Commissioner’s Decision #1491

Décision de la Commissaire #1491

TOPIC: K11 (Treatment)
O00 (Obviousness)

SUJET: K11 (Traitement)
O00 (Évidence)

Application No.: 2,760,920

Demande n°.: 2 760 920

IN THE CANADIAN PATENT OFFICE

DECISION OF THE COMMISSIONER OF PATENTS

Patent application number 2,760,920, 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 allow the application.

Agent for the Applicant:

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INTRODUCTION

[1] This recommendation concerns the review of rejected patent application number 2,760,920, which is entitled "Use of accommodative error measurements in providing ophthalmic lenses" 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 at the time lies outside the definition of "invention" in section 2 of the *Patent Act* 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, our recommendation is that the application be allowed.

BACKGROUND

The application

[2] Patent application 2,760,920 (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 November 11, 2010.

[3] The claimed subject-matter of the application relates to methods of providing and using ophthalmic lenses for reducing or preventing progression of myopia in a person in need thereof. More specifically, the disclosed methods are based on the observation that accommodative error measurements can be used in the selection of a suitable ophthalmic lens design.

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 subject-matter that lies outside the definition of "invention" in section 2 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 no new arguments or amendments and instead directed the Examiner to the Applicant's response dated July 24, 2013 (the 2013 Response) wherein the Applicant provided arguments as to why the subject-matter of the claims on file was patentable and 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 that the claims on file are directed to subject-matter that lies outside the definition of "invention" in section 2 of the *Patent Act* and would have been obvious, contrary to section 28.3 of the *Patent Act*. In a letter dated February 6, 2017, the Board forwarded 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 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, based on the record before us, the claims on file are not directed to subject-matter excluded from the definition of an invention as set out in section 2 of the *Patent Act* and why the subject-matter of the claims on file would have been obvious, contrary to section 28.3 of the *Patent Act*. 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.

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

ISSUES

[9] In view of the above, two issues are considered in this review:

- whether the claims on file define subject-matter that lies outside the definition of "invention" in section 2 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*.

LEGAL PRINCIPLES AND PATENT OFFICE PRACTICES

Purposive construction

[10] 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

[11] 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.

[12] 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).

[13] 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.

[14] 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*].

[15] 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 does not comply with section 2 of the *Patent Act*.

[16] 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.

Obviousness

[17] 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.

[18] 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?

[19] In the context of the fourth step, the Court in *Sanofi* accepted 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.

[20] 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

[21] In the PR Letter, although we generally agreed with the POSITA identified in the FA, we expressed the view that the identified team of "specialists in the field of ophthalmology" at least includes an ophthalmologist, an optometrist and an ophthalmic lens designer.

[22] In the RPR Letter and at the Hearing, the Applicant accepted the above identification of the POSITA.

[23] With respect to the CGK possessed by the POSITA, we considered in the PR Letter that such a team would know:

- Typical eye exams will test for the accommodation of the eye including when the patient is wearing his normal corrective lenses. Errors in accommodation (along with other visual deficiency) are measured, and corrected as needed with new lenses;

- The hypotheses that accommodative lag at near vision provides hyperopic defocus stimulus and promotes the development of myopia, and that the use of a lens that provides myopic defocus can remove the hyperopic defocus and thus reduces or prevents the progression of myopia (as evidenced by Gwiazda et al., "A Randomized Clinical Trial of Progressive Addition Lenses versus Single Vision Lenses on the Progression of Myopia in Children", *Invest Ophthalmol Vis Sci.*, 44(4), 2003, pages 1492-1500 [*Gwiazda 1*], Gwiazda et al., "Accommodation and Related Risk Factors Associated with Myopia Progression and Their Interaction with Treatment in COMET Children", *Invest Ophthalmol Vis Sci.*, 45(7), 2004, pages 2143-2151 [*Gwiazda 2*], Mitchell et al., "PALs for Children: Can They Slow Myopia", *Review of Optometry*, 2008, [*Mitchell*][1] and Aller et al., "Bifocal Soft Contact Lenses as a Possible Myopia Control Treatment: a Case Report Involving Identical Twins", *Clin Exp Optom*, 91(4), 2008, pages 394-399 [*Aller*]); and

