

## PLANT PATENTS IN EUROPE

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**July 16, 2015**

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Earlier this year the Enlarged Board of Appeal, the highest judicial body of the European Patent Office (EPO), has completed its hat-trick on plant patenting. By rendering its decisions in consolidated referrals G 2/12 and G 2/13, commonly known as the “Tomato II”- and “Broccoli II”-decisions, the Enlarged Board for the third time commented on the patent eligibility of plant-related inventions. The Enlarged Board addressed this issue for the first time in G 1/98 (“Transgenic plants”) and then again in consolidated cases G 2/07 (“Tomato I”) and G 1/08 (“Broccoli I”). The most recent decisions, taken together with the previous rulings, finally provide a reasonably solid framework for assessing the patent eligibility of plant-related inventions before the EPO. In sum, these decisions allow applicants to attain patent protection for plant-related inventions in Europe, with some limitations on eligible subject matter. Method claims for the production of plants, including traditional breeding steps, and plant varieties as such are essentially banned from patent protection.

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### 1. Background

Despite an overall tendency towards world-wide harmonization in patent law, major differences still exist among the different jurisdictions, in particular in regards to the protection of biotechnological inventions. Article 27(3)(b) of the TRIPS agreement<sup>1</sup> explicitly allows its member states to exclude plants from patentability and essentially biological processes for the production of plants. This exclusion is possible as long as the member states guarantee the protection of plant varieties, either by patents or by a *sui generis* system or by a combination of the two. This system fosters a divergent development in this area of the law and allows TRIPS member states to use this option to various degrees<sup>2</sup>.

For example, in the United States utility patents may be granted for plant-related inventions. There is no explicit statutory exemption of plant-related inventions in the United States. Claims can be directed to plants *per se*, plant parts, such as seeds and seedlings, and also methods for the production of plants. In 1980, the US Supreme Court decided in *Diamond v. Chakrabarty*<sup>3</sup> that genetically modified organisms constitute patent-eligible composition of matter under 35 U.S.C. § 101, and much later the same court confirmed in *J.E.M. Ag Supply v. Pioneer Hi-Bred*<sup>4</sup> the longstanding practice of the US Patent and Trademark Office to grant utility patents on plants. In contrast, some other countries take

a far more restrictive approach<sup>5</sup>. The Indian Patent Act, for example, excludes from patentability methods of agriculture or horticulture, plants in whole or parts thereof, and essentially biological processes for the production of plants<sup>6</sup>. Also China and some South American countries restrictively exclude biotechnological subject matter, in particular plant-related inventions from patentability<sup>7</sup>.

In Europe, at least as far as European patent applications before the European Patent Office (EPO) are concerned, one has settled on a middle ground. European patents are granted according to the European Patent Convention (EPC). In principle, according to Article 52(1) EPC, patents shall be granted for any inventions, in all fields of technology, provided that they are new, involve an inventive step and are susceptible of industrial application, thereby also covering plants as patentable subject matter. This liberal and all-encompassing approach is, however, counterbalanced by the exceptions to patentability explicitly listed in Article 53 EPC<sup>8</sup>. Among these, Article 53(b) EPC *inter alia* excludes “**plant varieties**” and

<sup>5</sup> Janis, Mark D., supra, at I.C

<sup>6</sup> Section 3 lit. h and j of The Indian Patent Act; [http://www.ipindia.nic.in/IPActs\\_Rules/updated\\_Version/sections/ps3.html](http://www.ipindia.nic.in/IPActs_Rules/updated_Version/sections/ps3.html)

<sup>7</sup> Janis, Mark D., supra, at I.C

<sup>8</sup> Article 53 (Exceptions to patentability)

European patents shall not be granted in respect of:

(a) inventions the commercial exploitation of which would be contrary to "ordre public" or morality; such exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States;

(b) **plant** or animal **varieties** or **essentially biological processes for the production of plants** or animals; this provision shall not apply to microbiological processes or the products thereof;

(c) methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body; this provision shall not apply to products, in particular substances or compositions, for use in any of these methods. (Emphasis added)

<sup>1</sup> AGREEMENT ON TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS administered through the World Trade Organization, which went into force on January 01, 1995; [https://www.wto.org/english/docs\\_e/legal\\_e/27-trips.pdf](https://www.wto.org/english/docs_e/legal_e/27-trips.pdf)

<sup>2</sup> Janis, Mark D. "Patenting Plants: A Comparative Synthesis." In Patent Law in Global Perspective, by Okediji, Ruth L., and Margo A. Bagley, eds., edited by Ruth L. Okediji, and Margo A. Bagley. New York: Oxford University Press, 2014. Oxford Scholarship Online, 2014. doi:

10.1093/acprof:oso/9780199334278.003.0008.

<sup>3</sup> *Diamond v. Chakrabarty*, 447 U.S. 303 (1980)

<sup>4</sup> *J. E. M. Ag Supply, Inc. v. Pioneer Hi-Bred International, Inc.*, 534 U.S. 124 (2001)

“**essentially biological processes for the production of plants**” from patentability.

The Articles of the EPC are accompanied by the Implementing Regulations to the EPC, which serve as a means of interpreting the Articles of the convention. Rules 26 to 34 of the Implementing Regulations relate to biotechnological inventions. Notably, current Rules 26 to 29 EPC<sup>9</sup> were added to the Implementing Regulations to bring the EPC into conformity with the European Union (EU) Directive for the legal protection of biotechnological inventions<sup>10</sup> (Biotech Directive), which came into force in 1998 and sought to harmonize European patent law with regard to biotechnological inventions. Rule 26(1) EPC even explicitly refers to the Biotech Directive as a supplementary means of interpreting the EPC.

