



Rx IP UPDATE

CANADIAN PHARMACEUTICAL INTELLECTUAL PROPERTY LAW NEWSLETTER

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Jean Chrétien Pledge to Africa Act Now in Force

Bill C-9, *An Act to Amend the Patent Act and the Food and Drugs Act* (the *Jean Chrétien Pledge to Africa Act*) and its accompanying regulations came into force on May 13, 2005. Bill C-9 seeks to implement the Decision of the World Trade Organization (WTO) General Council of August 30, 2003 ("Decision"). The Decision implements paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, and allows any member country to export pharmaceutical products made under compulsory licences within the terms set out in the Decision. A detailed overview of Bill C-9 was reported in our [June 2004](#) issue of *Rx IP Update*.

Industry Canada News Release

Regulations Amending the Food and Drug Regulations (1402 – Drugs for Developing Countries)

Regulations Amending the Medical Devices Regulations (Developing Countries)

Use of Patented Products for International Humanitarian Purposes Regulations

Schedule 1 of the amended *Patent Act* lists the eligible patented pharmaceutical products. On May 14, 2005, the Government published a proposed amendment to Schedule 1 to list lamivudine + nevirapine + zidovudine 150mg/200mg/300mg fixed-dose combination tablets. Interested parties may make representations on this proposal by June 13, 2005.

Order Amending Schedule 1 to the Patent Act

Court of Appeal Quashes NOC for Apo-Omeprazole Capsules, But Stays Decision

On May 18, 2005, the Federal Court of Appeal quashed Apotex's notice of compliance (NOC) for omeprazole capsules (AstraZeneca's LOSEC) (*AstraZeneca v. Apotex* (2005 FCA 189)). The appeal turned on the Court's interpretation of the "marketed" requirement in section 5(1) of the *Patented Medicines (Notice of Compliance) Regulations* ("Regulations"). The Minister of Health (the "Minister") had decided – and the applications judge agreed – that Apotex was not required to address two patents on the Patent Register because although AstraZeneca's LOSEC 20 mg capsules had been marketed in Canada pursuant to one or more NOCs, no drug had been marketed pursuant to the specific NOC in respect of which these patents had been listed. The majority decision of the Court of Appeal held that the first person's drug need only be marketed, pursuant to an NOC, and as LOSEC had been so marketed the Minister was bound to require Apotex to address the patents. Apotex's motion for a stay of the Court's decision pending an application for leave to appeal was granted on June 3, 2005.

Court of Appeal Finds that SNDSs for Changes in Name and Manufacturing Site Do Not Support Patent Listings

In two decisions released in May, 2005, *Hoffmann-La Roche v. Canada (Minister of Health)* (**trastuzumab (HERCEPTIN)**) (2005 FCA 140) and *AstraZeneca v. Canada (Minister of Health)* (**omeprazole (LOSEC)**) (2005 FCA 175), the Federal Court of Appeal held that a supplemental new drug submission (SNDS) cannot support the listing of a patent on the Patent Register if it is filed to reflect a change in the name of a drug or a drug manufacturer, or a change of manufacturing site. The basis for this finding was that such changes "cannot possibly be relevant to any potential claim for infringement of a patent for a medicine found in the drug".

Supreme Court of Canada Leave Applications

Apotex v. Minister of Health (Ontario) (**perphenazine (APO-PERPHENAZINE)**, **lisinopril (APO-LISINOPRIL)**), May 19, 2005

Leave has been denied. Apotex had filed an application for leave to appeal the Ontario Court of Appeal's dismissal of Apotex's challenge of two Ontario government policies related to drug benefit pricing.

Court of Appeal Decision

Janssen-Ortho v. Novopharm (**levofloxacin (LEVAQUIN)**), May 25, 2005

Janssen-Ortho's motion for an extension of time to file its leave application was dismissed. Janssen-Ortho sought leave to appeal the decision of the Federal Court of Appeal, which dismissed as moot an appeal of an Order dismissing its application for a prohibition Order. The Court found that there were no valid reasons for the delay.

Full Decision

Recent Court Decisions

Patented Medicines (Notice of Compliance) Regulations

Pfizer v. RhoxalPharma (**azithromycin (ZITHROMAX)**), April 12, 2005

Judge allows Pfizer's application for an Order of prohibition. Judge finds that RhoxalPharma's allegation of non-infringement was not justified and contains false information which could be considered deceptive and misleading. RhoxalPharma has appealed.

