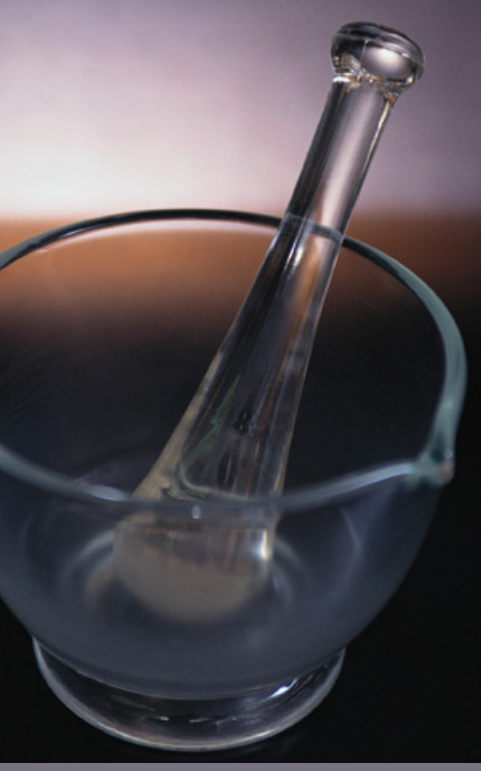

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Rx IP UPDATE

CANADIAN PHARMACEUTICAL INTELLECTUAL PROPERTY LAW NEWSLETTER

August 2008

Court of Appeal applies strict matching requirement for listing against SNDS for new use under amended *Regulations*

On July 25, 2008, the Federal Court of Appeal considered for the first time the "relevance" requirement for listing a patent on the Patent Register maintained pursuant to the amended *Patented Medicines (Notice of Compliance) Regulations* ("*Regulations*"): *Minister of Health v. Abbott*, 2008 FCA 244. The requirement was introduced by the October 2006 amendments. Specifically, the Court considered the "relevance" requirement of section 4(3)(c), which provides:

> 4(3) A patent on a patent list in relation to a supplement to a new drug submission is eligible to be added to the register if the supplement is for a change in formulation, a change in dosage form or a change in use of the medicinal ingredient, and
> ...
> (c) in the case of a change in use of the medicinal ingredient, the patent contains a claim for the changed use of the medicinal ingredient that has been approved through the issuance of a notice of compliance in respect of the supplement.

The Court of Appeal reversed the decision of the Applications Judge (*Abbott Laboratories Limited v. Canada (Attorney General)*, 2007 FC 797), which had allowed Abbott's judicial review of a Minister's decision to delist a patent listed against a supplemental new drug submission (SNDS). The Applications Judge had characterized the patent as follows:

> [5] The 053 Patent claims various methods for producing solvent-free lansoprazole crystals and the crystals themselves. There are also three claims related to the crystals' use in the treatment of ulcers. These use claims are the ones which are relevant in this case and are as follows: claim 10 claims a medicine comprising the solvent-free crystal for use as an anti-ulcer agent, claim 12 is for use of the solvent-free crystal for manufacturing a medicine for use as a anti-ulcer agent and claim 13 is for the use of the solvent-free crystal for treating or preventing ulcers.

The new drug submission (NDS) was approved for the use of PREVACID for the treatment of duodenal ulcers, gastric ulcers, and reflux esophagitis. The SNDS against which the patent was initially listed was approved for a new indication, "[h]ealing of NSAID-associated gastric ulcer and reduction of risk of NSAID-associated gastric ulcer". The patent could not be listed against the NDS in view of timing issues.

The first issue was the applicable standard of review, which was held to be correctness.

The second issue was whether the amended *Regulations* applied. The patent list had been submitted in July 2006. As a result of the transitional provisions that accompanied the October 2006 amended *Regulations* — which on their face applied, as the patent list was submitted after June 17, 2006 — the Minister delisted the patent after applying the amended *Regulations*. Justice Simpson held that the Minister was correct to apply the amended *Regulations* and the Court of Appeal affirmed.

