Intellectual Property: Patent and Copyright Law

Annual IP survey articles published in *Canadian Lawyer* Magazine February 1997

Edward Hore
Hazzard & Hore
141 Adelaide Street West, Suite 1002
Toronto, ON M5H 3L5
(416) 868-1340
edhore@ hazzardandhore.com

Pesky pill patents prove particularly perplexing

Much recent case law in the patent area has involved courts grappling with Canada's complex patent laws relating to prescription drugs. The law in this area is a patchwork created by two controversial sets of amendments, one passed in 1987 and the other in 1993.

Patented Medicine Prices Review Board clobbers drug company

Might regulating drug prices under the Patent Act, cause prices to increase, rather than decrease?

That's what patent lawyer Joseph Etigson says might happen as a result of recent rulings of the Patented Medicine Prices Review Board (PMPRB) and the Federal Court of Appeal about a drug called Virazole. The drug is an anti-viral used to treat babies.

Etigson represented ICN, a pharmaceutical company, in recent hearings before the PMPRB and the Federal Court Court of Appeal. ICN, as he put it, "got clobbered." The price of Virazole was held to be "excessive" even though ICN says it loses money on the drug.

Prices of patented medicines are regulated, due to changes to the Patent Act brought in by the Mulroney government in 1987. The political compromise was that the drug companies got a longer period patent exclusivity. At the same time, however, the PMPRB, a government watchdog, was created to monitor the prices of patented drugs. The Board has the power to roll-back any drug prices it considers "excessive".

In July 1996, the PMPRB found that the price of Virazole was excessive, the first time the Board had ever made such a ruling after a full hearing. ICN was ordered to pay the Canadian government 1.2 million dollars, and to reduce the price of Virazole to a level

which was only about half what the PMPRB deemed the "non-excessive" price (about $400.) So the price of Virazole dropped from $1,540 to about $200.

The ruling may be good medicine for consumers, but it's a bitter pill for ICN to swallow. ICN's argument was that the price of Virazole cannot be "excessive" because it was losing money on the drug. The PMPRB, however, held that if the price of a patentee's drug has gone up more than the Consumer Price Index, then it is "excessive", regardless of profitability. The Board noted that ICN had increased the price of Virazole about four-fold between 1992 and 1994.

ICN admitted it substantially increased the price of the drug. "ICN had been subsidizing the Canadian market for years," said Etigson, "and finally it said, we can't do this anymore." ICN put a forensic accountant before the PMPRB, who showed that ICN's costs had exceeded its revenues. The demand for Virazole was not what the company had originally anticipated, so it had to had to change its pricing strategy to adjust to a much smaller and more specific market, says Etigson. Since ICN was losing money, given the small quantities it was selling, it had to increase the price of the drug.

"I think any other company with a new drug is going to look at this case, and say 'we'll never be able to increase the price no matter what, so we'd better set the price as high as we possibly can at the start'," says Etigson. That's why he thinks the case may result in higher prices for new drugs coming on the market.

Also important to other pharmaceutical companies is the question of the Board's jurisdiction. While the PMPRB hearing was going on, ICN took the issue of the PMPRB's jurisdiction over Virazole up to the Federal Court of Appeal. The appeal court ruled that the PMPRB had jurisdiction over Virazole and that its jurisdiction is very wide indeed.

"It's an important case because its the highest court ruling we've had as to the extent of the Board's jurisdiction," said Wayne Critchley, Executive Director of the PMPRB, who is pleased with the Court's ruling. In fact, according to Gord Cameron, the lawyer who represented the PMPRB, the court's ruling as to the PMPRB's jurisdiction "is, if anything, wider than what the Board itself had said."

ICN's argument was that although it had three patents relating to Virazole, two had expired, and Virazole, as sold in Canada, was not being used within the scope of the claims of the third patent. ICN "disclaimed" part of the specification of the third patent, meaning that it made clear that the patent language should be read narrowly, so that Virazole, as actually used in Canada, would not be within the patent claims.

This squarely put before the Court a key issue about the jurisdiction of the PMPRB: what if the patentee's drug is not within its own patent claims? The PMPRB is designed to protect against excessive pricing where the patentee has market exclusivity because it has a patent. But if the patentee's product is not within its own patent claims, goes the

argument, any competitor could come out with an identical competing product, and not infringe the patent. Therefore, if the patent is not conferring market exclusivity on the patentee, should the patentee still be subject to price regulation?

