Commissioner=s Decision #1315
Décision du Commissaire #1315

TOPIC: B20, B22, C00, G00
SUJET: B20, B22, C00, G00

Application No. : 2,161,785
Demande n^{o}. : 2,161,785

IN THE CANADIAN PATENT OFFICE

DECISION OF THE COMMISSIONER OF PATENTS

Patent application number 2,161,785 having been rejected under subsection 30(3) of the *Patent Rules*, has been referred to the Patent Appeal Board for review. The findings of the Board and the ruling of the Commissioner are as follows:

Agent for the Applicant:

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INTRODUCTION

[1] This decision deals with a review of a Final Action on patent application no. 2,161,785.

[2] The joint Applicants are the Massachusetts Institute of Technology and the Children's Medical Center Corporation. The inventors are Linda Griffith-Cima, Anthony Atala, Charles A. Vacanti and Keith T. Paige and the invention is entitled AInjectable Polysaccharide-Cell Compositions@.

BACKGROUND

[3] The application is concerned with the use of a biocompatible, biodegradable cross-linkable hydrogel in order to deliver cells into a patient such that an organ- or tissue-equivalent is eventually created. According to the description, the hydrogel promotes engraftment and provides three-dimensional templates for new cell growth. Ultimately, the hydrogel degrades, leaving only the resultant newly formed organ- or tissue-equivalent.

PROSECUTION HISTORY

[4] The subject application was filed on April 29, 1994 and the Examiner in charge of the application issued a Final Action on August 13, 2009. In the Final Action, the Examiner rejected all the claims under subsection 138(2) of the *Patent Rules* and subsection 27(3) of the *Patent Act* for being broader in scope than the teachings of the description.

[5] On February 2, 2010 the Applicant responded to the Final Action. The Applicant made minor amendments unrelated to the rejection, added 3 new claims and submitted that the objections were traversed. According to the Examiner, the Applicant's reply to the Final Action did not overcome the objections raised in the Final Action. The application was therefore referred to the Patent Appeal Board for review. A Summary of Reasons was forwarded to the Patent Appeal Board since the Examiner still considered the use of polymers other than a specific type to be broader in scope than the teachings of the description.

REPRESENTATIVE CLAIM

[6] The following claim is representative of the claims found to be defective:

> 1. A use of a cell-polymeric solution for injecting a cell suspension into an animal under conditions which cross-link the cell-polymeric solution within the animal to form a three-dimensional open-lattice structure having cells dispersed therein, the solution comprising a biodegradable, biocompatible natural or synthetic organic hydrogel-forming polymer which can be cross-linked via covalent, ionic, or hydrogen bonds to create a three-dimensional open-lattice hydrogel which entraps water molecules to form a gel, mixed with dissociated cells selected from the group consisting of osteoblasts and other cells that form bone, muscle cells, fibroblasts, and organ cells.

THE ISSUES

[7] According to the Final Action, the specification only adequately describes alginate as a polymer having the features recited in the claims and thus, the specification does not provide a factual basis such that a person skilled in the art would have soundly predicted that the desired result would be obtained if a polymer other than alginate is used. The Final Action also

indicates that the specification does not broadly enable the person skilled in the art to formulate any number of suitable polymers.

[8] Therefore, having regard to the Final Action, the arguments submitted in response to the Final Action and the Summary of Reasons, we are faced with two questions that both relate to the scope of the claims:

(1) Given that the claims are not restricted to alginate-cell polymers, do they go beyond the limits of a sound prediction?

(2) Is the disclosure sufficient such that the claims do not exceed what has been described and enabled in the specification?

[9] Former claims 1 to 17 have been found to be not compliant with subsection 138(2) of the *Patent Rules* and subsection 27(3) of the *Patent Act*. These defects are also said to be present in the claims that were submitted in response to the Final Action.

