Commissioner’s Decision #1509

Décision de la Commissaire #1509

TOPIC: K11 (Treatment)
B00 (Ambiguity)

SUJET: K11 (Traitement)
B00 (Caractère ambigu)

Application No.: 2,858,601

Demande n°.: 2 858 601

IN THE CANADIAN PATENT OFFICE

DECISION OF THE COMMISSIONER OF PATENTS

Patent application number 2,858,601, having been rejected under subsection 30(3) of the *Patent Rules* (SOR/96-423) as they read immediately before October 30, 2019 (the former *Rules*), has been reviewed in accordance with paragraph 199(3)(*c*) of the *Patent Rules* (SOR/2019-251). The recommendation of the Board and the decision of the Commissioner are to refuse the application if the necessary amendments are not made.

Agent for the Applicant:

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INTRODUCTION

[1] This recommendation concerns the review of rejected patent application number 2,858,601, which is entitled "Reduction of galectin-3 levels by plasmapheresis" and is owned by Eliaz Therapeutics, Inc. The outstanding defects to be considered are whether the subject-matter of the claims on file lies outside the definition of "invention" in section 2 of the *Patent Act*, whether claims 9 to 20 on file lack clarity, contrary to subsection 27(4) of the *Patent Act* and whether page 1 of the description complies with paragraph 68(1)(*c*) of the former *Rules*. 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*. As explained in more detail below, the recommendation of the Board and the decision of the Commissioner are to refuse the application if the necessary amendments are not made.

BACKGROUND

The application

[2] Patent application 2,858,601 (the instant application), based on a previously filed Patent Cooperation Treaty application, is considered to have been filed in Canada on September 28, 2012 and was laid open to the public on June 13, 2013.

[3] The claimed subject-matter of the application relates to treatment of diseases and biological conditions mediated at least in part by one or more galectins. Galectins are a family of sugar binding proteins that are both expressed within the cell and secreted from the cell as a component of human plasma. Among the many functions that are mediated by extracellular galectins are inflammation, fibrosis formation, cell adhesion, cell proliferation, metastatic formation and immunosuppression. More specifically, the instant application discloses the use of plasmapheresis (a blood separation technology) to decrease elevated concentrations of galectin-3 (Gal-3) that can aggravate a disease or condition.

Prosecution history

[4] On February 26, 2016, a Final Action (the FA) was written pursuant to subsection 30(4) of the former *Rules*. The FA explained that the claims on file are directed to a method of medical treatment, and thus are directed to subject-matter that lies outside the definition of "invention" in section 2 of the *Patent Act*, that claims 9 to 20 on file lack clarity, contrary to subsection 27(4) of the *Patent Act*, that claim 7 contains a typographic error and that page 1 of the description on file was not free from cancellations, contrary to paragraph 68(1)(*c*) of the former *Rules*.

[5] In a response to the FA (the RFA) dated August 26, 2016, the Applicant submitted an amended claims set (the proposed claims), an amended page 1 of the description and arguments as to why the specification and the subject-matter of the proposed claims were not open to objections for the reasons outlined in the FA.

[6] As the Examiner was not persuaded by the Applicant's arguments, the application and an accompanying Summary of Reasons (the SOR) were forwarded to the Board for review. The SOR considered that the proposed claims and accompanying arguments addressed the defects identified in the FA but also stated that the proposed claims 1-4, 18, 19 and 23 introduce a new defect of ambiguity and could be interpreted as encompassing active steps of medical treatment, which would not be allowed under section 2 of the *Patent Act*. In a letter dated May 15, 2017, the Board sent the Applicant a copy of the SOR.

[7] The present Panel was formed to review the application under paragraph 30(6)(*c*) of the former *Rules* and to make a recommendation to the Commissioner as to its disposition. In a preliminary review letter dated October 21, 2019 (the PR Letter), we provided the preliminary opinion that the claims on file are directed to subject-matter excluded from the definition of an invention as set out in section 2 of the *Patent Act*, that claims 9 to 20 on file comply with subsection 27(4) of the *Patent Act*, that claim 7 contains a typographic error and that page 1 of the description does not comply with paragraph 68(1)(*c*) of the former *Rules*.

