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IP UPDATE

CANADIAN PHARMACEUTICAL INTELLECTUAL PROPERTY LAW NEWSLETTER

Federal Court Further Clarifies Thresholds for Patent Listing

The Federal Court was busy in March 2003 making law with respect to threshold requirements regarding the eligibility of patents for listing on the Patent Register under the *Patented Medicines (Notice of Compliance) Regulations*.

The following three decisions are important in providing guidance to pharmaceutical patentees on patent listing criteria. The decisions clarify the type of Supplemental New Drug Submission (SNDS) that may be relevant, the relevant patent application date and the type of patent claims that do not qualify.

On March 7, 2003, in *Janssen-Ortho v. The Minister of Health* (2003 FCT 286), the Trial Division decided that a patent claim covering a transdermal patch was not a claim to the medicine itself under the *Regulations* and hence, could not be listed on the Patent Register.

The patent in *Janssen* had been added to the Patent Register in 1993 in respect of Janssen's DURAGESIC fentanyl transdermal system. The DURAGESIC patches are a combination of the active medicinal ingredient fentanyl and inactive ingredients. The patches consist of several layers, including a drug reservoir, and are designed to administer the drug continuously through the skin into the bloodstream to relieve pain. In 1998, following an audit of the Patent Register, the Minister decided to remove the patent from the Register. The reason cited was that the patent covered a medical device and hence was ineligible pursuant to the Court of Appeal's decision in *Glaxo Group Ltd. v. Novopharm Ltd.* (1999), 87 C.P.R. (3d) 525 (F.C.A.).

In its analysis of *Janssen*, the Court accepted that the definition of "medicine" includes compositions of active and inactive ingredients. However, the Court interpreted *Glaxo* as requiring the active and inactive ingredients to be ingested into the body as a single composition. Since the DURAGESIC patch contains components which cannot be ingested into the body, the Court concluded the patch is not a medicine, just as the inhaler in *Glaxo* was found not to be a medicine.

This decision has been appealed by Janssen-Ortho. It is hoped that this decision will be reversed by the Court of Appeal, since it appears to be highly artificial and of no practical distinction to disqualify some dosage forms from being a "medicine" on the simplistic basis that they are not entirely ingested into the body. It is of interest, and noteworthy, that in *Hoffmann-La Roche v. Nu-Pharm* (1995), 62 C.P.R. (3d) 58, aff'd (1995), 67 C.P.R. (3d) 25, one of the claims found to be eligible for listing claimed a nasal spray and its *container*.

In the second decision, issued March 11, 2003 (*Ferring v. Apotex* (2003 FCT 293)), the Trial Division confirmed that an SNDS for a change of brand name qualifies to support the listing of a patent where there is no existing patent list. This is arguably a departure from the law as suggested by the existing jurisprudence and is of assistance to pharmaceutical patentees.

Ferring filed an SNDS to change the brand name for its desmopressin acetate nasal solution from DDAVP to MINIRIN, with the express purpose of facilitating the listing of a patent on the Register that would not otherwise qualify. On its Form IV, Ferring indicated that the purpose of the form was not to change an existing list but to create an original patent list for desmopressin acetate with the brand name MINIRIN.

The Minister concluded that the patent was not eligible for listing and a Notice of Compliance (NOC) issued to Apotex. Ferring sued the Minister, seeking the listing of the patent and the revocation of the NOC to Apotex.

The Court, in its analysis, concluded that an SNDS is required if a brand name that a company proposes to use is "significantly different" from the brand name given in a drug's New Drug Submission (NDS). The Court also concluded that an SNDS is a submission for an NOC within the meaning of the *Regulations*. The Court furthermore approved of the decision in *Apotex Inc. v. Canada (Minister of Health)* (1999), 87 C.P.R. (3d) 271 (F.C.T.D.), decided prior to the 1998 amendments and relating to the relevance of an SNDS, and specifically distinguished *Bristol Myers Squibb Canada Inc. v. Attorney General of Canada* (2001), 10 C.P.R (4th) 318 (F.C.T.D.) as being limited to the addition of a patent to an "existing" patent list.

Of particular interest is the Court's conclusion that the words "in respect of a drug" found in subsection 4(1) of the *Regulations* mean "in relation to" a drug and hence include NOCs that deal with a drug's brand name and all the other matters listed in subsection C.08.003(2) of the *Food and Drug Regulations*. The Court concluded that subsection 4(6) of the *Regulations*, brought in at the time of the 1998 amendments, simply confirms that subsection 4(4) is the only method available for adding a patent to an existing list. The Court found this interpretation to be consistent with the purpose of the *Regulations* namely, the prevention of patent infringement.

Consequently, this decision is of considerable interest and value to pharmaceutical patentees as it confirms that an SNDS concerning a brand name change can support a patent listing with respect to an *original* patent list. Apotex has appealed this decision.

The third decision, released March 14, 2003, is a decision of the Federal Court of Appeal in respect of three appeals heard at the same time (*Pfizer v. Attorney General of Canada; Schering v. Attorney General of Canada* (2003 FCA 138)). The issue before the Court was whether the term "filing date" in subsection 4(4) of the *Regulations* includes a priority date based on an earlier foreign filing or is confined to the date an application is actually filed in Canada.

Subsection 4(4) provides:

> A first person may, after the date of filing of a submission for a notice of compliance and within 30 days after the issuance of a patent that was issued on the basis of an application that has a filing date that precedes the date of filing of the submission, submit a patent list, or an amendment to an existing patent list, that includes the information referred to in subsection (2). [Emphasis added.]

