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.

*1. Scope of protection*

The Biopatent Directive[433] of the EU stipulates that patent protection is not exhausted with the first sales of the reproductive material, e.g. in the form of seed.[434] The patent protection therefore extends to any biological material derived from the protected biological material by propagation or multiplication in an identical or divergent form and possessing the same characteristics.[435] Exhaustion by sales of the reproductive material occurs only if the produced material is not used again as reproduction material. Thus, the rights of the patent owner are exhausted if the patented material is consumed as food or feed.[436]

The patent protection for a DNA sequence extends to all materials containing the DNA sequence and performing its functions.[437] The scope of protection for plants only encompasses specific plant varieties, even if these are not patentable as such. Hence, *Moufang* speaks of a rather formal exclusivity of the plant variety protection.[438]

*2. Term of protection*

The term of a patent lasts 20 years starting from the filing date of a patent application and begins in the R&D phase, when as a rule no marketable product is yet in place. The term of a plant variety right starts with its grant, when a marketable product is already available. A marketable plant variety is achieved after a costly development process of 15 years after the initial invention.

Seed companies invest approximately 12% of their annual turnover in R&D. Development periods of 7–15 years for plant varieties are on a par with pharmaceuticals.[439] Similarly, a genetically modified plant becomes a marketable plant variety only after intensive breeding. The development period of the first glyphosate-resistant soy variety

433 Directive 98/44/EC of the European Parliament and of the Council of July 6, 1998 on the Legal Protection of Biotechnological Inventions (Biopatent Directive), OJ 1998 L 213, 13. Available at www.europa.eu.int/eurlex/pri/en/oj/dat/1998/l_213/l_21319980730en00130021.pdf.

434 *Straus,* The Relationship Between Plant Variety Protection and Patent Protection for Biotechnological Inventions from an International Viewpoint, 18 IIC 723 (1987), *Straus,* Patent Protection for New Varieties of Plants Produced by Genetic Engineering – Should "Double Protection" be Prohibited?, IIC 1984, 426. *Hesse,* Zur Patentierbarkeit von Züchtungen, GRUR 1969, 650, *Beier&Straus,* Genetic Engineering and Industrial Property, Ind. Prop. 1986, 447, 456, *Lukes*, Das Verhältnis von Sortenschutz und Patentschutz bei biotechnologischen Erfindungen, GRUR Int. 1987, 318, 322.

435 Art. 8(1) of the Biopatent Directive.

436 Art. 10 of the Biopatent Directive.

437 Art. 9 of the Biopatent Directive.

438 The Interface between Patents and Plant Variety Rights in Europe, Doc. WIPO-UPOV/SYM/ 03/06, 8 (2003).

439 At least 7-12 years for annual plant varieties and 10-15 years for biannual plant varieties. *Meussen,* Commercialization of Transgenic Seed Products, 792 Annals of New York Academy of Sciences 172 (1996).

(Roundup®) was 12 years, of which 7 years were needed solely for traditional plant breeding activities.[440] Plant breeding and plant biotechnology procedures have sped up the development process. However, the necessary regulatory approvals then took up the time this would have saved. As a consequence, even today, the development period of genetically modified varieties still takes 12–18 years.[441]

High commercial risks are inherent in the development of genetically modified plants.[442] The probability that a genetically modified plant will reach the market is very low: 25,000 trials during the period from 1980 to 1996 led only to a few commercially successful plant varieties of corn, oil-seed rape, cotton and soy.[443] Aside from possible technical difficulties, political uncertainty adds to the risks of developing commercially viable plant varieties.[444]

Usually, only 5 years of protection remain once the variety reaches the market. This period is far too short to recoup the investments. For this reason, an "industry-specific patent extension legislation"[445] has been suggested. Supplementary protection certificates (SPCs) provide an established solution for products requiring regulatory approvals. Such SPCs are already used for pharmaceuticals[446] and agrochemicals.[447] They allow the patentee to market his invention before generic products are offered at lower prices. An SPC grants the same rights and is subject to the same restrictions as a patent.[448]

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440 *Meussen,* Commercialization of Transgenic Seed Products, 792 Annals of New York Academy of Sciences 172 (1996).

