Citation: Genentech, Inc. (Re), 2021 CACP 20
Commissioner's Decision #1573
Décision du commissaire nº1573
Date: 2021-05-04

TOPIC: J40 Mental Steps

SUJET: J40 Processus psychologique

Application No. : 2,569,520

Demande nº 2 569 520

IN THE CANADIAN PATENT OFFICE

DECISION OF THE COMMISSIONER OF PATENTS

Patent application number 2,569,520 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 2,569,520, which is entitled "KRAS Mutations For Identifying Colorectal Tumors Responsive to Cetuximab or Panitumumab" 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] 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 June 2, 2005. It was laid open to public inspection on December 15, 2005.

[4] The rejected application relates to diagnostic methods to identify colorectal tumors that will respond to treatment with cetuximab or panitumumab. Colorectal tumors are identified as susceptible to treatment based on the presence of wild-type KRAS protein.

[5] The application has 7 claims on file, which were received at the Patent Office on January 17, 2017.

Prosecution History

[6] On August 14, 2017, 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 1–7 (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 February 14, 2019, the Applicant proposed a set containing 33 claims. Notably, proposed claims 1–7 remained unchanged and the Applicant continued to argue why, in their view, these claims are compliant with section 2 of the *Patent Act*.

[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). The SOR also noted that in addition to being directed to non-patentable subject-matter, proposed claims 8–16 were defective for other reasons and that there was a unity issue with claims 17–33. On April 1, 2019 the Board forwarded a copy of the SOR to the Applicant. In a response dated August 1, 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*]. Notably 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 in the Patent Notice: "Examination Practice Respecting Medical Diagnostic Methods – PN2015-02" (June 2015).

ISSUE

[11] The sole issue to be considered by this review is whether claims 1–7 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 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] Claims 1 and 3 are the only independent claims on file:

> 1. A method for identifying a colorectal tumor in a human subject that will respond to treatment with cetuximab or panitumumab, comprising (i) experimentally determining the presence of a wild-type KRAS protein or gene in a sample of said tumor, wherein the presence of a wild-type KRAS protein or gene indicates that the tumor will respond to treatment with cetuximab or panitumumab; or (ii) determining the presence of a mutated KRAS protein or gene in a sample of said tumor, wherein the absence of a mutated KRAS protein or gene indicates that the tumor will respond to treatment with cetuximab or panitumumab, and wherein said mutated KRAS protein comprises, or said mutated KRAS gene encodes, at least one of the following mutations G12C, G12A, G12D, G12R, G12S, G12V, G113C, and G13D.
>
> 3. A method for determining whether a colorectal tumor in a human subject is not responsive to therapy with cetuximab or panitumumab comprising: experimentally determining the presence of a KRAS gene having a mutation in a sample of said tumor, wherein said mutated KRAS gene encodes one or more of the following mutations: G12C, G12A, G12D, G12R, G12S, G12V, G113C, and G13D; and wherein the presence of the KRAS gene mutation indicates that the tumor is not responsive to treatment with cetuximab or panitumumab.

[19] Dependent claims 2 and 4–7 provide further limitations relating to the specific mutation and the means for determining the presence of a wild-type or mutated KRAS gene.

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:

> The description refers to "a method for identifying a tumor in a human subject that is susceptible to treatment with an EGFR inhibitor" and "determining the presence of a wild-type KRAS protein or gene in a sample" (see page 3, lines 26-32). As such, the person skilled in the art to whom the application is directed can be characterized as a research team including clinical scientists working in the area of cancer treatment, and diagnosticians working in the area of detection of cancer biomarkers.
>
> It is well known in the common general knowledge of the skilled person in the art how to detect and identify KRAS mutant and/or KRAS wild-type in both the gene and protein of colorectal tumors (see D2, D3 and D4). Furthermore, the description outlines several methods known in the art to detect mutations on pages 14-18, including page 14, lines 8-11, explicitly indicating that "methods for determining the presence of K-Ras mutations are analogous to those used to identify EGFR mutations described in detail herein."

[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 1–7 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 the mutations in the KRAS protein that are listed as alternatives in claims 1 and 3. 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 1–7 as essential.

<u>Patentable subject-matter and diagnostic methods</u>

[25] According to the FA and the SOR, the essential elements of the diagnostic methods of claims 1–7 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 claims 1 and 3 on file, set out above, primarily relate to the steps of a diagnostic method for identifying if a colorectal tumor will respond to treatment with cetuximab or panitumumab or determining if a colorectal tumor is not responsive to treatment with cetuximab or panitumumab. The description, on page 13, explains the discovery that certain KRAS mutations are correlated with poor prognosis to chemotherapy:

> The tumor samples were also analyzed for mutations in KRAS (as referred to as p21a). Particular mutations detected in exon 1 are: G12C; G12A; G12D; G12R; G12S; G12V; G13C; G13D which correlated with poor prognosis to chemotherapy as well as chemotherapy with erlotinib therapy. Accordingly, the invention further provides a method for identifying patients not responsive to therapy with an EGFR inhibitor such as erlotinib or erlotinib in combination with chemotherapy comprising determining the presence or absence of a KRAS mutation whereby the presence of said mutation indicates that a patient will not respond to said therapy.

[28] In the RFA, on pages 5–7, the applicant argued that the essential elements are not limited to disembodied mental conclusions, explaining that without screening a colorectal tumor sample for the recited mutations in KRAS it would not be possible to determine whether or not a colorectal tumor has an increased likelihood of benefiting from treatment with cetuximab or panitumumab.

[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 colorectal tumors that will respond to treatment with cetuximab or panitumumab (claim 1) or the determination of colorectal tumors that are not responsive to treatment with cetuximab or panitumumab (claim 3). As the steps of (i) experimentally determining the presence of a wild-type KRAS protein or gene in a sample of said tumor and (ii) determining the presence of a mutated KRAS protein or gene in a sample of said tumor are clearly physical steps, the actual invention of claim 1 on file manifests a discernable effect or change. Likewise, the actual invention in claim 3 contains a step of experimentally determining the presence of a KRAS

gene having a mutation in a sample of said tumor which satisfies the physicality requirement. In comprising the use of data analysis elements and the physical steps of data acquisition, it is our view that the actual inventions of claims 1 and 3 on file also relate 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 and 4–7, being directly dependent on independent claims 1 and/or 3, 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 1–7 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.