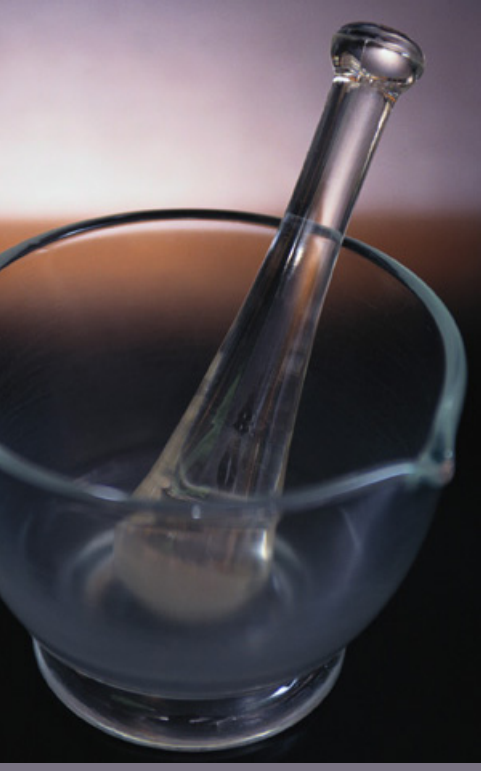

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Rx IP UPDATE

CANADIAN PHARMACEUTICAL INTELLECTUAL PROPERTY LAW NEWSLETTER

August 2007

Court of Appeal applies "relevance" requirement for patent listing under preamended *Regulations*

As reported in the May 2007 issue of *Rx IP Update*, a Judge had found that in order to be listed (or to remain listed) under the **preamended** *Patented Medicines (Notice of Compliance) Regulations* ("*Regulations*"), a patent must be relevant to the submission against which it is listed (*Wyeth Canada v. Ratiopharm Inc.*, 2007 FC 340).

The decision arose from a motion brought by ratiopharm for summary dismissal of a prohibition proceeding regarding a patent listed against Wyeth's drug, EFFEXOR XR (venlafaxine). The Judge, granting deference to the Minister's decision to list the patent, declined to find the patent was improperly listed in association with two NOCs and dismissed ratiopharm's motion.

On August 1, 2007, the Federal Court of Appeal allowed ratiopharm's appeal (*ratiopharm v. Wyeth*, 2007 FCA 264). It proceeded on the basis that the Judge was correct in finding that relevance was required between the patent and the NOCs against which it was listed. However, the Court found that the Judge erred in granting the Minister's decision deference, finding that the motion must be decided on the balance of probabilities standard, with the burden lying on the moving party (ratiopharm).

Applying this standard, the Court of Appeal found, based on the evidence, that the patent was not eligible for listing against the two NOCs at issue. The Court therefore granted ratiopharm's summary dismissal motion and dismissed Wyeth's prohibition proceeding.

The patent claimed use of the extended release formulation of venlafaxine hydrochloride for the treatment of depression (see claims). The first NOC sought a new indication for maintenance treatment of major depressive disorder. The Court rejected Wyeth's argument that maintenance treatment is a subset of treatment and that the claims should therefore be interpreted as including claims for the maintenance treatment of major depressive disorder. The second NOC sought approval for changes to the product monograph relating to nausea reduction with

Effexor XR as compared with immediate release tablets. The Court held, on a literal reading of the patent claims, that the reference to nausea reduction is merely descriptive of the effect of the extended release of venlafaxine hydrochloride in the body, and therefore concluded that this supplementary new drug submission (SNDS) also does not support the listing of the patent.

Despite this decision, and as confirmed by the Court, "the Minister has the discretion under section 3 of the NOC Regulations to remove any improperly listed patent from the register. That discretion is not limited by these proceedings or by anything in these reasons".

If Wyeth wishes to appeal, leave must be granted by the Supreme Court.

