



Medical Devices in Canada: Hot Legal and Regulatory Issues

Life Sciences Group Seminar
April 6, 2010



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Presentation by:
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Medical Devices Promotion:
Is Anyone Paying Attention



Presentation by:
Timothy M. Squire



Device Promotion Laws in Canada


- In some ways, device promotion is more difficult than drug promotion from a compliance perspective
- Direct to Consumer (“DTC”) advertising of prescription drugs is restricted to name, price and quantity
- DTC promotion of non-prescription drugs is subject to pre-clearance agency review
- Health Care Professional (“HCP”) directed promotion of prescription and non-prescription drugs is subject to Pharmaceutical Advertising Advisory Board (“PAAB”) pre-clearance



Device Promotion Laws in Canada

- Device companies are on their own
- No prescription based prohibitions
- No Health Canada pre-clearance policy directed at devices
- It is up to you to interpret and apply the law to your device marketing activities





Key Legislation: s.3(1) *Food and Drugs Act*

- “No person shall advertise any food, drug, cosmetic or device to the general public as a treatment, preventative or cure for any of the diseases, disorders or abnormal physical states referred to in Schedule A”
- Schedule A lists 40 conditions, including arthritis, asthma, diabetes, heart disease, impotence, kidney disease, liver disease and obesity



Key Legislation: s.27 *Medical Device Regs.*

- “No person shall advertise a Class II, III or IV medical device for the purpose of sale unless (a) the manufacturer holds a license in respect of that device [...] or (b) the advertisement is placed only in a catalogue that includes a clear and visible warning that the devices advertised in the catalogue may not have been licensed in accordance with Canadian law.”
- i.e. no pre-market promotion

Key Legislation: s.24 *Medical Device Regs.*

- “[...] a condom may be advertised and sold to the general public for the purpose of preventing the transmission of venereal disease if the advertisement and the label of the condom only claim that the condom reduces the risk of transmitting venereal disease [...] contraceptive devices other than intrauterine devices may be advertised to the general public by means other than by the distribution of samples of the devices door-to door or through the mail”

Key Legislation: s.20(1) *Food and Drugs Act*

- “No person shall [...] advertise any device in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its design, construction, performance, intended use, quantity, character, value, composition, merit or safety”
- “Advertisement” defined as any “representation by any means whatsoever for the purpose of promoting directly or indirectly the sale or disposal of any [...] device.”

Key Legislation: s.20(1) *Food and Drugs Act*

- All types of direct or indirect promotion:
 - Print
 - Radio
 - Television
 - Video
 - Internet
 - Trade-shows
 - Face to face



Guidelines for Compliant Promotion

- Make sure your commercial team knows the terms of your device's market authorization
- Involve your clinical team in advertising review
- Make "Fair Balance" your guiding principle (balance efficacy claims with risks and side effect disclosure)
- Use Health Canada's *Consumer Advertising Guidelines for Marketed Health Products* and your measuring stick



Health Canada *Consumer Advertising Guidelines for Marketed Health Products*

- The Guidelines are available at the Health Canada website
- Important Note: The Guidelines are directed at consumer advertising of non-prescription drugs and specifically exclude medical devices
- In the absence of any specific device promotion guidance, the Guidelines provide a good indication of how Health Canada interprets s.20(1) of the *Food and Drugs Act*



Health Canada *Consumer Advertising Guidelines for Marketed Health Products*

- The Guidelines address all types of health product promotional claims and provide examples of acceptable and unacceptable claims in each instance:
 - intended use
 - duration of use
 - onset of action
 - duration of action
 - efficacy
 - side-effects and absence of side-effects
 - safety and risks
 - comparative claims
 - visual claims
 - endorsements
 - new/improved
 - lifestyle
 - superscripts
 - testimonials



Other Resources

- US FDA “Draft” *Guidance for Industry: Presenting Risk Information in Prescription Drug and Medical Device Promotion* (May 2009)
- Does not apply in Canada (and non-binding in the US), but is a good secondary resource to measure promotion compliance
- More detailed, and addresses such things as improper use of “signals” in written materials, font size and style, amount of “white space” in printed material
- Available on the FDA website



