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European Patent Office
Registry of the Enlarged Board of Appeal
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München, October 21, 2019
OM/JAE/ES

Amicus curiae brief in the referral G 3/19

Vossius-ref.: PA-4604

This is in response to the Communication from the Enlarged Board of Appeal concerning Case G 3/19 published in OJ EPO 2019, A52:

I apologize for not having met the October 1, 2019 deadline and hope the Enlarged Board will nevertheless consider the comments provided herein.

I represented the Patentee in the “Tomato” cases G 1/08 and G 2/12 and would like to contribute some insights obtained in the context of those proceedings that could be useful for the Enlarged Board in the present case. Numerous amicus curiae briefs have already been filed which thoroughly and comprehensively demonstrate that

- the referral is inadmissible; and that
- even if the referral were admissible, both referred questions of law would have to be answered in the negative; i.e. new Rule 28(2) EPC cannot be applicable.

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Accordingly, it is generally referred herein to the amicus curiae briefs filed by

- Chartered Institute of Patent Attorneys (CIPA) on 30 September 2019
- FEMIPi on 26 September 2019
- FICPI on 25 September 2019
- IP Federation on 27 September 2019
- KSVR Patentanwälte on May 24, 2019
- KSVR Patentanwälte (opinion by Mr. Rennie-Smith) on 24 September 2019
- L.J. Steenbeek on 24 September 2019
- Prof. Haedicke on 23 September 2019
- Thomas Leconte on 1 October 2019
- VPP e.V. on 27 September 2019

These amicus curiae briefs provide a wealth of reasons for the Enlarged Board to declare the referral inadmissible and for answering the two questions of law in the negative. Thus, there is no need to again provide an exhaustive reasoning herein. The present submission will therefore be limited to address the following points:

- A. Rule of law-principles to be applied by the European Patent Organisation
- B. Critical review of the “clarification” idea
- C. Invalidating Rule 28(2) EPC would remove legal uncertainty

A. RULE OF LAW-PRINCIPLES TO BE APPLIED BY THE EUROPEAN PATENT ORGANISATION

1. The present referral revolves around the question as to who is entitled to provide an authoritative interpretation of Article 53(b) EPC. In its decisions G 2/12 and G 2/13, the Enlarged Board has decided that “the exclusion of essentially biological processes for the production of plants in Article 53(b) EPC does not have a negative effect on the allowability of a product claim directed to plants or plant material ...” (Catchword 1 of G 2/12 and G 2/13). The Administrative Council reacted thereto by amending the Implementing Regulations and inserted Rule 28(2) EPC, thereby reversing the Enlarged Board’s interpretation of Article 53(b) EPC. In the present referral, the President argues that the Administrative Council has the power for such a change of the law because, briefly, it is the standing practice that a Rule can define substantive provisions and Article 33(1)(c) EPC confers the Administrative Council the unlimited right to amend the Implementing Regulations. Since, according to Article 164(1) EPC, the Implementing Regulations are an integral part of the EPC, the Enlarged Board would have to take into account the new Rule when re-interpreting Article 53(b) EPC in view of the questions of law referred to it.

2. However, this conduct is not in line with the rule of law-principles to which the EPO is bound. In G 3/08, the Enlarged Board has made this very clear in the following considerations:

“7.2.1 According to current constitutional thinking, the predictability and verifiability of all state action are indispensable elements of a democratic legal order based on the separation of powers, the rule of law and respect for human rights including fundamental procedural rights. These principles have been subscribed to in substance at national level by all the EPC contracting states, despite differing constitutional traditions and despite several reservations made by different states. As a democracy is prohibited from signing an international treaty which would undermine its citizens' constitutional guarantees, the EPO must therefore support these fundamental principles either explicitly (e.g. Art. 113 EPC) or implicitly (e.g. liberty, equality) ...

The European Patent Organisation is an international, intergovernmental organisation, modelled on a modern state order and based on the separation of powers principle, which the sovereign contracting states have entrusted with the exercise of some of their national powers in the field of patents. Thus the EPC assigns executive power to the Office to grant patents and to its President to manage the Office in organisational respects (Articles 4(3) and 10 ff. EPC), while to the Administrative Council it assigns limited legislative powers restricted to lower-ranking rules (Article 33 EPC), along with financial and supervisory powers. Finally, the Boards of Appeal, which in their decisions are bound only by the EPC (Article 23(3) EPC), are assigned the role of an independent judiciary in this patent system (Articles 21 to 23 EPC; see also G 6/95, OJ EPO 1996, 649, Reasons, points 2 ff.), ...

7.2.2 Like the judiciary of any democratic entity based on the separation of powers principle, the EPO's Boards of Appeal as an independent judiciary guarantee the due process of law within the Organisation. They are also assigned interpretative supremacy with regard to the EPC in terms of its scope of application (see also Article 23(3) EPC). Under Article 21(1) EPC they are responsible for reviewing decisions taken by the Office in grant and opposition proceedings. Their interpretation of the EPC is the basis for the practice established by the Office for the examination of patent applications and oppositions to granted patents. Otherwise there would be no need for the President's right of referral.

7.2.3 Another essential element of a democratic legal order is the principle that a public authority is bound by law and justice. This is supplemented by the principle of uniform application of the law. Both principles are designed to ensure predictability of jurisdiction and hence legal certainty by preventing arbitrariness. Those subject to the law, in the case of the EPC the parties to proceedings before the Office, but also the public, must be able to expect that the Office as patent granting authority and consequently the Boards of Appeal will settle cases of the same nature in the same way and will apply comprehensible arguments and methods to justify any substantive differences in such decisions. For the stated reasons, these principles also constitute essential precepts for administration and jurisdiction in the European patent system as codified in the EPC. Ensuring compliance with

them is ultimately the task of the Boards of Appeal, including the Enlarged Board,...

