Commissioner’s Decision #1368
Décision du Commissaire #1368

TOPIC: B20
SUJET: B20

Application No.: 2,439,899
Demande n^{o}: 2,439,899

IN THE CANADIAN PATENT OFFICE

DECISION OF THE COMMISSIONER OF PATENTS

Patent application number 2,439,899 having been rejected under subsection 30(3) of the *Patent Rules*, has consequently been reviewed in accordance with subsection 30(6)(*c*) of the *Patent Rules* by the Patent Appeal Board and the Commissioner of Patents. The findings of the Board and the ruling of the Commissioner are as follows:

Agent for the Applicant:

Sim & McBurney
6th Floor
330 University Avenue
Toronto, Ontario
M5G 1R7

INTRODUCTION

[1] Patent application number 2,439,899 concerns an invention related to artificial skin. It was rejected in a Final Action for several reasons but now stands rejected after the Applicant's response because of only one reason: the claims are too broad and lack support.

BACKGROUND

The Technology

[2] Artificial skin compositions are of interest because they can be used, for example, as substitutes for natural skin when testing things such as cosmetics and therapeutic agents that may be suitable for wound healing. Their use obviates the need to use expensive human or animal skin patch testing methods.

[3] Natural skin is an organ that performs key physical and biological functions, including acting as a barrier to infectious and toxic agents and as a structure necessary for water retention. An artificial skin composition of the type claimed in the present application is grown in culture in the laboratory and is made up of a kind of naturally occurring cell known as a keratinocyte. When used as skin substitutes it is best that such compositions perform a barrier function similar to that of natural skin.

[4] The development of a natural skin barrier function requires the synthesis and metabolism of certain proteins and lipids that are assembled into the outermost skin layer, the stratum corneum. Ceramide is one of the required lipids and it exists in seven forms in normal human skin in differing amounts so as to yield what can be called a "ceramide profile". As taught in the application, the relative amounts of the various forms of ceramides can have an effect on barrier function. "Surface electrical capacitance" (SEC) is an electrochemical property that, according to the description, correlates with barrier function: lower SEC is taken as a measure of improved, more natural, barrier function. Measurement of SEC might therefore be used as a way to determine the effects of changes to the ceramide profile on barrier function.

[5] According to the description, the inventors have discovered that a particular type of keratinocyte (so-called "near diploid immortalized keratinocyctes", or "NIKS" cells) can be manipulated *in vitro* so that barrier function is improved. By culturing the cells in a special medium -- which consists of a basal growth medium with certain added supplements -- the

inventors have observed that the ceramide content of the cells is altered to more closely resemble that of natural skin. The supplements include ascorbic acid, oleic acid, linoleic acid, arachidonic acid, isoproterenol and α-tocopherol.

[6] The inventors have also observed that the SEC of the cells grown in the special medium is lower than the SEC of cells grown in more conventional medium. From the changed ceramide profile and the lowered SEC values, the inventors conclude that their artificial skin equivalents made with the altered cells have improved barrier function.

[7] The inventors also put forward a second manner of altering the ceramide profile of NIKS cells, thereby changing their SEC and again ultimately leading to improved barrier function. They hypothesize that NIKS cells genetically engineered to express certain genes ("GKLF" genes) will also be improved in their barrier function. The inventors expect improvement on the basis of a known association between lack of GKLF gene activity and defective barrier function. Although cells were apparently successfully engineered to express one such gene, the description does not indicate whether the expected improved barrier function was realized.

Prosecution history

[8] The application was rejected for lack of novelty under subsection 28.2(1)(*a*) of the *Patent Act*, lack of clarity under subsection 27(4) of the Act, and for lack of "support" under section 84 of the *Patent Rules* and subsection 27(3) of the Act. The Examiner's Summary of Reasons (SoR) provided to the Board indicates that only the lack of support issue remains unresolved; the other issues having been addressed through the Applicant's claim amendments and explanations made in response to the Final Action.

