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IP PERSPECTIVES

INTELLECTUAL PROPERTY AND TECHNOLOGY LAW NEWSLETTER

Spring 2010

Amendments to the *Patent Rules* to revise declaration of entitlement requirements come into force on October 1, 2010

A new, simplified declaration will avoid many of the difficulties posed by current declaration of entitlement requirements.

Rules amending the *Patent Rules* (SOR/2009-319, registered November 26, 2009) were published in Part II of the *Canada Gazette* on December 9, 2009, and will come into force on October 1, 2010. Although many of the amendments are essentially editorial in nature, the amendments concern at least one matter of substance. This relates to the current requirement for a "declaration of entitlement" in a Canadian patent application.

Prior to June 2, 2007, an applicant was required to register evidence (usually in the form of an assignment) that the applicant was the legal representative of the inventor. Pursuant to amendments to the Canadian *Patent Rules* that came into force on June 2, 2007, this requirement was removed and replaced with a requirement for a declaration as to the applicant's entitlement, as of the filing date, to apply for and be granted a patent.

Although the 2007 amendments were intended to simplify the application procedure, the complexity of the prescribed declaration of entitlement form has proven to be problematic. The current declaration of entitlement form, which is based on a general purpose form prescribed in the PCT Administrative Instructions, requires identification of a specific basis of entitlement selected from a prescribed list including terms such as "an agreement," "consent," or "transfer of entitlement," none of which is defined in the *Patent Act* or *Patent Rules*. Furthermore, the form requires specific dates to be attributed to most of these bases of entitlement.

The amendments coming into force on October 1, 2010, will replace the requirement for the relatively complex declaration of entitlement document with a simple

declaration that "the applicant is the legal representative of the inventor." The term "legal representatives" is defined broadly in the *Patent Act* as including "heirs, executors, administrators, guardians, curators, tutors, assigns and all other persons claiming through or under applicants for patents and patentees of inventions."

The consequence of any inaccuracies in a declaration of entitlement is uncertain. Therefore, applicants may wish to refrain from filing declarations of entitlement in anticipation of the coming into force of the amended *Patent Rules* on October 1, 2010. This should at least be possible with respect to applications filed or entering the national phase on or after April 1, 2010, as any term set for filing a declaration of entitlement could not expire before October 1, 2010.

Finally, although neither the existing declaration of entitlement regime nor the simplified declaration procedure requires that an assignment from the inventor to the original applicant be registered in the Patent Office, there nevertheless remain provisions in the *Patent Act* relating to assignments. The interplay between these provisions and the *Patent Rules* regarding the declaration of entitlement or simplified declaration is not entirely clear. In particular, while the *Patent Rules* suggest that an assignment to someone other than the applicant will not be recognized, the *Patent Act* provides that an unregistered assignment is void against a subsequent assignee's claim under a registered assignment. Therefore, where there is an assignment in favour of an applicant, we cannot preclude the possibility that, if the assignment is not registered, it might be considered void against a subsequent assignment if the subsequent assignee managed to register the subsequent assignment. In view of this possibility, applicants may wish to take the cautious course of registering assignments from the inventors to the original applicant.

Ronald D. Faggetter, Toronto

Federal Court introduces summary trial rules

Over the last several years, the Canadian Federal Court, which hears the majority of intellectual property cases in Canada, has implemented various new rules amendments and practice changes to ensure that intellectual property litigation proceeds efficiently. The goal of the Court — as expressed in various speeches of the Chief Justice and reflected in a May 1, 2009, Practice Direction of the Court — is that even the most complex cases may reach a final disposition (e.g., a decision following a full trial) within two years of the commencement of the proceeding.

In keeping with this goal is the recent introduction of a summary trial procedure, which was added to the *Federal Courts Rules* by amendments registered on December 10, 2009. The amendments to the *Rules* were published for comment in January 2009 (as reported in the Spring 2009 edition of *IP Perspectives*) and have been adopted in substantially the same form.

Prior to the amendments, the *Federal Courts Rules* contained a procedure for summary **judgment**, which was available where the Court was satisfied by motion that there was "no genuine issue for trial with respect to a claim or defence" or where the Court was able "on the whole of the evidence to find the facts necessary to decide the questions of fact and law." However, in several rulings in 2004, the Federal Court of Appeal adopted a narrow interpretation of the summary judgment rule, holding that credibility issues, "broadly defined," should not be decided on a summary judgment motion. Given that expert evidence will often be required in intellectual property litigation, an issue of credibility will almost invariably arise from the competing testimony of expert witnesses called by the opposing parties. The limited application of the former summary judgment rules was a source of frustration for both the intellectual property Bar and the Court.

The current rules amendments introducing summary trial are clearly designed to remedy the lack of an effective summary procedure in the Federal Court following the narrow interpretation of the summary judgment rules. Indeed, the problems with the summary judgment rules are expressly referenced in the *Regulatory Impact Analysis Statement* that accompanies the amendments:

> The current judicial interpretation of the summary judgment rules limits the instances in which summary judgment will be granted.

> The jurisprudence requires that a motion for summary judgment be dismissed where an issue of credibility arises or where there is conflicting evidence and the outcome of the motion turns on the drawing of inferences. Thus, the existing provisions for summary judgment in the Federal Court do not provide the flexibility needed to manage the Court's caseload efficiently by the expeditious disposition of cases that do not require a full trial.

The new summary trial rules are modeled after similar provisions in the rules of several Canadian provincial court systems.

