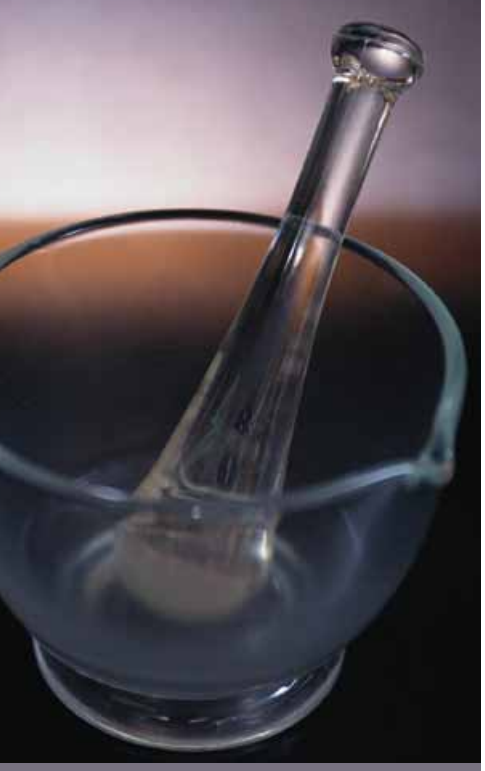

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Rx IP UPDATE

CANADIAN PHARMACEUTICAL INTELLECTUAL PROPERTY LAW NEWSLETTER

June 2009

Health Canada grants approval for subsequent entry biologic OMNITROPE

On April 20, 2009, Health Canada issued a notice of compliance (NOC) to Sandoz Canada Inc. for the drug product **OMNITROPE**, containing **somatropin** (a recombinant human growth hormone). According to Health Canada, OMNITROPE was approved based on "the similarity principles for the subsequent entry biologics" with a reduced clinical package, and using **GENOTROPIN** as the reference product.

The approval of OMNITROPE was made before Health Canada finalized its Guidance Document for Subsequent Entry Biologics (SEBs). Publication of the revised draft Guidance Document for SEBs was reported in the April 2009 edition of *Rx IP Update*. (Notice of decision.)

Court dismisses section 8 action against Roche

In the second action to proceed to trial under section 8 of the *Patented Medicines (Notice of Compliance) Regulations* ("*Regulations*"), the Federal Court has found that Roche is not liable to Apotex for damages arising from prohibition proceedings relating to **naproxen sustained release tablets** (Roche's **NAPROSYN SR**): *Apotex v. Hoffmann-La Roche Limited*, 2009 FC 494. As reported in the November 2008 issue of *Rx IP Update*, the Federal Court rendered its first section 8 decision on the merits in *Apotex v. Merck Frosst Ltd.*, 2008 FC 1185, which considered section 8 as enacted by the 1998 amendments to the *Regulations*. An appeal of that decision was heard in April and remains under reserve.

In the latest decision, the Federal Court has now considered the application and meaning of the pre-amended version of section 8 (i.e., the original 1993 version).

Roche had been successful in obtaining a prohibition Order, which was upheld on appeal, in 1996. In 1999, the patent at issue was held to be invalid and not infringed in an impeachment suit brought by Apotex. Apotex immediately

brought a motion to set aside the prohibition Order and dismiss the prohibition proceeding. Finding that the Order sought was unnecessary because the prohibition Order ceased to be operative when the patent was held invalid, the Motions Judge nevertheless granted the motion "for greater certainty." Apotex's NOC issued four days later.

Justice Hughes found that under the circumstances, the 1993 version, rather than the 1998 version, of section 8 was applicable: the transitional provisions in the 1998 amendments provide that the 1998 version of section 8 applies to applications "pending" as of March 11, 1998 (when the amendments came into force), and the word "pending" was interpreted to refer to legal proceedings in which there is no final judgment; the fact that a judgment is later varied or set aside does not mean that it was not "final" or pending as March 11, 1998.

Interpreting the 1993 version of section 8, which provides for liability when "the Minister delays issuing a notice of compliance beyond expiration of all patents that are the subject of an order pursuant to subsection 6(1)," Justice Hughes found that the circumstances did not trigger the section. The patent "expired" by operation of law upon the declaration of invalidity. Since the Minister issued Apotex's NOC only a few days after the impeachment judgment and the Order varying the prohibition Order, there was no unreasonable delay by the Minister in issuing the NOC. Furthermore, Apotex could not "reach back" and apply the finding of invalidity to argue that the patent had expired within the meaning of section 8: the prohibition application and appeal were fully argued on the issues raised, which did not include any allegation of invalidity. The patent had not expired (was not held to be invalid) during the period when the prohibition Order was made or affirmed on appeal. Apotex may appeal as of right.

