Citation: Abbott Molecular Inc. (Re), 2021 CACP 19
Commissioner's Decision #1572
Décision du commissaire nº1572
Date: 2021-05-04

TOPIC: J40 Mental Steps

SUJET: J40 Processus psychologique

Application No. : 2,599,445

Demande nº 2 599 445

IN THE CANADIAN PATENT OFFICE

DECISION OF THE COMMISSIONER OF PATENTS

Patent application number 2,599,445 having been rejected under subsection 30(3) of the *Patent Rules* (SOR/96-423) as they read immediately before October 30, 2019 (the former *Patent 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 2,599,445, which is entitled "Diagnostics Method For Identifying Candidate Patients For the Treatment With Trastuzumab" and is owned by Abbott Molecular 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] As explained in more detail below, our recommendation is that the Commissioner of Patents withdraw the rejection and that the application be allowed.

BACKGROUND

The Application

[3] The application was filed under the *Patent Cooperation Treaty* and has an effective filing date in Canada of March 8, 2006. It was laid open to public inspection on September 21, 2006.

[4] The rejected application relates to diagnostic methods to identify breast cancer patients suitable for treatment with an anti-ErbB2 antibody, such as trastuzumab. Patients are identified as suitable for treatment with trastuzumab if an increase in the copy number for HER-2/neu but no increase in the copy number for TOP2A can be detected relative to one or more corresponding chromosomal probes. Patients are unsuitable for treatment with trastuzumab if an increase in the copy number of both HER-2/neu and TOP2A is detected.

[5] The application has 6 claims on file, which were received at the Patent Office on February 15, 2017.

Prosecution History

[6] On February 4, 2019, a Final Action (FA) was written pursuant to subsection 30(4) of the former *Patent Rules*. The FA indicates that the essential elements of claims 1–6 (all claims on file) are limited to disembodied mental conclusions which do not fall into a category of invention defined in section 2 of the *Patent Act*.

[7] In a response to the FA (RFA) dated August 6, 2019, the Applicant did not propose any amendments but submitted arguments as to why the claims on file are directed to statutory

subject-matter.

[8] 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 September 24, 2019 the Board forwarded a copy of the SOR to the Applicant. In a response dated November 8, 2019, the Applicant indicated its continued interest in having the application reviewed.

[9] 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.

[10] Following the Examiner's SOR, 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*]. As this guidance supersedes the approach applied in the FA as set out in the *Manual of Patent Office Practice* (CIPO) at §12.02 (June 2015) and §17.03.04 (November 2017), 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 January 20, 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*.

ISSUE

[11] The sole issue to be considered by this review is whether claims 1–6 on file define patentable subject-matter that falls within the definition of "invention" in section 2 of the *Patent Act*.

LEGAL PRINCIPLES AND PATENT OFFICE PRACTICES

Purposive construction

[12] In accordance with *Free World Trust v Électro Santé Inc*, 2000 SCC 66 [*Free World Trust]* 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.

[13] *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 diagnostic methods

[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] Subsection 27(8) of the *Patent Act* also prescribes that:

> No patent shall be granted for any mere scientific principle or abstract theorem.

[16] *PN2020-04* describes the Patent Office's approach to determining if a claim is patentable subject matter:

> 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.

[17] With particular reference to the determination of patentable subject-matter in respect of diagnostic method claims, *PN2020-04* states that:

> A claim to a medical diagnostic method often includes an element correlating a specific analyte or the result of a medical test to a disease. A correlation, on its own, would generally be considered an abstract or disembodied idea. In many cases, a claim to a medical diagnostic method further includes one or more physical steps that comprise carrying out a

medical test or determining the presence or quantity of the analyte in a sample. Such steps may include, for example, means for identifying, detecting, measuring, etc. the presence or quantity of an analyte.

An abstract idea that is an element of a claim that cooperates with other elements of the claim becomes part of a combination of elements making up a single actual invention. In such cases, all of the elements of the combination are considered as a whole and may constitute patentable subject-matter if the actual invention either has physical existence or manifests a discernible physical effect or change.

Thus, a diagnostic method claim that defines a combination of elements that cooperate together so as to form a single actual invention that includes physical means for testing or for identifying, detecting, measuring, etc. the presence or quantity of an analyte in a sample would be considered to be patentable subject-matter and not to be prohibited under subsection 27(8) of the *Patent Act.*

ANALYSIS

Purposive construction

The claims on file

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

1. A method for identifying a candidate patient for treatment with trastuzumab, the method comprising:

a. contacting a biological sample comprising at least one breast cancer cell obtained from a patient with a set of two or more chromosomal probes and one or more corresponding chromosome enumeration probes under conditions sufficient to enable hybridization of the probes to chromosomes in said biological sample, wherein the two ore more chromosomal probes bind selectively to the polynucleotide sequence for HER-2/neu (17q11.2-q12) and the genetic loci TOP2A (17q21-q22);

b. detecting hybridization of the two or more chromosomal probes and the one or more chromosome enumeration probes;

c. determining copy number of HER-2/neu and copy number of TOP2A from the hybridization of the two or more chromosomal probes sample relative to the one or more chromosome enumeration probes; and

d. identifying the candidate patient as being suitable for treatment with trastuzumab based on detecting an increase in the copy number for HER-2/neu but no increase in the copy number of TOP2A in the sample relative to the one or more chromosome enumeration probes and identifying the candidate as being unsuitable for treatment with trastuzumab based on

> detecting an increase in the copy number for HER-2/neu and an increase in the copy number of TOP2A in the sample.

