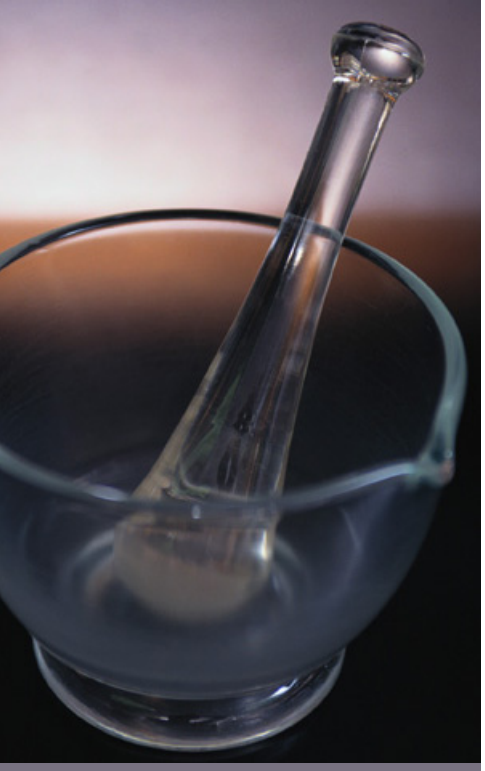

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Rx IP UPDATE

CANADIAN PHARMACEUTICAL INTELLECTUAL PROPERTY LAW NEWSLETTER

September 2008

PMPRB releases Draft Revised Excessive Price Guidelines

On August 18, 2008, the Patented Medicine Prices Review Board (PMPRB) released a stakeholder communiqué relating to the reporting of benefits. In 2000, the Board adopted a policy that permitted patentees to include or exclude certain benefits from the reporting of the average price. The communiqué states that the Board will insist upon mandatory reporting of benefits beginning with the January to June 2009 reporting period. In particular, it states that "the calculation of the Average Price must include any and all benefits listed in sub-section 4(4) of the Regulations that are connected to sales transactions: rebates (including rebates/payments to third parties); discounts; free goods; free services; gifts; and other benefits of like nature". (Stakeholder Communiqué.)

On August 20, 2008, the Board issued a Notice and Comment package, including Draft Revised Excessive Price Guidelines. In addition to a Draft Revised Compendium of Policies, Guidelines and Procedures, the package also includes a summary of the issues that have been under review, along with Stakeholders' and Working Groups' views and Board Positions.

The Draft Revised Guidelines include additions and revisions in six areas:

1. Four new levels of therapeutic improvement (breakthrough, substantial improvement, moderate improvement, and slight or new improvement) which replace the previous three categories;
2. Modified price tests aligned with the four levels of improvement;
3. Alternate processes for bioequivalent and licensed patented generic drug products regarding the selection of comparable drugs and the conduct of the Therapeutic Class Comparison (TCC) Test and the International Price Comparison (IPC) Test;
4. Guidelines on the conduct of selected any market price reviews at introduction and, thereafter, on a case-by-case basis as appropriate;
5. Guidance on the possible conduct of an International Therapeutic Class Comparison Test; and
6. A new exceptional De-Linking Methodology (DIP situation): where an apparent excessive price is due solely to

the termination of a benefit and the patentee provides evidence in this regard, the resulting average transaction price (ATP) should not be viewed as excessive if it simply "rebounds" to the pre-benefit price.

The deadline for submitting comments on the draft document is October 6, 2008. (Notice and Comment re: Draft Revised Excessive Price Guidelines. Present Compendium of Guidelines, Policies and Procedures (includes Excessive Price Guidelines).)

Separately, the Board considered a Joint Submission regarding the pricing of NICODERM and decided that the proposed resolution was not appropriate. The Board therefore ordered the parties to continue with a proceeding through to a hearing. In the Joint Submission, the parties had proposed that sales of NICODERM below its maximum non-excessive price (MNE) during the period from and after 1998 should be deemed to off-set excessive revenues alleged to have been earned from 1995, when the Board acquired jurisdiction over the pricing of NICODERM, until 1997. The Board found that this premise was not consistent with the Guidelines and therefore considered it inappropriate to rely on that premise as a reason to conclude the proceeding without a hearing. (Decision.)

Health Canada releases summary report regarding consultation on the regulatory framework for subsequent-entry biologics

On June 5 and 6, 2008, government and stakeholder representatives met and exchanged information and views with regard to subsequent-entry biologic products (SEBs) in Canada, including the draft Guidance Document dated January 31, 2008.

A series of presentations were followed by discussions around the key issues, including fundamental concepts, quality requirements, clinical requirements, intellectual property, comparability and post-market measures. A summary report on these consultations has been released.

Applications seeking to strike down data protection scheduled for December hearing

As reported in the December 2007 issue of *Rx IP Update*, both Apotex's (T-2047-06) and the Canadian Generic Pharmaceutical Association (CGPA)'s (T-1976-06) applications for judicial review, challenging the validity of the data protection provision of the Food and Drug Regulations, were permitted to proceed: *Apotex Inc. v. Canada (Governor in Council)*, 2007 FCA 374 and *Canada (Health) v. Canadian Generic Pharmaceutical Association*, 2007 FCA 375. These applications are scheduled to be heard together on December 16, 2008.

