Citation: Alexion Pharmaceuticals, Inc. (Re), 2021 CACP 41
Commissioner's Decision #1594
Décision du commissaire nº 1594
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| TOPIC: | J80 | Professional or Artistic Skill |
| | K11 | Treatment |
| SUJET: | J80 | Aptitudes professionnelles (artistiques) |
| | K11 | Traitement |

Application No. : 2,810,999

Demande nº 2 810 999

IN THE CANADIAN PATENT OFFICE

DECISION OF THE COMMISSIONER OF PATENTS

Patent application number 2,810,999, having been rejected under subsection 30(3) of the *Patent Rules* (SOR/96-423) as they read immediately before October 30, 2019 (the former *Rules*), has consequently been reviewed in accordance with paragraph 199(3)(c) of the *Patent Rules* (SOR/2019-251). The recommendation of the Patent Appeal Board and the decision of the Commissioner are to withdraw the rejection and allow the application.

Agent for the Applicant:

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## INTRODUCTION

[1] This recommendation concerns the review of rejected Canadian patent application number 2,810,999 which is entitled "Use of Lysosomal Acid Lipase for Treating Lysosomal Acid Lipase Deficiency in Patients" and is owned by Alexion Pharmaceuticals, Inc. (the Applicant). A review of the rejected application has been conducted by the Patent Appeal Board (the Board) pursuant to paragraph 199(3)(c) of the *Patent Rules*.

[2] The outstanding defect that is considered in this review is whether the claims are directed to methods of medical treatment, which is subject-matter that lies outside the definition of "invention" and does not comply with section 2 of the *Patent Act*. As explained below, our recommendation is that the Commissioner of Patents allow the application.

## BACKGROUND

### The Application

[3] The application was filed under the provisions of the Patent Cooperation Treaty and has an effective filing date in Canada of September 9, 2011 and has been open to public inspection since April 19, 2012.

[4] The application relates to the use of recombinant lysosomal acid lipase (LAL) in the treatment of human patients suffering from LAL deficiency.

### Prosecution History

[5] On June 21, 2018, a Final Action (FA) was issued pursuant to subsection 30(4) of the former *Rules*. The FA indicated that claims 1–5 on file are directed to a method of medical treatment, which is not patentable subject-matter within the definition of "invention" in section 2 of the *Patent Act*.

[6] The Applicant responded to the FA in a letter dated December 21, 2018 (RFA) by submitting arguments as to why the claims on file define patentable subject-matter that does not relate to methods requiring the expertise of a medical professional.

[7] The Examiner was not persuaded by the Applicant's arguments with respect to the claims on file and so, pursuant to paragraph 30(6)(b) of the former *Rules*, the application was forwarded to the Board along with a Summary of Reasons (SOR) for review. On June 18,

2019, the Board forwarded a copy of the SOR to the Applicant. In a response dated July 15, 2019, the Applicant indicated its continued interest in having the application reviewed.

[8] The present panel (the Panel) was formed to review the rejected application and make a recommendation to the Commissioner as to its disposition. Our conclusions are set out below.

[9] Before turning to our analysis, the Panel notes that as a result of the Federal Court Decision in *Choueifaty v Canada (Attorney General)* 2020 FC 837 the Patent Office published a Patent Notice and revised guidelines in respect of purposive construction and the assessment of patentable subject-matter: "Patentable subject-matter under the *Patent Act*" (CIPO, November 2020) [*PN2020–04*]. This guidance supersedes the previous guidelines applied in the FA as set out in "Patent Notice: Revised Examination Practice Respecting Medical Uses PN 2015-01" (CIPO, 2015) and the appended examples.

## ISSUES

[10] The sole issue to be considered by this review is whether claims 1–5 on file define patentable subject-matter that falls within the definition of "invention" in section 2 of the *Patent Act*.