LEGAL AUTHORITIES AND PRINCIPLES

[10] In relation to the first question, we consider that the nature of the alleged defect also brings into play the question of the utility of the invention, even if not explicitly stated in the Final Action. The requirement that an invention be useful, or have utility, is found in section 2 of the Act:

> Ainvention@ 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;

[11] In this case, the question of utility involves considering the soundness of the Applicant=s prediction in respect of all that is claimed. The doctrine of Asound prediction@ balances the public interest in early disclosure of new and useful inventions, even before their utility has been fully verified by tests, and the public interest in avoiding cluttering the public domain with useless patents and granting monopoly rights in exchange for speculation or misinformation: see *Apotex Inc. v. Wellcome Foundation Ltd.*, 2002 SCC 77, at para. 66 (*Wellcome*).

[12] According to the test set out in *Wellcome*, an invention that relies on a sound prediction of utility must satisfy three requirements:

(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 Asound@ line of reasoning from which the desired result can be inferred from the factual basis; and
(3) there must be proper disclosure.

[13] The relevant date for determining the soundness of a prediction is the filing date (see *Aventis Pharma Inc. v. Apotex Inc.*, 2005 FC 1283, 43 C.P.R. (4th) 161 at para.164; aff'd on this point 2006 FCA 64, 46 C.P.R. (4th) 401 at para. 30).

[14] The second question relates more directly to the requirements of subsection 138(2) of the

Patent Rules and subsection 27(3) of the *Patent Act*.

[15] Subsection 138(2) of the *Patent Rules* reads:

> Every claim must be fully supported by the description.

and subsection 27(3) of the *Patent Act* reads:

> 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;
>
> (c) in the case of a machine, explain the principle of the machine and the best mode in which the inventor has contemplated the application of that principle; and
>
> (d) in the case of a process, explain the necessary sequence, if any, of the various steps, so as to distinguish the invention from other inventions.

[16] Sufficiency of disclosure primarily relates to two questions that are relevant for the purpose of subsection 27(3) of the *Patent Act* (see *Consolboard v. MacMillam Bloedel*, [1981] 1 S.C.R. 504 at 526, 56 C.P.R. (2d) 145, at p.157): What is the invention? How does it work? 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 will be able, having only the specification, to make the same successful use of the invention as the inventor could at the time of his application and this, without having to display inventive ingenuity or undertake undue experimentation.

[17] Since the Final Action suggests that the cell-polymeric solution recited in the claims is defined by the desired result rather than by its distinctive features that achieve that result, the following passage from *Free World Trust v. Électro Santé Inc.*, [2000] 2 S.C.R. 1024, at paragraph 32 is also considered relevant:

> [T]he ingenuity of the patent lies not in the identification of a desirable result but in teaching one particular means to achieve it. The claims cannot be stretched to allow the patentee to monopolize anything that achieves the desirable result. It is not legitimate, for example, to obtain a patent for a particular method that grows hair on bald men and thereafter claim that anything that grows hair on bald men infringes.

[18] Although the sound prediction and the insufficiency of disclosure arguments have been presented as combined or related issues in the Final Action, it is clear from *Eli Lilly Canada Inc. v. Novopharm Limited*, 2010 FCA 197 at para. 120 that the proper disclosure requirement that appears in the test for a sound prediction and the sufficiency of disclosure requirement are separate and distinct:

> The trial judge correctly noted that there were two disclosure requirements in play: the AZT Aline of reasoning@ disclosure (the third condition for sound prediction) and the Aduty to set out the basis on which olanzapine is believed to have a substantial and peculiar advantage over the '687 compounds@ (the requirement that the patent set out what the invention is and how it works). However, the two requirements are separate and distinct. It is incorrect to equate one to the other. The Asufficiency@ attack on the patent=s validity relates to subsection 27(3) of the Act. [Emphasis added]

[19] Therefore, as indicated above, we will address the first question as an issue concerning the soundness of the Applicant=s prediction. We will then separately consider the second question as an issue relating to the sufficiency of disclosure requirement.