[8] Further, with respect the proposed claims, we stated that we understood the issue to be whether the amended medical use claims amount to a method of medical treatment and expressed the preliminary view that the subject-matter of the proposed claims set complies with section 2 of the *Patent Act*. We further stated that it was then our intention to recommend to the Commissioner that the proposed claims set submitted on August 26, 2016 should be considered a "necessary" amendment under subsection 30(6.3) of the former *Rules.*

[9] The PR Letter also offered the Applicant the opportunity to make further written submissions and to attend an oral hearing in response to the Panel's preliminary review, if desired.

[10] In a response letter dated November 4, 2019 (the RPR), the Applicant stated that in view of the Panel's preliminary finding that the proposed claims are compliant with the *Patent Act* and *Patent Rules* and that the Panel is inclined to recommend to the Commissioner that the claims be considered a "necessary" amendment under subsection 30(6.3) of the former *Rules* on that basis, the Applicant confirmed that an oral hearing was not required and that no further written submissions would be provided.

ISSUES

[11] In view of the above, the following issues are considered in this review:

- whether claims 1 to 23 on file define subject-matter that lies outside the definition of "invention" in section 2 of the *Patent Act*;;
- whether claims 9 to 20 on file lack clarity, contrary to subsection 27(4) of the *Patent Act*; and
- whether claim 7 contains a typographic error and page 1 of the description

complies with paragraph 13(1)(*c*) of the *Patent Rules* (paragraph 68(1)(*c*) of the former *Rules*).

[12] After considering the claims on file, we will consider the proposed claims.

LEGAL PRINCIPLES AND OFFICE PRACTICES

Purposive construction

[13] Essential elements are identified through a purposive construction of the claims. The exercise is conducted from the standpoint of a person skilled in the art by considering the whole of the disclosure, including the specification and drawings: *Free World Trust v Électro Santé Inc*, 2000 SCC 66; *Whirlpool Corp v Camco Inc*, 2000 SCC 67 at paras 49(f) and (g) and 52. According to the *Manual of Patent Office Practice* [*MOPOP*], §12.02 (revised June 2015), the first step in the construction of the claims of a patent application is to identify the person of ordinary skill in the art (the "POSITA") and the relevant common general knowledge (the "CGK"). The next step is to identify the problem addressed by the inventors and the solution disclosed in the application. Essential elements can then be identified as those elements of the claims that are required to achieve the disclosed solution.

Non-statutory subject-matter and methods of medical treatment

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

> [I]nvention 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] Methods of medical treatment and surgery are not considered to be directed to statutory subject-matter and are excluded from the definition of "invention" (see *Tennessee Eastman Co v Commissioner of Patents* (1970), 62 CPR 117 (Ex Ct), aff'd [1974] SCR 111).

[16] However, medical "use" claims have been considered to be directed to patentable subject-matter (see *Apotex Inc v Wellcome Foundation Ltd*, 2002 SCC 77 [*AZT*]). In

the *AZT* case, the Supreme Court suggested that a complication may arise in a case where a claim, although drafted as a medical use, nonetheless attempts to "fence in" an area of medical treatment by indicating "how and when" (e.g., by indicating a dosage range or treatment regime) a pharmaceutical composition is to be used. In that decision, the Supreme Court considered a claim directed to a pharmaceutical composition comprising an old compound (AZT) for a new use in treating AIDS and found at para 50 that the patentee had not attempted to fence in a method of medical treatment:

> The AZT patent does not seek to "fence in" an area of medical treatment. It seeks the exclusive right to provide AZT as a commercial offering. How and when, if at all, AZT is employed is left to the professional skill and judgment of the medical profession.

[17] A number of lower court decisions have also 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*].

