

Patents on Native Traits: What Scope of Protection?

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Axel Metzger*

I. Introduction

The recent practice of the European Patent Office (EPO) to grant patents on plants with “native traits” is highly controversial in Europe. While biotechnology and seed companies seek for protection of their investments that goes beyond the traditional protection scheme of plant variety rights, NGOs and SMEs fear that this new generation of plant patents may favour large international seed companies and endanger biodiversity.¹ In the last years, this controversial debate has mainly focused on the question of which materials from innovative plant breeding should be eligible for patent protection. Should patent protection be restricted to transgenic plants or genetic materials produced by technical means or isolated from its natural environment and to technical processes relating to plant breeding or should the patent system also encompass plants with new properties resulting from classical breeding methods of crossing and selecting? The EPO Enlarged Board of Appeal denied in its landmark decision “Broccoli I” (2010) the patentability of classical breeding methods based on crossing and selecting as process claims even if the selection is based on the screening of specific genetic combinations.² Yet in “Tomatoes II” (2015) the same Enlarged Board decided to open the door for patent claims on plants as products, irrespective whether the plants result from classical breeding efforts or from technical processes.³ But even though the fundamental questions on the interpretation of Art. 53 lit. b) EPC have now been answered, the exact patentability requirements for native traits and the effect of such patents are still under discussion. And even the fundamental questions could be reopened again if the European institutions would decide to clarify the Directive 98/44 on the legal protection of biotechnological inventions, as called for by the European Parliament.⁴ Therefore, from a long-term perspective, “Tomatoes II” may turn out be nothing but an intermediate step in the development. However, for the time being, breeders and biotechnology companies must live with the patents granted by the EPO. It is therefore indispensable to understand the effects of this new type of European plant patents for legal practice, especially to understand the scope of protection. This chapter will give an overview of recently granted patent claims on native traits (II), discuss the scope of protection with some details (III) and shed a light on the limitations (IV). Special emphasis will be given to the comparison with the scope of protection of plant variety rights under the Regulation 2100/94.

* Professor of Civil and Intellectual Property Law, Humboldt-University, Berlin. All cited websites have been visited on 3 March 2016.

1 The discussion is reflected in the amicus curiae letters submitted to the EPO in the case “Tomatoes II”, see <www.epo.org/law-practice/case-law-appeals/eba/pending/g2-12.html>.

2 EPO Enlarged Board of Appeal, 9 December 2010, G 2/07, OJ EPO 2012, 130.

3 EPO Enlarged Board of Appeal, 25 March 2015, G 2/12, not yet published in the Official Journal, see <www.epo.org/law-practice/case-law-appeals/eba/pending/g2-12.html>.

4 European Parliament resolution on patents and plant breeders’ rights of 15 December 2015, 2015/2981(RSP).

II. Patent claims on native traits: Differences in the drafting

1. Scope of protection depends on the drafting of the claims

The effect of a patent on legal practice and for the market depends on the drafting of the patent claims. According to Article 69 EPC, the extent of the protection conferred by a European patent shall be determined by the claims. However, the exact scope of the exclusive right has to be determined in accordance with the rights that would be conferred by a national patent granted in the state for which the patent has been granted, Article 64 EPC. National patent legislation in Europe provides a different scope of protection for products, processes, products obtained directly by a protected process, patents on the use of a substance, and – not explicitly regulated in the European patent acts – product-by-process claims, see e.g. section 9 German Patent Act, Article L 613-3 French Intellectual Property Code, section 60 UK Patents Act. Art. 25 UPC Agreement follows the same pattern. On the EU level, the scope of protection is harmonized for biotechnological inventions by Article 8 of the Directive 98/44 that also provides for a differentiated exclusive right for materials and processes. It is therefore necessary to have a closer look at the exact wording of the patent claims granted for native traits.

