

IN THE CANADIAN PATENT OFFICE

DECISION OF THE COMMISSIONER OF PATENTS

Patent application 471,056 having been rejected under Rule 47(2) of the Patent Regulations, the Applicant asked that the Final Action of the Examiner be reviewed. The rejection has consequently been considered by the Patent Appeal Board and by the Commissioner of Patents. The findings of the Board and the ruling of the Commissioner are as follows:

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COMMISSIONER'S DECISION SUMMARY

C.D. 1171... App'n 471,056

(B20), (F00)

Excessive Width of Claims and Lacking Novelty

The amended claim serves to differentiate the microorganism claimed from the microorganism as it exists in nature. Also the evidence submitted, particularly the fact that two other bacteria of the genus Alteromonas were found using the methods disclosed in the application, was persuasive that the three criteria used by the Supreme Court in Monsanto Co. v. Commissioner of Patents, 42 C.P.R. (2d) 161 in determining whether the description of a few members of a group entitled claims to the whole group. Rejection modified.

This decision deals with the Applicant's request for review by the Commissioner of Patents of the Final Action on application serial number 471,056 (Class 195-34.7), assigned to Research Corporation. The application is entitled "INDUCTION OF SETTLEMENT AND METAMORPHOSIS IN CRASSOSTREA VIRGINICA BY MELANIN-SYNTHESIZING BACTERIA AND OTHER DERIVATIVE METABOLIC PRODUCTS", and the inventors are R.M. Weiner, R.R. Colwell, D.B. Bonar and S.L. Coon. The Examiner issued a Final Action on January 24, 1990 refusing claims 1, 5, 11, 16, 24, 30 and 35 for being broad in view of the teachings of the disclosure and claim 1 for failing to distinguish the microorganism claimed from that as it exists in nature. The applicant further requested an oral hearing for the purposes of presenting verbally applicant's position.

Claims 1, 5 and 11 read:

1. A melanin-synthesizing marine bacterium of the genus *Altermonas* and mutants of said bacterium capable of inducing the settlement and metamorphosis of Crassostrea virginica larvae.

5. A method for inducing the settlement and metamorphosis of Crassostrea virginica larvae comprising exposing said larvae in an aqueous medium to melanin-synthesizing marine bacteria or to metabolic products of said bacteria.

11. In a method for producing DOPA by bacteria, the improvement comprising culturing melanin-synthesizing marine bacteria of the genus *Altermonas* in a growth medium to produce said DOPA as a metabolic product of said bacterium.

The other rejected claims are of the same format as claim 11 but relate to the production of acid polysaccharide exopolymer, melanin, tyrosine and tyrosinose respectively.

In response to the Final Action and to further communication with the Patent Office the applicant presented arguments and modified claims.

Modified claims 1 and 5 now read:

1. A biologically pure culture of a melanin-synthesizing marine bacterium of the genus *Alteromonas* and mutants of said bacterium capable of inducing the settlement and metamorphosis of Crassostrea virginica larvae.

5. A method for inducing the settlement and metamorphosis of Crassostrea virginica larvae comprising exposing said larvae in an aqueous medium to melanin-synthesizing marine bacteria of the genus *Alteromonas*, or to mutants thereof, or to metabolic products of said bacteria.

The remaining claims remain as prior to the Final Action.

The issue before the Board is whether a) the arguments and/or b) the amendments satisfy the objection raised by the Examiner in her Final Action.

In her Final Action the Examiner stated (in part):

...

Moreover, in claim 1, applicant is required to further define the marine bacterium of the genus Altermonas as being a "biologically pure culture" to distinguish the microorganism claimed from the microorganism as it exists in nature.

...

Claims 1, 5, 11, 16, 24, 30 and 35 are rejected as being broad in view of the teachings of the disclosure. Amendment is required under Rule 25 of the Patent Rules in order to specify that the melanin-synthesizing marine bacteria is Altermonas colweilliensis, ATCC numbers 33887, 33888 and 39565.