[18] Upon reviewing prior decisions, the Federal Court in *AbbVie* concluded the following at paras 112 to 114:

> [112] The respondent cautioned against relying on catch phrases rather than principles. In my view, the jurisprudence reflects that approach – the principle has been applied regardless of the Courts' references to "fencing in" or to "fixed dosages". The issue in every case has been whether the patent claims a method of medical treatment. In applying the same principles, claims to fixed dosages and schedules which do not involve any professional decision-making have been accepted as patentable.
>
> [113] However, just because the claims involve a fixed dosage and schedule does not mean that they are automatically patentable, nor does it mean that they constitute unpatentable subject matter. The fixed dosage and schedule may be a good signal or starting point, but the evidence about that claimed dosage regime and schedule may indicate that it is not exactly as it is claimed and that adjustments are needed which requires skill and judgment.

> [114] The review of the relevant case law supports the appellants' understanding of the principles from the jurisprudence and demonstrates that the Courts have consistently found 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. Contrary to the Commissioner's decision and the respondent's position, *Janssen* has not changed the law. [emphasis added]

[19] The Office's current practice with regard to the patentability of medical use claims is explained in Practice Notice 2015-01, entitled *Revised Examination Practice Respecting Medical Uses* [*PN 2015-01*]. According to *PN 2015-01*, medical use claims are generally permitted as long as they do not equate to methods of medical treatment (e.g., do not include an active treatment step) and they satisfy all other requirements of patentability.

[20] The determination of whether the subject-matter of a claim is statutory is based on the essential elements of the claim as determined by a purposive construction as outlined above. For medical inventions, the problem faced by the inventor may relate to "what" to use for treatment. Generally the solution to such a problem will be provided by an element or set of elements in a claim that embody a treatment tool. This tool may include a compound, composition, formulation, or a dosage unit form. 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*.

[21] Notably, *PN 2015-01* also recognizes that there may be instances where essential elements serve to instruct a medical professional "how" to treat a patient but are not considered to prevent, interfere with or require the professional skill of a physician.

For example, essential elements that narrow treatment to a fixed dosage, a fixed dosage regimen or to a patient sub-population are not considered to comprise a limitation of a physician's professional skill or judgment.

Indefiniteness and ambiguity in the claims

[22] Subsection 27(4) of the *Patent Act* states that "[t]he specification must end with a claim or claims defining distinctly and in explicit terms the subject-matter of the invention for which an exclusive privilege or property is claimed".

[23] In *Minerals Separation North American Corp v Noranda Mines Ltd*, [1947] Ex CR 306, 12 CPR 99 at 146, the Court emphasized the obligation of an Applicant to make clear in the claims the ambit of the monopoly sought and the requirement that the terms used in the claims be clear and precise:

> By his claims the inventor puts fences around the fields of his monopoly and warns the public against trespassing on his property. His fences must be clearly placed in order to give the necessary warning and he must not fence in any property that is not his own. The terms of a claim must be free from avoidable ambiguity or obscurity and must not be flexible; they must be clear and precise so that the public will be able to know not only where it must not trespass but also where it may safely go.

Presentation of documents

[24] Paragraph 13(1)(*c*) of the *Patent Rules* requires that a description filed in paper form in connection with patents and applications shall be free from interlineations, cancellations or corrections.

ANALYSIS

Purposive construction

The POSITA and the relevant CGK

[25] The FA identified the POSITA and the relevant CGK as follows:

> In view of statements in the description (e.g., para. 0014), the person skilled in the art to whom the application is directed can be characterized as a team including physicians and biochemists familiar with galectin-3 lectins and disorders characterized by elevated circulating levels of active galectin-3.
>
> The person skilled in the art would possess the following CGK: elevated levels of active galectin-3 can complicate or exacerbate a wide variety of disease and injury conditions, and molecules that bind galectin-3 are known.

[26] In the PR Letter, we adopted these characterizations for the purposes of our preliminary review. As no further submissions were provided by the Applicant in the RPR in that regard, we therefore also adopt them for the purposes of this final review.

The problem to be solved and the proposed solution

[27] The FA identified the problem to be solved and the proposed solution as follows:

> The person skilled in the art, having read the specification and in light of their CGK would consider that the problem addressed by the claimed invention is to reduce the levels of active galectin-3 circulating in the blood of a subject (e.g., para. 0015).
> The person skilled in the art, having read the specification and in light of their CGK, would consider that the description provides the following solution: galectin-3 can be removed from the plasma of a subject in significant amounts through the use of specific binding molecules and the return of the plasma with a reduced titer of active galectin-3. This solution offers immediate opportunities for therapy and intervention that may be superior to the reduction achieved by merely administering the binding molecules to the subject (e.g., para. 0025).

