

# Patentability of Plants: At the Crossroads between Monopolizing Nature and Protecting Technological Innovation?

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This article provides an in-depth critical analysis of pressing issues regarding the patentability of plants. There is no public interest overarching principle present in the European Patent Convention or any other convention for that matter which would exclude patent protection for plants. The expansionist behavior of some users of the patent system seeking to obtain patent protection for methods and products which are very akin to traditional breeding methods needs to be halted and patent applications in that context deserve very close scrutiny so as to avoid that the border is crossed. Patents for hybrid seeds ought not to be protected by patents, as they in effect protect plant varieties as such. If the patent system is not capable of keeping such innovations outside of the patent territory, the call for excluding all plant-related innovations from patentability will become more influential. Products produced by essentially biological processes should not be patentable. However, in the absence of a statutory basis, the current legal framework does not allow the judiciary to come to such conclusion. The EPC needs to be amended in this respect. Finally, introducing a breeders' exemption in the patent system could jeopardize the internal and external architecture of the patent system and one should be wary of introducing it.

**Keywords** patents; plants; breeding methods; breeders' exemption

Intellectual property rights for plant material are for many reasons controversial, not least because they relate to subject matter which is capable of affecting us all in our basic needs for food and our agricultural and biodiversity system. Despite those controversies and the apparent importance of the subject, it has remained for many years and to some extent still today, the realm of a limited number of scholars and predominantly practitioners, both in private practice and unsurprisingly from the plant and seed industry. For many years, it was a subject that did not appeal to most, witness whereof the relatively limited interest in the subject prior to the turn of the century.<sup>1</sup>

This all has dramatically changed the last decade. An ever expanding intellectual property system, the practices of a number of right holders and a growing awareness of public interest issues surrounding plant materials have made this subject a focal point of attention. That the field has seen a number of high profile cases, a number of which will be discussed in this article, has helped in maintaining attention on the subject.

What are now the most controversial issues in this area of plant material and intellectual property protection? First and foremost, one discussion centers around the question as to whether plants are patentable subject matter in the first place. That question is different from the one as to whether plants should be protectable by patents. The latter is a pure policy question, and it has been decided not to deal with it in this article, not because it is not a relevant question, but because it is a discussion which at the end of the day can have no winners or losers, as it is a question which boils down to more general issue of the desirability of having patent protection for biological material. Over the years, the discussion about the patentability of biological material has not effectively evolved considerably, everyone more or less circling around the nest of one's own arguments (biological material is not patentable because it is already in nature versus the point that biological material is patentable as it in most cases not identical to what is in

nature). Those who would like to argue that issues about intellectual property protection for plant material are of an entirely different quality than those about biological material in general are in the view of the author misled by their own argumentative adrenaline. There is no major difference, as intellectual property protection for material stemming from nature will in any event have an important influence on society. The only issue and maybe more immediate difference is that of biological diversity. The present author is not convinced, however, that the availability of patent protection for plant material is necessarily the cause for any loss of biodiversity. This loss is most probably due to a multitude of factors, of which patent protection may be one, if at all. There are many other reasons why a certain crop would be preferred at the expense of other crops and hence of a sustained biodiversity, and those reasons can be entirely disconnected from patent protection, even though not disconnected from financial benefits. Technological development, even in the absence of patent protection, has probably the most important effect. Certain technologies, which do not necessarily need to be patent protected but some of which have been patented, lead on the one hand to a situation of more dependence of farmers on suppliers of seeds (e.g., terminator technology, growing of hybrids which do not breed through to unlimited future generations, obligating farmers to buy new seeds every year), and on the other hand to the choice by farmers of certain seeds above others (e.g., a certain plant variety may be preferred because of its better resistance to disease, and such plant variety may have been bred without patent protection).

However interesting the above discussion may be, it will be left aside in this article, and our attention will be focused on trying to establish the parameters of patent protection for plant material and discussing some recent developments.

This article provides an in-depth critical analysis of pressing issues regarding the patentability of plants. The approach chosen is inspired by the lack of recent literature trying to critically analyze those issues from a semi-doctrinal approach. Most of the recent literature is very much policy based, ignoring the statutory and judicial framework in place in this area. This article uses a semi-doctrinal approach with a view to find solid and realistic solutions and suggestions while maintaining the foundational structure of the patent system without compromising amendments, which the patent system requires in this area. It seeks to provide a useful but critical appraisal of the patentability of plants, scrutinizing the most recent technological and legislative developments and provides suggestions for future legislative and judicial work in this field of the law.

It will be argued in this article that there is no public interest overarching principle present in the European Patent Convention or any other convention for that matter which would exclude patent protection for plants.

It will further be argued in this article that the expansionist behavior of some users of the patent system seeking to obtain patent protection for methods and products which are very akin to traditional breeding methods needs to be halted and patent applications in that context deserve very close scrutiny so as to avoid that the border is crossed. It is submitted that the patent system is there to protect technical innovation, and not to protect breeding methods. Certain technological innovations in plants merit patent protection, but the mere fact that it is possible to obtain patent protection for plant innovations should not be seen as a stimulus to patent traditional breeding methods by incorporating technical features in such methods which have no essential technical function or effect in the method claimed. It is crucial that those who administer and apply the patent rules maintain a critical view so as to avoid that patents are granted for innovations which were not meant to be protected by the framers of the patent system. It is argued in this context that if the patent system is not capable of keeping such innovations outside of the patent territory, the call for excluding all plant-related innovations from patentability will become more influential, and in case of such evolution probably also justified. Users of the patent system trying to expand patent protection to such innovations should also be warned that such practices are counterproductive in the long run and may lead to paradigm shifts.

It is further argued that products produced by essentially biological processes should not be patentable. However, in the absence of a statutory basis, the current legal framework does not allow the judiciary to come to such conclusion. It is submitted that the EPC needs to be amended in this respect. This could be done by changing the Implementing Regulations, as there is precedent in the statute and the history of the EPC that amendments introducing further exceptions based on a lacuna in the statute can be introduced in the Implementing Regulations.

It is finally argued in this article that, despite the fact that introducing a breeders' exemption in the patent system, allowing breeders to use patented material to develop new varieties and eventually commercialize such new varieties, might be a concept which has some appeal, it could jeopardize the internal and external architecture of the patent system and one should be wary of introducing it. Any exception created needs to be in proportion to the goals to be achieved, and one should ask whether interfering with the foundational structure of a system justifies those goals.

### **Plants versus Plant Varieties**

The European Patent system has chosen the route of allowing patents for plants, but excluding patent protection for plant varieties. Article 53(b) EPC200 says in this context:

[Patents shall not be granted in respect of:] plants 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.

This provision is unfortunately an example of unclear drafting, and it is not surprising to see that almost all concepts therein have been the subject of considerable discussion. Various issues have arisen about this provision, the most important of which are:

1. What is the difference between a plant and a plant variety and when is plant variety excluded from patentability?
2. Are only plant varieties excluded from patentability, or plants in general?
3. What are essentially biological processes for the production of plants?
4. Are the products obtained by essentially biological processes patentable or not?

Not surprisingly, most of the above-mentioned issues have given rise to case law at the highest level of the EPO, the Enlarged Board of Appeal (EBA).

#### ***What is the Difference Between a Plant and a Plant Variety and When is Plant Variety Excluded from Patentability?***

Despite the fact that asking what the difference is between a plant and a plant variety seems a somewhat straightforward question, as we have definitions of what constitutes a plant variety,<sup>2</sup> it has nevertheless proven somewhat more complicated in real life, as patent applicants have claimed inventions for plants in general, which inventions may in practice be carried out on plant varieties. This has given rise to the question as to what is exactly a plant variety, and whether the exclusion would in fact still apply if the invention did not claim a plant variety as such, but if the invention in the real world would be applied to plant varieties.

First of all, let us start with the easy part of the question. What is a plant variety? As said, we have a definition of what is a plant variety. Interestingly enough, the EPC did not have a definition of the term plant variety,<sup>3</sup> which has been the cause of a number of complications we know today (and also partly of

issue 2 as mentioned earlier). Case law has tried to resolve the problem,<sup>4</sup> and the biotech directive<sup>5</sup> has assisted by explicitly referring to the definition of plant variety as laid down in article 5(2) of Regulation 2100/94/EC establishing the Community Plant Variety Right system,<sup>6</sup> according to which a plant variety is:

2. For the purpose of this Regulation, “variety” shall be taken to mean a plant grouping within a single botanical taxon of the lowest known rank, which grouping, irrespective of whether the conditions for the grant of a plant variety right are fully met, can be:

- defined by the expression of the characteristics that results from a given genotype or combination of genotypes,
- distinguished from any other plant grouping by the expression of at least one of the said characteristics, and
- considered as a unit with regard to its suitability for being propagated unchanged.<sup>7,8</sup>

As the EBA explained in the G 1/98 case, the reference to the expression of the characteristics that results from a given genotype or combination of genotypes is a reference to the entire constitution of a plant or a set of genetic information.<sup>9</sup> The concept of plant variety requires plant groupings defined by their whole genome, not merely by individual characteristics.<sup>10</sup>

As the EBA in the G 1/98 case further explained, in contrast, a plant defined by single recombinant DNA sequences is not an individual plant grouping to which an entire constitution can be attributed. It is not a concrete living being or grouping of concrete living beings but an abstract and open definition embracing an indefinite number of individual entities defined by a part of its genotype or by a property bestowed on it by that part.<sup>11</sup>

In other words, any plant grouping that does not fulfil the requirements above, would not be a plant variety. For instance, a genetically modified plant which has inserted in its genome a gene that makes the plant herbicide resistant, would not be a plant variety, as such plant grouping would not be defined by its whole genome, but by an individual characteristic that is the herbicide resistance. An invention for such plants would embrace an indefinite number of individual entities defined by a part of its genotype or by a property bestowed on it by that part. Further in the words of the EBA in the G 1/98 case, such an invention aims at providing tools whereby a desired property can be bestowed on plants by inserting a gene into the genome of those plants.<sup>12</sup> It is as such not the creation of a new plant variety. There is no taxonomic category defined.<sup>13</sup>

Is a claim to a plant variety now only excluded if it is claimed as a plant variety, or also if it is claimed as a plant but would be applied to plant varieties? The invention is in such a hypothesis not limited to plant varieties, even though it is admitted that one of the main applications is plant varieties. But the result of the modification by genetic transformation is not necessarily a plant variety.<sup>14</sup> Hence, a claim for a plant in general, not limited to a specific plant variety, constitutes patentable subject matter and is not excluded from patent protection for being a claim for plant varieties.<sup>15</sup> A plant which has a single gene inserted into it in order to introduce a specific characteristic is defined by that single characteristic and is not a plant variety in the view of the EBA.<sup>16</sup>

Opponents have held that the above solution virtually annihilates the effectiveness of the exclusionary provision of article 53(b) EPC,<sup>17</sup> and furthermore the reasoning would be based on thin grounds. The argument basically is that the exclusion from patentability for plant varieties becomes without effect following the solution provided by the EBA in the G 1/98 case, as it suffices to formulate a patent claim to a plant to escape the exclusion. Furthermore, as any invention to plants will be carried out on plant varieties, one claims in effect and indirectly plant varieties.

Reason for the still lively debate about a supposedly settled matter is the fact that an invention relating to a genetically modified plant will in the real world be applied to plant varieties. Indeed, in the real world, the only tangible embodiments in the plant realm which one can use, see and touch are plant varieties. Any higher ranking of plants, such as species or genus are theoretical classifications, not real tangible embodiments. Consequently, it is not surprising to see that any invention pertaining to plants will in the real world be applied to plant varieties. That is an inevitable consequence of applying an abstract invention to a practical embodiment.

A different question is whether the mere fact that an invention pertaining to a plant which in practice will be carried out on plant varieties, brings such invention in the realm of plant varieties. In other words, does the invention then suddenly become a plant variety merely because it is applied to one or more plant varieties? If one would answer such question in the positive, then every invention to plants would become excluded from patentability, as the inevitable consequence of any patent claim to a plant is that such invention is going to be applied to plant varieties. Following such a reasoning would in fact expand the exclusionary provision of article 53(b) EPC not only to plant varieties but also to plants. There is a debate as to what extent the legislature has indeed maybe meant to exclude plants altogether from patentability, but we will deal with that later in this article.

### ***Why the EBA in the Novartis Case and the EU Directive Provide the Better View***

The view of the EBA in the G 1/98 case, and the identical stance taken by the legislature in the biotech directive are from a legal point of view to be supported. The contrary view is that a claim to a plant should be excluded as it covers in effect a number of plant varieties on which the invention for the plant will be carried out, is for reasons set out earlier not correct. This view is also supported in the literature.<sup>18</sup> If an individual plant variety is claimed it cannot be allowed to grant a patent for such a claim. But there is a difference between a claim embracing a plant variety and a claim to a variety. Every claim to plants will embrace plant varieties, since a plant variety is a plant grouping of the lowest possible rank. When claiming a species, or even a higher rank, it will always embrace plant varieties: all Golden Delicious apples (variety) are apples (species), but not all apples are Golden Delicious.

It is perfectly plausible to claim a plant grouping which totally lacks homogeneity (=group of different plants), except for one characteristic which all the plants of the plant grouping have in common. Following this reasoning, the plant grouping does not consist of a specific taxonomic unit of plants, but it may consist of a taxonomically non-specific plant grouping, which can lead to the development of a great number of plant varieties, but which *in se* are not confined to a certain specific taxonomic unit, and certainly not to a specific plant variety.<sup>19</sup>

The invention is not limited to and does not consist in the production of any concrete homogeneous and stable group of plants. This implies that the invention cannot be confined to the development of any specific plant variety. What is claimed is an invention for a generic concept of a plant, not a specific plant variety.<sup>20</sup>

It has further been submitted in the literature that if a patent claim is drafted for the protection of a transgenic plant, it embraces all plants falling within its scope, irrespective of whether or not such plants belong to any particular variety, and hence there is no reason to exclude such claim from patent protection.<sup>21</sup>

### ***Patent Protection and Hybrid Seeds***

Anyone who was not convinced about what has been discussed in the previous paragraphs about the statutory basis for allowing patent protection for plants but not for plant varieties will probably get somewhat even more concerned by the recent development in case law regarding the patentability of so-

called hybrid seeds. Indeed, recent case law by the TBA regarding hybrid seeds is likely to inflame the debate again regarding the patentability of plants and the non-patentability of plant varieties. The entire discussion is about the legal status of hybrid seeds (and the plants grown thereof) and whether they are deemed to be (parts of) plant varieties, or cannot be considered to be plant varieties from a legal point of view and can hence constitute patentable subject matter.

In case T 788/07,<sup>22</sup> it was held that hybrid seeds or plants thereof “are not considered as units with regard to their ‘suitability for being propagated unchanged’ (Rule 26(4)(c) EPC) and are therefore not regarded as plant varieties which are excluded from patentability (Article 53(b) EPC).”<sup>23</sup> The invention pertained to a hybrid seed or hybrid plant containing a stable fertility restorer gene produced by a cross between a plant obtained from certain deposited seed as a male parent and a second Brassica plant as a female parent wherein the second Brassica plant has a glucosinolate level that is sufficiently low to ensure that the hybrid plant yields oilseeds having a total glucosinolate content of less than 30  $\mu\text{mol/g}$  dry weight.<sup>24,25</sup>

It can be doubted whether the reasoning of the TBA in T 788/07 is correct. As we have seen, a plant variety is defined as:

(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
- (c) considered as a unit with regard to its suitability for being propagated unchanged.<sup>26</sup>

It can be reasonably concluded that the plant which is the result of the claimed crossing of two different plant varieties as in the present case results in a specific phenotype, which is the result of the combined genotypes of the plants crossed, thus fulfilling the criterion sub (a). It can also be reasonably concluded that the resulting plant grouping can be distinguished from the parent grouping and from other groupings, thus fulfilling the criterion sub (b).

The key issue is then whether the plant grouping is deemed to be stable as per the criterion sub (c). Article 9 of the UPOV 1991 Convention and Regulation 2100/94/EC gives further guidance in this regard:

A variety shall be deemed to be stable if the expression of the characteristics which are included in the examination for distinctness as well as any others used for the variety description, remain unchanged after repeated propagation or, in the case of a particular cycle of propagation, at the end of each such cycle.

