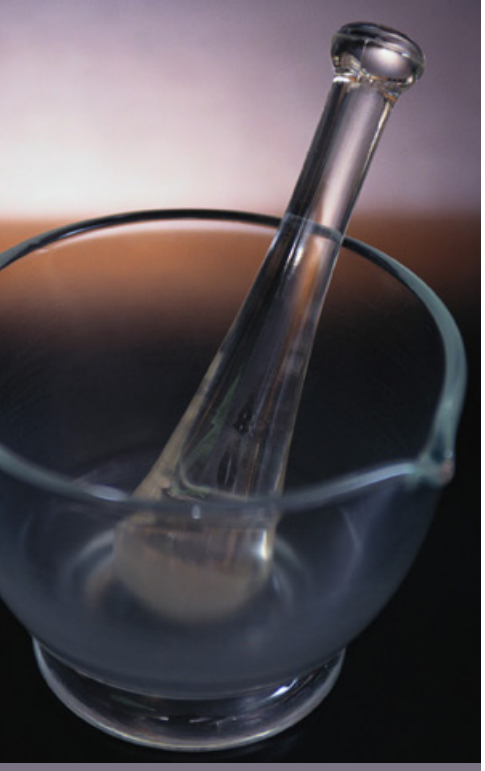

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Rx IP UPDATE

CANADIAN PHARMACEUTICAL INTELLECTUAL PROPERTY LAW NEWSLETTER

July 2007

Sufficiency test for selection patents tightened; abuse of process possible for second generic attacking validity under Linkage Regulations

On June 5, 2007, a Judge dismissed Lilly's application against Novopharm for a prohibition Order under the *Patented Medicines (Notice of Compliance) Regulations* ("*Regulations*") relating to olanzapine (Eli Lilly's ZYPREXA) (*Eli Lilly v. Novopharm*, 2007 FC 596). The patent at issue claims olanzapine.

As a preliminary matter, the Judge considered two separate bases of possible abuse of process against Novopharm and rejected both.

First, he found that it was not an abuse of process for Novopharm to withdraw its first notice of allegation (alleging invalidity), and then serve a second allegation in respect of the same patent (also alleging invalidity). The first application did not proceed to a hearing. The Judge found that this was the only practical way for Novopharm to amend its notice of allegation. He concluded that "[o]nce the Court is seized of the matter at a hearing of the merits...or where a decision has been made by the court...only then the generic has lost its possibility of furnishing a new NOA directed to the issue of validity unless a new matter not previously discoverable has arisen".

Second, the Court considered whether it would be an abuse of process to consider the invalidity allegations having regard to an earlier decision of the Court which granted an Order of prohibition regarding the same patent, but a different generic (*Eli Lilly v. Apotex*, 2007 FC 455). The Judge decided:

> ...this Court, in its own discretion, can review the Reasons given in *Apotex* by Justice Gauthier and determine whether there is "better evidence" or "more appropriate legal argument" made by the generic in the present proceeding as to validity of the '113 patent than was presented in Apotex. If so, the better evidence and more appropriate arguments must be considered. If no better evidence or more appropriate argument is found, it would be an abuse to permit the matter to be considered again.

Novopharm's allegations of anticipation, obviousness, and double patenting had been raised by Apotex and the Judge followed the

previous Judge's rejection of these attacks. However, there were three invalidity attacks that had not been raised by Apotex: insufficiency, section 53, and inutility. The Judge therefore considered these attacks as a matter of first principle.

The Judge found that Eli Lilly had not established that the allegation of insufficiency was not justified. The patent was a selection patent as a group of compounds containing olanzapine had been previously disclosed. The Judge held,

> ...in considering the law as to sufficiency in regard to selection patents, the following may be concluded:
>
> 1. A valid selection patent may be obtained where the invention lies in selecting a member or members from a previously disclosed group where the member or members selected possess a particular advantage not previously to be found or predicted in a large number of members of the class by a person skilled in the art.
>
> 2. The advantage may also be a disadvantage to be avoided.
>
> 3. The advantage must be clearly set out in the specification. A statement that the selected group possesses advantages or lack of disadvantages is not in itself sufficient; the advantage must be plainly and fully set out in sufficient detail so as to enable a person skilled in the art to know and appreciate what they are.

