Intellectual Property Weekly Abstracts Bulletin — Week of October 24

October 26, 2016

Patent Decisions

Patent anticipated by hearsay documents that met the test of necessity due to failure to comply with Federal Courts Rules
Gilead Sciences, Inc. v. Canada (Health), 2016 FC 856

The Federal Court dismissed Gilead's application for prohibition in respect to the combination drug TUVADA® covered in the '475 Patent. This combination drug is comprised of the drug VIREAD®, which is a medicine patented by the '619 Patent. In the companion case concerning the validity of the '619 Patent, the Court granted the prohibition application (see 2016 FC 857; our summary here). In the case at bar, Apotex alleged that the '475 Patent was invalid on the basis of anticipation, obviousness, lack of sound prediction of or demonstrated utility; infringement was conceded by not alleging non-infringement.

On the issue of expert blinding, the Court made the same comments as those in the companion case; the blinding issue is a question of relevance, reliability and weight, and is not a doctrinal matter.

On the ground of anticipation, the parties disagreed on the admissibility of certain documents put forward by Apotex. The Court found that the purported Press Release and the purported Conference Call Transcript were the most relevant documents to this proceeding. The Press Release states there would be a conference call and the Conference Call Transcript confirms the Conference Call took place before the key date for anticipation. The documents were both attached by Apotex to its NOA. Neither document was authenticated or introduced by affidavit or oral testimony of anyone associated with its preparation, nor was the truth of its contents deposed to by anyone associated with its preparation. As a result, Gilead objected to the reliance on both documents on the ground that they both constitute hearsay. The Court agreed that the documents were both hearsay, but held that the documents were admissible. When refusing to produce the documents, Gilead did not argue that the documents were not under its control, nor did it seek relief from production under Rule 94(2) of the *Federal Courts Rules*. Instead, Gilead unilaterally refused to make the required production under Rule 94(1). The Court found that Gilead's non-compliance with Rule 94(1) resulted in

the documents meeting the test of necessity. The documents were also found to be reliable and were admitted.

The Press Release was not found to disclose the invention, and therefore, not anticipate the ‘475 Patent. However, the Conference Call, as reflected in the Conference Call Transcript, was found to both disclose and enable the invention. The Court concluded that the '475 Patent was anticipated. Even though the patent was held to be anticipated, the Court still considered the other allegations of invalidity. Apotex's allegations of obviousness and obvious to try were successful, but its allegation of invalidity based on utility was not justified.

Amendments allowing a new defence of anticipation and issue estoppel are allowed in part
Alcon Canada Inc. v. Apotex Inc., 2016 FC 1055

The Federal Court has allowed Apotex to amend its statement of defence to include a new anticipation claim and a new defence of issue estoppel and abuse of process in part.

This is a ruling in a bifurcated infringement action scheduled to proceed to trial on November 27, 2017. This infringement action follows a prior PM(NOC) application between the parties.

Apotex moved to amend its statement of defence and counterclaim to add a new ground of invalidity by anticipation, a defence of ex turpi causa based on anti-competitive conduct, and two new defences based on the concepts of issue estoppel, abuse of process and the doctrine of election, arising from the prior prohibition proceedings commenced by Alcon in relation to the same patent and product.

The parties agreed the ex turpi causa defence relates solely to the quantification of damages, and thus it was adjourned to be addressed in the second half of the proceeding.

The new invalidity by anticipation defence alleges that the invention was disclosed to the public by Alcon during an annual conference, and in an abstract published at the conference. The Court held that the proposed amendments were sufficiently particularized and have a reasonable prospect of success.

The new allegations of issue estoppel, abuse of process and cause of action estoppel are based upon findings that were made in the prior PM(NOC) proceeding involving the same patent and parties. The delay in raising them was not found to be prejudicial, but the new defences would only be permitted to the extent that they raise an arguable defence.

The new allegation that Alcon is precluded from "contesting or making any allegation inconsistent with" Justice Kane's findings "that the patent is invalid on the basis of obviousness" was found to offend the Federal Court of Appeal's express ruling that cause of action estoppel in respect of the validity of a patent does not disclose a reasonable defence. Thus, this new pleading was not allowed.