The TBA in T 788/07 answers that question in the negative, as it concerns hybrid seeds which “are not considered as units with regard to their ‘suitability for being propagated unchanged’”. Looking at article 9 of the UPOV1991 Convention and Regulation 2100/94/EC leads one to the conclusion that the hybrid seeds can be considered to be a unit, as they can be propagated unchanged, be it with a limited propagation cycle. But article 9 specifically allows for such limited propagation cycle, and hence includes hybrid seeds which inherently have a limited propagation cycle within the definition.

In conclusion, the claims underlying the decision in T 788/07 are deemed to fall within the ambit of the exclusionary provision of article 53(b) EPC as being plant varieties. It is somewhat worrying that the TBA came to a different conclusion, as this can only heat the debate as to the patentability of plants versus the non-patentability of plant varieties. Cases such as this are not doing any favor to that discussion. They illustrate that the system is struggling with the distinction. If such confusion would persist, calls could become louder to abolish patent protection for plants altogether, as the system is not capable of guaranteeing that subject matter which has been excluded from patent protection remains indeed outside the patent system. It is therefore submitted that the EPO should have a policy of very strict interpretation of the rules pertaining to plant varieties with a view to avoid future developments which could harm patentability of plant-related inventions, if one would have the view that such inventions are desirable to be protected by patents in the first place.

A similar reasoning could be followed for EP 1553817,<sup>27</sup> currently under appeal under reference T 2645/11. The invention relates to a pepper plant with extended storability characteristics, and which plant is the progeny of a hybrid plant specified in the claims. Also in this case, the resulting progeny plant can be considered to be a plant variety. It can be reasonably concluded that the plant which is the result of the claimed crossing of two different plant varieties as in the present case results in a specific phenotype which is the result of the combined genotypes of the plants crossed, thus fulfilling the criterion sub Rule 26(4)(a). It can also be reasonably concluded that the resulting plant grouping can be distinguished from the parent grouping and from other groupings, thus fulfilling the criterion sub Rule 26(4)(b). And the resulting plant must remain stable within a certain propagation cycle, which the claimed plant must be, hence also the criterion of stability seems to be fulfilled sub Rule 26(4)(c).

### ***Are Only Plant Varieties Excluded from Patentability, or Plants in General?***

An even more fundamental question is whether the legislature has maybe meant to exclude plant patent protection altogether.<sup>28</sup> A literal wording of article 53(b) EPC would lead one to the contrary conclusion, but in view of a growing opposition against patenting plant inventions,<sup>29</sup> it is useful to look at the rationale of this provision and see whether indeed maybe the legislature had meant to exclude patent protection for all plant-related inventions but put it in somewhat clumsy wording.

The argument has been brought forward that the legislature wanted in fact to exclude all plant-related inventions, but as plant varieties were the only type of innovation the then legislature could think of as something which might be subject to intellectual property protection, reference was made to that wording. That argument is not fully tenable, as the legislative history shows that a deliberate distinction was made between plants and plant varieties, even though it can admittedly be questioned whether the legislature was very well aware of what exactly the differences were. There seems to be no evidence that the legislature was aware of the exact distinction between the two, but equally so no evidence that he should not have been aware. The language seems to remain somewhat covered in mystery.<sup>30</sup>

In order to answer this question, it is fundamental to look at the preparatory works of the EPC and see what can be learnt from those. There is a relatively straightforward historical rationale for the particular wording of article 53(b) EPC.<sup>31</sup> This was also clearly explained by the EBA in the G 1/98 case.<sup>32</sup> Even though there is a rationale for the wording of article 53(b) EPC, in view of its unclear wording, deriving a very precise conclusion is challenging to say the least.

Article 53(b) EPC is in fact based on article 2(b) Strasbourg Patent Convention (SPC).<sup>33</sup> It is not an identical copy of it because whereas the SPC left it to the member states to decide whether patent protection should be possible for plant varieties, the EPC expressly excludes the patentability of plant varieties.<sup>34</sup> Article 2(b) SPC says:

the Contracting States shall not be bound to provide for the grant of patents in respect of: plant or animal varieties or essentially biological processes for the production of plants or animals; this provision does not apply to micro-biological processes and the products thereof.

Interestingly, an earlier version of this provision did not refer to plant varieties, but used the term plants.<sup>35</sup> The preparatory works of the SPC do not give us any insight as to why the wording was changed.<sup>36</sup> One can only speculate as to why the wording has been changed, but it is not entirely unlikely to think that the introduction of the UPOV 1961 Convention<sup>37</sup> could have had an influence on this.<sup>38</sup> The UPOV 1961 Convention introduced a special intellectual property law regime for plant varieties, and it is not entirely illogical to think that the SPC legislature must have thought that, in view of this new regime for plant varieties, it might be better to pinpoint the option in article 2(b) SPC to plant varieties. It will have helped that UPOV 1961 also introduced a double protection prohibition for plant varieties,<sup>39</sup> that is it was not possible to grant both patents and plant variety rights for the plant varieties falling within the scope of the Convention (which was at that time a very limited number of varieties).

Important to observe is that the SPC did not formulate a ban on patent protection for plant varieties, nor did it put a ban on patent protection for plants for that matter. It left the choice to the member states to provide patent protection for plant varieties or not. That fact alone seems to suggest that the legislature, be it the SPC one or the EPC one, never had in mind to exclude patent protection for plants altogether.

In the subsequent article 53(b) EPC, a ban was formulated on patentability for plant varieties, and this must have been influenced by the double protection prohibition in UPOV 1961. Many of the future member states of the EPC had already signed and ratified the UPOV 1961 Convention and were consequently bound by the prohibition under article 2(1) UPOV 1961. Also, the EPC legislature did obviously not have the luxury to leave the issue open, as the EPC introduced a new central patent granting scheme, hence a choice had to be made as whether patents would be allowed or not for plant varieties with the now known result.<sup>40</sup> This has also been the view of the EBA in the G 1/98 case:

When the legislator drafted the requirements for patentability in the EPC, the basis was the harmonization already achieved by the SPC in the framework of the Council of Europe (Memorandum on the setting up of a European system for the grant of patents, Doc. BR/2/69, section II.1; Reports on the Preliminary Draft Convention for a European System for the Grant of Patents, Luxembourg 1970, General Report, point 5; Article 10(b) of this Draft is identical with the final version of Article 53(b) EPC). In the early nineteen sixties, the work on both Conventions proceeded in parallel. Whereas it was possible for most provisions of the SPC concerning patentability simply to be transferred to the EPC, this was not the case with Article 2(b) SPC since a choice had to be made whether or not to make use of the possible exclusion of patents in respect of plant varieties. It was not appropriate for the legislator to allow the grant of patents for plant varieties in general because some EPC Contracting States offered plant variety protection under the UPOV-System and were prevented under the ban on dual protection from granting patents. Nor was it possible under the EPC to exclude patent protection only in respect of those varieties for which a plant breeders' right was available (the approach taken by Belgium, Germany, France and Spain in their national legislation, see the preceding point). 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. To take account of the specific situation in each designated State for each individual application would have been contrary to the principle of uniform patent protection in all Contracting States (cf Article 118 EPC). For these reasons, the most obvious choice was to make full use of the possibility in Article 2(b) SPC to exclude the grant of patents in respect of plant varieties entirely.<sup>41</sup>



Equally interesting to observe is that the preparatory works of the EPC use interchangeably the terms plants and plant varieties, which seems to suggest that the drafters did not see any difference between both concepts. Whether such would suffice to say that it has consequently been the intention to exclude patent protection for plants is another matter, as the exclusion was at the end of the day included with a view to be in conformity with the UPOV prohibition on double protection, which is clearly a plant variety right system. Hence, one could say in retrospect that it has never been the intention of the legislature to exclude plants from patent protection, but only plant varieties, even though it may not have been very clear at that time what the difference between the two was, if any at all was seen. In that sense, one is pretty much at the same level of speculation as for the wording in article 2(1) SPC discussed earlier.

It has been argued that the double protection prohibition is not a sufficient ground to conclude that even though plant varieties are not patentable because they are already protection under a *sui generis* system, plants can as consequence be patent protected. The argument is that no such double protection prohibition system exists for animals, and nevertheless animal varieties are equally excluded from patentability.<sup>42</sup> The present author is not convinced this is a very strong argument, as it could be argued that, even though no animal variety right system existed at the time, the legislature could conceive that there may be one at some future point in time.

In conclusion, it is difficult to see how article 53(b) could have meant to exclude all types of plant patents, as there is clear evidence that even at the time of the drafting of the EPC, there was at least some knowledge that there was a difference between plant varieties and plants. And even if that knowledge would not have been there, fact remains that it has never been the intention of the EPC legislature to exclude all plant inventions, as it would have been possible to obtain patent protection for those plant varieties that were not protected under the UPOV system.<sup>43</sup>

Furthermore, as a distinction has been made between the non-patentability of plant varieties and the patentability of microbiological processes for the production of plants, the latter covering also the plants obtained by such processes, it is difficult to see how one could argue that there was a general goal of excluding plant-related inventions from patentability. The EBA in the G 1/98 also highlighted the point that the use of differentiating terminology between plants and plant varieties must have had a specific reason when the EPC was drafted:

whereas the exclusion for processes is related to the production of plants, the exclusion for products is related to plant varieties. The use of the more specific term “variety” within the same half-sentence of the provision relating to products is supposed to have some meaning. If it was the intention to exclude plants as a group embracing in general varieties as products, the provision would use the more general term plants as used for the processes.<sup>44</sup>

That does not take away from the fact that the legislature had probably very little knowledge at the time of drafting of the various possibilities which might exist, witness whereof is the fact that in the preparatory works, and even in the statute, no consequent distinction was made between plant varieties and plants. But it seems to be somewhat overreaching to derive there from that the legislature must have meant to exclude the entire plant realm from patentability. The EPC legislature never had the intention to exclude any and all types of materials derived from naturally occurring materials from patentability. The aim of the patent system as introduced was to provide patent protection for technical inventions in all fields of technology.<sup>45</sup> Why would it then have contemplated excluding technical inventions in the plant realm?

One could conceive a number of reasons why plants should not be patentable, but that is a different line of reasoning than reading an exclusion in the statute. One could argue that plants as a product of nature should never be the subject of patent protection. It could furthermore be brought forward that by allowing patent protection for plants, biodiversity and food supply may be seriously hampered. One could further

defend the thesis that access to plant germplasm is necessary and fundamental with a view not only to sustain food supply but also with a view to develop new varieties. The existence of patent protection would (or could) block such access.<sup>46</sup> These are very justified arguments, even though they probably fail the test of empirical evidence, as it is very difficult to prove that it is the patent system that is responsible for these effects, if present at all. One may not forget that effects on availability of seeds or plants for regrowing is also frequently limited by technologies which are not necessarily patent protected but some of which have been patented, such as, for example, hybrid lines which have a limited propagation cycle, or terminator technology, which are plants which do not breed through.

In other words, even though there may be justified or less justified reasons to argue that plants should be not be patentable, when pursuing such arguments, one should not be clouded by one's arguments and conclude that the EPC never meant to provide patent protection for plants. As we have seen, there seems to be no firm basis in the text or the travaux préparatoires to come to such conclusion. The situation is maybe different for the issue of essentially biological processes for the production of plants and the plants so produced, but that will be discussed later in the article.

## What are Essentially Biological Processes for the Production of Plants?

### *Setting the Scene*

Article 53(b) EPC must be one of the least successful provisions of the EPC in terms of wording. If the problems discussed earlier were not enough, a new layer of problems has been added to the already existing body of issues. More recent patent practices have shown that some patent applicants claim methods for producing a plant which, even if they are not entirely biological processes, are akin to at least being very much biological. Those methods for producing plants are admittedly almost like recipes which one could easily follow to produce plants without the addition of any technical innovation.<sup>47</sup>

This new trend in plant patenting<sup>48</sup> has presented the world and patent granting bodies with new challenges, as the fundamental question arises here as to whether the patent system is made to protect this kind of practices. The patent system is not made to protect simple breeding methods, but that as such does not give us a lot of certainty, as that triggers the question as to what is then a simple breeding method.

The EPC has tried to resolve this problem by introducing in article 53(b) a provision which excludes essentially biological processes for the production of plants from being patented. The provision seems at first glance rather straightforward, and the rationale looks also rather logical that is to avoid that the use of essentially biological processes would lead to patent protection. It is not illogical to assume that the framers of the provision in the fifties must have had the traditional crossing and selection methods in mind (=simple breeding methods) which were carried out by all farmers, and which consisted of influencing where necessary and possible the natural process by helping a "human hand." There is a good reason for not allowing patent protection for such methods, as otherwise it would give the power to patent holders to restrict traditional breeding methods used by farmers in their daily practice.

The wording of the provision is, however, very unsuccessful, as it refers to "essentially biological processes" which one would assume should be different from "entirely biological processes." The provision was never a major issue in the past, as no patent applicant took the venture of filing patent applications for such methods. As we now know, this has changed, and that has brought us to the discovery that we actually know very little about this provision, and even more, that we actually now realize its wording is extremely imprecise. The problem the world is faced with here is that the EPC does not say what the term "essentially biological process" meant.

The drafters of the biotech directive must have realized this, and have made an attempt to provide some clarification, probably not knowing that they would make confusion even more complete. Article 2 (2) Biotech Directive reads in this connection that:

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

It must be admitted, however, that it very much looks like it that the final provision was a work of considerable haste and little planning. Very little gives us guidance as to why the legislature has chosen the wording it has chosen. All what is clear from it is that it is very unclear, not to say utterly confusing. The provision of article 2(2) biotech directive puts various challenges on us. First of all, it says that a process is *essentially* biological if its consists *entirely* of natural phenomena. There seems to be an obvious inconsistency in wording here, which as we will see has proven to be insurmountable. Secondly, the provision also refers to *natural phenomena* such as *crossing or selection*. Problem with that is that crossing or selection are not necessarily natural phenomena. That is the second inconsistency in the wording of the provision, which has equally shown impossible to resolve.

The EPO had unfortunately the in retrospect not particularly brilliant idea to incorporate the provision of the biotech directive into the EPC by adding it to the Implementing Regulations.<sup>49</sup> Not surprisingly, a case was brought before the EBA<sup>50</sup> at the EPO (to be more precise, two cases) with a view to seek clarification as to the exact meaning of both the wording of article 53(b) and the then Rule 23(b)(5) EPC1973, now Rule 26(5) EPC2000.<sup>51,52</sup> The following questions needed to be answered by the EBA:

1. Does a non-microbiological process for the production of plants consisting of steps of crossing and selecting plants fall under the exclusion of article 53(b) EPC only if these steps reflect and correspond to phenomena which could occur in nature without human intervention?
2. If question 1 is answered in the negative, does a non-microbiological process for the production of plants consisting of steps of crossing and selecting plants escape the exclusion of article 53(b) EPC merely because it contains, as part of any of the steps of crossing and selection, an additional feature of a technical nature?
3. If question 2 is answered in the negative, what are the relevant criteria for distinguishing non-microbiological plant production processes excluded from patent protection under article 53(b) EPC from non-excluded ones? In particular, is it relevant where the essence of the claimed invention lies and/or whether the additional feature of a technical nature contributes something to the claimed invention beyond a trivial level?

### ***Rule 26(5) EPC is Contradictory and Cannot be Clarified***

In trying to clarify the meaning and scope of article 53(b) EPC, where it refers to essentially biological processes, the EBA had first to come to the rather embarrassing conclusion that Rule 26(5) EPC2000, allegedly clarifying the meaning of the term “essentially biological process,” is so contradictory in its terminology that it cannot be further clarified.<sup>53</sup>

Before coming to that conclusion, a first task was to see whether the definition of natural phenomena such as crossing or selection could withstand the test of scrutiny. The EBA established that:

the terms “crossing” and “selection” refer to acts performed by the breeder. These are characterised by the fact that the breeder intervenes in the processes in order to achieve a desired result. Hence, in that context, crossing and selection are not natural phenomena but are method steps which generally involve human intervention.<sup>54</sup>

That is obviously not a good start for the interpretation of Rule 26(5) EPC2000, as it looks like the wording used in this connection is contradictory to say the least.<sup>55</sup>

If the wording of a statutory provision is contradictory, a subsequent exercise would then be to look at the legislative history to see whether any meaning can be derived from the intentions of the legislature. The EBA made a thorough examination of those legislative works.<sup>56</sup> Interestingly, the original text of the provision which is now article 2(2) biotech directive read very different<sup>57</sup>: “A process in which human intervention consists in more than selecting an available biological material and letting it perform an inherent biological function under natural conditions shall be considered patentable subject matter.” Additionally, recital 17 provided that:

Whereas it is necessary to encourage potential innovation in the full range of human endeavours by recognizing that human intervention which consists of more than the selection of biological material and allowing such material to perform inherently biological functions under natural conditions should be considered patentable subject-matter and should not be regarded essentially biological.<sup>58</sup>

During the legislative process, the text eventually became what it is today. It was in particular the European Parliament that expressed concerns that the original definition was too narrow, and would lead to a very limited number of exclusions from patentability. Hence, we now know that the European legislature did not want the exclusion to be limited to those cases where the process consisted in nothing more than selecting an available biological material and letting it perform an inherent biological function under natural conditions. A broader definition was given, but that definition has never been given any consistent substance.

