Introduction

There were many decisions and developments of importance in Canadian intellectual property (IP) law in 2008. Patent cases again focused on pharmaceuticals. The Supreme Court of Canada upheld Sanofi’s PLAVIX patent rejecting generic drug maker Apotex’s appeal in Sanofi v. Apotex 2008 SCC 61. But in doing so it changed Canadian law, given developments in the UK and US, and the question is whether it will signal a shift in the law of obviousness against upholding patents. The most interesting trade-mark cases considered functional trade-marks, the special circumstances that justify non-use of a mark, and actionable trade libel. Proposed new Opposition Board practices will significantly change opposition proceedings if adopted. Important proposed amendments to the Copyright Act died with the federal election but are expected to be re-introduced. The Courts considered key copyright issues pertaining to ringtones, and digital audio recorders including iPods. The Federal Court, in which practically all IP cases are heard, started a new initiative to reduce delay and get IP cases to trial within two years.

Key Patent Cases:

Canadian Law of Anticipation and Obviousness no Longer Out-of-Step

In PLAVIX, Justice Rothstein for a unanimous Supreme Court re-wrote the law of anticipation and obviousness in light of UK and recent US law. Apotex attacked Sanofi’s selection patent for its blockbuster blood thinner on the basis that it was already included in an earlier first published Sanofi patent for a large class of such compounds. It is the Supreme Court’s first intellectual property decision since 2007 when it decided Euro-excellence Inc. v. Kraft Canada 2007 SCC 37, reported in last year’s article, following its busy year for IP in 2006.

On anticipation, the Court adopted the UK House of Lords in Synthon v. SKB [2006] RPC 10 overruling its own quite recent pronouncement on anticipation in Free World Trust v. Électro Santé Inc. 2000 SCC 66. Under Synthon, a patent is anticipated if the prior art firstly discloses the invention in that practicing the prior art would infringe the patent under attack, and secondly enables the invention in that it teaches how to practice it and no inventive step is needed. Synthon had already been adopted by the Federal Court of Appeal in another case, Abbott v. Ratiopharm 2006 FCA 187, so this is not a significant change.

On obviousness the Supreme Court overruled long standing authority rejecting “worth a try” to align it with the UK and US. The law of the UK is now to be followed. This includes “worth a try” which will apply in fields where there is experimentation such as pharmaceuticals but according to Justice Rothstein will only succeed where it is “self evident” that what is being tested ought to work.

“Obvious to try” has long been the law of the UK, and in KSR the US Supreme Court held it can invalidate in appropriate cases similar to what Justice Rothstein said. Our US colleagues tell us that KSR has tipped the balance against upholding patents in the lower courts in the US. The UK is reputed for being patent hostile due to “worth a try” especially for chemical and pharmaceutical patents. But if the PLAVIX decision is followed fairly, it should not have these effects in Canada. In substance there is not much change.

In the result, Sanofi’s PLAVIX patent was neither anticipated nor rendered obvious by its first patent under the new tests so the outcome was the same as in the lower courts.

Lastly, double-patenting was decided according to whether the patents had coterminous claims (they did not), and whether the second invention is obvious over the first which was already decided in Sanofi’s favour.

Good Faith Requirement Breached by Inadvertent Non-Response and Deemed Abandonment

As decided by the Court of Appeal in DBC Marine Safety Systems v. Canada 2008 FCA 256 ultimately upholding a decision of the Commissioner of Patents, the inadvertent failure to respond to even a single requisition in an office action will result in abandonment, unless the matter is redressed within the twelve months available for doing so, which presupposes that the error or omission was noticed in time. The Commissioner’s strict approach on abandonment was seen in another context in Sarroff v. AG 2008 FC 712. There a firm which had newly assumed responsibility for a patent application paid maintenance fees. The Commissioner accepted the payment, but later refused it because a formal appointment of agent had not been filed for the new firm. By then the final time for payment had passed so the patent was deemed abandoned. The Federal Court overturned the Commissioner’s decision, and re-instated the application on grounds relating to the interpretation of the Patent Rules and equity. The Attorney General has appealed.

These cases illustrate the necessity of strict compliance with the Patent Act and the Rules. All requisitions made by examiners must be fully and accurately answered, and the Commissioner cannot be relied upon to advise of failure to comply with even technical requirements.

Predecessor Good Faith Requirement not Breached by Inadvertent Failure to Disclose

Prior to current good faith reply
requirements, the duty of good faith owed an examiner was different. The point of delineation is patents issued pre-October 1, 1996, of which there are a very large number currently in force. Mere non-response or failure to adequately respond to a single requisition did not have the harsh result of the application being abandoned and the patent being invalid.

