Commissioner’s Decision #1493

Décision de la Commissaire #1493

TOPIC:	O00 (Obviousness) K11 (Treatment) C00 (Deficiency of description) B00 (Ambiguity)
SUJET:	O00 (Évidence) K11 (Traitement) C00 (Caractère inadéquat de la description) B00 (Caractère ambigu)

Application No.: 2,761,855

Demande n°.: 2 761 855

IN THE CANADIAN PATENT OFFICE

DECISION OF THE COMMISSIONER OF PATENTS

Patent application number 2,761,855, having been rejected under subsection 30(3) of the *Patent Rules*, has subsequently been reviewed in accordance with paragraph 30(6)(*c*) of the *Patent Rules*. The recommendation of the Patent Appeal Board and the decision of the Commissioner are to refuse the application if the necessary amendments are not made.

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INTRODUCTION

[1] This recommendation concerns the review of rejected patent application number 2,761,855, which is entitled "Contact lens sets and methods to prevent or slow progression of myopia or hyperopia" and is owned by Cooper International Holding Company, LP. The outstanding defects to be considered are whether the subject-matter of the claims on file lies outside the definition of "invention" in section 2 of the *Patent Act*, whether the specification fails to fully describe and enable the claimed subject-matter, whether claim 1 is unclear, ambiguous or indefinite and whether the subject-matter of the claims on file would have been obvious. A review of the rejected application has been conducted by the Patent Appeal Board ("the Board") pursuant to paragraph 30(6)(*c*) of the *Patent Rules*. As explained in more detail below, the recommendation of the Board and the decision of the Commissioner are to refuse the application if the necessary amendments are not made.

BACKGROUND

The application

[2] Patent application 2,761,855 (the instant application), based on a previously filed Patent Cooperation Treaty application, is considered to have been filed in Canada on May 3, 2010 and was laid open to the public on April 28, 2011.

[3] The claimed subject-matter of the application relates to methods of using ophthalmic lenses of different optical designs for reducing or preventing progression of myopia or hyperopia in a person in need thereof. More specifically, the disclosed methods include the use of two or more sets of contact lenses that have different optical designs, the contact lenses from each set providing defocused retinal images to human patients to prevent or slow the progression of myopia or hyperopia.

Prosecution history

[4] On July 26, 2016, a Final Action (FA) was written pursuant to subsection 30(4) of the *Patent Rules*. The FA explained that the claims on file are directed to a method of medical treatment, and thus are directed to subject-matter that lies outside the definition of "invention" in section 2 of the *Patent Act*, that the specification fails to fully describe and enable the claimed subject-matter and its operation or use, contrary to subsection 27(3) of the *Patent Act*, that claim 1 is unclear, ambiguous or indefinite, contrary to subsection 27(4) of the *Patent Act* and that the subject-matter of all claims on file would have been obvious, contrary to section 28.3 of the *Patent Act*.

[5] In a response to the FA (RFA) dated September 27, 2016, the Applicant submitted an amended claims set (proposed claims set-1) and arguments as to why the specification and the subject-matter of the proposed claims were not open to objections for the reasons outlined in the FA.

[6] As the Examiner was not persuaded by the Applicant's arguments, the application and an accompanying Summary of Reasons (SOR) were forwarded to the Board for review. The SOR maintained the defects as identified in the FA. The SOR further explained why the proposed claims set-1 fails to overcome the defects noted with respect to the claims on file. In a letter dated April 19, 2017, the Board sent the Applicant a copy of the SOR.

[7] The present Panel was formed to review the application under paragraph 30(6)(*c*) of the *Patent Rules* and to make a recommendation to the Commissioner as to its disposition. In a preliminary review letter dated January 30, 2019 (the PR Letter), we set out our preliminary analysis and rationale as to why: i) the claims on file are not directed to subject-matter excluded from the definition of "invention" set out in section 2 of the *Patent Act*; ii) the specification sufficiently describes and enables the claimed subject-matter in compliance with subsection 27(3) of the *Patent Act* except for an embodiment encompassed by claim 8; iii) claim 1 complies with subsection

27(4) of the *Patent Act* as it defines distinctly and in explicit terms the claimed subject-matter; and iv) the subject-matter of the claims on file does not comply with section 28.3 of the *Patent Act* because it would have been obvious at the claim date.

[8] Further, with respect the proposed claims set-1, we expressed our preliminary view that the subject-matter of these claims would have been obvious for the same reasons expressed with respect to the claims on file and that the specification does not comply with subsection 27(3) of the *Patent Act* insofar as it relates to the proposed claims because it fails to describe and enable subject-matter encompassed by their scope for the same reasons given with respect to claim 8 on file.

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

[10] On March 8, 2019, the Applicant provided written submissions in a letter (the RPR Letter) with respect to the PR Letter. In the same letter, the Applicant also submitted a second amended claims set (proposed claims set-2). An oral hearing was held on March 22, 2019 (the Hearing).

[11] In a letter dated May 21, 2019, the Panel sought clarification with regard to some of the Panel's preliminary observations that were not, in our view, fully addressed by either the Applicant's submissions of March 8, 2019 or Applicant's oral submissions at the hearing. In a response dated June 7, 2019, the Applicant submitted a third amended claims set (proposed claims set-3).