- The link between correcting larger accommodative lags with progressive addition lenses that provides myopic defocus and their

[1] Retrieved from: https://www.reviewofoptometry.com/article/pals-for-children-can-they-slow-myopia

> effectiveness in slowing progression of myopia. In other words, progressive addition lenses were most successful in slowing myopia progression in eyes with larger lags of accommodation (as evidenced by *Gwiazda 1*, *Gwiazda 2*, *Mitchell* and *Aller*).

[24] In the RPR Letter and at the Hearing, the Applicant submitted that although the CGK may have included the hypothesis that accommodative error may have some correlation with myopia progression, it was not CGK that such correlation was a strong one, let alone one that would have been clinically meaningful to the POSITA at the claim date:

> Regarding the Board's comments about progressive addition lenses (PALs), which were spectacles and not contact lenses, a POSITA will appreciate that while Gwiazda *et al*., demonstrated an effect of about 0.2 diopters that was statistically significant, the results were not clinically meaningful (see Mitchell Scheiman, the second paragraph of the COMET Study Results section). In the following paragraph, Mitchell states that the conclusion from the COMET study was that the small magnitude of the effect does <u>not warrant a change in clinical practice</u>, and that the standard of care should continue to be the use of single vision lenses for the correction of myopia. As summarized by Mitchell, and evidenced by Gwiazda 1 and Gwiazda 2, the link between myopia control success and larger lags of accommodation is not the conclusion reached. Mitchell actually states PALs were effective in slowing progression in a subset of children who had "larger accommodative lags <u>and</u> esophoria at near wearing single vision lenses" (emphasis added). Mitchell further states that children with a "combination of larger accommodative lags <u>and</u> lower baseline myopia" had a treatment effect of 0.48 D (emphasis added).
>
> Thus, the Applicant submits the link between accommodative error and progression of myopia is not as strong as the Board implies, and that it may simply be one of many factors relating to myopic development and progression (as stated by Mitchell, 5th paragraph).
>
> In view of this, the Applicant submits that the CGK may have included the hypothesis that accommodative error may have some correlation with myopia progression, but in 2009, it was not apparent that this is always true, and is evidenced by the results of the COMET studies cited by the Board. Therefore, the Applicant submits that the CGK did not provide a proper motivation to modify the teachings of D1. [emphasis in the original]

[25] We have reconsidered the references cited as evidence of the CGK in view of Applicant's submissions, notably *Mitchell*. In our view, *Mitchell* is a review article addressed to the ophthalmologist and optometrist members of the team constituting the POSITA and its disclosure is a fair representation of what the POSITA would have retained from the clinical trials that tested progressive addition lenses (PALs) in children. Insofar as the CGK is concerned, however, we now consider that the link between correcting larger accommodative lags with progressive addition lenses that provides myopic defocus and their effectiveness in slowing progression of myopia was a generally known *hypothesis* but that the derived inference of successfully slowing progression of myopia by correcting accommodative errors with progressive addition lenses that provides myopic defocus was, in our view, not yet accepted without question by the bulk of those who are engaged in the particular art of either optometry, ophthalmology or lens design: *Eli Lilly and Company v Apotex Inc*, 2009 FC 991 at para 97, citing *General Tire & Rubber Co v Firestone Tyre & Rubber Co Ltd*, [1972] RPC 457 at 482-483.

The problem to be solved and the proposed solution

[26] In the PR Letter, we stated that the problem to be solved as seen by the POSITA with their CGK is "a need for a predictable means for reducing or preventing the progression of myopia."