The issue was whether the advantages were sufficiently stated. The disclosure stated, "We have now discovered a compound which possesses surprising and unexpected properties by comparison with flumazepine and other related compounds". The Judge concluded that "Lilly...has not paid the price, by way of a clear and explicit disclosure to what the invention is, if any, in the properties of olanzapine alone that merit a further monopoly in a separate further patent". He indicated that no comparison between olanzapine and flumazepine and other related compounds was made in the patent, and that no data was given. The Judge therefore appears to have created a new requirement for comparative data in a selection patent.

The section 53 attack was rejected, and no finding was made regarding utility in view of the finding on sufficiency.

While Eli Lilly has appealed, the notice of compliance (NOC) was issued to Novopharm on June 6, 2007, and Novopharm has therefore brought a motion to dismiss the appeal. Eli Lilly has also commenced a patent infringement action against Novopharm.

Wyeth appeal heard

As reported in the May 2007 issue of *Rx IP Update*, a Judge decided that under the pre-amended *Regulations* relevance is required between the patented invention and the notice of compliance (NOC) against which it is sought to be listed (*Wyeth Canada v. Ratiopharm Inc.*, 2007 FC 340). Ratiopharm's appeal and Wyeth's cross-appeal of that decision was heard by the Federal Court of Appeal on June 25, 2007 and was taken under reserve.

Health Canada news

Draft Guidance Document released relating to data protection. On June 25, 2007, Health Canada released a draft Guidance Document relating to the administration of the data protection provision of the *Food and Drug Regulations*, amended on October 5, 2006. The draft includes a request to manufacturers as follows: "A manufacturer that believes that its drug should qualify as an innovative drug is requested to include such a statement in the cover letter accompanying the submission, or to provide a letter directly to the OPML drawing attention to the submission". Any comments on the guidance document should be submitted by September 17, 2007. (Draft Guidance Document: Data Protection under C.08.004.1 of the Food and Drug Regulations.)

Statistical report for Linkage Regulations and performance report for drug submissions released. The Therapeutic Products Directorate (TPD) has released a statistical report relating to the administration of the *Regulations*. The report provides a number of statistics relating to the maintenance of the Patent Register, the number of notices of allegation (NOAs) served, prohibition applications and outcomes of these applications, and other items. (Statistical Report 2006.)

The TPD and the Biologics and Genetic Therapies Directorate (BGTD) have also released their annual drug submission performance reports which provide statistical information relating to drug submissions, including average approval times. (Therapeutic Products Directorate (TPD) - 2006 Annual Drug Submission Performance Report - Part I. Biologics and Genetic Therapies Directorate (BGTD) - 2006 Annual Drug Submission Report - Part II.)

Guidance - Annual Drug Notification 2007. Health Canada has released a Guidance Document relating to the Annual Drug Notification form to assist the owners of Drug Identification Numbers in complying with section C.01.014.5 of the *Food and Drug Regulations*. This section requires owners to confirm annually before October that all information previously supplied with regard to the product is correct. (Guidance Document.)

Proposed amendments would permit certain advertising to general public. Presently, the *Food and Drug Regulations* prohibit preventative, treatment and cure claims in the labelling and advertising to the general public of diseases listed in Schedule A. Health Canada has proposed amendments that would revise Schedule A and would exempt natural health products and nonprescription drugs from the prohibition on preventative claims for the diseases remaining in Schedule A (which would include, for example, asthma, cancer, congestive heart failure, depression, diabetes, hypertension, and ulcer of the gastro-intestinal tract). The proposal replaces a former proposal advertised on November 19, 2005 and withdrawn on May 9, 2007. Representations on the proposed amendments may be made until **August 30, 2007**. (Regulations Amending Certain Regulations Made under the Food and Drugs Act (Project 1539). Withdrawal of Regulatory Proposal.)

