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## Supreme Court Decisions

This issue of IP Perspectives will focus on two important decisions rendered by the Supreme Court of Canada in patent cases on December 5, 2002, namely the Harvard Mouse case, relating to the

patentability of higher life forms, and the AZT case, relating to the extent to which a patent may be based on a sound prediction of utility.

## Supreme Court of Canada Disallows Patenting of Higher Life Forms

*Commissioner of Patents v. President and Fellows of Harvard College.*

In a 5:4 split decision released December 5, 2002, the Supreme Court of Canada overturned a Federal Court of Appeal ruling that patenting higher life forms is permissible under the Canadian *Patent Act*. David Morrow, Steven Garland and Colin Ingram of Smart & Biggar represented Harvard College in this landmark case.

With the Supreme Court's decision it appears unlikely that any higher life form, plant or animal, is patentable under Canadian law. In this regard, Canadian law has now fallen out of step with a number of other jurisdictions, including the United States, Europe and Japan. For example, the Applicant, the President and Fellows of Harvard College, had already been issued a patent in the United States for their "oncomouse" in 1988, and a European patent in 1991.

As no further appeal is possible, the only remaining avenue for the patenting of higher life forms in Canada is for Parliament to amend the *Patent Act* to expressly provide for their patentability.

The reasons of the majority are based on the conclusion that higher life forms do not fit within the definitions of "manufacture" or "composition of matter." The majority commented that the phrase "composition of matter" "does not fit well with common understandings of human and animal life" and that "patenting higher life forms would involve a radical departure from the traditional patent regime."

Although the decision means that higher life forms are not patentable, the majority accepts that unicellular life forms and cell cultures are patentable, and expressly declines to attempt to locate the line between patentable lower life forms and unpatentable higher life forms.

The majority repeatedly observes that this topic should be left to Parliament, stating that "if higher life forms are to be patentable, it must be under the clear and unequivocal direction of Parliament." The majority reasons can be read as a clear invitation for Parliament to take up the subject.

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Canadian law has now fallen out of  
step with other jurisdictions.

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In the immediate future, the Canadian patent profession will continue to explore effective ways of claiming genetically modified organisms short of claiming complete plants or animals. For example, the Patent Office accepts claims to modified genes, plasmids used to modify the genes, cells containing modified genes, methods of modifying genes, cells and life forms, methods of use of genes, cells and life forms, cultures of cells (including cultures of mammalian cells) and methods of use of cultures of cells. Claims to genes and cells may be effective to control the unauthorized reproduction of plants and animals.

Applicants with pending claims to genetically modified plants or animals who wish to attempt to retain those claims may elect to use various procedural techniques in order to keep the applications pending as long as possible, in the hope that amending legislation will intervene and render the claims patentable. Another possible technique is to make such claims the subject matter of a divisional application, while accepting a patent for allowable claims of the types discussed above. The divisional application would then be kept pending by various methods. Any such divisional application would be

subject to possible concerns about double patenting which should be carefully evaluated before deciding on such a course of action.

Since the majority judgment specifically addressed only the patentability of mammals, and expressly refrained from defining the line between higher and lower life forms, it would be possible to pursue claims to, for example, a plant or an invertebrate, through the appeal process and possibly as far as the Supreme Court.

*A. David Morrow & Colin B. Ingram, Ottawa*

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## Supreme Court of Canada Reaffirms the Doctrine of Sound Prediction in Canadian Patent Law

*Apotex Inc. v. Wellcome Foundation Ltd.*

In a unanimous decision released on December 5, 2002, the Supreme Court of Canada has upheld the validity of the AZT patent held by the Wellcome Foundation Limited and Glaxo Wellcome Inc. (Glaxo/Wellcome). The decision is of particular interest for its detailed review of the requirement of utility in Canadian patent law and the extent to which the doctrine of sound prediction can be relied upon in supporting the utility of a patent claim.

In the early 1980s, testing of the previously synthesised compound AZT on murine retroviruses led Glaxo/Wellcome researchers to believe the compound might have a use as a treatment for HIV. Glaxo sent the compound to two scientists at the U.S. National Institutes of Health (NIH) for further testing. Based on the success of those in vitro tests on human cells, Glaxo/Wellcome submitted a patent application to the U.K. patent office, and subsequently filed a patent application in Canada, claiming priority from the U.K. application. In 1990, the generic manufacturers Apotex and Novopharm instituted an action in Canada against Glaxo/Wellcome, claiming that the patent at issue was invalid.