ISSUES

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

- whether claims 1 to 16 on file define subject-matter that lies outside the definition of "invention" in section 2 of the *Patent Act*;

- whether the specification fails to fully describe and enable the claimed subject-matter, and its operation or use, contrary to subsection 27(3) of the *Patent Act*;

- whether claim 1 is unclear, ambiguous or indefinite, contrary to subsection 27(4) of the *Patent Act*; and

- whether the subject-matter of the claims on file would have been obvious, contrary to section 28.3 of the *Patent Act*.

[13] If we determine that the claims on file do not comply with the *Patent Act*, we will consider proposed claims set-3.

LEGAL PRINCIPLES AND PATENT OFFICE PRACTICES

Purposive construction

[14] Essential elements are identified through a purposive construction of the claims. The exercise is conducted from the standpoint of a person skilled in the art by considering the whole of the disclosure, including the specification and drawings: *Free World Trust v Électro Santé Inc*, 2000 SCC 66 [*Free World*]; *Whirlpool Corp v Camco Inc*, 2000 SCC 67 at paras 49(f) and (g) and 52 [*Whirlpool*]. According to the *Manual of Patent Office Practice* [*MOPOP*] §13.05, the first step in the construction of the claims of a patent application is to identify the person of ordinary skill in the art (POSITA) and the relevant common general knowledge (CGK). The next step is to identify the problem addressed by the inventors and the solution

disclosed in the application. Essential elements can then be identified as those elements of the claims that are required to achieve the disclosed solution.

Statutory subject-matter and methods of medical treatment

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

> [I]nvention means any new and useful art, process, machine, manufacture or composition of matter, or any new and useful improvement in any art, process, machine, manufacture or composition of matter.

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

[17] What would be considered a method of medical treatment is explained in *MOPOP*, §17.03.01 (January 2009):

> To be considered a method of medical treatment, the method should cure, prevent or ameliorate an ailment or pathological condition, or treat a physical abnormality or deformity such as by physiotherapy or surgery. Certain natural conditions such as ageing, pregnancy, baldness and wrinkles are not considered to be pathological, and methods to treat such conditions are therefore not proscribed.

[18] Also relevant is the Office's practice with regard to the patentability of medical use claims that is guided by Practice Notice PN 2015-01, entitled *Revised Examination Practice respecting Medical Uses* [*PN 2015-01*].

[19] According to *PN 2015-01*, medical use claims are generally permitted as long as they do not amount to a method of medical treatment. The determination of whether the subject matter of a claim is statutory is based on the essential elements of the claim as determined by a purposive construction as outlined above. For medical inventions, the problem faced by the inventor may relate to "what" to use for treatment. Generally the solution to such a problem will be provided by an element

or set of elements in a claim that embody a treatment tool. This tool may include a compound, composition, formulation, or a dosage unit form. Where an essential element only serves to instruct a medical professional "how" to treat a patient rather than "what" to use to treat the patient, it must be determined whether the essential element prevents, interferes with or requires the professional skill of a physician. If the answer is "yes", the claimed use will be considered to encompass a method of medical treatment that falls outside the scope of section 2 of the *Patent Act*.

[20] However, *PN 2015-01* also recognizes that there may be instances where essential elements serve to instruct a medical professional "how" to treat a patient but are not considered to prevent, interfere with or require the professional skill of a physician. For example, essential elements that narrow treatment to a fixed dosage, a fixed dosage regimen or to a patient sub-population are not considered to comprise a limitation of a physician's professional skill or judgment. We also note that *PN 2015-01* states that the emphasis of the guidance provided therein relates to the examination of claims that recite dosage regimens or dosage ranges.

Sufficiency of description

[21] The relevant portions of subsection 27(3) of the *Patent Act* read as follows:

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

[22] The courts have indicated that sufficiency of disclosure primarily relates to two questions that are relevant for the purpose of paragraphs 27(3)(*a*) and 27(3)(*b*) of the *Patent Act*: i) What is the invention? and ii) How does it work? (*Consolboard Inc v*

MacMillan Bloedel (Sask) Ltd, [1981] 1 SCR 504 at 526, 56 CPR (2d) 145 at 157). With respect to each question, the description must be correct and full in order that when the period of the monopoly has expired, the public, having only the specification, will be able to make the same successful use of the invention as the inventor could at the time of his application, without having to display inventive ingenuity or undertake undue experimentation.

Claims clarity

[23] Subsection 27(4) of the *Patent Act* states:

> (4) 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.

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

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

Obviousness

[25] Section 28.3 of the *Patent Act* sets out the statutory requirement that the claimed subject-matter must not have been obvious to the POSITA:

> The subject matter defined by a claim in an application for a patent in Canada must be subject matter that would not have been obvious on the claim date to a person skilled in the art or science to which it pertains, having regard to

> (a) information disclosed more than one year before the filing date by the applicant, or by a person who obtained knowledge, directly or indirectly, from the applicant in such a manner that the information became available to the public in Canada or elsewhere; and
>
> (b) information disclosed before the claim date by a person not mentioned in paragraph (a) in such a manner that the information became available to the public in Canada or elsewhere.