441 Of these, 5–10 years for R&D, at least 3 years for regulatory approval under the *Gentechnikgesetz*, plus 2–3 years for marketing acceptance under SaatG and testing for plant variety protection.

442 Research costs amount to at least U.S.$1.5 million, development costs to at least U.S.$1-5 million depending on the trait (see No. 12). More recent numbers for development are about U.S.$3-8 million because of increasing regulatory requirements.

443 Out of 25,000 field trials with 10 traits and more than 60 plant species only 51 plant varieties with 4 traits in 15 plant species resulted. However, only herbicide and insect resistance traits can claim commercial success. In: *Phillips,* IPRs an the Industrial Structure of the North American Seed Industry (2003),
available at www.farmfoundation.org/projects/documents/Phillips.iprsandindustry.final_000.pdf.

444 One example are the restrictive regulations for labelling and especially liability. In Germany farmers, which grow genetically modified crops, are facing a general liability even in cases without fault for "pollution" caused by cross-pollination. Farmers, which loose their ecological certification in consequence of the release of a genetically modified crop or become unable to commercialize their harvest, are entitled to compensation.
Available at www.bundesregierung.de/-,413.588691/artikel/Neues-Gentechnikgesetz-vom-Bun.htm. Insurance companies have already declared that the "risk cannot be calculated" and will not provide any corresponding insurance. Available at www.gdv.de/presseservice/24243.htm?IE.

445 *Malpass,* Life After the GATT TRIPs Agreement - Has the Competitive Position of U.S. Inventors Changed?, 19 Houston Journal of International Law. 207, 229 (1996).

446 Council Regulation (EEC) No. 1768/92 of June 18, 1992 concerning the creation of a SPC for medicinal products. ABl. EG Nr. L 182, 1.

447 Regulation (EC) No. 1610/96 of the European Parliament and of the Council of July 23, 1996 concerning the creation of a SPC for plant protection products. ABl. EG Nr. L 198, 30. *Schennen,* Auf dem Weg zum Schutzzertifikat für Pflanzenschutzmittel, GRUR Int. 1996, 102.

448 Art. 5 of Council Regulation 1768/92/EEC.

The term of the SPC is the period between the patent application and the market approval for the protected product.[449] The maximum term of an SPC is 5 years.[450]

The SPC compensates for the delay between the patent application and the first marketing approval for a product. For pharmaceuticals, this period lasts 9–10 years,[451] while a similar development time is observed for agrochemicals. The development time for genetically modified plant varieties is, at 15 years, even longer. Genetically modified plants are subject to regulatory approvals under the Directive on the deliberate release of genetically modified organisms[452] and the Seed Marketing Directive.[453] In addition, the directives for genetically modified food and feed products must be observed.[454]

The scope of protection of a SPC for genetically modified plants should be similar to the respective SPCs for pharmaceuticals and agrochemicals. Moreover, the SPC should be limited to the subject matter of the administrative approval, the so-called event. An event is the act of inserting or deleting a gene in a plant's genetic material according to Directive 2001/18/EC.[455] Hence, the event represents a specifiable value for the initial plant breeder and is a suitable point of reference for the SPC.[456]

The event is present in the seed in a replicable and simply isolatable form. After expiration of the term of a patent, competitors can take advantage of the event for their own plant breeding and can market it with the approval of the initial plant breeder. The competitor saves R&D costs and avoids the regulatory approval. This does not apply for pharmaceuticals or agrochemicals due to secondary applicant regulations.[457]

449 Relevant is the time of first authorization for market introduction in an EC member state.

450 *Mühlens*, Das Ergänzende Schutzzertifikat für Arzneimittel, Mitt. 1993, 213, 217.

451 *Suchy*, Patentrestlaufzeit neuerer pharmazeutischer Wirkstoffe, GRUR 1987, 268, 269.

452 Directive 2001/18/EC of the European Parliament and of the Council of March 12, 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC.

453 Council Directive 2002/53/EC on the common catalogue of varieties of agricultural plant species, Directives concerning respectively the marketing of beet seed (2002/54/EC), fodder plant seed (66/401/EEC), cereal seed (66/402/EEC), seed potatoes (2002/56/EC) and seed of oil and fiber plants (2002/57/EC).