Other Resources

- Health Canada Policy: *The Distinction Between Advertising and Other Activities* (August 2005)
- Important Note: Directed at drug products but is also a good overall guide for medical devices
- Addresses pre-market and off-label communications
 - Press releases
 - CME sponsorship/exhibits
 - International conferences
 - Journal articles
 - Clinical trial recruitment





Other Device Promotion Considerations

- Combination products:
 - Regulatory pathway determined by principal mechanism of action - Health Canada Policy: *Drug/Medical Device Combination Products* (March 2006)
 - No clear direction in relation to advertising
 - Follow the same approach with caution




Other Device Promotion Considerations

- Know your customer's scope of practice (e.g. what "controlled acts" they are authorized to perform – Ontario *Regulated Health Professions Act*)
- Become familiar with the restrictions on physician advertising (e.g. no product names or product spokesperson – Ontario *Medicine Act* Regulations)



Other Device Promotion Considerations

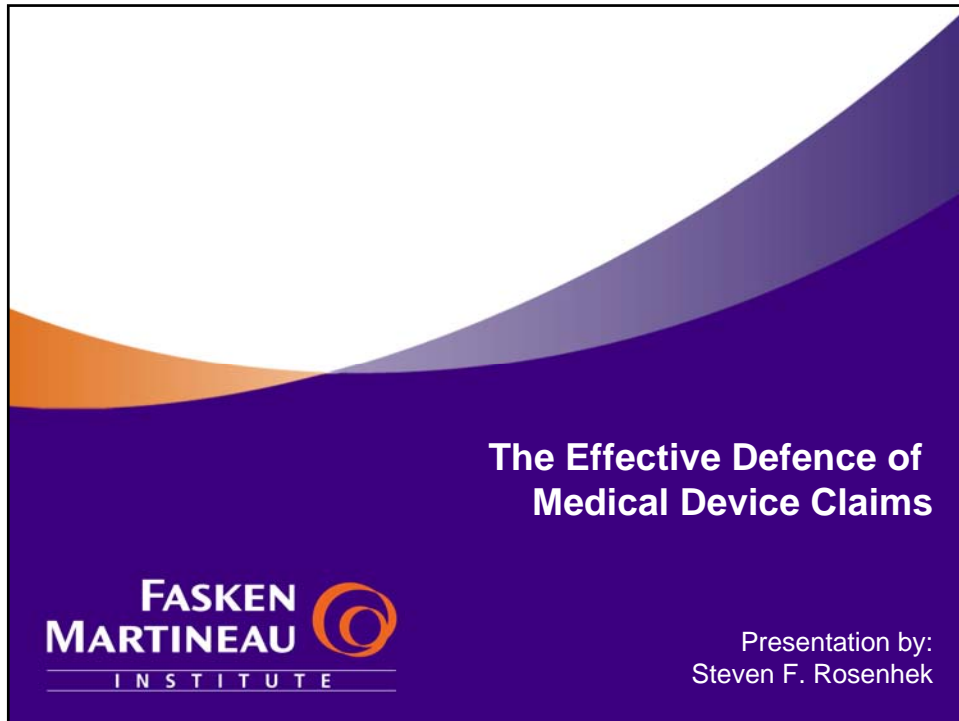
- Avoid unlawful inducements (direct or indirect benefits to physicians)
 - Ontario *Medicine Act* Regulations
 - MEDEC's *Code of Conduct on Interactions with Healthcare Professionals*
 - CMA Policy: *Guidelines for Physicians in Interactions with Industry*




Consequences of Non-Compliant Promotion

- s.31 *Food and Drugs Act*:
 - Fine not exceeding \$5,000 or imprisonment for a term not exceeding 3 years or both
- s.40(1) *Medical Device Regulations*
 - Suspension of Medical Device License
- s.49(1) *Medical Device Regulations*
 - Suspension of Establishment License
- Product liability litigation
 - Immeasurable





The Effective Defence of Medical Device Claims

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Presentation by:
Steven F. Rosenhek



Litigation landscape in Canada for medical devices

- Learned intermediary
- Consumer protection/sale of goods legislation
- Pre-emption and statutory compliance
- Juries
- Damages

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The Foundation: Understanding your approach to litigation

- "No surprises"
- Strategic assessments
- Budgets
- Extranet



Early Case Assessment: Liability

- Jury?
- Company File
 - Warnings/ product insert
 - Inspection reports, manufacturing records etc.