[9] The Applicant was provided with a copy of the SoR and informed that a review of the rejected application was to take place in due course. After being so informed, the Applicant submitted proposed claim amendments meant to address the concerns outlined in the SoR.

[10] The Board then completed an initial review of the rejected application, including the claims submitted in response to the Final Action. During that phase, no consideration was given to the newly proposed claims. An application that has been the subject of an examiner's Final Action cannot automatically be amended after the expiry of the time limit to respond to the Final Action. Proposed claims may be considered after the Board has reviewed the claims submitted in response to the Final Action, but there is no requirement under subsection 30(6.3) of the Rules to do so in all cases.

[11] The Applicant was informed of the outcome of the initial review and our finding that an issue of sound prediction of utility under section 2 of the Act also arises. The Applicant was encouraged to take note of this and respond accordingly when making any further submissions.

[12] A hearing on the matter was held on November 15, 2013 at which time the Applicant presented arguments that focussed largely on the patentability of the proposed claims. Subsequent to the hearing, further written submissions were provided to the Board on the issue of sound prediction that the Applicant was notified of following our initial review. Again, the submissions focussed on the proposed claims; however, in the eventuality that the proposed claims were found to be defective, the Applicant submitted a second set of proposed claims for consideration.

ISSUES

Clarification of the issues

[13] The issues identified in the SoR and Final Action concern excessive claim scope due to "lack of support." Section 84 of the Rules and subsection 27(3) of the Act have been cited as the relevant statutory provisions. However, as part of our initial review, the Board observed, as did the Applicant in its response to the Final Action, that the Examiner's phraseology and discussion of the support issue indicates that the matter to be resolved can be addressed as a question of the predicted utility of the claimed invention, i.e., an issue to be considered under section 2 of the Act.

[14] All of the claims on file were said in the Final Action to lack support because the "applicant is required to provide a factual basis and a proper disclosure that will enable a person skilled in the art to reproduce the skin equivalents as claimed." To the Applicant it appeared "that in referring to a 'factual basis', the Examiner is referring to the first component to the doctrine of sound prediction of utility, *i.e.*, that there must be a factual basis for the prediction." The Applicant submitted "that neither utility nor sound prediction is a requirement of section 84 of the *Patent Rules* or subsection 27(3) of the *Patent Act*."

[15] We also note that the present case involves considering an explicit promise of the utility of the invention (improved barrier function) and whether an element necessary to achieve the utility has been omitted from the claims. Thus, the question of sound prediction and of the promised

utility of the invention set the case apart from other cases which might appear similar but which were decided on the basis of enablement of the invention under subsection 27(3) of the Act and wherein the invention was claimed with all its necessary elements (as was the case, for example, in Commissioner's Decision 1359).

[16] Regardless of the manner in which the defect was expressed in the Final Action, we note that the Applicant responded with submissions arguing that the invention is based on a sound prediction of utility.

[17] In reviewing the claims submitted in response to the Final Action, the determinative question is whether the claims encompass subject matter whose utility has either been demonstrated or can be soundly predicted based on what has been disclosed.

Sound prediction: legal principles

[18] As of the filing date of the application, there must be either a demonstration or a sound prediction of the utility of all the subject matter that falls within the scope of a claim: *Apotex Inc v Wellcome Foundation Ltd.*, 2002 SCC 77 ("*AZT*"). In the present case, the claims are broad and encompass embodiments whose utility has not been demonstrated. The Applicant must therefore rely on a sound prediction to establish utility (see *Teva Canada Ltd v Pfizer Canada Inc*, 2012 SCC 60, at para.37 – "*Teva*").

[19] An invention that relies on a sound prediction of utility must satisfy three requirements (*AZT*):

(1) there must be a factual basis for the prediction;
(2) the inventor must have at the date of the patent application an articulable and "sound" line of reasoning from which the desired result can be inferred from the factual basis; and
(3) there must be proper disclosure.

