Citation: Merz Pharma GMBH & Co. KGAA (Re), 2022 CACP 3
Commissioner's Decision #1610
Décision du Commissaire nº 1610
Date: 2022-01-27

TOPIC:	G00	Utility
	J80	Professional or Artistic Skill
	K11	Treatment
	B00	Ambiguity or Indefiniteness

SUJET:	G00	Utilité
	J80	Aptitudes professionnelles artistiques)
	K11	Traitement
	B00	Caractère ambigu ou indéfini

Application No. : 2,654,214

Demande nº 2 654 214

IN THE CANADIAN PATENT OFFICE

DECISION OF THE COMMISSIONER OF PATENTS

Patent application number 2,654,214, 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 refuse the application if the necessary amendments are not made.

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INTRODUCTION

[1] This recommendation concerns the review of rejected Canadian patent application number 2,654,214, which is entitled “High frequency application of neurotoxic component of Botulinum toxin” and is owned by Merz Pharma GMBH & Co. KGAA (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 refuse the application if the necessary amendments are not made.

BACKGROUND

The application

[3] The application has a filing date of June 28, 2007, and was laid open to public inspection on January 3, 2008.

[4] The application generally relates to using the neurotoxic component of *Clostridium botulinum* (*C. botulinum*) toxin complex serotype A, devoid of any other protein of the *C. botulinum* toxin complex (herein the “pure” neurotoxic component) at a shortened dose interval that is below the standard minimum recommendation of at least three months, to treat conditions associated with hyperactive cholinergic innervation of muscles or for cosmetically reducing facial lines, wrinkles or asymmetries.

[5] The claims under review are claims 1 to 252 on file, dated October 4, 2016 (claims on file).

Prosecution history

[6] On May 31, 2018, a Final Action (FA) rejecting the claims on file was issued pursuant to subsection 30(4) of the *Patent Rules* (SOR/96–423) (the former *Patent Rules*) as they read immediately before October 30, 2019. The FA indicates that claims 1-248 on file at the time of the FA contravene section 2 of the *Patent Act* because the subject-matter lacks utility since success depends on the exercise of

skill and judgment of a physician, and is further directed to unpatentable subject-matter for the same reason. The FA also indicates that pages 20 and 26 contain statements incorporating other documents by reference, contrary to subsection 81(1) of the former *Patent Rules* (now subsection 57(1) of the *Patent Rules*). Further, the FA indicates that claims 3, 103-122, 125 and 127 contain minor clarity defects contrary to subsection 27(4) of the *Patent Act*. Finally, the FA indicates that claims 249-252 on file are allowable.

[7] On November 30, 2018, a response to the FA (RFA) was filed by the Applicant along with a proposed set of claims 1-252 amended to address the minor clarity defects and proposed description amendments to address the incorporation by reference defects. The RFA argues that claims 1-248 on file and the proposed claims are directed to patentable subject-matter that complies with section 2 the *Patent Act*.

[8] The Examiner was not persuaded that claims 1-248 on file or the proposed claims were compliant with section 2 of the *Patent Act* with respect to utility or patentable subject-matter, and so the application was forwarded to the Board along with a Summary of Reasons (SOR). In the SOR, the minor clarity defects identified for claims 3, 103-122, 125 and 127 on file were withdrawn.

[9] The SOR was forwarded to the Applicant on May 2, 2019. In a letter dated July 5, 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.

[11] During our review, additional questions arose as to whether claim 249 on file is directed to unpatentable subject-matter and whether claims 28-34, 103-124, 152-158 and 227-248 on file define subject-matter that is unclear, ambiguous and inconsistent with the description, and so the Applicant was notified of these issues pursuant to subsection 86(9) of the *Patent Rules*.

[12] In a preliminary review letter (PR letter) dated October 8, 2021, the Panel set out its preliminary views that the utility requirements are satisfied for claims 1-248, but

that claims 1-249 are directed to unpatentable subject-matter falling outside the definition of “invention” in section 2 of the *Patent Act*, that claims 28-34, 103-124, 152-158 and 227-248 are ambiguous, contrary to subsection 27(4) of the *Patent Act*, and that pages 20 and 26 of the description contain statements prohibited by subsection 57(1) of the *Patent Rules*. Since there is no meaningful difference between the claims proposed in response to the FA and the claims on file with respect to these issues, we expressed our preliminary view that the proposed claim amendments would not overcome these defects. We did agree, however, that the amendments to pages 20 and 26 proposed with the RFA would render the description compliant with subsection 57(1) of the *Patent Rules*. Finally, the Panel provided the Applicant with an opportunity to make oral and/or written submissions in response to the PR letter.

[13] In a response to the PR letter dated December 7, 2021 (RPR), the Applicant submitted a new set of proposed claims 1-220 (the proposed claims) and provided further arguments in favour of both the claims on file and the proposed claims.

[14] An oral hearing was held virtually on December 17, 2021.

[15] The Panel has completed its review and have set out our conclusions below.

ISSUES

[16] The issues addressed by the review are:

- whether claims 1-248 on file lack utility contrary to section 2 of the *Patent Act* because success depends on the exercise of skill and judgment of a physician;
- whether claims 1-249 on file are directed to unpatentable subject-matter that requires the exercise of skill and judgment of a physician and is therefore outside the definition of “invention” in section 2 of the *Patent Act*;
- whether claims 28-34, 103-124, 152-158 and 227-248 on file are ambiguous, unclear and inconsistent with the description; and
- whether pages 20 and 26 on file contain statements incorporating other documents by reference, contrary to subsection 57(1) of the *Patent Rules*.

LEGAL PRINCIPLES AND OFFICE PRACTICE

Purposive construction

[17] 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.

