

# IP PERSPECTIVES

INTELLECTUAL PROPERTY & TECHNOLOGY LAW NEWSLETTER

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## Pharma Patents – Amendments to Linkage Regulations and Data Protection Approved

Sweeping amendments to the *Patented Medicines (Notice of Compliance) Regulations* (“NOC Regulations”) and to the data protection provision of the *Food and Drugs Regulations* came into force on October 5, 2006 and were formally published on October 18, 2006.

### I. Amendments to the NOC Regulations

In general terms, the *NOC Regulations* protect patentees from patent infringement by linking the Minister’s ability to approve a generic drug on the basis of a previously approved innovator drug to the patent status of the innovator’s product.

In order to obtain a notice of compliance (“NOC”) enabling it to market a generic drug, the generic manufacturer must address each listed patent by alleging non-infringement and/or invalidity. The patentee may then challenge the allegation by an application to a court, in practice, the Federal Court. The generic manufacturer is only required to address patents listed on the Register, and the listing requirements are quite specific.

The most significant amendments fall into two categories: (1) patent listing requirements and (2) when a generic must address listed patents.

#### 1. Eligibility requirements for patent listing (section 4)

##### a. Relevance requirement

Amended section 4 requires that, in order to be listed on the Register, the patent must be relevant to the submission in relation to which listing is requested. Also, only supplemental new drug submissions (SNDs) for a change in formulation, dosage form, or use will support the listing of a patent. As a result, the requirements for listing are now — apart from now extending to dosage form patents — far stricter than under the previous *NOC Regulations*.

##### b. Dosage form patents eligible for listing

The amended *NOC Regulations* now permit the listing of dosage form patents.

#### 2. No requirement to address later-listed patents (section 5)

The Register has been “frozen” by a combination of provisions which limit the patents that must be addressed by a generic to those listed prior to the filing date of its submission.

#### 3. Damages provision amendment (section 8)

Section 8 provides for liability by the innovator where a prohibition application is withdrawn or discontinued, is dismissed, or a prohibition Order is reversed on appeal. Former section 8(4) provided for the recovery of profits, but this has now been deleted.

#### 4. Other amendments

A number of technical amendments have also been made to clarify certain procedural aspects of the *NOC Regulations*.

### II. Amendments to Data Protection

Data protection is based on international obligations which require that where a company submits confidential data to a regulatory authority when seeking approval for a drug composed of a new active substance, the data is protected from reliance by competitors for a certain period of time after the date the drug is approved.

The amendments prohibit the issuance of an NOC to a manufacturer that makes a direct or indirect comparison to an “innovative drug” until eight years after issuance of the innovator’s first NOC for the innovative drug (and an additional six months if the innovative drug has been the subject of clinical trials designed and conducted for the purpose of increasing the knowledge of the behaviour of the drug in pediatric populations).

Furthermore, a manufacturer that makes a direct or indirect comparison to the innovative drug will not be permitted to file such a submission until six years after issuance of the innovator’s first NOC for the innovative drug.

For a more detailed discussion of these amendments, please see the [October 2006 Special Edition](#) of our pharmaceutical newsletter, *Rx IP*

*Update*, which can be found under the Newsletters section of our website.

*Nancy P. Pei, Toronto*

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## Copyright – Supreme Court has the Last Word

This is an update on the *Robertson v. The Thomson Corporation et al.* case reported in the [February 2005](#) edition of *IP Perspectives*. In a judgment rendered on October 12, 2006, the Supreme Court of Canada has now ruled on the interplay between the copyright of a freelance author in an individual work published with authorization in a newspaper and the separate and distinct copyright in the newspaper as a collective work or compilation.

In the action, the Plaintiff, a freelance author, alleged that the Defendants had infringed the copyright in her articles by reproducing the works in electronic databases and on CD-ROMs. The Plaintiff had authorized the one-time publication of the articles in the Defendants' newspaper, but the agreements were silent on the issue of electronic rights. In defence, the Defendants asserted that they owned copyright in the newspaper as a collective work or compilation, and thus they had the exclusive right to copy the work, or a substantial part thereof, in any material form, including electronically. Thus, the Defendants asserted that the reproduction of the articles in the electronic databases and CD-ROMs fell within the scope of their copyright in the newspaper.

