Canada’s Utility Requirement for Patentability – Looking for Good News for the Innovative Pharmaceutical Industry

November 6, 2013
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Background

To be patentable in Canada, an invention must not only be new and non-obvious, it must also have utility.1 As evidenced by Eli Lilly’s recent filing of a Notice of Arbitration in a $500 million NAFTA2 dispute against Canada for the invalidation of two of its patents covering its key drug products, Strattera and Zyprexa, on the basis of lack of utility3, it is clear that the issue of utility is currently a controversial subject at the forefront of the Canadian patent law.

The utility requirement may be met by either demonstrating that the invention possesses the claimed utility or by relying on sound prediction. In either case, it has been established that the relevant date for determining utility is the Canadian filing date. Accordingly, post-filing evidence and/or knowledge is not presently of assistance for establishing utility.

Two sub-issues emerge upon review of the case law from the past 10 years related to utility of a claimed invention. These two sub-issues are (1) the doctrine of the promise of the patent and (2) the doctrine of sound prediction. One of the bases for Eli Lilly’s claims in its NAFTA challenge against Canada, is that the courts have established a “heightened disclosure requirement” for utility and, in their reasons, Lilly refers to these two doctrines.

Often cited as the case for the basis of the doctrine of the promise of the patent is the Supreme Court of Canada (SCC) decision in Consolboard Inc v MacMillan Bloedel5, “Consolboard”, in which it stated on page 525:

There is a helpful discussion in Halsbury's Laws of England, (3rd ed.), vol. 29, at p. 59, on the meaning of "not useful" in patent law. It means "that the invention will not work, either in the sense that it will not operate at all or, more broadly, that it will not do what the specification promises that it will do".

A more recent citation, Eli Lilly Canada Inc v Novopharm Limited6, “Olanzapine”, is also frequently referred to when addressing the promise of a patent in a utility analysis. In that decision, the following passage at paragraph 76 is often quoted:

Where the specification does not promise a specific result, no particular level of utility is required; a "mere scintilla" of utility will suffice. However, where the specification sets out an explicit "promise", utility will be measured against that promise: Consolboard; Pfizer Canada Inc. v. Canada (Minister of Health), [2009] 1 F.C.R. 253, 2008 FCA 108 (Ranbaxy). The question is whether the invention does what the patent promises it will do.

The seminal case for citations related to the doctrine of sound prediction is Apotex Inc v Wellcome Foundation Ltd7, “AZT”, in which the SCC confirmed that utility may be based upon a sound prediction so long as there is a factual basis for the prediction, the inventor has an articulable and sound line of reasoning from which the desired result can be inferred from the factual basis, and there is proper disclosure. However, as it was not at issue in the case, the SCC did not set out what is necessary to satisfy the requirement of "proper disclosure". Subsequent decisions of the Canadian Federal Court of Appeal (FCA) appeared to hold that the factual basis and the sound line of reasoning9 must be found in the patent itself.
While many reports tend to focus on the bad news, this article attempts to highlight some recent cases where helpful clarifying statements have been presented that may help patentees defend their inventions with the Canadian Patent Office as well as in Canada’s Courts.

Recent Cases

The recent decision of the FCA in *Sanofi-Aventis v Apotex Inc*, “Plavix II”, provides some good news on both the promise of the patent and the sound prediction fronts. As we previously reported, the Federal Court initially found Sanofi’s Canadian Patent No. 1,336,777 (the ‘777 Patent) invalid, holding that the utility of the invention had neither been demonstrated nor soundly predicted as of the filing date of the patent application.

On appeal, the FCA concluded that the Federal Court erred in reading into the ‘777 Patent a promise for use in humans on the basis of inferences and ultimately found that the ‘777 Patent was valid. Particularly helpful are the following comments at paragraph 50 by Justice Pelletier:

… it should not be taken to have assumed that every patent contains an explicit promise of a specific result since, subject to what is said below with respect to selection patents, there is no obligation on the part of the inventor to disclose the utility of his invention in the patent.

Further, *Plavix II* referred to earlier decisions that emphasized that, by simply alluding to the possibility of a result, for example, by reference to specific advantages or goals, does not necessarily mean that “the inventors were … promising that this result had been or would be achieved”.

In a very recent decision from the Federal Court, Justice Hughes reiterated this opinion:

The list of “advantages”, commencing at page 9 and over to page 10, has previously been set out in these Reasons. That list should not be elevated to a “promise”; it is simply an observation as to advantages expected to be achieved.