Patented Medicine Prices Review Board (PMPRB) matters

The PMPRB has accepted a Voluntary Compliance Undertaking (VCU) from Janssen-Ortho Inc. for **risperidone (RISPERDAL CONSTA)**. Accordingly, the proceeding is concluded. (Order. VCU.)

In its April 2007 newsletter, the PMPRB indicated its view that as a result of the Federal Court's decision in *Leo Pharma v. Canada (Attorney General)* (2007 FC 306), all reductions or benefits, regardless of whether they are supplied under a compassionate release program, must now be included in the calculation of the average transaction price (ATP) of a patented medicine. On June 28, 2007, the Board issued a communiqué indicating that in view of the timing of the *Leo* decision, patentees may elect to include or exclude all benefits and reductions in the calculations of ATPs for January to June 2007, provided this is consistent with their calculations in prior periods. The Board will advise shortly of the requirements for subsequent periods, indicating that "a priority of the Board is that consumers have access to compassionate programs, and ... is looking at operational options in this regard that will be consistent with the law".
(April 2007 newsletter. Communiqué.)

Recent Court decisions

Patented Medicines (Notice of Compliance) Regulations

sanofi-aventis v. The Minister of Health (cefotaxime (CLAROFAN)), May 24, 2007. sanofi-aventis had obtained an Order of prohibition against Mayne, and Mayne appealed. Subsequently, the Minister delisted the patent. The Court dismissed sanofi-aventis's application for judicial review, rejecting sanofi-aventis' argument that the Minister was estopped from delisting the patent. The Judge found that the Minister was not a party to the first proceeding because there was no lis between the Minister and sanofi-aventis or Mayne in that proceeding, and that the first decision was not final as there was an appeal pending. (Full judgment – 2007 FC 545.)

sanofi-aventis v. Laboratoire Riva and the Minister of Health (ramipril (ALTACE)), May 28, 2007. Judge dismisses sanofi-aventis' two applications for prohibition Orders. The Judge found that Riva's allegations of non-infringement of two use patents are justified. The Judge found that Riva's allegation of invalidity, on the basis of lack of sound prediction and double patenting regarding a third patent, is not justified. However, he held that he was bound by *sanofi-aventis v. Novopharm* (2007 FCA 163) to find it an abuse of process for sanofi-aventis to relitigate the allegation of invalidity in view of a prior unsuccessful decision against another generic, and therefore dismissed the application. (Full judgment – 2007 FC 532.)

Pfizer, Warner-Lambert and Parke, Davis & Company v. Apotex and the Minister of Health (quinapril hydrochloride (ACCUPRIL)), May 31, 2007. Court of Appeal allows Pfizer's appeal from a dismissal of a prohibition proceeding. The Court of Appeal concluded that Apotex's non-infringement allegation regarding one patent was not justified, and that Apotex's invalidity allegations of another patent on the grounds of overbreadth, obviousness, anticipation, double patenting and lack of utility were also not justified. (Court of Appeal decision – 2007 FCA 209. Applications Judge's decision – 2005 FC 1205.)

Abbott and TAP v. Novopharm and the Minister of Health (lansoprazole (PREVACID)), June 11, 2007. Prothonotary allows Novopharm's motion and dismisses Abbott and TAP's application for a prohibition Order on the basis that the patent at issue is not eligible for listing on the Patent Register. The patent had been listed under the pre-amended *Regulations*. The Prothonotary decided that the patent protects a delivery system and thus does not contain a claim for the medicine itself or for the use of the medicine. The Prothonotary also found that the balance of probabilities standard applied to the motion and that as amended section 6(5) applied to the motion, pre-amended section 6(5)(b) (which provided explicit grounds for attacking the listing of a patent on the basis of irrelevance to the dosage form, strength and route of administration of the product) was not applicable. Abbott has appealed. (Full judgment – 2007 FC 622.)

