Citation: Membrane Protective Technologies, Inc. (Re), 2021 CACP 1
Commissioner's Decision #1554
Décision du Commissaire #1554
Date: 2021-01-05

TOPICS:	B20	Excessive width
	G00	Utility
	B00	Indefiniteness
SUJETS:	B20	Portée excessive
	G00	Utilité
	B00	Caractère indéfini

Application No. : 2,602,636
Demande n^{o} 2 602 636

IN THE CANADIAN PATENT OFFICE

DECISION OF THE COMMISSIONER OF PATENTS

Patent application number 2,602,636, having been rejected under subsection 30(3) of the *Patent Rules* (SOR/96-423) as they read immediately before October 30, 2019 (former *Rules*) has consequently been reviewed in accordance with paragraph 199(3)(c) of the *Patent Rules* (SOR/2019-251) (*Patent Rules*). The recommendation of the Patent Appeal Board and the decision of the Commissioner are that the application be allowed only if the necessary amendments are made.

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INTRODUCTION

[1] This recommendation concerns the review of rejected Canadian patent application number 2,602,636, which is entitled "USE OF EXTRACTS OF HIPPOPHAE TO REDUCE LOSS OF REPRODUCTIVE CELL FUNCTION" and is owned by MEMBRANE PROTECTIVE TECHNOLOGIES, INC. (the Applicant). A review of the rejected application has been conducted by the Patent Appeal Board (the Board) pursuant to paragraph 199(3)(c) of the *Patent Rules*. As explained in more detail below, our recommendation is that the application be allowed only if the necessary amendments are made.

BACKGROUND

The Application

[2] The rejected application concerns methods of protecting reproductive cells, i.e., sperm cells, using extracts from plants of the genus *Hippophae*, commonly known as Sea Buckthorn. The methods may be used to better ensure the viability of such cells when collected as part of a livestock artificial insemination program.

[3] The claims under review are claims 1 to 31 dated March 11, 2015 that were rejected in the FA (claims on file).

Prosecution History

[4] On October 25, 2016, a Final Action (FA) was issued pursuant to subsection 30(4) of the former *Rules*. The FA rejected the application and noted the following defects:

- claims 1, 2 and 4-31 lack of support, contrary to section 84 of the former *Rules*;
- the description is insufficient and does not describe and enable the subject-matter of claims 1, 2 and 4-31, contrary to subsection 27(3) of the *Patent Act*;
- certain embodiments falling within the scope of claims 1, 2 and 4-31 lack utility, contrary to section 2 of the *Patent Act*; and
- claims 1, 2, 4, 15, 16 and 28 are indefinite and do not comply with subsection 27(4) of the *Patent Act*.

[5] In a May 4, 2017 response to the FA (RFA), the Applicant disagreed with the FA as to the

scope of the claims but nonetheless proposed an amended set of 14 claims (proposed claims set-1).

[6] The Examiner maintained the defects for the claims on file and considered that proposed claims set-1 comprised claims that did not comply with subsection 27(4) of the *Patent Act*. Therefore, pursuant to subsection 30(6)(c) of the former *Rules*, the application was forwarded to the Board for review, along with an explanation outlined in a Summary of Reasons (SOR). In a letter dated July 5, 2017, the Board forwarded a copy of the SOR to the Applicant and requested that the Applicant confirm its continued interest in having the application reviewed. An amended SOR correcting what appears to be a typographical error was provided on July 19, 2017 (inclusion of claim 2 of proposed claims set-1as part of the identified defective claims was done in error).

[7] The Applicant confirmed its continued interest in having the application reviewed in a letter dated August 18, 2017 and proposed a second amended set of 14 claims (proposed claims set-2).

[8] The present panel (the Panel) was formed to review the instant application under paragraph 199(3)(c) of the *Patent Rules*. The Panel sent a Preliminary Review (PR) Letter to the Applicant on August 14, 2020.

[9] In a written response to the PR letter (RPR) dated October 2, 2020, the Applicant provided written submissions and a third proposed set of claims (proposed claims set-3). In view of our preliminary opinions conveyed in the PR Letter and the reasons found below, the Applicant declined the opportunity for a hearing in a communication dated October 13, 2020.

