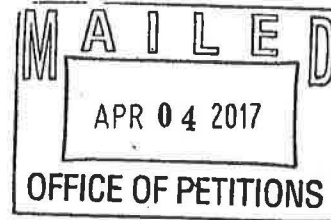




UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov



RICHARD ARON OSMAN
530 Lawrence Expy # 332
Sunnyvale CA 94085

In re Application of
Markus Pauly et al.
Application No. 14/123,482
International Filing date: June 1, 2012
For: PLANTS WITH ELEVATED LEVELS
OF GLUCAN

DECISION ON PETITION

This is a decision on the petition filed on February 12, 2017, which is being treated as a petition under 37 CFR 1.181, requesting that the Director exercise her supervisory authority and overturn the decision of the Director of Technology Center 1600 (Technology Center Director) mailed on January 27, 2017, which decision refused petitioners' request for withdrawal of the finality of the Office action of December 7, 2016 and entry of the reply filed on December 14, 2016.

The petition to withdraw the finality of the Office action of December 7, 2016 and enter the reply filed December 14, 2016 is **GRANTED**.

RELEVANT BACKGROUND

The above-identified application was filed as an international application under the Patent Cooperation Treaty (PCT) on June 1, 2012 (PCT/US2012/040544). A preliminary amendment was filed on December 2, 2013 (subsequent to entry of the above-identified application into the national stage as to the United States) canceling claims 12 through 27 and claims 32 through 49.

A non-final Office action (restriction requirement) was mailed on July 14, 2016. The non-final Office action of July 14, 2016, required restriction between Group I (Claims 1 through 11 and 28) drawn to a plant and Group II (claims 29 through 31) drawn to a method of increasing levels of a glucan in a plant.

A reply to the Office action of July 14, 2016, was filed on September 21, 2016. The reply of September 21, 2016 included an election of Group II and amendments to the claims. The reply of September 21, 2016 specifically canceled claims 1 through 11 and 28 through 31, and added new claims 50 through 69. Claims 50 and 52 as added in the reply of September 21, 2016 read as follows—

Claims 50: A method of increasing levels of glucan in a plant, comprising:

growing a plant comprising a mutant licheninase gene, wherein:

the licheninase gene is a mutant candy leaf-1 (Cal-1; (1,3; 1,4)- β -glucanase; Glycosylhydrolase family 17; genetic locus in maize: Chr. 6: GRMZM2G137535) licheninase gene comprising a mutation which results in decreased licheninase activity compared with a wild-type gene, and

the plant is selected from the group consisting of maize (corn, *Zea mays*), barley (*Hordeum vulgare*), rice (*Oryza sativa*), sorghum (*Sorghum bicolor*), foxtail millet (*Setaria italica*), sugar cane (*Saccharum* spp.), wheat (*Triticum* spp.), soy (*Glycine* sp.), cotton (*Gossypium* sp.), sugar beet (*Beta vulgaris*), sunflower (*Helianthus* sp.), miscanthus (*Miscanthus* sp.), giant miscanthus (*Miscanthus giganteus*), rape (*Brassica napus*), grass (*Poaceae* sp.), switchgrass (*Panicum virgatum*), giant reed (*Arundo donax*), reed canary grass (*Phalaris arundinacea*), sericea lespedeza (*Lespedeza cuneata*), millet (*Panicum miliaceum*), ryegrass (*Lolium* sp.), timothy-grass (*Phleum* sp.), kochia (*Kochia* sp.), kenaf (*Hibiscus cannabinus*), bahiagrass (*Paspalum* sp.), bermudagrass (*Cynodon dactylon*), pangolagrass (*Digitaria decumbens*), bluestem grass (*Andropogon* sp.), indiangrass (*Sorghastrum* sp.), bromegrass (*Bromus* sp.), elephant grass (*Pennisetum purpureum*), jatropha (*Jatropha* sp.), alfalfa (*Medicago* sp.), clover (*Trifolium*), sunn hemp (*Crotalaria juncea*), fescue (*Festuca* sp.), orchard grass (*Dactylis* sp.), purple false brome (*Brachypodium distachyon*), sesame (*Sesamum indicum*), poplar (*Populus trichocarpa*), spruce (*Picea* sp.), pine (*Pinuceae* spp.), willow (*Salix* sp.), eucalyptus (*Eucalyptus* sp.), castor oil plant (*Ricinus communis*), and palm tree (*Arecaceae* sp.), or a grass, such as maize, wheat, rice, sorghum, and switchgrass.

