Citation : Biogen MA Inc. (Re), 2022 CACP 2
Commissioner's Decision #1609
Décision du Commissaire nº 1609
Date: 2022-01-24

TOPIC:	J80	Professional or Artistic Skill
	K11	Treatment
	C00	Adequacy or Deficiency of Disclosure
	B22	Not Supported by Disclosure
SUJET:	J80	Aptitudes professionnelles (artistiques)
	K11	Traitement
	C00	Caractère adéquat ou inadéquat de la description
	B22	Non appuyée par la divulgation

Application No. : 2,477,178

Demande nº 2 477 178

IN THE CANADIAN PATENT OFFICE

DECISION OF THE COMMISSIONER OF PATENTS

Patent application number 2,477,178, having been rejected under subsection 30(3) of the *Patent Rules* (SOR/96–423) as they read immediately before October 30, 2019, 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.

Agent for the Applicant:

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INTRODUCTION

[1] This recommendation concerns the review of rejected Canadian patent application number 2,477,178, which is entitled “Administration of agents for the treatment of inflammation” and is owned by Biogen MA Inc. (the Applicant).

[2] 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* (SOR/2019-251) (the *Patent Rules*). As explained in more detail below, our recommendation is that the Commissioner of Patents allow the application.

BACKGROUND

The application

[3] The application has a filing date of February 25, 2003, and was laid open to public inspection on September 4, 2003.

[4] The application relates to using natalizumab for the chronic treatment of multiple sclerosis (MS). Natalizumab is an agent that inhibits the alpha-4 subunit of integrin receptors found on the surface of certain immune cells that are thought to play a role in pathological inflammation and MS. Inflammation is reduced or prevented by blocking alpha-4 integrin using natalizumab.

[5] The claims under review are claims 1 to 7 on file, dated January 19, 2017 (claims on file).

Prosecution history

[6] On August 31, 2017, a Final Action (FA) rejecting the claims on file was issued pursuant to subsection 30(4) of the *Patent Rules* (SOR/96–423) as they read immediately before October 30, 2019. The FA stated that the claims on file were rejected for encompassing non-patentable subject-matter under section 2 of the *Patent Act*, for lacking support under section 84 (now section 60) of the *Patent Rules* and because the description did not enable the claims as required by subsection 27(3) of the *Patent Act*.

[7] On February 28, 2019, a response to the FA (RFA) was filed by the Applicant. In

the RFA, the Applicant submitted a proposed set of claims 1 to 13 (proposed claims) and argued that the claims on file were compliant with the *Patent Act* and *Patent Rules*.

[8] The Examiner was not persuaded by the arguments or the proposed amendments provided in the RFA and so the application was forwarded to the Board, along with a Summary of Reasons (SOR).

[9] The SOR was forwarded to the Applicant on June 28, 2019. In a letter dated September 19, 2019, the Applicant expressed continued interest in having the application reviewed by the Board.

[10] This Panel was formed to review the rejected application and make a recommendation to the Commissioner as to its disposition. Our conclusions are set out below.

ISSUES

[11] This review will consider whether the subject-matter of claims 1 to 7 on file:

- encompasses the skill and judgment of a medical professional and is therefore not patentable subject-matter falling within the definition of “invention” in section 2 of the *Patent Act*;
- is fully supported by the description as required by section 60 of the *Patent Rules*; and
- is enabled by the description as required by subsection 27(3) of the *Patent Act*.

LEGAL PRINCIPLES AND OFFICE PRACTICE

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] "Patentable Subject-Matter under the *Patent Act*" (CIPO, November 2020) [*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

[14] The definition of invention is set out in section 2 of the *Patent Act*:

> "invention" means any new and useful art, process, machine, manufacture or composition of matter, or any new and useful improvement in any art, process, machine, manufacture or composition of matter

[15] *PN2020-04* clarified the Patent Office's approach with respect to the determination of patentable subject-matter under section 2 of the *Patent Act*. In general:

> To be both patentable subject-matter and not be prohibited under subsection 27(8) of the *Patent Act*, the subject-matter defined by a claim must be limited to or narrower than an actual invention that either has physical existence or manifests a discernible physical effect or change and that relates to the manual or productive arts, meaning those arts involving or concerned with applied and industrial sciences as distinguished in particular from the fine arts or works of art that are inventive only in an artistic or aesthetic sense.

