Double Trouble: Avoiding Pitfalls in Canadian Pharmaceutical Patent Practice

March 26, 2019

By Mike Fenwick

Over the past several years, the environment for pharmaceutical patents in Canada has improved significantly. As was widely reported at the time, the Supreme Court of Canada abolished the promise doctrine in 2017 (see articles here and here). Last year, the federal government enacted legislation to provide up to two years of patent term extension for patents covering certain medicines. Canada also has the benefit of strong linkage regulations which require a generic company to address certain patents protecting a medicine before regulatory approval. While things are looking up for pharmaceutical patentees in Canada, there are still a couple of pitfalls to watch out for in Canadian patent practice.

First, there remains uncertainty in the law with respect to whether certain methods of medical treatment constitute patentable subject matter. While most pharmaceutical medical treatment claims can simply be rewritten as use claims, patenting dosage regimens can be trickier and may require input from a Canadian patent agent. In general, if an essential element of a claim involves any type of variability, such as a dosage range or mg per kg calculation, the claim could be construed as a method of medical treatment, and therefore, not patentable subject matter. For example, a claim containing a dosage range limitation such as 13-15 mg/kg/day is often rejected by CIPO, on the basis that it arguably requires the skill and/or judgment of a physician to determine the required dose. To the contrary, a claim directed to a 1 mg tablet for the treatment of a disease is patentable, as embodying a vendible product, since a physician need only determine whether the medicine should be prescribed. In general, a claim containing a limitation having any variability with respect to a dosage, be it in the amount of the drug administered, the timing of the administration or the location of the administration, could be viewed as a method of medical treatment under CIPO's current aggressive policy, and potentially not patentable.

However, recent cases involving certain dosage limitations have softened the often-tough stance with respect to methods of medical treatment. In *Abbvie Biotechnology Ltd*. v. *Attorney General of Canada*, 2014 FC 1251, Abbvie appealed to the Federal Court after the Examiner and Patent Appeal Board refused an application containing a claim directed to a pre-loaded syringe containing 40 mg of Humira on a bi-weekly dosing schedule. While rejecting on several grounds, the PAB ruled that the claims were methods of medical treatment as the description described a titration regimen, and therefore, the patent as a whole sought to fence in the skill of a physician. Abbvie appealed to the Federal Court where the ruling was overturned on the basis that fixed dosages and precise scheduling regimes in a claim do not require the exercise of discretion or skill on the part of a physician. Likewise, in Commissioner's Decision 1418, the PAB reviewed a final rejection of a claim limitation involving the use of calcitonin (CT) which was to be administered to a patient from 5 minutes to 2 hours prior to a meal. CT has low bioavailability, and therefore, low plasma levels when administered with food. The PAB's decision was based on evidence presented that a skilled person would appreciate that administration during any time of the recited time window would overcome the negligible plasma levels observed when administering oral CT. Therefore, the PAB ruled that no skill or judgement of a physician was required.

Obviously, each case will turn on the facts, and the description can be used to determine whether a particular limitation amounts to a method of medical treatment. While there has been a softening concerning methods of medical treatment, it is still prudent to include claims directed to the specific commercial dosage and minimize the use of ranges or any other variability in the claims. For example, as there are no excess claim fees in Canada, separating a limitation reciting 1-10 mg/day into 10 separate claims each claiming a different dosage (i.e. 1 mg/day, 2 mg/day), is a strategy that can be considered by a cautious applicant.

The second aspect of Canadian patent practice of which applicants should be aware is double patenting, where a patentee is only entitled to one patent for one invention. Double patenting is a common issue in many jurisdictions. In Canada however, any application having the same applicant can be subjected to a double patenting allegation if the subject matter of a claim is not patentably distinct from the subject matter in the claims of another application or patent (usually an earlier filed application). Double patenting also applies to voluntary divisional applications having the same filing date, and therefore, the same expiry.

As there is no terminal disclaimer practice in Canada, applicants should devise a strategy early on to ensure they can address any double patenting issues that may arise at a later time. As noted above, applicants should be aware that voluntary divisional applications often attract double patenting rejections, and as such, it is prudent to pursue all desirable subject matter in a parent application to avoid double patenting. Applicants should be especially alert to double patenting in a patent prosecution highway (PPH) expedited examination request when using the allowed claims from another jurisdiction which may have already been subjected to a restriction requirement. If an applicant then attempts to pursue additional claims in a divisional application, they may be rejected for not being patentably distinct. The argument that both applications would have the same expiry date is not a defence that has been decided upon by courts in relation to double patenting in Canada.

Due to different filing strategies, applicants may still find themselves facing a double patenting rejection on two pending applications. While there has been caselaw which states that only an earlier filed patent may invalidate a later filed patent for double patenting (and not vice-versa), there is a dearth of caselaw in situations when the applications have the same filing date. In such a scenario, Applicants should endeavour to first obtain the issuance of the application containing the most important subject matter as a precaution, even though there is no court case considering this issue.

The environment for pharmaceutical patents in Canada is strong. However, like in any jurisdiction, there are issues to keep in mind, and devising an early strategy to address such issues can save headaches later on.