[26] In *Apotex Inc v Sanofi-Synthelabo Canada Inc*, 2008 SCC 61 [*Sanofi*] at para 67, the Supreme Court of Canada stated that it is useful in an obviousness inquiry to follow the following four-step approach:

> (1) (a) Identify the notional "person skilled in the art";
> (b) Identify the relevant common general knowledge of that person;
>
> (2) Identify the inventive concept of the claim in question or if that cannot readily be done, construe it;
>
> (3) Identify what, if any, differences exist between the matter cited as forming part of the "state of the art" and the inventive concept of the claim or the claim as construed;
>
> (4) Viewed without any knowledge of the alleged invention as claimed, do those differences constitute steps which would have been obvious to the person skilled in the art or do they require any degree of invention?

[27] In the context of the fourth step, the Court in *Sanofi* stated that it may be appropriate in some cases to consider an "obvious to try" analysis. For a finding that an alleged invention is "obvious to try", it must be more or less self-evident to try to obtain the alleged invention in advance of routine testing. The mere possibility that something might work is not sufficient.

[28] The Court in *Sanofi* listed the following non-exhaustive factors to be considered in an "obvious to try" analysis:

> (1) Is it more or less self-evident that what is being tried ought to work? Are there a finite number of identifiable predictable solutions known to persons skilled in the art?

(2) What is the extent, nature and amount of effort required to achieve the invention? Are routine trials carried out or is the experimentation prolonged and arduous, such that the trials would not be considered routine?

(3) Is there a motive provided in the prior art to find the solution the patent addresses?

ANALYSIS

Purposive construction

The POSITA and the relevant CGK

[29] In the PR Letter, although we generally agreed with the characterization of the POSITA recited in the FA and noted that the RFA did not express disagreement with it, we expressed the view that the identified team of "specialists in the field of ophthalmology" should more precisely be characterized to at least include an eye care practitioner and an ophthalmic lens designer.

[30] In the RPR Letter and at the Hearing, the Applicant expressed disagreement with this view and stated that "[s]ince the use of contact lenses is performed by an eye care practitioner (ECP), the Applicant submits that the POSITA is an ECP. The ECP would use fitting guides and information provided by contact lens manufacturers in determining which contact lens product would be suitable for a patient."

[31] We respectfully disagree and remain of the view that the POSITA includes at least an ophthalmic lens designer for the following reasons.

[32] Independent claim 1 reads as follows:

> 1. Use of contact lenses for slowing progression of myopia or hyperopia of a human patient, the contact lenses comprising a first set of contact lenses and a second set of contact lenses, the second set of contact lenses providing an improved visual performance to a human patient wearing the second set of contact lenses compared to the visual performance of the human patient provided by the

> first set of contact lenses, the visual performance being based on an ocular parameter of the human patient, a response of the human patient to a contact lens of the first set of contact lenses, or an ocular measurement through an ophthalmic lens, or any combinations thereof;
>
> wherein the first set of contact lenses comprises at least two contact lenses, each contact lens comprising a first vision correction area having a first refractive power and a first defocus area having a second refractive power, the second refractive power providing a defocused retinal image to a human patient at both near and far viewing distances when the contact lens is placed on the eye of the human patient, said first vision correction area and said first defocus area defining a first area ratio, and
>
> wherein the second set of contact lenses comprises at least two contact lenses, each contact lens comprising a second vision correction area having a third refractive power and a second defocus area having a fourth refractive power, the fourth refractive power providing a defocused retinal image to a human patient at both near and far viewing distances when the contact lens is placed on the eye of the human patient and effective to slow progression of myopia or hyperopia of the human patient, and the contact lenses of the second set have a different optical design than the contact lenses of the first set, and said second vision correction area and said second defocus area defining a second area ratio;
>
> said second area ratio being different than said first area ratio.

[33] It is trite law that the POSITA is the same whether the inquiry relates to claims construction or other patentability assessments wherein the POSITA's perspective, knowledge and skills are required. Notably, the POSITA is the addressee of the patent application and is expected to be able to practise the disclosed and claimed invention as of the filing date.

[34] With this in mind, we consider that a second set of contact lenses having a different optical design that includes a different vision correction/defocus area ratio that is effective to slow progression of myopia or hyperopia would be required to practise the

invention recited in claim 1. In other words, the second set of contact lenses must be provided to the patient in order to perform the subject-matter of the claims on file. Unless such sets of contact lenses were readily and commonly available at the filing date, the POSITA cannot be solely an ECP. Relevant to this point, albeit presented in the context of an non-obviousness argument, the Applicant submitted in the RPR, in a section titled "1(B) Common General Knowledge," that "[e]ven as late as 2010 when the Applicant began to make available myopia control contact lenses in Canada, there were no commercially available contact lens sets for controlling progression of myopia or hyperopia that had different optical designs, as recited in the present claims." This submission aligns with passages found at paras [0010] to [0013] of the instant description, which state that an aspect of the disclosed invention relates to the manufacture of a set of contact lens with a varied optical design for provision to the ECP:

> **[0010]** In practicing the present methods, sets of contact lenses are provided. At least a first set and a second set is provided. More than two sets of contact lenses can be provided.
>
> **…**
>
> **[0011]** Additionally, if the contact lens wearer doesn't satisfactorily respond to the contact lens of the second contact lens set, or is predicted by an eye care practitioner to not respond as desired to the effects provided by the contact lens of the second contact lens set, another contact lens may be provided by another set of contact lenses having different optical designs than the contact lenses of the first and second contact lens sets.
>
> **[0012]** It can be appreciated that another aspect of the present invention relates to sets of contact lenses, as described herein.
>
> **[0013]** In another aspect, the invention is directed to a method of providing a set of contact lenses. The methods comprise manufacturing a set of at least two contact lenses as described in the preceding paragraph, or in which the contact lens parameters of central zone diameter, area ratio, optical design, power profile, or power distribution, or any combinations thereof, are varied for each of the at least two lenses in the set. The methods also comprise a step of providing the set to an eye care practitioner in a manner such that a practitioner can select at least one

contact lens from among the set of contact lenses to provide to a contact lens wearer.

