Citation: Genentech, Inc. (Re), 2021 CACP 8
Commissioner's Decision #1561
Décision du Commissaire #1561
Date: 2021-03-17

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

Application No. : 2,382,100

Demande n^{o} 2 382 100

IN THE CANADIAN PATENT OFFICE

DECISION OF THE COMMISSIONER OF PATENTS

Patent application number 2,382,100, 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 2,382,100 which is entitled "Dosages for treatment with anti-ErbB2 antibodies" and is owned by Genentech, 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 considered in this review is whether the claims encompass subject-matter that lies outside the definition of "invention" and do 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 on August 25, 2000 and has been open to public inspection since March 8, 2001.

[4] The application relates generally to using an anti-ErbB2 antibody, such as HERCEPTIN™, in the treatment of disorders characterized by the overexpression of ErbB2, including breast cancer, according to a new dosage regimen that permits less frequent dosing.

Prosecution History

[5] On September 21, 2016, a Final Action (FA) was issued pursuant to subsection 30(4) of the former *Rules*. The FA indicated that claims 1-14 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 March 20, 2018 (RFA) by submitting arguments as to why the claims on file define patentable subject-matter that does not relate to methods that may require 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)(c) of the former *Rules*, the application was forwarded to the Board for review along with the Examiner's Summary of Reasons (SOR).

On May 4, 2018, the Board forwarded a copy of the SOR to the Applicant. In a response dated May 28, 2018, the Applicant indicated its continued interest in having the application reviewed.

[8] 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.

[9] Before turning to our analysis, the Panel notes that as a result of the Federal Court Decision in *Choueifaty v Canada (AG)* 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 approach that was followed in the FA.

ISSUE

[10] The sole issue to be considered by this review is whether claims 1-14 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

Claims construction

[11] 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).

[12] 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

[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; *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

The claims on file

[18] Claims 1 and 8 are the only independent claims on file. Claim 1 is illustrative:

> 1. Use of an anti-ErbB2 huMab4D5-8 antibody in the manufacture of a medicament for use in treating a human patient diagnosed with a breast cancer characterized by over expression of ErbB2, wherein the anti-ErbB2 huMab4D5-8 antibody is for use in dosage forms comprising an initial dose of 8mg/kg; and a plurality of subsequent doses in an amount that is 6mg/kg, wherein the doses are separated in time from each other by three weeks.

[19] Claim 8 is directed to an "anti-ErbB2 huMab4D5-8 antibody for use in formulating dosage forms of a medicament" and otherwise defines the same elements as claim 1.

[20] Dependent claims 2-7 and 9-14 provide further limitations relating to combination therapy, the dosage form and the serum concentration of antibody that is maintained by the regimen.

Claims construction

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

[21] On page 2, the FA identified the skilled person as a research team including immunologists, clinical scientists specializing in cancer, drug manufacturers and general practitioners. The CGK was said to include knowledge of the role of ErbB2 in the pathogenesis of ErbB2-overexpressing tumours and of the use of an anti-ErbB2 huMab4D5-8 antibody to treat breast cancer.

[22] 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

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

[24] 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.

[25] With respect to the claims on file, the skilled person 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, with the exception of paclitaxel and docetaxel which are defined as alternatives in claims 4 and 11. 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 1-14 as essential, including the dosage regimen comprising the 8mg/kg loading dose of the antibody followed by maintenance doses of 6mg/kg every three weeks.

Patentable subject-matter and methods of medical treatment

[26] 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 regimen 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 response.

[27] On page 3, the FA expressed the view that while the claims appear to be directed to a fixed dosage regimen, reading them in the context of the description reveals that the exercise of a physician's skill and judgment is required, providing three reasons in support. First, the description indicates that determining the appropriate dose is at the discretion of the physician and depends on patient-specific factors such as the severity and course of the disease and the patient's clinical and treatment history. Second, a physician would need to exercise their skill and judgment in order to determine how many subsequent doses should be used. Third, the dosage is not fixed because it is based on the weight of the patient, which is variable, and would need to be calculated to practice the claimed invention.

[28] The RFA disputed that the claims require the exercise of skill and judgment and submitted that the claimed subject-matter is a new use for a vendible product that does not relate to

methods requiring the expertise of a medical professional. The three reasons set out in the FA were addressed as follows.

