Intellectual Property Weekly Abstracts Bulletin — Week of April 25

April 28, 2016

Patent Decisions

The Federal Court of Appeal determines the incorrect date to assess obviousness-type double patenting, but leaves the determination of the correct date for another day
Mylan Pharmaceuticals ULC v. Eli Lilly Canada Inc., 2016 FCA 119
Drug: tadalafil

The Federal Court of Appeal has upheld an earlier decision (2015 FC 17) prohibiting Mylan from obtaining its Notice of Compliance until after the impugned patent expires. Mylan had alleged that Eli Lilly's patent was invalid on the basis of obviousness-type double-patenting and for lack of utility due to no sound prediction.

Three dates were considered as the correct date to assess obviousness-type double patenting: 1) The priority date of the first patent; 2) The priority date of the second patent; or 3) the publication date of the second patent. The Court of Appeal held that the third date is not appropriate. But, the Court of Appeal further held it was not necessary to determine the question of which of these remaining dates is the appropriate one, because on the facts of the case there was no double patenting.

Mylan's sound prediction allegation also failed, but the Court noted that even if it were successful it would not have affected the disposition of the appeal as it would not invalidate all of the claims in issue.

Other Decisions of Interest

Court orders Health Canada to issue a Product Licence Application for a Natural Health Product
Winning Combination Inc. v. Canada (Health), 2016 FC 381

The Plaintiff Winning Combination sought a Product Licence Application (PLA) for its natural health product RESOLVE, a smoking cessation aid. The Natural and Non-Prescription Health Products Directorate and its predecessor in Health Canada was said to have made two rejections: the first was a rejection based on safety and efficacy concerns; the second rejection a month later was made on the basis that it was not a

natural health product but rather a drug that should be regulated under the *Food and Drug Regulations*.

Winning Combination alleged those denials were a result of individual and institutional bias and bad faith in addition to the decisions being unreasonable and subject to procedural unfairness.

The Court held that the evidence showed a serious breach of procedural fairness in classifying this product as a drug without affording an opportunity to comment, especially after three prior classification decisions had found it was a natural health product. The subsequent removal of the active ingredient from the Dictionary of Natural Products list of natural substances was also done without notice or warning to the Plaintiff.

The Court also found procedural fairness concerns on the first decision relating to safety and efficacy, as well as questions as to the reasonableness of the decision.

Although there was a reconsideration process, the Court held that an administrative decision made in the absence of procedural fairness cannot be cured by a reconsideration process. Such a decision is *void ab initio*. In any event, the reconsideration process that was taken was also found to lack procedural fairness and showed evidence of a reasonable apprehension of bias.

In the end the Court quashed the refusals, ordered mandamus to grant a PLA within 30 days, and awarded full indemnity costs for the application.

Other Industry News

Health Canada has published a Notice on How Health Canada is managing safety updates when a serious health risk is identified under the Protecting Canadians from *Unsafe Drugs Act (Vanessa's Law)*.

Health Canada has published Notice of a Policy on Bioequivalence Standards for Highly Variable Drug Products.

Health Canada has published a Notice Regarding Dear Health Care Professional Letters for Notice of Compliance with Conditions.

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