

Abstract

Katrina McClatchey is a 2004 graduate of the University of Oklahoma College of Law. She wrote this eBrief under the direction of Professor Drew Kershen while she was participating in the Project on Intellectual Property Rights in Living Matter. Below, Ms. McClatchey discusses the impact of a decision in the year 2000 in the case of *NOVARTIS/Transgenic Plant* upon European Patent Convention (EPC) jurisprudence. Ms. McClatchey concludes that although the EPC may exclude a plant-related invention if the subject-matter claimed is a product which is strictly limited to a specific plant variety or specific plant varieties, the European patent nevertheless remains a viable option for biotechnologists with plant-related inventions.

Edited by Jennifer Stevenson

**THE IMPACT OF *NOVARTIS* ON THE EUROPEAN PATENT CONVENTION'S  
EXCEPTION TO PATENTABILITY FOR "PLANT VARIETIES"**

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**I. Introduction**

For biotechnological inventors of living inventions, Article 53(b) is a particularly interesting provision of the European Patent Convention (EPC). Particularly, Article 53(b) provides that "European patents shall not be granted in respect of... plant or animal varieties or essentially biological processes for the production of plants or animals; this provision does not apply to microbiological processes or the products thereof."<sup>1</sup> To give guidance on how Article 53(b) has been interpreted and implemented with regard to plant-related inventions, this eBrief discusses the recent and significant case of *NOVARTIS/Transgenic Plant*<sup>2</sup>. In *Novartis*, the European Patent Office (EPO) addressed issues of patentability under Article 53(b) for a patent

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<sup>1</sup> The European Patent Convention (also known as the Convention on the Grant of European Patents), Oct. 5, 1973, as amended by the act revising Article 63 EPC of Dec. 17, 1991 and by decisions of the Administrative Council of the European Patent Organisation of Dec. 21, 1978, Dec. 13, 1994, Oct. 20, 1995, Dec. 5, 1996 and Dec. 10, 1998, art. 53(b), at <http://www.european-patent-office.org/legal/epc/e/ma1.html#CVN> (last visited Feb. 20, 2004) [hereinafter EPC].

<sup>2</sup> *NOVARTIS/Transgenic plant* (G01/98), [2000] E.P.O.R. 303, available at <http://legal.european-patent-office.org/dg3/pdf/t961054eu1.pdf>.

application<sup>3</sup> relating to anti-pathogenic transgenic plants and to methods of producing the transgenic plants.

Before discussing the *Novartis* decision further, relevant background information regarding a plant protection scheme established in parts of Europe prior to the EPC will be briefly discussed. This plant protection scheme is known as the International Union for the Protection of New Varieties of Plants (UPOV). The UPOV is an intergovernmental organization established by the International Convention for the Protection of New Varieties of Plants, which was first adopted in Paris in 1961.<sup>4</sup> The UPOV Convention provides protection of new varieties of plants via a plant variety certificate.<sup>5</sup> In general, the UPOV Convention protects a plant breeder's right to a "new", "distinct", "uniform" and "stable" variety<sup>6</sup>, by providing that, for 20 years from the grant of the breeder's right<sup>7</sup>, certain acts relating to the plant variety will require the breeder's authorization. Such acts include those respecting the propagating material<sup>8</sup> (e.g., production or reproduction, conditioning for the purpose of propagation, offering for sale, selling, marketing, exporting, importing, or stocking), harvesting<sup>9</sup>, products made directly from harvested material<sup>10</sup>, varieties that are essentially derived from the protected variety or whose production requires the

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<sup>3</sup> The European patent application was titled "Anti-pathogenically effective compositions comprising lytic peptides and hydrolytic enzymes".

<sup>4</sup> UPOV, *Welcome to the International Union for the Protection of New Varieties of Plants*, <http://www.upov.int/index.html> (last visited Feb. 26, 2004).