Court releases first decision interpreting new patent listing requirements

As reported in the October 2006 Special Edition of *Rx IP Update*, the *Regulations* were substantially amended on October 5, 2006, including with regard to the patent listing requirements. The most significant amendment was the introduction of a "relevance" requirement between the patent claims and the submission against which it is listed (although, as found by the Court in *Wyeth*, above, relevance is also required under the preamended *Regulations*; whether the tests differ remains to be seen). The decision in *Abbott v. Attorney General*, 2007 FC 797, released on July 31, 2007, is the first Court decision to interpret and apply this relevance requirement.

The patent at issue claims methods of producing solvent-free lansoprazole crystals, as well as use claims, including use of the solvent-free crystals for treating or preventing ulcers.

The patent list at issue was submitted on July 20, 2006 and added to the Patent Register in relation to an SNDS for PREVACID on July 25, 2006. The SNDS was for approval of a new use of lansoprazole in the treatment of ulcers caused by non-steroidal anti-inflammatory drugs (NSAIDs). The parties agreed that the patent was properly listed under the *Regulations* in force at the time.

After the *Regulations* were amended, the Minister delisted the patent, deciding that (i) the new relevance requirement had not been met as the patent did not specifically mention the treatment of NSAID ulcers, and (ii) it was ineligible as it claimed a polymorphic form, which is not eligible for listing against an SNDS.

The Court found that the Minister erred and required the patent to be listed as of the date the patent was delisted.

First, it agreed with the Minister that the new *Regulations* were applicable in view of the transitional provision, which provides that the amended listing requirements do not apply to patents on a patent list submitted prior to June 17, 2006.

Second, it found that the patent contains a claim for the new use as required by amended section 4, based on expert evidence presented to the effect that the skilled person would understand "ulcer" to include NSAID ulcers.

Third, while the Court agreed that the patent contains claims to polymorphic forms, the listing prohibition did not apply to the use claims.

This decision supports the position that the relevance requirement under the amended *Regulations* does not require strict matching as between the patent claims and the submission, provided the approved use falls within the scope of the claims.

The Minister has not appealed to date, but may do so as of right.

Supreme Court grants Apotex leave to hear PLAVIX selection patent case

On July 5, 2007, the Supreme Court of Canada granted Apotex leave to appeal a decision of the Court of Appeal which had upheld a prohibition Order relating to **clopidrogel** tablets (Sanofi-Synthelabo's **PLAVIX**) (*Apotex v. Sanofi-Synthelabo*, 2006 FCA 421, affirming 2005 FC 390). Apotex had alleged that the patent, a selection patent which claims clopidrogel, was invalid on the basis of anticipation, obviousness, and double patenting. Clopidrogel is an isomer; the racemate containing clopidrogel had been previously disclosed.

The United States District Court for the Southern District of New York had rejected similar arguments made by Apotex in a June 19, 2007 ruling, which is presently under appeal. (U.S. judgment. Supreme Court case summary.)

Supreme Court of Canada matters

sanofi-aventis v. Novopharm (**ramipril (ALTACE)**), **June 22, 2007.** sanofi-aventis is seeking leave to appeal an Order of the Court of Appeal which, as reported in the May 2007 issue of *Rx IP Update*, affirmed a decision to dismiss sanofi-aventis' application for a prohibition Order as an abuse of process. The Motions Judge had dismissed the application in view of an Order dismissing a previous proceeding relating to the same drug and same patent, but against a different generic.
(Court of Appeal decision – 2007 FCA 163. Motions Judge's decision – 2006 FC 1135.)

sanofi-aventis v. Apotex (**ramipril (ALTACE)**), **June 28, 2007.** sanofi-aventis' leave application was dismissed. The application sought to appeal an Order of the Court of Appeal allowing Apotex's appeal of an Order which stayed the Minister's decision to issue an NOC to Apotex for **APO-RAMIPRIL**. The Court of Appeal held that the Motions Judge erred in issuing the stay, as sanofi-aventis had failed to show irreparable harm.
(Court of Appeal decision – 2007 FCA 71. Motions Judge's decision – 2006 FC 1559.)