[16] It is well established that methods of medical treatment and surgery are not patentable subject-matter falling within the manual and productive arts and are excluded from the definition of invention as defined in section 2 of the *Patent Act* (see *Tennessee Eastman Co v Commissioner of Patents* (1970), 62 CPR 117 (Ex Ct), aff'd [1974] SCR 111; *PN2020-04*). However, medical "use" claims have been considered to be directed to patentable subject-matter (see *Apotex Inc v Wellcome Foundation Ltd*, 2002 SCC 77).

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

Pharmascience Inc, 2010 FC 510; *Janssen Inc v Mylan Pharmaceuticals ULC*, 2010 FC 1123; *AbbVie Biotechnology Ltd v Canada (Attorney General)*, 2014 FC 1251 [*AbbVie*]). Upon reviewing prior decisions, the Federal Court in *AbbVie* concluded that the jurisprudence is consistent; Federal Court jurisprudence has developed the principle that:

> [A] claim directed to the exercise of professional skill or judgment is not patentable. However, a claim which does not restrict, or interfere with, or otherwise engage professional skill or judgment – including a claim for a fixed dosage and or a fixed dosage schedule or interval – is not impermissible subject matter where there is no evidence to contradict that claimed dosage. (para 114)

[18] With particular reference to the determination of patentable subject-matter in respect of medical use claims containing a dosage or dosing regimen, *PN2020-04* states that:

> [I]n cases where at least one of the essential elements of the actual invention limits the claimed use to a dosage…and/or a dosage regimen, regardless of whether these are fixed and/or cover a range, this fact alone is not determinative of whether the claim is patentable subject-matter. It is also necessary to consider whether the exercise of professional skill and judgment of a medical professional is part of the actual invention. For example, professional skill and judgment may be involved if a medical professional is expected to monitor or make adjustments to the treatment, or make a selection of a dosage from a claimed range (i.e., in cases where not all dosages in the range will work for all subjects within the treatment group).

Lack of support

[19] Section 60 of the *Patent Rules* (equivalent to section 84 of the former *Rules*) states:

> The claims must be clear and concise and must be fully supported by the description independently of any document referred to in the description.

[20] We note that there is little judicial guidance on the requirements of that section, or any of its predecessor equivalents. *Manual of Patent Office Practice* [*MOPOP*] section 16.05 (CIPO, October 2019) states:

> A claim must be fully supported by the description as required by section 60 of the *Patent Rules*. All the characteristics of the embodiment of the invention which are set forth in the claim must be fully set forth in the description (Section 60 of the *Patent Rules*). However, since any claims included in the application at the time of filing are part of the specification (see subsection 27(4) of the *Patent Act* and the definition of "description" in subsection 1(1) of the *Patent Rules*), any matter in the originally filed claims that was not included in the description as filed may be added to the description (except for divisional applications which have further requirements regarding new subject-matter see section 20.01.02a for more details).
>
> A claim is objected to for lack of support by the description if the terms used in the claim are not used in the description and cannot be clearly inferred from the description.

Lack of enablement

[21] Subsection 27(3) of the *Patent Ac*t requires, among other things, a specification of a patent to correctly and fully describe an invention, and to enable its practice:

> 27(3) The specification of an invention must
>
> (a) correctly and fully describe the invention and its operation or use as contemplated by the inventor;
>
> (b) set out clearly the various steps in a process, or the method of constructing, making, compounding or using a machine, manufacture or composition of matter, in such full, clear, concise and exact terms as to enable any person skilled in the art or science to which it pertains, or with which it is most closely connected, to make, construct, compound or use it; …

[22] A determination of whether the specification complies with paragraphs 27(3)(a) and 27(3)(b) of the *Patent Act* requires that three questions be answered: What is the invention? How does it work? Having only the specification, can the person of skill in the art produce the invention using only the instructions contained in the disclosure? see: *Teva Canada Ltd v Novartis AG*, 2013 FC 141 citing *Teva Canada Ltd v Pfizer Canada Inc*, 2012 SCC 60 [*Teva*] and *Consolboard v MacMillan Bloedel (Sask) Ltd*, [1981] 1 SCR 504 at 526 [*Consolboard*].

