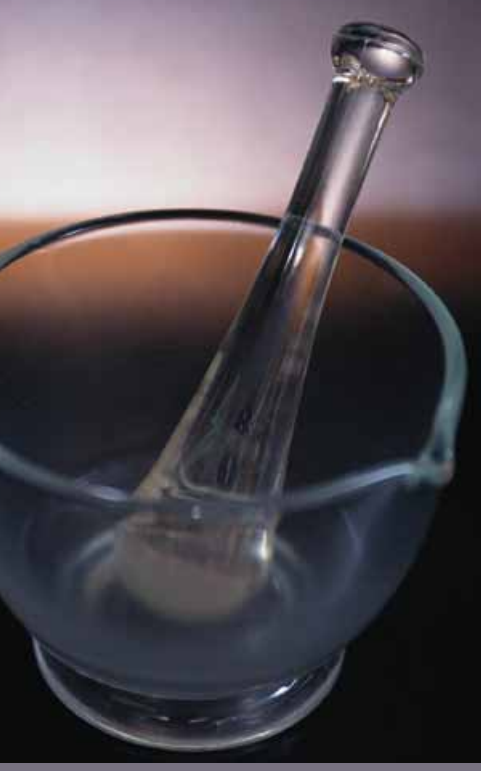

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Rx IP UPDATE

CANADIAN PHARMACEUTICAL INTELLECTUAL PROPERTY LAW NEWSLETTER

April 2009

Health Canada news

Health Canada releases revised draft Guidance Document on subsequent-entry biologics (SEBs). Further to its January 30, 2008 draft Guidance Document (reported in the February 2008 issue of *Rx IP Update*), Health Canada has published a revised draft Guidance Document for Sponsors of SEBs. (Draft Guidance Document. PDF version.) A "Questions and Answers" document was published to accompany the revised draft. (Questions and Answers document.)

The revised draft includes a number of changes over the January 2008 version. Notably, it clarifies the circumstances under which Health Canada intends to permit a SEB sponsor to rely upon a non-Canadian reference product.

According to the revised draft, a non-Canadian reference product can only be used in the demonstration of similarity between the SEB and an approved Canadian product. Moreover, where a non-Canadian reference product is used, the SEB submission "must explicitly and clearly explain the link between the reference product and the product authorized for sale in Canada." This is described as a comparison or reference to a Canadian drug triggering the protections of the *Patented Medicines (Notice of Compliance) Regulations* ("*Regulations*") and the data protection provisions of the *Food and Drug Regulations* in the proposed amended and revised Guidance Documents pertaining to each, concurrently released with the revised SEB draft Guidance Document. (Notice.)

Health Canada is accepting comments on each of the three draft Guidance Documents until **May 26, 2009**. Instructions for providing comments are available on the Health Canada website. (Instructions.)

Guidance Document released relating to data protection. On March 24, 2009, Health Canada released the Guidance Document "*Data Protection under C.08.004.1 of the Food and Drug Regulations*." A draft had been released on June 25, 2007. The Guidance Document outlines the roles and responsibilities of innovator manufacturers, second-entry manufacturers and Health Canada under the data protection provisions of the *Food and Drug Regulations* as amended on October 5, 2006. The Guidance Document became effective on March 30, 2009. A proposed revision to the Guidance Document was released on March 27, 2009. The proposed additions reflect the administration of the data protection provisions in light of the Draft Guidance for Sponsors for SEBs, discussed above. Comments on the proposed additions should be provided to Health Canada within

60 days of March 27, 2009. (Notice and Guidance Document. Proposed addition to Guidance Document Notice.)

Notice of compliance with conditions (NOC/c) Policy and Guidance Document revised. On March 17, 2009, Health Canada released a Notice informing stakeholders that, effective immediately, "it will be inviting manufacturers filing ANDS submissions to provide undertakings — similar, but not necessarily identical, to those provided by the manufacturer who sponsored the CRP — prior to the approval of an ANDS that references a CRP that was issued an NOC pursuant to the NOC/c Policy." Minimum undertakings are outlined, and the Notice advises that confirmatory studies will not be automatically sought from manufacturers who file ANDS submissions that reference a CRP that was issued an NOC pursuant to the NOC/c Policy. Health Canada will be reviewing its NOC/c Policy and Guidance Documents, and draft revisions will be made available once completed. Any feedback regarding this Notice should be directed to Health Canada within **30 days** of March 17, 2009. (Notice.)