ISSUES

[10] The issues to be addressed in the present review are whether :

- claims 1, 2 and 4-31 lack of support, contrary to section 84 of the former *Rules*;
- the description is insufficient and does not describe and enable the subject-matter of claims 1, 2 and 4-31, contrary to subsection 27(3) of the *Patent Act*;
- certain embodiments falling within the scope of claims 1, 2 and 4-31 lack utility, contrary to section 2 of the *Patent Act*; and

- claims 1, 2, 4, 15, 16 and 28 are indefinite and do not comply with subsection 27(4) of the *Patent Act*.

[11] If the claims on file are considered defective, we may turn to proposed claims set-3 and consider whether they constitute amendments necessary for compliance with the *Patent Act* and *Patent Rules*.

LEGAL PRINCIPLES AND OFFICE PRACTICE

Lack of support

[12] The first ground for rejection mentioned in the FA, lack of support, relies on section 84 of the former *Rules* (now section 60) as legislative authority. The concern over lack of support under section 84 of the former *Rules* gave rise to a corresponding ground for rejection under subsection 27(3) of the *Patent Act* for lack of description and enablement of the claimed subject-matter, as well as one under section 2 of the *Patent Act* for lack of utility. Of the three legislative provisions, the latter two have enjoyed extensive consideration by the courts. For the purposes of this case, we have therefore proceeded by considering only these latter two requirements; any concern over non-compliance with section 84 of the former *Rules* we take as being subsumed within those inquiries.

Utility

[13] Section 2 of the *Patent Act* requires that the subject-matter of a claim be "useful": "*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".

[14] In *AstraZeneca Canada Inc v Apotex Inc*, 2017 SCC 36 at paras 54-55 [*AstraZeneca*], the Supreme Court of Canada set out the approach to be taken when determining whether a claimed invention meets the utility requirement:

> 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)?
>
> 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).

[15] The soundness of a prediction is a question of fact (*AZT*, at para 71) and cannot be supported by evidence and knowledge that only became available after the filing date (*AZT*, at para 56). A sound prediction has three elements (*AZT*, at para 70):

1) there must be a factual basis for the prediction;

2) the inventor must have at the date of the patent application an articulable and "sound" line of reasoning from which the desired result can be inferred from the factual basis; and,

3) there must be proper disclosure of the factual basis and line of reasoning.

[16] The three elements are assessed from the perspective of the person of ordinary skill in the art to whom the patent application is directed, taking into account their common general knowledge. With the exception of the common general knowledge, the factual basis and the line of reasoning must be included in the application: see *Bell Helicopter Textron Canada Limitée v Eurocopter, société par actions simplifiée*, 2013 FCA 219, at paras 152-153.

[17] Although a prediction does not need to amount to a certainty to be sound, there must be a *prima facie* reasonable inference of utility: *Mylan Pharmaceuticals ULC v Eli Lilly Canada Inc*, 2016 FCA 119, at para 55, *Gilead Sciences, Inc v Idenix Pharmaceuticals Inc*, 2015 FC 1156, at para 251.

Description and enablement under subsection 27(3) of the *Patent Act*

[18] Paragraphs 27(3)(a) and (b) of the *Patent Act* require, respectively, that the specification of a patent (1) describe the invention, and (2) set out the steps for its production and use:

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

[19] A determination of whether the specification complies with paragraphs 27(3)(a) and

27(3)(b) of the *Patent Act* requires that three questions be answered: What is the invention? How does it work? Having only the specification, can the person of skill in the art produce the invention using only the instructions contained in the disclosure? see: *Teva Canada Ltd v Novartis AG*, 2013 FC 141 citing *Teva Canada Ltd v Pfizer Canada Inc*, 2012 SCC 60 and *Consolboard v MacMillan Bloedel* (1981), 56 CPR 2d 145 (SCC) [*Consolboard*]. Although the common general knowledge can be relied upon, an affirmative answer to the third question requires that the person of skill in the art not be called upon to display inventive ingenuity or undertake undue experimentation: *Aventis Pharma Inc. v Apotex Inc*, 2005 FC 1283; *Mobil Oil Corp v Hercules Canada Inc*, [1995] FCJ. No. 1243; *Merck & Co v Apotex Inc*, [1995] 2 FC 723.

