Part III. Intellectual property situation of today's food sector

Part I examined retrospectively the exemption to patentability of food, its reasons and the consequences of its abolition in Germany in comparison to Brazil, China, and India. Part I showed, that due to the TRIPs Agreement food must now be eligible for patent protection in most countries worldwide. The TRIPs Agreement led to an increase of food-related patent applications in developing countries, where food had often been excluded from patentability. This development is similar to the development in Germany after food-related substances became eligible for patent protection in 1967. Finally, it was shown that the food sector has an exceptional position which has been reflected in patent law by the exemption to patentability of food.

Part II focused on the technological developments in today's food sector. It became clear, that innovation is a key instrument for the food sector. Innovation in the food sector has been influenced to a large extent by the implementation of biotechnology. The use of genetically modified microorganisms in the processing of food seems widely accepted in Europe, whereas the cultivation of genetically modified plants seems to be rejected by consumers. Moreover the labeling requirements could make marketing of products derived of genetically modified plants difficult. Consequently Europe runs a great risk of losing out in this important field of technology.

Finally, the third part of this dissertation analyzes the intellectual property situation of the food sector of today. It shows that though the exemption has been abolished, the food sector's intellectual property situation is nonetheless different from the situation of other industrial sectors. This applies mainly to inventions related to the production of agricultural raw materials and particularly to inventions related to the production of plant-derived agricultural raw materials, whereas inventions related to the production of processed food are treated like inventions in any other industrial sector.

A. Protection of inventions related to the production of plant-derived raw materials

This section discusses the protection of inventions related to the production of plant-derived agricultural raw materials. The example of plant-biotechnological inventions shows that the food sector still has an exceptional position in intellectual property law. This exceptional position is shown by the exemption to patentability of plant varieties and the two exemptions from the scope of a patent and of a plant variety protection right, the breeders' exemption and the farm-saved-seed provision.

Innovations related to the production of plant-derived agricultural raw materials mainly concern plant varieties and plant-biotechnological inventions. There are two protection systems available. Plant varieties are protected under the plant variety protection system, whereas other plant-related inventions, including plants, can be protected under the patent system. Both the plant variety protection system and the patent system offer rather weak protection due to wide exemptions from the scope of protection. These exemptions from the scope of plant-related patents and plant variety protection rights have been recently harmonized in Europe.

I. Protection under the plant variety protection system

First, the term plant variety is defined. Then, the conditions and the scope of protection of a plant variety right, including essentially derived varieties, are explained. The exemptions to the scope of a plant variety protection right, especially the breeders' exemption and the farm-saved-seed provision, show that the intellectual property situation concerning inventions related to the production of plant-derived agricultural raw materials is exceptional compared to other fields of technology.

The protection of plant varieties is regulated in the German Plant Variety Protection Act, the *Sortenschutzgesetz* (SortG), on the German level, and in the Regulation (EC) No. 2100/94 on Community Plant Variety Rights (CPVR) on the European level.[378]

1. Plant variety as protectable subject matter

The protectable subject matter of the SortG is a plant variety. A plant variety is legally defined as a "plant grouping within a single botanical taxon of the lowest known rank, which grouping, irrespective of whether the conditions for the grant of a plant variety right are fully met, can be defined by the expression of the characteristics that results from a given genotype or combination of genotypes, distinguished from any other plant grouping by the expression of at least one of the said characteristics, and considered as a unit with regard to its suitability for being propagated unchanged."[379]

378 SortG of December 19, 1997, Regulation (EC) No .2100/94 on Community Plant Variety Rights of July 17, 1994, OJ L 227, 1.

379 Art. 5, No. 2 CPVR, Sec. 2 (1a) SortG.

This is how the International Union for the Protection of New Varieties of Plants (UPOV)[380] defines a plant variety. The European[381] and U.S. plant variety protection systems are also based on this definition of the UPOV Convention.[382]

2. Conditions of protection

Plant variety protection rights are granted if the plant variety is new,[383] uniform, stable, and distinct,[384] and meets the provisions regarding varietal designation.[385] These criteria fit perfectly for traditional plant breeding. Only distinctness causes difficulty with plant biotechnology aiming to develop economically valuable characteristics.[386]

A plant variety[387] is distinct if it is clearly distinguishable by the expression of at least one determining characteristic[388] from any other plant variety whose existence is a matter of common knowledge on the date of application. In Germany, distinctness is assessed by field trials as part of the examination of dinstinctness, uniformity and stability, the so-called DUS testing, by the Federal Plant Variety Office, the *Bundessortenamt*. The plant variety is examined in comparison with an assortment of other known plant varieties of the same species. This DUS testing is based on the UPOV Convention as well.[389] Many other countries follow a similar procedure.[390]

380 *Straus&von Pechmann*, Die Diplomatische Konferenz zur Revision des Internationalen Übereinkommens zum Schutz von Pflanzenzüchtungen, GRUR Int. 1991, 507. *Lange*, Abgeleitete Pflanzensorten und Abhängigkeit nach dem revidierten UPOV-Übereinkommen, GRUR Int. 1993, 137.