Patented Medicine Prices Review Board (PMPRB) matters

The PMPRB has accepted a Voluntary Compliance Undertaking (VCU) from Eli Lilly Canada Inc. for **teriparatide recombinant human parathyroid hormone 1-34 (rhPTH1-34) (FORTEO)**. (Notice. VCU.)

The PMPRB has released four publications:

1. Its inaugural edition of the *New Drug Pipeline Monitor*, a new web-based publication that summarizes information on new drugs that are expected to be launched in Canada within the next two to five years and could potentially have a significant impact on federal, provincial and territorial (F/P/T) drug plan expenditures.
(Notice. NDPM (June 2007).)
2. Its third quarterly report on Non-Patented Prescription Drug Prices, Market for New Off-Patent Drugs.
(Notice. Report (June 2007).)
3. Its 2006 annual report.
4. Its July 2007 newsletter.

Recent Court decisions

Patented Medicines (Notice of Compliance) Regulations

Ranbaxy v. Pfizer (atorvastatin calcium (LIPITOR)), June 20, 2007. Court of Appeal affirms the Motions Judge's Order granting leave to Pfizer to serve and file an amended notice of application, and extending the 24-month stay under the *Regulations*. Pfizer had discontinued its application regarding two patents in view of assurances and documents received from Ranbaxy's counsel. After learning that the assurances were not correct, Pfizer sought to bring the two patents back into the proceeding.
(Court of Appeal decision – 2007 FCA 244. Motions Judge's decision – 2007 FC 205.)

Novopharm v. Abbott (lansoprazole (PREVACID)), June 28, 2007. Court of Appeal dismisses Novopharm's appeal from a prohibition Order. The Applications Judge had found that Novopharm's allegation of non-infringement was not justified, given the nature of Novopharm's proposed product monograph and labelling for Novo-Lansoprazole, and on the strength of evidence of likely infringement given by Abbott's affiants relating to what will most probably happen under the Ontario Drug Benefit formulary and in the private payer market. The Judge disregarded Novopharm's submission that in view of *Apotex v. AstraZeneca*, 2006 SCC 49 (as reported in the November 2006 issue of *Rx IP Update*), the question to be decided was whether Novopharm took advantage of the early-working exception, as the argument had not been raised in Novopharm's notice of allegation (NOA). The Court of Appeal found that the Judge made no reviewable error in the claim construction, in the finding of induced infringement, and in disregarding Novopharm's early-working submission.
(Court of Appeal decision – 2007 FCA 251. Applications Judge's decision – 2006 FC 1411.)

AstraZeneca v. Apotex and The Minister of Health (omeprazole (LOSEC)), June 28, 2007. Judge dismisses AstraZeneca's application for a prohibition Order. The Judge found that AstraZeneca had not demonstrated that Apotex's allegations of anticipation of one patent and anticipation and obviousness of a second patent were not justified. The Judge further found that the use claims (for increasing bioavailability of an antibiotic) are ineligible for inclusion on the Patent Register as they do not contain any therapeutic aspects.
(Full judgment – 2007 FC 688.)

Janssen-Ortho v. AG Canada and the Minister of Health (methylphenidate hydrochloride (CONCERTA)), July 9, 2007. Judge dismisses Janssen-Ortho's application for judicial review of the Minister's decision refusing to list its patent on the Patent Register under the preamended *Regulations*. The Judge held that the Minister did not err, finding the patent relates to a particular form of a tablet that permits a desired release profile for the active ingredient, not for the medicine methylphenidate or for its use.
(Full judgment – 2007 FC 729.)

