



IP UPDATE

CANADIAN PHARMACEUTICAL INTELLECTUAL PROPERTY LAW NEWSLETTER

Supreme Court of Canada Finds Higher Life Forms Unpatentable

Commissioner of Patents v. President and Fellows of Harvard College

In a 5:4 decision released December 5, 2002, the Supreme Court of Canada has ruled that a genetically modified mammal is not patentable subject matter under the Canadian *Patent Act*.

The patent application at the center of the proceedings contains claims to a transgenic, non-human mammal, colloquially referred to as the “Harvard Mouse” or the “oncomouse”. The preferred embodiment of the invention is a laboratory mouse, whose genes have been modified to increase its susceptibility to cancer. Claims 1-12 of the application, the claims to the transgenic mammal, were rejected by the Commissioner of Patents in August of 1995 as being directed to non-patentable subject-matter. The remaining claims of the application, including claims to methods of producing the transgenic mammals and transgenic cell cultures, methods of testing materials suspected of being carcinogens using the transgenic mammals, and various plasmids and somatic cell cultures were found to be allowable during prosecution.

An appeal to the Federal Court Trial Division was dismissed. On a further appeal to the Federal Court of Appeal, it was held in a 2:1 decision that claims 1-12 of the application were patentable under the Canadian *Patent Act*.

The reasons of the majority of the Supreme Court were written by Justice Bastarache. Central to the majority’s decision is an extensive review of the definition of “invention” in the *Patent Act*, and an assessment as to whether a higher life form is a “manufacture” or “composition of matter” as those terms are used in that definition.

The analysis commences with a review of the words of the *Act*. The majority finds that while the words used in the definition of invention are broad, it does not follow that the definition encompasses “anything new and useful made by man” – an expression referred to by the U.S. Supreme Court during its analysis of the corresponding definition in the U.S. *Patent Act*. The majority notes that the Canadian definition is exhaustive, signaling a clear intention by Parliament to include certain subject matter as patentable, and to exclude other subject matter.

After a review of the definitions of “manufacture” and “composition of matter” the Court concludes that higher life forms do not fit within these terms. Moreover, in the majority’s view, the patenting of higher life forms would involve a “radical departure” from the traditional patent regime in Canada, requiring an “unequivocal direction from Parliament.”

The majority next reviews the scheme of the existing *Patent Act*. It finds that the patenting of higher life forms raises “unique concerns” which do not arise with respect to non-living inventions and which cannot be addressed by the scheme of the *Act*. Concerns considered by the Court include the ability of higher life forms to self-replicate, the complexity of higher life forms, and the spectre of patents on humans. In the majority’s view, the lack of direction within the current *Patent Act* to deal with such issues is further support for its position that higher life forms are not patentable.

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The majority also reviews the object of the *Patent Act*. They accept that the object of the *Patent Act* is to encourage and reward the development of innovations and technology, which suggests that the definition of invention should be given a broad reading. However, the majority reiterates that Parliament chose an exhaustive definition for invention, and therefore not everything is to be patentable.

The majority also places some reliance on the existence of related legislation, namely, the *Plant Breeders' Rights Act*. In this regard, the majority finds that the existence of the plant breeders' legislation is some indication of legislative intent, and also demonstrates that mechanisms other than the *Patent Act* may be used to encourage inventors to undertake innovative activity in the field of biotechnology.

Finally, the majority expressly addresses the question of whether it is appropriate to draw a line between lower life forms and higher life forms, which would not be patentable in view of the majority's reasons. The majority acknowledges that lower life forms have been accepted as patentable by the Canadian Patent Office since the decision in *Re Application of Abitibi Co.* (1982), 62 C.P.R. (2d) 81, noting that the issue has never been litigated in Canada. The majority holds that the distinction between lower and higher life forms is not explicit in the *Act*, but is nonetheless defensible on the basis of "common sense differences between the two".

Three broad justifications for the distinction are offered.

First, the majority observes that micro-organisms are produced *en masse* as chemical compounds are prepared, and are prepared and formed in large numbers in which any measurable quantity can possess uniform properties and characteristics. According to the majority, the same cannot be said of plants and animals.

Second, the majority focuses on distinctions that can be made between animals (the subject-matter of the patent claims in issue) and lower life forms. The majority highlights the capacity to display emotion and complexity of reaction and to direct behaviour in a manner that is not predictable as stimulus and response, traits that it states are unique to animal forms of life.

Finally, the Court notes that the World Trade Organization's *Agreement on Trade Related Aspects of Intellectual Property Rights* (TRIPS), and the *North American Free Trade Agreement* (NAFTA), each contain an article whereby members may "exclude from patentability" certain subject matter, including plants and animals other than micro-organisms. In the view of the majority, the fact that there is a specific exception in TRIPS and NAFTA for plants and animals does demonstrate that the distinction between higher and lower life forms is widely accepted as valid.

However, notwithstanding its efforts to justify the distinction between higher and lower life forms, the majority makes no effort to draw the line between (unpatentable) higher life forms and (patentable) lower life forms – an exercise that will apparently be left to the Patent Office.