381 The EU is the first intergovernmental organization that joined UPOV on June 29, 2005, UPOV Press Release No.65 of June 29, 2005, European Communities become first intergovernmental organization to join UPOV, available at www.upov.int/en/news/pressroom/pdf/pr65.pdf.

382 UPOV has 59 members in July 2005, covering most of developed countries, available at www.upov.int/en/about/members/pdf/pub423.pdf.

383 Novelty is linked to commercial launch of the variety, wherein generous novelty protection periods are granted, Sec. 6 SortG, Art. 10 CPVR.

384 Sec. 3 SortG, Art. 7 CPVR.

385 For an overview over the material conditions for the grant of Community Plant Variety Rights see, *Würtenberger et al.*, European Community Plant Variety Protection, New York 2006, 28 ss.

386 „The practice of the CPVO shows the distinctness condition as being the major hurdle for the grant of a PVR.“ *Würtenberger et al.*, European Community Plant Variety Protection, New York 2006, 32, 36.

387 Sec. 2(1a) SortG, Art. 5(2) CPVR.

388 Sec. 3(1) SortG. In contrast, Art. 7(1) CPVR only refers to characteristics in general without the limitation "determining" (*maßgebend*).

389 Beside a "General Introduction to the Examination of Distinctness, Uniformity and Stability and the Development of Harmonized Descriptions of New Varieties of Plants" (UPOV Doc. TG/1/3) UPOV provides test guidelines for 196 plant species with tables for specified characteristics.

390 In contrast, the U.S. Plant Variety Protection Office does not conduct own field trials but performs examination based on data provided by the applicant.

During the DUS testing Approximately 20–25 specified characteristics contained in the characteristics catalog for species of the UPOV are examined. Only one different characteristic is sufficient for distinctness. The catalog of the UPOV Convention covers mainly morphological[391] characteristics, which are usually monogenically[392] inherited, and are sufficiently uniform, stable and usually visually discernible.

Quality characteristics are economically valuable, but they are not considered at all in the DUS testing, being usually inherited polygenically and being strongly dependent on environmental factors. Hence, quality characteristics do not necessarily guarantee morphological distinctness.[393] They are only investigated in the plant variety registration procedure[394] as part of the examination of "value for cultivation and use."[395] As a consequence, plant varieties whose only distinct traits are economically valuable characteristics cannot be protected by plant variety protection rights.[396]

This gap in protection cannot be filled by the patent system.[397] Even though a plant variety can be within the scope of a patent, the lapse of the term of a patent renders protection almost ineffective.

Under the German and the European patent system, a generic patent claim on a plant is admissible.[398] Plant-related inventions are protectable if the technical feasibility of the invention is not restricted to plant varieties. Thus, a plant is patentable as long as the underlying invention is not restricted to one or many plant varieties. Plant groupings of a higher taxonomical unit than a plant variety are consequently patentable. A generic claim on a plant also extends to a specific plant variety.[399]

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391 Morphological means regarding the external shape.

392 Monogenically inherited means a trait caused by a single gene. In contrast, a polygenically inherited trait is caused by multiple genes.

393 A morphologic distinction can arise as a result of genetic change as a coincidental side effect to a value-determining characteristic. This is however neither foreseeable nor reproducible.

394 The plant variety market authorization regulated in Sec. 30 SaatG is a condition for the acceptance of seeds, planting and reproduction material in accordance with Secs. 4, 4a SaatG. This acceptance is again a condition for marketing of seeds, planting and reproduction material according to Sec. 3 SaatG. The conditions for a plant variety authorization are novelty, homogeneity, stability, distinctness and a designation by a suitable denomination (these prerequisites being identical with the conditions for plant variety protection rights) and – in addition - the "Value for Cultivation and Use" (*landeskultureller Wert*). For the examination of said national-cultural value also quality characteristics are assessed according to Sec. 30(1) SaatG.

