

IP THINKING

McCarthy Tétrault is proud to introduce our IP newsletter, *IP Thinking*.

It is our hope that *IP Thinking* will be read broadly by individuals who share an interest in Canadian intellectual property law. The articles in each issue will be selected to reflect important developments in each IP discipline, with commentary by specialists in those fields.

For example, in this edition you will find an analysis of the Supreme Court of Canada's decision in *Sanofi-Synthelabo*, an important patent law decision particularly on the question of obviousness. We explain the ill-fated Bill C-61, a much-debated piece of copyright reform legislation. The importance of brands as valuable assets is emphasized. Critical developments in *Patented Medicines (Notice of Compliance)* litigation are also highlighted, with a commentary on the first decision of the Federal Court to consider the issue of s. 8 liability.

We hope you find these articles both interesting and useful. If you have any ideas or suggestions that would make our newsletter more interesting and useful for you, please let us know.

Steven Mason and Steven Tanner (Editors)

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BRANDS: Valuable Assets that Need the Attention of Corporate Officers and Directors

By Brian D. Edmonds (Toronto)

In a 2006 decision, the Supreme Court of Canada noted that “The power of attraction of trade-marks and other ‘famous brand names’ is now recognized as among the most valuable of business assets.” Subsequent Canadian financial studies have also identified brands as very valuable corporate assets. The laws governing Canadian corporations require officers and directors to protect such assets. There are important questions that those entrusted with brand oversight should continuously address.

In June 2007, Brand Finance Canada released its “Index of Canada’s Most Valuable Brands,” which identified and ranked Canada’s 50 most valuable brands. The top five – RBC, TD, MANULIFE, BELL and CIBC – had an average value of \$3.5 billion. The value of each constituted, on average, 4.8 per cent of the total enterprise value of the brand owner. SEARS CANADA was ranked 50th in terms of brand value; however, its brand value/enterprise value ratio was the highest, at 48 per cent.

One contributor to the Brand Finance Canada Index stated, “In an increasingly open world economy the route to sustainable advantage is the creation of strong intangible assets including patents, designs and above all brands.” Another stated that “... one of the least recognized and most valuable aspects of the brand is its role as a business system ... and not just as a marketing communication initiative.”

A second study was published in June 2008. In that month Interbrand released its “Best Canadian Brands 2008” report, which identified and ranked Canada’s 25 most valuable brands. The top five – BLACKBERRY, RBC, TD CANADA TRUST, SHOPPERS DRUG MART and PETRO-CANADA – had an average value of \$4 billion. The report’s authors noted that:

Evidence is stronger each year that brands have the ability to create significant economic value for the businesses they serve ... If brands are managed correctly they can move seamlessly across geographies, creating demand for their goods and services around the world.

In September 2008, Interbrand released its 2008 “Best Global Brands” rankings. Two Canadian businesses appeared on the list this year for the first time. The THOMSON REUTERS brand was 44th and was valued at \$8.3 billion. In 73rd position was the BLACKBERRY brand, with a value of \$4.8 billion. Interbrand’s Global CEO commented:

The increasing complexities of the global economy reinforce the importance of protecting and growing a brand. It is a company’s most valuable asset – and a far less volatile asset than others during a time of economic uncertainty.

The duties of officers and directors of public and private corporations in Canada are set out in federal and provincial statutes and court decisions. Those duties include ensuring that the corporation’s assets are appropriately protected. Given the rising prominence of brands as valuable corporate assets, stakeholders may increasingly seek confirmation that the corporation has a well-developed and well-executed brand management program.

Although a corporate brand can include numerous components, at its core are one or more trade-marks. Proper trade-mark management is an essential element to a corporate brand management program. It is not simply an administrative or clerical function. Rather, it is a legal function that ideally interweaves the realities of trade-mark statutes and court decisions with the identification goals of all parts of a corporation – including product development, manufacturing, marketing, sales, human resources and stakeholder communications.

A corporation should continuously ask three key questions as part of its trade-mark management program:

1. Exactly what trade-marks is the corporation using?

Trade-marks can be words, phrases, symbols, designs, colours, shapes of wares or their containers, or modes of wrapping or packaging wares. Trade-marks can also be elements incorporated into the construction of wares. In some countries, even sounds and smells can be trade-marks.

