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Patenting Dosage Regimes in Canada: The Patent Office Loosens its Reins

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Overview

Similar to Europe, methods of medical treatment are generally not considered patentable subject matter in Canada.[1] Usually converting a method of medical treatment claim into such formats as "Use of compound X to treat disease condition Y" (standard Canadian format) or "Use of compound X in the manufacture of a medicament to treat disease condition Y" (Swiss-type) is sufficient to achieve allowance. However, there are instances when the inventive subject matter resides in a new treatment regime, or a dosage that is particularly effective and the line between what is patentable and what is not becomes less clear. Below are some approaches that can be taken in an effort to secure allowance of claims in these circumstances.

What is considered statutory subject matter?

At the outset it should be appreciated what the Canadian Patent Office considers statutory subject matter. The Patent Office often takes a tough stance that medical use claims directed to "how" rather than "what" are methods of medical treatment and therefore not patentable.[2] Two practice notices (PN 2015-01 and PN 2013-04) were published by the Canadian Patent Office that set forth what constitutes eligible subject matter. Generally, where a claim feature in question 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 feature prevents, interferes with or requires the professional skill and judgement of a physician.

Examples of claims that recite subject matter considered patent eligible are provided below:

Examples of claims considered statutory as per PN-2013-04:

- Use of a 100 mg dose unit of X to treat Y.
- Use of, first, 8 mg/day of X for 4 weeks, followed by 16 mg/day of X for 4 weeks, and finally 24 mg/day of X for the remainder of the treatment, to treat Y.
- Use of a dosage formulation of 70 mg of X, for weekly administration, to treat Y.
- Use of a 10 mg dosage unit of X to treat Y on a 3-5 week administration schedule.

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[1] Details of what is considered patent eligible subject matter in Europe can be found at the following link: https://www.epo.org/law-practice/legal-texts/html/guidelines/e/g_ii_4_2.htm

[2] As set out in *Abbvie Biotechnology Ltd. v The Attorney General of Canada*, 2014 FC 1251.

Notably, the above examples all encompass fixed dosages or a combination of fixed dosages and fixed time points of administration. The Patent Office takes the position that a range of doses in a treatment regimen relates to "how" since a medical professional must calculate the particular dose to administer to a patient within the range, notwithstanding that such dose can easily be determined based on the weight of an individual. When a claim might be considered directed to "how" instead of "what", a look at the particular facts at issue in the case must be investigated to obtain allowance of a claim.

Positive Developments

The tough stance outlined above was somewhat softened recently in light of Commissioner's Decision 1418 (March 10, 2017) pertaining to Canadian application No. 2,494,212.

A representative claim reads in part:

> Use of calcitonin [CT] in combination with one or more oral delivery agent…for the manufacture of a medicament…wherein said medicament is for oral administration to a human host from about 5 minutes to 2 hours prior to a meal. (Emphasis added).

The Final Action stated that the claim was directed to a method of medical treatment because the timing of the administration pertained to "How" rather than "What".
However, the Patent Appeal Board disagreed since the physician's skill and judgment was not expected to be exercised within the scope of the claims once the physician has decided to prescribe the oral CT formulation shortly before a meal in accordance with the claims on file. It should be noted, however, that the effect on the medicament was the same regardless of when the meal was taken within the claimed time range. Thus, a physician's judgement was not required in selecting a time for administration within the claimed range. While the patent application was ultimately rejected for obviousness, the foregoing illustrates that the Patent Office has been taking a more favourable position on the patentability of use claims reciting treatment regimes in certain instances.

Moving forward

The above line of reasoning articulated by the Board might open up the possibility for arguing that a use claim for a drug directed to a dosage range is patentable if the dosage is determined before administration (not adjusted after) and if any dose within the range has no bearing on the efficacy of the drug. While this is highly fact-dependent, a use claim reciting a dosage of X mg/kg/day – Y mg/kg/day might potentially be patentable if it could be argued successfully that the drug's effect is the same within the claimed dosage range. Keeping in mind that such an argument might prove challenging in light of PN 2015-01, which specifically excludes dosage ranges, there are notable examples of recently issued use claims in Canadian patents that recite dosage and time ranges:

Examples of claims recently issued by the Canadian Patent Office		
Patent number	**Issue date**	**Representative Claim**
CA2,443,555C	July 19, 2016	• Use of a recombinant N-acetylgalactosamine-4-sulfatase to prepare a medicament in a parenteral-infusion administrable form, at a dose

		of at least 1 mg/kg up to 2 mg/kg or at least 50 units/kg up to 100 units/kg weekly to a human subject with a disease caused all or in part by a deficiency in N-acetylgalactosamine-4-sulfatase activity, wherein the medicament is for use over a period of between about 2 to 4 hours.
CA2,682,598C	June 7, 2016	• Tetrahydrobiopterin (BH4) or a pharmaceutically acceptable salt thereof for use in treatment of hyperphenylalaninemia wherein the BH4 or salt thereof is for oral administration within 0-30 minutes after a meal.

Disclaimer

Of course, the foregoing should not be taken as legal advice since success in achieving issuance of use claims reciting a treatment regime is highly fact dependent. As will be appreciated, our advice depends on the particular facts of a case. Moreover, often a claim will be considered to fall within a statutory subject matter category by the examiner, but will then be rejected on other grounds, such as for obviousness (as was the case for CA2,494,212 discussed above). As such, any questions regarding a particular patent application can be directed to our patent group. We will be happy to assist you with legal advice tailored to your unique fact pattern.

Wendy Lamson is a Partner and Patent Agent in the Intellectual Property Law Group at Perley-Robertson, Hill & McDougall. With over 17 years of experience drafting and prosecuting patent applications, Wendy knows how to protect your invention. She understands clients' needs because, for over thirteen years, she worked in corporate practice interacting with scientists on a daily basis.

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