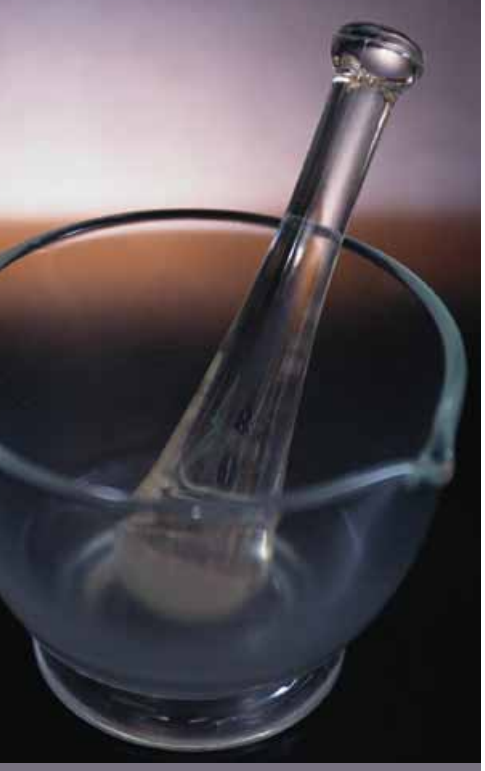

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Rx IP UPDATE

CANADIAN PHARMACEUTICAL INTELLECTUAL PROPERTY LAW NEWSLETTER

July 2009

Not abuse of process for generic to serve NOA after prior generic is unsuccessful

Apotex appealed a Federal Court decision granting Janssen-Ortho an Order of prohibition regarding a patent claiming **levofloxacin** (Janssen-Ortho's **LEVAQUIN**). The Applications Judge considered a previous Federal Court decision in a patent infringement action regarding the same patent and medicine at issue involving a different generic manufacturer, Novopharm, in which the patent was found to be valid and infringed (*Novopharm v. Janssen-Ortho and Daiichi Pharmaceutical*, 2006 FC 1234, aff'd 2007 FCA 217). The Judge found that Apotex had submitted no better evidence or more appropriate legal argument and therefore concluded that it was an abuse of process for Apotex to relitigate the issues that had been litigated in the Novopharm proceeding.

The Court of Appeal allowed Apotex's appeal. Justice Nadon, writing for the majority, found that the Applications Judge erred in his understanding of *sanofi-aventis Canada Inc. v. Novopharm Ltd.*, 2007 FCA 163 ("*sanofi*") regarding abuse of process. Justice Nadon held that the *sanofi* decision does not lead to the conclusion that "a second person can only put forward a [notice of allegation] on grounds similar to those put forward by a different generic in other proceedings when it has better evidence to offer or better legal arguments to make." The matter was therefore remitted back to the Applications Judge for redetermination on the basis that there was no abuse of process with the instruction to assess the evidence before him independently of any findings made in the Novopharm case.
(*Apotex Inc. v. Janssen-Ortho Inc.*, June 22, 2009. Court of Appeal decision – 2009 FCA 212. Applications Judge's decision – 2008 FC 744.)

Patented Medicine Prices Review Board news

Board releases revised Excessive Price Guidelines. As reported in the April 2009 issue of *Rx IP Update*, the Patented Medicine Prices Review Board released a draft revised version of its Compendium of Policies, Guidelines and Procedures ("Compendium") for stakeholder notice and comment. In June 2009, the Board released the results of the consultation, the revised Excessive Price Guidelines and the new Compendium. The Compendium will come into effect on January 1, 2010. (Results of the March 2009 Consultation and the Board's revised Excessive Price Guidelines.)

