5th Annual

DRUG PATENTS

Litigation Strategies and Regulatory Update

February 27 – 28, 2006 • St. Andrew’s Club and Conference Centre • 150 King Street West, Toronto

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

• The latest update on amendments to Notice of Compliance Regulations
• Data protection and the interplay with the NOC Regulations for life cycle management
• Key trends in the pharmaceutical industry – brand and generic perspectives from industry
• Disconnect in the Canadian courts’ approach to drug patents – favouring economic rights over exclusivity, yet falling short on compensation
• Hot topics for brands and generics: patent listing and notices of allegation
• Recent key drug patent decisions – highlights and head scratchers
• The genius is out of the bottle – class actions and pharma litigation
• Can competition law override patent law? – brand and generic perspectives

and much more…

JUDGES PANEL DISCUSSION

The Honourable James K. Hugessen, Federal Court of Canada
The Honourable Marshall E. Rothstein, Federal Court of Appeal of Canada
The Honourable Konrad W. von Finckenstein, Federal Court of Canada

POST-CONFERENCE WORKSHOPS – WEDNESDAY, MARCH 1, 2006

WORKSHOP A – Drafting and Prosecuting Pharmaceutical Patent Applications
WORKSHOP B – Advanced Licensing – Drafting Strategies for Patented Pharmaceuticals

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

The cost of drug discovery and the risks and potential liabilities of bringing a new drug to market are heating up patent disputes as never before given a very contentious legal and market environment.

The pharmaceutical industry is one of the most competitive and dynamic in the marketplace.

Stakes are high, both from a financial and legal perspective. This is an industry characterized by a variety of sophisticated stakeholders having significantly diverse interests and goals, whether they be innovator brand companies, generics, start-ups, or regulators.

The legal issues are complex, evolving and have a critical impact on each stakeholder in the field. Staying up to date on the latest regulatory, policy and business developments in definitely not optional if you want to survive as an effective player in this field.

It’s been said that the only constant is change and the pace of change continues to be quick in the Pharma Patents area. Competitive pressures from all sources make “staying current” critical. This conference offers the essential updates and insightful analysis.

Among the areas to be addressed are:

- Comparing/contrasting NOC Regulations and U.S. Hatch-Waxman
- Evergreening/protection of ongoing Innovation
- Trade-mark opposition board decisions
- Burden of proof in NOC proceedings – whose onus is it anyway? (applicant and respondent perspectives)
- Are the courts too eager to invalidate patents?
- Evidentiary issues in pharmaceutical litigation

Insight Information has convened this conference to allow you to benefit from the insights, analysis and expertise of leading judicial, legal, regulatory and industry representatives.

Attend to hear about the latest developments and ensure that you stay competitive. Meet some of the sector’s leading professionals from the pharmaceutical sector, legal and regulatory regimes.

We look forward to seeing you there!

Yours very truly,

Brian W. Gray  
Partner  
McCarthy Tétrault LLP

Joan M. Van Zant  
Senior Partner  
Patent & Trade-Mark Agent  
Ogilvy Renault LLP

Delegates will receive a set of original materials as well as online access to conference papers through Insight’s INCONFERENCE™ that will serve as invaluable reference sources after the program.
12:00 Networking Luncheon

1:15 Evergreening/Protection of Ongoing Innovation

Ian Godfrey  
Partner  
Heenan Blaikie LLP  
- NOC Reg permissiveness  
- The two branch prohibition against Double Patenting  
- The Gillette Defence  
- Fraud on the Patent Office

1:45 Key Trends in the Pharmaceutical Industry – Brand and Generic Perspectives

Moderator:  
Dino P. Clarizio  
Partner  
Bennett Jones LLP

Gavin T. Bogle  
Patent Counsel  
Biological Technologies  
Wyeth (U.S.A)

Ildiko Mehes  
Director, Legal Affairs  
Novopharm Limited  
(Member of the Teva Group)

