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Rx IP UPDATE

CANADIAN PHARMACEUTICAL INTELLECTUAL PROPERTY LAW NEWSLETTER

August 2010

Federal Court of Appeal overturns invalidity ruling in olanzapine infringement action

As reported in the November 2009 edition of *Rx IP Update*, on October 5, 2009, the Federal Court found Canadian Patent 2,041,113 ("'113"), which specifically claims **olanzapine** (Eli Lilly's **ZYPREXA**), invalid. The Trial Judge found that because Eli Lilly previously held a genus patent that encompassed and claimed 15 trillion compounds including olanzapine (the '687 patent), the '113 patent was considered a selection patent. The Court found that the '113 patent asserted various advantages of olanzapine over compounds claimed by the '687 patent as well as other antipsychotic compounds. The Court concluded that none of the alleged advantages were shown by the inventors prior to filing the patent, nor could they be soundly predicted. For these reasons, among others, the Court held that the '113 patent was an invalid selection patent. The Court briefly considered obviousness and held that olanzapine was an "almost invention": it was neither obvious nor a genuine invention.

On appeal, the Court of Appeal characterized the core issue as whether the conditions for a valid selection patent constitute an independent basis upon which to attack the validity of a patent. It concluded that there is no such independent basis. A selection patent is the same as any other patent. Its validity is open to attack on any of the grounds set out in the *Patent Act*. The Trial Judge concluded the opposite, and the Court of Appeal found that the Trial Judge therefore erred in determining the validity of the '113 patent on the basis that he did. The appeal was allowed on the issues of anticipation, obviousness and double-patenting, but it was sent back to the Federal Court on the issues of utility and sufficiency of disclosure.

On the issue of anticipation, the Court of Appeal concluded that the "disclosure" requirement had not been met:

> [52] ... Olanzapine was not one of the examples described in the '687 Patent. It was one of a large class of most preferred compounds described by reference to several criteria. It was not specifically disclosed in the '687 Patent. Nor had it been made before. Since its advantages (as alleged in the '113 Patent) could not

> have been ascertained until it was made, it was not disclosed ... by the '687 Patent.

Regarding obviousness, the Court of Appeal found that it was inconsistent for the Trial Judge to find that the selection of olanzapine was both non-inventive and non-obvious. It concluded that the inventive concept, olanzapine, coupled with its advantages was non-obvious.

The Court of Appeal found that the Trial Judge concluded without analysis that the '113 patent was invalid for double-patenting. The Court of Appeal found that the claims of the two patents were not coterminous and that the claims of the '113 patent were "patentably distinct" from the prior patent.

On the issue of utility, the Court of Appeal stated that a selection patent must promise an advantage. No specific number of advantages is required; one advantage may be enough, or any number of seemingly less significant advantages may combine to meet the requirement, provided the advantage is substantial. The Court of Appeal noted that the construction of the promise of the patent is fundamental to the utility analysis. In this case, the Court of Appeal noted its difficulty in determining what the Trial Judge construed the promise of the patent to be, and it also pointed to the lack of references in the decision to expert evidence on the issue.

Finally, regarding sufficiency of disclosure, the Court of Appeal agreed with the Trial Judge that two disclosure requirements were at play: (1) the "sound prediction" disclosure requirement, and (2) the disclosure required under section 27(3) of the *Patent Act*. However, the Court of Appeal found that the Trial Judge incorrectly equated the two. Similar to its findings on utility, the Court noted that there were insufficient factual determinations in the Trial Judge's reasons for the Court to review the issue. (*Eli Lilly Canada Inc. v. Novopharm Limited*, July 21, 2010. Court of Appeal decision – 2010 FCA 197. Trial Judge's decision – 2009 FC 1018.)

Health Canada news

Health Canada to review data protection inquiries process. In the current inquiry process for data protection pursuant to section C.08.004.1 of the *Food and Drug Regulations*, the Office of Patented Medicines and Liaison (OPML) accepts written inquiries challenging the innovative drug status of drugs eligible for data protection, which are publicly listed on the Register of Innovative Drugs. On July 27, 2010, Health Canada announced that this process is under review, citing opportunities for streamlining the process and concerns about the transparency of the decision-making process. Proposed changes will be posted, to be followed by stakeholder consultation. (Notice.)

Recent Court decisions

Patented Medicines (Notice of Compliance) Regulations

Federal Court "terminates" prohibition application as moot. On June 29, the Federal Court "terminated" a prohibition application that had been remanded by the Federal Court of Appeal to the Federal Court for "redetermination." With the relevant patent having expired and Apotex having been granted a notice of compliance (NOC), Apotex moved to have the prohibition application dismissed as moot. The Court found that, under the circumstances, the potential for section 8 liability was too remote and speculative to warrant not dismissing the proceeding as moot. The Court also found that the dismissal of the application as moot constituted a determination consistent with the judgment of the Federal Court of Appeal. The Court found that only a Court hearing a prohibition application could dismiss a prohibition application so as to trigger section 8 of the *Patented Medicines (Notice of Compliance) Regulations* ("*Regulations*"), and so it used the language "terminate" rather than "dismiss" so that section 8 of the *Regulations* was clearly not triggered. Apotex has appealed, and Janssen-Ortho and Daiichi have cross-appealed. (*Janssen-Ortho v. Apotex*, June 29, 2010. Full judgment – 2010 FC 711.)