[28] In the PR Letter, we adopted these characterizations for the purposes of our preliminary review. Again, as no further submissions were provided by the

Applicant in the RPR in that regard, we therefore also adopt them for the purposes of this final review.

The essential elements that solve the identified problem

[29] There are 23 claims on file. Method claims 1 and 23 are independent claims. Although claims 9 to 20 ultimately refer to independent claim 1, they are not technically dependent on claim 1 because the wording of the preamble, "Use of method of conducting plasmapheresis as claimed in…", indicates a different category of claims. Claims 9, 12, 14 and 18 to 20 are therefore considered independent claims. It is our view that independent claims 1, 9 and 23 are representative of the subject-matter of all claims on file. Claim 1 is narrower than claim 23 as it recites a minimum percentage of circulating galectin-3 to be removed by the method. Claims 1, 9 and 23 read as follows:

> 1. A method of conducting plasmapheresis on blood of a mammal in need of reduction of circulating levels of galectin-3, the method of conducting plasmapheresis comprising: using a galectin-3 binding molecule to conduct the plasmapheresis on the blood to reduce circulating levels of active galectin-3, wherein the plasmapheresis is conducted so as to selectively remove galectin-3 by contact with said galectin-3 binding molecule, such that at least ten percent of circulating galectin-3 is removed by said plasmapheresis.
>
> …
>
> 9. Use of the method of conducting plasmapheresis as claimed in any one of claims l to 8 to treat blood of a mammal in need of inhibition of a growth or spread of cancer mediated at least in part by galectin-3.
> …
>
> 23. A method of conducting plasmapheresis on blood of a mammal in need of reduction of circulating levels of galectin-3, the method of conducting plasmapheresis comprising: using a galectin-3 binding molecule to conduct the plasmapheresis on the blood to reduce circulating levels of active galectin-3, wherein the plasmapheresis is conducted so as to selectively remove galectin-3 by contact with said galectin-3 binding molecule.

[30] Claims 2 to 8 and 10 to 22 define further limitations, with regard to: the scope of galectin-3 levels reduction (claims 2 to 4), the plasmapheresis process (claim 5), the galectin-3 binding molecule and related conjugated element (claims 6 to 8), the condition or disease to be treated (claims 10 and 12 to 17), an additional concurrent therapy, pharmaceutical or pharmaceutical agent (claims 11, 18, 19, 21 and 22) and the condition to commence conducting plasmapheresis (claim 20).

[31] In the PR Letter, we preliminarily agreed with the FA and accordingly expressed the view that the POSITA would consider conducting plasmapheresis using a galectin-3 binding molecule to be an essential element of the purposively construed claims. Nevertheless, we further stated that we would consider all elements within our analysis of the claimed subject-matter.

[32] The RPR Letter did not indicate disagreement with the approach taken in the PR Letter, and we therefore adopt the above essential elements for the purposes of this review.

Subject-matter and methods of medical treatments

[33] The FA explained that claims 1 to 23 encompass subject-matter that lies outside the definition of "invention" and do not comply with section 2 of the *Patent Act* for the following reasons:

> Although plasmapheresis is not a step of surgery, claims 1-8, and 21-23 are considered to be defective because they encompass a method that provides a practical therapeutic benefit to a subject. A method of "plasmapheresis" plainly encompasses the removal, treatment, and return of blood of a mammal, and it is the examiner's position that this "method" could cure, prevent, or ameliorate an ailment or pathological condition. Methods of medical treatment can involve steps of physiotherapy or surgery, but the fact that a subject-matter does not involve physiotherapy or surgery does not mean that it does not encompass a medical treatment. Although the category of dependent claims 9-20 is ambiguous, as detailed *infra*, they are considered to encompass non-statutory subject-matter because they could be equated to methods of medical treatment.

