



SUMMER 2008

## IP Advocate

### HEENAN BLAIKIE VICTORY PUTS NOVO-PANTOPRAZOLE ON THE MARKET IN CANADA

by Andrew McIntyre

Once again, Heenan Blaikie has succeeded in patent litigation, allowing our client, Novopharm Limited, to bring a new generic pharmaceutical product to market. On April 11, 2008, Novopharm received a Notice of Compliance (“NOC”) to market Novo-pantoprazole, its generic version of Pantoloc. Pantoprazole is a proton pump inhibitor widely used to treat conditions where a reduction of gastric acid secretion is required.



ANDREW MCINTYRE

Novopharm’s NOC is a result of back-to-back wins by Heenan Blaikie in two separate applications, both launched by Nycomed (formerly Altana), which markets Pantoloc. The first application involved a patent for formulations containing pantoprazole. The second application involved two patents, both for the use of pantoprazole in treating *Helicobacter pylori*, a bacteria found in the stomach.

On March 6, 2008, the Federal Court dismissed the first application after finding that the patent at issue was improperly listed on the Canadian Patent Register (*Nycomed Canada Inc. et al. v. Novopharm Limited et al.*, 2008 FC 313). Accepting Heenan Blaikie’s submissions and applying the listing requirements set out by the Federal

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► Court of Appeal in *Wyeth et al. v. Ratiopharm Inc.*, 2007 FCA 264, Prothonotary Milczynski first determined that the “patented invention” was a particular formulation containing pantoprazole and not, as Nycomed argued, the use of pantoprazole as a proton pump inhibitor. In doing so, the Court confirmed that adding a known use to the end of a dependant claim merely establishes the utility of the formulation, since it adds nothing to the invention claimed.

Prothonotary Milczynski then considered whether there was a sufficiently relevant link between (1) the patented invention and (2) the Pantoloc drug submissions and resulting NOCs against which the patent was listed on the Register. The Court held that there was an insufficient link between the patented invention and the drug submissions in question and dismissed the application.

On April 8, 2008, Heenan Blaikie cleared the last hurdle in obtaining Novopharm’s NOC when the Federal Court dismissed the second application as an abuse of process (*Nycomed Canada Inc. et al. v. Novopharm Limited et al.*, 2008 FC 454). Heenan Blaikie showed that the application was an abuse of process in light of the decision of Justice Gauthier dismissing a related proceeding involving the same patents (*Solvay Pharma Inc. v. Apotex Inc. et al.*, 2008 FC 308).

Relying on the recent decision of the Federal Court of Appeal in *Sanofi-Aventis Canada Inc. v. Novopharm Limited*, 2007 FCA 163 (a case also successfully argued by Heenan Blaikie), Novopharm was able to draw a parallel between the two applications on the issues of infringement and inducing infringement. Prothonotary Lafrenière concluded that “[i]n light of the fact that Nycomed’s position with respect to infringement was found to be untenable in the Apotex Decision, and that Nycomed has not adduced any materially different evidence in this proceeding ... the application should be dismissed as an abuse of process.”

Of note, this is the first time that the Court has applied the abuse of process reasoning from *Sanofi-Aventis* to the issue of infringement. Previously, unsuccessful brand companies in NOC Proceedings had only been prevented from re-litigating the issue of validity against subsequent generics. However, as noted by Prothonotary Lafrenière, “[a]lthough allegations of infringement are generally fact-specific, it remains that the concerns expressed by Justice Sexton regarding the ‘integrity of the adjudicative process, the principle of finality, and the efficiency of the judicial system’ resonate just as strongly in prohibition proceedings raising such issues.” ■

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## HASTE MAKES WASTE: HURRIED AMENDMENTS TO THE PM(NOC) REGULATIONS MAY NOT WITHSTAND THE TEST OF TIME



NEIL FINEBERG

by Neil Fineberg

On April 26, 2008, the federal government surprised the generic drug industry and the provincial health ministries alike by announcing its intention to further amend the oft-litigated *Patented Medicines (Notice of Compliance) Regulations* (the “Regulations”). As drafted, the proposed amendments are expected to cause delay in the Canadian market entry of lower cost generic alternatives to patented medicines for, in some cases, years. The stated purpose of these unexpected amendments was to address a so-called “marked departure from precedent” flowing from the Supreme Court of Canada’s decision in *AstraZeneca Canada Inc. v. Canada (Minister of Health)*<sup>1</sup> and subsequent interpretations by the Federal Court. Only 15 days were provided for comment. Despite significant outcry from the generic industry, the provinces and the public, these amendments were proclaimed in force in a modified form on June 12, 2008. Their fate, however, is far from certain.

