claimed in the initial patent or in the initial plant variety. A public interest is not necessary any more. The term "significant technical progress of considerable economic interest" will be case-specifically interpreted by the court. A significant technical progress may be given if an inventive step of the dependent invention exists. A granted and valid patent acts as an indicator for a significant technical step. Only exceptionally will plant varieties constitute a "significant technical progress," since an inventive step is often denied.[480]

4. Assessment

The patent system is intended to foster all areas of technology including plant biotechnology and plant breeding. The following amendments under the European patent system and the European plant variety protection system seem necessary concerning plants: First, the exemption to patentability and the double protection prohibition for plant varieties should be abolished.[481] Second, the extensive breeders' exemption and farm-saved seed provision under the amended Patent Act should be limited. Third, a SPC for plant varieties should be introduced.

III. Increase in patent applications for non-genetically modified plants

After the analysis of the protection situation for inventions related to the production of plant-derived agricultural raw materials in the section above, a recent phenomenon is explained: the increasing number of patent applications for traditionally bred non-genetically modified plants at the European Patent Office. This phenomenon is particularly striking as traditionally bred plants were typically protected under the plant variety protection system but not under the patent system.

480 *Lange*, Pflanzenpatente und Sortenschutz - friedliche Koexistenz?, GRUR 1993, 801.

481 *Straus*, Patent Protection for New Varieties of Plants Produced by Genetic Engineering – Should "Double Protection" be Prohibited?, 15 IIC 426, 442 s. (1984), The Relationship Between Plant Variety Protection and Patent Protection for Biotechnological Inventions from an International Viewpoint, 18 IIC 723, 736 s. (1987), where Straus explains that "permitting competition between patent and plant variety protection for biotechnological inventions does not mean legal Darwinism (...)"; *Straus*, Pflanzenpatente und Sortenschutz - Friedliche Koexistenz, GRUR 1993, 794, 801.

More and more patents for non-genetically modified plants have been filed at the EPO, like the "biscuit patent,"[482] "corn plants with improved oil composition"[483] or "rapeseed with improved oil composition."[484] These patent applications are not based on genetically modified plants, but rather on traditional breeding methods comprising artificially induced mutation.

Mutation, selection and regeneration are generally considered elements of traditional plant breeding.[485] The European patent system regards essentially biological processes like selection and crossing as not patentable. However, artificially induced mutation combined with selection is patentable.

1. European patent on herbicide-resistant rice

An example of a patent application on non-genetically modified plants is the European patent on herbicide-resistant rice. The Louisiana State University is owner of the European patent on herbicide-resistant rice, particularly on rice resistant to herbicides that normally interfere with the plant enzyme acetohydroxyacid synthase (AHAS), such as imidazolinone herbicides and sulfonylurea. This patent is typical of patent applications on non-genetically modified plants which are based on artificially induced mutation and selection.

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482 EP 445 929 held by Monsanto covered a soft-milling wheat producing flour with favorable baking properties. The patent has been revoked during opposition. Claim 1 has been directed to: "Soft-milling wheat having an SDS-sedimentation volume, measured as in Experiment 2 described herein and corrected to 11% protein, of not greater than about 30ml."

483 EP 744 888 held by DuPont covered corn and products thereof with improved oil composition. The patent has been revoked during opposition. Claim 1 has been directed to: "A corn grain produced by planting in close proximity a corn plant of an agronomically elite highyielding female parent, having high oleic characteristics, and optionally having high-oil characteristics, with a corn plant of a high-oil and high oleic male parent, optionally having high-yielding characteristics and/or agronomically elite characteristics."

484 EP 813 357 held by Pioneer Hi-Bred International Inc covered an improved Brassica oilseed, an improved plant capable of forming the same, and an improved edible endogenous vegetable oil derived from oilseed Brassica. Claim 1 was directed to: "An improved edible vegetable oil having an improved distribution of fatty acids formed by the process consisting essentially of crushing and extracting Brassica napus oilseeds wherein said distribution of fatty acids is endogenously formed and said vegetable oil exhibits (1) an alpha-linolenic acid content of 1 to less than 3.5 percent by weight based upon the total fatty acid content, (2) an oleic acid content of at least 78 up to approximately 84 percent by weight based upon the total fatty acid content, (3) a total saturated fatty acid content of no more than 4.5 percent by weight based upon the total fatty acid content, and (4) an erucic acid content of no more than 2 percent by weight based upon the total fatty acid content, and wherein each of said recited traits of said oil was controlled by genetic means in the absence of cancellation as the result of the formation of the other recited traits."

485 *Willnegger*, Schutz nicht unterscheidbarer Pflanzensorten, GRUR Int. 2003, 815.