If the corporation has not yet used a mark but intends to use one in the foreseeable future, it can obtain rights in such a proposed trade-mark. In order for trade-mark rights to continue to exist, a mark must be continuously used in commerce. The decision not to use a mark is an important one.

2. In association with precisely what wares and services is the corporation using (or proposing to use) its mark?

Trade-marks must be used in association with wares and/or services. Some marks will be product-specific marks that are only used in association with one product or group of related products. Some will be corporate identifiers that are used in association with all of the corporation's products.

Trade-marks and product/service offerings come and go. It is important to regularly update lists of the corporation's trade-marks and of the wares and services in association with which they are used. They represent the core of the legal trade-mark rights that the corporation owns and can enforce.

3. Has the corporation filed applications with the federal government to register its trade-marks?

Such applications, and the resulting registrations, accord to the corporation valuable rights. For example, once a mark is registered, the corporation owns the exclusive right to use it across Canada, even though the corporation is actually only using the mark in one part of Canada. Registration also confers upon the corporation the right to stop others from using the mark, or a confusingly similar mark, anywhere in Canada.

In the case of a trade-mark that is already registered, the corporation should do periodic checks to ensure that the list of wares and/or services set out in the registration is up to date. As use of the corporation's marks expands, new applications should be filed to augment existing registrations.

A corporation's brands are valuable assets that constitute its public face and persona. The corporation's officers and directors are ultimately the guardians of its identity. They should ensure that an appropriate brand management strategy is in place within the corporation, and that it is followed.

Patentees Score a Victory in the Supreme Court of Canada: Validity of Selection Patents Upheld

By Alfred A. Macchione, Steven Mason, Anita Nador and Steven Tanner (Toronto)

Overview

On Thursday, November 6, 2008, the Supreme Court of Canada released its much-anticipated decision in *Sanofi-Synthelabo Canada Inc. v. Apotex Inc.*, 2008 SCC 61 (Sanofi). In this landmark decision, the Supreme Court gives considerable strength to pharmaceutical patents by rejecting Apotex's generalized attack on selection patents as "evergreening" and holding that selection patents do not differ in nature from any other type of patent. The case is also significant because it adds important clarification to the test for anticipation and brings the law with respect to obviousness into closer alignment with that of the United States and United Kingdom.

Background

The Sanofi case commenced as an application to the Federal Court of Canada brought pursuant to the *Patented Medicines (Notice of Compliance) Regulations*, in respect of the blockbuster drug PLAVIX (clopidogrel bisulfate). Sanofi is the holder of Canadian Patent No. 1,194,875. The '875 Patent contains "genus" claims that encompass about 250,000 compounds, including the racemate of clopidogrel. A racemate is a substance containing equal amounts of two structurally different compounds called optical isomers. Although isomers share the same molecular formula, they can have very different properties. Significantly, the '875 Patent does not distinguish between the isomeric forms of clopidogrel — both are encompassed within the claims.

Sanofi subsequently discovered that a particular isomer of clopidogrel is less toxic and better tolerated than its other isomer. It is the beneficial isomer that was claimed in Canadian Patent No. 1,336,777.

Apotex challenged the validity of the '777 Patent on the grounds of anticipation, obviousness and double patenting. Sanofi was successful at trial and on appeal. The Supreme Court also found in favour of Sanofi and dismissed Apotex's appeal. As a result, the Minister of Health is prohibited from issuing regulatory approval to Apotex in respect of its clopidogrel product prior to the expiry of the '777 Patent.

The Decision

The *Sanofi* decision involves a so-called "old Act" patent. While the statutory law cited by the court therefore comes from the *Patent Act* as it read pre-October 1989, the decision will undoubtedly have broad applicability even to so-called "new Act" patents.

Anticipation

Justice Rothstein (writing for the court) relies heavily upon the House of Lords' decision in *Synthon BV v. Smithkline Beecham plc*, [2005] UKHL 59, which articulates the two-step approach to the anticipation inquiry: "prior disclosure" and "enablement." This approach, which had already been applied in some cases in the lower courts, is now solidified in Canadian law.

