Commissioner's Decision #1375
Décision du Commissaire #1375

TOPICS: B22, F01
SUJETS: B22, F01

Application No: 2,563,893
Demande n^{o}: 2,563,893

IN THE CANADIAN PATENT OFFICE

DECISION OF THE COMMISSIONER OF PATENTS

Patent application number 2,563,893 having been rejected under subsection 30(3) of the *Patent Rules*, has been reviewed in accordance with paragraph 30(6)(*c*) of the *Patent Rules* by the Patent Appeal Board and the Commissioner of Patents. The recommendation of the Board and the decision of the Commissioner are as follows:

Agent for the Applicant:

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INTRODUCTION

[1] This recommendation deals with a review of the rejection of patent application number 2,563,893 entitled "USE OF POROUS MEMBRANE TO SUPPORT DEVELOPING CONIFER SOMATIC EMBRYOS" filed on October 12, 2006 by the Applicant Weyerhaeuser Company.

[2] For the reasons that follow, we recommend that the application be allowed.

BACKGROUND

[3] The practice of sustainable forestry requires the planting and growth of new trees on a mass scale to replace those that have been harvested. Reforestation is a slow process requiring many years. Advancements which improve or quicken this process could greatly increase productivity. Somatic embryogenesis, or somatic cloning as it is referred to by the Applicant, is an *in vitro* process which can produce genetically identical

clones of conifer trees which possess desirable properties, such as superior growth rate.

[4] Somatic cloning of conifers employs specialized growth medium to induce somatic cells taken from one tree to differentiate into mature embryos possessing "cotyledons", critical structures which will become the first leaves of a germinating seedling. After further processing these mature embryos are capable of germinating to produce seedlings that are clones of the original tree.

PROSECUTION HISTORY

[5] This application was rejected in a Final Action on September 5, 2012 on the basis that all 11 claims then on record were defective for the following reasons:

- Anticipation (paragraph 28.2 (1)(*b*) of the *Patent Act*;
- Lack of Support (section 84 of the *Patent Rules*).

[6] In response to the Final Action, on March 4, 2013, the Applicant amended the application to address both grounds of rejection by replacing the claims with 11 amended claims. These are the most recent claims on file and are the subject of this review. The Examiner did not consider the amendments to be sufficient to overcome the rejection and on August 23, 2013 referred the application to the Patent Appeal Board (the Board) along with a Summary of Reasons (SOR) detailing the rationale for maintaining the rejection.

[7] This panel of the Board conducted an initial review of the case and requested a Supplemental Analysis (SA) containing a purposive construction of the claims and an update of the anticipation analysis in light of the two-step approach set out by the Supreme Court of Canada in *Apotex Inc v Sanofi-Synthelabo Canada Inc*, 2008 SCC 61 [*Sanofi*]. This SA was provided to the Applicant on June 5, 2014 along with a letter containing observations of the panel as well as an invitation to attend an oral hearing, if desired.

[8] The Applicant did not provide any written response to the SOR, the SA or our letter. Although the Applicant had initially indicated a desire for an oral hearing, they confirmed on September 17, 2014 that they would not be attending a hearing and that they understood the recommendation of the panel would be based on the written record.

THE ISSUES

[9] Based on the grounds of rejection, the following two questions will be addressed:

- Are claims 1-11 anticipated?
- Are claims 1-11 supported by the description?

ISSUE 1: ARE CLAIMS 1-11 ANTICIPATED?

[10] Subsection 28.2(1) of the *Patent Act* defines information to be taken into account when assessing whether a claim is anticipated:

> The subject-matter defined by a claim in an application for a patent in Canada (the "pending application") must not have been disclosed
>
> *(a)* 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 subject-matter became available to the public in Canada or elsewhere;
>
> (*b*) before the claim date by a person not mentioned in paragraph (*a*) in such a manner that the subject-matter became available to the public in Canada or elsewhere.

[11] In *Sanofi* the Supreme Court endorsed a two-step approach in which the requirements of "prior disclosure" and "enablement" must both be satisfied. In *Free World Trust v Electro Santé Inc*, 2000 SCC 66 [*Free World Trust* at para. 25] the Supreme Court of Canada also clarified that a single prior art publication must disclose all of the essential elements of a claimed invention in an enabling manner for there to be anticipation. It follows that if a prior art publication fails to disclose even a single essential element of the claimed invention then it cannot be anticipatory.

