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Rx IP UPDATE

CANADIAN PHARMACEUTICAL INTELLECTUAL PROPERTY LAW NEWSLETTER

October 2010

Court of Appeal provides guidance regarding requirements for demonstrated utility

The Federal Court of Appeal has confirmed that a patentee need not demonstrate utility in a patent: *Novopharm Limited v. Pfizer*, 2010 FCA 242. Justice Nadon, writing for a unanimous Court, dismissed Novopharm's appeal from a decision of Justice Kelen, who had granted Pfizer's application under the *Patented Medicines (Notice of Compliance) Regulations* ("*Regulations*") (2009 FC 638).

The patent at issue claims the use of **sildenafil citrate** ("sildenafil," Pfizer's **VIAGRA**) for the treatment of erectile dysfunction. The patent disclosed a broad class of compounds together with progressively narrower groups of preferred compounds. Sildenafil was included in a list of especially preferred individual compounds. The patent referred to testing of certain especially preferred compounds in a study involving volunteers, although the details of the study were not described and the compounds tested were not specifically identified. Claim 1 covered the use of the entire genus while claim 7 covered only sildenafil.

Justice Nadon framed the issues on appeal as follows:

1. Was the Judge correct in concluding that the disclosure of the invention in the '446 patent was sufficient under section 27 of the *Patent Act*?

   (a) What is the relevant invention?

   (b) Given the determination of the invention, was there sufficient disclosure?

2. Was the Judge correct in concluding that the '446 patent met the requirement of utility under section 2 of the *Act*?

   (a) Was the respondent required to demonstrate utility in the patent disclosure?

   (b) If not, does the evidence disclose that the invention was useful?

Accordingly, the appeal squarely raised issues of disclosure and utility.

Regarding the identity of the relevant invention, Justice Nadon found that the claim to only sildenafil (claim 7) was a separate invention from the class. As a result, questions as to whether the patentee had satisfied the

statutory disclosure and utility requirements were to be assessed with respect to claim 7 and not by looking at the patent as a whole.

Justice Nadon also rejected Novopharm's suggestion that a best mode requirement applied, finding that best mode only applied in the case of a machine.

On the question of whether there was sufficient disclosure, Justice Nadon found that the patentee had answered the two questions: "What is your invention?" and "How does it work?" As to the former, the invention is the use of sildenafil to treat erectile dysfunction; as to the latter, the patent describes the mechanism of action. Further, the skilled reader would have been able to narrow the listed compounds down to the two especially preferred compounds described by claims 6 and 7.

The Court then considered whether the patent had met the utility requirements of the *Act*. Justice Nadon noted that as of the filing date, there must either be a demonstration of utility or a sound prediction of utility. Perhaps foreshadowing his disposition on the issue of whether the patent must demonstrate utility, Justice Nadon stated: "Evidence beyond that set out in the specification can and, normally, will be necessary."

Justice Nadon rejected the requirement that Pfizer needed to include proof of utility in the patent, providing that "the trier of fact finds it [utility] to be proven upon a legal challenge." He found that "there is nothing in the *Act* which leads one to conclude that such a demonstration is necessary" and that there is no *a priori* reason "that the patent disclosure should contain proof of all the elements required to obtain the patent."

The judgment also clarifies the role that the disclosure plays in the patent system. In particular, the Court emphasized the notice function of a disclosure, rejecting the suggestion that a disclosure must provide proof of utility. As Justice Nadon stated:

> ...the disclosure provides direction, not proof: it tells practitioners how to practice the invention. It does not prove to them its utility, though they can require proof through invalidity proceedings.

The final issue before the Court was whether the Judge erred in finding that the study relied upon by Pfizer disclosed utility (while referred to by the patent, the full study results were not provided). Finding that the issue was a question of fact, the Court of Appeal declined to interfere with the decision of Justice Kelen. The Court of Appeal, however, did confirm that "an inventor is not required to meet regulatory testing standards in order to demonstrate utility."

The Court of Appeal's decision is a significant victory for patentees on at least three fronts. First, the Court has rejected the assertion that a patent document must prove demonstrated utility. Second, the Court has rejected the introduction of a best mode requirement for patents other than machines (where the requirement is statute-based). Finally, the decision confirms the primacy of the *Act* in considering issues of invalidity. In particular, the decision recognizes that the utility and disclosure requirements serve distinct functions and confirms that compliance with those requirements must be assessed separately.

