The Canadian Institute’s 7th Annual Forum on

Pharma Patents
The Legal & Strategic Guide

Our outstanding faculty of speakers will review the latest legal developments and provide valuable analysis to bolster your pharma patent strategy.

TOPICS COVERED INCLUDE:

• Understanding the latest pharma patent litigation revolutionizing the industry
• Regulatory updates
• Identifying opportunities in patent listing and de-listing
• Catching up on the judicial viewpoint with The Honourable Justice Hughes
• Forward-thinking brand and generic patent strategies

And much more!

NEW FOR 2008!

• Demystifying selection patents
• Patent protection and regulation of biologics and subsequent entry biologics
• Understanding patent protection in a global context
• New speakers and perspectives

PRE-CONFERENCE WORKSHOP:

The Fundamentals of Pharma Patent Law in Canada

October 29, 2008

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It is essential to stay on top of the many legal and regulatory developments in the field of pharma patents to maintain your competitive edge. With so much at stake, keeping abreast of the law is an excellent way to both identify opportunities and institute proactive safeguards to advance your business objectives. That’s why the Canadian Institute’s 7th Annual Forum on Pharma Patents is beyond relevant – it is indispensable.

Join us and stay informed about the law, as well as benefit from in-depth analysis and strategic advice offered by our outstanding faculty of speakers representing both brand and generic perspectives.

Some highlights from this year’s agenda include:

- **Understanding** the latest in pharma patents litigation including selection patents, sufficiency, obviousness and disclosure requirements
- **Incorporating the latest legal developments** into your pharma patent strategy
- **Catching up with** the Honourable Justice Hughes and the Office of Patented Medicines & Liaison Health Canada

And much more!

Plus, if you’re new to the industry or in need of a refresher, don’t forget to register for our pre-conference workshop: **The Fundamentals of Pharma Patent Law in Canada.** This workshop, lead by both lawyers and patent agents, will introduce the legislative and regulatory underpinnings of the Canadian pharma patents regime and help you maximize your grasp of the conference to follow.

Spaces for this event always go quickly. Don’t delay!
Thursday, October 30, 2008

7:45  Registration Opens and Coffee Served

8:45  Opening Remarks from the Co-Chairs

Eileen McMahon  
Partner, Torys LLP (Brand)

Shonagh McVean  
Partner, Gilbert's LLP (Generic)

9:00  Catching up on Recent Pharma Patents Litigation to Enhance your Business Practices

Steven Mason  
Partner  
McCarthy Tétrault LLP (Brand)

Shonagh McVean  
Partner  
Gilbert’s LLP (Generic)

- Analysis of emerging jurisprudence from both generic and brand perspectives
- Reviewing the leading cases and understanding the current state of the law
- How have recent decisions impacted the industry?
- Identifying the latest trends with regard to patent infringement?
- Reconciling PM(NOC) requirements and amendments circa 2006 with recent judicial consideration
- Abuse of process allegations and relevant procedural issues

10:00  Networking Refreshment Break

10:15  Key Regulatory Developments

Anne Bowes  (Tentative Confirmation)  
Acting Director  
Office of Patented Medicines & Liaison Health Canada

Douglas Clark  
Director, Industry Canada  
Patent and Trade-mark Policy Directorate

David K. Lee  
Director, Progressive Licensing Project  
Health Canada

PM(NOC) Regulation:
- Recent proposed amendments to PM(NOC) Regulations and “grandfathering”
- Bill C-51, Amendments to the Food and Drugs Act
- Benchmarking the impact of the 2006 amendments to PM(NOC) regulations
- Sufficiency of disclosure requirements
- The future of pharma patents regulation in Canada

11:30  Patent Protection in a Global Context

Reza Yacoob  
Sr. Director of Intellectual Property, Sanofi Pasteur

Aiyaz Alibhai  
Partner, MBM Intellectual Property Law

- Patent strategy in our global economy
- Identifying opportunities and risks
- Instruments and tactics to best advance your objectives
- Discussing the Patent Prosecution Highway pilot programs in the U.S., Canada, U.K., and Japan in the context of pharma patent strategy:
  - Claim strategy considerations
  - Conflict between national patent laws
  - Timing and cost considerations
  - Market considerations.
- Comparing and contrasting select pharma and bio issues in Canada with the United States, United Kingdom and Japan including:
  - Pricing and reimbursement of pharmaceuticals
  - Data protection and patent term extension
  - Patent claim eligibility

12:30  Networking Luncheon for Delegates and Speakers

1:45  Demystifying Selection Patents

Andrew Bernstein  
Partner  
Torys LLP (Brand)

Paula Bremner  
Partner  
Hitchman & Sprigings (Generic)

- Attacking the validity of selection patents
- Sufficiency and utility in the context of selection patents
- Relationship with obviousness, anticipation and sound prediction
- How is the law evolving?
- Catching up with the SCC
- What is the future direction of sufficiency and selection patents given recent judicial consideration?
- Selection patents in the context of PM(NOC) regulations

2:45  Identifying Opportunities in Patent Listing and De-Listing

Nadine D’Aguiar  
Lawyer, Patent Agent and Trademark Agent  
Ogilvy Renault LLP

- Translating jurisprudence into practical tips useful to listing and de-listing patents
• How is the law developing?
• What’s changed?
• How can brands and generics benefit from these developments?
• PM(NOC) rules and policies
• Listing and eligibility issues
• Managing disclosure requirements

3:30 Networking Refreshment Break

3:45 Biologics and Subsequent Entry Biologics: Patent Protection and Regulation

Eileen McMahon
Partner, Torys LLP
• Where do we stand in terms of regulating biologics and subsequent entry biologics and where are we headed?
• Approval processes
• Possible trickle over effects from other jurisdictions
• New chemical entity laws and time lines