Supreme Court of Canada news

Disclosure requirement for sound prediction. Eli Lilly filed an application for leave to appeal a Federal Court of Appeal decision relating to a patent for a new use of the medicine **raloxifene (HCl) tablet** (Eli Lilly's **EVISTA**). The Court of Appeal dismissed Eli Lilly's appeal from a decision finding that Apotex's invalidity allegation is justified on the ground of lack of a sound prediction. The Court of Appeal disagreed with Eli Lilly's argument that the patent was not based on a prediction as the utility of the invention was conclusively established by the Canadian filing date, and it held that the Applications Judge proceeded on a proper principle when he held that where a patent is based on a sound prediction, the disclosure must include the prediction.
(*Eli Lilly Canada Inc. v. Apotex Inc.* Federal Court of Appeal decision – 2009 FCA 97. Federal Court decision – 2008 FC 142.)

Whether claim for damages against the Crown requires judicial review to determine unlawfulness of Crown's decision. The Supreme Court has granted Nu-Pharm leave. Nu-Pharm appeals from the Federal Court of Appeal's Order dismissing its action for damages against the Crown. Nu-Pharm alleged 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 proving the unlawful character of the government's decisions, which must be determined by way of judicial review. The Court of Appeal affirmed. (*Nu-Pharm Inc. v. Canada.* Federal Court of Appeal decision – 2008 FCA 227. Motions Judge's decision – 2007 FC 977.)

Recent Court decisions

Patented Medicines (Notice of Compliance) Regulations

Pfizer succeeds in its application for an Order of prohibition against Novopharm regarding VIAGRA. The Federal Court granted Pfizer's application to prohibit the Minister of Health ("Minister") from issuing a notice of compliance ("NOC") to Novopharm for **sildenafil** (Pfizer's **VIAGRA**). The Court found that Novopharm's invalidity allegation on the grounds of obviousness, utility and insufficiency was not justified. In relation to utility, while Novopharm had argued that demonstration of utility must be in the patent specification, the Court found that it is sufficient for the patent to state that the invention has been demonstrated to be useful and that the patentee is able to show evidence of demonstrated utility if the validity is challenged. As the Court found that the patent referred to a study and that study (provided in evidence) established demonstrated utility of the invention, Pfizer was not required to establish utility on the basis of sound prediction.
(*Pfizer Canada Inc. v. Novopharm Limited*, June 18, 2009. Full judgment – 2009 FC 638.)

Federal Court finds Novopharm's invalidity allegation regarding raloxifene justified. In the May 2009 issue of *Rx IP Update*, we reported that the Federal Court dismissed Eli Lilly's application for an Order of prohibition against Apotex relating to its **raloxifene tablets** (Eli Lilly's **EVISTA**), finding there was no reason to arrive at a different result from the

Novopharm case on the issues of anticipation and obviousness (*Eli Lilly Canada v. Apotex and Minister of Health,* 2009 FC 320). The Novopharm case dismissing Eli Lilly's application has since been released (*Eli Lilly Canada Inc. v. Novopharm Limited*, 2009 FC 301).

Federal Court of Appeal affirms purchase date as relevant date in assessing requirement to address. The Federal Court of Appeal has affirmed the Applications Judge's decision that Pharmascience was not required to address patents listed against **ALTACE** (sanofi-aventis's **ramipril**) for its submission for ramipril 1.25 mg. The Judge held that the relevant date for determining whether patents must be addressed pursuant to old section 5 (governing those generic submissions filed before October 5, 2006) is the date of purchase of the comparator drug and that because Pharmascience was not seeking approval for treatment post-heart attack, it "has not, in fact, made use of the patented inventions taught by" the patents. The Court of Appeal agreed with the Judge on both points. Relying primarily on *AstraZeneca v. Canada (Minister of Health)*, 2006 SCC 49, the Court of Appeal held that "the jurisprudence is clear that the patent specific analysis requires a generic to address only those patents in respect of which it takes advantage of the early working exception in the *Patent Act* for the purposes of demonstrating bioequivalence and obtaining a NOC." The Court also held that it is the Minister's responsibility to conduct the patent specific analysis and "to identify the precise patents which are relevant to a generic manufacturer's early working of a copycat product." It held that the date the comparator drug was purchased is the starting point, and the Minister must then evaluate the evidence before him to determine whether the generic has taken advantage of the teachings of any after-listed patents. The Court of Appeal agreed with the Applications Judge that in cases where the evidence is unclear or there is an absence of reliable evidence, the Minister may use the filing date of an ANDS (or a SANDS, where appropriate) as a fallback position.
(*The Minister of Health v. Pharmascience*, June 1, 2009. Court of Appeal decision – 2009 FCA 183. Applications Judge's decision – 2008 FC 922.)