<sup>5</sup> *Id.*

<sup>6</sup> International Convention for the Protection of New Varieties of Plants, Dec. 2, 1961, 33 U.S.T., as Revised at Geneva on Nov. 10, 1972, on Oct. 23, 1978, and on Mar. 19, 1991, *at* [http://www.upov.int/en/publications/conventions/1991/act1991.htm#\\_14](http://www.upov.int/en/publications/conventions/1991/act1991.htm#_14) (last visited Feb. 26, 2004) [hereinafter UPOV], ch. III, art. 5(1).

<sup>7</sup> *Id.* ch. IV, art. 19(2).

<sup>8</sup> *Id.* ch. IV, art. 14(1).

<sup>9</sup> *Id.* ch. IV, art. 14(2).

<sup>10</sup> *Id.* ch. IV, art. 14(3).

repeated use of the protected variety<sup>11</sup>, and possible additional acts as provided by individual contracting countries<sup>12</sup>.

Under the UPOV Convention, the term “variety” means a plant grouping within a single botanical taxon of the lowest known rank. That grouping can be:

- defined by the expression of the characteristics resulting from a given genotype or combination of genotypes,
- distinguished from any other plant grouping by the expression of at least one of the said characteristics and
- considered as a unit with regard to its suitability for being propagated unchanged.<sup>13</sup>

The *Novartis* case highlights the relationship between the plant breeders’ rights for plant varieties under the UPOV Convention and the “plant varieties” exception to patentability under Article 53(b) of the EPC. In *Novartis*, the patent application at issue is related to transgenic plants and methods of preparing the same. The product claims of the application claimed transgenic plants having specific foreign genes in their genomes.<sup>14</sup> The expression of the foreign genes resulted in the production of antipathogenically active substances which kill or inhibit the growth of disease-producing pathogens. The method claims of the application claimed methods of

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<sup>11</sup> *Id.* ch. IV, art. 14(5). For example, essentially derived varieties may be obtained by the selection of a natural or induced mutant, selection of a somaclonal variant, selection of a variant individual from plants of the initial variety, backcrossing, or transformation by genetic engineering.

<sup>12</sup> *Id.* ch. IV, art. 14(4).

<sup>13</sup> *Id.* ch. 1, art. 1(vi). Note that an identical definition for “plant variety” can be found in the Implementing Regulations to the Convention on the Grant of European Patents, Dec. 13, 2001 Rule 23b(4), at <http://www.european-patent-office.org/legal/epc/e/ma2.html#REG> (last visited Feb. 20, 2004) [hereinafter Implementing Regulations].

<sup>14</sup> For example, product claim 19 of the patent application read as follows:

*19. A transgenic plant and the seed thereof comprising recombinant DNA sequences encoding*

*(a) one or more lytic peptides, which is not lysozyme; in combination with*

*(b) one or more chitinases; and/or*

*(c) one or more beta-1, 3-glucanases in a synergistically effective amount.*

NOVARTIS/Transgenic plant (G01/98), [2000] E.P.O.R. 303, available at <http://legal.european-patent-office.org/dg3/pdf/t961054eu1.pdf>.

preparing such plants, which essentially consisted of introducing genes into an ancestral plant by recombinant DNA sequence encoding.<sup>15</sup>

The Examining Division<sup>16</sup> of the EPO refused a grant of a European patent for the *Novartis* application. The Examining Division deemed the application not to be allowable under Article 53(b) of the EPC, the “plant variety” exception. *Novartis* appealed to the EPO Technical Board of Appeals.<sup>17</sup> The Technical Board of Appeals decided that the following questions of law should be referred to the Enlarged Board of Appeals:<sup>18</sup>