[18] "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.

Utility

[19] Utility is required by 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

[20] In *AstraZeneca Canada Inc v Apotex Inc*, 2017 SCC at para 53 [*AstraZeneca]*, the Supreme Court of Canada stated that the "[u]tility will differ based on the subject-matter of the invention as identified by claims construction" and outlined the approach that should be undertaken to determine whether a patent discloses an invention with sufficient utility under section 2 of the *Patent Act*:

> [54] To determine whether a patent discloses an invention with sufficient utility under s. 2, courts should undertake the following analysis. First, courts must identify the subject-matter of the invention as claimed in the patent. Second,

> courts must ask whether that subject-matter is useful—is it capable of a practical purpose (i.e. an actual result)?
> [55] The Act does not prescribe the degree or quantum of usefulness required, or that every potential use be realized—a scintilla of utility will do. A single use related to the nature of the subject-matter is sufficient, and the utility must be established by either demonstration or sound prediction as of the filing date (*AZT,* at para 56).

[21] Therefore, utility must be established either by demonstration or sound prediction as of the Canadian filing date. Utility cannot be supported by evidence and knowledge that only became available after this date (see also *Apotex Inc v Wellcome Foundation Ltd*, 2002 SCC 77 at para 56 [*AZT*], cited in the passage above).

[22] The doctrine of sound prediction allows the establishment of asserted utility even where that utility had not been fully verified as of the filing date. However, a patent application must provide a “solid teaching” of the claimed invention as opposed to “mere speculation” (*AZT* at para 69).

[23] The soundness of a prediction is a question of fact (*AZT* at para 71). Analysis of that soundness should consider three elements (*AZT* at para 70):

- there must be a factual basis for the prediction;
- the inventor must have, at the date of the patent, an articulable and sound line of reasoning from which the desired result can be inferred from the factual basis; and
- there must be proper disclosure of the factual basis and line of reasoning.

[24] These elements are assessed from the perspective of the skilled person to whom the patent is directed, taking into account their CGK. Further, with the exception of the CGK, the factual basis and line of reasoning must be included in the patent application (See *Bell Helicopter Textron Canada Ltée v Eurocopter SAS*, 2013 FCA 219 at paras 152–153).

[25] Although a prediction does not need to amount to a certainty to be sound, there must be a *prima facie* reasonable inference of utility (*Gilead Sciences Inc v Idenix*

Pharmaceuticals Inc, 2015 FC 1156 at para 251; *Mylan Pharmaceuticals ULC v Eli Lilly Canada Inc*, 2016 FCA 119 at para 55).

Patentable subject-matter: skill and judgment

[26] As above, 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

[27] *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.

[28] 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).

[29] 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)

[30] 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).

Ambiguity

[31] 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.

[32] Section 60 of the *Patent Rules* requires claims to be clear:

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

[33] 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.

Incorporation by reference

[34] Subsection 57(1) of the *Patent Rules* prohibits the incorporation of documents by reference:

> The description must not incorporate any document by reference.

ANALYSIS

Purposive construction

[35] The claims under review can be divided into two general groupings. Claims 1-74, 125-198 and 249 are directed to the use of compositions, or compositions for use, comprising the pure neurotoxin component in the treatment of conditions associated with hyperactive cholinergic innervation. Claims 75-124 and 199-248 are directed to cosmetic methods or compositions comprising the pure neurotoxin component for use in reducing facial lines, wrinkles or facial asymmetries. Claims 1, 75 and 249 are representative:

> Claim 1. Use of a composition comprising a neurotoxic component of a *Clostridium botulinum* toxin complex serotype A, the composition being devoid of any other protein component of the *Clostridium botulinum* toxin complex for treating a disease or condition caused by or associated with hyperactive cholinergic innervation of muscles or exocrine glands in a patient, wherein
>
> (a) the patient is a human;
> (b) the composition is administrable by injection, and
> (c) the composition is for administration at an interval from 2 hours to eight weeks, the interval comprising a first treatment and a second treatment, wherein the amount for administration in the second treatment is lower, higher or identical to the amount for administration in the first treatment.

> Claim 75. A method of reducing facial lines or wrinkles of the skin or of removing facial asymmetries, the method comprising administering to an individual a composition comprising a neurotoxic component of a *Clostridium botulinum* toxin complex serotype A, the composition being devoid of any other protein component of the Clostridium botulinum toxin complex, wherein
>
> (a) the individual is a human;
>
> (b) the composition is administered by subcutaneous or intramuscular injection into, or in vicinity of, one or more facial muscles or muscles involved in the formation of the wrinkle of the skin or the asymmetry; and
>
> (c) the composition is administered at an interval from 2 hours to eight weeks, the interval comprising a first treatment and a second treatment, wherein the amount administered in the second treatment is lower, higher or identical to the amount administered in the first treatment.
>
> Claim 249. Use of an injectable composition comprising a neurotoxic component of a *Clostridium botulinum* toxin complex serotype A, the composition being devoid of any other protein component of the *Clostridium botulinum* toxin complex for treating cervical dystonia in a human patient, wherein the composition is for administration in a first dose of 300 U and a second dose of 300 U, wherein the second dose is for administration two weeks following the first dose.

Person skilled in the art

[36] On page 1, the FA characterized the skilled person as a team comprising a dermatologist, a plastic surgeon, and a pharmacologist or pharmacist. On page 8, we expressed the following preliminary view in the PR:

> The Applicant has not disputed this characterization, however this characterization does not include a physician or medical professional from any of the fields related to conditions associated with hyperactive cholinergic innervation or the first grouping of claims identified above. Our preliminary view is that the team would further include physicians or the appropriate specialists with knowledge and expertise relating to treating conditions associated with hyperactive cholinergic innervation, which are listed on pages 6-11 of the

> description and include the various forms of dystonia, bladder dysfunction and spastic conditions (as well as numerous other disorders).

