

III. Food as the product directly obtained by a patented process

Food can also be protected under Art. 64(2) EPC, which extends the protection of a process patent to the product directly obtained by that process. Similarly, Art. 28(1(b) TRIPs Sec. 9(3) of the German Patent Act encompass the product directly obtained by a process under the scope of a patent on a process. The patent owner can forbid the unauthorized sale and use of the product directly obtained by a patented process in the same way as for a product patent.⁵⁵⁸

Article 64(2) EPC applies to all processes whose starting materials differ from the end-product.⁵⁵⁹ In that way a process for the production of a food also protects the food directly obtained by that process, e.g. a patent on a process for the production of a transgenic plant extends to the transgenic plant resulting therefrom. The question arises in how far processing of the product might influence this extension of patent protection. Does a patent on the production of herbicide-resistant soy bean comprise the oil processed from such soy beans?

This question will be investigated in the following section, beginning with the difference from product-by-process claims, followed by a theoretical analysis of the legal situation in Europe, and concluding with a case study on three food-related patents which differ in one important aspect: the presence of the essential parameter in the processed food product.

1. Comparison with the protection by product-by-process claims

The protection of the product directly obtained by a process is different from the product-by-process claim explained above. The product-by-process claim, under the German Patent Act, also protects products that are produced in a different way than the process described in the claim.⁵⁶⁰ Condition for the grant of a product-by-process claim is a new and inventive product. Consequently, the subject of the product-by-process invention is a patentable product.

The protection of a product directly obtained by a process under Art. 64(2) EPC is not a product claim, but a mere process claim.⁵⁶¹ Thus, the product directly obtained by the process neither has to be new, nor does it have to be based on an inventive step. Decisive for patentability is alone novelty and inventive step of the process.⁵⁶²

558 Schennen&Stauder in: Singer&Stauder (eds.) European Patent Convention – A Commentary, 3rd ed., Cologne 2003, Art. 64, No. 14.

559 Jestaedt in Benkard (ed.), Europäisches Patentübereinkommen, München 2002, Art. 64, No. 22.

560 See Part III Section C Subsection II.

561 Jestaedt in Benkard (ed.), Europäisches Patentübereinkommen, München 2002, Art. 64, No. 20.

562 Jestaedt in Benkard (ed.), Europäisches Patentübereinkommen, München 2002, Art. 64, No. 21.

Consequently, the subject of the patent with respect to the product directly obtained by a process is a patentable process.

2. *The product directly obtained by a process*

Since the extension of protection of process claims to the product directly obtained therefrom, there have been two opposing views on the interpretation of the attribute “directly obtained,” briefly called the chronological approach and the parameter approach.⁵⁶³ A uniform European interpretation has not yet been established.⁵⁶⁴ Therefore, the next chapter is dedicated to the question of which interpretation is applicable to food patents, using literal, historical, systematic, and teleological interpretation. The following example will serve to explain both views:

Starting material + steps A, B, and C -----> intermediate product X

Intermediate product X + step D -----> end-product Y

Steps A, B, and C are protected under a process claim for processing a certain starting material into intermediate product X. Intermediate product X is the product resulting from step C. A further step D, which is not described under the process claim, leads to the end-product Y. In the food context, with focus on plant biotechnology, a process for the production of a transgenic soybean plant X comprises steps A, B, and C. The transformation of the seed obtained from the transgenic soybean plant into an oil represents step D, which is not comprised in the process claim. The oil obtained from the transgenic plant represents the end-product D.

3. *Interpretation of “directly obtained”*

a. Narrow interpretation: chronological approach

A rather narrow time-based observation is performed under the chronological interpretation in order to determine whether a product is directly obtained by a process. First, the steps of the process as described in the claim are analyzed. Only if the product in question is obtained as the result of the last step mentioned in the process claim does the scope of the patent on the process extend to the product.⁵⁶⁵

563 *Reimer*, Patentgesetz und Gebrauchsmustergesetz, 3 ed., München 1968, No. 63 c to Sec. 6 PatG.

564 *Jestaedt in Benkard* (ed.), Europäisches Patentübereinkommen, München 2002, Art. 64, 25.

Thus, an end-product that was transformed from an intermediate product by steps that are not mentioned in the process claim is not protected under that process claim.

The chronological interpretation seems to be strictly formal.⁵⁶⁶ There is no evaluation of whether the further steps needed to transform the intermediate product into the end-product are essential. Even the smallest step of transformation of the intermediate product would suffice to not render the end-product under the scope of the process claim. In the above-mentioned soybean example, X would only fall within the scope of the process claim under Art. 64(2) EPC. Y would not fall within the process claim under Art. 64(2) EPC.

b. Broad interpretation: parameter approach

A very different approach from the chronological interpretation is the parameter theory.⁵⁶⁷ This theory is based on the evaluation of the steps that are involved in the transformation of X into Y. If step C is not regarded as essential, both X and Y fall within the process claim, though the transformation of X into Y requires a further step D not described in the process claim. The evaluation of D as essential depends on whether the parameter of the intermediate product X, which is typical for the patented process comprising the steps A, B, and C, is still present in the end-product Y. Usually this parameter justifies the grant of a patent on the process. According to the parameter theory, the characteristic parameters of the intermediary product X and the end-product Y are compared. Only if the decisive characteristic of the intermediate product is still present in the end-product does the end-product fall within the process claim. Then, it does not matter which further steps must be performed to obtain the end-product Y.

In the above-mentioned example, the oil obtained from the transgenic soybean plant would still be covered by the process patent on the production of the transgenic plant under Art. 64(2) EPC as long as the special characteristic of the transgenic plant were present in the oil.

565 *Krieger*, in: *Beier, Haertel&Schricker* (eds.), *Europäisches Gemeinschaftsübereinkommen*, Münchener Gemeinschaftskommentar, Köln 1991, Art. 64, *Bruchhausen*, Sind Endprodukte unmittelbare Verfahrenserzeugnisse eines auf die Herstellung eines Zwischenprodukts gerichteten Verfahrens?, GRUR 1979, 743.