[23] With respect to this third question, “it is necessary that no additional inventive ingenuity be required in order to make the patent work” (*Aventis Pharma Inc v Apotex Inc*, 2005 FC 1283 at para 172). A patent will not be invalid for insufficient disclosure where routine experimentation is required of the skilled person, but the Supreme Court of Canada has held that a disclosure is insufficient if the specification “necessitates the working out of a problem” (*Idenix Pharmaceuticals, Inc v Gilead Pharmasset LLC*, 2017 FCA 161 at para 19, citing *Pioneer Hi-Bred v Canada* [1989] 1 SCR 1623 at 1641).

ANALYSIS

Purposive construction

[24] There are 7 claims on file, including independent claims 1, 5 and 7 and dependent claims 2-4 and 6.

[25] Independent claim 1 reads as follows:

> 1. Use of an agent that inhibits alpha-4 integrin or inhibits a dimer comprising alpha-4 integrin, for the chronic treatment of multiple sclerosis, wherein the agent is natalizumab, wherein an infusion dosage of the natalizumab is 300 mg every four weeks, for a period of at least 6 months.

[26] Independent claims 5 and 7 are directed to a medicament comprising natalizumab and to the use of the medicament for repeated regular administration according to the same regimen as claim 1.

[27] Dependent claim 2 further defines the period of treatment as being “at least 12 months”. Dependent claims 3, 4 and 6 define further limitations relating to the alpha-4 integrin (claims 3, 4) and to the formulation of the medicament (claim 6).

The person skilled in the art and their common general knowledge

[28] The FA (page 2) identified the skilled person and their CGK as follows:

> …the person skilled in the art to whom the application is directed can be characterized as a research team including immunologists, clinical scientists specializing in pathological inflammation and/or multiple sclerosis, drug manufacturers and general practitioners.

> The CGK of the person skilled in the art would be the role of alpha-4 integrin in pathological inflammation and/or multiple sclerosis. Further, said person would have some knowledge about the use of natalizumab to treat multiple sclerosis.

[29] The Applicant did not dispute, contest or comment on these characterizations of the skilled person and their CGK. We agree that these characterizations are reasonable and would add a neurologist to the skilled team since this is the speciality that is generally associated with treatment of MS. We adopt these characterizations for the purposes of this review.

The essential elements

[30] The assessment of essential elements in the FA was carried out in accordance with guidance that was superseded by *PN2020-04*. We have therefore undertaken a new assessment of the essential elements.

[31] As set out above, *PN2020-04* states 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. In our view, the skilled person reading claims 1-7 in the context of the specification as a whole and the CGK would understand that there is no use of language in the claims indicating that any of the elements are optional, preferred or were otherwise intended as being non-essential. Our view is therefore that all of the elements of claims 1-7 are essential.

Patentable subject-matter

[32] As stated above, the approach set out in *PN2020-04* considers whether the exercise of skill and judgment of a medical professional associated with a dosage regimen is part of the actual invention.

[33] The claims are explicit in their inclusion of the infusion dosage of “300 mg”, the dosing frequency of “every four weeks” and the treatment period of either “at least 6 months” (claims 1, 3-7) or “at least 12 months” (claim 2). Having read the claims in the context of the whole specification, our view is that the skilled person would consider the actual invention in each claim as including these elements. The remaining question is whether any of these elements require, restrict, prevent, interfere with or otherwise engage the exercise of professional skill and judgment.

[34] On page 3, the FA states that claims 1-7 encompass the skill and judgment of a physician because the description indicates that a physician must be responsive to the needs of a patient during treatment. Further, the elements “at least 6 months” and “at least 12 months” are problematic because determining the duration of treatment would require skill and judgment:

> …since the claims fail to define the treatment period, the subject matter of these claims still points to a limitation of a physician’s skill or judgment. The inclusion of the term “at least” in the phrases “at least 6 months” and “at least 12 months” implies an undefined range with an indefinite upper limit to the duration of treatment. Further, the description discloses that “treatment…will vary depending upon many factors, including…physiological state of the patient” and that “treatment dosages will need to be titrated to optimize safety and efficacy” (page 30, lines 21-25). Therefore, a physician must exercise skill and judgment and be responsive to the needs of the patient during said treatment, and must decide for how long beyond 6 or 12 months the natalizumab should be used. (emphasis in original)

[35] With regard to statements in the description indicating that a physician has to be responsive to the patient’s needs during the claimed treatment, the RFA on page 4 disputed that those statements pertain to the subject-matter of claims 1-7 and submitted that more pertinent excerpts relating directly to the claimed subject-matter were seemingly ignored.