2. Illustration by examples

The following list of patent claims illustrates the current practice of the EPO. After the decisions “Broccoli I” and “Tomatoes II” patent claims on native traits are granted as product claims or as product-by-process claims but not as pure process claims.

a) EP 1 211 926 – Naturally dehydrated tomato

The patent claims which were subject to the EPO decision “Tomatoes II” were upheld by the Enlarged Board of Appeal in the following form:

“1. A tomato fruit of the species *Lycopersicon esculentum* which is naturally dehydrated, wherein natural dehydration is defined as wrinkling of skin of the tomato fruit when the fruit is allowed to remain on the plant after a normal ripe harvest stage, said dehydration being generally unaccompanied by microbial spoilage.

2. A tomato fruit of the species *Lycopersicon esculentum* characterized by an untreated skin, dehydration of the fruit and wrinkling of the skin, said dehydration being generally unaccompanied by microbial spoilage.”

The patent claims describe a tomato fruit by reference to its phenotype only, without any reference to the material used to obtain a tomato fruit of the described characteristics. Also, the process of breeding is not described. One may therefore ask the question whether the application provides for a sufficient disclosure of the invention as required by Article 83 EPC. The answer will depend on the final text of the patent including the description.

b) EP 2 166 833 – Seedless pepper

The second example of a patent claim on a native trait is drafted in more specific language. Claim 1:

“A male sterile hybrid pepper plant, which grows normal-looking edible seedless fruits throughout the whole plant, wherein said seedless fruits are characterized by being at least 95% seedless, wherein the 'seedless' trait is controlled by a genetic determinant and is independent of the pollination and fertilization process, is independent of treatment with parthenocarpy-inducing plant hormones including auxins, gibberellins and cytokines, auxin transport inhibitors, or others and/or

other parthenocarpy-inducing exogenous factors and/or exogenously administered parthenocarpy-inducing agents such as growth regulating substances, either natural or synthetic, or plant extracts such as, for example, dead pollen extract, and is also independent of external climatic conditions and wherein the said 'seedless' trait is obtainable from a pepper plant selected from the group consisting of *Capsicum annuum* AR07-F1-56-b; *Capsicum annuum* AR07-F1-87-b; *Capsicum annuum* AR07-F1-166-b; *Capsicum annuum* AR07-F1-171-X; and *Capsicum annuum* AR07-F1-172-X, grown from seeds deposited with NCIMB, Aberdeen AB21 9YA, Scotland, UK on May 26, 2008 under accession number NCIMB 41558, NCIMB 41559, NCIMB 41560, NCIMB 41561 and NCIMB 41562, respectively.”

The claim describes the pepper plant by its phenotype but specifies that the plant is obtainable by selection from a group of deposited pepper plants. The claim also specifies what processes and factors have been irrelevant for the breeding of the described plant. Compared with the claims of EP 1 211 926, the claims of EP 2 166 833 disclose more information on the used material and the process of breeding.

c) EP 1 515 600 – Flavonol tomato

Another recent patent on tomato fruits claims a tomato with a higher flavonol value. Claim 1:

“A non-transgenic domesticated *L. esculentum* plant growing fruits with a content of flavonols in the flesh of the fruit that is greater than 0.5 mg/mg dwt and a content of flavonols in the peel of said fruit of at least 5 mg/mg dwt due to up-regulated flavonol biosynthesis in the fruit flesh of said plant and restored CHI expression in the fruit peel of said plant, wherein said non-transgenic domesticated *L. esculentum* plant is obtainable by introgressing the CHI gene and the [the] flavonol biosynthesis pathway genes CHS, FSH and FLS of *Lycopersicon* wild accessions LA1963, LA2884 and LA1926 into a domesticated *L. esculentum* plant.”

