

ATTORNEYS AT LAW EUROPEAN PATENT ATTORNEYS

European Patent Office  
Erhardtstrasse 27  
80298 MÜNCHEN  
Duitsland

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ATTORNEYS AT LAW\*

Mr. P.P.J.M. Verhaag  
Mr. M.A.A. van Wijngaarden  
Mr. D.J. Straathof  
Mr. L.L. Huisman  
Mr. F.A. Mol

TRADEMARK & DESIGN  
ATTORNEYS

Mr. P.P.J.M. Verhaag  
Ms mr. M.M.A. Galama  
Ms J. Zandberg  
Ms mr. J.H. van Bommel  
Ms drs. D. van der Vloodt  
Mr. F. Bouman  
Ms mr. K. Keijzer

Consultants

Ir. P.N. Hoorweg  
Ir. C.W. Bruin

PATENT ATTORNEYS

Dr. ir. H.W. Prins  
Ir. B.J. 't Jong  
Ir. A.A.G. Land  
Mr. drs. A.J.W. Hooiveld  
Ir. E. Bartelds  
Ms drs. P.F.H.M.

Van Someren  
Ir. J.A.M. Grootcholten  
S. Duxbury B.Sc.

Ms ir. M.M.J. Tabelaing  
Ir. P.J. Hylarides  
Ir. B.J. 't Jong jr  
Ir. R. Vernout  
Ms. dr. A. Manten  
Mr. drs. M.A. de Baat  
Ms dr. ir. N.V.T.C.

D'Halleweyn  
Dr. A. van Kooij  
Ir. M.W.J.B. Sjaauw-En-Wa  
Mr. ir. M. Korsten  
Dr. ir. G.J.C. Verdijck  
Ir. R.J.G. Haan

P.O. BOX 18558, NL-2502 EN THE HAGUE, 16 January 2006

Our ref.: L/DU62/ps/4

Your ref.:

Re.: European patent no. 1185161 (appl. no. 00943766.6)

Proprietor: Consejo Superior de Investigaciones  
Cientificas

Opponent: Greenpeace e.V.

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On behalf of the proprietor I herewith file  
observations.

**Requests**

I request that the opposition is rejected and the patent  
be maintained as granted. As a first auxiliary request I  
herewith file a new claim 17 to replace claim 17 as  
granted. In this request the other claims are maintained  
in their form as granted.

In case the Opposition Division would envisage any  
other decision than maintaining the patent as granted  
Oral Proceedings are requested.

**Reasons for the requests**

*Claims 12, 13 and 18-25*

It is first of all noted that the opponent only attacks  
claims 1-11 and 14-17 and only on the basis of Article  
53(b) EPC. Claims 12, 13 and 18-25 relate to subject  
matter that is not touched by the exclusion of Article  
53(b). No other grounds for opposition are invoked. It  
is therefore submitted that in any case the claims 12,  
13 and 18-25 are to be maintained as granted.

THE HAGUE\*  
Sweelinckplein 1  
T: +31 (70) 365 48 33  
F: +31 (70) 345 21 40  
M: thehague@  
arnold-siedsma.com

ANTWERP  
Meir 24  
T: +32 (3) 213 59 60  
F: +32 (3) 213 59 65  
M: antwerp@  
arnold-siedsma.com

MUNICH  
Isartorplatz 5  
T: +49 (89) 22 38 88  
F: +49(89) 29 26 95  
M: munich@  
arnold-siedsma.com

./..

ALICANTE  
Explanada de España 2  
T: +34 (96) 52 02 174  
F: +34 (96) 52 02 298  
M: alicante@  
arnold-siedsma.com

*Plant varieties*

The opponents sole argument to claims 1-10 and 14-16 is that they relate to plant varieties. Claims 1-10 relate to seeds, not plants. It is assumed that the opponent's arguments are directed to plants that can be grown from these seeds. Below seeds and plants may thus be used interchangeably.