The third issue was whether the Minister was correct in finding that the patent was not eligible for listing against the SNDS. Justice Simpson had accepted the expert evidence that an NSAID ulcer is a type of "ulcer" included within the scope of the claims and therefore found the patent eligible for listing. The Court of Appeal found that Justice Simpson had erred, finding that a stricter matching requirement was required as between the changed use in the SNDS and the claimed use. Specifically, the Court of Appeal held:

> [47] It stands to reason that if a patent must contain a claim for the changed use identified in Abbott's SNDS, that patent cannot simply claim the use which formed the basis of the original submission. Such a patent does not specifically claim the changed use, even though the changed use may come within the claims of the patent. In other words, the Regulations envisage as a condition of listing a patent in respect of a change in the use of a medicinal ingredient that the patent specifically claims the changed use as opposed to non-specific claims which are wide enough to include the changed use.
>
> ...
>
> [49] ...I conclude that paragraph 4(3)(c) of the Regulations requires, as a condition of listing a patent on the Patent Register, that the patent must specifically claim the very change in use which was approved by the issuance of a Notice of Compliance with respect to an SNDS.
>
> [50] As a result, I am of the view that Simpson J. erred in accepting the expert opinions which were placed before her as evidence that the '053 patent contained a claim for the changed use of the medicinal ingredient in PREVACID. That evidence went no further than showing that the '053 patent would have been eligible for listing against the original submission for PREVACID, had it not been for the fact that the date of the submission preceded the date of the patent application. To allow registration of the '053 patent against the SNDS for a changed use which was not the subject of a specific claim would be to undo the reform which the amended regulations seek to introduce.

Thus, the Court imposed a strict matching requirement for listing a use patent against an SNDS for a change in use.

Federal Court revisits test for requirement to address patents under old *Regulations*

The Federal Court had previously considered the test for addressing patents under the old *Regulations* in *Ferring Inc. v. Canada (Health)*, 2007 FC 300, aff'd 2007 FCA 276. In a July 29, 2008 decision, the Court revisited this test: *Pharmascience Inc. v. Canada (Health)*, 2008 FC 922. The Minister had decided following the Ferring decision that Pharmascience was required to address patents listed against ALTACE (sanofi-aventis' ramipril) for its submission for ramipril 1.25 mg as the submission against which the patents had been listed was approved before Pharmascience's submission was filed. Justice Simpson held that the Minister erred in so finding, stating that the relevant date was the date Pharmascience had purchased ALTACE, *i.e.* only patents listed against submissions approved by the date of purchase of the comparator product are required to be addressed. Justice Simpson stated:

> [31] ...the comparator drug, which was approved for the treatment of hypertension, is not the subject of the 387 and 549 patents and the Applicant does not seek approval for the drug in connection with treatment of patients with increased risk of heart attack. This means that the Applicant, to paraphrase the words of AstraZeneca at paragraph 38, has not, in fact, made use of the patented inventions taught by the 387 and 549 patents.
>
> [32] The fact that the Applicant in this case could have made use of the later patents (while in AstraZeneca, such use was an impossibility) doesn't alter what I view to be the gravamen of AstraZeneca. AstraZeneca stands for the proposition that a generic company need only address patents listed against NOC's filed at the time it purchases the comparator drug it selects for the purposes of its ANDS. The Minister therefore erred in law when he required the Applicant to address the 387 and 549 patents.

The Minister may appeal as of right.

Apotex enjoined from making and selling perindopril

In a July 2, 2008 judgment released following a 35-day trial, the Trial Judge, Justice Snider, found that Apotex Inc. and Apotex Pharmachem Inc. had infringed the patent covering perinodopril (Servier's COVERSYL) and that the patent was valid: *Laboratoires Servier, Adir, Oril Industries, Servier Canada Inc. v. Apotex Inc.*, 2008 FC 825. Apotex is enjoined from manufacturing and selling products containing perindopril and Servier is entitled to elect either an accounting of profits or damages.

While Justice Snider found that there was direct infringement, she was not persuaded that title to tablets sold by Apotex to foreign purchasers passed in Canada and therefore there was no inducement of infringement by such sales. Apotex also argued that it did not infringe one of the claims since the certificates of correction issued for that claim issued without legal basis. Justice Snider held that the Commissioner's decisions to issue the certificates of correction were reasonable and should not be overturned.

