Commissioner=s Decision # 1312
Décision du Commissaire # 1312

TOPIC: K10 (patentable subject matter, living things)
SUJET: K10 (objet des demandes, matières vivantes)

Application No. :2,306,317
Demande n^{o}. : 2,306,317

Commissioner=s Decision Summary

The subject application was rejected since it claimed products that were considered tissues or organs B subject matter that is outside the definition of invention under section 2 of the *Patent Act*. Upon review, it was found that the claimed products could not truly be considered organs or tissues. It was therefore recommended that the rejection be reversed and that the application proceed to allowance. The Commissioner agreed.

IN THE CANADIAN PATENT OFFICE

DECISION OF THE COMMISSIONER OF PATENTS

Patent application number 2,306,317 having been rejected under subsection 30(3) of the *Patent Rules*, has been reviewed in accordance with Subsection 30(6) 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:

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INTRODUCTION

[1] This decision deals with a review of the rejection of patent application number 2,306,317.

[2] The Applicant is L=Oréal, the inventors are Hervé Pageon, Daniel Asselineau and Pierre Tachon, and the invention is entitled AAGED SKIN EQUIVALENT.@

PROSECUTION HISTORY

[3] The subject application was filed on April 18, 2000 and presently contains 47 claims. The examiner in charge of the application issued a Final Action on August 22, 2007 at which time certain product claims were found to be defective under section 2 of the *Patent Act*. The defective claims are directed to aged dermis equivalents, epidermis equivalents and aged skin equivalents. The Final Action indicates that the defective claims are directed to tissues and organs that are not considered compositions of matter within the definition of invention set out in section 2 of the Act.

[4] On February 22, 2008, the Applicant replied to the Final Action and maintained that the defective claims define patentable subject matter. Only minor amendments were made to the description and claims.

[5] In the Examiner=s estimation, the Applicant=s reply to the Final Action did not overcome the rejection. The application was therefore referred to the Patent Appeal Board for review.

THE ISSUE

[6] We must determine whether the defective claims define subject matter that is within the definition of invention as set out in section 2 of the *Patent Act*.

BACKGROUND

[7] The rejected application relates to novel skin equivalents that find use as models for testing compositions that could reverse or slow the skin aging process. The models can also be used for the study of phenomena related to skin aging, such as wrinkling and photoaging. The invention avoids the ethical disadvantages of using real skin from natural sources.

[8] There are two basic components of the invention: an epidermis equivalent component and an aged dermis equivalent component. The former includes keratinocyte skin cells while the latter includes fibroblast cells and modified collagen. Both components are described as products prepared *in vitro* which can be combined to form a bilayer product that mimics aged skin.

[9] With respect to the epidermis equivalent component, the specification discloses that naturally aged epidermis comprises a protein termed Aintegrin β1@ that is distributed throughout most of its layers. To mimic this feature, the specification proposes to use an epidermis equivalent that comprises keratinocytes that present a modified expression of integrin β1 protein.

[10] With respect to the aged dermis equivalent component of the invention, the specification

teaches that fibroblasts can be incorporated into a support lattice comprising artificially Aglycated@ collagen. AGlycation@ is a non-enzymatic process that occurs naturally in many types of body tissues. It is part of the aging process and can result in stiffer and more inflexible skin tissue.

THE CLAIMS

[11] Claims 1 to 14 are indicated in the Final Action to be defective. Independent claims 1, 8, 9 and 13 are representative of the defective claims.

[12] Claim 1 relates to one component of the invention: an equivalent of an aged dermis. It reads:

> 1. An aged dermis equivalent comprising at least glycated collagen and fibroblasts, characterized by the fact that it presents a level of glycation between 2 and 30, said aged dermis equivalent being produced *in vitro*.

[13] Claims 8 and 9 relate to the second component of the invention: an epidermis equivalent. These claims read:

> 8. An epidermis equivalent comprising at least keratinocytes, characterized by the fact that it is obtained by seeding at least keratinocytes on a dermis equivalent as defined in any one of claims 1 to 7, said epidermis equivalent being produced *in vitro*.
>
> 9. An epidermis equivalent comprising at least keratinocytes, characterized by the fact that it presents a modified expression of integrin β1, said epidermis equivalent being produced *in vitro*.

[14] Claim13 is directed to an aged skin equivalent comprising an epidermis equivalent and an aged dermis equivalent:

> 13. An aged skin equivalent, characterized by the fact that it comprises at least an epidermis equivalent as described in any one of claims 8 to 12 and an aged dermis equivalent as described in any one of claims 1 to 7, said aged skin equivalent being produced *in vitro*.

THE FINAL ACTION

[15] The Final Action outlines the reasons why the claimed subject matter is considered to be outside the definition of invention as set out in section 2 of the Act:

$ The claims are open-ended and can encompass, or are indistinguishable from, things like natural dermis, epidermis and skin.

$ The claims are considered to be directed to tissues and organs, regardless of indications that the products are produced *in vitro*.

