Commissioner’s Decision #1409

Décision du commissaire #1409

TOPIC: J80 SUBJECT MATTER OF APPLICATIONS - Professional or Artistic Skill,
K11 SUBJECT MATTER OF APPLICATIONS - Living Things - Treatment of

SUJET: J80 OBJET DES DEMANDES - Aptitudes professionnelles (artistiques),
K11 OBJET DES DEMANDES - Matières vivantes - Traitement

Application No.: 2,504,868

Demande n°.: 2,504,868

IN THE CANADIAN PATENT OFFICE

DECISION OF THE COMMISSIONER OF PATENTS

Patent application number 2,504,868 having been rejected under subsection 30(3) of the *Patent Rules*, has subsequently been reviewed in accordance with paragraph 30(6)(*c*) of the *Patent Rules*. The recommendation of the Patent Appeal Board and the decision of the Commissioner is to allow the application.

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INTRODUCTION

[1] This recommendation concerns the review of rejected patent application number 2,504,868, which is entitled "MULTIPLE-VARIABLE DOSE REGIMEN FOR TREATING TNFα-RELATED DISORDERS" and is owned by AbbVie Biotechnology Ltd. The outstanding substantive defect to be addressed is whether the claims define subject-matter that lies outside the definition of "invention" found in section 2 of the *Patent Act*. A review of the rejected application has been conducted by the Patent Appeal Board pursuant to paragraph 30(6)(*c*) of the *Patent Rules*. For the reasons set out below, our recommendation is that the rejection ought to be withdrawn and the application to thereafter proceed to allowance.

BACKGROUND

The Application

[2] Patent application 2,504,868 (or the "'868 Application") was filed in Canada on April 11, 2005 and published on September 26, 2005.

[3] Very generally, the '868 Application discloses methods of using therapeutic agents to treat disorders in which tumour necrosis factor is implicated. Prominent among the therapeutic agents disclosed in the '868 Application is the monoclonal antibody D2E7 (also known as adalimumab), which is sold commercially, in Canada and throughout the world, in association with the trade-mark HUMIRA.

[4] More particularly, the "Background of the Invention" section begins by explaining that cytokines, including tumor necrosis factor, are molecules known to be mediators of inflammatory processes. Elevated levels of tumor necrosis factor (which can also be referred to as "TNF" or "TNFα"), have been implicated in the pathophysiology of a variety of human diseases and disorders. Of particular relevance, the background explains that (see page 2, lines 14-18):

> TNF has also been implicated in Crohn's disease…The treatment of Crohn's disease is challenging. Treatment is based on location, extent, and severity of disease. Current compounds and regimens do not completely abate the inflammatory process and have significant side effects.

[5] In view of this, the specification goes on to summarize the invention as follows (see page 2, lines 22 to page 3, line 2):

> **Summary of the Invention**
>
> There is a need to treat TNFα-related disorders, where TNFα activity is detrimental, in a safe and effective manner. The present invention includes multiple-variable dose methods for improved treatment of TNFα-related disorders where TNFα activity is detrimental.
>
> The invention describes a multiple-variable dose method for treating a disorder in which TNFα activity is detrimental, comprising administering to a subject in need thereof at least one induction dose of a TNFα inhibitor such that a threshold level of TNFα inhibitor is achieved within an induction phase; and subsequently administering to the subject at least one treatment dose of the TNFα inhibitor within a treatment phase, such that treatment occurs.
>
> The invention also describes a multiple-variable dose method for treating Crohn's disease, comprising administering to a subject in need thereof at least one induction dose of a TNFα inhibitor such that a threshold level of TNFα inhibitor is achieved within an induction phase; and subsequently administering to the subject at least one treatment dose of the TNFα inhibitor within a treatment phase, such that treatment occurs. The multiple-variable dose method of the invention can also be used to treat ulcerative colitis…

[6] The Detailed Description (see pages 10 to 101) explicitly teaches that there can be variability with respect to the parameters of this method, including:

> i. the TNFα inhibitor used (which can include etanercept, infliximab, or a TNFα antibody having various functional characteristics or sequence identities; see pages 18 to 30);
> ii. the nature of the TNFα disorder that can be treated (see pages 30 to 83);
> iii. the doses that can be given (see pages 86 to 87); and
> iv. the dosage forms and routes of administration that may be employed (see pages 83 to 85).

