HOW TO TREAT A REGIMEN: FEDERAL COURT OF CANADA CLARIFIES CASE LAW ON PATENTABLE SUBJECT MATTER, DOSAGE REGIMES AND METHODS OF MEDICAL TREATMENT

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On December 22nd, 2014, the Federal Court of Canada allowed Abbvie Biotechnology Ltd.'s ("Abbvie") appeal and request for judicial review of the Commissioner of Patents ("Commissioner") refusal to grant Abbvie a patent on Canadian Patent Application No. 2,385,745 (the '745 Application). Abbvie contested the Commissioner's findings that the claims of the '745 Application were not patentable subject matter under Canada's *Patent Act* [RSC 1985, c P-4 ; "the Act"] for being directed to methods of medical treatment. [*Abbvie Biotechnology Ltd. v. Canada (Attorney General),* 2014 FC 1251, FC 1251; "Abbvie"]

The '745 Application

Briefly, the '745 patent application related to the use of HUMIRA®, a known drug commonly used for the treatment of autoimmune diseases like rheumatoid arthritis. Abbvie is already the owner of a patent for HUMIRA® and in 2002, filed the '745 application, claiming the use of HUMIRA® for the treatment of autoimmune diseases, in a fixed dosage amount of the drug (a preloaded syringe containing 40 mg) and on a fixed schedule (every two weeks, or bi-weekly).

General Prohibition

In Canada, claims directed to a method of medical treatment are not patentable subject matter. This restriction finds its origins in the interpretation of the definition of invention in the *Act*, as well as from a Supreme Court of Canada's decision [*Tennessee Eastman Co v Commissioner of Patents*, [1974] SCR 111], which found that claims to the execution of a professional skill are not inventions and therefore cannot be patented.

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In the life sciences, this was interpreted as meaning that claims that interfered with the ability of a physician to exercise skill or judgment when prescribing a certain drug or providing a certain treatment are not patentable, specifically when such a claim would effectively cover the use of a known compound/treatment for a purpose that was already established by practice.

Canadian case law has also distinguished between claims to dosages and dosage regimes that are made to a *vendible product*, which are patentable, and claims that relate to the *exercise of a professional skill or judgment*, which aren't.

The Commissioner's Analysis

Prior to this appeal, the Commissioner, when commenting the Patent Office's final decision not to grant the '745 patent, found that the claims were directed to a method of medical treatment since a physician's skill and judgment was affected when prescribing a drug product already having a fixed dosage regimen. It found that this line of reasoning was consistent with its interpretation of the relevant case law, as well as a "new" practice notice adopted by the Canadian Intellectual Property Office which stated that "inventions preventing physicians from exercising their skill and judgment in using a known compound for an established purpose effectively cover a method of medical treatment". The novelty or non-obviousness of the alleged invention was not at issue.

While it was argued by Abbvie that the presence of a fixed dosage regime removed the possibility of a physician having to exercise any skill and judgment in the first place, the Commissioner interpreted the case law as establishing that the simple presence of a fixed dosage and a dosage schedule is not always sufficient to escape the scope of what is considered a method of medical treatment. The Commissioner did not agree that the restriction of a physician's ability to exercise skill and judgment is limited only to claims that cover a range of doses or dose intervals and as such, refused to grant the patent.

The Court's Decision

i) The parties' positions

The Appellant, Abbvie, submitted that the Commissioner applied the wrong definition of "method of medical treatment" and did not consider or misinterpreted established case law that dealt with the interpretation of "invention" as found in the Act.

Abbvie also submitted that the patent clearly provides for a fixed dosage at a fixed interval and that no skill or judgment needs to be exercised by a professional: "the patent does not restrict methods of medical treatment or the skill and judgment of the

physician, because no skill or judgment is needed to be exercised within the claim." [*Abbvie*, at para. 3]

Abbvie further submitted that "the focus should rather be on whether that choice [to use the invention] is restricted by the claims. The choices made and the skill and judgment exercised outside the claims of the patent (i.e., when determining whether the particular drug should be prescribed and used as set out in the claim) are not restricted." [*Abbvie*, at para. 52]

Abbvie also argued that the Commissioner's decision reflects its intent to implement a change of policy [Canadian Intellectual Property Office [CIPO] document, *Examination Practice Respecting Medical Uses*, PN 2013-14, dated June 10, 2013] and that this new policy attempts to create a new exclusion that was not based on the Act: "inventions preventing physicians from exercising their skill and judgment in using a known compound for an established purpose effectively cover a method of medical treatment".

In return, the Attorney General of Canada (the "Respondent") submitted that the Commissioner identified and applied the correct legal tests and that the Commissioner's finding that the claims were not patentable subject matter is a finding of fact, should therefore be reviewed under the standard of "reasonableness" and that deference is owed to the Commissioner who has a specific expertise in this field.

