

DRUG PATENTS AND LEGAL FORUM



Understand the latest developments and fine points of this challenging field with insights from legal and regulatory experts:

- Data protection as a form of exclusivity
- Recent cases from a Generic and Innovator perspective
- Find out about the proposed amendments to the *Patented Medicines Regulations*
- Gain insights into the implications of the Excessive Price Guidelines
- Latest developments in pharma patents and competition law
- Benefit from a US perspective on recent US and international developments
- Enhance your knowledge of the *Canadian Access to Medicines Regime*
- Double patenting in the context of pharmaceutical patents
- The downstream effects of the *AstraZeneca* decision of the Supreme Court of Canada
- Marketing pharmaceutical products in Canada – the regulatory regime and intellectual property implications

and much more...

Marketing Partners

Bio Business

CANADIAN **Lawyer**

**Contact
Canada**
Information Empowering Your Business

February 27 – 28, 2008
St. Andrew's Club and
Conference Centre
150 King Street West, Toronto

PROGRAM CO-CHAIRS

Jamie Mills
Partner
Gowling Lafleur Henderson LLP

Patrick E. Kierans
Partner
Ogilvy Renault LLP

LUNCHEON KEYNOTE ADDRESS *Court Reform to the NOC Procedure*

The Honourable
Mr. Justice Roger T. Hughes
Federal Court of Canada

ENROLL TODAY! Call 1 888 777-1707 or fax 1 866 777-1292
or register online at www.insightinfo.com

insIGHT
ALM

Sponsorship Opportunities

If you are interested in displaying your company's products or services to high level key decision makers within your target audience, please contact:

Amy Leung
1 866 456-2020 ext. 6128
aleung@insightinfo.com

Need additional information? Subscribe to *in*CONFERENCE™.

Gain online access to valuable conference papers and reports from any Insight conferences – whether it's energy, environment, finance, legal, or any of the other sectors covered at Insight conferences by subscribing today to *in*CONFERENCE™.

Delegates will receive a set of original materials as well as online access to fully searchable conference papers through Insight's *in*CONFERENCE™ that will serve as an invaluable reference source.

To find out more, or to receive a free trial subscription, please go to <http://inconference.insightinfo.com>

SPECIAL OFFER

First 60 delegates to register for this event will receive the **Pharma & Bio Pharma Industry Guide** courtesy of Contact Canada, a \$249.95 value!



Dear Colleagues,

Keeping up to date is a never-ending task, particularly in the fast moving pharmaceutical field. Not only are the legislation and regulations changing, but so is the political and policy climate at all levels of government. In addition, the courts play their role, sometimes clarifying the issues and sometimes confusing them.

While patent protection and patent litigation remain at the forefront, other forms of intellectual property are also important. Data protection is coming on the scene but has yet to be tested. Pricing issues challenge both innovative and generic pharmaceutical industries.

This **Insight Information** conference assembles skilled practitioners in all of these fields to provide the insight into the issues from both the innovative and generic perspectives on all of the key issues, including:

- The value and patentability of selection patents
- Recent PMPRB decisions plus their contribution in analyzing and reporting on pharmaceutical trends
- The case for patent infringement after the NOC Proceedings
- Arguments of abuse of process and mootness in PM(NOC) Proceedings and motions under Sections 6(5)(a) and (b) of the NOC Regulations
- Recent activities of the *Patented Medicine Prices Review Board*
- Administration of the Patented Medicines (NOC) Regulations and Data Protection
- Listing of patents on the Patent Register

They will bring you up to date and challenge traditional thinking where necessary.