566 *Jestaedt* in *Benkard* (ed.), *Europäisches Patentübereinkommen*, München 2002, Art. 64, No. 24.

567 *Beier&Ohly*, Was heißt "unmittelbares Verfahrenserzeugnis"? - Ein Beitrag zur Auslegung des Art. 64(2) EPÜ, GRUR Int. 1996, 973, *Benjamini*, Patent Infringement in the European Community, München 1993, 162 ss., *Hahn*, Der Schutz von Erzeugnissen patentierter Verfahren, München 1968, 94 ss., *von Pechmann*, Der Schutz für das unmittelbare Verfahrenserzeugnis und der mittelbare Stoffschutz, GRUR 1977, 377, 379, *Jestaedt* in *Benkard* (ed.), *Europäisches Patentübereinkommen*, München 2002, Art. 64, No. 25 ss, *Pioneer Electronics Capital Inc. v. Warner Music Manufacturing Europe GmbH*, decision of the UK High Court of 24.01.1995, see also *Russell&Hurdle*, What is the Direct Product of a Patented Process?, EIPR 1995, 249 ss.

4. Interpretation applicable to food-related inventions

a. Literal interpretation

The interpretation of the language of Art. 64(2) EPC supports the strict interpretation. The wording “directly obtained” of Art. 64(2) EPC indicates the application of the chronological approach.

Generally, directly has the meaning of without intermediate steps.⁵⁶⁸ Consequently, an end-product would not be regarded as directly obtained by the patented process for the intermediate product whenever a further step is required. This result would be independent of the question of the technical effect of this further step on the end-product.

On the other hand, this strict way of interpreting “directly obtained” does not rule out the parameter approach, as the term “directly” does not necessarily relate to a certain period of time. “Directly” can also mean that the further step is of no essential importance to the end-product.⁵⁶⁹ Thus the language of Art. 64(2) EPC does not clearly point towards one interpretation of “directly obtained.”

b. Legislative history of Art. 64(2) EPC

The historical genesis of Art. 64(2) EPC supports the wide interpretation of the parameter approach.⁵⁷⁰ Article 64(2) EPC was drafted according to Art. 29c Community Patent Convention, which has never entered into force.⁵⁷¹ The first President of the European Patent Office *van Benthem* voted during the discussions on the Community Patent Convention clearly in favour of the parameter approach:

“There seems to be a common understanding that the words “directly obtained” or “directly resulting” do not have to be read in the literal sense of the words, and that to provide reasonable protection for the owner of a patented process, the protection conferred on him should not always be restricted to the first sale or use of the infringing products. When the product embodying the patented process is subjected to other processes before the final product is made, the use or sale of the final product may infringe the patent for the process. According to German law, this is so if the value or

568 The Oxford Advanced Learner's Dictionary defines “directly” as in a direct line or immediately. Oxford Advanced Learner's Dictionary, Oxford 1989.

569 *Beier&Ohly*, Was heißt “unmittelbares Verfahrenserzeugnis”? - Ein Beitrag zur Auslegung des Art. 64(2) EPÜ, GRUR Int. 1996, 973, 983.

570 *Beier&Ohly*, Was heißt “unmittelbares Verfahrenserzeugnis”? - Ein Beitrag zur Auslegung des Art. 64(2) EPÜ, GRUR Int. 1996, 973, 983.

571 The Community Patent Convention intending to create a unitary Community patent title was signed on December 15, 1975 in Luxembourg followed by the agreement relating to the Community patent including a protocol on the settlement of litigation concerning the infringement and validity of Community patents of December 15, 1989. However, these agreements never entered into force because of lacking ratification by its Member Countries. Bericht der deutschen Delegation über die Luxemburger Konferenz über das Gemeinschaftspatent, GRUR Int. 1976, 187.

characteristics of the final product are largely determined by the use of the patented process; and in French law the product must be immediately dependent on the use of the process.”⁵⁷²

Article 64(2) EPC was proposed by the Swiss delegation and was accepted by the majority of the delegates at the Diplomatic Conference held in Munich in 1973 to agree on the European Patent Convention.⁵⁷³ Systematically, this provision regarding the scope of protection of a European Patent would not belong to the EPC. The EPC intended to create uniform patent prosecution and left infringement matters to its Members.⁵⁷⁴ Nevertheless, the Swiss delegation argued that only this provision could ensure protection of products which could not be described other than by their process of production. Moreover, imports from countries where no patents existed could be prohibited by that provision. This argument has already led to the introduction of a similar provision in the Amending Act of 1981 of the German Patent Act.⁵⁷⁵

The meaning of the term “directly obtained” was not discussed in particular.⁵⁷⁶ The Diplomatic Conference has not intended to create new approaches regarding the term “directly obtained” by deviating from the jurisprudence of its Members. Therefore, it can be concluded that the approaches of its Members were applicable.⁵⁷⁷ At that time, most European countries, including Switzerland, Austria, the United Kingdom, the Netherlands, Portugal, and partly also Germany⁵⁷⁸ had applied the parameter approach.⁵⁷⁹ Moreover, the Scandinavian patent systems did not limit the product protection by a patented process to such products that were directly obtained by the patented process.⁵⁸⁰ Thus, it can be concluded that the Diplomatic Conference intended the wide interpretation of the term “directly obtained.”

572 *Van Benthem*, The Rights Conferred by a Community Patent Under the Community Patent Conventions, in: *Pennington* (ed.), *European Patents at the Crossroads*, London 1976, 121, 126.

573 Diplomatic Conference Doc. M/67/I (1973), Doc. M/PR (1973), 200.

574 Art. 1 EPC clearly limits the EPC to patent prosecution: A system of law, common to the Contracting States, for the grant of patents for invention is hereby established.