Patented Medicine Prices Review Board news

Further draft Revised Excessive Price Guidelines released for final consultation. The Board has released a Notice and Comment package, including a further draft revised Compendium of Policies, Guidelines and Procedures. This consultation seeks final comments only on those sections of the draft revised Compendium that have been amended since the version released August 20, 2008. A summary of the issues that have been under review, along with a summary of Stakeholder Views and the Board's Position, are found in Part A of the package. Part B contains the draft revised Compendium. The Board anticipates publishing the final revised Compendium in early June 2009, with implementation scheduled for July 1, 2009. Any comments should be directed to the Board no later than **April 27, 2009**. (Update. August 20, 2008 draft.)

Court overturns PMPRB's decision asserting jurisdiction over U.S.-based sales. The Federal Court has set aside the Board's decision that found it had jurisdiction over Celgene's sales of **THALOMID (thalidomide)**. No NOC has been issued for the sale of THALOMID in Canada, but sales have been made pursuant to Health Canada's Special Access Program ("SAP").

The Board had found that its jurisdiction extended to sales made pursuant to the SAP. The Board also found that although the applicable principles of commercial common law establish New Jersey as the *locus* of THALOMID sales to Canadian patients (Celgene pointed in part to invoices marked "FOB New Jersey"), this was not germane to, and certainly not determinative of, its jurisdiction. The Board therefore concluded that it had jurisdiction to make a remedial Order concerning the pricing of THALOMID from the laid-open date of the relevant patents.

On judicial review, the Court held, "[a] textual, contextual, and purposive analysis of s. 80(1)(b) [of the *Patent Act*] does not support the Board's opinion of its own jurisdiction. Thalomid is sold **to** Canadians, but the medicine is not being sold 'in any market in Canada'; it is sold in the United States. Section 80(1)(b) is not capable of capturing these sales within the jurisdiction of the Board." (*Celgene Corporation v. Attorney General of Canada*, March 17, 2009. Full judgment – 2009 FC 271. Decision of Board.)

Notice of Hearing re: Amgen's NEULASTA. The PMPRB will hold a public hearing, commencing on September 28, 2009, to determine whether Amgen is selling or has sold **NEULASTA (PEG-filgrastim)** in any market in Canada at a price that, in the Board's opinion, is or was excessive, and if so, what order, if any, should be made. A pre-hearing conference is scheduled for June 3, 2009. (Update. Notice of Hearing.)

Recent Court decisions

Patented Medicines (Notice of Compliance) Regulations

Court of Appeal affirms heightened disclosure requirement for sound prediction. As reported in the March 2008 issue of *Rx IP Update*, in *Eli Lilly v. Apotex and the Minister of Health*, a decision relating to a patent for a new use of the medicine **raloxifene (HCl) tablets** (Eli Lilly's **EVISTA**), the Federal Court held that the factual basis and sound line of reasoning supporting a sound prediction must be disclosed in the patent, not elsewhere. The Applications Judge stated, "[t]he public should not be left to scour the world's publications in the hope of finding something more to supplement or complete a patent disclosure." The patent at issue did not disclose the specific study that provided the factual basis and sound line of reasoning for the sound prediction, and the Applications Judge concluded that Apotex's allegation of invalidity was justified.

Eli Lilly appealed the decision and moved for an interim stay of the Federal Court's Order pending disposition of the appeal; the stay was denied.

Eli Lilly's appeal was dismissed. Eli Lilly argued that the patent did not lack adequate disclosure and that the patent was not based on a prediction as the utility of the invention was conclusively established by the Canadian filing date. The Court of Appeal disagreed with the latter, holding that it was clear that the invention was based on a prediction. With respect to the disclosure requirement, the Court held that the Federal Court Judge proceeded on a proper principle when he held:

> [W]hen a patent is based on a sound prediction, the disclosure must include the prediction. As the prediction was made sound by the [specific] study, this study had to be disclosed.

