Law Dinner in Toronto on February 12, 2009. As chair of AIPLA's Women in IP Law committee, Mrs. Lainson also addressed attendees from 26 cities across North America during the dinner's teleconference.

**Brigide Mattar** was a moderator on a panel discussion regarding "La propriété intellectuelle dans le contexte des relations clients-fournisseurs" at the 2009 edition of the *Forum International de la Propriété Intellectuelle — Québec* (FORPIQ), held in Montreal on February 18 and 19, 2009.

**Brigide Mattar** was a delegate at the AIPLA European Committee's 2009 Annual European Trip where she presented on the topic of "Accelerating Patent Examination in North America" to the *Compagnie nationale des conseils en propriété industrielle* in Paris on March 3, 2009.

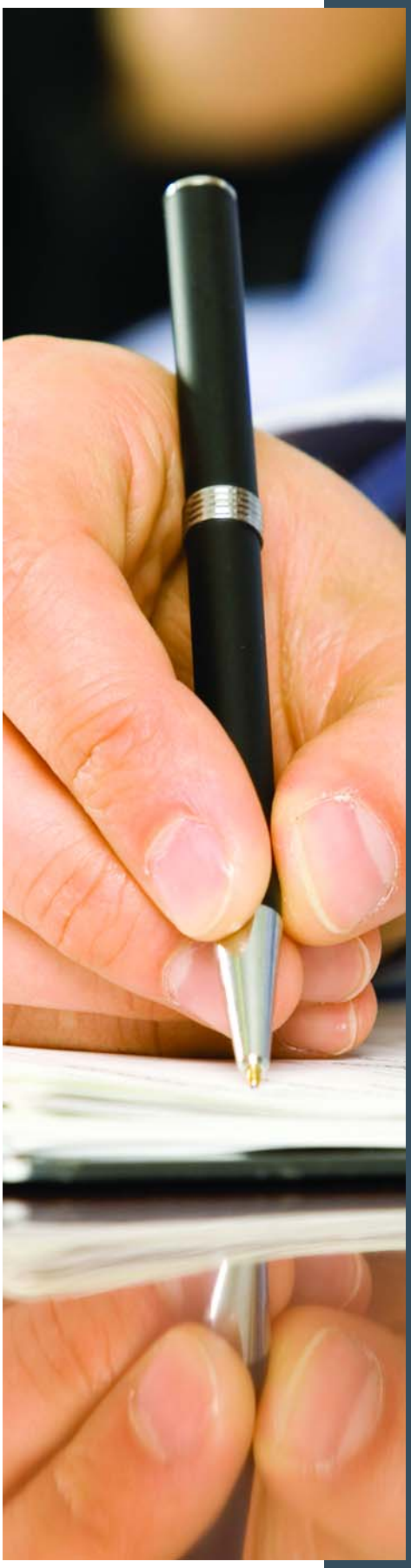
**Brian P. Isaac** spoke on the topic of "The challenges of searching registered non-traditional trademarks" at a workshop held by the Malaysian Intellectual Property Office in conjunction with INTA and the Malaysian International Chamber of Commerce, held in Kuala Lumpur on March 4, 2009.

**Christian Bolduc** chaired an INTA roundtable on the topic of "Non-traditional trade-marks", which was held in Montreal on March 31, 2009.

**Sanjay D. Goorachurn** was a moderator and panellist on the topic of "Strategic IP Portfolio Management" at the Canadian Corporate Counsel Association's Spring Conference, held in Montreal on April 7, 2009.

**Gunars A. Gaikis** will speak on the topic of "Pharma Patent Trials Within Two Years" at the Drug Patent and Legal Forum to be held in Toronto on May 28 and 29, 2009. **Nancy P. Pei** will speak at the same event as part of a panel on the topic of the "Supreme Court of Canada PLAVIX Decision: The Aftermath" from the patentee's perspective. **Yoon Kang** will also speak at this conference on the topic of "Manning the Barricades: New Chapter 17 of the MOPOP — CIPO's Policies Concerning the Patentability of Biotechnology-related Inventions."

**Sanjay D. Goorachurn** will co-present with **François Guay** on the topic of "La propriété intellectuelle, la contrefaçon et ses conséquences sur l'économie canadienne et sur les entreprises" at the *Congrès annuel du Barreau* to be held in Montreal on May 29, 2009.



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