7.2.4 In keeping with these principles, Article 112 EPC – like corresponding provisions in the legal orders of the Contracting States – defines the conditions in which legal uniformity within the European patent system may be established by means of a referral to the Enlarged Board of Appeal. It requires the Boards (Article 112(1)(a) EPC) or the President (Article 112(1)(b) EPC) to deem the referral necessary in order to ensure uniform application of the law or if points of law of fundamental importance arise, and a further admissibility criterion for a referral by the President is that two Boards of Appeal must have given different decisions on the question referred. Hence the Enlarged Board does not rule on abstract points of law, but only ever on real issues arising from the cited differing decisions, as well as on specific legal questions adduced in the referral...

7.2.5 Thus it is clear that the interpretation of the EPC is primarily the responsibility of the Boards of Appeal. As a rule they have interpretative supremacy with regard to the EPC because their decisions are subject to review only under the narrowly defined conditions of Article 112(1) and 112a(2) EPC. It is only when these apply that the Enlarged Board has the last word. The fact that the Enlarged Board takes action only on a referral from the Boards of Appeal or the President (with the exception of petitions for review under Article 112a EPC, which however concern procedural matters and have a very narrow scope) and thus does not constitute a further instance ranking above the Boards of Appeal within the EPC judicial system is a clear indication of the extent of its significance for legal uniformity. The exhaustive list of admissibility criteria for a referral under Articles 112(1)(a) and (b) EPC implies that the Enlarged Board takes decisions on specific legal questions and that neither the Boards of Appeal nor the President are authorised to consult it whenever they so wish in order to clarify abstract points of law. For that purpose the President can call upon a separate Legal Department within the Office.

7.2.6 On the same restrictive grounds, Article 112(1)(b) EPC as an additional constraint for a referral by the President as opposed to one by a Board of Appeal requires there to be differences in the rulings of two Boards of Appeal (in the sense already discussed) on a point of law. The "different decisions" criterion would appear to show that the President is only intended to be allowed to refer a question to the Enlarged Board when there is a divergence or, better, conflict in the case law making it difficult if not impossible for the Office to bring its patent granting practice into line with the case law of the Boards of Appeal. It is of course immaterial whether the initiative behind the referral comes from a third party, as long as there is objective evidence of divergent applications of the law.

7.2.7 Given its object and purpose, the right of referral does not extend to allowing the President, for whatever reason, to use an Enlarged Board referral as a means of replacing Board of Appeal rulings on CII patentability with the decision of a putatively higher instance. For example, a presidential referral is not admissible merely because the European Parliament and Council have failed to adopt a directive on CII patenting or because

consistent Board rulings are called into question by a vocal lobby (cf. the present referral, page 2, Section 1, paragraph 3). Even the essentially commendable desire for harmonisation expressed by Lord Justice Jacob in the *Aerotel/Macrossan* judgment can be taken up by the Enlarged Board only to the extent possible under the EPC, even if his suggestion might significantly advance the cause of legal uniformity in Europe. When judiciary-driven legal development meets its limits, it is time for the legislator to take over."

(G 3/08, points 7.2.1 to 7.2.7 of the Reasons; emphases added)

2. In the present case, the referral is defective regarding the compliance with the above-outlined basic principles,
 - (i) because the referral is beyond the limits set to the President by Article 112(1)(b) EPC; and
 - (ii) because of the Administrative Council's attempt to dominate the Enlarged Board's power to interpret the provisions of the EPC by creating a Rule counter-acting the Enlarged Board's interpretation of Article 53(b) EPC.

Both these defects have perfectly been analyzed by Prof. Haedicke in his *amicus curiae* brief. There is actually nothing to add.

Thus, should the Administrative Council and the President prevail with their coordinated activities to implement the new Rule and let the Enlarged Board confirm its applicability, which would match the roadmap outlined by the former President as Option 3 in *CA/PL 4/17* (items 45-54), the functionality and reliability of the European patent system could be severely damaged. This system necessarily requires a separation of the powers, in particular including an independent control by the Boards of Appeal, particularly by the Enlarged Board, of the Administrative Council's "limited legislative powers restricted to lower-ranking rules" (cf. *G 3/08* point 7.2.1 of the Reasons cited above) to ensure uniform application of the law as codified in the EPC. The Enlarged Board is urgently requested to faithfully carry out this control in view of the present referral.

B. CRITICAL REVIEW OF THE "CLARIFICATION" IDEA

1. The term "clarified" used in the first referral question is as such problematic, as it has already been pointed out by several commentators (see, e.g., the *amicus curiae* briefs filed by CIPA (pages 6-7), FICPI (pages 4-5), and IP Federation (page 2)). The words "clarify" or "clarification" have also been used in several official documents in preparation of Rule 28(2) EPC. According to the current online version of the Merriam-Webster dictionary the following definitions are given for the transitive use of the verb "clarify":
 - (1) to make understandable (e.g. clarify a subject; the president was forced to clarify his position on the issue)
 - (2) to free of confusion (e.g. needs time to clarify his thoughts)

- (3) to make (a liquid or something liquefied) clear or pure usually by freeing from suspended matter (e.g. clarify syrup)

Definitions (1) and (2) are relevant herein. But both do not reflect what happened by the enactment of Rule 28(2) EPC, which was the creation of a new exclusion clause for plant-related inventions, thereby effectively modifying the meaning of Article 53(b) EPC (see accordingly CIPA amicus curiae brief, page 7). This has nothing to do with a “clarification” in the usual sense of the term.

2. That Rule 28(2) EPC has no basis in Article 4 of the Biotech Directive 98/44/EC (in the following “BD”), and hence does not present a mere “clarification” of that Article, as the EU Commission alleges in its Notice, is immediately evident from reading the Article’s wording:

“Article 4

1. The following shall not be patentable:
 - (a) plant and animal varieties;
 - (b) essentially biological processes for the production of plants or animals.
2. Inventions which concern plants or animals shall be patentable if the technical feasibility of the invention is not confined to a particular plant or animal variety.
3. Paragraph 1(b) shall be without prejudice to the patentability of inventions which concern a microbiological or other technical process or a product obtained by means of such a process.”