The wording of the claim – as in the example EP 2 166 833 – specifies the materials used for the breeding process by reference to a deposit of wild accessions. In addition, the breeding process is explained even though without much detail.

d) EP 1 185 161 – Oil from modified sunflower seeds

Another interesting recent example concerns sunflower seeds with specific fat acid contents that may be preferable for the food industries. The Technical Board of Appeal upheld claim 1 with the following wording:⁵

“Sunflower seeds that contain an oil having an oleic acid content of more than 5% and less than 65% by weight based upon the total fatty acid content, a linoleic acid content of more than 1% and less than 65% by weight based upon the total fatty acid content, a palmitic acid content of more than 20% and less than 40% by weight based upon the total fatty acid content, a stearic acid content of more than 3% and less than 15% based upon the total fatty acid content, characterized in that the palmitoleic acid content is less than 4% based upon the total fatty acid content; and the asclepic acid content is less than 4% based upon the total fatty acid content, obtainable by crossing the high stearic line CAS-3, deposited on 14 December 1994 with the ATCC under deposit accession number ATCC-75968 with a high palmitic line to introduce the stearyl desaturase enzymatic activity of the high stearic line in the high palmitic line and selecting seed of F2 generations in which the amount of palmitoleic is decreased to less than 4% based upon the total fatty acid content and the amount of

⁵ EPO Technical Board of Appeal 3.3.4, 12 May 2010, T 1854/07.

asclepic acid is decreased to less than 3% based upon the total fatty acid content.”

The claim describes phenotypic traits of the sunflower seeds but further specifies the plant material used for the breeding of such sunflower plants by reference to deposited materials.

3. Current trends

The current trends at the EPO in the granting of patents on native traits may be described as follows: (1) the EPO is granting product claims on native traits; (2) plants as subject matter of product claims are described by reference to a small number of traits or even a single trait of their phenotype; (3) the claimed plants are specified by reference to the genetic material used for the breeding; (4) the specifications are drafted in a language typical for product-by-process claims (“obtainable by”).

Whether patent claims with mere descriptions of the phenotypic traits – like claims 1 and 2 in the example of the naturally dehydrated tomato (EP 1 211 926) – are still being granted by the EPO is not yet clear. There are considerable legal arguments against those claims being eligible. According to Article 13 of Directive 98/44 (and Rule 41 EPC Implementing Regulations), the description of an invention which involves the use of biological material which is not available to the public and which cannot be described in a patent application in such a manner as to enable the invention to be reproduced by a person skilled in the art, shall be considered inadequate for the purposes of patent law unless the biological material has been deposited and the patent application states the name of the depository institution and the accession number. The Directive does not require explicitly that the deposited material should be mentioned in the patent claims. However, according to Article 84 EPC, the claims shall define the matter for which protection is sought. The claims must therefore, as indicated by Rule 43 of the Implementing Regulations, define the matter “in terms of the technical features of the invention”. According to the EPO Board of Appeal decision in “Fuel Oils/Exxon”⁶ this requirement “reflects the general legal principle that the extent of the patent monopoly, as defined by the claims, should correspond to the technical contribution to the art in order for it to be supported, or justified.” The claims should therefore “not extend to subject-matter which, after reading the description, would still not be at the disposal of the person skilled in the art.”⁷ Therefore, if enablement can only be demonstrated with regard to specific biological material, this material should be specified in the claims.

III. Scope of protection

1. Interpretation of product-by-process claims – General principles

As highlighted in the examples, the current trend for plant patents on native traits is to describe the phenotypic traits in the patent claim with broad language and to specify the plant by a reference to the breeding process. The interpretation of such product-by-process claims is controversial in Europe and abroad.⁸ Some jurisdictions, e.g. German courts, interpret those claims to cover all products having the same characteristics as the claimed products irrespective of whether they have been obtained by the described process or by another process.⁹ Other jurisdictions, e.g. US courts, take the opposite view and restrict the scope of those claims to products resulting from the

⁶ EPO Technical Board of Appeal 3.3.1, 18 March 1993, T 409/91, Reasons 3.3.

⁷ Id.

⁸ See Walter, *Klassische und markergestützte Zuchtverfahren – Noch kein Patentrezept für Tomaten und Brokkoli*, GRUR-Prax 2010, 329, 331.