[36] The paragraph in question from page 30 of the description states the following, in reference to a variety of conditions that are described on pages 26-29 that include, but are not limited to, MS:

> Effective dosage regimes of the compositions of the present invention, for the treatment of the above described conditions will vary depending upon many different factors, including means of administration, target site, physiological state of the patient, and other medicaments administered. Thus, treatment dosages will need to be titrated to optimize safety and efficacy. In general, each administration of the dosage regime will range from about 0.0001 to 100 mg/kg, and more usually 0.01 to 5 mg/kg of the host body weight. (emphasis added)

[37] In our view, the skilled person reading this passage in the context of the whole description would understand that these broad statements pertain to a different

invention from the subject-matter of the claims on file, which is limited to treating MS using a fixed dose and timing without the need for titration. This is consistent with Example 1 wherein MS patients that had not received any immunosuppressive or immunomodulatory treatments for at least 3 months were given natalizumab at a fixed monthly dose without titration. We are therefore unable to agree with the FA that the above passage from page 30 indicates a need for the exercise of skill and judgment for the subject-matter of claims 1-7.

[38] With regard to a physician's decision to terminate treatment and when, the RFA argues on pages 5-8 that, similar to the circumstances in *AbbVie*, these activities are outside the scope of the claim and therefore do not interfere with or restrict a physician's professional skill or judgment (pages 6-7):

> The independent use claims that were considered and approved by the Federal Court in *AbbVie*, (now claims 13 and 26 in CA 2,385,745), read as follows:
>
> 13. Use of an isolated anti-TNF.alpha.antibody…for treating an arthritic disease or an inflammatory bowel disease…for subcutaneous administration and wherein the dosage is 40 mg according to a continuous schedule having an every other week dosing interval of 14 days.
> …
> Clearly, "a continuous schedule" does not mean forever, and thus a physician having made the use-of-treatment choice that is the subject matter of the use claims in CA 2,385,745, would necessarily have to decide how long to continue the treatment.
> …
> Put simply, a physician's decision regarding when to terminate natalizumab treatment lies outside the scope of the claims. An act, such as a decision to terminate treatment, cannot be said to be interfered with by the claims. Accordingly, the claims are patent-eligible because once the use-of-treatment choice has been made, the claims do not contravene, or even point to a limitation of, a physician's professional skill or judgment. (emphasis in the original)

[39] We agree with the RFA. In the same manner as the claims approved by the Court in *AbbVie*, the claims on file are explicit in defining a fixed dosage regimen for the ongoing treatment of patients having a specific condition. As in *AbbVie*, there is no

evidence in the present case that contradicts using natalizumab on an ongoing basis in patients with MS. The Court in *AbbVie* did not consider the "continuous schedule" with no fixed end point for the duration of treatment as an element requiring the exercise of skill and judgment within the scope of the claims (*AbbVie* 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. (emphasis added)

[40] In this view, the Court in *AbbVie* apparently regarded the decision to stop treatment as being outside the scope of the claim, in the same manner as the decision to prescribe the treatment in the first place. We agree with the RFA that, based on the facts in this case, defining the treatment period as "at least" 6 or 12 months would not interfere with the exercise of a physician's skill and judgment: the eventual decision by a physician to stop treatment would be outside the scope of claims 1-7.

[41] For all of the above reasons, our view is that the claims on file do not restrict, prevent, interfere with, require or otherwise encompass the exercise of professional skill and judgment. Our conclusion is that claims 1-7 are directed to patentable subject-matter that falls within the definition of "invention" in section 2 of the *Patent Act*.

Lack of support and enablement

[42] On pages 3-4, the FA contends that claims 1-7 are not "fully supported" by the description and that this renders the specification non-compliant with section 84 (now section 60) of the *Patent Rules* and subsection 27(3) of the *Patent Act*. Specifically, the dose "300 mg", the frequency "every four weeks" and the treatment durations "at least 6 months" (claims 1, 3-7) or "at least 12 months" (claim 2) are said to be unsupported by the description except for "mere literal support".

