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Paper No. 47

PAT.&T.M. OFFICE
BOARD OF PATENT APPEALS
AND INTERFERENCES
UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte RAYMOND S.C. WONG, WALLACE D. BEVERSDORF,
JAMES R. CASTAGNO, IAN GRANT AND JAYANTILAL D. PATEL

Appeal No. 93-3238
Application 07/286,708¹

ORDER REMANDING TO EXAMINER AND
VACATING NOTICE OF ORAL HEARING

On June 17, 1994, a Notice of Hearing was entered scheduling an oral hearing for August 4, 1994 (Paper No. 45). However, it is noted that on May 17, 1993, the applicant filed a timely Reply Brief (Paper No. 43). It is also noted that the Primary Examiner prepared a response to the Reply Brief (Paper No. 44). It is not apparent from the record whether this response was mailed as no mail date appears on the cover sheet of the response and the date of entry on the file is unclear.

¹ Application for patent filed December 20, 1988.

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Accordingly, it is

ORDERED that the Notice of Hearing is vacated, and
it is

FURTHER ORDERED that the application is remanded to the
Examiner for consideration of the Reply Brief, appropriate
handling of the response or for such further action as may be
appropriate.

The application, by virtue of its "special" status, requires
immediate action. See Manual of Patent Examining Procedure,
§ 708.01(d). It is important that the Board of Patent Appeals
and Interferences be informed promptly of any action affecting
the appeal.

BOARD OF PATENT APPEALS
AND INTERFERENCES

By:


MERRELL C. CASHION, JR.
Program and Resource Administrator

cc: Benton S. Duffett, Jr.
The George Mason Building
Washington & Prince Streets
P.O. Box 1404
Alexandria, VA 22313-1404

THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

The opinion in support of the decision being entered today
(1) was not written for publication in a law journal and
(2) is not binding precedent of the Board.

Paper No. 61

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte RAYMOND S. C. WONG,
WALLACE D. BEVERSDORF,
JAMES R. CASTAGNO, IAN GRANT,
and JAYANTILAL D. PATEL

MAILED

OCT 15 1996

Appeal No. 93-3238
Application 07/286,708¹

PAT.&T.M. OFFICE
BOARD OF PATENT APPEALS
AND INTERFERENCES

HEARD: March 7, 1996

Before WILLIAM F. SMITH, JOHN D. SMITH, and WEIFFENBACH,²
Administrative Patent Judges.

WILLIAM F. SMITH, Administrative Patent Judge.

DECISION ON APPEAL

¹ Application for patent filed December 20, 1988. According to appellants, the application is a continuation-in-part of Application 07/140,139, filed December 31, 1987.

² Administrative Patent Judges Goldstein and Turner participated in the oral hearing in this case but retired from the Patent and Trademark Office before this decision was rendered. They were replaced by Administrative Patent Judges William F. Smith and Weiffenbach. See In re Bose Corp., 772 F.2d 866, 869, 227 USPQ 1, 4 (Fed. Cir. 1985).

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This is an appeal from the final rejection of claims 1-4, 6-12, 14-20, 22-28, 30-34, 36-40, and 42-68, all the claims remaining in this case.

Claims 1, 17, 32, 44, and 54-56 are illustrative of the subject matter on appeal and read as follows:

1. A substantially homogeneous assemblage of mature rapeseeds, capable of yielding an endogenous vegetable oil of increased stability when exposed to heat, having (1) an oil which exhibits following crushing and extraction an unusually high oleic acid content of at least 80 percent by weight based upon the total fatty acid content wherein said oleic acid content is controlled by genetic means for the expression of such trait resulting from a mutation induced by man followed by selection, and (2) an oil which exhibits following crushing and extraction a erucic acid content of no more than 2.0 percent by weight based on the total fatty acid content.

