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Rx IP UPDATE

CANADIAN PHARMACEUTICAL INTELLECTUAL PROPERTY LAW NEWSLETTER

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New Court proceedings

Novo Nordisk denied Order of prohibition against Cobalt concerning repaglinide (GLUCONORM)

On August 3, 2010, Justice Mactavish of the Federal Court dismissed Novo Nordisk's application for an Order of prohibition against Cobalt regarding **repaglinide** (Novo Nordisk's **GLUCONORM**). Canadian Patent No. 2,111,851 (the "'851 patent") claims the (S) enantiomer, at least 95% pure, of a compound identified in a prior patent. While the Court concluded that Cobalt failed to prove allegations of invalidity based on anticipation and willful misleading, the Court found that the patent at issue was obvious.

Repaglinide is a benzoic acid derivative useful in the treatment of type 2 diabetes. Canadian Patent No. 1,225,398 (the "'398 patent") claimed approximately one million compounds of a general structure, one of which was the racemate of repaglinide. All of the claimed compounds were identified as possessing blood sugar lowering activity. A second patent, Canadian Patent No. 1,292,000 (the "'000 patent"), claimed two new solid forms of the racemate of repaglinide and their enantiomers. Neither repaglinide nor the (R) enantiomer of the racemate of repaglinide had been made at the time of filing of the priority application for the '000 patent.

The '851 patent asserted that the (S) enantiomer, repaglinide, rather than the (R) enantiomer, is the effective enantiomer for lowering blood sugar. Further, the patent asserted that repaglinide possessed improved pharmacokinetic properties over the racemate, including rapid elimination from the body, lower plasma levels and more rapid onset of effectiveness.

Novo Nordisk asserted that the '851 patent was a valid selection patent based on it being the first disclosure of how to make repaglinide and the first disclosure of the unexpected pharmacokinetic properties of the compound.

The Court dismissed the allegation of invalidity based on anticipation because there was no prior disclosure of repaglinide. The Court arrived at this conclusion on the basis that repaglinide had not been made before and that its special advantages were previously unknown and could not have been predicted.

Further, the Court dismissed Cobalt's allegation of invalidity based on section 53 of the *Patent Act* or "willful misleading" during patent prosecution on the basis that any omissions in the patent were inadvertent or unlikely to mislead. Notably, given the

"serious allegations of misconduct" levied against the inventors by Cobalt, the Court indicated that it was incumbent on Cobalt to "squarely question the inventors" as to whether any omissions in the patent were the product of an intent to mislead.

Finally, the Court accepted Cobalt's allegation that the '851 patent was invalid on the basis of obviousness. On the evidence, the Court concluded that while the skilled person could not have predicted that repaglinide would have the three advantageous properties identified in the patent, it was self-evident that a skilled person would test enantiomers for their pharmacokinetic properties and that these properties of repaglinide would inevitably have been discovered as a result of this routine testing. The Court agreed that the evidence demonstrated a six-year gap between the production of the racemate and the resolution of the enantiomers. However, the Court determined on closer examination that, on the evidence, once the "drug development team finally turned their minds to obtaining the enantiomers ... they were in fact able to do so quite quickly and relatively easily."

As such, the Court concluded that Cobalt's allegation of invalidity based on obviousness was justified and dismissed Novo Nordisk's application for an Order of prohibition. (*Novo Nordisk Canada Inc. v. Cobalt Pharmaceuticals Inc.*, August 3, 2010. Decision – 2010 FC 746.)

Patented Medicine Prices Review Board news

Amendment to Voluntary Compliance Undertaking for Andriol accepted. The Board recently accepted an amendment to the September 30, 2009, Voluntary Compliance Undertaking (VCU) for Schering-Plough's **Andriol (testosterone undecanoate)**. (Notice.)

Voluntary Compliance Undertaking for Vancocin. The Board recently approved a VCU for Iroko's **Vancocin (vancomycin hydrochloride)**. (Notice.)

Recent Court decisions

Patented Medicines (Notice of Compliance) Regulations

Court of Appeal dismisses Janssen-Ortho's motion to set aside its redetermination Order. As reported in the July 2009 edition of *Rx IP Update*, on June 22, 2009, the Court of Appeal allowed Apotex's appeal regarding a prohibition Order granted in respect of **levofloxacin** (Janssen-Ortho's **LEVAQUIN**) and remitted the matter back to the Applications Judge, Justice Shore, for redetermination (the "redetermination Order"). Justice Shore recused himself from the redetermination. Janssen-Ortho brought a motion to set aside the redetermination Order, asserting that Justice Shore's decision to recuse himself would have had a determining influence on the redetermination Order. The Court of Appeal dismissed the motion, finding that Justice Shore's decision to recuse himself was of no relevance. (*Apotex Inc. v. Janssen-Ortho Inc.*, August 20, 2010. Decision – 2010 FCA 213.)