The central issue of the case was a challenge to validity based on the argument that the necessary utility had not been established as of the priority

date of the Canadian patent — the filing of the U.K. application on March 16, 1985. The specific allegation was that the compound's prophylactic properties, as opposed to its treatment properties, had not been established as of that date. Validity was also challenged on the basis of a failure to name all of the inventors, because Glaxo/Wellcome did not name as co-inventors two individuals from the NIH who carried out in vitro testing of AZT in a human cell line.

### Utility

Section 2 of the Canadian *Patent Act* requires that an invention be "new and useful." The Court confirmed that a claimed invention must have "utility" — i.e., it must be useful for the purpose claimed. The Court stated that where the new use is the invention, "the utility required for patentability must, as of the priority date, either be demonstrated or be a sound prediction based on the information and expertise then available."

### The Doctrine of Sound Prediction

The doctrine of sound prediction has been established in Canadian law for some time. However, the Court, in this decision, has extensively reviewed the history, scope and applicability of the doctrine,

noting that it balances the public interest in having early disclosure of new and useful inventions prior to full verification of utility, while avoiding a grant of patent rights based on the disclosure of speculative information. The Court identified a three-component requirement of the doctrine:

1. There must be a factual basis for the prediction;
2. The inventor must have at the date of the patent application an articulable and “sound” line of reasoning from which the desired result can be inferred from the factual basis; and
3. There must be proper disclosure of the foregoing.

The Court was careful to note that the soundness of the prediction is a question of fact and each case will turn on the particular details associated with the discipline to which the subject matter relates, and the evidence in respect thereof.

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## Bare speculation will not amount to sound prediction.

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The Court reaffirmed a long-standing position that sound prediction will not successfully support a patent claim if either the prediction at the date of the application was not sound or, irrespective of the soundness of the prediction, there is evidence of lack of utility in respect of some of the areas covered by the claim.

### Sound Prediction and Pharmaceuticals

The Court has provided noteworthy clarification of certain issues that are of particular relevance to the pharmaceutical field.

- The Court recognized comments from earlier jurisprudence that the predictability of chemical reactions differed from the predictability of pharmacological effects and utility, while confirming that pharmacological utility is capable of prediction.

- The Court affirmed factual conclusions from the trial judge that the inventors possessed and disclosed in the patent application both the factual data on which to base the prediction and a line of reasoning to enable them to make a sound prediction at the time they applied for the priority patent.
- Moreover, the Court affirmed the trial judge’s conclusion that the *in vitro* tests to the human cell line would be adequate where the art would accept this as appropriately correlated to *in vivo* utility – i.e., testing in humans.
- The Court rejected the suggestion that Glaxo/Wellcome was required to demonstrate utility through prior human clinical trials.

### After-the-fact Validation

The Court confirmed that bare speculation, even if it afterwards turns out to be correct, will not amount to sound prediction. It rejected the suggestion, arising from earlier Canadian Federal Court of Appeal decisions, that mere speculation which later turned out to be true would be considered a sound prediction.

### Inventorship

In reviewing inventorship, the Court characterized the ultimate question as: who is responsible for the inventive concept? The Court distinguished those who participate in the conception of the invention from those who participate in its verification. Notwithstanding the significant contribution made by the two individuals from the NIH, which served to support the utility through sound prediction, the Court concluded that they were not co-inventors.

This decision of the Supreme Court of Canada provides an extensive and valuable review of the doctrine of sound prediction. The decision is a reminder of the importance to be placed on the documentation of invention and testing activity.

*John Bochnovic, Ottawa*

## International Patent Applications – Sequence Listing Requirements on Entry Into the National Phase in Canada

If an international patent application discloses a sequence of four or more amino acids or 10 or more nucleotides that is not identified as being in the prior art, then a sequence listing that complies with WIPO Standard ST.25 must be filed in the Canadian national phase.

Paper and computer readable copies of the sequence listing must be filed by the later of 36 months from the earliest priority date or six months after national entry. Unfortunately, the Canadian *Patent Rules* state that the application is deemed to be abandoned if the sequence listing requirements are not completed by this date.

The Canadian Patent Office often fails to review applications for compliance with formal requirements within the above-mentioned time period. As a result, the first communication received from the Patent Office concerning the sequence listing requirements may be a Notice of Abandonment for failure to file a sequence listing.