(emphasis added)

3. None of the documents submitted to support Rule 28(2) EPC (e.g., the President referral or the amicus curiae briefs filed by the EU Commission or the EPC member states or their respective patent offices) spell out the wording of Article 4 BD. This is not surprising as it is actually difficult, if not impossible, to convincingly demonstrate that the wording of Article 4 BD could anyhow support the exclusion of “plants or animals exclusively obtained by means of an essentially biological process.” Section (1) of the Article defines the non-patentability of plant varieties and essentially biological processes, as does Article 53(b) EPC. Section (2) is a positive provision allowing the patentability of plants, without any restriction except that the technical feasibility must not be confined to a particular plant variety (corresponding to Rule 27(b) EPC). Section (3) is another positive provision saying that the exclusion of section (1) does not prejudice patentability of microbiological or other technical processes or products obtained by means of such processes (corresponding to Article 53(b) EPC (2nd part) and Rule 27(c) EPC).

Thus, from nowhere in Article 4 BD, it can be derived that plants other than plant varieties are excluded from patentability. The definition is complete and leaves no gap.

4. In decisions G 2/12 and G 2/13, the Enlarged Board accordingly came to the conclusion that “the Biotech Directive, to which Rule 26(1) EPC refers as a supplementary means for interpreting the EPC in relation to biotechnological inventions, does not provide a basis for extending the process exclusion under Article 4(1) Biotech Directive and Article 53(b) EPC to products of such processes” (see G 2/12, section VII.4 of the Reasons).
5. Importantly, the CJEU has also already interpreted Article 4 BD. In the case C-377/98 (Netherlands v. Parliament and Council; decided in 2001; attached as Annex 1), the State of the Netherlands applied for annulment of the BD. In the third plea, it was argued that, “rather than helping to remove the legal ambiguities described in the recitals, the Directive tends to exacerbate them, thus breaching the principle of legal certainty”. To support this argument, it was asserted that “there are unclear provisions whose relationship with one another is ambiguous existing side by side in the Directive, particularly as regards the patentability of plant varieties, mentioned in Article 4(1) and (2), in Articles 8 and 9, and in the 31st and 32nd recitals of the preamble to the Directive” (C-377/98, item 35).

However, the Court did not concur with this view and held that “as regards the patentability of plant varieties, examination of the provisions mentioned in the application reveals no inconsistency” (C-377/98, item 42). The Court further reasoned:

“As the Parliament and the Council explained in their defence, Article 4 of the Directive provides that a patent may not be granted for a plant variety but may be for an invention if its technical feasibility is not confined to a particular plant variety.

That distinction is made clear by the 29th to 32nd recitals of the preamble to the Directive, which indicate that plant varieties as such are covered by the legislation on protection of new plant varieties, but that the protection of new varieties applies only to varieties which are defined by their whole genome. For plant groupings of a higher taxonomic level than the variety, defined by a single gene and not by the whole genome, there is no risk of conflict between the legislation on new varieties and the legislation on patents. Thus, inventions which incorporate only one gene and concern a grouping wider than a single plant variety may be patented.

It follows that a genetic modification of a specific plant variety is not patentable but a modification of wider scope, concerning, for example, a species, may be.”

(C-377/98, items 43 to 45)

Thus, the CJEU already considered the meaning of Article 4 BD and apparently agreed with the Parliament’s and Council’s position (at that time) that, according to Article 4 BD, a patent may not be granted for a plant variety, but for an invention if its technical feasibility is not confined to a particular plant variety. Contrary to the allegation in the

EU Commission Notice (see also section B.12, *infra*), there is, hence, no need to await a decision from the CJEU (which would have no directly binding effect anyway; see G 2/06, points 2 to 11 of the Reasons, and T 2221/10, points 38 and 39 of the Reasons).

6. The fact that Article 4 BD does not provide basis for a “clarification” in the sense of excluding plants produced by an essentially biological process (in the following “EBP-produced plants”) from patentability is also supported by the May 17, 2016 Report¹ of an Expert Group that had specifically been established by the EU Commission in November 2012 to evaluate the legal situation of patents directed to plants. This Report is mentioned in the EU Commission Notice only in passing (Introduction, 5th paragraph) and was completely ignored in the considerations provided. However, the Expert Group agreed in a majority vote with the Enlarged Board’s interpretation of Article 4 BD. In chapter 3.3, the Report accurately summarizes the results of G 2/12 and G 2/13. In chapter 3.4, the Report states that, despite concerns that patents on plants might cover essentially biological processes,

“a patent on a plant obtained by an essentially biological process is *in se* not at odds with the Biotech Directive: Art. 4(2) allows patents on plants if the technical feasibility of the invention is not confined to a particular plant or animal variety, i.e. irrespective of the technique used to create the plant” (Report, sentence bridging pages 36 and 37).

Thus, the Expert Group Report is not in line with the “clarification” attempted by Rule 28(2) EPC.

7. As it seems, the German legislator was the first who used the term “clarification” in this context. With effect of June 27, 2013, Section 2a of the German Patent Act was amended so as to read:

“Section 2a
(1) Patents shall not be granted for
...
2. essentially biological processes for the production of plants or animals
and plants and animals exclusively obtained by such processes;
...”
(added wording highlighted)

Thus, the German legislator decided to deviate from the Directive (in particular from the wording of Article 4(1)(b)) by supplementing the existing product and process exclusions with another product exclusion directed to plants (and animals) exclusively obtained by essentially biological processes. At face value, the need for this legislative act indicates

¹ EU Commission: Final Report of the Expert Group on the development and implications of patent law in the field of biotechnology and genetic engineering (http://ec.europa.eu/growth/industry/intellectual-property/patents/biotechnological-inventions/index_en.htm)

that the process exclusion without the supplement would not provide a basis for generally banning the products of essentially biological processors from patentability.