[20] The starting point in the analysis is a determination of the predicted utility. Predictions are measured taking into account any explicit "promises" made in the specification; however, "if there is no explicit promise of a specific result, then a mere scintilla of utility will do" (see *Sanofi-Aventis v Apotex Inc*, 2013 FCA 186 at para. 50).

CLAIMS UNDER REVIEW

Claim construction

[21] The scope of a claim is assessed by fixing the meaning of its terminology and determining, through a purposive construction, its essential elements. During purposive construction, the elements of the claimed invention are identified as either essential or non-essential. In order for an element to be considered "non-essential", "it must be shown either (i) that on a purposive construction of the words of the claim it was clearly not intended to be essential, or (ii) that at the date of publication of the patent, the skilled addressees would have appreciated that a particular element could be substituted without affecting the working of the invention" (*Free World Trust v Electro Sante Inc*, 2000 SCC 66 at para. 55).

[22] The problem addressed by the inventors and the solution put forth are relevant considerations that inform the construction given to the claims (see *Examination Practice Respecting Purposive Construction* - PN2013-02). In the present case, it is apparent that the inventors are concerned with ameliorating the deficiencies in skin cell compositions by improving their barrier function in order that they more closely mimic natural skin. They generally propose to do so by modifying skin cell compositions in order to lower their surface electrical capacitance (SEC).

[23] The SoR and Final Action focus on three contentious key features that affect the scope of the claimed invention and which bear on the question of sound prediction: SEC in relation to the ceramide profile of cells; genetic engineering of cells; and, skin cell culture conditions. These features were the topic of debate during prosecution and therefore attract our attention on review.

Product claims

[24] Claim 1 is the main claim which defines the Applicant's skin cell compositions:

> 1. A composition comprising a pre-graft human skin equivalent, said pre-graft skin equivalent having a surface electrical capacitance of from about 40 to about 240 pF measured as the difference in reading over a 10 second interval, wherein said pre-graft skin equivalent comprises Near Diploid Immortalized Keratinocyte cells; and a buffer.

[25] The claim is narrow in some respects but broader in others. In the narrow sense, it refers only to a particular cell line known as "Near Diploid Immortalized Keratinocyte cells", or "NIKS" (publically available as ATCC deposit number CRL-12191). In the broader sense, the claim says

that the NIKS cells have an SEC within a range of about 40 to 240 pF. This reflects an alteration of a physical property of the cells, but the claim is not limited by reference to a technical feature(s) responsible for the alteration. Although the use of the term "about" in relation to the end points of the range is somewhat imprecise, the scope of the claim in this case is not made so unclear that the skilled person would not be able to determine, as a matter of practicality, whether a given composition is within or outside its boundaries by measuring its SEC using the methodology described in the specification. The term "about" means within the margins of measurement error.

[26] Because its dependent claims are necessarily within its scope, inspection of the dependent claims allows for a better appreciation of two contentious issues that arose during prosecution and which relate to the scope of claim 1. Dependent claims 3 and 5 are informative.

[27] Dependent claim 3 indicates that the main claim broadly encompasses compositions that lack a technical feature (i.e., a particular ceramide profile) which the Examiner regards as responsible for the altered SEC. It is more restrictive than claim 1 and does mention ceramide content, but not in a manner relative to non-altered cells and not in relation to other ceramides which may be important (i.e., ceramides 3 and 4):

> 3. The composition of Claim 1, wherein the combined content of ceramides 5, 6, and 7 in said skin equivalent is from about 20 to about 50% of total ceramide content.

[28] The products of dependent claim 5 possess a feature (a "GKLF" gene inserted into the skin cells) which the Applicant predicts will impart improved barrier function to the composition – a prediction which the Examiner says is unsound:

> 5. The composition of Claim 1, wherein said keratinocytes express heterologous GKLF.