1. To what extent should the instances of the EPO examine an application in respect of whether the claims are allowable in view of the provision of Article 53(b) EPC that patents shall not be granted in respect of plant varieties or essentially biological processes for the production of plants, which provision does not apply to microbiological processes or the products thereof, and how should a claim be interpreted for this purpose?
2. Does a claim which relates to plants but wherein specific plant varieties are not individually claimed, *ipso facto*, avoid the prohibition on patenting in Article 53(b) EPC even though it embraces plant varieties?
3. Should the provisions of Article 64(2) EPC<sup>19</sup> be taken into account when considering what claims are allowable?
4. Does a plant variety, in which each individual plant of that variety contains at least one specific gene introduced into an ancestral plant by recombinant gene technology, fall outside the provision of Article 53(b) EPC that patents shall not be granted in respect of plant varieties or essentially biological processes for the

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<sup>15</sup> For example, method claim 23 of the patent application read as follows:

23. *A method of preparing a transgenic plant which is able to synthesize one or more lytic peptides together with one or more chitinases; and/or one or more beta-1, 3-glucanases in a synergistically effective amount; said method comprising the steps of preparing a transgenic plant comprising recombinant DNA sequences encoding one or more lytic peptides, which is not lysozyme together with one or more chitinases; and/or one or more beta-1, 3-glucanases. Id.*

<sup>16</sup> The Examining Divisions of the European Patent Office is responsible for the examination of European patent applications. See EPC, *supra* note 1, art. 18 at <http://www.european-patent-office.org/legal/epc/e/ma1.html#CVN>.

<sup>17</sup> The Technical Board of Appeals is responsible for the examination of appeals from the decisions of the Examining Divisions. See *id.* art. 21.

<sup>18</sup> The Enlarged Board of Appeals is responsible for deciding points of law referred to it by the Technical Boards of Appeal. See *id.* art. 22. Under article 112(1)(a) of the EPC, “[i]n order to ensure uniform application of the law, or if an important point of law arises... the Board of Appeal shall ... refer any question to the Enlarged Board of Appeal if it considers that a decision is required for the above purposes.” EPC, *supra* note 1, art. 112(1)(a).

<sup>19</sup> Article 64(2) provides: “If the subject-matter of the European patent is a process, the protection conferred by the patent shall extend to the products directly obtained by such process.” *Id.*, art. 64(2).

production of plants, which provision does not apply to microbiological processes or the products thereof?<sup>20</sup>

The Enlarged Board only fully addressed questions 2-4, as it found no further reply to question 1 was necessary beyond the answers given to the more specific questions 2, 3, and 4.<sup>21</sup>

## **II. Question 2 – To what extent are claims relating to plants patentable under Article 53(b)?**

In applying the “plant varieties” exception to patentability under Article 53(b), the Enlarged Board first determined whether the claimed subject matter of the *Novartis* invention was actually directed to “plant varieties”. Because the Enlarged Board found that the *Novartis* application was not necessarily limited to plant varieties, it also had to determine whether Article 53(b) should be broadly interpreted to cover claims to plants in general.

### **A. Part I – Does the invention claim “plant varieties”?**

To determine whether the subject matter claimed is a “plant variety,” the Enlarged Board distinguished between a “substantive approach” and a “literal approach.” Under the substantive approach, a patent is granted with respect to plant varieties if a claim covers plant varieties. Under the alternative literal approach, Article 53(b) is satisfied if the words “plant variety” do not appear in a claim.<sup>22</sup> The Enlarged Board concluded that the wording of the claim is not decisive.<sup>23</sup>

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<sup>20</sup> NOVARTIS/Transgenic plant (T1054/96), [1998] E.P.O.R. 123, 149.

<sup>21</sup> NOVARTIS/Transgenic plant (G01/98), [2000] E.P.O.R. 303, 311, available at <http://legal.european-patent-office.org/dg3/pdf/t961054eu1.pdf>. In the *Novartis* application, a claim had been made for every means of obtaining the stated plant, including “essentially biological processes for producing plants.” The Enlarged Board noted that in considering the crossing step using conventional breeding techniques, issues arose as to what process steps were allowable in a claim having regard to the prohibition in the first half-sentence in article 53(b) of the EPC. However, because *Novartis* expressed its willingness to meet these formal objections, the Enlarged Board assumed that *Novartis* was willing to restrict the method claims to identifiable method steps in order to exclude essentially biological processes. Therefore, the Enlarge Board declined to offer guidance on the issue because “[t]o offer guidance in this respect without having a sound factual basis for doing so is inappropriate.” Thus, no further reply to question one beyond the answers already given to questions two to four was needed. See NOVARTIS/Transgenic plant (G01/98), [2000] E.P.O.R at 321.