17. A substantially uniform stand of rape plants which upon self-pollination are capable of forming rapeseeds which yield an endogenous vegetable oil of increased stability when exposed to heat, said rapeseeds having (1) an oil which exhibits following crushing and extraction an unusually high oleic acid content of at least 80 percent by weight based upon the total fatty acid content wherein said oleic acid content is controlled by genetic means for the expression of such trait resulting from a mutation induced by man followed by selection, and (2) an oil which exhibits following crushing and extraction a erucic acid content of no more than 2.0 percent by weight based on the total fatty acid content.

32. An improved endogenous vegetable oil of increased stability when exposed to heat extracted from rapeseeds formed on said rape plants of step (d) of Claim 44, said rapeseeds having (1) an oil which exhibits following crushing and extraction an unusually high oleic acid content of at least 80 percent by weight based upon the total fatty acid content, (2) an oil which exhibits following crushing and extraction a erucic acid content of no more than 2.0 percent by weight based on the total fatty acid content, and (3) an oil which exhibits following crushing

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and extraction an alpha-linolenic acid content of less than 5 percent by weight based upon the total fatty acid content.

44. A method for enhancing the oleic acid content of rapeseeds comprising:

- (a) subjecting in at least one generation cells derived from a rapeseed plant which forms rapeseeds having an endogenous oleic acid content in the oil of less than 80 percent by weight based on the total fatty acid content to a technique selected from the group consisting of gamma irradiation, contact with a chemical mutagen, and a combination of the foregoing, in order to induce mutagenesis with respect to the increased production of oleic acid,
- (b) regenerating said cells to produce a rape plant and to form rapeseeds in at least one generation subsequent to that of step (a),
- (c) selecting a rapeseed produced in step (b) which has an endogenous oleic acid content in the oil following crushing and extraction of at least 80 percent by weight based upon the total fatty acid content, and
- (d) producing rape plants in a subsequent generation derived from said selection of step (c) having substantial genetic homogeneity and forming rapeseeds thereon which contain an endogenous oil which exhibits following crushing and extraction an oleic acid content of at least 80 percent by weight based upon the total fatty acid content wherein said oleic acid content is controlled by genetic means for the expression of such trait resulting from such mutagenesis.

54. A substantially homogeneous assemblage of rapeseeds according to Claim 1 wherein said genetic means for the expression of said unusually high oleic acid content is derived from FA 677-39.

55. A substantially homogeneous assemblage of rapeseeds according to Claim 1 wherein said genetic means for the expression of said unusually high oleic acid content is derived from FA677M5-132.

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The claims stand rejected under 35 U.S.C. § 103 as being unpatentable over the following combinations of references:

1. Claims 1-4, 6-12, 14-20, 22-28, 30-34, 36-40, 42-45, 48, and 50-68 over the teachings of Rakow, Robbelen, Stefansson, and any one of Pleines I, Pleines II or Pleines III.

2. Claims 46 and 47 over the teachings of Rakow, Robbelen, Stefansson, any one of Pleines I, II or III, and Sparano.

3. Claim 49 over the teachings of Rakow, Robbelen, Stefansson, any one of Pleines I, II or III, and King.

We reverse and make a new rejection under 37 CFR § 1.196(b).

Background

A. Procedural

This case is on appeal before the Board for the second time. See the decision on appeal in Appeal No. 92-2093, dated March 27, 1992, Paper No. 26. The presently claimed subject matter is the same as the subject matter of the previous appeal, and the rejections on appeal find their basis in a new ground of rejection by the previous merits panel. Appellants have submitted substantial evidence in rebuttal of the new ground of rejection. Thus, the merits of the rejection must be

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reconsidered in light of all the evidence of record. In re Piasecki, 745 F.2d 1468, 1472, 223 USPQ 785, 788 (Fed. Cir. 1984).

B. Technical

The instant claims are drawn to improved rapeseed oil, rapeseeds, and rape plants, as well as a method of making improved rapeseeds. Rapeseed oil (also known as canola oil) is the third most widely used vegetable oil in the world (specification, page 1, lines 5-11). Researchers have worked for many years to improve the quality of rapeseed oil. Among the notable successes of these research efforts have been the development of "double-low" rapeseed varieties which produce oil having low levels of erucic acid and glucosinolate (specification, page 1, lines 23 to 29) and varieties which produce oil having low amounts of alpha-linolenic acid (specification, page 3, line 19 to page 4, line 2).