Altana Pharma v. Novopharm and the Minister of Health (pantoprazole sodium (PANTOLOC)), June 14, 2007. Altana had filed affidavits of 11 experts on the issue of infringement. Prothonotary allows Novopharm's motion for an Order that Altana comply with the limits set out in section 7 of the *Canada Evidence Act* limiting each party to five witnesses per issue, finding that non-infringement is a single issue for this purpose. The Prothonotary also dismissed Altana's cross-motion for leave to file all the expert evidence tendered, finding that Altana had not established that it is reasonably necessary for them to call more witnesses. Altana has appealed. (Full judgment – 2007 FC 637.)

Pfizer v. Apotex and the Minister of Health (quinapril (ACCUPRIL)), June 15, 2007. Judge dismisses Pfizer's application for a prohibition Order relating to a "use" patent (treatment of cardiac and vascular hypertrophy), but also orders that any NOC to be issued shall contain a condition consistent with the Undertaking contained in Apotex's NOA (that it will only make, use or sell the Apo-Quinapril for the treatment of hypertension). The Judge decided that the Undertaking was a complete answer to Pfizer's allegation of infringement. (Full judgment – 2007 FC 642.)

Pfizer and Warner-Lambert v. Ranbaxy and Minister of Health (atorvastatin calcium (LIPITOR)), June 18, 2007. Judge affirms an Order of a Prothonotary dismissing Ranbaxy's motion to dismiss the application. Ranbaxy had two processes to make its product, only one of which was on file with Health Canada. Pfizer's evidence of infringement related to the second process. The Judge concluded that Ranbaxy has failed to meet its burden of proving that it is "plain and obvious" that the applicant cannot

succeed, including as the question of whether the Court hearing the application will be limited to consideration of the material on the Health Canada file has never been judicially determined. (Trial Judge's decision – 2007 FC 649. Prothonotary's decision – 2007 FC 452.)

Bayer v. Apotex and the Minister of Health (ciprofloxacin hydrochloride (CIPRO)), June 22, 2007. Court of Appeal dismisses Apotex's appeal from a prohibition Order. While an NOC had issued before the appeal was heard, the Court had previously allowed the appeal to continue because the outcome may affect Apotex's rights under section 8. The Court concluded that there was no basis for interfering with the Judge's decision that the allegation of obviousness was not justified. (Court of Appeal decision – 2007 FCA 243. Applications Judge's decision – 2003 FC 1199.)

Other decisions

Merck Frosst Canada Ltd. v. The Minister of Health (montelukast sodium (SINGULAIR)), October 12, 2006. Judge allows, in part, Merck's application for judicial review of a Minister's decision that that certain portions of documents relating to the supplemental new drug submission (SNDS) for SINGULAIR would be disclosed pursuant to an *Access to Information Act* ("*Act*") request. The Judge ruled that Merck is 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 without consulting Merck). The Judge then found that the disclosure of documents by the Minister without consultation was contrary to subsection 20(1) the *Act*. On the merits, the Judge agreed with Merck that certain portions of the documents should not be disclosed. An appeal is pending. (Full judgment – 2006 FC 1200.)

Klein v. American Medical Systems and The Attorney General of Canada (Silicone-Coated Sling/Mesh with InhibiZone), December 12, 2006. Klein had brought a claim against the Attorney General of Canada and the manufacturer and distributor of a medical device, claiming that Health Canada was negligent in its regulation of the device. The Ontario Divisional Court strikes the claim against the Attorney General of Canada, finding that the federal government does not owe a private duty of care to the plaintiff to test medical devices. (Full judgment – 2006 CANLII 42799.)

Novopharm v. Janssen-Ortho and Daiichi Pharmaceutical (levofloxacin (LEVAQUIN)), June 7, 2007. Court of Appeal dismisses Novopharm's appeal of a Trial Judge's decision which held that a claim of the patent covering levofloxacin was valid. The Court agreed with the Trial Judge's construction of the claim at issue and concluded that the Trial Judge did not err in finding that the claim is not ambiguous or obvious. (Court of Appeal decision – 2007 FCA 217. Trial Judge's decision – 2006 FC 1234.)