Claim 52: The method of claim 50, wherein the plant is maize.

A non-final Office action was mailed on October 26, 2016. The non-final Office action of October 26, 2016 included, *inter alia*: (1) a rejection of claims 50 through 67 under 35 U.S.C. § 101 as being directed to non-statutory subject matter; (2) a rejection of claims 50, 51, 53, 54,

56, 57, 59, 60, 62, 63, 65, and 66 under 35 U.S.C. § 112, ¶ 2,¹ as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention; (3) a rejection of claims 50, 51, 53, 54, 56, 57, 59, 60, 62, 63, 65, 66, and 68 under 35 U.S.C. § 112, ¶ 1, for failing to comply with its enablement requirement; and (4) a rejection of claims 50 through 69 under 35 U.S.C. § 103 as being unpatentable over AHLOOWALIA (Ahloowalia and Maluszynski, 2001, *Euphytica* 118: 167-173) in view of STEWART (Stewart *et al.*, 2001, *Protein Engineering* 14: 245-253) and the sequence of the Licheninase-2 from *Z. ea may*s, GenBank Accession No. NP_001148461.1, published April 10, 2009.

A reply under 37 CFR 1.111 (a reply to a non-final Office action) to the Office action of October 26, 2016, including an amendment to the claims, was filed on October 29, 2016. The reply of October 29, 2016 specifically amended claim 50, cancelled claims 51 through 69, and added new claims 70 through 88. Claim 50 as amended in the reply of October 29, 2016 reads as follows—

50. A method comprising:

growing a plant comprising a mutant licheninase gene to produce a grown plant having elevated levels of glucan compared with a wild-type plant; and

subjecting plant material from the grown plant to a saccharification or fermentation process, wherein:

the licheninase gene is a mutant candy leaf-1 (Cal-1; (1,3; 1,4)- β -glucanase; Glycosylhydrolase family 17; genetic locus in maize: Chr. 6: GRMZM2G137535) licheninase gene comprising a mutation which results in decreased licheninase activity compared with a wild-type gene, wherein the plant is a maize plant, and the mutation is non-naturally occurring and is derived from non-natural mutagenesis.

A final Office action was mailed on December 7, 2016. The final Office action of December 7, 2016 included, *inter alia*, a rejection of claims 50, 70-82, 87, and 88 under 35 U.S.C. § 112, ¶ 1, for failing to comply with its enablement requirement.

A reply to the final Office action was filed on December 14, 2016. The reply of December 14, 2016 indicated that the Office action of December 7, 2016 should have been made non-final, and

¹ Section 4 of the Leahy-Smith America Invents Act (AIA) designated 35 U.S.C. § 112, ¶¶ 1 through 6, as 35 U.S.C. §§ 112(a) through (f), effective as to applications filed on or after September 16, 2012. *See* Pub. L. No. 112-29, § 4, 125 Stat. 284, 293-97 (2011). Since the above-identified application was filed before September 16, 2012, this decision refers to the pre-AIA version of 35 U.S.C. § 112.

included a declaration (under 37 CFR 1.132) and an amendment that canceled claims 50 and 70 through 88 and added new claims 89 through 108.

An advisory action was mailed on December 28, 2016. The advisory action of December 28, 2016, treated the reply of December 7, 2016 as a reply under 37 CFR 1.116 (an after final reply) and denied entry of the amendment filed with the reply of December 14, 2016 on the basis that it raised new issues requiring further consideration and/or search, and would not place the application in better form for appeal.