In JOI and Daiichi v. Apotex 2008 FC 744, the Federal Court decided that the patentee Daiichi’s failure to inform the Canadian Patent Office of an interference in the US in response to a specific disclosure request was not a breach of the duty of good faith under the pre-October 1, 1996 regime. The failure to disclose was due to the inadvertence of its patent agent. During prosecution, the Canadian examiner issued an omnibus office action, making numerous requisitions, one of which was a request for disclosure of interference or other conflict proceedings. Daiichi’s overall response was complete and accurate, with the exception of the US interference. The Court held that Daiichi’s response as a whole met the statutory good faith duty then in force requiring it to make a bona fide attempt to advance the application to allowance. The decision is under appeal.

Disclosure Requirements for Selection Patents and Inventions Based on Sound Prediction

In Pfizer Canada and Warner-Lambert v. Ranbaxy 2008 FCA 108, the Federal Court of Appeal held that the requirement for sufficient disclosure of a selection patent is no different from any other patent, and that the disclosure need only answer “what is the invention?” and “how does it work?” For selection patents, answering “what is the invention?” involves disclosing the advantages of the selection. Sufficiency of the data underlying those advantages is a separate challenge to the utility of the invention. The Supreme Court has before it issues relating to the sufficiency of the disclosure of Sanofi’s PLAVIX selection patent (see discussion above), but they may not be decided.

Where an invention is supported by sound prediction, Eli Lilly Canada v. Apotex 2008 FC 142 decided that the disclosure must provide the basis for the sound prediction, applying the Supreme Court’s decision in AZT 2002 SCC 77, as opposed to an extraneous source publicly available as of the Canadian filing.

Where there is both selection and sound prediction, the Court had this to say in obiter in GlaxoSmithKline v. Pharmascience 2008 FC 593: “when a patentee is attempting to establish the utility of a selection by relying upon evidence of sound prediction, there may be an obligation to disclose in the patent the underlying facts and the line of reasoning which support the prediction . . . that is part of the quid pro quo for the claimed monopoly over the selection.”

Limiting PM(NOC) Proceedings Swamping the IP Docket

Most IP cases heard in the Federal Court are Patented Medicine (Notice of Compliance) (PM(NOC)) proceedings in which an innovator is seeking to prevent the grant of regulatory approval to a generic drug maker. These PM(NOC) proceedings arise from Canada’s counterpart to the US Hatch-Waxman regime. Due to their complexity, they easily account for most of the court’s hearing days on IP cases. These proceedings are applications, not actions, so there are no live witnesses in court. Instead they are paper trials on highly technical affidavit evidence and transcripts of out of court cross-examinations. Their purpose is to decide whether the generic should get regulatory approval, which involves issues of patent infringement and validity, but they are not final and binding on patent issues. For a final determination a full action must be brought.

After being overwhelmed by PM(NOC) proceedings for years, Federal Court judges at both the trial and appellate levels have been curtiling them substantively and procedurally. These developments were taking too much of the resources of the court, and other types of IP cases were taking a back seat.

Substantively, res judicata began to be applied to bar generics from reprising arguments of non-infringement and validity, which they had previously lost, or could have made. The recent development of importance came with the release of the Federal Court of Appeal’s decision in Sanofi-Aventis Canada v. Novopharm 2007 FCA 163. There the Court of Appeal said in obiter that if a first generic is unsuccessful in attacking the validity of a patent it would be an abuse of process for another generic to do so unless it has “better evidence” or “more appropriate argument” than in the first case. The lower courts have acted on this, and a series of cases since have applied the new rule, culminating very recently in Janssen-Ortho Inc. and Daiichi Sankyo v. Apotex 2008 FC 744 where Apotex was barred from attacking Daiichi’s levofloxacin patent in PM(NOC) proceedings after it had been upheld in a full action with Novopharm.

Second generics are now essentially left to start a full impeachment action for a final determination of validity.

Procedurally, it was also decided that reforms were needed. Firstly, each side is now limited to five experts unless leave is granted for more. Leave is sparingly granted, so, effectively, experts with multiple fields of expertise are used to cover all the issues. The five experts rule was not enforced in the past, and it was just in late 2007 that the court began doing so.

The five experts rule is also being enforced in other IP proceedings but it is usually only an issue in patent cases.

The second procedural reform in PM(NOC) proceedings is reversing the order of filing evidence. This is a corollary to limiting experts. The innovator normally files first, responding to all the issues raised by the generic. With the five experts rule,
innovators were put at a tactical disadvantage because after they had spread themselves thin covering all the issues in the evidence with their limited experts, the generic would concentrate its expert evidence on select issues chosen by it, thus prejudicing the innovator. The answer is making the generics go first on the evidence, and this is what the court is now starting to order as was done in *Lundbeck v. Ratiopharm* 2008 FC 579.