⁹ German Federal Supreme Court, 8 June 2010, X ZR 71/08, LMuR 2010, 153 – Substanz aus Kernen und

application of the process described in the claims.¹⁰ In the UK, the High Court has only recently taken a position in between: Claims using the words “obtained by” are restricted to products obtained by the described process whereas claims using the words “obtainable by” are also applied to products obtained by other processes as long as these products have “every single characteristic which is the inevitable consequence of that process”.¹¹ This will make it hard for the patent holder to plead for infringement if the defendant can show that his product lacks any of the inevitable marks caused by the described process.

2. Scope of protection according to Article 8 Directive 98/44

The construction of patent claims on native traits in EU member states must adhere to the special rules on biotechnological inventions of the Directive 98/44. One of the relevant provisions in this context is Article 8 paragraph 1:

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

According to the wording of the provision, the scope of protection of a patent on biological material shall extend to “any biological material derived from that biological material”. Some commentators understand Article 8 paragraph 1 as a mere extension of the scope of protection conferred to biological materials.¹² The patent on biological material shall not only cover material produced deliberately by the alleged infringer but also further material derived from the infringer's material. According to this interpretation, it is the purpose of Art. 8 paragraph 1 to make sure that those further materials are also covered by the patent even if this further reproduction occurred without the alleged infringer's intervention.¹³ However, such an extension is hardly necessary. If the derived material possesses the same characteristics as described in the product claim, which is the premise of Article 8 paragraph 1, then such derived material should be covered anyhow by the claim. One may certainly ask in case of an unintentional reproduction whether the alleged infringer may be held liable. But this is a question of liability not of infringement. Moreover, the wording of the provision is not as clear as suggested by the “mere extension theory”: The “shall extend to any biological material” (German: “umfaßt jedes biologische Material”; French: “s'étend à toute matière biologique”) does not necessarily imply an “extension” but may also refer to the more neutral “extent” of protection. If the legislator wanted to merely extend the scope of protection it would have been easy to introduce a phrase like “shall also extend to”. In addition, it is not clear whether the “from that biological material” language refers to the material produced by the alleged infringer or to the material used for the invention.

Given the fact that it was the Community legislature's approach to ensure the same protection for patents in all Member States,¹⁴ it is rather likely that Article 8 must be understood as an autonomous European definition of the scope of protection and not as a mere extension of the older national

Nüssen, at 23.

10 *Abbott Labs. v. Sandoz, Inc.*, 566 F.3d 1282, 1293 (Fed.Cir.2009).

11 *Hospira v. Genentech* [2014] EWHC 3857 (Pat), 148 et seq.

12 See e.g. Scharen in Benkard, *Patentgesetz*, (11th ed. Munich 2015) § 9a N° 2, 3.

13 See Zech/Uhrich in Metzger/Zech, *Sortenschutzrecht* (Munich 2016), § 9a PatG N° 3, 36.

14 See CJEU, 6 July 2010, C-428/08 – *Monsanto/Cefetra*, at 58 (explicitly on Chapter II of the Directive, scope of protection).

concepts. Such an autonomous definition may deviate from the older national concepts of patent protection and may lead to an extension on derived materials where necessary but it may also lead to a limitation of the scope of such claims. From this perspective, the wording makes it very clear that patents on biological material shall cover “all” material derived from the material used for the invention (and from the material produced by the alleged infringer). But the wording makes it also very clear that “only” material derived from the biological material used for the invention shall be covered by the product claim. Such an interpretation would streamline the scope of protection for biotechnological inventions with the older provisions of Article 13 of Regulation 2100/94 on Community plant variety rights that also limits the scope of protection to plant materials obtained through the use of the concrete protected variety. An argument for such a parallel interpretation could be that the legislator has also aligned other provisions of the two instruments concerning the scope of protection, especially the provisions on exhaustion, on the farmer's privilege, and on compulsory licences.¹⁵ By contrast, any interpretation that would include material produced by the alleged infringer and not derived from the material used by the inventor would go beyond Article 8 paragraph 1 and interfere with the exhaustive character of the Directive.