As a consequence of the very confusing legislative history which showed some kind of disconnect between European Parliament on the one hand, and the Commission and Council on the other hand, the EBA could only establish that the wording of article 2(2) biotech directive [and thus of Rule 26(5) EPC2000)] is based on contradictory assumptions and cannot be clarified:

Even though the wording of the texts as finally enacted by the Council is unclear and contradictory, it is nonetheless evident that the objective meaning of the definition given in Article 2(2) Biotech Directive corresponds neither to the amendments voted for by the European Parliament nor to the substance of the earlier drafts, but rather is definitely something different. While the first part of the definition, with its reference to processes consisting entirely of natural phenomena, might at first sight appear to take up the substance of earlier drafts comparing the claimed processes with processes which, as a whole, exist in nature, and which occur under natural conditions, the second part of the definition, which refers to crossing and selection, appears to take up the Parliament's definition according to which processes based on crossing (whole genomes) and selection should be excluded from patentability as being essentially biological. The effect of combining the two elements of different concepts into a single definition and citing one of these concepts as an example of the other was to reinforce the contradiction in meaning of the provision, as compared to the earlier drafts mentioned above. As a result, the legislative history of the Biotech Directive does not assist in determining what the legislator intended to say by the wording which was eventually adopted for Article 2(2) Biotech Directive. On the contrary, it must be concluded that the contradiction between the terms of the provision cannot be further clarified.<sup>59</sup>

As a consequence of this, the EBA saw itself being confronted, and probably so for the first time in the history of the EPC, with the situation that, as Rule 26(5) EPC is a literal transposition of article 2(2) biotech directive, and as no intelligible meaning could be given to the latter, no useful guidance can be taken from

Rule 26(5) EPC2000 in interpreting article 53(b) where it excludes essentially biological processes for the production of plants from patent protection.<sup>60</sup>

### *Autonomous Interpretation of Article 53(b) EPC*

The fact that Rule 26(5) EPC could not be given any sensible meaning left the EBA with the problem that it now had to interpret without any further assistance what is meant by “essentially biological process” in article 53(b) EPC. It quickly realized that a reliable literal meaning would never be found.<sup>61</sup> The EBA also concluded that the approach to the concept used in earlier case law<sup>62</sup> was flawed and hence not useful:

Basically, any approach that makes the decision on whether a claimed process for the production of plants is essentially biological and therefore excluded from patentability, or technical and therefore patentable, dependent on criteria which are determined by reference to the state of art is flawed because it conflates the considerations which are relevant for patentability with those relevant for novelty and inventive step.<sup>63</sup>

From a doctrinal point of view, this stance is to be supported, as it is a more than common mistake to make, and in fact it has been a practice which lasted for a while in EPO case law pertaining to computer implemented inventions.<sup>64</sup>

In giving an autonomous interpretation to article 53(b) EPC, looking at the legislative history of that provision seems to be the first task on the list. But also here, the legislative history is not very useful.

In the First Preliminary Draft Convention relating to a European Patent Law dated 14 March 1961, the text of the draft provision of what later became article 53(b) read in article 12:

[European patents shall not be granted in respect of: ...] 2. Inventions relating to the production of or a process for producing a new plant variety or a new animal species. This provision shall not apply to processes of a technical nature.<sup>65</sup>

In the comments to this draft provision, it was said that:

even if protection of new plant varieties and processes for producing new plants is excluded under European patent law, European patents will still have to be granted for processes which, while being applicable to plants, are of a technical nature, e.g., processes for producing new plants by irradiation of the plants themselves or the seeds with isotopes. It remains to be examined whether that possibility of patent protection must be expressly incorporated in European law or whether it is obvious from general principles.<sup>66</sup>

It can be noted that the first draft provision did not refer to the concept of “essentially biological” but merely stated the exclusion in a negative manner. Production of new plant varieties is not patentable, unless such production took place by means of a technical process.

By April 1961, the text of the then draft article 12 had already been amended and read: “[European patents shall not be granted in respect of: ...] 2. New plant varieties or new animal species and purely biological processes for producing them.”<sup>67</sup> One can clearly discern that the wording “purely biological processes” has been added. No clear insight can be obtained for this amendment in the legislative history, apart from a reference to the need to align the text of the provision with the forthcoming UPOV1961 Convention text,<sup>68</sup> and the observation by Mr. Pfanner that “a distinction had to be drawn between production by biological means and production involving external technical factors.”<sup>69</sup> The latter observation seems to point to the difference indeed between purely biological processes and technical

processes, which would one let to believe that the legislature at least at that moment in time envisaged to exclude purely biological processes only, without any clarification, however, as to what is exactly meant by a biological process.

In the meantime, in May 1961, a Preliminary draft Convention on the unification of certain points of substantive law on patents for inventions (the later SPC) was presented, which contained the following exclusion in draft article 2: “the contracting states shall not be bound to provide for the grant of patents in respect of new plants or animal species or of **purely biological**, horticultural or agricultural (agronomic) processes” (emphasis added).<sup>70</sup>

The draft SPC was subsequently amended in November 1961. Article 2 now read: “the contracting states shall not be bound to provide for the grant of patents in respect of new plants or animal varieties or of **essentially biological** processes for the production of plants or animals” (emphasis added). This amendment implied that the words “horticultural or agricultural (agronomic)” were deleted and the remaining phrase (“purely biological processes”) was replaced by the current wording “essentially biological processes for the production of plants and animals. A memorandum of the secretariat of the committee contains the following explanations:

The processes for the “production of plants or animals” referred to in the new text include those which may produce known varieties as well as those which may produce new ones, it being understood that only new varieties can eventually qualify for protection in themselves. Selection or hybridisation of existing varieties may be mentioned as examples of such processes (in the vegetable kingdom). The new text specifies that the processes which may be ineligible for patents are essentially (and no longer purely) biological. It was evident that the exclusion should be extended to cover processes which were fundamentally of this type even if, as a secondary feature, “technical” devices were involved (use of a particular type of instrument in a grafting process, or of a special greenhouse in growing a plant), it being understood that such technical devices may perfectly well be patented themselves, but not the biological process in which they are used.<sup>71</sup>

In the May 1962 draft of the future EPC, the then article 10(b) (now article 53(b)) had the wording corresponding to the draft article 2(2) SPC of November 1961: “[European patents shall not be granted in respect of: ...] (b) plants or animal varieties or **essentially biological** processes for the production of plants or animals”<sup>72</sup> (emphasis added). The documentation reveals that the EPC legislature indeed envisaged to align the text of the future EPC with that of the future SPC.<sup>73</sup> Not one single word has been said on why the wording “purely” has been exchanged for “essentially.” An issue was raised as to microbiological processes. A discussion to that effect took also place at the negotiation table for the SPC, where the exemption for microbiological processes was incorporated in the text of the SPC in 1962. In 1963, it was suggested to incorporate an identical provision in the text of the future article 53(b) EPC and hence to provide that the exception to patentability should not apply to microbiological processes and the product thereof in accordance with the Strasbourg Draft.<sup>74</sup>

The 1965 draft text of the then article 10(b) of the future article 53(b) EPC read: “[European patents shall not be granted in respect of: ...] (b) plants or animal varieties or essentially biological processes for the production of plants or animals; this provision does not apply to microbiological processes and the products thereof.”<sup>75</sup> The text has remained unchanged since then.

What does this overview of the legislative history of article 53(b) EPC1973 teach us? It cannot be denied that the legislature in the process exchanged the wording “purely biological” for the wording “essentially biological.” Even though this is a clear fact, finding out what was the exact rationale for this change in wording is less easy to evaluate. According to the EBA in G 2/07, the exchange of the word

“purely” for “essentially” was deliberate and reflects the legislative intention that the mere fact of using a technical device in a breeding process should not be sufficient to give the process as such a technical character and should not have the effect that such process is no longer excluded from patentability.<sup>76</sup>

### ***The Conclusion of the EBA in G 2/07***

According to the EBA in G 2/07:

it 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 plants (i.e. of their whole genomes) deemed suitable for the purpose pursued and on the subsequent selection of the plants having the desired trait(s). The application of technical means or other forms of human intervention in such processes which helped to perform them was already common. Nevertheless, the said processes were characterised by the fact that the traits of the plants resulting from the crossing were determined by the underlying natural phenomenon of meiosis.<sup>77</sup>

And further according to the EBA:

hence, it must be concluded that the provision of a technical step, be it explicit or implicit, in a process which is based on the sexual crossing of plants and on subsequent selection does not cause the claimed invention to escape the exclusion if that technical step only serves to perform the process steps of the breeding process.<sup>78</sup>

The EBA concludes then that:

the conclusion to be drawn is that a process for the production of plants which is based on the sexual crossing of whole genomes and on the subsequent selection of plants, in which human intervention, including the provision of a technical means, serves to enable or assist the performance of the process steps, remains excluded from patentability as being essentially biological within the meaning of Article 53(b) EPC. However, if a process of sexual crossing and selection includes within it 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 that process leaves the realm of the plant breeding, which the legislator wanted to exclude from patentability. Therefore, such a process is not excluded from patentability under Article 53(b) EPC but qualifies as a potentially patentable technical teaching.<sup>79</sup>

### ***Consequences of the Decision in G 2/07***

The solution provided by the EBA leads admittedly to at the same time a relatively narrow but also broad scope of the exclusionary provision, and it must be said, it is equally not entirely clear. It has the advantage that it excludes from patentability traditional breeding methods, even if technical steps are introduced, which will most probably displease patent applicants who have jumped on the easy route around the breeding method exclusion of patent protection bus. However, it allows patentability of breeding methods to the extent that a trait is introduced or modified in a plant genome which is not the result of the mere mixing of genes as a consequence of sexual crossing. There is obviously a risk that relatively unnecessary

technical interventions could be made in order to escape the exclusionary provision, if such technical interventions would be at the genetic level, without any real effect on the plants. It could be argued in that context, however, that the introduction of such step could be patentable in itself, which could then still constitute a way out of the exclusionary provision.

Furthermore, certain terminology in the decision will probably cause additional questions. One can wonder whether equalizing essentially biological processes with methods which contain or consist of crossing the entire genome of a plant and selecting useful plants is an accurate definition of what is an essentially biological process. One must remember that the EBA had held that Rule 26(5) EPC, which contained similar wording—at least partly—was deemed to be entirely non-useful for purposes of understanding article 53(b) EPC.

One can also wonder what is exactly meant by a “trait.” The EBA has not given any definition of the term.

Lastly, it is also unclear how to understand the wording pertaining to a process which contains “within the steps of sexually crossing and selecting an additional step of a technical nature.” If that step introduces or modifies a trait in the genome of the plant, the method could still be patentable. Would this also cover introduction or modification of traits which take place before or after the steps of sexually crossing and selecting, and if not, is there a rationale for limiting the patentability possibilities that the specific phase of “within the steps of crossing and selecting”?

In conclusion, even though the decision of the EBA has taken away at least some of the uncertainties, anyone who would have hoped that this part of the law would now be clear is bound to be disappointed.

An illustration of the remaining uncertainties after the G 2/07 decision, precisely as explained in the previous paragraph, is European patent application EP 1525317.<sup>80</sup> The Examining division has currently rejected the claims in its latest Office Action of 26 January 2012,<sup>81</sup> invoking G 2/07, where it was held that:

if a process of sexual crossing and selection includes within it 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 that process leaves the realm of the plant breeding, which the legislator wanted to exclude from patentability.<sup>82</sup>

The only technical step is the embryo rescue step. Of that step, the Examining Division held that it does not modify by itself the genome of the plant produced. Hence, such step cannot constitute an exemption to the exclusionary provision of article 53(b) EPC.<sup>83</sup> The patent applicant has replied in response to the Examining Division’s office action that the embryo rescue is in effect causing a modification of the trait within the genome of the plant, and would hence be entitled to patent protection, as it would fall within the exemption created by G 2/07. According to the patent applicant, the embryo rescue serves to modify a trait already present in a plant. In particular, further according to the patent applicant, the embryo rescue step serves to actively modify those parts of the plant’s genome, which, due to the sexual incompatibilities, cause disruptions in the development of the plant embryo such that it is not capable of developing into a mature and fully developed plant.

### **Product Obtained by an Essentially Biological Process Patentable?**

Even though the EBA has created at least some legal certainty with the G 2/07 decision, and has excluded a large part of traditional breeding methods from patentability, it was not called to resolve the obvious next step that is what about the products obtained by such processes. Can the products made by essentially biological processes still be patented, or should they share the same fate as the methods from which they



have been made? Intuitively, one might be tempted to say that the products obtained by essentially biological processes should not be patentable.<sup>84</sup> But in the law, intuition is not enough.<sup>85</sup> There must be a legal basis to support such view. And that might be somewhat difficult, as there is no explicit statutory provision covering this situation. The problem is also far from academic, as the claims of the patent which was subject to the referral in the G 1/08 case have been amended, by deleting the method claims, and maintaining the product (read, the tomato fruit) claims.

And this is unfortunately not the only case. There are currently a number of cases where products have been claimed which may admittedly have been produced by processes which might very well fall within the scope of what the EBA has defined as essentially biological processes.

For instance, EP 1962578, also called the melon patent, claims a CYSDV-resistant melon plant obtained by introgression.<sup>86</sup> Further clarification as to what is meant by “introgression” can be found in the description, where it is stated that introgression may mean crossing:

[0027] As used herein, the terms “introgression”, “introgressed” and “introgressing” refer to both a natural and artificial process whereby genes of one species, variety or cultivar are moved into the genome of another species, variety or cultivar, by crossing those species. The process may optionally be completed by backcrossing to the recurrent parent.<sup>87</sup>

In other words, the melon plant seems to have been obtained by a crossing process, and in the absence of anything in the process that would make it not essentially biological, it could be seen as a product obtained by an essentially biological process.

Another example is EP 1973397.<sup>88</sup> The invention relates to a cucurbita plant, which includes pumpkins, squashes etc, where said plant has cucumber mosaic virus resistance.

Having established that it is a problem that needs to be resolved as it is by no means unique to the referral to the EBA in the G 2/12 case, we will in what follows endeavor a quest to a possible solution for this new legal problem.

As we have already determined, there is no statutory provision dealing with this problem as such. In the absence of an explicit statutory provision, could we then take inspiration from other issues already resolved?

### ***Inspiration from Patentability of Microbiological Processes and their Products in Article 53(b) EPC?***

One of the questions which have arisen in the past was whether plant varieties could be protected as the product of a microbiological process. As we know from article 53(b) EPC, microbiological processes for the production of plant(s) (varieties) are patentable, and plant varieties are not. But are plant varieties made by such processes also patentable? Article 53(b) EPC uses the wording “microbiological processes or the products thereof.” One could argue, with support of at least some of the literature<sup>89</sup> and EPO case law,<sup>90</sup> that, as the statute refers to the generic wording “products thereof” (=products of microbiological processes) and as the patentability of microbiological processes and the products thereof is an exception to the general rule that plant varieties and essentially biological processes for the production of plants are not patentable, it should be possible to obtain patent protection for plant varieties as the products of microbiological processes. Following this line of reasoning, excluding plant varieties from patentability as the products made by microbiological processes would unduly limit the scope of patentability of microbiological inventions, and this could never have been the intention of the legislature.

