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Rx IP Update

Canadian Pharmaceutical Intellectual Property Law Newsletter

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Prior Allegation of Non-infringement Precludes Generic from Making Allegation of Invalidity

In the March 2005 edition of *Rx IP Update*, we reported on the decision in *AB Hassle v. Apotex* (2005 FC 234). This decision applied the doctrines of issue estoppel/abuse of process in a proceeding under the *Patented Medicines (Notice of Compliance) Regulations* ("*Regulations*") to prevent a generic from raising an allegation of invalidity subsequent to having unsuccessfully raised an allegation of non-infringement in respect of the same drug and the same patent.

On February 10, 2006, the Federal Court of Appeal (2006 FCA 51) dismissed the appeal of this decision and confirmed that a subsequent allegation, even where based on a different legal and factual basis, may be an abuse of process. The Court of Appeal provided specific examples of situations in which a second or subsequent notice of allegation (NOA) may not be an abuse of process, stating that for example "it may be that there would be no abuse of process if based on new facts, a newly discovered process, a change in the law, a situation that limits the scope or application of an existing prohibition order or a new and definitive decision as to the validity or construction of the patent." On the other hand, this decision confirms that where a generic could have raised invalidity allegations in a prior NOA asserting non-infringement, estoppel or abuse of process may apply to preclude the generic from raising invalidity allegations in a subsequent proceeding.

Manitoba Court of Appeal Reverses Formulary Listing Decision

In the July 2005 edition of *Rx IP Update*, we reported that a Manitoba Judge had declared a Manitoba Formulary regulation invalid which listed Apo-Omeprazole capsules as interchangeable with LOSEC tablets. The Judge so concluded because the list of indications approved by Health Canada for Apo-Omeprazole capsules did not include all the indications for which LOSEC tablets were approved. On February 13, 2006, the Manitoba Court of Appeal reversed the Judge's decision (*AstraZeneca v. Manitoba* (2006 MBCA 21)).

The Court of Appeal's reasons focus on the meaning of the term "interchangeable product" in the context of Manitoba's drug substitution legislation. The Court held that these words mean therapeutically interchangeable. Although Health Canada did not approve Apo-Omeprazole for all of the conditions for which LOSEC has approval, the Court of Appeal determined that it is proper to list the two products in the Formulary because "there exists a therapeutic equivalence between Losec and Apo-omeprazole". The Court added that the Manitoba Minister of Health "is entitled to assume that physicians and pharmacists will prescribe or dispense drugs according to the federal regulations."

Court of Appeal Confirms that the Relevant Date for Assessing Sound Prediction is Canadian Filing Date

In a February 13, 2006 decision (*Aventis v. Apotex*), relating to the medicine ramipril (ALTACE), the Court of Appeal dismissed Aventis' appeal of a decision which dismissed its prohibition application. In doing so, the Court made two significant findings. First, it agreed with the applications Judge's finding that the relevant date for assessing sound prediction is the Canadian filing date (rather than the priority date). Second, the Court rejected Aventis' argument that an attack on the validity of a patent in a proceeding under the *Regulations* should be reviewed on a reasonableness simpliciter standard, finding that "[t]he fact that a NOA may call the validity of a patent into question for the purpose of a NOC proceeding is not sufficient to attract the more onerous standard of proof applicable when the validity of the patent is determined in an infringement action." While the Court appeared to question the applications Judge's finding regarding the "proper disclosure" factor of the three-part sound prediction test, the Court declined to make a finding in this respect, finding that "the allegation that the patent is invalid would still be justified because all three parts of the test must be satisfied".