For a claim of a selection patent to be anticipated, the first requirement is that the prior patent must disclose subject matter that, if performed, would *necessarily* result in the infringement of the subsequent

patent. There is no room for trial and error or experimentation by the skilled person. If no such disclosure is apparent from reading the document, there is no anticipation. In the case of the '875 Patent, since it did not disclose the special advantages of the isomer claimed in the '777 Patent, the disclosure requirement was not met. It was not sufficient that the compound claimed in the selection patent was also encompassed within a claim in the '875 Patent.

If prior disclosure is found, the second requirement to prove anticipation is "enablement," which means that the skilled person would have been able to perform or work the invention of the new/selection patent as disclosed in the prior/genus patent in light of common general knowledge without "undue burden." For the enablement inquiry, the person skilled in the art may engage in some "routine" trial and error experiments in order to get the invention to work, but "prolonged and arduous trial and error experiments" are not permitted. The court noted that the evidence in this case demonstrated that the identification of a particular isomer of clopidogrel and its advantageous properties required extensive investigation over a period of months, which suggested that such investigation would have constituted an undue burden for the skilled person (although a determination on this issue was not made, given the court's holding that the first part of the test was not met).

Obviousness

The key issue in *Sanofi* was whether the law of obviousness in Canada should be brought more in line with jurisprudence in the United States and United Kingdom, both of which accept that the "obvious to try" test can be relevant in an obviousness inquiry (most recently in *KSR International Co. v. Teleflex Inc.*, 127 S.Ct. 1727). The court agreed it was time to incorporate an "obvious to try" test into Canadian law. However, it said that such a test was only one factor to consider, and, importantly, that it "will work only where it is very plain or ... more or less self-evident that what is being tested ought to work." The mere possibility that "something might turn up" in the experiment is not sufficient to meet the obvious to try test.

Justice Rothstein sets out a four-step approach for assessing an allegation of obviousness:

1. (a) Identify the notional "person skilled in the art."
(b) Identify the relevant common general knowledge of that person.
2. Identify the inventive concept of the claim in question or, if that cannot readily be done, construe it.
3. Identify what, if any, differences exist between the matter cited as forming part of the "state of the art" and the inventive concept of the claim, or the claim as construed.
4. Viewed without any knowledge of the alleged invention as claimed, do those differences constitute steps that would have been obvious to the person skilled in the art or do they require any degree of invention?

It is in the fourth step that the issue of obvious to try will arise (although it is only a factor to consider). In this respect, Justice Rothstein observed that the obvious to try test may only be appropriate in cases where advances are won by experimentation. In such cases, he held that the following factors should be considered:

1. Is it more or less self-evident that what is being tried ought to work? Are there a finite number of identified predictable solutions known to persons skilled in the art?

2. What is the extent, nature and amount of effort required to achieve the invention? Are routine trials carried out or is the experimentation prolonged and arduous, such that the trials would not be considered routine? On this issue, the court suggested that evidence about the actual course of conduct in reaching the invention might be useful (was it relatively straightforward or costly and time-consuming?).
3. Is there a motive provided in the prior art to find the solution the patent addresses?

The evidence in *Sanofi* was that there were just five methods that might be used to isolate the particular isomer of clopidogrel that was the subject of the '777 Patent, that all steps to test the isomers used to identify their benefits were known, and that there was a motivation to find compounds with the benefits disclosed in the '777 Patent. Importantly, Justice Rothstein held that just because there are known methods of separating the isomers, this "does not mean that a person skilled in the art would necessarily apply them." Justice Rothstein also held that nothing in the earlier patent or common general knowledge provided a specific motivation for the skilled person to pursue the invention of the selection patent. Although it was known that the properties of a racemate and its isomers may be different, it was not known what they would be or what these differences were. The possibility of finding the invention is not enough. The specific invention must be "self-evident" before the attempt is made. Justice Rothstein also observed that it took over a year for Sanofi to find the invention after spending millions of dollars developing the racemate without even exploring the possibility that a particular isomer would be superior. In light of these factors, the court found that the invention claimed in the selection patent was not self-evident or obvious from the prior art and common general knowledge.

Double patenting

Justice Rothstein reaffirmed the approach articulated by Justice Binnie in *Whirlpool Corp. v. Camco Inc.*, [2000] 2 S.C.R. 1067 to the prohibition against double patenting, which will invalidate a second patent covering the same invention as the first. There are two types of double patenting: (i) coterminous double patenting, and (ii) obviousness-type double patenting.

