Commissioner’s Decision No. 1495

Décision du commissaire n^{o} 1495

TOPICS: J80 Professional or Artistic Skill

K11 Treatment

B00 Indefiniteness

SUJETS: J80 Aptitudes professionnelles (artistiques)

K11 Traitement

B00 Caractère indéfini

Application No. 2,588,966

Demande n^{o} 2 588 966

IN THE CANADIAN PATENT OFFICE

DECISION OF THE COMMISSIONER OF PATENTS

Patent application number 2,588,966, having been rejected under subsection 30(3) of the *Patent Rules* (SOR/96-423), has consequently 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 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 Canadian patent application number 2,588,966, which is entitled "Cladribine Regimen for Treating Multiple Sclerosis" and is owned by Merck Serono S.A. (the Applicant). A review of the rejected application has been conducted by the Patent Appeal Board (the Board) pursuant to paragraph 30(6)(*c*) of the *Patent Rules*.

[2] As explained in more detail below, our recommendation is that the Commissioner of Patents notify the Applicant that specific claim amendments are considered "necessary" amendments under subsection 30(6.3) of the *Patent Rules* for compliance with the *Patent Act* and *Patent Rules* and that the patent application be allowed if amended accordingly.

BACKGROUND

The Application

[3] The application was filed on December 20, 2005 under the provisions of the *Patent Cooperation Treaty* and was laid open to the public on June 29, 2006.

[4] The application relates generally to the safe and effective dosing of cladribine when used for treating multiple sclerosis (MS), a disease in which the body's immune system attacks the central nervous system. Cladribine is a known immunosuppressive agent that selectively targets and suppresses lymphocytes, one of the types of white blood cells used in the body's immune system that are associated with MS lesions in the brain.

Prosecution History

[5] On October 16, 2014, a Final Action (FA) was issued pursuant to subsection 30(4) of the *Patent Rules*. The FA stated that that claims 1-63 on file are directed to a method of medical treatment which is subject-matter that falls outside the definition of invention as set out in section 2 of the *Patent Act*, and that claims 1, 3, 5, 7, 9, 11, 13, 15, 17, 19, 21, 23 and 25-63 on file are indefinite, contrary to subsection 27(4) of the *Patent Act*.

[6] In a response to the FA (RFA) dated January 15, 2016, the Applicant submitted arguments for the patentability of the claims on file and also submitted a new set of claims 1-25 along with a justification as to why the subject-matter of these claims was patentable and not defective for the reasons outlined in the FA.

[7] The Examiner was not persuaded by the Applicant's arguments with respect to the claims on file, and considered that the proposed claims 1-25 would not overcome the defects identified in the FA and would further introduce a new defect. Therefore, pursuant to paragraph 30(6)(*c*) of the *Patent Rules*, the application was forwarded to the Board for review along with an explanation outlined in a Summary of Reasons (SOR). The SOR set out the position that the claims on file were still considered to be defective due to non-statutory subject-matter and indefiniteness.

[8] In a letter dated January 11, 2017, the Board forwarded to the Applicant a copy of the SOR. In a response to the SOR (RSOR) dated February 16, 2018, the Applicant proposed three alternative sets of proposed claims sets (proposed claims set A, proposed claims set B and proposed claims set C) along with a justification as to why the subject-matter of these claims was patentable and not defective for the reasons outlined in the FA.

[9] The present panel (the Panel) was formed to review the instant application under paragraph 30(6)(*c*) of the *Patent Rules*. The Panel sent a Preliminary Review (PR) letter to the Applicant on February 28, 2019 clarifying that the proposed claims submitted with the RFA and RSOR have not been entered as an amendment and that the claims under review are, in accordance with paragraph 30(6)(*b*) of the *Patent Rules*, claims 1-63 on file at the time of the FA.

[10] In the PR letter, we set out our preliminary analysis and rationale as to why, based on the record before us, claims 1-63 on file are directed to methods of medical treatment, which is subject-matter that falls outside the definition of "invention" in section 2 of the *Patent Act*, and why claims 1, 3, 5, 7, 9, 11, 13, 15, 17, 19, 21, 23 and 25-63 are definite and comply with subsection 27(4) of the *Patent Act*. Finally, we expressed the view that the claims of proposed claims set A constitute a "necessary" amendment under subsection

30(6.3) of the *Patent Rules*. The PR letter indicated that if the Applicant did not wish to attend a hearing or provide further submissions, the Panel would complete the review and provide its recommendation to the Commissioner without further communication.

