

Sound Prediction in Canada: The Promise is Still Important

By Beverley Moore and Chantal Saunders Borden Ladner Gervais LLP.



In recent years, much has been written and discussed regarding patents for blockbuster drugs being invalidated in Canada for lacking utility. When faced with an invalidity challenge involving the utility of the patent, Canadian Courts first construe a “promise” from the patent. The Courts then decide whether that promise has been demonstrated as of the filing date of the patent, or whether the patentee must

rely on a sound prediction of utility in fulfilling the promise. If the promised utility is demonstrated as of filing, the inutility challenge fails. The Courts seem to accept that proof of that utility need not be in the patent.

However, if the patentee needs to rely on the sound prediction of utility, the Court moves on to a further test: 1) identify the factual basis for the prediction; 2) determine whether there is a sound line of reasoning from the prediction to the promise of utility; and 3) decide whether the factual basis and the line of reasoning are properly disclosed in the patent specification. Thus, it is not about whether a patent teaches how to make and use the invention. Without

disclosure of the factual basis and sound line of reasoning, the inventor is seen to be giving nothing to the public in exchange for the monopoly.

The construction of the “promise” is often the key to this discussion. The Courts pick through all of the language in the specification when looking for the “promise”. Many of the invalidated patents resulted from this standard. The promise in some of these earlier cases has been held to be treatment of a chronic disease in humans; long term treatment of a disease in humans; all of the stated advantages in the patent; and a reduction in side effects. With these types of promises, even clinical data in the patent was often held not to



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be sufficient to help meet the sound prediction test.

However, the Courts have started to recognize that the “promise” is different from the advantages and mere statements of a practical purpose. Furthermore, the Court allows different claims to have different promises. In particular, compound claims, process claims, use claims, and claims to medicaments containing compounds all have been held to have different promises when considering inutility allegations. In addition, the Courts have also recognized that a patent may not contain a specific promise. In such situations, a mere scintilla of utility is all that is required (however, no such situations have actually been found by the Court to date). Finally, there may be recognition from the Courts that the disclosure element of this test can be met by taking into account the

common general knowledge of the person skilled in the art.

Thus, it appears that the pendulum may be swinging back towards centre when it comes to patentees trying to uphold their patents in Canada. While the “promise” doctrine is still something that patentees do not have to contend with in other countries, an invalidity challenge based on inutility may not be the “crushing hammer” that it used to be. Patents covering drugs are being upheld in the face of such challenges, when the “promise” is construed reasonably, and the patentee has made appropriate disclosures.

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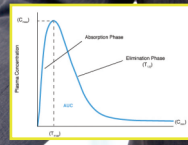

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