According to Rules 26 and 27 EPC<sup>11</sup>,

<sup>9</sup> Originally introduced as Rules 23b-3 EPC (1973)

<sup>10</sup> DIRECTIVE 98/44/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 6 July 1998 on the legal protection of biotechnological inventions; OJ 1999, 101; OJ 1999, 573; OJ 1999, 437;

<sup>11</sup> Rule 26 (General and definitions)

(1) For European patent applications and patents concerning biotechnological inventions, the relevant provisions of the Convention shall be applied and interpreted in accordance with the provisions of this Chapter. Directive 98/44/EC of 6 July 1998 on the legal protection of biotechnological inventions shall be used as a supplementary means of interpretation.

(2) "Biotechnological inventions" are inventions which concern a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used.

(3) "Biological material" means any material containing genetic information

and capable of reproducing itself or being reproduced in a biological system.

(4) "**Plant variety**" means any 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:

- (a) defined by the expression of the characteristics that results from a given genotype or combination of genotypes,
- (b) distinguished from any other plant grouping by the expression of at least one of the said characteristics, and

biotechnological inventions are generally patent eligible, emphasizing the basic legal principle of Article 52(1) EPC. Rule 27(b) EPC states that this is also true for plants, as long as the technical feasibility of the invention is not confined to a particular plant variety. Rule 26, which provides various legal definitions, also defines the exclusion alternatives of "**plant varieties**" and "**essentially biological processes for the production of plants**". The definition of "plant varieties" follows almost verbatim the definitions given in the 1991 UPOV Convention<sup>12</sup> and in the EC Regulation on Community plant variety rights<sup>13</sup>. The definition of "essentially biological processes for the production of plants" is taken from Article 2(2) of the Biotech Directive.

While the adaptation of the EPC in accordance with the Biotech Directive and the explicit reference to Biotech Directive in Rule 26 EPC is indicative of the EPO's

(c) considered as a unit with regard to its suitability for being propagated unchanged.

(5) A process for the production of plants or animals is **essentially biological** if it consists entirely of natural phenomena such as crossing or selection.

(6) "Microbiological process" means any process involving or performed upon or resulting in microbiological material. (Emphasis added)

Rule 27 (Patentable biotechnological inventions)

Biotechnological inventions shall also be patentable if they concern:

(a) biological material which is isolated from its natural environment or produced by means of a technical process even if it previously occurred in nature;

(b) **plants** or animals if the technical feasibility of the invention is not confined to a particular **plant** or animal **variety**;

(c) a microbiological or other technical process, or a product obtained by means of such a process other than a plant or animal variety. (Emphasis added)

<sup>12</sup> INTERNATIONAL CONVENTION FOR THE PROTECTION OF NEW VARIETIES OF PLANTS of December 2, 1961, as Revised at Geneva on November 10, 1972, on October 23, 1978, and on March 19, 1991; see Article 1(vi);

[http://www.upov.int/en/publications/conventions/1991/wup910.htm#\\_1](http://www.upov.int/en/publications/conventions/1991/wup910.htm#_1)

<sup>13</sup> COUNCIL REGULATION (EC) No 2100/94 of 27 July 1994 on Community plant variety rights; see Article 5(2); <http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:31994R2100>

overall tendency of working towards harmonization in European patent law, the EPO is not a member of the European Union and therefore not bound by EU law and the jurisprudence of the Court of Justice of the European Union (CJEU), which is the judicial authority of the European Union and has the last word in interpreting any EU law. The EPO has its own quasi-judicial bodies, the Boards of Appeal and the Enlarged Board of Appeal, the highest judicial body of the EPO. These quasi-judicial bodies are only bound by the EPC and to a certain extent by their own jurisprudence. The Enlarged Board is only involved when there are divergent decisions handed down by the Boards of Appeal, when a fundamental point of law arises that warrants the Enlarged Board's attention, or when a fundamental procedural violation occurs during appeal proceedings, which detrimentally affects one of the involved parties.

Over many years it has been contentiously discussed how far the exclusion of **“plant varieties”** and **“essentially biological processes for the production of plants”** in Article 53(b) EPC reaches. This question has drawn attention not only from within the patent community, but also from outside stake-holders, such as farmers' associations and various NGOs, as well as the wider public<sup>14</sup>. The Enlarged Board, in March of 2015, has addressed this question in the Broccoli II- and Tomato II-decisions for the third time, after previously issuing the decision G 1/98 (Transgenic plant/NOVARTIS II) and decisions in consolidated cases G 2/07 (Broccoli/PLANT BIOSCIENCE) and G 1/08 (Tomatoes/STATE OF ISRAEL). The most recent decisions of the Enlarged Board in this context, taken together with the preceding decisions, appear to finally provide a solid framework for assessing the eligibility of plant-related inventions for European patents. Reason enough to revisit the earlier decisions, to summarize the new one and to take a look at the present state of plant

patenting in Europe.

## 2. The scope of the “plant varieties” exclusion

The first decision of the Enlarged Board made in 1999, dealt with the eligibility of plant-related inventions under Article 53(b) EPC, G 1/98 (Transgenic plant/NOVARTIS II). In the patent application underlying the “Transgenic plant”-decision, the applicant had claimed, *inter alia*, transgenic plants comprising in their genomes specific foreign genes, the expression of which results in the production of anti-pathogenically active substances, and methods of preparing such plants. The examining division refused the application for noncompliance with Article 53(b) EPC based on the earlier case law (T 356/93)<sup>15</sup>. The applicant appealed this decision to the Technical Boards of Appeal, which felt it necessary to refer questions on important points of law to the Enlarged Board of Appeal. The question in contention was whether a claim that relates to plants in broad generic terms and where the specific plant varieties are not individually claimed, would *ipso facto* avoid the prohibition on patenting based on Article 53(b) EPC.