Generic drug companies obtain marketing approval by comparing their product to the equivalent brand product. This comparison could, in some cases, constitute patent infringement were it not for the so-called “early-working” exemption embodied in s. 55.2 of the *Patent Act*. This same section of the *Patent Act* also authorizes the Governor-in-Council to make regulations relating to “early-working” and is the legislative authority for the *Regulations* under discussion.

In *AstraZeneca*, the Supreme Court held that the application of the *Regulations* necessarily requires that the patents listed by a brand company against its product be capable of “early-working” by the generic applicant. Where it is impossible for a generic company to “early-work” a given patent,<sup>2</sup> the *Regulations* cannot apply and marketing approval for the generic should not be impeded. Underpinning this conclusion was the Court’s recognition that there must be a link between the patents

and the regulatory submissions associated with the product. The Supreme Court noted that this link is enshrined in section 4 of the *Regulations* as a precondition for the listing of patents on the Patent Register.<sup>3</sup> As mentioned, the Court also noted that the “early-working” link is the source of the Governor-in-Council’s regulation-making authority under the *Patent Act*.

Subsequent decisions, following the lead set in *AstraZeneca*, sought only to apply section 4 of the *Regulations* more exactly. In the leading case of *Ratiopharm Inc. v. Wyeth and Wyeth Canada*,<sup>4</sup> the Federal Court of Appeal recognized that the linkage between the patent at issue and the regulatory submission was not a mere “technical” one but was instead a critical component of the regulatory scheme. Where the patent at issue has no relationship to any of the submissions against which it was listed, a generic company cannot “early-work” it. If the patent cannot be

“early-worked” it cannot be eligible for listing on the Patent Register because the *Regulations* cannot apply to it.

It is this reasoning that the Regulatory Impact Analysis Statement (“RIAS”) accompanying the amendments on June 12 describes as a “marked departure from precedent.” By these amendments, the government seeks to retroactively list or re-list numerous patents that were refused or removed by the Minister following the *AstraZeneca* and *Wyeth* decisions. It also seeks to protect other patents from being removed from the Patent Register “solely on the basis that a patent ... submitted before June 17, 2006, is not eligible for inclusion on the register.”

The RIAS accompanying the April 26 pre-comment version of the amendments acknowledged that a “delayed savings to consumers and provincial drug plans” could be a consequence of their enactment. The concomitant benefits, of course, would flow directly to the brand pharmaceutical industry in Canada. Coupled with the short 15-day comment period, this situation precipitated a strong reaction from many quarters,<sup>5</sup> as well as several front page news stories in Canada’s national newspapers. ▶

- ▶ Despite this reaction, the amendments went ahead as scheduled, with one significant change. Transitional provisions were introduced that prevent refused or retroactively re-listed patents from affecting a generic company's marketing approval for submissions that have already been filed. Thus, generic companies that already have submissions filed with the government for products associated with patents listed or re-listed by virtue of these amendments should not be affected.

**Because patents unconnected to any submission made by a brand company cannot possibly be “early-worked” by a generic seeking marketing approval, there is serious doubt as to whether the government has the authority to make these amendments.**

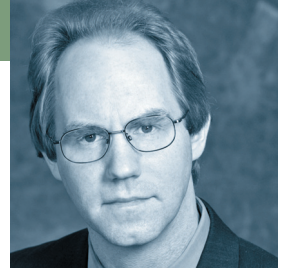
While these transitional provisions remove some of the immediate concerns voiced about these hurried amendments, the government did not address the serious jurisdictional concerns apparent on their face. As identified by the Supreme Court and Federal Court of Appeal, the *Regulations* require, as a pre-condition for listing, a link between the listed patent and the submission introducing it. Because patents unconnected to any submission made by a brand company cannot possibly be “early-worked” by a generic seeking marketing approval, there is serious doubt as to whether the government has the authority to make these amendments. It will be interesting to see if the shelf-life of these amendments is much longer than the six weeks they took to pass from proposal to enactment. ■