Supreme Court of Canada news

Availability of subsequent dismissal of applications in which prohibition Orders issued following separate finding of invalidity. Pharmascience has filed an application for leave to appeal a Federal Court of Appeal decision relating to the availability of an Order dismissing an application in which a prohibition Order issued (relating to **ramipril**, sanofi-aventis's **ALTACE**), as a result of a finding of invalidity of the relevant patent in a later action involving different parties. The Federal Court set aside the two relevant prohibition Orders but declined to dismiss the relevant applications; the Court of Appeal affirmed. (*Pharmascience Inc. v. Aventis Pharma Inc. et al.*, September 7, 2010 (SCC Case No. 33831). Court of Appeal decision – 2010 FCA 153. Federal Court decision – 2009 FC 915.)

Availability of recovery under pre-amended section 8 of the *Regulations*. Apotex has filed an application for leave to appeal the Federal Court of Appeal's decision relating to the recoverability of damages under pre-amended section 8 of the *Regulations*.

An Order of prohibition had been granted regarding **naproxen sustained-release tablets** (Roche's **NAPROSYN SR**); the patent was subsequently invalidated in an action. The Court of Appeal affirmed the Trial Judge's holding that the 1993 and not the 1998 version of section 8 applied and that Apotex could not recover under the 1993 version. (*Apotex Inc. v. Syntex Pharmaceutical International Inc. et al.*, September 9, 2010 (SCC Case No. 33832). Court of Appeal decision – 2010 FCA 155. Federal Court decision – 2009 FC 494.)

Eligibility for listing on the patent register. Bayer has filed an application for leave to appeal the Federal Court of Appeal's decision relating to the eligibility for listing of a formulation patent against the new drug submission (NDS) for **ethinyl estradiol/ drospirenone** (Bayer's **YAZ**). The Federal Court determined that the Minister's interpretation of paragraph 4(2)(b) of the *Regulations*, requiring patent claims to refer to both medicinal ingredients in a formulation for the patent to be eligible, was correct. Based on this interpretation, the Federal Court determined that the Minister was correct not to list the patent as the claims only referred explicitly to one of the medicinal ingredients. The Court of Appeal affirmed the decision for substantially the same reasons. (*Bayer Inc. v. Minister of Health et al.*, September 14, 2010 (SCC Case No. 33845). Court of Appeal decision – 2010 FCA 161. Federal Court decision – 2009 FC 1171.)

The availability of a validity attack based on "invalid selection." Novopharm has filed an application for leave to appeal the Federal Court of Appeal's decision setting aside a decision of the Federal Court finding Eli Lilly's patent for the compound **olanzapine (ZYPREXA)** to be invalid. The Court of Appeal held that the Trial Judge erred by using the conditions for a valid selection patent as an independent basis upon which to attack the validity of a patent and remitted the matter to the Trial Judge to consider the utility and sufficiency of disclosure grounds of alleged invalidity. (*Novopharm Limited v. Eli Lilly Canada Inc. et al.*, September 28, 2010 (SCC Case No. 33870). Court of Appeal decision – 2010 FCA 197. Federal Court decision – 2009 FC 1018.)

Recent Court decisions

Patented Medicines (Notice of Compliance) Regulations

Merck obtains Order of prohibition against Teva regarding ezetimibe. The Federal Court granted an Order of prohibition against Teva regarding **ezetimibe** (Merck's **EZETROL**). The central issue in the case was whether an earlier patent made the ezetimibe patent "obvious to try." Through expert evidence, Teva set out a 10-step process that it claimed a skilled person would have known and followed to arrive at the ezetimibe patent. The Court accepted Merck's expert evidence as more reliable since Merck's experts had more direct experience and expertise. The Court found that Teva's proposed 10-step process was too subject to potential missteps to qualify as something obvious, easy or self-evident. The Court noted that Merck's development work leading up to the invention was extensive, expensive and not without failures and that there was a disparity between this reality and Teva's thesis that the 10-step process was obvious. Finally, the Court noted that Teva's expert benefited from knowledge of the destination when charting the 10-step process to ezetimibe. (*Merck-Frosst-Schering Pharma GP v. Canada (Health)*, September 17, 2010. Decision – 2010 FC 933.)