This was not the prevailing view in the literature, however, where it was argued that, as plant varieties are not patentable, it should not be possible to circumvent that exclusion by claiming plant varieties as

products of microbiological processes. It was held that the exclusion from patentability of plant varieties should be complete.<sup>91</sup>

The text of the statute was obviously not very consistent and hence not very clear, reason why some of the literature and the EPO case law have gone one direction, and some of the literature another. The biotech directive did not bring a clarification in its articles either.<sup>92</sup> When the biotech directive was being transposed into the EPC, the legislature realized the uncertain position in this field and decided to make it clear that plant varieties cannot be protected as products obtained by a microbiological process.<sup>93</sup>

The above does not in fact give us the solution for the present issue, as what we deal with now is the situation that a product which is not explicitly excluded from patentability (=a plant) is produced by a process which is excluded (=an essentially biological process), while in the case of plant varieties as products of microbiological processes, one deals with the case that an excluded product (=a plant variety) is produced by a patentable process (=a microbiological process).

The case of microbiological processes was in fact comparatively easy to resolve, as it pertained to obtaining a patent for a product which is as such explicitly excluded from patentability. There was in other words an explicit statutory basis for the exclusion. The absence of a specific wording in the statute regulating the matter led to conflicting views which could both be intellectually defended. The EPC legislature has subsequently also clarified the issue by expressly regulating the matter. One can only guess why it has not taken the opportunity to regulate also expressly the issue of plants produced by an excluded essentially biological process.

### ***Inspiration from Article 64(2) EPC Cases?***

Under article 64(2) EPC,<sup>94</sup> the scope of protection of a process patent for making a product extends to the product directly obtained by such process.<sup>95</sup> For example, the product directly obtained by a microbiological process could be a plant variety. The plant variety will as a consequence be indirectly protected by the patented process. Indeed, while article 53(b) EPC covers the cases where direct protection could be obtained that is product protection *per se* for the plant (but not the plant variety as we have seen) produced by the patented microbiological process, article 64(2) EPC covers the eventuality that a process for making a product is patented, and protection will then extend to the products directly obtained by the patented process, even if that would be a plant variety which is non-patentable in itself. This obviously limits the scope and effect of the exclusion of plant variety protection (PVP) under article 53(b) EPC, but there is still the difference that no product protection can be obtained as such for the plant variety, as such is excluded under said article 53(b) EPC.

There are a number of points that should be made in this context. It is first of all doubtful whether much inspiration can be gained from an analysis of article 64(2) EPC issues, as both article 53(b) and article 64(2) EPC deal with two different concepts. While article 53(b) deals with (non-)patentable subject matter, article 64(2) EPC deals with scope of protection of the patent granted. These two concepts must be kept separate, as they pertain to different features of the patent system. The scope of protection of a patent is obviously quite different from what is protectable subject matter. Further evidence of the need to keep both concepts separate can also be obtained from the very purpose of the EPC. The European patent system and the EPO deals exclusively with the grant of patents. Scope of protection, which is determined in a post-grant infringement context is subject to national law, be it that article 64(2) EPC provides a template for the national statute of the member states of the EPC.<sup>96</sup> Consequently, conflating protectable subject matter with scope of protection should be avoided as otherwise the exact boundaries of the competence of the EPO versus the national courts would become unclear. Furthermore, if the EPO would take any decision relating to a patent application which would be based on a scope of protection concepts, such decision would clearly be “*ultra vires*.”

Secondly, both provisions have a different rationale, which is obviously linked to the fact that both provisions serve a different purpose and relate to separate features of the patent system, as explained in the previous paragraph. The rationale for article 64(2) EPC has been that patent protection for a process for making a product would not be adequate if the product directly obtained by such process would not be protected as well, as that would allow third parties to make the product which would make the process patent relatively invaluable. Furthermore, article 64(2) EPC will cover in many cases the situation that the product as such is no longer new, while the process for making it is new. Without elaborating further on all intricacies of this provision, it must be observed however, that one of the key requirements is that only products *directly obtained* by the patented process are protected by the process patents, which has obviously a limiting effect, but which has also proven not always easy to define.<sup>97</sup>

The underlying rationale was well explained in an early English case:

If the patented process were the last stage in the production of the article sold, the importation and sale of the product would, in my opinion, plainly be an infringement; and does it make it any the less an infringement that the article produced and sold is manufactured by the use of the patented process with the subsequent use of certain other processes? In my opinion it does not. By the sale of saccharin, in the course of whose production the patented process is used, the patentee is deprived of some part of the whole profit and advantage of the invention, and the importer is indirectly making use of the invention.<sup>98</sup>

Hence, under article 64(2) EPC, a product which may otherwise not be patentable (e.g. it is known, or it is for instance a plant variety) can indirectly be protected by a process patent, which has also been confirmed in the G 1/98 case:

if a plant variety may be covered by a product claim, there is little room for the argument that protection for the variety derived from a claimed process could be inconsistent therewith. For the avoidance of any doubt, question 3 is answered in conformity with the established case law according to which 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.<sup>99</sup>

The underlying rationale of article 64(2) EPC and the fact that article 53(b) EPC, dealing with exclusion of certain processes for making plants, pertains to the reign of protectable subject matter, over which the EPO has competence to judge, while it has no such competence regarding article 64(2) which covers scope of protection, can indeed lead to somewhat at first sight remarkable solutions. While a plant variety is not protectable as such, as it is contrary to article 53(b) EPC, it could theoretically be protected as the product directly obtained by a patentable process under article 64(2) EPC, as falling within the scope of protection of a process patent. One could obviously ask questions about this result, as a reasoning such as the one followed by the EBA, which admittedly is based on solid-legal reasoning, would allow that PVP sneaks back in through the back door of indirect protection. However, the entire rationale of article 64(2) EPC is based on the principle that it should protect the interests of the patent holders of process patents by providing indirect protection for the products directly obtained, even if such products would not be protectable in themselves.

The German legislature, when transposing the biotech directive, was of the opinion that it could never have been the intention of the legislature to allow such indirect protection for excluded subject matter. The travaux préparatoires to the German Patent Act amending the biotech directive state explicitly that it could NOT have been the intention of the legislature to allow indirect protection for plant varieties which are

excluded from patentability, and hence, according to the will of the legislature in Germany, plant varieties as the product directly obtained by a patented process could not benefit from protection.<sup>100</sup>

In conclusion, also article 64(2) EPC is not helping us in answering the questions whether a patent can be obtained for a product which may *in se* constitute patentable subject matter but which is produced by a non-patentable process, which is in fact exactly the reverse situation as the one covered in article 64(2) EPC.<sup>101</sup>

### *Any Solutions?*

#### Introduction

No or at least very limited inspiration can be gained from the statutory regimes already in place discussed earlier. It looks very much like it that there is simply a gap in the legislative framework.

Not surprisingly, a new referral has been made to the EBA with a view to resolve the conundrum.<sup>102</sup> The questions read as follows:

1. Can the exclusion of essentially biological processes for the production of plants in article 53(b) EPC have a negative effect on the allowability of a product claim directed to plants or plant material such as a fruit?
2. In particular, is a claim directed to plants or plant material other than a plant variety allowable even if 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?
3. Is it of relevance in the context of questions 1 and 2 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?

It looked for some time as if the EBA could have saved itself the trouble of looking at the questions. The only opponent in the case has withdrawn from the present appeal. Procedurally, this might have implied that there is only the patent holder left as sole appellant, and any decision by the EBA which would adversely affect the patent holder being sole appellant would hence imply a *reformatio in peius*, against which the patent holder is protected.<sup>103</sup> That was the position of the patent holder in this case. Recently, the EBA stated in a preliminary Opinion that it disagrees with that position.<sup>104</sup> In the preliminary view of the EBA in the case underlying the present referral, the patent holder defends the patent in the version maintained by the opposition division only as its auxiliary request. However, as its main request, the patent holder defends the position in a different, technically broader version. In the view of the EBA, the principle of prohibition of *reformatio in peius* does not mean that the Board of Appeal would be bound by the reasons given by the first instance for its decision, when the Board has to assess the same questions in the context of a different request (in this case the main request which is broader than the auxiliary request) which the first instance has not decided positively but for which these questions are also relevant.<sup>105</sup> In other words, the patent which was maintained in opposition is in the version of the narrower claims of the auxiliary request, while the patent holders defends the patent in the version of the broader main request. As the opposition division has never ruled positively over the main request, and as the patent holder still defends the patent in that broader main request form, there can be no *reformatio in peius*, as the ruling will cover the broader main request claims, on which no positive decision has been taken. In the absence of a positive decision on a set of claims, there can be no *reformatio in peius*, as there is no legal situation to become “worse.” Whether this line of argumentation is sustainable is a matter which goes beyond the scope of this article.

Hence, the issue has definitely not become irrelevant. First of all, there is the preliminary opinion of the EBA. But even if the case would for some reason not be continued, the present author has the view that

it is a problem that requires urgent attention in the light of patent claim drafting practice, a good reason to scrutinize the problem. Secondly, even if the present referral were not to survive, it is not impossible that the same issue will lead to a new referral, as there are presently still some other patent applications pending or under opposition, even admittedly not many.<sup>106</sup> Thirdly, it is also not impossible that the issue becomes at some point the subject of a referral to the CJEU, in the context for instance of interpreting article 2(2) biotech directive relating to essentially biological processes for the production of plants.<sup>107</sup> Indeed, the Dutch Cresco case<sup>108</sup> would be a worthy case.<sup>109</sup>

## Two Approaches

There are basically two possible ways of approaching the issue.

*Approach 1.* One approach is to conclude that the legislature does not seem to have foreseen the present constellation of a claim for a product, which is obtained by a non-patentable essentially biological process, in which case the only remedy would be an amendment of the statute. One could in that case expect a debate as to where the solution is to be formulated that is in the Articles or in the Rules.<sup>110</sup> There is a fundamental difference between the two solutions in that the former requires an amendment of the EPC with an accompanying Diplomatic Conference, always a burdensome and unpredictable procedure, and the latter merely needs an amendment of the Rules with a majority in the administrative Council. There is precedent for the latter solution, as it has been a Rule that has introduced the principle that the product of a microbiological process as a patentable product cannot be a plant variety.<sup>111</sup> That was despite case law to the contrary. Hence, this solution has not been seen as the introduction of a new principle, which would require an amendment of an Article the EPC, but merely a clarification or further implementation of principles already present in the Articles, in which cases Rules suffice.

*Approach 2.* The second approach could be to say that the situation was envisaged by the legislature, but then the question remains what solution the legislature would have envisaged. Nothing in the legislative works is of any assistance in this respect. That has been true for most issues regarding plant-related inventions, in view of the inconsistent terminology used in both the legislative history and the statute (plants and plant varieties for instance are not very consistently distinguished).

Under this approach, there are obviously only two solutions. The legislature has envisaged to allow patent protection for products which are produced by non-patentable essentially biological processes, or he has not. In all instances, reference will have to be made to the Vienna Convention on the Law of Treaties.<sup>112</sup> According to article 31(1) of the Vienna Convention, "A treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose." Article 32 will also be extremely relevant:

Recourse may be had to supplementary means of interpretation, including the preparatory work of the treaty and the circumstances of its conclusion, in order to confirm the meaning resulting from the application of article 31, or to determine the meaning when the interpretation according to article 31:(a) leaves the meaning ambiguous or obscure; or (b) leads to a result which is manifestly absurd or unreasonable.

### *In favor of patenting products produced by an essentially biological process*

In favor of concluding that such products should be patentable, the following arguments can be made.

#### 1. Claim categories must be interpreted independently

Any claim category has to be seen independently and every claim in such category must be evaluated on its own merits. That would imply that a product claim must be examined on its own merits, whether a pure product or a product-by-process claim, and for that matter it is irrelevant whether or not it happens

to be a product that has been obtained by an essentially biological process. There is a lot to say for this argument, as it is a fundamental principle underlying the patent system that each claim must be judged on its own merits. Difficulty, however, is that it takes away any utility and effectiveness of the exclusionary provision for essentially biological processes.

One could rebut this argument by saying that what is suggested here is nothing more than what we already have in the medical area. Medical treatment methods are excluded from patentability, while the products used therein are patentable.

There is in the present author's view a fundamental difference, however. While the products in the medical field will be used in medical treatment methods, they are not products made by such methods. In the case at hand, one deals with products which have been produced by excluded processes. In T 1854/07,<sup>113</sup> the TBA held in relation to a product-by-process claim, strictly adhering to generally accepted policy regarding this type of claims, that:

Claim 1 refers to a product defined in terms of the process by which it is produced. Such "product by process" claim remains a product claim irrespective of the process it refers to. Appellant's argument that claim 1 refers to an essentially biological process for the protection of plants which is excluded from patentability according to Article 53(b) EPC, must therefore fail.<sup>114</sup>

The TBA in this case thus followed the approach that each claim must be judged upon its own merits, irrespective of the process used to produce the product.

This decision has led to some upheaval, as it is used by some as an argument to say that the EPO TBA has created precedent that products made by essentially biological processes are patentable.<sup>115</sup> What the decision in fact does, is ignoring the fact that the products are made by essentially biological processes,<sup>116</sup> and it could indeed be seen as an indirect condoning of filing patent claims in the form of a product-by-process claim as a tool to avoid an objection on the basis of essentially biological process for the production of plants.

There is another problem with using the argument of having every type of claim being examined in its own right. The EBA held in G 2/06<sup>117</sup> that:

what needs to be looked at is not just the explicit wording of the claims but the technical teaching of the application as a whole as to how the invention is to be performed. Before human embryonic stem cell cultures can be used they have to be made. Since in the case referred to the Enlarged Board the only teaching of how to perform the invention to make human embryonic stem cell cultures is the use (involving their destruction) of human embryos, this invention falls under the prohibition of Rule 28(c) [...] To restrict the application of Rule 28(c) [...] to what an applicant chooses explicitly to put in his claim would have the undesirable consequence of making avoidance of the patenting prohibition merely a matter of clever and skilful drafting of such claim.<sup>118</sup>

The same principle has been applied in the CJEU *Brustle* decision C-34/10:

(49) Accordingly, on the same grounds as those set out in paragraphs 32 to 35 above, an invention must be regarded as unpatentable, even if the claims of the patent do not concern the use of human embryos, where the implementation of the invention requires the destruction of human embryos. In that case too, the view must be taken that there is use of human embryos within the meaning of Article 6(2)(c) of the Directive. The fact that

destruction may occur at a stage long before the implementation of the invention, as in the case of the production of embryonic stem cells from a lineage of stem cells the mere production of which implied the destruction of human embryos is, in that regard, irrelevant. (50) Not to include in the scope of the exclusion from patentability set out in Article 6(2)(c) of the Directive technical teaching claimed, on the ground that it does not refer to the use, implying their prior destruction, of human embryos would make the provision concerned redundant by allowing a patent applicant to avoid its application by skilful drafting of the claim.<sup>119</sup>

Obviously, a reasoning like the one followed in the G 2/06 case opens the door for a reasoning that other considerations might put aside the principle that a patent claim must be examined in its own right. One such other consideration could obviously be that the patent system should not protect products, which are made by non-patentable essentially biological processes.

In a recent case, the TBA has held that the exception of article 53(b) EPC belongs to a different category than the one of article 53(a) EPC, and that hence there is no reason to apply the teaching of G 2/06 and C-43/10 to the exception laid down in article 53(b):

The present Board does not see any reason to apply this approach of decision G 2/06 to the situation underlying present claim 1. Said approach has been developed in the context of a particular exception to patentability governed by Article 53(a) EPC in view of Rule 28(c) EPC which focuses on the patentability of inventions related specifically to the ethical concerns associated with the destruction of a human embryo, whereas for present claim 1 the context to be considered is the one of another exception to patentability which is governed by Article 53(b) EPC.<sup>120</sup>

The present author is not convinced that this is a proper reading of G 2/06. It is difficult to see how the general principle that one has to look at the whole contents as to how the invention has come into existence should only be limited to article 53(a) EPC exceptions for a variety of reasons. Firstly, there is nothing to be found in the G 2/06 decision that would lead to such a narrow conclusion. Secondly, if one would accept that the teaching would be limited to article 53(a) EPC exceptions, then this would imply that there would be multiple approaches applicable in parallel as to how patent claims and patent applications have to be looked at. It would be contrary to the principle of legal certainty, equal treatment and protection of legitimate expectations for all patent applicants and applications if that would be the case. Consequently, it is submitted that the reasoning of the TBA in T 1199/08 is erroneous and is not helping us any further.