This situation is in fact quite common. Many patentee drug companies have patents that, although they may relate to the product on the market somehow, may not keep out generic or other competition because competing products do not infringe.

The Federal Court of Appeal, in a decision by Justice Robertson released in August, 1996, noted that the Patent Act says that PMPRB has jurisdiction to monitor prices if there is a patent "pertaining to" the product. The court rejected ICN's argument that the Board only has jurisdiction if the patentee's product falls within its own patent claims. "Because of the broad scope of the terms 'pertaining to' and 'pertains to' as used in [the relevant subsections of the Patent Act]," Justice Robertson wrote, "the nexus can be one of the merest slender thread."

Gord Cameron points out this could mean that if a new use for ASA (aspirin) was patented, ASA would then be subject to price regulation, even though it has been on the market for a hundred years or so. "No one knows yet what the limits on the Board's jurisdiction are, if any," he said.

ICN has not sought leave to the Supreme Court of Canada.

Dedicating patents to escape price regulations won't work.

Even before the Virazole case, the question of the PMPRB's jurisdiction was much debated. The issue revolved around the practice of "dedicating" pharmaceutical patents to the people of Canada to avoid the jurisdiction of the PMPRB. "Dedicating" a patent is an arcane procedure not set out in Canada's Patent Act, but recognised by the Commissioner of Patents. Essentially, a patentee can donate a patent to the public.

This used to be very rare. In 1987, however, the creation of the PMPRB meant that drug patentees for the first time were subject to price regulation. Many drug companies suddenly became interested in making a magnanimous dedication of their valuable patent rights to the people of Canada. Since it might be two years before a generic could appear on the market due to regulatory delays, the former patentee, by giving up its patent, escaped price regulation, while also having de facto market exclusivity.

The PMPRB at first took the position that if the relevant patents were "dedicated" it then lost jurisdiction. But it then changed its mind in 1995 and said that it still had jurisdiction after all. Its reasoning was that patent-dedicating was not mentioned in the Patent Act, and therefore the Board could ignore it.

So far, there has been no court challenge to this, according to Wayne D. Critchley, Executive Director of the PMPRB.

Notice of Compliance Regulations a patent battleground

Another aspect of Canada's pharmaceutical patent laws is also keeping Canada's courts busy - the Patented Medicine (Notice of Compliance) Regulations ("NOC Regulations").

These regulations came into force suddenly and without any consultation with the generic industry in March of 1993, during the political firestorm over abolishing compulsory licensing. The Regulations tie the granting of regulatory approval of generic drugs to the patent status of the originator drug.

The Regulations give pharmaceutical patentees, but not patentees in other industries, a remedy in addition to the normal remedies that any patentee has. The result has been a deluge of litigation. There have been over a hundred cases commenced under the Regulations.

In any other industry, a patentee who believes another's product infringes its patentee sues for patent infringement, and if successful, gets damages and a permannent injunction. As in any other kind of court case, a plaintiff can also seek an interlocutory injunction, if it thinks it can establish irreparable harm.

In the pharmaceutical industry, however, the Regulations make it much easier to get what amounts to an interlocutory injunction against an alleged infringer. If a generic company applies for regulatory approval for a new generic drug but a product or use patent is "listed" with the health and safety regulator by the patentee as relating to its originator drug, the generic company must notify the patentee it is applying for regulatory approval for a generic version. If the generic asserts that its product would not infringe the patent, or that the patent is invalid, the patentee can seek a court order by judicial review. In the court proceeding, the patentee asks the court to prohibit the health and safety regulator, the Health Protection Branch or HPB, from granting regulatory approval (a Notice of Compliance or NOC) to the generic product.

Merely by starting an application in the Federal Court, the originator automatically stops the NOC from issuing to the generic, for 30 months or until a hearing is held, which may be years later. The generics of course object to this. They say they should not be in effect enjoined from entering the market for years without a hearing, because they claim their generic products often do not infringe the patents in question. Patentees say that the Regulations are necessary to prevent their patents from being infringed.

The hearing itself is a summary application, not a trial, and the key issues of infringement or validity are not determined. There are complex rules as to onus, which greatly favour

the brand name company. The brand name company has a much better chance of winning and keeping the generic off the market until patent expiry, than it would in a conventional interlocutory injunction motion. The patentee neednot establish irreparable harm, deal with the balance of convenience, or make an undertaking as to damages. Instead it must in effect only show a likelihood that its listed patent would be infringed by the generic.