The opponents argument under Article 53(b) argument appears to be based on the definition of plant variety under Article 1(vi) of the UPOV Convention and used in decision G1/98, which states that:

*"a variety is inter alia defined by the expression of the characteristics resulting from a given genotype or combination of genotypes."*

The opponent has argued that the claimed features are the result of genetic and epigenetic features of the genotype and not of a single transferable technical feature or genetic building block. However, even if the claimed feature is the result of more than one genetic element or even the interplay of multiple genetic elements this still is not an indication that the claims relate exclusively to a variety.

Decision G1/98 has clearly stated that

*"the reference to the expression of the characteristics that results from a given genotype or combination of genotypes is a reference to the **entire constitution** of a plant or a set of genetic information. (emphasis added)"*

and:

*"In contrast, a plant defined by single recombinant DNA sequences is not an individual plant grouping to which an **entire constitution** can be attributed. It is not a concrete living being or grouping of concrete living beings but an abstract and open definition embracing an indefinite number of individual entities defined by **a part of its genotype** or by a property bestowed on it by that part." (emphasis added)*

Thus, in the definition of variety the entire genetic constitution or the complete genotype are to be considered. In case a trait is caused by only a part of the genotype the plant is not necessarily a variety, even if this part is more than one genetic element.

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Clearly, in the plants as presently claimed only **a part of the genotype** is responsible for the technical feature claimed. This technical feature can be bestowed upon many different varieties and the claim is thus not limited to varieties.

The technical feature claimed is a change in the fatty acid composition of the sunflower plant. The fact that only a part of the genotype is responsible for that feature follows from the genetic and biochemical data published about these sunflower mutants by the inventors.

Both parental lines of the plant seed protected in the patent were biochemically characterized. In the articles cited, the parent IG-1297M is identified as CAS-12. In both cases only a limited number of enzymes were found to be responsible for the claimed traits. See the article by Cantisán S, E Martínez-Force & R Garcés (2000) *Enzymatic studies of high stearic acid sunflower seed mutants*, Plant Physiol. Biochem. 38(5) 377-382. In the abstract it is said that:

*"two enzymatic activities are found to be involved in the mutant phenotype, the acyl-ACP thioesterase (EC 3.1.2.14) and the stearyl-ACP desaturase (EC 1.12.99.6). Our data suggest that the high stearic phenotype is due to the combined effect of a reduced stearyl-ACP desaturase activity and an acyl-ACP thioesterase with higher activity on stearyl-ACP".*

And in Martínez-Force E, R Álvarez-Ortega & R Garcés (1999) *Enzymatic characterisation of high-palmitic acid sunflower*, Planta 207, 533-538 it is said:

*"The enzymatic activities found to be responsible for the mutant characteristics are  $\beta$ -keto-acyl-acyl carrier protein synthetase II (KASII; EC 2.3.1.41) and acyl-acyl carrier protein thioesterase (EC 3.1.2.14). Our data suggest that the high-palmitic acid phenotype observed in both mutant lines is due to the combined effect of a lower KASII activity and a higher thioesterase activity with respect to palmitoyl-acyl carrier protein (16:0-ACP)."*

In the paper the inventors show a biochemical pathway for the synthesis of palmitoleic and asclepic acids on page 537. It follows therefrom that a discrete number of enzymes is involved in the new mutant trait.

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In the paper by Pérez-Vich B, R Garcés, JM Fernández-Martínez (2000) *Epistatic interaction among loci controlling the palmitic and stearic in the seed oil of sunflower*, Theor. Appl. Genet. 100, 105-111 it is shown that it is possible to reduce the level of palmitoleic acid by recombination of high-stearic and high palmitic mutant lines and that this is due to a limited number of genes, not the entire genome:

*"When F3 C16:0 segregating generations in both a high- and a low-C18:0 background were compared, the high-C16:1 levels were not expressed as expected in the high-C18:0 background (CAS-3 background). In this case, the C16:1 content decreased to values below 1.5%, compared with >5% in a low-C18:0 background."*

On page 110, figure 4b some segregating seeds with high palmitic and low palmitoleic are shown.

