

Patent Survey

Annual IP survey articles published in *Canadian Lawyer Magazine* February 2001

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John Wayne once said "Talk slow, talk low, and don't say too much."

That's what I want to do in this article (my fifth annual survey on patents and copyright). Keep it simple. Avoid bogging down in the details.

But it's tough to follow Big John's advice when writing about this stuff. There's a lot going on, affecting very different industries, like pharmaceuticals and broadcasting. And it can get complicated.

Keeping it simple, and talkin' real slow, here are the major recent developments in Canada:

Canada's patent laws were the subject of two international disputes before the World Trade Organization (WTO). We won one dispute (mostly), but lost the other. The terms of some patents may be extended as a result.

The Federal Court of Appeal recently upheld Glaxo's patent for AZT, the AIDS drug.

There was the usual litigation slug-fest on various other drugs.

The Federal Court of Appeal found that the "Harvard Mouse", a mouse modified by genetic engineering, was protectable by a patent, overturning the lower court.

In the copyright area, the Federal Court of Appeal revisited compilations, reaching the opposite result from the leading case, *Télé-Direct*.

The Copyright Board is now grappling with big new age issues about TV over the internet.

The Federal Court of Appeal upheld the Copyright Board's decision on the blank tape levy.

The recording industry is scared to death of Napster, and wants changes to Canadian law that would shut down Napster-like sites.

Two WTO disputes: Canada's patent laws have recently been the subject of two different rulings by World Trade Organization (WTO) dispute panels. We more or less won one, and lost the other, so I guess that's not bad.

The first one, the one we mostly won, arose from a complaint brought by the European Union. It was about the so-called "early working" exception, also known as the "Bolar" exception (after a US case). The Bolar exception says that it is not an infringement to use a patented invention for purposes reasonably related to the development and submission of a regulatory submission (s. 55.2(1)). This allows generic drug products to go through the regulatory process while the brand patent is on force, so that the generic can get on the market sooner, after expiry. The US also has a "Bolar" provision, but the European Union does not.

There was also another, less important exception at issue: the so-called "stockpiling" exception. It allowed a generic company to manufacture, but not sell, ie. to "stockpile" drugs, for six months prior to the expiry of a patent.

Many countries around the world were watching this case carefully. Most developing nations are just bringing their laws into compliance with TRIPS. They want to know whether a Bolar provision is acceptable or not.

The European Union argued both exceptions were contrary to the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), the WTO agreement that sets standards for intellectual property laws around the world. TRIPS requires that a patentee have 20 years of exclusive use of the invention in the patent, and that patent rights be available without discrimination as to field of technology. If a country's law is found inconsistent with TRIPS, it can be subject to trade sanctions unless it brings its law into compliance.

The Panel found the Bolar exception was saved by a somewhat vaguely-worded general exception for patents, Article 30, which allows a country to have "limited exceptions" to TRIPS in its law. However, it found the stockpiling exception inconsistent with TRIPS (Canada - Patent Protection of Pharmaceutical Products WT/DS114/R 17 March 2000).

In October, 2000, Canada responded by repealing the Manufacturing and Storage of Patented Medicines Regulations, the very short regulations under the Patent Act that gave effect to the stockpiling exception.

The other WTO dispute, the one that Canada lost, was about the length of the patent term. Although patents in all industry sectors were theoretically affected, only the pharma industry seemed to care much about the outcome. This time the complainant was the United States.

TRIPS requires a patent term of 20 years from filing of the patent application. All patents in Canada based on applications filed after October 1, 1989 have such a term. The dispute was about patents based on applications filed before that date, sometimes referred to as "Old Act" patents. "Old Act" patents get a term of 17 years from the date the patent issues (s. 45).

That means that any Old Act patent that issued in under three years from filing has a term less than 20 years from the date it was filed. Conversely, if you're still with me, any "Old Act" patent that issued in more than three years has a term of more than 20 years from filing. But TRIPS requires a minimum of 20 years from filing, argued the US. The evidence was that about 66,000 Canadian patents fall into this category, roughly a third of existing "Old Act" patents.