### Two Years to Trial IP Case Initiative

The Federal Court is giving the option of getting IP cases to trial within two years. While such a request may be opposed, the court now routinely sets two-year timetables for reasonably complex IP cases. This is part of the court’s overall initiative for limiting delays that were inherent in the past.

#### Properly Listing and Addressing Pharmaceutical Patents

The courts have had a large volume of cases relating to the proper listing of pharmaceutical patents by the Minister of Health which generics must address to get regulatory approval under the pre- and post-October 5, 2006 amended PM(NOC) Regulations. In addition, yet more amendments to the PM(NOC) Regulations were made relating to listing which came into force on June 12, 2008. Under these, any patent listed before June 17, 2006 must remain listed and any patent submitted for listing before that date must be listed, with limited exceptions. June 17, 2006 was the final date for submitting patents for listing under the less stringent listing requirements of the pre-amended PM(NOC) Regulations. The amendments cure the decision in *Ratiopharm v. Wyeth* 2007 FCA 264 where the Court reinterpreted the pre-amended PM(NOC) Regulations as requiring relevance between the invention claimed in the patent to be listed and the submission. Innovators had until July 14, 2008 to request relisting of any patents delisted or refused listing by the Minister.

On listing, in *Canada (AG) v. Abbott Laboratories et al.* 2008 FCA 244, the Federal Court of Appeal decided that in order to be listed with a Supplemental New Drug Submission (SNDS) for a new use under the amended PM(NOC) Regulations, a patent must contain a claim for that new use and not simply a claim to the use in the original submission, even though the new use may fall within the scope of that claim.

In *GD Searle and Pfizer v. Minister of Health* 2008 FC 437 the Court considered the eligibility for listing of a patent claiming formulations of the drug Celebrex under the amended PM(NOC) Regulations with a SNDS for a change in use. Searle argued that because it was well established in law that under the pre-amended PM(NOC) Regulations a claim for a formulation of a medicine was a “claim for the medicine itself”, it should likewise be that a formulation claim qualifies as a claim for a “medicinal ingredient” under the amended PM(NOC) Regulations. The Court rejected this proposition because the amended PM(NOC) Regulations distinctly define differently claims to formulations and claims to medicinal ingredients, unlike the pre-amended Regulations. It then found that the claims of Searle’s patent were for dosage forms and not the use of the medicinal ingredient, and therefore the patent was ineligible for listing with the SNDS.

There are now conflicting decisions on how the Minister is to decide which patents must be addressed under the pre-amended PM(NOC) Regulations. In *Pharmascience v. Minister of Health* 2008 FC 922, Pharmascience sought judicial review of the Minister’s decision requiring it to address two patents in respect of its Supplementary Abbreviated New Drug Submission (SANDS) for an additional dose of generic ramipril capsules under the pre-amended PM(NOC) Regulations. This is another part of the saga of generic ramipril. The two patents had been listed when Sanofi-Aventis received a new NOC for a new indication. The Minister interpreted the Supreme Court’s decision in *AstraZeneca v. Minister of Health* 2006 SCC 49 (discussed in last year’s article) to require all listed patents to be addressed as of the date of the Abbreviated New Drug Submission (ANDS) or SANDS, following *Ferring v. Minister of Health* 2007 FC 300, affirmed on appeal at 2007 FCA 276. Ferring also involved generic ramipril. But the Court held that the Ferring interpretation was wrong. It was based on the mere fact that Pharmascience could have used the teachings of the patents because they were listed before filing of its SANDS and so it could be required to address a patent not relevant to its drug submission, contrary to *AstraZeneca*. The Court remitted the matter back to the Minister to decide which patents were relevant and thus had to be addressed. The Minister has appealed in *Pharmascience*.

#### Key Proposed Patent Legislation:

**Biologics**

Health Canada released its revised draft guidance document on subsequent entry biologics titled “Information and Submission Requirements for Subsequent Entry Biologics (SEBs)” and held industry consultations. Under the draft, if a biologic is “similar” to an approved reference product through comparative studies, the approval process would be stream-lined analogous to generics under the PM(NOC) Regulations although the scope of innovator protection, including data protection, remains to be determined.