Apparently, such a neutral interpretation of Article 8 paragraph 1 has not been tested in court so far. However, if the above-cited patent claims would be interpreted accordingly, the scope of protection would be limited to plants that are derived from the materials described in the claims. Competitors using other original materials for the breeding of plants would not infringe the patent even if the plants would show the same characteristics as the patented plants. Needless to say that such an approach would require a clear concept of “derived material”. In this regard the experience from the Plant Variety Regulation 2100/94 could be useful. According to Article 13 paragraph 5 of this Regulation, the scope of protection of a plant variety right covers also varieties that are “essentially derived” from the protected variety.¹⁶ The concept of “essentially derived varieties” has already been subject to court cases.¹⁷ At least all “essentially” derived material should as well be encompassed as “derived material” by Article 8 paragraph 1 of Directive 98/44.

3. Scope of protection according to Article 9 Directive 98/44

According to Article 9 Directive 98/44 the protection conferred by a patent on a product containing or consisting of genetic information shall extend to all material in which the product is incorporated and in which the genetic information is contained and performs its function. The provision is only applicable with regard to genetic information or more precisely DNA that has been isolated and is described in the respective patent claim.¹⁸ The reproduction of naturally occurring DNA is not covered by Article 9. Patents on native traits, as seen above, do not use the DNA to identify the protected plants but describe the phenotype and refer to the plant material used for the breeding of the plants. Thus, Article 9 is of no relevance for the types of patent claims discussed here.

4. Comparison with Article 13 Plant Variety Regulation 2100/94

Even though the scope of protection of patents on native traits has its limitations, it is still considerably broader than the scope of a European plant variety right. According to Article 13

15 The legislative materials do not clarify the purpose behind Article 8, see <eur-lex.europa.eu/legal-content/DE/HIS/?uri=CELEX:31998L0044&qid=1457013568018>.

16 For an interpretation see Würtenberger/van der Kooij/Kiewiet/Ekqvad, *European Union Plant Variety Protection* (2nd ed. Oxford 2015), N° 6.20.

17 See e.g. Regional Court of Mannheim, 10 December 2010, 7 O 442/04, reprinted in Metzger (ed.), *Rechtsschutz von Pflanzenzüchtungen* (Tübingen 2014), 189-194.

18 Zech/Uhrig in Metzger/Zech, *op.cit.*, § 9a PatG N° 25.

paragraph 2 Plant Variety Regulation 2100/94, the right holder of a plant variety right may exclude others from the reproduction, offering for sale etc. of “variety constituents”. Variety constituents are defined in Article 5 paragraph 3 as “entire plants or parts of plants as far as such parts are capable of producing entire plants”. For “harvested materials” the scope of protection is more limited. Under Article 13 paragraph 3 the exclusive right covers harvested material only if obtained through the unauthorized use of variety constituents of the protected variety. The provision is of importance for cases of unauthorized reproduction in third countries: If the harvested materials are later imported in the EU, the right holder may enforce his plant variety right even with regard to harvested materials.¹⁹ But if the material was produced with his consent he will have difficulties to forbid a later use of the material. The difference between variety constituents and harvested materials is therefore of high practical importance. It is evident that plant breeders and producers of plant materials, e.g. crops, fruits, vegetables or cut flowers, have a strong interest to define their products as variety constituents and not as mere harvested materials because only for variety constituents they can enjoy the full level of protection.²⁰ It is also evident that other market actors push for a broad concept of harvested materials to do business without consideration of plant variety rights. Thus, the dividing line is controversial.²¹ But whatever the exact concept of harvested material may be, it should be clear that many typical plant products will be covered with the result that the exclusive right of the plant breeder will be limited with regard to those products. In view of the examples cited above, it is not implausible that a European court would characterise dehydrated tomatoes, seedless pepper or flavonol tomatoes as harvested material and not as variety constituents. So if breeders would decide to register plant variety rights for certain varieties comprising the mentioned native traits they would not be in a position to prevent others from offering for sale any legally produced harvested materials. If the breeder decides to register a patent, the exclusive right would cover all plant materials possessing the patented characteristics. Under certain conditions, the patent right may be exhausted according to Article 10 Directive 98/44. But this depends on the specific requirements of the exhaustion principle.

