At long last, the Supreme Court of Canada will hear a case involving the promise of the patent. The promise of the patent is a judge-made doctrine in which courts review the specification of a patent to determine whether the inventors have made a promise concerning the invention’s utility. If a court subsequently finds that the inventors made a promise, whether explicitly or implicitly, the patent will only have utility if that promise is fulfilled. Not surprisingly, the promise doctrine has become a very contentious matter, especially in pharmaceutical litigation, where numerous patents covering successful drugs have been invalidated as a result of the promise doctrine (see our previous discussion of the promise of the patent here and here). In a separate case, Eli Lilly & Co. has even taken the novel approach of suing the Government of Canada under the NAFTA rules after invalidation of their patents covering the drugs Strattera and Zyprexa (see our review here).

In the current case, the Supreme Court of Canada granted leave to appeal from the Federal Court of Appeal’s decision in AstraZeneca Canada Inc. v. Apotex Inc., 2015 FCA 158 (AstraZeneca). The Court of Appeal upheld the decision of the trial court where Justice Rennie held that AstraZeneca’s patent (CA2,139,653) covering the drug Esomeprazole (Nexium®) was invalid for lacking utility. Esomeprazole is a proton pump inhibitor, which is used in the reduction of gastric acid, reflux esophagitis and other related conditions. The trial court focused on one particular passage of the ’653 patent which stated that compounds of the invention “will give an improved therapeutic profile such as a lower degree of interindividual variation”. AstraZeneca characterized this statement simply as a goal that falls short of an explicit promise. To the contrary, Apotex argued that the statement was an explicit promise, and therefore, the data in the patent must demonstrate that the compounds in the patent, including Esomeprazole, “have an improved therapeutic profile”. The trial court carefully parsed the language in the impugned statement, focusing on the use of the word “will” as evidence that the statement should be characterized as having a high threshold of probable or certain outcomes that will occur. Accordingly, the trial court concluded that the above-noted statement constituted an explicit promise, and as a result, the data in the patent needed to support this heightened threshold of utility. Unfortunately for AstraZeneca, Justice Rennie subsequently found that the data in the patent could not support this promise. As a result, the trial court invalidated the patent for a lack of utility. The Court of Appeal subsequently upheld the trial judge’s decision.

Many cases involving the promise doctrine involve in the court reviewing the specification to determine whether simple words or statements by the inventor amount to a promise, or if the patentee is fortunate, simply a goal or an objective of the invention. For example, in Mylan Pharmaceuticals ULC v. AstraZeneca Canada Inc., 2012 FCA 109, the Federal Court of Appeal agreed with the trial judge that the phrase “It is a particular object of the present invention”, did not rise to the level of a promise. Likewise, in Pfizer Canada Inc., v. Mylan Pharmaceuticals ULC, 2014 FC 38, the Court analyzed the word “may” to determine whether a statement amounted to a promise. In some ways, the analysis by the courts with respect to the promise doctrine amounts to a grammatical exercise, focusing on words which have no real bearing on the utility of an invention.

In AstraZeneca, this will be the first time the Supreme Court of Canada hears a case specifically related to the promise doctrine. Hopefully, we will receive guidance as to whether the promise doctrine, which has resulted in the invalidation of numerous patents and which has no statutory basis, is valid law in the context of a utility analysis. Further, if it is found to be valid law, we hope that guidelines are provided regarding the construction of statements in a patent application related to the possible uses of the claimed invention, and what types of statements can and should be elevated to the level of a
promise under this law. The eyes of the pharmaceutical world have been focused on Canada for some time with respect to
the promise doctrine. We will look forward to a decision from the Supreme Court that is well-reasoned and which is fair to
all parties.