Federal Court of Appeal affirms Judge's denial of innovator's profits and refuses compensation for generic's future losses in section 8 liability action. As reported in the January 2009 issue of *Rx IP Update*, both Merck and Apotex appealed the Federal Court's first decision on the merits regarding section 8 of the *Regulations* (**alendronate**, Merck's **FOSAMAX**). The Court of Appeal dismissed Apotex's cross-appeal and allowed Merck's appeal in part. The Court affirmed the Trial Judge's finding that Apotex is not entitled to compensation by way of a disgorgement of Merck's profits. Further, the Court allowed Merck's appeal from the Judge's ruling that Apotex is entitled to claim certain "future losses", i.e. damages beyond the dismissal date that Apotex alleged it had suffered and will continue to suffer as a result of the prohibition proceedings; the Court of Appeal held that Apotex's claim must be confined to losses incurred during the section 8 period. The Court also upheld the Trial Judge's findings that section 8 is enabled by the *Patent Act* and *intra vires* the constitutional authority of the federal Parliament of Canada and within the competence of the Federal Court to hear and determine.
(*Merck Frosst Canada Ltd. v. Apotex Inc.*, June 4, 2009. Court of Appeal decision – 2009 FCA 187. Trial Judge's decision – 2008 FC 1185.)

Federal Court dismisses Pfizer's summary judgment motion to dismiss Apotex's section 8 claim regarding fluconazole. Apotex had commenced an action against Pfizer to recover damages pursuant to section 8 of the *Regulations* in relation to its **fluconazole** product. Apotex alleges Pfizer's unsuccessful application for a prohibition Order regarding the drug (sold by Pfizer as **DIFLUCAN**) delayed the Minister from issuing an NOC to Apotex. Pfizer brought a motion for summary judgment, arguing that it did not cause any damages to Apotex. Pfizer argued that an NOC could not be issued to Apotex until Nu-Pharm amended its ANDS and Apotex's cross-referenced ANDS to include a non-infringing process. This did not occur until months after the relevant prohibition proceeding was dismissed. The Court dismissed Pfizer's motion for summary dismissal, finding that there is a genuine issue for trial as to whether an NOC could have been issued "in the absence of these *Regulations*" at an earlier date and that summary judgment is not appropriate to determine the meaning of this phrase as contained in section 8.
(*Apotex Inc. v. Pfizer Canada Inc.*, June 12, 2009. Full judgment – 2009 FC 631.)

Other decisions

Federal Court of Appeal allows the Minister's appeals relating to the *Access to Information Act*. The Federal Court of Appeal allowed the Minister's appeals from two Federal Court decisions finding (i) that Merck was entitled to a declaratory Order about the illegality of the process followed by the Minister in handling the access request (the Minister disclosed certain pages relating to Merck's drug submissions for **SINGULAIR** without consulting Merck), (ii) that the disclosure of documents by the Minister without consultation was contrary to section 20(1) the *Access to Information Act* ("*Act*"), and (iii) that certain portions of the documents should not be disclosed. The Court of Appeal found that the Judge, in both cases, was incorrect to conclude that a federal institution cannot disclose information to a requesting party when the interested party was not given prior notice and that Merck was therefore not entitled to a declaratory Order about the illegality of the process followed by the Minister in handling the access request. The Court also held the Judge erred in concluding that the disclosure was contrary to section 20(1) of the *Act* as the information was not shown to be a trade secret or confidential, and Merck did not show how the information would cause the damages pleaded. The Court further ruled that the only obligations under section 27(1) of the *Act* on the Minister is to indicate in its decision of disclosure which passages of the documents requested are likely to or do contain trade secrets or information falling under sections 20(1)(b), (c), and (d) of the *Act*. (*Canada (Santé) v. Merck Frosst Canada Ltée*, May 26, 2009. Court of Appeal decision – 2009 CAF 166. Trial Judge's decisions – 2006 FC 1200, 2006 FC 1201.)