#### Key Trade-mark Cases:

**Expungement Under s. 45 of the Trade-Marks Act - “Special Circumstances” Revisited**

The Federal Court of Appeal in *Scott Paper v. Smart and Biggar* 2008 FCA 129 decided that intention to resume use does not qualify as special circumstances excusing non-use, overruling *Oyen Wiggs*
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Trade Libel Under s. 7(a) of the Trade-Marks Act

The Federal Court has decided that trade libel claims for “false and misleading statements intended to discredit the wares or services of a competitor” under s. 7(a) of the Trade-Marks Act are only available for claims against actual competitors. Thus non-competitors who make false and misleading statements about other companies are immune to s. 7(a) claims. They may however be liable under the common law tort of trade libel in the provincial superior courts. In Canadian Copyright Licensing Agency v. Business Depot 2008 FC 737, Business Depot was sued for copyright infringement. The plaintiff’s business is licensing copyright in a repertoire of works. After the litigation got underway, Access Copyright issued a press release to which Business Depot objected. Business Depot counter-claimed under s. 7(a), but its claim was struck. The court rejected Business Depot’s position that the parties were competitors because they did not compete for the same customers, or sell the same products in the same market. In addition, the court held that s. 7(a) was limited to causes of action relating to false and misleading statements relating to a trade-mark or other intellectual property of the claimant if it can be constitutionally valid and within the authority of parliament. The court held that s. 7(a) was limited to causes of action relating to false and misleading statements relating to a trade-mark or other intellectual property of the claimant if it can be constitutionally valid and within the authority of parliament. The court held that s. 7(a) was limited to causes of action relating to false and misleading statements relating to a trade-mark or other intellectual property of the claimant if it can be constitutionally valid and within the authority of parliament.

Functional Design May Still be a “Trade-Mark”

In Crocs Canada Inc. v. Holey Soles Holdings Ltd. (2008), 64 C.P.R. (4th) 467 (FC) the plaintiff commenced an action for passing off and copyright infringement against Holey Soles Holdings, for selling footwear closely resembling the well known CROCS clogs. Holey Soles moved for summary judgment on the basis that the get-up of circles and semi-circles on Crocs clogs is not a “trade-mark” under the Trade-Marks Act because it is functional, and therefore no action lies for passing off under the statute. The action was in the Federal Court, which only has jurisdiction under the Trade-Marks Act. Under the common law tort of passing off available in the provincial courts the statutory definition of “trade-mark” need not necessarily be met. Holey Soles relied on the leading case on functional trade-marks, Kirkbi AG v. Ritzvik Holdings Inc. (2005), 43 C.P.R. (4th) 385 (SCC) (the LEGO case), which decided that trade-mark protection is not available under the Trade-Marks Act for get-up that is “purely” functional, even if otherwise actionable at common law because it has the requisite goodwill and its use by the defendant causes confusion and damage.

The Court decided that Kirkbi did not exclude from protection “any and every mark which displayed some functional features” and that the proper question is whether the get-up is primarily functional, which could not be decided on summary judgment.

Changes To Trade-Mark Opposition Proceedings:

The Trade-marks Office has proposed significant new changes in opposition practice designed to limit delays and encourage early settlement. The most important would add an early “cooling off” period, permitting parties to explore settlement before evidence or written arguments are filed. The Office is considering comments, and expected to finalize its new practice by the end of the year.

Key Copyright Legislative Developments and Case Law:

Proposed Legislation to Update Canada’s Copyright Act

Bill C-61 (2nd Sess, 39th Parl., 2008) was intended to update Canada’s copyright laws for the digital and Internet age, and to align with international standards reflected in World Intellectual Property Organization’s Copyright, and Performances and Phonograms Treaties, adopted in 1996. The proposed legislation would have granted rights holders additional protections comparable to those in the US Digital Millennium Copyright Act. The Bill addressed digital media and Internet issues such as time-shifting and media-shifting, the liability of Internet service providers, technological protection measures and digital rights management, as well as technology-enhanced learning. It also lowered statutory damages for infringements done for private purposes, and gave photographers the same ownership rights as other creators. The Bill died with the call of the Federal election. Had the Bill passed, it would have marked the first major reform to Canada’s copyright laws in over a decade. Since it has been re-elected, the Conservative government may reintroduce the same or a similar Bill as it promised, although of course, political priorities could change.

