SMART & BIGGAR | FETHERSTONHAUGH DECEMBER 2006

Rx IP UPDATE

CANADIAN PHARMACEUTICAL INTELLECTUAL PROPERTY LAW NEWSLETTER

Data Protection Rule Challenged

As reported in our October 2006 Special Edition of *Rx IP Update*, the data protection provision of the *Food and Drug Regulations* was substantially amended on October 5, 2006. Two separate proceedings have recently been commenced, challenging the new provision. In the first, commenced on November 14, 2006, the Canadian Generic Pharmaceutical Association (CGPA), an industry association representing most generic drug manufacturers in Canada, seeks a declaration that the provision is unlawful and without legal force and effect, arguing that it is beyond the Governor in Council's power to make regulations under the *Food and Drugs Act*. In the second, commenced on November 22, 2006, Apotex seek a declaration that both the data protection provision and the enabling provision under the *Food and Drugs Act* are without legal force or effect. Apotex's attacks include one based on division of powers, namely that as the data protection provision is designed to protect the unfair commercial use of trade secrets and undisclosed data, it is beyond federal legislative authority.

Notice of Application (*Canadian Generic Pharmaceutical Association v. The Governor in Council, The Minister of Health and The Attorney General of Canada*)

Notice of Application (*Apotex Inc. v. The Governor in Council, The Minister of Health and The Attorney General of Canada*)

Erratum to Linkage Regulations Published

As reported in our October 2006 Special Edition of *Rx IP Update*, sweeping amendments to the *Patented Medicines (Notice of Compliance) Regulations* ("*Regulations*") came into force on October 5, 2006. The Government published erratum, correcting typographical errors, on November 18, 2006.

Erratum

Amendments Regulations Amending the Patented Medicines (Notice of Compliance) Regulations (HTML) (Bilingual PDF/official)

Timely Filings Under Linkage Regulations Critical

As previously reported, timing requirements for patent listing remain under the "new" *Regulations* but in relation to the specific submission in connection with which the patent is submitted. Given the strict "relevance" requirement between the patent and submission, if the deadline for the first listing opportunity is missed, there may be no further listing opportunity. It is therefore critical that the timing requirements are met, namely that: if the patent has issued, it be submitted with the relevant regulatory submission (section 4(5)); and if the patent has not issued by the date of the filing of the regulatory submission that it be submitted within 30 days after patent issuance (section 4(6)). However, the latter listing opportunity only exists if the regulatory submission is filed after the patent application is filed in Canada (section 4(6)). It is therefore important that before filing any regulatory submission, sponsors consider whether all relevant patent applications have been filed in Canada, even if this is well before the expiry of the priority deadline.

Recent "Use" Cases Under Linkage Regulations

In a November 2, 2006 decision, the Court of Appeal declined to grant an Order of prohibition for a "use" patent under the *Regulations* (*Sanofi-Aventis v. Apotex and Minister of Health* (regarding **ramipril,** Sanofi-Aventis' **ALTACE**), 2006 FCA 357, affirming 2005 FC 1461). The issue was whether Apotex would infringe the patent by mere sale of its drug product, where it was conceded that infringement by patients would occur. The Court of Appeal found that the issue raised in the appeal was squarely addressed and dealt with in *Pharmascience v. Sanofi-Aventis*, 2006 FCA 229 (reported in our July 2006 issue of *Rx IP Update*). The Court added that mere sale by Apotex of its Apo-ramipril for the treatment of hypertension, for which use a notice of compliance (NOC) will be issued, does not constitute infringement, and that "something more" than sale – conduct that would make Apotex liable in an action for infringement, including procuring or inducing others to infringe – was required to constitute indirect infringement.

In a subsequent decision, a Judge granted an Order of prohibition relating to a "use" patent (*Abbott v. Novopharm,* 2006 FC 1411 (**lansoprazole** (Abbott's **PREVACID**)). The Judge found that Novopharm's allegation of non-infringement was not justified given the nature of Novopharm's proposed product monograph and labelling for Novo-Lansoprazole, and on the strength of evidence of likely infringement given by Abbott's affiants relating to what will most probably happen under the Ontario Drug Benefit formulary and in the private payer market.

Notably, Novopharm sought to argue that in view of *Apotex v. AstraZeneca,* 2006 SCC 49 (see our November 2006 issue of *Rx IP Update*), the question to be decided was whether Novopharm took advantage of the early-working exception with respect to the patent in submitting its abbreviated new drug submission (ANDS). The Judge disregarded this submission, as the argument had not been raised in Novopharm's notice of allegation (NOA).

Both cases were decided under the "old" *Regulations*. As previously reported, the test for assessing an allegation of non-infringement under the recent amendments may be different.