Claim 1 of European patent EP 1 126 756 is directed to

> "A rice plant wherein:
> (a) the growth of said plant is resistant to inhibition by one or more of the following herbicides, at levels of herbicide that would normally inhibit the growth of a rice plant: imazethapyr, imazapic, imazapyr, nicosulfuron, sulfometuron methyl, imazaquin, imazamox, chlorimuron ethyl, metsulfuron methyl, rimsulfuron, thifensulfuron methyl, tribenuron methyl, pyrithiobac sodium, or a derivative of any of these herbicides; and
> (b) said plant is a derivative of at least one of the plants selected from the group of plants with ATCC accession numbers 203419, 203420, 203421, 203422, 203423, 203431, 203432, 203433, and
> (c) said plant has the herbicide resistance characteristics of at least one of the plants selected from the group of plants with ATCC accession numbers 203419, 203420, 203421, 203422, 203423, 203424, 203425, 203426, 203427, 203428, 203429, 203430, 203431, 203432, 203433."

ATCC stands for American Type Culture Collection. This collection comprises over 400 strains of patented seeds.[486]

Twenty-seven new rice plants resistant to AHAS-inhibiting herbicides were identified after rice seeds were exposed to the mutagen methanesulfonic acid ethyl ester. Approximately 52 million mutated rice seeds were screened in the process. One hundred seventy kilograms of seed were soaked with the mutagen and then planted, harvested and stored over the winter. The second-generation seed was screened for herbicide-resistance the following spring by application of an AHAS-inhibiting herbicide. The surviving plants had genetic mutations making them resistant to that herbicide.

The experiments were done on the specific rice varieties *Cypress* and *Bengal*. Thus, the invention is solely based on plants of a certain plant variety and is therefore a subject matter inherent to plant variety protection. However, the technical teaching of the patent is not limited to these two rice varieties. Therefore, the EPO granted the European patent EP 1 126 756 on this plant variety-based invention. The patent has not been opposed by any third party during the 9 month opposition period. Claim 1 covers a process for reproducibly producing rice plants resistant to a herbicide, comprising artificially induced mutation, regeneration and selection under presence of an AHAS-inhibiting herbicide, whereas selected plants express an acetohydroxyacid synthase with a resistance to inhibition by said herbicide.

Furthermore, certain individual rice plants resistant to AHAS-inhibiting herbicides with ATCC accession numbers 203419, 203420, 203421, 203422, 203423, 203431, 203432, including their mutants, recombinants, genetically-engineered derivatives or progeny are patented. Finally, a process for controlling weeds in the vicinity of said plants comprising the application of said herbicide has been claimed and granted.

486 Available at www.lgcpromochem-atcc.com/common/catalog/plantSeeds/plantSeedsIndex.cfm.

2. *Exemption to patentability of essentially biological processes and patentability of artificially induced mutation*

Essentially biological processes are excluded from patentability according to Art. 53(b) EPC. The Biopatent Directive defines a process for the production of plants as essentially biological if it consists entirely of natural phenomena such as crossing or selection. Plant-related inventions that are only based on crossing and selection are not patentable *per se*.[487] This legal definition has been implemented in Rule 23(b)(3) EPC.

Inventions that apply artificially induced mutation are patentable, because they are not merely based on selection and crossing. Natural mutations occurring with much less frequency represent mere discoveries and are therefore not patentable. Thus, the mutation has to be man-made meaning artificially induced, e.g. by employing radiation or mutagenic chemicals, to be patentable.

3. *Assessment*

The increasing number of European patent applications for non-genetically modified plants indicates the insufficiency of the European plant variety protection system. Plant variety protection rights are weak.[488] Moreover, the requirements for a plant variety protection right are perfectly adapted to traditional plant breeding, while they do not fit the new developments of plant breeding and plant biotechnology.[489] Plant variety protection does not consider economically valuable characteristics because distinctness is measured mostly in terms of morphological characteristics. Plant varieties with economically valuable characteristics generated by artificial mutation are therefore not always distinct in the sense of the plant variety protection system. The plant breeders' exemption and regulations on farm-saved seed weaken plant variety protection rights. Although, these exemptions have been introduced in the PatG as well as in the patent systems of most other countries of the EU, patents offer a broader scope by not being limited to a specific plant variety. The danger of imitations of plant-related inventions is higher than in other industrial sectors because of the biological material's ability to reproduce itself.

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487 Art. 2(2) of the Biopatent Directive.

488 *Kock, Porzig, Willnegger*, Der Schutz von pflanzenbiotechnologischen Erfindungen und von Pflanzensorten unteer Berücksichtigung des Umsetzung zur Biopatentrichtlinie, GRUR Int. 2005, 183, 192. This weak protection is internationally criticized because it stunts investments in germplasm generation, in: *Willnegger*, ISF International Seminar "Protection of Intellectual Property and Access to Plant Genetic Resources", GRUR Int. 2004, 611, 613, *Straus* points out, that "patents and other industrial property rights are seemingly the only means which could help host countries in generating funds supporting biodiversity in conformity with the principles of the market economy." *Straus*, Patents on Biomaterial – A New Colonialism or a Means for Technology Transfer and Benefit-Sharing, in: *Thiele&Ashcroft* (eds.), Bioethics in a Small World, Heidelberg 2005.