The abandoned application can be reinstated by filing the sequence listing, requesting reinstatement, and paying a \$200 government fee within one year of the date of abandonment. If the one-year deadline passes without reinstatement, the application can not be revived for any reason.

It is not known what the Patent Office would do if the failure to comply with the sequence listing requirements were identified only after the expiry of the one-year reinstatement period after the date of deemed abandonment. If it followed its current practices consistently, the Patent Office should declare such an application to be irrevocably abandoned. We do not know if the Patent Office would take this drastic step during examination, but the issue might well be raised during litigation over the validity of a patent issuing on the application.

Moreover, because the *Rules* speak of *deemed* abandonment for failure to comply with the sequence listing requirements, an application could be considered abandoned even if the Patent Office never raises the sequence listing requirements during prosecution.

We expect that this anomaly in the Canadian *Patent Rules* will be corrected in the next amendments to the *Rules*. But we cannot predict when such corrective amendments will be made, or if they will be of retroactive effect. In the meantime, it is incumbent on applicants entering the national phase in Canada to alert their Canadian agent to the presence of nucleotide or amino acid sequences in the international application.

*David E. Schwartz, Ottawa*

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## Firm Sponsors Summer Program in International Intellectual Property Law

*Unique partnership of leading educational institutions and law firms.*

Smart & Biggar is pleased to announce the second year of a unique professional education and training program for legal practitioners and academics who want to gain a comprehensive understanding of both the theory and practice of international IP law. The

Summer Program in International and Comparative Intellectual Property Law is the only course of its kind to combine academic coverage by three leading educational institutions with practical instruction by respected leaders of the international IP community.

The program is offered jointly by the University of Victoria Faculty of Law in Canada; St. Peter's College at Oxford University and the Oxford Intellectual Property Research Centre in the U.K.; and the University of Illinois College of Law in the United States. It is delivered in partnership with Smart & Biggar in Canada, Brinks Hofer Gilson & Lione in the United States and Bird & Bird in Europe and Asia.

This year, the program is offered in July and August at St. Peter's College at Oxford University in the United Kingdom.

For more information, please contact Michael D. Manson in our Vancouver office. You may also visit the program web site to register at [www.ipint.org](http://www.ipint.org) (click professional specialization certificate program) or <http://www.uvcs.uvic.ca/ip>.

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## Firm Tops LEXPERT Survey - Again

LEXPERT/American Lawyer Media has published *The 2003 Guide to the Leading 500 Lawyers in Canada* and the Guide has once again acknowledged the Firm and several of its partners.

"...it is important to note that many intellectual property practitioners have national practices, with their work in no sense being limited to the city where the firm has its principal office. The Toronto, Ottawa, Montreal, Vancouver and Edmonton offices of the IP boutique Smart & Biggar warrant special comment, however, in that it is the only firm in this practice area with multiple offices and leading lawyers in major centers across Canada."

For the fifth consecutive year, *LEXPERT/American Lawyer Guide to the Leading 500 Lawyers in Canada*

has identified Smart & Biggar as having more leading lawyers in the areas of intellectual property law and intellectual property litigation than any other firm. We are proud of this recognition and congratulate all of our partners who are listed in this year's Guide:

**James D. Kokonis, Q.C.** (Intellectual Property Law and Intellectual Property Litigation)

**A. David Morrow** (Intellectual Property Law and Intellectual Property Litigation)

**John R. Morrissey** (Intellectual Property Law)

**François Guay** (Intellectual Property Law and Intellectual Property Litigation)

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## Three Members of the Firms Retiring as Active Partners

*Alan R. Campbell* has retired as a managing partner of Fetherstonhaugh and Smart & Biggar and will continue as a non-managing partner.

*Hugh O'Gorman* has retired as a managing partner of Fetherstonhaugh, and will continue his association with the firm as a non-managing partner.

*Michael E. Wheeler* has retired as a managing partner

of Fetherstonhaugh, and will continue as a non-managing partner.

The partnerships extend their heartfelt thanks and best wishes to Alan, Hugh and Michael for their many decades of loyal and valuable service to the firms and their clients, and wish them a long, healthy and enjoyable retirement.

## New Partners

The partners of Smart & Biggar / Fetherstonhaugh are pleased to announce that effective January 1, 2003, *Timothy P. Lo*, *Elliott S. Simcoe* and *Theodore W. Sum* have become partners of the Firms, and *R. Allan Brett*, *Neil S. Clark* and *A. Oliver Stone* have become partners of our patent and trade-mark agency firm Fetherstonhaugh.