454 Resolution on the proposal for a European Parliament and Council regulation on genetically modified food and feed COM/2001/425 (Novel Food and Feed Regulation), regulation concerning traceability and labeling of genetically modified organisms and traceability of food and feed products produced from genetically modified organisms (COM/2001/182).

455 Here, an event refers to insertion of a specific DNA sequence at a specific location within the plant genome. The definition and description requirements for an event are specified in Directive 2001/18/EC Appendix III-B-D.

456 Any other independent type of event is not covered by the approval and should therefore not be the subject of the SPC.

457 The secondary applicant regulation for pharmaceuticals according to Sec. 24a of the German Pharmaceuticals Law and for agrochemicals according to Sec. 20a SortG specifies that a registration is possible by third parties with reference to the initial application after 10 years.

*3. Limitations of protection*

Research exemption, plant breeders' exemption and the provision on compulsory licenses limit the protection for inventions related to the production of plant-derived agricultural raw materials under the patent system considerably.

*a. Research exemption and plant breeders' exemption*

The research exemption[458] does not cover the development of new plant varieties using patent-protected plant varieties for further plant breeding. Only in exceptional cases does the research exemption justify the breeding of new plant varieties.[459]

Generally, the protection conferred by a patent on a biological material possessing specific characteristics as a result of the invention extends to any biological material derived from that biological material through propagation or multiplication in an identical or divergent form and possessing those same characteristics.[460] Dependency pyramids are not to be feared if the patent-protected gene is out-crossed in the course of the plant breeding process.[461] However, the first plant breeding step with the patent-protected plant requires permission from the patentee.[462] This restriction of the use of genetic resources is considered a possible threat to future plant breeding efforts. Plant breeders therefore demand a provision equivalent to the plant breeders' exemption in the plant variety protection system for patents allowing the use of the genetic background of patent-protected plant varieties.[463] *Straus* pleads for an amendment to the PatG, because

458 Research relating to the subject matter of the invention is exempted from the patent right, Sec. 11(2) PatG. However, research with the subject of the invention is in general not exempted. BGH, Clinical Trial I *(Klinische Versuche I)*, GRUR 1996, 109, BGH, Clinical Trial II *(Klinische Versuche II),* Mitt. 1997, 253, *Fähndrich&Tilmann,* Patentnutzende Bereitstellungshandlungen bei Versuchen, GRUR 2001, 901, IPR Helpdesk document "Patenting and the Research Exemption" available at www.iprhelp-desk.org/documentos/docsPublicacion/pdf_xml/-8_BP-Patenting-and-the-Research-Exemption[0000003268_00].pdf.

459 Breeding is only in exceptional cases leading to generation of new knowledge about an invention and rarely involves an inventive step, *Lange*, Pflanzenpatente und Sortenschutz - friedliche Koexistenz?, GRUR 1993, 801.

460 Art. 8 para. 1 Biopatent Directive.

461 *Lukes*, Das Verhältnis von Sortenschutz und Patentschutz bei biotechnologischen Erfindungen, GRUR Int. 1987, 328, *Mooney*, Seeds of the Earth, Ottawa 1979. See also *Straus,* Abhängigkeit bei Patenten auf genetische Information - ein Sonderfall?, GRUR 1998, 314

462 *Straus,* Pflanzenpatente und Sortenschutz - Friedliche Koexistenz*,* GRUR 1993, 794, No. 21, *Straus,* Zur Zulässigkeit klinischer Untersuchungen am Gegenstand abhängiger Verbesserungserfindungen, GRUR 1993, 308, 312.

