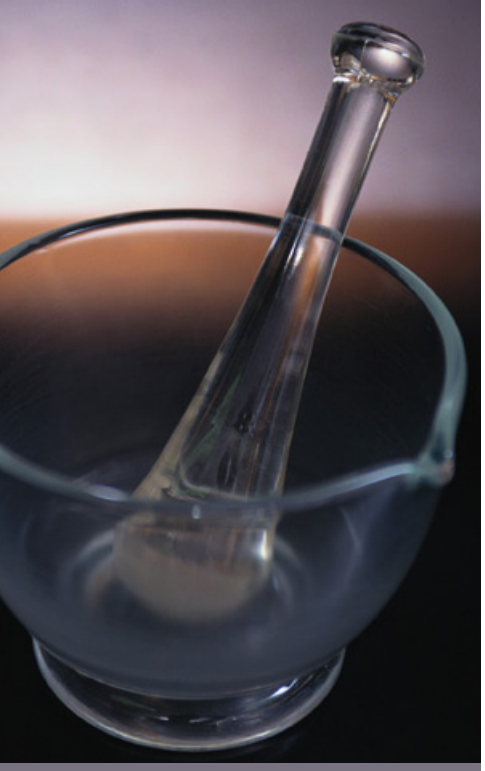

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Rx IP UPDATE

CANADIAN PHARMACEUTICAL INTELLECTUAL PROPERTY LAW NEWSLETTER

January 2008

Patented Medicines (Notice of Compliance) Regulations Guidance Document released

Health Canada has released the final version of its Guidance Document regarding the *Patented Medicines (Notice of Compliance) Regulations* ("*Regulations*"). The Guidance Document outlines Health Canada's understanding as to the roles and responsibilities of first persons, second persons and the Therapeutic Products Directorate. It applies to patent lists submitted on and after June 17, 2006, and all second-person generic submissions, including those filed prior to the coming into force of the amended *Regulations* on October 5, 2006. A draft of the Guidance Document had been released for comment in February 2007. (Guidance Document.)

Federal Court implements Practice Direction for NOC proceedings

In an effort to ensure the growing number of applications under the *Regulations* in the Federal Court are disposed of promptly while ensuring the just, most expeditious and least expensive determination of every proceeding, effective January 7, 2008, the Federal Court has implemented a Practice Direction to manage proceedings commenced under the *Regulations*. Pursuant to the Direction:

(1) A Judge or Prothonotary will be assigned as a case management Judge to each new proceeding and will convene a conference shortly after all parties have appeared during which counsel will be expected to address scheduling matters, including whether it is appropriate to reverse the order in which some or all of the evidence is submitted (under the Federal Courts Rules, the innovator, as applicant is required to serve its evidence first) and

(2) At least six weeks before the hearing date, the presiding Judge may hold a hearing

management conference to discuss matters including provision of a compendium of documents, identification of and settlement of issues, and agreement as to any facts and documents.

(Notice to the Parties and the Profession.)

Prior to the implementation of this Practice Direction, the Court recently dismissed two motions, seeking a reversal in which the evidence in NOC proceedings was to be served (*Purdue Pharma v. Pharmascience Inc.* (**oxycodone (HCl) tablets (OXYCONTIN)**), 2007 FC 1196 and *Abbott and TAP v. Novopharm, Minister of Health and Takeda* (**lansoprazole (PREVACID)**), 2007 FC 1291).

Federal Court confirms PMPRB has jurisdiction during laid-open period

On December 13, 2007, a Federal Court Judge dismissed two applications for judicial review of decisions of the Patented Medicine Prices Review Board (PMPRB) which held that the Board has jurisdiction to review the pricing of drug products during the "laid-open" period (the period between the date the patent application is laid open for public inspection and the patent issuance date). (*Shire Biochem v. Attorney General; Canada's Research-Based Pharmaceutical Companies (intervenor)* (**mixed salts amphetamines (ADDERALL XR)**); *Janssen-Ortho v. Attorney General* (**methylphenidate (CONCERTA)**), 2007 FC 1316. Janssen-Ortho has appealed.)

Food and Drug Regulations amended to permit certain advertising to general public

Presently, the *Food and Drug Regulations* prohibit preventative, treatment and cure claims of diseases listed in Schedule A in labelling and advertising to the general public.

A recent amendment has revised Schedule A.

(*Regulations Amending Schedule A to the Food and Drugs Act and the Medical Devices Regulations (Project 1539)*).

A separate amendment now exempts:

- natural health products;
- nonprescription drugs (apart from drugs regulated as Class A precursors under the Precursor Control Regulations); and
- prescription drugs that are veterinary drugs listed in Part II to Schedule F (so long as the drug is in a form not suitable for human use or is labelled for veterinary use only)

from the prohibition on **preventative** claims for the diseases listed in Schedule A.

Both sets of amendments were published on December 26, 2007 and will come into force on June 1, 2008.

