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Rx IP Update

Canadian Pharmaceutical Intellectual Property Law Newsletter

Doctrine of Sound Prediction Tested and Presumption of Validity Unsettled

In two recent Federal Court decisions under the *Patented Medicines (Notice of Compliance) Regulations* ("*Regulations*") involving angiotensin converting enzyme ("ACE") inhibitors (Aventis' ALTACE (ramipril) (*Aventis v. Apotex*, 2005 FC 1283) and Pfizer's ACCUPRIL (quinapril) (*Pfizer v. Apotex* 2005 FC 1205), the Court adopted differing analyses for the test for sound prediction. In both cases, Apotex alleged that patents were invalid on numerous grounds, including lack of sound prediction. In one case the Court concluded the test had been met, while in the other case the Court ruled there had not been a sound prediction. The decisions also differ in the application of the presumption of validity. However, both applications for an Order of prohibition were dismissed, each for a different reason.

In this issue of *Rx IP Update* we focus on the sound prediction and presumption of validity analyses.

The doctrine of sound prediction, as articulated by the Supreme Court of Canada in *Apotex v. Wellcome Foundation*, [2002] 4 S.C.R. 153, allows a patentee to claim subject matter not made or tested provided there was: a) a factual basis for the prediction; b) an articulable line of reasoning from which the desired result can be inferred from the factual basis and c) proper disclosure. While the general principles had been laid down, their specific application had not been considered and a number of questions remained as to how the test would be applied, including the relevant date for assessing the soundness of the prediction.

In *Aventis*, the Court assessed sound prediction as of the Canadian filing date. In contrast, the Court in *Pfizer* used the priority date, meaning that the patentee could not rely on work performed post-priority date, but pre-filing date, to establish sound prediction. In addition, the standard for sound prediction remains uncertain given the differing findings based on arguably analagous evidence. Furthermore, the test for proper disclosure (the third element of the test for sound prediction) remains unclear, as the Court in *Aventis* adopted a high threshold holding that sufficiency of the disclosure of the patent generally and not of the prediction alone was required. The Judge in *Aventis* found that Aventis had failed on all three arms of the test for sound prediction. The Judge in *Pfizer* did not consider the three elements individually, dealing only with the broad question.

The two decisions also differ in the application of the presumption of validity with respect to an allegation of patent invalidity. In *Aventis*, the Judge stated the law was "well settled", relying on several Court of Appeal decisions. She determined that while Aventis had the overall burden of establishing that none of Apotex's allegations were justified, the statutory presumption of validity shifted the burden to Apotex to establish or prove that the patent was invalid on a balance of probabilites. In contrast, the Judge in *Pfizer* determined that Apotex had only to put the allegation of invalidity into "play", and once this was done the statutory presumption of validity was spent. Pfizer, accordingly, bore the burden of establishing that Apotex' allegation of invalidity was not justified.

Both decisions are under appeal.

Kavita Ramamoorthy

Supreme Court of Canada Leave Applications

AstraZeneca v. Apotex (**omeprazole (LOSEC, APO-OMEPRAZOLE)**), September 15, 2005

Leave has been denied. AstraZeneca had applied for leave to appeal a judgment of the Court of Appeal which dismissed AstraZeneca's appeal of a Judge's decision. The Judge had dismissed its application for judicial review of a Minister's decision to not require Apotex to make an allegation under the *Regulations* in respect of certain formulation patents. An earlier proceeding regarding an allegation of non-infringement involving the patents was dismissed. Subsequently, Apotex changed its formulation. However, the Minister decided that Apotex was not required to address the patents a second time. The Court of Appeal found that the Judge applied the correct standard of review in assessing the Minister's decision (reasonableness) and it was open to the Judge to find that the Minister had acted reasonably.

A subsequent Court of Appeal decision regarding different patents quashed Apotex's notice of compliance (NOC) on the basis of its interpretation of "marketed" in section 5(1) of the *Regulations*. However, this decision was stayed pending disposition of Apotex's application for leave to appeal to the Supreme Court of Canada, which remains pending.

Court of Appeal Decision (2005 FCA 58)

Applications Judge's Decision (2004 FC 1278)

Patented Medicines Prices Review Board (PMPRB) Matters

The PMPRB has accepted a Voluntary Compliance Undertaking (VCU) from Janssen-Ortho for norethindrone-ethinyl, estradiol (ORTHO 7/7/7).