Four members of the Court concurred in dissenting reasons, written by Justice Binnie. While the law of Canada is now reflected in the majority's reasons, discussed above, it is interesting to note that the minority was highly critical of the majority's reasons, and in particular the distinction drawn by the majority between higher and lower life forms in terms of patentability.

On strict legal theory, it may be arguable that the decision does not exclude plants or lower, but multicellular, animals such as invertebrates from patentability. However, the majority's reasons are broadly worded, and assess issues underlying the patentability of the transgenic mammal that is the subject-matter of the claims, as well as other so-called higher life forms, such as plants. It is therefore unlikely that any higher life form, plant or animal, would be accepted as patentable under Canadian law by the Commissioner or any tribunal lower than the Supreme Court itself. In this regard, Canadian law has now fallen out of step with a number of other jurisdictions, including the United States, Europe and Japan where patents have been granted to Harvard for this invention.

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

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.

A. David Morrow, Steven B. Garland and Colin B. Ingram of Smart & Biggar represented Harvard College in this appeal.

A. *David Morrow and Colin B. Ingram*

Supreme Court of Canada Decisions

Canada (Commissioner of Patents) v. Harvard College, December 5, 2002

Supreme Court of Canada finds higher life forms not patentable under Canada's *Patent Act*. For more information, please see the article on page 1 of this issue and our December 5, 2002 issue of *IP Update*.

[Supreme Court Bulletin](#)

[IP Update](#)

Apotex Inc. v. Wellcome Foundation Ltd. (zidovudine, AZT (RETROVIR)), December 5, 2002

Supreme Court of Canada dismisses appeal of decision finding valid Glaxo/Wellcome's patent for the use of AZT for the treatment of AIDS. For more information, please see our December 6, 2002 issue of *IP Update*.

[Supreme Court Bulletin](#)

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Recent Court Decisions

Patented Medicines (Notice of Compliance) Regulations

Bristol-Myers Squibb v. Attorney General of Canada (paclitaxel for injection (TAXOL)), November 22, 2002 & December 20, 2002

In a decision dated November 22, 2002, a Court considers for the first time subsection 5(1.1) of the *Patented Medicines (Notice of Compliance) Regulations* ("Regulations"). Biolyse had submitted a new drug submission (NDS) for its paclitaxel, which did not designate a Canadian reference product and where no second drug was used for comparative purposes to assess the safety and efficacy of Biolyse's paclitaxel. The Court quashes a Notice of Compliance (NOC) issued to Biolyse based on its NDS. The Court finds that the Minister should have required Biolyse to serve a Notice of Allegation (NOA) on Bristol-Myers Squibb, since subsection 5(1.1) of the *Regulations* applied: Biolyse's product contains a medicine which is

found in another drug, TAXOL, that has been marketed in Canada pursuant to an NOC and in respect of which a patent list has been submitted.

In a decision dated December 20, 2002, Biolyse is granted a stay of the above decision pending the disposition of its appeal.

[Decision to Quash NOC](#) (*For a printer friendly version, please scroll down to the end of the Judgment)

[Decision to Stay](#) (*For a printer friendly version, please scroll down to the end of the Judgment)

AstraZeneca AB v. Apotex Inc. (omeprazole tablets (LOSEC)), December 2, 2002

Motion to have AstraZeneca's application dismissed as frivolous, vexatious and an abuse of process is dismissed. One of the issues raised in the application is the sufficiency of the NOA. The Court, considering only this issue, finds that this issue is not so clearly improper as to be bereft of any possibility of success.

[Full Judgment](#) (*For a printer friendly version, please scroll down to the end of the Judgment)

AstraZeneca Canada Inc. v. Apotex Inc. (omeprazole tablets (LOSEC)), December 2, 2002

Motion to have AstraZeneca's application dismissed as redundant, scandalous, frivolous, vexatious or an abuse of process is dismissed. One of the issues raised in the application is whether Apotex is precluded from relying on the related NOA by reason of the doctrines of *res judicata*, abuse of process and estoppel. The Court, considering only this issue, finds that this issue is not so clearly improper as to be bereft of any possibility of success.

[Full Judgment](#)

Eli Lilly Canada Inc. v. The Minister of Health (COMPUDOSE implants), December 2, 2002

Court upholds Minister's decision to remove patent for COMPUDOSE implants from the patent register. The Court finds, *inter alia*, that the claims of the patent relate to an implant and a method of preparing that implant that is designed to administer a medicine, and concludes that they do not relate to a claim for the medicine or a claim for the use of a medicine.

[Full Judgment](#) (*For a printer friendly version, please scroll down to the end of the Judgment)

Other Decisions

Apotex Inc. v. Ontario (Minister of Health) (**lisinopril (APO-LISINOPRIL)**, **perphenazine (APO-PERPHENAZINE)**), November 14, 2002

Court dismisses judicial review application of decision of Minister of Health refusing to recognize, process and accept price increases for Apo-Lisinopril and Apo-Perphenazine. Apotex had submitted, *inter alia*, that Ontario regulations governing the drug benefit price for interchangeable drug products and the “no price increase” policy were *ultra vires*, and even if *intra vires*, were unlawful as arbitrary, discriminatory, irrational and directed to extraneous purposes.