[11] In correspondence received on March 13, 2019, the Applicant declined the opportunity to make further written or oral submissions and confirmed its interest in seeking allowance of the claims of proposed claims set A. Therefore, the Panel proceeded to issue this recommendation based on the current written record including the PR letter.

ISSUES

[12] This review considers the following two defects identified in the FA with respect to claims 1-63[1] on file:

i) whether claims 1-63 on file encompass a method of medical treatment and therefore fall outside of the definition of "invention" in section 2 of the *Patent Act*; and

ii) whether claims 1, 3, 5, 7, 9, 11, 13, 15, 17, 19, 21, 23 and 25-63 on file are indefinite, contrary to subsection 27(4) of the *Patent Act*.

[13] A third potential issue was identified in the RFA, where the Applicant submitted that there was no basis for issuing a final action, and asked that the finality of the office action be withdrawn. These submissions were not addressed in the SOR, and the Applicant did not mention them again in the RSOR in relation to our review. Instead, the RSOR asked that our review assist in moving the case forward. On that basis, and in view of our observations relating to claims set A, the PR letter explained that we considered the issue moot and did not addressed it as part of our preliminary review. As the Applicant did not contest this and has declined to make any further submissions on this or any issue, this issue is not addressed as part of our review.

[1]The SOR further noted that certain claims on file were redundant because identical claims were repeated within the claim set, but no formal defect under any section of the *Patent Act* or *Patent Rules* was identified.

LEGAL PRINCIPLES AND OFFICE PRACTICE

Purposive construction

[14] In accordance with *Free World Trust v Électro Santé*, 2000 SCC 66, 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 v Camco*, 2000 SCC 67 at paragraphs 49(f) and (g) and 52). In accordance with the *Manual of Patent Office Practice*, (*MOPOP*) at §13.05, revised June 2015 (CIPO*)*, the first step of purposive claim construction is to identify the person of ordinary skill 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 elements of the claims that are required to achieve the disclosed solution.

Statutory subject-matter and methods of medical treatment

[15] 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.

[16] Method claims that encompass a medical treatment 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 CR), aff'd [1974] SCR 111).

[17] 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 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. (para 50)

[18] A number of lower court decisions have considered the validity of medical use claims that concern a dosage range or regime (*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 "issue in every case has been whether the patent claims a method of medical treatment" and that in "applying the same principles, claims to fixed dosages and schedules which do not involve any professional decision-making have been accepted as patentable" (para 112).

[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)*. The Office's practice was revised during the course of prosecution of the present application between the sending of the FA and the SOR, in response to the decision in *AbbVie*.

[20] According to *PN 2015-01*, 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 in *MOPOP* §13.05. If it is determined after a purposive construction that a dosage range, or dosage regimen that includes a range, is an essential element of a claim encompassing the use of a known compound in an established treatment, then the claim may cover a method of medical treatment. 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* 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 or a fixed dosage regimen are not considered to point to a limitation of a physician's professional skill or judgment.

Indefiniteness

[22] Subsection 27(4) of the *Patent Act* requires claims to distinctly and explicitly define subject-matter:

> The 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 at 352, 12 CPR 99, the Court emphasized both 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.

ANALYSIS OF THE CLAIMS ON FILE

Claims construction

The skilled person and the relevant CGK

[24] In the PR letter we noted that, upon reviewing the prosecution, it was apparent that the characterization of the skilled person was in dispute. According to the FA, the Applicant characterized the skilled person as a product manufacturer or researcher, and not as a doctor or medical practitioner. In disagreement with the Applicant, the FA characterized the skilled person as a doctor or medical practitioner on the basis that the claims are directed to how cladribine is to be used, and how to use a drug is knowledge within the domain of a medical practitioner.

[25] In the PR letter we expressed our view that, in light of the specification as a whole, including notably the "Background of the Invention" section, the two competing characterizations should be effectively combined to define the skilled person as including a clinician or neurologist with experience in treating MS and experience in conducting experimental clinical trials in order to determine safe and effective dosing. In our view, the skilled person is a team made up of individuals including a product manufacturer or researcher in the pharmaceutical field and a clinician or neurologist with experience in treating MS and general experience in conducting experimental clinical trials. This composite person would have significant and extensive knowledge in experimental medicine and would be well versed in treatment options for MS.