While the major issue with respect to the utility analysis in *Plavix II* related to the controversial “promise of the patent” doctrine, the concurring reasons of Justice Gauthier are also noteworthy for their comments on sound prediction disclosure requirements, suggesting that these requirements may differ depending on the subject-matter claimed in the patent. For example, at paragraphs 134-135 of the decision, Justice Gauthier states:

In contradistinction with the situation in *AZT*, where the invention claimed was the new use/utility and thus the quid pro quo for the grant of the monopoly was a full disclosure in respect of such utility, the public here received all the information necessary to make and use clopidogrel, the invention claimed in the ‘777 Patent. …

In such a case, the level of disclosure required by law should be lower. …

In other words, Justice Gauthier seems to suggest here that the level of disclosure required to support the utility of a new compound should be less than that to support a new use. As noted by Justice Gauthier, this is in line with the seminal sound prediction case, *AZT*, where Justice Binnie stated at paragraph 56:

Where the new use is the gravamen of the invention, the utility required for patentability (s. 2) must, as of the priority date, either be demonstrated or be a sound prediction based on the information and expertise then available. …

Another recent decision of the FCA also suggested that a more contextual approach to determining what is necessary to satisfy the requirement of “proper disclosure” is being developed. In *Bell Helicopter Textron Canada Limitée v Eurocopter, société par actions simplifiée*, “Eurocopter” it was held that:
... where the sound prediction is based on knowledge forming part of the common general knowledge and on a line of reasoning which would be apparent to the skilled person (which is often the case in mechanical inventions), the requirements of disclosure may readily be met by simply describing the invention in sufficient detail such that it can be practiced. A contextual approach is thus appropriate in each case.

Regarding this contextual approach, the decision of the FCA in Eurocopter went further and suggested that the requirements for sound prediction in a particular case will be dependent on the determination of who the skilled person is and what is their common general knowledge:

... the factual basis, the line of reasoning and the level of disclosure required by the doctrine of sound prediction are to be assessed as a function of the knowledge that the skilled person would have to base that prediction on, and as a function of what that skilled person would understand as a logical line of reasoning leading to the utility of the invention.

Going even further, the FCA in Eurocopter provided that, if the factual basis can be found in the common general knowledge of a person skilled in the art, it also does not necessarily need to be disclosed in the patent:

Where the factual basis can be found in scientifically accepted laws or principles or in information forming part of the common general knowledge of the skilled person, then no disclosure of such factual basis may be required in the specification.

The Federal Court in Teva Canada Limited v Novartis AG also stated that the common general knowledge of a person skilled in the art can be used to bridge a “gap” in the disclosure between a factual basis provided in the patent and the prediction of the inventor, so long as the patent provides more disclosure than the prior art.

The holdings in Imatinib and Eurocopter are generally in line with the stated position of the Canadian Patent Office, which, in its Manual of Patent Office Practice, “MOPOP” suggests that elements of the factual basis and/or the sound line of reasoning forming part of the common general knowledge of a skilled person do not need to be explicitly disclosed in an application.

While the majority of the claims at issue in Eurocopter ultimately failed to meet the sound prediction disclosure requirements, this case, along with Imatinib, provide validity to the argument that the disclosure requirement for sound prediction can be met by relying on the knowledge of a person skilled in the art, when the technology allows.

Summary

The statements found in the cases referred to above regarding disclosure requirements for sound prediction as well the impropriety of improperly using the Applicant’s own disclosure to make inferences that result in a heightened level for the promise of the patent, provide some hope and good news for innovative pharmaceutical patentees in Canada. This is most welcome in a time which has seen a considerable amount of bad news when it comes to upholding the validity of pharmaceutical patents in court challenges and we hope signals a move to a more moderate approach.

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6 Eli Lilly Canada Inc v Novopharm Limited, 2010 FCA 197.
8 Eli Lilly Canada Inc v Apotex Inc, 2009 FCA 97.
9 Apotex Inc v Pfizer Canada Inc, 2011 FCA 236.
10 Sanofi-Aventis v Apotex Inc, 2013 FCA 186.
12 Apotex Inc v Sanofi-Aventis, 2011 FC 1486.
14 Plavix II confirmed that selection patents must set out an explicit promise because both “the novelty of the selection and its advantages (including disadvantages to be avoided) are the invention and must be described in the patent”. Plavix II at para 51.
15 For example: AstraZeneca Canada Inc v Mylan Pharmaceuticals ULC, 2011 FC 1023 at para 139; Pfizer Canada Inc v Mylan Pharmaceuticals ULC, 2012 FCA 103 at para 61; and Mylan Pharmaceuticals ULC v Canada (Minister of Health), 2012 FCA 109 at paras 32-33.
16 Plavix II at para 67.
17 Bayer Inc v Cobalt Pharmaceuticals Company, 2013 FC 1061.
18 Ibid at para 152.
19 Bell Helicopter Textron Canada Limitée v Eurocopter, société par actions simplifiée, 2013 FCA 219. This decision is also of interest for its holding that the doctrine of sound prediction can apply to the field of mechanical inventions and is not limited to pharmaceutical inventions (See Eurocopter, para 146).
20 Ibid at para 155.
21 Ibid at para 152.
22 Ibid at para 153.
23 Teva Canada Limited v Novartis AG, 2013 FC 141.
25 See, for example: MOPOP, § 12.08.04.

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