## LEGAL PRINCIPLES AND OFFICE PRACTICE

Purposive construction

[11] In accordance with *Free World Trust v Électro Santé Inc*, 2000 SCC 66 and *Whirlpool Corp v Camco Inc*, 2000 SCC 67, purposive construction is performed from the point of view of the person skilled in the art in light of the relevant common general knowledge (CGK), considering the whole of the disclosure including the specification and drawings. In addition to interpreting the meaning of the terms of a claim, purposive construction distinguishes the essential elements of the claim from the non-essential elements. Whether or not an element is essential depends on the intent expressed in or inferred from the claim, and on whether it would have been obvious to the skilled person that a variant has a material effect upon the way the invention works.

[12] *PN2020–04* also discusses the application of these principles, pointing out that all elements set out in a claim are presumed essential unless it is established otherwise or such presumption is contrary to the claim language.

Patentable subject-matter and methods of medical treatment

[13] The definition of invention is set out in section 2 of the *Patent Act*:

> "invention" means 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.

[14] *PN2020-04* clarified the Patent Office's approach with respect to the determination of patentable subject-matter under section 2 of the *Patent Act*. In general:

> To be both patentable subject-matter and not be prohibited under subsection 27(8) of the *Patent Act*, the subject-matter defined by a claim must be limited to or narrower than an actual invention that either has physical existence or manifests a discernible physical effect or change and that relates to the manual or productive arts, meaning those arts involving or concerned with applied and industrial sciences as distinguished in particular from the fine arts or works of art that are inventive only in an artistic or aesthetic sense.

[15] It is well established that methods of medical treatment and surgery are not patentable subject-matter falling within the manual and productive arts and are excluded from the definition of invention as defined in section 2 of the *Patent Act* (see *Tennessee Eastman Co v Commissioner of Patents* (1970), 62 CPR 117 (Ex Ct), aff'd [1974] SCR 111; *PN2020-04*). However, medical "use" claims have been considered to be directed to patentable subject-matter (see *Apotex Inc v Wellcome Foundation Ltd*, 2002 SCC 77).

[16] A number of lower court decisions have considered the validity of medical use claims (*Axcan Pharma Inc v Pharmascience Inc*, 2006 FC 527 [*Axcan*]; *Merck & Co, Inc v Pharmascience Inc*, 2010 FC 510; *Janssen Inc v Mylan Pharmaceuticals ULC*, 2010 FC 1123; *AbbVie Biotechnology Ltd v Canada (Attorney General)*, 2014 FC 1251 [*AbbVie*]). Upon reviewing prior decisions, the Federal Court in *AbbVie* concluded that the jurisprudence is consistent; Federal Court jurisprudence has developed the principle that:

> [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. (para [114])

[17] With particular reference to the determination of patentable subject-matter in respect of

medical use claims containing a dosage or dosing regimen, *PN2020-04* states that:

> [I]n cases where at least one of the essential elements of the actual invention limits the claimed use to a dosage…and/or a dosage regimen, regardless of whether these are fixed and/or cover a range, this fact alone is not determinative of whether the claim is patentable subject-matter. It is also necessary to consider whether the exercise of professional skill and judgment of a medical professional is part of the actual invention. For example, professional skill and judgment may be involved if a medical professional is expected to monitor or make adjustments to the treatment, or make a selection of a dosage from a claimed range (i.e., in cases where not all dosages in the range will work for all subjects within the treatment group).

## ANALYSIS OF THE CLAIMS ON FILE

Purposive construction

*The claims on file*

[18] Claims 1–3 are the independent claims. Claim 1 is representative:

> 1. Use of a recombinant human lysosomal acid lipase (LAL) for treating a human patient having a predetermined weight in kilograms and suffering from a LAL deficiency, wherein the recombinant LAL is for administration once a week as an intravenous infusion in an amount that is equal to 1 milligram for every kilogram of the predetermined weight of the patient.

[19] Claim 2 is directed to a dosage "in an amount that is equal to 3 milligrams for every kilogram of predetermined weight of the patient" and otherwise defines the same elements as claim 1.

[20] Claim 3 is directed to a schedule of "administration once every other week" and otherwise defines the same elements as claim 1.