At first instance, on a motion for summary judgment, the Defendants were found to have

infringed the Plaintiffs' copyright by reproduction of the articles on the electronic databases and on the CD-ROMs. As reported in the February 2005 edition of *IP Perspectives*, the Ontario Court of Appeal upheld the finding of infringement in a 2:1 split decision.

The Supreme Court of Canada unanimously concluded that the majority of the Court of Appeal erred in holding that the reproduction of the articles on the CD-ROMs constituted an infringement of the Plaintiff's copyright. The nine judges of the Supreme Court were all of the view that the CD-ROMs sufficiently preserved the originality of the newspaper to constitute a copy of a "substantial part" thereof. However, in a 5:4 split decision, the Court concluded that the reproduction of the articles on the database were decontextualized to the point that they were no longer presented in a manner that maintained the originality of the newspaper. The majority of the Court was of the view that the databases reproduced the originality of the articles themselves rather than that of the newspaper and thus, infringed the Plaintiff's copyright in the articles.

*Kevin K. Graham, Ottawa*



**Kevin K. Graham**

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## Inaugural Canadian Survey by *Best Lawyers* Reinforces Firm's Reputation as IP Leader

In the inaugural edition of *The Best Lawyers in Canada*, Smart & Biggar/Fetherstonhaugh has been recognized as having twelve pre-eminent lawyers in the areas of biotechnology law and intellectual property law – more than any other firm.

Best Lawyers has been regarded as "the definitive guide to legal excellence in the United States." Nearly 65 000 highly ranked lawyers in the U.S.

who had engaged in significant amounts of cross-border work nominated outstanding Canadian lawyers in various legal specialties. Lawyers are selected based solely on the votes of their peers, and only those who are highest on the referral list are recognized in the publication.

We are proud of this recognition and wish to congratulate all of our firm members who are listed:

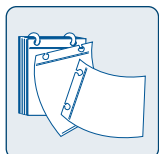
**Biotechnology Law**

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**Intellectual Property Law**

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Gunars A. Gaikis

Steven B. Garland  
Robert D. Gould  
François Guay  
Michael D. Manson  
John R. Morrissey  
A. David Morrow  
Joy D. Morrow  
J. Christopher Robinson



## Notes

### Announcements

*Joseph J. Fraresso* has returned after his articles to join our Toronto office as an associate. Mr. Fraresso holds a B.Sc. in electrical engineering from Queen's University and an LL.B. from Osgoode Hall.

*Jean-Charles Grégoire* has returned after his articles to join our Ottawa office as an associate. Mr. Grégoire holds a B.A.Sc. in electrical engineering and an LL.B. from the University of Ottawa.

*Stacey E. Grubb* has joined our Vancouver office as an associate. Ms. Grubb holds a B.Sc. in integrated science from the University of British Columbia and an LL.B. from the University of Alberta.

*Sharon S. Ho* has returned after her articles to join our Toronto office as an associate. Ms. Ho holds a B.A.Sc. in engineering physics from the University of British Columbia and an LL.B. from Queen's University.

*Cheryl M. Ng* has returned after her articles to join our Toronto office as an associate. Ms. Ng holds a B.Sc. in computer science and a J.D. from the University of Toronto.

*Timothy O. Stevenson* has returned after his articles to join our Ottawa office as an associate. Mr. Stevenson holds a B.Sc. in biochemistry and an LL.B. from the University of Victoria.

### Seminars and Presentations

*Christian Bolduc* spoke on "Preparing a Trade-mark Application, Use and Registrability Opinions" and led the workshop "Tips and Strategy in Opposition" as part of the IPIC/McGill summer courses in intellectual property, held in Montreal from July 31 to August 23, 2006. *Philip D. Lapin* spoke on "Opposition Proceedings: Overview and Context" and led the workshop "Tips and Strategy in Opposition" as part of the same program.

*Brian P. Isaac* chaired a meeting on Canada's strategy regarding IP in China between Foreign Affairs

and International Trade Canada, the Canadian Intellectual Property Office, and representatives of Canadian industry, held in Toronto on August 11, 2006.

*Brian P. Isaac* attended as a representative of Canadian industry at a meeting titled "Fake Free North America" IPR Initiative – SPP Trilateral (Canada, Mexico, and the U.S.) Public/Private Sector Meeting, held in Washington on September 14, 2006.