*Allan Brett's* practice involves complete patent portfolio development and management for clients in various sectors including telephony, Internet, communications systems and components, wireless systems, photonics, control systems, digital rights management, software, computers and computing industries. Allan is a registered patent agent.

*Neil Clark* handles patents, trade-marks and industrial designs. In his patent work, Neil specializes in the field of mechanical devices. He has worked with both large and small clients in preparing patent applications for such diverse inventions as log handling and processing equipment, residential heating and fireplace systems, and medical equipment for in vivo detection of cancer. Neil is a registered patent agent.

*Timothy Lo's* practice extends to all areas of intellectual property law, including litigation before the Federal Court of Canada and the British Columbia Supreme Court. He has extensive experience preparing and prosecuting trade-mark applications domestically and abroad, and has assisted with the preparation and prosecution of patent applications, particularly those relating to nucleotide and protein sequences. Tim is a registered patent and trade-mark agent.

*Elliott Simcoe* has a broad range of experience in all aspects of intellectual property and computer law including litigation, licensing, prosecution and counseling, with an emphasis on patent, trade-mark and copyright litigation in the Federal Court of Canada. He has also advised clients on Canada's newly enacted *Personal Information Protection and Electronic Documents Act*. In addition, he has extensive experience in counseling clients and litigating matters involving the Internet, including copyright infringement, trade-mark infringement and related domain name matters. Elliott is a registered patent and trade-mark agent.

*Oliver Stone's* practice includes the drafting and prosecution of patent applications primarily in the fields of electronics and telecommunications. He handles inventions in a wide range of technologies, including power generation, semiconductor device fabrication, mass spectrometry, surface analysis, lasers and electrical and electromechanical devices. Oliver is a registered Canadian patent agent, a chartered U.K. patent agent and a European patent attorney.

*Theodore Sum's* practice covers all aspects of intellectual property law and information technology law with particular emphasis on licensing and commercialization, patent and trade-mark prosecution, online issues including privacy and security, and advising Canadian, U.S. and foreign clients on protecting and commercializing their intellectual property. Ted is a registered patent and trade-mark agent.

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## Notes

### Announcements

We are pleased to announce that the following individuals have joined the Firms:

*Elizabeth A. Hayes* has joined our Ottawa office as a technical consultant. Ms. Hayes has a B.Sc. in Biochemistry from the University of British Columbia and an M.Eng. in Biomedical Engineering from McGill University.

*Beverly C. Lai* has joined our Montreal office as a technical consultant. Ms. Lai has a B.Eng. in Computer Engineering from McGill University.

*Tai W. Nahm* has joined our Toronto office. Mr. Nahm has a B.A.Sc. in Systems Design Engineering from the University of Waterloo. He received his LL.B. from Osgoode Hall Law School and was called to the Ontario Bar in 1998. Mr. Nahm became a registered patent agent in 2002.



*Susan M. Tees* has joined our Vancouver office as a technical consultant. Ms. Tees has a B.Sc. in Microbiology from the University of British Columbia and became a registered U.S. patent agent in 1999.

*Helen Ka Fung Wong* has joined our Edmonton office. Ms. Wong has a B.Sc. in Honours Physiology from the University of British Columbia and an LL.B. from the University of Alberta. She was called to the British Columbia Bar in 2002.

### Seminars and Presentations

*Sanjay D. Goorachurn* presented on the topic of "IP Management" at PPRICAN on November 6, 2002, in Montreal.

*Philip Lapin* wrote a paper and gave a presentation on the subject of section 12(1)(d) of the *Trade-marks Act* to new trade-mark examiners at the Canadian Trade-marks Office on November 18, 2002.

*Stephan P. Georgiev, Sanjay D. Goorachurn* and *François Guay* gave a presentation entitled "Intellectual Property – Guidelines for Entrepreneurs and Investors" to Investissements Desjardins in Montreal on November 26, 2002.

*Jean-Sébastien Brière, Stephan P. Georgiev, Sanjay D. Goorachurn* and *Brigide Mattar* presented on the topic of intellectual property management in a presentation entitled "Le capital de propriété intellectuelle : comment en tirer le maximum de profits?" on November 27, 2002, at the Parc Technologique du Québec Métropolitain in Québec City.

*Kavita Ramamoorthy* gave a lecture entitled "Intellectual Property in Drug Development" at the University of Toronto as part of a course entitled "Topics in Drug Development." The lecture was held November 27, 2002.