In line with earlier case law (T 356/93), the referring Technical Board was of the opinion that it would not comply with the normal rules of logic if the argument were accepted that the prohibition under Article 53(b) EPC could be avoided by merely drafting a broad and generic claim, encompassing the explicitly excluded plant varieties<sup>16</sup>. According to the referring board and in regards to Article 53(b) EPC, a claim had to be construed in the same manner as for the assessment of

<sup>14</sup> As evidence, for example, by the great number of amicus curiae briefs submitted to the Enlarged Board in G 2/07, G 1/08, G 2/12 and G 2/13; <https://www.epo.org/law-practice/case-law-appeals/eba/pending.html>

<sup>15</sup> T 0356/93 (Plant cells) of 21.2.1995; Headnote No. 7: “A claim is not allowable if the grant of a patent in respect of the invention defined in said claim is conducive to an evasion of a provision of the EPC establishing an exception to patentability. Hence, a claim which encompasses plant varieties is only allowable, if the exception to patentability under Article 53(b), first half-sentence, EPC, concerning plant varieties does not apply, because the subject-matter of the claim is to be regarded as the product of a microbiological process (see points 40.7 and 40.8 of the reasons).”

<sup>16</sup> T 1054/96 (Transgenic plant/NOVARTIS) of 13.10.1997, Reasons, points 36 and 37

novelty and inventive step, i.e., if a single potential embodiment was a plant variety, the claim was not patentable<sup>17</sup>. This wide interpretation of Article 53(b) EPC was shared by a great number of third parties submitting *amici curiae* to the Enlarged Board.

The Enlarged Board, however, did not agree with the referring Technical Board. In response to the referred question the Enlarged Board held that a claim wherein specific plant varieties are not individually claimed is not excluded from patentability under Article 53(b) EPC even though the claim may encompass plant varieties.

To arrive at this narrow interpretation of the exclusion statute, the Enlarged Board considered the historical background of the provision. Article 53(b) EPC is derived from Article 2(b) of the Strasbourg Patent Convention (SPC)<sup>18</sup>, which stipulated that the contracting states do not necessarily have to provide patent protection for plant varieties. The purpose of this statute was closely intertwined with the 1961 UPOV Convention, which provided the legal basis for the protection of new plant varieties. On the one hand, SPC contracting states were obliged under Article 1 SPC to grant patents for any inventions, which are susceptible of industrial application and are new and involve an inventive step. On the other hand, the UPOV member states, under Article 2(1) of the 1961 UPOV Convention, were not allowed to provide for simultaneous protection of a plant variety through a patent and a plant breeders' right. Article 2(b) SPC was intended to solve this problem by allowing the SPC contracting states that were also UPOV member states to exclude patent protection for plant varieties. In consequence, the Enlarged Board considered that Article 53(b) EPC could only exclude subject matter for which protection under a plant variety rights' system was available, i.e., plant varieties as such<sup>19</sup>.

In addition to the above holding, the Enlarged Board also ruled that Article 64(2) EPC is not to be taken into consideration when a claim to a process for the production of a plant variety

is examined under Article 53(b) EPC, i.e., a process for the production of a plant variety is not prohibited under Article 53(b) EPC<sup>20</sup>. The Enlarged Board thus followed the established case law that the protection conferred by a process patent is extended to the products obtained directly by the process, even if the products are not patentable *per se*.

By interpreting Article 53(b) EPC as a simple delimitation statute vis-à-vis the plant variety rights and by denying any relationship to the concept of *ordre public* and morality as set forth under Article 53 (a) EPC, the Enlarged Board arrived at a very patentee friendly ruling, with little impact on every day prosecution practice in the field of transgenic plant inventions. As long as the claimed subject matter is not directed to an individualized plant variety (or multiple plant varieties as individual options) then it does not fall under the plant variety exclusion of Article 53(b) EPC.

### 3. The scope of the “essentially biological processes” exclusion

#### 3.1. G 2/07 and /08

As stated above, Article 53(b) EPC covers multiple aspects and not only excludes “**plant varieties**” from patentability, but also “**essentially biological processes for the production of plants**”. The first exclusion alternative, which is interpreted very narrowly by the EPO (G1/98), is explicitly limited to products, whereas the second alternative is directed to processes (at least on the face of it). Further, the product exclusion is explicitly limited to plant varieties, whereas the process exclusion more broadly relates to plants in general.

Already in G 1/98 the question arose of how to interpret the exclusion of essentially biological processes for the production of plants. In this case, however, the Enlarged Board left this question unanswered. A few years later, in the mid 2000s, two independent post-grant opposition cases went on appeal before the Technical Boards of Appeal of the EPO and in both cases one ground of opposition to the granted European

<sup>17</sup> Id., at Reasons, points 26 and 37

<sup>18</sup> G 1/98 (Transgenic plant/NOVARTIS II) at Reasons, point 3.4

<sup>19</sup> Id., points 3.6 and 3.7

<sup>20</sup> Id., point 4

patent was Article 53(b) EPC. In both appeal cases, the underlying patents contained claims that were directed to methods of breeding, including the steps of crossing and selecting with additional steps of a technical nature. One patent<sup>21</sup> concerned the production of broccoli plants, which produced an elevated level of anti-carcinogenic substances. The other patent<sup>22</sup> concerned the production of tomato fruits with reduced water content. Naturally, the two cases have been commonly referred to as the Broccoli- and the Tomato-case.

In both cases the same Technical Board of Appeal (3.3.04), albeit in different composition, was concerned with the question of whether the claimed methods constituted essentially biological processes for the production of plants in the sense of Article 53(b) EPC.