## ENDNOTES

- <sup>1</sup> [2006] 2 S.C.R. 560, 2006 SCC 49 (“*AstraZeneca*”).
- <sup>2</sup> The generic company in *AstraZeneca* had compared its product to (and sought to make a version of) LOSEC as it was in 1989. The patents at issue related to formulations of LOSEC that were no longer on the market, said patents having been filed in the 1990s. The inventions described in these patents, if any, could not possibly have been incorporated into the 1989 LOSEC product. Early-working of those mid-1990s patents in the process of pursuing the 1989 LOSEC product was therefore impossible.
- <sup>3</sup> The “Patent Register” is a special list of patents maintained on a per-drug basis by the Minister of Health. Each drug has a list of patents that must be addressed by each generic pharmaceutical company seeking to obtain marketing approval.
- <sup>4</sup> (2007), 60 C.P.R. (4th) 375, 2007 FCA 264 (“*Wyeth*”).
- <sup>5</sup> Jim Keon, President of the Canadian Generic Pharmaceutical Association, had this to say: “The brand-name pharmaceutical industry is the spoiled child of Canada’s intellectual property regime. Despite 20 years of government concessions, Big Pharma’s investments in research and development continue to fall below the levels they committed to when their government-granted monopolies were first increased in 1987. Now the Government of Canada is prepared to ignore the Supreme Court in order to let them continue their abuse of the patent system.”

## INVENTOR'S PAPERS CITED AGAINST HIS OWN PATENT APPLICATIONS

by Glenn Arnold



GLENN ARNOLD

In a recent decision (Decision No. 1282 of the *Decisions of the Commissioner of Patents*, issued April 30, 2008), the Canadian Patent Appeal Board (“PAB”) upheld a patent Examiner’s rejection of a Canadian patent application, on the basis that the invention had been previously disclosed in an article written by the inventor and published in a technical journal almost 12 years before the filing date of the application. The Commissioner concurred. The decision is a good reminder of the fact that while published patents are the most commonly found type of prior art, papers published by the inventor him or herself may also be cited as prior art.

The inventor and Applicant, Mr. Ioan Dancea, filed a Canadian patent application on February 27, 2001, for an invention related to integrated circuits called “Method and VLSI Circuits Allowing to Change Dynamically the Logical Behaviour.” The patent Examiner issued a Final Action on December 23, 2003, objecting to claims 1 to 12 for lack of novelty, obviousness and insufficient elements for proper operation. At the Applicant’s request, the Patent Appeal Board conducted a hearing on April 5, 2005, at which time the inventor represented himself.

For a patent to be granted for an invention, the invention must have novelty. The invention cannot be anticipated or publicly disclosed before the patent application is filed. In Canada there is a one year grace period before filing a patent application during which inventors can disclose the invention without anticipating their own invention.

Publicly available and searchable published patents are the most common type of prior art references cited by patent examiners. The Decision Summary lists

three references applied by the Examiner in objecting to the claims. Interestingly, all three were papers published by the inventor in the 1980s, including a 1989 Institute of Electrical and Electronic Engineers (“IEEE”) journal. The IEEE article was most important in the Examiner rejecting the application as it was the Examiner’s position that the IEEE paper anticipated the invention by disclosing the invention’s essential elements. The Decision Summary does not list any prior art patents as being cited by the Canadian Examiner. The IEEE paper was published almost 12 years before the filing of Dancea’s application, putting it far outside the grace period for prior disclosure by an inventor.

The decision includes a summary of relevant case law, and concludes that, “As the test for infringement permits the omission or substitution of non-essential elements of a claim (Free World Trust), it follows that a prior disclosure can omit or substitute non-essential elements and still anticipate a claim.” After an analysis comparing the claims with the IEEE paper, the Patent Appeal Board agreed with the Examiner that the claims are anticipated

by the IEEE paper. The PAB also agreed with the Examiner that the claims are obvious in view of a combined reference to the three papers cited by the Examiner.

In contrast, the Applicant was granted US patent 7,047,166 for the corresponding US application on May 16, 2006. Prior art references listed on the cover page of the US patent include 19 US patents, a 1999 FPGA Symposium paper and Dancea’s 1989 IEEE paper. The other two papers cited by the Canadian Examiner were not listed. Dancea’s 1989 IEEE paper was cited in an Office Action by the US Examiner against Dancea’s US application. In the Office Action, the US Examiner suggested to Dancea, who acted as his own patent agent, how to amend the claims for allowance. After a series of correspondences, a patent was granted with amended claims.

