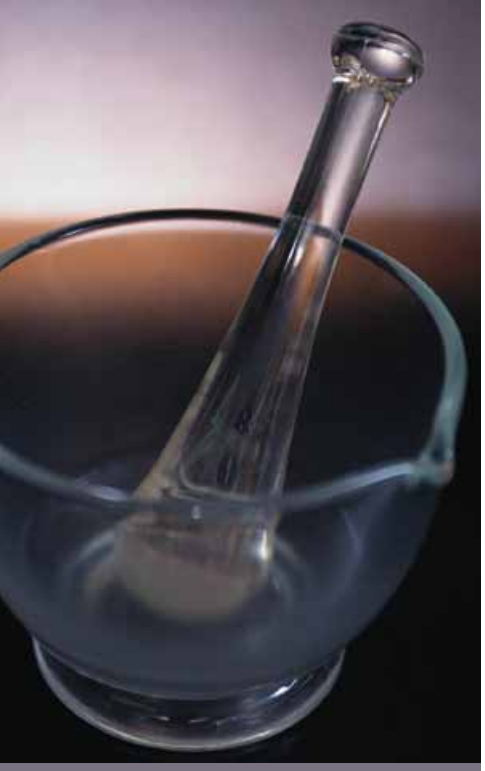

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Rx IP UPDATE

CANADIAN PHARMACEUTICAL INTELLECTUAL PROPERTY LAW NEWSLETTER

December 2009

Federal Court considers good faith requirement in Canadian patent prosecution

On November 23, 2009, the Federal Court publicly released its decision in *Lundbeck v. ratiopharm*, 2009 FC 1102, in which a patent relating to Lundbeck's **EBIXA (memantine hydrochloride)** was considered invalid for failure to respond in good faith to an Examiner's requisition. As a result, the extent of the good faith requirement in Canadian patent prosecution is currently uncertain. For a detailed discussion of this issue, please refer to the Autumn 2009 issue of *IP Perspectives*.

The Court also found the patent invalid on the basis that the synergistic effect of the claimed combination was neither demonstrated nor soundly predicted at the relevant time, although it did not find that the patent was anticipated or obvious. Finally, the Court found the second patent at issue invalid on the grounds of anticipation and obviousness. The Court therefore dismissed Lundbeck's application for a prohibition Order.

PMPRB and other news

New NEWSletter released. The PMPRB has released its October 2009 NEWSletter.

European Medicines Agency releases concept paper. Health Canada has been invited to make submissions to the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency on its paper titled "Concept paper on the development of a guideline on similar biological medicinal products containing monoclonal antibodies," released on October 22, 2009. The deadline for comments is January 31, 2010. (Paper.)

Alberta unveils the second phase of its pharmaceutical strategy. On October 20, 2009, the Government of Alberta announced the implementation of phase two of the Alberta Pharmaceutical Strategy. Phase two includes:

- the reduction of generic drug prices from 75 per cent of the brand name drug price to 45 per cent; this price will be made available to all Albertans;
- product listing agreements between the Government and brand name drug manufacturers, which will reduce costs through volume discounts; and,
- a new pharmacy compensation model, which will not affect the current practice of generic drug rebates.

(News release.)

Canadian Intellectual Property Office news

Patent branch consultation on MOPOP Chapter 9: Description. On November 16, 2009, the Canadian Intellectual Property Office (CIPO) released a draft of a revised Chapter 9 of its *Manual of Patent Office Practice* (MOPOP). The MOPOP is a guide explaining the operational procedures and examination practices of the Canadian Patent Office and does not reflect binding legal authority. Chapter 9 concerns the requirements for the description portion of the specification of a patent application.

The current version of Chapter 9 of the MOPOP, which has been in place since March 1998, focuses largely on matters of form; very limited detail is provided concerning the substantive legal requirements for sufficiency of description.

The proposed revisions expand Chapter 9 substantially, and greater detail is provided concerning CIPO's interpretation of the jurisprudence concerning sufficiency of disclosure of an invention, a requirement that finds its current statutory basis in section 27(3) of the *Patent Act*. Most notably, the matter of establishing utility of the invention, and particularly the issue of "sound prediction" of utility, is addressed at some length. The current Chapter 9 is silent on this topic, which is given separate treatment in other chapters of the MOPOP. Revised Chapter 9 is open for public comment until **December 30, 2009**.