Under the new *Rules*, the Court may direct a summary trial when, on a motion for summary judgment, it finds that there is a genuine issue for trial (for example, where issues of credibility exist). Additionally, a party may bring a motion for summary trial directly.

Evidence on a summary trial may include affidavits, expert statements, admissions and discovery testimony. The Court is also given broad discretion to make orders with respect to the conduct of a summary trial, and it may order witnesses or experts who have given statements to attend for cross-examination before the Court.

The Court may dismiss the motion for summary trial on or before its hearing if the issues raised are not suitable for summary trial or if a summary trial would not assist in the efficient resolution of the action. If the summary trial proceeds to a hearing on the merits and the Court is satisfied that there is sufficient evidence for adjudication, 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.

Overall, the intention of the Court is that the rule amendments will expand the circumstances in which an action may be disposed of summarily without a full trial. While there has yet to be a case decided in the Federal Court under the new summary trial rules, the experience in British Columbia, where such a procedure has existed for a number of years, has been very positive. It can be expected that summary trial will prove to be a valuable tool in intellectual property cases where the issues are relatively simple and the expense of a full trial is not justified.

Colin B. Ingram and Daniel M. Anthony, Ottawa

Supreme Court of Canada to hear trade-mark appeal

The Court will consider whether a likelihood of confusion between two trade-marks can exist if both marks are not already in use in the same geographic area.

Canada's highest Court will soon be hearing an appeal with respect to an application for expungement of a trade-mark registration under section 57 of the *Trade-marks Act*, involving the test for a likelihood of confusion between two trade-marks. The Supreme Court of Canada has granted leave to hear an appeal of the Federal Court of Appeal decision in the matter of *Masterpiece Inc. v. Alavida Lifestyles Inc.*, 2009 FCA 290, marking the Supreme Court's first trade-mark appeal since it clarified the law relating to famous marks in 2006.

The facts of the case are relatively straightforward. The parties operate in the retirement residence industry. Masterpiece had used an evolving series of unregistered

trade-marks incorporating the word "masterpiece," some including the word "living," since 2001. Alavida Lifestyles started using the trade-mark MASTERPIECE LIVING in late 2005 or early 2006 and applied to register this trade-mark on December 1, 2005. In 2006, Masterpiece applied to register its trade-marks, MASTERPIECE and MASTERPIECE LIVING, but its applications were refused by the Canadian Intellectual Property Office on the basis of Alavida's prior application. Alavida's application subsequently issued to registration, at which point Masterpiece filed an application with the Federal Court to expunge Alavida's registration based on Masterpiece's prior use of confusingly similar trade-marks in Canada. The expungement application was denied by the Trial Judge, and that decision was upheld by the Federal Court of Appeal.

The main issue before the Supreme Court relates to whether a likelihood of confusion between two trade-marks can exist if the marks are not already in competition in the same geographic area. The Federal Court Trial Judge indicated in his reasons that he had considered the entirety of the evidence and found no likelihood of confusion based on an analysis of the usual factors to be considered. The Federal Court of Appeal, in being asked to consider whether the Trial Judge had erred in not considering a future likelihood of confusion, appears to have held that because Masterpiece's use of its trade-marks at the time of filing of Alavida's application was not in the same geographic area as Alavida's use, there was no likelihood of confusion to prevent registration of Alavida's trade-mark.

The Federal Court of Appeal held that the *Trade-marks Act* requires that there be a present likelihood of confusion on the relevant date (namely the filing date of Alavida's application) for prior use by another party to bar registration; a future likelihood of confusion is not enough. In the circumstances before the Court, where the parties were not operating in the same geographic location at the time of the application, there was no likelihood of confusion. Future plans for geographic expansion were held to be irrelevant to the analysis.

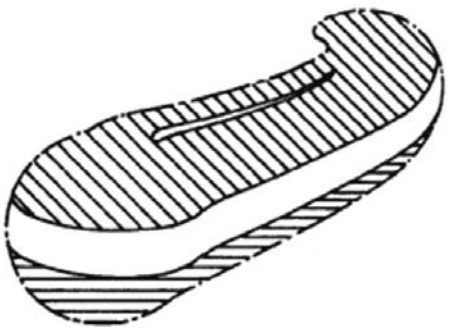
Also at issue before the Supreme Court is whether the Court of Appeal has, by its application of the test for likelihood of confusion, elevated the test for expungement to that of a common law action for passing off, which requires a reputation in the geographic area in question to enforce unregistered trade-mark rights. The Court is also being asked to consider whether the lower Courts erred in holding that a likelihood of confusion can be overcome by aspects of "get-up" surrounding use of the trade-marks.

IP practitioners in Canada will be closely watching the outcome of this appeal, in view of both the rare opportunity to hear from Canada's highest Court on issues of trade-mark law and the potential ramifications to the commonly held view that a prior user of a trade-mark in Canada can prevent registration by another of a confusingly similar trade-mark regardless of the precise geographic location in Canada in which the prior use occurred.

Karen F. MacDonald, Vancouver

Federal Court rejects opposition to distinctive toothpaste design

Mark Evans of Smart & Biggar's Toronto office successfully represented Colgate-Palmolive Canada Inc. in *Procter & Gamble Inc. v. Colgate-Palmolive Canada Inc.*, 2010 FC 231, February 26, 2010, a decision of Canada's Federal Court rejecting an opposition by Procter & Gamble Inc. to the registration of a trade-mark consisting of toothpaste with distinctive coloured stripes.