Patrick E. Kierans
Partner
Ogilvy Renault LLP

Jamie Mills
Partner
Gowling Lafleur Henderson LLP

WHO SHOULD ATTEND

- In-house Counsel
- Patent and Intellectual Property Lawyers
- Pharmaceutical Lawyers
- Patent Consultants
- Patent Agents
- Patent Examiners
- Pharmaceutical Consultants

Also

- VPs, Directors and Heads of:
 - Legal Affairs
 - Professional and Government Affairs
 - Regulatory Affairs
 - Health Care Strategies
 - Therapeutic Products
 - Patented Medicine Prices Review
 - Government Health Services

WEDNESDAY | FEBRUARY 27, 2008

8:00 | 8:45

Registration and Continental Breakfast

8:45 | 8:50

Welcoming Remarks from Insight Information

8:50 | 9:00

Co-Chair's Opening Address

Patrick E. Kierans

Partner

Ogilvy Renault LLP

9:00 | 9:45

Listing of Patents on the Patent Register

Jamie Mills

Partner

Gowling Lafleur Henderson LLP

- Claim for the dosage form
- Claim for the formulation
- Claim for the medicinal ingredient
- Claim for the use of the medicinal ingredient
- When can patent lists be carried forward

9:45 | 10:30

Data Protection – A Form of Exclusivity

John A. Myers

Partner

Taylor McCaffrey LLP

- Purpose of Data Protections Schemes
- Constitutional validity of the Market Exclusivity Regulations
- Compliance with International obligations under NAFTA and TRIPS
- Scope of the new regulations – any unintended consequences?
- Status of the Legal challenges

10:30 | 10:45

Networking Coffee Break

10:45 | 12:00

PANEL DISCUSSION

Generic vs. Innovator – Recent Cases

Patentee's Perspective

Anthony Creber

Partner

Gowlings Strathy Henderson LLP

William H. Richardson

Partner

McCarthy Tétrault LLP

Generic's Perspective

Edward Hore

Partner

Hazzard & Hore

Richard Naiberg

Partner

Goodmans LLP

- Greater availability of early dismissal motions under s. 6(5) of amended Regulations, if
 - same invalidity allegation by different generic manufacturer was successful
 - patent not relevant to NOC
 - patent need not be addressed, per *Astra-Zeneca* case
 - first person evidence “speculative”
- When must a s. 6(5) motion be brought?

12:00 | 1:00

Networking Luncheon

1:00 | 1:30

LUNCHEON KEYNOTE ADDRESS

Court Reform to the NOC Procedure

The Honourable Mr. Justice Roger T. Hughes

Federal Court of Canada

1:30 | 2:15

Recent Activities of the Patented Medicine Prices Review Board

Barbara Ouellet

Executive Director

Patented Medicine Prices Review Board (PMPRB)

- Proposed Amendments to the *Patented Medicines Regulations*
- Review of the *Board's Excessive Price Guidelines* and its implications
- Recent decisions of the Board
- The PMPRB's contribution in analyzing and reporting on pharmaceutical trends

2:15 | 3:00

Administration of the Patented Medicines (NOC) Regulations and Data Protection

Anne Bowes

Associate Director

Office of Patented Medicines and Liaison Therapeutic Products Directorate

Health Canada

- Update on issues before the *Office of Patented Medicines and Liaison*
 - listing decisions
 - section 5 issues

- Statistical update on activities under the PM(NOC) Regulations
- Statistical update on data protection activities Revised Guidance documents Complaint process

3:00 | 3:15

Networking Refreshment Break

3:15 | 4:15

The Value and Patentability of Selection Patents

Patentee's Perspective

Peter R. Wilcox

Partner

Torys LLP

Generic's Perspective

Angela M. Furlanetto

Partner

Dimock Stratton LLP

- What is a proper selection patent and when can it be asserted?
- How to allege invalidity / defend the validity of selection patents
- The interplay between selection patents and insufficiency
- A review of the recent jurisprudence, including the Eli Lilly olanzapine decisions, and the upcoming SCC hearing in *Apotex v. Sanofi*

4:15 | 5:00

Developments in Drug Pricing

Alice Tseng

Partner

Blake, Cassels & Graydon LLP

- Impact of *Ontario's Bill 102* now
- Highlights of Québec's pharmaceutical policy
- Update on drug rebates
- Recent formulary cases

5:00

Co-Chair's Summation and Conference Adjourns for the Day

THURSDAY | FEBRUARY 28, 2008

8:30 | 9:00

Continental Breakfast

9:00 | 9:05

Remarks from Insight Information

9:05 | 9:15

Co-Chair's Opening Address

Jamie Mills

Partner

Gowling Lafleur Henderson LLP

9:15 | 10:15

Pharma Patents and Competition Law Issues

Patentee's Perspective

Gunars A. Gaikis

Partner

Smart & Biggar/Fetherstonhaugh & Co.