*Stephan P. Georgiev* presented on the topic of "Stratégies pour maintenir, protéger et maximiser votre portefeuille de brevets" as part of an Infonex summit entitled Sommet Québécois, sur la Propriété Intellectuelle. The summit was held December 2 - 3, 2002, in Montreal.

*Sanjay D. Goorachurn* presented on the topic of "Issues in Managing and Commercializing Intellectual Property – NCE Perspective" on December 3, 2002, at the Annual Meeting of Canadian National Centres of Excellence in Ottawa.

*Elliott S. Simcoe* and *Philip Lapin* are teaching a course entitled "Intellectual Property and Technology Law for Engineers" at the Department of Engineering of the University of Ottawa from January to April 2003.

*Ron D. Faggetter* spoke on the topic of the patentability of computer software at the Infonex Intellectual Property Summit 2003, held in Toronto on January 20, 2003.

*Stephan P. Georgiev, Sanjay D. Goorachurn* and *Brigide Mattar* presented on the topic of intellectual property management in a presentation entitled "Le capital de propriété intellectuelle : comment en tirer le maximum de profits?" on February 6, 2003, at the Parc Technologique du Québec Métropolitain in Québec City.

*L. Catherine Eckenswiller* spoke on the topic of "Licensing concepts and Issues with Genetics" at an Insight conference on genetic patents held February 10 - 11, 2003, in Ottawa. At the same conference, *Joy D. Morrow* was a panel member, discussing the topic of "Genetic Patents in the International Arena: Recent Cases, Outcomes and Legislation."

*Michael D. Manson* spoke on the topic of "Infringement Remedies" at a meeting of the Licensing Executives Society – Edmonton Chapter, held on February 12, 2003.

*Michael D. Manson* will give a talk on the topic of IP Protection entitled "IP Rights – Litigate, Negotiate, or Collaborate" at a University of British Columbia/Westlink conference to be held in Vancouver on March 4, 2003.

*Michael D. Manson* will be speaking on the topic of "Commercialization Options for Intellectual Property" at a conference co-sponsored by Alberta Innovation and Science and the Alberta Research Council. The conference will be held in Edmonton on March 5, 2003.

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*A. David Morrow* will be speaking on the "Examination of Biotech Patent Issues – The Harvard Mouse Case" at an Insight conference on drug patents to be held March 27 - 28, 2003, in Toronto. *Gunars A. Gaikis* will be speaking at the same conference during a session entitled "Recent Developments: Are the Patented Medicines NOC Regulations Working?" He will examine the question from a patentee's perspective.

*A. David Morrow* will speak on patent issues at the IPIC Spring Meeting to be held in Ottawa on April 14 - 15, 2003.

*Gunars A. Gaikis* will be speaking on patent issues relating to pharmaceuticals at a Federated Press Conference to be held April 28 - 30, 2003, in Toronto.

*Michael D. Manson* will be speaking at the INTA symposium to be held May 2 - 4, 2003, in Amsterdam.

*A. David Morrow* will be a panel member during the "Standards of Review (in Appeals)" session at an

event entitled "Advocacy Before the Federal Court on Intellectual Property Matters," presented by the Canadian Bar Association's National Intellectual Property Section and the Continuing Legal Education Committee, to be held in Ottawa on May 15, 2003.

## Publications

*Gunars A. Gaikis*, "Canadian Court Delays Registration of AstraZeneca's Trade-marks for the Appearance of its Plendil (Felodipine) Tablets," *Law Lore & Practice (LLP)*, December 2002.

*Elliott S. Simcoe*, "Satellite Television Piracy in Canada," *Copyright World*, February 2003.

*Michael D. Manson* and *David A. Gileff*, "Evidentiary Issues Relating to Affidavits in Trade-mark Oppositions Proceedings," 18 C.I.P.R. 659.

*L. Catherine Eckenswiler*, "Cost-Effective Intellectual Property Management," *Inside Counsel*, Spring 2003.

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The preceding is intended as a timely update on Canadian intellectual property law. In order to request a copy of any decision, paper or legislative document, or for more detailed information or suggestions, kindly contact an author of the relevant article, or the Editor, *A. David Morrow*. The contents of our Newsletter are informational only, and do not constitute legal or professional advice. To obtain such advice, please communicate with our offices directly. To be put on the *IP Perspectives* mailing list, or to amend address information, please call (416) 593-5514 (extn. 386).