

# Patents and Copyright

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Top court rules on ‘sound predictions’ and the patentability of the famous ‘Harvard oncomouse.’ Supremes grant leave to Law Society of Upper Canada in legal text copyright infringement case. Will Internet service providers be obliged to collect royalties from their subscribers accessing music on-line? Drug NOC regs come under fire again. International IP program in Oxford.

## TOP COURT MAKES SOUND PREDICTION

Orville and Wilbur Wright applied for a patent on a heavier-than-air flying machine almost precisely a century ago, on March 23, 1903, without the aid of a patent lawyer. They filed the patent application some months before their historic 12 second flight at Kitty Hawk on December 17 of that year.

To borrow a term from Canadian recent caselaw, the Wright brothers had made a “sound prediction” that their machine would work, as of the date they filed. They had conducted hundreds of experiments with gliders, which suggested their powered machine would fly, but they hadn’t actually tested it.

The Wrights’ patent application was rejected by the U.S. patent office, on numerous grounds, including vagueness, anticipation by several previous patents, and, most of all, inoperability (everyone knew a heavier-than-air flying machine was impossible).

Realizing they were out of their depth, the Wrights engaged a patent lawyer who amended the application and eventually persuaded the U.S. patent office to issue it. Patent no. 821,393 for a “Flying Machine,” inventors: Orville and Wilbur Wright, issued on May 22, 1906. The ’393 patent was later litigated several times, and found valid and infringed.

So it’s fitting that, almost exactly a century later, the Supreme Court of Canada should mention the Wright Brothers several times in *Apotex v. Wellcome Foundation Ltd.*, 2002

SCC 77, likely to be the leading Canadian case for many years case on the doctrine of “sound prediction.”

One of two patent judgments released by the Supreme Court on the same day (Dec. 5, 2002), *Apotex v. Wellcome* concerned a patent on the use of the drug AZT to treat AIDS. The issue was whether a patent is valid if, when the patent application was filed, the invention had not yet been tested and shown to work. In other words, as the generic appellants put it, can you patent a lucky guess?

In late 1984, Wellcome discovered that AZT, a known compound, was effective in fighting HIV in a petri dish containing mouse T-cells. HIV was the recently-discovered retrovirus that causes AIDS. Mouse and human T-cells are sufficiently different that this did not necessarily mean the drug would work in humans.

Wellcome nevertheless applied for a patent right away, and ultimately, clinical trials did establish effectiveness in humans.

Two generic companies, Apotex and Novopharm challenged the validity of the patent on the basis that, at the time the application was filed, Wellcome did not know whether AZT would work.

The Supreme Court upheld the lower courts in finding some claims of the patent valid, on the grounds Wellcome’s researchers had made a “sound prediction,” based on the information and expertise then available. The key, Justice Ian Binnie said, was not whether the invention had been fully tested, but whether the patent disclosed to the public an invention that was operable.

Binnie mentioned the Wright Brothers more than once in his reasons, using them as a kind of archetype for all inventors. He described what they would have had to include in a notional patent application (without discussing their actual patent, or that their application was in reality filed before their machine flew).

“The mere idea of a ‘heavier-than-air flying machine’ is no more patentable than would be ‘anything that grows hair on bald men.’ The Wright Brothers’ patent ‘would have to teach precisely how the machine could be made to fly.’”

In the case of the AZT patent, the disclosure was adequate, the court found, and therefore the patent was valid, even though Wellcome had not known for sure that the invention would work when it filed.

## **MOUSE IN THE COURTHOUSE**

Another important patent case released the same day as *Apotex v. Wellcome*, was the “Harvard Mouse” case, *Harvard College v. Commissioner of Patents*, 2002 SCC 76, File no. 28155. Here the issue was whether a higher life form (a mouse) is patentable.

By narrow five-to-four margin, the court said no, holding Harvard was not entitled to a patent on its “oncomouse,” an animal modified by genetic engineering to be susceptible to cancer.

Justice Ian Binnie, who spoke of the court in unanimous *Apotex v. Wellcome* decision, wrote a feisty dissent, pouring scorn on the majority opinion penned by Justice Michel Bastarache.

Several intervenors such as the Canadian Council of Churches, Greenpeace and the Animal Alliance of Canada said patenting higher life forms should not be permitted for ethical reasons.