I furthermore file two papers about the study of the genetic control of high-palmitic showing that three genes control the trait and of the genetic control of high-stearic showing that two genes control the trait. Clearly, the fatty acid biosynthetic pathway involves only a limited amount of enzymes and is not dependent on the entire genetic constitution or the entire genotype of the sunflower.

In the abstract of the first paper by Serrano-Vega, MJ, E. Martínez-Force & R Garcés ((2005) *Lipid characterization of seed oils from high-palmitic, and very high-stearic acid sunflower lines*, Lipids 40, 369) the inventors say:

*"The new high-palmitic, low-palmitoleic lines CAS-18 and CAS-25, the latter on a high oleic background, have been selected from the high-stearic mutant CAS-3 by introducing a deficient stearic acid desaturase in a high-palmitic background from the previously developed mutant lines CAS-5 and CAS-12, respectively. As such, the desaturation of palmitic acid and the synthesis of palmitoleic acid and its derivatives (asclepic and palmitolinoleic acids) was reduced"*.

On the second page it is said:

*"For example, the introduction of the mutated SAD gene from the CAS-3 line into high-palmitic lines should reduce the amount of palmitoleic, asclepic, and palmitolinoleic acids that accumulate in the storage oil"*.

In the present invention the lower stearyl-ACP-desaturase gene from CAS-3 is introduced in the high-palmitic lines thus reducing the levels of palmitoleic and asclepic acids.

As shown in the above quotations, the trait as presently claimed is determined by a limited number of enzymes and genes encoding them and not by a complete genetic constitution. Moreover, these genes can be transferred to other sunflower lines. Thus, the invention does not claim a variety and is not limited to a variety but the teaching is applicable to plants in general. The exclusion of Article 53(b) EPC does not apply and it is requested that the opposition against claims 1-10 and 14-16 be rejected.

*Essentially biological processes*

Claim 11 is objected to as being an essentially biological process. Claim 11 is however not a process claim but a product-by-process claim. Such a claim comprises method steps but the claim as such is directed to a product, i.e. seeds. It has been shown above that the seeds as claimed are not plant varieties and consequently claim 11 is not a variety either.

The fact that the plant as claimed is obtainable by a process that comprises biological steps is only a matter of defining the plant as claimed. G1/98 has stated that a plant variety bred as a result of genetically modifying a particular plant variety is still excluded from patent protection, even if the genetic modification is the result of a biotechnological process. The opposite is of course also true. Subject matter that is patentable *per se* does not become unpatentable because it is made by an excluded process. It is nowhere in the EPC or in the case law stated that a product that is obtainable by a method that in itself may not be patentable would also not be patentable. It is thus requested to reject the opposition against claim 11.

Please note in this respect that the proprietor does not admit that the method of the "obtainable by"-clause of claim 11 would be excluded from patentability.

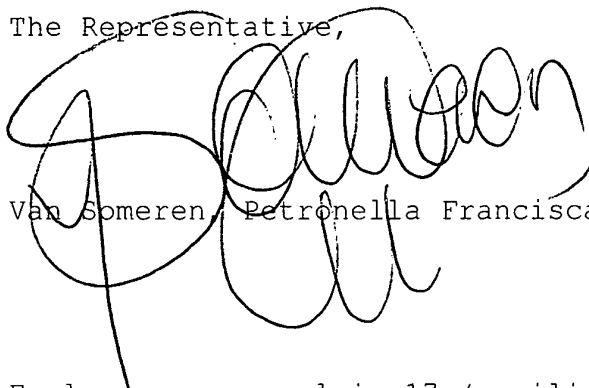
It is submitted that the parental lines of step a) in claim 17 inherently disclose a step of human intervention because they are the result of mutation,

as follows from the fact that they are called "mutant sunflower lines". However, as a first auxiliary request I herewith file a new claim 17 in which the mutation step is introduced.

**Conclusion**

From the above it follows that none of the claims 1-11 and 14-16 fall under the exclusion of Article 53(b) EPC, nor does claim 17. The opposition should thus be rejected.

The Representative,



Van Someren, Petronella Francisca Hendrika Maria

Enclosures: new claim 17 (auxiliary request)  
6 publications