The opposition related to an application for a striped toothpaste design filed in 1994 based on proposed use in Canada. The trade-mark

drawing (previous page) consists of a slug of toothpaste with coloured stripes. The top stripe is green, the middle is white and the bottom is blue. The representation of a slug of toothpaste was disclaimed.

Procter & Gamble raised six grounds of opposition, all of which were ultimately rejected by the Opposition Board. Of particular interest are the grounds of opposition in which Procter & Gamble alleged that the toothpaste design was not in fact a trade-mark at all. The Opposition Board dismissed these grounds for having been improperly raised under section 38(2)(b) of the *Trade-marks Act* but did comment on each of them.

On appeal to the Federal Court, Justice Boivin upheld the finding that these grounds were improperly pled but also added some interesting comments.

One of the grounds of opposition alleged that the toothpaste design was purely for ornamental purposes. Previous decisions, such as *W.J. Hughes & Sons "Corn Flower" Ltd. v. Morawiec* (1970), 62 C.P.R. 21 (Ex. Ct.), had found marks that were applied to wares solely for the purpose of ornamentation to be unregistrable as trade-marks. In a later decision, *Adidas (Canada) Ltd. v. Colins Inc.* (1978), 38 C.P.R. (2d) 145 (F.C.T.D.), a mark relating to stripes applied to clothing was refused in light of expert evidence that stripes make a garment more attractive. In considering this argument, the Board also considered case law that had found that all design marks have an ornamental component to some extent: *Samann v. Canada's Royal Gold Pinetree Mfg. Co. Ltd.* (1986), 9 C.P.R. (3d) 223 (F.C.A.).

The Board ultimately decided that Procter & Gamble had not satisfied its initial evidential burden to demonstrate that the mark was ornamental in nature. The Board specifically found that it could not consider that a proposed-use mark might ultimately be used solely for a purpose other than indicating source in the absence of corroborating evidence.

Justice Boivin agreed with the findings of the Opposition Board, drawing attention to the fact that *Adidas* had dealt with express expert evidence stating that striping made garments more attractive and had a slenderizing effect. By comparison, in this proceeding, Colgate had filed an affidavit stating that the striping in the toothpaste served no purpose and that the colouring was arbitrarily chosen. Procter & Gamble offered no expert testimony to rebut this affidavit and chose not to cross-examine Colgate's witness as his affidavit was only one page long.

In a further ground of opposition raised as an alternative to the one discussed above, Procter & Gamble alleged that the toothpaste design was unregistrable for being primarily functional in nature. Procter & Gamble argued that other toothpaste companies that had distributed striped products had used the stripes as separate functional elements of the toothpaste — for example, one stripe fights cavities while the other freshens breath. The Board was unwilling to accept the evidence that other companies had used stripes to separate functions over the uncontested evidence that the stripes served no purpose.

At the Federal Court, Procter & Gamble raised the issue of patents held by Colgate relating to striped toothpaste. These patents dealt with how to maintain chemical equilibrium in a toothpaste container and keep a stable striped appearance in the toothpaste as it was dispensed. Justice Boivin found that the patents, manufacturing process, flavours and colouring agents did not conclusively indicate a primary function of the striped toothpaste and that, while stripes can perform a function, there was no evidence presented that the stripes in Colgate's toothpaste in issue did so.

Another ground of opposition dealt with the display of the toothpaste design to the public. Procter & Gamble argued that since the design was on the toothpaste inside an opaque tube, possibly contained inside a cardboard box, the design would not be visible to consumers at the time the goods were transferred and that the design could therefore not be "used" as defined in section 4 of the *Trade-marks Act*. In response, Colgate brought evidence of several manners in which toothpaste can be sold that allow the purchaser to see the toothpaste inside the tube. The Board accepted this as evidence that it is not impossible to use the design in accordance with section 4. Justice Boivin also upheld this finding.

Finally, on the ground of opposition related to lack of distinctiveness, Procter & Gamble noted that the toothpaste design incorporates the three most common colours in the toothpaste industry and that striped toothpaste, such as AQUAFRESH, has been offered for sale since 1984. Justice Boivin found that there was no evidence of another party using the same appearance and striping present in the design and that there was thus no evidence establishing that the design could not serve to distinguish Colgate's toothpaste.

Margaret M. Hing, Toronto

CIPO releases new chapters 12 and 13 of the MOPOP

The controversial approaches to examination and statutory subject matter adopted in these chapters are being challenged in the Federal Court.

Despite opposition from the Canadian patent profession during the public consultation period, on December 4, 2009, the Canadian Intellectual Property Office (CIPO) announced that it has released new versions of chapters 12 and 13 of the Manual of Patent Office Practice (MOPOP).

These new chapters, titled "Subject-Matter and Utility" and "Examination of Applications" respectively, summarize CIPO's new approaches to examination and the assessment of statutory subject matter in Canada. Although these chapters introduce many novel concepts, the most controversial aspects relate to the assessment of statutory (patent-eligible) subject matter, particularly the introduction of a "form-and-substance" approach, a new "technological subject matter" requirement, and the concept of "excluded subject matter."

In Canada, section 2 of the *Patent Act* defines the categories of statutory subject matter by stating that an "invention" means "any new and useful art, process, machine, manufacture or composition of matter" or improvement therein. However, under the new form-and-substance approach, CIPO takes the position that it is no longer sufficient for the form of the claims to constitute statutory subject matter and imposes an additional requirement that the substance of the invention must also be statutory. As a result, a claim directed to the statutory category of "machine," for example, can now be rejected as non-statutory subject matter if the substance of the invention is considered to be non-statutory. Although it is difficult to predict how the substance of an invention will be characterized in practice, these chapters appear to suggest that an Examiner will disregard features that are known or obvious from the prior art, as well as features that are viewed as non-technological or otherwise non-statutory. Thus, the form-and-substance approach is intertwined with the new technological subject matter requirement and excluded subject matter proposition.