[12] In accordance with *Free World Trust*, essential elements are identified through a purposive construction of the claims done by considering the whole of the disclosure, including the specification and drawings: see also *Whirlpool Corp v Camco Inc*, 2000 SCC 67 at paragraphs 49(f) and (g) and 52. In accordance with the Office Practice Notice entitled "*Examination Practice Respecting Purposive Construction"* (PN2013-02) the first step of purposive claim construction is to identify the person skilled in the art and their relevant common general knowledge (CGK). The next step is to identify the problem addressed by the inventors and the solution put forth in the application. Essential elements can then be identified as those required to achieve the disclosed solution as claimed.

The Person Skilled in the Art and their Common General Knowledge

[13] A purposive construction of the claims was performed in the SA which characterized the person skilled in the art as "a team that includes a plant biologist working in the field of tissue culture and a tree biologist specialized in conifer propagation". The SA also indicated that the CGK of that person would include "expertise in tissue culture methods, including alternative recipes and forms of tissue culture medium commonly used in conifer tissue culture (i.e. liquid, solid, etc.), expertise in the optimization of said medium for specific tissue culture conditions and expertise in the identification of the various stages of cotyledonary development".

[14] While we agree with the above determinations, it is our view that the relevant CGK is more expansive and would include knowledge of methods for the somatic cloning of conifer embryos. Such methods are summarized in the Background of the Invention at page 1, lines 15 to page 2, line 2. Somatic cloning is achieved through three main stages each lasting several weeks, ending with the development stage. During this last stage, immature embryos (those without cotyledons) are developed to the point where they have produced one or more cotyledons and are ready for germination and subsequent growth into genetically identical conifer trees.

[15] The Background of the Invention does not explicitly provide further details of the commonly known methods of conifer somatic cloning. However, the remainder of the description and other publications are of assistance in establishing the relevant CGK. These other publications include, for instance, the background art referenced in the cited prior art document EP1063881 (D1), including a seminal United States patent, US 5,563,061 (US '061) and a review article published before the filing date of the present application (*Gupta et al. Advances in Conifer Tree Improvement Through Somatic Embryogenesis;* 2000, Ch. 29, pages 303-309 of *Proceedings of the 12th Toyota Conference: Challenge of Plant and Agricultural Sciences to the Crisis of Biosphere on the Earth in the 21st Century.* Ed. K. Watanabe and A. Komamine; henceforth "Gupta"). From these sources the relevant CGK can be summarized as including the following:

- Inducing cotyledonary development of immature embryos requires the use of liquid medium with high osmolarity (Gupta page 304, left column, 2nd and last paragraphs; present description page 4, line 13; US '061, column 16, lines 25-27). Consistent with this, the background of D1 also states that high osmolarity causes a stress on the immature embryos which in turn triggers development and maturation (see paragraph 3);
- "[M]aturation has not been achieved for embryos immersed in liquid medium" (Gupta, page 305, right hand column) and immature conifer embryos are therefore typically developed by placing them on top of absorbent pads situated above the surface of development medium (Gupta, page 306, left hand column; present description page 2, lines 18-20; US '061, column 21, lines 17-22);
- "[T]issue culture as a whole is a highly unpredictable science. This statement has even greater applicability to somatic embryogenesis" (US '061 column 26, lines 11-13).

The Problem and Solution

[16] According to the Background of the Invention there are problems in the art which generally relate to "stimulating efficient formation of viable somatic embryos that are capable of germinating to yield plants" (page 2, lines 3-4) and there is a "continuing need for methods for producing viable conifer somatic embryos" (page 2, lines 8-9).

[17] Unlike commonly known liquid-based methods that rely on disposing immature embryos on top of an absorbent pad, the Summary of the Invention indicates that the inventors have "discovered that a porous membrane, such as a nylon membrane, can be used to support plant tissue during the development phase of plant somatic embryo production" (page 2, lines 10-12). Unlike an absorbent pad, a non-absorbent

membrane is "sufficiently strong to resist tearing when the membranes are lifted in order to transfer somatic embryos from the development stage to subsequent stages of the somatic embryo production process" (page 2, lines 21-24). The skilled person would understand the inventors to be asserting that the development of conifer embryos on a non-absorbent membrane is an improvement over known methods, given that the various stages in the production process require many weeks to complete and that the provision of a support that remains strong and stable throughout this time would be desirable. The Examples of the description (pages 10-15) show that viable, cotyledonary, conifer embryos can in fact develop when disposed directly on non-absorbent membranes and that the use of absorbent pads can be dispensed with.