Generic's Perspective

Shonagh McVean

Partner

Gilbert's LLP

- *Shionogi* case
- Authorized generics
- Competition law issues in pending ACE Inhibitor actions
- Issues facing innovators and generics
- Future trends and strategies

10:15 | 10:30

Networking Coffee Break

10:30 | 11:15

The Case for Patent Infringement After the NOC Proceedings

Neil Belmore

Partner

Gowling Lafleur Henderson LLP

- The case for patent infringement and declaration of patent validity after a NOC application dismissal
 - whether and when to commence the action
 - counterbalance the s. 8 PMNOC regs action
- Interim steps:
 - motion for speedy trial v. motion for interlocutory injunction
 - discoveries – written and interrogatory
 - expert reports – distinguishing the evidence from the NOC proceeding – motion for leave to file more than 5 experts
- Trial:
 - onus at trial as distinguished from application
 - remedies in the context of the generic already being on the market
- Post-trial preparation:
 - bringing/defending the stay application pending appeal

11:15 | 12:00

Arguments of Abuse of Process and Mootness in PM(NOC) Proceedings and Motions Under Sections 6(5)(a) and (b) of the NOC Regulations

Jonathan Stainsby

Partner
Heenan Blaikie LLP

- Standard of review in dismissal motions
- Abuse by re-litigation
- Abuse where no evidence capable of finding infringement or inducement
- Abuse by withdrawing and resending the Notice of Allegation
- Abuse by arguing matters not raised in a party's written material (Notice of Allegations, Notice of Application or Memorandum of Fact and Law)
- Mootness following the dismissal of an application for an order of prohibition

12:00 | 1:00

Networking Luncheon

1:00 | 1:45

Update on Recent US and International Developments

Janine A. Carlan

Partner
Arent Fox LLP (Washington)

- The Supreme Court's *KSR International Co. v. Teleflex Inc.* decision regarding obviousness (and how it has been applied)
- The Federal Circuit's decision in *In Re Seagate Technology* regarding the scope of privilege and work-product waiver associated with an opinion-of-counsel defense to willfulness
- The impact of the new e-discovery rules

1:45 | 2:45

Canadian Access to Medicines Regime

Patentee's Perspective

Josée S. Gravelle

Lawyer
Ogilvy Renault LLP

Generic's Perspective

Barbara J. Murchie

Partner
Bennett Jones LLP

- Overview of the *Canadian Access to Medicines Regime*
- Application(s) recently granted by the Commissioner of Patents

- Issues regarding the procedure imposed by the legislation
- Proposed amendments to the legislation

2:45 | 3:00

Networking Refreshment Break

3:00 | 3:45

Double Patenting in the Context of Pharmaceutical Patents

A. David Morrow

Partner
Smart & Biggar/Fetherstonhaugh & Co.

- Origin and history of double patenting doctrine
- *Camco* decision of the *Supreme Court of Canada*
- Application of doctrine to current act patents
- Assertion of double patenting in pharma cases

3:45 | 4:15

The AstraZeneca Decision of the Supreme Court of Canada – Downstream Effects

Nancy P. Pei

Partner
Smart & Biggar/Fetherstonhaugh & Co.

- Subsequent interpretation by the Courts: *Ferring, Wyeth*
- Requirement to address patents under "old" regulations
- Impact on patent listing under "old" regulations
- Meaning of "second person" in different contexts

4:15 | 5:00

Marketing Pharmaceutical Products in Canada – the Regulatory Regime and Other Intellectual Property Implications

Jason C. Markwell

Partner
Ogilvy Renault LLP

- Marketing requirements under the *Food and Drug Regulations* (Data Protection) and the *Patented Medicines* (Notice of Compliance Regulations)
- The role of the Pharmaceutical Advertising Advisory Board (PAAB) in relation to the advertising of pharmaceutical drugs
- Direct-to-consumer advertising – current issues
- The impact of the *Transparent Drug System for Patients Act* (Bill 102) – prohibited practices and professional allowances
- Other intellectual property issues