The RPR did not dispute, contest or comment on this expanded characterization of the skilled team and so we adopt it for the purposes of our review.

Common general knowledge

[37] The FA characterized the CGK as including (pages 1-2):

> the use of *Clostridium botulinum* A protein complex (description pages 2-5), wherein the composition is devoid of any other protein component of the *Clostridium botulinum* toxin complex, in the treatment of various conditions, in particular the treatment of diseases or conditions associated with, or caused by, hyperactive cholinergic innervation of muscles or exocrine glands in a patient.

[38] On page 9 of the PR we expressed the following preliminary view:

> The Applicant did not dispute this characterization. We agree that this characterization is reasonable and our preliminary view is that, based on the teachings of the description and the characterization of the skilled person as including a dermatologist, the CGK would further include the following knowledge:
>
> • *C. botulinum* is used in the cosmetic treatment of facial lines, wrinkles and facial asymmetries;
> • the effect of Botulinum toxin is only temporary which is why repeated administration may be required to maintain a therapeutic effect (page 3);
> • it is common practice to strictly avoid administering Botulinum toxin at intervals less than every three months to reduce the risk of inducing an immune response forming neutralizing antibodies that block the activity of the neurotoxic component (pages 3-4 and 15);
> • physicians are strongly advised to administer BOTOX™ or DYSPORT™ not more often than once every three months and this applies in particular to patients that require high doses of the Botulinum toxin (page 5); and
> • the pure neurotoxic component of serotype A devoid of any other proteins of the *C. botulinum* toxin complex was commercially available under the trade name XEOMIN (page 14).

[39] The RPR did not dispute, contest or comment on this expanded characterization of

the CGK and so we adopt it for the purposes of our review.

The essential elements

[40] The assessment of essential elements in the FA was carried out using the problem-solution approach in accordance with guidance that was superseded by *PN2020-04*. We therefore performed a fresh assessment of the essential elements in the PR in consideration of the guidelines in *PN2020-04*. The following assessment of the claim elements from pages 9-11 of the PR considers the nature of the claimed invention and the way it works in relation to the scope of the claims, which is also relevant to the issues of utility and patentable subject-matter:

> With respect to claim language, our preliminary view is that the skilled person reading representative claims 1, 75 and 249 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.
>
> Claim 249 defines the second dose in terms of a specific amount, 300 U, whereas claims 1 and 75 express the second dose amount as being “lower, higher or identical” to the first. Since the three alternatives in the latter claims cover all possibilities, our view is that it is appropriate that the skilled person would consider whether this element has a material effect on the way the invention works. In this case, a brief discussion of the nature of the claimed invention and the way it works in consideration of the scope of the claims under review is warranted and is also relevant to the issues of utility and patentable subject-matter.
>
> The subject-matter of the invention that is common to all of claims 1-248 includes, among other things, that pure neurotoxin is used for therapeutic or cosmetic treatments in humans at a short interval from two hours to eight weeks between the first two doses and wherein the second dose amount is lower, higher or identical to the first. While it is not explicitly stated in the claims, the description teaches that neutralizing antibodies which are known to render the neurotoxic component ineffective by blocking its activity will not be induced at the shorter interval, provided the pure neurotoxin devoid of other complex proteins is used. Such a property is inherent to the subject-matter as claimed.

The description explains that the ability to avoid forming neutralizing antibodies at the claimed interval allows for a number of applications that would not have been available with the conventional use involving a minimum of three months between doses. For example, subsequent treatments can be given sooner if efficacy begins to decline or improved symptomology begins to wane before the three month mark (see ex. page 15, lines 29-31; page 19, lines 23-27; page 23, lines 6-7). Also the ability to split a dose allows for more appropriate dosing by, for example, approaching the optimal dose by using a series of smaller doses given close together, or increasing the dose if the initial response is not sufficient (see ex. page 15, lines 14-22; page 26, lines 22-29). Further, conditions requiring larger doses can be treated by splitting a large dose into a series of smaller doses given close together to limit systemic spread to surrounding non-target muscles or to allow for far higher total doses that would otherwise be non-compliant (see ex. page 4, line 28-page 5, line 19, lines 25-26 and 30-32; page 13, lines 10-12; page 18, lines 17-20; page 19, lines 1-3 and 20-22).

In our preliminary view, the skilled person would understand that these are different facets or aspects of the invention. These aspects all relate directly to the dosing interval, the relative amount of the second dose compared to the first, or both and so our preliminary view is that the skilled person reading these claims in the context of the description would regard them as being encompassed by the broad scope of the subject-matter as claimed in claims 1 and 75. That is not to say that these aspects are limitations. Rather, the description provides insight as to the purpose and some of the ways that the subject-matter of the invention would be used in practice.