Careful review of medical records

- Hospital
- Consultants (pre-op and post-op)
- Early demand – new limits on oral discovery



Experts

- Inspection demand
- When to retain
- "Trump" the plaintiff
- The right expertise
- Simplify
- Simulations




Early Case Assessment: Damages

- Jury?
- Pre-existing condition
- Contributory negligence - misuse, etc



Defence Medicals

- Condition/pre-condition
- Rehabilitation/mitigation
- Contributory negligence
- Future care costs assessment



Offers to Settle

- Whether and when?



Pre-trials/ Trials

- Convey determination, readiness
- Strike jury?
- Simplify
- Easy themes

Advisories, Recalls and Class Action Lawsuits: Dear Doctor, What Can I Do?



Presentation by:
Paul J. Martin





Quintessential Class Actions?

- Single common event – the notice or recall
- Common question – is it defective?
- Common injury - the explant
- Identifiable class – medical records
- Damages can be substantial – attractive to entrepreneurial plaintiffs’ counsel



Canada’s Class Action Regime

- Different thresholds
- Different outcomes
- Need for different approaches





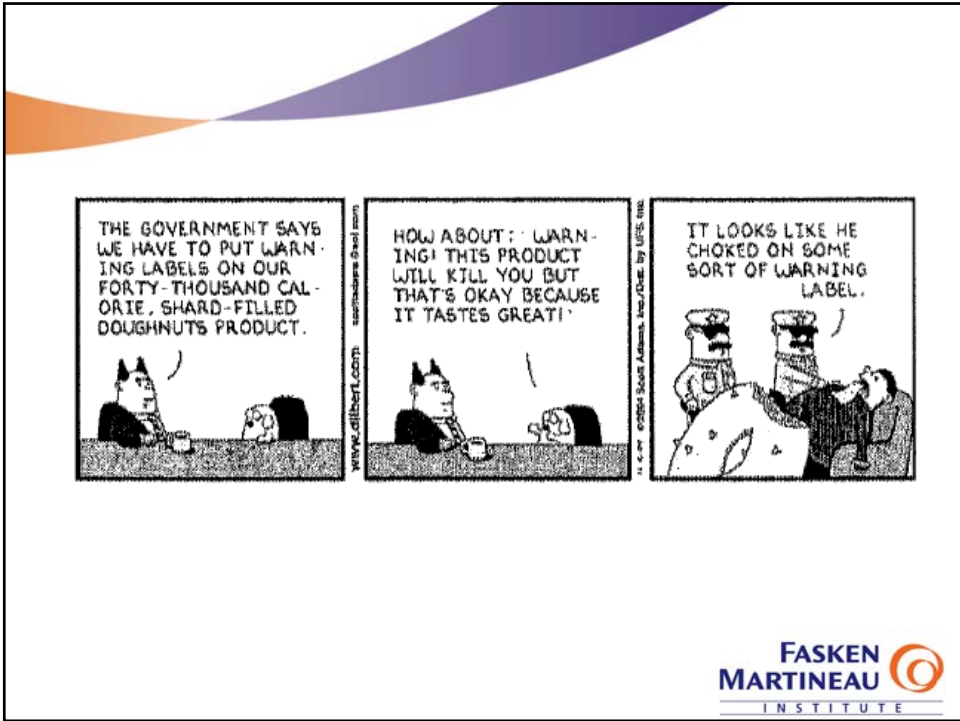
Good News/Bad News

- Psychological harm
- Punitive damages
- Waiver of tort
- Process “immaturity”



Compliance or Catastrophe: A Balance

- A penny saved?
- Record and report
- Communicate to all constituents
- A holistic approach



Questions?