[7] Accordingly, the invention as disclosed can be understood to be methods having the following limitations:

- they must make use of a TNFα inhibitor;
- they must be for treatment of a TNFα-related disorder; and
- the whole must result in treatment.

[8] The disclosure ends with four examples, the most relevant of which is Example 1, entitled "Study of Efficacy of Multiple-Dose Therapy for Treatment of Crohn's Disease." This example discloses the results of a clinical trial in which patients suffering from Crohn's disease who received 160 mg D2E7 followed by 80 mg D2E7 two weeks later had a statistically significant clinical benefit compared to subjects who were given placebo. This example also discloses that patients suffering from Crohn's disease who received 80 mg D2E7 followed by 40 mg D2E7 two weeks later had a better clinical benefit compared to placebo, although these differences are not reported to be statistically significant.

[9] Throughout prosecution, various claims were sought by the Applicant that encompass variability in dosing parameters. However, the claims submitted by the Applicant in response to the Final Action, which we consider to be the claims on file, are substantially more limited and precise in terms of the specific parameters than the invention as described. In particular, claim 1, the only independent claim in this claim set, provides as follows:

> 1. Use of D2E7 in multiple doses for treating inflammatory bowel disease in a human subject, wherein the multiple doses comprise:
>
> a first dose of 160 mg of D2E7 for subcutaneous administration;
>
> a second dose of 80 mg of D2E7 for subcutaneous administration two weeks following administration of the first dose; and
>
> a third dose of 40 mg of D2E7 for subcutaneous administration two weeks following administration of the second dose.

[10] There are numerous statements in the disclosure to the effect that the parameters recited in the current claims are all either preferred or most preferred embodiments (see, for example, page 88, lines 5 to 9 and 26 to 27). Therefore, in contrast to the breadth and variability of parameters in the disclosure and previous claim sets, it appears the above claim 1 is explicitly drawn to a specific set of dosing parameters, which is supported by the regimens tested in Example 1 and contemplated on page 88.

The Evolution of the Office's Position on Claims Respecting Medical Uses

[11] As explained in more detail below, the '868 Application was rejected on the basis that the sought after claims encroached upon the physician's right to determine how to treat a particular patient and therefore were directed to a method of medical treatment, which is subject-matter that is not within the definition of "invention" in section 2 of the *Patent Act*. However, the Patent Office's (the "Office") position on how to determine whether claims directed to medical uses constitute patentable subject-matter has changed during prosecution of the '868 Application. As such, prior to explaining the prosecution history of the '868 Application, it is helpful to explain the evolution of the Office's practice on claims to medical uses that occurred during prosecution.

[12] In particular, on June 10, 2013, the Office issued Practice Notice 2013-04 *Examination Practice Respecting Medical Uses* ("PN 2013-04"), which took the position that if, "after a purposive construction, it is determined that a dosage regimen is an essential element of a claim encompassing the use of a known compound in an established treatment, then the claim covers a method of medical treatment, and thus, is not compliant with section 2 of the *Patent Act.*"

[13] In addition to being applied in the present case (as explained below), PN 2013-04 was also relied upon for the Commissioner's refusal of a different application relating to D2E7 and owned by AbbVie. Specifically, in the Commissioner's Decision in *Re AbbVie Biotechnology Ltd.* (C.D. 1362), the Commissioner refused Canadian Patent Application No. 2,385,745 on the basis that the claims at issue "effectively cover a method of medical treatment" and therefore did not comply with section 2 of the *Patent Act*.

[14] AbbVie appealed this decision to the Federal Court of Canada, which, by way of a decision issued December 22, 2014, granted AbbVie's appeal and directed the Commissioner to allow the application; see *AbbVie Biotechnology Ltd. v. The Attorney General of Canada*, 2014 FC 1251 (*AbbVie*).

[15] The Office thereafter released a modified approach as to how it would treat claims that relate to medical uses. In particular, on March 18, 2015, the Office released Practice Notice 2015-01, entitled *Revised Examination Practice Respecting Medical Uses* ("PN 2015-01"), which rescinded PN 2013-04 and articulated the Office's revised position *vis-à-vis* medical uses in view of *AbbVie*.