Independent claims 1 and 75 are not directed to treating one specific condition or symptom. Claim 1 is broadly directed to using the pure neurotoxic component for treating “a disease or condition caused by or associated with hyperactive cholinergic innervation of muscles or exocrine glands”. The diseases or conditions falling within this group, which are listed on pages 6-11 of the description, are broad and diverse. The examples show that there is significant variation in the regimens depending on the specific condition being treated. For example, a blepharospasm patient receives two identical doses of 48 MU 7 weeks apart in Example 2, a patient with generalized spasticity receives two identical 250 MU doses 1 day apart in Example 3, and in Example 1 the initial dose had to be increased beyond the initial 300 MU after two weeks. In this view, the skilled person would understand that the claims

> broadly encompass a variety of regimens by virtue of defining the time interval as a range of “2 hours to eight weeks” and the relative amount of the second dose as being “lower, higher or identical” to the first. Furthermore, the regimen used would depend on the specific condition that is treated.
>
> Regardless of whether practicing the claimed subject-matter involves using it for the purpose of providing the appropriate dose interval, providing the optimal dose amount, or to split up a large dose, our preliminary view is that the amount of the second dose in relation to the first will have a material effect on how the invention works in respect of the therapeutic response. The expectation is that the therapeutic response to the second dose would be higher, lower or the same as the therapeutic response to the first dose, in direct correlation with the relative amount of the second dose, and this would be the case for any of the conditions encompassed with claims 1 and 75. Our preliminary view is therefore that the skilled person would regard this element as an essential element of independent claims 1, 75, 125 and 199.
>
> For the above reasons, our preliminary view is that all of the elements of claims 1-249 under review are essential, including the dosing interval and the relative dose amounts. Subject to any comments or clarifications the Applicant wishes to make, the Panel intends to take all of the elements of claims 1-249 as essential elements for the purposes of our analysis.

[41] The RPR did not dispute or contest our assessment of the essential elements, the nature of the claimed invention or the scope of the claims as set out in the above passage, and so we will take all of the elements of claims 1-249 as essential for the purposes of our review.

[42] Regarding the broad scope of the conditions and dosage regimens encompassed by the claims, the RPR agreed saying the following on page 2:

> Taking claim 1 as an example, this claim does indeed cover a wide range of conditions and doses. This is because, as is known in the art, *Clostridium botulinum* toxin complexes are useful for treating a wide range of conditions and differing conditions require differing doses.

Utility

[43] On page 3, the FA contended that claims 1-248 on file encompassed subject-

matter that lacks utility because success in treating the disease or condition is dependent upon a person's skill, judgment or reasoning which are needed to determine the dose interval and the second dose to be administered.

[44] The RFA did not address this issue, though the Applicant did dispute that there was a lack of utility in their letter of October 4, 2016.

[45] On page 12 of the PR, we said the following:

> The analysis in the FA did not use the framework set out in *AstraZeneca*, which requires identifying the subject-matter of the invention as claimed as the first step. We have already identified above that the subject-matter of the invention that is common to all of claims 1-248 is the use of pure neurotoxin for therapeutic or cosmetic treatment in humans at a short interval from two hours to eight weeks between the first two doses and wherein the second dose amount is lower, higher or identical to the first.
>
> The second step of the analysis considers whether the subject-matter is capable of a practical purpose or an actual result. The therapeutic or cosmetic utility is explicitly asserted within the independent claims. The description attributes that utility not only to the well known activity of the neurotoxin component in treating the conditions and symptoms claimed, but also to the absence of neutralizing antibodies blocking that activity (even at the shortened dose interval). As stated in *AstraZeneca* at para 55, a single use related to the nature of the subject-matter is sufficient, and the utility must be established by either demonstration or sound prediction as of the filing date. In our view, the therapeutic or cosmetic utility of the neurotoxic component at the shorter dose interval without inducing neutralizing antibodies constitutes a single use related to the subject-matter of the invention and this is the utility that had to be established by demonstration or sound prediction before the filing date.
>
> Examples 1-4, considered cumulatively, provide a factual basis that symptomology is already improved after the first dose in four different patients with different conditions. Since symptomology is already improved after the first dose, it stands to reason that it will be improved to at least some extent regardless of whether the second dose amount is lower, higher or equal to the first. Further, the four examples use different dose intervals ranging from one day to seven weeks between the first two doses and neutralizing antibodies were not induced in any of the examples. When these facts are considered

> together with the established and well known utility of *C. botulinum* toxin in the art our preliminary view is that there is a factual basis and sound line of reasoning supporting the therapeutic or cosmetic utility and the absence of neutralizing antibodies across the full scope of the subject-matter of the four independent claims.
>
> With regard to the position in the FA that success depends on the exercise of skill and judgment of the practitioner, we have already identified above under purposive construction that applications that involve finding the appropriate interval or the optimal dose amount based on a patient's response are encompassed within the broad scope of claims 1 and 75. We acknowledge that it is necessary to consider whether practicing the claimed subject-matter implicates decision-making or the activities of a physician, as is discussed further in the following section. However, to the extent that "success" in respect of therapeutic or cosmetic utility relates to the activity of the neurotoxin and the avoidance of neutralizing antibodies at the shorter interval, the examples indicate that these are achieved regardless of the relative amount of the second dose or the dosing interval that is selected from the claimed ranges. As stated above, our preliminary view is that this is sufficient to satisfy the mere scintilla of utility requirement.

[46] The RPR did not dispute or contest the above analysis set out in the PR. For the reasons set out above, we are satisfied that the scintilla of utility that is required by section 2 of the *Patent Act* was established across the full scope of the claims by sound prediction at the filing date.

Patentable subject-matter: skill and judgment

[47] The PR performed a fresh assessment of patentable subject-matter in light of the guidelines in *PN2020-04* which superseded those relied on in the FA.

[48] According to *PN2020-04*, where at least one of the essential elements of the actual invention limits a claimed use to a dosage regimen it is necessary to consider whether the exercise of professional skill and judgment of the practitioner is part of the claimed invention. This is consistent with the Federal Court of Canada's articulation of this principle in *Hoffman-La Roche Ltd v Sandoz Canada Inc*, 2021 FC 384 at para 195 [*Hoffman-La Roche*]:

> Patent claims are invalid where they prevent or restrict physicians from applying their skill and judgment...As I have previously discussed in *Janssen*, there are inconsistencies in Canadian law on what constitutes a method of medical treatment, which has been highlighted by judges of this Court and the Federal Court of Appeal…However the crucial question remains of whether the…(c)laims encroach on the skill and judgment of physicians.

