IS YOUR MEDICAL TREATMENT CLAIM MORE PATENTABLE NOW? HINT: A LITTLE

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In the pharmaceutical field, when both the molecule and the use are known and the invention is only about the administration mode or the dosage range, it might be difficult to get a patent in Canada.

In fact, *The Patent Act* defines an "invention" in section 2 as:

> any new and useful art, process, machine, manufacture or composition of matter, or any new and useful improvement in any art, process, machine, manufacture or composition of matter.

Case law has excluded medical methods of treatment on the human or animal body from this definition, on the grounds that they were not processes and that they would compromise the work of healthcare professionals and therefore would also compromise the patient care. More particularly, claims which describe an active step of surgery or of administration and/or provide a therapeutic benefit are rejected, whereas claims directed to cosmetic or diagnostic methods, or related to natural states considered non pathological like pregnancy, baldness, wrinkles and ageing are allowed.

These claims had to be replaced with use claims, without any step of administration:

- Use of product X for treating disease Y;
- Use of product X for the manufacture of a medicament for treating disease Y;
- Product X for treating disease Y.

However, when the claims describe a dosage range or a range of administration, they are rejected if a healthcare professional must not only decide whether or not to prescribe a treatment to a patient ("what"), but must also exercise professional judgement ("how": what dosage, for how long, according to the patient's profile and his response to treatment). Case law requires that the dosage and the calendar of administration be fixed. To obtain patentable claims, sometimes many claims must be drafted, each with a specific dosage and calendar, such as:

> Claim 1: 10mg for 10 days, then 20mg for 5 days

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Claim 2: 10 mg for 5 days, then 20mg for 10 days.

In the judgement of January 20th 2015 of *AbbVie Biotechnology Ltd v. Canada* [2014 FC 1251], the Federal Court overturned the Commissioner's decision to reject the patent application 2,385,745 on the grounds that the claims were directed towards methods of treatment, with an indeterminate period of administration, and ordered rather that the claims be amended to become patentable before being sent to the examiner. The patent was issued February 17th 2015 with the following claim 13, in the form of use and an administration every two weeks:

> 13. Use of an isolated human anti-TNFα antibody wherein said antibody (a) comprises a light chain variable region (LCVR) comprising a CDR3 domain comprising the amino acid sequence of SEQ ID NO: 3, a CDR2 domain comprising the amino acid sequence of SEQ ID NO: 5, and a CDR1 domain comprising the amino acid sequence of SEQ ID NO: 7; and (b) comprises a heavy chain variable region (HCVR) comprising a CDR3 domain comprising the amino acid sequence of SEQ ID NO: 4, a CDR2 domain comprising the amino acid sequence of SEQ ID NO: 6, and a CDR1 domain comprising the amino acid sequence of SEQ ID NO: 8; in the manufacture of a medicament for treating an arthritic disease or an inflammatory bowel disease in a human subject, wherein said medicament is adapted for subcutaneous administration and wherein the dosage is 40 mg according to a continuous schedule having an every other week dosing interval of 14 days.

The CIPO has prepared practice notice PN 2015-012 [http://www.ic.gc.ca/eic/site/cipointernet-internetopic.nsf/eng/wr03916.html] for examiners following the Federal Court's decision and also provided some examples [http://www.ic.gc.ca/eic/site/cipointernet-internetopic.nsf/eng/wr03919.html]. If the claim's purpose is to answer the "what", as in what is needed to treat a patient (a compound, a molecule, a composition, a formulation, a dosing unit, a sub-population of patients, a distinct population of patients), it's patentable. If the claim's purpose answers the "how", and informs the medical professional as to how to treat the patient (a dosage range, a large/vague administration calendar) requiring both his professional skills and judgement, the claim is not patentable.

In conclusion, the claim must describe the use of a saleable and isolatable product as much as possible. The patent agent community welcomes this decision with relief, since a growing number of inventions consist precisely in new dosages and/or administration calendars, and it is unfortunate to see these inventions be protected all around the world, yet not in Canada. This decision represents a step in the right direction.

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