The generics are unhappy because the Regulations put them in a "no-win" situation. They can "lose" in the sense that their product may be kept off the market, but cannot "win" in that even if the application is dimissed and the NOC is issued, the generic can still be sued on the same patent by the same party, since the issue of validity and infringement remains unresolved.

Understandably, the generic have been lobbying vigourously to get rid of these regulations, arguing pharmaceutical patent disputes should be decided in the same way as other patent disputes. The federal government, however, although claiming to be sympathetic, has not so far repealed the Regulations because of concerns that any change that hurts the brand name drug industry might upset Quebec, since many multi-national drug companies are located around Montreal.

The generics have gone to court to argued that the NOC Regulations are improper and not authorized by the Patent Act, but as of the time of writing, no decision has been released.

Harvard Mouse Application rejected

Build a better mousetrap, they say, and the world will beat a path to your door.[1] But what if you build a better mouse?

It seems you may not be able to patent your new furry friend in Canada in view of a recent decision of the Commissioner of Patents in what is called the "Harvard Mouse" case.

Harvard researchers recently applied for a patent containing certain process and product claims relating to a "non-human mammal" whose cells contain an activitated "oncogene" sequence, meaning in plain English a mouse that had been modified by adding viral genetic material making the mouse susceptible to tumors. Mice modified in this way are useful in cancer research.

The Commissioner allowed certain claims for the process for modifying the mouse (essentially a gene splicing technique), but refused to allow the "product" claim, that is, a claim for the animal itself, modified in this way.

[1] Actually a corruption of something Ralph Waldo Emerson once said in a lecture: "If a man can write a better book, preach a better sermon, or make a better mousetrap than his neighbor, though he builds his house in the woods the world will make a beaten path to his door".

Although the case has received some attention from people who think that it heralds nighmarish Brave New World-style genetic engineering, Joy Morrow of Ottawa's Smart & Biggar which represents the applicant, insists that all that is at stake is some straightforward patent issues. "The same claim was permitted in the United States, and in the European Patent Offfice," she said. "We think that the decision is wrong, as a matter of basic patent law. There's a new and useful invention, and the steps that you need to follow to reproduce the invention are fully set out in the disclosure, so that anyone skilled in the art can follow the steps and make the modifications time and time again."

The Commisioner's concern was the mouse could not necessarily be reproduced identically by someone reading the patent disclosure. You never know how higher life forms such as mammals are going to turn out when they grow up, as my mother has often complained.

A patent is a bargain between the inventor and the state, whereby the inventor gets exclusive rights to the invention for 20 years, in returning for fully disclosing how the invention works, so others can use it once the patent expires. It is fundamental therefore that someone skilled in the art be able to reproduce the invention.

Morrow says that, in fact, concern about reproducability is misplaced. "It doesn't matter what colour fur or eyes the mouse has. The point is that a mouse or other animal, if modified using the steps in the patent, will have the useful modification that is the subject matter of the invention. The Commissioner may be trying to address wider ethical issues, but these are up to Parliament."

The Commissioner's decision in the has been appealed to the Federal Court, Trial Division, but no date has yet been set for the hearing.

It has been possible to patent simpler life forms in Canada for some time. The Patent Act was recently amended to add section 38.1 permitting the "deposit" of "biological materials" so that living things can be kept on file, as it were. "They've just brought out regulations as of October 1 of this year as to what you have to deposit, where you deposit it, and so on." says Eileen McMahon, a biotech lawyer in Toronto. "You can basically deposit anything, bacteria, seeds, tissues, genetic vectors, whatever," said McMahon. "What you deposit then becomes part of the patent disclosure"

Will copyright law change to accommodate the internet?

So far there has been no amendment to Canada's Copyright Act to address the issues raised by the growth of the internet as a communication media.

The internet raises copyright concerns because it is not only easy, but often actually necessary, to infringe copyright when using the internet. There mere act of reviewing a

Web page involves downloading (i.e. copying) text and graphics into your computer's random access memory (RAM) at least temporarily. If what was downloaded was an original literary or artistic work (as almost anything on the Web probably is, regardless of merit), it attracts copyright protection, and the reproduction of it will in theory infringe the copyright owner's sole right of reproduction.

The internet also presents many other possibilities for infringement. A copyrighted work can be downloaded onto a hard disk. Copies of the copyrighted material can easily be distributed to computer systems all over the world. Web pages can have hotlinks to other sites, which themselves attract copyright. Issues also arise as to the possible liability of carriers such as on-line service providers.