The issue turned on the meaning of the definition of “invention” in Patent Act (s. 2): “any new and useful ... manufacture or composition of matter, or any new and useful improvement in any ... manufacture or composition of matter.”

It’s clear lower life forms themselves, such as plants and bacteria, can be patented. The dissenters reasoned that a mouse, like a lower life form, is a composition of matter, and therefore potentially patentable.

But the majority disagreed, finding there is more to a mouse than mere matter: “The fact that animal life forms have numerous unique qualities that transcend the particular matter of which they are composed makes it difficult to conceptualize higher life forms as mere ‘composition[s] of matter’. It is a phrase that seems inadequate as a description of a higher life form.”

As the issue of patenting high life forms was complex and far-reaching in its implications, Parliament, not the court should decide. “If higher life forms are to be patentable, it must be under the clear and unequivocal direction of parliament,” Bastarache wrote.

Binnie’s vigorous dissent mocked the majority for fuzzy thinking. “If the oncomouse is not composed of matter, what, one might ask, are such things as oncomouse ‘minds’ composed of? The court’s mandate is to approach this issue as a matter (that slippery word in yet another context!) of law, not murine metaphysics.”

The Supreme Court is not “a forum that can properly debate the mystery of mouse life,” wrote Binnie. As to the intervenors’ ethical concerns: “Today the oncomouse; tomorrow Frankenstein’s creature. I do not agree. There is a qualitative divide between rodents and human beings.” (I could go on recounting all the memorable bon mots in the dissent, but you get the idea.)

There was never any doubt that Harvard’s claims for a method of modifying the mouse (as opposed to the mouse itself) were permissible. So Harvard will still be able to pursue mouse-making infringers in the courts. Be warned.

## **PUBLISHERS v. LAW SOCIETY GETS NOD FROM TOP COURT**

Switching for the moment to copyright, the most interesting recent decision is CCH Canadian et al. v. Law Society of Upper Canada, partly because of the way the decision has played out since the Federal Court of Appeal's judgment last May 14: (2002), 212 D.L.R. (4th) 385. Most noteworthy is the fact the Supreme Court's now granted the law society leave to appeal last year on Dec. 12.

Three major legal publishers, CCH, Thomson and Canada Law Book, sued the Law Society which operates the Great Library at Osgoode Hall in downtown Toronto. The Library copies law reports and law books at lawyers' request, and also makes photocopiers available to the public.

This, the publishers say, infringes their copyright. The publishers lost at trial, for the most part, but won on appeal, in a manner of speaking. Now Canada's highest court will rule.

Here's the story: the case seeks a declaration as to the copyright status of various sample legal publications: a textbook, a legal article (or "monograph"), a reported case with a headnote, a book of case summaries, a topical index, and an annotated statute.

At trial, Federal Court Trial Division Justice Frederick E. Gibson surprised everyone by finding that there was no copyright in a headnote, nor in a case summary or topical index, because these lack the necessary degree of creative spark to attract copyright.

In reaching this result he applied the Federal Court of Appeal's ruling in Tele-Direct (Publications) Inc. v. American Business Information Inc., (1998) 154 D.L.R. (4th) 328, where the court declined to find copyright in a telephone directory because the compilation lacked even a "minimal degree of skill, judgment and labour in its overall selection or arrangement." (The Supreme Court was refused leave to appeal in Tele-Direct on May 21, 1998)

Since most of the photocopying done at the law society's Great Library is of reported cases, this meant the publishers were unlikely to ever get much of a license fee out of the society.

On appeal, Justices Allen M. Linden and Marshall E. Rothstein wrote concurring opinions. Both overturned Gibson's finding that headnotes, case summaries and topical indexes do not attract copyright protection, finding that he had "misinterpreted the decision in Tele-Direct and other jurisprudence as shifting the standard of originality away from the traditional Anglo-Canadian approach." Rather than requiring a creative spark, "the classic precondition to copyright is that a work must be independently produced and copied from another person."

"In particular, the summaries of the facts, reasons and conclusions could have been long or short, technical or simple, dull or dramatic, well-written or confusing; the organization

and presentation might have varied greatly,” wrote the court: (1999), 179 D.L.R. (4th) 609.