[18] Therefore, considering the problem, the specification and the CGK, the solution proposed by the inventors is an improved method for developing conifer, cotyledonary embryos using liquid medium by disposing the embryos on an upper surface of a porous, non-absorbent membrane.

Essential Elements of the Claims

[19] Claim 1 is representative of the 11 claims on file and includes three steps:

> 1. A method for developing conifer, cotyledonary, somatic embryos, the method comprising the steps of
>
> (a) disposing conifer pre-cotyledonary somatic embryos on an upper surface of a porous membrane wherein the porous membrane does not absorb liquid development medium;
>
> (b) intermittently contacting the lower surface of the porous membrane with liquid development medium wherein the liquid development medium wets a portion of each somatic embryo disposed on the porous membrane but does not completely immerse the somatic embryos in liquid development medium; and
>
> (c) culturing the conifer pre-cotyledonary somatic embryos on the porous membrane for a period of time sufficient to develop conifer, cotyledonary, somatic embryos from the pre-cotyledonary somatic embryos.

[20] In the first step of the claimed method, pre-cotyledonary embryos are "disposed" on "an upper surface of a porous membrane". The skilled person would view this as essential since it cannot be substituted or omitted in achieving the solution identified at paragraph 18. This step, in the context of the specification, would be further understood by a person skilled in the art to mean that embryos are disposed on the upper surface of, and supported by, the membrane. As mentioned above, the solution provided by the present application is to provide a method to develop embryos on the upper surface of a porous, non-absorbent membrane. Moreover, the examples in the description disclose the direct disposal of developing embryos on the surface of a non-absorbent nylon membrane and conclude that "good quality (zygotic-like) embryos developed" (page 15, line 21).

[21] Although the term "membrane" in the context of a biological system can often refer to a thin selectively

permeable layer, in this application the skilled person would instead understand that it refers to a type of physical support upon which the embryos are developed.

[22] The term "membrane" is used in the present application to refer to fully permeable materials which "can be used to support plant tissue during the development phase of plant somatic embryo production" (page 2, lines 11-12). In Figure 1, which shows a representative system for carrying out the claimed methods, the porous membrane is a thin nylon screen suspended above a bath of liquid medium. As mentioned above at paragraph 17, the description states that the membrane should be sufficiently strong and stable to prevent tearing when membranes are lifted to different stages of the production process. Therefore, an informed consideration of the whole of the specification, including the description and drawings, indicates to the skilled person that the expression "porous membrane wherein the porous membrane does not absorb liquid development medium" means a thin screen capable of supporting growing embryos, which is sufficiently strong to resist tearing, with sufficiently sized pores to allow liquid medium to freely flow through and, unlike commonly used pads, having no ability to absorb or hold said medium.

[23] The skilled person would consider a non-absorbent, porous membrane to be essential because the solution to the problem requires that the membrane be both non-absorbent and porous. The membrane must also be porous to allow the liquid medium to reach the developing embryos disposed on its surface.

[24] The use of liquid development medium would also be understood by the skilled person to be essential because it is required for embryo development. This element is common to both the first and second steps of the claimed method. As mentioned above at paragraph 15 cotyledonary development of conifer embryos commonly requires the use of liquid development medium that has high osmolarity and which triggers embryo maturation.

[25] In the second and third steps of the claimed method the embryos are partially wetted, but not immersed, until the cotyledonary stage is reached. Because there is no absorbent pad between the embryos and the liquid development medium the embryos are exposed directly to the medium rather than via an absorbent pad. This partial wetting of the embryos would be understood by the skilled person to be essential since immersion of embryos prevents cotyledonary development, as outlined above at paragraph 15.

[26] Taking the above into account we find that the skilled person would find the following elements of claim 1 essential:

1) Disposing conifer, pre-cotyledonary, somatic embryos on the upper surface of a membrane that is porous and non-absorbent;

2) The use of liquid development medium; and

3) The partial-wetting of embryos for sufficient time to produce cotyledonary conifer embryos.