[43] The FA did not consider Example 1 and its results as supporting the claims in

accordance with section 60 of the *Patent Rules* because patients were treated using a dose of 3 or 6 mg/kg, not 300 mg, and because the treatment period was only 6 months. The FA considered the absence of testing 300 mg specifically for more than 6 months as raising uncertainty as to whether this dosage regimen would work in all MS patients of any weight.

[44] On page 4, the FA explains why this lack of a supporting example further amounts to a lack of enablement, contrary to subsection 27(3) of the *Patent Act*:

> In view of the above, it follows that the specification as it relates to claims 1-7 does not comply with subsection 27(3) of the *Patent Act*. The description does not enable the use of 300 mg of natalizumab every four weeks for a period of at least 6 months, to treat any patient regardless of their weight, age and/or medical condition. In applicant's correspondence of January 19, 2017, applicant states that "the disclosure in pages 4A and 4B, along with the teaching throughout the description of the use of the treatment, clearly fully describe the invention". Applicant's arguments have been carefully considered but not deemed persuasive. Nowhere in the description is the use of natalizumab in an amount of *300 mg* every four weeks, for a period of *at least* 6 months enabled. (emphasis added)

[45] In response, the RFA submitted on pages 8 and 13 that these grounds for rejection are improper and that these defects ought to be withdrawn.

[46] With respect to a lack of supporting examples, the RFA submitted that uncertainty about utility is not a proper basis for a support objection under section 84 of the *Patent Rules* (now section 60).

[47] With respect to enablement, the RFA submitted that the correct legal question is whether the application as filed and the sum of the CGK in the art enables the skilled person to make and use the invention without undue experimentation. On page 13, the RFA submitted that there is no question that the skilled person would be able to perform the steps of the claims and that the use of natalizumab is well within the ability of an ordinary skilled person.

[48] For the reasons that follow, we agree with the RFA.

[49] First, there is no language in section 60 of the *Patent Rules* or subsection 27(3) of

the *Patent Act* that explicitly requires the disclosure of examples or experimental results supporting that the invention works.

[50] Second, the following excerpt from the *MOPOP* §16.05 appears to endorse adding literal support from the original claims in order to render a description compliant with section 60 of the *Patent Rules*:

> A claim must be fully supported by the description as required by section 60 of the *Patent Rules*. All the characteristics of the embodiment of the invention which are set forth in the claim must be fully set forth in the description (Section 60 of the *Patent Rules*).
> …
> any matter in the originally filed claims that was not included in the description as filed may be added to the description
> …
> A claim is objected to for lack of support by the description if the terms used in the claim are not used in the description and cannot be clearly inferred from the description. (emphasis added)

[51] There is no indication from this passage of a requirement to provide an example, evidentiary support or anything beyond literal support for the purposes of satisfying section 60 of the *Patent Rules*. To the extent that "mere literal support" means the use of verbatim language that mirrors the claim language, we are unable to agree that literal support alone may not be enough in some cases, or that examples necessarily have to be disclosed, in order to satisfy the requirements of section 60 of the *Patent Rules*.

[52] In our view, based on the facts in this case, the claims are fully supported for the purposes of section 60 of the *Patent Rules* by at least the following excerpt from the description on page 30, lines 26-28, as originally filed:

> One preferred dosage regimen is 300 mg administered once per month for a period of at least 6 months, more preferably 12 months and perhaps over the course of several years.

[53] Third, with respect to enablement, we agree with the RFA that the test is whether a skilled person armed only with the specification and their CGK would be able to make and use the invention without the need for inventive ingenuity.

[54] Subsection 27(3) of the *Patent Act* requires disclosure of the invention. According to the Supreme Court of Canada in *Teva*, subsection 27(3) of the *Patent Act* does not require disclosure of the utility, the disclosure of examples or the disclosure of test results in the description in order to fulfill the requirements of sufficiency or enablement (*Teva* at para 40):

> Nothing in this passage suggests that utility is a disclosure requirement; all it says is that "the utility required for patentability (s.2) must, as of the priority date, either be demonstrated or be a sound prediction". Utility can be demonstrated by, for example, conducting tests, but this does not mean that there is a separate requirement for the disclosure of utility. In fact, there is no requirement whatsoever in s. 27(3) to disclose the utility of the invention: see e.g., *Consolboard*, at p. 521, per Dickson J.: "I am further of the opinion that s. 36(1) [now s. 27(3)] does not impose upon a patentee the obligation of establishing the utility of the invention". (emphasis added)

[55] In our view, the skilled person, who has been defined as a team including an immunologist, neurologist and general practitioner, would have been able to use natalizumab at the claimed dose and interval without the need for inventive ingenuity, even in the absence of any examples. An example was provided, however, and our view is that repeating the same protocol of Example 1 using 300 mg of natalizumab instead of 3 or 6 mg/kg would not have required inventive ingenuity on the part of the skilled person.