As illustrated by the different results of Dancea’s two patent applications, prior art searches performed by different searchers may turn up different prior art, and furthermore, patent Examiners from different Offices can apply the same prior art references differently. ■

## APPLICANT MUST SHOW USE OF MARK ABROAD AT TIME OF CANADIAN FILING

By Lilly Sormaz



LILLY SORMAZ

The Canadian Trade-marks Opposition Board (“Opposition Board”) has stated definitively that an applicant in Canada must demonstrate use of a mark in a foreign country in respect of its associated wares (or services) where an application in Canada is based on a foreign registration or application. The Opposition Board refused an application on this basis in *Allergan Inc. v. Lancôme Parfums and Beauté & Cie* (published in the Canadian Patent Reporter on April 23, 2008; (2007), 64 C.P.R. (4<sup>th</sup>) 147).

The applicant, Lancôme Parfums and Beauté & Cie, filed an application to register the trade-mark DERMOTOX in respect of the wares “cosmetics, namely milk, creams, gels, oils and powders for the face, body and hands” (the “Mark”). The application was filed on the basis of registration of the mark in France and use of the mark in association with the wares “cosmetic and make-up products.” The application was opposed by Allergan Inc. on the basis of its numerous registered trade-marks consisting solely of, or comprising, the word BOTOX.

The application was opposed on several grounds, one of which was s. 30(d) of the *Trade-marks Act*. Section 30(d) stipulates that if a trade-mark has not been used or made known in Canada, the name of a country in which the trade-mark has been used by the applicant (or the applicant’s named predecessor in title, if any) must be provided, in association with each of the general classes of wares or services described in the application.

Pursuant to s. 30(d), the Opponent argued that the application for DERMOTOX did not meet the requirements of this section as the Mark was not used in France by the Applicant and/or its licensee in association with each and every one of the wares described in the application. The

Opponent argued, in the alternative, that if the Mark was used, such use was discontinued and the mark was abandoned.

The Opposition Board accepted the s. 30(d) argument of the Opponent, and in doing so, assessed the foreign use requirement as of the date of the filing of the Canadian application. To support its argument, the Opponent submitted affidavit evidence of various Internet searches which showed there was no use of the Mark in France. The Applicant failed to adduce any evidence of use of the Mark in France, or in any other country or territory. The Opposition Board refused the application because it was satisfied that the evidence adduced by the Opponent raised serious questions regarding the use of the Mark in France by the Applicant. The Opposition Board further stated that it would have been simple for the Applicant to adduce evidence of use of the Mark.

This case is important because, while not proper practice, applications in Canada have been filed on the basis of use and registration in a foreign country when there was no actual foreign use of the mark as of the Canadian filing date, but use in a foreign country could be demonstrated when requested by the Registrar. Moreover, applications filed on the basis of s. 30(d), alongside s. 30(e) (which covers applications filed on the basis of proposed use in Canada) are considered preferable, as the s. 30(e) basis can be removed once the Registrar allows the application. Accordingly, the application is allowed on the basis of s. 30(d) and the applicant is not required to file a declaration of use in Canada. The cautious, and correct, approach for applicants filing an application for registration of a mark on the basis of s. 30(d) is to ensure that the mark is in use abroad as of the Canadian filing date. ■

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## CIRA IMPLEMENTS NEW REGISTRANT INFORMATION POLICY

by Matt Diskin

Faced with increasing concerns about individual privacy, the Canadian Internet Registration Authority (“CIRA”) has introduced a new procedure for accessing information about the holders (Registrants) of domain names. WHOIS is the Internet protocol used to look up the contact information of domain name Registrants, through an official database which contains the Registrant’s name, address, phone number, and email address. CIRA’s new policy limits access to such Registrant information through the WHOIS system. This information was publicly available before June 10, 2008, and CIRA has now placed itself as gatekeeper of this information.

In the case of individual Registrants, the new policy will, by default, keep personal information (name, address, *etc.*) private, while in the case of non-individual Registrants that information will be public by default. Non-individual Registrants can request that their contact information be kept private, but for CIRA to agree it must be satisfied that the Registrant has a legitimate need to protect the privacy of its information, specifically, that the nature of that Registrant’s operations or activities are such that disclosure of its information through the WHOIS protocol would likely to cause harm to individuals or to that Registrant.

