



Rx IP UPDATE

CANADIAN PHARMACEUTICAL INTELLECTUAL PROPERTY LAW NEWSLETTER

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Generic Estopped from Alleging Invalidity and Non-Infringement Under Linkage Regulations

In a February 14, 2005 decision, a Judge of the Federal Court held in *AB Hassle v. Apotex* (2005 FC 234) that a generic manufacturer, Apotex, was precluded by the doctrine of issue estoppel from alleging non-infringement and invalidity under the *Patented Medicines (Notice of Compliance) Regulations* ("Regulations") in view of a previous allegation of non-infringement.

In a previous proceeding, AstraZeneca had obtained an Order of prohibition (affirmed by the Court of Appeal) with respect to Apotex' third notice of allegation (NOA) relating to omeprazole magnesium tablets (AstraZeneca's LOSEC) and the patent at issue. Apotex had solely alleged non-infringement.

The decision at issue related to Apotex' fourth NOA. The Judge found that the allegation of non-infringement was not justified as it was based on an incorrect construction of the claims of the patent. However, the Judge proceeded to determine whether issue estoppel applied in case this determination was later found to be incorrect, and found that Apotex was estopped from alleging both non-infringement and invalidity. With respect to Apotex' allegation of invalidity, the Judge accepted AstraZeneca's argument that "Apotex, by alleging only non-infringement in the previous proceeding, necessarily accepted the validity of the ...patent because if the patent was not valid, Apotex's formulation could not infringe the patent". The Judge declined to exercise her discretion to not apply the doctrine, finding that Apotex should not have more than one full opportunity to allege non-infringement and invalidity with respect to the same patent and the same formulation.

Finally, the Judge concluded that if she was wrong in her determination that issue estoppel applied, Apotex' NOA constituted an abuse of process for substantially the same reasons. Accordingly, the Judge granted an Order of prohibition. Apotex has not yet appealed this decision.

In another decision rendered on the same day (*RhoxalPharma v. Novartis* (2005 FCA 11)), the Court of Appeal also considered the doctrine of issue estoppel in the context of a proceeding under the Regulations. In a previous proceeding, RhoxalPharma had alleged non-infringement with respect to one strength of cyclosporin (Novartis' NEORAL). The Court dismissed Novartis' application, and a notice of compliance (NOC) was subsequently issued. In a subsequent proceeding relating to an identical allegation of non-infringement, but with respect to another strength of cyclosporin, the Applications Judge granted an Order of prohibition. The Court of Appeal agreed with the Applications Judge that the conditions of issue estoppel were met and found it unwarranted to interfere with the Applications Judge's discretion to not apply the doctrine, including for the reason that RhoxalPharma had previously raised the doctrine in a motion for summary dismissal.

These decisions confirm that the doctrine of issue estoppel may apply in proceedings under the Regulations. Furthermore, the AstraZeneca decision recognizes a significant limitation on the ability of a generic manufacturer to serve multiple NOAs under the Regulations: an unsuccessful allegation of non-infringement may not only preclude the generic manufacturer from alleging non-infringement again, but may also preclude the generic manufacturer from alleging invalidity.

Nancy P. Pei

Patented Medicines Prices Review Board (PMPRB) Matters

Amendments to the *Patented Medicines Regulations* have been proposed which set out patentees' filing requirements with respect to the PMPRB. Comments on the proposal should be filed no later than April 15, 2005.

Proposed Amendments

The PMPRB has accepted a Voluntary Compliance Undertaking from Janssen-Ortho for EVRA (norelgestromine/ethinyl estradiol transdermal patches).

VCU Notice

Recent Court Decisions

Patented Medicines (Notice of Compliance) Regulations

Mayne Pharma v. Aventis (cefotaxime sodium (CLAFORAN)), February 4, 2005

Court of Appeal allows Mayne's appeal in part, setting aside the Judge's order insofar as it had allowed Aventis' motion to strike certain paragraphs of the affidavit of Mayne's affiant. Court of Appeal finds that these paragraphs did not raise new facts which are not found in Mayne's detailed statement.

