Claims that Involve a Fixed Dosage and Schedule Can Constitute Patentable Subject Matter

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The Canadian Intellectual Property Office (CIPO) has just issued a revised guidance for the examination of patent applications featuring medical use claims following the recent

Federal Court decision *AbbVie Biotechnology Ltd.* v. *The Attorney General of Canada* (PDF) *("AbbVie")*. The revised guidance supersedes the previous practice notice published on June 10, 2013.

It is well established that methods of medical treatment and surgery are not statutory subject matter and are excluded from the definition of *invention*. Medical use claims are generally permitted as long as they do not equate to medical or surgical methods. However, a number of jurisprudential interpretations have concluded that certain types of medical use claims, including dosage regimens and dosage ranges, fall outside the scope of section 2 of the *Patent Act* and are not patentable.

In *AbbVie*, the appellant contested the Commissioner's finding that claims were not patentable under section 2 of the *Patent Act* because they were directed to methods of medical treatment[1]. The Federal Court considered the case law on the issue. Its review revealed that the principles from the jurisprudence demonstrate that the Courts have consistently found that a claim directed to the exercise of professional skill or judgment is not patentable, whereas a claim directed to a fixed dosage and a precise scheduling regime and which does not involve the exercise of a discretion or skill on the part of a professional is patentable. However, the Court also warned that, just because a claim involves a fixed dosage and schedule, it does not mean that it is automatically patentable, nor does it mean that such claim constitutes unpatentable subject matter. The Court indicated that the fixed dosage and schedule *may be* a good signal or starting point, but the evidence about this claimed dosage regime and schedule may indicate that it is not exactly as it is claimed and that adjustments, requiring skill and judgment, are needed. Therefore, a claim which does not restrict, or interfere with, or otherwise engage professional skill or judgment – including a claim for a fixed dosage and/or a fixed dosage schedule or interval – is not impermissible subject matter where there is no evidence to contradict this claimed dosage. In its judgment, the Federal court sided with *AbbVie Biotechnology Ltd. and found that* the medical use claims were patentable because they covered a vendible product, and they did not restrict a physician's choice or skill that would be relied on, at the outset, to determine whether this vendible product should or should not be prescribed.

In considering the recent *AbbVie* decision, the revised guidance reinforces the importance of purposive claim construction when assessing patentability of claims that recite a dosage regimen or dosage range since the mere recitation of either of these does not *necessarily* mean that the claim is non-statutory. The revised guidance indicates that, if it is determined after a purposive construction that a dosage range, or dosage regimen that includes a range, is an *essential element* of a claim encompassing the use of a known compound in an established treatment, then the claim *may* cover a method of medical treatment. Where an essential element only serves to instruct a medical professional "how" to treat a patient, rather than "what" to use to treat the patient, it must be determined whether the essential element prevents, interferes with or requires the professional skill of a physician. If the answer is "yes", this will lead to the conclusion that the claimed use encompasses a method of medical treatment that does not comply with section 2 of the *Patent Act*.

The revised guidance further sheds light as to which elements might be essential in this analysis. Essential elements that point to a limitation of a physician's professional skill or judgment include those that provide details of a dosing schedule encompassing a range and those that represent a range of potential dosages that a patient may receive (as distinct from a range of dosage forms). In contrast, essential elements that narrow treatment to a fixed dosage, a fixed dosage regimen, a patient sub-population or to a particular administration site are not considered to point to a limitation of a physician's professional skill or judgment.

Comments: The *AbbVie* decision is good news for the pharmaceutical industry. By recognizing the patent eligibility of claims that involve a fixed dosage and/or a fixed dosage schedule or interval, the Federal Court confirms that the current Canadian patent system provides means to pharmaceutical companies to protect their discoveries so they can recoup their investment in the search for new therapeutics. This is in accordance with what is currently patentable in other industrialized countries. The revised guidance provides clear instructions to Canadian examiners on how to approach medical use claims and determine whether such claims are eligible for patent protection. To maximise chances of patentability, medical use claims should not include elements that point to a limitation of a physician's professional skill or judgment.

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[1] There was no dispute about the constructions of the claims. The essential elements are: a preloaded syringe of 40 mg of the drug Humira™ (anti-human TNFα antibodies) for the treatment of arthritic disease or an inflammatory bowel disease; administered subcutaneously; for use on an every other week dosing interval of 14 days (i.e., bi-weekly).