The justification for imposing the prohibition against double patenting is to prevent evergreening. However, Justice Rothstein stated that "a generalized concern about evergreening is not a justification for an attack on the doctrine of selection patents."

Justice Rothstein held that the invention claimed in the two patents was not the same, even though the same clopidogrel isomer claimed in the selection patent was also encompassed within the claims of the '875 Patent. The breadth of the invention claimed in the previous patent was larger than the breadth of the invention claimed in the selection patent, and the particular isomer claimed in the selection patent had beneficial and non-obvious properties over those compounds claimed in the prior patent.

Conclusion

This decision is an important victory for patentees in Canada. According to the evidence in the case, about eight out of every 10 pharmaceuticals currently on the market involve selection patents. It is important that financial incentives are available to drug researchers to continue searching for new and better drugs, and this decision decisively confirms that protection for such innovation is available in Canada. In dismissing Apotex's appeal, the court clearly held that selection patents in Canada are valid in principle.

Moreover, the court articulated a clear test for anticipation and obviousness that should present serious obstacles for validity challenges in view of how those tests were considered and applied to the facts of this case.

Finally, this decision demonstrates the court's willingness to revamp Canadian patent law by taking into account foreign jurisprudence to a degree never before witnessed in other Supreme Court decisions involving patents. Notably, the "worth a try" test, previously discredited by lower courts as a consideration in the obviousness inquiry, was incorporated into Canadian law in part based on the confluence of the law in the United States and the United Kingdom. That approach points towards potential further harmonization of Canadian law as further issues of patent law come before the court.

Addendum

By Ariel Neuer (Toronto)

The first Federal Court of Appeal decision to consider Supreme Court Justice Rothstein's decision regarding the obviousness inquiry, *Apotex Inc. v. Pfizer Canada Inc et al.*, 2009 FCA 8 held that the Canadian "obvious to try test" is not equivalent to the UK "worth a try test." Whereas the English test appears to be satisfied if something *may* work, the Canadian test will only be satisfied if it is *self-evident*. The Court of Appeal's decision confirms that in the "obvious to try" test, an invention is not made obvious because the prior art would have alerted the skilled person to the *possibility* that something might be worth trying. Mere *possibilities* are not enough. Rather, the invention must be more or less **self-evident**.

Litecubes LLC v. Northern Light Products, Inc.: "Free on Board" ≠ "Free from Liability"

By Ian K. Bies (Toronto)

On April 28, 2008, the United States Court of Appeals for the Federal Circuit released its decision in *Litecubes, LLC v. Northern Light Products, Inc.* The appeals court upheld a district court's dismissal of Northern Light Products Inc.'s (NLP) motion to dismiss the action for lack of subject matter jurisdiction, and upheld the jury's verdict that NLP was liable for patent and copyright infringement.

NLP, carrying on business as GlowProducts.com, was a Canadian corporation purchasing novelty items from Chinese manufacturers and selling them primarily in North America. One such novelty product was a lighted artificial ice cube. The owner and co-founder of Litecubes, LLC, which owns a US patent for a similar novelty lighted ice cube, sued GlowProducts for patent and copyright infringement.

GlowProducts operated in Victoria, B.C., and did not have offices, facilities or assets in the United States. At trial, the evidence showed that GlowProducts sold the ice cubes directly to customers located in the United States and that the products were shipped "free on board" (FOB) from its Canadian office to buyers

in the United States. FOB is a method of shipment whereby goods are delivered to a designated location at which legal title and risk of loss passes from seller to buyer. In this case, the FOB shipments were structured so that title would change hands in Canada prior to the goods entering the United States.

GlowProducts appealed the finding of infringement on the basis that the district court did not have subject matter jurisdiction to review the case since the sale was made in Canada and not the United States. The court found that because the plaintiff had filed a “well-pled complaint” that properly alleged all of the elements of infringement, the district court (part of the US federal court system) had subject matter jurisdiction. In order to succeed in the action for infringement, the plaintiff would have to show that the allegedly infringing act took place in the United States. However, failure to prove this would not mean that federal court did not have subject matter jurisdiction.