[34] In the RFA, the Applicant did not argue that the claims on file are directed to statutory subject-matter. Instead, the Applicant submitted new proposed claims 1 to 23 and arguments as to why the subject-matter of the proposed claims is not a method of medical treatment and is therefore patent-eligible.

[35] In the PR Letter, we expressed the preliminary view that the methods recited in claims 1 to 8 and 21 to 23 provide a practical therapeutic benefit to a subject through the return of treated plasma to a subject and are therefore considered methods of medical treatment. A method of plasmapheresis, by definition, necessarily involves the return of treated plasma to a subject for their therapeutic benefit, as indicated in the description at para [0008]:

> This invention makes use of plasmapheresis, sometimes referred to as therapeutic plasma exchange, to control levels of gal-3, and more specifically biologically active galectin, in circulation. Plasma is led through a fluid pathway and either intermixed with a gal-3 binding agent which can be separated from the plasma, or returned to the body with blocked inactivated gal-3, or led past a solid support which binds gal-3, the plasma being subsequently returned to the body with a reduced level of gal-3. [Emphasis added]

[36] With regard to claims 9 to 20, we stated that whether or not the wording "[u]se of the method of claim…" that is used in the preamble is interpreted to indicate a different claim category (i.e., an art instead of a method), we were of the preliminary view that the scope of these claims would nevertheless encompass the method of conducting plasmapheresis as recited in any one of claims 1 to 8, a method that we preliminarily considered to be a method of medical treatment.

[37] As no further submissions were provided by the Applicant in the RPR, we therefore conclude that claims 1 to 23 on file are directed to subject-matter excluded from the definition of an invention as set out in section 2 of the *Patent Act*.

Indefiniteness and ambiguity in the claims

[38] The FA stated that claims 9 to 20 are indefinite and do not comply with subsection 27(4) of the *Patent Act* because "[t]he expression 'Use of the method' renders the category of these claims ambiguous". In that regard, the FA elaborated and added

that "[s]pecifically, it is unclear whether these claims are intended to be directed to a use or to a method because it does not seem possible for a person to use a method without actively performing a method".

[39] In the RFA, the Applicant did not argue that the claims on file are compliant with subsection 27(4) of the *Patent Act*. Instead, the Applicant submitted new proposed claims 1 to 23.

[40] In the PR Letter, we expressed the preliminary view that the POSITA would consider claims 9 to 20 to be use claims that incorporate method steps and that their preamble does not cause ambiguity. We noted that there is no *per se* rule against use claims that include method steps, nor is there any guidance that such claims are necessarily ambiguous on that basis. However, a problem can arise if the incorporated method steps amount to a method of medical treatment, since that is not statutory subject-matter (as outlined above under "Legal Principles"). In that regard, *MOPOP* §16.10.02 indicates:

> **Guidelines for use claims**
>
> i. Use claims are permitted. Moreover, use claims <u>incorporating method steps are acceptable</u> as long as the use has been clearly identified and it is not a method of medical treatment. If the claim is complete and understandable without the method steps, then the claim as a whole is acceptable. The method steps merely provide a restriction to the previously recited use. [underlining emphasis in the original]

[41] We noted that the method steps encompassed by claims 9 to 20 were considered clear and explicit in the referred claims 1 to 8, as no clarity defect was identified in the FA with regard to the method claims 1 to 8. Notwithstanding our preliminary opinion that claims 9 to 20 encompass a method of medical treatment, it was our preliminary view that claims 9 to 20 are not ambiguous.

[42] Our conclusion is therefore that claims 9 to 20 are compliant with subsection 27(4) of the *Patent Act*.

Other formalities

[43] In the PR Letter, we agreed with the FA and expressed the preliminary view that claim 7 on file contained a typographic error and that page 1 of the description on file was not free from cancellations. We noted that in response, the Applicant proposed amendments that would correct the typographic error in the proposed claims set and the cancellations in page 1 of the description.

[44] As no further submissions were provided by the Applicant in the RPR, we therefore conclude that claim 7 on file contains a typographical error and that page 1 of the description is not free from cancellations, contrary to paragraph 13(1)(*c*) of the *Patent Rules*.