Apotex's motion for an Order setting aside and dismissing prohibition Order regarding olanzapine is dismissed. Justice Gauthier dismissed Apotex's motion to set aside and dismiss a prohibition Order (which had been affirmed on appeal) regarding the patent claiming **olanzapine** (Eli Lilly's **ZYPREXA**) that Apotex had requested on the ground that a matter arose or was discovered subsequent to the making of the Order. Apotex submitted that a subsequent *in rem* finding by Justice O'Reilly (2009 FC 1018) that all of the claims of the relevant patent were invalid constitutes a new matter and warranted reconsideration of the prohibition Order. Following the hearing of the motion, the Court awaited the outcome of the appeal of Justice O'Reilly's decision. The Court of Appeal reversed Justice O'Reilly's decision and remanded the matter back to Justice O'Reilly for redetermination of the utility and sufficiency of disclosure grounds of alleged invalidity. Apotex argued that the Court should await Justice O'Reilly's redetermination. Justice Gauthier elected to decide the motion regardless of the result of Justice O'Reilly's redetermination. The Court found that it was clear from recent case law

that there is no need to set aside a prohibition Order when the underlying patent expires through a declaration of invalidity. In any event, Apotex had already received a notice of compliance (NOC). Moreover, the Court found that the balance of fairness was not in Apotex's favour given that Apotex had an opportunity to (i) raise all possible allegations regarding invalidity in its notice of allegation (NOA), which did not extend to the grounds to be redetermined by Justice O'Reilly, and (ii) seek expungement from day one. (*Eli Lilly Canada Inc. v. Apotex Inc.*, September 24, 2010. Decision – 2010 FC 952.)

Other decisions

Federal Court of Appeal dismisses Novopharm's motion for reconsideration regarding olanzapine. The Court of Appeal dismissed Novopharm's motion for reconsideration of its decision allowing Eli Lilly's appeal of a judgment of the Federal Court (2009 FC 1018). In allowing Eli Lilly's appeal, the Court of Appeal set aside the judgment of the Federal Court, which in part provided that Novopharm was entitled to relief under section 8 of the *Regulations* to be determined in a separate proceeding (its claim for damages under section 8 having been bifurcated) and its costs. Prior to the Federal Court of Appeal's decision allowing the appeal, costs were determined and paid by Eli Lilly. No appeal was taken. In the instant motion, Novopharm moved for reconsideration out of concern that the Order setting aside the Federal Court's decision was unclear in that it could be interpreted to preclude Novopharm from claiming section 8 damages or the Trial Judge from awarding costs to the successful party. The Court elected not to reconsider its Order but provided comments on how the Order was to be interpreted, noting that the question of Novopharm's claim for section 8 damages was not in issue in the appeal and that the judgment was not intended to affect Novopharm's section 8 claim and did not do so. On the issue of costs, the Court noted that the award of costs was set aside; however, as the quantum of costs was determined and paid and no appeal was made regarding quantum, it will be open for the Trial Judge to determine what (if anything) should be done regarding costs. (*Eli Lilly Canada Inc. v. Novopharm Limited*, September 7, 2010. Decision – 2010 FCA 219.)

Novopharm (Teva) successful in having patent for STRATTERA declared invalid. On September 14, 2010, Justice Barnes released his judgment in an impeachment action brought by Novopharm (now known as Teva) regarding Eli Lilly's patent claiming the use of **atomoxetine** (Eli Lilly's **STRATTERA**) to treat attention deficit hyperactivity disorder (ADHD). Novopharm argued that the patent was invalid on the grounds of obviousness, incomplete disclosure regarding selection from a previous patent, anticipation and inutility. The Judge rejected Novopharm's allegations of obviousness and anticipation and found that the patent at issue was not a selection patent. However, the Judge held that the patent was invalid on the basis of inutility.

Eli Lilly relied on a particular clinical study in asserting that utility had been demonstrated by the Canadian filing date. Novopharm argued that the study failed to demonstrate utility and at most might have formed the basis for a sound prediction of utility. The Judge found that the inventive promise of the patent was an effective treatment of ADHD in humans, which requires that atomoxetine work "in the longer term." Based on the evidence, the Judge found that the study was "too small in size and too short in duration" to provide anything more than interesting but inconclusive data and that the results were promising but only preliminary.

Although he noted that the study might provide a basis for sound prediction, the Judge found that the patent was invalid to the extent that it was based on a sound prediction because there was no disclosure of the study in the patent. (*Novopharm Limited v. Eli Lilly and Company*, September 14, 2010. Decision – 2010 FC 915.)