[27] With respect to the solution, we expressed the view that the proposed solution is "to use ophthalmic lens designs to reduce or prevent the progression of myopia based on a measurement of the accommodative error of the eye of the person wearing the first ophthalmic lens."

[28] 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

[29] Independent claim 1 reads as follows:

> 1. Use of a first ophthalmic lens and a second ophthalmic lens for reducing or preventing progression of myopia in a person in need thereof, wherein
>
> the first ophthalmic lens has a first lens design and is for wearing by the person in need of the reduction or prevention of progression of myopia; and
>
> the second ophthalmic lens has a second lens design different than the first lens design, the second ophthalmic lens design being selected based on a measurement of accommodative error of the eye of the person wearing the first ophthalmic lens, and the second ophthalmic lens is for wearing by the person on the same eye as the first ophthalmic lens after the first ophthalmic lens is removed.

[30] In the PR Letter, we expressed the view that an essential element of independent claim 1 is the sequential use of a first ophthalmic lens that has a first lens design followed by a second ophthalmic lens that has a different lens design, the second lens design being selected based on a measurement of the accommodative error of the eye of the person wearing the first ophthalmic lens, for reducing or preventing progression of myopia in a person in need thereof. We further expressed the view that said essential element serves to instruct "what" to use for reducing or preventing progression of myopia in a person in need thereof.

[31] Finally, we were of the opinion that the POSITA would understand the phrase "the second ophthalmic lens design being selected based on a measurement of accommodative error of the eye of the person wearing the first ophthalmic lens" to mean that the second ophthalmic lens design is an ophthalmic lens design that reduces the accommodative error of the eye of the person wearing the first ophthalmic lens, and would consider that the reference to a measurement of accommodative error of the eye of the person wearing the first ophthalmic lens amounts to a technical requirement that instructs the design of the second ophthalmic lens.

[32] In the PR Letter, we noted that dependent claims 2 to 13 further define and/or limit the essential element identified above as they specify: that the accommodative error is an accommodative lag (claim 2); the time frame within which the second ophthalmic lens should be worn (claims 3 and 4); the final accommodative error obtained after selecting the second ophthalmic lens (claim 5); that each of the first ophthalmic lens and the second ophthalmic lens comprise a clear vision region having a first refractive power and a myopic defocus region having a second refractive power that is more positive than the first refractive power (claim 6); further limitations on the clear vision region and the myopic defocus region (claims 7 and 8); the amount of myopic defocus provided by the second ophthalmic lens (claims 9 and 10); and the use of a third ophthalmic lens (claim 11) or further specificity regarding the type of the second ophthalmic lens (claims 12 and 13).

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

Subject-matter and methods of medical treatments

[34] 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.

[35] In the PR Letter we identified two related areas of disagreement 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.

[36] In the PR Letter, we stated our view that the foremost consideration should address whether the claimed subject-matter cures, prevents or ameliorates a natural human condition as opposed to a pathological condition or a disease, as methods of treating natural conditions are not considered non-statutory methods of medical treatment according to Office practice (see *MOPOP*, §17.03.01 above).

[37] 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:

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

[38] Having identified above the POSITA as including an ophthalmologist, we remain of the view expressed in the PR Letter that the POSITA in this case would consider that myopia is not a disease but a human natural condition, so that the claimed use, or method, for reducing or preventing progression of myopia is not a method of medical treatment since no pathological condition is treated.

[39] Had we expressed the view that myopia is a pathological condition, we would have turned to the specific guidance on medical use claims provided in *PN 2015-01*.

[40] 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"[2], we would have been of the opinion that the claimed subject-matter is statutory.

[41] 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*.

Obviousness

Identify the POSITA and the relevant CGK

[42] 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 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

[43] In the PR Letter, we identified the inventive concept of the claims on file as "the sequential use of ophthalmic lenses in the prevention or reduction of myopia wherein a second lens design is being selected based on a measurement of the

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

accommodative error of the eye of the person wearing a first ophthalmic lens in order to reduce said accommodative error."