On the issue of infringement, GlowProducts submitted that Litecubes had not satisfied the “territorial” element of infringement that requires the act to be within the United States. Relying principally on *North American Philips Corp. v. American Vending Sales, Inc.*, the court explained that the territorial element may be satisfied regardless of the location where legal title passes, and that the location where the contract was entered into and performance was carried out must also be taken into account. Thus, the federal circuit in the United States may have jurisdiction over an action for patent or copyright infringement even if the sale took place FOB outside the United States.

In *Litecubes*, the court held that (i) the buyers were undisputedly located in the United States, (ii) the buyers contracted for the goods while in the United States, and (iii) the goods were delivered directly to the United States. Therefore, the court had jurisdiction over both the copyright action and patent action since there was substantial evidence to establish a sale in the United States.

This is an important case for Canadian and other non-US businesses that deal with US customers directly. Simply delivering products FOB to US customers will not necessarily avoid an action for patent or copyright infringement in the United States.

Federal Court Decision in First Section 8 Damages Case under the *PMNOC Regulations*: Section 8 remedy found not to include innovator's profits

By Glynnis P. Burt, Steven Mason and William H. Richardson (Toronto)

Apotex Inc. v. Merck & Co., Inc. et al. (21 October 2008), Ottawa, T-1144-05 (Fed. Ct.)

In the first trial decision in an action brought pursuant to Section 8 of the *Patented Medicines (Notice of Compliance) Regulations (Regulations)*, Justice Hughes of the Federal Court has decided that generic pharmaceutical companies are not entitled to disgorgement of the innovator company's profits made during the period of the Section 6 *PMNOC* proceedings in the event the innovator company's application for a prohibition order is dismissed.¹

Justice Hughes also determined that the Federal Court has jurisdiction to hear and determine actions instituted under Section 8, that Section 8 is properly enabled, and that the federal Parliament had the constitutional authority to pass Section 8.

Finally, Justice Hughes decided that the plaintiff in the case at bar could recover its damages or lost profits for the period it was kept off the market as well as those which extended beyond that period for loss of permanent market share, if the damages could not have been or were not rectified in the same period.

Background of the *PMNOC Regulations*

The *Regulations* were originally enacted in 1993 and replaced a compulsory licence scheme for the sale of patented medicines in Canada. Under the *Regulations*, a generic pharmaceutical company may apply for a notice of compliance by comparing its product to an innovator product but must give notice to the innovator that its product will not infringe the innovator product, or that the patent is invalid, among other things. The innovator company may then bring an application under Section 6 to prevent the issuance of a notice of compliance to the generic, thereby instituting an automatic 24-month stay. If the innovator's application is withdrawn, discontinued or dismissed, the generic company may bring an action under Section 8 to recover its losses.

The Action

In this action, Apotex claimed recovery against Merck for the delay in launching Apo-alendronate due to the proceeding commenced by Merck on May 29, 2003. That proceeding was dismissed by the Federal Court on May 27, 2005, and the Minister immediately issued a Notice of Compliance to Apotex.

The Issues

The following issues were raised for preliminary determination: whether the Federal Court lacked jurisdiction to hear an action pursuant to Section 8; whether Section 8 was *ultra vires* Section 55.2(4) of the *Patent Act*; whether Section 8 was outside the scope of Parliament's power to make laws in relation to patents of invention and discovery, and was an intrusion into the exclusive jurisdiction of the provinces under Section 92(13) of the *Constitution Act*; whether Apotex was entitled to an election as between the damages it had

¹ This decision was decided under the old version of Section 8 of the *Regulations*. The *Regulations* were amended in October 2006 to expressly disallow an award of the innovator's profits.

allegedly suffered and the profits made by Merck; the period of time in respect of which Apotex could claim recovery; and whether Apotex was entitled to recover for damages that continued after the period expired.

The Decision

Justice Hughes found that the Federal Court has jurisdiction to hear an action pursuant to Section 8, that Section 8 is enabled by Section 55.2(4), and that Section 8 meets all the criteria required for valid federal legislation, all with reference to specific provisions of the *Regulations*, the *Patent Act*, and the *Federal Courts Act*. Justice Hughes held that the *Regulations* are, in their pith and substance, regulations dealing with patents.