IV. Limitations

1. Exhaustion principle according to Article 10 Directive 98/44

It is the very nature of plants and other living organisms to reproduce. This has implications on the exhaustion of patent rights. Under the general principles of patent law, exhaustion covers the offering, placing on the market or using of a product but not its reproduction.²² For biological material this concept is too narrow because reproduction may be the purpose of the product and should therefore not be prohibited by the patent holder once he has placed the product on the market. This specificity of biological material is reflected in Article 10 Directive 98/44 which clarifies that the exclusive right of the patent holder “shall not extend to biological material obtained from the propagation or multiplication of biological material placed on the market in the territory of a Member State by the holder of the patent or with his consent, where the multiplication or propagation necessarily results from the application for which the biological material was

19 See Recital 14 of the Regulation 2100/94.

20 See e.g. the position of CIOPORA (International Community of Breeders of Asexually Reproduced Ornamental and Fruit Varieties), www.upov.int/edocs/mdocs/upov/en/caj_ag_13_8/caj_ag_13_8_www_250068.pdf.

21 UPOV is currently working on an Explanatory Note on Propagating Material under the UPOV International Convention for the Protection of New Varieties of Plants of 1991, see www.upov.int/meetings/en/details.jsp?meeting_id=38787. The definition developed for UPOV will also be of importance for the interpretation of Article 13 Regulation 2100/94.

22 See e.g. Section 9a paragraph 1 Swiss Patent Act.

marketed, provided that the material obtained is not subsequently used for other propagation or multiplication”. In the case of patent protected sunflower seeds that have been sold by the patent holder, any subsequent buyer could use the seeds for the production of one generation of sunflower plants and seeds. The grown plants and the harvested material would be exempted from Article 8 Directive 98/44. However, any subsequent use of the seeds grown by the buyer as material for reproduction would not be justified. The example illustrates that the exhaustion principle in Article 10 may lead to similar results with regard to authorized harvested materials as the provision in Article 13 paragraph 3 Plant Variety Regulation 2100/94.²³ Still, the handling of authorised harvested material is an issue of exhaustion in patent law whereas it is an issue of the scope of the exclusive right in plant variety law. This difference may have noticeable consequences, e.g. for the burden of proof regarding the authorisation.²⁴ The patent law solution seems therefore as more favourable for the right holder than the plant variety solution.²⁵

2. Farmer's privilege according to Article 11 paragraph 1 Directive 98/44

Article 11 paragraph 1 Directive 98/44 provides for a special limitation for farmers to use the product of his harvest for propagation or multiplication by him on his own farm. The provision is a legal transplant from Article 14 Plant Variety Regulation 2100/94. The extent and conditions of the derogation corresponding to those under Article 14 Plant Variety Regulation 2100/94. Under this provision, farmers are free to use most agricultural plant species on their own farms without the right holder’s authorisation. However, farmers – with the exception of small farmers – are required to pay an equitable remuneration to the right holder. The so called “farmer's privilege” has been subject to several CJEU decisions concerning the amount of the “equitable remuneration” and the enforcement of the duty to pay remuneration.²⁶ Cases concerning the farmer's privilege with regard to native trait patents have not been reported so far.

3. Breeder's exemption

Some European jurisdictions have implemented special limitations for plant breeders in their patent acts, e.g. Germany in Section 11 Nr. 2a Patent Act,²⁷ France in Article L 613-5-3 of the Intellectual

23 The exhaustion rule in section 16 Plant Variety Regulation 2100/94 is mainly applicable to variety constituents since harvested materials are only exceptionally covered by the exclusive right.

24 The burden of proof for the facts justifying exhaustion is on the defendant, see Keukenschrijver in Busse/Keukenschrijver (eds.), *Patentgesetz* (7th ed. Berlin 2013) § 9c N° 4. By contrast, the burden of proof with regard to the requirements for harvested material are on the plaintiff, see Keukenschrijver, *Sortenschutzgesetz* (Köln 2001), § 10 N° 42.