Recent Court decisions

Ontario formulary listing decision for Apo-perindopril affirmed. Apotex had applied to have Apo-perindopril listed in the Ontario Drug Benefit Formulary at 85% of the drug benefit price of the original brand name product (COVERSYL). The Executive Officer of the Ontario Public Drug Programs ("EO") was prepared to list the drug on the Formulary but only at 50% of the price at which the original brand name drug is listed. The Court dismissed Apotex's application for judicial review of the EO's decision in which it sought an Order compelling the EO to list the drug at the price it had proposed. The rationale that Apotex had offered the EO for the increase above 50% was that (i) even at 85%, there would still be significant costs savings and (ii) Apotex had been sued by Servier for patent infringement

and the proposed pricing was necessary to cover the cost of its legal defence. Apotex argued that its potential liability if it lost the litigation made it impossible to reduce its prices further than proposed unless the Ontario Government would agree to indemnify Apotex in the event it was ordered to pay damages to Servier. The EO refused to list the price at higher than 50%, stating that this was because the EO had a listing agreement in place with Servier and stating that the government was "unable to accommodate" the request for an indemnification in connection with the litigation. The Court found that the decision of the EO was reasonable in light of the circumstances. As previously reported, Servier's patent infringement action against Apotex was successful: *Laboratoires Servier, ADIR, Oril Industries, Servier Canada Inc. v. Apotex Inc.*, 2008 FC 825. (Full judgment – 2008 ONSC 39429.)

Court dismisses Ivax's summary judgment motion re: contract dispute with Apotex. Apotex had brought a claim for damages in the Ontario Superior Court arising from an alleged breach of an agreement with Ivax Pharmaceuticals for the supply of cabergoline. Ivax brought a motion for summary judgment, arguing that it was clear that there never was an agreement. The Court dismissed the motion, finding that the question of whether a contract exists is a genuine issue for trial. (Full judgment – 2008 ONSC 40961.)

Motion to strike claim against the Crown for damages dismissed. Apotex had brought a section 8 claim against AstraZeneca Canada for damages and/or profits arising from alleged delayed market entry of its omeprazole capsule product. In its counterclaim, AstraZeneca sought contribution and indemnity and damages from the Crown on the basis that the Minister of Health was negligent in requiring an allegation from Apotex. A Prothonotary dismissed the Crown's motion to strike. The Crown has appealed. (Full judgment.)

Trade-mark Opposition Board decisions

Board rejects application for ZELOXZAR in view of prior application for ZELDOX. AstraZeneca had filed an application for the trade-mark ZELOXZAR based on proposed use in association with "pharmaceutical preparations and substances for the prevention and/or treatment of cancer". Pfizer opposed registration of the application on the basis of confusion with its trade-mark ZELDOX filed for use in association with "pharmaceutical for the treatment of neurological conditions". While the Board considered that the opponent's wares should be narrowed to read "prescription pharmaceutical for the treatment of neurological conditions namely, schizophrenia and acute psychotic agitation", it found that "when the parties' wares are prescription pharmaceuticals (dispensed by health-care professionals), a further subdivision of the wares based on their intended therapeutic effect will not weigh heavily in deciding the issue of confusion". The Board also held that while the applicant's evidence supports its submission that doctors and pharmacists would not be prone to be confused about the source of a branded pharmaceutical, it found that the patient must also be taken into account and there was no evidence that the average patient would be similarly vigilant when dealing with pharmaceutical products. Finding that the probability of the likelihood of confusion or not was equally balanced, in view of the onus on the applicant, the application was refused. (Decision.)

New Court proceedings

Patented Medicines (Notice of Compliance) Regulations

Medicine:	sildenafil citrate tablets (REVATIO)
Applicants:	Pfizer Canada Inc, Pfizer Inc and Pfizer Ireland Pharmaceuticals
Respondents:	ratiopharm Inc and The Minister of Health
Date Commenced:	July 25, 2008
Court File No:	T-1157-08
Comment:	Application for an Order of prohibition until expiry of Patents Nos. 2,044,748 and 2,285,733. ratiopharm alleges non-infringement and ineligibility for listing in respect of both patents and further alleges invalidity of the '748 patent.

Medicine:	repaglinide (GLUCONORM)
Applicants:	Novo Nordisk Canada Inc and Dr. Karl Thomae GmbH
Respondents:	Cobalt Pharmaceuticals Inc and The Minister of Health
Date Commenced:	August 6, 2008
Court File No:	T-1221-08
Comment:	Application for an Order of prohibition until expiry of Patent No. 2,111,851. Cobalt alleges invalidity and non-infringement.

Medicine:	memantine hydrochloride tablets (EBIXA)
Applicants:	Lundbeck Canada Inc and H. Lundbeck A/S
Respondents:	Cobalt Pharmaceuticals Inc and The Minister of Health
Date Commenced:	August 8, 2008
Court File No:	T-1226-08
Comment:	Application for an Order of prohibition until expiry of Patent No. 2,426,492. Cobalt alleges ineligibility for listing and non-infringement.

Other new proceedings

Medicine:	ramipril (ALTACE)
Plaintiffs:	sanofi-aventis Canada Inc, Schering Corporation and sanofi-aventis Deutschland GmbH
Defendant:	Laboratoire Riva Inc
Date Commenced:	August 1, 2008
Court File No:	T-1201-08
Comment:	Patent infringement action relating to Patent No. 1,341,206.

Medicine:	desloratadine and pseudoephedrine sulfate (AERIUS D-12 HOUR)
Applicants:	Schering-Plough Canada Inc and Schering Corporation
Respondents:	Attorney General of Canada and The Minister of Health
Date Commenced:	July 28, 2008
Court File No:	T-1170-08
Comment:	Application for an Order requiring the Minister to list Patent No. 2,325,014 on the Patent Register.

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

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