Full Decision (2005 FC 487)

AstraZeneca v. Apotex (**omeprazole magnesium (LOSEC)**), May 13, 2005

Court of Appeal dismisses AstraZeneca's appeal of an Order dismissing its application for an Order of prohibition. The Court finds that the applications judge did not err in concluding that Apotex's notice of allegation (NOA) was sufficient and was not an abuse of process, or in his assessment of the evidence.

Court of Appeal Decision ([2005 FCA 183](#))

Applications Judge's Decision ([2004 FC 44](#))

Other Proceedings

AstraZeneca v. Canada (Minister of Health) (**esomeprazole magnesium trihydrate (NEXIUM)**), February 8, 2005

Court dismisses AstraZeneca's application for review of the Minister's decision to release certain information pursuant to the *Access to Information Act* relating to AstraZeneca's drug submission for NEXIUM tablets. On a motion for reconsideration, the Judge held that the Minister may change the decision under review in certain circumstances. AstraZeneca has appealed the decision on the merits.

Reasons for Order ([2005 FC 189](#))

Motion for Reconsideration ([2005 FC 623](#))

Supplemental Reasons for Order ([2005 FC 648](#))

AstraZeneca v. Canada (Minister of Health) (**omeprazole, omeprazole magnesium (LOSEC, LOSEC MUPS)**), May 9, 2005

In three related decisions, the Court dismisses AstraZeneca's applications for review of the Minister's decisions to release certain information pursuant to the *Access to Information Act* relating to AstraZeneca's drug submissions for LOSEC tablets and capsules and LOSEC MUPS tablets.

Decision re: LOSEC Tablets ([2005 FC 645](#))

Decision re: LOSEC MUPS Tablets ([2005 FC 646](#))

Decision re: LOSEC Capsules ([2005 FC 647](#))

New Court Proceedings

Patented Medicines (Notice of Compliance) Regulations

Medicine: **salbutamol sulphate inhalation (VENTOLIN HFA)**
Applicants: GlaxoSmithKline Inc and Glaxo Group Limited
Respondents: Genpharm Inc and The Minister of Health
Date Commenced: April 28, 2005
Comment: Application for Order of prohibition until expiry of Patent Nos. 2,125,665; 2,125,667; 2,303,685. Genpharm alleges non-infringement (685 patent); non-infringement and invalidity (667 patent); non-infringement and ineligibility for listing on the Patent Register (685 patent).

Medicine: **olanzapine (ZYPREXA)**
Applicant: Eli Lilly Canada Inc
Respondents: Apotex Inc, The Minister of Health, and Eli Lilly and Company Limited
Date Commenced: May 4, 2005
Comment: Application for Order of prohibition until expiry of Eli Lilly and Company Limited's Patent No. 2,041,113. Apotex alleges invalidity. The application relates to a second NOA, correcting a December 16, 2004 NOA which omitted reference to the 10mg tablets.

Medicine: **levofloxacin (LEVAQUIN)**
Applicants: Janssen-Ortho Inc and Daiichi Pharmaceutical Co Ltd
Respondents: Apotex Inc and The Minister of Health
Date Commenced: May 11, 2005
Comment: Application for Order of prohibition until expiry of Daiichi's Patent No. 1,304,080. Apotex alleges invalidity on the basis that "any such claim...is invalid for the reasons given by Federal Court in Court File T-214-03".

Medicine: **clarithromycin (BIAXIN BID)**
Applicants: Abbott Laboratories and Abbott Laboratories Limited
Respondents: Apotex Inc and The Minister of Health
Date Commenced: May 13, 2005
Comment: Application for Order of prohibition until expiry of Patent Nos. 2,419,729 and 2,471,102. Apotex alleges non-infringement and invalidity.

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Medicine: amlodipine besylate (NORVASC)
Applicants: Pfizer Canada Inc and Pfizer Limited
Respondents: Novopharm Limited and The Minister of Health
Date Commenced: May 17, 2005
Comment: Application for Order of prohibition until expiry of Patent No. 1,253,865. Novopharm alleges invalidity.

Other New Proceedings

Medicine: isotretinoin (ACCUTANE)
Applicant: Hoffmann-La Roche Limited
Defendant: The Minister of Health
Date Commenced: May 2, 2005
Comment: Application for an Order that the Minister refuse to disclose records filed with Health Canada by the applicant in response to a request for "a copy of the most recent educational materials to be given by prescribers to patients about the Accutane Pregnancy Prevention Program", pursuant to an *Access to Information Act* request.

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