But the amendment was officially presented as a mere “clarification”; see:

“The Federal Government is of the opinion that, according to the object and purpose of Article 4 of the Biopatent Directive, the patentability exclusion should mandatorily also apply to such animals and plants. The non-patentability of conventional breeding processes could otherwise be easily circumvented.

...

Products derived from biologically bred animals or plants, such as plant oils, should remain patentable provided they comply with the other patentability requirements. Only with a formulation which clearly relates the patentability exclusion of processes and products to the same matter, i.e. “plants and animals”, it will be possible to comply with the available scope for national regulations defined by the EU-Biopatent Directive which is particularly restricted to **clarifications**.”

(Bundestagsdrucksache 17/14222, part IV, “Zu Nummer 1”, English translation; emphasis added)

However, in view of the above explanations on the meaning of Article 4(1) and (2) BD (section B.2, supra), it is evident that the amendment of the German law clearly goes beyond a mere clarification. These provisions do not foresee the exclusion of plants other than plant varieties, as has been confirmed by the Enlarged Board in G 2/12 and G 2/13, by the CJEU in C-377/98 and by the Commission’s own Expert Group in its report. The use of the term “clarification” likely served the purpose of avoiding an impermissible discordance with the Directive, potentially bearing the risk of a trial before the CJEU.

8. However, from then on, the wrong term “clarification” was continuously used by those promoting a change of the law so as to prohibit the patenting of EBP-produced plants.

In this context, the “European Parliament resolution of 17 December 2015 on patents and plant breeders’ rights (2015/2981(RSP))” is of particular importance (copy thereof enclosed as Annex 2). It can be seen as the starting point of the development that ultimately led to Rule 28(2) EPC. Faced with the Enlarged Board decisions G 2/12 and G 2/13, that were handed down in March 2015, the opponents to plant-patents moved forward and asked the Members of the EU Parliament to vote on this topic. As a result, it was concluded that

- the EU Commission should clarify scope and interpretation of Articles 4 BD “in order to ensure legal clarity regarding the prohibition of the patentability of products obtained from essentially biological processes” (item 2),
- the EU Commission should communicate the clarification “to the EPO so that it can be used as a supplementary means of interpretation” (item 3),

- the EU Commission President is instructed “to forward this resolution to the Council, the Commission and the European Patent Office” (item 7)
(selection of conclusions as far as relevant herein)

This Resolution triggered the preparation of the EU Commission Notice that was released on November 3, 2016, which in turn was ultimately picked up by the Administrative Council as a basis for establishing Rule 28(2) EPC.

9. However, what needs to be made aware to the Enlarged Board is that the Members of the EU Parliament were presented an incorrect summary of the content of Article 4 BD as a basis for their conclusions; see:

“having regard to Directive 98/44/EC [...], in particular Article 4 thereof, which states that products obtained from essentially biological processes shall not be patentable”

(Resolution (Annex 2), second item of the list of legal sources to be considered; emphasis added)

This passage is part of the introduction in which the legal sources for the political conclusions to be drawn are outlined. Some amicus curiae briefs already mention this incorrectness in the Resolution (e.g. those filed by Steenbeek (page 4, 2nd para.) and by KSVR (the first one; see items [5] and [191])). However, what needs to be understood is that this incorrectness was already in the draft resolution that was given to the parliamentarians to vote on (see attached as Annex 3 the Joint Motion for the Resolution). Thus, the opinion making was actually manipulated by those who drafted the resolution text. The mindset of the Members of the Parliament was guided to the belief that, by its decision to allow the patenting of EBP-produced plants in G 2/12 and G 2/13, the Enlarged Board must have violated the Directive. The average Member will hardly have had the resources for checking the correctness of the facts noted in the resolution draft². Of course, one can imagine that, in this way, it was not difficult to gather a majority for actions to be taken for reversing the Enlarged Board’s decision.

Interestingly, in its former 2012 Resolution on plant patenting, Article 4 BD was still correctly reflected:

“having regard to Directive 98/44/EC [...], and in particular Article 4 thereof, which states that plant and animal varieties and essentially biological processes for the production of plants or animals shall not be patentable”

(European Parliament motion for a resolution of 10 May 2012 on the patenting of essential biological processes (2012/2623(RSP); copy attached as Annex 4; emphasis added)

² Note that the EU Parliament sometimes does up to 200 votes per day (<https://www.suedkurier.de/ueberregional/politik/Bis-zu-200-Abstimmungen-pro-Tag-im-EU-Parlament-Wenn-Abgeordnete-nicht-durchblicken:art410924.10102175>).

In the latest Resolution dated September 19, 2019 (attached to the amicus curiae brief filed by the EU Commission on October 1, 2019), the incorrect wording of the 2015 Resolution was maintained.

10. Thus, in the critical period after the issuance of G 2/12 and G 2/13, the Resolution text regarding Article 4 BD was modified compared to the 2012 version by taking over the interpretation of the German legislator and putting it in the very direct language that “Article 4 ... states (!) that products obtained from essentially biological processes shall not be patentable”.
11. In a report on the patenting of plants that the German government rendered in 2016 to the national Parliament (Bundestag), the 2015 resolution of the EU Parliament is mentioned (see attached as Annex 5 copy of the corresponding Bundestagsdrucksache 18/9462 of August 18, 2016, section 2.2). In section 2.4 of that document, talking about further steps to be taken, the German government indicates:

“Das BMJV und das BMEL werden sich in weiteren bilateralen Gesprächen mit der Europäischen Kommission dafür einsetzen, dass in der angekündigten „clarifying notice“ der Europäischen Kommission, die nach Auffassung der Bundesregierung auch vom Europäischen Rat und dem Europäischen Parlament mitgetragen werden sollte, ein Verständnis der Biopatent-Richtlinie in dem Sinne formuliert wird, wie es der Deutsche Bundestag mit § 2a PatG zum Ausdruck gebracht hat, das heißt, dass keine Patente auf Pflanzen und Tiere als Produkte im Wesentlichen biologischer Verfahren erteilt werden können.“

(Annex 5, section 2.4)

Unofficial translation:

The Federal Ministry of Justice and Consumer Protection and the Federal Ministry of Food and Agriculture will continue, in bilateral talks with the European Commission, to endeavour that in the “clarifying notice” which was announced by the European Commission and which, according to the Federal Government, should be supported by the European Council and the European Parliament, the interpretation of the Biotech Directive shall be formulated in line with Section 2a German Patent Act as provided by the German parliament (Bundestag), that is that no patents shall be granted for plants or animals as products of essentially biological processes.