Patented Medicine Prices Review Board news

New NEWSletter released. The PMPRB has released the April 2009 NEWSletter. (NEWSletter.)

Revised Excessive Price Guidelines implementation deferred. On May 11, 2009, the Board advised that it will defer the implementation of its Revised Excessive Price Guidelines to January 1, 2010. Nevertheless, the Board will release the revised Guidelines as planned in mid-June. (Communiqué.)

Ontario government news

Control over Drug Purchasing scheme expands. As reported in the May 2009 issue of *Rx IP Update*, as a result of audits conducted by the Ministry of Health and Long-Term Care's Ontario Public Drug Programs, it was found that some pharmacies have been purchasing a greater amount of generic drugs than they require, collecting professional allowances on the full amount and then returning what they do not need to the wholesaler. The wholesaler was then reselling the product, triggering a second professional allowance payment. According to the Ontario Ministry, this scheme enables professional allowances to be collected multiple times.

The Ontario government took a number of enforcement actions in what it calls the "Drug Purchasing" scheme. In May, it took further enforcement actions, including issuing demand letters that require three pharmacy groups to provide information on professional allowances, indicating that these may be followed by full-scale audits. The previous enforcement actions were limited to individual pharmacies, wholesalers and generic drug companies. (News release.)

Filling prescriptions to get easier in Ontario. The Ontario government is proposing to introduce legislation amending the *Drug and Pharmacies Regulations Act* (*DPRA*) and the *Ontario Drug Benefit Act* (*ODBA*) to allow prescriptions to be filled without the pharmacist being physically present. This "remote drug dispensing" would allow drugs to be dispensed (including through dispensing machines) where the pharmacist is involved through video conferencing, as well as mail order where medications for chronic

conditions are dispensed and delivered regularly to patients' homes. Benefits include increasing access to medications and improving convenience for patients, especially those in remote areas of the province. (News release.)

Recent Court decisions

Patented Medicines (Notice of Compliance) Regulations

Federal Court of Appeal affirms Judge's decision on "dosage form" eligibility. The Federal Court of Appeal dismissed Bayer's appeal from a Judge's decision dismissing its application seeking judicial review of the Minister's refusal to list a patent on the Patent Register for Bayer's **MENOSTAR**. The patent claims a package, a desiccant and a transdermal patch containing **estradiol**. The Court concluded that the Judge correctly found that the patent did not claim a dosage form but rather a form of a protective packaging. (*Bayer Inc. v. Canada (Health)*, April 28, 2009. Court of Appeal decision – 2009 FCA 133. Motions Judge's decision – 2008 FC 857.)

Novopharm's appeal challenging 2008 amendments relating to pre-October 2006 "relevance" requirement dismissed. The Federal Court of Appeal dismissed Novopharm's appeal from a Judge's decision dismissing Novopharm's section 6(5)(a) summary dismissal motion in a prohibition proceeding relating to **orally disintegrating olanzapine tablets** (Eli Lilly's **ZYPREXA ZYDIS**). Novopharm had sought a declaration that sections 2, 3 and 4 of the 2008 amendments to the *Regulations* are *ultra vires* and of no force and effect on the basis that they are retroactive and/or not authorized by section 55.2(4) of the *Patent Act*. The Court concluded that declaratory relief related to the validity of a law is not available in the context of an application brought under the *Regulations*; the proper course is for Novopharm to commence a judicial review application. (*Novopharm Limited v. Eli Lilly Canada Inc.*, May 4, 2009. Court of Appeal decision – 2009 FCA 138. Motions Judge's decision – 2008 FC 1221.)

