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Rx IP UPDATE

CANADIAN PHARMACEUTICAL INTELLECTUAL PROPERTY LAW NEWSLETTER

May 2010

Supreme Court to hear case relating to jurisdiction of PMPRB over US-based sales

As reported in the January 2010 issue of *Rx IP Update*, the Federal Court of Appeal reversed a decision of the Federal Court that set aside a decision of the Patented Medicine Prices Review Board ("Board"). The Board had ruled that it had jurisdiction over Celgene's sales of **THALOMID (thalidomide)** made pursuant to Health Canada's Special Access Programme ("SAP"). On April 22, 2010, the Supreme Court granted Celgene leave to appeal the Court of Appeal's decision. The parties had agreed previously that common law commercial principles would establish New Jersey as the locus of THALOMID sales as Celgene ships the medicine f.o.b. from its factory there. The majority of the Federal Court of Appeal concluded that the Applications Judge made an interpretive error by viewing the words "sold in any market in Canada," contained in section 80(1)(b) of the *Patent Act*, through the lens of a commercial law dispute rather than the price regulation provisions of the *Patent Act* as protective consumer legislation. The majority agreed with the Board's interpretation of the phrase "sold in any market in Canada" as connoting the existence of a demand for a medicine, which was satisfied when it was purchased by a physician for the treatment of a patient in Canada; i.e., the phrase "in Canada" identifies the location of the market, not of the sale. The dissenting Judge agreed with the decision of the Applications Judge and concluded that the correct interpretation of section 80(1)(b) was that the jurisdiction of the Board was not engaged unless it was established that the medicine in question had been the subject of a sale that took place in Canada. (Supreme Court summary – 33579. Court of Appeal decision – 2009 FCA 378. Trial Judge's decision – 2009 FC 271.)

Patented Medicine Prices Review Board news

Voluntary Compliance Undertakings. The Board recently approved Voluntary Compliance Undertakings (VCUs) for Baxter Corporation's **FSME-IMMUN** (VCU) and GlaxoSmithKline's **PAXIL CR (paroxetine hydrochloride)** (VCU).

Board issues NICODERM decision. On April 9, 2010, the Board issued a decision on the merits regarding Hoechst Marion Roussel's nicotine patch **NICODERM** in which it concluded that NICODERM was not excessively priced. At the time of its first sale in Canada, NICODERM was priced above the only other patented nicotine patch available. However, another unpatented nicotine patch, **NICOTROL**, was sold at a higher price. Board Staff excluded this drug from consideration as it found NICOTROL to be excessively priced itself. The Board found that it could not characterize the price of a non-patented medicine as "excessive" without evidence. As none was presented, NICOTROL was included in the therapeutic class for price comparison. Given that NICOTROL was priced above NICODERM throughout the relevant periods, NICODERM's maximum non-excessive price ought to have been set by reference to the price of NICOTROL with the result being that NICODERM was not sold at excessive prices. (Full decision – PMPRB-99-D10-NICODERM.)

Amendments proposed to Ontario prescription drug system

On April 7, 2010, the Premier of Ontario announced proposed reforms to the prescription drug system, including plans to lower the cost of generic drugs to 25% of the corresponding innovator drugs (from the present 50%) and end "professional allowance" payments from generic drug companies to pharmacies (reported to total $750 million in 2009). The Government is using YouTube and a new website to explain the facts and benefits of the reforms. (Press release on reform (see link to Backgrounder and Fact Sheet). Press release on social media.)

Recent Court decisions

Patented Medicines (Notice of Compliance) Regulations

Pfizer obtains Order of prohibition against Apotex regarding latanoprost. On April 26, 2010, the Federal Court granted Pfizer's application for an Order of prohibition against Apotex regarding **latanoprost** (Pfizer's **XALATAN**). The patent claims latanoprost and the use of latanoprost in the treatment of glaucoma or ocular hypertension "without causing substantial ocular irritation." The Court found that Pfizer had demonstrated that Apotex's invalidity allegation was not justified. Apotex had alleged invalidity on the bases of anticipation, obviousness, lack of utility, lack of sound prediction, overbreadth, double patenting, lack of sufficiency and the Gillette Defence, and had also alleged non-infringement. (*Pfizer Canada Inc. v. Canada (Health)*, April 26, 2010. Full judgment – 2010 FC 447.)