Court of Appeal Decision (2005 FCA 50)

Motions Judge's Decision

AstraZeneca v. Minister of Health and Apotex (omeprazole (LOSEC, APO-OMEPRAZOLE)), February 9, 2005

Court of Appeal dismisses AstraZeneca's appeal. In the Federal Court's decision, a Judge dismissed AstraZeneca's application for judicial review of a Minister's decision to not require Apotex to make an allegation in respect of certain formulation patents. An earlier proceeding regarding an allegation of non-infringement involving the patents was dismissed. Subsequently, Apotex changed its formulation. However, the Minister decided that Apotex was not required to address the patents a second time. Court of Appeal finds that the Judge applied the correct standard of review in assessing the Minister's decision (reasonableness) and it was open to the Judge to find that the Minister had acted reasonably.

Court of Appeal Decision (2005 FCA 58)

Motions Judge's Decision (2004 FC 1278)

AB Hassle v. Apotex (omeprazole magnesium (LOSEC)), February 14, 2005

Judge grants Order of prohibition. Apotex had alleged non-infringement and invalidity. For further information, please see the article on page one.

Full Judgment (2005 FC 234)

RhoxalPharma v. Novartis (cyclosporin (NEORAL)), February 14, 2005

Court of Appeal allows RhoxalPharma's appeal and sets aside an Order of prohibition. Court of Appeal finds that the Judge erred in "adopt[ing] blindly" Novartis' experts' conclusions to construe the claim at issue. Court of Appeal finds that it was the Judge's duty to refer back to the words of the claim and that he should have concluded that the claim made no reference to a pharmaceutical preparation occurring *in situ* and "that what is not claimed is considered disclaimed". The finding with respect to issue estoppel is summarized in the article on page one.

Court of Appeal Decision (2005 FCA 11)

Motions Judge's Decision (2004 FC 474)

Other Proceedings

Merck v. Brantford Chemicals (sodium enalapril-sodium iodide and sodium enalapril), February 2, 2005

Court of Appeal dismisses Merck's appeal, which arose from Merck's motion for a declaration that Brantford was barred from proceeding with a second application for a compulsory licence on the grounds of *res judicata* or *functus officio*. Brantford's first application had been refused in part as it was premature. Court of Appeal finds that the Judge did not err by concluding that the Commissioner's decision in the first proceeding was not a final decision and therefore the doctrines of *res judicata* and *functus officio* did not apply.

Court of Appeal Decision (2005 FCA 48)

Motions Judge's Decision (2004 FC 516)

Trade-mark Opposition Board Decisions

Sanofi-Synthélabo v. Sabex 2002 (SAB-BETAXOLOL), August 5, 2004

Board rejects Sanofi's opposition to Sabex's application for the trade-mark SAB-BETAXOLOL for "pharmaceutical products, namely ophthalmic drops for the treatment of glaucoma and having betaxolol as an ingredient". The Board accepted that while betaxolol is a descriptive or generic term referring to a pharmaceutical product for the treatment of hypertension, the mark being applied for is not clearly descriptive, nor is it non-distinctive, in view of the prefix "SAB-".

Full Decision

New Court Proceedings

Patented Medicines (Notice of Compliance) Regulations

Medicine: olanzapine (ZYPREXA)
Applicant: Eli Lilly Canada Inc
Respondents: Eli Lilly and Company Limited, Apotex Inc and the Minister of Health
Date Commenced: January 28, 2005
Comment: Application for Order of prohibition until expiry of Eli Lilly and Company's Patent No. 2,041,113. Apotex alleges invalidity.

Medicine: lisinopril/hydrochlorothiazide (ZESTORETIC)
Applicant: AstraZeneca Canada Inc
Respondents: Merck & Co Inc, Apotex Inc and the Minister of Health
Date Commenced: January 31, 2005
Comment: Application for Order of prohibition until expiry of Merck's Patent No. 1,276,559. Apotex alleges non-infringement and invalidity.