[29] Claim 1 therefore encompasses compositions which do not necessarily have the ceramide profile shown to correlate with improved barrier function and which is found in the exemplary products described in the description. It also embraces compositions of unspecified ceramide content in which NIKS cells have been genetically engineered but which the description does not indicate have improved barrier function. These issues were points of dispute between the Examiner and the Applicant.

Method claims

[30] The claim set under review also includes method claims which generally reflect two ways of modifying skin cell compositions so that their SEC is altered and their barrier function thereby improved: a cell culturing method and a genetic engineering method. The first type of method claim is illustrated in claim 7:

> 7. A method of making skin equivalents having improved barrier function comprising: a) providing keratinocytes and a culture media comprising ascorbic acid and linoleic acid; b) culturing said keratinocytes under conditions such that a pre-graft skin equivalent having improved barrier function is formed, wherein said pre-graft skin equivalent has a surface electrical capacitance of from about 40 to about 240 pF measured as the difference in reading over a 10 second interval, wherein said pre-graft skin equivalent comprises Near Diploid Immortalized Keratinocyte cells.

[31] When grown in a buffered culture, skin cells must be given supplements in order that they thrive and produce the proteins and lipids required for barrier function equivalency. The particular components of the growth medium relevant to the issue of sound prediction are ascorbic acid, oleic acid, linoleic acid, arachidonic acid, isoproterenol and α-tocopherol.

[32] Claim 7 directs the reader to the desired result of the method (skin equivalents having improved barrier function), and a measurable parameter (SEC). However, it minimally speaks of only two growth medium supplements, ascorbic acid and linoleic acid, but no others. Because the claim is not restricted through the inclusion of any additional supplements, the scope of the claim has been brought into question.

[33] Claim 16 is representative of the second type of method claim which relates to genetic engineering of skin cells:

> 16. A method of making skin equivalents having improved barrier function comprising: a) providing keratinocytes and a DNA construct comprising a sequence encoding GKLF operably linked to an exogenous promoter; b) transfecting said keratinocytes with said DNA construct to provide transfected keratinocytes, and c) culturing said transfected keratinocytes under conditions such that a pre-graft skin equivalent having improved barrier function is formed, wherein said pre-graft skin equivalent has a surface electrical capacitance of from about 40 to about 240 pF measured as the difference in reading over a 10 second interval, wherein said pre-graft skin equivalent comprises Near Diploid Immortalized Keratinocyte cells.

[34] This type of claim, like claim 5, reflects the notion that genetic modification of skin cells with a GKLF gene will improve their barrier function.

ANALYSIS

What is the predicted utility?

[35] The product and method claims reflect the promise that the compositions will have improved barrier function. The promise is stated explicitly in the method claims and is one consistent both with the Summary of the Invention (see page 3, lines 6-7) as well as the problem discussed in the Background to the Invention. Concerning the latter, the description indicates (on page 2, line 22 - page 3, line 3) that "In order to test compounds or formulations early in the development process with speed and accuracy, it would be beneficial to have an *in vitro* test system that mimics the barrier properties of human skin. However, published studies indicate that existing skin equivalent cultures . . . have very poor barrier function." Accordingly, the inventors proclaim that "a great need exists for skin substitutes having improved barrier function."

[36] The utility issued can be resolved by asking whether the skilled person would predict that the claimed subject matter lives up to the promise of improved barrier function.

Product claims

Factual basis

[37] The Examiner has identified at least two concerns in respect of the product claims and the factual basis upon which their predicted utility rests. We agree that both are valid concerns. The first is the failure to accurately define the ceramide content of the claimed compositions. This is an important consideration because the description discloses a relationship between ceramide content, the technical parameter that appears to be responsible for lowered SEC, and the promised utility itself. The second concern relates to the idea of inserting a GKLF gene into skin cells so that barrier function is improved, i.e., as clearly indicated in claim 5.