*Brian P. Isaac* and *Sally A. Hemming* gave the presentation "Intellectual Property: What You Need to Know" at Laurentian University on September 18, 2006.

*François Guay* gave a seminar on "Marques de commerce et brevets: ce que tous pensent savoir, sans le savoir vraiment" as part of the 1er Sommet des Professionnels de l'Exportation, held in St-Marc-sur-Richelieu, QC on October 2, 2006.

*A. David Morrow*, *François Guay*, *Michael D. Manson* and *Brian P. Isaac* held two seminars titled "IP Litigation in Canada: What U.S. Attorneys Need to Know" in Houston and Dallas, TX on October 3 and 4, 2006.

*Sanjay Goorachurn* gave the presentation titled "Elaborer une stratégie de vérification du portefeuille de propriété intellectuelle: un guide, étape par étape" in conjunction with the Canadian Institute conference Fusions et Acquisitions, held in Montreal on October 4-6, 2006.

*Steven B. Garland*, *L. Catherine Eckenswiller*, *Colin B. Ingram* and *Jeremy E. Want* spoke at a Continuing Legal Education seminar for the County of Carleton Law Association titled "Intellectual Property Rights: Practical Advice for the Non-IP Practitioner", held in Ottawa on October 17, 2006.

*A. David Morrow* spoke on the topic of patentable subject matter to the clerks of the Federal Court of Canada in Ottawa on October 18, 2006.

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*Christian Bolduc* spoke to microbiology students about the microbiologist profession at Université Laval in Quebec City on October 27, 2006.

*Christian Bolduc* will be speaking on the topic of "Le traitement de la propriété intellectuelle sur Internet : usurpation des droits d'auteur et emploi des marques" at the IP Insight Conference E-Discovery Informatique Légale to be held in Montreal on November 1-2, 2006.

*A. David Morrow* will speak about trade-mark surveys as one of a series of informal presentations by the Intellectual Property Institute of Canada, to be held in Ottawa on November 9, 2006.

*Gunars A. Gaikis* will be speaking on "Preventing, Defending, and Financing IP Litigation" at the Insight/ALM conference titled Intellectual Property: Building, Protecting, and Profiting From Your IP Portfolio, to be held in Toronto on November 27-28, 2006.

Partners of Smart & Biggar will present a day-long course on pharmaceutical patents to represen-

tatives of the pharmaceutical industry. The course will be chaired by *Gunars A. Gaikis*. A few spaces remain available. Interested parties are invited to contact Mr. Gaikis at [ggaikis@smart-biggar.ca](mailto:ggaikis@smart-biggar.ca) promptly. The course will be held in Mississauga, ON on November 29, 2006.

*A. David Morrow* will present an update on developments in patent law during the last year in the context of a seminar sponsored by the Law Society of Upper Canada. The presentation will be based on a paper authored jointly by himself and Donald MacOdrum of the firm of Lang Michener LLP in Toronto. The seminar will be held in Ottawa on January 12, 2007.

## Publications

*Steven B. Garland* and *Jeremy E. Want*, "The Enforcement of Intellectual Property Rights in Canada", Intellectual Property and Innovation in the Knowledge-Based Economy (Industry Canada research volume), February 2006.

## Barristers &amp; Solicitors, Patent &amp; Trade-mark Agents

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Elliott S. Simcoe	Timothy P. Lo+	Theodore W. Sum+	Marc Gagnon*	L. Catherine Eckenswiler
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Unless otherwise indicated, the lawyers listed are members of the Law Society of Upper Canada only.

† of the British Columbia Bar also    ★ of the Quebec Bar also    ‡ of the Alberta Bar also  
+ of the British Columbia Bar only    \* of the Quebec Bar only

## Disclaimer

The preceding is intended as a timely update on Canadian intellectual property law. In order to request a copy of any decision, paper or legislative document, or for more detailed information or suggestions, kindly contact an author of the relevant article, or the Editor, *A. David Morrow*. The contents of our Newsletter are informational only, and do not constitute legal or professional advice. To obtain such advice, please communicate with our offices directly. To be put on the *IP Perspectives* mailing list, or to amend address information, please call (416) 593-5514 (ext. 318).