Federal Court upholds Minister's patent listing decision refusing listing of dosage form patent against a combination product. The Federal Court dismissed an application by Purdue that sought to set aside a decision by the Minister that a patent claiming a controlled-release oxycodone formulation is not eligible for listing on the Patent Register against a new drug submission (NDS) for **TARGIN** (a controlled-release product containing two medicinal ingredients, oxycodone and naloxone). While there was expert evidence that TARGIN fell within the scope of the claims (including a claim for an oral dosage form), there was only specific reference made to oxycodone and none made to naloxone. The Court concluded that the OPML was correct in (1) interpreting the *Regulations* as requiring a match between the dosage form claimed and the dosage form that was approved and (2) finding that there was no such match. (*Purdue Pharma v. Canada (Attorney General)*, July 8, 2010. Full judgment – 2010 FC 738.)

Other decisions

Federal Court of Appeal rules on effect of invalid disclaimer. In a non-pharmaceutical decision, the Federal Court of Appeal upheld a Trial Judge's decision regarding a disclaimer. The Trial Judge found that the appellant's disclaimer added new inventive elements to the invention and was therefore invalid as a disclaimer can only narrow the scope of a patent. The Trial Judge also found that the disclaimer itself was invalid as it was not prompted by "mistake, accident or inadvertence." The appellants did not challenge the Trial Judge's finding of law before the Court of Appeal but instead submitted that they had discharged their burden to prove "mistake, accident or inadvertence." The Court of Appeal upheld the Trial Judge's ruling on this issue in finding that the Trial Judge did not make a palpable and overriding error. The Court of Appeal also upheld the Trial Judge's finding that when a disclaimer is found invalid, the patent is also invalid. Filing a disclaimer is a "significant, formal, public act," and the Court of Appeal characterized it as a concession by the patentee that the original patent was too broad in scope. (*Hershkovitz v. Tyco Safety Products Canada Ltd.*, July 19, 2010. Court of Appeal decision – 2010 FCA 190. Trial Judge's decision – 2009 FC 256.)

Federal Court of Appeal upholds declaration of invalidity of amlodipine besylate patent. The Court of Appeal upheld a Trial Judge's decision that the patent claiming the **besylate salt** of **amlodipine** (Pfizer's **NORVASC**) is obvious. Pfizer had argued, among other things, that the Trial Judge erred in law by asking whether the process used by the inventors in developing the invention was more or less self-evident (or predictable). The appropriate question, according to Pfizer, was whether the result of the process was self-evident (or predictable). The Court of Appeal found that the Trial Judge stated the correct legal criteria for obviousness and that the criteria are concerned with the solution (or the result). The Court of Appeal concluded that the pivotal factual finding that the result of the besylate salt screening (its advantages) was predictable or obvious to try was that "a person skilled in the art would be motivated to test sulphonic acid salts in general and would have every reason to test the besylate salt as this had already been shown to offer advantages over other salts in terms of stability." The Court of Appeal also found that the Trial Judge's determination that the patent was misleading and invalid under section 53 is *obiter* and is "confined to the unique and particular circumstances of this matter" and "has limited, if any, value as a precedent." (*Pfizer Limited v. ratiopharm Inc.*, July 29, 2010. Court of Appeal decision – 2010 FCA 204. Trial Judge's decision – 2009 FC 711.)

New Court proceedings

Patented Medicines (Notice of Compliance) Regulations

Medicine:	fenofibrate (LIPIDIL EZ)
Applicants:	Fournier Pharma Inc and Laboratoires Fournier SA
Respondents:	Sandoz Canada Inc and The Minister of Health
Date Commenced:	June 30, 2010
Court File No.:	T-1051-10
Comment:	Application for Order of prohibition until expiry of Patent No. 2,219,475. Sandoz alleges invalidity and non-infringement.

Medicine:	lamivudine/zidovudine (COMBIVIR)
Applicants:	ViiV Healthcare ULC, GlaxoSmithKline Inc and The Wellcome Foundation Limited
Respondents:	Apotex Inc and The Minister of Health
Date Commenced:	June 30, 2010
Court File No.:	T-1052-10
Comment:	Application for Order of prohibition until expiry of Patent No. 2,216,634. Apotex alleges non-infringement and invalidity and that the patent is improperly listed on the Patent Register.

Medicine:	lamivudine (3TC)
Applicants:	ViiV Healthcare ULC, GlaxoSmithKline Inc and The Wellcome Foundation Limited
Respondents:	Apotex Inc and The Minister of Health
Date Commenced:	June 30, 2010
Court File No.:	T-1053-10
Comment:	Application for Order of prohibition until expiry of Patent No. 2,216,634. Apotex alleges non-infringement and invalidity and that the patent is improperly listed on the Patent Register.

Medicine:	atomoxetine hydrochloride (STRATTERA)
Applicant:	Eli Lilly Canada Inc
Respondents:	Mylan Pharmaceuticals ULC and The Minister of Health
Respondent/Patentee:	Eli Lilly and Company
Date Commenced:	July 14, 2010
Court File No.:	T-1121-10
Comment:	Application for Order of prohibition until expiry of Patent No. 2,209,735. Mylan alleges invalidity.

Other proceedings

Medicine:	oxaliplatin (ELOXATIN)
Applicant:	Teva Canada Limited
Respondents:	sanofi-aventis Canada Inc and The Minister of Health
Date Commenced:	July 21, 2010
Court File No.:	T-1172-10
Comment:	Application for judicial review of Minister's decision not to grant Teva's request to have ELOXATIN removed from the Register of Innovative Drugs. Teva alleges that Eloxatin was not an innovative drug "because ... oxaliplatin, was previously approved by the Minister through the widespread authorization and pervasive use of Eloxatin and generic products containing oxaliplatin under the [Special Access Programme]."

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

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