Justice Snider rejected Apotex's validity attacks of obviousness, inutility, lack of sound prediction and improper inventorship/ anticipation.

Apotex also sought damages pursuant to section 36 of the *Competition Act*. Some of the claims of the patent were placed into a conflict proceeding that was resolved by settlement among ADIR, Schering and Hoechst. Apotex argued that the actions of the parties to the settlement agreement ensured that the parties would gain effective control over the manufacture and supply of a number of ACE inhibitors — including those within the scope of the claims of the patent — and thereby prevent, limit or lessen unduly competition in the market for ACE inhibitors. Justice Snider rejected this claim, finding that ADIR was merely exercising its rights under the *Patent Act* to obtain patents and nothing more and, in any event, Apotex brought the action beyond the two-year limitation set out in the *Competition Act*.

Significantly — and consistent with the speed at which patent infringement actions have recently been proceeding in the Federal Court — this case was decided less than two years after being commenced. Apotex has appealed.

Health Canada releases Draft Guidance Document regarding Schedule A and section 3 to the *Food and Drugs Act*

Presently, the *Food and Drug Regulations* prohibit preventative, treatment and cure claims of diseases listed in Schedule A in labelling and advertising to the general public.

Schedule A was recently amended. (*Regulations Amending Schedule A to the Food and Drugs Act and the Medical Devices Regulations (Project 1539)*).

A further amendment now exempts:

- natural health products;
- nonprescription drugs (apart from drugs regulated as Class A precursors under the Precursor Control Regulations); and
- prescription drugs that are veterinary drugs listed in Part II to Schedule F (so long as the drug is in a form not suitable for human use or is labelled for veterinary use only) from the prohibition on preventative claims for the diseases listed in Schedule A.

Both sets of amendments came into force on June 1, 2008. (*Regulations Amending Certain Regulations Made under the Food and Drugs Act (Project 1539)*).

Health Canada has released a draft revised Guidance Document relating to Schedule A/section 3 to include information relating to these regulatory amendments. Comments will be accepted until September 21, 2008. (Consultation notice. Draft Guidance Document - Schedule A and Section 3 to the *Food and Drugs Act*.)

PMPRB News

PMPRB to conduct hearings into pricing by two generics. The Board will be conducting hearings relating to the pricing of medicines by two generic companies, Apotex (relating to Apo-Salvent CFC Free) and ratiopharm (relating to ratio-Salbutamol HFA).

The Apotex hearing is scheduled for December 8, 2008 and the ratiopharm hearing is scheduled for January 12, 2009. (Notice of hearing – ratio-salbutamol HFA. Notice of hearing – Apo-Salvent CFC Free.)

July newsletter released. The Board released its July newsletter, which indicates that on August 18 the Board will issue a Communiqué to clarify what information patentees will be required to report regarding average transaction prices pursuant to the *Patented Medicines Regulations* beginning in January 2009. Further, a Notice and Comment package, including draft revised Excessive Price Guidelines, will be released on August 20. The deadline for submitting comments on the draft revised Guidelines will be October 6. (Newsletter.)

Recent Court decisions

Patented Medicines (Notice of Compliance) Regulations

Apotex's evidence on testing tendered after the date of the NOA struck. In an application regarding escitalopram oxalate (CIPRALEX), a Motions Judge allowed Lundbeck's appeal insofar as it relates to its motion to strike an affidavit regarding test results tendered by Apotex. The Judge found that the affidavit goes beyond the notice of allegation (NOA) as the test results did not exist at the date of the NOA. He held that to allow the affidavit to stand or even giving Lundbeck a right to reply would be to allow Apotex to split its case. Apotex has appealed. (*Lundbeck v. Minister of Health and Apotex*, June 23, 2008, reasons – 2008 FC 787.)

