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Eli Lilly and Company v Government of Canada: Solidifying the Sovereignty of Canadian Courts

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Recently, a Chapter 11 NAFTA tribunal (the "**Tribunal**") decided not to interfere with the Canadian Courts' treatment of utility in the context of patent law. The Tribunal noted that Canadian patent law had not experienced a dramatic shift through the Canadian Courts' treatment of utility, and that the application of utility in Canada was neither arbitrary nor discriminatory.

This ruling means that patentees and prospective patentees in Canada should be mindful of the developments in the law, not only when applying for and prosecuting patent applications, but also when managing portfolios and assessing future risks either in the day-to-day operation of the business or in the context of a commercial transaction.

Under the Patent Act in Canada, an invention must be new and useful to be patentable. Utility of an invention can either be demonstrated or soundly predicted. Canadian Courts have, moreover, clarified such requirements through the promise utility doctrine,[1] which Eli Lilly and Company ("Eli Lilly") challenged before the Tribunal after the Supreme Court of Canada refused leave to appeal of two of Eli Lilly's patent invalidations for lack of utility (Zyprexa Patent and Strattera Patent). Eli Lilly claimed over CDN$500 million in damages. On March 16, 2017, however, the Tribunal dismissed Eli Lilly's claims. In doing so, it made several consequential remarks.

(1) Deference to National Courts

According to the Tribunal, NAFTA Chapter 11 tribunals should grant national courts considerable deference:

> "…a NAFTA Chapter Eleven tribunal is not an appellate tier in respect of the decisions of the national judiciary. It is not the task of a NAFTA Chapter Eleven tribunal to review the findings of national courts and considerable deference is to be accorded to the conduct and decisions of such courts. It will accordingly only be in very exceptional circumstances, in which there is clear evidence of egregious and shocking conduct, that it will be appropriate for a NAFTA Chapter Eleven tribunal to assess such conduct against the obligations of the respondent State under NAFTA Article 1105(1)." [para 224]

In clarifying its special role, the Tribunal reaffirmed the importance of the patent application process in Canada. This means the law on utility in Canada remains the same and prospective patent applicants should put their best foot forward in the initial application.

(2) No Dramatic Shift in Utility

The Tribunal acknowledged that Canadian patent law experienced incremental and evolutionary changes between the time that the two patents in question were granted and invalidated, but ultimately reasoned that Eli Lilly failed to demonstrate that Canadian patent law experienced a fundamental or dramatic change and was applied in a manner that violated Eli Lilly's legitimate expectations. The Tribunal reasoned that the Canadian case law, in comparison to other jurisdictions and other evidence Eli Lilly presented, demonstrated a progressive development in the law and that Eli Lilly's perception that the utility requirement was a low threshold was insufficient to amount to a legitimate expectation.[2]

(3) Utility Application Is Neither Arbitrary Nor Discriminatory

The Tribunal rejected Eli Lilly's claims that the promise of utility doctrine was arbitrary and discriminatory, noting at paragraph 430 that "the Tribunal will not question the correctness of the policies or the courts' decisions." According to the Tribunal, examples of courts reaching inconsistent determinations, generic drug manufacturer submissions and other evidence do not mean that Canadian Courts arbitrarily apply the promise of utility doctrine, especially when there are legitimate public policy justifications. And, the fact that the world's largest pharmaceutical companies are not Canadian and that foreign pharmaceutical companies have experienced most of the patent invalidations in Canada does not mean that the promise utility doctrine discriminates against foreign patent holders. In doing so, the Tribunal reaffirmed its earlier statements that it will give domestic courts deference, especially in the absence of a fundamental or dramatic change in the law.

(4) Costs

Relying on the loser pays principle, the Tribunal ordered Eli Lilly to pay US$5,198.323.29, comprised of US$749,697.97 in arbitration costs, including the Tribunal's fees and expenses, ICSID's administrative fees and direct expenses, and 75% of the Government of Canada's costs of legal representation and assistance, amounting to US$4,448,625.32, on the grounds that the Government of Canada prevailed on the merits but not on jurisdiction. In doing so, the Tribunal helped to solidify the importance of presenting a comprehensive patent application from the start because challenging a judicial decision through a NAFTA Chapter 11 tribunal can be expensive, especially if it does not result in the desired outcome.

A copy of the decision is available here.

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[1] Three elements of the promise utility doctrine challenged by Eli Lilly were:

"(i) the identification of a "promise" in the patent disclosure, against which utility is measured; (ii) the prohibition on the use of post-filing evidence to prove utility; and (iii) the requirement that pre-filing evidence to support a sound prediction of utility must be included in the patent." [para 313 of the award]

[2] The Tribunal reasoned:

"the evidence before the Tribunal shows that Canada's utility requirement underwent incremental and evolutionary changes between the time that the Zyprexa and Strattera Patents were granted and then invalidated, in particular during the six-year period that Claimant highlights (2002-2008). Over those years, there was an increase in the number of utility-based challenges of pharmaceutical patents, which appears to have increased the pace of the development of the law most relevant to that sector. The Tribunal also sees that each of the three rules that Claimant considers part of the promise utility doctrine has a reasonably solid foundation in prior authority, even if there is a question about the extent to which that prior authority was applied in practice." [para 386 of the award]

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