The law society, however, argued that even if there was copyright in the works, it was entitled to the protection of the “fair dealing” section of the Act:

Fair dealing for the purpose of research or private study does not infringe copyright.”

The law society also relied on a recent amendment to the Copyright Act, made after the trial, which entitles a library to claim the benefit of any defence to which someone working in the library would be entitled. “In essence, the law society can vicariously claim an individual end user’s fair dealing exemption, and step into the shoes of its patron.”

The Federal Court of Appeal accepted the law society’s fair dealing argument, in general terms, although it noted there was a lack of evidence before the court as to why users of the library copy cases. Linden also set out various criteria for deciding when “dealing” is “fair” within s. 29. The jurisprudence lacked any previous guidance on this point.

So, on the face of it, the appeal is a win of sorts for the publishers. The court granted the appeal of the publisher’s appeal in part (in particular, on the headnote point), and granted “a declaration that copyright subsists in their materials in issue before this court, and the law society has infringed copyright in the works that were reproduced.”

However, the court went on to imply that an overwhelming number of patrons of the Great Library were probably covered by the “fair dealing” defence. “That fair dealing might apply in an overwhelming number of cases does not establish that every patron’s dealing is fair. Hopefully through these reasons, I have provided the parties with sufficient guidance to enable them to negotiate a just compromise among themselves.”

The practical result of the case is that the law society is not liable, to the extent it can establish users of the library are engaged in “private study” within section 29.

So far, the main effect of CCH Canadian v. Law Society case seems to have been to reduce unemployment among Canada’s youth. If you go into the Great Library (as I do fairly often), and want to make a photocopy, you will find a student sitting in the room where the copiers are, whose job is to make sure you sign a form in which you declare that you are “fair dealing,” defined by the law society to include doing legal research for the purpose of preparing a memorandum of law or a factum. I recently interviewed one of the students (as part of my exhaustive research for this article). He said it was a pretty good job — not much pressure.

## **THE TARIFF 22 UPDATE**

Another notable copyright case recently decided by the Federal Court of Appeal is the Tariff 22 case, SOCAN v. Canadian Association of Internet Providers. As with CCH

Canadian et al. v. Law Society, leave is being sought to appeal to the Supreme Court of Canada. The issue was whether Internet service providers must collect a royalty from their subscribers, to compensate music publishers for people accessing music on-line. The Federal Court of Appeal's recent judgment did little to clarify the vexed topic of copyright on the Internet: (2002) 215 D.L.R. (4th) 118.

The Federal Court upheld the Copyright Board decision (reported at: (1999), 1 C.P.R. (4th) 417) for the most part. Internet service providers, agreed the court, are ordinarily covered by the common carrier exemption in the Copyright Act s. 2.4(1)(b). They provide a way for people to access the Internet, but don't broadcast content.

However, Justice John M. Evans disagreed with the Board's finding on one important point: It found the Copyright Act did not apply to Internet transmissions from servers outside Canada.

Evans held that content providers outside Canada might sometimes be liable under the Canadian Copyright Act, if their transmission had a "real and substantial connection" with Canada. His reasons did not explain when a site outside Canada might have a real and substantial connection with Canada. He said only that this would have to be determined by the Copyright Board on a case-by-case basis.

The "location of the end user is a particularly important factor in determining if an Internet communication has a real and substantial connection with Canada," wrote Evans, which would seem to cast the net fairly widely, to say the least.

If Supreme leave is not granted, the Copyright Board will have to consider these words, and work out when, if ever, a site on a server outside Canada might be said to have a "real and substantial connection" with Canada, and how the copyright owner might collect revenues, as a practical matter. At the moment, no one seems to have any idea, and a hearing on the issue seems unlikely before 2004.

## **DRUG PATENTS**

The year 2002 saw the usual deluge of drug patent litigation, much of it concerning the blockbuster ulcer drug omeprazole (LOSEC), for many different patents listed. In short, no generic version of omeprazole looks may be available in Canada for years to come, although a generic version is imminent in the U.S., as I write.

Speaking of many different patents on a single drug, there has been much activity recently as to when patents can be listed on the register under the Patented Medicines (Notice of Compliance) Regulations. The more that can be listed, the better for the patentee (as the omeprazole example illustrates) and the worse for the generic.