Court of Appeal reverses decision on striking notice of appearance by respondent-patentee. Sepracor, a patentee, had been named as a respondent in a prohibition proceeding. Pharmascience brought a motion to strike Sepracor's notice of appearance on

the basis that it had replaced "oppose" with "participate" in the form. The Motions Judge struck the notice of appearance. While he determined that Sepracor was properly named as a respondent, he held that if Sepracor wishes to make representations that *support* the application, it must seek intervener status or apply to be joined as an applicant. The Court of Appeal reversed the decision, finding that respondents who do not oppose an application are entitled to file a notice of appearance by modifying the form. (*Sepracor v. Schering-Plough and Schering and Pharmascience*, June 28, 2008, reasons – 2008 FCA 230, rev'g 2008 FC 359.)

Court of Appeal affirms dismissal of action for damages against Crown. Nu-Pharm brought an action for damages against the Crown, alleging that the Crown unlawfully advised provincial regulatory authorities, pharmacists, distributors, and public and private insurers that the sale of Nu-Enalapril is unlawful following the quashing of Nu-Pharm's NOC. The Motions Judge granted the Crown's motion for summary judgment and found that obtaining damages is entirely dependent upon Nu-Pharm's showing of the unlawful character of the Government's decisions, which must be determined by way of judicial review. The Court of Appeal upheld the decision. The Court found that Nu-Pharm, by its actions, seeks to challenge the lawfulness of a decision rendered by a Federal Board and it must therefore do so by commencing an application for judicial review. (*Nu-Pharm v. Canada*, July 3, 2008, reasons – 2008 FCA 227, aff'g 2007 FC 977.)

Federal Court considers "dosage form" eligibility. Bayer sought judicial review of a Minister's decision that a patent was not eligible for listing pursuant to the amended *Regulations*. The case was the first to interpret the meaning of the new provisions, a "claim for the dosage form" and sections 4(2) and 4(3) that now permit the listing of dosage form patents. The patent claimed a package, a desiccant and a transdermal patch containing estradiol (Bayer's MENOSTAR and CLIMARA products). The Minister refused to list the patent, deciding that the patent did not claim a dosage form that was approved by issuance of a notice of compliance (NOC). For CLIMARA, the Judge additionally reasoned that the change in strength was not a change in dosage form. The Judge found that the invention was not a dosage form for the purpose of the *Regulations* as the desiccant and package are not part of the transdermal administration of the medicinal ingredient and that the dosage form, the patch, was not part of the invention but merely incidental to the invention. The Judge also concluded that the SNDS for a change in strength was not an SNDS for a change in dosage form. (*Bayer Inc. v. Canada (Health)*, July 10, 2008, reasons – 2008 FC 857.)

Federal Court confirms reversal of the filing of evidence on validity. In a prohibition proceeding relating to olanzapine (Eli Lilly's ZYPREXA), a case management Prothonotary had ordered that Novopharm's evidence regarding validity of the patent at issue be filed first. Novopharm's appeal was dismissed. (*Eli Lilly v. Novopharm and Minister of Health*, July 16, 2008, reasons – 2008 FC 875.)

Patent found ineligible for listing under old *Regulations*. A motion for dismissal of a proceeding was brought on the basis that the patent, listed under the old *Regulations*, was ineligible for listing. The patent claimed "[s]pherical granules having a core coated with spraying powder containing a drug and low substituted hydroxypropylcellulose having a hydroxypropyl group content of from about 4 to about 20% by weight". A dependent claim defined the drug as lansoprazole or omeprazole. Considering the evidence, the Court held that the patent claims a delivery system and does not include a claim for lansoprazole, the medicine itself. Accordingly, the Judge dismissed the proceeding. The Order was granted before the June 2008 amendments that now preclude dismissal of a proceeding on the basis of ineligibility of a patent listed under the old *Regulations* (apart from motions brought before April 26, 2008). Abbott has appealed. (*Abbott Laboratories Ltd. v. Canada (Health)*, July 29, 2008, reasons – 2008 FC 919.)