<sup>22</sup> *Id.* at 312.

<sup>23</sup> *Id.*

Rather, it is the substance of a claim that is decisive in assessing the subject-matter to which the claim is directed.<sup>24</sup>

To determine the substance of a claim, the Enlarged Board noted that the breadth of the invention's practical applications should be identified, i.e. whether the underlying invention has generic or specified uses.<sup>25</sup> In assessing the subject-matter of the claimed *Novartis* invention, the Enlarged Board noted that the process of the invention was capable of being carried out by modifying plants which may or may not be varieties, i.e. the carrying out of the invention was not restricted to individual varieties to be modified.<sup>26</sup>

The Enlarged Board also determined that the method of the invention, i.e. modification by genetic transformation, did not necessarily result in a product that constituted a "plant variety." After reviewing various definitions of the phrase "plant variety" (including Article 1(vi) of the 1991 UPOV Convention, Rule 23(b)(4) of the Implementing Regulations, and other EPO case law definitions), the Enlarged Board concluded that the expression of characteristics of a plant variety that results from a given genotype, or combination of genotypes, is a reference to the entire constitution of a plant or set of genetic information.<sup>27</sup> In contrast, a plant defined by single recombinant DNA sequences is not an individual plant grouping to which an entire constitution can be attributed.<sup>28</sup> Because the claimed transgenic plant products at issue were defined only by those certain characteristics that allowed the plants to inhibit the growth of plant pathogens, the Enlarged Board found that the such a definition did not specify which taxonomic category within

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<sup>24</sup> *Id.*

<sup>25</sup> *Id.* This notion is also reflected in the Implementing Regulations, *supra* note 16, Rule 23c(b) at <http://www.european-patent-office.org/legal/epc/e/ma2.html#REG> ("Biotechnological inventions shall also be patentable if they concern... plants or animals if the technical feasibility of the invention is not confined to a particular plant or animal variety.").

<sup>26</sup> NOVARTIS/Transgenic plant (G01/98), [2000] E.P.O.R at 312.

<sup>27</sup> *Id.* at 313.

<sup>28</sup> *Id.*

the traditional classification of the plant kingdom the transgenic plants belonged, let alone provide the further characteristics necessary to assess the homogeneity and stability of varieties within a given species.<sup>29</sup>

Therefore, the Enlarged Board concluded that the resulting products of the *Novartis* invention did not expressly or implicitly define a single variety, or a multiplicity of varieties which necessarily consists of several individual varieties.<sup>30</sup> It held that “[i]n the absence of the identification of specific varieties in the product claims, the subject-matter of the claimed invention is neither limited nor even directed to a variety or varieties.”<sup>31</sup> In other words, product claims having subject-matter which covers or embraces plant varieties, but which do not identify or individually claim specific plant varieties, are not claims to a plant variety or varieties within the meaning of Article 53(b).<sup>32</sup>

**B. Part II – Should Article 53(b) be interpreted broadly to cover claims for plants in general?**

The Enlarged Board also determined whether the Article 53(b) provision proclaiming that “European patents shall not be granted in respect of plant ...varieties or essentially biological processes for the production of plants” should be broadly interpreted to exclude all plants from patentability. The Enlarged Board noted that, in Article 53(b), the more specific term “varieties” was used for products within the same half-sentence where only the term “plant” was used for biological production processes.<sup>33</sup> The Enlarged Board concluded that if it were the EPC

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<sup>29</sup> *Id.*

<sup>30</sup> *Id.*

<sup>31</sup> *Id.*

<sup>32</sup> Guidelines for Examination, Part C, ch. IV, § 2a.2(ii), at [http://www.european-patent-office.org/legal/gui\\_lines/index.htm](http://www.european-patent-office.org/legal/gui_lines/index.htm) (last visited Mar. 25, 2004).