[26] We consider that the following CGK elements are relevant for the purposes of this review:

- knowledge of oral dosing of cladribine
- knowledge of treating MS with cladribine

- knowledge of previous experimental clinical trials investigating the safety, efficacy and bioavailability of cladribine in the treatment of diseases, including MS
- knowledge that cladribine produces an immunosuppressed state by reducing lymphocyte counts, and that lymphocyte reduction is lengthy but impermanent
- knowledge that cladribine has relatively low toxicity towards other tissues
- knowledge of the immunity-related adverse effects associated with using cladribine to reduce lymphocyte counts, including risk of infection

The problem to be solved and the proposed solution

[27] In our view, consistent with the characterizations put forth in the FA, we consider the problem to be solved is the "need for an improved treatment of MS using cladribine" and the proposed solution is "a dosage regimen wherein cladribine is administered during an induction period and maintenance period, alternating with cladribine-free periods where the drug is not administered".

The claims on file

[28] All of claims 1-24 on file are independent claims. We consider that claims 1 and 2 are representative of the independent claims:

> 1. Use of cladribine:
> in the manufacture of an oral formulation for treating multiple sclerosis in a patient in an induction period, wherein the induction period is followed by a first cladribine-free period of about 8 months; and
> in the manufacture of an oral formulation for subsequently re-treating multiple sclerosis in the patient in at least one maintenance period, wherein each maintenance period is followed by a further cladribine-free period.

> 2. Use of an oral formulation of cladribine to:
> treat multiple sclerosis in a patient in an induction period, wherein the induction period is followed by a first cladribine-free period of about 8 months; and
> subsequently re-treat multiple sclerosis in the patient in at least one maintenance period, wherein each maintenance period is followed by a further cladribine-free period.

[29] Independent claim 1 is a "Swiss" style use claim. The form of this type of claim is typically the use of compound X in the manufacture of a medicament for the treatment of Y. A literal interpretation may suggest that the contemplated use is simply for the manufacture of a medicament but the format also permits an interpretation of the claim as relating to a therapeutic use for the compound, the latter interpretation being in line with the jurisprudence (for example, see *GD Searle & Co v Canada (Minister of Health)*, 2008 FC 437, aff'd 2009 FCA 35; *Eli Lilly Canada Inc v Apotex Inc*, 2008 FC 142; and *Pfizer Canada Inc v Apotex Inc*, 2007 FC 971, aff'd 2009 FCA 8). Although the use recited in the preamble of claim 1 is focused on the manufacture of a medicament, the claim specifies a therapeutic use. In our view, the claimed use goes beyond utilizing cladribine to make a medicament; it further requires the actual use of that medicament according to an induction period and maintenance period, alternating with a cladribine-free period, to treat MS. Therefore, although claim 1 is worded in the "Swiss" format, our view is that the skilled person would consider it as essentially claiming the same subject-matter as claim 2.

[30] The remaining independent claims 3-24 are analogous to claims 1 and 2 in that they contain minor variations but are otherwise the same. Specifically, in some claims the duration of the cladribine-free period is changed from 8 months to either 9 or 10 months (claims 3-6 and 9-12). In addition, some claims specify that the use is either for reducing the risk of relapse (claims 7-12), is for long-term therapy (claims 13-18) or is for decreasing the occurrence or severity of at least one adverse event associated with MS treatment (claims 19-24).

[31] The dependent claims 25-63 provide further limitations to the durations of the induction, maintenance or cladribine-free periods (claims 25-27 and 47-52), the total dose reached at

the end of the induction or maintenance period (28-46 and 53), the daily dose amount (claim 54), the dosing frequency (claims 55-61), the use in combination with interferon-beta (claim 62) and the specific types of MS that are treated (claim 63).

Essential elements

[32] In our view, the skilled person would consider that the essential elements of claims 1 and 2 comprise:

- the use of an oral formulation of cladribine
- to treat MS in a patient
- in an induction period, wherein the induction period is followed by a first cladribine-free period of about 8 months, and
- subsequently re-treating MS in the patient in at least one maintenance period
- wherein each maintenance period is followed by a further cladribine-free period

[33] As mentioned above, we consider claims 1 and 2 as representative of the independent claims. All of the independent claims 3-24 contain elements that are either the same or analogous to those in claims 1 and 2 and so in our view, in light of the problem and solution, the skilled person would also consider those corresponding elements as essential.

[34] Further, since claims 25-63 depend on independent claims 1-24, they too encompass at least those same essential elements.

[35] Our views as outlined above were shared with the Applicant in the PR letter and were not contested.

Statutory subject-matter and methods of medical treatment

[36] The analysis in the FA was conducted in accordance with the Office's Practice Notice PN 2013-04 *Examination Practice Respecting Medical Uses* (*PN2013-04*) that is now out of date. The analysis in the FA concluded that the subject-matter of claims 1-63 on file is directed to a method of medical treatment because the essential elements relate to "how" to treat a patient, rather than "what" to use to treat the patient:

> 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, this leads to the conclusion that the claimed use encompasses a method of medical treatment (referring to *PN2013-04*). The present claims instruct the medical practitioner how to treat a patient using the defined dosage regimen and so are directed to a method of medical treatment, which is outside the scope of an invention as defined in section of the *Patent Act*.