[16] The most relevant change effected by PN 2015-01 was in the position towards claims for dosage regimens, providing, in relevant part, as follows:

> Where an essential element only serves to instruct a medical professional "how" to treat a patient, rather than "what" to use to treat the patient, it must be determined whether the essential element prevents, interferes with or requires the professional skill of a physician. If the answer is "yes", this will lead to the conclusion that the claimed use encompasses a method of medical treatment that does not comply with section 2 of the *Patent Act*.
>
> Essential elements that point to a limitation of a physician's professional skill or judgment include those that provide details of a dosing schedule encompassing a range and those that represent a range of potential dosages that a patient may receive (as distinct from a range of dosages forms). In contrast, essential elements that narrow treatment to a fixed dosage, a fixed dosage regimen, a patient sub-population or to a particular administration site are not considered to point to a limitation of a physician's professional skill or judgment. [Citations omitted.]

[17] Therefore, whereas PN 2013-04 appears to have provided a *per se* prohibition on the patenting of dosage regimens involving known compounds in established treatments, PN 2015-01 now directs that the parameters of a dosage regimen should be the subject of a further enquiry into whether the essential elements prevent, interfere with or require the exercise of a physician's professional skill or judgment.

Prosecution history

[18] Returning to specific details of the prosecution of the '868 Application, after six Office Actions and subsequent responses, prosecution culminated with the issuance of a Final Action (FA) on September 25, 2013 in which the Examiner determined that the application did not comply with the *Patent Act* and *Patent Rules* for a number of reasons. Among these was the view that the 93 claims that were then on file were directed to subject-matter that was outside the definition of "invention" and

therefore did not comply with section 2 of the *Patent Act*. In this regard, the Examiner, relying on PN 2013-04, stated that "[a] claim in which an essential element is a dosage range…limits the professional skill and judgment of a physician, and therefore is a method of medical treatment."

[19] The FA also took the view that all the claims were obvious and most of the claims either lacked support or were indefinite.

[20] As per subsection 30(4) of the *Patent Rules*, the Applicant's response to the FA was required by March 25, 2014. However, the Applicant did not respond by this deadline, such that the application was deemed to be abandoned pursuant to paragraph 73(1)(*a*) of the *Patent Act* ("the *Act*").

[21] On March 20, 2015, two days after the release of the revised Practice Notice 2015-01, the application was reinstated pursuant to subsection 73(3) of the *Act* and the Applicant provided their response to the FA (the "R-FA"), along with three declarations seeking to establish that the subject-matter was not obvious. In the R-FA, the Applicant indicated that they wished to amend the application so as to replace the 93 claims that were the subject of the FA with a claim set of five new claims, taking the view that these new claims overcame or rendered moot many of the defects identified in the FA under subsections 27(3) and 27(4) of the *Act* and section 84 of the *Patent Rules*. The Applicant also provided various arguments as to why the 93 claims that were the subject of the FA complied with the *Act* and *Patent Rules*.

[22] There was at this point some dispute between the Office and the Applicant as to whether the application had been amended. Ultimately, the Examiner considered the R-FA and took the view that neither claim set overcame all the defects set out in the FA. The Examiner therefore prepared a Summary of Reasons ("SOR"), which was forwarded to the Patent Appeal Board ("the Board").

[23] In the SOR, with respect to the 93 claims that were the subject of the FA, the Examiner maintained that all the defects raised in the FA persist. Additionally, the Examiner offered an "Informal Opinion" on the five new claims that were provided by the Applicant in its R-FA. Of note, the Examiner agreed that these claims would resolve the obviousness, lack of support and indefiniteness defects. The Examiner also acknowledged that these claims were restricted to a specific dosage regimen. Further, the Examiner applied PN 2015-01 for the first time to this application, but nonetheless concluded that the five new claims still encompassed non-patentable subject-matter.

[24] In a letter dated July 27, 2015 (the "Acknowledgement Letter") the Board forwarded the Applicant a copy of the SOR and offered the Applicant the opportunity to make further written submissions and attend an oral hearing.