Apotex Brings Section 8 Damages Claim in Ontario Superior Court

Section 8 permits recovery of losses suffered by a generic if an application for a prohibition Order is withdrawn, discontinued, dismissed, or an Order of prohibition is reversed on appeal. To date, approximately 18 actions – 16 by Apotex – have been commenced by generics in the Federal Court. None have proceeded to trial, although a trial date has recently been set in *Apotex v. Bristol-Myers Squibb* (T-485-02) for October 2007, relating to the medicine **pravastatin (PRAVACHOL)**.

Apotex has now brought such an action in the Ontario Superior Court against Laboratoires Fournier SA, Solvay SA and Solvay Pharma Inc. relating to the medicine **fenofibrate (LIPIDIL SUPRA)**. Although the Solvay defendants were not parties to the prohibition proceedings, Apotex is suing them on the basis of a "co-promotion agreement" between Fournier and Solvay Pharma, and that Fournier was acquired by Solvay in 2005. On November 10, 2006, a motion was brought by the Solvay defendants and the Judge struck the following causes of action from Apotex's claim: (i) oppression under the federal and provincial business corporations legislation (with leave to amend given the posibility that Apotex was oppressed by the institution of the second prohibition proceeding at which time, arguably, it was a future or potential creditor because of the improper institution of the first prohibition proceeding), (ii) misrepresentation under section 52 of the *Competition Act*, and (iii) the joinder of the Solvay defendants as necessary parties in the proceeding. However, the Judge refused to strike the section 8 damages claim against the Solvay defendants, noting that it is not plain and obvious that the "joint liability under s. 8" cause of action has no chance of success. The Judge also refused to strike out Apotex's civil conspiracy claim both at common law and under section 45 of the *Competition Act*.

Full Judgment (2006 ONSC 16590)

Government Seeking Submissions on CAMR Consultation Paper

Canada's Access to Medicines Regime (CAMR) came into force on May 14, 2005 and allows the grant of compulsory licences allowing the manufacture and export of lower cost versions of patented pharmaceutical products to developing and least-developed countries. To date, there have been no exports under the CAMR. The *Patent Act* requires the Minister of Industry to review the relevant provisions by May 2007. To initiate that process, the Government has released a discussion paper and is accepting submissions until January 24, 2007. A report summarizing the submissions, identifying specific features of CAMR believed to be problematic and proposing possible legislative or regulatory alternatives, will be posted on the CAMR website and tabled in Parliament.

CAMR Homepage

Consultation Paper

Recent Court Decisions

Patented Medicines (Notice of Compliance) Regulations

GlaxoSmithKline v. Canada (Attorney General) (**salmeterol xinafoate/fluticasone propionate (ADVAIR, ADVAIR DISKUS), fluticasone propionate (FLOVENT HFA), salbutamol sulphate (VENTOLIN HFA)**), October 27, 2006

In a decision rendered under the patent listing requirements of the "old" *Regulations*, Court of Appeal agrees with an Applications Judge that GlaxoSmithKline's patent is not eligible for listing on the Patent Register. The patent includes a claim for "a pharmaceutical formulation comprising an aerosol suspension of a medicine selected from the group consisting of salbutamol…, in a propellant, said formulation further comprising an aerosol container comprising a valve for administering the aerosol suspension, said valve comprising…". Court finds that the patent "would fall unequivocally on the delivery system side of the [payload/delivery] dichotomy, even though specific drugs are named in the patent as the payload" and that the patent does not as a whole claim a combination of substances (such as a medicine and an excipient) since "substance" is not broad enough to include a mechanical device.

Court of Appeal Decision (2006 FCA 347)

Applications Judge's Decision (2005 FC 1444)

Other Decisions

Novartis AG v. Apotex (**terbinafine (LAMISIL, APO-TERBINAFINE)**), October 25, 2006

Judge dismisses Apotex's appeal from a Prothonotary's decision refusing to strike Novartis statement of claim in a patent infringement action against Apotex.

Full Judgment (2006 FC 1277)

Merck v. Nu-Pharm, Sherman and Benyak (**enalapril maleate (VASOTEC)**), November 7, 2006

Judge dismisses Dr. Sherman's appeal from a Prothonotary's decision requiring Dr. Sherman to comply with a production Order. The Judge found that the Prothonotary did not err in concluding that Brantford Chemicals Inc. was included in the "Apotex group of companies" or in classifying Merck's production requests.

Full Judgment (2006 FC 853)

Brantford Chemicals (now Apotex Pharmachem) v. Commissioner of Patents, Attorney General of Canada and Merck (**sodium enalapril-sodium iodide, sodium enalapril**), November 7, 2006

Judge dismisses Brantford's appeal from a decision of the Commissioner of Patents to refuse Brantford's application for a compulsory license from Merck under the "abuse provision" of the *Patent Act*. The Judge held that Commissioner had not erred in determining that patent abuse had not been established. It was reasonably open to the Commissioner to find on the evidence that there was no genuine market demand for SESIC or an existing market demand for SE-based medicines. It was also reasonable to find that not enough time had been afforded Merck to respond to Brantford's request for a licence such that Merck's silence could not be construed as a refusal.