[38] Starting with the first concern, we find that the factual basis evident in the description is sufficient to support only improvements that are attributable to changes in relative amounts of certain ceramides. As they read now, the product claims reflect an ill-founded promise that

compositions comprising skin cells lacking the appropriate amounts of key ceramides will, nonetheless, still be improved in their barrier function.

[39] From a reading of the description the skilled person would understand the fact that a critical change in the ceramide profile of the outer surface of a skin cell composition occurs before an improvement in barrier function is seen (see page 25, line 1 - page 27, line 4; page 33, line 18 - page 35, line 5; page 40, line 22 - page 43, line 7). The description also discloses the fact that certain ceramides play the "unusual role of forming covalent bonds" with other cell surface molecules (page 27, lines 12-14) and that human skin cells contain a full spectrum of ceramides whereas known skin cells culture produced "very little of ceramides 6 and 7" (page 34, lines 26-28). Example 1 (page 61, lines 8-15) explains that artificial skin equivalents grown *in vitro* using conventional basal media have a ceramide content that is unfavourably lower than that found in natural skin, and that embodiments of the invention are beneficially changed in that respect.

[40] Consistent with this understanding, the Examiner explains in the SoR that "applicant has disclosed that growing his cells in the presence of a base medium with 'additional constituents' yields keratinocytes with higher levels of the polar ceramides 3-6 when cultured in optimal media as disclosed in example 6." Accordingly, the Examiner required that the claims be limited to "skin equivalents which feature higher levels of the polar ceramides 3-6 when cultured in the disclosed optimal media."

[41] The Examiner's reasoning is also consistent with the notion that the improved culture media allows skin cells to synthesize higher relative amounts of ceramides 3, 4, 5, and 6. Claim 1 fails to indicate anything about ceramide content. Claim 1 does mention a measurable technical parameter, SEC, but we do not regard the range claimed as a feature which appropriately limits the claim in a manner consistent with the factual basis. The skilled person would understand from the description how to measure SEC and which ranges reflect improvements in barrier performance. However, in this case, the claim is not rendered soundly predictable simply by including a reference to a parameter range disclosed to correlate with barrier function unless the claim further defines the technical feature actually responsible for the improvement in that function. Although other claims, such as claim 3, do mention ceramide content, they do so in a non-relative manner and do not mention ceramides 3 and 4.

[42] In relation to the issue of sound prediction, the Applicant responded to the Final Action by arguing that "exemplification is not an absolute requirement in Canada. A skilled person must simply be able to predict, based upon the teachings of the description, that the claimed invention

would have the desired characteristics." We agree that exemplification is not an absolute requirement, but the ultimate question is whether the claims are based on a sound prediction and, in that regard, examples can form part of the factual basis. Working examples reflect exploration of the claimed area and are therefore relevant considerations, especially in disciplines that, by their nature, are unpredictable. Examples 6 and 13 represent the extent of actual exploration of the claimed subject matter. It is highly relevant that examples 6 and 13 and the other facts discussed above indicate the importance ceramides 3, 4, 5 and 6. Moreover, the Applicant has not pointed to other facts that could aid in establishing a sound prediction.

[43] Turning now to the second concern related to the idea of genetically engineering skin cells to express a GKLF gene, we find an insufficient factual basis to support a prediction that a skin cell so engineered would have improved barrier function.