[49] The RPR did not contest our position in the PR that the time interval and second dose amount limit the claimed subject-matter to a dosage regimen and so it is necessary to consider whether the claims prevent, restrict, require or otherwise engage the exercise of professional skill and judgment.

Claims 1-248

[50] On pages 14-15, the PR expressed the following views with respect to claims 1-248:

> *PN2020-04* explains that the subject-matter of a claimed invention may involve professional skill and judgment 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).
>
> As explained above under purposive construction, independent claims 1, 75, 125 and 199 are broadly directed to treating a variety of conditions with distinct patient groups. For instance, in Examples 1, 2 and 3 patients with cervical dystonia, blepharospasm and generalized spasticity are treated, which are different patient groups but are all under the umbrella of diseases or conditions "caused by or associated with hyperactive cholinergic innervation of muscles or exocrine glands" as defined in claims 1 and 125. These examples show that, in practice, different conditions use different dosing intervals and dose amounts from one another, and so our preliminary view is that this is not a case where all dosages or time intervals falling within the claimed range will work all subjects within the claimed treatment group.
>
> Further, as stated above the independent claims encompass a number of applications with different purposes. One such application is to use the claimed subject-matter to determine the appropriate dose interval by monitoring a patient and administering a second dose when the therapeutic response to the

> first dose begins to wane. A second is to use the claimed subject-matter to determine the optimal dosing amount by monitoring the patient's therapeutic response to a first dose and determining whether the amount of the second dose ought to be adjusted. When the claimed subject-matter is used to treat a patient with, for example, limb dystonia or wrinkles at the appropriate time interval or optimal dose amount, the practitioner would be expected to monitor the patient and make selections from the ranges based on the patient's response to the first dose.
>
> The manner in which the subject-matter of the invention is claimed in respect of the dose and timing elements implicates decision-making and the exercise of skill and judgment within the scope of the claims, which in our preliminary view runs afoul of the jurisprudence pertaining to unpatentable subject-matter and the claiming of methods of medical treatment or professional skills. Our preliminary view is therefore that independent claims 1, 75, 125 and 199 encompass subject-matter that requires the skill and judgement of a medical professional which is not patentable subject-matter within the definition of "invention" in section 2 of the *Patent Act*.
>
> Likewise, claims 2-74, 76-124, 126-198 and 200-248 which depend on these claims each require decision-making in respect of, at a minimum, the dose amounts or relative dose amounts. Our preliminary view is therefore that these claims also encompass unpatentable subject-matter falling outside the definition of "invention" in section 2 of the *Patent Act*.

[51] The RPR disputed the that the subject-matter of claims 1-248 require the skill and judgment of a medical professional making three main arguments.

[52] First, the RPR argued that determining the timing interval and second dose amount do not require the skill and judgment of a physician because the decisions are made by the patient based on their own self-monitoring:

> Taking claim 1 as an example, this claim does indeed cover a wide range of conditions and doses. This is because, as is known in the art, *Clostridium botulinum* toxin complexes are useful for treating a wide range of conditions and differing conditions require differing doses. Once the condition to be treated is determined, the first dosage amount is easily determined and would be expected to work for all subjects being treated for that particular condition. The timing interval and dose for the second treatment is then typically

> determined based on self-monitoring that is carried out by the patient, not by the medical professional. See, for example, page 16 of the application as filed, which states that the Blepharospasm Disability Index (BSDI) is a self-rating scale that is answered by the patient…See, also, the bottom of page 19 of the application as filed, which states that "decreases of the therapeutic effect can be monitored by treatment calendars in which the patient records the severity of his disorder on a day-to-day basis". Example 4 further supports that it is the patient, not the medical professional, making decisions about whether or not treatment is satisfactory.
>
> …
>
> It is not the practitioner determining whether the limb dystonia has subsided. Rather, it is the patient who intuitively knows whether their symptoms have been relieved or not. If not, a higher dose may be provided. If so, a lower or the same dose may be provided. Similarly with wrinkles, the patient decides if they have received a sufficient dose or not based on their desired cosmetic outcome. In neither case is a complicated set of tests required that need any kind of special review or analysis by a medical professional. It is the patient that self-monitors and decides whether the first treatment was sufficient or not. (emphasis in the original)

[53] In contrast to the second dose amount and the timing interval, the Applicant does not dispute that the physician has to determine the first dosage amount that is claimed in association with the first treatment. For the rest of the dosage regimen, we agree that the patient's response to that first dose is the main factor in determining the second dose amount and the time interval between doses. We further agree that patient feedback, based on their impressions and self-monitoring, would be considered as part of this factor. However, that does not mean that the patient is the one making the decisions.

[54] We acknowledge that the BSDI self-rating scale and treatment calendars are tools for collecting specific information from patients that is based on self-monitoring. We further agree that patients would inform the physician of their opinions and impressions of whether a treatment was satisfactory or sufficient. However, in our view it is more reasonable that the skilled person reading the specification as a whole would understand that the physician takes that information into account when deciding what the second dose amount ought to be and when it should be given.