The Panel found that Old Act patents that get less than the full 20 years from filing were not TRIPS-compliant.

Canada appealed to the WTO Appellate Body, but its appeal was dismissed (Canada - Term of Patent Protection, WT/DS170/AB/R 18 September 2000).

At the time of writing (late November), it is not yet clear what steps Canada will take in response to the ruling. Canada may adopt a "greater of" term similar to that in the US. In 1995, the US also made a transition from a 17 year from grant term to a 20 year from filing term, but all patents in the application process as of the transition date get the greater of the two terms.

I should disclose I had some involvement in assisting the government in both WTO cases on behalf of the generic drug industry.

Drug cases: In 2000, there was the usual slug-out in the courts over drug patents, under the Patented Medicines (Notice of Compliance) Regulations. Any generic drug manufacturer that challenges a brand patent is automatically prevented from getting regulatory approval for a generic version until it wins litigation under these Regulations.

Generic manufacturers won court battles over a number of drugs in 2000, including Glaxo's anti-biotic cefuroxime, Novartis' fungus treatment terbinafine. Merck's eye solution timolol, Astra's omeprazole and Eli Lilly's nizatidine, both ulcer drugs. Brand company Janssen, however, won a case about another ulcer drug, cisapride.

In the case of omeprazole, a top-selling drug sold by Astra under the brand LOSEC, the basic patent has expired, but court battles are on-going with several generic companies over various later formulation and use patents. The generics attacked the Regulations themselves as ultra vires, but in May, 2000 the Federal Court of Appeal found that the Regulations had been properly passed *Apotex v. Canada* (A-922-96) May 12, 2000. Leave is being sought to appeal that decision to the Supreme Court of Canada.

The AZT case: AZT, as everyone knows, is an AIDS drug. It interferes with the replication of HIV retroviruses. The Federal Court recently upheld most claims of Glaxo's patent on AZT in *Novopharm and Apotex v. the Wellcome Foundation et al.*, (A-211-98, A-213-98, A-214-98), October 26, 2000.

AZT was known as long ago as 1964, when it was tested as a cancer treatment. The patent was not on the known compound, but on its use to treat HIV.

One issue was who invented the new use. Apotex and Novopharm, two generic drug companies, argued that two scientists at the National Institute of Health (NIH), a research facility operated by the US government, were joint inventors of AZT. They had done the first test that showed effectiveness of the compound against human retroviruses. Since those two doctors weren't named as co-inventors in the 'patent, the generics argued, the patent was invalid.

The appeal court disagreed. It found the two doctors were not inventors. "They played no part in coming up with the idea of using AZT against HIV. Both doctors agreed to test a substance that was unknown to them on behalf of Glaxo," wrote Justice Edgar Sexton, noting that the US courts in parallel litigation had reached the same conclusion.

Apotex and Novopharm also argued that the patent was invalid because it lacked utility, meaning no one knew if the compound was effective in patients at the time the patent was filed. The Court dismissed that argument, saying it was enough that it later became apparent that the compound worked.

Apotex and Novopharm also argued the patent was obvious, and lacked novelty. These are questions of fact. The Court of Appeal found no reason to overturn the trial judge.

Mouse may go to Supreme Court of Canada: In early August, the Federal Court of Appeal, in a split decision, ruled that a genetically-modified mouse was patentable (*President and Fellows of Harvard v. Canada (Commissioner of Patents)* A-334-98, August 3, 2000). Commonly known as the "Harvard Mouse", the furry creature referred to in the patent is an "onco-mouse," meaning it's been modified to be susceptible to cancer. This may not be pleasant for the mouse, but it's helpful in cancer research.

The ruling overturned the trial court, which had upheld the Commissioner of Patents' refusal to allow a patent on claims to the animal itself. There was no dispute that claims to the method of performing the genetic modification were patentable.

In dissent, Justice Julius Isaac would have dismissed the decision for reasons turning on the standard of review.