Practice Notice on obviousness, revised MOPOP chapters in effect. On November 2, 2009, a Practice Notice on obviousness became effective. The Notice concerns the practice guidance relied upon by Examiners when considering whether a claimed invention is obvious and refers to the test set out by the Supreme Court in Apotex Inc. v. Sanofi-Synthelabo Canada, Inc., 2008 SCC 61. Also, two revised MOPOP chapters are effective as of December 2009. (Practice Notice. Revised MOPOP chapter on: Subject-Matter and Utility (Chapter 12); Examination of Applications (Chapter 13).)

Recent Court decisions

Patented Medicines (Notice of Compliance) Regulations

Court overturns Prothonotary's decision granting leave to file additional evidence after cross-examinations completed. In an application for an Order of prohibition relating to an extended-release formulation of **methylphenidate HCl** (Janssen-Ortho's **CONCERTA**), Novopharm appealed a Prothonotary's decision granting the applicants leave to file additional evidence after its application record was filed. The evidence consisted of exhibits of two web pages that were broadly referred to in an expert's affidavit. The appeal, heard at the beginning of the hearing on the merits, was allowed. The Hearings Judge held that the applicants knew the two web pages were relevant at the time of filing their initial evidence but had failed to properly tender them in evidence. Allowing the applicants to tender the web pages into evidence after cross-examinations were completed would permit the applicants to split their case — and, in any event, the evidence was hearsay as it was tendered by the law clerk rather than the expert who was relying on it. (*Janssen-Ortho Inc. v. Novopharm Limited*, October 22, 2009. Full judgment – 2009 FC 1179.)

Federal Court refuses to set aside prior successful application on ground of declaration of invalidity. In light of the recent Federal Court decision in *ratiopharm Inc. v. Pfizer Limited* (2009 FC 711, appeal pending) declaring invalid the patent claiming **amlodipine besylate** (Pfizer's **NORVASC**), ratiopharm brought a motion to set aside the prohibition Order previously granted by the Federal Court of Appeal relating to the same patent (*Pfizer Canada Inc. v. Canada (Minister of Health)*, 2006 FCA 214). The Motions Judge dismissed ratiopharm's motion on three grounds: (i) the Federal Court has no jurisdiction to set aside the Order of the Federal Court of Appeal; (ii) the matter is moot; and (iii) the Order of the Federal Court of Appeal is dispositive of the matter, and no Order of dismissal of this application can now be made. (*Pfizer Canada v. ratiopharm Inc.*, November 16, 2009. Full judgment – 2009 FC 1165.)

Federal Court holds that a formulation patent must name all approved medicinal ingredients to be eligible for listing. On November 18, 2009, the Federal Court dismissed Bayer's application for judicial review of a Minister's decision holding that a formulation patent referring to **ethinyl estradiol** was ineligible for listing on the Patent Register against Bayer's new drug submission for **YAZ** containing **drospirenone** and **enthinyl estradiol**. The Judge upheld the Minister's decision that, when the approved formulation contains two medicinal ingredients, the claims must specifically refer to both. (*Bayer Inc. v. Canada (Minister of Health)*, November 17, 2009. Full judgment – 2009 FC 1171.)

Court considers disclaimed patent, finds disclaimer invalid and dismisses application. The Federal Court dismissed an application for an Order of prohibition relating to the drug **docetaxel** (sanofi-aventis's **TAXOTERE**). After service of the notice of application but prior to commencing the application, sanofi-aventis filed a disclaimer with the Patent Office that limited the claims of the patent at issue. The Court declined a decision in line with three recent cases standing for the proposition that the claims of the patent should be considered as they were before the disclaimer was filed (*Bristol-Myers Squibb Canada Co. v. Apotex Inc.*, 2009 FC 137; *Abbott Laboratories v. Sandoz Canada Inc.*, 2009 FC 648; *Janssen-Ortho Inc. v. Apotex Inc.*, 2009 FC 650, aff'd 2009 FC 783). The Court held that it was bound by the Supreme Court of Canada decision in *Merck Frosst Canada Inc. v. Canada (Minister of National Health and Welfare)* [1998] 2 S.C.R. 193, which held that the relevant date for assessing the justification of a notice of application is the date of the hearing. On this basis, the Court held the relevant claims for consideration were the disclaimed claims. However, the Federal Court held the disclaimer invalid, finding that sanofi-aventis had failed to meet its burden of establishing that the disclaimer met the prerequisites of section 46(1) of the *Patent Act*. On this basis, the Court dismissed the application. In the alternative, the Court also considered Hospira's allegations of invalidity and non-infringement in reference to the disclaimed patent and found Hospira's allegation of obviousness justified. (*sanofi-aventis Canada Inc. v. Hospira Healthcare Corporation*, October 22, 2009. Full judgment – 2009 FC 1077.)