575 See Part I, section A, subsection II.

576 *Beier&Ohly*, Was heißt “unmittelbares Verfahrenserzeugnis”? - Ein Beitrag zur Auslegung des Art. 64(2) EPÜ, GRUR Int. 1996, 973, 975.

577 *Beier&Ohly*, Was heißt “unmittelbares Verfahrenserzeugnis”? - Ein Beitrag zur Auslegung des Art. 64(2) EPÜ, GRUR Int. 1996, 973, 983.

578 The most prominent commentator on the German Patent Act, *Benkard*, still regards the question of how to interpret “directly obtained” as unsolved: “Es ist streitig, ob und gegebenenfalls wann in (Fällen der Weiterbearbeitung eines zunächst geschaffenen Verfahrenserzeugnisses) § 9 S. 2 Nr. 3 eingreift.” *Scharen in Benkard* (ed.), *Patentgesetz Gebrauchsmustergesetz*, 10th ed., München 2006, § 9, No. 57.

579 *Beier&Ohly*, Was heißt “unmittelbares Verfahrenserzeugnis”? - Ein Beitrag zur Auslegung des Art. 64(2) EPÜ, GRUR Int. 1996, 973, 976 ss.

580 *Beier&Ohly*, Was heißt “unmittelbares Verfahrenserzeugnis”? - Ein Beitrag zur Auslegung des Art. 64(2) EPÜ, GRUR Int. 1996, 973, 982.

c. Systematic interpretation

The systematic analysis of Art. 64(2) EPC seems to confirm this conclusion. The EPC creates “a system of law, common to the Contracting States, for the grant of patents.”⁵⁸¹ In addition to the provisions on the grant of a patent, provisions on the effects of a patent have been included into the EPC in order to improve the protection delivered by a European patent.⁵⁸² Clearly, the intention to improve the protection delivered by a process patent supports the broad interpretation of “directly obtained” delivered by the parameter approach.

In contrast, the narrow interpretation would weaken the protection delivered by a patented process. But a narrow protection was not intended. Thus, from a systematic point of view, the wide interpretation seems to be preferred. On the other hand, Art. 64(2) EPC is a provision on the scope of a patent. Thus, Art. 64(2) EPC has to be read in context with Art. 69(1) EPC, according to which the extent of the protection conferred by a European patent or a European patent application shall be determined by the terms of the claims.⁵⁸³ In the light of Art. 69(1) EPC, end-products that involve steps that are neither mentioned in the claim nor in the description should not be considered as directly obtained by the patented process for an intermediate product.

d. Teleological interpretation

Finally, the teleological method of interpretation supports the broad interpretation of “directly obtained.” Based on the *rationale* of a provision, the teleological interpretation evaluates the contradicting interests in order to find an adequate solution.⁵⁸⁴ The *rationale* behind Art. 64(2) EPC is to grant the patentee of a process patent effective protection without inappropriately limiting the public's freedom of action.⁵⁸⁵ The inventor is granted a patent as a merit for the contribution of his invention to the state of the art. The technical contribution of an invention lies within its essential parameters that render the invention new and inventive over the state of the art. Therefore, it seems justified to include all those products obtained from the patented process that are characterized by these parameters. It should not matter how many steps might be involved in order to obtain an end-product. Consequently, the teleological interpretation results in a broad interpretation of the attribute “directly obtained.”

581 Art. 1 EPC.

582 *Haertel*, Die Münchener Konferenz und ihre wesentlichen Ergebnisse, GRUR Int. 1974, 48, 50, *Schennen&Stauder* in: *Singer&Stauder* (eds.) European Patent Convention – A Commentary, 3rd ed., Cologne 2003, Art. 64, No. 15.

583 *Jestaedt* in *Benkard* (ed.), Europäisches Patentübereinkommen, München 2002, Art. 64, No. 27.

584 *Beier&Ohly*, Was heißt “unmittelbares Verfahrenserzeugnis”? - Ein Beitrag zur Auslegung des Art. 64(2) EPÜ, GRUR Int. 1996, 973, 983.

585 *Schennen&Stauder* in: *Singer&Stauder* (eds.) European Patent Convention – A Commentary, 3rd ed., Cologne 2003, Art. 64, No. 15.

e. *Parameter approach appropriate*

Based on historical and teleological interpretation, the parameter approach seems appropriate for the interpretation of Art. 64(2) EPC. The literal and the systematic interpretation do not expressly contradict or support the parameter approach.

5. *Burden of proof with regard to the product directly obtained by a process*

The effectiveness of the protection by Art. 64(2) EPC largely depends on the question of the burden of proof. Generally, the burden of proof lies with the person who claims a certain fact.⁵⁸⁶ The patentee of a patented process claims that the alleged infringer has used the patented process to produce the product in question. Thus, the burden of proof lies with the patentee.⁵⁸⁷ The burden of proof is reversed under Sec. 139(3) PatG⁵⁸⁸ only when the product obtained by the patented process is new.⁵⁸⁹ According to that provision, there is a presumption that a product put on the market by a third party has been manufactured according to the protected process. It is then up to the third party to refute this presumption.⁵⁹⁰

6. *Biological inventions*

The question of whether biological products, e.g. seeds derived of a transgenic plant, are considered to be products directly obtained by a patented process for the production of such a transgenic plant is solved by the Biopatent Directive.⁵⁹¹ Art. 8(2) states in this respect:

586 *Heinrichs in Palandt*, 65. ed., München, 2006, Vorbemerkung zu § 249, No. 162. “Der Geschädigte hat die Beweislast für die objektiven und subjektiven Voraussetzungen des Schadensersatzanspruchs.”

587 *Scharen in Benkard* (ed.), *Patentgesetz Gebrauchsmustergesetz*, 10th ed., München 2006, § 9, No. 57, *Jestaedt in Benkard* (ed.), *Europäisches Patentübereinkommen*, München 2002, Art. 64, No. 35.