## 2. Exclusions must be interpreted restrictively

A second argument could be to say that exclusions must be interpreted restrictively. One should be wary of expanding exclusions unnecessary. If the legislature has expressly stated in the Convention that essentially biological processes are not patentable, but has not said anything about products made by using such processes, this must imply that the legislature has not wanted to have those products excluded; otherwise, he would have stated so. It is always risky to read exclusions in the statute which have not been mentioned therein.

Inspiration could in that sense be taken from the issue of microbiological processes. The second-half sentence of article 53(b) expressly says that products of microbiological processes are patentable in their own right. It could be questioned why this express reference was necessary, as one could logically assume that if the processes are patentable, the products thus obtained should also be patentable. The

legislature has nevertheless decided to make special reference to the products, and this must have had a reason. In the absence of any teaching in the legislative history, one can speculate that the legislature wanted to make sure that products became patentable subject matter in their own right, and not merely as products falling within the scope of protection of the process patent as the products directly obtained by a patentable process under article 64(2) EPC.

The reasoning goes further and it could then be said that by not making any reference to products obtained by non-patentable essentially biological processes, the legislature has refrained from excluding such products from patent protection. The legislature was in that line of reasoning very exhaustive about what he wanted to be patentable and what not, hence leaving no room for reading into the statute exclusions which it does not mention. That conclusion would be an interpretation of the EPC in conformity with article 31 of the Vienna Convention on the Law of Treaties where it requires an interpretation of a convention in good faith and by giving an ordinary meaning to the terms of the convention in their context and in the light of its object and purpose.

### 3. An appeal to pragmatic thinking

A third line of reasoning is based on a certain degree of pragmatic thinking. It could be argued that, as there is no statutory basis for denying patent protection for product claims for plants produced by an essentially biological process, such product claims constitute patentable subject matter.<sup>121</sup> However, it is rather unlikely that such product claim will be deemed to fulfil the inventive step requirement or for that matter the enabling disclosure requirement, as it is based on an essentially biological process.

Similarly, it has been held in EPO case law in the field of computer-implemented inventions that if an invention consists of both technical and non-technical features (and provided one would know what technical means, which has shown to be rather complicated),<sup>122</sup> the invention as such is deemed to be technical and to the extent that the computer programs is not claimed as such, the invention is not excluded from patentability as being excluded subject matter.<sup>123</sup> However, it has been held in that very same case law that in order to evaluate whether the invention constitutes an inventive step, only technical features are taken into account.

#### *Against patenting products produced by an essentially biological process*

Against the conclusion that such products could be patentable, the following could be said. One could argue that it would defy the rule of logic to claim that a product obtained by an otherwise not protectable process would still be able to receive patent protection. If that would be possible, the exclusion from patentability of the process would become entirely futile, as it would be very easy to circumvent it by claiming the product instead of the process, possibly in the format of a product-by-process claim.<sup>124</sup> Invoking article 32 of the Vienna Convention on the Law of Treaties, it could be argued that the circumstances of conclusion of the EPC were that the legislature wanted to exclude essentially biological processes from being patentable. Holding that the same would not be true for products produced by such processes would lead to a manifestly absurd or at least unreasonable result, hence the legislature must have meant to exclude also the products made with essentially biological processes from patentability.

There is some merit in this argument, and support could be found in the otherwise controversial decision of the CJEU in the Monsanto case.<sup>125,126</sup> It must be emphasized, however, that this decision dealt with an issue of scope of protection, and not with an issue of protectable subject matter.<sup>127</sup> In the Monsanto case, one of the issues was whether article 9<sup>128</sup> combined with article 5(3)<sup>129</sup> of the biotech directive should be read in such a manner that at least for DNA sequences, product protection is limited to the specific purpose or function disclosed in the patent application and which function is also performed by the claimed product. Applying existing national provisions relating to exclusive rights that is any use or importation of a patented product (e.g. a patented DNA sequence) by a third party without the consent of the patent holder constitutes an infringement to the product patent claim (e.g. the DNA sequence),<sup>130</sup>



would normally not involve any evaluation as to the purpose or function of the patented product. Hence, applying the existing provisions of the national statute pertaining to exclusive rights without consideration of what has been laid down in article 5(3) and article 9 biotech directive would make the entire provision of article 9 and 5(3) of the biotech directive virtually useless, as the national statute does not stipulate any limitation as to scope of protection defined by purpose or function of the patented product.<sup>131</sup> Consequently, the CJEU held that at least for DNA sequences, scope of protection is limited to the specific purpose or function of the DNA sequence and in order to constitute an infringement, it is not only required that the allegedly infringing DNA sequence performs the same function, but it is also required that the protected DNA sequence effectively performs that function, and hence not merely constitute a hypothetical performance of that function. The CJEU has also here limited existing statutory provisions with a view to provide a reasonable interpretation to a provision of EU law.<sup>132</sup>

It is not entirely illogical to follow a similar reasoning for the case of products produced by non-patentable essentially biological processes.

Against this line of reasoning it could be argued that doing what is suggested here would amount to more than just interpreting a provision, it would amount to supplementing the law. The present case relating to products obtained by essentially biological processes differs in one crucial aspect from the above-mentioned DNA sequences case, and that is that the CJEU could come to its conclusion based on an interpretation of a specific statutory provision that is article 9 and 5(3) biotech directive. Regarding essentially biological processes, we are confronted with the fact that there is no statutory provision at all which provides any guidance. Reading into the existing framework a limitation which is not in it is indeed akin to supplementing a lacuna in the statute more than interpreting it.

Further support for the argument against granting patents for plants produced by essentially biological processes could also be obtained from what happened with plant varieties as products obtained by microbiological processes. The legislature has decided at some point that it would be inconsistent with the general exclusion of patentability for plant varieties to allow such varieties to obtain product protection as products made by microbiological processes, despite the fact that article 53(b) EPC says that products of microbiological processes are patentable. A logical conclusion, and one that has been taken in TBA case law and at least some of the literature, is that the statute allows products of such processes to be patentable and it is hence irrelevant whether these products could fall within an excluded category. The legislature has decided that this was an unreasonable situation, and has amended the statute so as to achieve a consistent exclusion from patentability of plant varieties.<sup>133</sup>

One could follow a similar reasoning in the present situation. It would consequently be unreasonable to allow a statutory provision excluding patent protection for essentially biological processes for the production of plants to become entirely ineffective by allowing claims to products made by excluded processes. Such argument could be based on an interpretation of the EPC in conformity with article 32 of the Vienna Convention. But that would consequently require an amendment of the statute and not a decision of the EBA.

A further argument against giving patent protection to products obtained by essentially biological processes is the following. As far as microbiological processes are concerned, specific reference to products thereof was envisaged by the legislature and express reference was made in the statute to provide patent protection to those products in their own right and not merely by operation of article 64(2) EPC. In contrast, as essentially biological processes for the production of plants are not patentable, the products obtained by such essentially biological processes would never gain protection through article 64(2) EPC anyway. Consequently, the legislature did not see it necessary to make specific reference to the products of essentially biological processes as being equally excluded from patentability, as they would not gain patent protection by operation of any other provision of the EPC, hence it would seem logical that they would not be patentable in their own right.

A counterargument to this reasoning could be the lack of consistency of the legislator. The logic should be the same for all embodiments: if it is self-explanatory that the products of microbiological processes are patentable if the processes are patentable, there is no reason for explicitly referring to the products. If it is not self-explanatory, an express reference is necessary. Similarly, if it is entirely obvious that the products obtained by essentially biological processes are not patentable as they are the products of non-patentable processes, then it is not necessary to make an explicit reference. But if that inference would not be completely straightforward, one would then expect an explicit reference to the products obtained by the essentially biological processes. Again, following that train of reasoning, one has to conclude that the only manner to settle the matter would be to amend the statute.

### ***Conclusion on Products Produced by Essentially Biological Processes***

The problems presented at the occasion of the new referral to the EBA—and it is not that relevant whether the questions are now going to be resolved by the EBA in the present case or in a later case and/or eventually different setting—is a bit of a conundrum. Intuitively, one would be tempted to think that one should not be able to obtain patent protection for products made by non-patentable essentially biological processes. And there may even be policy reasons why such a conclusion might be preferable. One could ask the question in that connection whether allowing such product claims would not go beyond what the legislature would have wanted to protect in the plant realm. Policy considerations can be important, but in the absence of a clear guidance in the legislative history or an agreement on an amendment of the statute, it is not recommendable for (administrative) courts to come to such conclusion hastily.

If one distinguishes both types of claims, which is what is the standard principle in the patent system, it could be said that there is no reason to deny patent protection for product claims, irrespective of whether these products are made by non-patentable processes or not. What needs to be examined is the product claim in its own right. That sounds logical, but we also know that this principle is no longer without exceptions since the decision of the EBA in the G 2/06 case. Ensuring that patents are not granted for products which would normally not be patentable as the products obtained by a non-patentable essentially biological process could be one of the motives for lifting the principle.

However, lifting the principle for this particular situation is a risky strategy, as it would ignore and set aside one of the fundamental principles of the patent system that is the separation of patent claim categories.

With no useful teaching from the legislative history and with a certain degree of speculation as to whether such product claims merit patent protection or not, witness whereof the various arguments analyzed earlier, we maybe have to conclude that this is not a matter for courts but for the legislature to act upon. As is also apparent from the analysis above, many of the possible solutions would need to involve an amendment of the statute.

That would have the advantage that a clear policy choice can be made. As we said earlier, one could conceive good policy reasons to come to such conclusion. If an essentially biological process is not patentable, because the legislature has deemed it not opportune to reward such innovations with patent protection, it is not out of the ordinary logical to think that the legislature might also want to exclude the products made by such processes. If that would not be the case, the patent system would in effect provide patent protection for sub-protectable subject matter. The only issue is that an amendment of the EPC is not straightforward, as it requires a complicated diplomatic conference or a majority decision in the Administrative Council if the amendment would be implemented in the Rules.<sup>134</sup> The latter would obviously be easier to put into practice, but it would still involve a quite loaded debate in the member states of the stakeholders involved prior to such decision. A diplomatic conference amending the Articles of the EPC in this respect seems less likely to be successful in any short or even medium term.

## Breeders' Exemption

Another very sensitive discussion concerns the existence or introduction and scope of the breeders' exemption. More precisely, there is currently an ever growing number of both academics and people in the field (the latter predominantly people in the seed industry and predominantly smaller companies within the industry) who call for the introduction of a breeders' exemption in the patent system.<sup>135</sup> Apart from Germany and France, such a breeders' exemption is unknown in the patent system. It is a concept derived from the plant variety right system.

The breeders' exemption is indeed a concept known in PVP systems. The exemption allows breeders to use the protected variety to develop new varieties.<sup>136</sup> In other words, breeders are allowed to use the protected variety with a view to develop their own new variety—potentially competing with the variety used for the development—and subsequently bring that new variety on the market without committing any infringement to the plant variety right. The measure stems from the philosophy behind the original PVP system that gave prevalence to novelty in breeding to full protection. The scope of this exemption was originally also very broad indeed. It did not only cover breeding of new varieties, but included also protection against infringement claims from the right holder for commercialization activities.<sup>137</sup>

The underlying rationale for this concept is that breeders must get the incentives to innovate, and in the absence of a breeders' exemption, there would not be any such incentive. Not only would there be no incentive, but the success of breeding depends also on availability of the initial genetic variation as the basis for breeding new varieties.<sup>138</sup> In the absence of such availability, advances in plant breeding would be hampered. It has also been argued that the exemption fits within the more public interest character of the plant variety right system.<sup>139</sup> The present author is not sure that this is a very strong argument, as it is difficult to see why one intellectual property right would have more of a public interest character than another, let alone that one would start ranking them.

It can be admitted though that the plant variety right system is one that has been frequently used in the traditional breeding sector, and one could argue that there is obviously a public interest issue in having as much choice in agricultural products as possible at an affordable price. The breeders' exemption, because of its nature, facilitates development of new varieties without the accompanying risks of infringement.

Be it as it is, there is obviously also a downside to having the breeders' exemption, as it is not necessarily conducive to new technological development. If there are no consequences attached to using a protected variety to develop a new variety, the question can be asked what the use and purpose could be of having a plant variety right in the first place, as enforceability sinks to virtually zero levels. The question becomes even more important if one would decide to embark upon a risky and expensive breeding program. The existence of a breeders' exemption might deter people from making such risky investments without the prospect of effective protection. It speaks for itself that this exemption as such influences PVP protection for right holders, as they cannot enforce their rights *vis-à-vis* competitor breeders.

Because of the mixed feelings which users had over the breeders' exemption, and also with a view to enhance protection for right holders, UPOV 1991 has amended the breeders' exemption, thus limiting its scope. The advent of new technologies at considerable cost made it no longer defensible to have a system where enforcement of any right obtained would be virtually annihilated by a very broad breeders' exemption. While under the UPV1961 version breeders were allowed to use protected plant varieties to develop their own and market such new varieties without committing an infringement, the UPOV 1991 system, with the introduction of the concept of "essentially derived variety," limited the scope. Use of protected varieties is still possible to develop new varieties, but commercializing those new varieties will now constitute an infringement if the new variety is an essentially derived variety.<sup>140</sup>

As said earlier, the patent system does not know a breeders' exemption as such. The patent system, however, contains a research exemption,<sup>141</sup> which in European countries is a statutory one.<sup>142</sup> Even

though research exemption provisions are purely national and may hence differ to some extent, the large majority of statutes embraces the principle that the research exemption covers research activities **on** the subject matter of the patent for research purposes, with a view to learn more about the subject matter of the patent.<sup>143</sup> That is obviously more limited than a breeders' exemption, which by definition entails activities **with** the protected subject matter with a view to develop a new variety. In other words, whereas a research exemption is traditionally limited to activities which one performs on the subject matter of the protected invention with a view to gain a better understanding and knowledge of the protected subject matter, a breeders' exemption goes an important step further, and is also going to use the protected subject matter to develop a new variety.

It must be noted, however, that France and Germany have provisions in their patent acts which have introduced a breeders' exemption.<sup>144</sup> This is rather unique in Europe and indeed in the industrialized world. It must be said, however, that the scope of the exemption is limited. Only use of the protected plant material for developing a new plant is allowed. Commercializing this new plant is, however, not included in the exemption.

There has been quite some discussion lately as to whether a breeders' exemption should be introduced in the patent system.<sup>145</sup> Some claim that a full blown breeders' exemption should be introduced, while others argue that a limited version like the one currently existing in Germany and France would suffice.<sup>146</sup> Still others maintain the position that there is no room for a breeders' exemption in the patent system.

There are obviously some at first sight appealing advantages to introducing a breeders' exemption in the patent system. One of the most frequently claimed benefits would be that such an exemption would guarantee access to genetic material and relevant germplasm with a view to develop new varieties, thus protecting biological and genetic biodiversity. In the absence of a breeders' exemption, the argument goes, all this material is locked up in patents and not accessible to third parties without obtaining a license, which in turn will go at the expense of further technological development and in the long run a loss of biodiversity.<sup>147</sup>

There may be justified causes for limiting patent protection for plant-related inventions, and the above-mentioned argument is definitely an important one. There are, however, many more facets to the discussion, which is partly influenced also by the desire to abolish patent protection for plant-related invention altogether. The discussion is furthermore also influenced by the difficult arguments around the place and future of PVP as the sole intellectual property regime for plant innovations and the question whether it is a system, which is still suitable to protect today's needs of the industry. It would, however, be beyond the scope of this article to make this a centrepiece of our attention. We would like to focus here on the problems which the introduction into the patent system of a breeders' exemption would bring with it.

First of all, one cannot deny that the underlying rationale of both the PVP system and the patent system is quite different, which makes it inherently risky to perform legal transplants. Originally, the PVP system was devised to provide some form of IP protection for the investment made in developing new varieties, which was a welcome compensation for the effort put in plant variety innovation. Investment in developing new varieties was in the early days less a matter of financial investment as it was a matter of time-consuming labor, hence the focus of the PVP system has traditionally always been more on having strict criteria for protection and a good examination of those criteria with a view to obtain stable varieties which would be beneficial to the relevant industry than it was on scope of protection and hence the strength of the exclusive right.