463 ISF, 2003, Position: "Therefore ISF considers that a commercially available variety protected only by Breeder's Rights and containing patented elements should remain freely available for further breeding. If a new plant variety, not an essentially derived variety resulting from that further breeding, is outside the scope of the patent's claims, it may be freely exploitable by its developer. On the contrary, if the new developed variety is an essentially derived variety or if it is inside the scope of

"otherwise molecular plant breeding will be deprived of an important basis for R&D, a disadvantage not only to plant breeders but to the public in general."[464]

The implementation of the Biopatent Directive[465] into the PatG (Implementation Act) regulates the conflict between patent protection and plant variety protection.[466]

Regarding plant variety development, the new paragraph (2a) was added to Sec. 11(2) PatG: "The effect of the patent does not extend to (...) the use of biological material for the purpose of breeding, discovering and developing a new plant variety."[467]

In contrast to the plant breeders' exemption under the SortG, the plant breeders' exemption of the patent system does not extend to the commercialization of the new plant variety if this is within the scope of the patent. The legislature's intent is avoiding any unreasonable obstruction to plant variety development involving the use of patent-protected plant varieties.[468]

This provision of the Implementation Act not only strays from an identical implementation of the Biopatent Directive,[469] but runs contrary to its aim of harmonization.[470] It goes far beyond what is actually required. The exemption applies to the genetic background[471] of a patented plant as well as to the subject matter of the patent *per se*.

The systematic position of the new Sec. 11(2a) PatG after the research exemption in Sec. 11(2) PatG suggests that their contents are related. However, this wording implies a royalty-free compulsory license in practice.[472] It exempts even the commercial development of a plant variety with the subject matter of the invention and prevents any enforcement of a patent in this phase.

The extensive scope of the exemption under Sec. 11(2a) PatG seems to allow an independent and simultaneous development by the competitors, starting with cloning a protected gene, transforming, and breeding the final plant variety. The patentee must expect a commercial launch of a competitor's plant variety as soon as his own patent expires.

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the patent's claims, a consent from the owner of the initial variety or of the patent must be obtained."

464 *Straus*, Optionen bei der Umsetzung der Richtlinie EG 98/44 über den rechtlichen Schutz biotechnologischer Erfindungen, Eidgenössisches Institut für Geistiges Eigentum, Publikation No. 2 (2004), available at www.ige.ch/D/jurinfo/documents/j10015d.pdf.

465 The *Bundestag* passed the Implementation Act of the Biopatent Directive on December 3, 2004.

466 *Haedicke*, Die Harmonisierung von Patent- und Sortenschutz im Gesetz zur Umsetzung der Biotechnologie-Richtlinie, Mitt. 2005, 241.

467 The wording of this regulation is taken from the Regulation (EC) No. 2100/94 on Art. 15(c) CPVR. However, neither the different prerequisites for the grant of a patent (especially autonomous reproducibility) nor divergences in the scope of protection were properly considered. For example, the impact of the exemption on method or use claims is completely ambiguous.

468 No. 1 of the Draft for the Implementation Act, Bundestags-Drucksache (Parliament Publication) 15/1709 (October 15, 2003), available at www.dip.bundestag.de/btd/15/017/1501709.pdf.

469 The Biopatent Directive does not comprise a regulation corresponding to a breeders' exemption.

470 Reasoning 3 of the Biopatent Directive.

471 Genetic background means the genome with exception of the patent protected gene.

472 *Von Pechmann,* Zum Problem des Schutzes gentechnologischer Erfindungen bei Pflanzen durch Sortenschutz und/oder Patente, GRUR 1985, 717.

The plant breeders' exemption in the plant variety protection system is based on different parameters. The competitors start plant breeding under the plant breeders' exemption only after the market introduction of the initial plant variety. This is because a plant variety is not an autonomously repeatable subject, but a unique biological individual. Commercialization of the initial plant variety by the owner of a plant variety protection right and the legal acquisition by the competitor are implicitly presupposed. Thus, competitive plant breeding takes place not simultaneously but subsequently. The owner of a plant variety protection right enjoys a longer period of *de facto* exclusivity.[473] A more appropriate exemption from patent protection for further plant breeding would be bound to material commercially or otherwise deliberately released by the patentee. The corresponding wording could read as follows: "The effect of the patent does not extend to (....) the use of biological material that is released commercially by the patentee or with his consent for the purpose of breeding, discovering and developing a new plant variety."[474]

This is an acceptable compromise. A compulsory right to use the patented invention is only avoided if the patent-protected genetic element or trait is out-crossed and only the genetic background is used for further plant breeding. Accordingly, the newly bred plant variety would no longer fall within the scope of the patent,[475] thus ruling out an intentionally commercial use of the subject matter of the patented invention.