Patent is properly added to Patent Register as of date it is deemed eligible for listing, not date of filing patent list. In November 2006, Eli Lilly submitted patent lists to the Minister to add a patent relating to **olanzapine dihydrate (ZYPREXA ZYDIS)** to the Patent Register against several supplementary new drug submissions (SNDSs). The initial request was refused by the Minister, but after an exchange of correspondence, in November 2007, the Minister agreed to list the patent against three SNDSs. The Minister refused Eli Lilly's request to list the patent as of the date the patent lists were filed. Eli Lilly sought judicial review, submitting that the correct interpretation of section 5 would require a generic manufacturer to address a patent included in a patent list as of the date the list is filed. The Court held that the Minister's interpretation of the *Regulations* was correct in law: a patent cannot be added to the Register before it is deemed eligible by the Minister. While the Court recognized that a delay in the listing of a patent may, in some cases, provide a generic manufacturer with a procedural advantage, it held that this "does not deprive the innovator of its substantive patent rights which can always be the subject of judicial enforcement." (*Eli Lilly Canada Inc. v. Canada (Health)*, May 8, 2009. Full judgment – 2009 FC 474.)

Other decisions

Federal Court affirms Health Canada's refusal to issue an NOC for Apotex's ASA. Apotex filed an abbreviated new drug submission (ANDS) with Health Canada for its acetylsalicyclic acid ("ASA") 81 mg enteric-coated tablets using Bayer-ASA as the reference product. In its ANDS, Apotex excluded the bioavailability results from two subjects in the fed study, taking the position that the reference drug was defective. Health Canada refused to issue an NOC based on the existing submitted data, and Apotex sought judicial review of the Minister's decision. The Court dismissed Apotex's application, finding that the Minister's decision was not unreasonable: the Minister applied the Guidelines in a manner that recognized a possibility of exceptions but was not satisfied,

on reasonable grounds, that an exception should be granted. Apotex has appealed. (*Apotex Inc. v. Canada (Health)*, May 5, 2009. Full judgment – 2009 FC 452.)

Lundbeck loses appeal of decisions striking its judicial review applications relating to EBIXA. Lundbeck had brought an application for judicial review of the Minister's decision to accept ANDSs by ratiopharm and Cobalt for **memantine** (Lundbeck's **EBIXA**). Lundbeck sought to quash this decision on the basis that Lundbeck had only been issued a notice of compliance with conditions (NOC/c). Further, Lundbeck also sought a declaration that EBIXA was an "innovative drug". As reported in the February 2009 issue of *Rx IP Update*, the Motions Judge struck Lundbeck's judicial review application on three grounds: (1) lack of standing; (2) that the applications were premature; and (3) Lundbeck's applications were bereft of any chance of success. Lundbeck appealed unsuccessfully. The Federal Court of Appeal held that the Motions Judge committed no error in concluding that the applications were bereft of any chance of success. In so holding, the Court of Appeal adopted the reasoning set out in the reasons of the Motions Judge on this issue. The Court of Appeal held it was unnecessary to examine the other two grounds on which the applications were also struck. (*Lundbeck Canada Inc. v. Canada (Health)*, April 29, 2009. Court of Appeal decision – 2009 FCA 134. Motions Judge's decision – 2008 FC 1379.)

Court of Appeal affirms decision that a submission is not bound by an Order of prohibition relating to a submission to which it is cross-referenced. sanofi-aventis sought judicial review of a decision of the Minister of Health that permitted Riva to receive an NOC for its ramipril capsules, despite that the fact that its drug submission was cross-referenced to that of Pharmascience in respect of which prohibition Orders precluded issuance of an NOC. The application was dismissed, as was sanofi-aventis's appeal. The Court of Appeal rejected the argument that the ANDS filed by Pharmascience is so linked to the prohibition Order against Pharmascience that the Order necessarily bars an independent generic manufacturer (in this case, Riva) from relying on the Pharmascience ANDS by way of a "cross-reference" submission. The Court of Appeal also rejected the argument that Riva had circumvented the *Regulations*, finding that it was a submission of sufficient substance to engage the *Regulations* so that Riva was required to independently address the patents, which it did successfully. (*sanofi-aventis Canada v. Laboratoire Riva*, May 26, 2009. Court of Appeal decision – 2009 FCA 169. Motions Judge's decision – 2008 FC 1062.)