Also, in view of the specifics of the PVP system that protects a certain commercial variety (i.e. a product at the end of the development chain) and not an abstract technology such as is the case with the patent system, having a breeders' exemption in the PVP system would not have a devastating effect on the PVP right holders, as there was a considerable lead time advantage given to the PVP right holder.<sup>148</sup> Under the "traditional" PVP system, it also took many years before a competing breeder would be able to come

on the market with a new variety developed on the basis of the protected variety by invoking the breeders' exemption.<sup>149</sup> The aforementioned lead time advantage present in the PVP system is not available in the patent system, as patents protect a technology as such, and not only a specific commercial embodiment. Once the patent application has been published (which is in principle 18 months after filing date), competitors can start using the technology with a view to make their own innovations, which will be many years before any commercial embodiment is brought on the market by the patent holder.<sup>150</sup> That implies that introducing a breeders' exemption immediately interferes with patent protection at its heart, while this is not the case for PVP systems. Or put in other words, the breeders' exemption has been devised with the specificities of the PVP system in mind, and has not been devised for other intellectual property rights.

If a full blown breeders' exemption (i.e. including development and commercialization of new varieties) would be introduced in the patent system, this could affect the integrity of the system, as one can ask oneself what would be left of patent protection. The patent virtually becomes entirely unenforceable, as breeders would be allowed to develop new plants on the basis of the protected invention AND commercialize such plants without committing any patent infringement. Introducing a full blown breeders' exemption annihilates any useful patent protection, hence it pretty much amounts to not having patent protection at all. Such exemption would also be broader than the current exemption in the PVP system, as UPOV 1991 has introduced the principle of essentially derived variety, which is not foreseen in the patent system.

The discussion becomes even more complicated if one looks at the international level and other jurisdictions. Looking at the United States also provides us with a rather complicated picture. A breeders' exemption exists under the PVPA.<sup>151</sup> However, under US law, utility patents can also be obtained for plant varieties. It was held in the *J.E.M. Ag Supply v Pioneer Hi-Bred Int'l., Inc* case<sup>152</sup> that the Patent Statute contains no provision, nor is there any reason to believe that the framers of the statute had any reason to exclude plant varieties from patent protection. As a consequence of the Pioneer Hi-Bred case, patent protection is also available for plant varieties. But if there is patent protection for a certain plant variety, it is reasonable to assume that such protection will be subject to the rules and conditions of the Patent Act. The US Patent Act does not contain any breeders' exemption, or even a research exemption for that matter. Hence, on the face of it, there is no basis to assume that a patented plant variety in the United States should be subject to a breeders' exemption.

The second best alternative to the breeders' exemption would then be the research exemption. However, the judicially construed research exemption in the United States is extremely narrow in scope, as was explained in the *Madey v Duke* case,<sup>153</sup> where it was held that:

regardless of whether a particular institution or entity is engaged in an endeavour for commercial gain, so long as the act is in furtherance of the alleged infringer's legitimate business and is not solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry, the act does not qualify for the very narrow and strictly limited experimental use defense. Moreover, the profit or non-profit status of the user is not determinative.<sup>154</sup>

It is very difficult to see how breeders' activity with a view to develop a new variety could possibly fall within that very narrow interpretation. JANIS says in this regard:

On the basis of existing law, courts should decline to engraft the PVPA research exemption onto the utility patent regime. There is no evidence that Congress intended to exempt plant breeding research from the reach of the utility patent regime—or any other federal IP regime—when it chose to exempt plant breeding research from liability under the PVPA regime. More broadly, Congress certainly must be free to exempt specific activities from

liability under individual IP regimes without elevating those activities to privileged, “bulletproof” status vis-à-vis all other federal IP regimes.<sup>155</sup>

It is also important to realize in this discussion that the PVP system has not remained unaffected by new developments either. As financial investment became more important with the advent of gene technology in plants, there was a call also in the PVP system to put a limit to the breeders’ exemption. That resulted in the introduction of the essential derived variety concept in the UPOV 1991 version and the consequent limitation of the breeders’ exemption. Hence, claiming today for a full blown breeders’ exemption in the patent system would even run counter to new developments in the PVP system. The loss of the lead time advantage which the right holder de facto enjoyed under the “traditional” breeding scheme with the advent of genomic technologies<sup>156</sup> equally raises serious concerns about the viability of a breeders’ exemption under the current PVP system.

Furthermore, serious questions have been raised about the effectiveness of the exemption under present day’s technology. If hybrids are protected under a PVP system, and in view of the fact that the right holder does not need to provide an enabling disclosure as is the case under patent law, or comply with the requirement to make a deposit, the right holder may very well decide not to disclose or provide otherwise to the public the parental lines. In the absence of parental lines, the breeders’ exemption becomes pretty much without effective use.<sup>157</sup>

In conclusion, there may be good reasons for introducing a breeders’ exemption in the patent system for plants, but the present author is not sure that the proponents of such a solution have considered all implications of such choice. First of all, there is no compelling reason to limit the introduction of such an exemption to plants only. Other interested communities might come and argue that they deserve a special regime for their area as well. It is difficult to sustain the argument that plants are fundamentally different from any other area of technology. Introducing this kind of piecemeal special regimes for specific areas of technology affects the architecture of the patent system in its foundations. At the end of the journey, there could be a special regime for each and every field of technology, each with its own parameters. It would probably be better at that moment not to have a patent system any longer. That is presumably also the omega of some who profess the introduction of the breeders’ exemption, but that does not mean that the legislature has to be lured in that process.

Secondly, fitting a breeders’ exemption into the patent system is also an invitation for trouble, as the origins of the exemption are in a very different right, and it is never wise to transplant concepts from one intellectual property regime into another without examining first whether structural consistency is maintained. Introducing a breeders’ exemption into the patent system affects the consistency of the patent system more than it could bear without negative side effects.

### **Breeders’ Exemption Introduced into the Unitary Patent System**

Somewhat surprisingly, the Unitary Patent was adopted by the European Parliament on 11 December 2012.<sup>158</sup> This article is not the place to scrutinize the adopted compromise in full. It suffices to say that the system is going to be very complicated to say the least and is far away from a uniform system. The adopted texts contain quite a few surprises and inconsistencies, which is not very promising for the future functioning of the system. One of these surprises, which has largely remained unnoticed, is that the system has introduced a breeders’ exemption. One has to look into the Agreement on a Unified Patent Court<sup>159</sup> to find, surprisingly, that the system as now introduced contains a breeders’ exemption. Article 27(c) states: “[The rights conferred by a patent shall not extend to any of the following: ...] (c) the use of biological material for the purpose of breeding, or discovering and developing other plant varieties.” In other words, if this Agreement ever gets ratified in the member states and enters into force, it implies that member states

have introduced such exception into their national statutes. The present author is quite puzzled about this, as he cannot understand the legality of this move.

The confusion in his mind becomes even greater if one looks at the Regulation of the European Union and Parliament and of the Council implementing enhanced cooperation in the area of the creation of unitary patent protection,<sup>160</sup> where article 5 covers the scope of the exclusive rights of the patent right holder. Article 5(3) in particular seems to be relevant, as it says that the:

acts against which the patent provides protection referred to in paragraph 1 and the applicable limitations shall be those defined by the law applied to European patents with unitary effect in the participating Member State whose national law is applicable to the European patent with unitary effect as an object of property in accordance with Article 7.

In other words, the exclusive rights and the limitations thereto shall be determined in accordance with the national law applicable as per article 7. The latter provision says in turn in paragraph 1 that:

European patent with unitary effect as an object of property shall be treated in its entirety and in all the participating Member States as a national patent of the participating Member State in which that patent has unitary effect and in which, according to the European Patent Register: (a) the applicant had his residence or principal place of business on the date of filing of the application for the European patent; or (b) where point (a) does not apply, the applicant had a place of business on the date of filing of the application for the European patent.

There are supplementary provisions for patent holders with no place of business or residence in a member state in article 7, but we leave these aside for now as they are not necessary for the argument we want to make. It is the present author's understanding that the law of the member state as defined in article 7 will determine what the exclusive rights are and which limitations apply. A research exemption and indeed also a breeders' exemption are such limitations. As already emphasized earlier, most Member States do not have a breeders' exemption in their statute. And to the extent that the law of one such member state would be applicable, a breeders' exemption is not a limitation to the patent with unitary effect according to the applicable law. Consequently, applying the Regulation regarding the Unitary Patent would lead to the consequence that in most cases no breeders' exemption would need to be reckoned with by the patent holder.

However, a contrary solution has now been prescribed in the Agreement on the Unitary Patent Court. It would be the present author's view that the Regulation would be applicable, as that instrument defines the Unitary Patent and its scope, while the Agreement on the Unitary Patent Court is an instrument defining and organizing that Patent Court. It is very surprising indeed to find substantive patent law provisions in that Agreement, and serious questions can be asked about the legality of such provisions and the Agreement indeed. We know that during the legislative process certain provisions of substantive patent law have been deleted from the draft regulation relating to the unitary patent, specifically because there was no agreement on whether to incorporate such substantive patent law provisions in the unitary patent system.<sup>161</sup> It was exactly those provisions that have been deleted that now show up in the Agreement on the Unitary Patent Court. It is hoped that national member states will reflect on this particular issue before they ratify the Agreement.

## Conclusion

Plant patents have quite a turbulent history. This article started with the rather uncomfortable determination that we do not really know very well what the legislature has meant to exclude or allow in

terms of plant-related inventions. There is a very inconsistent use of terminology in the EPC, but it could indirectly be derived that the European legislature has not meant to exclude any type of plant material to be susceptible to patent protection. Once the judiciary had come to that conclusion, and subsequently very much influenced by modern technology, we witnessed a wave of expansion in patent practice, a trend which is not confined to plant patents alone, but which has been a general and probably unfortunate evolution of the patent system and indeed of all intellectual property right systems. This expansion blurred more and more the distinction between what is patentable subject matter and what should be reserved for the realm of plant variety right protection. The fact that both the judiciary and the legislature at some point came to the conclusion that plant patents can be granted if the technical feasibility of the invention is not limited to one or more individual varieties has not helped very much, even though it was in the view of the author a legally sound and probably also inevitable conclusion to be drawn from what the statute told us, if one wanted to maintain plant innovations in the patent system. There seems to be no evidence of any public order exception in the statute or its legislative history for an exclusion of plants from the patent system. It can, however, be reasonably submitted that plant innovations do not always fit comfortably within the patent system, but that as such is not a good reason to exclude plants from patentability.

Drawn towards the benefits of the patent system, and probably also disappointed by the limitations of the plant variety rights systems available, plant innovators turned to the patent system also to obtain patent protection for methods which at least looked very akin to traditional breeding methods. Even though a limited number of patent applications have been filed in this regard, they triggered vehement discussions, leading many to call for a ban on patents for plants, as the system invited excessive patenting without substantive technical contributions. The patent system has not yet recovered from that storm. It has been argued in this article that actors within the patent system need to act responsibly. Traditional breeding methods have no place in the patent system. Patents for hybrid seeds ought not to be protected by patents, as they in effect protect plant varieties as such. The present author has the impression that the patent granting authorities and the EPO Technical Boards of Appeal struggle to adhere to a consistent policy with regard to patenting plant innovations. If one wishes to keep plant innovations within the patent system, it is essential that a much stricter examination and scrutiny takes place of innovations in this area so as to avoid that sub-patentable innovations obtain patent protection.

The uncertainty and lack of consistency threatening the continuing existence of plant innovations in the patent system have been exacerbated by the fact that there is an apparent gap in the statute when it comes to determining whether products made by non-patentable essentially biological processes are patentable or not. Intuitively relatively simple to resolve, this article has shown that the issue is less easy to resolve following a more doctrinal approach, which, however, difficult it sometimes may be, is still the preferred route instead of the often hollow policy claims which do not tend to be based on any support in the statute or the entire legal system in suit for that matter.

Confronted with a patent system which spreads wider and wider, some have found refuge in the breeders' exemption with a view to halt the unstoppable patent hunger of patent applicants in the plant area. The breeders' exemption, a concept which has found its place in the plant variety system, seems to be very much ill-suited for the patent system, despite maybe justified calls for guaranteeing genetic and biological diversity. Whether the patent system is responsible for this is a discourse which is often weakly supported, but it would be unwise to categorically exclude it as being at least partly culpable, just as it is unwise to categorically point out the patent system being the cause of all evil. The European legislature has, in an unconventional and probably debatable manner introduced the limited version of a breeders' exemption in the Unitary Patent system. This system is yet to enter into force, and the instrument in which it has been placed that is the Agreement on the Unitary Patent Court needs to be ratified by the member states first, which presents an occasion to recontemplate the idea and take into account what has been said in this article.



What all the discussions about the patentability of plants and all its effects show is that the plant variety right system has lost most of its attraction. Intellectual property systems do not live in a vacuum, but are instruments of economic regulation, and also influence economic behavior. If the plant variety system is classified as being unsuited for those active in it, one could question whether it is a sound step to force everyone into that system by claiming that there should be no patent protection for plants. That is nevertheless what one often sees. Adapting the plant variety system to make it more “popular” is always possible but probably not very efficient, as there is first of all a limitation on how far a system can be stretched, and secondly if it is stretched towards what is suitable for the users of the system, it will probably become very much something like a patent system.

No one will deny that the patent system and its users have equally gone very far in claiming patent rights for subject matter which we would maybe not have been able to conceive some time ago. The challenge for the future will be how to deal with this, and that challenge should not include strengthening the plant variety system, but should be to limit patent protection to what is still suitable but fair, or to abolish patent protection for plants altogether and look for a completely different and yet unknown solution. There are obviously risks involved in whatever strategy one takes, as plants (food crops) are crucial for our existence. Abolishing patent protection altogether might have a negative effect on technological development in this area in an ever more challenging world with more risks and dangers to crops than ever before, while limiting it will imply walking on a thin line so as to achieve fairness for the public at large but also providing protection worthwhile having for innovators. Those who take on the job will not have an easy one, unless by that time the intellectual property system has collapsed altogether, which is not at all implausible looking at the current pace of expansion of intellectual property rights. Hubris<sup>162</sup> comes before the downfall.

## About the Author

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## Notes

1. The discussions around the TRIPS Agreement being a notable exception, as this Agreement has led to a heated debate as to the desirability of introducing patent protection for plants, allowing member states to choose whether to protect plant innovations by any means of intellectual property protection, letting member states choose between patent protection or plant variety protection, or obligating member states to introduce some form of intellectual property protection for plants, but letting them decide which regime to use and allowing them to develop a *sui generis* system if so desired. The TRIPS Agreement has at the end chosen for the last option [see article 27(3)(b) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), annexure 1C of the Marrakesh Agreement Establishing the World Trade Organization, signed in Marrakesh, Morocco on 15 April 1994].
2. In order to avoid confusion in the literature of the further analysis and in order to be able to place the variety in this system, the hierarchy of taxonomic classes will be given here (hierarchy is given starting from the highest ranking and descending to the lowest ranking): regnum (kingdom), phylum (division), classis (class), ordo (order), familia (family), genus, species, [varietas (variety)]. Taxonomy based on the International Code of botanical nomenclature (Tokyo Code), adopted by the 15th International Botanical Congress, August–September 1993.
3. At least, it was not in the 1973 version. The revision of the EPC, which came after the biotech directive had already seen daylight, has introduced a definition of a plant variety—thereby copying the corresponding

- provision from the biotech directive which was in turn derived from article 5(2) of Regulation 2100/94/EC establishing the Community Plant Variety Right system—in Rule 26(4) EPC2000.
4. See G 1/98, “Transgenic plant/NOVARTIS II,” Decision of the Enlarged Board of Appeal de dato 20/12/1999, OJ EPO, 2000, 111 et seq.
  5. Directive 98/44/EC on the legal protection of biotechnological inventions, OJ L 213, 30 July 1998 (hereinafter biotech directive), article 2(3).
  6. Council Regulation (EC) No. 2100/94 of 27 July 1994 on Community plant variety rights, OJ L 227, 1 September 1994, pp. 1–30.
  7. This definition is virtually identical to article 1(vi) of the UPOV 1991 Convention (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).
  8. An identical provision has been incorporated in Rule 26(4) EPC.
  9. G 1/98, point 3.1 of the reasons.
  10. T 1242/06, Tomatoes II/STATE OF ISRAEL, decision of Technical Board of Appeal 3.3.04 de dato 31 May 2012, referring a number of questions to the EBA (referral pending as G 2/12), point 26 of the reasons.
  11. G 1/98, point 3.1 of the reasons.
  12. G 1/98, point 3.8 of the reasons.
  13. See fn. 11.
  14. See fn. 11.
  15. See also article 4(2) biotech directive.
  16. Llewellyn and Adcock (2006, p. 314). See also at p. 301 where the authors state that according to ROBERTS, a plant variety is characterized by essentially all of its genes (phenotype), and not simply by one gene.
  17. For example, Funder (1999, pp. 501, 522); European Patents at crossroads, No Patents on seeds, March 2012, found at [http://www.evb.ch/cm\\_data/npos\\_patente\\_report\\_march\\_2012\\_en.pdf](http://www.evb.ch/cm_data/npos_patente_report_march_2012_en.pdf) (Accessed 14 July 2012).
  18. Roth (1987, p. 47), Teschemacher (1988, p. 32), Straus (1987b, p. 728, 1993, p. 796), Crespi (1992, p. 173 et seq.), Christie (1989, p. 395).
  19. See Moufang (1991, article 53, at Rdn. 78).
  20. See also Straus (1993, p. 796). The author refers also to Teschemacher, who has compared the plant variety with the working example of a patent application. See Teschemacher (1992, p. 1015). This reasoning is very well applicable to the situation which is the subject of the present discussion.
  21. Crespi (1992, p. 174) and Christie (1989, p. 395).
  22. T 788/07, “Brassica/PIONEER,” decision of Technical Board of Appeal 3.3.04 de dato 7 January 2008, not yet published. It deserves mentioning that the case has been remitted to the Examining Division after the appeal, and that the decision of the Examining Division has been the subject of a subsequent opposition which decision is currently again pending under appeal with reference T 1208/12.
  23. T 788/07, reasons 3.
  24. The invention is claimed in European Patent EP 0 891 130. Claim 1 of the new main request filed at the occasion of the appeal proceedings reads: “A hybrid seed comprising an inheritable and stable fertility restorer gene for ogura cytoplasmic male sterility, or hybrid plant thereof, produced by a cross between a plant obtained from seed deposited as Brassica napus olifera 97SN-1650, 97SN-1651, 97FNW-1792-03 or 96FNW-1822-07 having the respective ATCC accession numbers 97838, 97839, 209001 or 209002 as a male parent and a second Brassica plant as a female parent, wherein the second Brassica plant has a glucosinolate level that is sufficiently low to ensure that the hybrid plant yields oilseeds having a total glucosinolate content of less than 30  $\mu\text{mol}$  per gram dry weight.”
  25. The patent raises also issues relating to the non-patentability of essentially biological processes for the production of plants, which will be further discussed sub 3 and 4 of this contribution. It must be noted, however, that T 788/07 predates the G 2/07 decision, and has hence not taken into account the latter’s teaching.