Significantly, Justice Hughes dismissed Apotex's submission that it was entitled to elect between Apotex's damages or Merck's profits during the relevant period. This action was commenced prior to the 2006 amendments to the *Regulations*. Those amendments included a change to Section 8 to remove the right of a generic company to elect "profits." The issue remained regarding what "profits" were referred to in the section prior to the amendment. Justice Hughes decided that what is provided for is an Order compensating a generic company for *loss* for the period it was kept off the market, something different from a claim for damages or an account of profits by an innovator for an act of *infringement*. Justice Hughes held that the reasonable interpretation of the words in Section 8 is that the generic may seek, as a measure of its damages in the alternative, "the profits that it would have made if it had been able to market its product at an earlier time."

Justice Hughes permitted Apotex to continue with its claim for damages for lost sales and lost permanent market share due to the delay in launch "provided that the marketplace did not rectify itself or Apotex could not have remedied the marketplace disadvantage before May 26, 2005."

This is the Federal Court's first Section 8 damages case, some 15 years after the institution of these *Regulations*. Typically, the issue of Section 8 damages has been resolved between the parties by agreement. While this decision clarifies the law and should enable lawyers to better advise their clients as to the likely extent of damages should a Section 8 case proceed to trial, this is by no means the last word on this issue. Both parties have appealed the decision, and so pharmaceutical litigants now await the Federal Court of Appeal's decision.

Proposed Canadian Copyright Reform — Bill C-61

By Barry B. Sookman, forward by Steven Tanner (Toronto)

After much anticipation, the federal government released Bill C-61, *An Act to Amend the Copyright Act*. If passed, the Bill will (i) amend the Copyright Act in order to implement the World Intellectual Property Organization Copyright Treaty (WCT) and Performances and Phonograms Treaty (WPPT), (ii) create exceptions for certain uses of copyright material for private purposes, (iii) create exceptions for Internet service providers (ISPs), and (iv) permit certain uses for educational and research purposes of Internet and other digital technologies.

Bill C-61 passed its first reading in the House of Commons on June 12, 2008, but died on the order paper when the Conservative Party called a federal election on September 7, 2008. Thus it met the fate of its predecessor, Bill C-60, which also attempted to reform copyright law consistent with the WCT and WPPT treaties.

In its throne speech on November 19, 2008, the Conservative Party stated that it will "proceed with legislation to modernize Canada's copyright laws and ensure stronger protection for intellectual property." It appears likely that the Conservative Party will again seek to implement reforms to copyright law as it has attempted to do previously. The article below, commenting on Bill C-61, informs the ongoing debate regarding this next round of copyright law reform.

Implementation of WCT and WPPT

(a) Making available

The bill contains a making available right that applies to sound recordings. There is no express enactment of a making available right for works such as music, computer programs, books and films. In briefing documents accompanying the bill's introduction, the government stated that this right already exists in Canadian law for works.

(b) Protection of technological protection measures (TPMs)

The bill contains legal protection against the circumvention of technological measures. It includes provisions against both circumvention of access control TPMs and trafficking in access control and copy control TPMs. It also includes generally accepted exceptions to the prohibitions on circumvention to allow for reverse engineering, security testing and encryption research, and creation of interoperable computer programs, and to enable persons with perceptual disabilities to access materials and consumers to protect their personal information.

The bill creates remedies for the circumvention of access control TPMs including injunctive relief, damages and statutory damages of up to \$20,000. However, statutory damages are available only if the purpose of the circumvention is to enable infringement.

(c) Distribution and performers' rights

The bill contains a number of other provisions designed to implement the WPPT and WCT:

- a distribution right to allow owners of works to control the distribution of tangible copies of copyright works, which provides control over the first sale of a medium such as a CD or DVD;
- an extension of the term of protection for producers and performers of sound recordings to 50 years after the publication of the recording;
- a reproduction right for performers to authorize the direct and indirect reproduction of their performances by, for example, broadcasters, consumers and record producers; and
- a moral rights provision for performers.

Exceptions for Private Uses of Copyright Material and Remedies for Violations

The bill contains a number of exceptions for private-non-commercial use:

(a) Private use of music exception

The bill will permit individuals to copy a legally acquired sound recording to each separate device they own, such as an iPod or other MP3 player and a computer. The copy must have been legally obtained; it cannot be borrowed or rented. The copy must also be made for private purposes. Also, the right to make copies for the exception is subject to any terms of use agreed to by the individuals with an online music site.