Trade-mark decisions

PHARMACLIK is not confusing with PHARMACYCLICS. The Opposition Board rejected Pharmacyclics's opposition of McKesson's application for registration of the trade-mark PHARMACLIK. Pharmacyclics opposed the application on the bases that (amongst others) the trade-mark was not inherently distinctive and that it was confusing with Pharmacyclics's trade-mark application for PHARMACYCLICS. The Board held that both marks were inherently distinctive, albeit weakly. The inherent distinctiveness of PHARMACLIK was found to be enhanced because of its considerable use in Canada, in contrast to PHARMACYCLICS, which had been used mostly as a trade name and only in limited circumstances. PHARMACLIK was associated with services that consisted of a transactional Internet site that allows retail and institutional pharmacies to access a catalogue of pharmaceutical and parapharmaceutical products, place and send orders, and use other supply management tools. These services were found to be directed at a specialized clientele (retail and institutional pharmacies) distinct from Pharmacyclics clientele (which included doctors and the general public). All of these factors, combined with evidence that the term "pharma" is extensively used in trade-marks in the pharmaceutical field, led the Board to conclude that there was no likelihood of confusion between the two marks. (*Pharmacyclics Inc. v. McKesson Canada Corporation*, September 11, 2008. Full decision.)

New Court proceedings

Patented Medicines (Notice of Compliance) Regulations

Medicine:	ramipril/hydrochlorothiazide (ALTACE HCT)
Applicant:	sanofi-aventis Canada Inc
Respondents:	Apotex Inc and The Minister of Health
Respondent/Patentee:	Schering Corporation
Date Commenced:	May 8, 2009
Court File No.:	T-748-09
Comment:	Application for Order of prohibition until expiry of Patent No. 1,341,206. Apotex alleges invalidity.

Medicine:	methylphenidate hydrochloride extended release tablets (CONCERTA)
Applicants:	Janssen-Ortho Inc and Alza Corporation
Respondents:	Apotex Inc and The Minister of Health
Date Commenced:	May 14, 2009
Court File No.:	T-775-09
Comment:	Application for Order of prohibition until expiry of Patent No. 2,264,852. Apotex alleges non-infringement, invalidity and ineligibility.

Medicine:	memantine hydrochloride (EBIXA)
Applicants:	Lundbeck Canada Inc, H. Lundbeck A/S and Merz Pharma GmbH & Co KGaA
Respondents:	Apotex Inc and The Minister of Health
Date Commenced:	May 14, 2009
Court File No.:	T-778-09
Comment:	Application for Order of prohibition until expiry of Patents Nos. 2,014,453 and 2,426,492. Apotex alleges invalidity, non-infringement and ineligibility.

Medicine:	rosuvastatin (CRESTOR)
Applicants:	AstraZeneca Canada Inc, AstraZeneca AB and Shionogi Seiyaku Kabushiki Kaisha
Respondents:	Cobalt Pharmaceuticals Inc and The Minister of Health
Date Commenced:	May 14, 2009
Court File No.:	T-780-09
Comment:	Application for Order of prohibition until expiry of Patents Nos. 2,072,945 and 2,313,783. Cobalt alleges non-infringement and invalidity.

Medicine:	candesartan cilexetil tablets (ATACAND)
Applicants:	AstraZeneca Canada Inc and Takeda Pharmaceutical Company Limited
Respondents:	Sandoz Canada Inc and The Minister of Health
Date Commenced:	May 14, 2009
Court File No.:	T-781-09
Comment:	Application for Order of prohibition until expiry of Patent No. 2,083,305. Sandoz alleges non-infringement and ineligibility.

Medicine:	tamsulosin hydrochloride controlled-release tablets (FLOMAX CR)
Applicants:	Boehringer Ingelheim (Canada) Limited and Astellas Pharma Inc
Respondents:	Apotex Inc and The Minister of Health
Date Commenced:	May 22, 2009
Court File No.:	T-821-09
Comment:	Application for Order of prohibition until expiry of Patent No. 2,144,077. Apotex alleges non-infringement and invalidity.

Medicine:	olopatadine 0.1% topical ophthalmic solution (PATANOL)
Applicants:	Alcon Canada Inc, Alcon Research, Ltd and Kyowa Hakko Kirin Co, Ltd
Respondents:	Sandoz Canada Inc and The Minister of Health
Date Commenced:	May 26, 2009
Court File No.:	T-843-09
Comment:	Application for Order of prohibition until expiry of Patent No. 2,195,094. Sandoz alleges invalidity, non-infringement and ineligibility.

Other proceedings

Medicine:	sildenafil (VIAGRA)
Plaintiff:	Apotex Inc
Defendant:	Pfizer Ireland Pharmaceuticals and Pfizer Canada Inc
Date Commenced:	May 13, 2009
Court File No.:	T-772-09
Comment:	Action seeking declaration of invalidity and non-infringement of Patent No. 2,163,446.

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

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