Apotex v. AstraZeneca (omeprazole (LOSEC, APO-OMEPRAZOLE)), July 10, 2007. Judge dismisses AstraZeneca's motion appealing a Prothonotary's Order, which dismissed AstraZeneca's motion to strike Apotex's claim for section 8 damages. The Judge found that Apotex has pleaded material facts to establish the legal conclusion for consideration that Apotex is a second person under the *Regulations*. The Judge held that the interpretation of "second person" in section 8 should be left for trial. AstraZeneca has appealed.
(Motions Judge's decision – 2007 FC 696. Prothonotary's decision.)

Other decisions

Merck Frosst Canada Ltd. v. The Minister of Health (montelukast sodium (SINGULAIR)), October 12, 2006. Applications Judge allows, in part, Merck's application for judicial review under the *Access to Information Act* relating to the lawfulness of the procedure followed by the Minister in processing the access request and to the disclosure of certain records pertaining to Merck's NDS for SINGULAIR. This decision is similar to one reported last month in relation to Merck's supplemental new drug submission (SNDS) for SINGULAIR (2006 FC 1200), and was released on the same day. The Minister has appealed.
(Full judgment – 2006 FC 1201.)

Janssen-Ortho Inc. v. Canada (Minister of Health) (cisapride (PREPULSID)), June 26, 2007. Court of Appeal dismisses the Minister's appeal of the Judge's decision that documents at issue

should not be disclosed pursuant to the *Access to Information Act*. The Motions Judge had found that the documents, requested in relation to the withdrawal of PREPULSID from the market, were exempt from disclosure as being confidential or containing employee personal information. The Court of Appeal held that it was not shown that the Motions Judge made a palpable and overriding error.
(Court of Appeal decision – 2007 FCA 252. Application Judge's decision – 2005 FC 1633.)

Apotex v. AB Hassle (omeprazole (LOSEC)), June 27, 2007. Judge dismisses Hassle's motion appealing a Prothonotary's Order. The Prothonotary had dismissed Hassle's motion to dismiss Apotex's impeachment action on the basis that the action is moot as the patent at issue had expired. The Judge found that it is not "plain and obvious" that the case has become moot, and that Apotex's pleading allows Apotex to submit that if it succeeds in the impeachment action, the prohibition Order relating to that patent falls and it is therefore entitled to section 8 damages.
(Motions Judge's decision – 2007 FC 683. Prothonotary's decision.)

CanWest Mediaworks v. the Minister of Health and AG (Canada), July 16, 2007. Judge dismisses a judicial review application brought by CanWest seeking an Order of *mandamus* requiring that the Minister of Health investigate and prosecute alleged breaches of prohibitions against "direct-to-consumer advertising" of prescription drugs by American media. The Judge found that CanWest lacks standing as it is not directly affected by the Order of *mandamus* being sought, and that it does not meet the criteria for public interest standing. Separately, CanWest has brought an action in the Ontario Superior Court seeking to have the relevant provisions of the *Food and Drugs Act* and the *Food and Drug Regulations* declared contrary to the Charter.
(Full judgment – 2007 FC 752.)

New proceedings

Patented Medicines (Notice of Compliance) Regulations

Medicine:	cefepime hydrochloride powder (MAXIPIME)
Applicants:	Bristol-Myers Squibb Canada Co and Bristol-Myers Squibb Company
Respondents:	The Minister of Health and Apotex Inc
Date Commenced:	May 23, 2007
Court File No:	T-891-07
Comment:	Application for an Order of prohibition until expiry of Patent No. 1,298,288. Apotex alleges invalidity.

Medicine:	escitalopram (oxalate) tablets (CIPRALEX)
Applicant:	Lundbeck Canada Inc
Respondents:	The Minister of Health and Apotex Inc
Respondent/Patentee:	H Lundbeck A/S
Date Commenced:	May 31, 2007
Court File No:	T-991-07
Comment:	Application for an Order of prohibition until expiry of Patent No. 1,339,452. Apotex alleges non-infringement and invalidity.