[56] Finally, for completeness, the Panel notes that while the FA did express concerns relating to "uncertainty as to the utility" because of a lack of data showing that 300 mg would work in patients of any weight, it did not formally raise a utility defect under section 2 of the *Patent Act*. We agree that such a defect is not warranted in this case. It is well established in the case law that a prediction need not amount to a certainty to be sound, rather there must be a *prima facie* reasonable inference of utility: *Monsanto Co v Commissioner of Patents* [1979] 2 SCR 1108 at page 1117; *Mylan Pharmaceuticals ULC v Eli Lilly Canada Inc*, 2016 FCA 119 at para 55.

[57] In response to these concerns, the RFA submitted on page 9 that the skilled person would understand that weight-based dosing is not an absolute requirement and may often be unnecessary, and as such the position in the FA is speculative: a scenario is posited without any factual basis to suggest that it is a realistic

scenario.

[58] The RFA further submitted on pages 11-12 that the results of the clinical study of Example 1 provide a clear factual basis for the sound prediction of a chronic dosage regimen, adding the following:

> For example, Fig. 2 shows that although clinical efficacy is achieved by short-term dosing, the patient's disease activity rapidly worsened after cessation at 6 months. The application as filed teaches that therefore some of the more important advantages of natalizumab are only realized with a chronic dosing regimen.

[59] We agree that there is no evidence supporting a clear link between efficacy and the need for weight-based dosing. By contrast, there is clear evidence of a link between efficacy and maintaining a chronic monthly dosing interval.

[60] The factual basis provided in Example 1, which was specific to treatment groups receiving doses of 3 and 6 mg/kg, can be considered in terms of being equivalent to using 300 mg in patients weighing 100 kg (i.e., 220 lbs) and 50 kg (i.e., 110 lbs), respectively. Table 2 and Figures 1-2 show that the efficacy in preventing new enhancing lesions in both groups was apparent after the first month compared to placebo and that efficacy was maintained as long as patients continued to receive natalizumab every month: the number of new enhancing lesions were 9.6 (placebo), 0.7 (3 mg/kg) and 1.1 (6 mg/kg). By contrast, when treatment was stopped and the patients were re-evaluated 3 and 6 months later, the number of new enhancing lesions and clinical relapses were about the same for the placebo group and the 3 and 6 mg/kg groups. Further, Figures 3-5 show that the therapeutic serum concentrations and receptor saturation levels of natalizumab were maintained with ongoing dosing but dropped off once monthly dosing stopped.

[61] In our view, this factual basis is sufficient to support a sound prediction of therapeutic efficacy, to at least some extent, at a dose of 300 mg provided that the patient continues to receive the dose every month on an ongoing basis.

[62] For all of the above reasons, our view is that the subject-matter of the claims is fully supported and enabled by the description, and that the requirements of section 60 of the *Patent Rules* and subsection 27(3) of the *Patent Act* are satisfied.

CONCLUSIONS

[63] The subject-matter of claims 1 to 7 on file:

- does not encompass the skill and judgment of a medical professional and is patentable subject-matter falling within the definition of “invention” in section 2 of the *Patent Act*;

- is fully supported by the description in accordance with the requirements of section 60 of the *Patent Rules*; and

- is enabled by the description as required by subsection 27(3) of the *Patent Act*.

RECOMMENDATION OF THE BOARD

[64] In view of the above, the Panel is of the view that the rejection is not justified on the basis of the defects 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 application is withdrawn and that the application has been found allowable.

Cara Weir	Ryan Jaecques	Christine Teixeira
Member	Member	Member

DECISION OF THE COMMISSIONER

[65] 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 24th day of January 2022