The rapeseeds that are the subject of this appeal are said to be distinct from previous rapeseeds in that the content of oleic acid in the claimed rapeseeds is at least 80%. Previously existing rapeseeds had oleic acid contents of 70% or less (see the Declaration of Ian Grant, Paper No. 27, paragraphs no. 12 and 15). The increased oleic acid content of the claimed

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rapeseed oil increases the stability of the oil to heat and thereby prolongs its useful life in applications such as frying (specification, page 21, last two lines to page 22, line 4). Oils with a high content of monounsaturated fatty acids such as oleic acid are also considered healthier than oils high in saturated or polyunsaturated fatty acids (specification, page 4).

Appellants created the claimed rapeseeds by exposing rapeseeds to known mutagens (gamma irradiation and/or ethylnitrosourea), then screening the resulting mutants for those with seeds having increased oleic acid content. Specification, pages 11-12 and 16-27.

Appellants' mutagenesis using gamma irradiation (Example I) produced a mutant plant having seeds with 85% oleic acid content, but this plant "was lost in the next generation through raceme breakage in the greenhouse" (specification, page 20, lines 17-18). The highest content of oleic acid in a propagated rape variety in the gamma irradiation mutagenesis was 79.2% (specification, page 21). This variety was designated FA 677-39, and samples of the seeds were deposited with the American Type Culture Collection (ATCC) (specification, page 22).

Appellants further mutagenized seeds of the FA 677-39 line, using the chemical mutagen ethylnitrosourea (specification, pages

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22-24). One of the plants resulting from the second round of mutagenesis was found after self-pollination to produce seeds with an oleic acid content of 81.9%. This variety was designated FA677M5-132, and also was deposited with the ATCC (specification, pages 23-24).

In a third mutagenesis experiment, appellants subjected a prior art variety of rapeseeds (Topas), having an oleic acid content of 65%, to mutagenesis with ethylnitrosourea. Of the 10,000 seeds mutagenized, one grew into a plant that, after self-pollination, produced seeds having an oleic acid content of 81.17%. This variety was designated Topas H6-90, and also was deposited with the ATCC (specification, page 26). The Topas H6-90 variety was subjected to additional selection, resulting in a variety that produced seeds having an oleic acid content of 85.84%. This variety was designated Topas H6-90-99, but was not deposited.

Discussion

All three of the obviousness rejections on appeal rely on a similar rationale and therefore we will consider the three rejections together. As understood, the basis of the rejections is that it would have been obvious to a person of ordinary skill in the art to subject the high-oleic acid rape varieties taught

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by Pleines (I, II or III) to either conventional plant breeding techniques (taught by Stefansson and Robbelen) or to known mutagenic treatments (taught by Sparano and King) and screen the resulting rape plants (as taught by Rakow) in order to make and isolate the claimed rape varieties. According to the examiner, since the rape varieties taught by Pleines contained up to 79% oleic acid, those skilled in the art would reasonably have expected that conventional breeding and/or mutagenesis would have resulted in variants having at least 80% oleic acid.

Appellants argue that the rejections are improper because (1) the references by Pleines are not enabling, and therefore the starting material of the posited experimental program was not publicly available, and (2) plant breeding and mutagenesis are highly unpredictable, and therefore those skilled in the art would not have had a reasonable expectation of success. Appellants have submitted declaratory evidence to support their arguments.