A petition was filed under 37 CFR 1.181 on December 30, 2016, requesting entry of the amendment, declaration, and response filed on December 14, 2016, on the basis that the Office action mailed December 7, 2016, was not properly made final because the examiner raised a new ground of rejection that was not necessitated by amendment.

The petition of December 30, 2016 was denied by the Technology Center Director in a decision mailed January 27, 2016.

The instant petition was filed on February 12, 2017, and requests supervisory review of the Technology Center Director's decision mailed on January 27, 2016, and again requests entry of the amendment, declaration, and response filed on December 14, 2016.

STATUTE AND REGULATION

35 U.S.C. § 132(a) states:

Whenever, on examination, any claim for a patent is rejected, or any objection or requirement made, the Director shall notify the applicant thereof, stating the reasons for such rejection, or objection or requirement, together with such information and references as may be useful in judging of the propriety of continuing prosecution of his application; and if after receiving such notice, the applicant persists in his claim for a patent, with or without amendment, the application shall be reexamined. No amendment shall introduce new matter into the disclosure of the invention.

37 CFR 1.113 provides that:

(a) On the second or any subsequent examination or consideration by the examiner the rejection or other action may be made final, whereupon applicant's, or for ex parte reexaminations filed under § 1.510, patent owner's reply is limited to appeal in the case of rejection of any claim (§ 41.31 of this title), or to amendment as specified in § 1.114 or § 1.116. Petition may be taken to the

Director in the case of objections or requirements not involved in the rejection of any claim (§ 1.181). Reply to a final rejection or action must comply with § 1.114 or paragraph (c) of this section. For final actions in an *inter partes* reexamination filed under § 1.913, see § 1.953.

(b) In making such final rejection, the examiner shall repeat or state all grounds of rejection then considered applicable to the claims in the application, clearly stating the reasons in support thereof.

(c) Reply to a final rejection or action must include cancellation of, or appeal from the rejection of, each rejected claim. If any claim stands allowed, the reply to a final rejection or action must comply with any requirements or objections as to form.

OPINION

Petitioners assert that the final Office action of December 7, 2017 contains a new ground of rejection not necessitated by an amendment. Petitioners specifically assert that: (1) the claims presented in the amendment of September 21, 2016 encompassed a mutant candy leaf gene in a plant selected from a list of plants; (2) the Office action of October 26, 2016 included a rejection under 35 U.S.C. § 112, ¶ 1, of a number of claims on the basis that the enablement provided in the specification did not extend to all possible plants, but did not include such a rejection of the claims limited to maize plants (claims 52, 55, 58, 61, 64, 67 and 69); (3) the reply of October 29, 2016 limited the claims to maize plants, since the dependent claims limited to maize plants were not subject to an enablement (or any) rejection under 35 U.S.C. § 112, ¶ 1; and (4) the Office action of December 7, 2016 rejected the claims (now limited to maize plants) under 35 U.S.C. § 112, ¶ 1. Petitioner argues that this new rejection under 35 U.S.C. § 112, ¶ 1, was not necessitated by an amendment as this rejection (if appropriate) was equally applicable to the claims limited to maize plants (claims 52, 55, 58, 61, 64, 67 and 69) as presented in the amendment of September 21, 2016. Petitioners contend that the inclusion of this new ground of rejection not necessitated by an amendment in the Office action of December 7, 2016 precludes it from being made final.

United States Patent and Trademark Office (USPTO) final action practice is set forth in section 706.07 of the Manual of Patent Examining Procedure (MPEP). MPEP § 706.07 provides in part that:

Before final rejection is in order a clear issue should be developed between the examiner and applicant. To bring the prosecution to as speedy conclusion as possible and at the same time to deal justly by both the applicant and the public, the invention as disclosed and claimed should be thoroughly searched in the first action and the references fully applied; and in reply to this action the applicant should amend with a view to avoiding all the grounds of rejection and objection.

Switching from one subject matter to another in the claims presented by applicant in successive amendments, or from one set of references to another by the examiner in rejecting in successive actions claims of substantially the same subject matter, will alike tend to defeat attaining the goal of reaching a clearly defined issue for an early termination, i.e., either an allowance of the application or a final rejection.