On the other hand, internet-users are often fierce individualists who hate anything that curbs their digital freedom in cyberspace, including intellectual property laws.

There has been no shortage of talk about what to do. The Canadian government is looking at the question of copyright and the internet, but it is as yet unclear what changes to Canada's copyright law will be made, if any. An Advisory Council on the Information Highway made indefinite recommendations in 1995. According to Glen Bloom of Osler Hoskin's Ottawa office, who practises in the copyright and internet-related area, experts have been retained by the federal government to advise on the current state of the law, and are due to report in November. As well, there is an international conference of the World Intellectual Property Organization (WIPO) in December, 1996 where draft international treaties will be discussed. However, the content of the treaties is not yet finalized, and no one knows if Canada will become a signatory.

Discussion about the net and copyright law generally focusses on how to amend the Act to deal with "browsing", and whether to change the doctrine of "fair dealing" - the idea that limited quotation from copyrighted works is not infringement, if done for reasons of serious study or research.

It has been suggested that "browsing" should be made a permitted use (the Advisory Council took this position). Others believe browsing should be clearly identified as infringement, unless the copyright-owner consents, a position apparently taken by the drafters of the international treaties under discussion this fall. The issue may be academic because copyright owners may be unlikely to sue anyone for browsing anyway. Even if technical infringement were established, damages would be too small to be worth pusuing.

It is also far from clear that the present "fair dealing" subsection of the Act need be changed. There has been no case law under the present section (s. 27(2)(a) and (a.1)). As the present wording essentially requires the court to be reasonable in the circumstances, there may be no reason to change it.

A bill to amend the Copyright Act, Bill C-32, is currently before Parliament, but, The new bill stiffens what are known as neighbouring rights (rights which give copyright owners additional right to collect revenues for performance of copyrighted works). Bill 32 also clarifies remedies in certain situations, changes the rules applying to what are known as copyright collectives, and makes a number of technical amendments designed to generally update Canada's copyright law. However, according to Bloom, Bill C-91 "doesn't really address the issues raised by digital communication or the internet."

The fundamental principles of copyright law are not likely to change in the digital age. Copyright law in roughly its present form will probably work as well for the internet as it worked for previous types of electronic technology, such as audio tapes, videos, and software. Content providers with a serious financial investment in copyrights (publishers, movie and TV studios, software companies) will pursue internet bootleggers just as they pursue other bootleggers. At the same time, de minimis copyright infringement will probably always go on the internet just as it does in the rest of the world.

Free-lance writers start class action alleging copyright infringement

Free-lance journalists have started a copyright infringement lawsuit against one of Canada's leading publishing empires, Thomson Newspapers, owners of the Globe and Mail among other things.

Free-lance writers are a downtrodden and misunderstood class of humanity, whose lot in life is to create the elegant and informative prose found in newspapers and magazines, which so enriches the lives of Canada's citizens. Unfortunately, these noble but ink-stained wretches (among whose numbers, from time to time, may be found your humble scribe) often receive minimal pecuniary compensation, despite the excellence of their literary handiwork.

Free-lance writer Heather Robertson hopes to change all this. She is the plaintiff in a lawsuit against Thomson, alleging that reproducing free-lance articles in electronic form without paying journalists extra money is copyright infringement. Her lawyer Michael McGowan hopes to get the action certified as a class under the Ontario Rules. Robertson would then be a nominal plaintiff representing a class consisting of anyone whose literary or artistsic work has been reproduced by Thomson on-line, on CD-ROM or in some other electronic media.

"We hope to arrive at some kind of court-approved mechanism that will enable free-lance journalists to be paid if their work is reproduced in electronic form," said McGowan. However, the action was commenced only in September, and is still at a fairly early stage. The motion for certification as a class action is still some months away, McGowan said.

Free-lancer writers generally sell what is known as a “first use” in their work, meaning that they retain copyright in their deathless prose, and sell only the right to reproduce the work once to the newspaper or magazine. In recent years newspapers have begun to put back issues on-line or on CD-ROMs. Journalists argue they should therefore be paid more if their old articles are being essentially republished on-line. The problem for publishers is that on-line publishing and CD-ROMs do not generally make money, so they say they can’t afford to pay journalists more.

Many publishers are now routinely asking journalists to assign all rights, but without offering more money, and this is causing bitterness in journalistic circles. The case is therefore being watched with interest by both publishers and journalists.