[20] In *Consolboard*, at pages 154-155, the Supreme Court referred to the textbook *Canadian Law and Practice Relating to Letters Patent for Inventions* (1969, 4th ed.) from which it quoted H.G. Fox as saying "the inventor must, in return for the grant of a patent, give to the public an adequate description of the invention with sufficiently complete and accurate details as will enable a workman, skilled in the art to which the invention relates, to construct or use that invention when the period of the monopoly has expired".

Utility under section 2 and the requirements of subsection 27(3) of the *Patent Act* are separate considerations

[21] The prosecution record indicates that the concept of a "sound prediction" of utility under section 2 of the *Patent Act* and its disclosure requirements have been considered in a manner seemingly interwoven with concepts related to the requirements of subsection 27(3) of the *Patent Act*. As such, it warrants clarifying that the two concepts are separate and distinct: see *Eli Lilly v Novopharm*, 2010 FCA 197 at para 120 and *AstraZeneca* at paras 42-43.

Indefiniteness

[22] Subsection 27(4) of the *Patent Act* states that "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 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.

[24] A claim is not indefinite simply because it has broad scope; an applicant is the "master of his claims, within the breadth of his invention, and entitled to draft them in words wide enough to secure the protection desired": *Riddell v Patrick Harrison & Co*, [1956-60] ExCR 213, 28 CPR 85 at para 66.

ANALYSIS

The claims

[25] There are 31 claims on file, all of which save claim 3 have been rejected in the FA. Claims 1 and 15 are the independent claims considered representative of the claimed subject-matter:

> 1. A method of reducing loss of function of sperm cells, comprising the steps of:
>
> a. obtaining an extract of *Hippophae* selected from the group consisting of *Hippophae* salicifolia, *Hippophae* tibetana, *Hippophae* neurocarpa, *Hippophae* gvantsensis, and *Hippophae* rhamnoides;
>
> b. obtaining sperm cells from a male mammal; and
>
> c. combining said sperm cells with said extract;
>
> wherein said extract of *Hippophae* is selected and present in an amount, and the conditions are adjusted, so that said extract is effective in reducing loss of function of said sperm cells.
>
> 15. A method of reducing loss of function of reproductive cells, comprising the steps of:
>
> a. obtaining an extract of *Hippophae*;
>
> b. obtaining reproductive cells of an animal; and
>
> c. combining said reproductive cells with said extract;
>
> wherein said extract of *Hippophae* is selected and present in an amount, and the conditions are adjusted, so that said extract is effective in reducing loss of function of said reproductive cells.

Utility

[26] The utility of the claimed subject-matter concerns "reducing loss of function" of reproductive cells, such as sperm cells, by using *Hippophae* extracts. Claims 1, 2 and 4-31 were rejected in the FA because they were considered too broad and encompassing embodiments which may lack this utility. Their scope was of concern in relation to two aspects:

1) the nature of the *Hippophae* extract to be used to reduce loss of reproductive cell function; and

2) the type of reproductive cell said to be reduced in loss of function by the extract.

[27] With regard to the first aspect relating to the type of *Hippophae* extract, there was an assertion in the FA that "some of [the] claims encompass embodiments which lack utility". In support of that argument, certain passages in the description were cited as evidence of inutility since two of the extracts described therein were not demonstrated to be effective in reducing loss of reproductive cell function: "For example, the description discloses that some extracts, including berry sediment and a 2.5% leaf paraffin extract are not effective (see page 15, line 34; page 17, lines 32-34)" (FA, page 2). This was said to raise "uncertainty as to the utility of all of the encompassed extracts."