[55] The RPR further states on page 3 that:

> …at the top of page 18 of the application as filed it is indicated that the medicament could be packaged with instructions to the patient for self-treatment and administration, clearly teaching that no special knowledge or judgment is required to use the invention as claimed. (emphasis in the original)

[56] In our view, the RPR has overstated what is said on page 18 by implying that the leaflet provides instructions for patients to inject themselves with a neurotoxin, and that the injection of a neurotoxin into muscles would not require any special knowledge. The top of page 18 says the following:

> The above specified (and claimed) modes of administration of the medicament as used within the present invention belong usually to the activities of the physicians treating patients. However, the mode of administration can also be part of the manufacture of the medicament in that e.g. the package of the medicament contains a specifically adapted leaflet with instructions to the physician and/or patient and/or the package is specifically adapted to allow the mode of administration according to the present invention.

[57] While this passage indeed mentions adapting the instructions for the physician and/or patient, there is no mention of self-treatment or self-administration by the patient.

[58] In our view, the skilled person (which includes a physician with expertise in treating conditions associated with hyperactive cholinergic innervation and a dermatologist) reading this paragraph in the context of the specification would more reasonably consider it as describing a product embodiment, as distinct from the use of the pure neurotoxic component or the process of administering it. More specifically, our view is that the skilled reader would regard this paragraph as distinguishing the product embodiment from the well known and commercially available XEOMIN™ product by adapting the leaflet.

[59] For these reasons we do not agree that it is the patient that is making the decisions. Rather, the physician factors the information obtained from patients into their decisions.

[60] Second, the RPR argued that the claimed subject-matter is well within the purview of the skilled person and, based on their CGK and the teachings in the description,

they would readily be able to use the first and second treatments (RPR pages 4-5):

> Moreover, application of the first and second treatments, within 2 hours to eight weeks of each other, is well within the purview of the skilled person, and does not require any further skill or judgement of the physician…Therefore, since the specification as originally filed provides the skilled person with knowledge of suitable first and second treatment amounts (see, e.g. page 19, lines 4-10), including parameters associated with selecting optimal doses of first and second treatments (see e.g. page 15, lines 14-22), suitable muscles for administration for the claimed compositions (see e.g., page 22, lines 3 to 7), including the possible number of injections required for different muscles (see, e.g. page 18, lines 10-13), in conjunction with guidance from the Examples demonstrating exemplary dosages and treatment schedules falling within the scope of the claims, the skilled person would readily be able to use the claimed composition to treat "a disease or condition caused by or associated with hyperactive cholinergic innervation of muscles or exocrine glands" wherein "the second treatment is lower, higher or identical to the amount for administration in the first treatment."

[61] Although it is not stated as such, the above position seems to be that the description provides sufficient information to enable the skilled person to use the claimed subject-matter without *the exercise of inventive ingenuity* or undue experimentation. In our view this conflates the requirements of enablement with those of patentable subject-matter and whether a claim encompasses *the exercise of skill and judgment*. We agree that physicians would readily be able to make the necessary decisions, the problem is that these decisions are required within the scope of the claims.

[62] Third, the RPR pointed to a recent Commissioner's Decision *Re. Amgen Research (Munich) GmbH*, 2021 CACP 2 that also considered a claim containing a range of doses and a range of treatment duration and ultimately concluded that the claim was directed to patentable subject-matter "at least because the claims did not require, restrict, prevent or interfere with the skill and judgment of a physician".

[63] Every application is reviewed on its own merits considering the facts in that particular case, the relevant caselaw and the Applicant's submissions. Accordingly, the outcome of a previous review of another application is not determinative of the current application under review.

[64] Based on the specific facts of this case, the manner in which the subject-matter of the invention is claimed in respect of the dose and timing elements implicates decision-making and the exercise of skill and judgment within the scope of the claims. This runs afoul of the jurisprudence pertaining to unpatentable subject-matter and the claiming of methods of medical treatment or professional skills.

[65] As stated above, the Applicant has acknowledged that the physician has to determine the condition and, in turn, the first dose amount of the claimed regimen. Further, the physician has to determine the amount of the second dose and the interval based on the patient's response to the first dose. In our view, these are straightforward examples of the need for a physician to exercise their skill and judgment. Our conclusion is therefore that claims 1-248 encompass the exercise of skill and judgment of a medical professional within their scope.

Claim 249

[66] On pages 15-16 the Panel expressed the following preliminary view with respect to claim 249:

> As mentioned above, *PN2020-04* cites *AbbVie* at para 114 for the proposition that claims which do 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–are not impermissible subject-matter where there is no evidence to contradict that claimed dosage. This is consistent with *Hoffman-La Roche,* where claims for fixed doses and intervals were considered and found to be unpatentable subject-matter, based in part on evidence that the dosage regimen was not appropriate for all patients (paras 197, 201, 202 and 208):
>
> > Fixed dosages or a fixed dosage schedule does not restrict, interfere with, or engage professional skill or judgment, unless there is evidence to contradict the claimed dosage (*AbbVie*, above at para 114).
> > …
> > Although the line between fixed dosages and a range of dosages may not provide clear guidance when determining patentability, a range of dosages has been more readily found to constitute a method of medical treatment (*Bayer Inc v Cobalt Pharmaceuticals Company*, 2013 FC 1061 at para 162, aff'd 2015 FCA 116)

> …
> That said, the presence of fixed dosages is not the end of the inquiry. In *AbbVie*, the Federal Court considered specifically whether the fixed dosage amount of "Humira" on a fixed schedule (bi-weekly) nevertheless required the exercise of a physician's skill and judgment (*AbbVie* at para 10). In *AbbVie*, the Federal Court found that there would be no exercise of a physician's skill and judgment after determining if the claimed use is appropriate for a patient. The evidence had established that the claimed dosage at a bi-weekly interval was appropriate for all those to whom it was administered (*AbbVie* 121).
> …
> This is not a situation where the dosage regimen is appropriate for all those to whom it is administered (*AbbVie* at para 121). The claimed dosage escalation regime is therefore not a vendible product, and improperly interferes with a physician's skill and judgment. (emphasis added)

Claim 249 defines using the neurotoxic component to treat a single specific condition, cervical dystonia, according to a fixed regimen of two doses of 300 U with two weeks between doses.