In support of their position that the disclosures of Pleines are not enabling, appellants have submitted declarations stating that those skilled in the art would have had available to them rapeseed varieties having oleic acid contents ranging only from 55% to 70% (declarations submitted May 20, 1992 of Konrad Kraling

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(paragraph 9), Ian Grant (paragraph 12), Jayantilal Patel (paragraph 12), and Wallace Beversdorf (paragraph 14)). The declarations also state that the inventors conducted an extensive screening of known rape varieties to identify those with the highest content of oleic acid and found no varieties with oleic acid content higher than 70.6% despite screening in excess of 100,000 samples (Grant declaration of May 20, 1992, paragraph 15); that the information provided by Pleines was inadequate to enable those skilled in the art to replicate the research described therein (Kraling, Grant, Patel and Beversdorf declarations of May 20, 1992, paragraphs 12, 17, 15 and 17, respectively); that the authors of Pleines did not fulfill a request for samples of the disclosed rape variety (Grant declaration of May 20, 1992, paragraph 20); and that the specific strains disclosed by Pleines were never publicly available and no longer exist (Kraling declaration of December 21, 1992, paragraphs 9 and 10).

In support of their position that those skilled in the art would not have had a reasonable expectation of succeeding in the posited research, appellants have submitted declarations stating that it "was not possible to modify with any degree of predictability a predetermined plant trait in a predetermined

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direction by mutagenesis of any type" (Kraling, Grant, Patel and Beversdorf declarations of May 20, 1992, paragraphs 16, 22, 19, and 21, respectively); that those skilled in the art "regarded mutagenesis of all types to be random in nature and highly unpredictable" (Kraling, Grant, Patel and Beversdorf declarations of May 20, 1992, paragraphs 17, 23, 20 and 22, respectively); that the disclosure of the claimed rape varieties was received with "overwhelming praise" by those skilled in the art (Patel declaration of May 20, 1992, paragraph 24); that because of the complexity of genetic inheritance in plants, a given example of modification of a specific trait to a specific degree by mutagenesis would not lead those skilled in the art to expect that other traits could be modified to a predetermined degree by mutagenesis (Kraling, Grant and Beversdorf declarations of December 21, 1992, paragraphs 12, 12, and 11, respectively); and that "mutagenesis generally was recognized to be highly unpredictable" (Kraling, Grant and Beversdorf declarations of December 21, 1992, paragraphs 15, 15, and 14, respectively).

The requirements of 35 U.S.C. § 103 have been explained many times by the Court of Appeals for the Federal Circuit.

Where claimed subject matter has been rejected as obvious in view of a combination of prior art references, a proper analysis under § 103 requires, inter alia, consideration of two factors: (1) whether

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the prior art would have suggested to those of ordinary skill in the art that they should make the claimed composition or device, or carry out the claimed process; and (2) whether the prior art would also have revealed that in so making or carrying out, those of ordinary skill would have a reasonable expectation of success. Both the suggestion and the reasonable expectation of success must be founded in the prior art, not in the applicant's disclosure.

In re Vaeck, 947 F.2d 488, 493, 20 USPQ2d 1438, 1442 (Fed. Cir. 1991), citing In re Dow Chemical Co., 837 F.2d 469, 473, 5 USPQ2d 1529, 1531 (Fed. Cir. 1988).

"[O]bvious to try is not the standard of 35 USC 103." In re Antonie, 559 F.2d 618, 620, 195 USPQ 6, 8 (CCPA 1977) (emphasis in original).

The admonition that "obvious to try" is not the standard under § 103 has been directed mainly at two kinds of error. In some cases, what would have been "obvious to try" would have been to vary all parameters or try each of numerous possible choices until one possibly arrived at a successful result, where the prior art gave either no indication of which parameters were critical or no direction as to which of many possible choices is likely to be successful. In others, what was "obvious to try" was to explore a new technology or general approach that seemed to be a promising field of experimentation, where the prior art gave only general guidance as to the particular form of the claimed invention or how to achieve it.

In re O'Farrell, 853 F.2d 894, 903, 7 USPQ2d 1673, 1681 (Fed. Cir. 1988) (citations omitted).