Regarding the new technological requirement and excluded subject matter, the new chapters assert that any art or process that solves a problem outside a field of technology is considered non-statutory. Fields of industry such as economics, commerce, accounting, record-keeping, marketing, law, teaching, bartering, trading, selling, advocating and lobbying are given as examples of non-technological fields. Citing a 2009 Patent Appeal Board decision currently under appeal, the chapters assert that "business methods" are non-statutory, reversing the position stated in the previous version of chapter 12.

During the public consultation period in 2009, CIPO received detailed submissions from the patent profession, including submissions from the Intellectual Property Institute of Canada (IPIC) and the Canadian branch of the Fédération Internationale des Conseils en Propriété Industrielle (FICPI Canada), opposing the adoption of these new chapters as being inconsistent with Canadian law. The public comments received by CIPO can be viewed online at the CIPO website (http://www.cipo.ic.gc.ca/eic/site/cipointernet-internetopic.nsf/eng/wr02082.html).

On April 19, 2010, the Federal Court of Canada heard an applicant's appeal from a decision of the Patent Appeal Board that was based on approaches very similar to those found in the new MOPOP chapters. The Court's decision is expected to be handed down later in the year.

In the meantime, patent applicants are encouraged to maintain their usual Canadian filing and prosecution strategies pending resolution of these issues by the Court in the case under appeal. However, any decision to accelerate examination of a patent application should only be made after careful consideration and consultation with an expert Canadian practitioner.

Stephen J. Ferance, Vancouver

Federal Court grants stay of re-examination proceedings pending outcome of patent infringement and validity trial

The Court's decision was influenced by the need for live testimony and cross-examination to resolve credibility issues arising on the facts of the case.

In a rare decision relating to the interplay between an action before the Federal Court and parallel re-examination proceedings before the Canadian Intellectual Property Office (CIPO) involving the same patent, the Federal Court has granted a stay of re-examination proceedings pending the outcome of the Court action. Conversely, on an earlier motion in the same action, the Court had refused a request to stay the Federal Court action pending the outcome of re-examination.

These decisions are of particular importance, not only due to the scarce jurisprudence dealing with re-examination proceedings but also since they provide guidance with respect to the occasional strategic tactic by a defendant in an infringement action of requesting re-examination of the patent at issue.

Prenbec Equipment Inc. v. Timberblade Inc., 2010 FC 23, involved a motion by the plaintiffs, Prenbec Equipment Inc. and Quadco Equipment Inc., seeking a stay of re-examination by CIPO of Canadian Patent No. 2,084,013 pending the outcome of their Federal Court action against Timberblade Inc. for infringement of the same patent. The patent relates to a detachable saw tooth that can be mounted on a circular saw disc for a felling head or a feller buncher. The defendant had denied infringement and counterclaimed that the patent is invalid due to a publication by others showing a prior saw tooth incorporating all the essential elements of the patented saw tooth. One day prior to service of its Statement of Defence and Counterclaim, the defendant had filed a request for re-examination of the patent

with the Commissioner of Patents based on essentially the same arguments and prior art references raised in its Federal Court pleadings.

A re-examination proceeding, provided for in sections 48.1 to 48.5 of the *Patent Act*, is a relatively inexpensive summary procedure by which any person can request that the Commissioner of Patents reconsider claims of a patent in light of prior art publications submitted by the requesting party. If a Re-examination Board established by the Commissioner concludes that a substantial new question of patentability has been raised, the patent is then re-examined in an ex parte summary proceeding between the patentee and the Board.

In opposing the defendant's earlier motion, which had effectively sought a stay of the Federal Court action pending the outcome of re-examination, the plaintiffs had alleged that the prior saw tooth was either the actual tooth conceived by the patentee or a copy thereof. As a result, the plaintiffs alleged that the prior saw tooth publication was not citable prior art because it fell within the one-year grace period provided by the *Patent Act* for disclosures by the patent applicant or by those who derived their knowledge from the applicant. In dismissing the defendant's motion (2009 FC 584), the Court stated:

> "The Re-examination Board does not deal with credibility issues and cannot determine the real issue at play in this case as credibility is central to the dispute between the Plaintiffs and Timberblade. No cross-examination of witnesses or indeed the hearing of oral testimony from witnesses is contemplated in the re-examination process."

In considering the plaintiffs' subsequent motion for a stay of the re-examination proceedings pending the outcome of the Federal Court action, the Court first addressed a number of preliminary issues. Notably, the Court confirmed that section 50(1)(b) of the *Federal Courts Act*, which authorizes the Court to stay proceedings in any cause or matter, is not limited to Federal Court proceedings but also encompasses other proceedings, including those of administrative tribunals. The Court also concluded that the strict statutory deadlines for re-examination proceedings set forth in the *Patent Act* do not override the Court's authority to grant a stay. The Court further reiterated that the grant or refusal of a stay is within the discretionary power of the Judge and that the onus is on the party seeking a stay to satisfy the two-part test applied by the Federal Court, namely that (1) a continuation of the proceeding will cause

it prejudice, and (2) the stay will not work an injustice to the other party.