Does D1 disclose all essential elements?

[27] We will now consider whether the essential elements are disclosed and enabled by D1.

[28] The prior art cited by the Examiner is EP1063881 (D1), published on January 3, 2001; which is before the claim date of the present application. Recall from paragraph 15 above that the use of high osmolarity liquid development medium was thought to impose a stress on the embryos that in turn induces cotyledonary development. In general, D1 is focussed on alternative means for inducing this stress in maturing conifer embryos; namely through the use of solid medium with very high levels of gelling agent or through the use of thick supports which take up and hold liquid and which physically separate embryos from non-conventional normal-osmolarity liquid medium. Both of these methods induce stress by limiting the availability of water to developing embryos.

[29] The methods of D1 which involve using high levels of gelling agent in solid medium are not relevant to the analysis because the proposed solution concerns liquid-based methods.

[30] Although D1 does disclose other conifer embryo supports for use in liquid culture, the skilled person would find these supports to be functionally and materially different from the porous, non-absorbent membranes of claim 1. In D1 these supports are used for physically separating the growing embryos from the liquid medium by a distance that restricts the availability of liquid to said embryos. This separation is achieved by using a thick support that extends from the bottom of a container of liquid medium to a desired distance above the surface of the medium (see Figures 2 and 3). The liquid medium reaches the embryos only by being absorbed through the support. That is, it must work its way, by capillary action, through the thick internal matrix of the support. At paragraph 97, D1 describes the supports as being made from "foam material". Although the precise type of "foam" is not disclosed, the skilled person would view these supports as thick absorbent blocks and not similar to the porous, non-absorbent membranes of claim 1. Also, the use of conventional high-osmolarity medium in these methods is not taught.

[31] The Supplemental Analysis does point (at page 5, lines 3-7) to one example in D1 in which a porous, non-absorbent membrane is used in combination with liquid medium. This example is summarized in Table 12. However, in this example the embryos are not disposed on the upper surface of a porous, non-absorbent membrane. Instead the embryos are disposed on an absorbent membrane which is in turn placed on a non-absorbent support. The Supplemental Analysis makes note of this, stating that in Table 12 of D1 "data are provided for development of spruce embryos *on filter paper* which was placed on a nylon screen of 500 um pore size over liquid medium" (emphasis added).

[32] It is evident from the above analysis that D1 does not disclose disposing conifer, cotyledonary, somatic embryos on the upper surface of a membrane that is porous and non-absorbent, which is the first essential element of claim 1 identified above at paragraph 30. As mentioned above at paragraph 11, if a prior art publication fails to disclose all essential elements of the claimed invention then it cannot be anticipatory. Since D1 fails to disclose an essential element of claim 1, we can conclude on this basis that claim 1 is not anticipated by D1.

[33] Claim 10 is the only other independent claim on file. It is directed to the same method of developing conifer,

cotyledonary, somatic embryos as claim 1, but adds two steps at the beginning of the method. These steps are necessary for producing the pre-cotyledonary embryos used in the later steps. As such, claim 10 shares all of the essential elements identified for claim 1. It must also, therefore, not be anticipated by D1. Since claims 2-9 and 11 are dependent on claims 1 and 10, respectively, they also share the above essential element and are not anticipated by D1.

Conclusion

[34] Claims 1-11 are not anticipated by D1.

ARE THE CLAIMS NONETHELESS OBVIOUS?

[35] Although not raised in the Final Action or Summary of Reasons, for the sake of completeness we will also consider whether the claims are obvious in view of D1.

[36] Section 28.3 of the *Patent Act* sets out the information that may be considered in assessing whether a claim is obvious:

> 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.

[37] A four-step approach for assessing obviousness was set out by the Supreme Court in *Sanofi* as follows:

> (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?

Analysis under the Sanofi Four-Step Approach

Step 1: Identify the notional "person skilled in the art" and the common general knowledge of that person

[38] The skilled person and their CGK have already been identified above at paragraphs 13-15.

Step 2: Identify the inventive concept of the claim in question or if that cannot readily be done, construe it

[39] The present description states on page 2 that "there is a continuing need for methods for producing viable conifer somatic embryos from conifer embryogenic cells." The summary of the invention goes on to describe that efficient formation of somatic embryos that are capable of germinating to yield plants can be achieved by disposing conifer embryos on the upper surface of a porous and non-absorbent membrane.