[25] By way of correspondence dated August 13, 2015, the Applicant responded, taking the view that the claim set submitted to the Office on March 20, 2015 was the proper subject of the Board's review and therefore made certain proposals as to the procedure to be followed when the Board conducted its review. The Applicant sent further letters dated October 27, 2015 and February 12, 2016, confirming that they wished to make further submissions and attend an oral hearing, and reiterating their views on the amended claims.

[26] A Panel of the Board (the "Panel") was thereafter established to review the application. As a preliminary matter, the Panel considered the matters raised in the Applicant's correspondence of August 13, 2015. On May 30, 2016, the panel sent a letter indicating that it was of the view that according to subsection 30(4) of the *Patent Rules* and the transitional provisions found in the *Rules Amending the Patent Rules* (SOR 2013-212), the set of five claims that the Applicant sought to have entered by its March 20, 2015 response to the Final Action are the claims on file for this application.

[27] In this letter, the Panel noted that it was not clear from the record if the dispute about the claims on file was the result of a disagreement as to whether an application that had received a Final Action could be amended following reinstatement, or whether the amendments were not entered according to paragraph 30(6)(*b*) of the *Patent Rules* because the Examiner did not consider them to have overcome the defects raised in the FA. Either way, the Panel was of the view that the application had been amended, concluding, in summary, that:

- paragraph 73(3)(*b*) of the *Act* and subsection 30(4) of the *Rules* permit an Applicant to amend an application that has been subject to a Final Action and gone abandoned concurrently with reinstatement of that application; and

- paragraph 30(6)(*b*) of the *Patent Rules* means that amendments made after a Final Action that do not convince the Examiner to recommend allowance "shall be considered not to have been made." However, in this case, due to the operation of the various transitional provisions that governed the amendments that brought paragraph 30(6)(*b*) into effect in 2013, paragraph 30(6)(*b*) does not apply to this application.

[28] This letter therefore concluded, in relevant part, as follows:

> The overall effect of the above is that the claim amendments that the Applicant indicated it wished to make in the R-FA were, following reinstatement, permitted pursuant to s. 30(4). At the same time, having regard to the relevant legislation [*sic*] transitional provisions, s. 30(6)(*b*) does not apply to this application, such that the amendments sought in the R-FA ought to have been entered, even though they did not convince the Examiner to recommend allowance of the application.
>
> Accordingly, we are of the view that the current claims that are the subject of our review under paragraph 30(6)(*c*) of the *Patent Rules* are the 5 claims [submitted with the R-FA]. Our substantive review will therefore be based on the understanding that the "rejected application" contains the 5 claims [submitted with the R-FA].

[29] As such, our substantive review proceeded on this basis. For greater clarity, we express no view regarding the patentability of the 93 claims that were the subject of the FA. However, to the extent that it is necessary to distinguish between the claim sets below, we will refer to the 93 claim set and the five claim set as, respectively, the "FA Claims" and the "Claims on File."

[30] Finally, although our invitations to make further written submissions and attend an oral hearing were both accepted by the Applicant, we consider that, in light of our recommendation that the rejection be withdrawn and the application be allowed, these are no longer necessary.

ISSUES

[31] Based on our reading of the FA, the SOR and the Applicant's R-FA, the only substantive issue remaining is whether the Claims on File are within the definition of "invention" under section 2 of the *Act*.

LEGISLATION AND LEGAL PRINCIPLES

Purposive construction

[32] In accordance with *Free World Trust v Électro Santé Inc*, 2000 SCC 66 [*Free World Trust*] essential elements are identified through a purposive construction of the claims 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.) In accordance with the *Manual of Patent Office Practice*, §13.05 [revised June 2015], the first step of purposive claim construction is to identify the person skilled in the art and their relevant common general knowledge ("CGK"). The next step is to identify the problem addressed by the inventors and the solution put forth in the application. Essential elements can then be identified as those required to achieve the disclosed solution as claimed.

Statutory subject-matter

[33] The definition of invention is set out in section 2 of the *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.