To answer this question the Technical Board drew on earlier case law that had already provided definitions on what constitutes an essentially biological process for the production of plants<sup>23</sup>. In addition to this case law, the board considered the Implementing Regulations to the EPC, in particular Rule 26(5) EPC, which provides a definition for the essentially biological process exclusion. The Technical Board, in both cases, independently came to the conclusion that there was an inconsistency between the earlier case law on Article 53(b) EPC and Rule 26(5) EPC (previous Rule 23b(5) EPC), which was highly relevant for the outcome of each case<sup>24</sup>. In essence, the board found that the earlier case law had established a rather wide interpretation of the exclusion clause relating to essentially biological processes, while Rule 26(5) EPC necessitated a more

narrow interpretation of the exclusion clause, in particular when considering the adverb “*entirely*” in “*consists entirely of natural phenomena*” of Rule 26(5) EPC<sup>25</sup>.

Therefore, the Technical Board in both cases decided to refer questions of law to the Enlarged Board on the correct interpretation of the essentially biological process exclusion of Article 53(b) EPC. The Enlarged Board was essentially asked whether a non-microbiological process for the production of plants which contains the steps of crossing and selecting plants would escape the exclusion of Article 53(b) EPC merely because it contains an additional feature of a technical nature; if not, what would be the relevant criteria for distinguishing between excluded and non-excluded processes.

The Enlarged Board decided to combine both referrals in consolidated proceedings. In its decision, the Enlarged Board considered the role of Rule 26(5) EPC and its influence on the interpretation of Article 53(b) EPC. The Enlarged Board, taking into account the Biotech Directive from which Rule 26(5) EPC has been derived and its legislative history<sup>26</sup>, surprisingly came to the conclusion that due to the self-contradictory wording of Rule 26(5) EPC (“*essentially*” vs. “*entirely*”), this statute could not be used for the interpretation of the essentially biological process exclusion of Article 53(b) EPC<sup>27</sup>. Article 53(b) EPC was therefore considered independently on its own authority.

Similar to the earlier decision in G 1/98, the Enlarged Board took into consideration that the process exclusion of Article 53(b) EPC traces back to the SPC and was drafted against the backdrop of the 1961 UPOV Convention containing the so-called ban on dual protection (*vide supra*)<sup>28</sup>. Through a historical analysis of the *travaux préparatoires*, the Enlarged Board arrived the conclusion that the legislator wanted to widely exclude from patentability plant breeding processes that are based on the

<sup>21</sup> EP1069819: METHOD FOR SELECTIVE INCREASE OF THE ANTICARCINOGENIC GLUCOSINOLATES IN BRASSICA SPECIES

<sup>22</sup> EP1211926: METHOD FOR BREEDING TOMATOES HAVING REDUCED WATER CONTENT AND PRODUCT OF THE METHOD

<sup>23</sup> T 0320/87 (Hybrid plants) of 10.11.1988, T 0019/90 (Krebsmaus) of 3.10.1990, T 0356/93 (Plant cells) of 21.2.1995, T 1054/96 (Transgene Pflanze) of 13.10.1997

<sup>24</sup> see T 0083/05 (Broccoli/PLANT BIOSCIENCE) of 22.5.2007, at Reasons, points 65 and 66; T 1242/06 (Tomatoes/STATE OF ISRAEL) of 4.4.2008, at Reasons, points 8 and 16

<sup>25</sup> see T 0083/05 (Broccoli/PLANT BIOSCIENCE) of 22.5.2007, at Reasons, point 54

<sup>26</sup> Consolidated G 2/07 and G 1/08 at Reasons, point 4.7

<sup>27</sup> *Id.*, point 5

<sup>28</sup> Consolidated G 2/07 and G 1/08 at Reasons, point 6.4.2.2

sexual crossing of plants, that is the crossing of their entire genomes, leading to new plant varieties, for which a special property right was going to be available under the UPOV Convention<sup>29</sup>. According to the Enlarged Board, the conventional breeding methods at the time the SPC was conceived already included technical steps to facilitate the breeding steps. The board stated that this did however not change the fact that these breeding methods made use of the natural phenomenon of meiosis to introduce new traits into the offspring. This led the Enlarged Board to conclude that the mere addition of a technical step to traditional breeding steps does not help to escape the exclusion under Article 53(b) EPC.

In summary, the Enlarged Board answered the referred questions as follows:

*“1. A non-microbiological process for the production of plants which contains or consists of the steps of sexually crossing the whole genomes of plants and of subsequently selecting plants is in principle excluded from patentability as being “essentially biological” within the meaning of Article 53(b) EPC.*

*2. Such a process does not escape the exclusion of Article 53(b) EPC merely because it contains, as a further step or as part of any of the steps of crossing and selection, a step of a technical nature which serves to enable or assist the performance of the steps of sexually crossing the whole genomes of plants or of subsequently selecting plants.*

*3. If, however, such a process contains within the steps of sexually crossing and selecting an additional step of a technical nature, which step by itself introduces a trait into the genome or modifies a trait in the genome of the plant produced, so that the introduction or modification of that trait is not the result of the mixing of the genes of the plants chosen for sexual crossing, then the process is not excluded from patentability under Article 53(b) EPC.*

*4. In the context of examining whether such a process is excluded from patentability as being “essentially biological” within the meaning of Article 53(b) EPC, it is not relevant whether a step of a technical nature is a new or known measure, whether it is trivial or a fundamental alteration of a known process, whether it does or could occur in nature or whether the essence of the invention lies in it.”*

Hence, in essence, the Enlarged Board held that methods directed to or merely including the sexual crossing of whole plant genomes and the subsequent selection of plants with particular traits are excluded from patentability under Article 53(b) EPC. Importantly, the Enlarged Board explicitly stated that the exclusion also applies to methods that are directed to genetically engineering the plant genome, as long as those methods explicitly or implicitly include further steps of sexually crossing and selecting plant varieties<sup>30</sup>.