Medicine: tamsulosin (FLOMAX)
Applicants: Boehringer Ingelheim (Canada) Ltd and Yamanouchi Pharmaceutical Co Ltd
Respondents: Novopharm Limited and the Minister of Health
Date Commenced: February 4, 2005
Comment: Application for Order of prohibition until expiry of Yamanouchi's Patents Nos. 1,177,849 and 1,164,293. Novopharm alleges that the 849 patent has expired and non-infringement and invalidity with respect to the 293 patent.

Medicine: galantamine (REMINYL)
Applicants: Janssen-Ortho Inc and Janssen Pharmaceutica NV
Respondents: Ratiopharm Inc and the Minister of Health
Date Commenced: February 4, 2005
Comment: Application for Order of prohibition until expiry of Patents Nos. 2,257,431 and 2,310,926. Ratiopharm alleges non-infringement and invalidity with respect to the 431 patent and non-infringement with respect to the 926 patent.

Medicine: **lansoprazole (PREVACID)**
Applicants: Abbott Laboratories Limited and TAP Pharmaceuticals Inc
Respondents: The Minister of Health, Novopharm Limited and Takeda Pharmaceutical Company Limited
Date Commenced: February 7, 2005
Comment: Application for Order of prohibition until expiry of Takeda's Patents Nos. 1,255,314, 1,312,548 and 2,009,741. Novopharm alleges non-infringement with respect to the 548 and 741 patents.

Medicine: **epirubicin (PHARMORUBICIN PFS)**
Applicants: Pfizer Canada Inc and Pharmacia Italia SpA
Respondents: Novopharm Limited and the Minister of Health
Date Commenced: February 11, 2005
Comment: Application for Order of prohibition until expiry of Patent No. 1,291,037. Novopharm alleges non-infringement.

Medicine: **risperidone (RISPERDAL)**
Applicants: Janssen-Ortho Inc and Janssen Pharmaceutica NV
Respondents: Novopharm Limited and the Minister of Health
Date Commenced: February 11, 2005
Comment: Application for Order of prohibition until expiry of Patents Nos. 1,256,867 and 2,194,564. Novopharm alleges non-infringement.

Medicine: **levofloxacin (LEVAQUIN)**
Applicants: Janssen-Ortho Inc and Daiichi Pharmaceutical Co Ltd
Respondents: Novopharm Limited and the Minister of Health
Date Commenced: February 11, 2005
Comment: Application for Order of prohibition until expiry of Daiichi's Patent No. 1,304,080. Novopharm alleges non-infringement and invalidity.

Medicine: **amlodipine besylate and atorvastin calcium (CADUET) and amlodipine besylate (NORVASC)**
Applicant: Pfizer Canada Inc
Respondents: The Minister of Health and the Attorney General of Canada
Date Commenced: February 16, 2005
Comment: Application for an Order requiring the Minister to list Patent No. 2,296,726 on the Patent Register.

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Medicine: **lisinopril (ZESTRIL)**
Applicant: AstraZeneca Canada Inc
Respondents: Merck & Co Inc, Cobalt Pharmaceuticals Inc and the Minister of Health
Date Commenced: February 17, 2005
Comment: Application for Order of prohibition until expiry of Merck's Patent No. 1,275,350. Cobalt alleges invalidity.

Other New Proceedings

Applicant: Ratiopharm Inc
Respondent: The Minister of Health
Date Commenced: February 14, 2005
Comment: Application for judicial review of the decision of the Therapeutic Products Directorate dated February 4, 2005, to publish an internet database entitled *Notice of Compliance (NOC) On-Line Database*. Ratiopharm seeks an Order that the Department, if it proceeds to publish the Database, identify the Canadian reference product for licensed second-entry products for which an NOC was issued pursuant to a policy, where the Canadian-referenced product remains on the market.

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