FCA affirms cefaclor decision. The Federal Court of Appeal dismissed Eli Lilly's appeal of a Trial Judge's determination that Eli Lilly had failed to prove that after June 3, 1998, Apotex's Indian supplier had produced bulk **cefaclor** from an intermediate compound made by a process covered by any of eight process patents owned by Eli Lilly. The Court of Appeal also dismissed Apotex's cross-appeal from the Trial Judge's determination that Apotex had infringed Eli Lilly's patents by importing bulk cefaclor before June 3, 2008. In dismissing Eli Lilly's appeal, the Court of Appeal declined to revisit factual determinations made by the Trial Judge as they lacked any significant or obvious errors. Further, the

Court of Appeal determined that the Trial Judge did not err in law by admitting certain disputed evidence through the course of the trial. In dismissing Apotex's cross-appeal, the Court of Appeal held that the Trial Judge correctly applied the *Saccharin* doctrine when she determined that it was enough to establish infringement if the patented process played an "important part" in the manufacture of the imported product. (*Eli Lilly and Company et al. v. Apotex Inc.*, September 22, 2010. Decision – 2010 FCA 240.)

EpiCept denied data protection for CEPLENE. EpiCept filed an NDS for **CEPLENE (histamine dihydrochloride)** and requested that it be designated an innovative drug. The Office of Patented Medicines and Liaison (OPML) denied the request. In her decision, the Minister stated, among other things, that the medicinal ingredients histamine and histamine dihydrochloride had previously received drug identification numbers (DINs) as they had previously been approved in several drugs by the Minister; the definition of "innovative drug" contemplates that medicinal ingredients not previously approved in "any drug" are to be considered in the assessment of eligibility of data protection and not just those drugs that receive an NOC; and that while CEPLENE's NDS contained new clinical data and the use is unrelated to the uses of histamine that have been previously approved, the nature or extent of the data becomes relevant only where it is unclear as to whether the drug meets the definition of "innovative drug."

EpiCept sought judicial review of the Minister's decision. The Federal Court dismissed the application and found that the Minister was correct to deny the request for data protection. The Judge considered the relevant legislation and found that the *Regulations* are intended to protect "new chemical entities" and that not all "new drugs" are new chemical entities. The Judge reasoned that drugs approved by the DIN process or the process under the *Natural Health Products Regulations* are not new chemical entities that have not been approved. The Judge proposed a two-step process for the Minister when assessing eligibility for data protection: first, the Minister must consider whether the data concerns a "new chemical entity"; if so, then the Minister must consider whether the data is undisclosed and if other data is necessary to determine safety and effectiveness. In this case, the medicinal ingredient was an old ingredient, and CEPLENE was therefore not a new chemical entity. On this basis, the Judge dismissed EpiCept's application. (*EpiCept Corporation v. Canada (Health)*, September 24, 2010. Decision – 2010 FC 956.)

New Court proceedings

Patented Medicines (Notice of Compliance) Regulations

Medicine:	erlotinib (TARCEVA)
Applicants:	Hoffmann-La Roche Limited and OSI Pharmaceuticals Inc
Respondents:	The Minister of Health, Teva Canada Limited and Pfizer Products Inc
Date Commenced:	September 20, 2010
Court File No.:	T-1501-10
Comment:	Application for Order of prohibition until expiry of Patents Nos. 2,216,796 and 2,389,333. Teva alleges non-infringement and improper listing with respect to the '796 and '333 patents and invalidity with respect to the '796 patent.

Medicine:	rosuvastatin (CRESTOR)
Applicants:	AstraZeneca Canada Inc, AstraZeneca Canada AB and Shionogi Seiyaku Kabushiki Kaisha
Respondents:	The Minister of Health and Mylan Pharmaceuticals ULC
Date Commenced:	September 24, 2010
Court File No.:	T-1535-10
Comment:	Application for Order of prohibition until expiry of Patents Nos. 2,072,945, 2,313,783 and 2,315,141. Mylan alleges non-infringement and invalidity.

Other proceedings

Medicine:	omeprazole (LOSEC)
Applicant:	Apotex Inc
Respondents:	The Minister of Health and Attorney General of Canada
Date Commenced:	August 26, 2010
Court File No.:	T-1372-10
Comment:	Application for an Order quashing the decision to revoke the approvability status of Apo-Omeprazole tablets and to remove Apotex's submission from patent hold.

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

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