After considering the words "a filing date," read in their entire context and in their grammatical and ordinary sense, harmoniously with the scheme of the *Patent Act* and the intention of Parliament, the Court indicated it was satisfied that the meaning of "filing date" in subsection 4(4) is clear and unambiguous and is confined to the filing of an application in Canada in conformity with the *Patent Act*.

This decision is highly prejudicial to pharmaceutical patentees, since its effect is to preclude reliance on a priority date to satisfy the Patent Register requirement that a patent application must have a filing date that precedes the filing date of a regulatory submission. The interpretation seems particularly harsh, given that applicants for patents in Canada have historically relied on a foreign priority application and have filed in Canada towards the end of the one-year priority period. The effect of the Court of Appeal's decision is that patent applications should be filed in Canada at the earliest opportunity or at the latest, prior to the filing of a submission for an NOC, in order to avoid potential limitations with respect to the eligibility of patents for listing on the Patent Register under the *Regulations*. If Pfizer and/or Schering wish to appeal this decision further, leave to appeal must be granted by the Supreme Court of Canada.

We will report on the outcome of the *Janssen-Ortho* and *Ferring* appeals in future issues of *Rx IP Update*.

Gunars A. Gaikis

Supreme Court of Canada Leave Applications

AstraZeneca v. Novopharm (**felodipine** (**PLENDIL**)), April 7, 2003

On April 7, 2003, AstraZeneca filed an application seeking leave to appeal from a decision of the Federal Court of Appeal, which dismissed AstraZeneca's appeal of a motions judge's decision. The motions judge had dismissed AstraZeneca's appeal of a decision of the Registrar, allowing Novopharm's opposition to registration of AstraZeneca's application for the trade-mark relating to the appearance (colour and shape) of its felodipine 2.5 mg yellow tablets.

For further information regarding the Court of Appeal decision, please see the lead article in the March 2003 issue of *Rx IP Update*.

Recent Court Decisions

Patented Medicines (Notice of Compliance) Regulations

Biolyse v. Bristol-Myers Squibb (**paclitaxel for injection** (**TAXOL**)), March 19, 2003

Court of Appeal dismisses appeal of applications judge's decision, quashing Biolyse's NOC. Biolyse had submitted an NDS for its paclitaxel, which contained many references to and comparisons with TAXOL, but not for the purpose of establishing bioequivalence. Court of Appeal affirms applications judge's finding that the Minister should have required Biolyse to serve a Notice of Allegation (NOA) on BMS, since subsection 5(1.1) of the *Regulations* applied. Court of Appeal rejects Biolyse's argument that subsection 5(1.1) only applies when subsection 5(1) does not apply but when a second person has still applied for regulatory approval to market a drug by filing an Abbreviated New Drug Submission (ANDS) and has compared its drug with or made reference to the drug of a first person for the purpose of establishing its bioequivalence to the second person's drug on the basis of pharmaceutical and, where relevant, their bioavailability characteristics.

Federal Court of Appeal Decision (2003 FCA 180)
(*For a printer friendly version, please scroll down to the end of the Judgment)

Trial Division Decision (2002 FCT 1205)
(*For a printer friendly version, please scroll down to the end of the Judgment)

Apotex v. Bristol-Myers Squibb (**pravastatin** (**PRAVACHOL**)), April 8, 2003

In an action for damages or profits, and costs under section 8 of the *Regulations*, motions judge dismisses BMS' motion for partial summary judgment with respect to Apotex' claim for profits, but grants motion for partial summary judgment with respect to Apotex' claim for legal expenses incurred with respect to the underlying NOC proceeding. Apotex had consented to a discontinuance of the NOC proceeding on a "without costs basis." BMS has appealed.

Full Judgment (2003 FCT 414)
(*For a printer friendly version, please scroll down to the end of the Judgment)

New Court Proceedings

New NOC Proceedings

Medicine: **buproprion sustained release tablets (WELLBUTRIN SR)**
Applicants: GlaxoSmithKline Inc and The Wellcome Foundation Limited
Respondents: Novopharm Limited and The Minister of Health
Date Commenced: March 31, 2003
Comment: Application for Order of prohibition until expiry of Patents Nos. 1,321,754; 2,142,320 and 2,168,364. Novopharm alleges invalidity and non-infringement with respect to the 754 and 320 patents and non-infringement with respect to the 364 patent.

Medicine: **alendronate sodium (FOSAMAX)**
Applicants: Merck & Co, Inc and Merck Frosst Canada & Co
Respondents: Apotex Inc and The Minister of Health
Date Commenced: April 10, 2003
Comment: Application for Order of prohibition until expiry of Patent No. 2,018,477. Apotex alleges invalidity and non-infringement.

Medicine: **cetirizine hydrochloride (REACTINE)**
Plaintiff: Apotex Inc
Defendant: Pfizer Canada Inc
Date Commenced: April 23, 2003
Comment: Action for damages allegedly suffered by Apotex by reason of commencement of a prohibition proceeding by Pfizer or, in the alternative, an accounting of Pfizer's profits.

Other New Proceedings

Products: **VIREX and VIRALEX (disinfectants)**
Plaintiff: JohnsonDiversey
Defendant: Alda Pharmaceuticals Inc
Date Commenced: March 27, 2003
Comment: Trade-mark infringement action regarding Trade-mark Registration No. 516,698 for the trade-mark VIREX for germicidal detergents, and disinfecting and deodorizing cleaners for use on inanimate surfaces. Alda is alleged to sell a surface spray disinfectant in association with VIRALEX.

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Patented Medicine Prices Review Board (PMPRB) Matters

Medicine: **infliximab (REMICADE)**
Respondent: Schering Canada Inc
Date: March 31, 2003
Comment: PMPRB approves of the terms in Schering's Voluntary Compliance Undertaking relating to pricing of REMICADE.

Order

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