A common problem faced by many Internet users is the “bad faith” registration of domain names. This occurs when a user without rights to a given name registers it as a domain name, primarily for the purposes of financial gain. There is a dispute resolution procedure available, and the first step usually taken by those seeking to challenge the registration of a particular domain name is to contact the administrative contact for the domain in order to demand that the name be transferred, or to negotiate a settlement. Under the newly implemented system, to access private information about a Registrant, a

requester must fill out a prescribed form and show that it has a “good faith” dispute with the site’s Registrant. These disputes include those relating to: trade-mark, patent or copyright infringement; infringement of a registered corporate, business or trade name; or the unauthorized use of the requestor’s personal information for unlawful purposes. Ironically, contact information requests can only be made by regular “snail mail” or courier. In addition to this program, CIRA has also implemented an online message delivery system that allows users to send correspondence to a Registrant’s administrative contact email address, however, the service does not guarantee that the message will be read or received.

There is also a special exemption for law enforcement agencies seeking private Registrant information. A law enforcement requestor must show CIRA that the information sought is required for carrying out an investigation relating to child exploitation, a denial of service attack (making a website unavailable), malicious hacking, phishing (fraudulently seeking confidential information) or pharming (redirecting users to illegitimate websites).

While this new system adds a somewhat onerous first step for those with a legitimate or “good faith” dispute, it also recognizes a right to privacy of those individuals who have registered domain names, and whose contact information would otherwise be laid out for any malicious Internet user to access. ■

**Under the newly implemented system, to access private information about a Registrant, a requester must fill out a prescribed form and show that it has a “good faith” dispute with the site’s Registrant.**



MATT DISKIN

## LIBEL CHILL SLOWLY WARMING

by Simon Chester

The Supreme Court of Canada has recently changed Canadian defamation law to give greater protection to shock jocks and opinionated commentary. In a decision released in late June (*Simpson v. Mair* [2008] SCC 40), it held that Vancouver talk-show host Rafe Mair had not defamed activist Kari Simpson in an editorial commentary on BC station CKNW. He was protected by the defence of fair comment. The court clarified how that defence worked, and expanded the space for spirited public debate.

In 1999, Kari Simpson was leading a campaign to prevent BC schools from teaching students about homosexuality in ways she suggested “promoted a homosexual lifestyle.” Rafe Mair took to the airwaves to criticize her in an editorial that suggested that Simpson was as bigoted as Hitler, as well as a couple of notoriously racist Governors in the southern United States at the height of the desegregation crisis, and that her position implicitly condoned violence against homosexuals. She sued for defamation.

While she lost at trial, Kari Simpson won in British Columbia’s Court of Appeal. The Court of Appeal held that Mair could not defend himself because he didn’t meet the technical requirements of the law. Similar restrictions have led many commentators to assert that Canadian commentators faced “libel chill,” since stories that would not be actionable in the United States could prompt law suits here.

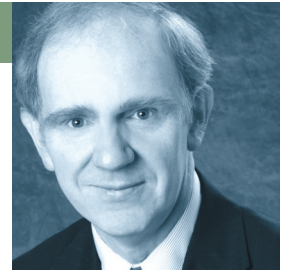
However, the Supreme Court overturned the Court of Appeal decision and effectively relaxed the requirement that an author must honestly believe in the comment made. Instead, it set the test as being whether anyone could hold that belief. It is not a very strong test.

So how do you now meet the fair comment defence?

- the comment must be on a matter of public interest;
- it must be based on fact;
- although it can include inferences of fact, it must be recognisable as comment;
- the opinion must be one that some person could honestly express, based on the proved facts; and
- the defendant must not be [subjectively] actuated by express malice.

While the court declined invitations to constitutionalize media rights (as was done in the pivotal US decision in *New York Times v. Sullivan*), it did recognize that the law must evolve in ways that reflect a proper balance between the Charter values of freedom of expression and the worth and dignity of each individual embodied in personal reputation.

Even so, spirited debate on matters of public interest should not be chilled unnecessarily. The caricatures of cartoonists or the lampoons of satirists should be respected – Justice Binnie comments on their “democratic right to poke fun at those who huff and puff in the public arena.”



SIMON CHESTER

Mair was as much an entertainer as a journalist, jousting with opponents in an environment where significant latitude should be given. What is important in such a debate on matters of public interest is that all sides of an issue are forcefully presented, although the limitation that the opinions must be ones that could be “honestly express[ed] . . . on the proved facts” provides some boundary to the extent to which private reputations can be trashed in public discourse.