395 A plant variety possesses "Value for Cultivation and Use" according to Sec. 34 SaatG, if - based on the whole of its value-determining characteristics - it demonstrates a clear improvement for crop farming or for utilization of the harvested crop or of products obtained from the harvested crop in relation to plant varieties registered in the plant variety list. The value-determining characteristics, which relate to cultivation, resistances, yield, quality and application opportunities, are examined under cultivation and in the laboratory.

396 *Willnegger*, Schutz nicht unterscheidbarer Pflanzensorten, GRUR Int. 2003, 815, 817.

397 Although there are much higher material hurdles to protect a plant variety under a patent, protection is possible despite the exclusion of plant varieties *per se*, Art. 53(b) EPC, Sec. 2(2) PatG.

398 EPO, Enlarged Board of Appeal decision G 1/98 of December 20, 1999, OJ EPO 2000, 111.

399 ECJ, Kingdom of the Netherlands v. European Parliament and Council of the EU, Suspension of Directive 98/44/EC, Case-377/98, European Court Reports 2001, I-07079, Reasoning No. 46.

Patent protection, however, begins in the R&D phase. The long development periods for genetically modified plant varieties lead mostly to an exhaustion of the 20-year term of a patent until the new plant variety reaches the market. Therefore, there is hardly enough time for the plant breeder to recoup his investment.[400]

As a last chance, a plant breeder can exceptionally request the Plant Variety Protection Office to include a special quality characteristic in the test for distinctness.[401] Such an examination is at the sole discretion of the respective Plant Variety Protection Office. Hence, a plant breeder faces a certain degree of legal insecurity.

In Germany, a plant variety protection right lasts 25 years starting from the date of grant,[402] at which point the plant variety already exists as a marketable product. A plant variety protection right offers a longer duration of protection than a patent.

3. Scope of protection

A plant variety protection right covers constituents like seed of the plant variety[403] as a concrete material subject,[404] but it does not provide generic protection.[405]

400 *Willnegger*, Schutz nicht unterscheidbarer Pflanzensorten, GRUR Int. 2003, 815, 816.

401 *Willnegger*, Schutz nicht unterscheidbarer Pflanzensorten, GRUR Int. 2003, 815, 820. Representatives of the German Plant Variety Protection Office seem to be open for this approach based on statements made on the 2004 meeting of the GRUR Committee for the Protection of Plant Varieties (Munich, March 19, 2004). Special examinations are also possible after special approval of the CPVO President in proceeding before the Community Plant Variety Protection Office (Angers, France).

402 The plant variety protection term starts in the calendar year following on the grant of a plant variety protection right. For hops, potato, wine and tree varieties the protection term is 30 years according to Sec. 13 SortG, Art. 19(1) CPVR.

403 Art. 13(2) CPVR.

404 *Straus,* Pflanzenpatente und Sortenschutz - Friedliche Koexistenz, GRUR 1993, 794, 801. The scope of protection also extends to other plant material (e.g., harvested material) if the owner has had no reasonable opportunity to exercise his right in relation to the variety constituents according to Sec. 10 (1), No. 2 SortG, Art. 13(3) CPVR.

405 For an overview on the scope of a plant variety right see *Würtenberger et al.*, European Community Plant Variety Protection, New York 2006, 115 ss.

a. Essentially derived plant varieties

The plant variety protection right also extends to plant varieties that are essentially derived from a protected plant variety,[406] which is called initial plant variety.[407] A plant variety is considered essentially derived if the initial plant variety was predominantly[408] used for its breeding. The exact definition of an essentially derived plant variety still depends on a definite interpretation of the respective court. Usually, the overall genetic conformity[409] serves as definition.[410] The transformation[411] of an initial plant variety always leads to an essentially derived plant variety[412], since the overall genetic conformity is only changed minimally by inserting a foreign gene into the genome of the initial plant variety.

In the past, the result of traditional plant breeding generally could not be linked to individual genes. It was assumed that the result was due to an improvement of the entire genome. Today, molecular breeding and plant biotechnology provide economically valuable characteristics such as disease resistance in plant varieties. These characteristics are identifiable within and separable from the genome as they often are linked to individual genes. The out-crossing of such a favorable gene from an initial plant variety by crossing with another plant variety leads to an independent plant variety, because there is conceptually no essential derivation involved in the process.[413] Consequently, an economically valuable characteristic cannot be protected under the plant variety protection system, as the concept of the essentially derived plant variety fails as soon as one crossing step is performed. The rapid isolation and use of economically valuable characteristics or certain genes by competitors is unavoidable, discouraging innovation and investment.