Jennifer Kaufman-Shaw, PhD, LLB  
Chief Patent Counsel  
QLT Inc.
- Latest U.S. legal and industry developments  
- Cross border update  
- Internet sales trends and implications  
- Pricing developments  
- Biologics and biotechnology developments

3:00 Refreshment Break

3:15 Disconnect in the Canadian Courts’ Approach to Drug Patents – Favouring Economic Rights Over Exclusivity Yet Falling Short on Compensation

Jane E. Caskey  
Partner  
Ogilvy Renault LLP  
- Canadian courts’ preference of economic rights over protection of exclusivity  
- Illustration of the Canadian experience  
- Traditional approach to remedies for infringement cases and the resulting gap in compensation  
- Uncertainty in remedies in Section 8 PMNOC cases  
- New approach to compensation: how will the Canadian courts respond?

4:15 Hot Topics for Brands and Generics: Patent Listing and Notices of Allegation

Andrew Bernstein  
Lawyer  
Torys LLP
- Developments in the law of listing: what is a “claim to the medicine”?
• The law relating to use claims
• New cases about the sufficiency of an allegation
• When can you make a second allegation about the same patent?

5:00 Conference Adjourns for the Day

TUESDAY
FEBRUARY 28, 2006

8:15 Continental Breakfast
8:45 Co-Chair’s Opening Remarks

Joan M. Van Zant
Senior Partner
Patent & Trade-Mark Agent
Ogilvy Renault LLP

9:00 The Anatomy of a Pharma Proceeding – NOC Regulations, Applications and Patent Actions

Moderator:
Neil Belmore
Partner
Gowling Lafleur Henderson LLP

The Honourable James K. Hugessen
Federal Court of Canada

The Honourable Marshall E. Rothstein
Federal Court of Appeal of Canada

The Honourable
Konrad W. von Finckenstein
Federal Court of Canada

• Preliminary motions – to exclude evidence; to bifurcate liability from damages/profits; the pretrial conference; to dismiss
• Motions at the outset of the hearing – to strike evidence
• Appeal of motions
• Demonstrative evidence
  - the Tutorial
  - substantive evidence via power point slides, bristol board, etc.
• Oral presentation
  - an opening statement?
  - do and don’t
• Trials – and expert witnesses: extensive evidence in chief or taking the report as having been read?
• Written materials – preferred styles at trial division and on appeal
• Additional materials post hearing

10:15 Coffee Break

10:30 Trade-mark Opposition Board Decisions

Lee Webster
Partner
Osler, Hoskin & Harcourt LLP
• Drug Trade-marks/Subject matter
• Registrability/Entitlement/Distinctiveness
• Procedural issues
• Recent decisions of note

11:15 Recent Drug Patent Decisions

Allyson Whyte Nowak
Partner
Ogilvy Renault LLP
• Federal Court and Federal Court of Appeal key recent decisions
• Highlights and head scratchers
• Discerning the trends

12:00 Networking Luncheon

1:15 Burden of Proof in NOC Proceedings – Whose Onus is it Anyway? (Applicant and Respondent Perspectives)

Angela M. Furlanetto
Partner
Dimock Stratton LLP
• Who needs to prove what
• Trends from the latest cases
• Infringement and validity – is the burden different?
• Has the framework changed?

2:00 Are the Courts Too Eager to Invalidate Patents?

Andrew Brodkin
Partner
Goodmans LLP

Anthony Creber
Partner
Gowling Lafleur Henderson
• Is there a different burden in pharma cases v. non-pharma cases?
• Does the inability to appeal many pharma cases distort the jurisprudence?
• Does the “preliminary” nature of s. 55.2 Proceedings encourage judges to err on the side of permitting the generic to come to market?
• Will the court in a full infringement proceeding truly consider the case de novo?
• Review of the score card to date