AYC Pharmacy's judicial review application survives motion to strike. First Canadian Health Management Corp. ("FCH") administers the direct billing and payment process related to claims made under the Non-Insured Health Benefits Program ("NIHB"). The latter was created by Health Canada to provide eligible registered members of First Nations and recognized Inuit and Innu persons with medically necessary health-related goods and services not otherwise covered by other federal, provincial, territorial or third-party insurance plans. AYC Pharmacy ("AYC") and FCH entered into an agreement allowing AYC to be a provider of pharmaceutical products to clients of the NIHB. FCH later sent AYC a notice of termination. AYC brought a judicial review application that the respondents sought to strike on the grounds that the termination of the agreement is not subject to judicial review and that the application is bereft of any possibility of success. The Prothonotary dismissed the motion, and the respondents appealed. The Motions Judge dismissed the appeal, finding that AYC's position that it is the alter ego, or an administrative arm, of the Minister of Health, although somewhat tenuous, cannot be said to be bereft of any possibility of success, particularly as a full record has not yet been developed. The Judge also held that at this stage, this case is not one where the possibility of judicial review is clearly and obviously not available.
(*AYC Pharmacy Ltd. v. Canada*, May 27, 2009. Full judgment – 2009 FC 554.)

Federal Court of Appeal affirms Judge's ruling in perindopril infringement action. The Court of Appeal dismissed Apotex's appeal from the Trial Judge's decision that Apotex had infringed the patent covering perinodopril (Servier's COVERSYL) and that the patent was valid. The Court concluded that the Judge did not error in following the proper jurisprudence to determine the nature of the invention. The Court also found that Apotex had not demonstrated that the Judge erred in rejecting Apotex's validity attacks of obviousness, first inventorship/anticipation, inutility and lack of sound prediction and in finding that the certificate of correction was properly issued by the Commissioner of Patents. The Court agreed with the Trial Judge that predicting the making of a compound claimed is not a matter of sound prediction but rather sufficiency of disclosure. Finally, regarding Apotex's appeal on the *Competition Act* issue, the Court reiterated that undue impairment of competition cannot be inferred from evidence of the exercise of rights under the *Patent Act* alone; Apotex had not demonstrated the Judge made a palpable and overriding error in concluding that ADIR was merely exercising its rights under the *Patent Act* to obtain patents and nothing more.
(*Apotex Inc. v. Adir and Servier Canada Inc.*, June 30, 2009. Court of Appeal decision – 2009 FCA 222. Trial Judge's decision – 2008 FC 825.)

Trade-mark decisions

BELLATOX confusing with BOTOX. Camille Toutounghi had filed an application for BELLATOX for use in association with "[c]osmetics namely a topical anti-wrinkle cream and a topical anti-wrinkle patch." Allergan opposed on the basis of confusion with its ten trade-marks and one pending application containing the mark BOTOX for use in relation to a variety of wares and services, including "[p]harmaceutical preparations for alleviating wrinkles" and "[c]osmetics; namely face creams and lotions, skin creams and lotions." The Board rejected the application on the basis of confusion in view of the fame of Allergan's marks, that they have acquired the reputation of being a "cosmetic treatment" rather than merely a "pharmaceutical product," the potential overlap of the parties' products and the degree of resemblance between the marks, especially in ideas. (Full decision.)

New Court proceedings

Patented Medicines (Notice of Compliance) Regulations

Medicine:	irbesartan/hydrochlorothiazide (AVALIDE)
Applicant:	sanofi-aventis Canada Inc
Respondents:	Genpharm ULC and The Minister of Health
Respondent/Patentee:	sanofi-aventis
Date Commenced:	May 15, 2009
Court File No.:	T-792-09
Comment:	Application for Order of prohibition until expiry of Patents Nos. 2,057,913 and 2,177,772. Genpharm alleges non-infringement and invalidity with respect to the '772 patent.