[37] However, under the current practice derived from *AbbVie* and reflected in *PN 2015-01*, the inclusion of an essential element that serves to instruct a medical professional "how" to treat a patient is not necessarily determinative of the question of whether a claimed use encompasses a method of medical treatment; it must be determined whether the essential element prevents, interferes with or requires the professional skill of a physician. Also, *PN 2015-01* states 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.

[38] It must therefore be determined whether any of the essential elements listed above prevent, interfere with or require the professional skill of a physician.

[39] The SOR, which was issued after *PN 2015-01*, added that the claims on file "encompass both non-fixed dosages and variable scheduling regimes", and that for each claim the physician must use their professional skill and judgment in either selecting how much drug to use or in determining how long the period of administration or re-administration is to be.

[40] Also relevant is the following statement in the FA:

> Despite the applicant's comments to the contrary, the present claims still contain ranges in the timing periods. In particular, the induction periods, the maintenance periods, and further cladribine free periods, are not explicitly limited to specific time periods and thus encompass ranges of time periods. The vagueness about these periods defined in claims 1-24 rely on the medical practitioner to determine the length of the induction periods, the maintenance periods, and further cladribine free periods. Claims 25-27 and 47-52 also contain ranges with the language "up to about x months". (emphasis added)

[41] The RFA disputed that claims 1-63 on file are directed to a method of medical treatment. Further, the RFA disagreed with the suggestion that those claims define a "dosage regimen". The Applicant explained that efforts were made to remove "all references to dosing from the independent claims" in order to "shift away from dosing" and focus on "other embodiments in the disclosure that were not tied to a dosage regimen". Further, the Applicant stated that the independent claims were restricted to "different stages and periods of treatment and re-treatment" that represented an improvement over the prior art, and that the claims define a selection that is "particularly beneficial" and also "reduced adverse effects".

[42] In our view, the skilled person would not consider a dosage regimen as being limited to the amount of drug alone, it would also include elements relating to the route of administration and the dosing schedule, such as the frequency of dosing and the duration of treatment. As such, it is reasonable to consider the different stages and periods of treatment and re-treatment defined within the claims as being part of a dosage regimen. With respect to the elements purportedly representing a selection, a benefit or an improvement over the prior art, in our view those considerations are not material to determining whether or not the elements would prevent, interfere with or require the professional skill of a physician.

[43] In our view, the skilled person would recognize that the essential elements of the dosage regimen of claims 1 and 2 are not fixed. The dosage amounts, dosing frequencies and the duration of the induction period and the maintenance period would each need to be determined. In our view, in light of the specification as a whole, those determinations would require the professional skill of a physician.

[44] Likewise, the remaining independent claims 3-24 contain the same or analogous essential elements as claims 1 and 2, and so the same determinations would be required for each of those claims. We therefore consider that claims 3-24 would require the professional skill of a physician.

[45] Since claims 25-63 depend on independent claims 1-24 they encompass those same essential elements, and so it follows that claims 25-63 would also require the professional skill of a physician.

[46] Our views were shared with the Applicant in the PR letter and were not contested.

[47] In light of the above, it is our view that the the claims on file are directed to subject-matter that falls outside the definition of an invention as set out in section 2 of the *Patent Act*.

Indefiniteness of claims 1, 3, 5, 7, 9, 11, 13, 15, 17, 19, 21, 23 and 25-63 on file

[48] The FA explains that the subject-matter of claims 1, 3, 5, 7, 9, 11, 13, 15, 17, 19, 21, 23 and 25-63 on file is indefinite because the "Swiss" format is used to define a dosage regimen comprising various dosing and timing limitations. According to the FA, interpreting the claims as being for a medicament or "vendible product" in the manner suggested by the Applicant is at odds with the inclusion of details relating to the dosing and timing limitations surrounding how the compositions are used. Consequently, the FA concludes that if the claims are for a vendible product, than the vendible product is not clearly defined.

[49] As we mentioned previously in "Claim Construction", the Swiss style is a common and judicially accepted claim format that is used to claim a therapeutic use, despite what a literal interpretation of the wording may suggest. We have already expressed our view that, although the use recited in the preamble of claim 1 is focused on the manufacture of a medicament, the claim specifies a therapeutic use and would be considered by the skilled person as claiming a therapeutic use. Consequently, we do not consider that the

use of the Swiss format in these claims would render the claim unclear to the skilled person. It is our view that, to the extent that the Swiss format is used, the claims on file are definite and comply with subsection 27(4) of the *Patent Act*.