Thus, it seems to be fair to say that the German government is at least one driving force behind the counter-measures against the effect of the Enlarged Board’s decisions G 2/12 and G 2/13.

12. The “clarifying notice” mentioned in the above quotation was then issued by the EU Commission on November 3, 2016 (OJ EU C411/3 of November 8, 2016). The promoters of Rule 28(2) EPC in the present proceedings argue that this document should be taken

by the Enlarged Board as a means to interpret the true intention behind Article 4 BD. However, the EU Commission Notice fails to provide any valid reason for departing from the Enlarged Board's interpretation of Article 4 BD. In fact, none of the points addressed in the EU Commission Notice supports the conclusion that Article 4 BD could be interpreted as excluding EBP-produced plants from patentability. CIPA already commented thereon to this effect (see their amicus curiae brief, pages 25-28). Here are some further brief comments:

- i. A conflict with Plant Breeders' Rights was alleged, which however does not exist (cf. EU Commission Notice, Introduction, 4th paragraph).
- ii. The preparatory history leading to the EU Commission Notice does not support the Commission's view. In particular, the Resolution adopted by the European Parliament in December 2015 (to which the President also repeatedly refers as support) was flawed (see section B.9, supra). Furthermore, the Report of the Expert Group that had specifically been established by the EU Commission to evaluate the legal situation (section B.6, supra) was completely ignored by the EU Commission Notice, despite the Expert Group's majority vote agreeing with the Enlarged Board's interpretation of Article 4 BD (cf. EU Commission Notice, Introduction, 5th paragraph).
- iii. The EU Commission Notice itself admits that it produces legal uncertainty by pointing out that its findings do not prejudice any future position of the Commission and that only the CJEU is competent to interpret union law (cf. EU Commission Notice, Introduction, penultimate paragraph).
- iv. The arguments given to support the allegation that the EU jurisprudence would come to a different result than the Enlarged Board are not convincing. In a very systematic approach following Articles 31 and 32 of the Vienna Convention, the Enlarged Board has thoroughly considered in G 2/12 and G 2/13 the relevant Articles and Rules of the EPC and the Directive in their entirety. It is not apparent – and this has not been substantiated in the EU Commission Notice – why the CJEU should come to a different interpretation of Article 4 BD than the Enlarged Board (cf. EU Commission Notice, chapter 1.1).
- v. The Commission's attempt to derive support from the legislative history of the Directive also fails because it is based on a very early draft version of the provision that finally became Article 4, whereby through the process of counseling between Commission and Parliament the text has been amended so as to finally read as it reads now. Abandoning the initial wording speaks for itself (cf. EU Commission Notice, chapter 1.2).
- vi. Contrary to the Commission's interpretation, the provisions of the Directive do not support that conventionally produced plants are to be excluded from patentability, as the Enlarged Board has convincingly shown in G 2/12 and G 2/13 (cf. EU Commission Notice, chapter 1.3).

Thus, even if the EU Commission Notice were to be considered by the Enlarged Board, and if this document had any significance for the EPO's interpretation of the EPC, in view of its apparent weaknesses, it could not even support Rule 28(2) EPC.

13. The fact that the European Council, the EU Parliament in its 2019 Resolution (attached to the EU Commission's amicus curiae brief) and many EU member states have followed the German guideline for the "clarification" of Article 4 BD can only be explained by the assumption that there has been no political will for critically scrutinizing this unsupported interpretation. Actually, since EU member states are bound by a EU directive and have to implement it in their national legislation, as regards the patentability of EBP-produced plants, the national patent law or the respective implementing regulations would have had to be adapted to the Directive as it stands. Actually, this national implementation was initially done more or less accurately. However, the development of the past few years, wherein the most powerful EU member state enacts a provision deviating from the Directive and, via the EU, the national legislators as well as the Administrative Council of the European Patent Organisation follow suit, is against the codified rules of the EU and the EPC.
14. As a consequence, if it is indeed politically desired to exclude EBP-produced plants from patentability under the EPC, this could only be done in compliance with the rule of law-principles referred to in section A (supra) by either revising Article 53(b) EPC according to Article 172 EPC or by revising Article 4 BD at the EU level and then amending Article 53(b) EPC according to Articles 33(1)(b) and 33(5) EPC on the basis of the revised "European Community legislation". However, the "clarification" that resulted in Rule 28(2) EPC must fail.

C. INVALIDATING RULE 28(2) EPC WOULD REMOVE LEGAL UNCERTAINTY

Apart from the urgent need to generally achieve legal certainty as regards the patentability of plant-related inventions at the EPO, which was again jeopardized by the President's referral, two further aspects need to be taken into account, as is discussed in the following:

1. Removal of the unsatisfactory dual meaning of the term "essentially biological process" in the EPC

Rule 28(2) EPC stipulates that, "[u]nder Article 53(b), European patents shall not be granted in respect of plants or animals exclusively obtained by means of an essentially biological process."

However, according to the Guidelines, G-II, 5.4 and 5.4.2 (current version), the term “essentially biological process” used in Rule 28(2) EPC is supposed to have a meaning narrower than in the process exclusion of Article 53(b) EPC, reading “European patents shall not be granted in respect of ... essentially biological processes for the production of plants or animals”, as it was interpreted in G 2/07 and G 1/08. In the former case, an essentially biological process is supposed not to comprise any “technical intervention”, but merely crossing and selection for the desired offspring. The Guidelines try to derive this narrow interpretation from the term “exclusively” in Rule 28(2) EPC (Guidelines, G-II, 5.4).