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BIOGRAPHIES



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Areas of Practice

Technology and Intellectual Property

Intellectual Property

Life Sciences

Education

L.L.B.,
University of Windsor, 1995

B.A.,
University of Windsor, 1992

Year of Call

Ontario, 1997

Timothy Squire is a partner in the Toronto office's Intellectual Property Group. Prior to joining the firm in September 2008, Tim was the Chair of the Intellectual Property Group at another large Toronto law firm. Tim's practice involves the protection and commercialization of intellectual property, with a particular focus on medical and biomedical devices and other health and life science innovation. Tim brings a unique perspective to the firm's Intellectual Property Group as he has considerable insight and experience across the entire spectrum of technology development. He regularly counsels clients on patent and commercialization strategies, regulatory matters (including device and establishment licensing, product labeling, regulatory compliance, marketing, advertising and related ethical standards), the negotiation and drafting of sophisticated intellectual property agreements (including licenses, technology and material transfer agreements, joint R&D agreements, funding agreements, and employee, consultant and content specific confidentiality agreements), and a broad range of other issues involving patents, trademarks, industrial design, copyright and confidential information.

Tim has become the trusted advisor to many organizations in the pursuit to protect and commercialize innovation and in their efforts to navigate the regulatory landscape in Canada. He has worked with private and public companies, start-ups and established innovators, as well as institutional organizations. Tim is also involved in many industry groups, and is currently the Chair of the Licensing Executives Society Biomedical Device Subsector.

In addition to his commercial intellectual property and regulatory practice, Tim has extensive experience in the resolution of disputes involving intellectual property and technology. Tim is an accomplished litigator, and has appeared before all levels of the Federal Court and the Ontario Superior Court prosecuting and defending intellectual property infringement cases and commercial cases involving technology, licensing and engineering issues. He is also experienced in alternative dispute resolution, including arbitration, mediation and license based settlements and is the former Chair of the Licensing Executives Society Biomedical Device Subsector.

Timothy M. Squire

Presentations

- Medical Devices in Canada: Hot Legal and Regulatory Issues, Life Sciences Group Seminar, April 6, 2010
- Managing Intellectual Property in a Soft Economy, November 27, 2008
- Licensing Executives Society 2008 Annual Meeting, October 19-23 2008

Publications

- "Fasken Martineau's Life Sciences Newsletter", Life Sciences Newsletter, October 2009
- "Regulatory - Health Products Alert", Technology and Intellectual Property Bulletin, August 2009
- "Intellectual Property: The Year 2008 in Review", By the Intellectual Property Practice Group, February 2009

Memberships and Affiliations

- Canadian Bar Association
- Ontario Bar Association
- Advocates Society
- Licensing Executives Society
- Patent and Trademark Institute of Canada
- Metropolitan Toronto Lawyers Association
- Toronto Intellectual Property Group
- International Association for the Protection of Intellectual Property (AIPPI)



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Areas of Practice

Antitrust/Competition & Marketing

Litigation and Dispute Resolution

Health

Alternative Dispute Resolution

Employment Law Advice

Class Actions

Estate Litigation

Product Liability

Retailing, Franchising and Distribution

Transportation

Life Sciences

Cartels & Other Competition Criminal Matters

Competition Litigation, including Class Actions

Marketing & Advertising

Insurance

Education

LLM, University of Cambridge, 1984

As a leading Ontario litigator, Steven Rosenhek has broad experience before all levels of Court and a wide range of provincial and federal administrative tribunals. His practice encompasses all aspects of civil and administrative litigation, with a particular focus on complex commercial litigation, hospitality law, shareholder disputes, securities, class actions, antitrust/competition law, product liability, employment law, health law, insurance and commercial arbitration. He has handled both prosecution and defence briefs before professional disciplinary, regulatory and administrative bodies.

Steven has written and lectured extensively in numerous areas, including commercial litigation, class actions, advocacy and dispute resolution, and professional liability.

He is a well-known instructor whose teaching credits include:

- Special Lecturer, Trial Advocacy, Faculty of Law, University of Toronto, 1987 to 2000
- Instructor, Advanced Trial Advocacy, Osgoode Hall Law School Part-time L.L.M. in Civil Litigation and Dispute Resolution
- Instructor and Team Leader, Intensive Trial Advocacy Workshop, Osgoode Hall Law School, 1988 to present

Steven is a Past-President of the Ontario Bar Association and currently chairs its Paralegals Task Force.

