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…

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

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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 Consultant
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

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
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 Blaire 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

Networking Luncheon

Update on Recent US and International Developments

Janine A. Carlan
Partner
Arent Fox LLP (Washington)

• The Supreme Court’s KSR International Co. v. Telexel Inc. decision regarding obviousness (and how it has been applied)
• The Federal Circuit’s decision 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

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

Networking Refreshment Break

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

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

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

Co-Chair’s Summation and Conference Concludes
February 27 – 28, 2008 | St. Andrew's Club and Conference Centre | 150 King Street West, Toronto

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