489 *Willnegger*, Schutz nicht unterscheidbarer Pflanzensorten, GRUR Int. 2003, 815.

Consumers in the EU seem to be careful about products made of genetically modified plants.[490] Though a plant derived from artificial mutation is everything but natural, products derived from artificially mutated plants seem to be generally accepted.

The concept of non-genetically modified, herbicide-resistant plants is well established outside Europe, as the Clearfield® production system shows. BASF Corp. in the U.S. distributes the seed of the Clearfield® production system successfully. According to BASF Corp.: "The system is a combination of herbicides and seeds that are tolerant to these herbicides. The seeds are obtained using traditional breeding methods and not using genetic engineering."[491] The first Clearfield® production system was launched in the U.S. in 1992 for corn. New Clearfield® seed lines are being developed and sold in worldwide partnerships with more than 100 seed companies, in particular for wheat, rice, sunflower and canola.[492] The EU is a new target for such non-genetically modified systems, as genetically modified seed is not accepted there.

The rising number of patent applications of non-genetically modified plants shows that exemptions to patentability are rather doubtable. In practice, the courts allow a circumvention of this exemption. Thus, the exemption to patentability of plant varieties only complicates the application processes and therefore should be abolished.

Patents are the answer to weak plant variety protection rights. Patents grant generic protection and thus guarantee better protection than plant variety protection rights, which are confined only to the protected plant variety as such with exception of essentially derived plant varieties. Patentees are not only interested in protecting seed of their plant variety, but also in products derived from that biological material. These interests are best protected by the generic protection of patents.

490 *Jaeger*, Dr. Jekyll und Mr. Mais, Spiegel Special No. 5, 2005, Besser Essen, besser Leben – Ernährung und Gesundheit, 96.

491 BASF AG, available at www.corporate.basf.com/en/innovationen/preis/2001/clearfield.htm?id =er-5cG7AJKbcp3KK.

492 The group of imidazolinones consists of six active ingredients. As a result, BASF AG can offer custom-designed products that best control typical weeds in a particular crop or region. In the coming years, BASF AG will launch several Clearfield systems and expects them to yield annual sales of approximately U.S.$300 million.
Available at www.corporate.basf.com/en/innovationen/preis/2001/clearfield.htm?id=er5cG7AJKbcp3KK.

B. Protection of inventions related to the production of animal-derived agricultural raw materials

Inventions related to the production of animal-derived agricultural raw materials are protected under the patent system only, as there is no *sui generis* protection system for animal breeding. Art. 53(b) EPC and Sec. 2, No. 2, of the PatG except animal varieties and essentially biological processes for animal breeding from patent protection. Animals are not excluded from patentability, as long as higher taxonomic units than varieties are claimed.[493] The German translation of term animal varieties in Art. 53(b) EPC, as well as in former Sec. 2, No. 2, PatG read *Tierarten*, meaning animal species. Animal species is a higher taxonomical rank than animal variety. But according to the rationale of the EPC based on the Strasbourg Convention, only animal varieties are excluded from patentability. Thus, the German wording *Tierarten* is to be read as animal varieties.[494] Moreover, Art. 4(1)(a) of the Biopatent Directive used the correct term of animal varieties. Meanwhile, the German Implementation Act to the Biopatent Directive introduced a new § 2a(1) PatG also reading *Tierrassen*. So, only animal varieties are excluded from patentability but not animal species.

Up to now, there is no *sui generis* protection system for animal varieties that could compensate for the exemption to patentability of animal varieties. *Straus*[495] has already suggested introducing an animal variety protection system similar to the European or German plant variety protection system.[496]

C. Protection of inventions related to the production of processed food

The protection of inventions related to the production of processed food is considerably more favorable than that of inventions related to the production of agricultural raw materials. There are three areas particularly concerning the production of processed food. On the one hand, savor nuances comprise a field of inventions that is considered characteristic of inventions concerning processed food. Next the product-by-process claim is discussed. Finally, the protection provided by Art. 64(2) EPC for the product directly obtained by the patented process is analyzed and exemplified with three patents on food-related inventions.

493 EPO decision T19/90, Onco-mouse/Harvard II, OJ 1990, 476.

494 *Moufang,* in: *Schulte* (ed.), Patentgesetz mit EPÜ, München 2004, Sec. 2, No. 78, *Hansen&Hirsch*, Protecting Inventions in Chemistry, Weinheim et al. 1997, 273.

495 *Straus*, Ethische, rechtliche und wirtschaftliche Probleme des Patent- und Sortenschutzes für die biotechnologische Tierzüchtung und Tierproduction, GRUR Int. 1990, 913.

496 *Von Pechmann*, Ausschöpfung des bestehenden Patentrechts für Erfindungen auf dem Gebiet der Pflanzen- und Tierzüchtung, GRUR 1987, 475, *Hansen&Hirsch*, Protecting Inventions in Chemistry, Weinheim et al. 1997, 275.