25 Harvested material produced without authorisation is covered by the exclusive right of Article 13 paragraph 3 Regulation 2100/94; in this case, the exhaustion principle of Article 16 does not apply since the material has been not been disposed of to others by the holder or with his consent, CJEU, 20 October 2011, C-140/10 – Greenstar Kanzi/Hustin.

26 CJEU, 25 June 2015, C-242/14 – Saatgut-Treuhandverwaltungs GmbH/Vogel; CJEU, 15 November 2012, C-56/11 – Raiffeisen-Waren-Zentrale Rhein-Main/Saatgut-Treuhandverwaltungs GmbH; CJEU, 5 July 2012, C-509/10 – Geistbeck/Saatgut-Treuhandverwaltungs GmbH; CJEU, 8 June 2006, C-7/05-C-9/05 – Saatgut-Treuhandverwaltungs GmbH/Deppe; CJEU, 14 October 2003, C-336/02 – Saatgut-Treuhandverwaltungs GmbH/Brangewitz; CJEU, 10 April 2003, C-305/00 – Schulin/Saatgut-Treuhandverwaltungs GmbH.

27 “Die Wirkung des Patents erstreckt sich nicht auf die Nutzung biologischen Materials zum Zweck der Züchtung, Entdeckung und Entwicklung einer neuen Pflanzensorte.”

Property Code²⁸ and the Netherlands in Art. 53b paragraph 2 Dutch Patent Act.²⁹ Other European jurisdictions such as ³⁰the UK have not followed that path. The Biotechnology Directive 98/44 does also not envisage such an exemption. By contrast, Article 27 lit. b) UPC-Agreement provides a solution which is in line with the German and French approach: “The rights conferred by a patent shall not extend to the use of biological material for the purpose of breeding, or discovering and developing other plant varieties.” The provision is more explicit than the Directive 98/44 but is still tighter than the breeder's exemption in Article 15 lit. c) and d) of the Plant Variety Regulation 2100/94. According to the Plant Variety Regulation, breeders are allowed to use protected varieties for the purpose of breeding, or discovering and developing other varieties and – this is the difference – to market the new varieties without the authorisation of the owner of the older varieties. The combination of the two regimes, patent and plant variety, may lead to conflicting results: The marketing of new varieties based on older protected plant varieties is permitted by law, whereas patents on native traits may be used to prohibit the commercialisation of new varieties.

One possible solution for this conflict could be found in the Biotechnology Directive's provision on compulsory licences. According to Article 12 Directive 98/44 breeders may apply for a compulsory licence for the non-exclusive use of an invention protected by the patent insofar as the licence is necessary for the exploitation of a plant variety, subject to payment of an appropriate royalty. However, the requirements for compulsory licences under Article 12 paragraph lit. b) 3 are rather strict. Applicants must demonstrate that the plant variety constitutes “significant technical progress of considerable economic interest compared with the invention claimed in the patent or the protected plant variety”.³¹ It has been suggested to streamline this test with the test used for the registration of agricultural varieties in the official catalogue of varieties.³² To be listed in the catalogue, which is a prerequisite for varieties to be marketed in the EU, varieties must have “satisfactory value for cultivation and use”.³³ If the two tests would be aligned, all agricultural varieties of economic significance would be eligible for a compulsory licence under Article 12. Yet one should keep in mind that the “satisfactory value”-test is only applicable to some agricultural varieties, especially to cereals and potatoes, but not to vegetables, fruits and grasses that are not intended for the production of fodder plants. For those other varieties the “satisfactory value” test could only be applied in analogy. Still, such a solution would lower the hurdle for compulsory licences significantly. Holders of patents on native traits could not obviate the breeding and marketing of new plant varieties but only ask for an appropriate royalty.

28 “Les droits conférés par les articles L 613-2-2 et L 613-2-3 ne s'étendent pas aux actes accomplis en vue de créer ou de découvrir et de développer d'autres variétés végétales.”