Presentations

- Medical Devices in Canada: Hot Legal and Regulatory Issues, Life Sciences Group Seminar, April 6, 2010
- Legal Issues in the New Economic Order, Presented in conjunction with the Italian Chamber of Commerce of Toronto, October 22, 2009

Steven F. Rosenhek

LLB, University of Toronto,
1978

Year of Call

Ontario, 1984

England and Wales, 2009

Languages

English

French

- Turn Adversity Into Advantage, Fasken Martineau/Deloitte Joint Seminar, May 21, 2009
- Addressing Patient and Staff Safety Issues in Your Hospital, Hospitals and Foundations Seminar Series, May 14, 2008
- Litigation Risk III: Management of Ongoing Litigation, Speaker, CCCA 2008 National Spring Conference, April 2008
- Who Will Pay for Your Company's Mistakes? A Primer on Indemnity and Insurance Clauses, co-chair, Canadian Corporate Counsel Association, 2006
- Divine Discoveries: Building a Great Case; and Preparing Yourself for Discovery: The Basics, co-chair and speaker, Ontario Bar Association, December 2006
- Flexible Fee Arrangements with External Counsel - What's Out There?, co-chair, Canadian Corporate Counsel Association programme, November 2006
- Mastering Mediation: What you Need to Know for a Successful Mediation, speaker, Ontario Bar Association (Young Lawyers Division/Alternative Dispute Resolution Section joint programme), May 2006
- Causes of Action against Corporations, speaker, Commercial Litigation 2006, Law Society of Upper Canada, April 2006
- Class Actions, speaker, The Advanced Roundtable in Civil Litigation, The Law Society of Upper Canada, March 2006
- Divine Discoveries: Building a Great Case; and Preparing Yourself for Discovery: The Basics, co-chair and speaker, Ontario Bar Association, December 2005
- Winning Advocacy Skills, demonstrator (cross-examination), Canadian Bar Association Annual Conferencr, August 2005
- Best Practices and Procedures in Civil Litigation Case Management, speaker, Advanced Skills for Litigation Law Clerks, Insight Information, July 2005

Steven F. Rosenhek

- Presentation of Evidence in Chief, Young Lawyers Nutshell Programme on Trial Skills, Toronto Lawyers Association, October 2004
- Essential Tips and Techniques for Today's Corporate Counsel, co-chair, Joint Programme of the Canadian Corporate Counsel Association and Ontario Bar Association, June 2004
- Insurance Claims: Learn from the Pros, chair, Ontario Bar Association, April 2004
- The E-Counsel Primer - Going Boldly Where Your Practice Did Not Go Before, co-chair, Corporate Counsel Programme, OBA Annual Institute, January 2004
- Keeping One Step Ahead: The Latest in Shareholder Disputes and Remedies, chair, Ontario Bar Association, May 2003
- The In-House Essentials, co-chair, OBA Institute of Continuing Legal Education, Counsel Association Programme, 2003
- An Overview of Employer Liability and Legal Responsibilities, speaker, Ontario Public Health Association, November 2002
- Mass ADR: Class Actions and Settlement, speaker, Essential ADR Seminar, ADR Institute Conference, October 2002
- Multi-Jurisdictional Class Actions, speaker, Canadian Corporate Counsel Association Annual Meeting, August 2002
- The Determination of Class Counsel Fees in Different Jurisdictions, speaker, The Canadian Institute, May 2002
- Litigating Class Actions, speaker, The Canadian Institute, May 2002
- Troublesome Business Torts, chair, Ontario Bar Association, April 2002
- The Duty of Good Faith, speaker, Canadian Bar Association Annual Meeting, 2002
- Bringing Evidence from American Litigation into Canada: The Vitapharm Litigation, speaker, Insight Information Class Action Litigators Conference, January 2002

Steven F. Rosenhek

- Business Host Liability: Practical Tips, speaker, Insight Information Seminar, 2002
- Troublesome Business Torts, chair, Ontario Bar Association, November 2001
- Evidence Pitfalls in Complex Litigation, speaker, Metropolitan Toronto Lawyers Association, May 2001
- Class Actions: Exploding onto the Scene, chair, Ontario Bar Association, April 2001