Furthermore, the Respondent also alleged that since the claims include bi-weekly dosage regimes it is therefore not simply a "vendible product". It further submitted that any claim that includes a dosage (fixed, range or otherwise) restricts a physician's ability to exercise its own skill and judgment and therefore seeks to patent a method of medical treatment.

The Respondent also put forward that HUMIRA ® was already patented and was already in a syringe. The only difference now being the 40mg fixed amount and the bi-weekly dosage. This element therefore: "adds the "how and when" and "fences in" the prescribing practice. If physicians must decide not to prescribe it because 40 mg bi-weekly is not appropriate for the patient, this "fences in" the prescribing practice" [*Abbvie*, at para. 74].

ii) The Court's Analysis

On appeal for judicial review, a Court must first determine if the first decision rendered by the Commissioner was *correct* or *reasonable* depending on the applicable standard of review. If the appropriate standard is "reasonability", then the issue is if the Commissioner's decision is within the range of possible, defensible outcomes. If the standard of review is correctness, then it needs to be determined if the Commissioner applied the correct definition of invention under the Act and

correctly interpreted that the claims were directed towards a “method of medical treatment”.

After representations from both parties, the Court reviewed the Commissioner’s decision using the “correctness” standard”, since the scope of the patentable subject matter is purely a question of law, having to do with the statutory limitations of what consists of patentable subject matter, and what does not. Since the facts were not in dispute, the matter becomes purely a question of law, or more particularly, the correct application of this law: “[T]he only issue is the Commissioner’s interpretation of patentable subject matter, and more specifically, the scope of the prohibition on methods of medical treatment”” [*Abbvie*, at para. 48

The Respondent alleged that since HUMIRA® was already previously available and that the ‘745 application simply added a syringe with a specific dosage of the drug and dosing schedule, that this boxed in the medical professional and interfered with the physician’s prescribing habits or normal exercise of skill and judgment.
The Court found that the distinction should not be whether or not a patent claims a dosage or dosage range but if the claims contain a restriction with regards to a professional’s use of skill or judgment. If there is no such restriction, the invention is a vendible product:

> “a claim directed to the exercise of professional skill or judgment is not patentable. However, 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 that claimed dosage” [*Abbvie*, at para. 114].

Therefore, the Court found that the case law has been consistent to the effect that a claim directed to the exercise of a professional skill is not patentable. Furthermore, if a claim is being made to a vendible product, evaluation of the skill and judgment required to prescribe the product needs to be made:

> “the distinction is not simply whether or not the patent claims a dosage range. The issue is whether the claims contain within them the restriction on choice – i.e., whether they restrict the use of skill. A dosage range signals that the exercise of skill is being monopolized. However, if there is no range claimed, there is no attempt to monopolize the exercise of skill since none is needed.” [*Abbvie*, at para. 61]

The Court found that there is nothing to suggest that a bi-weekly dosage is not “fixed and precise” and that further skill and judgment would need to be exercised when prescribing the product. As such “claims to fixed dosages and schedules which do not involve any professional decision-making have been accepted as patentable” [*Abbvie*, at para. 112].

Conversely, just because a claim involves a fixed dosage and schedule does not make it automatically patentable. Evidence may be presented that shows that additional skill and judgment are still in fact needed.

The Court ultimately found that Abbvie's reading and understanding of the caselaw was correct and demonstrates that "the present claim is for a vendible product. It does not restrict the physician's choice or skill that would be relied on at the outset to determine whether that vendible product should or should not be prescribed. The case law has established that a use claim may be a vendible product." [*Abbvie*, at para.115]

Since the Commissioner had already determined that the claims at issue were novel and not obvious, and that only the issue of patentable subject matter remained, the Court found that there was nothing left for the Patent Office to examine and ordered the Commissioner to allow the claims to issue to patent.

Conclusion

This decision clarifies what was an ongoing debate regarding the patentability of certain claims containing dosage regimes in Canada. Contrary to the practice adopted by the Canadian Intellectual Property Office, the Court found that claims containing such dosage regimens aren't always automatically considered methods of medical treatment and can be allowable. More specifically, the Court found that the presence of a specific dosage regimen that provides the "how and when" for the administration of a drug product does not automatically "fence in" the skill and judgment of a medical practitioner and is therefore allowable on a case by case basis. It therefore remains to be seen how this decision will affect day to day prosecution of patent applications containing similarly worded claims and what arguments would need to be provided to further distinguish a dosage regimen that "fences in" a practitioner's exercise of skill and judgment, from one that doesn't like in the present case.

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