[44] Although such cells have been made (see Example 7), the Examiner points out that such cells were never tested for either SEC, ceramide content, or any other measure that would lend support to a finding that compositions comprising such cells would have improved barrier function. The Applicant has argued that the description establishes that GKLF genes were known to be implicated in barrier function. This is true, because as the Applicant said in response to the Final Action, "the factual basis lies in the known defective barrier function in mice lacking the klf4 transcription factor [a GKLF gene]." However, it does not necessarily follow, based on that fact alone, that skin cells genetically engineered to express a GKLF gene will be useful in the preparation of artificial skin equivalents with improved barrier function. Based on their common general knowledge the skilled person knows that transcription factors, such as GKLF, are responsible for regulating the expression of numerous genes and that manipulating their expression can have unpredictable consequences. In fact, the Examiner pointed out, by referring to a scientific article, that the functions of klf4 (the Applicant's preferred GKLF gene) are even more complex, diverse and unpredictable than the skilled person might have expected. Thus, the unpredictable nature of transcription factors and GFLK genes establishes to our satisfaction that, while there is the germ of an idea in the description, there is an insufficient number of additional facts to lead a skilled person to conclude that the promised utility would be realized.

[45] We therefore conclude that the factual basis upon which the utility of claim 5 rests (and, by extension, that of claim 1 as well) is insufficient.

Sound line of reasoning

[46] The articulable and sound line of reasoning from which improved barrier function can be

inferred from the factual basis would not be evident to the skilled person. As explained above, the factual basis is limited and we do not see how the skilled person could draw an inference from the limited facts disclosed that would allow that person to predict that the claimed subject matter lives up to the promise of improved barrier function. The same applies in respect of genetically engineered skin cells.

Proper disclosure

[47] Having found the factual basis to be lacking and a sound line of reasoning to be elusive, it is self-evident that there has not been proper disclosure.

Conclusion on sound prediction of the product claims

[48] We find that the product claims submitted in response to the Final Action do not comply with section 2 of the Act because they embrace subject matter whose promised utility is not soundly predicted.

Method claims

[49] In these claims the question of sound prediction may be approached by asking whether the promised improved barrier function will occur as a consequence of following the steps of the method claims.

Factual basis

[50] In respect of method claim 7, it is understood that its factual basis rests on the disclosure of improvements to skin cell compositions when they are made through culturing in a medium containing not only ascorbic acid and linoleic acid, but also oleic acid, arachidonic acid, isoproterenol and α tocophenol (see examples 6 and 13). Through the use of this method and these supplements a change in the ceramide profile is effected such that SEC is lowered and barrier function is improved. However, no example suggests that the same results would be achieved by using a medium containing only ascorbic acid and linoleic acid. The skilled person would not appreciate how such a significant change in culture conditions would be successful unless additional facts were evident.

[51] In the case of the genetic engineering method of claim 16, the factual basis of this method can be seen as resting on the notion that inserting a GKLF gene into NIKS skin cells will result in

changes to the cells (their SEC) and hence improved barrier function. As was explained in relation to product claim 5, the GKLF art field is highly unpredictable and the inventors have not adequately explored the claimed area. Again, the skilled person would not appreciate how this approach could be successful unless further facts were available.

[52] In this case, we need not belabour the analysis with a consideration of the second and third prongs of the *AZT* test.

[53] The method claims are therefore not based on a sound prediction of utility.

PROPOSED CLAIMS

[54] Our finding that the claims are not in compliance with section 2 of the Act is sufficient to recommend refusal of the application. It also permits us to entertain the possibility that the Applicant's proposed claims of May 1, 2012 may remedy their defects.

[55] Proposed claim 1 is representative of the product claims and it includes features absent in the rejected product claims; including a reference to the relative amounts of ceramides 3, 4, 5 and 6:

> A composition comprising a pre-graft human skin equivalent and a buffer, said pre-graft skin equivalent having a surface electrical capacitance of from about 40 to about 240 pF measured as the difference in reading over a 10 second interval, wherein said pre-graft skin equivalent comprises Near Diploid Immortalized Keratinocyte cells and wherein said skin equivalent is cultured in a media comprising ascorbic acid, linoleic acid, oleic acid, arachidonic acid, isoproterenol and α-tocophenol and has a higher ceramide content of ceramides 3, 4, 5 and 6 than if the culture media lacked ascorbic acid, linoleic acid, oleic acid, arachidonic acid, isoproterenol and α-tocophenol.