In granting the stay, the Court recognized that, while the *Patent Act* defines the procedure and framework for re-examination proceedings, it does not provide the Board with any means for testing credibility to assess contested issues of fact. Accordingly, given that the Board could not question the origin of the prior saw tooth or appreciate the credibility issues surrounding its disclosure, the Court determined that the Board would most likely invalidate the patent, considering that the prior saw tooth incorporates all the essential elements of the claimed saw tooth.

The Court then concluded that the plaintiffs would suffer irreparable harm by the continuation of the re-examination proceedings since the prior saw tooth publication *prima facie* anticipates the claimed saw tooth and would render the patent invalid if it is treated as citable prior art. On the other hand, the Court was of the view that the stay would not constitute an injustice for the defendant since the Court could hear any and all invalidity arguments raised by the defendant and, unlike the Board, could also hear witnesses and test credibility.

In its decision, the Court also noted that preference should be given to the forum that is more comprehensive. As between the re-examination proceedings and the infringement/validity action, the Court concluded that the latter is the most comprehensive forum.

While this decision is useful in that it reaffirms the Federal Court's jurisdiction to stay proceedings other than its own, the Court's decision was influenced by the significant issues of credibility that arose on the facts of this particular case. The extent to which this decision may be relied upon to stay re-examination proceedings under different circumstances remains to be seen in future cases.

Marc Gagnon and Tomek Nishijima, Montreal

New restrictions on extensions of time in trade-mark and industrial design prosecution

As of March 11, 2010, the availability of extensions of time for responding to Examiner's reports in connection with pending trade-mark and industrial design applications has become more limited. Unless there are circumstances beyond the control of the applicant or which are otherwise exceptional to justify a further extension, only one extension of time of six months will be granted during prosecution. If, following the expiry of the extension of time, the applicant fails to reply, the application will be considered abandoned.

Examples of exceptional circumstances that could justify an additional extension of time beyond the first six-month extension include a recent change in the applicant (because of an assignment), or illness, accident, death, bankruptcy or other serious and unforeseen circumstances.

This is a significant change from the previous practice and will require trade-mark and industrial design applicants to make decisions and move forward with handling the Examiner's objections and other requirements in a timelier manner.

Health Canada releases Guidance concerning requirements for authorization of subsequent entry biologics ("SEBs") in Canada

On March 8, 2010, Health Canada released to the public its Guidance Document titled "Guidance for Sponsors: Information and Submission Requirements for Subsequent Entry Biologics (SEBs)" to assist sponsors of SEBs to satisfy the requirements under the *Food and Drug Act* and the *Food and Drug Regulations* concerning the authorization of SEBs in Canada.

This article provides a brief overview of key principles outlined in the Guidance Document and its implications for aspects of the drug approval process relating to intellectual property protection in Canada.

Overview of the SEB approval process. The Guidance Document explains that the SEB approval process applies to all biologic drug submissions where the sponsor: 1) seeks authorization for sale based on demonstrated similarity to a previously approved biologic drug, and 2) relies in part on prior information regarding the previously approved biologic drug so that a reduced clinical and non-clinical data package may be submitted.

Key policy statements include the following:

- The basis for accepting a reduced non-clinical and clinical data package for an SEB hinges on demonstrated similarity between the SEB and a suitable reference biologic drug.
- SEBs are not "generic biologics," and authorization of an SEB is not a declaration by Health Canada of pharmaceutical or therapeutic equivalence to the reference biologic drug.
- An SEB submission involves a comparison to another product and SEBs are thus subject to the data protection provisions of the *Food and Drug Regulations*, the provisions of the *Patented Medicines (Notice of Compliance) Regulations*, and the *Patent Act*.
- An SEB is not to be used as a reference biologic drug for another SEB submission.

Biologic drugs are described in the Guidance Document as being those drugs listed in Schedule D to the *Food and Drug Act*. The Guidance Document explains that biologic drugs are derived through the metabolic activity of living organisms and tend to be significantly more variable and structurally complex than chemically synthesized drugs. An SEB is a biologic drug that enters the market subsequent to a version previously authorized in Canada and has demonstrated similarity to a reference biological drug.

The Guidance Document explains that the reference biologic drug to which similarity of the SEB is to be demonstrated should be a drug authorized for sale and should be marketed in Canada. Significantly, a non-Canadian reference biologic drug may be used in some instances, and considerations are outlined for such use.

The Guidance Document sets out information required for a new drug submission (NDS) seeking approval of an SEB, such as chemistry and manufacturing data, and data concerning the demonstration of similarity with the reference biologic drug.

Importantly, the Guidance Document concludes that the demonstration of similarity between the SEB and the reference biologic drug does not signify that the quality attributes of the SEB and the reference

product are identical but that they are highly similar such that: (1) the existing knowledge of both products is sufficient to predict that any differences in quality attributes should have no adverse effect on safety or efficacy of the SEB; and (2) non-clinical and clinical data previously generated with the reference biologic drug are relevant to the SEB.

The Guidance Document explains that an SEB product sponsor is eligible to apply for one or more clinical indications granted to the reference biologic drug in Canada and details the nature of the safety and efficacy data that must be presented. In certain instances, clinical data may not be needed to support eligibility for an additional existing clinical indication. However, it appears that where a clinical indication sought for the SEB is not held by the reference biologic drug, full clinical trial data shall be provided in support of that indication.

The Guidance Document stresses that comparative clinical trials are of critical importance for demonstrating the similarity and efficacy and safety profiles between the SEB and the reference biologic drug. However, there may be exceptions, and the example is given of recombinant human soluble insulin products for which the Guidance Document states that only a comparative clinical safety study is required.