ANALYSIS OF THE PROPOSED AMENDMENTS

[45] As this review has determined that the claims on file are directed to subject-matter excluded from the definition of an invention as set out in section 2 of the *Patent Act*, that claim 7 contains a typographic error and that page 1 of the description does not comply with paragraph 13(1)(*c*) of the *Patent Rules*, we consider the Applicant's proposed claims set and amended page 1. The proposed claims set contains claims 1 to 23 wherein former claims 1 to 23 have been amended to recite "Use of a galectin-3 binding molecule to conduct plasmapheresis ...", the typographic error in claim 7 has been corrected and amended page 1 is free of cancellations.

[46] With regard to the proposed claims, the SOR stated that the "Applicant has redrafted method of medical treatment claims as medical use claims, which overcomes the defects as described in the Final Action". However, the SOR also stated that the proposed claims 1-4, 18, 19, and 23 introduce a new defect of ambiguity in the claims and could be interpreted as encompassing active steps of medical treatment:

> A new defect in the claims arises as a result of the last proposed amendments:
>
> Claims 1-4, 18, 19, and 23 are ambiguous and do not comply with subsection 27(4) of the *Patent Act.* As currently formulated, these use claims could be interpreted as

> encompassing active steps of medical treatment, i.e., "said plasmapheresis is conducted" (claims 1 and 23), "circulating galectin-3 is removed" (claim 1), "circulating levels of galectin-3 are reduced" (claim 2-4), and "after administering a pharmaceutical to said mammal" (claims 18 and 19), which would not be allowed under section 2 of the *Patent Act*.
>
> Regarding the defect identified in claims 1-4, the active step of removing or reducing "circulating levels" of galectin-3 is interpreted as actively removing or reducing galectin-3 present within the circulatory system of a mammalian subject, a result that necessarily includes return of blood to the subject and that provides a practical benefit to the subject.
>
> It is noted that that it may be argued claim 5 also encompasses active steps of medical treatment, i.e., "including diverting", "removing red blood cells", "contacting said separated plasma", and "separating out any said moieties". MOPOP 12.06.08 indicates that a true use claim is defined only in terms of the physical means to be applied, the circumstances of this application, and the result to be achieved, and that a purported use claim must be examined as a method if it defines specific steps to be followed. The examiner does not interpret the active steps defined in claim 5 *per se* resulting in a medical treatment because they do not constitute plasmapheresis, or more specifically, do not include the return of the blood to the mammal. However, the distinction between a use and a method may be of practical importance having regard to claim 1 purportedly directed to a "Use of a galectin-3 binding molecule to conduct plasmapheresis" in view of the specific steps recited in claim 5. In other words, claim 5 may be viewed as rendering the whole set of claims ambiguous as to whether the applicant is claiming a use of a galectin-3 binding molecule or a method to conduct plasmapheresis.
>
> It is further noted that it may be argued claims 17 and 18 encompass the active administration of a pharmaceutical; however, the examiner interprets the language in these claims as defining the patient population to which the use may be applied, i.e., the circumstances of application. Pharmaceutical administration in claims 17 and 18 has unambiguously occurred "prior to practicing" the claimed subject matter, and thus, these claims are not interpreted as encompassing an active step of medical treatment.

[47] In the PR Letter, we considered the issue as being whether the amended medical use claims amount to a method of medical treatment, subject-matter that lies outside the definition of "invention" in section 2 of the *Patent Act* and we turned to *PN 2015-01* introduced above and its specific guidance on medical use claims.

[48] According to PN 2015-01, the determination of whether the subject-matter of a claim amount to a method of medical treatment must be performed by using purposive

construction. We noted that the purposive construction of the proposed claims was not explicitly performed in the SOR.

Purposive construction of the proposed claims and statutory subject-matter

[49] In the PR Letter, we considered that the identifications of the POSITA, the relevant CGK, the problem to be solved and the proposed solution provided above also apply to the proposed claims.