2:45 Refreshment Break

3:00 The Genie is Out of the Bottle – Class Actions and Pharma Litigation

Mary M. Thomson
Partner
McCarthy Tétrault LLP
• Québec’s uniqueness – the Pharmascience decision
• National class proceedings
• International class proceedings
• The role of the regulator
• What the future may bring
3:35  Evidentiary Issues in Pharmaceutical Litigation
David M. Reive  
Partner  
Dimock Stratton LLP  
• Making your case  
• Experts and their role  
• Use of inventors  
• Drafting the affidavits  
• Procedural tips and traps

William L. Vanveen  
Partner  
Gowlings LaFleur Henderson  
• Competition law in the drug regulatory process  
• Does co-operative behaviour between pharmaceutical firms pose competition law risks?  
• The Cefaclor case – “mere exercise” of patent rights, or “something more”?  
• What works better – a private remedy, or complaining to the Competition Bureau?  
• Licensing issues  
• Competition law as a defence in infringement actions  
• Litigation settlements

4:10  Can Competition Law Override Patent Law?  
Peter L. Glossop  
Partner  
Osler, Hoskin & Harcourt LLP

5:00  Co-Chair’s Summation and Conference Concludes

POST CONFERENCE WORKSHOPS – WEDNESDAY, MARCH 1, 2006

Drafting and Prosecuting Pharmaceutical Patent Applications

Yoon Kang, Partner, Barrister and Solicitor, Patent and Trade-mark Agent  
Smart & Biggar/Fetherstonhaugh

Scott A. Beeser, Associate, Barrister and Solicitor, Smart & Biggar/Fetherstonhaugh

This workshop will focus on patent drafting and prosecution issues of concern to top pharmaceuticals. Two main areas will be discussed related to Patented Medicines (Notice of Compliance) Regulations and Patented Medicines Prices Review Board:

• Patent strategies and rights under the Regulations – implication of timing of application and patent, appropriate claim drafting, claim relevance
• Patent strategies and jurisdiction of PMPRB – implication of dedication, abandonment, withdrawal, timing of patent issuance, claim relevance

Yoon Kang, a partner of Smart & Biggar/Fetherstonhaugh, focuses on pharmaceutical patent litigation, the preparation and prosecution of biotechnology and pharmaceutical patent applications, infringement and validity opinions. She is a registered patent and trade-mark agent also registered to practise before the United States Patent and Trademark Office.

Scott Beeser, an associate of Smart & Biggar/Fetherstonhaugh, focuses on biotech and pharmaceutical patent prosecution and litigation. His technical training includes a doctoral degree in biology and he is a patent and trademark agent.

Advanced Licensing – Drafting Strategies for Patented Pharmaceuticals

Sheldon Burshtein, Partner, Blake, Cassels & Graydon LLP
Christopher C. Hale, Partner, Blake, Cassels & Graydon LLP

This workshop will focus on key challenges in the negotiation and drafting of licenses related to patented pharmaceuticals. This in-depth coverage will also present the opportunity for individual questions. The focus on particular issues will be based on the interests and preferences of participants. Among the issues to be considered are:

• Definitions of key terms  
• Identification of relevant rights to be licensed  
• Grant of specific rights  
• Representations and warranties  
• Improvements in products and processes  
• Indemnities and limitations  
• Protection and enforcement of licensed rights  
• Termination and post termination  
• Ultra-generic licenses

Sheldon Burshtein is a Partner of Blake, Cassels & Graydon LLP and practises exclusively in intellectual property and technology. This includes clearance, prosecution, acquisition, enforcement and exploitation of patents, trade-marks, copyright, industrial designs, licensing, franchising and other transactions involving intellectual property in pharmaceuticals and life sciences.

Chris Hale is a Partner of Blake, Cassels & Graydon LLP and practises the full range of intellectual properties including trade-marks, copyright, patents, industrial designs, trade secrets and personality rights. He acts in the filing and prosecution of applications for protection of intellectual property and the licensing of such properties in food products, pharmaceuticals and others.
Yes! Please register the following delegate(s) (photocopy for additional delegates)

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Title:

Company:

Address:

City: □ Province: □ Postal Code:

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

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If you register after February 6, 2006, your order is firm. A refund will not be given, however a delegate substitution is welcome at any time.

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