<sup>33</sup> NOVARTIS/Transgenic plant (G01/98), [2000] E.P.O.R at 314.

legislator's intention to exclude plants as products in general, then the provision would have used the more general term "plants" that it used in the exception for biological processes.<sup>34</sup>

The Enlarged Board also reviewed the legislative history behind Article 53(b). It reasoned that the EPC legislator could not allow the granting of patents for plant varieties in general because some EPC-contracting member countries offered plant variety protection under the UPOV system, and thus were prevented from granting patents under the ban on dual protection in the UPOV Convention.<sup>35</sup> However, the legislator also could not exclude patent protection only for those varieties for which a plant breeders' right was available because plant breeders' rights at a European level were not available, and at the national level, the availability of plant breeders' rights differed from country to country.<sup>36</sup> Further, the legislator could not account for the specific situation in each designated country for each individual application because that would defeat the purpose behind the EPC of providing uniform patent protection in all its member countries.<sup>37</sup> Thus, the Enlarged Board reasoned that the most obvious choice was to exclude the granting of patents with respect to plant varieties entirely.<sup>38</sup>

Against this background, the Enlarged Board concluded that the purpose of Article 53(b) was only to preclude the granting of European patents for subject-matter that would result in dual protection in violation of the UPOV Convention.<sup>39</sup> Therefore, it held that "inventions ineligible for protection under the plant breeders' rights system were intended to be patentable under the

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<sup>34</sup> *Id.*

<sup>35</sup> *Id.* at 316. Member States were allowed under Article 2(1) of the UPOV Convention of 1961 to recognize the right of a breeder by the grant of either a special plant breeders' right or a patent, but not both. However, the UPOV Convention of 1991 deleted art. 2(1) and the ban on dual protection, with the clear implication being that member States now can grant both forms of protection.

<sup>36</sup> NOVARTIS/Transgenic plant (G01/98), [2000] E.P.O.R at 316.

<sup>37</sup> *Id.*

<sup>38</sup> *Id.* at 316-17.

<sup>39</sup> *Id.* at 317.



EPC provided that they fulfilled the other requirements of patentability.”<sup>40</sup> Because a claim having subject-matter covering but not identifying plant varieties is not a claim to a “variety” or “varieties,” such an invention could not qualify for the protection of a plant breeders' right.<sup>41</sup> Therefore, such an invention would be patentable provided that the other requirements of patentability were satisfied.

### C. Summary of Answer to Question 2

In summarizing its answer to question 2, the Enlarged Board held that according to Article 53(b), a patent is "in respect of plant varieties" and shall not be granted if the claimed subject-matter is directed to plant varieties.<sup>42</sup> However, in the absence of the identification of a specific plant variety in a product claim, the subject-matter of the claimed invention is not directed to a plant variety or varieties within the meaning of Article 53(b).<sup>43</sup> Thus, while it is not permitted to claim a specific plant variety, or several specific plant varieties, “[i]t is not sufficient for the exclusion of Article 53(b) EPC to apply that one or more plant varieties are embraced or may be embraced by the claims.”<sup>44</sup> Further, “Article 53(b) defines the borderline between patent protection and plant variety protection.”<sup>45</sup> Therefore, the extent of the exclusion for patents on plant varieties under Article 53(b) of the EPC is the “obverse” of the availability of plant variety rights under UPOV.<sup>46</sup>

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<sup>40</sup> *Id.*

<sup>41</sup> *Id.* at 318.

<sup>42</sup> *Id.* at 319.

