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Rx IP UPDATE

CANADIAN PHARMACEUTICAL INTELLECTUAL PROPERTY LAW NEWSLETTER

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Judge Finds Patents Which Do Not Explicitly Claim the Medicine Ineligible for Listing on the Register

On December 10, 2004, the Federal Court dismissed GlaxoSmithKline's application for an Order requiring the Minister of Health (Minister) to list two patents on the Patent Register in connection with PAXIL CR (paroxetine hydrochloride) (*GlaxoSmithKline v. The Minister of Health* (2004 FC 1725)), finding that the patents were not eligible for listing. The *Patented Medicines (Notice of Compliance) Regulations* require a patent submitted for listing to contain a "claim for the medicine itself" or a "claim for the use of the medicine".

The Judge found:

> "…both the 393 patent and the 479 patent refer to "active substances". There is no mention of paroxetine hydrochloride, the medicine in question. The line of case [sic] referred to above makes it clear that patents which can be registered (i.e. that qualify under s. 4 (2)(b)) must have a claim involving the medicine in question in the patent. One skilled in the art of patent interpretation can properly find (as Dr. McGinity did) that active substances, as referrred to in the 393 patent and the 479 patent, include within their scope paroxetine hydrochloride. However, even one skilled in the art of patent interpretation cannot equate active substance with paroxetine hydrochloride. Yet the provisions of s. 4(2)(b) require that the patent contain a claim for the medicine itself i.e. a claim in the patent for the medicine itself when prepared or produced by the methods or processes of manufacture particularly described and claimed. That is not the case with the 393 patent and the 479 patent."

Curiously, in apparent error, the Judge then found that the patents are process patents, referred to a decision that found that process patents are ineligible for listing, and concluded that the patents were therefore ineligible for listing.

This decision raises an important and novel question as to the scope of patents that are eligible for listing, specifically whether patents with claims that do not make explicit mention of the medicine at issue include a "claim to the medicine itself". As GSK has appealed, this question should be resolved by the Court of Appeal.

Correction

There was an error in the article entitled "Government of Canada Proposes Sweeping Amendments to Linkage Regulations and to Data Protection Provisions" from the December 2004 special edition of *Rx IP Update*: the consultation period for the proposed amendments ends on February 2**4**, 2005, not February 2**5** as originally stated.

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Patented Medicines Prices Review Board (PMPRB) Matters

The PMPRB will hold a public hearing on February 21, 2005, to determine if Leo Pharma is selling or has sold **DOVOBET** (calcipotriol/betamethasone dipropionate) in any market in Canada at a price that is or was excessive and if so, what order, if any, should be made.

Notice of Hearing

On November 16, 2004, the PMBRB accepted a Voluntary Compliance Undertaking from ESP Pharma for **BUSULFEX** (IV busulfan).

VCU Notice

Recent Court Decisions

Patented Medicines (Notice of Compliance) Regulations

Pfizer v. Apotex (**azithromycin (ZITHROMAX)**), November 25, 2004

Court of Appeal dismisses Pfizer's appeal of an Order, dismissing Pfizer's application for an Order of prohibition. Court finds that the Applications Judge did not make a palpable and overriding error in not drawing an adverse inference from Apotex's refusal to produce tablets in its possession, as the Judge was entitled to find that Pfizer did not lack the means to discover the content of Apotex's tablets. The Court also found that it was open to the Judge to conclude that Apotex's notice of allegation was sufficient by stating that its tablets contained "azithromycin itself" and not "crystalline azithromycin dihydrate", even though Apotex did not state that the tablets will contain the monohydrate.

Court of Appeal Decision (2004 FCA 398)

Applications Judge's Decision (2003 FC 1428)

Pfizer v. Rhoxalpharma (**azithromycin (ZITHROMAX)**), December 1, 2004

Judge allows RhoxalPharma's appeal of a Prothonotary's Order which allowed Pfizer to file testing evidence after completion of cross-examinations.

Full Judgment (2004 FC 1685)

Prothonotary's Order and Reasons for Order (2004 FC 1580)

The Minister of Health v. Pfizer (**azithromycin (ZITHROMAX)**), December 1, 2004

Court of Appeal allows Minister's appeal of an Order requiring the Minister to produce to Pfizer confidential information provided to the Minister by a third party manufacturer (Teva) and incorporated by reference into RhoxalPharma's abbreviated new drug submission. Court finds that section 6(7)(a) of the *Regulations* only permits an Order directed at the second person, not at the Minister.

Full Judgment (2004 FCA 402)

Genpharm v. AstraZeneca (**omeprazole (LOSEC)**), December 2, 2004

Court of Appeal dismisses Genpharm's appeal of a prohibition Order.

Reasons for Judgment (2004 FCA 413)

Full Judgment (2003 FC 1443)

Fournier Pharma v. Cipher Pharmaceuticals (**fenofibrate (LIPIDIL SIPRA)**), December 14, 2004

Judge dismisses application for Order of prohibition. Cipher had alleged non-infringement.

Full Judgment (2004 FC 1718)

Other Proceedings

Johnson & Johnson v. Boston Scientific (**stent**), November 30, 2004

Judge grants defendant's motion for summary judgment, dismissing claim for patent infringement and declaring the patents invalid. The applicants had incorrectly paid filing fees based on small entity status, then sought to correct the deficiency by paying the difference in fees between small and large entities. Johnson & Johnson has appealed.