Patent claims on higher life forms are old news elsewhere in the world. The practical issue arising out of the case was whether Canadian patent applications on genetically-modified higher animals must be worded differently from those filed in other countries, ie. must claim only a method of modifying the animal, not the animal itself.

Industry Canada decided to seek leave to appeal to the Supreme Court of Canada in early October. "We think that if there's going to be a change in the law on this issue, the public and parliament should have input," Serge Dupont of Industry Canada told me, explaining the government's decision to seek leave.

So much for patents. Now for copyright.

Copyright in compilations: Compilations have always been a vexed area of copyright law. A compilation is a work resulting from the selection or arrangement of data, like a telephone directory or database.

The Federal Court of question revisited this recently in *Édutile Inc. v. Automobile Protection Assn.* Court File no. A-4-98, released April 19, 2000. Édutile published a used car guide. When a competitor published a similar guide, it sued.

The court quoted extensively from the leading case, *Télé-Direct (Publications Inc. v. American Business Information, Inc.* [1998] 2 F.C.22. In that case, the Federal Court of Appeal decided a phone directory did not attract copyright protection because there had not been the necessary "minimal degree of skill, judgment or labour in its overall selection or arrangement."

But the court found that this was a different case. The pricing data about the used cars in the plaintiff's directory was presented in an original way so there was copyright in it. The price data on the used cars was presented into three columns, giving three different prices: the "Private Sale" price, the "Trade-in" Price, and the "Retail" price.

Even the witness for the defendant admitted at trial that presenting the "Private Sale" price next to the "retail" price was original. He even agreed it was "brilliant" and "innovative." The court granted an injunction, and (unusually in Canada) sent the case back to the trial judge for the issue of damages to be dealt with.

TV and the internet: Remember iCrave TV? iCrave was a Canadian company that briefly distributed TV signals over the internet, before being crushed under an avalanche of litigation in the US in the summer of 2000.

Now another company, JumpTV.com wants to bring you TV over the internet. They say they will not infringe anyone's copyright. The Copyright Board will decide whether they can go ahead or not. Content providers want the government to change the Copyright Act to stop them.

It a nutshell, the question is this: is sending TV signals over the internet similar to what cable TV companies do?

Under the "re-transmission of distant signals" regime in the Copyright Act (s. 31), cable companies and direct-to-home (DTH) companies are not infringing copyright by

transmitting someone else's signals to their subscribers, provided they pay a royalty to content providers.

The royalty is in a tariff approved by the Copyright Board. The royalties are calculated per "premises" - basically, per household. Currently, the rate is usually about 70 cents per premises, per month. The Board also decides how that money gets divided up among various "collective societies," representing content providers. In other words, s. 31 essentially gives cable companies a compulsory license.

JumpTV.com argues it is much the same as a cable company. It wants the board to set an interim tariff, meaning that it could go ahead and start transmitting to your computer right now, while paying some money to copyright owners, perhaps a percentage of its revenues. Then, whatever hearings are necessary can take place later.

Existing cable companies and broadcasters don't want this. They say JumpTV is not like a cable company, and not entitled to the benefit of s. 31. They point out it will not have subscribers. Instead, it plans to sell advertising. Thus, it is competing with broadcasters for ad dollars, unlike cable companies. There may also be cultural issues: the CRTC has decided not to try to regulate the internet, so internet TV won't necessarily have any Canadian content.

There are two big differences between iCrave and JumpTV.com. Most important, iCrave impetuously started transmitting before the copyright issues were resolved, causing the US courts to shut it down. JumpTV.com, however, says it will not start transmitting until a tariff is in place. Perhaps most important, iCrave had no effective way to prevent its internet transmissions from being picked up in the US, where no equivalent of s. 31 exists. That is what led to the US litigation that killed it. JumpTV.com says it has solved this problem by using screening technology called "BorderControl."

Claude Majeau, secretary to the Copyright Board, described the JumpTV case as one of the most important issues facing the Board, but of course it's too early to say how it will turn out.