By contrast, in the context with the process exclusion of Article 53(b) EPC, the Guidelines follow the interpretation of G 2/07 and G 1/08 and consider a process for the production of plants or animals as being essentially biological if it “is based on the sexual crossing of whole genomes and on the subsequent selection of plants or animals”. This is said to apply “even if the process comprises human intervention, including the provision of technical means, serving to enable or assist the performance of the process steps or if other technical steps relating to the preparation of the plant or animal or its further treatment are present in the claim before or after the crossing and selection steps” (Guidelines, G-II, 5.4.2).

Thus, in the former case, an “essentially biological process” may not comprise additional technical steps, in the latter case, it may comprise additional technical steps. The use of the term “exclusively” in Rule 28(2) EPC does not change this deviation in meaning. Consequently, when a plant is “exclusively” obtained by an essentially biological process according to the broad definition, it may still be a transgenic plant because the process may comprise crossing and selection as well as a genetic modification step.

The existence of a term in the EPC (including the Implementing Regulations; see Article 164(1) EPC) having two different meanings is an intolerable situation. That is another reason for invalidating Rule 28(2) EPC.

2. Removal of legal uncertainty created by the product-by-process definition of the exemption

Finally, Rule 28(2) EPC creates further legal uncertainty by its product-by-process language (“obtained by”). Nowadays, it is often not possible to distinguish a conventionally bred plant from plants produced by new technologies of homologous recombination, e.g. “gene-editing” such as CRISPR-Cas. The EU Commission Notice has omitted to consider this although the EU Commission’s own Expert Group (see section B. 6, supra) has pointed to this problem in its Report on pages 37 and 38. The Guidelines, by contrast, are aware of this problem and suggest utilizing a disclaimer to exclude plants from the claimed subject-matter that are produced by an essentially biological process

(Guidelines, G-II, 5.4)³. This solution is unfortunate since it leaves patentees in a permanent legally uncertain situation. If one gets a patent with a claim comprising such a disclaimer and the Enlarged Board later decides that Rule 28(2) EPC is not applicable, this could lead to an inescapable Article 123(2)/(3) EPC trap. That is another reason for removing Rule 28(2) EPC in order to re-establish legal certainty.

D. CONCLUSION

In line with the above explanations and the amicus curiae briefs referenced in the introductory part of this submission, it is noted that the referral put forward by the President cannot be admissible. In judging on this, the Enlarged Board is respectfully requested to provide a detailed reasoning (similar to the case G 3/08) with the aim to strengthen the rule of law-principles to be applied by the European Patent Organisation and to confirm that T 1063/18 provides valid guidance for how to handle Rule 28(2) EPC.

Respectfully submitted,



Dr. Olaf Malek

Encl.:

Annexes 1-5

³ Of note, in section G-II, 5.4.2.1, the Guidelines suggest the following example of a disclaimer-containing claim that is supposed to be a “typical formulation of subject-matter not excluded from patentability under Art. 53(b)”:

“A cultivated pepper plant expressing a mutated AHAS enzyme with the proviso that the plant is not exclusively obtained by means of an essentially biological process.”
(emphasis added)

Due to the ambiguous meaning of the term “essentially biological process” explained in section C.1 (supra), this disclaimer is unclear and can therefore not comply with Article 123(2) EPC (see G 1/03 and G 2/03, Headnote 2.4).

JUDGMENT OF THE COURT

9 October 2001 *

In Case C-377/98,

Kingdom of the Netherlands, represented by M.A. Fierstra and I. van der Steen,
acting as Agents,

applicant,

supported by

Italian Republic, represented by U. Leanza, acting as Agent, assisted by P.G.
Ferri, avvocato dello Stato, with an address for service in Luxembourg,

and by

Kingdom of Norway, represented by H.W. Longva, acting as Agent,

interveners,

* Language of the case: Dutch.

European Parliament, represented by J. Schoo and E. Vandenbosch, acting as Agents, with an address for service in Luxembourg,

and

Council of the European Union, represented by R. Gosalbo Bono, G. Houttuin and A. Lo Monaco, acting as Agents, with an address for service in Luxembourg,

defendants,

supported by

Commission of the European Communities, represented by K. Banks and P. van Nuffel, acting as Agents, with an address for service in Luxembourg,

intervener,

APPLICATION for annulment of Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions (OJ 1998 L 213, p. 13),

THE COURT,

composed of: G.C. Rodríguez Iglesias, President, P. Jann, F. Macken, N. Colneric and S. von Bahr (Presidents of Chambers), C. Gulmann, D.A.O. Edward, A. La Pergola, J.-P. Puissochet (Rapporteur), L. Sevón, M. Wathelet, V. Skouris and J.N. Cunha Rodrigues, Judges,

Advocate General: F.G. Jacobs,
Registrar: H.A. Rühl, Principal Administrator,

having regard to the Report for the Hearing,

after hearing oral argument from the parties at the hearing on 13 February 2001, at which the Kingdom of the Netherlands was represented by J. van Bakel, acting as Agent, the Italian Republic by D. Del Gaizo, avvocato dello Stato, the Kingdom of Norway by H. Seland, acting as Agent, the European Parliament by J. Schoo and E. Vandenbosch, the Council by G. Houttuin and A. Lo Monaco and the Commission by K. Banks and P. van Nuffel,

after hearing the Opinion of the Advocate General at the sitting on 14 June 2001,

gives the following

Judgment

- 1 By application lodged at the Court Registry on 19 October 1998, the Kingdom of the Netherlands brought an action under Article 173 of the EC Treaty (now, after amendment, Article 230 EC) for annulment of Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions (OJ 1998 L 213, p. 13, hereinafter ‘the Directive’).