[40] According to the description, the developing somatic embryos are disposed on the upper surface of a porous, non-absorbent membrane which is then contacted with liquid development medium. The porous membrane provides a stable support that is resistant to tearing when the membranes are lifted in order to transfer somatic embryos from the development stage to subsequent stages of the somatic embryo production process. As noted above at paragraph 17, the skilled person would view this as an improvement over conventional methods which dispose embryos on absorbent pads.

[41] Therefore, it is apparent from a reading of the specification as a whole that the inventive concept of the independent claims is an improved method for developing conifer, cotyledonary embryos using liquid medium by disposing the embryos on the upper surface of a porous, non-absorbent membrane.

Step 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.

[42] As we established in our analysis under anticipation, the cited reference D1 does not disclose the essential element of disposing embryos on the upper surface of a porous membrane that does not absorb liquid development medium. It would appear then that the difference between D1 and the inventive concept is that the claimed invention requires disposing conifer embryos on the upper surface of a porous non-absorbent membrane.

Step 4: 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?

[43] As mentioned above in the anticipation analysis, D1 is generally concerned with somatic cloning methods that employ solid medium or use a combination of thick foam blocks with non-conventional normal-osmolarity liquid medium. As such these disclosures are not relevant to the present claims which involve liquid medium and thin, porous, non-absorbent membranes. However, as pointed out in the Supplemental Analysis, Table 12 of D1 discloses a method of developing embryos on an absorbent filter paper support which was held on a non-absorbent nylon screen.

[44] As mentioned previously, commonly known methods of somatic cloning involved the growing of embryos directly on absorbent pads. In that respect, the method disclosed in Table 12 of D1, therefore, is similar to CGK methods. In fact it is used in D1 to compare the performance of the new solid medium methods to the established CGK method. However, D1 does not suggest that the absorbent filter paper support upon which embryos are disposed in Table 12 could be removed and the embryos then grown directly on the nylon screen beneath. Moreover, given the CGK that tissue culture methods as a whole are highly unpredictable, and somatic cloning methods even more so (see paragraph 15 above), the skilled person would not have been led by D1, in light of their CGK, to remove the absorbent support and attempt to develop embryos directly on a nylon screen. We therefore conclude that the claims are not obvious because the skilled person would have required a degree of ingenuity to arrive at the inventive concept of the claims.

Conclusion

[45] The claims are not obvious in view of D1 and the CGK of the skilled person.

ISSUE 2: ARE CLAIMS 1-11 SUPPORTED BY THE DESCRIPTION?

[46] 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.

[47] In finding that claims 1-11 do not comply with section 84 of the *Patent Rules* the Final Action states that "spraying or atomizing of the liquid medium onto the underside of the porous membrane is an essential feature of the alleged invention and consequently, must be incorporated in the claims".

[48] It is our view that the skilled person would find that the feature of spraying or atomizing of the liquid medium onto the underside of the porous membrane is simply one of several possible means disclosed in the application for contacting the embryos with liquid medium. In fact, it appears only to be a secondary means as the description affords considerably more emphasis on the system described on pages 5-7, and used in Example 3, which employs a pump to fill a chamber with liquid medium up to a level equal with the bottom of the porous membrane. Moreover, none of the exemplified embodiments make use of spraying or atomizing means. We find that, based on the description, the feature of spraying or atomizing of the liquid medium onto the underside of the porous membrane is not essential, and that the claims are fully supported by the description.

Conclusion

Claims 1-11 are not defective with respect to section 84 of the *Patent Rules*.

RECOMMENDATION OF THE BOARD

[49] We recommend that the rejection be withdrawn and the application proceed to allowance in accordance with subsection 30(6.2) of the *Patent Rules*.

Michael O'Hare	Ed MacLaurin	Christine Teixeira
Member	Member	Member

DECISION OF THE COMMISSIONER

[50] I concur with the findings and the recommendation of the Board. In accordance with subsection 30(6.2) of the *Patent Rules*, the rejection of the application is withdrawn and the application is to proceed to allowance.

Sylvain Laporte

Commissioner of Patents

Dated at Gatineau, Quebec,

this 5th day of February, 2015