[28] In the RFA, the Applicant disagreed with this assessment but did not provide arguments beyond those already on record. Instead proposed claims of narrower scope were submitted to secure allowance of the application. The Applicant's correspondence of June 4, 2014 (page 3) provides a clearer indication of some of its reasons for disagreement. Although the passages of the description cited in the FA indicate certain types of berry and leaf extracts are not suitable for use in the invention, the Applicant pointed out that the same passages provide direction to the skilled person on which extracts are effective in reducing loss of reproductive cell function and how ineffective extracts can be avoided by adjusting concentrations or pH:

> At page 17, lines 32-34, the description states:
>
> Only 2.5% leaf paraffin extract (36) (**but effective at 5% leaf paraffin extract**) does not appear to be effective by itself, for cooled sperm cells but might be effective in combination with other extracts, or for frozen sperm cells.
>
> [emphasis in original]

> Thus, the skilled person would conclude that leaf paraffin extract is effective at 5% concentration.
>
> At page 15, lines 34, the description states:
>
> Cyclodextrin again proved to be spermicidal in this study, and therefore motility data is not shown for those treatments. In addition the berry sediment was spermicidal (**likely due to pH related issues, not issues inherent to the berry sediment**), and therefore motility data is not shown.
>
> [emphasis in original]
>
> Thus, the person skilled in the art would conclude that the berry sediment is not inherently spermicidal but that any inutility is likely due to pH related issues.

[29] Accordingly, the claims presently on file include an indication that a *Hippophae* extract is "selected and present in an amount, and the conditions are adjusted, so that said extract is effective in reducing loss of function". The Applicant subsequently submitted in its correspondence of February 4, 2016 that the quoted phrase provides a meaningful limitation on the claimed subject-matter:

> Accordingly, all claims are directed to extracts of ***Hippophae*** **that are selected and present in an amount, and used in a method wherein the conditions are adjusted, so that said extracts are effective in reducing loss of function of reproductive or sperm cells**. The claims are not directed to the use of any extract of *Hippophae*, as alleged by the Examiner. The claims are, by definition, directed to *only* useful embodiments. It is improper for the Examiner to ignore express claim limitations that define the invention in terms of working embodiments. Accordingly, all claimed subject matter have utility. [emphasis in original]

[30] Having reviewed the prosecution record, we expressed the preliminary view in the PR Letter that the claims comply with section 2 of the *Patent Act* insofar as they concern the nature of the *Hippophae* extract that is to be used:

> According to *AstraZeneca*, *supra*, the first tasks in the utility assessment is to identify the subject-matter of the invention as claimed and a use related to the nature of the subject-matter. In our view, the claimed subject-matter and its related utility are readily identifiable from the claim itself. The utility that must be established by either demonstration or sound prediction as of the filing date for the claimed method is reducing loss of sperm cell function (independent claim 1) or reducing loss of reproductive cell function (independent claim 15).
>
> According to the Applicant, the concern that the claims encompass useless embodiments, i.e., the berry and leaf extracts described on pages 15 and 17 of the description, is offset by the limitation of the claims to an extract that is "selected and present in an amount, and the conditions are adjusted, so that said extract is effective in reducing loss of function" because "[t]he claims are, by definition, directed to only useful embodiments".

> We respectfully disagree. Functional language does not necessarily serve to exclude non-useful subject-matter. As mentioned above, the claims would be directed to useful subject-matter if the recited utility of reducing loss of function by using the contemplated types of *Hippophae* extract within the claimed method is established by either demonstration or sound prediction. Further, our view is that the claim language is consistent with what the skilled person would understand from considering the claim as a whole:
>
> - the amount of extract and the conditions surrounding its use must be workable ones; and
> - it is the underlying utility of the extract in reducing loss of function that provides the overall utility of the claimed method.
>
> Although the matter does not appear to have been fully explored during prosecution, we are of the preliminary opinion that the claims are directed to embodiments whose utility has been soundly predicted insofar as the type of *Hippophae* extract is concerned. Applying the tri-partite test of a sound prediction to the present claims, we are satisfied that application discloses both an adequate factual basis and a sound line of reasoning for predicting that the encompassed *Hippophae* extracts, when present in a sufficient amount and under suitable conditions as disclosed in the specification, the claimed subject-matter would be useful for reducing loss of sperm cell function. The factual basis includes the disclosure of considerable testing of various *Hippophae* extracts for their ability to reduce loss of sperm cell function when a sufficient amount of said extracts is used under suitable conditions. Extending these results in broader form to the claimed subject-matter represents a sound line of reasoning. [emphasis in the original]

[31] Apart from the type of *Hippophae* extract to be used in the claimed invention, the FA also raises concerns that certain claims are too broad and lack utility because they encompass all types of reproductive cells. This aspect stands out in relation to independent claim 15 and dependent claims 16-23 and 30-31 which, unlike independent claim 1 and claims 24-29, do not limit the reproductive cell to a sperm cell. The FA states (page 2) that a sound prediction of utility is lacking insofar as the claims concern all types of reproductive cells: "the factual basis which is limited to sperm cells is insufficient to extend the teaching of the description to any and all reproductive cells encompassed by claims 15-23, 30 and 31".