[35] In view of the above, we are of the view that the POSITA is a team of specialists in the field of ophthalmology that should include at least an eye care practitioner and an ophthalmic lens designer, the team having access to lens manufacturing facilities.

[36] With respect to the CGK possessed by the POSITA, we stated in the PR Letter that the following elements were CGK:

- Contact lenses that include a vision correction area and a myopic defocus area are known to slow progression of myopia or hyperopia;

- The normal course of treatment for any ophthalmic correction using contact lenses also involves the monitoring of the lens performance on a regular basis by an ophthalmologist or optometrist, and the adjustment of the lens specification in response to changes in the lens performance;

- Use of conventional equipment and techniques as well as the customary practice to be followed when evaluating the progression of myopia, or the absence thereof, of a patient that has been wearing or not wearing ophthalmic lenses through measurements such as the associated axial eye length elongation and refractive error progression (these effects usually take longer to occur than the time of a visit to an eye care practitioner, typically months);

- Use of conventional equipment and techniques as well as the customary practice to be followed when selecting contact lenses designs on the basis of different parameters including a degree of distance refractive error of the patient, a pupil size of the patient, visual acuity of the patient, accommodative lag of the patient, fixation disparity of the

patient, a phoria of the patient, an ocular wavefront aberration profile of the patient, a peripheral refraction of the patient, and/or an axial length measurement of the patient (as evidenced by the instant description at paragraph [0033]); and

- Use of conventional equipment and techniques as well as the customary practice to be followed when assessing contact lens fit as well as how to improve lens fit if needed on the basis of different parameters including visual stability, lens movement, corneal coverage, centration, and/or lens tightness (as evidenced by the instant description at paragraphs [0044] and [0047]).

[37] In the RPR Letter and at the Hearing, the Applicant expressed disagreement with certain of the above findings on CGK.

[38] The Applicant submitted that while the normal course of treatment for correction of refractive error and providing clear visual acuity using contact lenses may involve the monitoring of the lens performance on a regular basis by an ophthalmologist or optometrist and the adjustment of the lens specification in response to changes in the lens performance, such monitoring and adjustments steps did not necessarily form part of a normal course of treatment for longer term treatments such as slowing the progression of myopia through the use of contact lenses. The Applicant further submitted that it was not CGK to provide different contact lens designs with different vision correction/defocus area ratios to slow the progression of myopia. Rather, CGK protocols to slow the progression of myopia or hyperopia included (i) increasing the amount of time spent outdoors to help increase natural light exposure and reduce reading time, (ii) pursuing a pharmaceutical treatment with the use of atropine, or (iii) reshaping the cornea.

[39] We note that our identification of the CGK on those points is limited to ophthalmic correction. Further, although we consider the broad principle of replacing a contact

lens set that is nonperforming for a given usage with an alternate treatment option to be CGK, we otherwise agree that adjusting the lens specification in response to changes in lens performance in controlling the progression rate of myopia or hyperopia was not CGK and that the protocols to slow the progression of myopia or hyperopia submitted by the Applicant were CGK.

The problem to be solved and the proposed solution

[40] In the PR Letter, we stated that the problem to be solved, as seen by the POSITA with their CGK, was "a need for reducing or preventing the progression of myopia or hyperopia in contact lens wearers who do not satisfactorily respond to the effects provided by contact lenses intended to reduce progression of myopia or hyperopia (e.g., the myopic defocus contact lenses as described in US 20080218687)."

[41] With respect to the solution, we expressed the view that the proposed solution is "to use a second myopic defocus contact lens design that differs from a first ineffective myopic defocus contact lens design to slow the progression of myopia or hyperopia wherein the second myopic defocus contact lens design takes into account the pupil size of the contact lens wearer, the central zone diameter of the contact lens, the ratio of the area of a myopic defocus region to the area of a vision correction region of the contact lens, or combinations thereof."

[42] In the RPR letter, the Applicant agreed with the problem and the solution above to the extent it is consistent with the inventive concept submitted by the Applicant. For the reasons detailed below in the obviousness analysis section, we accept the Applicant's proposed inventive concept, and therefore we also adopt the above identified problem and solution for the purposes of this review.

The essential elements that solve the identified problem

[43] In the PR Letter, we expressed the view that the essential element of independent claim 1 is the sequential use of a first set of contact lenses that has a first optical design followed by a second set of contact lenses that has a different optical design, the second lens design being selected on the basis that it provides an improved visual performance compared to the first set, is effective to slow progression of myopia or hyperopia of the human patient and has a vision correction/defocus area ratio that is different than the vision correction/defocus area ratio of the first set of contact lenses. We further expressed the view that this essential element serves to instruct "what" to use for slowing progression of myopia or hyperopia in a human patient.

[44] Also in the PR Letter, we stated our opinion that the POSITA would understand that the reference to an improved visual performance compared to the first set, a stated effectiveness to slow progression of myopia or hyperopia of the human patient and a vision correction/defocus area ratio that is different than the one of the first set of contact lenses respectively, amount to functional limitations and a technical requirement that instructs the design of the second set of contact lenses.