These Patent Act regs create an enforcement scheme that applies only to pharmaceuticals. They allow brand name companies to list patents on a "patent register" maintained by Health Canada. If a patent is listed for a brand-name drug, the regs allow the brand to get

an automatic injunction preventing any generic version from getting regulatory approval for 24 months, or until the outcome of patent litigation. And listing a new patent for the drug can start the 24 month injunction all over again.

This means there can be multiple stays, if multiple patents are listed. This might seem an esoteric point, but it has recently received an extraordinary degree of attention in the United States, including direct action by President George W. Bush himself.

In November, 2002, Bush announced changes to the regulations under the equivalent U.S. scheme, the Waxman-Hatch Act to prevent brand name drug companies from getting multiple stays for a single drug. He said multiple stays were an abuse of the scheme because they unfairly delay generic drugs.

The issue is whether Canada should follow suit. This question has been the focus of much lobbying and litigation in Canada. In the interest of full disclosure, your correspondent has been involved representing the generic side of the industry, both in court and as a lobbyist.

There have been several cases in the Federal Court on the regs' s. 4, the provision that governs when patents can be listed on the patent register. The Minister of Health (as I write it's Anne McLellan), who has responsibility to administer the patent register, evidently finds the cases unclear and contradictory, and so was in doubt as to what patents to list, and which to refuse.

That's why, in early 2002, the minister commenced a "Reference from a Tribunal" in the Federal Court, posing questions to the court as to the interpretation of s. 4, using as an example a certain patent on a sample product, Eli Lilly's olanzapine, an anti-depressant.

After some months of motions and procedural confusion, the olanzapine reference was struck out on the grounds Minister's materials filed with the court were ambiguous and in dispute. The minister appealed, but the dismissal was upheld by Federal Court Trial Division Justice Frederick E. Gibson last Sept. 25: Reference re: Patented Medicines (Notice of Compliance) Regulations, (2002) FCT 1000.

Still seeking guidance, in November the Minister posed certain hypothetical questions on the interpretation of s. 4 and sought written representations from concerned trade associations. The minister's officials then heard oral presentations at a meeting in Ottawa on Dec. 2, 2002 (inconveniently scheduled just before this article's deadline!). Various lawyers, including your faithful correspondent, duly appeared and urged competing interpretations of s. 4 and the case law on Health Canada.

What patents the Minister of Health will henceforth accept or refuse for listing, and whether the regulations might be amended, along the lines of the recent Bush amendments in the U.S., remains unclear at the time of writing.

**SUMMER IN OXFORD**

The University of Victoria's law faculty in conjunction with University of Illinois College of Law and St. Peter's College, Oxford University plan to continue with their novel International Intellectual Program (IIP) this summer from July 3 to Aug. 19.

The program presents a unique endeavour by the three school to offer a comparative and multi-jurisdictional program of international and comparative intellectual property law and policy. In the past the programs attracted not only law students looking for credits in IP but practitioners seeking professional development opportunities.

The course is divided into two parts, the first focusing on copyright and trademark practice, and the second on patents and trade secret. The course is taught by faculty from the three schools and related practical sessions are being handled by IP players from major IP "sponsoring firms" in the three jurisdictions — including Canada's Smart & Biggar, the London-based Bird & Bird and Chicago-headquartered Brinks Hofer Gilson & Lione.

While the course moves around, the summer it's being held at St. Peter's College, which also houses the Oxford Intellectual Property Research Centre (OIPRC).

Program directors include UVic professor Robert G. Howell and Oxford's David Vaver (who's also the OIPRC director). Michael D. Manson of Smart & Biggar's Vancouver branch will also be on hand for the practical seminars. Other Canadians participating include professors Ysolde Gendreau and Ejan Mackaay of Université de Montreal and UBC's Bob Paterson.

Howell says last summer, when the program was held at UVic, participants were keen on discussing the implication of the famous "Harvard Mouse" case. Now that the Supreme Court's ruled on the case, it will doubtless fuel future debate this summer in Oxford.

"The uniqueness of this program stems from not only the combination of three academic institutions from three countries, but also from the integration of academic issues with practical perspectives provided by three leading IP firms from the three jurisdictions."

Participants come from all over the world, says Howell. In this age of globalization, international IP is "the way of the future," he says.

For more information go to: <http://www.uvcs.uvic.ca/ip>.