[32] As indicated above, the RFA is limited in its reasons for disagreeing with the FA. As discussed above, earlier correspondence from the Applicant dated June 4, 2014 explains why the claims encompass useful subject-matter insofar as the type of extract is concerned but does not appear to adequately explain why all type of reproductive cells would be expected to be protected from loss of function by using the extracts.

[33] In the PR Letter, we noted that page 4 of that correspondence points to a passage in the description (spanning page 13, line 27 to page 14, line 12) which concludes that assessing sperm cells for loss of function can be used as a model for assessing loss of function of

other types of reproductive cells, possibly suggesting that the breadth of the claims can be justified as a sound prediction on that basis. We further noted, however, that the conclusion is tentative and extends from a scientific article discussing techniques that may be used to assess sperm cell motility after cryopreservation. Notably, the article makes no mention of the same techniques being suitable for assessing other types of reproductive cells. Bearing in mind that the description does not confirm through experimentation that a sperm cell model for assessing loss of function can be used to assess loss of function of other types of reproductive cells, it was our preliminary view that the skilled person would regard the statement as speculative rather than an established fact. Therefore, we stated in the PR Letter that conclusions drawn from using a spermatozoa model provides a limited factual basis to predict that all types of reproductive cells can also be protected by *Hippophae* extracts.

[34] We further noted that the description provides no indication of successful reduction in loss of function in reproductive cells other than spermatozoa by using a *Hippophae* extract—a concern that recognizes reproductive cells may have different cellular structures, physiologies and membrane biochemistries rendering them unresponsive to treatment.

[35] In the RPR, the Applicant made no submissions in respect of the claims on file and instead submitted proposed claims set-3 and corresponding written submissions.

[36] In view of the foregoing, we are not satisfied there is a factual basis underlying claims 15-23, 30 and 31 sufficient to support a sound prediction that *Hippophae* extracts can be used to reduce loss of function in all types of reproductive cells. As such, our view is that claims 15-23, 30 and 31 on file encompass subject-matter that lacks utility, contrary to section 2 of the *Patent Act*.

Description and enablement under subsection 27(3) of the *Patent Act*

[37] Considered from the separate standpoint of the requirements of subsection 27(3) of the *Patent Act*, the FA (page 2) further took issue with the scope of the claims because the limitation "wherein said extract of *Hippophae* is selected and present in an amount, and the conditions are adjusted, so that said extract is effective in reducing loss of function" fails "to define what extract is selected and in what amount it is present, and how the conditions are adjusted in order to achieve the desired result" and it was submitted that undue experimentation would be required on the part of the skilled person to determine which *Hippophae* extracts would be effective in reducing loss of reproductive cell function.

[38] In the PR Letter, we disagreed with the position expressed in the FA for the following reasons.

[39] Firstly, it was our view that the limitation "wherein said extract of *Hippophae* is selected and present in an amount, and the conditions are adjusted, so that said extract is effective in reducing loss of function" explicitly states what the skilled person can be expected to achieve, bearing in mind that what the inventors have actually achieved and disclosed is considerable. In that regard, the description reveals that a number of working embodiments were prepared consisting of various types of *Hippophae* extracts. The description also provides direction on those to avoid, as the Applicant has pointed out during prosecution. The present case is therefore not one of an applicant simply trying to claim a desired result without an appropriate basis; rather, the claim language represents a fair generalization of an invention actually achieved and which may be otherwise difficult to define in precise formulaic terms.

[40] We also noted in the PR Letter that our views were aligned with the Applicant's arguments provided in its correspondence of February 4, 2016 that points out that the description provides considerable guidance to the skilled person on how to obtain the *Hippophae* extracts of the invention.