VCU Notice

Recent Court Decisions

Patented Medicines (Notice of Compliance) Regulations

Aventis v. Mayne (**cefotaxime sodium (CLAFORAN)**), August 31, 2005

Judge allows Aventis' application for an Order of prohibition, finding that Mayne's allegation of invalidity on the basis of double patenting is not justified.

Full Judgment (2005 FC 1183)

Axcan v. Pharmascience (**ursodiol (URSO; pms-URSODIOL)**), September 12, 2005

Judge dismisses Axcan's application for a prohibition Order, finding that Axcan had not established that Pharmascience's allegation of non-infringement was not justified. The patent claimed use for the treatment of choestatic liver diseases, such as primary biliary cirrhosis. Pharmascience's product monograph stated that pms-URSODIOL is indicated for the dissolution of gallstones and specifically stated that Pharmascience's product is not approved for the management of cholestatic liver diseases.

Full Judgment (2005 FC 1231)

Apotex v. Roche and Syntex Pharmaceuticals International Limited (**naproxen slow-release tablets (NAPROSYN SR)**), September 26, 2005

Apotex had brought a claim for damages pursuant to section 8 of the *Regulations* against Roche and the patentee, Syntex Pharmaceuticals International Limited (SPIL). Following discovery of Apotex, the defendants brought a motion to strike SPIL on the basis of alleged admissions made by Apotex that it had no knowledge or information to support the allegations of control exercised by SPIL over Roche. Judge affirms Prothonotary's decision, dismissing the motion. Roche and Syntex have appealed.

Applications Judge's Decision (2005 FC 1310)

Prothonotary's Decision

Other Decisions

Merck and AstraZeneca v. Apotex (**lisinopril (PRINIVIL, ZESTRIL)**), September 13, 2005

Judge dismisses Apotex's motion to further amend its statement of defence and counterclaim to raise new validity attacks, close to the start of trial. Apotex has appealed.

Full Judgment

Ontario (Minister of Health and Long Term Care) v. Apotex, Cobalt, Pharmascience, and RhoxalPharma; Genpharm (intervenor) (**citalopram (CELEXA, GEN-CITALOPRAM, APO-CITALOPRAM)**), September 16, 2005

Ontario Court of Appeal dismisses appeals of the Minister and Genpharm on the basis of mootness. The Applications Judge had allowed applications by Apotex, Cobalt, Pharmascience, and RhoxalPharma for judicial review. The Judge quashed the Minister's extension of a cut-off date for completion of drug submissions for listing on the Ontario Drug Benefit Formulary/Comparative Drug Index (the "Formulary"), and thereby nullified the listing of Genpharm's product as the first new generic version to be listed on the Formulary. The appeal was dismissed as moot because in July 2004, the Minister published a new Formulary which included the products of all five drug companies.

Court of Appeal Decision

Applications Judge's Decision

Trade-mark Opposition Board Decisions

Biomune v. Matol Biotech Laboratories (**BIOMUNE OSF, application no. 877201; MATOL BIOMUNE OSF PLUS & Design, application no. 877202**), June 29, 2005

Board refuses Matol's applications to register the trade-marks BIOMUNE OSF, proposed for use in association with "food supplements destined to human containing a formula using a herb, colostrum and whey extract; nasal spray for humans; homeopathic preparations and remedies for humans for relief of the symptoms associated with the common cold, influenza, sinusitis, otitis media and similar conditions". BIOMUNE OSF PLUS & Design was proposed for use with similar wares. Biomune opposed registration of the applications on the basis of, among other grounds, confusion with its trade-mark, BIOMUNE, registered for use in association with "avian and animal vaccines". The Board refused registration of the trade-marks on the basis of confusion and lack of distinctiveness.

BIOMUNE OSF Decision

MATOL BIOMUNE OSF PLUS & Design Decision

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New Court Proceedings

Patented Medicines (Notice of Compliance) Regulations

Medicine: **levofloxacin (LEVAQUIN)**
Applicants: Janssen-Ortho Inc and Daiichi Pharmaceutical Co, Ltd
Respondents: Apotex Inc and The Minister Health
Date Commenced: September 2, 2005
Comment: Application for Order of prohibition until expiry of Daiichi's Patent No 1,304,080. Apotex alleges non-infringement and invalidity.

Medicine: **olanzapine (ZYPREXA)**
Applicants: Eli Lilly Canada Inc
Respondents: Novopharm Limited, The Minister of Health, and Eli Lilly and Company Limited
Date Commenced: September 8, 2005
Comment: Application for Order of prohibition until expiry of Eli Lilly and Company Limited's Patent No 2,041,113. Novopharm alleges non-infringement and invalidity.

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