<sup>43</sup> *Id.*

<sup>44</sup> *Id.*

<sup>45</sup> *Id.*

<sup>46</sup> *Id.*

### III. Question 3 – What is the effect of Article 64(2) on the interpretation of Article 53(b)?

Article 64(2) of the EPC instructs member countries that: “[i]f the subject-matter of the European patent is a process, the protection conferred by the patent shall extend to the products directly obtained by such process.”<sup>47</sup> Because of the Enlarged Board’s finding that a specific plant variety cannot be claimed in a product claim under Article 53(b), it also had to address the relevance of Article 64(2) on process claims if the claimed process results in a product that is, or covers, a plant variety.

In light of its answer to question 2, that a plant variety may be covered or embraced (but not individually identified and claimed) by a product claim, the Enlarged Board reasoned that protection for a variety derived from a generally-applicable claimed process would not be inconsistent therewith.<sup>48</sup> The Enlarged Board also recognized that established case law establishes that protection conferred by a process patent extends to products obtained directly by the process, even if the products are not patentable *per se*.<sup>49</sup> Furthermore, the Enlarged Board determined that such a practice would be in accordance with the placement of Article 64(2) in the EPC.<sup>50</sup> Article 64(2) is not within the requirements on patentability to be examined by the EPO. Rather, Article 64(2) is located within the section of the EPC concerning the effect and scope of a patent’s protection that the national courts are to apply when deciding on infringement cases brought before them.<sup>51</sup>

Because it did not find Article 64(2) relevant to the examination of claims by the EPO, the Enlarged Board held that “[w]hen a claim to a process for the production of a plant variety is

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<sup>47</sup> EPC, *supra* note 1, art. 64(2) at <http://www.european-patent-office.org/legal/epc/e/ma1.html#CVN>.

<sup>48</sup> NOVARTIS/Transgenic plant (G01/98), [2000] E.P.O.R at 319.

<sup>49</sup> *Id.*

<sup>50</sup> *Id.* at 319-20.

<sup>51</sup> *Id.* at 320.

examined, Article 64(2) EPC is not to be taken into consideration.”<sup>52</sup> As such, a process claim for the production of a plant variety or plant varieties would not be automatically excluded from patentability merely because the resulting product constitutes or may constitute a plant variety.<sup>53</sup>

#### **IV. Question 4 – Are plant varieties produced by recombinant gene technology patentable as products of a “microbiological process” under Article 53(b)?**

The second half-sentence of Article 53(b) provides that the exclusion of plant and animal varieties, and essentially biological processes for their production, does not apply to “microbiological processes or the products thereof.” Therefore, the Enlarged Board had to determine whether the process claimed by the *Novartis* application constituted a “microbiological process”, and if so, whether plant varieties resulting from the microbiological process would be patentable as “products thereof”.

The Enlarged Board reasoned that processes of genetic engineering were not identical with “microbiological processes” as the term was used by the EPC legislator.<sup>54</sup> Rather, the Enlarged Board found that the term “microbiological processes” as used in the provision was synonymous with processes using microorganisms, and that microorganisms were “different from the parts of living beings used for the genetic modification of plants.”<sup>55</sup>

In the current practice of the EPO, however, cells and parts thereof, including plant cells, are themselves treated as microorganisms when determining the patentability of such microorganisms or products derived therefrom.<sup>56</sup> While the Enlarged Board found this practice

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<sup>52</sup> *Id.* at 322.

<sup>53</sup> Guidelines for Examination, *supra* note 32, § 3.4.1, at [http://www.european-patent-office.org/legal/gui\\_lines/index.htm](http://www.european-patent-office.org/legal/gui_lines/index.htm).

<sup>54</sup> NOVARTIS/Transgenic plant (G01/98), [2000] E.P.O.R at 320.

<sup>55</sup> *Id.*

<sup>56</sup> For example, see Guideline for Examination, *supra* note 32, at § 3.5.1 (“The term ‘micro-organism’ includes bacteria and other generally unicellular organisms with dimensions beneath the limits of vision which can be propagated and manipulated in a laboratory..., including plasmids and viruses and unicellular fungi (including yeasts), algae, protozoa and, moreover, human, animal and plant cells.”).