[41] Importantly, we further considered two declarations provided to the United States Patent and Trademark Office in respect of corresponding applications that were included with the same correspondence. Both declarations provide information on how the skilled person could routinely practise the invention as it has been similarly claimed in Canada, contrary to the assertions made in the FA. The first declaration is dated December 22, 2008 and has been signed by Dr. George Seidel; the second is dated December 18, 2008 and has been signed by Dr. William Schroeder.

[42] According to the first declaration, Dr. Seidel is a researcher with expertise in "sperm capacitation treatments in horses and in vitro fertilization media and the artificial insemination of cattle with sperm including additives which enhance fertilization". After explaining in detail why the specification describes and enables each of the three steps of the method of claim 1, his declaration concludes with the opinion that "a person of ordinary skill in laboratory procedures pertaining to animal reproduction having read the description of the Application coupled with information known in the art and performing only routine experimentation as would be typical in that art would be able to perform the [claimed]

method…".

[43] In the second declaration, Dr. Schroeder explains that he is a plant scientist with "extensive knowledge of research techniques related to agriculture including agroforestry design, stress physiology, and genetics and specifically have extensive knowledge of the plant physiology of the variety of plants encompassed by the genus *Hippophae*". In seeming disagreement with statements made in the FA, Dr. Schroeder indicates (at para 11) that while they may have phenotypic differences, "it is known that the chemical and biochemical composition of the fruiting bodies and leaves between [*Hippophae*] species is similar, creating a range of concentration within a given set of chemical components". He states his opinion at para 12 that "the above described difference in phenotypic traits or the chemical composition of the fruiting bodies and leaves between the six known species of *Hippophae* would not require a change in the stepwise methods described in Applicant's specification . . .". He concludes:

> [i]n my opinion the guidance provided by description of the Application as to how to generate extracts of *Hippophae* coupled with information known in the art including the references cited in paragraph 14 and 15 and the availability of extracts from the variety of sources disclosed in the description of the Application, would allow a person reasonably skilled in routine laboratory procedures to produce or otherwise obtain the broad variety of extracts of *Hippophae* encompassed by element (a) of claim 25 for all the species of *Hippophae* including those species listed in claim 26.

[44] Since the FA does not specifically address either declaration from the standpoint of the requirements of subsection 27(3) of the *Patent Act*, and we had no reason to doubt their veracity, we expressed the preliminary view that the specification is compliant.

[45] In the RPR, the Applicant made no submissions in respect of the description and its compliance under subsection 27(3) of the *Patent Act*.

[46] In view of the above, we are of the view that the specification complies with subsection 27(3) of the *Patent Act*.

Indefiniteness

[47] The FA stated that claims 1, 2, 4, 15 and 16 are indefinite and therefore non-compliant with subsection 27(4) of the *Patent Act*. According to the FA, the use of the following terms in the claims causes a lack of clarity:

- "an extract" (claims 1 and 15);

- "wherein said extract of *Hippophae* is made from *Hippophae* seeds" (claim 2);
- "a pulp oil extract" (claims 4 and 16);
- "a juice extract" (claims 4 and 16); and
- "a fruit extract" (claim 16).

[48] The FA stated that "it is still unclear to what extract the term 'an extract' refers" and "it is unclear whether said term refers to a seed oil extract, a leaf hydroglycerin extract, or a different extract". It was also said the term "extract" encompasses extracts "not disclosed or contemplated by the applicant".

[49] In the PR Letter, we expressed the preliminary view that if the skilled person was in doubt as to what the terms mean or encompass, any ambiguity in that regard can be resolved by referring to the definitions provided on page 5, lines 17-24 of the description:

> The term "extract or extracts" refers to any moiety or moieties isolated from a plant; a portion of a plant such as the leaves, fruit, or seeds; or a plant product of Hippophae as above-described regardless as to whether such moiety or moieties are isolated singularly, or in multiple simultaneous fashion, or is a product of combining such moiety or moieties, or produced by molecular biology techniques or chemical synthesis techniques, and specifically includes, without limiting the forgoing, Extracts 1-9, as described below, any combination of such Extracts or any compound isolated from such Extracts.