(b) Time-shifting exception

The bill will permit individuals to make a single recording of a television or radio program, including on-demand programs, cable and satellite programs, and programs aired simultaneously on the Internet and TV or radio. No further copies can be made, and time-shifted copies cannot be sold, distributed or performed in public. The bill would also prohibit individuals from creating libraries of digital copies for subsequent viewing. Individuals can keep the recording no longer than necessary in order to listen to or watch the program at a more convenient time.

(c) Format-shifting exception

The new provisions respecting format-shifting allow users to make one copy of content they own for each device (e.g., a copy of a videocassette onto a DVD for use in a home device). The copies must be made for private purposes and cannot be given or sold to someone else. If the user sells or gives away the original, they must destroy all copies that they have made. The provision is restricted to content in certain formats, specifically books, periodicals, newspapers, photographs and videocassettes.

(d) Statutory damages amendments

The bill would substantially reduce the potential liability of individuals who infringe copyright for private, non-commercial purposes to a maximum fine of \$500 for all infringements involved in the suit, regardless of the number of copies made, the number of different works copied or the number of owners who pursue claims against the individual. Commercial infringers could still be liable for up to \$20,000 in damages for each work infringed (e.g., posting music using the Internet or peer-to-peer [P2P] technology).

In all cases, the court would retain the power to award damages, including punitive damages, to ensure an appropriate deterrent against future infringement.

Internet Service Providers

The bill contains exceptions for search engines such as Google and Yahoo! and for ISPs where they act as a mere conduit, provide caching or provide hosting services. The immunities also apply in most cases, even if the ISPs have knowledge of infringing activities.

The bill does not adopt a notice and takedown regime as exists in the US and Australia, but rather prescribes a "notice and notice" regime to deal with online infringement. That is, the ISPs would have to pass on notices from the content holder to the subscriber. Upon receipt of a notice, ISPs must also retain for prescribed periods information required to identify infringers. The failure to comply with the notice and notice regime results in a fine in the range of \$5,000 to \$10,000.

Access for Research and Education

The bill contains several provisions to address concerns from educators and research about reasonable access by:

- allowing schools to use publicly available material that has been legitimately posted on the Internet by rights holders to sites that are not protected by TPMs, or which do not contain a clearly visible notice that prohibits the relevant act;
- allowing schools to transmit materials used in classroom study to students located off-campus so that they can interact with the teacher during the lesson or view it at a time chosen by them, provided that the institution takes reasonable measures to restrict access to students only;
- allowing schools that already have licences to make photocopies of works to make digital copies of those works to send to students, subject to payment; and
- enhancing the ability of researchers to gain quicker access to material stored in distance libraries via the Internet.

McCarthy Tétrault Notes:

According to the government, the reforms in Bill C-61 represent a balance between the rights of copyright owners and the needs of users to access copyright works. From the content holders' perspective, the adoption of the WIPO treaties, the protection of TPMs and the legal remedies for unauthorized copying are welcome changes. As well, the amendments should help ISPs to clarify their liability in cases of infringement. The bill is also very favourable for individual users of copyright materials.

PMNOC Update: Efficiency and the Reversal of Evidence

By Ariel Neuer (Toronto)

Applications pursuant to the *PMNOC Regulations* are often complex and must typically be decided within 24 months of the start of the case. This is because innovators want to prevent the need for the consent to extend past the 24-month timeline provided by the *Regulations*, or for alternative approaches. Generic drug manufacturers also usually prefer to have these cases progress efficiently in order to expedite the entry of their generic product on the market, if successful.

Case Management

One device the Federal Court uses to promote the smooth operation of these cases is the “Case Management” system. Typically, a Prothonotary is assigned at an early stage in the application to manage the application prior to the hearing. Case Management permits the parties to seek interlocutory relief from the court, often on a more informal basis (i.e., without the need to file a motion). This is especially true for matters counsel can agree on, such as scheduling and protective orders.

Filing of Evidence

In the ordinary course, applicants must first deliver their evidence in applications brought in the Federal Court. This requirement can sometimes produce an inefficient result in *PMNOC* applications, particularly when the generic drug manufacturer has alleged that the claims of numerous patents are not valid. Innovators often file extensive expert evidence in response to allegations of invalidity contained in the Notice of Allegation (NOA), yet generics never actually pursue these allegations in the course of filing their responding evidence.