To sum up, economically valuable characteristics are not considered in the DUS testing. However, plant breeders of initial plant varieties should be granted protection for economically valuable characteristics. Inventive step offers a proper remedy for the assessment of economically valuable characteristics.[414]

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406 Sec. 10(2) SortG, Art. 13(5) CPVR.

407 The concept of essentially derived varieties is an important exception to the prinicple of independence in plant variety protection. *Würtenberger et al.*, European Community Plant Variety Protection, New York 2006, 121.

408 This requires a genetic conformity of more than 50%.

409 "Overall" in this context means an assessment based on the entire genome but not on specific genetic elements or characteristics.

410 Plant breeders currently try to develop reliable criteria for a limit value for the genetic conformity. The International Seed Federation (ISF) proposes a conformity of 80-85% of the genotype. Available at www.worldseed.org/Position_papers/derivg.htm.

411 Transformation of a plant variety means the genetic modification of a plant by the insertion of genetic elements into its genome.

412 Transformation with a specific genetic element can alternatively also result in a non-distinct plant variety if said genetic element is not linked with a phenotype distinguishable according to the requirements of the plant variety protection regulations.

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

414 *Willnegger*, Schutz nicht unterscheidbarer Pflanzensorten, GRUR Int. 2003, 815, 820.

b. Exemptions to plant variety protection

The scope of a plant variety protection right does not extend to plant breeding, discovering or developing other plant varieties, or their commercialization, with the exemption of essentially derived plant varieties.[415] The rationale of the plant breeders' exemption in the context of interest is to guarantee advances in food production by ensuring the free availability of genetic material. The success of plant breeding mainly depends on the genetic variation of the initial plant variety.[416] Traditional plant breeders insist on an unrestricted plant breeders' exemption ensuring genetic variability.[417]

The *de facto* exclusivity of a new plant variety comprising an economically valuable characteristic has now been shortened tremendously. In the past, the initial plant breeder enjoyed a *de facto* exclusivity for 10–15 years after market introduction for new economically valuable characteristics of his plant varieties. Modern technologies speed up plant breeding, including the use of economically valuable characteristics from third parties' plant varieties. Nowadays, it is only 4-5 years, which can be too short for an amortization.[418]

The current plant variety protection system encourages low-risk and inexpensive copying of existing plant varieties leading to small genetic changes. On the other hand, the high expense of screening indigenous plant varieties, that have not been subject to systematic breeding, for new characteristics is hard to justify in view of an unrestricted use by competitors.

A further restriction unique to plant variety protection is the farm-saved seed provision. It is also called farmers' privilege, because it entitles farmers to use harvested seed on their own land for the next crop.[419]

New plant-biotechnological inventions are only profitable if the high investments can be returned, something that depends on the existence of strong intellectual property rights. For this system to work properly, a farmer[420] using harvested seed for his next crop must be obliged[421] to pay the plant breeder a reasonable fee,[422] which must be substantially

415 Sec. 10a(1), No.3 SortG, Art.15(c) CPVR.

416 The initial plant variation is the genetic variation of parental plants used for the plant breeding process.

417 *Le Buanec,* The Management of Intellectual Property Rights in Plant Biotechnology, Doc. WIPO-UPOV/SYM/03/11, 6 (2003).

418 *Meussen,* Commercialization of Transgenic Seed Products, 792 Annals of New York Academy of Sciences 172 (1996). The embryo rescue technique results in a decrease of the development time for new wheat varieties from previously 13 years to 4 years.
Available at www.isaaa.org/kc/CBTNews/2003_Issues/Aprn il/CBT_April_25.htm. For more information see Part III Section A Subsection II.2.

419 Worldwide the extent of farm saved-seed is substantial. In Germany it accounts for 46%. *Toledo,* Saving the Seed: Europe's Challenge (2002), available at www.grain.org/seedling/?id =191.

420 This regulation does not affect small farmers according to Sec. 10a(5) SortG.

421 Sec. 10a(3) SortG, Art. 14 CPVR.

lower than a normal royalty.[423] In its recent judgement of June 8, 2006 the ECJ[424] ruled that a flat-rate remuneration calculated at 80% of the certified seed fee cannot be considered as satisfying the requirement that the remuneration has to be 'sensibly lower' than the normal royalty.[425] Additionally, such a farmer has to inform the plant breeder of the respective plant variety protection right of his use of farm-saved seed of the protected plant variety.[426] However, the ECJ denies the plant breeder a right to information without probable cause of such use.[427] This probable cause should be facilitated by a general right to information for the plant breeder.[428]

4. Assessment

The plant variety protection system is well established and adapted to the plant world. However it does not adequately protect economically valuable characteristics.