Example 1 from the Applicant's description is a demonstration of the neurotoxin component used to treat a cervical dystonia patient at a first dose of 300 U. On re-evaluation after two weeks the symptomology was improved but there was a need to include additional target muscles and increase the dose amount that was initially injected into the originally targeted muscles beyond 300 U. This constitutes evidence that contradicts the claimed dosage. This example indicates that the claimed regimen is not appropriate for all those to whom it is administered and is suggestive of a continued need for monitoring and adjustments (*i.e.*, the exercise skill and judgment on the part of the physician). Our preliminary view is therefore that the subject-matter of claim 249 is not patentable subject-matter falling within the definition of "invention" in section 2 of the *Patent Act*.

[67] While the RPR disputed that claim 249 is directed to unpatentable subject-matter, the Applicant proposed amendments to claim 249 to bring it into alignment with Example 1 rather than provide arguments.

[68] Example 1 is evidence contradicting that the fixed dosage regimen defined in claim 249 is appropriate for all those to whom it is administered. The example shows that continued monitoring is needed and that decision-making is required with respect to whether or not the second dose requires adjustment, and whether it is necessary to target additional muscles. For the same reasons explained above for claims 1-248, our view is that the skilled person would understand that it is the physician, not the patient, that monitors the patient's response to the first dose and makes the necessary decisions.

[69] For these reasons, our conclusion is that the subject-matter of claim 249 encompasses the exercise of skill and judgment within its scope.

[70] As a final matter, the Applicant asked in the RFA if multiplying the claims to cover fixed regimens of every possible combination of dose and timing would secure an allowance. To address this question, we said the following in the PR:

> Examples 1-4 mentioned above test the pure neurotoxin in patients with cervical dystonia, blepharospasm, generalised spasticity and frown lines, respectively. The evidence from the examples is that different conditions require different dose amounts and timing intervals of administration. When considered together, our preliminary view is that the totality of the evidence from these examples contradicts the notion that each possible permutation of dose and timing would be appropriate for all those to whom they would be administered.
>
> Further, while such theoretical claims are not before us, it stands to reason that any new claims for treating blepharospasm, generalized spasticity and frown lines according to dosing regimens that are different from those of claims 250-252 would presumably be contradicted by examples 2-4, respectively. For at least these reasons, our preliminary view is that including a single claim to each separate permutation of dose and timing would not address this outstanding issue for claims 1-248.

[71] The RPR disagreed, stating the following on page 5:

> While we agree that each permutation of dose and timing might not be appropriate for all given conditions, once the condition afflicting the patient is determined, the starting dose and timing requires no exercise of a physician's skill and judgment. Moreover, the second dose is based on patient self-

> monitoring of symptoms and also requires no exercise of a physician's skill and judgment.

[72] For the reasons already explained above we do not agree that the first and second dose amounts are determined without the exercise of a physician's professional skills and judgment.

[73] At the hearing, the Applicant again expressed its willingness to amend the claims in any way necessary to secure an allowance of a patent that more meaningfully covers what XEOMIN™ can do. The Applicant emphasized that it is not the dosages that are critical, rather it is the frequency of administration of less than three months which is made possible because they have taken those extra proteins out of the complex.

[74] It is challenging to speculate about the patentability of claims that are not before us. That said, our view is that claims removing all of the elements associated with the exercise of skill and judgment to more broadly claim a shortened dosing frequency of less than three months would, in our view, reintroduce previously resolved prior art defects. For example, the third examiner report specifically addressed that it was known before the claim date that removing the extra proteins reduced or eliminated the antibody response (report dated March 1, 2013, on page 2):

> It would have been therefore obvious to one skilled in the art, a doctor for example, to use the "neurotoxic component" of the botulinum toxin instead of "botulinum toxin complex", as taught in D1, for the treatment of disorders that respond to botulinum toxin such as those listed in D2 and D3. The person skilled in the art would expect to be able to use the "neurotoxic component" of the botulinum toxin with a shorter dosing schedule since the "neurotoxic component" has been shown to avoid or minimize the formation of neutralizing antibodies…It is therefore within the expertise of one skilled in the art to determine appropriate doses or optimal dosing schedules of pure "neurotoxic component" of botulinum toxin A with the expectation that repeated and even frequent administration thereof at appropriate dose would provide effective and safe therapeutic or cosmetic use, with no or minimal immunogenicity.

[75] The Applicant has not proposed any specific amendments to claims 1-248 to address patentable subject-matter in response to our analysis in the PR, although

amendments were proposed to claim 249 which will be considered below.

[76] For all of the reasons set out above, our conclusion is that claims 1-249 on file encompass the exercise of skill and judgment which is not patentable subject-matter falling within the definition of “invention” in section 2 of the *Patent Act*.