- 2 The Directive was adopted on the basis of Article 100a of the EC Treaty (now, after amendment, Article 95 EC), and its purpose is to require the Member States, through their patent laws, to protect ‘biotechnological inventions, whilst complying with their international obligations.

- 3 To that end the Directive determines *inter alia* which inventions involving plants, animals or the human body may or may not be patented.

- 4 The applicant states, as a preliminary point, that it is acting at the express request of the Netherlands Parliament, in the light of the opposition expressed there to genetic manipulation involving animals and plants and to the issuing of patents for the products of biotechnological procedures liable to promote such manipulation.

- 5 By order of the President of the Court of 28 April 1999, the Commission of the European Communities was granted leave to intervene in support of the forms of order sought by the European Parliament and the Council of the European Union. By orders of the President of the Court of 3 May 1999 the Italian Republic and the Kingdom of Norway were granted leave to intervene in support of the forms of order sought by the Kingdom of the Netherlands.

Admissibility of intervention by the Kingdom of Norway

- 6 The Parliament and the Council submit that the statement lodged on 19 March 1999 by the Kingdom of Norway merely draws the attention of the Court to certain problems which the implementation of the Directive might pose in connection with the Agreement on the European Economic Area (hereinafter 'the EEA Agreement'), without itself seeking the form of order sought in the application or seeking annulment of the Directive. Consequently, it does not constitute an intervention in support of the forms of order sought by the Kingdom of the Netherlands and is therefore not admissible.

- 7 In that regard, Article 37 of the EC Statute of the Court of Justice provides that applications to intervene are to be limited to supporting the form of order sought by one of the parties.

- 8 As it states in its conclusion, the statement lodged by the Norwegian Government seeks to make the point that '[s]everal of the questions presented by the Netherlands Government in its action for annulment of Directive 98/44 may have a bearing on whether or not the Directive falls within the EEA Agreement and on the implementation of the Directive into the EEA Agreement', and to request the Court to 'take due account of the arguments' set out by the Norwegian Government in that connection.

- 9 Although, read literally, the objective so described appears different from that which a statement in intervention can legitimately pursue, it is clear that the intention of the Norwegian Government was not to seek further forms of order in addition to those sought by the applicant nor to ask the Court to rule on separate issues, but to contribute to the success of the action of the Netherlands Government by shedding further light on the dispute.

- 10 That analysis is confirmed by the fact that all the arguments contained in the Norwegian Government's statement reiterate, and on some points develop, the views stated in the application of the Kingdom of the Netherlands.

- 11 The statement lodged by the Kingdom of Norway taken overall and in its context, must therefore be held to be admissible as a statement in intervention in support of the forms of order sought by the applicant.

The pleas relied on in the application

- 12 The applicant puts forward six pleas: that Article 100a of the Treaty was the incorrect legal basis for the Directive, breach of the principle of subsidiarity, breach of the principle of legal certainty, breach of obligations in international law, breach of the fundamental right to respect for human dignity and breach of procedural rules in the adoption of the Commission's proposal.

The first plea

- 13 The applicant submits that the Directive does not fall within the definition of measures for approximation of the provisions laid down by law, regulation or administrative action in Member States which have as their object the establishment and functioning of the internal market, and was incorrectly adopted on the basis of Article 100a of the Treaty.
- 14 In the first place, the differences in the laws and practices of the Member States and the likelihood of their becoming greater, to which the fifth and sixth recitals of the preamble to the Directive allude, stating that they could create barriers to trade, do not exist or only concern secondary issues which do not justify harmonisation.
- 15 In that regard, it must be borne in mind that recourse to Article 100a as a legal basis is possible if the aim is to prevent the emergence of future obstacles to trade resulting from multifarious development of national laws provided that the emergence of such obstacles is likely and the measure in question is designed to prevent them (Case C-350/92 *Spain v Council* [1995] ECR I-1985, paragraph 35, and Case C-376/98 *Germany v Parliament and Council* [2000] ECR I-8419, paragraph 86).
- 16 The examples given by the Parliament and the Council suffice to establish that, even if the relevant national provisions predating the Directive are most often taken from the Convention on the Grant of European Patents, signed at Munich on 5 October 1973, (hereinafter 'the EPC'), the differing interpretations to which those provisions are open as regards the patentability of biotechnological inventions are liable to give rise to divergences of practice and case-law prejudicial to the proper operation of the internal market.

- 17 Moreover, in addition to the risk of divergent trends, at the time the Directive was adopted marked differences with significant consequences were already apparent between certain national laws on specific points such as the patentability of plant varieties and that of the human body,
- 18 By requiring the Member States to protect biotechnological inventions by means of their national patent law, the Directive in fact aims to prevent damage to the unity of the internal market which might result from the Member States' deciding unilaterally to grant or refuse such protection.
- 19 However, the applicant submits, secondly, that if the application by the Member States of the relevant provisions of international law left a measure of legal uncertainty, it should have been removed not by Community harmonisation but by renegotiation of international legal instruments such as the EPC, in order to clarify their rules.
- 20 That argument is unfounded. The purpose of harmonisation is to reduce the obstacles, whatever their origin, to the operation of the internal market which differences between the situations in the Member States represent. If divergences are the result of an interpretation which is contrary, or may prove contrary, to the terms of international legal instruments to which the Member States are parties, there is nothing in principle to prevent recourse to adoption of a Directive as a means of ensuring a uniform interpretation of such terms by the Member States.
- 21 Moreover, it does not appear, in the present case, that such an approach is inconsistent with the Member States' honouring their obligations under the EPC or is unsuitable for achieving the objective of creating uniform conditions for the patentability of biotechnological inventions.