[19] Dependent claims 2–6 provide further limitations relating to the source of the biological sample, type of chromosomal and enumeration probes and whether the patient has been diagnosed with breast cancer.

The skilled person and the relevant CGK

[20] The FA, on page 3, said the following in regard to the skilled person and the CGK:

> In view of statements in the description on pages 1-2 and the examples, the person skilled in the art to whom the application is directed can be characterized as a team including an oncologist, a molecular biologist, and a medical technologist.
>
> The person skilled in the art would possess the following CGK:
>
> - overexpression of the HER-2 receptor protein (ERBB2) is associated with more aggressive breast cancer and results primarily from amplification of the HER-2/neu gene;
> - topoisomerase II-alpha (TOP2A) gene aberrations are associated with HER-2 amplified breast cancers;
> - chromosomal probes useful for detecting solid breast tumours, including commercial fluorescence *in situ* hybridization (FISH) probe sets (for example, see page 22 of the description which discloses the use of a 3-colour probe set, LSI TOP2/HER-2/CEP 17, which was commercially available from Vysis, Inc. and marketed as FISH probes for detecting solid breast cancer tumours);
> - means for detecting hybridization of labelled chromosomal probes that bind selectively to HER-2/neu and TOP2A for the purpose of determining the copy numbers of HER-2/neu and TOP2A in breast tumour cells; and
> - breast cancer therapies, including the use of trastuzumab.

[21] The Applicant did not contest or comment on this characterization, and so we adopt it for the purposes of this review.

Essential elements

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

[23] As set out above, *PN2020-04* indicates 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.

[24] With respect to the claims on file, the skilled person reading claims 1–6 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 1–6 as essential.

Patentable subject-matter and diagnostic methods

[25] According to the FA and the SOR, the essential elements of the diagnostic methods of claims 1–6 are limited to disembodied mental conclusions. However, this assessment is based on guidance that has since been rescinded. As explained above, the Office's revised position *vis-à-vis* diagnostic methods considers whether the actual invention is a combination of elements that has physical existence or manifests a discernible physical effect or change.

[26] In light of the revised essential elements identified above and the guidance as to the assessment of patentable subject-matter set out in *PN2020-04*, we set out below a revised assessment of patentable subject-matter.

[27] Representative claim 1 on file, set out above, primarily relates to the steps of a diagnostic method for identifying if a candidate patient is suitable for treatment with trastuzumab. The description, on pages 1–2, explains that:

> HER-2 amplification is an established predictor of tumor response to trastuzumab

and that

> there is a need for methods for identifying those tumors that can be treated more successfully with trastuzumab […] thereby avoiding prescription of trastuzumab therapy for patients unlikely to benefit from trastuzumab and further avoiding the attendant patient morbidity and cost of doing so.

[28] In the RFA, on pages 3–4, the applicant argued that data acquisition and data analysis elements interact with each other and therefore are a combination:

> [I]n order for the method to identify a candidate patient for treatment with trastuzumab (*i.e.* provide an operable solution to the problem clearly identified in the application) the data

> acquisition and data analysis steps must interact. In particular, HER-2/neu and TOP2A copy number must first be determined in a sample from the candidate patient by detecting hybridization of chromosomal probes. Patients are next identified based on analysis of the copy numbers of HER-2/neu and TOP2A determined from the hybridization of the chromosomal probes. The Applicant submits that the identification of particular patients requires both the screening of patients with the chromosomal probes and the analysis of the data obtained from screening the patients. Accordingly, the Applicant submits that the data acquisition and data analysis elements interact with each other to achieve a unitary result (*i.e.* identification of a patient susceptible to effective treatment with trastuzumab) and therefore are a combination.

[29] We agree. In our view, it is evident from the claim language and the rest of the specification that the data acquisition elements and the data analysis elements cooperate to form a single actual invention that allows for the identification of patients who are suitable for treatment with trastuzumab. As the steps of a. contacting a biological sample with chromosomal probes for HER-2/neu and TOP2A and chromosome enumeration probes and b. detecting hybridization of said probes are clearly physical steps, the actual invention of claim 1 on file manifests a discernable effect or change. In comprising the use of data analysis elements and the physical steps of data acquisition, it is our view that the actual invention of claim 1 on file also relates to the manual or productive arts and is not prohibited subject-matter under subsection 27(8) of the *Patent Act*.

[30] We consider that dependent claims 2–6, being directly dependent on independent claim 1, also comprise actual inventions that manifest a discernable effect or change, are related to the manual or productive arts and that are not prohibited subject-matter under subsection 27(8) of the *Patent Act*.

[31] In light of the above, our conclusion is therefore that claims 1–6 are directed to patentable subject-matter and therefore comply with section 2 of the *Patent Act*.

RECOMMENDATION OF THE BOARD

[33] In view of the above, the Panel considers 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.

Christine Teixeira	Marcel Brisebois	Ryan Jaecques
Member	Member	Member

DECISION OF THE COMMISSIONER

[34] 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, Quebec

this 4th day of May, 2021.