WHEN A STATEMENT BECOMES A PROMISE: CANADIAN FEDERAL COURT OF APPEAL STUDIES "PROMISE DOCTRINE" IN CELECOXIB PATENT UTILITY FINDING

JASON MOSCOVICI*
ROBIC, LLP
LAWYERS, PATENT & TRADEMARK AGENTS

On October 30th, 2014, the Canadian Federal Court of Appeal dismissed two appeals brought by Mylan Pharmaceuticals ULC and Apotex Inc. ("Appellants"), heard jointly, in a decision that further clarifies the "promise doctrine" applied to patent validity cases involving the evaluation of utility. These appeals followed the Federal Court's granting of prohibition orders applied for by Pfizer Canada Inc and G.D. Searle & Co. ("Respondents"), as part of Canada's Notice of Compliance market approval process for patented medicines. The prohibition orders prohibit the Minister of Health from issuing market approvals (Notices of Compliance) to Appellants for generic versions of a drug containing Celecoxib, until expiry of a patent held by Respondents. **(**Apotex Inc. v. Pfizer Canada Inc., 2014 FCA 250)

FACTUAL BACKGROUND

The patent at issue is Canadian patent No. 2,177,576 ("'576") for Celecoxib, a molecule that is part of a family of pharmaceutical non-steroidal anti-inflammatory drugs (NSAIDS), used to help reduce inflammation. The `576 patent describes a new class of NSAID compounds and claims Celecoxib itself, as well as its use in a therapeutically effective amount.

The description of the '576 patent also addresses the common issue of side effects normally associated with NSAIDS and states that "(t)he compounds are useful as anti-inflammatory agents, such as for the treatment of arthritis, with the additional benefit of having significantly less harmful side effects". It is also stated in the description of this patent that the selectivity of the preferred compounds used in the patent "may indicate an ability to reduce the incidence of common NSAID-induced side effects". In addition, at least one of the claims is directed to the prevention of colorectal cancer.

* Lawyer with ROBIC, LLP, a multidisciplinary firm of lawyers, and patent and trade-mark agents. Published at (2015), 29:1 *World Intellectual Property Report* 41-42. Publication 142.287.

The Federal Court Decisions and the Promise Doctrine

At the Federal Court level, Appellants alleged that the patent did not deliver the promised results and is therefore invalid for lack of utility under Canada`s promise doctrine. Respondents argued that the patent did not make promises as to any specific results and that Appellants are wrong in asserting that the patented invention promises to 1) treat inflammation in Humans, 2) reduce side effects, and 3) prevent colorectal cancer.
The Federal Court judge sided with Respondents in both Federal Court cases. Under the *Patent Act* R.S.C., 1985, c. P-4, an invention must be useful. The threshold to meet this requirement has always been low. This utility is either shown to be demonstrated or can be soundly predicted at the patent's filing date. As such, a patent need only show more than a "scintilla of utility" to meet this threshold.

An exception to this is what is referred to as the "promise doctrine". An inventor is not required to describe the particular utility of its invention, but if a promise is made regarding a specific result, then the issued patent will be held to that promise in order to prove utility. The Federal Court Judge, in this case, specified that this higher standard applies only where it is clear and unambiguous that a promise has indeed been made and the Courts, when studying patent validity matters, have generally favored saving an invention rather than invalidating a patent due to ambiguity.

In its representations, the Appellants submitted that the patent lacks utility in treating inflammation in humans specifica lly, does not reduce side effects and lacks utility in preventing colorectal cancer.

It was argued that at the time of filing of the patent application, only a reduction of inflammation in rats could be demonstrated. Respondents submitted that once proper patent construction was applied, no "promise of (the) specific result" of treatment of inflammation in humans appears in the '576 Patent. Respondents further submitted that it was clear that treatment on humans was soundly predicted. The Federal Court judge found that since the '576 patent speaks to treating "a subject", this should be interpreted broadly to include both rats and humans and that utility was therefore demonstrated.

In support of the position that the patent lacked utility because it promised reduced side effects, Appellants argued that the description states that the compounds benefit from having significantly less side effects. Respondents put forward that no such promise could be found explicitly in the patent, which also contained statements that Celecoxib "may" be able to reduce side effects. The Federal Court judge once again sided with Respondents and found that uses that do not appear in the claim specification are mere statements of advantage, unless there is a clear and unequivocal promise.

Furthermore, pertaining to the promise of utility for colorectal cancer specifically, Appellants argued that any promise of treatment for colorectal cancer should apply to all claims found in the patent. The Federal Court judge held that different claims can relate to different promises and that not every promise needs to be construed as "overarching and inherent" to a patent's invention and to each of its claims. While this promise was found to have been made in at least one claim, the Federal Court judge found that this claim could be severed from the rest of the patent, thereby saving the patent.

The prohibition orders were therefore granted and the Minister of Health was precluded from issuing market approvals for generic versions of Celecoxib until expiry of the '576 patent, which expired in November 2014.
Appellants appealed these decisions and since both appeals followed the same lines of reasoning, they were heard together.