The study at issue had been published between the priority and Canadian filing dates. The Court of Appeal agreed with the Federal Court Judge that the patent did not disclose any more than a prior art article did, and as such, the person skilled in the art was given, by way of disclosure, no more than such a person already had available in the prior art. (*Eli Lilly v. Apotex and the Minister of Health.* Federal Court decision – 2008 FC 142. Decision re: interim stay – 2009 FCA 65. Federal Court of Appeal decision – 2009 FCA 97.)

Court of Appeal affirms dismissal of Abbott's application for Order of prohibition. As reported in the January 2009 issue of *Rx IP Update*, the Federal Court dismissed Abbott's application for an Order prohibiting the Minister from issuing an NOC to Sandoz for its generic version of Abbott's **BIAXIN XL** until the expiry of Abbott's patent claiming a particular crystalline form of **clarithromycin** ("Form I"). (*Abbott Laboratories v. Sandoz*, 2008 FC 1359.) The Applications Judge found that while Sandoz's allegation of non-infringement was not justified, Abbott had failed to satisfy the Court that Sandoz's allegations of anticipation and obviousness were not justified. The Court of Appeal dismissed Abbott's appeal, ruling only on the issue of anticipation. The Court of Appeal agreed that the patent, which claimed Form I of clarithromycin, was anticipated since the experts agreed that at least some of the crystalline forms produced using the prior art would be Form I. Abbott argued that the Applications Judge erred in finding a prior art patent anticipatory as the prior art failed to disclose the special advantages (improved bioavailability and formulation advantages) of Form I over Form II.

The Court of Appeal held that since the claims covered the use of clarithromycin where very little is Form I, the advantages were not essential elements. Therefore, the Court of Appeal held that the Applications Judge did not err by failing to consider whether the prior art patent disclosed the special advantages of Form I. (*Abbott Laboratories v. Canada (Health)*, March 20, 2009. Full judgment – 2009 FCA 94).

Federal Court issues three Orders of prohibition regarding escitalopram. The Federal Court issued Orders of prohibition (against Genpharm, Apotex, and Cobalt) in three separate applications under the *Regulations*, heard consecutively, relating to the medicine **escitalopram** (Lundbeck's **CIPRALEX**), an antidepressant. The patent at issue claims escitalopram, the *S*-enantiomer of citalopram. The three generic companies alleged, among other grounds of invalidity, that the patent at issue was an invalid selection patent in view of two U.S. patents. The activity of the enantiomer disclosed in the patent was 1.6 times greater than the racemate; such a level, according to the Court, was not sufficiently unexpected to serve as a basis for a selection

patent, nor was there an indication that escitalopram has other desirable or surprising traits. However, the Court held that the generics' selection patent argument falls for lack of prior disclosure because if the subject matter of the prior patents was worked, the result would be the racemate, not the enantiomer. The patent was found not anticipated; apart from the U.S. patents, certain articles were found not to disclose escitalopram as useful in the treatment of depression and were in no way enabling. The allegation of obviousness was held unjustified because the resolution of the enantiomers was inventive. The Court also held unjustified other alleged grounds of invalidity, including ambiguity, lack of sound prediction, inutility, insufficiency, overbreadth and breach of section 53 of the *Patent Act*. Genpharm, Apotex and Cobalt have appealed. (*Lundbeck Canada Inc. v. Genpharm ULC; Lundbeck Canada Inc. v. Apotex Inc; Lundbeck Canada Inc. v. Cobalt Pharmaceuticals Inc.*, February 25, 2009. Full judgment – 2009 FC 146.)

Application for Order of prohibition for raloxifene fails for lack of utility and non-infringement. In a proceeding relating to a different patent listed against Eli Lilly's **EVISTA** product, the Federal Court dismissed Eli Lilly's application seeking an Order prohibiting the Minister from issuing an NOC to Novopharm for its **raloxifene hydrochloride tablets**. The patent at issue was directed to a particle size range of raloxifene. The Court held that Novopharm's allegation of non-infringement was justified. Novopharm had also alleged the patent was invalid for obviousness and lack of utility.

The Court reasoned that "[i]t is clear that unexpected utility can support an otherwise obvious invention," but "that utility must be clearly stated in the description." The surprising utility asserted in the patent was the consistency of *in vivo* absorption/bioavailability across the claimed particle size range. However, the patent only contained data relating to this utility for a single point in the range. The Court held that "[a] single point cannot define a range" and held that there had not been an actual demonstration of utility. The Court further found that the patent did not provide sufficient information to enable a person skilled in the art to "soundly predict" the asserted utility. The Court concluded that Novopharm's allegation of invalidity for lack of utility was justified because "the utility of the promised invention ... has not been described and could not have been soundly predicted based on what was described." (*Eli Lilly Canada Inc. v. Novopharm Limited*, March 19, 2009. Full judgment – 2009 FC 235.)