### **3.2. G 2/12 and G 2/13 – does the process exclusion extent to products**

Following the ruling of the Enlarged Board in referrals G 2/07 and G 1/08, both cases went back to the Technical Board for further consideration. Given the outcome of the referrals, all of the then pending process claims in both appeal cases were effectively barred from patentability under the process exclusion of Article 53(b) EPC and therefore deleted by the patentees. This left only product claims directed to an “*edible Brassica plant*” explicitly characterized by its method of production, i.e., a product-by-process claim, in the *Broccoli*-case<sup>31</sup>, and product claims directed to a “*tomato fruit*” in the *Tomato*-case<sup>32</sup>.

In both appeal cases the Technical Board felt that the Enlarged Board in its G 2/07- and G 1/08- decisions had not addressed, whether a plant which can only be produced by an essentially biological process, or a plant that

<sup>29</sup> Id., point 6.4.2.3

<sup>30</sup> Id.

<sup>31</sup> Consolidated G 2/12 and G 2/13 at III.4

<sup>32</sup> Id., at II.4

is explicitly characterized by such a process (product-by-process claim), is also excluded from patentability under the process exclusion of Article 53(b) EPC<sup>33</sup>. Therefore, in both cases, within little more than a year, the Technical Board again referred questions of law to the Enlarged Board. This is the first time in the history of the EPO that two referrals to the Enlarged Board were made in the same appeal proceedings.

In essence, the Enlarged Board was asked whether the process exclusion of Article 53 (b) EPC can have a negative effect on the allowability of a product claim directed to plants, in particular when the product is explicitly defined by an essentially biological process (product-by-process claim) or when the only method available at the filing date for generating the plant is an essentially biological process. Further, the Enlarged Board was asked whether it is of any relevance in this context that the scope of protection of a product claim directed to a plant also includes any method for generating the claimed plant<sup>34</sup>.

The Enlarged Board approached these questions in a very structured manner in its March 25, 2015 decision. First, the Enlarged Board affirmed the admissibility of the referral, which was challenged by the patent proprietor of the tomato patent. Then, the Enlarged Board defined the applicable law, the scope of the referred questions and the legal nature of the claimed invention, in particular emphasizing that with regard to the question of patentability and the scope of protection, there is essentially no difference between a basic product claim and a product-by-process claim. Before the board turned to the substantial questions at hand, it took the time to consider the principles of interpretation that need to be applied to the EPC. It found that the EPC itself does not contain any general rules for its own interpretation. In accordance with its previous case law<sup>35</sup>, it further held that the Vienna

convention on the Law of treaties<sup>36</sup> should be used when interpreting the EPC, even though it does not apply to the EPC *ex lege*<sup>37</sup>. In particular Articles 31 and 32 of the Vienna Convention<sup>38</sup> are relevant for this purpose. Further, the board made clear that there is no automatism of interpreting exclusions from patentability in a narrow fashion, as has been argued by some parties, but that the question of a narrow or wide interpretation of an exclusion clause must be answered in each individual case based on the accepted means of interpretation<sup>39</sup>.

Applying the approved means of interpretation, set out in Articles 31 and 32 of the Vienna Convention, the Enlarged Board found that neither a grammatical nor a systematic or teleological interpretation warrants an extension of the process exclusion clause of Article 53(b) EPC to products. This conclusion was largely based on the structure of Article 53(b) EPC itself, which features a product exclusion in the first alternative, which is limited to varieties only and has been interpreted very narrowly by the Enlarged Board already (G 1/98), and a process exclusion in the second alternative, which is more broadly directed to plants in general<sup>40</sup>. Also, the overall placement of Article 53(b) EPC within the EPC would not speak for a broad interpretation of the exclusion, in particular taking into account the general entitlement to patent protection for any invention in all technical fields stipulated in Article 52(1) EPC<sup>41</sup>. Finally, taking into account Rules 27(b) and (c) EPC would also

<sup>33</sup> T 1242/06 (Tomatoes II/STATE OF ISRAEL) of 31.5.2012 at Reasons point 74; T 0083/05 (Broccoli II/PLANT BIOSCIENCE) of 8.7.2013 at Reasons points 19 and 20

<sup>34</sup> Consolidated G2/12 and G2/13 at II.1 and III.1

<sup>35</sup> G 1/83; G 5/83; G 2/02 and G 3/02, OJ 2004, 483; G 2/08, OJ EPO 2010, 456

<sup>36</sup> Vienna Convention on the Law of Treaties, done at Vienna on 23 May 1969, entered into force on 27 January 1980

<sup>37</sup> Because at the time of conclusion of the EPC, the Vienna Convention was not in force

<sup>38</sup> Article 31(1) of the Vienna Convention essentially refers to the grammatical, the systematical and the teleological interpretation of a statute as the primary general rule of interpretation. In addition, Article 32 of the Vienna Convention states that the preparatory works (travaux préparatoires) may be used as a supplementary means of interpretation to confirm a finding according to Article 31 or when the interpretation according to Article 31 leaves the meaning of the statute ambiguous or obscure or leads to a result which is manifestly absurd or unreasonable.

<sup>39</sup> Consolidated G2/12 and G2/13 at Reasons VI

<sup>40</sup> Id., at Reasons VII.2.2

<sup>41</sup> Id., at Reasons VII.2.3

speak for a “*wide notion of the patentability of biotechnological inventions*” and not for a broader interpretation of the exclusion clause. As regards the teleological interpretation of Article 53 (3) EPC, i.e. the *ratio legis* of the statute, the board merely referred to its previous rulings in G 2/07 and G 1/08 and essentially held that the purpose of the provision cannot be discerned. Finally, the board also turned to a historic interpretation, considering the *travaux préparatoires* of the EPC, and found that “*there is no reason in the travaux préparatoires to assume that a product that is characterized by the method of its manufacture but claims protection regardless of that (or any other) method was meant to be excluded.*”<sup>42</sup>

Notably, the Enlarged Board did not stop at this point, but further took into account what it considered secondary considerations, concerning issues raised in various *amici curiae* briefs.