Here, appellants' evidence of the unpredictability of plant breeding and mutagenesis show that the rejections on appeal fall

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into the second category of "obvious to try" rejections that the O'Farrell court cautioned against: those in which the prior art would have made it obvious to "explore a . . . general approach that seemed to be a promising field of experimentation," id., but where the prior art provided no specific guidance on making the particular invention claimed. The references cited by the examiner show that plant breeding and induced mutagenesis of rape plants were well known techniques at the time the invention was made. The references also show that increasing the oleic acid content of rapeseeds was a desirable goal. Where the cited references fall short in meeting the legal standard of obviousness is in providing those skilled in the art with a reasonable expectation that applying these known techniques to known and available varieties of rape would produce the desired goal. None of the cited references shows the application of plant breeding techniques or induced mutagenesis to reliably and predictably produce rapeseeds having an oleic acid content of 80% or more. In fact, none of the references show production of rapeseeds having greater than 80% oleic acid content by any means.

Appellants' declaratory evidence convincingly establishes that no plant breeding or mutagenesis experiment could be so

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predictable. Viewed in light of appellants' unrebutted evidence of unpredictability, it is apparent that the obviousness rejections of record are founded on a rationale that:

1) mutagenesis produces variability, and 2) if one screens enough mutants, one is likely to find a mutant with the desired variation. This degree of predictability does not meet the "reasonable expectation of success" which is required in order to reach a conclusion of obviousness under § 103.

In addition, we hold that appellants' evidence shows that none of the Pleines references relied upon by the examiner provides an enabling disclosure. Appellants' evidence shows that the specific strains disclosed by Pleines were never publicly available, and that the experimental protocols disclosed by Pleines could not have been followed by those skilled in the art with a reasonable expectation of reproducing the results disclosed by Pleines. Thus, the record shows that those skilled in the art did not have available to them rape varieties which produced seeds having 79% oleic acid content. On the contrary, the available rape varieties available at the time the invention was made had oleic acid contents no greater than 70%. See, e.g., the May 20, 1992 Grant declaration, paragraph 12.

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Thus, to the extent the examiner's position is premised on the predictability of increasing oleic acid content in a rapeseed variety by just one percent (see appellants' summary of the examiner's statements, pages 5-6 of the Reply Brief), that position does not lead to a conclusion of obviousness since the evidence of record, considered as a whole, establishes that the needed starting material, a rape variety having an oleic acid content of 79%, was not available. Since appellants' evidence shows that the results of mutagenesis are highly unpredictable, a person skilled in the art would not have reasonably expected that mutagenesis of a prior art rape variety producing seeds with 70% oleic acid would result in a variety producing seeds having greater than 80% oleic acid.

New grounds of rejection.

Under the provisions of 37 CFR § 1.196(b), we make the following new grounds of rejection.

A.

Claims 1-4, 6-12, 14-20, 22-28, 30-34, 36-40, 42-53, and 63-68 are rejected under 35 U.S.C. § 112, first paragraph, as not being fully enabled by the specification.

As set forth in In re Vaeck, 947 F.2d at 495, 20 USPQ2d at 1444 (Fed. Cir. 1991):

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The first paragraph of 35 U.S.C. § 112 requires, inter alia, that the specification of a patent enable any person skilled in the art to which it pertains to make and use the claimed invention. Although the statute does not say so, enablement requires that the specification teach those in the art to make and use the invention without "undue experimentation." In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). That some experimentation may be required is not fatal; the issue is whether the amount of experimentation required is "undue." Id. at 736-37, 8 USPQ2d at 1404 (emphasis in original).

The court considered the issue of undue experimentation in In re Wands, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988) stating:

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in Ex parte Forman, [230 USPQ 546, 547 (Bd. Pat. App. Int. 1986)]. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims (footnote omitted).

Id. at 737, 8 USPQ2d at 1404.

In considering this issue, the following statement by the court in Vaech, 947 F.2d at 496, 20 USPQ2d at 1445, must be kept in mind:

[W]e do not imply that patent applicants in art areas currently denominated as "unpredictable" must never be allowed generic claims encompassing more than the particular species disclosed in their specification. It is well settled that patent applicants are not required to disclose every species encompassed by their

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claims, even in an unpredictable art. In re Angstadt, 537 F.2d 498, 502-03, 190 USPQ 214, 218 (CCPA 1976). However, there must be sufficient disclosure, either through illustrative examples or terminology, to teach those of ordinary skill how to make and how to use the invention as broadly as it is claimed. This means that the disclosure must adequately guide the art worker to determine, without undue experimentation, which species among all those encompassed by the claimed genus possess the disclosed utility. (emphasis in original, footnote omitted).

