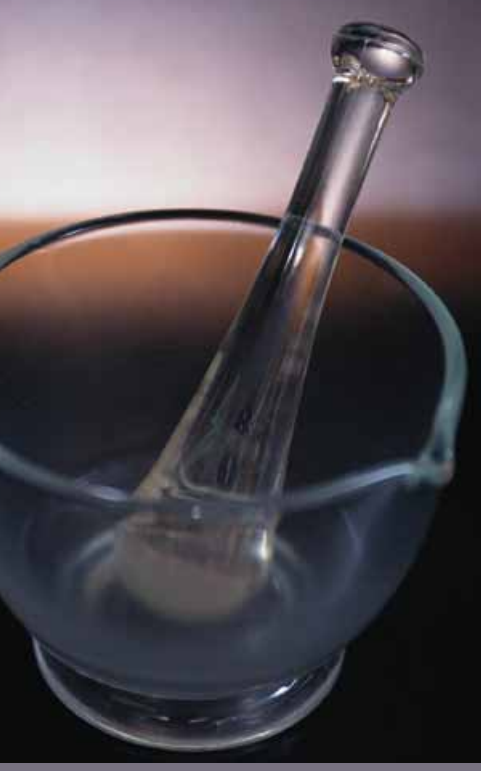

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Rx IP UPDATE

CANADIAN PHARMACEUTICAL INTELLECTUAL PROPERTY LAW NEWSLETTER

January 2010

Pfizer obtains Order of prohibition against Pharmascience regarding latanoprost

On December 18, 2009, the Federal Court granted Pfizer's application for an Order of prohibition against Pharmascience 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 Pharmascience's invalidity allegation was not justified. Pharmascience had alleged invalidity on the bases of anticipation, obviousness, insufficiency, lack of utility/lack of sound prediction, overbreadth and also asserted the Gillette Defence. (*Pfizer Canada Inc. v. Pharmascience Inc.*, December 18, 2009. Full judgment – 2009 FC 1294.)

Canadian Agency for Drugs and Technologies in Health (CADTH) initiates pilot project

The Canadian Agency for Drugs and Technologies in Health announced a pilot project on December 7, 2009, to conduct concurrent therapeutic reviews of drugs, drug classes or categories undergoing Common Drug Review. The most recent public evidence available for the drug, drug class or category will be reviewed. More details of the project will be available in the near future. (CADTH news release.)

Trade-mark decisions

Board finds VIAGRA tablets lack distinctiveness. Pfizer filed applications to register trade-marks for 25, 50, and 100 mg tablets of VIAGRA. The design consisted of a blue, diamond-shaped tablet. Novopharm and Apotex opposed based on non-compliance with section 30 of the *Trade-marks Act*, non-registrability and non-distinctiveness. The applications were heard at the same time. The Board rejected both applications on the ground of lack of distinctiveness. Specifically, the Board found that Pfizer had not, as of the relevant dates, established that pharmacists, patients or doctors associated the mark with a single source, or that patients or doctors used the mark in requesting or prescribing VIAGRA. (Full decision for 100 mg tablets; full decision for 25 and 50 mg tablets.)

Recent Court decisions

Patented Medicines (Notice of Compliance) Regulations

Federal Court refuses to have section 8 actions in respect of ramipril heard together but orders actions to be heard consecutively by same Judge. On December 8, 2009, the Federal Court dismissed sanofi-aventis's motion, supported by Apotex, for a joint hearing of three section 8 actions brought by Novopharm (T-1161-07), Riva (T-1201-08) and Apotex (T-1357-09) regarding **ramipril** (sanofi-aventis's **ALTACE**). In particular, the Motions Judge found that the records will be significantly different in each action and, more significantly, neither sanofi-aventis nor Apotex had discharged the two-pronged onus that (a) they would be prejudiced by the continuation of separate trials and (b) Novopharm and Riva would not suffer prejudice should the consolidation occur. To address the concern of sanofi-aventis and Apotex regarding the possibility of inconsistent findings in the three cases, the Motions Judge ordered the three actions to be heard consecutively by a single Judge and to be case managed by the same case management Prothonotary or Judge. (*sanofi-aventis Canada Inc. v. Novopharm Limited*, December 17, 2009. Full judgment – 2009 FC 1285.)