588 Sec. 139(3) PatG: “Ist Gegenstand des Patents ein Verfahren zur Herstellung eines neuen Erzeugnisses, so gilt bis zum Beweis des Gegenteils das gleiche Erzeugnis, das von einem anderen hergestellt worden ist, als nach dem patentierten Verfahren hergestellt.” = A new product obtained by a patented process is considered as produced by a patented process unless the opposite is proved.

589 Bundesgerichtshof, *Alkylendiamine II*, BGHZ 67, 38, 42 ss.

590 The same is provided in Art. 35 of the Community Patent Convention, Commission of the European Communities, Proposal for Council Regulation on the Community patent, Doc. COM(2000) 412, 22.

591 Contra the protection of seeds as products directly obtained by the process of production: *Hesse*, GRUR 1969, 644, 659; Pro protection of seeds as products directly obtained by the process of production: *Heydt*, GRUR 1969, 674, 676, *Moufang* in: *Beier, Haertel&Schricker* (eds.), *Europäisches Gemeinschaftsübereinkommen*, Münchner Gemeinschaftskommentar, Köln 1991, Art. 53, No. 123 ss.

“The protection conferred by a patent on a process that enables a biological material to be produced possessing specific characteristics as a result of the invention shall extend to biological material directly obtained through that process and to any other biological material derived from the directly obtained biological material through propagation or multiplication in an identical or divergent form and possessing those same characteristics.”

Basically, this clause embodies the parameter approach when defining that only biological material “possessing those same characteristics”⁵⁹² of the biological material directly obtained by a process for the production of biological material is falling under the scope of the patent on that process. The German Patent Act now has clarity on that subject by implementing Art. 8(2) of the Biopatent Directive in Sec. 9a(2) PatG.⁵⁹³

7. Case study on food products obtained by a patented process

Three examples of food-related patents are analyzed regarding the scope of protection provided by Art. 64(2) EPC. Two have become rather prominent at the EPO, each causing a press release on the official website of the EPO. Though both being granted plant patents held by the world leader in plant biotechnology Monsanto,⁵⁹⁴ they differ in one important aspect regarding the protection for a product directly obtained by a process. EP 445 929, with the title “Plants,” became well known under the synonym “biscuit patent.” It covers a product which still shows the essential technical characteristic which justified the patentability of the invention: a protein composition of the grains that allows for soft-milling wheat to be processed into biscuits that are normally produced of hard-milling wheat. EP 546 090 covers a process for the production of herbicide-tolerant plants. The essential technical characteristic of herbicide tolerance is present in the plants obtained by the process, but not in the processed plants. The oil or the meal obtained by these herbicide-resistant plants is essentially equivalent to any other oil or meal. The biscuit patent represents the class of output traits. The patent on herbicide-resistant plants is a typical example of an agronomic input trait. Finally, EP 270 615 constitutes the third class dealing with basic technology independent from agronomic or qualitative traits. It is directed at the genetic transformation of the plant of the *Brassica* species, including oilseed rape as its most important representative. Thus the most important fields of plant biotechnology as described in part II.A.I are mirrored in the following case study on the relevance of the protection of the product directly obtained by a process for processed food.

592 Art. 8(2) Biopatent Directive.

593 §9a(2) PatG: “Betrifft das Patent ein Verfahren, das es ermöglicht, biologisches Material zu gewinnen, das auf Grund einer Erfindung mit bestimmten Eigenschaften ausgestattet ist, so erstrecken sich die Wirkungen von §9 auf das mit diesem Verfahren unmittelbar gewonnene biologische Material und jedes andere mit denselben Eigenschaften ausgestattete biologische Material, das durch generative oder vegetative Vermehrung in gleicher oder abweichender Form aus dem unmittelbar gewonnenen Material gewonnen wird.”

594 In addition to Monsanto's seeds and traits business, Monsanto manufactures the world's best-selling herbicide, Roundup[®]. Available at www.monsanto.com.

aa. *Background*

The biscuit patent aims to protect an invention in the field of wheat breeding. It was originally applied for by one of the globally leading food companies, Unilever PLC and Unilever NV in 1991, going back to the priority date of February 19, 1990. During prosecution the patent application was assigned to Monsanto Technology LLC. The inventor is UK national *Peter Payne*. Its grant was published in Europe on May 21, 2003. In the U.S., an essentially identical patent was granted.⁵⁹⁵ The biscuit patent has been opposed by five opponents and has been the focus of public interest in patent law during its opposition.⁵⁹⁶

The biscuit patent was transferred to Société RAGT 2N, seated in Rodez, France from Monsanto Technology LLC on July 28, 2004, as Monsanto sold all its European seed activities in the wheat business to Société RAGT 2N. Immediately after transferral, the new patent proprietor, by statement filed on September 10, 2004, requested that the patent be revoked, leading to the revocation of the patent by the opposition division on September 23, 2006. No appeal was filed against this decision within the time period, rendering the revocation final.

Nevertheless, the question of how far the granted claims of the biscuit patent would have reached is analyzed in the following. Firstly, the claims have not been found invalid by the Board of Appeals, as the patent proprietor revoked the biscuit patent himself. Secondly, the biscuit patent is a good example of a transgenic plant whose essential properties are present in the products made thereof.

bb. *The invention of the biscuit patent*

The technical teaching underlying the biscuit patent is a soft-milling wheat which produces dough having exceptionally low visco-elasticity. The visco-elasticity of a dough is defined as the balance between extensibility and elasticity. This balance varies significantly between wheat varieties and generally determines the uses of the wheat variety in food production. The ratio of elasticity to extensibility needs to be high for leavened bread, middle for noodles and flat breads and very low for biscuits. The visco-elasticity of a dough is largely influenced by the protein of the endosperm called gluten which occurs from 8% to 15% of the dry weight of wheat flour. High-molecular-weight (HMW) subunits of glutenin are the key components in conferring elasticity and dough-mixing