Thus, the first paragraph of 35 U.S.C. § 112 requires that the scope of the claims be commensurate with the scope of the enabling disclosure. Here, the claims read on products and methods involving rapeseeds having any oleic acid content greater than 80%. The record shows that the specification does not provide adequate guidance to enable a person of ordinary skill in the art to practice the full scope of the claimed invention without undue experimentation.

The specification provides several examples of rapeseeds having oleic acid contents greater than 80%. Specifically, examples are provided of rapeseeds having oleic acid contents of 85.0% (page 20), 81.9% (page 23), 81.17% (page 26), and 85.84% (page 27). However, the exemplary rape varieties producing seeds having 85% or greater oleic acid are not enabled by the specification.

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The first such example, FA 677, is disclosed to have been "lost in the next generation through raceme breakage in the greenhouse" (specification, page 20, first full paragraph). There is no evidence of record that seeds of the FA 677 variety were deposited prior to loss of the plant through raceme breakage.

The second, Topas H6-90-99, is disclosed to have been derived by "[f]urther selection within the M3 generation of Topas H6-90" (specification, page 26, last paragraph). The record contains no evidence that seeds of the Topas H6-90-99 strain have been deposited. Although seeds of the Topas H6-90 variety, from which the selection was done that resulted in Topas H6-90-99, have been deposited with the American Type Culture Collection (ATCC), there is no evidence in the record that the ATCC deposit contains seeds comparable to those which gave rise to Topas H6-90-99. In other words, appellants' success in selecting a higher oleic acid producing variety from within the Topas H6-90 variety indicates that some variation in oleic acid content exists in Topas H6-90, but how much variation exists, and how much of the potential variability is represented in the seeds deposited with the ATCC, is impossible to determine. The record does not support a conclusion that Topas H6-90-99 or the

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equivalent could be selected from the sample of Topas H6-90 deposited with the ATCC.

The other two examples of rapeseeds within the instant claims are enabled by deposit of the seeds: FA677M5-132 (81.9% oleic acid; specification, pages 23-24) and Topas H6-90 (81.17% oleic acid; specification, page 26).³ Thus, the highest oleic acid percentage that is enabled by deposit of a specific exemplification is 81.9%.

In regard to the enablement of embodiments beyond those exemplified, appellants have shown that the effect of mutagenesis on the oleic acid content of rapeseeds is completely unpredictable. See, e.g., paragraphs 22 and 23 of the May 20, 1992 Grant declaration (it "was not possible to modify with any degree of predictability a predetermined plant trait in a predetermined direction by mutagenesis of any type"; those skilled in the art "regarded mutagenesis of all types to be random in nature and highly unpredictable"). See also paragraph 15 of the December 21, 1992 Grant declaration ("mutagenesis generally was recognized to be highly unpredictable"). These statements are supported by substantially

³ A third deposited variety, FA677-39, falls outside the scope of the invention because its seeds have an oleic acid content of only 79.2%. Specification, pages 21-22.

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the same statements in the Kraling, Beversdorf and Patel declarations filed May 20, 1992 and December 21, 1992. See also page 18 of the Appeal Brief, "[t]he results achievable with mutagenesis are recognized by those of ordinary skill in plant technology generally to be random in nature and highly unpredictable. Mutagenesis would have been expected to impact across the entire genome of a plant which is enormous in an [sic] substantially uncontrollable manner" (emphasis in original).

Thus, the record shows that mutagenesis is inherently unpredictable, and therefore the demonstration that a given mutagenic treatment created a given phenotype from a given starting material in one experiment is of little, if any, value in predicting the results of repeating the experiment. Thus, appellants' exemplification of rape varieties having oleic acid contents of more than 80% cannot be taken to mean that the work described could be repeated in order to obtain the same results.