*b. Farm-saved seed and coincidental production*

If seed of a patent-protected plant variety is grown on the field of a third farmer as a consequence of cross-pollination and that farmer makes no deliberate use of it, that farmer cannot be made liable for any patent infringement.

However, an injunction against commercialization or any other further use of the patent-protected material can be enforced against the farmer *de lege lata* regardless of negli-

473 The Scientific Service of the German Parliament (Wissenschaftlicher Dienst des Deutschen Bundestages) comes to a similar conclusion in a legal opinion dated November 9, 2004. Resolution Recommendation and Report, Bundestags-Drucksache (Parliament Publication) 15/4417 (December 1, 2004), 14-16, available at www.dip.bundestag.de/btd/15/044/15044 17.pdf. Herein the following wording is suggested: "The effect of the patent does not extend to (...) 2a. the use of biological material to the purpose of breeding, discovering and developing of a new plant variety starting from the time, when the biological material can be commercially released by the patentee or with his consent." This solution seems however less suitable due to the material deviation from the plant variety protection rights regulations and conceptual ambiguities.

474 Such a compromise was discussed in the hearing on the draft of the Implementation Act in the legal committee of the *Bundestag* on September 29, 2004. Both the experts of the biotechnology industry (*Wallmeyer*) and the national breeders association (*Herrlinger*) supported such modification.

475 An acceptable exemption could read: "The effect of the patent does not extend to […] the use of biological material, which was commercially released by the patentee or with his consent, for the purpose of breeding, discovering and developing a plant variety, provided that said new plant variety itself is not within the scope of protection of the patent." This wording would allow the breeder to use the genetic background of a patent protected variety but not the invention as such.

gence or fault. In Germany, this natural circumstance is taken into consideration by the Implementation Act, stating in addition to a farm-saved seed provision in accordance with the CPVR Directive 2100/94[476] that patent protection does not extend to biological material that "is obtained in the field of agriculture coincidentally or unavoidably."[477]

This causes legal insecurity, as the exhaustion provisions of the Biopatent Directive concerning the later use of patent-protected material are based on the assumption of protected material. The patent protection cannot be revived in later reproduction cycles if coincidentally obtained material is not subject to patent protection from its genetic source as stipulated in the Implementation Act. In the end, a farmer can use material that has been obtained "coincidentally" without restriction and can even commercialize it as seed. This farmer needs not buy seed of a patent-protected plant variety, and he is not obliged to pay appropriate compensation for any reproduction under the farm-saved seed provision. Furthermore, bringing counter-evidence is difficult when a farmer claims to have coincidentally obtained the respective material.

Clause 2 of the new § 9c(3) PatG stipulates that "(...) a farmer in general cannot be made liable for infringement of a patent if he grows seed or planting material not subject to this patent protection." This formulation is unfortunate, since the interpretation and scope of the term "in general" is completely unclear.

A limitation of the liability payments and the injunction could balance the interests of the patentee and the farmer. In any event, the sale of coincidentally obtained material for seed purposes is to be prevented.

The new § 9c(3) PatG has to be amended at least by reviving patent protection if a farmer takes note of the presence of patent-protected material and intentionally uses it in the next crop. This would subject a farmer who coincidentally obtains seed to the same farm-saved seed provisions as any other farmer who acquires this seed.

*c. Compulsory license*

The Biopatent Directive introduces a modified compulsory license with regard to interdependence between a plant variety protection right and a patent.[478] The Implementation Act extends this provision to interdependent patents.[479]

A compulsory license can be granted if the owner of the dependent right has unsuccessfully tried to obtain a contractual license from the owner of a patent or a plant variety protection right. Furthermore, the plant variety or the invention must constitute significant technical progress of considerable economic interest compared with the invention

476 Art. 11(1) of the Biopatent Directive. For the conditions and the extent of this exemption Art. 14 CPVR as well as the implementation regulations therefore apply. Any claim of the patentee has to be made in accordance to the implementation regulation for Art. 14(3) CPVR.

477 Art. 1, No. 6 of the Implementation Act, implementation of new Sec. 9c(3) PatG.

478 Art. 12 of the Biopatent Directive.

479 Art. 1, No. 9 of the Implementation Act, amendment of Sec. 24 PatG.

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.