While applicant does not have the right to amend as often as the examiner presents new references or reasons for rejection, examiners should not make hasty and ill-considered final rejections. The applicant who is seeking to define his or her invention in claims that will give him or her the patent protection to which he or she is justly entitled should receive the cooperation of the examiner to that end, and not be prematurely cut off in the prosecution of his or her application.

The examiner should never lose sight of the fact that in every case the applicant is entitled to a full and fair hearing, and that a clear issue between applicant and examiner should be developed, if possible, before appeal. However, it is to the interest of the applicants as a class as well as to that of the public that prosecution of an application be confined to as few actions as is consistent with a thorough consideration of its merits.

MPEP § 706.07(a) specifically set forth the USPTO's second action final practice, and provides in part that:

Second or any subsequent actions on the merits shall be final, except where the examiner introduces a new ground of rejection that is neither necessitated by applicant's amendment of the claims, nor based on information submitted in an information disclosure statement filed during the period set forth in 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p). Where information is submitted in an information disclosure statement during the period set forth in 37 CFR 1.97(c) with a fee, the examiner may use the information submitted, e.g., a printed publication or evidence of public use, and make the next Office action final whether or not the claims have been amended, provided that no other new ground of rejection which was not necessitated by amendment to the claims is introduced by the examiner. See MPEP § 609.04(b). Furthermore, a second or any subsequent action on the merits in any application will not be made final if it includes a rejection, on newly cited art, other than information submitted in an information disclosure statement filed under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p), of any claim not amended by applicant or patent owner in spite of the fact that other claims may have been amended to require newly cited art. Where information is submitted in a reply to a requirement under 37 CFR 1.105,

the examiner may NOT make the next Office action relying on that art final unless all instances of the application of such art are necessitated by amendment.

Whether there is a new ground of rejection depends upon whether the basic thrust of a rejection has remained the same. *See In re Kronig*, 539 F.2d 1300, 1303 (CCPA 1976). A new ground of rejection may be present when a rejection relies upon new facts or a new rational not previously raised to the applicant. *See In re Biedermann*, 733 F.3d 329, 337 (Fed. Cir. 2013) (quoting *Leithem*, 661 F.3d at 1319).

The basic thrust of the enablement rejection in the final Office action of December 7, 2016 differs from the basic thrust of the enablement rejection in the Office action of October 26, 2016. The Office action of October 26, 2016 took the position that the specification did not provide enablement for producing all possible mutagenized plants that exhibit increased glucan levels while comprising a maize mutant licheninase gene which is a mutant candy leaf-1 (Cal-1, (1,3; 1,4)- β -glucanase, glycosylhydrolase family 17, genetic locus in maize is GRMZM2G137535 on chromosome 6), but that that the specification did provide enablement for increasing glucan levels in a maize plant. The final Office action of December 7, 2016 took the position that the specification did not provide enablement for producing all possible mutagenized maize plants that exhibit increased glucan levels while comprising any and all possible mutations in a maize licheninase gene which is a mutant candy leaf-1 (Cal-1, (1,3; 1,4)- β -glucanase, glycosylhydrolase family 17, genetic locus in maize is GRMZM2G137535 on chromosome 6), but that the specification did provide enablement for increasing glucan levels in a maize plant that comprises a Glu262Lys mutation in a maize Cal-1 T01 licheninase gene or a Glu242Lys substitution in a maize Cal-1 T02 licheninase gene. The rational that the specification is non-enabling for producing all possible mutagenized plants that exhibit increased glucan levels while comprising **any and all possible mutations in a maize licheninase gene** was not raised prior to the Office action of December 7, 2016. This new rational changed the basic thrust of the rejection of claim 50 under 35 U.S.C. § 112, ¶ 1, vis-à-vis the Office action of October 26, 2016. This change in position between the basic thrust of the enablement rejection in the Office action of October 26, 2016 and the basic thrust of the enablement rejection in the final Office action of December 7, 2016 amounts to a new ground of rejection. *See In re Waymouth*, 486 F.2d 1058, 1061 (CCPA 1973) (reliance upon a different feature or aspect of the claim in support of a rejection under 35 U.S.C. § 112, ¶ 1, held to constitute a new ground of rejection). Therefore, the rejection of claim 50 under 35 U.S.C. § 112, ¶ 1, for failing to comply with its enablement requirement, in the Office action of December 7, 2016, is considered a new ground of rejection.²