Considering the Forman factors, then, we find that the guidance and working examples provided by the specification, as well as the high level of skill in the art, are outweighed by the unpredictability of the effect of mutagenesis on rapeseed oleic acid content. In addition, this unpredictability makes the

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quantity of experimentation that would be required to produce a rape variety with the recited characteristics a complete unknown; and the claims are so broad that they read on any rape variety having seeds with an oleic acid content greater than 80%, up to and including 100% oleic acid. On this record, we hold that the specification fails to provide adequate guidance to enable practice of the full scope of the claimed invention without undue experimentation.

A similar situation was presented in In re Fisher, 427 F.2d 833, 166 USPQ 18 (CCPA 1970). The claim at issue in Fisher was drawn to a hormone preparation "containing at least 1 International Unit of ACTH per milligram", id. at 835, 166 USPQ at 20, similar to the recitation in the claims on appeal of "an unusually high oleic acid content of at least 80 percent." The court considered that

[t]he issue thus presented is whether an inventor who is the first to achieve a potency of greater than 1.0 for certain types of compositions, which potency was long desired because of its beneficial effect on humans, should be allowed to dominate all such compositions having potencies greater than 1.0, including future compositions having potencies far in excess of those obtainable from his teachings plus ordinary skill.

Id. at 839, 166 USPQ at 23-24. Similarly here, the issue is whether appellants should be granted a patent which would allow

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them to dominate all future rape varieties and rapeseed oil having oleic acid contents greater than 80%.

The Fisher court concluded that an inventor

must not be permitted to achieve this dominance by claims which are insufficiently supported and hence not in compliance with the first paragraph of 35 U.S.C. 112. That paragraph requires that the scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art. . . . In cases involving unpredictable factors, such as most chemical reactions and physiological activity, the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved. In the present case we must conclude, on the record before us, that appellant has not enabled the preparation of ACTHs having potencies much greater than 2.3, and the claim recitations of potency of 'at least 1' render the claims insufficiently supported under the first paragraph of 35 U.S.C. 112.

Id. at 839, 166 USPQ at 24.

Here, as we have stated repeatedly, the record shows that creation of new varieties of rape through mutagenesis is highly unpredictable. Due to this unpredictability, the scope of appellants' enabling disclosure is limited by the rape varieties which have been deposited with the ATCC. Based on the present disclosure, we hold here, as the court held in Fisher, that appellants should not be allowed to dominate all rapeseed varieties having oleic acid contents above 80%, when their

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specification does not enable practice of the full range of claimed products.

We find appellants' evidence of unpredictability especially probative of the non-enablement of the method claims 44-53, 63, and 68. Appellants have declared that it "was not possible to modify with any degree of predictability a predetermined plant trait in a predetermined direction by mutagenesis of any type" and that those skilled in the art "regarded mutagenesis of all types to be random in nature and highly unpredictable" (e.g., the Grant declaration of May 20, 1992, paragraphs 22 and 23, respectively); that a given example of modification of a specific trait to a specific degree by mutagenesis would not lead those skilled in the art to expect that other traits could be modified to a predetermined degree by mutagenesis and that "mutagenesis generally was recognized to be highly unpredictable" (e.g., the Grant declaration of December 21, 1992, paragraphs 12 and 15).

Based on appellants' own evidence, it is clear that mutagenesis is inherently unpredictable, and the possible or likely phenotypes of the resulting mutants cannot be predicted beforehand. It is therefore clear that the mere demonstration that a given mutagenic treatment created a given phenotype from a given starting material is of no value in predicting the results

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of repeating the experiment. Thus, appellants' exemplification of rape varieties producing seeds having greater than 80% oleic acid cannot be taken to mean that a person skilled in the art, reproducing exactly the work described in the specification, would be likely to obtain the same results.

This unpredictability is demonstrated by the experiments described in the specification. When appellants mutagenized using gamma irradiation, they obtained mutants producing seeds having up to 85% oleic acid (specification, page 20) but this mutant plant was lost in the next generation. The gamma irradiation experiment is disclosed to have resulted in variety FA677-39, seeds of which were deposited, but which produced seeds with an oleic acid content of only 79.2%.