Publications

- "Canada Targets State Sponsors of Terrorism", IBA Litigation Committee Newsletter, September 2009
- "Preparing Yourself for Examination for Discovery: The Basics", Ontario Bar Association, Continuing Legal Education, December 2, 2008
- "Mastering Mediation: What You Need to Know for a Successful Mediation", Ontario Bar Association (Young Lawyers Division/Alternative Dispute Resolution Section joint programme), Toronto, 2006
- "Class Counsel Fees and Costs Awards in Canadian Class Actions", Author, Class Action Reports, Vol. 27, September 2006
- "The Duty of Good Faith Bargaining and International Interference with Economic Interests", Law Society of Upper Canada, April 2006
- "Antitrust Class Actions North of the Border: Uncharted Territory", co-author, Class Action Reports, Vol. 26, No. 3, May-June 2005
- "Multi-Jurisdictional Class Actions: Emerging Issues and Future Dilemmas", Canadian Corporate Counsel Association Annual Meeting, August 2002
- "The Determination of Class Counsel Fees in Different Jurisdictions", by Steven Rosenhek, May 2002
- "Bringing Evidence from American Litigation into Canada: The Vitapharm Litigation", by Steven Rosenhek, January 2002

Steven F. Rosenhek

- "Class Actions: Exploding onto the Scene", by Steven Rosenhek, April 2001
- "Class Actions Across the Border - A New Kind of Litigation Comes to Ontario", by Steven Rosenhek, January/February 2001
- "Mandatory Mediation: The Ontario Experience", By Steven F. Rosenhek, presented at AIJA Annual Congress, Helsinki, Finland, August 2000

Memberships and Affiliations

- President, Ontario Bar Association, (1998 to 1999) and Chair, Paralegals Task Force (1999 to present)
- Law Society of Upper Canada
- International Bar Association
- l'Association Internationale des Jeunes Avocats
- l'Association des Juristes d'Expression Française de l'Ontario
- The Advocates' Society

Rankings and Awards

- Dean's Key, University of Toronto Law School, 1982



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Areas of Practice

Antitrust/Competition & Marketing

Litigation and Dispute Resolution

Insurance

Product Liability

Alternative Dispute Resolution

Class Actions

Defamation

Employment Law Advice

Estate Litigation

Human Rights

Pensions and Benefits

Competition Litigation, including Class Actions

Cartels & Other Competition Criminal Matters

Education

LLB, University of Toronto, 1982

B Comm, Queen's University, 1979

Paul Martin is the director of the Toronto office's Class Actions practice group. He has an extensive practice in all aspects of civil, administrative and quasi-criminal litigation at all levels of court in Ontario, with particular emphasis in the areas of class actions, product liability, defamation, shareholder rights, employment, financial institutions, insurance, securities regulation, competition, taxation and intellectual property. He has been counsel in matters before the Federal Court, the Supreme Court of Canada, the Ontario Municipal Board, the Tax Court of Canada, the Ontario Securities Commission, the Commercial Registration Appeal Tribunal, the Pensions Appeal Board and various administrative tribunals.

Paul is also an Adjunct Lecturer at Queen's University Faculty of Law where he teaches a course on class actions.

Representative Experience

- *Guidant Corporation v. Lefrancois*, [2009] (ON S.C.D.C.)
Counsel to Guidant Corporation, Guidant Canada Corporation, Guidant Sales Corporation and Cardiac Pacemakers Inc. in class proceeding
- *LeFrancois v. Guidant Corp.*, [2008] O.J. No. 1397 (S.C.J.)
Counsel to Guidant Corporation, Guidant Canada Corporation, Guidant Sales Corporation and Cardiac Pacemakers Inc.
- *Tele-Mobile Co. v. Ontario*, [2008] S.C.J. No. 12 (S.C.C.)
Counsel to the intervener the Canadian Bankers Association <http://www.cba.ca>
- *Bristol-Myers Squibb subject of Class Actions litigation in Canada*
Counsel to Bristol-Myers Squibb
- *Dumoulin v. Ontario*, 2006 CanLII 9598 (ON S.C.)
Counsel to the Ontario Realty Corporation