[56] It is evident that the proposed claim set also addresses problems concerning the genetic engineering of cells (whether they be product or method claims) and methods of cell culturing because the proposed claims no longer mention anything in relation to the former, but do include, as required by the Examiner, a reference to the later (i.e., an indication of the particular culture conditions that allow the skin cells to grow and produce ceramides 3, 4, 5 and 6 and hence have improved function).

The proposed claims are free of other possible support defects

[57] Since the first set of proposed claims cures the claims of all issues related to sound prediction, in order to completely address all possible the issues identified by the Examiner we need only now consider whether they are also free of any other defects that might be considered as relating to lack of support.

[58] Section 84 of the Rules and subsection 27(3) of the Act were cited as the relevant statutory provisions for the rejection on the basis of lack of support.

[59] Section 84 of the Rules and subsection 27(3) of the Act are related since both are concerned with the relationship between the extent of disclosure and the scope of the claims.

[60] Section 84 of the *Patent Rules* reads :

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

[61] Section 84 of the Rules operates in conjunction with subsection 27(3) of the Act, the relevant paragraphs of which read:

> 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; . . .

[62] Although not necessarily the only relevant questions, compliance with subsection 27(3) of the Act hinges on the description answering two questions: What is the invention? How does it work? (*Consolboard v. MacMillam Bloedel*, [1981] 1 S.C.R. 504 at 526, 56 C.P.R. (2d) 145 at 157; *Teva* at para 70). The description of the invention must be correct and full and the specification must enable the invention across its entire scope as claimed. Although the skilled person must not be asked to exercise inventive ingenuity, that person can be asked to undertake

routine experimentation, but such experimentation must not amount to an undue burden.

[63] Having reviewed the specification, Final Action, the SoR and the Applicant's submissions we find that the skilled person could have answered both of the so-called *Consolboard* questions in a straightforward manner. The invention claimed in the first set of proposed claims is both well-described and implementable by the skilled person without the need for undue experimentation.

[64] The NIKS cell line mentioned in the proposed claims was known and available to the skilled person. As was explained by the Applicant in response to the Final Action, the general methods of culturing the cells are well-described and involve standard techniques. Because the claims are constrained by a reference to an SEC range, particular culture supplements and ceramide profile, there are no indications that the skilled person would not be able to practise the invention across its scope as claimed.

[65] We therefore find that the proposed claims are compliant with subsection 27(3) of the Act and section 84 of the Rules.

Second set of proposed claims

[66] On December 6, 2013 the Applicant asked that we consider a second set of proposed claims, but only in the alternative that the first set of proposed claims was found to be non-compliant. As such we decline to consider the second set of proposed claims in detail. That said, we note that they do not refer to the SEC range found both in the rejected claims and in the first proposed claim set. We further note that, in response to the Final Action, the Applicant argued that the SEC range was a feature that distinguished the claimed invention over the prior art. On page two of the response the Applicant submitted that "an SEC of 40 to 240 pF is a material difference between pre-graft equivalents of the present invention and [the prior art]."

RECOMMENDATION OF THE BOARD

[67] We recommend that the Applicant be informed that the amendment in the form of the claim set proposed on May 1, 2012 is necessary for compliance with the Act and Rules.

Ed MacLaurin	Philip Brown	Mark Couture
Member	Member	Member

DECISION OF THE COMMISSIONER

[68] I concur with the findings and recommendation of the Board. In accordance with subsection 30(6.3) of the *Patent Rules*, the amendments of May 1, 2012 must be made within three months after the date of this decision, failing which I intend to refuse the application. Therefore, under paragraph 31(*b*) of the *Patent Rules* I invite the Applicant to make these amendments, and only these amendments, as recommended by the Board.

Sylvain Laporte
Commissioner of Patents

Dated at Gatineau, Quebec
this 11th day of July, 2014