595 US Patents 5,859,315 and 5,763,741.

596 EPO, Press Release of 27.01.2004, Biscuit Patent.

stability.⁵⁹⁷ The inventor backcrossed an Indian landrace called “Nap Hal” which lacks two HMW subunits, into an elite hard-milling wheat germplasm. By a second backcross into a soft-milling wheat a high-performing soft-milling wheat with only two HMW subunits was obtained.

cc. Claims and claim interpretation

The biscuit patent consists of 22 claims comprising all claim categories with 18 product claims, one process claim and 3 use claims. The granted claims are directed at the wheat, the flour and dough obtained from it, and the resulting foodstuff. It is striking that the EPO granted 12 independent product claims, though it is generally recognized within the EPO case law that as a rule there should be not more than one independent claim of each claim category in each case. Nevertheless, unity of the invention under Art. 82 EPC was fulfilled because all the different independent products were linked through a new and inventive common technical concept: the provision of soft-milling wheat which produces dough having exceptionally low visco-elasticity.

Independent claims 1 to 8 each refer to soft-milling wheat with reduced HMW glutenin subunits. Claim 1 claims:

“Soft-milling wheat with reduced HMW glutenin subunits having an SDS-sedimentation volume, corrected to 11% protein, of not greater than 30ml.”⁵⁹⁸

Independent claims 1 to 3 refer to a soft-milling wheat with reduced HMW glutenin subunits having an SDS-sedimentation volume, corrected to 11% protein, of not greater than 30 ml. This means that when being dissolved in water the protein does not form a gel but dissolves more than in usual soft-milling wheat, leading to a low sedimentation value. Independent claim 4 also refers to soft-milling wheat with reduced HMW glutenin subunits, whereas this parameter is measured by a different method.

Independent claims 5 to 8 address the absence or inactivity of the genes that are responsible for high visco-elasticity in wheat, the so-called Glu-D1 locus. Claim 5 is directed to:

597 *MacRitchie & Wrigly*, Journal of Cereal Science, vol. 7, 109-112 (1988).

598 The SDS-sedimentation volume is defined in experiment 2 of EP 445 929: “The SDS(sodium dodecyl sulphate)-sedimentation test, described by Axford, McDermott and Redman, Cereal Chemistry, vol. 56, pages 582-584 (1979), measures the volume of sediment after mixing wholemeal flour in a lactic acid, SDS solution under controlled conditions and then allowing to settle for a specified period. The larger glutenin molecules which are primarily responsible for elasticity and dough strength form a gel and increase the volume of the sediment. The protein molecules imparting extensibility dissolve. The method is used extensively in wheat breeding programmes to select for bread-making quality (large sedimentation volumes) and at wheat mills as a quick test for bread quality prior to accepting a grain load. The SDS volume of the “Galahad-7” (6.0g flour at 15% w/v water content) sample was 22ml (protein content = 14.2%), that of “Galahad” was 51ml (10.2% protein). By contrast the volume of “Apostle”, a good bread-quality wheat, was 85ml at about 10.5% protein.”

“Soft-milling wheat in which each of the "x" and "y" genes at Glu-D1 is inactive or absent.”

Claims 9 to 12 address flour. Claim 9 reads:

“Flour prepared from wheat as claimed in any one of claims 1 to 6.”

Dependent claim 9 involves the flour prepared from wheat of independent claims 1 to 6. Independent claim 10 refers to soft wheat flour containing fewer than 3 different HMW glutenin subunits. Dependent Claims 11 and 12 are special embodiments of claims 10.

Dependent claims 13 to 15 finally claim the dough made from the claimed flour, an edible product made from such a dough, and the biscuits prepared from the claimed flour. Claim 13 is directed to:

“Dough or batter prepared from flour as claimed in any one of claims 9 to 12.”

Finally, claim 15 claims:

“Biscuits or the like prepared from the flour as claimed in any one of claims 9 to 12.”

All in all, the whole food chain of soft-milling wheat with reduced HMW glutenin subunits, from the wheat seed, through the processed wheat and including the final product, biscuits, is claimed.

dd. Impacts for products obtained from the biscuit patent technology

The granted claims protect the wheat, the flour, the dough, and edible products made from the flour. These products are patentable when they differ from the products of the state of the art in a non-obvious way. However, the scope of the process claim is not clear as far as the products obtained by that process are concerned.

Claim 19 of the biscuit patent addresses:

“The production of a strain of wheat, involving the steps of:

- a) selecting a hard-milling wheat strain possessing the Glu-D1 double null trait;
- b) crossing the hard-milling strain with a soft-milling wheat strain which naturally produces relatively elastic dough;
- c) back-crossing the resulting strain into a soft-milling wheat strain;
- d) selecting grains exhibiting the Glu-D1 double null trait at half the normal gene dosage, by analysis of embryo-less half grains, the corresponding half-grains being retained for germination;
- e) germinating the corresponding half-grain of the selected soft-milling Glu-D1 double null strain, and conducting a further back-crossing and half-grain analysis for the Glu-D1 double null trait;
- f) germinating the corresponding half-grains from step (e), and growing and allowing to self-pollinate grains containing the Glu-D1 double null trait in the homozygous state; and
- g) determining which of the resulting lines homozygous for the Glu-D1 double null trait are soft.”

The scope of claim 19 comprises the wheat obtained therefrom. Regarding the flour obtained from such wheat, further steps which are not expressly described in the process of the claim are involved. According to the chronological approach, the flour would not be protected under the above mentioned claim, as the step of milling the wheat is not claimed. In contrast thereto, the parameter approach would certainly protect the flour obtained from the wheat. This is because the essential parameters that justified patentability are still present in the flour.

For the reasons mentioned above, the parameter approach should be followed in this case. The merits of the biscuit patent lie exactly in the changed baking quality of the wheat. Therefore, the flour characterized by this baking quality should also be protected by the process claim for the production of the wheat.