ANALYSIS OF THE PROPOSED CLAIMS

[50] The Panel may consider a set of proposed claims. The Applicant submitted three sets of proposed claims with the RSOR without indicating which of the three sets it preferred, and so the first set, proposed claims set A containing claims 1-30, was considered. According to the RSOR, all of the independent claims recite fixed dosage amounts and fixed dosing schedules, all of the proposed claims find support in the specification as filed, and no new matter is introduced.

[51] We note that there is a clear correspondence between the proposed claims set A and the dosage amounts and time periods disclosed in Example 1, Table 3 on page 26 of the description, and that the claims find support in the specification as filed. Further, the subject-matter of proposed claims set A does not necessitate another prior art search. Accordingly, we considered proposed claims set A.

[52] In the same manner as the corresponding claims on file, proposed claims 1-30 recite dosage regimens where oral cladribine is used to treat MS according to an induction period and a maintenance period, alternating with a cladribine-free period. Proposed claim 1 is considered as representative of the independent claims:

> 1. Use of an oral cladribine formulation for the treatment of multiple sclerosis in a patient weighing 40-44.9 kg, the oral cladribine formulation comprising cladribine or a pharmacologically-acceptable salt thereof, the treatment comprising:
>
> a daily dose of 10 mg of cladribine for 4 consecutive days at the beginning of the first month of a two-month induction period;
> a daily dose of 10 mg of cladribine for 3 consecutive days at the beginning of the second month of the two-month induction period;
> a daily dose of 0 mg of cladribine, in a cladribine-free period lasting 10 months;
> a daily dose of 10 mg of cladribine for 4 consecutive days at the beginning of the first month of a two-month maintenance period;

> a daily dose of 10 mg of cladribine for 3 consecutive days at the beginning of the second month of the two-month maintenance period; and
> a daily dose of 0 mg of cladribine, in a cladribine-free period lasting 10 months.

[53] Based on the problem and solution, which in our view would remain the same, the skilled person would consider all of the elements relating to the dosage regimen to be essential.

[54] The RSOR states that proposed claims 1-30 define fixed daily doses of cladribine according to specific administration schedules, and that the "target doses and ranges" of the claims on file that were rejected in the FA are no longer recited in the claims.

[55] We consider that the dose amounts, dosing frequencies and the durations of the induction, maintenance and cladribine-free periods set out in the proposed claims 1-30 are all fixed. Notably, there is one range that is used to define the patient subpopulation according to their weight "40-44.9 kg", however it is our view that this range would not require any determination to be made. It simply defines a limitation on who the regimen is meant for. It is our view that the essential elements of claims 1-30 of proposed claims set A would not prevent, interfere with or require the professional skill of a physician and that these claims would comply with section 2 of the *Patent Act.*

[56] In light of the above, it is our view that the claims of proposed claims set A meet the requirements of a "necessary" amendment under subsection 30(6.3) of the *Patent Rules.*

CONCLUSIONS

[57] We conclude that the claims on file are directed to subject-matter that falls outside the definition of "invention" in section 2 of the *Patent Act*. We also conclude that claims 1, 3, 5, 7, 9, 11, 13, 15, 17, 19, 21, 23 and 25-63 on file are definite and comply with subsection 27(4) of the *Patent Act*.

[58] Further, we conclude that the claims of proposed claims set A meet the requirements of a "necessary" amendment under subsection 30(6.3) of the *Patent Rules*.

RECOMMENDATION OF THE BOARD

[59] We recommend that the Applicant be notified, in accordance with subsection 30(6.3) of the *Patent Rules*, that the deletion of the claims on file and the insertion of claims 1-30 of claims set A proposed in the letter of February 16, 2018 are "necessary" for compliance with the *Patent Act* and *Patent Rules*.

Cara Weir Member	Marcel Brisebois Member	Ed MacLaurin Member

DECISION

[60] I concur with the conclusions and recommendation of the Board. In accordance with subsection 30(6.3) of the *Patent Rules*, I hereby notify the Applicant that the above amendments must be made within three (3) months of the date of this decision, failing which I intend to refuse the application.

[61] In accordance with paragraph 31(*b*) of the *Patent Rules*, the following amendments, and only these amendments, may be made to the application :

i) delete claims 1-63 on file; and

ii) insert claims 1-30 of claims set A as proposed in the letter of February 16, 2018.

Johanne Bélisle
Commissioner of Patents

Dated at Gatineau, Quebec,

this 19th day of September, 2019.