[45] In the PR Letter, we noted that dependent claims 2 to 16 specify: the selection parameters for the second set of contact lenses (claims 2, 5 and 13); what constitutes improved visual performance (claim 3); what constitutes improved visual quality (claim 4); the accommodative error is an accommodative lag (claim 2); the time frame after which the second set of contact lenses is selectable based on a response of the patient to the first set of contact lenses (claims 6 and 7); the response of the patient upon which the second set of contact lenses is selectable (claim 8); the eye in which the response is measured (claim 9); show different the second defocus area is in comparison to the first defocus area (claim 10); that the first and second sets of contact lenses comprise a central zone and an annular zone (claim 11); that the first and/or second sets of contact lenses each comprises at least two identical contact lenses (claim 12); where the first and/or second sets of contact lenses provide defocus in relation to the eye (claims 14 and 15); and that at least one contact lens of

the first and/or second sets of contact lenses comprises a single effective refractive power providing visual acuity (claim 16).

[46] The RPR Letter did not indicate disagreement with the above characterizations, and therefore we adopt them for the purposes of this review.

Subject-matter and methods of medical treatments

[47] Under the heading "Medical Method," the FA stated that the claims on file are directed to "subject-matter that lies outside the definition of 'invention' and do not comply with section 2 of the *Patent Act*." The Applicant submitted in response that the claimed uses are not methods of medical treatment.

[48] In the PR Letter, we identified two related areas of disagreement that existed between the Examiner and the Applicant: i) whether the claims should be assessed as "use" claims or as "method" claims; and ii) whether use claims incorporating one or more method steps are acceptable. However, we noted that the analysis in the FA was conducted as per portions of a previous version of *MOPOP* Chapter 12 that do not appear in the current version of *MOPOP*, and are contrary to guidelines found in current *MOPOP* §11.10.02. We also expressed the view that addressing these matters would not be determinative on the issue of subject-matter and methods of medical treatment. In that regard, we considered that the more relevant inquiry is whether the subject-matter of the claims is directed or equates to a method of medical treatment on the basis of the relevant legal principles and current Office practice.

[49] In the PR Letter, we expressed our view that the foremost consideration should address whether the claimed subject-matter cure, prevent or ameliorate a natural human condition as opposed to a pathological condition or a disease, as methods to treat natural conditions that are not considered to be pathological are not considered as non-statutory methods of medical treatment according to Office practice (see *MOPOP*, §17.03.01, noted above).

[50] In that regard, we cited *VISX Inc v Nidek Co* (1999), 3 CPR (4th) 417, at para 173, wherein the Federal Court held that claims related to a device for use in laser eye surgery were not medical methods, partly on the basis that the conditions to be treated by the claimed device were not diseases. The Court relied on the testimony given by an expert witness, an ophthalmologist who gave evidence relating to refractive conditions of the eye, including myopia and hypermyopia (i.e., hyperopia):

> [I]n accordance with Dr. Sher's evidence, myopia, hypermyopia and astigmatism are not diseases, they are human conditions.

[51] Having identified above the POSITA as including an eye care practitioner, we maintain the view expressed in the PR Letter that the POSITA in this case would consider that myopia and hyperopia are not diseases but human natural conditions, so that the claimed use, or method, for slowing progression of myopia or hyperopia should not be considered a method of medical treatment.

[52] Had we expressed the view that myopia and hyperopia are pathological conditions, we would have turned to the specific guidance on medical use claims provided in *PN 2015-01*.

[53] According to *PN 2015-01*, the determination of whether the subject-matter of a claim amount to a method of medical treatment must be performed by using purposive construction in place of other approaches to claim analysis. The purposive construction of the claims was not explicitly performed in the FA. However, we purposively construed the claims above and we expressed the preliminary view that the identified essential element serves to instruct "what" to use for reducing or preventing progression of myopia in a person in need thereof. Therefore, and in accordance with the guidance found in *PN 2015-01* as well as the related "examples of purposive construction analysis of medical use claims for statutory subject-matter

evaluation"[1], we would have been of the opinion that the claimed subject-matter is statutory.

[54] In light of the above, we are of the view that the claims on file are not directed to subject-matter excluded from the definition of "invention" as set out in section 2 of the *Patent Act*.

Sufficiency of description

[55] The FA indicated that the specification does not enable the POSITA to produce the claimed invention, since the determination of the area ratios of the two sets of lenses constitute necessary information in order for the desired result of slowing progression of myopia or hyperopia to be obtained and would require undue experimentation by the POSITA.

[56] In the RFA, the Applicant submitted that the Examiner is merely speculating that the claims do not define all the necessary features to obtain the desired result and has not provided any evidence that the POSITA would not be able to reproduce the invention and obtain the desired result in view of the CGK.

[57] As stated in the "Legal principles and office practices" section above, we consider that the relevant question is whether the POSITA, having only the specification, will be able to make the same successful use of the claimed invention as the inventor could at the time of his application, without having to undertake undue experimentation.