In short, the board asked the question whether a dynamic interpretation of the statute would be necessary considering the developments that have taken place since its inception and whether the legislature’s intentions concerning the process exclusion of Article 53 (b) EPC could be frustrated by merely drafting a claim as a product claim, e.g., a product-by-process claim. Both questions were answered in the negative. In regards to the second question, the Enlarged Board justified its position mostly by arguing that extending the exclusion clause to the product “*would require that the method applied would be traceable in the product*”, that “[b]roadening the scope of the process exclusion to the extent that it included also the product obtained by essentially biological processes for the production of plants would introduce an inconsistency in the system of the EPC” and that “*the aspect of the scope of protection [...] has no direct impact on the point of law referred.*”<sup>43</sup>

In conclusion, the Enlarged Board answered the referred questions in both cases G 2/12 and G 2/13 essentially identical and explicitly held in G 2/13:

“1. *The exclusion of essentially*

<sup>42</sup> Id., at Reasons VII.5

<sup>43</sup> Id., at Reasons VIII.2

*biological processes for the production of plants in Article 53(b) EPC does not have a negative effect on the allowability of a product claim directed to plants or plant material such as plant parts.*

2.(a) *The fact that the process features of a product-by-process claim directed to plants or plant material other than a plant variety define an essentially biological process for the production of plants does not render the claim unallowable.*

2.(b) *The fact that the only method available at the filing date for generating the claimed subject-matter is an essentially biological process for the production of plants disclosed in the patent application does not render a claim directed to plants or plant material other than a plant variety unallowable.*

3. *In the circumstances, it is of no relevance that the protection conferred by the product claim encompasses the generation of the claimed product by means of an essentially biological process for the production of plants excluded as such under Article 53(b) EPC.”*

Hence, the Enlarged Board saw no reason to extend the exclusion of essentially biological processes for the production of plants of Article 53(b) EPC to products under any circumstances, independent of how the product is actually described in the claim.

### 3.3. Further case law – T 1729/06 (Seedless watermelon/SYNGENTA)

In a more recent decision, T 1729/06 (Seedless watermelon/SYNGENTA), rendered in September 2014, a Technical Board of Appeal revisited the question of what kind of processes are excluded for being essentially biological processes for the production of plants according to Article 53 (b) EPC. In underlying European patent, the claimed invention *inter alia* was defined as a method for producing triploid seedless watermelon fruit, comprising the steps of planting triploid watermelon plants, planting a particular diploid watermelon plant (a

“pollenizer”) and allowing the pollination of the triploid plants by the diploid plants to obtain the triploid seedless watermelon fruit<sup>44</sup>. During prosecution of the underlying patent the examining division of the EPO refused the European patent application for claiming an essentially biological process excluded from patentability under Article 53(b) EPC. The applicant appealed this decision to a Technical Board of Appeal.

Of course, in approaching this case, the competent Technical Board took into consideration the ruling of the Enlarged Board in consolidated cases G 2/07 and G 1/08 on the exclusion of essentially biological processes for the production of plants. Correctly, the Technical Board noted that in decisions G 2/07 and G 1/08 the Enlarged Board held that any non-microbiological process for the production of plants that contains or consists of the steps of sexually crossing the whole genome of plants and of subsequently selecting plants is in principle excluded from patentability as being an essentially biological process for the production of plants within the meaning of Article 53(b) EPC. The Technical Board emphasized that according to the Enlarged Board these excluded processes are characterized by the fact that the traits of the plant resulting from the crossing were determined by the underlying natural phenomenon of meiosis, which determined the genetic make-up of the plants produced, and the breeding result was achieved by the breeder’s selection of plants having the desired trait(s). The invention underlying T 1729/06, however, does not include the sexual crossing of plants, since the triploid watermelon plants that are being pollinated by the diploid watermelon plants are sterile. Therefore, the Technical Board correctly came to the conclusion that, *inter alia* due to the fact that the invention in question does not involve sexually crossing the whole genomes of plants, the invention does not fall under the process exclusion as defined by

<sup>44</sup> In this method, pollination triggers the development of the fruit, i.e., the watermelon, but no mature seeds (“embryos”) develop, due to the triploidy of the fruit. As with other fruits, e.g., table grapes, the lack of seeds typically makes consumption more pleasant and therefore constitutes a valuable trait.

the Enlarged Board in its decisions G 2/07 and G 1/08.

One might think that the Technical Board could have stopped here, but importantly, the board pointed out that in decisions G 2/07 and G 1/08 the Enlarged Board has not given a comprehensive and exhaustive definition of the subject-matter to which the process exclusion in Article 53(b) EPC applies. According to the Technical Board, this becomes clear when looking at the rulings in G 2/07 and G 1/08. For example, in its decisions the Enlarged Board stated that:

*“[i]t must be concluded that the legislator’s intention was to exclude from patentability the kind of plant breeding processes which were the conventional methods for the breeding of plant varieties of that time. These conventional methods included in particular those (relevant for the present referrals) based on the sexual crossing of the plants (i.e. of their whole genomes) genes suitable for the purpose pursued and on the subsequent selection of the plants having the desired trait(s).”<sup>45</sup>*

Therefore, the Technical Board in T 1729/06 deemed it necessary to still answer the question whether the process in question falls under the process exclusion of Article 53(b) EPC, albeit not fulfilling the criteria defined in G 2/07 and G 1/08.

