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Rx IP UPDATE

CANADIAN PHARMACEUTICAL INTELLECTUAL PROPERTY LAW NEWSLETTER

March 2010

Section 8 claims for first person's profits, unjust enrichment, permanent loss of market share struck

As reported in the February 2010 issue of *Rx IP Update*, the Supreme Court of Canada denied Apotex leave to appeal the Federal Court of Appeal's first decision on the merits relating to section 8 of the *Patented Medicines (Notice of Compliance) Regulations* ("*Regulations*") (**alendronate**, Merck's **FOSAMAX**). The Court of Appeal affirmed the Trial Judge's holding that Apotex is not entitled to compensation by way of disgorgement of Merck's profits. The Court of Appeal also held that Apotex is confined to losses incurred during the section 8 period and is not entitled to claim certain "future losses," i.e., damages Apotex alleged it had suffered beyond the dismissal date of the prohibition proceeding. (*Apotex Inc. v. Merck Frosst Canada Ltd.* Court of Appeal decision – 2009 FCA 187. Federal Court decision – 2008 FC 1185.)

Following release of the Supreme Court's decision, a Judge granted Pfizer Canada's motion to strike two aspects of Apotex's claim in a section 8 action relating to **Apo-Azithromycin** (Pfizer's **ZITHROMAX**): (i) an accounting of profits, and (ii) the alternative claim of disgorgement of Pfizer's revenues realized as a result of delay in issuance to Apotex of its NOC for Apo-Azithromycin tablets. (*Apotex Inc. v. Pfizer Canada Inc.*, January 28, 2010. Order – T-825-06.)

In a separate section 8 action brought by Novopharm relating to **ramipril** (sanofi-aventis's **ALTACE**), a Prothonotary struck paragraphs in Novopharm's claim referring to a "permanent loss of market share," finding they are not relevant to a calculation of damages under section 8 as these damages are restricted to compensation for losses suffered during the operation of the automatic stay under the *Regulations*. The Prothonotary also struck the claim as against the patentee, Schering, but permitted the claim against Sanofi Germany to proceed — despite its argument that it is not a "first person" under the *Regulations* — finding that this issue should be left for determination at trial. Novopharm has appealed. (*sanofi-aventis*

Canada Inc. v. Novopharm Limited, February 12, 2010. Order – 2010 FC 150.)

Similarly, in a section 8 action brought by Apotex also relating to ramipril, the Prothonotary declined to strike Apotex's Statement of Claim as against Sanofi France and Sanofi Germany, finding that contentious issues of statutory interpretation or legal argument are best left to the Trial Judge. (*sanofi-aventis Canada Inc. v. Apotex Inc.*, February 22, 2010. Order – T-1357-09.)

Patented Medicine Prices Review Board news

Voluntary Compliance Undertakings. The Board recently approved Voluntary Compliance Undertakings (VCUs) for Schering-Plough's **CLARITIN (loratadine/pseudoephedrine sulphate)** (Notice) and Fresenius Kabi's **VOLUVEN (hydroxyethyl starch)** (Notice).

New NEWSletter released. The PMPRB has released its January 2010 NEWSletter. (NEWSletter.)

Recent Court decisions

Patented Medicines (Notice of Compliance) Regulations

Motion to maintain confidentiality denied. EpiCept Corporation filed a new drug submission (NDS) and requested that its product be designated an innovative drug. The request was denied, and EpiCept commenced a judicial review proceeding. It then brought a motion under the Federal Courts Rules to maintain the confidentiality of the information in its NDS, including the identity of the company, its employees, the brand name and medicinal ingredient (or variations) in its drug product, and the disease at issue. A previous motion for similar relief, which also included a request that the existence of a judicial review be kept confidential, was dismissed without prejudice to bring a further motion. The Prothonotary denied the further motion with the exception of granting confidentiality to the NDS filed with the Minister. Although EpiCept argued that it would be harmed if the information at issue was made public as its competitors would be given a head start in preparing regulatory submissions, the Prothonotary found that it had failed to identify any interest outweighing the public interest in open and accessible court proceedings. (*EpiCept Corporation v. Canada (Health)*, February 4, 2010. Full judgment – 2010 FC 120.)

Other decisions

Issuance of Letters of Request denied with respect to Sweden and granted conditionally with respect to Japan. Apotex brought a motion for issuance of Letters of Request for examination for discovery of named inventors resident in Sweden and Japan. The Prothonotary denied the request relating to the Swedish inventors but granted the request relating to the Japanese inventors provided that the Letter of Request was revised, including to list the precise questions to be asked. Apotex has appealed. (*Apotex Inc. v. AstraZeneca Canada Inc. et al.*, February 18, 2010. Order – T-2300-05.)