[44] In the RPR Letter, the Applicant generally agreed with the identified inventive concept, with the exception that the technical effect should be to reduce or prevent progression of myopia rather than reducing the accommodative error.

[45] We agree with the Applicant's submission as it is better aligned with the introductory portion of the claims, which recites the utility of the claimed subject-matter.

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

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

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

[47] Having reviewed the content of D1, we understand the following with regard to its disclosure. D1 discloses a lens including a vision correction area and a myopic defocus area to slow progression of myopia. D1 explains at para [0004] that:

> [t]he aetiology of myopia is poorly understood. Both genetic and environmental factors have been implicated and in susceptible individuals myopia progression is thought to be associated with excessive near work (eg reading, writing/drawing, playing video games, and similar), possibly because the prolonged muscular effort of focussing the eyes at near (accommodation) results in a lag of accommodation (insufficient accommodation) and hyperopic retinal de-focus. The correction of myopia requires minus-powered lenses which demand a greater accommodative effort for near work than is required without the lenses. This greater effort (and thus greater accommodative lag) has been implicated in exacerbating myopia progression.

[48] We note that such knowledge is aligned with the CGK identified above with regard to a potential, but not established, link between an accommodative lag and exacerbating myopia progression.

[49] On that basis, we expressed the view in the PR Letter that the POSITA would consider that the main difference between the disclosure of D1 and the subject-matter of independent claim 1 is that D1 does not specifically disclose or teach reducing an accommodative error observed from the eye of a person wearing a first ophthalmic lens by the use of a second ophthalmic lens in order to reduce or prevent progression of myopia.

[50] In the RPR Letter, the Applicant disagreed with the difference identified by the Panel and submitted that the main difference between D1 and the subject-matter of claim 1 is instead that D1 "does not teach or suggest that a second ophthalmic lens having a different lens design can be selected based on an accommodative error measurement and reduce or prevent progression of myopia for a person who previously wore the first ophthalmic lens recited in claim 1". Given that D1 does not expressly disclose selection of lenses based on an accommodative error measurement, and consistent with the identified CGK of a potential but not established link between an accommodative lag and exacerbating myopia progression, we adopt the Applicant's identification of the difference between D1 and the subject-matter of claim 1.

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?

[51] In the PR Letter, we offered the following analysis supporting 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:

> As mentioned above in the "The POSITA and the relevant CGK" section, we consider that the relationship between accommodative lag at near vision, hyperopic defocus stimulus and the promotion of the development of myopia were CGK at the claim date. We also consider that the link between correcting larger measured accommodative lags with ophthalmic lenses that provides myopic defocus and their effectiveness in slowing progression of myopia was CGK at the claim date. Therefore, we consider that the alleged discovery that accommodative error measurements can be linked to effectiveness of a treatment for myopia progression

> was already in the CGK or at least directly derivable from the CGK and we thus consider that the identified difference between D1 and the claimed subject-matter can be bridged by the POSITA through the application of the relevant CGK available.
>
> It is therefore our preliminary view is that it would have been obvious to the POSITA to measure the accommodative error of the eyes of a person wearing ophthalmic lenses for correcting its myopic vision and, using the measured accommodative error to design new lenses to prevent or reduce myopia progression wherein the new lens design is selected among known lenses that provides a myopic defocus area in addition to a vision correction area, including the lenses disclosed in D1.

[52] The key consideration underlying our preliminary view regarding the obviousness of the claimed subject-matter was that the identified difference between D1 and the subject-matter of claim 1 could be bridged by the POSITA through the application of the relevant CGK, i.e., that accommodative error measurements can be linked to effectiveness of a treatment for myopia progression.