$ The Supreme Court has established that life forms, such as microorganisms, that are produced in large quantities and in such a manner that they possess uniform characteristics, are patentable subject matter. However, one cannot say the same in respect of plants, animals, organs, and tissues. Organs and tissues are much more complex than microorganisms since they include many types of differentiated cells that form a highly specialized cellular network.

$ According to an Office Practice Notice dated June 20, 2006 (the Practice Notice), tissues and organs are created by complex processes, elements of which require no human intervention, and are not made up of ingredients or substances that have been combined or mixed together by a person.

THE RESPONSE TO THE FINAL ACTION

[16] In response to the Final Action the Applicant submitted, in brief, that:

$ The Final Action relies on the Practice Notice of June 20, 2006 which indicates that tissues and organs are not patentable subject matter. However, the Practice Notice is based on an erroneous interpretation of *Harvard College v. Canada (Commissioner of Patents)*, 2002 SCC 76 [*Harvard*] B a decision that concerned the patentability of higher life forms. A tissue or organ is not a higher life form. Also, the Supreme Court in *Harvard* and *Monsanto Canada Inc. v. Schmeiser*, 2004 SCC 34 indicated that a fertilized egg is a patentable composition of matter.

$ The claimed skin, dermis, and epidermis equivalents are clearly the result of mixing ingredients and substances, and that mixing involves human intervention.

$ A dictionary definition of the expression A*in vitro*@ indicates that it relates to something that occurs in an Aartificial@ laboratory environment, and that a dictionary definition of the term Aartificial@ indicates something produced by a human technique and not by nature.

$ The claimed subject matter is indicated to be Aequivalent@ to organs or tissues and that, through the use of that term, the person skilled in the art would understand that natural tissues or organs are excluded from the scope of the claims.

$ Although the claims use open-ended terminology, they are nonetheless still directed to Aequivalents@ and, by definition, the claims cannot be enlarged to encompass natural tissues or organs.

$ The application is directed to a person of skill in the art and that person would interpret the claims, in light of the description, to be directed to products that have characteristics of aged skin, that mimic aged skin, or that are models of aged skin.

ANALYSIS

[17] The Final Action is based on the Practice Notice of June 20, 2006 which states that tissues and organs are not patentable subject matter. The language and reasoning in the Practice Notice echoes the reasoning in *Harvard*. For instance, compare the language of the Practice Notice:

> Further, the Office takes the position that organs and tissues are not compositions of matter for the purposes of the definition of invention under section 2 of the *Patent Act* and are therefore not patentable subject matter. Organs and tissues are created by complex processes, elements of which require no human intervention, and do not consist of ingredients or substances that have been combined or mixed together by a person.

with paragraph 162 of *Harvard*:

> [t]he process by which a fertilized egg becomes an adult mouse is a complex process, elements of which require no human intervention. The body of a mouse is composed of various ingredients or substances, but it does not consist of ingredients or substances that have been combined or mixed together by a person.

[18] In *Harvard* there was no dispute, unlike the present case, regarding the Anature of the specific invention@ since it was agreed that an oncomouse was a higher life form (see para 150). The Court had to decide as a question that approached a pure determination of law whether or not a higher life form can be considered a Acomposition of matter@ or a Amanufacture.@

[19] In the present case, the question we are faced with involves more a question of fact than of law and the outcome depends heavily on determining the nature of the invention. In relation to factual determinations, the Supreme Court indicated in *Harvard* at para 151 that the Commissioner is well-situated to decide whether a particular life form should be classified as a higher or lower life form:

> If, for example, the question to be decided was whether or not a particular life form such as a fungus should be classified as a higher life form or as a lower life form, the Commissioner=s decision would likely be accorded deference. As noted, s. 40 of the Act states that it is the Commissioner who must be Asatisfied@ that a patent should not be issued. In such an instance, the Commissioner=s scientific expertise suggests that the courts defer to his decision in respect to whether he is satisfied that the life form falls within a category of patentable subject matter.

[20] It follows in the present case that the same prerogative applies in deciding whether the claimed subject matter should be classified as a tissue or an organ. Indeed the Practice Notice indicates that there is latitude in making such determinations:

> Artificial organ-like or tissue-like structures, generated substantially through the hand-of-man by combining various cellular components and/or inert components, may be considered, on a

case-by-case basis, to be compositions of matter and therefore patentable subject matter.