4:30 Co-Chair’s Closing Remarks
Conference Adjourns for the Day

Friday, October 31, 2008

8:00 Registration Opens and Coffee Served

8:45 Opening Remarks from the Co-Chairs

9:00 Pharma Patents Roundtable: Understanding Key Issues Impacting the Industry Today

Marguerite Ethier
Counsel, Lenczner Slaght

Gunars A. Gaikis
Partner, Smart & Biggar / Fetherstonhaugh

Bill Mayo
Partner, Patent Agent and Trademark Agent
Heenan Blaikie LLP

Anthony M. Prenol
Partner, Blake, Cassels & Graydon LLP

This panel discussion will bring together industry experts to discuss the most pressing patenting issues effecting pharmaceutical companies today.

Topics covered may include:
• Sufficiency
• Obviousness
• Formulation patents
• Disclosure
• Utility

10:30 View from the Bench

The Honourable Roger T. Hughes
Federal Court Trial Division

11:15 Forward-Thinking Brand and Generic Patent Strategies

Christopher C. Van Barr
Partner
Gowling Lafleur Henderson LLP (Brand)

J. Bradley White
Partner
Osler, Hoskin & Harcourt LLP (Generic)

This session will help you digest the latest developments in pharma patents and incorporate them into your business strategy and patent portfolio management.
• Synthesizing the latest legal developments into your patent portfolio management
• Recognizing opportunities for both brand and generic companies
• Discussing how to proactively prepare for future changes in applicable laws and regulation
• Tips, traps and trends

12:15 Networking Luncheon for Delegates and Speakers

1:30 Strategies to Prolong and Limit the Length of Patent Protection

Speaker to be Announced

• Identifying openings for brand and generic companies
• How is regulation impacting patent time lines?
• The latest on Patent Term Extension:
  - What is it?
  - When is it available?
• Patent life cycle management:
  - What to file
  - When to file
  - Where to file
• The interplay between the timeline of a patent versus the timeline to drug approval

2:30 Notices of Allegation and Section 8 Damages

Jason Markwell
Partner
Ogilvy Renault LLP (Brand)

Richard Naiberg
Partner
Goodmans LLP (Generic)

• Best practices for offence and defense of pharma patents
• What factors should you consider when you are deciding whether to file?
• What can we glean from emerging case law?
Notice of Allegation (NOA)
- Effective pre-NOA preparation
- What constitutes a “sufficient” NOA?
- What is considered an invalid allegation?
- What is the standard to be met and how do you meet it?
- What are the legal and evidentiary burdens?
- Summary dismissal motions: what should you use and when?

Section 8 Damages
- Practical strategies to minimize your risk
- When does liability under s. 8 arise?
- Availability of innovator profits
- Effect of subsequent infringement
- Generic v. innovator/brand name approaches

WHO SHOULD ATTEND
- In-house Counsel from Pharmaceutical and Biotech companies
- VPs, Directors and Managers of:
  - Regulatory Affairs
  - Formulation Development
  - Health Policy
  - Research & Development
  - Compliance
- Patent and IP Litigators
- Life Sciences Lawyers
- Patent Agents and Officers

SPONSORSHIP & EXHIBITION OPPORTUNITIES
Maximize your organization’s visibility in front of key decision-makers in your target market. For more information, contact Director Business Development Daniel Gellman at 416-927-0718 ext. 389, toll-free 1-877-927-0718 ext. 389 or by email at d.gellman@CanadianInstitute.com

Pre-Conference Workshop • October 29, 2008
The Fundamentals of Pharma Patent Law in Canada

1:30 pm – 4:30 pm

Workshop Leaders:

Nadine D’Aguiar
Lawyer
Patent Agent and Trademark Agent
Ogilvy Renault LLP

Jennifer A. Conroy
Associate
Torys LLP

- The legal and regulatory framework
  - Patent Act and regulations
  - Food and Drugs Act and regulations
- The regulators: their roles and mandates
  - Health Canada and Industry Canada
  - Therapeutic Products Directorate
  - Patented Medicine Price Review Board
- The critical Patented Medicines (Notice of Compliance) Regulations:
  - Purpose
  - Application
  - Key elements and critical timelines
  - Procedures for protecting your rights
  - Filing and responding to Notice of Compliance, Notice of Allegation and patents lists
- Patent Listing:
  - To list or not to list: advantages and disadvantages
  - What patents should be listed and when
  - Practical strategies for getting patents listed on the patent register
  - What you should include, or avoid including, in drafting successful patent applications
  - Understanding patent construction, the way that they're put together, and interpreting them effectively
  - Latest developments in timing issues
  - Identifying what examiners are looking for
- Patent enforcement:
  - How does it operate?
  - What exactly does the patent grant and what are its limits?
  - A comparison of Canadian, US and other international systems
- Pharma patent litigation:
  - Identifying seminal cases
  - Identifying cases currently before the courts and analyzing potential implications

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REGISTRATION FORM

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ATTENTION MAILROOM: If undeliverable to addressee, please forward to: VP Regulatory Affairs, Counsel, Patent Agent

Top Reasons to Attend

- Review and synthesize key legal developments on the subject of pharma patents
- Learn from a balanced faculty of speakers representing both brand and generic perspectives
- Meet and network with leading industry professionals, lawyers and policy makers

5 EASY WAYS TO REGISTER

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Payment Policy

Payment must be received in full by the conference date. All discounts will be applied to the Conference Only fee (excluding add-ons), cannot be combined with any other offer, and must be paid in full at time of order. Group discounts available to individuals employed by the same organization.

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