Ambiguity

[77] On pages 17-18, the PR expressed the views that the intervals defined in claims 28-34 and 152-158 and the high doses defined in claims 103-124 and 227-248 render these claims ambiguous:

> *Claims 28-34 and 152-158*
>
> These claims define the interval between doses as being either 2, 3, 4, 5, 6, 7 or 8 hours. Our preliminary view is that this introduces avoidable ambiguity contrary to subsection 27(4) of the *Patent Act* because these intervals are outside the scope of 1 day to 8 weeks as defined in claims 4 and 128, which these claims depend on.
>
> *Claims 103-124 and 227-248*
>
> These claims are directed to cosmetic methods and compositions for using the pure neurotoxin at high doses in the order of 550-1800 U in adults or 16-20 U/kg in children. However, using doses of this magnitude for cosmetic applications is neither supported by or consistent with the teachings of the description (see page 18, lines 28-30, page 20, lines 16-23, examples) which associate high dosing with the therapeutic treatment of severe medical conditions. This embodiment is further inconsistent with the following statements from page 26:
>
> > Typically, smaller amounts of neurotoxic component are used in such cosmetic treatment. Such amounts are preferably in the range of 1 to 5, 5 to 10, 10 to 20 or 20 to 50 Units. Such total amounts may be administered on the same day or on a subsequent day of treatment.
>
> Further, in our preliminary view, the inclusion of children within the patient group in claims 118-123 and 242-247 for the cosmetic reduction or removal facial lines, wrinkles or to remove facial asymmetries would be counter-intuitive

> to the skilled person since children do not generally have or require treatment for wrinkles, for example. There are no teachings in the description that support cosmetic applications in children.
>
> For these reasons, our preliminary view is that the subject-matter of claims 103-124 and 227-248 cause a lack of clarity that results in ambiguity when the claims are read in the context of the description, contrary to subsection 27(4) of the *Patent Act*.

[78] The RPR did not dispute or comment on these views, instead proposing claim amendments which we agree would address the concerns raised in the PR.

[79] In view of the above, our conclusion is that claims 28-34, 103-124, 152-158 and 227-248 on file are ambiguous contrary to subsection 27(4) of the *Patent Act*.

Incorporation by reference

[80] On page 3, the FA indicates that pages 20 and 26 contain statements incorporating other documents by reference, contrary to subsection 81(1) (now subsection 57(1)) of the *Patent Rules*. In response, the RFA proposed amending the pages to delete these statements without providing any further comment.

[81] On reviewing these pages, we agreed in the PR that these statements contravene subsection 57(1) of the *Patent Rules*, and that the proposed amendments to these pages would render them compliant with the *Patent Rules*.

Proposed claims 1-220

[82] As mentioned above, the RPR submitted a set of proposed claims 1-220 that would amend claims 28-34, 103-106, 123, 227-230, 247 and 249 on file, delete claims 107-122 and 231-246 outright and adjust the claim numbering and dependencies of the remaining claims accordingly.

[83] As stated above, the amendments in proposed claims 1-216, which correspond to claims 1-248 on file, were proposed to address ambiguity defects, and as stated above we are satisfied that these amendments would render the claims compliant with subsection 27(4) of the *Patent Act*.

[84] However, there is no meaningful difference between these claims and claims 1-

248 on file in respect of patentable subject-matter. Accordingly, for the same reasons as claims 1-248 on file, our conclusion is that these claims encompass the exercise of professional skill and judgment and are therefore not directed to subject-matter falling within the definition of “invention” in section 2 of the *Patent Act*.

[85] Proposed claims 217-220 correspond to claims 249-252, respectively. We have already acknowledged above that claims 250-252 on file satisfy the requirements of patentability.

[86] Proposed claim 217 is identical to claim 249 on file except that the second dose amount would change from a fixed value of “300 U” to “greater than 300 U”. The RPR explains that this amendment would bring the subject-matter in line with Example 1 and that any need for continued monitoring would be carried out by the patient, not the physician.

[87] We agree that this amendment would bring the claim in line with Example 1. However, defining the second dose amount in this way would require the dose amount to be determined. For the same reasons as claims 1-248 on file, our view is that the skilled person would understand that it is a physician, not the patient, that would make that determination using their professional skills and judgment.

[88] Consequently, our conclusion is that proposed claim 217 would not be directed to patentable subject-matter falling within the definition of “invention” in section 2 of the *Patent Act*.

CONCLUSIONS

[89] We have concluded that:

- claims 1-248 on file have the scintilla of utility that is required by section 2 of the *Patent Act*;
- claims 1-249 encompass the exercise of professional skill and judgment and are therefore not directed to patentable subject-matter falling within the definition of “invention” in section 2 of the *Patent Act*;
- the subject-matter of claims 28-34, 103-124, 152-158 and 227-248 is ambiguous, contrary to subsection 27(4) of the *Patent Act*;
- pages 20 and 26 of the description contain statements incorporating other documents by reference, contrary to subsection 57(1) of the *Patent Rules*; and

- proposed claims 1-217 would not comply with section 2 of the *Patent Act* and so the proposed claim amendments are not “necessary” for compliance with the *Patent Act* and *Patent Rules*.

RECOMMENDATION OF THE BOARD

[90] In view of the above, the Panel recommends that the Applicant be notified, in accordance with subsection 86(11) of the *Patent Rules*, that the following specific amendments are “necessary” for compliance with the *Patent Act* and *Patent Rules*, and that you intend to refuse the application unless these amendments, and only these amendments, are made:

• the deletion of claims 1-249 on file;

• the corresponding adjustment of claim numbering of claims 250-252 on file (*i.e.*, as claims 1-3); and

• the deletion of the statements from pages 20 and 26 of the description that were proposed with the Applicant’s letter dated November 30, 2018.

Cara Weir	Marcel Brisebois	Philip Brown
Member	Member	Member

DECISION OF THE COMMISSIONER

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

• the deletion of claims 1-249 on file;

• the corresponding adjustment of claim numbering of claims 250-252 on file (*i.e.*, as claims 1-3); and

• the deletion of the statements from pages 20 and 26 of the description that were proposed in the Applicant's letter dated November 30, 2018.

Virginie Ethier

Assistant Commissioner of Patents

Dated at Gatineau, Quebec,

This 27th day of January 2022