ANALYSIS AND FINDINGS

[20] The following passages from the Final Action illustrate the Examiner=s position:

> Claims 1-17 are broader in scope than the teachings of the description and do not comply with subsection 138(2) of the *Patent Rules* and subsection 27(3) of the *Patent Act*. Said claims are directed to the use of a cell-polymeric solution for implanting tissue into an animal, to an injectable cell-polymeric solution and to a kit for forming new tissue but said claims extend beyond the full scope of the teachings of the present application. Applicant has only taught a method for preparing a calcium alginate chondrocyte solution.
> ...
>
> Claims 1, 10 and 14 define an injectable cell-polymeric solution by the desired result of forming a three-dimensional open lattice structure that is biodegradable, biocompatible and that can be cross-linked via covalent, ionic or hydrogen bonds to create an open lattice hydrogel that entraps water molecules rather than defining the injectable cell-polymeric solution by distinctive features that achieve that result. Although applicant discusses the different compounds that can be used to produce three-dimensional open-lattice on pages 15-18, a person skilled in the art could not produce a Athree-dimensional open-lattice@ using any of the compounds discussed without undue experimentation because applicant has only characterized an alginate three-dimensional open-lattice.
> ...
>
> After reading the present application a person skilled in the art has no factual basis to predict any polymer for injecting cells into an animal but alginate.

[21] The Applicant addressed the Examiner=s arguments in the response to the Final Action. In summary the Applicant submitted the following:

- The invention is the use of a biocompatible, biodegradable cross-linkable hydrogel to deliver certain types of cells into a patient to create an organ equivalent or tissue. It is the combination of suspending cells in such a material and demonstrating that this cell suspension forms tissue or an organ equivalent inside the patient that is the invention.

- The description on page 15, line 4, to page 20, line 24 provides detailed information concerning the types of polymers that can be used to make suitable hydrogels to practice the presently claimed invention.

- A hydrogel, by definition, is a three-dimensional open-lattice structure and a person skilled in the art of hydrogels would know how to make such a structure. The description provides a list of representative materials that can be used to form a suitable hydrogel for use in the present invention (i.e., biodegradable, biocompatible and cross-links within the animal), which includes polysaccharides, polyphosphazines, polyacrylates, certain block copolymers (e.g., Pluronics™, Tetraonics™, Polyethylene oxide-Polypropylene Glycol (PEO-PPG)), proteins, polyvinylpyrrolidone, hyaluronic acid and collagen. The description further teaches the specific characteristics of each of these types of polymers that make them suitable for use in the claimed invention.

- The description provides detailed teachings of how to cross-link the disclosed polymers to form the three-dimensional open-lattice structure (page 19, line 10, to page 20, line 24).

- The knowledge of a person skilled in the art with respect to the preparation of biocompatible hydrogels was high. A person skilled in the art, in view of their common general knowledge and the teachings in the description, would understand that a wide variety of polymers would be suitable for the claimed use. Further, based on the teachings in the disclosure and common knowledge, the skilled person would be able to readily make and use the invention as presently claimed without undue experimentation.

[27] Firstly, as the Applicant has submitted, it is important to note that the subject matter of the claims is not the polymer *per se*. The claims concern the use of a polymer, with defined qualities, in an injectable cell-polymeric solution such that dissociated cells are dispersed in a three-dimensional open-lattice hydrogel following injection into an animal.

Sound prediction

[28] Based on the specification, the application promises that a solution comprising certain polymers and certain cells will be useful for delivering the cells into an animal so as to promote cell engraftment and eventual formation of organ- and tissue-equivalents. The polymer must be one which is biodegradable, biocompatible and be capable of forming a three-dimensional open-lattice hydrogel when cross-linked via covalent, ionic, or hydrogen bonds. The cells may be osteoblasts or other cells that form bone, muscle cells, fibroblasts, and organ cells.

[29] In order for all of the claimed subject matter to pass the test for a sound prediction, the patent application must include the factual basis for the prediction, it must include an articulable and sound line of reasoning from which the desired result could be inferred, and there must be a proper disclosure of the factual basis and the line of reasoning. All of this should be in the patent application as of the filing date.