“justified since modern biotechnology has developed from traditional microbiology and cells are comparable to unicellular organisms,” the Enlarged Board determined that this broad definition of “microorganism” did not mean that genetically modified plants should be treated as “products of microbiological processes” within the meaning of Article 53(b).<sup>57</sup> “Such an analogy and formal use of rules of interpretation would disregard the purpose of Article 53(b) to exclude, as unpatentable, subject-matter that is eligible for protection under the plant breeders' rights system.”<sup>58</sup>

The Enlarged Board also reasoned that refusing to allow genetically modified plants to be treated as products of microbiological processes would not preclude inventors from adequate intellectual property protection. The Enlarged Board found that a plant variety resulting from genetic engineering could qualify for protection under the UPOV Convention just as equally as those resulting from traditional breeding techniques.<sup>59</sup> It reasoned that neither technique affected the UPOV criteria of distinctness, homogeneity and stability, or the examination thereof.<sup>60</sup>

As such, the Enlarged Board concluded that the term “plant variety” remained appropriate to define the borderline between patent protection and plant breeders' rights protection, irrespective of the origin of the variety.<sup>61</sup> It held that the exception to patentability of Article 53(b) applied to all plant varieties irrespective of the way in which they are produced.<sup>62</sup> Therefore, a specific claim to new plant variety bred as a result of genetically modifying a particular plant

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<sup>57</sup> *Id.*

<sup>58</sup> *Id.*

<sup>59</sup> *Id.*

<sup>60</sup> *Id.* at 320-21.

<sup>61</sup> *Id.* at 321.

<sup>62</sup> *Id.*

variety, such as by introducing genes into an ancestral plant by recombinant gene technology, would still be excluded from patent protection.<sup>63</sup>

## V. Summary of the *Novartis* Decision

In accordance with the *Novartis* decisions, an inventor of a plant-related invention should consider the following with respect Article 53(b):

- If the claimed subject-matter of the application is directed to a specific plant variety or specific plant varieties (for which plant variety rights under the UPOV convention would be available), then a European patent would be “in respect of plant varieties”, and therefore will not be granted. In other words, if the technical feasibility of an invention concerning plants is confined to a particular plant variety, then the invention is unpatentable.
- A patent can be granted for an invention when specific plant varieties are not individually identified as the claimed subject-matter, even if varieties may fall within the scope of its claims. In other words, it is not sufficient for the exclusion of Article 53(b) to apply just because one or more plant varieties are embraced or may be embraced by the claims.
- When a process for the production of a plant variety is examined, EPC Article 64(2) will not be taken into consideration. In other words, a process claim is not excluded from patentability merely because the resulting product of the process is a plant variety.
- The exception to patentability for “plant varieties” applies irrespective of the way in which the plant varieties are produced. In other words, even if a plant variety could be considered a product of a microbiological process (e.g. genes introduced into an ancestral plant by recombinant gene technology), the plant variety remains unpatentable under the “plant varieties” exception.

## VI. Conclusion

In view of the narrow interpretation of Article 53(b) by the *Novartis* decision by the EPO, biotechnologists seeking protection in Europe under a European patent for plant-related inventions should not be apprehensive of the Article 53(b) prohibition on “plant varieties”. The exception to patentability for “plant varieties” seems to only exclude a plant-related invention if the subject-matter claimed is a product which is strictly limited to a specific plant variety or specific plant

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<sup>63</sup> *Id.*

varieties. Although, if the claimed invention falls within this narrow category, the exception will be strictly applied (i.e. how the plant variety was produced is irrelevant as to the application of the “plant varieties” exception to a product claim). Ultimately however, the European patent remains a viable option for biotechnologists with plant-related inventions, even with the “plant varieties” exception of Article 53(b).