Finally, it can be concluded that whenever the parameter that led to the patent on a process for the production of a plant is still present in the products obtained from the plant, the parameter theory should be applied. However, in these cases the products themselves will generally be patentable as such. Here, the baking quality was the essential parameter leading to patentability of the invention underlying the biscuit patent. This parameter is present in the flour. Therefore, the flour is patentable as a substance. Thus, the question of whether the flour is protected under Art. 64(2) EPC arises only when the patentee has not drafted a substance claim.

b. Herbicide-tolerant plants – EP 546 090

aa. Background

The patent is titled “Glyphosate Tolerant 5-Enoylpyruvulshikimate-3-Phosphate Synthases,” the so-called EPSPS. The applicant is Monsanto, the world's leading transgenic seed company focusing on corn, cotton, and oilseeds. Monsanto also manufactures the world's best-selling herbicide, Roundup[®].⁵⁹⁹ It is registered in more than 130 countries and approved for weed control in more than 100 crops.⁶⁰⁰ The basic ingredient of Roundup is glyphosate. The patent claims the priority of a U.S. patent application of August 31, 1990. It has been opposed by Greenpeace for political reasons, by its competitor, the seed company Syngenta, and by two private persons, *Then* und *Schweiger*. As a result of the opposition an amended set of claims was granted.

bb. Technology underlying the patent

The claims are directed to genes encoding class II EPSPS enzymes. The genes are useful in producing transformed plants which are tolerant to the herbicide glyphosate. The technology underlying the invention is the provision of several novel genes providing more efficient herbicide tolerance than the known Class I EPSPS genes, the so-called Class II EPSPS genes in the presence of glyphosate. Plants transformed with Class II EPSPS genes are also disclosed, as well as a method for selectively controlling weeds in a planted crop field.

599 Available at www.monsanto.com/monsanto/layout/about_us/default.asp.

600 For mor information on Roundup

see www.monsanto.com/monsanto/content/products/productivity/roundup/back_history.pdf.

The set of claims that was amended during opposition consists of 33 claims. Four independent and eight dependent claims are directed to the Class II EPSPS genes. Independent Claim 1 as amended during appeal claims:

“An isolated DNA sequence encoding a Class II EPSPS, said enzyme being an EPSPS enzyme having a K_m for phosphoenolpyruvate (PEP) between 1-150 μM and a $K(\text{glyphosate})/K_m(\text{PEP})$ ratio between 3-500, which DNA sequence is capable of reacting with antibodies raised against a Class II EPSPS enzyme selected from the group consisting of the enzymes of SEQ ID NO:3, SEQ IDNO:5.”

One independent and five dependent claims address the method of producing genetically transformed plants which are tolerant toward glyphosate herbicide using Class II EPSPS genes. Independent Claim 14 as amended during appeal is directed to:

“A method of producing genetically transformed plants which are tolerant toward glyphosate herbicide, comprising the steps of:

a) inserting into the genome of a plant cell a recombinant, double-stranded DNA molecule comprising:

i) a promoter which functions in plant cells to cause the production of an RNA sequence,

ii) a structural DNA sequence that causes the production of an RNA sequence which encodes a fusion polypeptide comprising an amino terminal chloroplast transit peptide and a Class II EPSPS enzyme capable of reacting with antibodies raised against a Class II EPSPS enzyme selected from the group consisting of the enzymes of SEQ ID NO:3, SEQ IDNO:5,

iii) a 3' non-translated DNA sequence which functions in plant cells to cause the addition of a stretch of polyadenyl nucleotides to the 3' end of the RNA sequence

where the promoter is heterologous with respect to the structural

DNA sequence and adapted to cause sufficient expression of the fusion polypeptide to enhance the glyphosate tolerance of a plant cell transformed with said gene;

b) obtaining a transformed plant cell; and

c) regenerating from the transformed plant cell a genetically transformed plant which has increased tolerance to glyphosate herbicide.”

One independent and three dependent claims are directed to a glyphosate-tolerant plant cell. Independent Claim 20 is directed to:

“A glyphosate tolerant plant cell comprising a DNA molecule of Claims 8, 9, 12 or 13.”

One independent and three dependent claims address a glyphosate-tolerant plant. Independent claim 24 as amended during appeal claims:

“A glyphosate tolerant plant comprising plant cells of Claim 20.”

Finally, a method for selectively controlling weeds in a field containing a crop having glyphosate-tolerant plants is claimed in one independent and five dependent claims. Independent claim 28 addresses:

“A method for selectively controlling weeds in a field containing a crop having planted crop seeds or plants comprising the steps of:

a) planting said crop seeds or plants which are glyphosate tolerant as a result of a recombinant double-stranded DNA molecule being inserted into said crop seed or plant, said DNA molecule having::

- i) a promoter which functions in plant cells to cause the production of an RNA sequence,
- ii) a structural DNA sequence that causes the production of an RNA sequence which encodes a polypeptide which comprises an amino terminal chloroplast transit peptide and a Class II EPSPS enzyme selected from the group consisting of the enzymes of SEQ ID NO:3, SEQ IDNO:5 ,
- iii) a 3' non-translated DNA sequence which functions in plant cells to cause the addition of a stretch of polyadenyl nucleotides to the 3' end of the RNA sequence

where the promoter is heterologous with respect to the structural DNA sequence and adapted to cause sufficient expression of the fusion polypeptide to enhance the glyphosate tolerance of a plant cell transformed with said gene; and

- b) applying to said crop and weeds in said field a sufficient amount of glyphosate herbicide to control said weeds without significantly affecting said crop.”

None of the substance claims is directed to products derived of the transgenic glyphosate-tolerant plant. Thus crucial for the protection of processed oil as the product obtained by the patented process is the independent method claim 14 directed to the production of genetically transformed glyphosate tolerant plants.