New proceedings

Patented Medicines (Notice of Compliance) Regulations

Medicine:	ramipril (ALTACE)
Applicants:	Laboratoire Riva Inc
Respondents:	The Minister of Health and The Attorney General of Canada
Date Commenced:	May 24, 2007
Court File No:	T-896-07
Comment:	Judicial review of Minister's decision that Riva is not entitled to an NOC for its 2.5, 5 and 10 mg capsules until and unless Pharmascience secures an NOC. Riva's abbreviated new drug submission (ANDS) was cross-referenced to Pharmascience's ANDS.

Medicine:	ramipril (ALTACE)
Applicants:	sanofi-aventis Canada Inc
Respondents:	The Minister of Health, The Attorney General of Canada and Novopharm Limited
Date Commenced:	June 1, 2007
Court File No:	T-997-07
Comment:	Application for an Order quashing the decision of the Minister of Health that Novopharm does not have to address Patents Nos. 2,382,387 and 2,382,549 in respect of its 2.5, 5.0 and 10 mg capsules and an Order quashing the NOC issued to Novopharm. The Minister so decided on the basis of its interpretation of *AstraZeneca v. Minister of Health* (2006 SCC 49).

Medicine:	ramipril (ALTACE)
Applicants:	sanofi-aventis Canada Inc
Respondents:	The Minister of Health, The Attorney General of Canada and Novopharm Limited
Date Commenced:	June 1, 2007
Court File No:	T-998-07
Comment:	Application for an Order quashing the decision of the Minister of Health that Novopharm does not have to address, or in the alternative has addressed, Patents Nos. 2,382,387 and 2,382,549 in respect of its 1.25 mg capsules and an Order quashing the NOC issued to Novopharm. The Minister so decided on the basis of its interpretation of *AstraZeneca v. Minister of Health* (2006 SCC 49). The NOC has since been declared invalid by the Minister.

Medicine:	clarithromycin tablets (BIAXIN XL)
Applicants:	Abbott Laboratories and Abbott Laboratories Limited
Respondents:	The Minister of Health and Sandoz Canada Inc
Date Commenced:	June 19, 2007
Court File No:	T-1129-07
Comment:	Application for an Order of prohibition until expiry of Patents Nos. 2,209,714; 2,285,266; 2,325,541 and 2,358,395. Sandoz alleges non-infringement and invalidity. Sandoz also asserts that the patents are not eligible for listing on the Patent Register.

Other decisions

Product:	creatine (HYPER GROWTH and CREATINE D2T)
Plaintiffs:	Cell Formulations Ltd, New Cell Formulations Ltd, MTOR Formulations Ltd and Mass Formulations Ltd
Defendants:	WellNx Life Sciences Inc (f/k/a Nxcare Inc.), Derek Woodgate and Bradley Woodgate
Date Commenced:	May 25, 2007
Court File No:	T-905-07
Comment:	Patent infringement action relating to Patent No. 2,208,047.

Product:	creatine malate (VASO, VASO XP, HYPER GROWTH, LEAN HYPER GROWTH, MUSCLE EXPANSION PACK and MASS SYSTEM)
Plaintiffs:	Multi Formulations Ltd, and New Cell Formulations Ltd
Defendants:	WellNx Life Sciences Inc. (f/k/a Nxcare Inc.), Derek Woodgate and Bradley Woodgate
Date Commenced:	May 25, 2007
Court File No:	T-906-07
Comment:	Patent infringement action relating to Patent No. 2,194,218.

Medicine:	ramipril (ALTACE)
Plaintiffs:	sanofi-aventis Canada Inc and Schering Corporation
Defendant:	Novopharm Limited
Date Commenced:	June 22, 2007
Court File No:	T-1161-07
Comment:	Patent infringement action relating to Patent No. 1,341,206.

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

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