[34] As previously explained, the Office's practice towards the patentability of medical use claims has changed during the course of prosecution of the present application and is now governed by PN 2015-01, which provides:

> Section 2 of the *Patent Act* requires the subject-matter of an invention to fall within one of the categories of invention, *i.e.* an art, process, machine, manufacture, composition of matter, or an improvement in one of the foregoing.
>
> Medical inventions, in particular, have been subject to a number of jurisprudential interpretations whereby certain types of matter have been found to fall outside the scope of section 2. For instance, it is well established that methods of medical treatment and surgery are not statutory subject-matter and are excluded from the definition of *invention*.
>
> Medical use claims, however, are generally permitted as long as they do not equate to medical or surgical methods (*e.g.* do not include an active treatment or surgical step) and they satisfy all other requirements of patentability. The Federal Court has concluded, however, that inventions preventing physicians from exercising their skill and judgment in using a known compound for an established purpose effectively cover a method of medical treatment. [Citations omitted]

[35] As discussed in more detail below, PN 2015-01 thereafter sets out the Office's approach to determining whether or not a claim constitutes patentable subject-matter.

Other Legislative Provisions

[36] For completeness, the relevant abandonment and reinstatement provisions of the *Patent Act* referred to in paragraphs 20 to 28 above, provide as follows:

> **73(1)** An application for a patent in Canada shall be deemed to be abandoned if the applicant does not
>
> > **(*a*)** reply in good faith to any requisition made by an examiner in connection with an examination, within six months after the requisition is made or within any shorter period established by the Commissioner;
> > **(*b*)** comply with a notice given pursuant to subsection 27(6);
> > **(*c*)** pay the fees payable under section 27.1, within the time provided by the regulations;
> > **(*d*)** make a request for examination or pay the prescribed fee under subsection 35(1) within the time provided by the regulations;
> > **(*e*)** comply with a notice given under subsection 35(2); or
> > **(*f*)** pay the prescribed fees stated to be payable in a notice of allowance of patent within six months after the date of the notice.
>
> …
>
> **(3)** An application deemed to be abandoned under this section shall be reinstated if the applicant

> **(*a*)** makes a request for reinstatement to the Commissioner within the prescribed period;
> **(*b*)** takes the action that should have been taken in order to avoid the abandonment; and
> **(c)** pays the prescribed fee before the expiration of the prescribed period.

[37] Further, subsection 30(6) of the *Patent Rules*, also referred to in paragraphs 20 to 28 above, provides as follows:

> **(6)** If the applicant amends the application or provides arguments within the time referred to in subsection (4) but, after the expiration of that time, the examiner does not have reasonable grounds to believe that the application complies with the Act and these Rules,
>
> > **(a)** the Commissioner shall notify the applicant that the rejection has not been withdrawn;
> > **(b)** any amendments made within the time referred to in subsection (4) shall be considered not to have been made; and
> > **(c)** the rejected application shall be reviewed by the Commissioner.

[38] Finally, s. 10 of the *Rules Amending the Patent Rules*, SOR 2013-212, which governs those applications to which subsection paragraph 30(6)(*b*) of the *Patent Rules* applies, reads as follows:

> Paragraph 30(6)(b) of the *Patent Rules*, as enacted by subsection 3(1) of these Rules, does not apply in respect of an application that was, before the coming into force of this section, rejected by an examiner in accordance with subsection 30(3).

ANALYSIS

Claim Construction

[39] For ease of reference, claim 1, the only independent claim among the Claims on File, provides as follows:

> 1. Use of D2E7 in multiple doses for treating inflammatory bowel disease in a human subject, wherein the multiple doses comprise:
>
> > a first dose of 160 mg of D2E7 for subcutaneous administration;
> >
> > a second dose of 80 mg of D2E7 for subcutaneous administration two weeks following administration of the first dose; and
> >
> > a third dose of 40 mg of D2E7 for subcutaneous administration two weeks following administration of the second dose.

The person skilled in the art

[40] In the SOR the Examiner identified the person skilled in the art as:

> A team of scientists that may comprise a medical practitioner with experience in treating TNFα-related inflammatory diseases, an immunologist with experience in molecular biology and biochemistry, and a clinician having experience with therapeutic treatments of TNFα-related inflammatory diseases and disorders, in particular, antibody therapies.

This characterization was the same as that provided by the Examiner in the FA in the obviousness analysis.

[41] In the R-FA (sent by the applicant in response to the FA before the SOR), the Applicant disagreed with this characterization, taking the view instead that the person skilled in the art is "an unimaginative clinical immunologist with clinical trial management and general knowledge in fundamental immunology." In support of this position, the Applicant noted that the Office had characterized the skilled person in this fashion for a previous application filed by the Applicant and relating to D2E7.

