Recent developments on patent-eligibility of medical use claims in Canada

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Last December, the Federal Court of Canada overturned a decision of the Commissioner of Patents to refuse a patent claiming a fixed dosage regimen for the drug Humira® (Adalimunab) used in rheumatoid arthritis. The Court's decision [1] is found here: 2014 FC 1251.

This Court decision was an appeal of Decision No. 1362 of the Commissioner of Patents ("the Commissioner"), refusing to grant Canadian Patent Application No. 2,385,745 ("the '745 application") to AbbVie Biotechnology Ltd. ("AbbVie") on the grounds that the claims at issue encompass an unpatentable method of medical treatment.

The claims at issue, relating to the use of Humira® as a treatment using a fixed dosage (40 mg) on a fixed (bi-weekly) schedule, were deemed to be patentable by the Federal Court.

Patent Appeal Board (PAB) Proceedings – Commissioner's Decision

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Before the PAB, AbbVie argued that because the claims defined a fixed dose and a fixed dosing schedule, they avoided the exercise of skill or judgment of a medical professional, and thus related to patentable subject matter. However, the PAB interpreted the case law, notably the decision of *Janssen Inc. v Mylan Pharmaceuticals ULC* [2] (*Janssen*), as having established the rule "that the mere presence of these two features [i.e., a fixed dosage and fixed dosing schedule] in a claim is not always sufficient to avoid the method of medical treatment prohibition", and asserted that the claims at issue, by placing restrictions on "how and when" the drug is to be administered, would interfere with the ability of physicians to exercise their judgment in the administration of Humira® when generic versions of this drug become available. The PAB thus concluded that the claims encompassed an unpatentable method of medical treatment. The Commissioner adopted the PAB's recommendation, and issued a decision confirming the refusal to grant the '745 application.

Federal Court Decision

AbbVie was successful upon appeal of the Commissioner's Decision to the Federal Court of Canada, Trial Division. Justice Kane of the Federal Court acknowledged that the prohibitions against claims to methods of medical treatment and to claims relating to the exercise of professional skill have been consistently applied by Canadian Courts. However, Justice Kane remarked that such decisions are based on the specific facts of each case. Justice Kane referred to three decisions, *Merck & Co Inc v Apotex Inc.* [3], *Merck & Co. Inc. v Pharmascience Inc.* [4], and *Bayer Inc. v Cobalt Pharmaceuticals Company* [5], in which claims comparable to AbbVie's claims had been found to be patent-eligible on the basis that if no professional skill or judgment is involved, the claimed invention is not a method of medical treatment.

The Court noted that the Commissioner overlooked the specific facts of *Janssen*, more particularly that the *Janssen* claims involved a dosage range with several variables, and a known approach (a titration regimen), requiring a physician to monitor the patient and make adjustments. Therefore the Commissioner's reliance on the *Janssen* case was not warranted.

The Federal Court thus drew a clear distinction between cases where professional skill and judgment is exercised, for example where adjustments by the physician would be required, and those where no adjustments and therefore no professional skill and judgement are required, such as in this case where the claims recite a fixed dosage on a fixedschedule.

Revised Examination Guidelines

Taking into consideration the Federal Court Ruling, the Canadian Intellectual Property Office recently issued revised Examination practice guidelines [6] and examples of patent-eligible and patent-ineligible medical use claims [7], confirming that claims reciting features that do not involve a physician's professional skill or judgment, such as a fixed dosage, a fixed dosage regimen, a patient sub-population or a particular administration site, are patent-eligible.

Conclusion

This decision and the new practice guidelines provides a welcome clarification on the patent-eligibility of claims involving dosage regimens, and indicates that medical use claims that do not entail professional skill and judgment, including those defining fixed dosages and/or dosing schedules, constitute patent-eligible subject matter under Canadian Patent law.

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Patent applicants would be well advised to consider this important change to Canadian patent practice when seeking patent protection in Canada.

1. *AbbVie Biotechnology Ltd. v Canada (Attorney General)*, 2014 FC 1251.
2. 2010 FC 1123.
3. 2005 FC 755.
4. 2010 FC 510.
5. 2013 FC 1061.
6. PN 2015-01, issued March 18, 2015
7. Examples of purposive construction analysis of medical use claims for statutory subject-matter evaluation, http://www.ic.gc.ca/eic/site/cipointernet-internetopic.nsf/eng/wr03919.html, issued March 31, 2015

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