Judge Rejects Argument that SNDS Cannot Support Patent Listing

On January 24, 2006, in *Abbott v. Ratiopharm* (2006 FC 69) (relating to clarithromycin (BIAXIN)), a Judge considered a motion to strike a prohibition application under the *Regulations*. Ratiopharm argued that the patent at issue was not eligible for inclusion on the Patent Register as it was listed in connection with a supplementary new drug submission (SNDS), which is not a "submission" within the meaning of section 4 of the *Regulations*. Ratiopharm relied upon the following comment by the Supreme Court of Canada in *Biolyse Pharma v. Bristol-Myers Squibb* (2005 SCC 26):

> The Federal Court has consistently held that the word "submission" in s. 4(1) does not include all submissions. It does not include a *supplementary* NDS.

The Judge rejected the argument, finding that "when the sentence is read in context it can be understood as saying 'It does not include a supplementary NDS [*in certain circumstances*]'."

On the merits of the application, the Judge granted an Order of prohibition, finding that the allegations of non-infringement and invalidity (obviousness) were not justified. Ratiopharm may appeal this decision, as of right.

Supreme Court of Canada Leave Applications

Pharmascience v. Abbott Laboratories and Minister of Health (**clarithromycin (BIAXIN BID)**), January 19, 2006

Leave has been denied. Pharmascience had applied for leave to appeal a Court of Appeal decision upholding a prohibition Order.

Court of Appeal Decision (2005 FCA 250)

Motions Judge's Decision (2004 FC 1349)

Patented Medicines Prices Review Board (PMPRB) Matters

The Patented Medicines Prices Review Board will hold a hearing on April 24, 2006, to determine whether Shire BioChem is selling or has sold ADDERALL XR (amphetamines) in any market in Canada at prices that are or were excessive and if so, what Order (if any) should be made. A pre-hearing conference will be held on March 8, 2006.

Notice of Hearing

Recent Court Decisions

Patented Medicines (Notice of Compliance) Regulations

Janssen-Ortho v. Canada (Minister of Health) (**norelgestromin/ethinyl estradiol transdermal system (EVRA)**), January 10, 2006

Court of Appeal allows Janssen-Ortho's appeal from a Judge's decision, upholding the Minister's refusal to add Janssen-Ortho's patent to the Patent Register. The Court considered that the argument before the Judge and Minister was based on issues only recently settled by decisions of the Court, and that the present record is inadequate to address the new argument raised by Janssen-Ortho. The Court referred the matter back to the Minister for reconsideration based on any such new submissions.

Court of Appeal Decision (2006 FCA 9)

Motions Judge's Decision (2005 FC 765)

AstraZeneca v. Apotex (**omeprazole magnesium (LOSEC)**), January 18, 2006

Judge dismisses AstraZeneca's application for an Order of prohibition, finding AstraZeneca did not establish that Apotex's allegation of non-infringement is not justified. AstraZeneca has appealed.

Full Judgment (2006 FC 7)

Trade-mark Opposition Board Decisions

Apotex and Novopharm v. SmithKline Beecham (**TABLETS and Sun Design, application no. 1001651**), December 16, 2005

Board rejects the opposition by Apotex and Novopharm to SmithKline's application to register the trade-mark TABLETS and Sun Design, proposed for use in association with "anti-depressants and preparations for the treatment of diseases of the central nervous system" and with various printed materials, educational and information services. The Board rejected the opponents' argument that the applied-for mark is a three-dimensional mark for the colour, shape or size of tablets, and found that the grounds of opposition failed based on non-distinctiveness, non-compliance with section 30, and non-registrability.

Full Decision

New Court Proceedings

Patented Medicines (Notice of Compliance) Regulations

Medicine: **galantamine hydrobromide (REMINYL)**
Applicants: Janssen-Ortho Inc and Janssen Pharmaceutica NV
Respondents: Novopharm Ltd and The Minister of Health
Date Commenced: December 22, 2005
Comment: Application for Order of prohibition until expiry of Patents Nos 2,257,431 and 2,310,926. Novopharm alleges non-infringement and invalidity.