[29] With respect to the first point, the RFA disputed that the teachings of the description contradict the claims, explaining on page 4 that the passages discussing the physician's discretion in selecting the dosage based on patient-specific factors relate to different aspects or different inventions from the claims on file:

> The words of the claims are clear in relating to new uses, not methods. The statement at page 31, lines 30-33 of the Description regarding attending physicians, relied upon in the Requisition, is clearly a passage that relates to aspects of the prevention or treatment of disease. This is indeed a characterization that is potentially relevant to medical methods, which are patentable in a significant number of other jurisdictions, and the Description is necessarily written to meet the requirements for patentability in those other jurisdictions. However, the claims under consideration in Canada *do not recite methods of prevention or treatment of disease*, the claims recite a new use for a vendible product. Reliance on this aspect of the Description, which relates to a different invention, to construe the subject matter that is presently claimed is accordingly unnecessary, and therefore inappropriate.
>
> …
>
> With respect, in the Requisition, the reference to the Description is used not merely to vary the scope of the claims, but to cast the claims as being directed to an entirely different category of subject matter. (emphasis in the original)

[30] To the extent that the Applicant is saying that it would be inappropriate to consider and apply statements from the description that pertain to a different invention from a claim under review, we would agree. However, if these statements are meant to suggest that it is inappropriate to read medical use claims in the context of the specification as a whole, then we would not agree. 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).

[31] The independent claims are explicit in their inclusion of the dosage regimen. In our view, the actual invention in each of the claims on file includes using the antibody at an initial dose of 8mg/kg and subsequently at a dose of 6mg/kg every three weeks thereafter. Having considered these claims in the context of the specification as a whole, we agree with the Applicant that the broad statements referred to in the FA and RFA do not pertain to the subject-matter or the actual invention of any of the claims on file.

[32] With respect to the second point that a physician would have to determine the duration of

treatment, the RFA said the following:

> With respect, this category of decision is one that is inherent to putting into practice any new therapeutic use. If a claim merely recites "the use of X for treating Y", a decision must be made to implement the new use, and this necessarily involves a decision as to how long the use should continue. Claims of this kind are routinely granted, and enforced by our courts, so that it cannot be the case that subject matter falls outside the scope of Section 2 merely because the implementation of the new use requires a decision to do so, and to continue doing so.

[33] We agree that claims of the kind "the use of X for treating Y" are routinely granted and enforced by our courts, provided there is no indication that a physician is required to exercise their skill or judgment within the scope of such a claim. The Federal Court in *AbbVie* considered such a claim that also included a fixed 40 mg bi-weekly dosage and concluded that the claim would not require or restrict the exercise of professional skill or judgment (para 121):

> In the present case, the physician's skill is not expected to be exercised within the claim. The prescribing practices are not restricted. The physician must exercise skill and judgment to determine if the claimed use is appropriate for the patient. The physician decides to prescribe it as is or not at all. If prescribed, there would be no restriction on the exercise of skill or judgment.

[34] In the same manner as the decision to prescribe that was discussed in *AbbVie*, our view is that the decision to stop treatment in the instant application is also outside the scope of the claims.

[35] With respect to the last point that a patient's weight is variable and the use would require a dosage calculation, the RFA argued on page 6 that this does not transform a "use" claim into a method claim, and that the need to weigh a patient does not invoke a requirement for professional expertise. The Applicant further submitted a Declaration from Laura Shields, the Director of Medical Strategy at Roche Canada, stating the following:

> Biologics are often sold for intended use in dosages that are given in mg/kg, and the administration of drugs in such dosages is a routine mechanical clinical exercise that does not in and of itself invoke a requirement for the exercise of discretionary medical skill or judgement.

[36] We agree with the Applicant that weighing a patient does not invoke a requirement for professional expertise. We further agree that the expression of a dose in mg/kg is not, on its own, determinative that skill and judgment is required merely because, in practice, the dose would have to be calculated for a patient based on their weight.

[37] There is no evidence contradicting that the doses in these claims are fixed at 8mg/kg and 6mg/kg, or that the physician would need to make adjustments or select a different dose. Likewise, there is no indication on the record that changes in the patient's weight would be expected or that monitoring of any kind, including the monitoring of a patient's weight, would be required. Based on the record as it stands, our view is that the doses are fixed and the calculation to convert each dose from mg/kg to a specific dose based on a patient's weight would not require the skill and judgment of a medical professional.

[38] 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 1-14 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

[39] 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	Marcel Brisebois	Christine Teixeira
Member	Member	Member

DECISION OF THE COMMISSIONER

[40] 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 17th, day of March, 2021