Trade-mark decisions

Rejection of PREOS upheld as confusing with PROTOS. The Court dismissed NPS's appeal of the Registrar's decision, refusing its application for the trade-mark **PREOS** on the basis of a likelihood of confusion with Biofarma's **PROTOS**. Both were proposed to be used in relation to pharmaceutical preparations for the prevention or treatment of osteoporosis.

NPS argued that the Registrar erred in not giving weight to the differences between the actual wares of the parties and the fact that purchasers of pharmaceuticals would take particular care that would lessen the likelihood of confusion. The Court held that in comparing the nature of the wares and nature of trade, it is the statement of wares in the application that is to be considered, rather than the actual use. The Court rejected NPS's argument that the Registrar did not take into account the principle that particular care is taken by purchasers where the wares are prescription drugs, thus lessening the likelihood of confusion. The Court held that the Registrar did not err in finding support for the proposition that the standard of confusion in cases involving pharmaceuticals is not different than that applicable to other wares and the essential question to be determined is related to the source of the product (rather than the possibility of errors in prescribing or dispensing) and also in including patients (in addition to physicians and pharmacists) as an average consumer of prescription drugs. NPS has appealed. (*NPS Pharmaceuticals, Inc. v. Biofarma, Société Par Actions Simplifiée*, February 19, 2009. Full judgment – 2009 FC 172.)

New Court proceedings

Patented Medicines (Notice of Compliance) Regulations

Medicine:	finasteride (PROPECIA)
Applicants:	Merck & Co, Inc and Merck Frosst Canada Inc
Respondents:	Sandoz Canada Inc and The Minister of Health
Date Commenced:	March 20, 2009
Court File No:	T-424-09
Comment:	Application for an Order of prohibition until expiry of Patents Nos. 1,331,601 and 2,173,457. Sandoz alleges non-infringement ('457 and '601 patents), invalidity ('457 patent) and ineligibility for listing ('601 patent).

Other proceedings

Medicine:	gabapentin (NEURONTIN)
Applicants:	Purepac Pharmaceutical Co, Faulding Inc and Actavis Elizabeth LLC
Respondents:	Apotex, Inc and Torpharm, Inc (now Apotex, Inc)
Date Commenced:	February 27, 2009
Court File No:	CV-09-00373395
Comment:	Application for an Order enforcing the Letters Rogatory issued by the U.S. District Court of New Jersey seeking an order to obtain the production of documents, samples, and oral examination from the respondents in respect of an action entitled *In re Gabapentin Patent Litigation*, Multi-district Litigation No. 1384, Civil Action No. 00-CV-2931.

Medicine:	gabapentin (NEURONTIN)
Applicants:	Warner-Lambert Company LLC, Pfizer Inc, Pfizer Pharmaceuticals LLC and Gödecke GMBH
Respondents:	Apotex, Inc and Torpharm, Inc (now Apotex, Inc)
Date Commenced:	March 2, 2009
Court File No:	CV-09-373509
Comment:	Application for an order enforcing the Letters Rogatory issued by the U.S. District Court of New Jersey seeking an order to obtain the production of documents, samples, and oral examination from the respondents in respect of an action entitled *In re Gabapentin Patent Litigation*, Multi-district Litigation No. 1384, Civil Action No. 00-CV-2931.

Medicine:	Confidential
Applicant:	Procter & Gamble Pharmaceuticals Canada Inc
Respondent:	The Minister of Health
Date Commenced:	March 6, 2009
Court File No:	T-338-09
Comment:	Application for judicial review seeking an Order declaring that the Minister erred in deciding that a patent was not eligible to be added to the Register. P&G pleads that the patent issued after a notice of non-compliance withdrawal letter (NON/W) issued for the NDS. The TPD later rescinded the NON/W. P&G submitted the Form IV with the additional information required to re-activate the NDS. The OPML decided that the patent was ineligible for listing on the basis that the timing requirements were not met.

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

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