This program has been accredited by the Law Society of Upper Canada towards the professional development requirement for certification.

This year’s distinguished faculty of legal and industry experts will provide you with current, in-depth information on the latest legal developments and regulatory changes in pharmaceutical and biotechnology patents. 

**Highlights include:**

- Hot new issues in pharmaceutical litigation
- Recent Developments in Utility Law
- Section 8 Damages - recent developments
- Subsequent entry biologics update
- Balancing justice and expedition in patent litigation
- The art of calling and cross-examining the expert witness
- PMPRB sneak preview on the revised Excessive Price Guidelines
- New chapter 17 of the MOPOP – CIPO’s policies concerning the patentability of biotechnology-related inventions
- How important changes in U.S. patent practice may impact your business and legal strategy
- An update on the Patent Prosecution Highway Pilot Program
- Canada’s Access to Medicines Regime – a public policy fiasco or promise?

**and much more…**

**KEYNOTE – Patent Protection in a Global Context**

Lenni Carreiro, Patent Counsel, Intellectual Property Dept., Sanofi Pasteur

**SPECIAL PANEL PRESENTATION:**

Supreme Court of Canada PLAVIX Decision: The Aftermath

(a patentee and generic perspective)

**PROGRAM CHAIR**

Andrew Bernstein
Partner
Torys LLP

**Organizations represented:**

Bennett Jones LLP
Bereskin & Parr
Canadian Intellectual Property Office, Industry Canada
Davidson, Davidson & Kappel LLC
Dimock Stratton LLP
Gowling Lafleur Henderson LLP
Heenan Blaikie LLP
Leslie Dan Faculty of Pharmacy, U of T
Ogilvy Renault LLP
Patented Medicine Prices Review Board
Sanofi Pasteur
Smart & Biggar/Fetherstonhaugh & Co. Torys LLP

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**8th Edition**

DRUG PATENTS and LEGAL FORUM

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ENROLL TODAY! Call 1 888 777-1707 or fax 1 866 777-1292
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Dear Colleague,

The last twelve months have seen some fascinating legal developments in the pharmaceutical and biotechnology industry. From amendments to the PM(NOC) regulations to subsequent entry biologics, changes to the regulatory environment continue to come at the industry at a fast-and-furious pace. The Courts continue to resolve the biggest legal issues of the day, but creative counsel are always pushing the envelope to find new arguments to assist their clients. This is not only true in substantive patent law, where this past year has seen even the Supreme Court weigh in, but also areas like data protection, pricing regulation, and the s. 8 damages remedy.

In such a busy environment, it can be challenging to keep up to date on all of these legal and regulatory changes. This Insight conference assembles skilled practitioners in all of these fields to provide the insight on the issues from both the innovative and generic perspectives on all of the key developments, including:

• The Supreme Court’s decision in Apotex v. Sanofi-Synthelabo on obviousness and anticipation
• Section 8 damages
• Patent lawsuits: getting to trial in two years
• Recent Developments in Utility Law
• Revised guidelines by the Patented Medicine Prices Review Board
• Canada’s Access to Medicines Regime
• The obligation to address patents on the Patent Register

Don’t miss Insight’s line-up of outstanding speakers, carefully chosen to give you a range of different, and sometimes competing perspectives. They will bring you up to date on the latest developments and maybe even challenge your thinking on these difficult issues.

I look forward to seeing you on May 28-29, 2009!

Andrew Bernstein
Partner, Torys LLP

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THURSDAY | MAY 28, 2009

8:00 | 9:00
Registration and Continental Breakfast

9:00 | 9:10
Welcome and Opening Remarks from the Chair

Andrew Bernstein
Partner
Torys LLP

9:10 | 10:00
KEYNOTE
Patent Protection in a Global Context

Lenni Carreiro
Sanofi Pasteur

10:00 | 10:45
The Rush to Judgment: Balancing Justice and Expedition in Patent Litigation

Jonathan Stainsby
Partner
Heenan Blaikie LLP

Current practice in patent litigation before the Federal Court:
- How have Court sponsored initiatives to expedite patent litigation affected practice?
- How have recent changes to procedure in applications under the PM(NOC) Regulations impacted practice?
- Is case management in PM(NOC) applications and in patent infringement and impeachment actions working?
- Actions and trials – how to manage in the era of expedited trials
- Pros and cons of proceeding under the PM(NOC) Regulations as compared to impeachment actions
- Do the PM(NOC) Regulations continue to have relevance?

10:45 | 11:00
Networking Coffee Break

11:00 | 11:45
What Patents Must be Addressed in PM(NOC) Proceedings? It Depends on When you Ask!

Michael E. Charles
Partner
Bereskin & Parr

11:45 | 12:30
Pharma Patent Trials Within 2 Years

Gunas Gaikis
Partner
Smart & Biggar/Fetherstonhaugh & Co.

- The new reality in the Federal Court
- Practical considerations
- Lessons from the Perindopril and Ramipril actions
- How this changes prior strategies for innovators

12:30 | 1:45
Networking Luncheon

1:45 | 2:30
Advocacy and Evidence: the Art of Calling and Cross-examining the Expert Witness

Neil Belmore
Partner
Gowling Lafleur Henderson LLP

- Proper retention of the expert
- Instructing the expert on the law
- Preparation: of evidence and for cross-examination
- Cross-examining the expert

2:30 | 3:15
SNEAK PREVIEW
PMPRB’s Upcoming Revised Excessive Price Guidelines

Barbara Ouellet
Executive Director
Patented Medicine Prices Review Board (PMPRB)

Participants will hear a comprehensive update of the Board’s review of its price review process and highlights of the upcoming release of its revised Guidelines.