[58] Having considered the specification as a whole, and notably the following passage found at paras [0009] and [0010] of the description, we expressed the view in the PR Letter that the POSITA would understand that specific factors, including the pupil size of the contact lens wearer, the central zone diameter of the contact lens and/or

[1] https://www.ic.gc.ca/eic/site/cipointernet-internetopic.nsf/eng/wr03919.html

the ratio of the area of a myopic defocus region to the area of a vision correction region of the contact lens, can affect the contact lens wearer's response to the treatment provided by the contact lens:

> **[0009]** Thus, for a myopic defocus contact lens which prevents or slows the progression of myopia, where the contact lens simultaneously provides a contact lens wearer with a myopic defocused retinal image and with a focused retinal image, it has been discovered that a number of factors can affect the contact lens wearer's response to the treatment provided by the contact lens. These factors include the pupil size of the contact lens wearer, the central zone diameter of the contact lens, the ratio of the area of a myopic defocus region to the area of a vision correction region of the contact lens, or combinations thereof. The discovery of the relationship between these parameters and treatment results provides means for altering treatment outcomes by varying contact lens parameters, by selecting a lens from a set of lenses with varied contact lens parameters, or both.
>
> **[0010]** In practicing the present methods, sets of contact lenses are provided. At least a first set and a second set is provided. More than two sets of contact lenses can be provided. Each set of contact lenses includes two or more contact lenses. In other words, a set of contact lenses comprises a first contact Jens and a second contact lens. As used herein, a set may also include more than two contact lenses, e.g., three contact lenses, four contact lenses, five contact lenses, etc. The contact lenses of the first set and the contact lenses of the second set have different lens designs or different design dimensions, or both. Thus, if a contact lens wearer in need of treatment doesn't satisfactorily respond to the treatment provided by a contact lens of the first contact lens set, a contact lens of the second contact lens set is provided to obtain a more effective treatment. For example, in certain lens designs for reducing progression of myopia, the percentage of lens wearers or patients who show no noticeable effect in reduction of myopia progression is about 25%. It has been discovered that there may be a correlation between effect and pupil size. [emphasis added]

[59] We are of the view that the POSITA would understand that the premise for the use of a second set of contact lenses is that a first set of contact lenses is ineffective to slow the progression of myopia or hyperopia for the reason that the central zone diameter of the first set of contact lenses and/or the ratio of the area of a myopic defocus region to the area of a vision correction region of the first set of contact lenses were inadequate because the pupil size of the lens wearer was not taken into account or was incorrectly taken into account in the design of the first set of contact lenses. We

have considered in the "Purposive construction" section above that it is customary practice for the POSITA to select a contact lenses design on the basis of the pupil size of the patient, and thus we consider that it would be CGK for the POSITA to correlate a given pupil size with an appropriate central zone diameter and vision correction/defocus area ratio, and accordingly we find that the POSITA, having only the specification and its CGK, would be able to make the same successful use of the claimed invention as the inventor could at the time of his application, without having to undertake undue experimentation.

[60] We have also considered whether the specification sufficiently describes and enables the subject-matter of claim 8, more specifically embodiments wherein the response of the patient to the first set of contact lenses is an axial ocular elongation measurement or a refractive error correction progression measurement and wherein said response is measured after a short period of time such as about 10 minutes.

[61] In the PR Letter, we expressed the view that the specification fails to describe and enable embodiments wherein the response of the patient to the first set of contact lenses is an axial ocular elongation measurement or a refractive error correction progression measurement and wherein said response is measured after a period of time of about 10 minutes. In response, the Applicant did not specifically address our preliminary view but instead submitted that claim 8 of the proposed claim set-2 has been amended to remove such embodiments.

[62] In view of the foregoing, and with respect to the claims on file, we consider that the specification does not comply with subsection 27(3) of the *Patent Act* because it fails to describe and enable subject-matter encompassed by the scope of claim 8.

Claims clarity

[63] The FA indicated that claim 1 is indefinite and does not comply with subsection 27(4) of the *Patent Act* as the claim does not provide sufficient details to allow the POSITA to know clearly what the claimed invention is; notably, the recited area ratios are ill-defined and it is unclear what makes the lenses of the second set "better" than the lenses of the first set.

[64] As stated in the "Legal principles and office practices" section above, we consider that the obligation of an Applicant under section 27(4) of the *Patent Act* is to make clear in the claims the ambit of the monopoly sought and to ensure that the terms used in the claims are clear and precise.

[65] Having reviewed claim 1, we consider that the POSITA, with regard to the recited first and second area ratios, would readily understand what "being different" means (i.e., not the same). Further, we consider that the first and second sets of contact lenses are defined in an explicit and clear manner given that the vision correction and defocus areas of the lenses are technically described by reference to their respective refractive power and an explicit functional limitation (i.e., providing a defocused retinal image to a human patient at both near and far viewing distances when the contact lens is placed on the eye of the human patient). Therefore, we are of the view that claim 1 complies with section 27(4) of the *Patent Act* because it is free from ambiguity and the POSITA would readily understand its scope.

Obviousness

Identify the POSITA and the relevant CGK

[66] The POSITA and the relevant CGK have been set out above as part of the purposive construction of the claims. Although the identification of the relevant CGK above was performed on the basis of the common general knowledge of the worker skilled in the art to which the patent relates as of the publication date of the instant

application in accordance with *Free World* at para 54 and *Whirlpool* at para 55, we consider that the identified elements of knowledge also formed part of the POSITA's CGK as of the claim date.