Full Judgment (2004 FC 1672)

Trade-mark Opposition Board Decisions

Boehringer Ingelheim v. Braintree Laboratories (**MIRALAX**), August 6, 2004

Board rejects Boehringer's opposition to MIRALAX for "laxatives". Boehringer had alleged confusion with MIRAPEX for "pharmaceutical preparations for the treatment of central nervous system disorders". Board finds that, while the degree of resemblance between the marks is very high and the parties' wares are of the same general class, it cannot conclude that Boehringer's licensee's use accrued to the benefit of Boehringer as there was no evidence that it had direct or indirect control of the character or quality of the MIRAPEX wares, nor was there evidence of public notice of a licence and therefore concludes that there is not a reasonable likelihood of confusion. Boehringer has appealed.

Full Decision

Genencor International v. Gencor The Genetic Corporation (**GENCOR THE GENETIC CORPORATION & Design** and **GENCOR & Design**), August 31, 2004; *Genencor International v. Gencor The Genetic Corporation* (**GENCOR & Design**), August 31, 2004

Board rejects Genencor's oppositions to three applications, including GENCOR & Design for "products in the field of animal reproduction, namely livestock semen and embryos" and services including "provision of in house and on site laboratory and consulting services namely cryogenic storage". Genencor had alleged confusion with GENENCOR for "full line of enzyme preparations".

Full Decisions

Novopharm v. Eli Lilly (**PROZAC CAPSULE DESIGN (10MG)**), November 9, 2004; *Novopharm v. Eli Lilly* (**PROZAC CAPSULE DESIGN (20MG)**), November 9, 2004

Board rejects Novopharm's opposition to Eli Lilly's application for the trade-mark PROZAC CAPSULE DESIGN (10MG) consisting of the colours pale green and pale grey applied to the whole visible surface of the capsule, for use in association with a pharmaceutical preparation, namely, an antidepressant, antiobsessional and antibulimic preparation containing fluoxetine hydrochloride. Board finds that Novopharm failed to discharge its evidential burden with respect to alleged use of other green and grey capsules as of the relevant date. Board refuses Eli Lilly's application for the trade-mark PROZAC CAPSULE DESIGN (20MG) consisting of the colours pale green and whitish yellow applied to the whole visible surface of the capsule, for the same wares, on the basis of non-distinctiveness. Board finds that res judicata does not arise from a passing-off decision.

Decision for 10mg Capsule

Decision for 20mg Capsule

Canadian Medical Association v. Dr. C. Soldan (**DR. C. SOLDAN**), November 22, 2004

Board rejects application for DR. C. SOLDAN for "pharmaceutical drugs and preparations, namely medications for treating colds, flus and congestion" on the basis that "it is reasonable to conclude on a balance of probabilities, the average consumer would as a matter of first impression interpret the mark as indicating that a medical doctor named Dr. C. Soldan stood behind such wares. As the applicant has not proven that Dr. C. Soldan was a medical doctor, the mark is deceptively misdescriptive with respect to [these wares]".

Full Decision

OTTAWA

55 Metcalfe Street, Suite 900
P.O. Box 2999, Station D
Ottawa, Ontario Canada
K1P 5Y6
t. 613.232.2486
f. 613.232.8440

ottawa@smart-biggar.ca

TORONTO

438 University Avenue
Suite 1500, Box 111
Toronto, Ontario Canada
M5G 2K8
t. 416.593.5514
f. 416.591.1690

toronto@smart-biggar.ca

MONTREAL

1000 de La Gauchetière St. W.
Suite 3300
Montreal, Québec Canada
H3B 4W5
t. 514.954.1500
f. 514.954.1396

montreal@smart-biggar.ca

VANCOUVER

650 West Georgia Street
Suite 2200
Box 11560, Vancouver Centre
Vancouver, B.C. Canada
V6B 4N8
t. 604.682.7780
f. 604.682.0274

vancouver@smart-biggar.ca

EDMONTON

10060 Jasper Avenue, Suite 1501
Scotia Place, Tower Two
Edmonton, Alberta Canada
T5J 3R8
t. 780.428.2960
f. 780.423.6975

edmonton@smart-biggar.ca

www.smart-biggar.ca

New Court Proceedings

Patented Medicines (Notice of Compliance) Regulations

Medicine: **sildenafil (VIAGRA)**
Applicants: Pfizer Canada Inc and Pfizer Inc
Respondents: Apotex Inc and The Minister of Health
Date Commenced: December 1, 2004
Comment: Application for Order of prohibition until expiry of Patent No. 2,044,748. Apotex alleges invalidity.

Medicine: **clarithromycin (BIAXIN BID)**
Applicants: Abbott Laboratories and Abbott Laboratories Limited
Respondents: Pharmascience Inc and The Minister of Health
Date Commenced: December 23, 2004
Comment: Application for Order of prohibition until expiry of Patent No. 2,393,614. Pharmascience alleges invalidity.

Other Proceedings

Medicine: **levofloxacin (NOVO-LEVOFLOXACIN, LEVAQUIN)**
Plaintiffs: Janssen-Ortho Inc and Daiichi Pharmaceutical Co Ltd
Defendant: Novopharm Limited
Date Commenced: December 6, 2004
Comment: Patent infringement action relating to Daiichi's Patent No. 1,304,080.

Contact Info

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

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

Pharmaceutical Practice Group

James D. Kokonis, Q.C.
John Bochnovic
Keltie R. Sim
J. Christopher Robinson
J. Sheldon Hamilton
Yoon Kang
Daphne C. Ripley
May Ming Lee
Scott A. Beeser
A. David Morrow
Joy D. Morrow
Michael D. Manson
Solomon M.W. Gold
David E. Schwartz
Nancy P. Pei
Denise L. Lacombe
James Jun Pan
John R. Morrissey
Gunars A. Gaikis
Tokuo Hirama
Steven B. Garland
Brian G. Kingwell
Thuy H. Nguyen
Sally A. Hemming
Kavita Ramamoorthy

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