Novopharm unsuccessful in designating notice of allegation as confidential. On April 14, 2010, the Federal Court dismissed Novopharm's motion to designate its notice of allegation ("NOA") confidential in a proceeding regarding **pregabalin** (Pfizer's **LYRICA**). Novopharm had argued that: it made a substantial investment in the production of the NOA; there was no public benefit in disclosing the NOA; and, if Novopharm is successful in the proceeding and the NOA is not designated confidential, Novopharm's competitors could use the NOA to springboard into the market at less expense than Novopharm. The Prothonotary found this to be a truly exceptional request. Although she accepted that the NOA required substantial time, effort, resources and money to develop, she also found that the information in the

NOA was not of a confidential nature. In considering the test for confidentiality Orders, she found that Novopharm's market position cannot be characterized as an important commercial interest within the meaning of the test as the commercial interest identified by Novopharm is narrow and personal to Novopharm, namely its first-to-market status and its investment of time and money in the preparation of its NOA. She also found that the deleterious effects of the proposed confidentiality Order outweigh any salutary effects. Finally, she pointed to the likelihood of even greater secrecy surrounding the proceedings if the NOA was designated confidential as any documents referring to the arguments in the NOA may need to be designated confidential or be redacted as a result and any hearings in the proceeding may need to be conducted *in camera*. Novopharm has appealed. (*Pfizer Canada Inc. v. Novopharm Limited*, April 14, 2010. Full judgment – 2010 FC 409.)

Prothonotary orders partial reversal of order of evidence. AstraZeneca's motion for a reversal of the order of evidence was granted in a proceeding related to **esomeprazole magnesium** (AstraZeneca's **NEXIUM**). A similar motion was denied in a prior proceeding related to the same drug between Apotex and AstraZeneca (reported in the November and December 2008 editions of *Rx IP Update*). In the latest case, the Prothonotary pointed to the volume and complexity of the proceeding and the lack of prior litigation between the parties on the drug as factors weighing in favour of a reversal. She also noted that the NOA in this proceeding raises and reprises all of the invalidity allegations in the prior proceeding and that Mylan has the benefit of access to the evidence from that proceeding. Overall, she found that granting the order for reversal would likely lead to the just, most expeditious and least expensive determination of the application. (*AstraZeneca Canada v. Mylan Pharmaceuticals ULC*, April 20, 2010. Full judgment.)

Federal Court of Appeal upholds decision refusing to strike affidavit. On April 21, 2010, the Federal Court of Appeal dismissed AstraZeneca's appeal of a Motions Judge's decision to uphold a Prothonotary's decision refusing to strike portions of Apotex's evidence in a proceeding regarding **esomeprazole magnesium** (AstraZeneca's **NEXIUM**). AstraZeneca argued that, in removing one of two suppliers from its abbreviated new drug submission (ANDS), Apotex was making an impermissible change to the factual basis for its NOAs, thereby depriving AstraZeneca of the right to make an informed decision about initiating a prohibition proceeding under the *Patented Medicines (Notice of Compliance) Regulations* ("*Regulations*"). The Court accepted the Judge's holding that the ANDS listed the suppliers as alternatives and not joint suppliers, and therefore, by removing one supplier, Apotex was not materially altering the NOAs but was merely narrowing them. (*AstraZeneca Canada Inc. v. Apotex Inc.*, April 21, 2010. Court of Appeal decision – 2010 FCA 111. Motions Judge's decision – 2010 FC 65. Prothonotary's decision.)

Other decisions

Federal Court upholds denial of issuance of Letters of Request. As reported in the March 2010 issue of *Rx IP Update*, a Prothonotary denied Apotex's motion for issuance of Letters of Request for the examination for discovery of named inventors resident in Sweden. This decision was upheld on appeal. The Judge found that the Prothonotary applied the correct test for issuance of Letters of Request and properly weighed the evidence of the parties. (*Apotex Inc. v. AstraZeneca Canada Inc. et al*, April 19, 2010. Order – T-2300-05.)

Federal Court of Appeal upholds striking of AstraZeneca's CRESTOR patent infringement action against Novopharm. As reported in the January 2010 edition of *Rx IP Update*, the Federal Court struck out AstraZeneca's Statement of Claim in a patent infringement action against Novopharm concerning **rosuvastatin calcium** (AstraZeneca's **CRESTOR**) without prejudice to the plaintiffs to file a new action. The action had been commenced before determination of a pending application under the *Regulations*. The Court of Appeal upheld the lower Court's decision. Regarding the allegation of current infringement — that Novopharm was currently making or having made for it commercial quantities of the infringing product — the Court pointed to a lack of any evidentiary foundation for the allegation. Regarding future infringement, the Court found that a quia timet action must be based on more than mere possibilities. Finally,

the Court found that the appellant's argument that Novopharm's NOA was in itself an act of infringement raised a novel act of infringement that would need to be specifically pleaded before being addressed and that no such allegation was made in the Statement of Claim. (*AstraZeneca Canada v. Novopharm Limited*, April 22, 2010. Court of Appeal decision – 2010 FCA 112. Motion Judge's decision – 2009 FC 1209.)