Paul J. Martin

Year of Call

Ontario, 1984

- *Wawanesa Mutual Insurance subject of class action alleging breach of contract*
Counsel to Wawanesa Mutual Insurance Company
- *David Polowin Real Estate Ltd. v. Dominion of Canada General Insurance Company (2005), 76 O.R. (3d) 161 (Ont. C.A.)*
Counsel to The Dominion of Canada General Insurance Co., ING Halifax Insurance Company, Wawanesa Mutual Insurance Company and Belair Insurance Company Inc.
- *Vennell v. Barnardo's, 2004 CanLII 33357 (ON S.C.)*
Counsel to Barnardos
- *McArthur v. Canada Post Corp., [2004] O.J. No. 1406 (S.C.J.)*
Counsel to Canada Post Corporation, Cybersurf Corp. and 3WEB Corp.
- *Hughes v. Sunbeam Corp. (Canada) Ltd., 2002 CanLII 45051 (ON C.A.)*
Counsel to the Underwriters' Laboratories of Canada
- *Major Canadian automobile insurers in multijurisdictional class actions in respect of allegations of improper retention of salvage and charging of deductibles in total loss accident scenarios*
Counsel to a number of major Canadian automobile insurers
- *Competition class actions relating to allegations of price fixing conspiracies*
Counsel in numerous class actions
- *Dupont Canada subject of class action regarding allegations of competition law related activities*
Counsel to Dupont Canada Inc.
- *Guidant Corporation subject of multijurisdictional class and individual actions*
Counsel to Guidant Corporation and its affiliates

Presentations

- Medical Devices in Canada: Hot Legal and Regulatory Issues, Life Sciences Group Seminar, April 6, 2010
- Class Actions Litigation, The Canadian Institute's 10th Annual National Forum, September 23-24, 2009

Paul J. Martin

- 9th Annual Forum on Litigating Class Actions, The Canadian Institute, September 22 - 23, 2008
- Follow the Money: Damages in Product Liability and Insurance Lawsuits - Recent Developments, Fasken Martineau Seminar, November 21, 2006
- Recent 'Must Know' Developments in Canadian Competition Law, Antitrust/Competition & Marketing Law Group Seminar, November 17, 2006
- Is Toxic Mold the New UFFI?, Speaker, 2006
- Drug Safety Conference, January 23-24, 2006
- Key differences between U.S. and Canadian antitrust/competition laws, Antitrust/Competition & Marketing Law Group Seminar, October 26, 2005
- Recent Developments in Canadian Competition Law, Antitrust/Competition & Marketing Law Group Seminar, September 29, 2005

Publications

- "Antitrust/Competition & Marketing Group 2009 Year in Review", Antitrust/Competition & Marketing Bulletin, January 2010
- "Podcast of Financial Institutions Seminar: "Legal and Regulatory Developments Affecting Financial Institutions"", Podcast of Financial Institutions Seminar, July 2008
- "An Insight into Antitrust/Competition Class Actions in Canada (Podcast)", March 2008
- "Cross-Border Class Actions: Opportunities and Challenges", 2008 Lexpert/American Lawyer Guide to the Leading 500 Lawyers in Canada, January 2008
- "2006 Year in Review: Cartels and other Criminal Matters, Class Actions and Private Access", Antitrust/Competition & Marketing Bulletin by Huy A. Do, Paul J. Martin and Mark D. Magro, March 2007

Paul J. Martin

- "Damages and Remedies in Class Actions: From Proof to Assessment", by Paul J. Martin and Richard D. Butler presented at Fasken Martineau client conference "Follow the Money: Damages in Product Liability and Insurance Lawsuits", November 2006
- "Antitrust Class Actions North of the Border: Uncharted Territory", co-author, Class Action Reports, Vol. 26, No. 3, May-June 2005
- "Class Action and Defamation: Haitian and Arab Taxi Drivers Authorized to Institute Class Action Against Radio Host André Arthur", June 2003
- "The Developing Role of Class Actions in Canadian Civil Justice Reform", by Paul J. Martin Reprinted from Metropolitan Corporate Counsel, November 2000
- "Class Actions - Recent Developments of Importance", by Paul J. Martin and Shelly M. Feld, January 2000

Memberships and Affiliations

- Member, Canadian Bar Association
- Member, American Bar Association (Section of Litigation - Class Action and Derivative Suits Committee and Antitrust Litigation Committee)
- Member, American Association for Justice - Commercial Litigation and Product Liability Subsections
- Member, Toronto Lawyers Association
- Instructor, Bar Admission Course and Ontario Centre for Advocacy Training (OCAT)

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