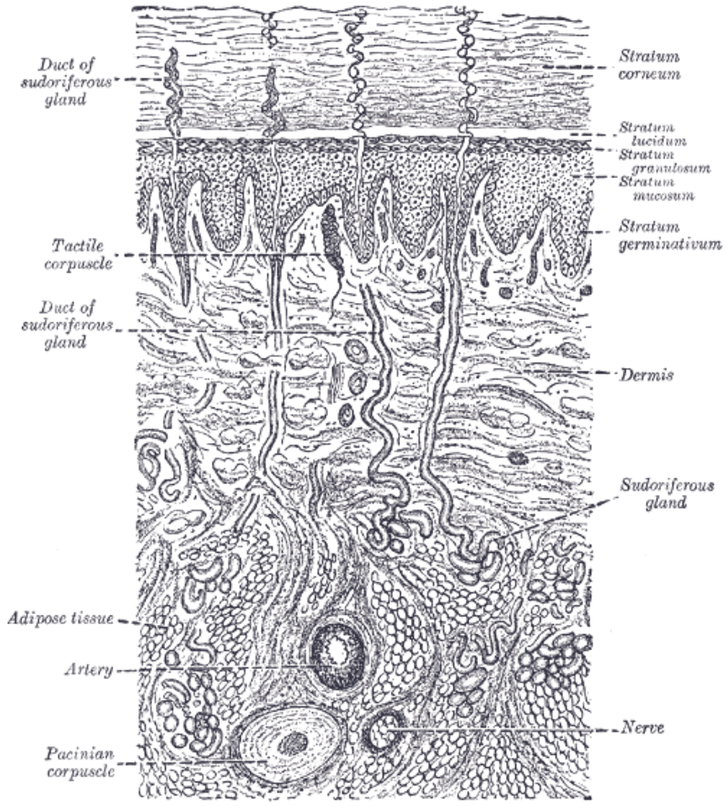
[21] The question before us can therefore be narrowed to ask whether the claimed subject matter can be considered an artificial organ and/or an artificial tissue that has been generated substantially through the hand-of-man.

[22] The most complex of the Applicant=s products are those defined in claims 13 and 14. These claims are directed to aged skin equivalents and comprise the two components of the invention: an epidermis equivalent as defined in any one of claims 8 to 12 and an aged dermis equivalent as defined in any one of claims 1 to 7. The components themselves and the combination of the two are all claimed as being products made *in vitro*. That everything claimed is the result of *in vitro* manipulations is made clear from the description which teaches that the aged dermis component is made by first generating a support lattice comprising glycated collagen that itself has been prepared through a chemical reaction. Fibroblast cells are then mixed with the collagen support lattice and incubated. The final product is then prepared by seeding keratinocyte cells onto the supporting aged dermis followed by incubation to allow for cell growth. All of the steps leading to the claimed products are performed *in vitro,* in a laboratory, and are performed by scientists or technicians.

[23] While the *in vitro* nature of the invention does inform our analysis, that is not necessarily the key consideration. The key considerations are set out in *Harvard* and demand that the complexity of the process and the degree of human intervention be examined.

[24] All of the ingredients in the claimed products B whether they be fibroblasts, keratinocytes or collagen B are themselves patentable *per se* and have been combined or mixed together by a person. The most complex of the Applicant=s products, the claimed aged skin equivalents, therefore do not truly equate to tissues or organs in the sense conveyed through either the Practice Notice or *Harvard*. A person of skill in the art would understand that the Applicant=s aged skin equivalents could not further develop B through a Acomplex process, elements of which require no human intervention@ B into things that may more closely approximate real skin or tissues. Therefore, the present case is distinguishable from *Harvard*.

[25] To visualize the high degree of organization and complexity of natural skin, reference is made to the following figure (from *Gray=s Anatomy*, copyright expired):



[26] From this figure it can be better appreciated that B even though it is stratified into dermal and epidermal layers like the presently claimed products B natural skin is complex and comprises things such as hairs, hair follicles, pores, glands, muscles, nerves, nerve endings and blood vessels, many of which can transverse one or more skin layers.

[27] The basic structure of a representative embodiment of the subject matter defined in claims 13 and 14 is depicted in figure 1, photograph 2. In comparison to normal skin, this embodiment is markedly simple in terms of its structure: it is a bilayer product minimally containing glycated collagen, fibroblasts and keratinocytes and does not contain structures such as blood vessels and nerve endings. The claimed subject matter is therefore anatomically distinguishable from naturally occurring skin.

[28] Although claimed as Aequivalents@, we do not see that the subject matter should be interpreted to be something that is functionally equivalent to natural skin since none of the subject matter appears to be capable of doing things such as perspiring, secreting sebaceous material, providing for thermal regulation, or responding to environmental stimuli. The claimed subject matter is Aequivalent@ to natural skin or tissues, but only insofar as it meets the Applicant=s very limited requirements.

[29] Even if the epidermis equivalents of claims 8 to 12 can additionally contain melanocytes and/or Langerhans cells as indicated in certain dependent claims, we are still not convinced that they approach the complexity of a corresponding natural counterpart.

CONCLUSIONS

[30] We find in the Applicant=s favour based on the record as it currently stands. The claimed products are compositions of matter because they are made up of ingredients or substances that have been combined or mixed together by a person and because they are anatomically and functionally distinguishable from true tissues or organs. Claims 1 to 14 are therefore compliant with section 2 of the Act.

RECOMMENDATION

[31] We recommend that the Examiner's rejection of the application be reversed and that the application proceed to allowance.

Ed MacLaurin	Marcel Brisebois	Serge Meunier
Member	Member	Member

COMMISSIONER=S DECISION

[32] I concur with the findings and the recommendation of the Board. The Examiner's rejection of the application is reversed and the application is to proceed to allowance.

Mary Carman

Commissioner of Patents
Dated at Gatineau, Quebec
this 31 day of March, 2011