In doing so, the competent Technical Board emphasized the principle that biotechnological inventions are generally patentable, as emphasized in Rules 26 and 27 EPC and the Biotech Directive. Then, the board considered the object and purpose of Article 53(b) EPC, once again pointing out that the earlier versions of the process exclusion now found in Article 53(b) EPC were drafted against the background of the so-called ban on dual protection contained in the new 1961 UPOV convention<sup>46</sup>. As mentioned above, Article 53(b) EPC in its present version dates back to the Strasbourg Patent Convention (SPC). It was pointed out by the Technical Board that early drafts of the

<sup>45</sup> T 1729/06 (Seedless watermelon/SYNGENTA) at Reasons point 21

<sup>46</sup> *Id.*, point 27

SPC contained exclusion clauses directed to “purely biological, horticultural or agricultural (agronomic) processes”<sup>47</sup>. This rather broad exclusion clause was ultimately given up for the present formulation “essentially biological processes for the production of plants”, which is still present in Article 53(b) EPC.

Based on these considerations the Technical Board in T 1729/06 came to the conclusion that “*the legislator drafting Article 53(b) EPC did not have the intention to exclude from patentability a whole class of inventions, i.e. horticultural or agricultural (agronomic) processes*” but “*only wished to exclude from patentability, in the context of the process aspect of the exclusion in relation to plant inventions, the – then conventional – processes applied by plant breeders in connection with new plant varieties for which a special property right was available under the UPOV Convention and processes which were fundamentally of this type*”.

This decision is highly relevant and interesting because the Technical Board again took a step back and reconsidered the holding of the Enlarged Board in G 2/07 and G 1/08. According to this decision, the process exclusion of Article 53(b) EPC, as far as it relates to plants, is considered to only relate to processes including the steps of sexually crossing the whole genome of plants and subsequently selecting the plants, not including other agricultural or horticultural processes, which is a question still left unanswered by the Enlarged Board.

#### 4. National law

This article is particularly concerned with the EPO’s position on the patentability of plants, which is, of course, important for obtaining a European patent. When considering the state of plant patents in Europe more generally, however, not only the EPC and the case law of the Boards of Appeal and Enlarged Board is relevant, but also the national laws of the individual contracting states. On the one hand, applicants might choose not to file for a European patent with the EPO, but for one or more national patents with the national patent office(s). In this case, the patent examination

of the competent patent office(s) will be conducted according to national laws and national jurisprudence. On the other hand, readers are reminded that European patents upon grant by the EPO break up into a bundle of national patents in the designated contracting states<sup>48</sup>. Infringement of these national parts of a European patent is dealt with under national law by the national courts<sup>49</sup>. Furthermore, upon lapse of the post-grant opposition period, validity of the European patent may be only challenged before the national courts with effect for the respective contracting states<sup>50</sup>. While the national courts in revocation proceedings or in infringement proceedings (if invalidity is used as a defense) have to assess the validity of the European patent according to the EPC, they are not bound by the jurisprudence of the Boards of Appeal, or the Enlarged Board. For example, in Germany, the Federal Court of Justice (“Bundesgerichtshof”) held that German courts have to consider decisions of the judicial bodies of the EPO, when rendering judgments on essentially identical questions; however, they are not required to follow them<sup>51</sup>. Interestingly, also the Enlarged Board considered the national jurisprudence and legislation in its decisions G 2/12 and G 2/13<sup>52</sup>.

For all of the above reasons, the national laws and jurisprudence on the patentability of plants also may have to be taken into account, depending on whether a European patent or national patents are filed and in which countries a granted European patent is validated. The situation in a few countries is exemplarily highlighted.

In the German Patent Act (PatG), for example, the relevant provisions were phrased essentially identical to the EPC upon implementation of the Biotech Directive in 2005<sup>53</sup>. However, more recently Section 2a

<sup>48</sup> Article 64 EPC

<sup>49</sup> Article 64 (3) EPC

<sup>50</sup> Article 138 EPC

<sup>51</sup> BGH, April 15, 2010 – Xa ZB 10/09 –

„Walzenformgebungsmaschine“

<sup>52</sup> Consolidated G2/12 and G2/13 at Reasons VIII.2.6.c and d

<sup>53</sup> German Patent Act (as amended by the Law of July 31, 2009); see in particular Section 2a;

<sup>47</sup> Id., point 27.2

PatG has been amended to not only exclude essentially biological processes for the production of plants, but also explicitly plants that are produced by such processes. Hence, the relevant statute of the German Patent Act now explicitly excludes from patentability plants that are generated by essentially biological processes. This statutory law stands in stark contrast to the ruling of the Enlarged Board in G 2/12 and G 2/13. According to the German legislator's interpretation of Article 4(1)(b) of the Biotech Directive, whose wording is identical to the process exclusion of Article 53(b) EPC, also products directly obtained by essentially biological processes should be excluded from patentability, because the process exclusion could otherwise be easily avoided, that is by skillful drafting<sup>54</sup>. In light of these developments in Germany, it is somewhat uncertain how the German part of a European patent with claims directed to plants that are produced by an excluded essentially biological process will be treated by German courts.

In the Netherlands, the District Court of The Hague held in *Taste of Nature Holding B.V. vs. Cresco Handels B.V.* that in the absence of an explicit exclusion in Article 53(b) EPC, product claims to plants, other than individual plant varieties, obtainable by an essentially biological process for the production of plants, were in principle allowable, even if the essentially biological processes themselves were not.<sup>55</sup> However, subsequent to this decision, also the Dutch Patent Act was amended to exclude products directly obtained by an essentially biological process, as in Germany<sup>56</sup>. In contrast, the United Kingdom, France and Austria, have not yet enacted such explicit statutory limitations<sup>57</sup>.

In principle, all EU-member states have implemented the Biotech Directive and should therefore provide (the same) protection of plant-related inventions as stipulated under Articles 1 to 4 of the Biotech

Directive. However, as can be seen from the above, the actual situation in the individual EU-member states might vary to a great extent.