29 “Het recht, bedoeld in artikel 53a, strekt zich evenmin uit over handelingen met biologisch materiaal die dienen tot het kweken, of ontdekken en ontwikkelen van andere plantenrassen.” In the Netherlands, the breeding industry is claiming for the recognition of a “full breeder's exemption” as in the Plant Variety Regulation, see the position of Plantum (Dutch association for the plant reproduction material sector) at <www.plantum.nl/321519667/Dossier-detail?dossierid=56131592>.

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31 The language is taken over from Article 31 lit. l) TRIPS. Experience shows that applicants can hardly ever meet this requirement.

32 See the statement of the German Association for the Protection of Intellectual Property (GRUR) of 25 February 2016 at <http://www.grur.org/uploads/tx_gstatement/2016-02-25-GRUR-Stn-Aenderung_der_Biopatentrichtlinie.pdf>. See also Section 36a paragraph 1 Swiss Patent Act.

33 See Article 4 Council Directive 2002/53/EC of 13 June 2002 on the common catalogue of varieties of agricultural plant species.

In this regard, it is of interest that the breeding industries have reacted to the “Tomatoes II” decision with different initiatives aiming at a standardized and facilitated licensing process.³⁴ A more generous test for compulsory licences would strengthen the bargaining position of potential licensees noticeably.

V. Conclusions

After a long-lasting controversial discussion, the Enlarged Board of Appeal in “Tomatoes II” has now settled the dispute and decided that native traits of plants may be eligible for protection as product patents as long as the claims are not restricted to single varieties but are drafted in a more general way. Competitors and other actors on the seeds market will have to live with this new type of intellectual property for plants. This chapter has analysed the scope of protection of this new type of patent claims. The scope of protection above all depends on the drafting of the patent claims. In its current practice, the EPO seems to abstain from granting patents based on mere phenotypic descriptions as claims, as apparently accepted in the “Tomatoes II” decision by the Enlarged Board of Appeal. The trend is rather to grant product-by-process claims that describe a small number of phenotypic traits and specify the protected plants by reference to the genetic material used for the breeding. This approach is not chosen by coincidence but has its basis in Article 13 of Directive 98/44 (and Rule 41 EPC Implementing Regulations) that requires patent applicants to refer to deposited biological material if the described invention would otherwise not enable a person skilled in the art to reproduce the plants. EPO examiners should be careful in the application of this rule and continue to require that deposited materials are cited in the claims.

If the breeding process is used in a claim to describe the product obtained, it is controversial whether only products obtained by exactly this process or whether all products falling under the phenotypic description are covered. In the EU, this question has to be answered in light of Article 8 of Directive 98/44 according to which only biological material derived from the biological material described in the claims is covered. If Article 8 is interpreted as suggested here, plant material showing the traits described in the claims but not derived from the materials cited in the claims should not be covered. Such an interpretation limits the scope of protection of patents on native traits significantly. Still, plant breeders would have to live with the fact that any breeding based on the materials cited in the claims would be covered. Patents could therefore be used to prohibit the use of derived plant materials. Directive 98/44 does not acknowledge an exemption comparable to the breeder's exemption in Article 15 lit. c) and d) of the Plant Variety Regulation 2100/94. Only licence agreements or compulsory licences according to Article 12 Directive 98/44 may help. For the latter, it should be considered to lower the bar for licence seekers.

Summing up, patents on native traits will increase dependency issues in the breeding industry. However, the effects may be mitigated by a careful interpretation of Directive 98/44. In this regard, it would be desirable to achieve a swift clarification of the open questions, be it by case law, by an amendment to the Directive 98/44 or by a declaratory statement of the European Council and Commission on the interpretation of Articles 8, 12 and 13 of the Directive³⁵

34 Examples are: “International Licensing Platform for vegetable plant breeding” (ILP), <www.ilp-vegetable.org>; “Syngenta E-Licensing”, <www3.syngenta.com/global/e-licensing/en/e-licensing/Pages/home.aspx>.

35 Such a statement would not be unprecedented, see e.g. the Statement on Articles 15 and 73 of the Regulation 44/2001, <ec.europa.eu/civiljustice/homepage/homepage_ec_en_declaration.pdf>.