(*Regulations Amending Certain Regulations Made under the Food and Drugs Act (Project 1539)*).

Health Committee reports on the Common Drug Review

The Common Drug Review (CDR) is a single Federal/Provincial/Territorial (F/P/T) process that is used to review both the clinical efficacy and cost-effectiveness of new drugs and new indications for old drugs. This review process leads to a recommendation regarding formulary listing under participating publicly-funded drug insurance plans.

On December 12, 2007, the Standing Committee on Health tabled a report in the House of Commons regarding the CDR,

following hearings held from April to June 2007 involving representatives of the F/P/T funded Canadian Agency for Drugs and Technologies in Health (CADTH) along with representatives of federal and provincial governments, the pharmaceutical industry, patient advocacy groups, health professionals, researchers and academics.

The Committee made five recommendations:

1. The federal government work with its provincial and territorial CDR counterparts to require an independent, external performance evaluation of the CDR within a year, and at five year intervals, and to make them immediately available to the public.
2. The federal government work with its provincial and territorial CDR counterparts to enhance transparency by increasing the level of scientific and price information disclosure through discussions with pharmaceutical manufacturers at the time of submission.
3. The federal government work with its provincial and territorial CDR counterparts to increase the current level of public involvement in the CDR through public attendance at open Canadian Expert Drug Advisory Committee (CEDAC) meetings and the creation of a public advisory body.
4. The federal government work with its provincial and territorial CDR counterparts to create a set of specific appeal criteria which, if met, would lead to a new and distinct appeal process for CEDAC recommendations which will:
   - require a separate group of expert reviewers;
   - extend requests for appeal beyond manufacturers to the public; and,
   - establish a clear timeframe for an appeal decision.
5. The federal government work with its provincial and territorial CDR counterparts to urge CADTH to establish a specifically designed approach for the review of drugs for rare disorders and for first-in-class drugs.

(News Release. Report of the Standing Committee on Health: Prescription Drugs Part 1 — Common Drug Review: An F/P/T Process.)

Industry Canada Releases CAMR Report

Industry Canada has released its report on the review of sections 21.01 to 21.19 of the *Patent Act* related to *Canada's Access to Medicines Regime* (*CAMR*). *CAMR* came into force on May 14, 2005 and enables a Canadian pharmaceutical manufacturer to apply to the Commissioner of Patents for a compulsory licence to export a lower cost, generic version of a patented pharmaceutical product to a developing or least-developed country unable to manufacture its own. On September 19, 2007, the first compulsory licence was issued to Apotex for a HIV/AIDS drug, APOTRIAVIR. The report concludes that the case for making legislative or regulatory changes to CAMR has not yet been made out. (Report.)

Supreme Court denies Novopharm leave in Novo-levofloxacin (LEVAQUIN) case

On December 6, 2007, the Supreme Court of Canada denied Novopharm leave to appeal a Federal Court of Appeal decision, which had upheld a Trial Judge's decision in Janssen-Ortho's patent infringement action that the patent relating to **levofloxacin (LEVAQUIN)** was valid (Novopharm had admitted infringement). (*Novopharm v. Janssen-Ortho and Daiichi Pharmaceutical*, 2007 FCA 217, affirming 2006 FC 1234.)

Recent Court decisions

Patented Medicines (Notice of Compliance) Regulations

Abbott Laboratories and TAP Pharmaceuticals v. AG Canada (lansoprazole (PREVACID)), December 14, 2007. Abbott had sought an Order prohibiting the Minister from issuing an NOC to any generic who has a filed a submission comparing its drug to PREVACID without requiring that company to address the two patents in issue. The Judge held that it would be inappropriate for the Court to grant such an Order in the circumstances, as these matters are fact-specific and the jurisprudence is evolving. The Judge also held that it is equally inappropriate to grant such an Order respecting a specific fact situation in the absence of the party engaged in that situation. (Applications Judge's decision – 2007 FC 1318.)

Pfizer v. Novopharm (quinapril (ACCUPRIL); quinapril + hydrochlorothiazide (ACCURETIC)), January 2, 2008. Judge grants Pfizer's applications for a prohibition Order, finding that Novopharm has not demonstrated that there is any better evidence or more appropriate argument in the present proceeding on the same invalidity questions as raised by Apotex in an earlier NOC proceeding respecting the same patent. In *Pfizer v. Apotex* (2007 FCA 209), the Court of Appeal concluded that Apotex's invalidity allegations on the grounds of overbreadth and lack of sound prediction were not justified. (Full judgment – 2008 FC 11.)

New proceedings

Patented Medicines (Notice of Compliance) Regulations

Medicine:	docetaxel (TAXOTERE)
Applicant:	sanofi-aventis Canada Inc
Respondents:	Hospira Healthcare Corporation and The Minister of Health
Respondent/Patentee:	Aventis Pharma S.A.
Date Commenced:	November 29, 2007
Court File No:	T-2080-07
Comment:	Application for an Order of prohibition until expiry of Patents Nos. 2,102,777 and 2,102,778. Hospira alleges non-infringement and invalidity. Hospira further asserts that the '777 and '778 patents are not properly listed on the Patent Register.