Risk management plans are discussed, as are post-market requirements.

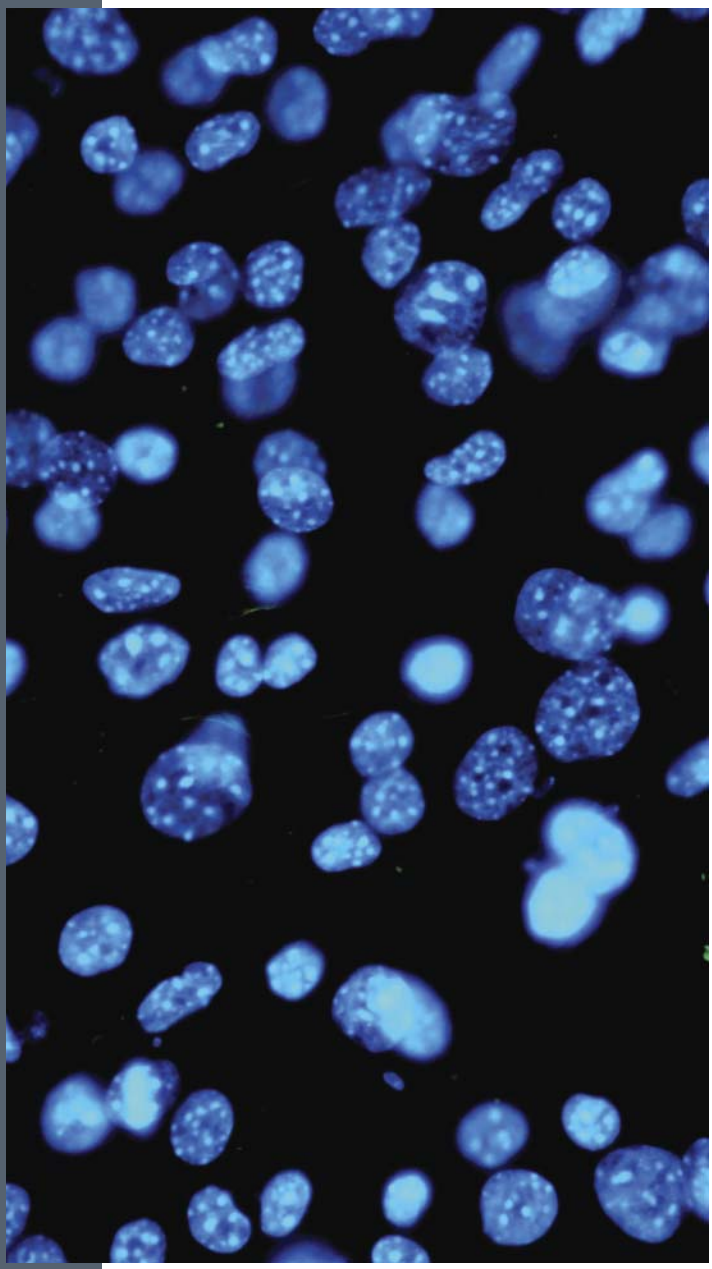
There are special labeling requirements for SEBs, including, for example, requirements that the product monograph identify the product as an SEB and that claims not be made for bioequivalence or clinical equivalence with the reference biologic drug.

The *Patented Medicines (Notice of Compliance) Regulations*. In an update to its Guidance Document: *Patented Medicines (Notice of Compliance) Regulations*, published concurrently with the SEB Guidance Document, Health Canada confirms that NDSs and supplemental new drug submissions (SNDSs) submitted in accordance with the SEB Guidance make a comparison or reference within the meaning of section 5 of the *Patented Medicines (Notice of Compliance) Regulations* ("*PM(NOC) Regulations*") such that patents on the Patent Register must be addressed.

Under section 5 of the *PM(NOC) Regulations*, a requirement to address a patent on the Patent Register is triggered when a second person files a submission for a notice of

compliance (NOC) in respect of a drug and the submission "...directly or indirectly compares the drug with, or makes reference to, another drug marketed in Canada under a Notice of Compliance issued to a first person and in respect of which a patent list has been submitted".

Health Canada also confirms that if an SEB submission contains a demonstration of similarity with a non-Canadian reference biologic drug, such a submission is considered to contain a comparison with, or reference to, the Canadian drug as contemplated by section 5 of the *PM(NOC) Regulations*.



Data protection under C.08.004.1 of the *Food and Drug Regulations*. Concurrently with issuance of the SEB Guidance Document, Health Canada has updated its Guidance Document: Data Protection under C.08.004.1 of the *Food and Drug Regulations* to explain the application of the data protection provisions to SEBs.

Part C.08.004.01 of the *Food and Drug Regulations* provides a term of data protection for innovative drugs that have received or will receive an NOC on or after June 17, 2006. These provisions implement aspects of the North American Free Trade Agreement (NAFTA) and the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) concerning the requirement for data protection.

Health Canada explains that an SEB submission containing a demonstration of similarity to a reference biologic drug or to a non-Canadian reference biologic drug is considered to make a comparison to an innovative drug as described above. Accordingly, such submissions will not be accepted for filing within the six-year period from the issuance of the NOC for the reference biologic drug.

An NOC will not be issued to the SEB sponsor before the end of the period of eight years after the day on which the first NOC was issued for the innovative drug (or eight years and six months where the innovative drug qualifies for the pediatric extension).