Federal Court dismisses Hospira's application for judicial review of rejection of new drug submission. The Federal Court has rejected Hospira's application for judicial review of the Minister of Health's rejection of its new drug submission (NDS) for an unidentified drug on the grounds that it does not comply with the *Food and Drug Regulations*, pointing to the lack of pre-clinical and clinical data. Hospira argued that the *Food and Drug Regulations* do not require data from pre-clinical and clinical trials; the plain words of the *Food and Drug Regulations* give the Minister a considerable degree of flexibility regarding what the Minister can accept as evidence of a new drug's safety and effectiveness, and this grant of discretionary flexibility was improperly fettered by Health Canada's policy of requiring pre-clinical and clinical data. The Court reviewed the decision on a standard of reasonableness and found that the Minister's view that the *Food and Drug Regulations* require pre-clinical and clinical data to be submitted with an NDS was reasonable. The Court went on to find that, even if the Minister's interpretation was unreasonable, the *Food and Drug Regulations* at least allow the Minister the discretion to request that clinical data be provided with an NDS and that the particular circumstance of the applicant was considered extensively before the Minister finally decided that it would apply its policy to require clinical data. Hospira has appealed. (*Hospira Healthcare Corporation v. Canada (Attorney General)*, February 25, 2010. Full decision – 2010 FC 213.)

New Court proceedings

Patented Medicines (Notice of Compliance) Regulations

Medicine:	methylphenidate hydrochloride (CONCERTA)
Applicants:	Janssen-Ortho Inc and Alza Corporation
Respondents:	Pharmascience Inc and The Minister of Health
Date Commenced:	March 23, 2010
Court File No.:	T-428-10
Comment:	Application for Order of prohibition until expiry of Patent No. 2,264,852. Pharmascience alleges non-infringement, invalidity and ineligibility.

Medicine:	brimonidine tartrate/timolol maleate (COMBIGAN)
Applicants:	Allergan Inc and Allergan, Inc
Respondents:	Sandoz Canada and The Minister of Health
Date Commenced:	March 31, 2010
Court File No.:	T-487-10
Comment:	Application for Order of prohibition until expiry of Patent No. 2,357,014. Sandoz alleges non-infringement and invalidity.

Medicine:	rosuvastatin calcium (CRESTOR)
Applicants:	AstraZeneca Canada Inc, AstraZeneca AB and Shionogi Seiyaku Kabushiki Kaisha
Respondents:	Pharmascience Inc and The Minister of Health
Date Commenced:	April 7, 2010
Court File No.:	T-528-10
Comment:	Application for Order of prohibition until expiry of Patents Nos. 2,072,945 and 2,313,783. Pharmascience alleges non-infringement and invalidity with respect to both patents.

Medicine:	repaglinide (GLUCONORM)
Applicants:	Alcon Canada Inc, Alcon Research, Ltd, and Kyowa Hakko Kirin Co, Ltd
Respondents:	Apotex Canada Inc and The Minister of Health
Date Commenced:	April 14, 2010
Court File No.:	T-564-10
Comment:	Application for Order of prohibition until expiry of Patent No. 2,195,094. Apotex alleges non-infringement and invalidity.

Other proceedings

Medicine:	raloxifene hydrochloride (EVISTA, APO-RALOXIFENE)
Plaintiffs:	Eli Lilly Canada Inc, Eli Lilly and Company, Eli Lilly SA and Lilly, SA
Defendant:	Apotex Inc
Date Commenced:	April 6, 2010
Court File No.:	T-512-10
Comment:	Action for infringement of Patent No. 2,250,191.

Medicine:	raloxifene hydrochloride (EVISTA, APO-RALOXIFENE, NOVO-RALOXIFENE, TEVA-RALOXIFENE)
Plaintiffs:	Eli Lilly and Company, Eli Lilly Canada Inc, Eli Lilly SA and Lilly, SS
Defendants:	Apotex Inc and Teva Canada Limited
Date Commenced:	April 6, 2010
Court File No.:	T-516-10
Comment:	Action for infringement of Patents Nos. 2,101,356 and 2,158,400.