Both the parameter and the chronological approach would render oil obtained from plants transformed according to claim 14 outside the scope of claim 14. Under the chronological approach, the step of oil extraction is not expressly described in claim 14. Thus, an oil obtained from such plants would clearly not fall within claim 14. Under the parameter approach, the essential parameter of the method of claim 14 is the use of genes delivering herbicide tolerance. This parameter is not present in the oil obtained from such plants. Consequently, also under the parameter approach the oil is outside the scope of claim 14.

c. Patent on transformation technology – EP 270 615

Having discussed patents which cover plants with certain useful traits, the third category analyzed with respect to Art. 64(2) EPC comprises patents that cover the technology of generally generating transgenic plants independent of their traits. Here again, the question arises how far the protection delivered by such patents may reach. The so called *Moloney* patent,⁶⁰¹ named after its principal inventor, is directed to a method of transforming plants of a *Brassica* species. It shows that the commercial use of an oil extracted from a plant transformed according to the technical teaching of the *Moloney* patent would not infringe the process claim on the transformation technology under Art. 64(2) EPC. This conclusion is based on the observation that the product in question is not a direct product of the claimed process, as the product would be found materially changed from the transgenic plant. However, production of transgenic oilseed rape falls within the scope of the *Moloney* patent.

601 EP 270 615: Transformation and foreign gene expression in *Brassica* species = US 55,188,958, US 5,463,174, US 5,750,871.

aa. Background

The European *Moloney* patent was revoked after an opposition by 7 parties involved in plant science or the agrochemical business: Novartis, Mogen International N.V., DSM Gist Holding B.V., Groupe Limagrain Holding, Agrigenetics LP, Aventis CropScience S.A. and the Max Planck Society for the Advancement of Science. The fact that so many parties opposed it indicates the importance of the *Moloney* patent. The decision of the Opposition Division was confirmed by the Technical Board of Appeal mainly because the main and auxiliary requests were not in compliance with Art. 123(2) and (3) EPC.⁶⁰² Under Art. 123(2) EPC changes of the patent are only allowed as long as they were originally disclosed in the description. Under Art. 123(3) EPC, claims cannot be changed in a way that would broaden the scope of the patent during opposition. Here, claim 1 was originally filed as follows:

“Transformed Brassica species cells having a DNA construct resulting from in vitro joining of at least two fragments, wherein said fragments comprise:

- (1) a transcription initiation region functional in said Brassica;
- (2) a DNA sequence comprising an open reading frame having an initiation codon at its 5' terminus or a sequence complementary to an endogenous transcription product;
- (3) a transcription termination region functional in said Brassica;
- (4) a right border of T-DNA;
- (5) a structural gene capable of expression in said Brassica providing for selection of transformed Brassica cells; wherein said fragments provide an expression cassette capable of expression in said Brassica cells.”

Independent claim 1 was granted as follows:

“Transgenic Brassica species cells and progeny thereof comprising an expression cassette wherein said cells are characterized as oncogene-free and capable of regeneration to morphologically normal whole plants and wherein said expression cassette comprises in the 5' to 3' direction of transcription

- (1) a transcription initiation region functional in said Brassica;
- (2) a DNA sequence comprising an open reading frame having an initiation codon at its 5' terminus or a nucleic acid sequence complementary to an endogenous transcription product;
- (3) a transcription termination region functional in Brassica species cells; and
- (4) a structural gene capable of expression in said Brassica providing for selection of transgenic Brassica species cells;

wherein said expression cassette is capable of altering the phenotype of said Brassica species cells when said cells are grown under conditions whereby said DNA sequence or said nucleic acid sequence is expressed.”

602 Decision of the Board of Appeal of 28.07.2000, T289/97 – Brassica/CALGENE, not published, available at <http://legal.european-patent-office.org/dg3/pdf/t970289eu1.pdf>.

The changes during prosecution to the granted claim 1 were not considered to fulfill Art. 123(2) EPC. During opposition, these changes could not be undone without violating Art. 123(3) EPC leading to the revocation of the patent.

The U.S. and the Canadian patents have not yet been challenged in court. One reason might be that the cost-effective opposition procedure of the EPC is not available in these patent systems and litigation is regarded as consuming tremendous amounts of financial resources. Thus, the U.S. and the Canadian market for transgenic Brassica plants is monopolized by the *Moloney* patent.

bb. The Moloney patent and its scope

The *Moloney* patent claims the priority of a U.S. patent application of May 29, 1986 and has been assigned to Calgene LLC. Calgene LLC is a subsidiary of the U.S.-based seed company Monsanto, which dominates the transgenic seed market.⁶⁰³ It is titled “Transformation and Foreign Gene Expression in *Brassica* Species.” The technical teaching underlying the *Moloney* patent is the Agrobacterium transformation of a cell of a plant of a *Brassica* species. One independent claim and nine claims depending thereon are substance claims directed to transgenic *Brassica* species cells, cell culture of cells, and plants, including a product-by-process claim.

None of the product claims mentions oil or products produced from the claimed transgenic plants or cells. Thus, the substance claims do not cover oil processed from transgenic plants according to the *Moloney* invention. An import of an oil product isolated from a transgenic *Brassica* plant into the EU would not fall within the scope of any of the product claims of the *Moloney* patent. This result is independent of the question of whether a transgenic DNA construct can be analytically determined in the oil, as none of the claims addresses such a DNA construct.

Crucial for the above-raised question on the processed oil are the process claims. One independent method claim with six method claims dependent thereon are directed to a method of transforming *Brassica* species cells to produce morphologically normal whole Brassica plants having an altered phenotype as a result of said transformation. Independent process claim 5 is directed to:

“A method for transforming Brassica cells to produce Brassica plants, said method comprising:

co-cultivating Brassica cells with disarmed *A. tumefaciens* comprising a disarmed plasmid containing an insertion sequence resulting from joining in vitro a transcription cassette to at least the right T-DNA border of Ti or Ri plasmid, whereby said-Brassica cells are transformed with said insertion sequence which becomes integrated into the plant cell genome to provide transformed oncogene-free cells;

transferring said transformed oncogene-free cells to callus inducing media containing at least one auxin and selective for cells comprising said marker to produce callus from said transformed cells;

603 Available at www.monsanto.com/monsanto/layout/about_us/timeline/default.asp.

transferring said callus to regeneration media containing less than about 2% sucrose or organic caloric equivalent to produce shoots; and

transferring said shoots to a growing medium to produce plants capable of having an altered phenotype when grown under conditions whereby a DNA sequence in said insertion sequence is expressed.”