[21] Dependent claims 4 and 5 provide further limitations relating to the disease associated with the LAL deficiency.

Claims construction

*The person skilled in the art and the relevant common general knowledge*

[22] The FA, on page 2, said the following in regard to the skilled person and the CGK:

> In view of statements throughout the description which refer to "a practitioner of ordinary skill in the art of medical sciences", as well as the discussion of lysosomal acid lipase deficiency diseases on page 1 of the description, the person skilled in the art to whom the application is directed can be characterized as a team composed of clinicians specialized in biochemical lipid analyses, liver disorders, cardiology, gastroenterology, and pharmacology.
>
> The person skilled in the art would possess the following CGK: knowledge of biochemical lipid analyses, lysosomal enzyme therapies, lysosomal acid lipase deficiencies, the design of clinical trials to determine safety and efficacy of therapeutic agents, and use of lysosomal acid lipase (LAL) to treat a LAL deficiency such as Wolman disease and cholesteryl ester storage disease as exemplified in D1.

[23] In response, the RFA did not contest or comment on these characterizations, and so we adopt them for the purposes of our analysis.

*Essential elements*

[24] In light of the revised guidance set out in *PN2020-04*, we have undertaken a new assessment of the essential elements.

[25] As set out above, *PN2020-04* states that:

> In carrying out this identification of essential and non-essential elements, all elements set out in a claim are presumed essential, unless it is established otherwise or is contrary to the language used in the claim.

[26] With respect to the claims on file, the skilled person reading claims 1–5 would understand that there is no use of language in any of the claims indicating that any of the elements are optional, a preferred embodiment or one of a list of alternatives. Further, there is no indication on the record before us that any claim elements are non-essential. In our view, the skilled person would consider all of the elements of claims 1–5 as essential, including the use of LAL, at a dosage of 1 or 3 mg/kg, for administration once a week or once every two weeks, for treating a human patient suffering from a LAL deficiency.

<u>Patentable subject-matter and methods of medical treatment</u>

[27] As stated above, the approach set out in *PN2020-04* considers whether the exercise of skill and judgment of a medical professional is part of the actual invention. With respect to the actual invention, claim 1 is explicit in its inclusion of the dosage of 1 mg/kg for administration once a week. Having read claim 1 in the context of the specification as a whole, our view is that the skilled person would consider the actual invention in claim 1 as

including the use of LAL, at a dosage of 1 mg/kg, once a week for treating a human patient suffering from a LAL deficiency. Likewise, the actual inventions in claims 2 and 3 include the use of LAL at a dosage of 3 mg/kg for administration once a week and a dosage of 1mg/kg for administration once every two weeks, respectively. The remaining question is whether these dosage regimens require, restrict, prevent, interfere with or otherwise engage the exercise of professional skill and judgment.

[28] The Panel notes that while the assessment in the FA was carried out using a different approach, the dosage regimen was construed as an essential element and the analysis considered whether the dosage involves the exercise of professional skill and judgment. Accordingly, the arguments in the FA remain relevant and are considered and addressed below in consideration of the Applicant's submissions made in the RFA.

[29] The position in the FA was that the claims are not to a fixed dosage, rather the amount of LAL to be administered is expressed as mg LAL per kg patient body weight, a calculation that would require the professional skill or judgment of a physician (pages 3–4).

[30] On pages 2–6, the RFA disputed that the claims are to a method of medical treatment, stating that any choices or skill and judgment exercised are outside the claims and would therefore not be restricted by the claims on file. With respect to the position set out in the FA, the RFA submitted that it is not supported by the Court's decision in *Axcan* and that in view of *AbbVie* the fixed dosage amount in the claims means that no professional skill is required. In support of its submissions, the Applicant provided a Declaration from Dar Dowlatshahi, an attending neurologist at the Ottawa Hospital who also holds the titles of Associate Professor of Medicine at the University of Ottawa and Scientist and stroke researcher with the Ottawa Hospital Research Institute, which stated the following:

> 8. In my opinion, a physician looking to use the medicine as directed in the claims of the 999 Application would not require any special medical education, training or experience. While medical training would be needed to decided whether to treat a patient suffering from a LAL deficiency with a recombinant human lysosomal acid lipase, once that decision is made, the dosing regimen described in the claims of the 999 Application do not require any special medical education, training or experience to implement.
>
> 9. The dosing in the claims of the 999 Application is effectively a fixed dose regimen provided every week (claim 1) or every other week (claims 2 and 3). The amount of medicine used is fixed by the patient's body weight, that is, 1mg/kg or 3 mg/kg. The claims of the 999 Application do not require that the physician make a decision regarding the amount of medicine needed. The simple arithmetic to determine the amount of medicine needed is something that is taught in grade school and not during medical training.

> 10. In most cases, the physician will not even be involved with physically preparing the dose. The physician will instead instruct a nurse or pharmacist to prepare the medication at, for example, 1mg/kg of the patient's body weight. The physician will rely on the nurses or pharmacists to weigh the patient and then prepare the medicine in the appropriate dose. These nurses and pharmacists do not have the same medical training as a physician and are not legally permitted to treat patients. However, it is perfectly within their training to prepare a medicine based on simple arithmetic, such as a specific amount of medicine fixed by the patient's body weight.

[31] We agree with the Applicant that the dosage is fixed by the patient's body weight. However, we consider that the expression of a dosage in mg/kg is not, on its own, determinative that skill and judgment is not required. As explained in *AbbVie*, a fixed dosage and schedule in a use claim may be a good signal or starting point, but the evidence may indicate that the dosage regime and schedule are not exactly as claimed, and that adjustments requiring skill and judgment are needed (para [113]). Accordingly, it is appropriate to consider any evidence that may contradict the dosage or schedule as it is claimed.

[32] Having reviewed the description, we do not find any indication that the physician would need to make any adjustments to the claimed dosage or dosing frequency. It is noted that the description indicates that changes in the patient's weight are expected—efficacy endpoints of LAL replacement therapy include weight gain in some patients. However, there is no evidence that the evaluation of a patient's weight results in the physician making adjustments to the claimed dosage or dosing frequency. To the extent that a change in a patient's weight may necessitate a re-calculation of the specific dose for administration, the evidence is that the dosage remains at 1 or 3 mg/kg. Therefore, based on the record as it stands, our view is that the dosage schedules are fixed and the calculation to convert each dosage from mg/kg to a specific dose based on a patient's weight would not require the skill and judgment of a physician.

[33] We consider that dependent claims 4 and 5, which further define the disease associated with LAL deficiency, also would not require the skill and judgment of a physician.

[34] In light of the above, our conclusion is that the claims on file do not encompass a method of medical treatment or otherwise restrict, prevent, interfere with or require the exercise of professional skill and judgment. It is therefore our view that claims 1–5 on file are directed to patentable subject-matter that falls within the definition of "invention" in section 2 of the *Patent Act*.

**RECOMMENDATION OF THE BOARD**

[35] In view of the above, the Panel is of the view that the rejection is not justified on the basis of the defect indicated in the Final Action notice and we have reasonable grounds to believe that the application complies with the *Patent Act* and *Patent Rules*. We recommend that the Applicant be notified in accordance with subsection 86(10) of the *Patent Rules* that the rejection of the instant application is withdrawn and that the application has been found allowable.

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| Christine Teixeira | Marcel Brisebois | Ryan Jaecques |
| Member | Member | Member |

**DECISION OF THE COMMISSIONER**

[36] I concur with the conclusions and recommendation of the Board. In accordance with subsection 86(10) of the Patent Rules, I hereby notify the Applicant that the rejection of the instant application is withdrawn, the instant application has been found allowable and I will direct my officials to issue a Notice of Allowance in due course.

Virginie Ethier
Assistant Commissioner of Patents

Dated at Gatineau, Québec
this 9th day of September, 2021