Health Canada explains that because approval for an SEB is sought by filing an NDS in which the sponsor seeks to reduce the clinical and non-clinical study requirements by demonstrating similarity to a previously approved reference biologic drug, an SEB itself will not be considered to be an "innovative drug".

Conclusions. As acknowledged by Health Canada, its various Guidance Documents are administrative instruments and do not have the force of law. Ultimately, there must be compliance with the relevant provisions of the *Food and Drug Regulations*, the *PM(NOC) Regulations* and the *Patent Act*. While there is an extensive body of law concerning the application of many aspects of these provisions to traditional small-molecule pharmaceuticals, the application of these statutory instruments to biologics has not yet been explored to any significant degree.

David E. Schwartz, **Ottawa**

Firm recognized in multiple international surveys

Smart & Biggar/Fetherstonhaugh recognized as Copyright Firm of the Year by *Managing Intellectual Property* magazine. Smart & Biggar/Fetherstonhaugh has been named Canadian Copyright Firm of the Year for 2010 by U.K. publication *Managing Intellectual Property* magazine (MIP). The awards were presented at MIP's annual North America Awards ceremony, held on April 16th in Washington, DC. MIP has for several years recognized Smart & Biggar/Fetherstonhaugh as a highly ranked IP firm in patents, trademarks and copyrights.

***Managing Intellectual Property*'s 2010 World IP Survey.** Smart & Biggar/Fetherstonhaugh has once again been ranked as a Tier One firm in all five categories relating to intellectual property: patent prosecution, patent contentious, trade mark prosecution, trade mark contentious and copyright.

Chambers Global — The World's Leading Lawyers for Business. Smart & Biggar/Fetherstonhaugh has been recognized as having more lawyers listed in the areas of intellectual property and intellectual property litigation than any other firm in Canada in the 2010 edition. The firms were recognized in the coveted Band 1 of the rankings, with eight of our lawyers selected to appear.

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

Selected in IP litigation: Gunars A. Gaikis, Steven B. Garland, François Guay, J. Sheldon Hamilton, Michael D. Manson.

The 2010 Lexpert/American Lawyer Guide to the Leading 500 Lawyers in Canada. Four of our lawyers were recognized in the areas of biotechnology, intellectual property and IP litigation. No other firm in Canada has more lawyers appearing across all three areas.

Selected in biotechnology: Joy D. Morrow.

Selected in intellectual property: François Guay, Michael D. Manson.

Selected in IP litigation: Gunars A. Gaikis, François Guay.

The iam 250 – The World's Leading Life Sciences Patent Litigators. Gunars A. Gaikis, Steven B. Garland and J. Sheldon Hamilton have been recognized by this publication, distributed by *Intellectual Asset Management* (IAM) magazine, as being among the world's top ranked life science patent litigators.

The International Who's Who of Patent Lawyers. In the 2010 edition, Smart & Biggar had six lawyers selected to appear in the guide, more than any other firm in Canada: John Bochnovic, Gunars A. Gaikis, Steven B. Garland, François Guay, Michael D. Manson and John R. Morrissey.

The International Who's Who of Life Sciences Lawyers. Three of our lawyers have been selected to appear in the 2010 edition: Gunars A. Gaikis, Joy D. Morrow and J. Christopher Robinson. In addition to being selected, Gunars A. Gaikis was named as one of the most highly regarded individuals in the guide as a practitioner in the area of life sciences.

***PLC Cross-border Life Sciences Handbook* 2009/2010.** Smart & Biggar has once again been recognized as a leading firm in the area of patent counselling and is the only firm in Canada given this distinction. The firms had two lawyers recognized in this category: Joy D. Morrow and J. Christopher Robinson. Smart & Biggar was also chosen as a leading firm in the area of intellectual property, and Gunars A. Gaikis was named a leading practitioner in this field.

***PLC Cross-border IP in Business Transactions Handbook* 2009/10.** Six Smart & Biggar lawyers were selected in the areas of patent litigation, non-patent litigation and commercial IP. No other firm in Canada had more lawyers appearing in these areas.

Listed in patent litigation: Gunars A. Gaikis, François Guay, John R. Morrissey.

Listed in non-patent litigation: John Bochnovic, Mark K. Evans, Brian P. Isaac.

Listed in commercial IP: John Bochnovic.

The Legal Media Group *Guide to the World's Leading Trade Mark Law Practitioners.* In the 2009 edition, Smart & Biggar/Fetherstonhaugh had seven pre-eminent lawyers selected to appear in the guide: John Bochnovic, Daniel S. Drapeau, Mark K. Evans, Brian P. Isaac, Philip Lapin, Michael D. Manson, Kohji Suzuki.

2009 Lexpert Guide to the Leading US/Canada Cross-border Litigation Lawyers in Canada. Two of our lawyers appear in the area of IP litigation: Gunars A. Gaikis and François Guay. No other firm in Canada has more lawyers listed in this area.

Notes

Announcements

Vik Tenekjian has joined our Toronto office as an associate. Mr. Tenekjian's practice will focus on patent litigation as well as copyright and trade-mark enforcement. He holds a B.Sc. in microbiology and immunology from McGill University and a J.D. from Osgoode Hall Law School, and he was called to the Ontario Bar in 2006.

Seminars and Presentations

Timothy P. Lo, **Karen F. MacDonald** and **J. Christopher Robinson** jointly taught the winter session of the intellectual property course at the University of British Columbia.