[42] We disagree with the Applicant's suggestion that the Office's characterization of the skilled person with respect to one application is determinative of the characterization for a different application. Each application will have different facts, including different arguments made by an Applicant during prosecution. Further, to the extent that there is any meaningful difference between the positions of the Examiner and the Applicant, we consider the Examiner to have expressed the better view. The present application is replete with references to TNFα and TNFα inhibitors, with a particular emphasis on therapeutic antibodies. It is therefore appropriate to consider that the person skilled in the art is not only knowledgeable in immunology generally, but rather specifically in TNFα-related matters.

[43] More generally, although the Examiner's finding was made in relation to the FA Claims, we consider that, having reviewed the specification, this characterization of the person skilled in the art applies equally to the Claims on File.

The common general knowledge

[44] The SOR indicates that the common general knowledge includes knowledge of "therapeutic reagents including TNFα antibodies, TNFα inhibitors, methods and use of said antibodies and inhibitors for the treatment of inflammatory disorders related to TNFα."

[45] Again noting that the Examiner's finding was made in relation to the FA Claims, we agree that this is an accurate statement of the common general knowledge having regard to the Claims on File.

The problem to be solved

[46] The SOR indicates the problem to be solved is the need to provide improved treatment of TNFα-related disorders where the TNFα activity is detrimental.

[47] Although we agree with the Examiner in this respect, we would clarify that the "improvement" must be understood as providing an alternative treatment that has been shown to work in patients (for example as against placebo) and not an improvement in the sense of overcoming a disadvantage of the prior art treatments referred to in the disclosure. In this regard, we note that although the disclosure states that there exist known treatments for psoriasis and Crohn's disease, it only alludes to the fact that these treatments may have undesirable aspects (see page 2, lines 4 to 25). As such, we cannot conclude that the problem addressed by the specification relates to any particular benefit over the known treatments. Rather, having regard to the specification as a whole, we consider the problem to be solved is the need to provide alternative treatments for TNFα-related disorders where the TNFα activity is detrimental.

The solution proposed

[48] The SOR states that the proposed solution is:

> Use of a multiple dose regimen that comprises administration of an induction dose of TNFα inhibitor (D2E7) to a subject, and subsequently administering at least one treatment dose to arrive at the desired results. [Emphasis Added.]

[49] Here, the fact that the Examiner's assessment was directed toward the FA Claims, and the Panel is assessing the Claims on File, results in the Panel having a somewhat different view of the solution proposed. In particular, whereas the FA Claims characterize the doses in the regimen as being either an "induction dose" or a "treatment dose", the Claims on File simply characterize the doses as a "first", "second" and "third" dose, each with specific parameters.

[50] Further, given the discussion above on the problem to be solved, we would clarify that in our view "the desired result" would be a treatment that is better than placebo, but not necessarily superior to other known treatments. More particularly, having regard to the Claims on File, the Panel is of the view that the solution proposed is the use of a multiple dose regimen that comprises subcutaneous administration of a first dose of 160 mg D2E7, followed by a second dose of 80 mg D2E7 and a third dose of 40 mg D2E7, all of which will result in treatment of a human subject.

The essential elements

[51] The SOR assessed the essential elements of the 93 FA Claims as follows:

> The essential element to solve the problem in the present case is a multiple dose regimen using an induction dose of the TNFα inhibitor and at least one subsequent treatment dose.

[52] Here, again, the fact that the Examiner's assessment was directed toward the FA Claims, and the Panel is assessing the Claims on File, results in the Panel having a different view of the essential elements. Specifically, in view of the above-discussed

problem and solution, and taking into account the specific language of the Claims on File, we are of the view that the essential elements of claim 1 are as follows:

1) the specific therapeutic antibody D2E7;
2) for use in a regimen for treating inflammatory bowel disease in a human subject;
3) this regimen, having the following parameters:

    a. a subcutaneous route of administration;
    b. three doses, each of which is two weeks following the previous one; and
    c. wherein the first dose is at 160 mg, the second dose is at 80 mg and the third dose is at 40 mg.