[50] There are 23 proposed claims. Medical use claims 1 and 23 are the only independent claims and read as follows:

> 1. Use of a galectin-3 binding molecule to conduct plasmapheresis on blood of a mammal in need of reduction of circulating levels of galectin-3 to reduce circulating levels of active galectin-3, wherein said plasmapheresis is conducted so as to selectively remove galectin- 3 by contact with said galectin-3 binding molecule, such that at least ten percent of circulating galectin-3 is removed by said plasmapheresis.
> …
>
> 23. Use of a galectin-3 binding molecule to conduct plasmapheresis on blood of a mammal in need of reduction of circulating levels of galectin-3 to reduce circulating levels of active galectin-3, wherein said plasmapheresis is conducted so as to selectively remove galectin-3 by contact with said galectin-3 binding molecule.

[51] Dependent claims 2 to 22 define further limitations, with regard to: the scope of galectin-3 levels reduction (claims 2 to 4), the plasmapheresis process (claim 5), the galectin-3 binding molecule and related conjugated element (claims 6 to 8), the condition or disease to be treated (claims 9, 10 and 12 to 17), an additional concurrent therapy, pharmaceutical or pharmaceutical agent (claims 11, 18, 19, 21 and 22) and the condition to commence conducting plasmapheresis (claim 20).

[52] In the PR Letter, we expressed the preliminary view that the elements of proposed claims 1 to 23 are focused on and instruct "what" to use to conduct plasmapheresis on blood of a mammal in need of reduction of circulating levels of galectin-3. No element of the claims relating to the recited use of a galectin-3 binding molecule to

conduct plasmapheresis constitutes an active method step. Specifically, we considered the phrase "wherein said plasmapheresis is conducted so as to selectively remove galectin-3 by contact with said galectin-3 binding molecule" in claims 1 and 23 as an explanation of why the galectin-3 binding molecule is used (i.e., "to reduce circulating levels of active galectin-3") as opposed to an active step or an instruction on "how" to use it such that a physician's skill and judgement is involved.

[53] Further, we noted that the SOR is not unequivocal in its assessment that certain expressions of claim 5 (i.e., "including diverting", "removing red blood cells", "contacting said separated plasma", and "separating out any said moieties") are problematic since it indicates that claim 5 may be interpreted as including active steps merely suggestive of a method of medical treatment. We were of the view that the POSITA reading the claim as a whole would consider claim 5 as relating to "what" to use to conduct plasmapheresis on blood, and would consider the expressions as generally describing plasmapheresis, and not as active steps.

[54] Therefore, in accordance with the case law and the guidance found in *PN 2015-01*, our view was that the subject-matter of the proposed claims does not amount to a method of medical treatment.

[55] In view of the above, our conclusion is that the subject-matter of the proposed claims set complies with section 2 of the *Patent Act*, that the proposed amendments address the typographic error of claim 7 on file and the cancellations found on page 1 of the description on file. The proposed amendments would therefore qualify as "necessary" amendments under subsection 86(11) of the *Patent Rules* for compliance with the *Patent Act* and *Patent Rules*.

RECOMMENDATION OF THE BOARD

[56] For the reasons set out above, we recommend that the Applicant be notified, in accordance with subsection 86(11) of the *Patent Rules*, that the deletion of the claims on file, the deletion of page 1 of the description on file and the insertion of the proposed claims 1 to 23 and proposed page 1 of the description as presented in the Applicant's letter of August 26, 2016 are "necessary" for compliance of the application with the *Patent Act* and *Patent Rules*.

Marcel Brisebois	Ed MacLaurin	Cara Weir
Member	Member	Member

DECISION OF THE COMMISSIONER

[57] I concur with the findings and the recommendation of the Panel. In accordance with subsection subsection 86(11) of the *Patent Rules*, I hereby notify the Applicant that the following amendments and only the following amendments must be made in accordance with paragraph 200(*b*) of the *Patent Rules* within three (3) months of the date of this decision, failing which I intend to refuse the application:

- delete the claims on file as well as page 1 of the description and insert proposed claims 1 to 23 and page 1 of the description as presented in the Applicant's letter of August 26, 2016.

Johanne Bélisle
Commissioner of Patents
Dated at Gatineau, Quebec,
this 27th day of December, 2019