Janssen-Ortho denied Order of prohibition against Novopharm concerning methylphenidate (CONCERTA). On January 18, 2010, the Federal Court dismissed Janssen-Ortho's application for an Order of prohibition against Novopharm regarding **methylphenidate (CONCERTA)**. Justice Zinn concluded that Novopharm's allegation of non-infringement was justified because Novopharm's product does not release methylphenidate from its dosage form in a sustained-ascending dose over time. Janssen-Ortho has appealed. (*Janssen-Ortho Inc. v. Canada (Health)*, January 18, 2010 (public reasons released January 29, 2010). Full judgment – 2010 FC 42.)

New Court proceedings

Patented Medicines (Notice of Compliance) Regulations

Medicine:	esomeprazole magnesium (NEXIUM)
Applicants:	AstraZeneca Canada Inc and AstraZeneca AB
Respondents:	Mylan Pharmaceuticals ULC and The Minister of Health
Respondent/Patentee:	Takeda Pharmaceutical Company Limited
Date Commenced:	January 29, 2010
Court File No.:	T-134-10
Comment:	Application for Order of prohibition until expiry of Patents Nos. 1,338,377, 2,139,653, 2,166,483, 2,166,794, 2,170,647, 2,186,037, 2,290,531, 2,290,963 and 2,346,988. Mylan alleges non-infringement with respect to the '483, '794 and '647 patents and non-infringement and invalidity with respect to the remaining patents.

Medicine:	sildenafil citrate (VIAGRA)
Applicants:	Pfizer Canada Inc, Pfizer Inc, Pfizer Ireland Pharmaceuticals and Pfizer Research and Development Company NV/SA
Respondents:	Mylan Pharmaceuticals ULC and The Minister of Health
Date Commenced:	January 29, 2010
Court File No.:	T-139-10
Comment:	Application for Order of prohibition until expiry of Patents Nos. 2,163,446, 2,277,017, 2,285,733, 2,290,766 and 2,324,324. Mylan alleges non-infringement and invalidity with respect to the '446 patent and alleges non-infringement, invalidity and improper listing with respect to the remaining patents at issue.

Medicine:	topical brimonidine tartrate/timolol maleate solution (COMBIGAN)
Applicants:	Allergan Inc, Allergan Sales Inc and Allergan, Inc
Respondents:	Sandoz Canada Inc and The Minister of Health
Date Commenced:	February 8, 2010
Court File No.:	T-154-10
Comment:	Application for Order of prohibition until expiry of Patents Nos. 2,225,626 and 2,440,764. Sandoz alleges invalidity with respect to both patents and non-infringement with respect to the '626 patent.

Medicine:	candesartan cilexetil HCTZ (ATACAND PLUS)
Applicants:	AstraZeneca Canada Inc and Takeda Pharmaceutical Company Limited
Respondents:	Mylan Pharmaceuticals ULC and The Minister of Health
Date Commenced:	February 25, 2010
Court File No.:	T-268-10
Comment:	Application for Order of prohibition until expiry of Patents Nos. 2,083,305 and 2,215,251. Mylan alleges non-infringement, invalidity and improper listing with respect to both patents.

Other proceedings

Medicine:	fluticasone furoate (AVAMYS)
Applicant:	Canadian Generic Pharmaceutical Association
Respondents:	The Minister of Health and GlaxoSmithKline Inc
Date Commenced:	February 3, 2010
Court File No.:	T-152-10
Comment:	Application for judicial review of the Minister's decision to refuse to remove AVAMYS from the Register of Innovative Drugs. CGPA asserts that fluticasone furoate is ineligible as it is an ester variation of a previously approved medicinal ingredient (fluticasone propionate). The Minister decided that because fluticasone furoate is not an ester of fluticasone propionate but rather an ester of fluticasone, it is not a variation of a previously approved medicinal ingredient; she also determined that approval was not sought primarily on the basis of previously submitted clinical data and concluded that fluticasone furoate was therefore an "innovative drug."

Medicine:	extended release metformin hydrochloride (GLUMETZA)
Plaintiffs:	Biovail Corporation and Depomed, Inc
Defendant:	Apotex Inc
Date Commenced:	February 8, 2010
Court File No.:	T-175-10
Comment:	Patent infringement action regarding Patent No. 2,290,624.

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

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