The new defence of issue estoppel and abuse of process was allowed in part, with the Court striking the part stating that Alcon is precluded from "making any allegation inconsistent with" a prior finding of fact. That was held to preclude a party from leading evidence different from that led in the prior proceeding and cannot disclose an arguable defence.

The new defence of election was not allowed given the prior jurisprudence that both an application under the PM(NOC) Regulations and an infringement action can both be pursued. Furthermore, the jurisprudence provides that it is permissible to introduce in an action a better evidentiary record than on a prior prohibition proceeding between the same parties. Therefore, what prior art experts considered when considering obviousness was not held to be fixed by the prior PM(NOC) proceeding.

Supreme Court Updates

Amgen Canada Inc., Amgen Inc. v. Apotex Inc., Minister of Health (FC) (Civil) (By Leave) (37124)

On October 27, the Supreme Court will announce the result of a leave application which asks, in determining whether to hear moot appeals, should appellate courts apply categorical rules for certain classes of cases that will eliminate any right of appeal for entire class, or are courts required to exercise discretion on a case by case basis in accordance with the decision in *Borowski v. Canada*. The following summary was provided by the Supreme Court.

Intellectual property – Patents – Medicines – *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 – Appeals – Mootness – Federal Court dismissing Amgen's motion for order of prohibition and Minister issuing notice of compliance to Apotex to market generic version of Amgen's drug – Apotex bringing action for section 8 damages – Amgen appealing after issuance of notice of compliance – Apotex's motion to dismiss appeal as moot granted – In determining whether to hear moot appeals, should appellate courts apply categorical rules for certain classes of cases that will eliminate any right of appeal for entire class, or are courts required to exercise discretion on a case by case basis in accordance with decision in *Borowski v. Canada (Attorney General)*, [1989] 1 S.C.R. 342?

Amgen applied for an order under the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133("Regulations") prohibiting the Minister of Health from issuing a notice of compliance to Apotex for its generic version of Amgen's filgrastim pharmaceutical drug. The Federal Court dismissed this application and Amgen appealed that decision. Before the appeal could be heard, however, the Minister issued a notice of compliance to Apotex for its generic version of filgrastim. Apotex moved to dismiss the appeal on the ground that the subject-matter of the appeal was moot as there was no longer anything to prohibit.

AstraZeneca Canada Inc., AstraZeneca Aktiebolag, AstraZeneca UK Limited v. Apotex Inc., Apotex Pharmachem Inc.(Federal Court of Appeal) (Civil) (By leave) (36654)

On November 8, the Supreme Court is scheduled to hear AstraZeneca's appeal in its application which asks the correct applicable standard for patent utility in Canada and

whether a promised utility doctrine properly exists. The following summary was provided by the Supreme Court.

Intellectual property – Patents – Medicines – Utility – Validity of patent for drug used in treatment of gastric acid conditions challenged in infringement and impeachment action – Whether a promised utility doctrine properly exists – Whether lower courts erred in law in finding that the 653 patent invalid: (i) on the basis of a "promise of the patent" utility doctrine; and/or (ii) by applying an incorrect standard for patent utility.

The appellants, (collectively, "AstraZeneca") owned the Canadian '653 patent for the compound, esomeprazole, a proton pump inhibitor used in the reduction of gastric acid, reflux esophagitis and related conditions. It was sold under the name Nexium, and was a very successful drug for AstraZeneca. The respondents (collectively, "Apotex") applied to the Minister of Health to obtain a Notice of Compliance which would allow it to sell its generic version of the drug. In response, AstraZeneca brought a prohibition application under the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 to prevent Apotex from entering the market until after the expiry of the '653 patent. In 2010, that application was dismissed and Apotex received its Notice of Compliance and commenced sales of its generic esomeprazole. AstraZeneca brought an action against Apotex for patent infringement. Apotex counter-claimed to impeach the '653 patent on several grounds.

By

Chantal Saunders, Beverley Moore, Adrian J. Howard, Jillian Brenner

Expertise

Intellectual Property, Copyright, Licensing, Patents, Trademarks

---

Montréal

1000 De La Gauchetière Street West
Suite 900
Montréal, QC, Canada
H3B 5H4

T 514.954.2555
F 514.879.9015

Toronto

Bay Adelaide Centre, East Tower
22 Adelaide Street West
Toronto, ON, Canada
M5H 4E3

T 416.367.6000
F 416.367.6749