The scope of protection and the enforcement of plant variety protection rights is unsatisfactory. Any use of plant breeding results short of plagiarism or product piracy cannot be prevented. The enforcement was not a major concern when plant variety protection laws were being formulated, as business among traditional plant breeders was often based on gentlemen's agreements. However, globalization, product piracy and hard competition are now influencing plant breeding. An appropriate balance between the interests of plant breeders and the public must be sought. Furthermore, the incentive to develop new plant varieties with economically valuable characteristics must be maintained. A modernization of the plant breeders' exemption and the farm-saved-seed provision is overdue. Technological progress makes a modernization of the UPOV Convention necessary.

422 This remuneration accounts – depending on the plant species – up to 50% of the common license fee. Available at www.bayerischerbauernverband.de/sro.php?redid=6050.

423 Art. 5(2)(3), Commission Regulation (EC) No. 1768/95 of July 24, 1995 on the implementing rules on the agricultural exemption provided for in Art. 14(3) of Council Regulation (EC) No. 2100/94 on Community Plant Variety Rights.

424 Joined cases C-7/05 to C9/05, Saatugut-Treuhandverwaltuns GmbH, European Court Reports 2006, available at http://eur-lex.europa.eu.

425 Joined cases C-7/05 to C9/05, Saatugut-Treuhandverwaltuns GmbH, European Court Reports 2006, Reasoning No. 20, 29, available at http://eur-lex.europa.eu. The ECJ seems to regard a remuneration to be paid to plant variety protection right holders, a rate of 50% of the certified seed fee and even transitionally fixed a rate of 40% as adequate in order to encourage the conclusion of agreements between holders and farmers, Reasoning No. 27.

426 Sec. 10a(6) SortG, Art. 14(3) CPVR, Art. 8 Regulation (EC) No. 1768/95.

427 ECJ, Schulin, European Court Reports 2004, I-02263, Reasoning No. 57, 62. The *Bundesgerichtshof* decided similar with regard to national plant variety protection rights (Nachbau-Auskunftspflicht, GRUR 2002, 238, 240).

428 *Würtenberger*, Der Auskunftsanspruch beim Nachbau von geschützten Pflanzensorten, GRUR 2003, 838, 845.

First, a stronger international harmonization of the requirements for the DUS testing, including a deposit system and a generally accessible database[429] of the plant varieties' characteristics, is proposed. Second, amendments to the plant breeders' exemption are necessary, comprising:

- Limitation of the breeders' exemption for hybrid parental lines being coincidentally present in seed,
- Suspension of the breeders' exemption for a certain time after the grant of the plant variety protection right, or the allowance of earlier use of a protected plant variety for appropriate remuneration, and
- Mandatory use of deposited seeds as a condition for plant breeding under the plant breeders' exemption.[430]

Third, a general right to information for the plant breeder regarding reproduction under the farm-saved seed provision is recommended. Fourth, additions to the system of essentially derived plant varieties should be made with regard to the protection of economically valuable characteristics. Fifth, plant variety protection rights should be extended to harvested material. Last but not least, the effective enforcement of plant variety protection rights is crucial. Molecular-biological analyses must replace the lengthy and expensive cultivation of the plant varieties in question for comparison to the protected plant variety, on which the courts still insist.[431] The present burden of proof and probable cause make it difficult to obtain a preliminary injunction.[432]

II. Protection under the Patent System

Innovation related to the production of plant-derived agricultural raw materials comprising new plant varieties and plant-biotechnological inventions can also be protected by patents. Though patents offer generic protection, the intellectual property situation concerning inventions related to the production of plant-derived agricultural raw materials is nevertheless rather weak. This weak intellectual property situation is mainly due to wide exemptions from the scope of protection similar to the exemptions of the plant variety protection system.

429 Available at www.worldseed.org/Position_papers/UPOVdatabasee.htm.
430 This would solve problems of the burden of proof regarding essentially derived varieties.
431 A reversion of the burden of proof and an obligation to disclose breeding books in case of a high genotypic conformity are desirable. The efforts of breeders' federations go into this direction.
432 *Würtenberger,* Beweisrechtliche Fragen im Sortenschutzverletzungsverfahren, GRUR 2004, 566.