With a sly reference to the subject of Kari Simpson’s crusade, Justice Binnie noted that:

“Public controversy can be a rough trade, and the law needs to accommodate its requirements.”

The decision is important for Canada’s creative community because it broadens an important defence. In doing so, it moves Canada closer to recent moves by courts in England and Australia to give the media more latitude to make strong comments about public figures.

Canada’s creative community used to worry about libel chill. But the law is definitely warming. ■

## RECENT PROFESSIONAL ACTIVITIES

**Priscilla Platt** chaired a Heenan Blaikie conference entitled “Hot Issues in Ontario’s *Freedom of Information and Protection of Privacy Act* (FIPPA) and *Municipal Freedom of Information and Protection of Privacy Act* (MFIPPA)” on June 18 in North Bay, Ontario.

**Andrea Rush** and **Glenn Arnold** wrote an article entitled “Business Method Patents - More Spins on the Idea,” published in the *Intellectual Property Journal*, in which they analyze two recent Patent Appeal Board decisions in a light which might advance the case for business-method patentability in Canada. Andrea is a member of the editorial board of the *Intellectual Property Journal*, published quarterly by Federated Press.

**Andrea Rush** was a speaker on copyright issues affecting the computer hardware, software and gaming sector, at the 8th Annual IT Law Spring Training Program, put on by the Canadian IT Law Association and The Law Society of Upper Canada in Toronto on May 1, 2008

On June 5, **Andrea Rush**, chaired the Law Society of Upper Canada’s Continuing Legal Education program, Intellectual Property Law Primer – Focus on Trade-Mark Law, and on June 13 she moderated a discussion on “How to Comply with Consumer Protection Regulations Around the World” at Stanford Law School’s Fifth Annual E-Commerce Best Practices Conference – How to Deal with the Uncertainties of Online Business.

An article written by **Jonathan Stainsby**, **Bill Mayo**, **Neil Fineberg** and **Keya Dasgupta**, entitled “Trends in intellectual property litigation in Canada,” was published in the 2008/09 edition of the Practical Law Company *Cross-border Dispute Resolution Handbook*.

**Adam Kardash** spoke at a session entitled “Dealing with the Office of the Privacy Commissioner of Canada (OPC)” at The Conference Board of Canada’s Meeting of the Council of Chief Privacy Officers in Montreal on June 3.

**John Salloom** gave a presentation entitled “Adopting Proactive Measures: Preventing Liability for Privacy Breaches” at a workshop hosted by the Society of Public Insurance Administrators of Ontario on May 27. On May 28 and May 29 he gave a presentation entitled “Advertiser and Promotions in China and Canada, and Marketing in Connection with the Olympic Games” at the American Conference Institute’s 21st Corporate Counsel Forum on Advertising Law, held in Las Vegas.

**Martha Harrison** and **Mark Edward Davis** gave a presentation entitled “When the Competition Rips Off Your Idea ... Who Do You Go To?” at the 2008 National Conference of the Forum for International Trade Training (FITT) held on June 1-2 in Ottawa, with more than 250 international trade professionals in attendance from the private, public and educational sectors. FITT is an international trade training and professional certification body.

**Mark Edward Davis** was interviewed for an article which appeared in *The Lawyer’s Weekly* newspaper on changes to Canada’s domain name WHOIS policy.