## 5. Discussion

Taken together the above discussed decisions provide a rather clear structure as to what kind of plant-related inventions are or are not patent eligible at the EPO. As far as product claims are concerned, plants or plant parts, such as fruits or seeds, can be patented, as long as the subject matter of the claim is not limited to one or more specific plant varieties. This position, which was originally established in G 1/98 still applies. If protection for a specific plant variety is needed, plant variety rights may be obtained either through the national Plant Variety Offices on a national level<sup>58</sup> or community plants variety rights with effect for the entire EU that may be obtained through the Community Plant Variety Office (CPVO)<sup>59</sup>.

In light of the rulings in G 2/12 and G 2/13 it is clear that plants or plant parts can be claimed as such, independent of whether they can only be generated by using an essentially biological process for the production of plants in the sense of G 2/07, G 1/08 and T 1729/06 or whether this process is even explicitly used in the claim to define the product. Hence, very much in favor of applicants, there is almost no practically relevant restriction on obtaining product protection for plant-related inventions before the EPO. In contrast, some national states, for example Germany, have statutory laws in place, which explicitly exclude plants that are generated by essentially biological processes from patentability. Applicants that seek protection for such inventions are therefore well advised to prosecute such applications before the EPO.

<http://www.wipo.int/wipolex/en/details.jsp?id=6128>

<sup>54</sup> Parliamentary publication ("Bundestags-Drucksache") 17/14222 of 26 June 2013, pages 2 and 3

<sup>55</sup> Consolidated G 2/12 and G 2/13 at Reasons VIII.2.6.c

<sup>56</sup> Id., VIII.2.6.d

<sup>57</sup> Id.

<sup>58</sup> For example, the German Plant Variety Office ("Sortenschutzamt")

<sup>59</sup> Community Plant Variety Rights may be obtained through the Community Plant Variety Office (CPVO), located in Angers, France, based on Council Regulation (EC) No 2100/94 of 27 July 1994 on Community plant variety right; <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31994R2100:EN:HTML>

Some commentators considered the reaction of the German and Dutch legislator to explicitly extend the exclusion of essentially biological processes for the production of plants to the products generated by such processes as an indication that these legislators found that Article 53(b) EPC does not unambiguously exclude such products from patentability<sup>60</sup>. We would rather argue that these amendments of the German and Dutch Patent Act indicate that at least the German and Dutch legislator interpret the Biotech Directive accordingly. This raises the question of how the CJEU would interpret the Biotech Directive with regard to the exclusion of essentially biological processes under Article 4(1)(b) of the Biotech Directive. Would the CJEU follow the Enlarged Board's interpretation of the process exclusion Article 53(b) EPC (worded essentially identical to Article 4(1)(b) of the Biotech Directive), or would the CJEU follow the German and Dutch legislator's interpretation? In the end, a decision on this matter by the CJEU might in turn also impact the granting practice at the EPO<sup>61</sup>.

As pointed out above, European patents granted by the EPO break up into a bundle of national parts of a European Patent. Infringement of these national parts is dealt with under national laws by national courts. Further, validity of these national parts of a European patent may also only be challenged before national courts with effect for the national part in question. The national courts are typically not bound by the jurisprudence of the EPO. This begs the question of how the national courts will consider product claims, which are directed to products that can only be generated by an essentially biological process. Will they follow the Enlarged Board's interpretation or not? It is conceivable that a German court, for

example, in revocation proceedings, with an eye on the recently passed German legislation, might consider such a product claim non-patentable under Article 53(b) EPC, openly rejecting the Enlarged Board's interpretation.

In this regard, despite the rather clear position of the EPO, some legal uncertainty still remains with regard to the validity and enforcement of such European patents in the individual national states and with regard to the impact that any potential future ruling of the CJEU on this matter, within the framework of the Biotech Directive, might have.

When it comes to claims directed to methods for the production of plants, the situation is still less applicant friendly and this situation has not changed at all with G 2/12 and G 2/13<sup>62</sup>. Yet, decision T 1729/06 has at least brought some further clarification in this matter. As long as the method includes steps of sexually crossing the whole genome of plants and subsequent selection of particular plants with the desired trait, such a method is excluded from patentability, irrespective of any other additional steps of technical nature that are also part of the method. Decision T 1729/06, however, clarified that the process exclusion of Article 53(c) EPC does not apply to agricultural or horticultural steps other than the above mentioned sexually crossing and selecting.

Despite these advances towards a clear and predictable interpretation of the patentability requirements for plant-related inventions at the EPO one mystery still remains. What did the Enlarged Board mean with its third answer in G 2/07 and G 1/08, with which it tried to provide some exception from the process exclusion under Article 53(b) EPC (*"within the steps of sexually crossing and selecting an additional step of a technical nature, which step by itself introduces a trait into the genome or modifies a trait in the genome of the plant produced"*)?

Overall, at least as far as patent prosecution before the EPO is concerned, the situation for applicants interested in protecting their plant-related inventions is fairly clear and predictable. In the end, there are still plenty of

<sup>60</sup> Timo Minssen and Ana Nordberg, The Impact of Broccoli II & Tomato II on European Patents in Conventional Breeding, GMO's and Synthetic Biology: The Grand Finale of a Juicy Patents Tale?, *Biotechnology Law Report*, Vol. 34, No. 3 (2015), pp. 81-98; page 16

<sup>61</sup> In T2221/10 the competent Technical Board of Appeal held in point 39 that *"although judgements of the ECJ [CJEU] are not legally binding on the EPO or its boards of appeal, they should be considered as being persuasive."*

<sup>62</sup> Consolidated G2/12 and G2/13 at Reasons III

options available which allow applicants to gain patent protection in this area of technology in Europe. The take-home message is to use product claims whenever possible.

For further reading on this and other topics of life science patenting in Europe we refer to *“Protecting and Enforcing Life Science Inventions in Europe under EPC and EU Law – From Antibodies to Zebrafish”*, by Zimmer, Zeman, Hammer, Goldbach and Allekotte, published by C.H. Beck et al in 2015 (ISBN 978-3-8487-1781-1).

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