Court of Appeal’s Analysis on “Making Available” and “Offering to the Public” in Finding Ringtones Subject to Copyright Tariff Could Impact Future Cases

In C.W.A. v. Society of Composers, Authors & Music Publishers 2008 FCA 6, the Federal Court of Appeal found that the transmission of ringtones to cell phones are “communications to the public by telecommunication” under the Copyright Act, and subject to copyright royalties. The Court considered whether ringtones were: (i) “communications”, and (ii) “to the
public”. The Court found the transmission of ringtones were "communications", regardless of whether the recipient accesses the ringtone immediately in order to hear the music, or at some later time. The Court also found that the communications were "to the public", and analogized to a television broadcast, which is public "even if no one is watching it or everyone who is watching it is doing so in private, because it is made available to a sufficiently large and diverse group of people.” The Court found "the fact that the ringtones are offered to the public, or to a significant segment of the public, supplies the requisite degree of ‘openness’ to be to the public”. The Supreme Court refused leave to appeal. It will be interesting to see how this analysis will be interpreted in future Internet and mobile telecommunications cases.

iPods, Other Digital Audio Recorders, and their Memory are not Subject to Canada’s Copyright Levy on Blank Audio Recording Media

The issue of whether iPods and other digital recorders and their memory are subject to the “blank audio recording medium” copyright levy under Canada’s private copying regime appears to have been put to rest. In Apple Canada Inc. et al v. Canadian Private Copying Collective et al 2008 FCA 9, the Federal Court of Appeal, following an earlier case, found that the Copyright Board has no authority to certify a copyright levy on digital audio recorders or memory permanently embedded in digital audio recorders, as these technologies do not fit within the statutory definition of a “blank audio recording medium”.

Record Damage Award Against Counterfeitters - the Awarding of Maximum Statutory Damages for Copyright Infringement Continues

In Louis Vuitton Malletier SA v. 486353 BC Ltd. 2008 BCSC 799, the British Columbia Supreme Court awarded what appear to be the highest Canadian damages against a counterfeiter. The Court awarded statutory damages at the highest end of the scale at $20,000 per work for copyright infringement. The Court held that damages ought to be awarded at the high end of the scale where the conduct of the defendants is dismissive of law and order and demonstrates need for deterring future infringement. In addition to damages for copyright and trade-mark infringement, the Court also awarded a total of $300,000 in punitive and exemplary damages. This follows two earlier decisions of the Federal Court against counterfeitters with significant damage awards (Louis Vuitton Malletier SA v. Lin Pi-Chu 2007 FC 1179 and Microsoft Corporation v. 9038-3746 Quebec Inc. 2006 FC 1509).

Kraft Canada Inc. Restarts Toblerone Case

Finally, as discussed in our previous article in this publication in 2007, the Supreme Court of Canada denied Kraft Canada Inc., as an exclusive licensee of Canadian copyright, the right to stop parallel importation into Canada of product bearing a copyright design where the product was made by the owner of the Canadian copyright. The Court said in essence that only the copyright owner could do so. Kraft Canada Inc. was assigned the copyright and commenced a fresh proceeding as copyright owner. It originally relied on copyright because parallel importation could not be stopped under trade-mark law. This case will be watched to see if copyright will finally be successful.

1. One of the authors, Michael Charles, represented Daiichi in that proceeding.
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Senior partner. Practices in IP litigation, primary emphasis on chemical, pharmaceutical and biotech litigation. Appears before the federal court, federal court of appeal and the SCC as senior counsel in patent and trade-mark matters, including the Schmeiser Appeal on behalf of BIOTECanada. Listed by Global Counsel as a leading lawyer in Canada for IP litigation in life sciences; by Lexpert as one of few IP litigators in the top rank category, by National Post as one of the “Top 100 Cross-border Lawyers in Canada”. Listed in the Lexpert®/ALM Guide to the Leading 500 Lawyers in Canada and in The International Who’s Who of Patent Lawyers. Regularly appears on behalf of many brand name pharmaceutical and biotech companies and organizations. Registered Patent and Trade-Mark Agent; licensed to practice before the USPTO as a patent agent. Extensive technical experience; expertise in biotechnology, chemistry, nuclear science, geology and general mechanical matters. Member, CBA, IBA, IPIC. Past co-chair of the Joint Liaison Committee with the Canadian Patent Office. Ontario Bar (1981).

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Specialized intellectual property practice with a focus on litigation involving patents, trademarks, industrial designs, copyright, unfair competition, trade secrets and computer related technology. More than 100 of the cases he has been involved in thus far have been reported in Canada. Vast experience with extraordinary recourses such as interim or interlocutory injunctions and seizures before judgment. Appears before all levels of Quebec and Federal Courts. Frequent lecturer in the area of intellectual property matters. Listed in the Lexpert® Guide to the Leading US/Canada Cross-Border Corporate Lawyers in Canada, the Chambers Global Guide, and The Best Lawyers in Canada. Fellow of IPIC. Member of CBA, INTA, AIPPI, ECTA, LIDC. L.L.L. Registered trade-mark agent. Called to the Quebec Bar in 1982.