Other decisions

Pfizer's *res judicata* defence based on decisions under *Regulations* permitted to stand. A Prothonotary dismissed Apotex's motion to strike a *res judicata* pleading from Pfizer's Statement of Defence in response to Apotex's claim for impeachment of a patent relating to **sildenafil citrate** (Pfizer's **VIAGRA**). Apotex sought to strike Pfizer's pleading that previous findings in proceedings under the *Patented Medicines (Notice of Compliance) Regulations* ("*Regulations*") should preclude Apotex from contesting the validity of the patent in the proceeding under consideration. The Prothonotary noted that Pfizer's pleading of *res judicata* was directed towards evidence and witnesses who make the same statements in the impeachment proceeding and found that it should be open to the Trial Judge to determine if *res judicata* principles based on

prior proceedings under the *Regulations* were applicable. Apotex has appealed. (*Apotex Inc. v. Pfizer Ireland Pharmaceuticals*, June 11, 2010. Decision – 2010 FC 633.)

Lundbeck counterclaim for a *quia timet* action permitted to stand. Following the issuance of a prohibition Order relating to **escitalopram** (Lundbeck's **CIPRALEX**; appeal pending), Apotex brought an action for a declaration of invalidity and non-infringement (certain claims only) of the patent that is the subject of the prohibition Order. Lundbeck counterclaimed for damages for infringement of all claims on a *quia timet* basis. The Court dismissed Apotex's motion to strike Lundbeck's counterclaim, finding that it is arguable that the criteria for a quia timet action should be applied more flexibly when brought in response to an action for a declaration of non-infringement. The Court also found that Lundbeck should be exempted from the requirement to post security for costs, including in view of the dependent nature of its counterclaim. (*Apotex Inc. v. H. Lundbeck A/S*, August 5, 2010. Decision – 2010 FC 807.)

Shire can plead "grave consequences" defence to section 8 claim. The Federal Court granted in part Shire's motion for leave to amend its Statement of Defence. Shire was denied an Order of prohibition against Apotex regarding **modafinil** (Shire's **ALERTEC**), and Apotex subsequently commenced an action pursuant to section 8 of the *Regulations*. On this motion, Shire sought to introduce two new defences. The first was an allegation that should Cephalon (owner of the relevant patent) be successful in a separate infringement action, Apotex should not be entitled to recover any damages pursuant to section 8. The Court refused this amendment on the grounds that the pleading was speculative and would unreasonably delay, embarrass and prejudice the trial as it could not be determined until the other action was resolved. Second, Shire sought to introduce an allegation that Apotex breached an undertaking that it would not make, use or sell Apo-Modafinil for certain patented uses regarding a second listed modafinil patent. Shire was permitted to plead that this gave rise to "grave consequences" in the form of a denial of any remedy under section 8. Apotex has appealed. (*Apotex Inc. v. Shire Canada Inc.*, August 19, 2010. Decision – 2010 FC 828.)

New Court proceedings

Patented Medicines (Notice of Compliance) Regulations

Medicine:	fenofibrate (LIPIDIL EZ)
Applicants:	Fournier Pharma Inc and Fournier Laboratories Ireland Ltd
Respondents:	The Minister of Health, Elan Pharma International Ltd and Sandoz Canada Inc
Date Commenced:	July 22, 2010
Court File No.:	T-1184-10
Comment:	Application for Order of prohibition until expiry of Patent No. 2,487,054. Sandoz alleges non-infringement and invalidity and that the patent is improperly listed on the Patent Register.

Medicine:	losartan potassium/hydrochlorothiazide (HYZAAR, HYZAAR DS)
Applicants:	Merck Frosst Canada Ltd and EI Dupont De Nemours and Company
Respondents:	The Minister of Health and Mylan Pharmaceuticals ULC
Date Commenced:	July 23, 2010
Court File No.:	T-1189-10
Comment:	Application for Order of prohibition until expiry of Patent No. 1,338,238. Mylan alleges non-infringement and invalidity and that the patent is improperly listed on the Patent Register.