[30] The factual basis, as disclosed in the instant specification, includes the fact that alginate was successfully used to achieve the desired results, i.e., to deliver chondrocytes, osteoblasts or muscle cells into mice or pigs.

[31] Further, the description teaches that hydrogel-forming ability is not unique to alginate and the description conveys that such information was part of the common general knowledge expected from the person skilled in the art at the time of filing. The description also provides a list of representative materials that can form a suitable hydrogel for use in the claimed invention.

[32] What has not been exemplified in the description, but which is covered by the claims, is the use of suitable polymers other than alginate for the delivery of cells into an animal.

[33] The line of reasoning is that any three-dimensional open-lattice hydrogel that is formed by a suitable polymer will be useful to deliver certain cells into an animal and thereby provide a template for new cell growth. In view of the factual basis described above, we consider that line of reasoning reasonable and therefore supportive of the predicted utility in respect of all that is claimed. With regard to the proper disclosure requirement for sound prediction, we find that both the factual basis and the sound line of reasoning have been adequately disclosed in the specification. Therefore, the claims satisfy all three requirements of the test.

Sufficiency of disclosure

[34] In addition to meeting the test of sound prediction for utility, the claimed subject matter must also be sufficiently disclosed. This means that the specification must adequately describe and enable the claimed subject matter.

[35] It is apparent from the Final Action that the Examiner is not convinced that a hydrogel having the desired properties, and suitable for the claimed use, could be obtained by a person skilled in the art if a polymer other than alginate is used. In other words, the Examiner questions whether the person skilled in the art would be able to practice the claimed invention over the entire scope of the claims without having recourse to undue experimentation.

[36] The polymer alginate is used as a hydrogel-forming polymer in the exemplary portion of the description to support the utility of cell-polymeric solutions to deliver isolated cells into a recipient animal so as to promote engraftment. The description, notably on pages 15 to 20, clearly indicates that alginate was not the only biocompatible polymer known to be capable of creating a three-dimensional open-lattice hydrogel. The same passage also points out that the exact nature of the polymer is not critical so long as it is biodegradable, biocompatible and is capable, upon injection, of creating a three-dimensional open-lattice hydrogel when cross-linked via covalent, ionic, or hydrogen bonds. That is to say, the recited biocompatible, biodegradable polymer capable of creating a three-dimensional open-lattice hydrogel is part of the means to achieve the desired result rather than the desired result itself.

[37] Functional language typically provides breadth to a claim and is not objectionable *per se*. However, the specification must provide sufficient disclosure with regard to what is encompassed by such language for the purpose of subsection 27(3) of the *Patent Act*. Although routine trials and experiments not amounting to new inventions might be required to put the alleged invention into practice, the person skilled in the art, having read the description, must be able to formulate a suitable polymer without having to rely on inventive ingenuity or undertake

undue experimentation.

[38] Given the significant amount of information and details provided by the description with regard to the physical and chemical properties of different types of polymers that make them adequate alternatives to alginate, we are satisfied that inventive or undue experimentation would not be required by the person skilled in the art to identify polymers, other than alginate, that also fit the claim requirements. We also find that the skilled person could use routine techniques to determine the proper cross-linking conditions so the alternate polymers disclosed in the description would form a three-dimensional open-lattice hydrogel once injected into an animal.

CONCLUSIONS

[39] We find in the Applicant=s favour based on the record as it currently stands. We conclude that the claims do not go beyond the limits of a sound prediction and do not exceed what has been disclosed. Claims 1 to 20 are therefore compliant with subsection 138(2) of the *Patent Rules* and the specification is compliant with subsection 27(3) of the *Patent Act*.

RECOMMENDATION

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

Marcel Brisebois — Member

Ed MacLaurin — Member

Serge Meunier — Member

COMMISSIONER=S DECISION

[41] 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.

Sylvain Laporte
Commissioner of Patents

Dated at Gatineau, Quebec
this 6th day of July, 2011