Other decisions

Defendant must be identified in patent impeachment action. A Prothonotary dismissed an *ex parte* motion brought by Novopharm for a confidentiality Order to allow its statement of claim to be issued identifying the defendant only as "Company X", the patent as the "X" patent and the drug as the "X" drug. Novopharm had argued in part that the confidentiality of its business strategy is important and that if it is prematurely disclosed to its competitors, Novopharm would suffer serious prejudice and lose any advantage gained by its early development of the product. Novopharm also submitted that the protective order would ultimately benefit the public by avoiding NOC proceedings. The Prothonotary held that the public has an interest in knowing the information Novopharm seeks to protect. He also found that the conservation of judicial resources raised by Novopharm as a public interest matter to support the confidentiality Order is a matter to be managed by the Court and should not enter into the Court's exercise of discretion in the granting of confidentiality Orders. An amended claim was subsequently filed identifying the defendant as Eli Lilly and the drug as atomoxetine (Eli Lilly's STRATTERA). (*Novopharm v. "Company X"*, July 4, 2008, reasons – 2008 FC 840.)

New Court proceedings

Patented Medicines (Notice of Compliance) Regulations

Medicine:	lansoprazole (PREVACID)
Applicants:	Abbott Laboratories Limited, Tap Pharmaceuticals Inc, Takeda Pharmaceutical Company Limited and Takeda LLC
Respondents:	The Minister of Health and Novopharm Limited
Date Commenced:	June 27, 2008
Court File No:	T-1028-08
Comment:	Application for an Order of prohibition until expiry of Patent No. 2,009,741. Novopharm alleges non-infringement and invalidity.

Medicine:	latanoprost ophthalmic solution (XALATAN)
Applicants:	Pfizer Canada Inc and Pharmacia Aktiebolag
Respondents:	The Minister of Health and Cobalt Pharmaceuticals Inc
Date Commenced:	July 15, 2008
Court File No:	T-1085-08
Comment:	Application for an Order of prohibition until expiry of Patent No. 1,339,132. Cobalt alleges non-infringement and invalidity.

Medicine:	tazobactam sodium/piperacillin sodium (TAZOCIN)
Applicant:	Wyeth Canada
Respondents:	The Minister of Health and Apotex Inc
Date Commenced:	July 18, 2008
Court File No:	T-1116-08
Comment:	Application for an Order quashing the NOC issued to Apotex to market a generic version of a previous formulation of Tazocin. Wyeth alleges, among other grounds, that Apotex failed to comply with the *Regulations* and that the Minister has exposed the Canadian public to serious risk of grievous harm as Apotex and Wyeth's products cannot be used under the same clinical conditions.

Medicine:	escitalopram (CIPRALEX)
Applicant:	Lundbeck Canada Inc
Respondents:	The Minister of Health, Novopharm Limited and Teva Pharmaceutical Industries Ltd
Respondent/Patentee:	H. Lundbeck A/S
Date Commenced:	July 23, 2008
Court File No:	T-1142-08
Comment:	Application for an Order of prohibition until expiry of Patent No. 1,339,452. Novopharm alleges non-infringement and invalidity.

Other new proceedings

Medicine:	atomoxetine capsules (STRATTERA, Novo-atomoxetine)
Plaintiff:	Novopharm Limited
Defendant:	Eli Lilly and Company
Date Commenced:	May 22, 2008, amended July 17, 2008
Court File No:	T-811-08
Comment:	Patent impeachment action relating to Patent No. 2,209,735. Pleadings originally marked confidential and sealed.

Medicine:	memantine (EBIXA)
Applicant:	Lundbeck Canada Inc
Respondents:	The Minister of Health (Canada) and Cobalt Pharmaceuticals Inc
Date Commenced:	July 23, 2008
Court File No:	T-1143-08
Comment:	Application for an Order quashing and setting aside any decision of the Minister accepting a filing relating to an abbreviated new drug submission (ANDS) identifying memantine as an alleged Canadian Reference Product, including an ANDS by Cobalt relating to Co Memantine and an Order prohibiting the Minister from accepting the filing of such an ANDS until six years after the issuance of an unconditional NOC for memantine. At the time of filing Cobalt's ANDS, memantine had conditional marketing authorization under a notice of compliance with conditions (NOC/c).

To check the status of Federal Court cases, please click here.

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