26. See Rule 26(4) EPC.
27. Claim 1 of currently pending main request reads: “A *Capsicum annum* plant, which is capable of producing fruits exhibiting extended storability when kept on the plant after full coloring of said fruits, wherein about 100% of said fruits when kept on the plant retain the following characteristics about 5 after full coloring, when grown under standard Dutch glasshouse conditions wherein said characteristics are:
- i) firmness remaining at the rating obtained at full coloring according to the scale of 0-9 described in Example 4
  - ii) resistance to wilting at score higher than 4 according to the scale of 1-5 described in Example 4;
  - iii) resistance to climacteric spots defined by 5 yellow spots or less;
  - iv) brightness at score higher than 2 according to the scale of 1-5 described in Example 4 and
- wherein said *Capsicum annum* plant is progeny of hybrid Y1194 representative seed of which is deposited under Accession No. NCIMB 41187, or, progeny of line ZORO\_27.42.7:\_DH1004, representative seed of which is deposited under Accession No. NCIMB 41241 producing fruit exhibiting said extended storability.”
28. It will be noted that this is an exclusively European problem, as in the United States, both plant varieties and plants are protectable under patent protection. Plant varieties are protectable under three different systems: PVPA, Plant patents and utility patents. There has been some discussion in the past as to whether utility patents could be granted for plant varieties, very much along similar lines as the reason for the exclusion in Europe. However, the US Supreme Court has held in the Pioneer Hi-Bred case that there is no statutory basis for excluding utility patent protection for plant varieties [*J.E.M. Ag Supply v Pioneer Hi-Bred Int'l, Inc.*, 122 S. Ct. 593 (2001), rehearing denied, 122 S. Ct. 1600 (2002)].
29. See, for example, Pila (2009, pp. 436–62), who argued unconvincingly and without any support that article 53(b) contains a public policy exception to patentability of plants, not only plant varieties.
30. Llewellyn and Adcock (2006, p. 255).
31. See, for example, Straus (1987a, pp. 433, 439) and Lange (1996, pp. 586, 587).
32. G 0001/98 “Transgenic plant/NOVARTIS II,” decision of the Enlarged Board of Appeal de dato 20/12/1999, OJ EPO, 2000, 111 et seq.
33. Convention on the Unification of Certain Points of Substantive Law on Patents for Inventions, Strasbourg, 27 November 1963, European Treaty Series No. 47.
34. Apart from the lack of openendedness in the text of article 53(b) EPC, the text is otherwise identical to that of article 2(b) SPC. The exclusion of plant varieties could already be found in early drafts (e.g. Travaux préparatoires EPC, Doc. IV/2071/61, which preceded the SPC and which explains the wording of the SPC). The provision relating to microbiological processes was added in a later stage of the negotiations (see Minutes of the Proceedings of the 10th meeting of the Patents Working Party, Brussels, 16–27 September 1963, Doc. 9081/IV/63-E-Final, where the wording was first suggested), and was then inserted into the text of the Preliminary Draft Convention in 1965 (see Doc. 2335/IV/65-E). This text was also the final text as we still know it today.
35. The May 1961 draft article 2(b) read: the contracting states shall not be bound to provide for the grant of patents in respect of new plants or animal species or of purely biological, horticultural or agricultural (agronomic) processes.” See, Document EXP/BREV (61) 2 revised, p. 26.
36. See fn. 30.
37. INTERNATIONAL CONVENTION FOR THE PROTECTION OF NEW VARIETIES OF PLANTS (UPOV), 1 December 1961.
38. See fn. 30.

39. See article 2(1) UPOV 1961: “(1) Each member State of the Union may recognise the right of the breeder provided for in this Convention by the grant either of a special title of protection or of a patent. Nevertheless, a member State of the Union whose national law admits of protection under both these forms may provide only one of them for one and the same botanical genus or species.”
40. This view is broadly supported in the literature: Lange (1996, pp. 586, 587), Winter (1996, pp. 270, 273), Moufang (1992, pp. 328, 343), and Straus (1992, pp. 252, 259).
41. G 1/98, at 3.5 of the reasons.
42. Gersteuer (2008, pp. 370, 371).
43. UPOV 1961 had a double protection prohibition in article 2. UPOV 1961 was also limited in scope, as it did not cover all varieties, but only a limited number of varieties.
44. G 1/98, at 3.3.1 of the reasons.
45. As was also inserted into article 27 TRIPS Agreement and article 52 EPC2000.
46. The breeders’ exemption and the alternative solutions are discussed further in this article (see sub 5).
47. Two examples, which have also given rise to the EBA case law discussed further are the following: Claim 1 of European patent application EP 1 069 819 in the Main Request discussed in the oral proceedings before the referring Technical Board of Appeal in the T 0083/05 case read as follows:

“A method for the production of *Brassica oleracea* with elevated levels of 4-methylsulfinylbutyl glucosinolates, or 3-methylsulfinylpropyl glucosinolates, or both, which comprises:

**crossing** wild *Brassica oleracea* species selected from the group consisting of *Brassica villosa* and *Brassica drepanensis* with broccoli double haploid breeding lines;

**selecting** hybrids with elevated levels of 4-methylsulfinylbutyl glucosinolates, or 3-methylsulfinylpropyl glucosinolates, or both, elevated above that initially found in broccoli double haploid breeding lines;

**backcrossing and selecting** plants with the genetic combination encoding the expression of elevated levels of 4-methylsulfinylbutyl glucosinolates, or 3-methylsulfinylpropyl glucosinolates, or both; and

**selecting a broccoli line** with elevated levels of 4-methylsulfinylbutyl glucosinolates, or 3-methylsulfinylpropyl glucosinolates, or both, capable of causing a strong induction of phase II enzymes,

**wherein molecular markers are used** in steps (b) and (c) to select hybrids with genetic combination encoding expression of elevated levels of 4-methylsulfinylbutyl glucosinolates, or 3-methylsulfinylpropyl glucosinolates, or both, capable of causing a strong induction of phase II enzymes.”

Claim 1 of the main request of European patent EP 1 211 926 (which was the subject of TBA decision T 1242/06) reads:

“A method for breeding tomato plants that produce tomatoes with reduced fruit water content comprising the steps of:

**crossing** at least one *Lycopersicon esculentum* plant with a *Lycopersicon* spp. to produce hybrid seed;

**collecting** the first generation of hybrid seeds;

**growing** plants from the first generation of hybrid seeds;  
**pollinating** the plants of the most recent hybrid generation;  
**collecting** the seeds produced by the most recent hybrid generation;  
**growing** plants from the seeds of the most recent hybrid generation;  
**allowing fruit to remain on the vine** past the point of normal ripening; and  
**screening** for reduced fruit water content as indicated by extended preservation of the ripe fruit and wrinkling of the fruit skin.”

Claims 15–17 of the main request correspond to claims 14–16 of auxiliary request I and read:

“15. 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 natural dehydration being generally unaccompanied by microbial spoilage.

16. 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.

17. A tomato plant having the tomato fruit of claim 15 or 16 on the vine.”

48. This trend is admittedly limited, if one looks at the statistics provided by the EPO in this regard. Of the 13,848 patent applications relating to plants published by the EPO since 1990, 1,690 ended with the grant of a European patent. Of these, only 88 are patents for non-GM plants, while 1,602 relate to genetically modified plants (see <http://www.epo.org/news-issues/issues/melon.html>, Accessed 31 December 2012).
49. Rule 23(b)(5) EPC1973 (Rule 26(5) EPC 2000) reads: “A process for the production of plants or animals is essentially biological if it consists entirely of natural phenomena such as crossing or selection.”
50. G 2/07, Broccoli/PLANT BIOSCIENCE, decision of the Enlarged Board of Appeal de dato 9 December 2010, OJ EPO, 2012, 130; G 1/08, Tomatoes/STATE OF ISRAEL, decision of the Enlarged Board of Appeal de dato 9 December 2010, OJ EPO, 2012, 206.
51. The two referring decisions are: T 0083/05, Broccoli/Plant Bioscience, decision of Technical Board of Appeal 3.3.04 de dato 22 May 2007, OJ EPO, 2007, 644; T 1242/06, Tomatoes/STATE OF ISRAEL, decision of Technical Board of Appeal 3.3.04 de dato 4 April 2008, OJ EPO, 2008, 523.
52. For an overview of arguments in this discussion, see also, Bostyn (2009a, pp. 549–58).
53. G 2/07, at 4.8.3 of the reasons.
54. G 2/07, at 4.4 of the reasons.
55. G 2/07, at 4.5 of the reasons: “Admittedly, this result does not make the interpretation of Rule 26(5) EPC easier, since on the one hand (only) processes which consist entirely of natural phenomena are considered to be essentially biological processes for the production of plants. On the other hand, crossing and selection are given as examples of natural phenomena, but the systematic crossing and selection carried out in plant breeding are not natural phenomena but measures implemented by means of human intervention. Hence, the wording of Rule 26 (5) EPC is ambiguous, if not contradictory.”
56. G 2/07, at 4.7 of the reasons.
57. Article 7 of the first Council Directive on the legal protection of biotechnological inventions submitted by the Commission on 20 October 1988 (COM(88) 496 final—SYN 159, 13.1 1989, OJ C 10, p. 3).

58. G 2/07, at 4.7.1 of the reasons.
59. See fn. 53.
60. G 2/07, at 5 of the reasons.
61. G 2/07, at 6.1.3 of the reasons.
62. T 320/87, Hybrid plants/LUBRIZOL, OJ EPO, 1990, 71.
63. G 2/07, at 6.4.1 of the reasons.
64. See, for example, T 0931/95, "Improved pension benefits system/Pension Benefit Systems Partnership," OJ EPO, 2001, 441, where the so-called technical contribution approach was held to be an incorrect approach towards patentability. The contribution approach held that it was not sufficient that the claimed invention had technical features to conclude that it constitutes patentable subject matter, but the technical features must constitute a contribution to the art. If the technical features do not constitute such contribution to the art, the invention does not constitute patentable subject matter. The correct approach is that the presence of technical features brings the invention within the realm of patentable subject matter. However, for evaluating novelty and inventive step, it will be taken into account whether those technical features provide a contribution to the art. If those technical features merely describe or represent state of the art, then there will be no novelty or inventive step, as only technical features can contribute to fulfilling those patentability requirements. This has more recently been confirmed in T 0258/03, "Auction method/HITACHI," OJ EPO, 2004, 575.
65. Document IV/2071/61-E, section 13: 3.
66. Document IV/2071/61-E, section 14: 6.
67. Document IV/2498/1/61-E:3.
68. Document IV/2767/61-E, section 5: 45.
69. Document IV/2767/61-E, section 5: 8.
70. Document EXP/BREV (61) 2 revised, p. 26.
71. Document EXP/Brev 61(8), pp. 4–5.
72. Document 4488/IV/62-E.
73. Document 6551/IV/62-E, section 7: 7.
74. Proceedings of the 10th meeting of the Patents Working Party held at Brussels from 16 to 27 September 1963, Document 9081/IV/63-E Final, p. 65.
75. Document 2335/IV/65-E.
76. G 2/07, at 6.4.2.3 of the reasons.
77. *Ibid.*
78. *Ibid.*
79. *Ibid.*
80. Currently pending claim 1 reads: "A method for producing a *B. oleracea* plant comprising a monogenic and dominant resistance to clubroot comprising the steps of:
  - (b) obtaining a *B. rapa* plant resistant to clubroot comprising a monogenic and dominant resistance to clubroot;
  - (c) crossing said *B. rapa* plant with a *B. oleracea* plant,
  - (d) rescuing embryos resulting from the cross of step b);
  - (e) regenerating a plant from a embryo of step c);
  - (f) selecting a plant of step d) that is resistant to clubroot comprising a monogenic and dominant resistance to clubroot;
  - (g) back-crossing a plant resulting from step e) with a *B. oleracea* plant;
  - (h) rescuing embryos resulting from the back-cross of step f); and
  - (i) selecting a plant of step g) that is resistant to clubroot comprising a monogenic and dominant resistance to clubroot."
81. The claim of fn. 93 is the amended claim after the said Office Action. Steps g) and h) have been added.