Colin B. Ingram presented the Patents paper as part of the Law Society of Upper Canada's 14th Annual Intellectual Property Law Year in Review, held in Ottawa on January 15, 2010.

Christian Bolduc spoke on the topic of "Practical Considerations Regarding Trade-marks and Copyrights" at the *École de dessin industriel* in Montreal on April 6, 2010.

Brian P. Isaac and **Karen F. MacDonald** led a full-day seminar titled "Identifying Counterfeit Products," held in Vancouver on January 18, 2010. **Émilie Dubreuil** joined Mr. Isaac for a reprise of the seminar, held in Toronto on April 14, 2010. **Daniel S. Drapeau** joined Ms. Dubreuil for a third session, held in Montreal on April 15, 2010.

Sanjay D. Goorachurn co-presented on the topic of "Tax Aspects of Licensing IP" at the Canadian Institute conference titled *Aspects fiscaux des conventions commerciales*, held in Montreal on February 24, 2010.

John R. Morrissey moderated a program put on by the Federal Court and Federal Court of Appeal on the proposed rules regarding expert witnesses, held in Toronto on March 11, 2010.

Brian G. Kingwell, **Andris D. Macins**, **Jeffrey D. Morton** and **J. Christopher Robinson** presented three two-hour workshops on "The role of patents in drug research" for the Centre for Drug Research and Development, held in Vancouver on March 22, 24 and 26, 2010.

Brigide Mattar and **Martin Tremblay** made a presentation titled "*Protéger le « look and feel » de produits électroniques*" to members of the *Association des manufacturiers en électronique de Québec*, held in Quebec City on March 30, 2010.

Philip Lapin spoke on the topic of "The Protection of Geographical Indications in Canada" to the economic and commercial representatives of the European Union in Ottawa on March 31, 2010.

Brian G. Kingwell and **Timothy P. Lo** presented a seminar titled "Canadian IP Law Update: Practical Tips and Information for U.S. Practitioners," held in San Diego on April 6, 2010. **Michael D. Manson** joined Mr. Kingwell and Mr. Lo for a reprise of the presentation, held in Los Angeles on April 8, 2010.

Stephan P. Georgiev and **Brigide Mattar** made a presentation titled "*La gestion de la propriété intellectuelle et les temps de crise*" to the *PÔLE Québec-Chaudière Appalaches*, held in Quebec City on April 12, 2010.

Mark G. Biernacki ran a workshop on "Motions Before the Federal Court — Actions Involving Intellectual Property" as part of a seminar titled The Practical Guide to Federal Court Advocacy and Practice, held at Osgoode Hall Law School of York University's Professional Development Centre in Toronto on April 14, 2010.

Sanjay D. Goorachurn will participate in a panel discussion on the topic of "Relevance of IP Management in Creating IP Value for Investors and Investee Companies in M&A and Strategic Alliances" as part of the Tremblant Venture Forum, to be held in Mont-Tremblant, QC on May 5 and 6, 2010.

J. Sheldon Hamilton will co-chair Insight's 9th conference on Drug Patents in Canada, to be held in Toronto on May 6 and 7, 2010. **Gunars A. Gaikis** will present on the topic of "Strategies in Pharma Patent Litigation" as part of the same conference.

Sanjay D. Goorachurn will lecture on the topic of "IP Strategy during Mergers & Acquisitions" as part of the Federated Press's 3rd conference on Patents as a Competitive Strategy, to be held in Toronto on May 12 and 13, 2010.

Daniel S. Drapeau will speak on the topic of "Review Motions for Anton Piller Orders" to the Canadian Bar Association's IP Section in Ottawa on May 13, 2010.

Michael D. Manson will speak on the topic of "IP Litigation, Trade-marks, Copyright & Trade Secrets in Canada" at the IPIC Basics of Law Evidence Module, to be held in Vancouver on June 8, 2010.

Daniel S. Drapeau will be a panelist at a workshop titled "*Contrer le piratage : la France, un modèle à suivre ?*" organized by the *Association québécoise de l'industrie du disque, du spectacle et de la vidéo*, to be held in Montreal from June 14 to 17, 2010.

Matthew Zischka will speak on the topic of "Patent Claims" as part of the IPIC-McGill summer program Understanding Patents, to be held in Montreal from July 26 to 30, 2010.

Christian Bolduc will speak on the topic of "Preparing Trade-mark Applications and Use and Registrability Opinions" and will tutor workshops on "Trade-mark Filing Strategies" and "Tips and Strategy in Opposition," and **Philip Lapin** will speak on the topic of "Opposition Proceedings: Overview, Context and Strategy" as part of the IPIC-McGill summer program Understanding Trade-marks, to be held in Montreal from August 2 to 6, 2010.

Geneviève M. Prévost is the Director of the 2010 IPIC-McGill Advanced Trade-marks Course titled "The Trade-marks Practitioner," which is being held in Montreal from August 9 to 13, 2010. Ms. Prévost will also be co-presenting an Interactive Comparative Discussion of U.S. and Canadian Trade-mark Prosecution Practice during this course. **Brian P. Isaac** will speak on the topic of "Anti-counterfeiting Issues," **Daniel S. Drapeau** will lead a presentation titled "Practical Approach to Co-existence and Other Settlement Agreements," and **François Guay** will participate in a workshop titled "Mock Trial with Oral Testimony" as part of the same program.

Michael D. Manson will speak on the topic of grey goods and counterfeiting issues as part of the Canadian Bar Association summer program, to be held in Niagara Falls, ON on August 17, 2010.

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