Sports programming: The Copyright Board also looked at the retransmission of distant signals, s. 31, in its most recent decision, decided before the JumpTV issue came up. The Board decided not to change the existing tariff.

There were several issues. The most interesting was about the value of sports programming.

The Copyright Board decides how the proceeds of the "distant signal" royalty under s. 31 gets divided up among the music people, the US networks, sports, and so on. It does so mostly based on "actual viewing" data, ie. how many people watch any given show.

The collectives representing pro sports wanted “a new allocation method,” for the years 1998 through 2000, meaning a bigger slice of the royalty pie. They argued that the “actual viewing” method did not reflect the true value of sports programming to cable operators. Under the existing tariff, sports get only a little over 3% of the re-transmission royalty.

They relied on survey evidence, purporting to show that cable operators viewed sports as premium content, for which they could charge higher advertising. The sports collectives claimed that therefore their share of the royalty should be about 10 times higher.

Other collectives of course disagreed. The Board refused to make any substantive change, saying the “actual viewing” method was objective, and should not be changed. Re-Transmission of Distant Radio and Television Signals [2000] C.B.A. No. 3, February 25, 2000.

Federal Court of Appeal defers to Copyright Board: During the summer of 2000, the Federal Court of Appeal, as usual, refused to interfere with the Copyright Board. The issue was the blank tape levy.

The levy is something new. It was created by the Bill C-32 amendments to the Copyright Act. Under the amendments, it is no longer an infringement to make copy of a musical work for “private use” (s. 80(1)), since you can't stop people from taping music at home anyway. As a quid pro quo to the music industry, manufacturers and importers of blank "audio recording media" must pay a levy to the music industry meant to compensate them for home taping.

The Copyright Board had to decide how the levy would be calculated and collected. The levy was controversial; the Board received over 3,000 objections and letters of comment, including arguments that the levy was an improperly enacted tax, and contrary to the Charter.

The Board's decision, released in December 1999, found the levy constitutional, and approved a tariff. It estimated the levy would generate approximately \$8.85 million in the year 2000.

One issue was what widgets levy applied to. The Board decided it covered not only tapes but also minidisks and certain types of compact discs. The Canadian Storage Media Alliance (CSMA), an organization representing major importers of blank tapes and CDs, sought judicial review on this point to the Federal Court of Appeal

CSMA argued wanted the levy to apply to fewer kinds of CDs. The court disagreed. In brief reasons, Justice Allen Linden said the Board, an expert tribunal, was entitled to considerable deference. "The Board ... should know the Industry it is regulating better than the Court," he commented. (AVS Technologies et al. v. Canadian Mechanical Reproduction Rights Agency et al., Court File no. A-19-00, June 14, 2000.)

This may be bad news for SOCAN. The music collective is seeking judicial review of the Board's well known Tariff 22 decision (see last year's survey). That decision in effect said internet service providers should not have to collect copyright fees on behalf of the music industry. The materials are being filed as I write, so the appeal will probably not be heard until later in 2001.

The Music Business: As everyone knows, the big issue facing the music business is Napster, the website that allows free swapping of music. As I write, Napster is involved in litigation with the record labels in the US. Ken Thompson of the Canadian Recording Industry Association tells me he thinks the case will be settled. "The music companies don't want to stop Napster, they want to own it," he said.

Could a Napster-like site, based in Canada, be stopped in the courts? The music companies are afraid the answer may be no, unless changes are made to the Copyright Act.

The recording industry wants the government to stiffen Canada's laws to add to existing copyright protection by creating a new exclusive right, the right to "make available" (ie. to make accessible to download over the net. They also want other changes that would make it easier to stop activities that, although not infringing in themselves, assist others to infringe copyright. In 1997, Canada signed two international treaties that call for such changes, the World Intellectual Property Organization Copyright Treaty (WCT) and the WIPO Performers and Phonograms Treaty (WPPT).

But progress is slow. Ken Thompson complains that since the fall of 1998, "there has been a palpable lack of activity" on the part of the government. Serge Dupont of Industry told me, "Discussion with stakeholders are on-going."