Medicine: **atorvastatin calcium (LIPITOR)**
Applicants: Pfizer Canada Inc and Warner-Lambert Company, LLC
Respondents: Apotex Inc and The Minister of Health
Date Commenced: January 5, 2006
Comment: Application for Order of prohibition until expiry of Patent No 2,021,546. Apotex alleges invalidity.

Medicine: **methylphenidate hydrochloride (CONCERTA)**
Applicant: Janssen-Ortho Inc
Respondents: Attorney General of Canada and The Minister of Health
Date Commenced: January 12, 2006
Comment: Application for an Order directing the Minister of Health to add Patent No 2,265,668 to the Patent Register.

Medicine: **galantamine hydrobromide (REMINYL)**
Applicants: Janssen-Ortho Inc and Janssen Pharmaceutica NV
Respondents: Cobalt Pharmaceuticals Inc and The Minister of Health
Date Commenced: January 13, 2006
Comment: Application for Order of prohibition until expiry of Patents Nos 2,257,431 and 2,310,926. Cobalt alleges non-infringement (431 patent) and non-infringement and invalidity (926 patent).

Medicine: **ramipril (ALTACE)**
Applicants: Sanofi-Aventis Canada Inc and Sanofi-Aventis Deutschland GmbH
Respondents: Apotex Inc and The Minister of Health
Date Commenced: January 17, 2006
Comment: Application for Order of prohibition until expiry of Patents Nos 2,382,549 and 2,382,387. Apotex alleges non-infringement and invalidity.

Medicine: **3TC lamivudine (HEPTOVIR), abacavir sulfate (ZIAGEN), zidovudine (RETROVIR AZT)**
Applicant: GlaxoSmithKline Inc
Respondents: Attorney General of Canada and The Minister of Health
Date Commenced: January 20, 2006
Comment: Application for an Order directing the Minister to add Patent No 2,216,634 to the Patent Register.

Other Proceedings

Subject Matter: **γ-interferon analogue**
Plaintiff: Intermune, Inc
Defendant: Genentech, Inc
Date Commenced: December 19, 2005
Comment: Claim arising from a conflict proceeding in respect of Intermune's Patent Application No 462,319 and Genentech's Patent Application No 413,671.

Trade-mark: **SERRAPEPTASE**
Applicant: Nutraceutical Corporation
Respondent: Enerex Botanicals Ltd
Date Commenced: December 21, 2005
Comment: Application for an Order striking registration TMA646,478 for SERRAPEPTASE from the Trade-marks Register. Nutraceutical alleges that the trade-mark is clearly descriptive and not distinctive.

Medicine: **omeprazole (APO-OMEPRAZOLE, LOSEC)**
Plaintiff: Apotex Inc
Defendant: AstraZeneca Canada Inc
Date Commenced: December 29, 2005
Comment: Action brought pursuant to section 8 of the *Regulations* for damages (or an accounting of profits) allegedly suffered by Apotex by reason of initiation of a prohibition proceeding by AstraZeneca.

Medicine: **enalapril (VASOTEC)**
Plaintiff: Bernard Charles Sherman and Apotex Inc
Defendant: Merck & Co Inc, Merck Frosst Canada & Co and Merck Frosst Canada Ltd
Date Commenced: January 6, 2006
Comment: Patent infringement action relating to Bernard Sherman's Patent No 2,166,001 entitled "Stable solid formulation of enalapril salt and process for preparation thereof".

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Trade-mark:	**VIAGRA**
Plaintiff:	Pfizer Canada Inc and Pfizer Products Inc
Defendants:	Mayaka International Inc and Ke Chin Jimmy Ho
Date Commenced:	January 19, 2006
Comment:	Trade-mark infringement action relating to five VIAGRA trade-mark registrations. Pfizer alleges that the Defendants have used the ViagForce trade-mark in association with a product advertised as improving sexual drive and sexual ability in men in an effort to capitalize on the fame of the VIAGRA trade-marks and the VIAGRA product.

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