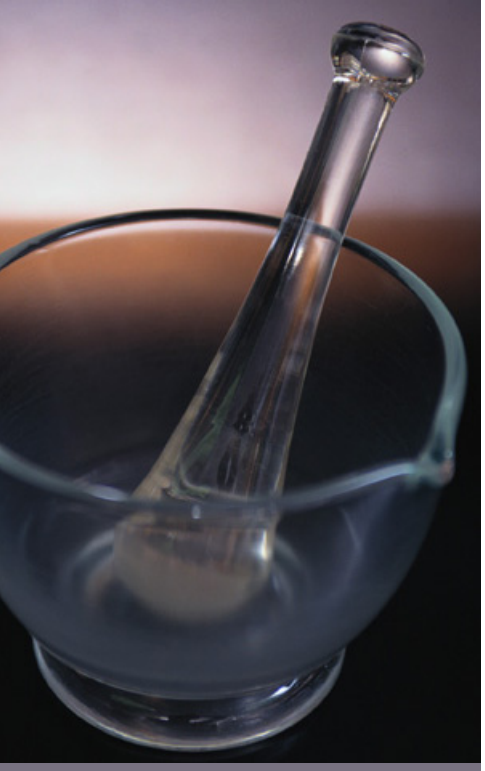

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Rx IP UPDATE

CANADIAN PHARMACEUTICAL INTELLECTUAL PROPERTY LAW NEWSLETTER

February 2008

Health Canada releases draft Guidance on Subsequent Entry Biologics

Health Canada has released its long-awaited draft Guidance for Sponsors regarding information and submission requirements for subsequent entry biologics ("SEBs"). The document has been released for comment purposes only. The Guidance Document states that the term SEB is used by Health Canada to describe a biologic product that would be similar to and would enter the market subsequent to an approved innovator biologic. Eligible reference products include those that can be well characterized by a set of modern analytical methods, such as well characterized proteins derived from recombinant DNA and/or cell culture. An SEB relies on publicly available information from the reference drug, and an approval could be granted based on a reduced amount of clinical information tailored to each class of products and/or case. While the reference product should be a product approved and marketed in Canada, according to the Guidance Document foreign reference products may be appropriate. The eleven policy statements outlining the concepts and principles constituting the basis of the regulatory framework include:

- Where appropriate, the regulatory principles and practices for the regulation of generic pharmaceuticals shall be applicable to SEBs: all the laws, patent and intellectual property principles outlined within the *Patent Act*, *Food and Drug Regulations (Data Protection)*, and *Patented Medicines (Notice of Compliance) Regulations* ("*Regulations*") are applicable to SEBs;
- The *Food and Drug Regulations* will be amended to provide a comprehensive legal basis for the regulatory framework for SEBs. In the interim, the regulatory pathway for new biologic drugs affords the appropriate flexibility for SEBs;
- Approval of a product through the SEB pathway is not an indication that the SEB may be automatically substituted with its reference biologic product. Substitutability with the reference biologic product may be granted from and/or subsequent to market authorization of an SEB. However, there is no clear indication in the Guidance

Document regarding the generic name (International Nonproprietary Name) for the SEB other than a general intention for harmonization with the World Health Organization and the International Conference for Harmonization;

- An SEB cannot be used as a reference biologic product.

Unlike for a generic pharmaceutical, the sponsor of an SEB will not be able to use the Product Monograph (PM) of the reference product, but will be required to develop a PM as outlined in the guidance document for PM.

Health Canada will accept comments on this document (directed to patrick.bedford@hc-sc.gc.ca or kwasi.nyarko@hc-sc.gc.ca) until March 15, 2008. Health Canada expects to release a further draft document in the Fall, followed by a further consultation period. (Draft Guidance for Sponsors: Information and Submission Requirements for Subsequent Entry Biologics (SEBs).)

European and Canadian Regulatory Authorities agree to exchange confidential information

Health Canada and the European Commission (EC), together with the European Medicines Agency (EMEA), have concluded confidentiality arrangements to facilitate the exchange of documents and information related to therapeutic products (Canada) / medicinal products (European Union), including safety, quality and efficacy issues. ("Closer ties" news release. EC and EMEA letter. Health Canada letter.)

TPD releases Annual Report

Health Canada has released the Therapeutic Products Directorate's first annual report, which outlines the directorate's progress and accomplishments over the past fiscal year in support of its strategic plan. The Report is for the 2006-2007 fiscal year. (Annual Report 2006-2007.)

Special Access Programme Guidance Document released

In the December 2007 issue of *Rx IP Update*, we reported that Health Canada had undertaken a comprehensive review to modernize the policy and regulatory frameworks supporting the Special Access Programme ("SAP"), which allows practitioners to gain access to drugs or medical devices that have not yet been authorized for sale in Canada through a regulatory exemption. On January 30, 2008, Health Canada released the final Guidance Document for Industry and Practitioners – Special Access Programme for Drugs and associated request and reporting forms. (Guidance Document. Special Access Request Form A. Future Use Request Form B. Patient Follow-up Form C.)