[Full Judgment](#)

Richter Gedeon Vegyészeti Gyar RT v. Apotex Inc. (**famotidine (APO-FAMOTIDINE)**), December 10, 2002

Appeal of Order requiring Apotex to produce a one-gram sample of famotidine to allow the plaintiff to determine whether Apotex' famotidine is of the claimed Form B is dismissed. This decision arises in the context of a patent infringement action. Apotex has appealed.

[Full Judgment](#) (*For a printer friendly version, please scroll down to the end of the Judgment)

Board Staff of the Patented Medicines Prices Review Board v. Hoechst Marion Roussell (**nicotine patches (NICODERM)**); *Patented Medicines Prices Review Board v. Hoechst Marion Roussell* (**nicotine patches (NICODERM)**), December 17, 2002

Appeals of decision refusing the Staff of the Patented Medicines Prices Review Board (PMPRB) party/intervener status and granting the PMPRB a qualified intervener status in judicial review proceedings regarding the price of NICODERM, dismissed.

[Appeal](#) (*For a printer friendly version, please scroll down to the end of the Judgment)

[Appeal](#) (*For a printer friendly version, please scroll down to the end of the Judgment)

[Lower level decision](#)

Aussant v. Canada (Minister of Health), December 18, 2002

Motion for stay of class action in Federal Court against the Crown for alleged negligence in granting regulatory approval for breast implants is dismissed. There are corresponding class actions in provincial courts and the Court found, *inter alia*, that granting the stay at this time may adversely affect the progress of the corresponding Ontario court case, which has an important motion scheduled for January 2003.

[Full Judgment](#) (*For a printer friendly version, please scroll down to the end of the Judgment)

Decisions of the Trade-marks Opposition Board

Reckitt & Colman (Overseas) Limited v. Femme Biomedica Inc. (FEMMEGESIC), November 25, 2002

Opposition to application for trade-mark FEMMEGESIC for “pharmaceutical products, namely analgesics” is unsuccessful. The opponent alleged, *inter alia*, that the applied for trade-mark is confusing with the opponent’s trade-mark TEMGESIC for “pharmaceutical preparations and substances, namely analgesics.”

[Full Decision](#)

New Court Proceedings

New NOC Proceedings

Medicine:	omeprazole (LOSEC capsules)
Applicant:	AstraZeneca Canada Inc
Respondent:	The Minister of Health
Date Commenced:	November 21, 2002
Comment:	Application for a declaration that Patent No. 2,186,037 is eligible for listing on the Patent Register.

Medicine:	fenofibrate (LIPIDIL SUPRA)
Applicants:	Fournier Pharma Inc and Laboratoires Fournier SA
Respondents:	Cipher Inc and The Minister of Health
Date Commenced:	December 11, 2002
Comment:	Application for Order of prohibition until expiry of Patent No. 2,219,475. Cipher alleges non-infringement and invalidity.

Medicine:	carvedilol (COREG)
Applicants:	GlaxoSmithKline Inc and SmithKline Beecham Corporation
Respondents:	Apotex Inc and The Minister of Health
Date Commenced:	December 16, 2002
Comment:	Application for Order of prohibition until expiry of Patent No. 2,212,548. Apotex alleges non-infringement, invalidity, and improper listing of patent on the Patent Register.

Other New Proceedings

Medicine: **implantable radiation device (BRACHYSEED Pd-103)**
Plaintiff: Theragenics Corporation
Defendants: Draxis Health Inc, Draximage Inc and Cytogen Corporation
Date Commenced: November 22, 2002
Comment: Patent infringement action regarding Patent No. 2,199,945.

Medicine: **tadalafil**
Plaintiffs: Pfizer Research and Development Co NV/SA and Pfizer Canada Inc
Defendants: Lilly Icos LLC and Eli Lilly Canada Inc
Date Commenced: December 5, 2002 & December 12, 2002
Comment: Patent infringement actions regarding Patent No. 2,163,446 entitled "Pyrazolopyrimidinones for the Treatment of Impotence".

Medicine: **ildenafil**
Plaintiffs: Pfizer Research and Development Co NV/SA and Pfizer Canada Inc
Defendants: Bayer Aktiengesellschaft and Bayer Inc
Date Commenced: December 5, 2002 & December 12, 2002
Comment: Patent infringement actions regarding Patent No. 2,163,446 entitled "Pyrazolopyrimidinones for the Treatment of Impotence".

Medicine: **ildenafil**
Plaintiffs: Bayer Aktiengesellschaft and Bayer Inc
Defendants: Pfizer Research and Development Co NV/SA
Date Commenced: November 22, 2002 & December 13, 2002
Comment: Patent impeachment actions regarding Patent No. 2,163,446 entitled "Pyrazolopyrimidinones for the Treatment of Impotence".

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