Meaning of Specific Terms

[53] Having regard to the specification as a whole, we do not consider that there is any ambiguity as to the meaning of the terms used in claim 1 to specify the parameters of the dosage regimen. Consequently, we consider the dosage regimen to be fixed in terms of the route of administration ("subcutaneous"), the doses of D2E7 (160 mg, 80 mg, 40 mg) and the timing between them (two weeks).

[54] This being said, the meaning of two aspects of claim 1 warrants brief discussion.

[55] The first is the nature of the use referred to in the phrase "use of D2E7 in multiple doses for treating inflammatory disease...". For clarity, we construe this to be a use of the known therapeutic monoclonal antibody D2E7 in a regimen to be employed by a physician when treating a patient; i.e. the claimed "use" requires the actual administration of D2E7 by a physician (or similar professional) when treating a human patient suffering from inflammatory bowel disease, according to the parameters set out in claim 1. In this way, we construe the claims to go beyond a claim to a composition of matter itself (i.e. D2E7 in specified amounts) to include a regimen directing how to use D2E7 according to certain dosing parameters.

[56] Secondly, we construe the use of the word "comprise" in claim 1 to admit the possibility of additional doses of D2E7 after the "first", "second" and "third" doses

are administered. This understanding is confirmed by claim 2, which specifically recites additional 40 mg subcutaneous doses of D2E7. However, we do not consider that any additional doses are necessary to solve the problem identified by the description. Rather, having regard to the specification as a whole, the proposed solution is directed towards the initial doses of D2E7 therapy, such that the inclusion of the word "comprise" in claim 1 serves only to make clear that the claim cannot be avoided by merely adding an additional dose.

[57] We regard claims 2 to 5 to relate to refinements of the essential elements set out in claim 1. For ease of reference, these claims read as follows:

> 2. The use according to claim 1, additionally comprising further doses of 40 mg of D2E7 for subcutaneous administration two weeks apart commencing two weeks following the administration of the third dose.
>
> 3. The use according to claims 1 or 2, wherein the first dose and the second dose are provided in four and two dosage unit forms of 40 mg of D2E7 each, respectively.
>
> 4. The use according to any one of claims 1 to 3, wherein the inflammatory bowel disease is Crohn's disease.
>
> 5. The use according to any one of claims 1 to 3, wherein the inflammatory bowel disease is ulcerative colitis.

We do not consider there to be any ambiguity as to the meaning of the terms used in claims 2 to 5.

Subject-Matter

The Examiner's Application of PN 2015-01

[58] In the "Informal Opinion" in the SOR, written less than three months after PN 2015-01 was published, the Examiner applied PN 2015-01 to the Claims on File and took the view that these claims were directed to excluded subject-matter. In this regard, it appears to the Panel that the Examiner's conclusion was not based on a finding that the claimed parameters were not fixed, but rather on the fact that the specification states that "specific dosage regimens should be adjusted over time". In particular, the Examiner wrote as follows:

> Applicant has restricted the independent claim (claim 1) to a specific dosage regimen wherein the three different fixed doses of D2E7 are to be administered at three different fixed time periods for the treatment of inflammatory bowel disease. In the first dependent claim (claim 2), Applicant has introduced additional doses of D2E7. While performing the claim construction, the Examiner takes the position that:
>
> > 1. The use of D2E7 in multiple doses for treating the inflammatory disorder would require a physician's judgment.
> >
> > 2. The use of D2E7 in multiple doses for treating the inflammatory disorder would require a continuous monitoring of the patient by the physician.
> >
> > 3. The multiple doses, as claimed in claim 1–3, amount to a titration schedule of the D2E7 to achieve the desired results.
>
> In this regard, the specification (in particular, pages 88–89) clearly indicates that "*specific dosage regimens should be adjusted over time according to the individual need and the professional judgment of the person administering or supervising the administration*…" Therefore the Examiner considers that the proposed claims 1–5 still appear to encompass non-statutory subject-matter and do not comply with section 2 of the *Patent Act*.

The Panel's Position on the Subject-Matter of the Claims on File

[59] As noted above, we construed the claims to go beyond a claim to a composition of matter itself (i.e. D2E7 in specified amounts) to include a regimen directing how to use D2E7 according to specified dosing parameters. Or, in the words of PN 2015-01, we construe the claim to include an essential element that serves to "instruct a medical professional 'how' to treat a patient."