Only when the plants resulting from the gamma irradiation experiment were subjected to further mutagenesis with a chemical mutagen did the oleic acid content of the seeds exceed 80%. The experimental results disclosed in the specification support appellants' declarations of the unpredictability of mutagenesis. In light of the record, the results of the method described in claims 44-53, 63 and 68 are so unpredictable that a person of ordinary skill in the art could not practice the method with a reasonable expectation of achieving any given result, including

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increasing oleic acid content, and therefore the claimed method is not enabled by the specification.

B.

Claims 54, 57, and 60 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite.

Claims 54, 57 and 60 are drawn to rapeseeds, rape plants and oil having oleic acid contents greater than 80%, where the "genetic means for the expression of said unusually high oleic acid content is derived from FA 677-39." However, the specification shows that oil derived from the seeds of variety FA 677-39 has an oleic acid content of only 79.2%, not 80% as required by the instant claims.

The intended meaning of the "derived from" language of the instant claims is unclear, but to the extent that the claims are intended to encompass seeds, plants, and oil from rape variety FA 677-39, the oleic acid content recited by the claims is inconsistent with the properties of FA 677-39 disclosed in the specification.

The claims should be amended to clarify their intended meaning and to ensure that the claims are consistent with the specification. "[D]uring patent prosecution when claims can be amended, ambiguities should be recognized, scope and breadth of

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language explored, and clarification imposed." In re Zletz, 893 F.2d 319, 321 USPQ2d 1320, 1322 (Fed. Cir. 1989). In view of the court's observation in In re Moore, 439 F.2d 1232, 1235, 169 USPQ 236, 238 (CCPA 1971) that enablement issues cannot be reached until the metes and bounds of a claim have been determined, we have not included these claims in the enablement rejection supra. However, if these claims are determined to be definite in the future, the examiner should revisit the issue of enablement.

Other Issues

Our review of the file wrapper of this case shows that the claimed invention has never been searched in the class and subclass(es) where vegetable oils per se are classified. If the claims drawn to rapeseed oil are subject to further prosecution, the examiner should search all relevant subclass(es) and commercial data bases. In addition, the examiner should consider whether oil from sources other than rapeseed would read on the instant oil claims. We note in this regard that vegetable oils with greater than 80% oleic acid content are known in the prior art. See, e.g., U.S. Patent No. 4,743,402 (claiming sunflower oil with greater than 80% oleic acid).

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In considering this issue the examiner should take into account that "[W]here the Patent Office has reason to believe that a functional limitation asserted to be critical for establishing novelty in the claimed subject matter may, in fact, be an inherent characteristic of the prior art, it possesses the authority to require the applicant to prove that the subject matter shown to be in the prior art does not possess the characteristic relied on." In re Best, 562 F.2d 1252, 1254-55, 195 USPQ 430, 433 (CCPA 19977), quoting In re Swinehart, 439 F.2d 210, 212-213, 169 USPQ 226, 229 (CCPA 1971).

Any request for reconsideration or modification of this decision by the Board of Patent Appeals and Interferences based upon the same record must be filed within one month from the date of the decision (37 CFR § 1.197). Should appellants elect to have further prosecution before the examiner in response to the new rejection under 37 CFR § 1.196(b) by way of amendment or showing of facts, or both, not previously of record, a shortened statutory period for making such response is hereby set to expire two months from the date of this decision.

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No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

REVERSED; 37 CFR § 1.196(b)

William F. Smith
WILLIAM F. SMITH
Administrative Patent Judge)
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John D. Smith
JOHN D. SMITH
Administrative Patent Judge)
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Cameron Weiffenbach
CAMERON WEIFFENBACH
Administrative Patent Judge)
)
)

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Burnes, Doane, Swecker & Mathis
George Mason Bldg.
Washington & Prince Streets
P.O. Box 1404
Alexandria, VA 22313-1404