Applicant's alleged invention relates to a melanin-synthesizing marine bacterium, Altermonas colweilliensis and variants and mutants thereof. The bacterium is alleged to elaborate certain metabolic products (for example, dihydroxyphenylalanine, (DOPA), melanin, tyrosine, tyrosinose and a polysaccharide exopolymer) which function as oyster larvae attractants. As such, the bacterium via the metabolic products is useful in inducing the settlement and metamorphosis of the oyster, Grassostrea virginica larvae.

Applicant's discovery of one species of Altermonas said to be capable of inducing settlement and metamorphosis of C. virginica, does not entitle applicant to all species of this genus, known or unknown. Had applicant taught several species of Altermonas, he would be entitled to a broad claim to that genus.

The disclosure lacks support for species of Altermonas other than A. colweilliensis, ATCC numbers 33887, 33888 and 39565.

In his amendment of July 11, 1989, applicant made reference to Monsanto vs. the Commissioner of Patents (Supreme Court) 42 C.P.R. 161. It is submitted that this decision is not applicable to the present case.

The Monsanto decision related to a class of chemical compounds wherein it was held that a sound prediction could be made for a group of di-imido chemical compounds whose physical data was not provided in the disclosure. Claims to these compounds was based on three specific compounds that were fully characterized and supported by the disclosure, and differed from the former in the substituents on a given moiety. The Monsanto case was for a pioneer invention in an unexplored field of chemical compounds useful as inhibitors of premature vulcanization of rubber.

...

In response to the Final Action the applicant states (in part):

... at page 2 thereof

In the action, the Examiner has also requested amendment to claim 1 to specify that the bacterium of the genus Alteromonas is a "biologically pure culture"; applicant would agree with this requested amendment and for the purposes of this appeal, it is respectfully requested that amended claim 1 be entered. To this end, a new page of claims (in duplicate) containing claim 1 is submitted herewith.

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The applicant would like to point out that claim 1, and the others involved, is in fact a specific type of claim directed only to certain specific features commensurate with the scope of the invention. An analysis of the claim (that is claim 1) will show that this claim has the following features:

(a) that it is only for a melanin-synthesizing marine bacterium which is a biologically pure culture;

(b) that the claim is only directed to such bacterium which are of the genus Alteromonas (and mutants thereof); and

(c) that the only claim is to bacterium of the genus Alteromonas (and mutants thereof) which are capable of inducing the settlement of and metamorphosis of C. virginica larvae.

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From the above analysis of claim 1, it will be seen that this claim is quite specific in that only bacterium of one single genus are being claimed and amongst those bacterium only those which have the characteristic of being capable of inducing the settlement of the defined larvae are included in the scope of the claim. The claim does not extend to other genres nor does it extend to even those members of the genus Alteromonas which do not have the feature of the present invention.

Claim 1 and the other claims under rejection, are clearly supported by the disclosure. Page 4, lines 20 et. seq. specifically teach that the disclosure relates to the class of bacteria which are species of Alteromonas; page 5, lines 1 to 4 clearly state that the invention relates to a melanin-synthesizing marine bacterium which is capable of performing certain functions; etc.

The disclosure clearly exemplifies various examples of the genus Alteromonas (as discussed hereinafter in greater detail; the three examples which are shown are clearly taught as being only preferred embodiments of the invention. These examples show that three different bacterium, which are abbreviated as LST, DIP and HYP, are specifically taught and can be employed in a process for inducing the settlement and metamorphosis of Crassostrea virginica larvae.

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The Appeal Board's attention is directed to the decision held in the Supreme Court of Canada case of Monsanto Co. v. Commissioner of Patents, 42 C.P.R. (2d) 161 at 171 et. seq. wherein it is indicated that where disclosure in the specification is insufficient for a layman, i.e. one lacking skill in the art, it may very well be sufficient for one skilled in the art.

Attached to this submission is an Affidavit by Dr. R. Weiner and it is respectfully requested that it be entered as part of this submission. With respect to the sworn statements of this affiant, attention is respectfully directed to Dr. Weiner's profession, namely, that of a Professor of Microbiology; thus Dr. Weiner is qualified as "a person skilled in the art to which this invention pertains".