² The Office action (page 5) of December 7, 2016, notes that the rejection of claim 50 under 35 U.S.C. § 112, ¶ 1, for failing to comply with its enablement requirement, is “modified” from the rejections set forth in the Office action of October 26, 2016.

Claim 52 as presented in the amendment of September 21, 2016 is dependent upon independent claim 50, and if written in independent form would read as follows—

A method of increasing levels of glucan in a plant, comprising:

growing a plant comprising a mutant licheninase gene, wherein:

the licheninase gene is a mutant candy leaf-1 (Cal-1; (1,3; 1,4)- β -glucanase; Glycosylhydrolase family 17; genetic locus in maize: Chr. 6: GRMZM2G137535) licheninase gene comprising a mutation which results in decreased licheninase activity compared with a wild-type gene, and

the plant is maize.

Comparing claim 50 as amended in the reply of October 29, 2016 to claim 52 as presented in the amendment of September 21, 2016 (if written in independent form), which claim was not rejected under 35 U.S.C. § 112, ¶ 1, for failure to comply with its enablement requirement in the Office action of October 26 2016, yields the following—

A method [of increasing levels of glucan in a plant,] comprising:

growing a plant comprising a mutant licheninase gene *to produce a grown plant having elevated levels of glucan compared with a wild-type plant; and*

subjecting plant material from the grown plant to a saccharification or fermentation process, wherein:

the licheninase gene is a mutant candy leaf-1 (Cal-1; (1,3; 1,4)- β -glucanase; Glycosylhydrolase family 17; genetic locus in maize: Chr. 6: GRMZM2G137535) licheninase gene comprising a mutation which results in decreased licheninase activity compared with a wild-type gene, [and] *wherein the plant is a maize plant, and the mutation is non-naturally occurring and is derived from non-natural mutagenesis.*

The changes to claim 52 as presented in the amendment of September 21, 20016 (now incorporated into claim 50) in the reply of October 29, 2016 (*i.e.*, changing “increasing levels of glucan in a plant” to “to produce a grown plant having elevated levels of glucan compared with a wild-type plant,” and adding “subjecting plant material from the grown plant to a saccharification or fermentation process” and “the mutation is non-naturally occurring and is derived from non-natural mutagenesis”) are simply **not** related to the change in position in the rejection under 35 U.S.C. § 112, ¶ 1 (*i.e.*, that the specification does not provide enablement for any and all possible mutations in a maize licheninase gene, but only for a maize plant that comprises a Glu262Lys mutation in a maize Cal-1 T01 licheninase gene or a Glu242Lys substitution in a

maize Cal-1 T02 licheninase gene). Thus, the Office action of December 7, 2016 included a new ground of rejection of claim 50 under 35 U.S.C. § 112, ¶ 1, for failing to comply with its enablement requirement that was not necessitated by applicant's amendment of the claims (nor based on information submitted in an information disclosure statement filed during the period set forth in 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p)). Therefore, the finality of the Office action of December 7, 2016 is not consistent with the USPTO's final action practice set forth in MPEP § 706.07.

DECISION

For the previously stated reasons, the petition to withdraw the finality of the Office action of December 7, 2016 is **GRANTED**. The finality of the Office action mailed on December 7, 2016 is withdrawn.

This application is being returned to Technology Center 1600 for entry and action on the reply of December 14, 2016 (including the amendment and declaration) as a reply under 37 CFR 1.111 to the (now) non-final Office action of December 7, 2016.



Robert W. Bahr
Deputy Commissioner for
Patent Examination Policy