Medicine:	irbesartan (AVAPRO)
Applicant:	sanofi-aventis Canada Inc
Respondents:	Genpharm ULC and The Minister of Health
Respondent/Patentee:	sanofi-aventis
Date Commenced:	May 15, 2009
Court File No.:	T-793-09
Comment:	Application for Order of prohibition until expiry of Patents Nos. 2,057,913 and 2,177,772. Genpharm alleges non-infringement and invalidity with respect to the '772 Patent.

Medicine:	olanzapine orally disintegrating tablets (ZYPREXA ZYDIS)
Applicant:	Eli Lilly Canada Inc
Respondents:	Apotex Inc and The Minister of Health
Respondent/Patentee:	Eli Lilly and Company Limited
Date Commenced:	May 19, 2009
Court File No.:	T-794-09
Comment:	Application for Order of prohibition until expiry of Patent No. 2,041,113. Apotex alleges invalidity and relies on the decision of Justice Hughes in Court File No. T-1535-05.

Medicine:	irbesartan (AVAPRO)
Applicant:	sanofi-aventis Canada Inc
Respondents:	Sandoz Canada Inc and The Minister of Health
Respondent/Patentee:	sanofi-aventis
Date Commenced:	June 12, 2009
Court File No.:	T-956-09
Comment:	Application for Order of prohibition until expiry of Patents Nos. 2,057,913 and 2,177,772. Sandoz alleges non-infringement, invalidity and ineligibility with respect to the '772 patent.

Medicine:	ramipril (ALTACE)
Applicants:	sanofi-aventis Canada Inc and sanofi-aventis Deutschland GmbH
Respondents:	Pharmascience Inc and The Minister of Health
Respondent/Patentee:	Schering Corporation
Date Commenced:	June 25, 2009
Court File No.:	T-1029-09
Comment:	Application for Order of prohibition until expiry of Patents Nos. 2,055,948, 1,341,206, 2,023,089, 2,382,387 and 2,382,549. Pharmascience alleges non-infringement and invalidity.

Other proceedings

Medicine:	gabapentin (NEURONTIN)
Applicants:	Warner-Lambert Company LLC and Pfizer Inc
Respondent:	Apotex Inc
Respondent/Patentee:	Schering Corporation
Date Commenced:	April 17, 2009
Court File No.:	CV-09-376777
Comment:	Application for Order enforcing Letter Rogatory issued by United States District Court for District of New Jersey seeking an order to obtain the production of documents and oral examination, under oath, from Apotex Inc. in respect of *In re Neurontin Antitrust Litigation*, Multi-District Litigation No. 1479.

Medicine:	venlafaxine hydrochloride (EFFEXOR XR)
Plaintiffs:	Wyeth and Wyeth-Whitehall Pharmaceuticals, Inc
Defendant:	Cobalt Pharmaceuticals Inc
Date Commenced:	May 19, 2009
Court File No.:	T-804-09
Comment:	Patent infringement action regarding Patent No. 2,199,778.

Medicine:	clopidogrel (PLAVIX)
Plaintiffs:	sanofi-aventis and Bristol-Myers Squibb Sanofi Pharmaceuticals Holding Partnership
Defendant:	Apotex Inc, Apotex Pharmachem Inc and Signa SA de CV
Date Commenced:	June 8, 2009
Court File No.:	T-933-09
Comment:	Patent infringement action regarding Patent No. 1,336,777.

Trade-mark:	VIREXX
Plaintiff:	Vertex Pharmaceuticals Inc
Defendant:	Virexx Medical Corp
Date Commenced:	June 10, 2009
Court File No.:	T-942-09
Comment:	Trade-mark infringement action regarding Trade-mark Registrations Nos. TMA672,883 and TMA672,725 for VERTEX and VERTEX & Design for use in association with pharmaceutical preparations for the therapeutic treatment of HIV infection and AIDS. The Plaintiff alleges that Virexx is selling pharmaceuticals under the name VIREXX in Canada.

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

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