82. See G 2/07, at 6.4.2.3 of the reasons.
83. European patent application number 03 766 293.9 (corresponding to EP 1 525 317), Office Action Examining Division, dated 26 January 2012 (can be retrieved from Espacenet EPO online services), at point 4 of the reasoning.
84. See, for example, Sterckx and Cockbain (2012), chapter 6, and more in particular, p. 191, who express a view which seems to be devoid of underlying argumentation and is consequently unsatisfactory.
85. Somewhat surprisingly, a Dutch court has recently held in summary proceedings that it is obvious that products made by essentially biological processes are not patentable, as that would otherwise undermine the exclusion of article 53(b) EPC, and reference was also made to article 64(2) EPC (Court the Hague, 31 January 2012, *Taste of Nature v Cresco*, case 408315/KG ZA 11-1414). This decision is surprising as the court ignores to give any kind of substantive justification for its ruling, which was even more worrying as it was a case in summary proceedings. As we will demonstrate in what follows, the situation is somewhat more complicated. On 8 May, the Hague Court held in proceedings on the merits that it is incorrect to assume that products produced by an essentially biological process should be excluded from patent protection by virtue of the non-patentability of the process by which the plant is produced (case C/09/416501/HA ZA 12-452).
86. Claim 1 of the patent, which is currently under opposition, reads: "1. A CYSDV-resistant plant of the species *Cucumis melo*, said plant comprising an introgression from a plant of melon accession PI 313970, which introgression comprises a CYSDV-resistance—conferring QTL or a CYSDV-resistance-conferring part thereof linked to at least one marker located on the chromosome equivalent to linkage group (LG) 6 of melon accession PI 313970, wherein said marker is E11/M49-239, and wherein said QTL or said part thereof is present in homozygous form." The patent is currently in Opposition.
87. See patent specification, p. 5, paragraph [027].
88. Currently pending claim 1 reads: "1. A *Cucurbita* plant comprising a *Cmv-2* gene (for CMV resistance) obtainable from a plant of *C. moschata* cv. Seminole pumpkin, wherein, when said *Cucurbita* plant is crossed with a plant of inbred line 90-3588, 100% of F1 plants resulting from said cross are resistant to CMV, and 100% of said F1 plants produce 100% of F2 progeny plants resistant to CMV, when said *Cucurbita* plant is homozygous for a *Cmv-2* gene and wherein said plant is not a plant of *C. moschata* cv. Seminole Pumpkin and said plant is an inbred and wherein resistance to CMV is monogenic."
89. Straus has said that this position would derive from the intention of the legislature of the SPC on which article 53 (b) is based. See Straus (1998, p. 8) and Christie (1989, pp. 394, 397).
90. In case T 0019/90 it was held that "art. 53(b) EPC, first half-sentence, is an exception to the general principle of patentability contained in art. 52(1) EPC. The second half-sentence is an exception to this exception, ensuring that the patentability bar does not cover microbiological processes or the products thereof. In other words, the general principle of patentability under art. 52(1) EPC is restored for inventions involving microbiological processes and the products of such processes." T 19/90, "Onco-mouse/HARVARD," decision of Technical Board of Appeal 3.3.2. de dato 03/10/1990, OJ EPO, 1990, 476. at 4.10 of the reasons. In case T 0356/93 the Board held, with reference to case T 0019/90, that "from this decision follows that animal varieties are patentable if they are the product of a microbiological process within the meaning of art. 53(b) EPC, second half-sentence. In the Board's judgement, this principle applies mutatis mutandis to plant varieties." T 356/93, "Plant cells/PLANT GENETIC SYSTEMS," OJ EPO, 1995, 545, at 30 of the reasons.
91. Lange (1985, p. 93, 1996, pp. 586, 587), Teschemacher (1988, p. 31), Von Pechmann (1985, p. 722), Roth (1987, p. 45), Lukes (1987, p. 325).
92. The Preamble, however, gives in recital (32) a hint towards a complete exclusion of plant varieties from patentability: "(32) Whereas, however, if an invention consists only in genetically modifying a particular plant variety, and if a new plant variety is bred, it will still be excluded from patentability even if the genetic modification is the result not of an essentially biological process but of a biotechnological process."

93. Rule 27(c) EPC2000: “[Biotechnological inventions shall also be patentable if they concern: a microbiological or other technical process, or a product obtained by means of such a process other than a plant or animal variety.]”
94. The provision has national equivalents. For the UK, see s. 60(1)(c) UK Patents Act 1977.
95. For biotech inventions, one equally needs to look at articles 8 and 9 of Directive 98/44/EC.
96. As is article 69 EPC.
97. It can be questioned in this context whether a plant variety can be deemed to be the product directly obtained by a patented microbiological process. This question seems to have lost at least some of its value as the biotech directive has inserted in article 8(2) the rule that “The protection conferred by a patent on a process that enables a biological material to be produced possessing specific characteristics as a result of the invention shall extend to biological material directly obtained through that process and to any other biological material derived from the directly obtained biological material through propagation or multiplication in an identical or divergent form and possessing those same characteristics.” This would allow the plant variety to be protected as the product obtained by the patented process.
98. Buckley J. in *Saccharin Corporation, Ltd. v Anglo-Continental Chemical Works* [1901] 1 Ch. 414, 416, (1900) 17 R.P.C. 307, 319.
99. G 1/98, at 4 of the reasons.
100. Begr. RegE zu article 1 Nr. 6, BT-Drucksache 15/1709, 14 re. Sp.; see also Mes (2005, sub PatG § 9a) and Krasser (2004, p. 218).
101. See also T 1242/06, Tomatoes II/STATE OF ISRAEL, decision of Technical Board of Appeal 3.3.04 de dato 31 May 2012, referring a number of questions to the EBA (referral pending as G 2/12), at 57 of the reasons.
102. See T 1242/06, Tomatoes II/STATE OF ISRAEL, decision of Technical Board of Appeal 3.3.04 de dato 31 May 2012, referring a number of questions to the EBA (referral pending as G 2/12).
103. See G 9/92, Non-appelling party/BMW, OJ EPO, 1994, 875.
104. Communication from the Enlarged Board of Appeal in G 2/12, 31 January 2013, see <https://register.epo.org/espacenet/application?documentId=ET75TEUE1693684&number=EP00940724&lng=en&npl=false> (Accessed 4 February 2013).
105. Point 3 of the preliminary opinion.
106. See, for example, the melon patent, discussed earlier.
107. A sample question could be: “Does Article 2(2) also exclude from patent protection the product produced by an essentially biological process?”
108. See, Court the Hague, 31 January 2012, Taste of *Nature v Cresco*, case 408315/KG ZA 11-1414. On 8 May, the Hague Court held in proceedings on the merits that it is incorrect to assume that products produced by an essentially biological process should be excluded from patent protection by virtue of the non-patentability of the process by which the plant is produced (case C/09/416501/HA ZA 12-452).
109. It is important to add here that the Dutch Patents Act seems to have a provision regarding essentially biological processes different from the one found in the article 53(b) EPC and article 4(1)(b) biotech directive. According to article 3(1)(d) Dutch Patents Act, essentially biological processes and the products obtained by such processes are excluded from patentability (“werkwijzen van wezenlijk biologische aard [...], voor de voortbrenging van planten of dieren **alsmede de hierdoor verkregen voortbrengselen**”). In essence, following the text of the Dutch Patents Act, there would be no problem to be solved here, as the statute already excludes the products obtained by essentially biological processes from patentability. Questions arise, however, as to conformity of this provision with both EPC and the biotech directive. Worth observing is also that in the aforementioned Cresco cases, the Hague Court applied the provisions of the EPC and did not refer to the provisions of the Dutch Patents Act.
110. For instance, the “ultra vires” character of Rule 26(5) that is that what the Rule prescribes is beyond the scope of what the Article would allow to dictate, has been discussed in G 2/07 where the EBA saw no reason to assume



that there was an issue of *ultra vires* here, as the said Rule was implementing article 53(b) EPC. See, G 2/07, at 22 of the reasons. As we have seen, Rule 26(5) remains inapplicable as it is internally contradictory.

111. Rule 27(c) EPC2000.
112. Done at Vienna on 23 May 1969. Entered into force on 27 January 1980. United Nations, Treaty Series, vol. 1155, p. 331.
113. T 1854/07, Oil from seeds/CONSEJO SUPERIOR, decision of Technical Board of Appeal 3.3.04 de dato 12 May 2010.
114. T 1854/07, at 5 of the reasons.
115. See, for example, European Patents at crossroads, No Patents on seeds, March 2012, p. 10, found at [http://www.evb.ch/cm\\_data/npos\\_patente\\_report\\_march\\_2012\\_en.pdf](http://www.evb.ch/cm_data/npos_patente_report_march_2012_en.pdf) (Accessed 30 December 2012).
116. On the face of claim 1, it is in any event nothing more than a traditional breeding method. Claim 1 reads: "1. 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 and the amount of asclepic acid are decreased to less than 4% based upon the total fatty acid content." Question is whether it is also an essentially biological process in the sense of G 2/07.
117. G 2/06, "Use of embryos/WARF," decision of the Enlarged Board of Appeal de dato 25 November 2008, OJ EPO, 2009, 306. For a detailed and critical analysis of this decision, see Bostyn (2009b).
118. G 2/06, at point 22 of the reasons.
119. C-34/10, *Oliver Brüstle v Greenpeace e.V.*, Judgement of the Court dated 18 October 2011, reasons 49–50.
120. T 1199/08, "Selected sperm/XY," decision of TBA 3.3.08 de dato 3 May 2012, not yet published.
121. In that sense, the situation is very different from the hypothesis that one tries to protect a plant variety as the product directly obtained by a patentable process, as in such hypothesis one tries to claim non protectable subject matter, while in the situation of a plant claimed as a product, being produced by a non-patentable essentially biological process, the claim as such pertains to subject matter which is not excluded in the statute.
122. See, for example, T 1173/97, "Computer program product/IBM," OJ EPO, 1999, 609; T 154/04, "Estimating sales activity/DUNS LICENSING ASSOCIATES," OJ EPO, 2008, 46. See also UK case law: *Aerotel v Telco Holding Ltd* [2006] EWCA Civ 1371; *Symbian v Comptroller General of Patents* [2009] RPC 1.
123. See, for example, T 0931/95, "Improved pension benefits system/Pension Benefit Systems Partnership," OJ EPO, 2001, 441, where the so-called technical contribution approach was held to be an incorrect approach towards patentability. The contribution approach held that it was not sufficient that the claimed invention had technical features to conclude that it constitutes patentable subject matter, but the technical features must constitute a contribution to the art. If the technical features do not constitute such contribution to the art, the invention does not constitute patentable subject matter. The correct approach is that the presence of technical features brings the invention within the realm of patentable subject matter. However, for evaluating novelty and inventive step, it will be taken into account whether those technical features provide a contribution to the art. If those technical features merely describe or represent state of the art, then there will be no novelty or inventive step, as only technical features can contribute to fulfilling those patentability requirements. This has more recently been confirmed in T 0258/03, "Auction method/HITACHI," OJ EPO, 2004, 575.
124. Which is allowable, see EPO Guidelines For Examination of Patent Applications (June 2012), F-IV, 4.12: "Claims for products defined in terms of a process of manufacture are allowable only if the products as such fulfil

- the requirements for patentability, i.e. *inter alia* that they are new and inventive. A product is not rendered novel merely by the fact that it is produced by means of a new process (see T 150/82). A claim defining a product in terms of a process is to be construed as a claim to the product as such. The claim may for instance take the form “Product X obtainable by process Y”. Irrespective of whether the term “obtainable”, “obtained”, “directly obtained” or an equivalent wording is used in the product-by-process claim, it is still directed to the product *per se* and confers absolute protection upon the product (see T 20/94).”
125. Judgment of the Court (Grand Chamber) of 6 July 2010 (reference for a preliminary ruling from the *Rechtbank’s Gravenhage—the Netherlands*)—*Monsanto Technology LLC v Cefetra BV*, *Cefetra Feed Service BV*, *Cefetra Futures BV*, *Alfred C. Toepfer International GmbH*, Case C-428/08, OJ C 234, 28.08.2010, p. 7.
  126. See, Bostyn (2011, pp. 221, 229 *et seq.*)
  127. See in this regard the discussion earlier where it has been emphasized that it is important to keep both concepts separate.
  128. Article 9 biotech directive reads: “The protection conferred by a patent on a product containing or consisting of genetic information shall extend to all material, save as provided in Article 5(1), in which the product is incorporated and in which the genetic information is contained and performs its function.”
  129. Article 5(3) biotech directive reads: “The industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application.”
  130. See, for example, s. 60 UK Patents Act 1977.
  131. See ECJ, C-428/08, at point 47 of the reasons.
  132. The present author disagrees with the view taken by the CJEU in this case, see Bostyn (2011, pp. 232–33).
  133. See Rule 27(c) EPC2000, already referred to earlier.
  134. We have said earlier that there is precedent for such solution.
  135. The predominant rationale for introducing a breeders’ exemption being access to germplasm and preservation of biological and genetic diversity. In the subsequent footnotes, references will follow.
  136. See article 15(iii) UPOV 1991: “The breeder’s right shall not extend to [...] (iii) acts done for the purpose of breeding other varieties, and, except where the provisions of Article 14(5) apply, acts referred to in Article 14(1) to Article 14(4) in respect of such other varieties”; article 15 CPVR 2100/94/EC: “(c) acts done for the purpose of breeding, or discovering and developing other varieties; (d) acts referred to in Article 13 (2) to (4), in respect of such other varieties, except where the provisions of Article 13 (5) apply, or where the other variety or the material of this variety comes under the protection of a property right which does not contain a comparable provision.”
  137. See article 5(3) UPOV 1961: “(3) Authorization by the breeder or his successor in title shall not be required either for the utilization of the new variety as an initial source of variation for the purpose of creating other new varieties or for the marketing of such varieties. Such authorization shall be required, however, when the repeated use of the new variety is necessary for the commercial production of another variety.”
  138. Kock *et al.* (2006, pp. 136, 142).
  139. See, for example, Lukes (1987, p. 325).
  140. It is beyond the scope of this Chapter to deal in detail with the relatively obscure concept of what is exactly an essentially derived variety.
  141. The US does not have a statutory research exemption, but one based on case law. It has been very narrowly defined, however, which has led to discussion. See *Madey v Duke Univ.*, 307 F.3d 1351; 2002 U.S. App. LEXIS 20823; 64 U.S.P.Q.2D (BNA) 1737 (Fed. Cir. 2002).
  142. For example, UK, s. 60(5)(b)(2) UK Patents Act 1977: “(5) An act which, apart from this subsection, would constitute an infringement of a patent for an invention shall not do so if—[...] (b) it is done for experimental purposes relating to the subject-matter of the invention.”
  143. Notable exception to this rule is Belgium, where the research exemption is not only covering activities **on** but also activities **with** the patented subject matter for scientific purposes [see article 28(1) Belgian Patents Act]. This is obviously a very broad indeed, as it covers activities which one traditionally would not subsume as falling

- within the research exemption, i.e., activities **with** the subject matter of the patented invention, which admittedly opens the door to an unlimited number of activities. It could be argued even that the research exemption as formulated in the Belgian statute even covers activities which would fall within a breeders' exemption.
144. § 11(2a) PatG reads: "Die Wirkung des Patents erstreckt sich nicht auf: [...] 2a. die Nutzung biologischen Materials zum Zweck der Züchtung, Entdeckung und Entwicklung einer neuen Pflanzensorte"; article L 613-5-3 du Code de la propriété intellectuelle: "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."
  145. See, for example, Janis and Smith (2007, p. 1557 et seq.), Janis and Kesan (2002, p. 1161 et seq.), Kock *et al.* (2006, p. 136 et seq.), Kingston (2007, pp. 294, 300), Van Der Kooij (2010, p. 545 et seq.).
  146. See, for example, Straus (2004, p. 26).
  147. See, for example, Louwaars *et al.* (2009).
  148. The PVP system is subject to a considerable number of very time-consuming field trials, *de facto* giving the right holder a lead time advantage, as a third-party breeder would have to go through a similar time-consuming exercise before he could ever bring his new variety on the market. Furthermore, the PVP system protects the commercial variety, and competitors would have to start analyzing and "reverse engineering" the protected variety once it has entered the market, hence the lead time advantage.
  149. Janis and Smith (2007, pp. 1557, 1603).
  150. Irrespective of any type of intellectual property right, many regulatory obligations and tests are to be fulfilled before any plant (variety) can be brought on the market.
  151. See Plant Variety Protection Act, as amended, 7 U.S.C. 2321 et seq. For breeders' exemption, which is strangely enough called research exemption, see 7 USC 2544 (section 114 PVPA).
  152. *J.E.M. Ag Supply v Pioneer Hi-Bred Int'l, Inc.*, 122 S. Ct. 593 (2001), rehearing denied, 122 S. Ct. 1600 (2002).
  153. *Madey v Duke Univ.*, 307 F.3d 1351; 2002 U.S. App. LEXIS 20823; 64 U.S.P.Q.2D (BNA) 1737 (Fed. Cir. 2002)
  154. *Madey v Duke Univ.*, 307 F.3d 1362.
  155. Janis and Kesan (2002, pp. 1161, 1163).
  156. Genomic technologies increase speed of creation of new varieties dramatically. See, Janis and Smith (2007, pp. 1604–5).
  157. Janis and Smith (2007, pp. 1603–4).
  158. Press release European Parliament 20121210IPR04506, dated 11 December 2012 (<http://www.europarl.europa.eu/news/en/pressroom/content/20121210IPR04506/html/Parliament-approves-EU-unitary-patent-rules>, Accessed 6 January 2013).
  159. European Council Document 16351/12 PI 148 COUR 77 of 11 January 2013 on the Agreement on a Unified Patent Court.
  160. Regulation 1257/2012/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 17 December 2012 implementing enhanced cooperation in the area of the creation of unitary patent protection, OJ L 361/1, 31 December 2012.
  161. It concerns more in particular article 6–8 of the original proposal which have been deleted. See for those provisions the Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL implementing enhanced cooperation in the area of the creation of unitary patent protection, COM(2011) 215 final, 13 April 2011.
  162. From the Greek ὄβρις.

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