According to the description, altered oil production is one of the contemplated “altered phenotypes.”⁶⁰⁴ The oil does not constitute a product directly obtained by the patented process under Art. 64(2) EPC. Both the parameter approach and the chronological approach come to this result. Neither is the transformation method as the essential parameter present in the oil, nor is the step of oil milling mentioned in the process claim. This result seems appropriate, as the *Moloney* patent's contribution to the state of the art is merely a tool independent of an agronomically or physiologically valuable characteristic.

The legal situation in the U.S. seems to be similar to the European situation. According to 35 U.S.C. 271(g),⁶⁰⁵ products made by the patented process fall within the process claim unless they are “materially changed by subsequent processes.” The products made by the patented process are transformed *Brassica* cells, not an oil extracted from a plant. The question whether the oil product is materially changed is answered by a two-step test. Firstly, “the end product will be deemed to be made by the patented process if it would not be commercially feasible to make the end product other than by using the patented process.”⁶⁰⁶ The oil produced from plants obtained by the patented process is generally identical to conventional oil which has been obtained from non-transgenic *Brassica* plants. Therefore the oil product will not be regarded as made by the *Moloney* process according to the first step of the test. Regarding the second part of the test for identifying a “material change,” the production of oil from a transgenic *Brassica* species would require substantial additional steps. These substantial additional steps are not disclosed in the *Moloney* patent and essentially change the physical and chemical properties of the product produced from the patented process, including extraction of the oil from the harvested seed and its purification and stabilization. However, the product produced by the patented process is limited to transformed cells to produce plants having an altered phenotype. Thus the oil product is physically and chemically completely different than the products produced by the patented process.⁶⁰⁷ Therefore, the oil product would not be considered as “made by” the patented process because the patented process

604 EP 270 615 B1, 6 line 20.

605 “Whoever without authority imports into the United States or offers to sell, sells, or uses within the United States a product which is made by a process patented in the United States shall be liable as an infringer, if the importation, offer to sell, sale, or use of the product occurs during the term of such process patent. In an action for infringement of a process patent, no remedy may be granted for infringement on account of the noncommercial use or retail sale of a product unless there is no adequate remedy under this title for infringement on account of the importation or other use, offer to sell, or sale of that product. A product which is made by a patented process will, for purposes of this title, not be considered to be so made after -

(1) it is materially changed by subsequent processes; or

(2) it becomes a trivial and nonessential component of another product.”

606 *Eli Lilly and Co.*, 82 F.3d at 1575.

was not used directly in the manufacture of the product and because the product is materially changed under both parts of the applicable test. There is at least one known commercial method for making the oil product that does not use the patented process, and the additional processing steps essentially change the physical and chemical properties of the product. In conclusion, the U.S. interpretation of the scope of the *Moloney* patent leads to the same result as the European approach.

8. Summary on Art. 64(2) EPC

Summarizing, Art. 64(2) EPC enhances the scope of method claims, also in the case of food-related inventions. The wide parameter approach leads to reasonable results, as was shown by the biscuit patent in comparison to the patent on herbicide-resistant plants. However, whenever the parameter approach is applicable, independent product claims are generally allowable. Thus, Art. 62(2) EPC provides additional protection only when the patentee has not drafted product claims. In contrast thereto, the chronological approach leads to an inappropriately narrow scope, as it does not acknowledge the essential parameters of the invention. In the case of basic technology, both approaches lead to the same result, which seems appropriate as the essential features of the invention are not present in further processed products.

607 In *Bio-Technology General Corp. v. Genentech, Inc.* the CAFC interpreted “made by” to include a polypeptide expressed by a plasmid where the claim was drawn only to a process for making the plasmid. *Bio-Technology General Corp. v. Genentech, Inc.*, 80 F.3d 1561. This decision can be regarded as distinct from the present case, as the oil product is not a product resulting from the direct expression of a specific sequence used in the claimed method for transforming cells. In *Bayer AG* the CAFC distinguished *Bio-Technology General* by stating that the product could not be made by the patented process because the process was not used in the actual synthesis of the drug product and held that “the process must be used directly in the manufacture of the product.” *Bayer AG*, 340 F.3d 1377.

D. Summary

The patentability and the scope of protection of inventions related to the production of agricultural raw materials and the production of processed food vary substantially. There are specific provisions concerning the production of agricultural raw materials, including an exemption to patentability of plant varieties and animal species as well as exemptions from the scope of protection concerning inventions related to the production of plant-derived agricultural raw materials. In contrast to inventions related to the production of agricultural raw materials, there are no specific provisions or exemptions to patentability for inventions relating to the production of processed food. Inventions relating to the production of processed food are treated like inventions in any other industrial sector. The exemptions to patentability and the considerable exceptions from the scope of protection of inventions related to the production of agricultural raw materials lead to a rather weak intellectual property situation, particularly as far as inventions related to the production of plant-derived agricultural raw materials are concerned. The exemption to patentability of plant and animal varieties, the provisions on farm-saved seed and the breeders' exemption in the plant variety protection system and now also in the German patent system are specifically designed for the food sector. These provisions reflect the exceptional position of the production of agricultural raw materials in the German and European patent system. Thus inventions involving the production of agricultural raw materials need to be kept free from restrictions of plant variety protection rights and patents. This is even more astonishing and contradictory as agriculture in Europe is highly industrialized and far from being subsistence farming. All in all, the rather weak protection conferred by the plant variety protection system and the patent system could be a future obstacle to R&D investments in the field of the production of agricultural raw materials.