Other decisions

Federal Court sets aside PMPRB's decisions on excessive pricing in respect of Teva's COPAXONE. On November 12, 2009, the Federal Court granted Teva's applications for judicial review of the PMPRB's decisions holding that Teva had priced its medicine, **COPAXONE**, excessively and ordering payment of approximately $2.4 million to the Crown as a result. The Applications Judge found that, in concluding that Teva sold the medicine at an excessive price, the Board acted unreasonably and outside the mandate it was given under sections 85(1) and (2) of the *Patent Act* by (i) focusing only on the Consumer Price Index (CPI) factor under section 85(1)(d) while failing to give proper, if any, consideration to the other factors under the same section; and (ii) considering section 85(2) without giving any reasons why this section was considered and again focusing only on the CPI. The Judge also found that the Board's reasons were inadequate. Further, he held that the Board's decision fixing the sum of excessive revenues unintelligible in that no basis for arriving at that figure is provided in the Board's reasons. As a result, the Judge set aside the Board's decision on excessive pricing and returned the matter to the Board for redetermination. In his further reasons, the Judge ordered that the sum paid by Teva to the Crown be returned. (*Teva Neuroscience v. Attorney General of Canada*, November 12, 2009. Full judgment – 2009 FC 1155. Further reasons – 2009 FC 1206.)

Trade-mark decisions

MANGEN confusing with MACUGEN. The applicant, Frank Burczynski, had filed an application for MANGEN for use in association with drugs, medicines and pharmaceutical products. The opponent, OSI Eyetech, opposed on the basis of confusion and distinctiveness. OSI Eyetech has a pending trade-mark application for MACUGEN in relation to a therapy used in the treatment of all types of neovascular age-related macular degeneration to slow vision loss. The Board rejected the application on the basis of confusion, specifically the fair degree of resemblance between the parties' marks and of the potential for overlap between the parties' wares and services and their channels of trade. (Full decision.)

New Court proceedings

Patented Medicines (Notice of Compliance) Regulations

Medicine:	tamsulosin hydrochloride (FLOMAX CR)
Applicants:	Boehringer Ingelheim (Canada) Limited and Astellas Pharma Inc
Respondents:	Novopharm Limited and The Minister of Health
Date Commenced:	November 5, 2009
Court File No.:	T-1828-09
Comment:	Application for Order of prohibition until expiry of Patent No. 2,144,077. Novopharm alleges improper listing and non-infringement.

Medicine:	repaglinide (GLUCONORM)
Applicants:	Novo Nordisk Canada Inc and Dr. Karl Thomae GmbH
Respondents:	Mylan Pharmaceuticals ULC and The Minister of Health
Date Commenced:	November 12, 2009
Court File No.:	T-1856-09
Comment:	Application for Order of prohibition until expiry of Patent No. 2,111,851. Mylan alleges improper listing, invalidity and non-infringement.

Medicine:	pregabalin (LYRICA)
Applicants:	Pfizer Canada Inc, Warner-Lambert Company and Warner-Lambert Company LLC
Respondents:	Novopharm Limited, The Minister of Health, Northwestern University and The Board of Regents for the University of Oklahoma
Date Commenced:	November 13, 2009
Court File No.:	T-1868-09
Comment:	Application for Order of prohibition until expiry of Patents Nos. 2,134,674, 2,255,652, 2,325,045, 2,297,163 and 2,327,285. Novopharm alleges improper listing, non-infringement and invalidity with respect to all patents.

Medicine:	mycophenolate mofetil (CELLCEPT)
Applicant:	Hoffmann-La Roche Limited
Respondents:	Mylan Pharmaceutical ULC and The Minister of Health
Respondent/Patentee:	Roche Palo Alto LLC
Date Commenced:	November 16, 2009
Court File No.:	T-1873-09
Comment:	Application for Order of prohibition until expiry of Patent No. 1,333,285. Mylan alleges ineligibility, non-infringement and invalidity.

Other decisions

Medicine:	Drug "B"
Applicant:	Novopharm Limited
Respondents:	The Minister of Health and the Attorney General of Canada
Date Commenced:	November 13, 2009
Court File No.:	T-1862-09
Comment:	Application for judicial review concerning a decision of the Minister of Health that Novopharm must address Patent No. X to receive an NOC for its ANDS concerning Drug "B."

Medicine:	Drug "A"
Applicants:	Novopharm Limited
Respondents:	The Minister of Health and the Attorney General of Canada
Date Commenced:	November 13, 2009
Court File No.:	T-1863-09
Comment:	Application for judicial review concerning a decision of the Minister of Health that Novopharm must address Patent No. X to receive an NOC for its ANDS concerning Drug "A."

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

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