As will be noted from Dr. Weiner's affidavit, he has stated that "I have discovered that several members of the genus Alteromonas have the characteristics contemplated by the present invention. In particular, this includes the production of metabolic products ... associated with metabolism and exopolymer synthesis. These organisms are Alteromonas, and like A. colwelliana exhibit the ability to induce the settlement and metamorphosis of Crassostrea virginica larvae. Using methods disclosed in the Specification for identification of A. colwelliana (see Specification, Page 26, Table 1), I have found that two other melanin-synthesizing bacteria of the genus Alteromonas, A. hanedai (ATCC No. 33224) and A. nigrifaciens (ATCC No. 23327) each synthesize PAVE, which also plays an important role in inducing settlement and metamorphosis of C. virginica".

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The leading case of authority in this area is that of Monsanto v. Commissioner of Patents, supra, pages 161 et. seq.; it is a Supreme Court decision dealing specifically with the identical issues raised by the Examiner in this application.

The decision involving the Monsanto application under Rule 25 dealt with a di-imido compound in which there were a large number of substituents attached to the basic moiety; the question addressed by the Supreme Court was whether, having regard to the preparation of three compounds taught in the disclosure, the product claims including broad claim 9 (encompassing a generic class of compounds) and a subgeneric claim 16 (listing one hundred and twenty-six species) was adequately supported and whether the invention which was taught could be said to be fairly described in the disclosure having regard to the scope of the claims.

Another specific issue in the Monsanto case was whether the product species, which is not specifically described and exemplified in the specification, could be claimed.

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Turning now to the specifics of the Monsanto decision in the Supreme Court, the majority decision of the Court dealt with issues relating to (i) "conclusions as to prediction"; (ii) whether a person skilled in the art could prepare the compounds claimed based on the teachings of the patent application; and (iii) evidence of lack of utility.

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Clearly, this Supreme Court decision in Monsanto has found that it is essential that before a patent is to be considered invalid, it is a matter of fact and law that some or all of the claims containing compounds would not have utility.

In the present instance, there is not one piece of evidence put forth by the Examiner, nor is there any evidence in the file, that there is any bacterium, which has no utility, within the scope of the present invention and claims and conversely, there is no evidence of inutility for the corresponding process and method of use claims rejected by the Examiner.

As noted in the Supreme Court decision, page 173 of C.P.R., the Supreme Court held that it appeared to the Court that the lower Court had completely overlooked "... the rule that a patent specification is addressed to a person 'skilled in the art'". In the Monsanto decision, an affidavit was put before the Patent Office and in that affidavit, a person skilled in the art attested to the fact that by following the teachings of the specification, one could prepare all of the described compounds even though specific directions were given for three or less compounds.

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Clearly, there is a complete and proper teaching of the invention to one skilled in the art, which is fully supported throughout the disclosure and not only is fully supported, but also is fully exemplified by sufficient examples to enable such person skilled in the art to which the present invention appertains to fully practice the invention in its broadest scope.

In addition, the Affidavit Dr. Ronald Weiner, a person skilled in the art, has further emphasized and confirmed that the teachings of the present disclosure enable one skilled in the art to fully practice the present invention. As Dr. Weiner has attested to, the present invention is applicable to those bacterium of any of the species of Alteromonas which are capable of inducing the settlement and metamorphosis of Crassostrea virginica larvae.

... at page 23

Applicant respectfully requests the Board to consider what evidence there is on record relative to the Examiner's statement. On one hand, there are the teachings of the application which, as noted above, clearly say that those bacterium and only those bacterium of the genus Alteromonas which are melanin-synthesizing marine bacterium are those which are claimed in accordance with the invention to have the utility described in the disclosure and that it has been "surprisingly discovered" that those bacterium have such utility. There is also the evidence of the Affidavit of record by Dr. Ronald Weiner. Conversely, there is absolutely no evidence to the contrary; the Examiner has only made a flat statement not supported by any prior art nor any other type of evidence which would go towards establishing a case of non-utility as required by the Supreme Court in the Monsanto decision.