Medicine: olanzapine (ZYPREXA/ZYPREXA ZYDIS)
Applicant: Eli Lilly Canada Inc
Respondents: The Minister of Health and Sanis Health Inc
Respondent/Patentee: Eli Lilly and Company and Eli Lilly and Company Limited
Date Commenced: July 23, 2010
Court File No.: T-1195-10
Comment: Application for Order of prohibition until expiry of Patent No. 2,214,005. Sanis alleges non-infringement and invalidity.

Medicine: ezetimibe (EZETROL)
Applicants: Merck Frosst – Schering Pharma GP and Schering Corporation
Respondents: The Minister of Health and Mylan Pharmaceuticals ULC
Date Commenced: August 5, 2010
Court File No.: T-1280-10
Comment: Application for Order of prohibition until expiry of Patent No. 2,172,149. Mylan alleges non-infringement and invalidity.

Medicine: bupropion hydrochloride (WELLBUTRIN XL)
Applicants: Biovail Corporation and Biovail Laboratories International SRL
Respondents: The Minister of Health and Mylan Pharmaceuticals ULC
Date Commenced: August 6, 2010
Court File No.: T-1283-10
Comment: Application for Order of prohibition until expiry of Patents Nos. 2,168,364 and 2,524,300. Mylan alleges non-infringement of the '364 Patent and that the '364 Patent is improperly listed on the Patent Register. Mylan alleges non-infringement and invalidity with respect to the '300 Patent.

Medicine: mycophenolate mofetil (CELLCEPT)
Applicant: Hoffmann-La Roche Limited
Respondents: The Minister of Health and Cobalt Pharmaceutical Company
Respondent/Patentee: Roche Palo Alto LLC
Date Commenced: August 12, 2010
Court File No.: T-1303-10
Comment: Application for Order of prohibition until expiry of Patent No. 1,333,285. Cobalt alleges non-infringement and invalidity.

Medicine: riluzole (RILUTEK)
Applicants: sanofi-aventis Canada Inc and Aventis Pharma SA
Respondents: The Minister of Health and Apotex Inc
Date Commenced: August 19, 2010
Court File No.: T-1333-10
Comment: Application for Order of prohibition until expiry of Patents Nos. 2,117,466, 2,152,280 and 2,151,604. Apotex alleges non-infringement of the '466, '280 and '604 Patents and invalidity of the '466 Patent.

Medicine:	rosuvastatin (CRESTOR)
Applicants:	AstraZeneca Canada Inc and AstraZeneca AB
Respondents:	The Minister of Health and Ranbaxy Pharmaceuticals Canada Inc
Date Commenced:	August 26, 2010
Court File No.:	T-1367-10
Comment:	Application for Order of prohibition until expiry of Patent No. 2,313,783. Ranbaxy alleges non-infringement and invalidity.

Medicine:	rosuvastatin (CRESTOR)
Applicants:	AstraZeneca Canada Inc and AstraZeneca AB
Respondents:	The Minister of Health and Ranbaxy Pharmaceuticals Canada Inc
Date Commenced:	August 26, 2010
Court File No.:	T-1368-10
Comment:	Application for an order of prohibition until expiry of Patent No. 2,315,141. Ranbaxy alleges non-infringement and invalidity.

Medicine:	rosuvastatin (CRESTOR)
Applicants:	AstraZeneca Canada Inc and Shionogi Seiyaku Kabushiki Kaisha
Respondents:	The Minister of Health and Ranbaxy Pharmaceuticals Canada Inc
Date Commenced:	August 26, 2010
Court File No.:	T-1369-10
Comment:	Application for Order of prohibition until expiry of Patent No. 2,072,945. Ranbaxy alleges non-infringement and invalidity.

Other proceedings

Medicine:	repaglinide (GLUCONORM)
Plaintiff:	Novo Nordisk Canada Inc
Defendants:	Cobalt Pharmaceuticals Inc and Dr Karl Thomae GmbH
Date Commenced:	July 23, 2010
Court File No.:	T-1192-10
Comment:	Action for infringement of Patent No. 2,111,851.

Medicine:	gatifloxacin (ZYMAR)
Plaintiffs:	Allergan Inc, Allergan Sales LLC, Allergan USA Inc and Kyorin Pharmaceutical Co Ltd
Defendants:	Apotex Inc and Apotex Pharmachem Inc
Date Commenced:	August 5, 2010
Court File No.:	T-1267-10
Comment:	Action for infringement of Patent No. 1,340,316.

Medicine:	methylphenidate (CONCERTA)
Plaintiff:	Apotex Inc
Defendant:	Janssen-Ortho Inc
Date Commenced:	August 5, 2010
Court File No.:	T-1272-10
Comment:	Action for section 8 damages.

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

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