[53] As mentioned above, we are now of the view that the CGK possessed by the POSITA on the claim date included the knowledge that among a number of known contributory causes to the progression of myopia, the accommodative error was one that potentially had some correlation with myopia progression. Further, we now consider, based on the Applicant's arguments in the RPR Letter and at the Hearing, that the link between correcting larger accommodative lags with progressive addition lenses that provide myopic defocus, and their effectiveness in slowing progression of myopia, was a hypothesis rather than a well-established and clinically relevant concept. We will now reconsider our previous analysis on the basis of these latest views.

[54] In the context of the fourth step, the Supreme Court in *Sanofi* accepted that it may be appropriate in some cases to consider an "obvious to try" analysis, notably in areas of endeavour where advances are often won by experimentation. The claimed subject-matter relates to the use of different lens designs for reducing myopia or hyperopia progression rates and we are of the view that this is an area in which

advances are often made by experimentation, as evidenced by the COMET studies cited above and the exemplary portion of D1. We therefore consider that it is appropriate to examine whether the difference between the "state of the art" and the inventive concept constitutes a step which would have been "obvious to try" to the POSITA.

[55] The "obvious to try" factors are largely concerned with how the POSITA would have acted in the light of the prior art and the relevant CGK. According to the first factor, it must be more or less self-evident that what is being tried ought to work in advance of routine testing in order to find that a claimed invention is "obvious to try." The mere possibility that something might work is not sufficient.

[56] In view of the foregoing, we consider that the appropriate question is whether it would have been more or less self-evident to the POSITA, based on the disclosure of D1 and the relevant CGK, that using a second ophthalmic lens having a different lens design selected on the basis of an accommodative error measurement ought to reduce or prevent progression of myopia for a person who previously wore the first ophthalmic lens recited in claim 1.

[57] D1 does not disclose or teach that accommodative errors is an important factor to consider in designing ophthalmic lenses that provide myopic defocus to slow progression of myopia. With respect to the CGK, it is our view that the POSITA would have considered the hypothesis that accommodative error measurements can be linked to effectiveness of a treatment for myopia progression to be a reasonable possibility. This would lend some support to the idea of trying a second ophthalmic lens having a different lens design selected on the basis of an accommodative error measurement. However, it is also our view that the POSITA would consider, as argued by the Applicant, that reducing or preventing progression of myopia was a complex problem, and that a number of contributory causes were possible.

[58] Against this background of conjectures and hypothetical inferences, it is our view that it would not have been more or less self-evident to the POSITA that using a second ophthalmic lens having a different lens design selected on the basis of an accommodative error measurement ought to work for reducing or preventing progression of myopia in a person who previously wore the first ophthalmic lens recited in claim 1. We consider that this assessment is largely determinative of the "obvious to try" inquiry in this case and therefore we won't address the other non-exhaustive factors to be considered in an "obvious to try" analysis.

[59] In view of the above, we are of the view that the subject-matter of claims 1 to 13 on file would not have been obvious at the claim date to the POSITA, having regard to D1, in view of the relevant CGK.

RECOMMENDATION OF THE BOARD

[60] For the reasons set out above, we are of the view that the rejection is not justified on the basis of the defects indicated in the Final Action notice and we have reasonable grounds to believe that the instant application complies with the *Patent Act* and the *Patent Rules*. We recommend that the Applicant be notified in accordance with subsection 30(6.2) of the *Patent Rules* that the rejection of the instant application is withdrawn and that the instant application has been found allowable.

Marcel Brisebois Member	Lewis Robart Member	Andy Wong Member

DECISION OF THE COMMISSIONER

[61] I concur with the findings and the recommendation of the Board. In accordance with subsection 30(6.2) of the *Patent Rules*, I hereby notify the Applicant that the rejection of the instant application is withdrawn, the instant application has been found allowable and I will direct my officials to issue a Notice of Allowance in due course.

Johanne Bélisle
Commissioner of Patents
Dated at Gatineau, Quebec,
this 5th day of August, 2019