As a result, and in particular where allegations of invalidity have been made, the Federal Court has recently recognized that reversing the order of evidence may be appropriate. This way, the innovator will restrict its responding evidence to matters actually addressed by the generic’s evidence.

This development has not come overnight. Citing basic principles of civil procedure, innovators have long argued that a generic drug manufacturer alleging invalidity of a patent should be required to deliver its evidence of invalidity first. Since a patent is presumed to be valid absent evidence (and not allegations) to the contrary, a generic attacking the validity of a patent in light of that presumption should first be required to serve evidence sufficient to displace that presumption.

In December 2007, the Federal Court issued a Practice Direction which, amongst other things, directed the Case Manager to consider whether a reversal of the order of evidence was appropriate. While such an order had been granted prior to the issuance of this Practice Direction, it signalled a new direction of the court — one that implicitly acknowledges the inefficiencies inherent in the former approach.

Recent Decisions on Reversal

Four recent Federal Court decisions have provided guidance to the parties on reversing the order of evidence in these applications:

In *Astrazeneca Canada Inc. v. Apotex Inc.* 2008 FC 537, Prothonotary Aalto noted that in order to reverse the order of the evidence, there must be a reasonable prospect of savings in time and expense. On the

facts of this case, Prothonotary Aalto did not find that reversal would achieve any savings, and therefore declined to order that delivery of evidence be reversed. Specifically, Prothonotary Aalto held that given the history of litigation and the fact that Apotex's NOAs were very detailed and outlined the evidence with great detail, it could hardly be said that the innovator did not have sufficient insight into Apotex's position on invalidity. Nor was the court inclined to order reversal solely on the basis of the number of pieces of prior art (60) cited by Apotex, since many of them were only a few pages in length.

In *Lundbeck Canada Inc. v. Ratiopharm Inc.* 2008 FC 579, Prothonotary Aronovitch addressed the same issue, but with a twist. Ratiopharm had argued that if the court was inclined to order reversal, it should only order partial reversal of the evidence. That is, the innovator should still be first required to file any factual evidence relating to certain grounds of validity. Prothonotary Aronovitch held that it was not practical to attempt to dissect the grounds for validity, and therefore declined to order partial reversal. Prothonotary Aronovitch held that a full reversal on validity would result in the substantial narrowing of the issues on invalidity, along with the likely commensurate limits on the number of experts — thereby offering substantial economies, including the likelihood of the need for reply evidence.

In *Eli Lilly Canada Inc. v. Novopharm Limited*, 2008 FC 875, Justice Tremblay-Lamer was asked by Novopharm to set aside Prothonotary Tabib's scheduling order, in which Prothonotary Tabib had reversed the order of evidence with respect to invalidity. Notably, Prothonotary Tabib ordered Novopharm to deliver its evidence on validity prior to receiving any evidence from Eli Lilly. This meant that Eli Lilly had received the tactical advantage of seeing Novopharm's evidence on claims construction prior to delivering its own evidence (though often generic drug manufacturers detail their claims construction in their NOA). Justice Tremblay-Lamer dismissed Novopharm's appeal, emphasizing Prothonotary Tabib's experience in dealing with these matters. While Justice Phelan had previously stated that the order of evidence could be reversed in certain circumstances, this is the first considered decision of a judge of the Federal Court granting such relief.

In *Biovail Corporation v. Canada (Minister of Health)*, 2008 FC 1162, Prothonotary Aalto found that invalidity was the dominant issue in the application. The court ordered reversal because it found that reversal would more sharply define the issues, avoid splitting the case, and ensure Biovail did not file evidence "in a vacuum." The dominant consideration for the reversal is whether it will streamline the proceeding or cause delay and increase expenses as a result of further motions seeking to file reply evidence.

Conclusion

Reversal is now a reality in the Federal Court, and the recent cases that have considered it express consistent themes. The court has recognized the intuitive, common-sense appeal of ordering reversal on the issue of invalidity. However, while there is no comprehensive list of factors to consider for ordering a reversal of evidence, the primary consideration for it will be whether it will streamline the proceeding — and in particular, whether it will prevent the need for the filing of reply evidence. Whether the court will embrace a full reversal of the order of evidence, including allegations of non-infringement, remains to be seen.

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