5:00

Co-Chair's Summation and Conference Concludes

DRUG PATENTS AND LEGAL FORUM

FIVE EASY WAYS TO REGISTER Call 1 888 777-1707 | Fax 1 866 777-1292 | Internet: www.insightinfo.com
Email: order@insightinfo.com | Mail Insight Information, 214 King Street West, Suite 300, Toronto, Ontario M5H 3S6

Conference Code: PHC08217

HOTEL RESERVATIONS:

The St. Andrew's Club and Conference Centre is conveniently located at 150 King Street West (the 27th floor), Toronto, ON. Tel: 416-366-4228. For overnight accommodation, please contact The Hilton Toronto, located at 145 Richmond St. West, Toronto, ON. Tel: 416-869-3456 or Fax: 416-869-3187. Please ask for the Insight corporate rate.

CANCELLATION AND REFUND POLICY:

Refunds will be given for cancellations received in writing by February 6, 2008 subject to an administration fee of \$200.00 plus \$12.00 GST for a total of \$212.00. If your fees have not been paid and you are cancelling, you are still liable for the cancellation fees of \$200.00 plus \$12.00 GST for a total of \$212.00.

Please note that if you register for the conference and do not attend, you are liable for the full registration fee unless you cancel within the period stated above. If you register after February 6, 2008, your order is firm. A refund will not be given; however a delegate substitution is welcome at any time.

SPECIAL OFFER: Send 4 people for the price of 3!

Register 3 delegates for the main conference at regular price at the same time and you're entitled to register a fourth person from your organization at no charge. To take advantage of this special offer, payment for all delegates must be made with one cheque or credit card charge.

INSIGHT REWARD PROGRAM: Attend multiple Insight conferences in 2008 and/or register during 2008 and save! Attend and/or register for a 2nd conference in the calendar year (January to December) and receive a 25% discount and attend and/or register for a 3rd conference and receive a 50% discount. Buy more and save!

PRIVACY POLICY: You may receive by mail, telephone, facsimile or e-mail information regarding products and services from either Insight Information or third parties with whom we partner. If you do not wish to receive such information from either Insight Information or third parties, please inform us by email at privacy@insightinfo.com or by telephone at 1 888 777-1707.

February 27 – 28, 2008 | St. Andrew's Club and
Conference Centre | 150 King Street West, Toronto

Yes! Please register the following delegate(s) (photocopy for additional delegates)

PRIORITY CODE: 8217-PDF

Mr. Ms. Name: _____

Title: _____

Area of practice: _____

Company: _____

Business Address: _____

City: _____ Province: _____ Postal Code: _____

Telephone: [] _____ Fax: [] _____

E-mail: _____

Type of Business: _____ #of Employees: _____

Registrant's Signature Required: _____

Signature _____ Date _____

REGISTRATION FEE: (Includes meals, documentation and *in*CONFERENCE™, fully searchable online access to this conference's papers*)

Please check your choice:

Early Bird Special \$1,495.00 + GST (\$89.70) = \$1,584.70
(Register and pay before December 7, 2007)

Regular Conference Price: \$1,695.00 + GST (\$101.70) = \$1,796.70

I would like to order an extra copy of the conference binder (1 conference binder is included in the registration fee) \$100.00 + 6% GST

Payment enclosed. Payment to follow. (GST Reg. #856568779RT0001)

Charge to my VISA® AMEX® MasterCard®

Card Number: _____ Exp. Date: _____

Card Holder's Name: _____

Signature: _____ Date: _____

* Please allow 4-6 weeks after conference for activation of login and password.

PLEASE NOTE: Full payment is required in advance of conference dates. Please make all cheques payable to **Insight Information**. If payment is made by credit card, your credit card statement will quote "**ALM Events Canada, Inc.**" as the vendor.

INSIGHT reserves the right to change program date, meeting place or content without further notice and assumes no liability for these changes. ©2008 Insight Information