Identify the inventive concept of the claim in question or, if that cannot readily be done, construe it

[67] In the PR Letter, we identified the inventive concept of the claims on file as "the use of at least two different sets of contact lenses for slowing progression of myopia or hyperopia of a human patient by substituting an inoperative first set of contact lenses that comprise a first vision correction area and a defocus area with a second set of contact lenses having a different optical design that comprise a different vision correction/defocus area ratio and that provide an improved visual performance compared to the first set of contact lenses and that is effective to slow progression of myopia or hyperopia of the human patient."

[68] In the RPR Letter, the Applicant submitted that the inventive concept arose from the realization that using contact lenses with a refractive power and defocus area for this condition may not actually slow the progression of myopia or hyperopia at all or sufficiently, and that the use of a second set of contact lenses with a different optical design was necessary to achieve the desired control of myopia or hyperopia. Thus, the inventive concept is the use of two different sets of contact lenses for slowing progression of myopia or hyperopia, where the contact lenses of the second set have a different optical design compared to the contact lenses of the first set such that the claimed second area ratio is different than the first area ratio, and as a result of the use, the second set of contact lenses provides an improved visual performance and slows the progression of myopia or hyperopia.

[69] We consider that both characterizations of the inventive concept are generally aligned and we further note that both characterizations address the problem to be solved as identified in the "Purposive construction" section above.

Differences between the matter cited as forming part of the "state of the art" and the inventive concept of the claim or the claim as construed

[70] The obviousness analysis found in the FA relies on the following prior art document:

- D1: Patent application US2008/0218687A1, Philips, September 11, 2008.

[71] In the PR Letter, we identified the difference between the disclosure of D1 and the inventive concept of independent claim 1 as being that D1 does not disclose the sequential use of two sets of contact lenses to slow the progression of myopia or hyperopia wherein the second set of contact lenses has a different vision correction/defocus area ratio and provides an improved visual performance compared to the first set of contact lenses and is effective to slow the progression of myopia or hyperopia.

[72] In the RPR Letter, the Applicant agreed with the identified difference. We therefore adopt it for the purposes of this review.

Viewed without any knowledge of the alleged invention as claimed, do those differences constitute steps which would have been obvious to the person skilled in the art or do they require any degree of invention?

[73] In the PR Letter, we offered the following analysis as to why it was our preliminary view that the subject-matter of claim 1 on file would have been obvious at the claim date to the POSITA taught by D1 in view of the relevant CGK:

> In our view, once the POSITA, using conventional equipment and techniques, has determined in a patient wearing a set of contact lenses that is supposed to provide a focused retinal image and a myopic defocused retinal image simultaneously during both near and distance viewing that:
>
> - myopia or hyperopia progression has occurred (e.g., by using measurements such as the associated axial eye length elongation and refractive error progression) or has not slowed; and/or
>
> - the visual performance provided by the current contact lens set is suboptimal and has degraded over time in response to the current set of contact,

the POSITA will be highly motivated to provide an alternate and superior set of contact lenses to the patient in need thereof as it is customary practice to be followed.

It is also our view that it is self-evident that the selection of the second set of contact lenses by the POSITA would take into account all the current relevant CGK parameters of the lens wearer (e.g., the degree of distance refractive error, the pupil size, the visual acuity, the presence of an accommodative lag, fixation disparity, a phoria, an ocular wavefront aberration profile, a peripheral refraction, and/or an axial length measurement) as well as CGK lens fitting parameters to improve visual performance/acuity of the lens wearer in addition to addressing progression of myopia or hyperopia.

With regard to modifying the contact lens design of the first inoperative set of contact lenses in order to effectively slow the progression of myopia or hyperopia with a second lens optical design, it is our view that the POSITA, having been taught by D1, would design the second set taking into account the pupil size to determine the appropriate number of vision correction and treatment zones and/or their respective areas so that a number of vision correction and treatment zones fell within the pupil under both photopic and mesopic conditions and during distance and near viewing. Hence, once the POSITA has determined that the vision correction and/or treatment zones areas of the first set of contact lenses were evidently inadequate for the larger/smaller pupil size of the patient under both photopic and mesopic conditions, it would be obvious to the POSITA to expand/lessen the total vision correction area in the new lens optical design to address it. It also follows that the vision correction/defocus area ratio will differ from the first set of contact lenses in such cases.

It is therefore our preliminary view is that it would have been obvious to the POSITA, in view of D1 and the CGK, to interrupt the use of a first set of contact lenses that have been found ineffective over time to slow the progression of myopia and hyperopia and to commend the use of a different second set of contact lenses that provides a focused retinal image and a myopic defocused retinal image simultaneously during both near and distance viewing wherein the vision correction/defocus area ratio will differ from the first set of contact lenses so that sufficient vision correction and treatment areas fell within the pupil under both photopic and mesopic conditions.

[74] In the RPR Letter and at the Hearing, the Applicant submitted the following:

(1) there is a difference between the use of contact lenses for slowing progression of myopia and hyperopia as taught by the instant application and

D1 and the use of CGK contact lenses for correcting the refractive error caused by myopia and hyperopia condition;

(2) there exists a proportion of lens wearers who do not satisfactorily respond to the effects provided by myopic defocus contact lenses intended to reduce progression of myopia or hyperopia, and this was an unknown problem at the claim date; and

(3) the CGK includes alternate protocols to slow progression of myopia or hyperopia such as (i) increasing the amount of time spent outdoors to help increase natural light exposure and reduce reading time, (ii) pursuing a pharmaceutical treatment with the use of atropine, or (iii) reshaping the cornea.