Medicine:	dorzolamide hydrochloride ophthalmic solutions (TRUSOPT)
Applicants:	Merck & Co, Inc and Merck Frosst Canada Ltd
Respondents:	The Minister of Health and Apotex Inc
Date Commenced:	July 3, 2007
Court File No:	T-1220-07
Comment:	Application for an Order of prohibition until expiry of Patent No. 1,329,211. Apotex alleges non-infringement and invalidity.

Medicine:	20 µg HPV type 16 L1 + 20 µg HPV type 18 L1 protein/0.5 ml suspension (CERVARIX human papilloma virus vaccine)
Applicant:	GlaxoSmithKline Inc
Respondents:	The Minister of Health and The Attorney General of Canada
Date Commenced:	July 6, 2007
Court File No:	T-1250-07
Comment:	Judicial review of the Minister's decision not to list Patent No. 2,157,376 on the Patent Register. The patent list was submitted pursuant to the amended *Regulations*. The Minister stated that the claims in the patent are directed toward vaccine compositions comprising antigens and their use, none of which specify the medicinal ingredient human papilloma virus type 16 L1 and 18 L1.

Medicine:	granisetron hydrochloride solution (KYTRIL)
Applicant:	Hoffmann-La Roche Limited
Respondents:	The Minister of Health, Apotex Inc
Respondent/Patentee:	F Hoffmann-La Roche AG
Date Commenced:	July 11, 2007
Court File No:	T-1269-07
Comment:	Application for an Order of prohibition until expiry of Patent No. 2,100,777. Apotex alleges non-infringement.

Medicine:	desmopressin (acetate) tablets (MINIRIN AND DDAVP)
Applicants:	Ferring Inc and Ferring BV
Respondents:	The Minister of Health and Pharmascience Inc
Date Commenced:	July 13, 2007
Court File No:	T-1287-07
Comment:	Application for an Order of prohibition until expiry of Patents Nos. 2,486,833 and 2,490,335. Pharmascience alleges non-infringement and invalidity. Pharmascience also asserts that the patents are not eligible for listing on Patent Register.

Medicine:	pioglitazone hydrochloride tablets (ACTOS)
Applicant:	Eli Lilly Canada Inc
Respondents:	The Minister of Health and Apotex Inc
Respondent/Patentee:	Takeda Pharmaceutical Company Limited
Date Commenced:	July 13, 2007
Court File No:	T-1293-07
Comment:	Application for an Order of prohibition until expiry of Patent No. 2,531,834. Apotex alleges non-infringement. Apotex also asserts that the patent is not eligible for listing on the Patent Register.

Medicine:	ramipril capsules (ALTACE)
Applicant:	sanofi-aventis Canada Inc
Respondents:	The Minister of Health, The Attorney General of Canada and Laboratoire Riva Inc
Date Commenced:	July 23, 2007
Court File No:	T-1351-07
Comment:	Judicial review of Minister's Decision that Riva will be eligible to receive a notice of compliance (NOC) for ramipril capsules, regardless of whether Pharmascience's submission, to which it is cross-referenced, has received an NOC.

Other new proceedings

Medicine:	fluticasone propionate intranasal suspension (FLONASE)
Applicant:	GlaxoSmithKline Inc
Respondents:	The Minister of Health, The Attorney General of Canada and Apotex Inc
Date Commenced:	June 1, 2007
Court File No:	T-1000-07
Comment:	Application for an Order quashing the decision of the Minister of Health to issue an NOC for Apo-fluticasone. GSK also seeks an Order directing the Minister to abide by its policy dated December 5, 1995 and refuse to use a U.S. product for the purpose of a Canadian Reference Product for a nasal corticosteroid.

Product:	olanzapine tablets (ZYPREXA)
Plaintiffs:	Eli Lilly Canada Inc, Eli Lilly and Company, Eli Lilly and Company Limited and Eli Lilly SA
Defendant:	Novopharm Limited
Date Commenced:	June 6, 2007
Court File No:	T-1048-07
Comment:	Patent infringement action relating to Patent No. 2,041,113.

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

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