Full Judgment (2006 FC 1341)

New Court Proceedings

Patented Medicines (Notice of Compliance) Regulations

Medicine: **lansoprazole (PREVACID)**
Applicants: Abbott Laboratories Limited and Tap Pharmaceuticals Inc
Respondents: The Minister of Health, Apotex Inc and Takeda Pharmaceutical Company Limited
Date Commenced: November 9, 2006
Court File No: T-1953-06
Comment: Application for Order of prohibition until expiry of Takeda's Patent No. 2,269,053. Apotex alleges non-infringement, invalidity, the patent is not properly listed on the Patent Register, and that the statement pursuant to s. 4(2)(c) is false.

Medicine: **piperacillin sodium/tazobactam sodium powder for reconstitution (TAZOCIN)**
Applicant: Wyeth Canada
Respondents: Apotex Inc and The Minister of Health
Respondent/Patentee: Taiho Pharmaceutical Co Ltd
Date Commenced: November 9, 2006
Court File No: T-1956-06
Comment: Application for Order of prohibition until expiry of Patent No. 2,145,078. Apotex alleges non-infringement.

Medicine: **perindopril (COVERSYL)**
Applicants: Servier Canada Inc and Adir
Respondents: Minister of Health and Apotex Inc
Date Commenced: November 10, 2006
Court File No: T-1971-06
Comment: Application for a declaration that the *Regulations* apply to a pending ANDS filed by Apotex.

Medicine: **atorvastatin (LIPITOR)**
Applicants: Pfizer Canada Inc and Warner-Lambert Company LLC
Respondents: The Minister of Health and Apotex Inc
Date Commenced: November 16, 2006
Court File No: T-1995-06
Comment: Application for Order of prohibition until expiry of Patents Nos. 2,521,958 and 2,521,980. Apotex alleges non-infringement.

Medicine: **quinapril (ACCUPRIL)**
Applicants: Pfizer Canada Inc, Warner-Lambert Company LLC and Parke, Davis & Company LLC
Respondents: The Minister of Health and Apotex Inc
Date Commenced: November 16, 2006
Court File No: T-1996-06
Comment: Application for Order of prohibition until expiry of Patents Nos. 1,300,510, 1,297,023 and 1,297,024. Apotex alleges non-infringement.

Medicine: **quinapril (ACCUPRIL)**
Applicants: Pfizer Canada Inc, Warner-Lambert Company LLC and Parke, Davis & Company LLC
Respondents: The Minister of Health and Apotex Inc
Date Commenced: November 16, 2006
Court File No: T-2000-06
Comment: Application for Order of prohibition until expiry of Patents Nos. 1,331,615 and 1,291,999. Apotex alleges non-infringement.

Medicine: **quinapril (ACCUPRIL)**
Applicant: Pfizer Canada Inc
Respondents: The Minister of Health and Apotex Inc
Respondent/Patentee: Sanofi-Aventis Deutschland GmbH
Date Commenced: November 16, 2006
Court File No: T-2001-06
Comment: Application for Order of prohibition until expiry of Patent No. 2,023,089. Apotex alleges non-infringement.

Medicine: **lansoprazole (PREVACID)**
Applicant: Abbott Laboratories Limited, Tap Pharmaceuticals Inc, and Tap Pharmaceutical Products Inc
Respondents: Attorney General of Canada and The Minister of Health
Date Commenced: November 16, 2006
Court File No: T-2011-06
Comment: Application for a declaration that Patent No. 2,338,792 is eligible for listing on the Patent Register. The Minister concluded that the patent was not relevant to the dosage form of PREVACID delayed-release capsules.

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Other Proceedings

Applicant: Canadian Generic Pharmaceutical Association
Respondents: The Governor in Council, The Minister of Health, and The Attorney General of Canada
Date Commenced: November 14, 2006
Court File No: T-1976-06
Comment: Application for a declaration that all or part of the data protection provision of the *Food and Drug Regulations* is unlawful, *ultra vires* and without legal force or effect (see article, above).

Applicant: Apotex Inc
Respondents: The Governor in Council, The Minister of Health, and The Attorney General of Canada
Date Commenced: November 22, 2006
Court File No: T-2047-06
Comment: Application for a declaration that the data protection provision of the *Food and Drug Regulations* and the enabling provision of the *Food and Drugs Act* are *ultra vires* and without legal force or effect (see article, above).

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