Citation: Nektar Therapeutics (Re), 2021 CACP 13
Commissioner's Decision #1566
Décision du Commissaire #1566
Date: 2021-03-25

TOPIC:	J80	Professional or Artistic Skill
	K11	Treatment
SUJET:	J80	Aptitudes professionnelles (artistiques)
	K11	Traitement

Application No. : 2,736,939

Demande n^{o} 2 736 939

IN THE CANADIAN PATENT OFFICE

DECISION OF THE COMMISSIONER OF PATENTS

Patent application number 2,736,939, 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.

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INTRODUCTION

[1] This recommendation concerns the review of rejected Canadian patent application number 2,736,939 which is entitled "Means of achieving sustained-therapeutic SN-38 concentrations in a subject" and is owned by Nektar Therapeutics (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 23, 2009 and has been open to public inspection since April 1, 2010.

[4] The application relates generally to the use of a prodrug of the chemotherapy agent irinotecan in the treatment of breast cancer according to a new dosage that maintains a therapeutic concentration in plasma at a level that permits infrequent dosing of every 21 days.

Prosecution History

[5] On June 28, 2019, a Final Action (FA) was issued pursuant to subsection 30(4) of the former *Rules*. The FA indicated that claims 1-8 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 23, 2019 (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. The Applicant also raised a procedural issue regarding whether the issuance of a FA was appropriate in view of the prosecution record.

[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 October 19, 2020, the Board forwarded a copy of the SOR to the Applicant. In a response dated January 19, 2021, the Applicant indicated its continued interest in having the application reviewed.

[8] As a result of the Federal Court Decision in *Choueifaty v Canada (AG)* 2020 FC 837 and the subsequent publication of the Patent Office Patent Notice in respect of patentable subject-matter, "Patentable subject-matter under the *Patent Act*" (CIPO, November 2020) [*PN2020–04*], which 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, the Examiner re-evaluated the instant application for compliance with section 2 of the *Patent Act* and provided a Supplemental Summary of Reasons (SSOR) dated March 12, 2021 to the Board. The SSOR indicated that the Examiner now considered the claims on file to be compliant with section 2 of the *Patent Act*.

[9] This 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.

ISSUES

[10] There are two issues to be considered by this review:

- whether the issuance of the FA was appropriate; and
- whether claims 1-8 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

Issuance of a Final Action

[11] Subsection 30(3) of the former *Rules* sets out the requirements that must be met before a Final Action notice rejecting an application can be issued:

> Where an applicant has replied in good faith to a requisition referred to in subsection (2) within the time provided but the examiner has reasonable grounds to believe that the

> application still does not comply with the Act or these Rules in respect of one or more of the defects referred to in the requisition and that the applicant will not amend the application to comply with the Act and these Rules, the examiner may reject the application.

Claims construction

[12] In accordance with *Free World Trust v Électro Santé Inc*, 2000 SCC 66, purposive construction of a claim is done by considering the whole of the disclosure, including the specification and drawings (see also *Whirlpool Corp v Camco Inc*, 2000 SCC 67 at paras 49(f) and (g) and 52). This consideration is performed from the point of view of the person skilled in the art in light of the relevant common general knowledge (CGK).

[13] With respect to the determination of the essential/non-essential elements of a claim, *PN2020-04* clarified the Patent Office's approach to this determination:

> During purposive construction of a claim, the elements of the claimed invention "are identified as either essential elements (where substitution of another element or omission takes the device outside the monopoly) or non-essential elements (where substitution or omission is not necessarily fatal to an allegation of infringement)." 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.

Patentable subject-matter and methods of medical treatment

[14] 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

[15] *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.

[16] 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).

[17] A number of lower court decisions have considered the validity of medical use claims (*Axcan Pharma Inc v Pharmascience Inc*, 2006 FC 527; *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)

[18] 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

Issuance of a Final Action

[19] In the RFA the Applicant raised the following procedural issue:

> Applicant respectfully submits that the issuance of a Final Action in this matter is premature (…) To "reject" an application, the Examiner must additionally have reasonable grounds to believe that the Applicant will not amend the application to comply with the *Act* and *Rules* (…) Neither the number of official actions nor passage of time constitute grounds to reject an application. A failure to overcome defects alone is not sufficient grounds for an Examiner to issue a Final Action.

> (…)
>
> Applicant has demonstrated and continues to demonstrate its willingness to amend the application so as to comply with the *Patent Act* and *Rules*. Since Applicant has again provided amendments to the application in order to comply with the *Act* and *Rules* the Examiner cannot have reasonable grounds to believe that Applicant will not amend the application to comply with the *Act* and *Rules*.

[20] In reviewing the prosecution record of the application, the Panel notes that the patentable subject-matter defect was identified in four Office actions immediately prior to the FA. In the last of those four actions dated April 4, 2018, the Examiner clearly indicated that any subsequent report may be made "final" if the same defect was addressed. Although the use claims were amended to adopt a Swiss format in response to that action, the FA regarded the defect as being essentially the same, which the SOR correctly pointed out is consistent with the interpretation of Swiss claims in the jurisprudence, citing *Novartis Pharmaceuticals Canada Inc v Cobalt Pharmaceuticals Company*, 2013 FC 985 at para 101. In our view, the Examiner had reasonable grounds to believe that the application still did not comply with the *Act* and *Rules* and that the Applicant would not amend the application to comply. Accordingly, it was reasonable for the Examiner to make the subsequent action "final" and reject the application under subsection 30(3) of the former *Rules*.