[60] However, according to PN 2015-01, this is not the end of the matter; the current Office practice is to now ask "whether the essential element prevents, interferes with or requires the professional skill of a physician." In so doing, PN 2015-01 takes the view that "essential elements…that narrow treatment to…a fixed dosage regimen…are not considered to point to a limitation of a physician's professional skill or judgment."

[61] In this regard, we agree with the Examiner that independent claim 1 is restricted to a specific dosage regimen wherein the three different fixed doses of D2E7 are to be administered at three fixed time periods for the treatment of inflammatory bowel

disease. More to the point, the scope of the Claims on File, as construed, is specific to the particular parameters set out. Consequently, a physician's determination that an alternative dosage regimen is appropriate for their patient, would not, in our view, fall within the scope of these claims. Moreover, the disclosure, and in particular Example 1, referred to above, provide strong support for the notion that the claimed regimen will, in fact, work in patients without the need for modification, which further supports the understanding that the claimed dosage regimen is 'fixed'.

[62] In the SOR, the Examiner expressed the view that the possibility of additional doses in claim 2 and the need for a physician to monitor a patient receiving D2E7 mean that the claims amount to a titration, which results in the claims encompassing excluded subject-matter. In support of this position, the Examiner cited passages of the specification that contemplate that the disclosed dosage regimens must be adjusted according to the judgment of an administering professional. For example, the specification states (see page 89, lines 6 to 11):

> It is to be further understood that for any particular subject, specific dosage regimens should be adjusted over time according to the individual need and the professional judgment of the person administering or supervising the administration of the compositions, and that dosage ranges set forth herein in are exemplary only and are not intended to limit the scope or practice of the claimed composition.

[63] Such language in the specification does not, in our view, render the Claims on File an attempt to monopolize the medical decisions made by a physician. Rather, these passages seem to relate to the various embodiments disclosed in the specification for which specific parameters are not provided. In any event, having considered passages such as this in construing the language of the claims, we are of the view that the Claims on File must be construed as being limited to a specific, fixed dosage regimen from among the many possible permutations that are said to be within the scope of the invention in the disclosure.

[64] Moreover, we do not disagree with the Examiner to the extent that in an actual clinical setting there may well be the need for a physician to monitor a patient

receiving D2E7, or that the claims contemplate additional doses. However, where we see the matter differently from the Examiner is the impact that these observations have on the claim construction and consequent analysis of patentable subject-matter. In our view, the key point from a subject-matter perspective as set out in PN 2015-01 is that we do not construe these claims to monopolize the activities involved in this physician monitoring; any judgment or skill exercised by the physician would be outside the claim.

[65] Finally, we take note of the examples that accompanied publication of PN2015-01. Of course these examples are meant only for demonstration purposes, but we observe that our finding here appears to align with the suggestion from Example 5.1 that a claim that defines a fixed dosing regimen will likely be statutory unless, upon purposively construing the claim, it is determined that the claim actually encompasses a titration or otherwise attempts to monopolize the skill and judgment of a physician.

[66] Accordingly, we are of the view that the Claims on File have been restricted to a fixed dosage regimen, which does not seek to limit a physician's professional skill or judgment and are therefore patentable subject-matter within section 2 of the *Act*.

RECOMMENDATION OF THE BOARD

[67] For the reasons set out above, we are of the view that the rejection is not justified on the basis of the defects indicated in the Final Action notice and have reasonable grounds to believe that the application complies with the *Act* and the *Patent Rules*. We recommend that you notify the applicant in accordance with subsection 30(6.2) of the *Patent Rules*.

T. Nessim Abu-Zahra Member	Ryan Jaecques Member	Stephen MacNeil Member

DECISION

[68] I concur with the findings and recommendation of the Board. In accordance with subsection 30(6.2) of the *Patent Rules*, I hereby notify the Applicant that the rejection of the application is withdrawn, the application has been found allowable and I will direct my officials to issue a Notice of Allowance in due course.

Johanne Bélisle
Commissioner of Patents
Dated at Gatineau, Quebec,
this 23rd day of August, 2016