[75] Although we agree with the first point, we reiterate our view that lenses that include a vision correction area and a myopic defocus area to slow progression of myopia or hyperopia were CGK. We also accepted in the "Purposive construction" section above that the alternate protocols recited in the third point above were CGK. Finally, we also agree with the second point as we are of the view, on the basis of the record before us, that the existence of a proportion of wearers who do not satisfactorily respond to the effects provided by myopic defocus contact lenses intended to reduce progression of myopia or hyperopia was not known at the claim date, let alone commonly known. In that regard, the Applicant further submitted that the disclosure of D1 fails to point to the problem of potential non-responders, a problem specifically addressed by the instant application and the inventive concept identified above. In sum, the Applicant submitted in the RPR Letter and at the Hearing that if the problem was unknown and the corresponding solutions could not be expected based on the information available at the time of the invention, the present invention must be unobvious.

[76] There may be inventive ingenuity in the recognition of a problem in the prior art (*Cabot Corp v 318602 Ontario Ltd* (1988), 20 CPR (3d) 132 (FCTD), citing H.G.

Fox in his book *Canadian Law and Practice Relating to Letters Patent for Inventions*, at pp 70 and 71):

> There may be an inventive step in recognizing that a problem exists at all: but given a problem which is known to exist which it is the object of the invention to solve, the question always is: "Is the solution claimed by the patentee one which would have occurred to everyone of ordinary intelligence and acquaintance with the subject-matter of the patent who gave his mind to the problem?".

[77] The obviousness analysis presented in the PR Letter cast the question of obviousness as if the problem of non-responders who do not satisfactorily respond to the effects provided by myopic defocus contact lenses was appreciated by the POSITA at the claim date. We are now of the view that it would not be the case and therefore consider that there is inventive ingenuity associated with the instant inventive concept that arose from the realization that using contact lenses with a refractive power and defocus area for this condition may not actually slow the progression of myopia or hyperopia at all or sufficiently.

[78] Although D1 discloses several embodiments of contact lenses that include a vision correction area and a myopic defocus area to slow progression of myopia, including contact lenses with different correction/defocus area ratio, and generally teaches that the pupil size should be taken into account when designing contact lenses effective to slow progression of myopia, it does not disclose that some contact lens wearers do not satisfactorily respond to the treatment provided by these contact lenses and does not teach or suggest how to address this problem. Having the foregoing in mind, we are of the view that the POSITA would have been generally motivated to replace a contact lens that include a vision correction area and a myopic defocus area with another treatment option if the POSITA was made aware of the problem that the contact lens did not slow progression of myopia or hyperopia. However, neither the CGK nor D1 points toward the use of a second set of contact lenses that has a different vision correction/defocus area ratio as a solution among many other possible lens design parameters, as disclosed in D1, or other CGK protocols to slow progression of myopia or hyperopia, such as increasing the amount of time spent

outdoors, pursuing a pharmaceutical treatment with the use of atropine or reshaping the cornea. In other words, we are of the view that using a second set of contact lenses that has a different vision correction/defocus area ratio was not an obvious option among the many known options. Rather, it was a solution to an unknown problem, which required a degree of invention.

[79] In light of the above, we are of the view that the subject-matter of claims 1 to 16 on file would not have been obvious at the claim date to the POSITA, having regard to D1, in view of the relevant CGK.

ANALYSIS OF THE PROPOSED CLAIMS

[80] As this review has determined that the specification does not comply with subsection 27(3) of the *Patent Act* because it fails to describe and enable subject-matter encompassed by the scope of claim 8, we consider the Applicant's latest proposed claims. Accompanying the letter dated June 7, 2019, the Applicant submitted proposed claim set-3 containing claims 1 to 15, in which the subject-matter of claim 8 on file has been deleted.

[81] Accordingly, we consider that proposed claims set-3 overcomes the lack of sufficiency defect noted with respect to the specification insofar as it relates to embodiments of claim 8 on file, and we therefore are of the view that proposed claims set-3 should be considered a "necessary" amendment under subsection 30(6.3) of the *Patent Rules* for compliance with the *Patent Act* and *Patent Rules.*

RECOMMENDATION OF THE BOARD

[82] For the reasons set out above, we recommend that the Applicant be notified, in accordance with subsection 30(6.3) of the *Patent Rules*, that the deletion of the claims on file and the insertion of the proposed claims set-3 as presented in the letter of June 7, 2019 (identified as "Amended Set-2 claims" in the letter) are "necessary" for compliance of the application with the *Patent Act* and *Patent Rules*.

Marcel Brisebois Member	Lewis Robart Member	Andy Wong Member

DECISION OF THE COMMISSIONER

[83] I concur with the findings and the recommendation of the Panel. In accordance with subsection 30(6.3) of the *Patent Rules*, I hereby notify the Applicant that the following amendments and only the following amendments must be made in accordance with paragraph 31(*b*) of the *Patent Rules* within three (3) months of the date of this decision, failing which I intend to refuse the application:

- delete the claims on file and insert claims 1-15 of the claims set identified as "Amended Set-2 claims" as proposed in the letter of June 7, 2019.

Johanne Bélisle
Commissioner of Patents
Dated at Gatineau, Quebec,
this 16th day of August, 2019.