The claims on file

[21] Claim 1 is the only independent claim on file:

> 1. Use of a pharmaceutical composition comprising a prodrug of irinotecan corresponding to structure (I) or a pharmaceutically acceptable salt thereof, to prepare a medicament in an intravenous infusion-administrable form for administration at a dose of 145 mg/m^2 every 21 days for treating breast cancer in a human subject having breast cancer.

[22] Dependent claims 2-8 provide further limitations relating to the molecular weight, the type of treatment, the type of breast cancer and the formulation of the composition.

Claims construction

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

[23] On page 2, the FA identified the skilled person as including a medical practitioner with experience in studying and treating cancer, a medicinal chemist with experience in preparing and testing polymer conjugates of various chemotherapeutic agents including

camptothecins and a pharmacologist with experience in formulating and dosing polymer conjugates.

[24] In response, the RFA did not contest or comment on this characterization, and so we adopt it for the purposes of our analysis.

Essential elements

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

[26] 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.

[27] With respect to the claims on file, the skilled person reading claims 1-8 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 1-8 as essential, including the use of the prodrug for administration at a dose of 145 mg/m^2 every 21 days for treating cancer.

Patentable subject-matter and methods of medical treatment

[28] 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 dose of 145 mg/m^2 every 21 days. Having read claim 1 and its dependent claims in the in the context of the specification as a whole, our view is that the skilled person would consider the actual invention in each claim as including the use of the prodrug at that dose every 21 days for treating breast cancer. The remaining question is whether this requires, restricts, prevents, interferes with or otherwise engages the exercise of professional skill and judgment.

[29] The Panel notes that while the assessment in the FA was carried out using a different approach, the analysis considered whether the dose involves the exercise of professional skill and judgment. Accordingly, the assessment in the FA remains relevant and is

addressed below in consideration of the Applicant's submissions made in response in the RFA.

[30] The position in the FA was that a dose defined in terms of mg/m^2 requires the skill and judgment of a medical practitioner because, even though the calculations involved are simple, the dose has to be calculated. Further, unlike a fixed unit dose, a dose given in mg/m^2 is variable because there is more than one formula for calculating a patient's body surface area (BSA) and selecting the appropriate formula requires the skill and judgment of a medical practitioner. In support, the FA refers to Canadian patent application CA 2,594,713 at para 0020, which identifies five different well-known formulae that are conventionally used for calculating BSA, all of which are based on the patient's height and weight.

[31] On pages 2-3, 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 said the following (page 6):

> The Examiner maintains that medical skill is required in calculating the specific dosage on the amount 145 mg/m^2. This statement is contrary to the Court's decision in *Axcan* where the Court held that it would be a simple arithmetic, "the Court does not need the expert advice of a physician." Applicant disagrees. The fixed dosage amount in the claims as well as the fixed dosing frequency means that no skill or judgment of a physician is required to practice the subject matter of the claims. There is no choice involved. Determination of the dose amount for a particular patient is a matter for an ordinary worker using standard chemotherapy calculations to determine the amount. Thus, in light of the fixed nature of the features of the claims, 145 mg/m^2 the claims do not require skill and judgment of the medical doctor.

[32] We agree with the Applicant that the dose amount and dosing frequency are fixed in the claims at 145 mg/m^2 and 21 days, respectively. However, 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 is not exactly as it is 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 as it is claimed.

[33] Having reviewed the description, we do not find any indication that the physician would need to make any adjustments to the claimed dose amount or dosing frequency. Likewise, there is no evidence that monitoring of a patient's BSA is required, or that the choice of formula or manner of determining BSA is critical or requires the skill and judgment of a

medical professional. How to determine BSA is not addressed in the description, which suggests that this aspect is left to the skilled person using the conventional methods and CGK from their field. This is consistent with the document that is cited in the FA and with the Applicant's position that the determination of the dose amount for a particular patient is a matter of arithmetic for an ordinary worker who would use the calculations that are standard in the field of chemotherapy. To the extent that skill and judgment may be involved in selecting the BSA formula, based on the evidence we are satisfied that this would be outside the claims.

[34] Based on the record as it stands, our view is that the claimed dose of 145 mg/m^2 is fixed and the calculation to convert to a specific dose based on a patient's BSA would not require the skill and judgment of a medical professional.

[35] For all of the above reasons, our view 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. Claims 1-8 on file are therefore directed to patentable subject-matter that falls within the definition of "invention" in section 2 of the *Patent Act*.

RECOMMENDATION OF THE BOARD

[36] 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.

Cara Weir	Blair Kendall	Christine Teixeira
Member	Member	Member

DECISION OF THE COMMISSIONER

[37] 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 25th day of March, 2021