## IP PROFESSIONALS

**Key Contacts**

Andrea Rush	416 360.3541	arush@heenan.ca
Jonathan Stainsby	416 360.3568	jstainsby@heenan.ca
Bill Mayo	416 643.6861	bmayo@heenan.ca
François A. Raymond	514 846.2225	fraymond@heenan.ca
Glenn Arnold	416 360.6336	garnold@heenan.ca
Sandra Barton	416 643.6809	sbarton@heenan.ca
Catherine Bate	416 643.6875	cbate@heenan.ca
Cindy Bélanger	514 846.2234	cibelanger@heenan.ca
Lesley Caswell	416 643.6842	lcaswell@heenan.ca
Dean Chenoy	514 846.2342	dchenoy@heenan.ca
Simon Chester	416 643.6905	schester@heenan.ca
Mark Edward Davis*	416 643.6867	mdavis@heenan.ca
Keya Dasgupta	416 643.6825	kdasgupta@heenan.ca
Matthew Diskin	416 360.3538	mdiskin@heenan.ca
Étienne Dubreuil	514 846.2265	edubreuil@heenan.ca
Joanna Fine	416 360.3599	jfine@heenan.ca
Neil Fineberg	416 643.6859	nfineberg@heenan.ca
Louise Foong	416 643.6920	lfoong@heenan.ca
Ian Godfrey	416 360.3551	igodfrey@heenan.ca
Adam Goodman	416 643.6857	agoodman@heenan.ca
Rob Graham	416 360.3524	rgraham@heenan.ca
Orit Greenberg	416 643.6919	ogreenberg@heenan.ca
George Karayannides	416 360.3521	georgek@heenan.ca
Adam Kardash	416 360.3559	akardash@heenan.ca
Peter Mantas	613 237.1733	pmantas@heenan.ca
Geneviève Marcotte	514 846.2238	gmarcotte@heenan.ca
Andrew McIntrye	416 643.6930	amcintyre@heenan.ca
Gary D.D. Morrison	514 846.2268	gmorrison@heenan.ca
Priscilla Platt	416 360.3520	pplatt@heenan.ca
Andy Radhakant	416 643.6915	aradhakant@heenan.ca
Susan Rancourt	416 643.6813	srancourt@heenan.ca
Wendy S. Reed	416 360.3542	wreed@heenan.ca
Jim Russell	416 360.3561	jrussell@heenan.ca
Andrea Safer*	416 643.6801	asafer@heenan.ca
John Salloum	416 643.6818	jsalloum@heenan.ca
Douglas J. Simsovic	514 846.2340	dsimsovic@heenan.ca
Andrew Skodyn	416 360.3498	askodyn@heenan.ca
Lilly Sormaz	416 643.6897	lsormaz@heenan.ca
David Steinberg	416 360.3552	dsteinberg@heenan.ca
Julian Worsley*	416 643.6871	jworsley@heenan.ca
Stephen Zolf	416 643.6811	szolf@heenan.ca

\* *Editors*



# Canadian

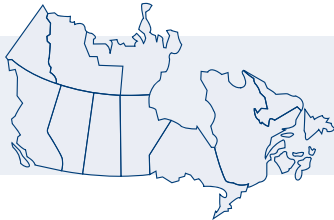
## Patent Case of the year

*NOVOPHARM ats SANOFI-AVENTIS*

A win for our client

A ground-breaking case

A typical day for our award winning team



1. **Bill Mayo**  
416 643.6861  
bmayo@heenan.ca

2. **Jonathan Stainsby**  
416 360.3568  
jstainsby@heenan.ca

3. **Mark Edward Davis**  
416 643.6867  
mdavis@heenan.ca

# Heenan Blaikie

Heenan Blaikie LLP • Lawyers | Patent and Trade-mark Agents • Ontario Quebec British Columbia Alberta • [heenanblaikie.com](http://heenanblaikie.com)



#### Toronto

P.O. Box 185, Suite 2600  
200 Bay Street  
South Tower, Royal Bank Plaza  
Toronto, Ontario M5J 2J4  
T 416 360.6336  
F 416 360.8425

#### Montreal

1250 René-Lévesque Blvd. West  
Suite 2500  
Montreal, Quebec H3B 4Y1  
T 514 846.1212  
F 514 846.3427

#### Vancouver

1055 West Hastings Street  
Suite 2200  
Vancouver, British Columbia V6E 2E9  
T 604 669.0011  
F 604 669.5101

#### Quebec

900, boul. René-Lévesque Est  
Bureau 600  
Québec (Québec) G1R 2B5  
T 418 524.5131  
F 418 524.1717

#### Calgary

12th Floor, Fifth Avenue Place  
425 - 1st Street SW  
Calgary, Alberta T2P 3L8  
T 403 232.8223  
F 403 234.7987

#### Sherbrooke

455, rue King Ouest  
Bureau 210  
Sherbrooke (Québec) J1H 6E9  
T 819 346.5058  
F 819 346.5007

#### Ottawa

55 Metcalfe Street  
Suite 300  
Ottawa, Ontario K1P 6L5  
T 613 236.1668  
F 613 236.9632

#### Trois-Rivières

1500, rue Royale  
Bureau 360  
Trois-Rivières (Québec) G9A 6E6  
T 819 373.7000  
F 819 373.0943

#### Victoria

737 Yates Street  
Suite 514  
Victoria, British Columbia V8W 1L6  
T 250 381.9321  
F 250 381.7023

## Heenan Blaikie



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