The Federal Court of Appeal's Analysis

The issue at bar in these appeals is whether or not the Federal Court properly determined i) that the patent did not make promises regarding specified results and ii) that the Appellants allegations of invalidity for failing to provide these results was unjustified.

As per the applicable standard of review in such matters under appeal, the Court separated its analysis into five categories: a) Utility in Treating Inflammation in Humans, b) Utility in Reducing Side Effects, c) Utility in Preventing Colorectal Cancer, d) Insufficiency of disclosure and e) Abuse of Process/*Stare Decisis*. As this decision is notable for its analysis of the utility requirements, we will only be discussing categories 1 to 3 above.

a) Utility in Humans

Regarding the question of the promise of treating inflammation in humans, the Court found that contrary to Appellants' representations, there was no clear promise of treatment in humans. The claims speak of "subjects" and no unequivocal language found in the description represents otherwise. The Court was therefore of the opinion that the Federal Court judge held correctly that the promise of the patent did not extend explicitly to humans.

b) Utility in Reducing Side Effects

On the question of the promise of reduced side effects, Appellants argued that the Federal Court judge erred in stating that for the promise doctrine to apply, a promise needs to be clearly and unequivocally stated in the patent. The Appellants put

forward that the '576 Patent did in fact promise reduced side effects, which Celecoxib does not provide.

The Court found that there was no such error and agreed with the Federal Court judge that a statement as to utility should be presumed to be just that, a statement, unless this statement is unequivocally presented as an advantage that is part of a promised utility. Then the statement becomes a promise. The Court agreed that any statements found in the description as to the reduction of side effects were "equivocal" and therefore since there was no clear promise, statements regarding reduction of side effects were just statements of advantages, not promises.

c) Utility in Colorectal Cancer

As briefly mentioned above, the Court agreed that noted promises should not necessarily be interpreted as applying to all the claims of the patent being construed. A lack of utility in one claim of the ‘576 Patent should not have an “automatic” impact on every other claim. Any claim not meeting an explicit promise can be severed from the rest of the patent, thereby saving the validity of the patent. The Court agreed with the Federal Court Judge that by and large, any promise found in a patent should not be read as applying to each and every one of the patent's claims. The Court recognized that certain promises may be overarching while at the same time, there is nothing to support the allegation that every promise must extend to each claim.

The appeal was therefore dismissed and the validity of the ‘576 patent was upheld.

Conclusion

This decision is relevant for its discussion of the principles applicable to the analysis of patent utility, more particularly relating to the “promise doctrine”. The Court clarified that this doctrine should only be applied when promises are clearly and unequivocally being made. This is not a new assessment of the promise doctrine but a clarification on the application of an already established legal approach. An equivocal statement of advantage found in the description of the patent, if not also found in the claim specification, is essentially just that: a statement of advantage. Furthermore, while claims should be held to any promises that may have been made, not every promise applies to each claim and claims failing to meet any such promise can be severed from the patent for not having the promised utility, thereby saving the patent, and the invention, from invalidity.

ROBIC + LAW + BUSINESS + SCIENCE + ART

ROBIC, LLP
www.robic.ca
info@robic.com

MONTREAL
1001 Square-Victoria - Bloc E - 8th Floor
Montreal, Quebec, Canada H2Z 2B7
Tel.: +1 514 987-6242 Fax: +1 514 845-7874

QUEBEC
2828 Laurier Boulevard, Tower 1, Suite 925
Quebec, Quebec, Canada G1V 0B9
Tel.: +1 418 653-1888 Fax.: +1 418 653-0006

ROBIC, LLP
www.robic.ca
info@robic.com

MONTREAL
1001 Square-Victoria - Bloc E - 8th Floor
Montreal, Quebec, Canada H2Z 2B7
Tel.: +1 514 987-6242 Fax: +1 514 845-7874

QUEBEC
2828 Laurier Boulevard, Tower 1, Suite 925
Quebec, Quebec, Canada G1V 0B9
Tel.: +1 418 653-1888 Fax.: +1 418 653-0006

ROBIC, LLP
www.robic.ca
info@robic.com

MONTREAL
1001 Square-Victoria - Bloc E - 8th Floor
Montreal, Quebec, Canada H2Z 2B7
Tel.: +1 514 987-6242 Fax: +1 514 845-7874

QUEBEC
2828 Laurier Boulevard, Tower 1, Suite 925
Quebec, Quebec, Canada G1V 0B9
Tel.: +1 418 653-1888 Fax.: +1 418 653-0006

ROBIC, LLP
www.robic.ca
info@robic.com

MONTREAL
1001 Square-Victoria - Bloc E - 8th Floor
Montreal, Quebec, Canada H2Z 2B7
Tel.: +1 514 987-6242 Fax: +1 514 845-7874

QUEBEC
2828 Laurier Boulevard, Tower 1, Suite 925
Quebec, Quebec, Canada G1V 0B9
Tel.: +1 418 653-1888 Fax.: +1 418 653-0006