Other decisions

Federal Court strikes AstraZeneca's CRESTOR patent infringement action against Novopharm. On November 24, 2009, 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 *Patented Medicines (Notice of Compliance) Regulations*. AstraZeneca has appealed. (*AstraZeneca Canada v. Novopharm Limited*, November 24, 2009. Full judgment – 2009 FC 1209.)

Federal Court affirms refusal by the Commissioner of Patents to grant a patent to Bayer. Bayer obtained a patent claiming a process for a particular compound as well as a compound produced by a particular process ("parent patent") pursuant to the pre-October 1989 *Patent Act*. While the application at issue was pending, the *Act* was amended to remove the restriction on product claims for medicines. Thereafter, Bayer asserted claims to the medicine in non-process-dependent form in a divisional application. The Commissioner rejected the claims on a number of grounds but particularly on the ground of obviousness double patenting, and Bayer appealed. The Applications Judge dismissed Bayer's application. Bayer submitted that, on the basis of jurisprudence, double patenting has no application when comparing a product claim with an earlier product-by-process claim and that the rejection of these claims must therefore be reversed on this basis alone. The Court held that the standard of review was such that the Commissioner's conclusion would not be reversed in the absence of palpable and overriding error. The Court found that there was no material difference between the compound described in the non-process-

dependent claim of the application at issue and the compound described in the process-dependent claim of the parent patent and, as such, the requirement of inventive ingenuity was not met. (*Bayer Schering Pharma Aktiengesellschaft v. Canada (Attorney General)*, December 8, 2009. Full judgment – 2009 FC 1249.)

Federal Court of Appeal reverses lower Court's decision regarding PMPRB's jurisdiction over U.S-based sales. On December 23, 2009, in a 2:1 decision, the Federal Court of Appeal reversed a decision of the Federal Court (2009 FC 271, reported in the April 2009 edition of *Rx IP Update*), setting aside a decision of the Patented Medicine Prices Review Board ("Board"). The Board held that it had jurisdiction over Celgene's sales of **THALOMID** (**thalidomide**) made pursuant to Health Canada's Special Access Programme ("SAP") since 1995. The parties agreed that common law commercial principles would establish New Jersey as the locus of THALOMID sales (Celgene shipped the medicine f.o.b. from its factory in New Jersey). The majority of the Court 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 through the vision of 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; that is, the phrase "in Canada" identified 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. (*Attorney General of Canada v. Celgene Corporation*, December 23, 2009. Full judgment – 2009 FCA 378.)

New Court proceedings

Other decisions

Medicine:	tramadol hydrochloride/acetaminophen (TRAMACET)
Plaintiffs:	Ortho-McNeil Pharmaceutical, Inc, Janssen-Ortho Inc, Janssen-Cilag S.p.A. and Cilag GmbH
Defendant:	Apotex Inc
Date Commenced:	December 4, 2009
Court File No.:	T-2039-09
Comment:	Patent infringement action regarding Patent No. 2,095,523.

Medicine:	valacyclovir hydrochloride (VALTREX)
Plaintiffs:	GlaxoSmithKline Inc, The Wellcome Foundation Limited and Glaxo Group Limited
Defendants:	Pharmascience Inc, Laboratoire Riva Inc, Pro Doc Limitée, Dominion Pharmacal, Zymcan Pharmaceuticals Inc and Pharmel Inc
Date Commenced:	December 16, 2009
Court File No.:	T-2101-09
Comment:	Patent infringement action regarding Patent No. 1,340,083.

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

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