3:15 | 3:30
Networking Refreshment Break
3:30 | 4:15
The Changing Patent Landscape in the U.S.
Clifford Davidson, Esq.
Founding Partner, Davidson, Davidson & Kappel LLC

The new Obama administration, recent important court decisions, and the possible implementation of a vast array of new rules will greatly impact U.S. patent practice. It is important for life science companies to have some understanding of these changes and to re-evaluate how these changes in U.S. patent practice impact their strategy.

Topics to be covered include:
• Recent court decisions on pharma patent validity (obviousness), inequitable conduct and willful infringement
• Pending USPTO rule changes/legislation
• Tips for maximizing benefits from your company’s IP

4:15 | 5:00
Recent Developments in Utility Law
Barbara Murchie
Partner, Bennett Jones LLP

The Federal Court of Appeal has now confirmed that, at least in some circumstances, proof of utility must be disclosed in the patent. The disclosure requirement of the sound prediction test requires that both the factual basis and sound line of reasoning for the predicted utility be set out in the patent.

In this presentation, the following key questions will be discussed:
• Is this decision limited to cases where sound prediction is the “quid pro quo” for the monopoly?
• Does it apply to demonstrated utility as well as predicted utility?
• How does it interface with the sufficiency requirements under the Patent Act?

5:00
Conference Adjourns for the Day

8:00 | 9:00
Continental Breakfast

9:00 | 9:10
Opening Remarks from the Chair
Andrew Bernstein
Partner
Torys LLP

9:10 | 10:00
Canada’s Access to Medicines Regime – A Public Policy Fiasco or Promise?
Dr. Jillian Clare Kohler
Assistant Professor
Leslie Dan Faculty of Pharmacy
University of Toronto

In 2004, Canada became the first World Trade Organization member to amend its drug patent law to create a compulsory licensing regime allowing for the manufacture and export of medicines to developing countries without manufacturing capabilities. The legislation, now known as Canada’s Access to Medicine Regime (CAMR), was passed to help lessen the health burden caused by lack of access to medicines that can ideally lead to improving lives and saving lives. The CAMR has been the subject of much political debate in Canada, as well as substantial consultations from interest groups, and yet has still not reached its humanitarian objectives, despite a recent shipment of anti-retroviral drugs to Rwanda by Apotex.

This presentation will examine the all important question “Is this the right humanitarian policy for the Canadian government or should the government be exploring other policies for improving drug access globally?”

10:00 | 10:45
Biosimilars/Subsequent Entry Biologics: Canadian Legal Update
Eileen McMahon
Partner
Torys LLP

• Status of current proposals
• Impact of proposals on patent register listings
• Impact of proposals on data protection
• Patent strategies and patent infringement disputes
10:45 | 11:00
Networking Coffee Break

11:00 | 11:45
Manning the Barricades: New Chapter 17 of the MOPOP – CIPO’s Policies Concerning the Patentability of Biotechnology-Related Inventions

Yoon Kang
Partner
Smart & Biggar/Fetherstonhaugh & Co.

- Fertilized eggs and totipotent stem cells – the bar to patenting “higher life forms”
- Patentability related to methods of medical treatment
- Monoclonal antibodies: a new theory for rejection
- Sufficiency of disclosure and promised utility of claimed compounds – don’t make a promise you can’t establish
- Working examples required! – a statutory basis in the Patent Rules?
- Requirement for valid priority claims

11:45 | 12:30
Section 8 Damages – Recent Developments

Jason C. Markwell
Partner
Ogilvy Renault LLP

- Object and purpose of Bill C-91 and the PM(NOC) regulations
- Scope of section 8 remedies
- Recent jurisprudence

12:30 | 1:45
Networking Luncheon

1:45 | 3:00
Supreme Court of Canada PLAVIX Decision: The Aftermath

Patentee Perspective:
Andrew Bernstein
Partner
Torys LLP

Nancy P. Pei
Partner
Smart & Biggar/Fetherstonhaugh & Co.

Generic Perspective:
Angela Furlanetto
Partner
Dimock Stratton LLP

Dominique T. Hussey
Partner
Bennett Jones LLP

- Anticipation: we know what the test is, but how does it work in practice?
- Obviousness: has the standard been watered down? If so, by how much? What have subsequent courts said?
- Selection: what is the relationship between obviousness, anticipation and the three-part test for a selection patent?

3:00 | 3:15
Networking Refreshment Break

3:15 | 4:00
Hot Issues in Pharmaceutical Litigation

David Reive
Partner
Dimock Stratton LLP

Learn about recent developments in substantive, evidentiary and procedural issues in pharmaceutical litigation. Gain insights into what’s next and how the courts are grappling with these important issues.

- Sound prediction, utility and section 53 attacks
- Key recent decisions
- The Federal Court Practice Direction – is it working?
- Litigation strategies – the rise of actions
- Key evidentiary developments
- The latest on motions to dismiss

4:00 | 4:30
Patent Prosecution Highway Pilot Program Update

Javier Jorge
Project Manager, PPH Pilot Project
Patent Branch, Canadian Intellectual Property Office
Industry Canada

The report will provide the latest information on how this pilot program is unfolding, the challenges encountered to date and what the next steps will be.

4:30
Conference Concludes
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 Incisive Media corporate rate # 2687149 (subject to availability).

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