... at page 36

The decision of Rouleau, J. of the Federal Court, is extremely similar on the points in issue here to the decision in Monsanto v. Commissioner of Patents. Once again, the facts addressed are evidence for the lack of utility and "sound and reasonable" predictions thereof, which in both cases were held to be insufficient grounds to deny an applicant a patent. As previously stated herein, the Examiner has not provided any evidence for inutility of any bacterium within the scope of the invention and secondly, the case is devoid of such evidence to corroborate the rejected process and method claims, and the Affidavit submitted herewith clearly establishes the soundness of prediction and utility.

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It must further be pointed out in this respect that if the Examiner's statements were correct, then not only in biological cases such as the present one, but also in every mechanical case where an applicant disclosed one embodiment or a broader "means" could not claim anything but the specific one embodiment described and exemplified in the specification.

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Moreover, the Examiner further appears to be misconstruing Rule 25 as applied to the specific embodiments of an application. There is absolutely no requirement whatsoever, in Section 34, that each and every embodiment embraced within the broader invention must be exemplified before it can be claimed. The examples of an application are only that - they are examples of certain preferred compounds or preferred mechanical means within the broader context of the invention. There is not one decision, or one section in the Act or Rules, which contemplates that an applicant has to set out a whole genus as an example - if so, this would mean that even mechanical patents would run to hundreds of pages of disclosure as would chemical patents, by the time that every mechanical component or every bacterium or compound forming part of the invention was exemplified.

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The rejection of claim 1 for failing to distinguish from the microorganism as it exists in nature no longer holds as the applicant has introduced the qualifier "biologically pure culture" to said claim; this point needs no more consideration here.

The rejection of claims 1, 5, 11, 16, 24, 30 and 35 needs further consideration in view of the affidavit submitted by the co-inventor Dr. Weiner and in view of the jurisprudence dealing with Rule 25 of the Patent Rules and Section 34 of the Patent Act.

In his affidavit Dr. Weiner submits that using methods disclosed in the specification for identification of A. colwelliana he found two other bacteria of the genus Alteromonas meeting the characteristics of the organisms that are the subject of the rejected claims.

The Board accepts applicant's view of the applicability of Monsanto Co. v. Commissioner of Patents, 42 C.P.R. (2d) 161 to the present case. The Supreme Court considered three criteria in determining whether in fact the description of a few members of a group entitled claims to the whole group: (i) conclusions as to prediction; (ii) whether a person skilled in the art could prepare the compounds claimed based on the teachings of the patent application; and (iii) evidence of lack of utility. Regarding criterion (i) the Board is satisfied that no evidence or arguments have been submitted to support a rejection on lack of predictability. Although it is true that biological systems are highly variable and not as predictable as say mechanical systems it does not follow that all biological systems are

totally unpredictable and follow no particular rhyme or reason. The fact is that biological systems are complex and are acted upon by their environment in a complex fashion. However the patent field is replete with examples of how biological systems have predictably been used in industrial processes. The production of a variety of products by a variety of organisms leads one to conclude that it is not wholly unpredictable that families of organisms exist or can be made to exist to carry out a particular function or produce a particular product.

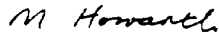
The second criterion is certainly met by the submission of Dr. Weiner's affidavit. There is no question that Dr. Weiner is skilled in the art and he was able to find organisms comparable to those of the rejected claims using the teachings of the disclosure.

The third criterion is met by the formulation or language of the claims. Each claim in fact incorporates a statement of utility and thus useless embodiments are clearly excluded. Each organism covered by the claims must a) be a member of the genus Alteromonas, b) be a melanin-synthesizer, and c) either induce the settlement and metamorphosis of Crassostrea virginica oyster or product a specified metabolic product.

We recommend the acceptance of the claims as amended as a result of the Final Action and of further discussion with the Board.



F.H. Adams
Chairman
Patent Appeal Board

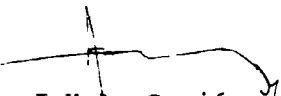


Dr. M. Howarth
Member
Patent Appeal Board



A. Legris
Member
Patent Appeal Board

I concur with the findings and the recommendation of the Board. Accordingly I remand the application to the examiner for prosecution consistent with the findings of the Board.



J.H.A. Gariépy
Commissioner of Patents

Dated at Hull, Quebec
this 7th day of February 1992

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