Discussion paper on Canada's safety system for food, health and consumer products

On January 10, 2008, Health Canada published a discussion paper on Canada's Food and Consumer Action Plan. Comments on the discussion paper will be accepted by Health Canada until February 13, 2008. (Paper.)

Supreme Court of Canada matters

Wyeth Canada v. ratiopharm Inc. (venlafaxine (EFFEXOR XR)), October 1, 2007. As reported in the August 2007 issue of *Rx IP Update*, the Federal Court of Appeal had affirmed an Applications Judge's finding that there is a "relevance" requirement under the pre-amended *Regulations* between a patent and the submission against which it is listed. Wyeth has sought leave to appeal the Federal Court of Appeal's decision.
(Court of Appeal decision – 2007 FCA 264. Motions Judge's decision – 2007 FC 340.)

Ranbaxy v. Pfizer (atorvastatin calcium (LIPITOR)), January 17, 2008. Leave has been denied. Ranbaxy had sought leave to appeal from the Court of Appeal's decision affirming an Order granting leave to Pfizer to serve and file an amended notice of application and extending the 24-month stay under the *Regulations*. Pfizer had discontinued its application regarding two patents and sought to bring them back after learning that assurances from Ranbaxy's counsel were not correct.
(Court of Appeal decision – 2007 FCA 244. Motions Judge's decision – 2007 FC 205.)

Recent Court decisions

Patented Medicines (Notice of Compliance) Regulations

sanofi-aventis v. Laboratoire Riva (ramipril (ALTACE)), December 14, 2007. Judge grants sanofi-aventis's motion and reverses a Prothonotary's Order which had granted Riva leave to file further evidence. The Judge found that the Prothonotary misapprehended the facts in concluding that Riva is not "splitting its case" at this late stage of the litigation, or made an error in law by incorrectly applying the applicable jurisprudential test for the filing of further evidence in a prohibition proceeding. The Judge also found that allowing Riva to split its case at the late stage of the litigation appears prejudicial to sanofi-aventis's position on the merits, and that Riva's proposed evidence does not assist the interests of justice.
(Full judgment – 2007 FC 1317.)

Pfizer Canada and Warner-Lambert v. Apotex and the Minister of Health (atorvastatin calcium (LIPITOR)), January 4, 2008. Judge dismisses Pfizer's application for a prohibition Order finding that Pfizer has not satisfied the overall legal burden on a balance of probabilities that its patent at issue is a valid selection patent. Pfizer has appealed.
(Full judgment – 2008 FC 13.)

Pfizer v. Pharmascience and Minister of Health; Pfizer v. Cobalt and Minister of Health (amlodipine (NORVASC)), January 10, 2008. Court of Appeal dismisses appeals by Pharmascience and Cobalt from separate decisions of the Motions Judge (having identical reasons). The Judge had granted the applicants leave to add Pfizer Limited, a patentee, as a party to the proceedings and dismissed the respondents' motions to strike the proceedings as a nullity because Pfizer Limited was not a party at the outset. The Court of Appeal found that the Judge had not erred in exercising his discretion as permitted by the *Federal Courts Rules*. The Judge had permitted applicants to add Pfizer Limited, patentee of one of the patents at issue, as a party to two proceedings under the *Regulations*.
(Court of Appeal decision – 2008 FCA 15. Motions Judge's decision (Pharmascience) – 2007 FC 167. Motions Judge's Decision (Cobalt) – 2007 FC 169.)

sanofi-aventis v. Riva (ramipril (ALTACE)), January 31, 2008. Judge reverses decision of a Prothonotary which had allowed Riva's motion to strike sanofi-aventis's application for judicial review. The decision sought to be reviewed relates to whether Riva can obtain a notice of compliance (NOC) if the Minister is prohibited under the *Regulations* from granting an NOC to Pharmascience. Riva's submission is cross-referenced to Pharmascience's submission. The Judge found that it was not clear and beyond doubt that sanofi-aventis did not have standing to bring the application.
(Full judgment – 2008 FC 129.)

Other decisions

Apotex v. sanofi-aventis and Bristol-Myers Squibb (clopidogrel bisulfate (PLAVIX)), January 14, 2008. Apotex brought an action in Ontario for damages for breach of a settlement agreement made in New York arising out of litigation in the state of New York. The defendants are not Canadian entities and were served outside the jurisdiction. The Ontario Superior Court grants the defendants' motion to set aside service *ex juris* and stay the action on the grounds that there is no real and substantial connection between Ontario and the subject matter of the action. The Court also grants the defendants' motion to stay the action on the grounds of forum *non conveniens*.
(Full judgment – 2008 CANLII 574.)