Medicine:	Apo-Omeprazole 20mg capsules (LOSEC)
Applicant:	Apotex Inc
Respondent:	Minister of Health
Date Commenced:	December 3, 2007
Court File No:	T-2100-07
Comment:	Application for judicial review of Minister's decision requiring Apotex to address all eight patents listed on the Register in respect of LOSEC 20mg capsules in the SNDS. Apotex alleges it is only required to address six of the eight listed patents in light of the Supreme Court decision of *AstraZeneca Canada Inc. v. Canada (Minister of Health)*, 2006 SCC 49.

Medicine:	desloratadine (AERIUS)
Applicants:	Schering-Plough Canada Inc and Schering Corporation
Respondents:	Pharmascience Inc, Sepracor Inc and The Minister of Health
Date Commenced:	December 3, 2007
Court File No:	T-2102-07
Comment:	Application for an Order of prohibition until expiry of Patents Nos. 2,267,136 and 2,325,014. Pharmascience alleges non-infringement and invalidity.

Medicine:	testosterone undecanoate (ANDRIOL)
Applicants:	Organon Canada Limited and N.V. Organon
Respondents:	Pharmascience Inc and The Minister of Health
Date Commenced:	December 13, 2007
Court File No:	T-2165-07
Comment:	Application for an Order of prohibition until expiry of Patent No. 2,366,856. Pharmascience alleges non-infringement and invalidity. Pharmascience further asserts that the '856 patent is not properly listed on the Patent Register.

Medicine:	latanoprost (XALATAN)
Applicants:	Pfizer Canada Inc and Pharmacia Atkiebolag
Respondents:	The Minister of Health and Pharmascience Inc
Date Commenced:	December 20, 2007
Court File No:	T-2221-07
Comment:	Application for an Order of prohibition until expiry of Patent No. 1,339,132. Pharmascience alleges non-infringement and invalidity.

Other new proceedings

Medicine:	QUADRACEL and PENTACEL vaccines
Applicant:	sanofi pasteur Limited
Respondent:	Attorney General of Canada
Date Commenced:	November 28, 2007
Court File No:	T-2072-07
Comment:	Application for judicial review of the decision by the Patented Medicine Prices Review Board (the "Board") not to accept the recommendation by Blake Cassels & Graydon LLP that it step down as Board counsel. sanofi pasteur alleges that the fact that Blakes has a current relationship with an entity that advocated an interest clearly contrary to the applicant raises a reasonable apprehension of bias.

Medicine:	enalapril sodium tablets (Apo-Enalapril, CO Enalapril)
Plaintiffs:	Bernard Charles Sherman and Apotex Inc
Defendant:	Cobalt Pharmaceuticals Inc
Date Commenced:	November 28, 2007
Court File No:	T-2074-07
Comment:	Patent infringement action relating to Patent No. 2,166,001.

Medicine:	enalapril sodium tablets (Apo-Enalapril, Riva-Enalapril)
Plaintiffs:	Bernard Charles Sherman and Apotex Inc
Defendant:	Laboratoire Riva Inc
Date Commenced:	November 28, 2007
Court File No:	T-2075-07
Comment:	Patent infringement action relating to Patent No. 2,166,001.

Medicine:	Apo-Omeprazole capsules, Apo-Medroxy tablets, Apo-Levocard CR tablets, Apo-Simvastatin tablets, Apo-Clarithromycin tablets, Apo-Digoxin tablets
Plaintiff:	Apotex Inc
Defendants:	Her Majesty The Queen in Right of Canada, Attorney General of Canada, Minister of Health, Mr. Eric Ormsby and Dr. Craig Simon
Date Commenced:	November 29, 2007
Court File No:	07-CV-344635PD1
Comment:	Action for damages suffered as a result of the defendants' alleged failure to consider Apotex's regulatory submissions and appeals from refusals to approve submissions in good faith.

Medicine:	purple inhaler trade-mark (ADVAIR)
Applicants:	Apotex Inc, Apotex Fermentation Inc, Cangene – Corporation, Novopharm Limited, Pharmascience Inc, Ranbaxy Pharmaceuticals Canada Inc, ratiopharm Inc, Sandoz Canada Inc, Taro Pharmaceuticals
Respondents:	Registrar of Trade-marks and Glaxo Group Limited
Date Commenced:	December 21, 2007
Court File No:	T-2240-07
Comment:	Application for an Order that Trade-mark Registration No. 687,313 be struck from the Register. The registration pertains to the colour purple applied to an inhaler for administration of pharmaceuticals. Specifically, the plaintiffs allege that the mark is not a "trade-mark", there is a misrepresentation in the application (the mark as depicted is inaccurate), and the mark is not distinctive of the wares of Glaxo.

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

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