[50] We also regarded the declarations by Seidel and Schroeder as objective confirmation that the terminology would not be considered ambiguous by the skilled person.

[51] In the PR Letter, we further stated that it appeared to us that the alleged defects were identified in the FA as if the scope of the claims is more the issue. However, the objectionable terms do not operate in isolation of other claim language, the totality of which serves to define the metes and bounds of the claimed subject-matter. Therefore, a *Hippophae* extract of the claims can, for example, be any of the alternatives suggested in the FA, such as a seed oil extract, a leaf hydroglycerin extract, or a different extract.

[52] Another indefiniteness defect was identified in the FA solely in relation to claim 28. That claim ultimately depends on claim 15 and uses the term "increased mortality" to further qualify the nature of the "loss of function of said reproductive cells" (emphasis on plural; i.e., a population or collective of cells) recited in the parent claim. The FA states, however, that "it is unclear in what manner increased mortality further defines loss of function" and

the "subject matter for which protection is sought is unclear."

[53] In the PR Letter, we expressed the view that it would be self-evident to the skilled person that (1) the scope of protection sought in claim 28 is less than that of the parent claim since it is a dependent claim, and (2) reproductive cells can collectively lose function if there is increased mortality in a population of such cells.

[54] In the RPR, the Applicant made no submissions in respect of the defects identified under subsection 27(4) of the *Patent Act*.

[55] We are therefore of the view that claims 1, 2, 4, 15, 16 and 28 are compliant with subsection 27(4) of the *Patent Act*.

Proposed claims

[56] In response to the PR Letter, the Applicant provided written submissions relating to proposed claims set-3 wherein claim 15 has been amended to incorporate the subject-matter of claim 24, which has been cancelled. Specifically, the phrase "reproductive cells of an animal" has been changed to "at least one sperm cell from a male mammal". Claims 30 and 31 have been cancelled. Claims 25-29 have been renumbered as claims 24-28, respectively. Renumbered claims 24 and 26-28 were made dependent on claim 15. Renumbered claim 25 was made dependent on renumbered claim 24.

[57] It is our view that this amendment would overcome the defect noted above with respect to claims 15-23, 30 and 31 and their non-compliance with section 2 of the *Patent Act*.

[58] We therefore consider that proposed claims set-3 qualifies as amendments that are necessary in order to make the application allowable under subsection 86(11) of the *Patent Rules*.

CONCLUSION

[59] With regard to the claims on file, we have determined that:

- insofar as they concern the nature of the *Hippophae* extract, claims 1, 2 and 4-31 comply with section 2 of the *Patent Act* and section 84 of the former *Rules*;
- claims 15-23 and 30-31 do not comply with section 2 of the *Patent Act* to the extent they encompass any type of reproductive cell;

- the specification complies with subsection 27(3) of the *Patent Act*; and
- claims 1, 2, 4, 15, 16 and 28 are compliant with subsection 27(4) of the *Patent Act*.

[60] With regard to the proposed claims, we determined proposed claims set-3 qualifies as amendments that are necessary in order to make the application allowable under subsection 86(11) of the *Patent Rules*.

RECOMMENDATION OF THE BOARD

[61] In view of the above, we recommend that the Applicant be notified, in accordance with subsection 86(11) of the *Patent Rules*, that the deletion of the claims on file and the insertion of the proposed claims set-3 submitted on October 2, 2020 as the amended claims are necessary for compliance with the *Patent Act* and *Patent Rules*.

Marcel Brisebois	Ryan Jaecques
Member	Member

DECISION OF THE COMMISSIONER

[62] I concur with the conclusion and recommendation of the Board. Accordingly, under subsection 86(11) of the *Patent Rules*, I notify the Applicant that the above amendment must be made within three months of the date of this decision, failing which I will refuse to grant a patent for this application.

[63] In accordance with subsection 200(*b*) of the *Patent Rules*, this is the only following amendment that may be made to the application:

- Delete the claims on file; and
- Insert proposed claims set-3 submitted on October 2, 2020.

Virginie Ethier

Assistant Commissioner of Patents

Dated at Gatineau, Quebec

this 5th day of January, 2021