Canadian Internet Registration Authority decisions

Genzyme v. Johnny Carpela (SYNVISC; synvisc.ca), November 9, 2007. Arbitrator orders transfer of the domain name synvisc.ca to the complainant, Genzyme. The Arbitrator found that Genyzyme had established its rights to the trade-mark SYNVISC, which predated the registration of the disputed domain name, and that the registrant's registration of the disputed domain name was in bad faith. (Decision.)

New proceedings

Patented Medicines (Notice of Compliance) Regulations

Medicine:	esomeprazole magnesium trihydrate tablets (NEXIUM)
Applicants:	AstraZeneca Canada Inc and AstraZeneca Aktiebolag
Respondents:	Apotex Inc and The Minister of Health
Date Commenced:	January 2, 2008
Court File No:	T-2-08
Comment:	Application for an Order of prohibition until expiry of Patent No. 2,139,653. Apotex alleges non-infringement and invalidity.

Medicine:	esomeprazole magnesium trihydrate tablets (NEXIUM)
Applicants:	AstraZeneca Canada Inc and AstraZeneca Aktiebolag
Respondents:	Apotex Inc and The Minister of Health
Date Commenced:	January 2, 2008
Court File No:	T-3-08
Comment:	Application for an Order of prohibition until expiry of Patent No. 2,290,963. Apotex alleges non-infringement and invalidity.

Medicine:	esomeprazole magnesium trihydrate tablets (NEXIUM)
Applicants:	AstraZeneca Canada Inc and AstraZeneca Aktiebolag
Respondents:	Apotex Inc and The Minister of Health
Date Commenced:	January 4, 2008
Court File No:	T-9-08
Comment:	Application for an Order of prohibition until expiry of Patents Nos. 2,166,483 and 2,166,794. Apotex alleges non-infringement.

Medicine:	esomeprazole magnesium trihydrate tablets (NEXIUM)
Applicants:	AstraZeneca Canada Inc, AstraZeneca AB and Aktiebolaget Hässle
Respondents:	Apotex Inc and The Minister of Health
Date Commenced:	January 8, 2008
Court File No:	T-22-08
Comment:	Application for an Order of prohibition until expiry of Patents Nos. 1,292,693; 1,302,891; and 2,186,037. Apotex alleges non-infringement and invalidity.

Medicine:	perindopril erbumine tablets (COVERSYL)
Applicants:	Servier Canada Inc and Adir
Respondents:	The Minister of Health and Apotex Inc
Date Commenced:	January 11, 2008
Court File No:	T-45-08
Comment:	Application for an Order of prohibition until expiry of Patent No. 1,341,196. Apotex alleges non-infringement and invalidity.

Medicine:	esomeprazole magnesium trihydrate tablets (NEXIUM)
Applicants:	AstraZeneca Canada Inc and AstraZeneca AB
Respondents:	Apotex Inc and The Minister of Health
Date Commenced:	January 11, 2008
Court File No:	T-46-08
Comment:	Application for an Order of prohibition until expiry of Patent No. 2,290,513. Apotex alleges non-infringement.

Medicine:	esomeprazole magnesium trihydrate tablets (NEXIUM)
Applicant:	AstraZeneca Canada Inc
Respondents:	Apotex Inc and The Minister of Health
Respondent/Patentee:	Takeda Pharmaceutical Company Limited
Date Commenced:	January 11, 2008
Court File No:	T-47-08
Comment:	Application for an Order of prohibition until expiry of Patent No. 1,338,377. Apotex alleges non-infringement.

Medicine:	perindopril erbumine/indapamide tablets (COVERSYL PLUS and COVERSYL PLUS LD)
Applicants:	Servier Canada Inc and Adir
Respondents:	The Minister of Health and Apotex Inc
Date Commenced:	January 11, 2008
Court File No:	T-48-08
Comment:	Application for an Order of prohibition until expiry of Patent No. 1,341,196. Apotex alleges non-infringement and invalidity.

Medicine:	esomeprazole magnesium trihydrate tablets (NEXIUM)
Applicants:	AstraZeneca Canada Inc and AstraZeneca AB
Respondents:	Apotex Inc and The Minister of Health
Date Commenced:	January 11, 2008
Court File No:	T-49-08
Comment:	Application for an Order of Prohibition until expiry of Patent No. 2,170,647. Apotex alleges non-infringement.

Other new proceedings

Medicine:	gemcitabine (GEMZAR)
Plaintiffs:	Eli Lilly Canada Inc and Eli Lilly and Company
Defendant:	Sandoz Canada Incorporated
Date Commenced:	January 11, 2008
Court File No:	T-51-08
Comment:	Patent infringement action relating to Patents Nos. 2,098,881 and 2,098,886.

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

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