Medicine:	tramadol hydrochloride/acetaminophen (TRAMACET, APO-TRAMADOL-ACET)
Plaintiffs:	Ortho-McNeil-Janssen Pharmaceuticals, Inc, Janssen-Ortho Inc, Janssen-Cilag SPA and Cilag GmbH
Defendant:	Apotex Inc
Date Commenced:	April 7, 2010
Court File No.:	T-527-10
Comment:	Action for infringement of Patent No. 2,095,523.

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

SMART & BIGGAR
FETHERSTONHAUGH

Barristers & Solicitors • Patent & Trade-mark Agents

OTTAWA
55 Metcalfe Street Suite 900
PO Box 2999 Station D
Ottawa ON K1P 5Y6
Canada
t. 613.232.2486
f. 613.232.8440
ottawa@smart-biggar.ca

TORONTO
Box 111 Suite 1500
438 University Avenue
Toronto ON M5G 2K8
Canada
t. 416.593.5514
f. 416.591.1690
toronto@smart-biggar.ca

MONTREAL
Suite 3300
1000 De La Gauchetière Street West
Montreal QC H3B 4W5
Canada
t. 514.954.1500
f. 514.954.1396
montreal@smart-biggar.ca

VANCOUVER
Box 11560 Vancouver Centre
2200-650 West Georgia Street
Vancouver BC V6B 4N8
Canada
t. 604.682.7780
f. 604.682.0274
vancouver@smart-biggar.ca

smart-biggar.ca

Pharmaceutical Practice Group

John R. Morrissey, B.Eng. (Elec.Eng.), S.M., LL.B.
Joy D. Morrow, B.Sc., M.Sc. (Cell Bio.), LL.B.
Keltie R. Sim, B.Sc. (Mycology), LL.B.
Solomon M.W. Gold, B.Sc., M.Sc. (Bio.), LL.B.
J. Sheldon Hamilton, B.A.Sc. (Chem.Eng.), LL.B.
Brian G. Kingwell, B.Sc. (Biochem.), M.Sc. (Mol. Cell Bio.), LL.B.
Nancy P. Pei, B.Sc.Phm., LL.B.
Thuy H. Nguyen, B.Sc., Ph.D. (Biochem.)
Colin B. Ingram, B.A.Sc. (Elec.Eng.), LL.B.
Sally A. Hemming, B.Sc., Ph.D. (Biochem.), J.D.
Christian Bérubé, B.Sc. (Chem.), M.Sc. (Inorganic Chem.)
Daniel M. Anthony, B.Sc. (Cell Bio. & Genetics), J.D.
Andrew Mandlsohn, B.Sc. (Pharm.), J.D.
Vik Tenekjian, B.Sc. (Microbio./Immun.), J.D.
Ivan C. Fong, B.Sc. (Microbio./Immunology), Ph.D. (Mol. Bio.), LL.B.
Urszula Wojtyra, B.Sc. (Applied Biochem.), M.Sc. (Biochem.), J.D.
John Bochnovic, B.Eng. (Elec.Eng.), S.M., LL.B.
Gunars A. Gaikis, B.Sc.Phm., LL.B.
J. Christopher Robinson, B.Sc., M.Sc. (Genetics), LL.B.
Steven B. Garland, B.Eng. (Chem.-Biochem.Eng.), LL.B.
David E. Schwartz, B.Sc. (Genetics), LL.B.
Yoon Kang, B.Sc., M.Sc. (Molec.Bio. & Genetics), LL.B.
Mark G. Biernacki, B.A.Sc. (Mech. Eng.), LL.B.
Jeremy E. Want, B.Sc. (Chem.), LL.B.
Daphne C. Lainson, B.Sc., M.Sc. (Chem.), LL.B.
James Jun Pan, B.Eng. (Eng.Phys.), Ph.D. (Chem.), LL.B.
Y. Lynn Ing, B.Sc. (Biochem.), Ph.D. (Molec.Bio.), J.D.
Junyi Chen, B.A. (Chem.), M.Sc. (Chem.), Ph.D. (Chem.), J.D.
Timothy O. Stevenson, B.Sc. (Biochem.), LL.B.
Elizabeth A. Hayes, B.Sc. (Biochem.), M.Eng. (Biomed. Eng.)
David J. Suchon, B.Sc. (Biochem.), LL.B.
Tracey L. Stott, B.Sc. (Chem.), Ph.D. (Chem.), LL.B.

Contact Information

For more information, or to request a copy of any decision, pleading or legislation, please contact:

Gunars A. Gaikis
ggaikis@smart-biggar.ca

J. Sheldon Hamilton
jshamilton@smart-biggar.ca

Yoon Kang
ykang@smart-biggar.ca

Nancy P. Pei (Editor)
nppei@smart-biggar.ca

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