- 22 Accordingly, there was nothing to prevent the Community legislature from having recourse to harmonisation by means of a directive in preference to the more indirect and unpredictable approach of seeking to amend the wording of the EPC.
- 23 Thirdly, according to the applicant, the Directive goes beyond what ought to fall within the definition of a measure for approximation of the legislation of the Member States, given that, in fact, it creates a new type of property right distinct in several respects from the rights covered by existing patent law. In particular, apart from the fact that it concerns products previously excluded from patentability in certain Member States such as the Kingdom of the Netherlands, the Directive is different from existing patent law in that, by virtue of Articles 8 and 9, the protection it provides for applies not only to specific biological material but also to biological material obtained from it by reproduction or multiplication, and that under Article 11 the right of the holder of the patent, as against farmers, is limited.
- 24 As the Court has already stated at point 59 of Opinion 1/94 of 15 November 1994 ([1994] ECR I-5267), the Community is competent, in the field of intellectual property, to harmonise national laws pursuant to Article 100 of the EC Treaty (now Article 94 EC) and Article 100a of the Treaty and may use Article 235 of the EC Treaty (now Article 308 EC) as the basis for creating new rights superimposed on national rights, as it did in Council Regulation (EC) No 40/94 of 20 December 1993 on the Community trade mark (OJ 1994 L 11, p. 1).
- 25 The patents to be issued under the Directive are national patents, issued in accordance with the procedures applicable in the Member States and deriving their protective force from national law. As the creation of a Community patent is neither the purpose nor the effect of the Directive, it does not introduce a new right which would require recourse to the legal basis afforded by Article 235 of the Treaty. That view is not affected by the fact that the inventions covered were

not previously patentable in certain Member States — that, indeed, is precisely why harmonisation was warranted — nor by the fact that the Directive makes certain clarifications and provides for derogations from patent law as regards the scope of the protection.

26 Fourthly, and finally, the Italian Government takes the view, in its intervention in support of the applicant, that the Directive should have been adopted on the basis of Articles 130 and 130f of the EC Treaty (now Articles 157 EC and 163 EC), and not Article 100a of the Treaty since the chief aim of the Directive, as the first three recitals of the preamble show, is to support the industrial development of the Community and scientific research in the genetic engineering sector.

27 The legal basis on which an act must be adopted should be determined according to its main object (see Case C-155/91 *Commission v Council* [1993] ECR I-939, paragraphs 19 to 21). Whilst it is common ground, in that regard, that the aim of the Directive is to promote research and development in the field of genetic engineering in the European Community, the way in which it does so is to remove the legal obstacles within the single market that are brought about by differences in national legislation and case-law and are likely to impede and disrupt research and development activity in that field.

28 Approximation of the legislation of the Member States is therefore not an incidental or subsidiary objective of the Directive but is its essential purpose. The fact that it also pursues an objective falling within Articles 130 and 130f of the Treaty is not, therefore, such as to make it inappropriate to use Article 100a of the Treaty as the legal basis of the Directive (see, by analogy, Case C-62/88 *Greece v Council* [1990] ECR I-1527, paragraphs 18 to 20).

- 29 It follows that the Directive was correctly adopted on the basis of Article 100a of the Treaty and that the first plea must, therefore, be rejected.

The second plea

- 30 The applicant submits that the Directive breaches the principle of subsidiarity laid down by Article 3b of the EC Treaty (now Article 5 EC) and, in the alternative, that it does not state sufficient reasons to establish that this requirement was taken into account.

- 31 It should be borne in mind that, under the second paragraph of Article 3b of the EC Treaty, in areas which do not fall within its exclusive competence, the Community is to take action only if and in so far as the objectives of the proposed action cannot be sufficiently achieved by the Member States and can therefore, by reason of the scale or effects of the proposed action, be better achieved by the Community.

- 32 The objective pursued by the Directive, to ensure smooth operation of the internal market by preventing or eliminating differences between the legislation and practice of the various Member States in the area of the protection of biotechnological inventions, could not be achieved by action taken by the Member States alone. As the scope of that protection has immediate effects on trade, and, accordingly, on intra-Community trade, it is clear that, given the scale and effects of the proposed action, the objective in question could be better achieved by the Community.

33 Compliance with the principle of subsidiarity is necessarily implicit in the fifth, sixth and seventh recitals of the preamble to the Directive, which state that, in the absence of action at Community level, the development of the laws and practices of the different Member States impedes the proper functioning of the internal market. It thus appears that the Directive states sufficient reasons on that point.

34 The second plea in law must, therefore, be rejected.

The third plea in law

35 The applicant submits that, rather than helping to remove the legal ambiguities described in the recitals, the Directive tends to exacerbate them, thus breaching the principle of legal certainty. First, it gives the national authorities a discretion in applying concepts expressed in general and ambiguous terms, such as *ordre public* and morality which appear in Article 6. Second, there are unclear provisions whose relationship with one another is ambiguous existing side by side in the Directive, particularly as regards the patentability of plant varieties, mentioned in Article 4(1) and (2), in Articles 8 and 9, and in the 31st and 32nd recitals of the preamble to the Directive.

36 The two specific grounds relied on by the applicant in support of its submission of breach of legal certainty should be examined separately.

- 37 As regards, first, Article 6 of the Directive, which rules out the patentability of inventions whose commercial exploitation would be contrary to *ordre public* or morality, it is common ground that this provision allows the administrative authorities and courts of the Member States a wide scope for manœuvre in applying this exclusion.
- 38 However, that scope for manœuvre is necessary to take account of the particular difficulties to which the use of certain patents may give rise in the social and cultural context of each Member State, a context which the national legislative, administrative and court authorities are better placed to understand than are the Community authorities. That sort of provision, which allows patents to be refused where there is a threat to *ordre public* or morality is, moreover, a well known one in patent law and appears *inter alia* in the relevant international legal instruments, such as the EPC.
- 39 Furthermore, the scope for manœuvre left to Member States is not discretionary, since the Directive limits the concepts in question, both by stating that commercial exploitation is not to be deemed to be contrary to *ordre public* or morality merely because it is prohibited by law or regulation, and by giving four examples of processes or uses which are not patentable. Thus, the Community legislature gives guidelines for applying the concepts at issue which do not otherwise exist in the general law on patents.
- 40 Finally, a directive cannot be considered contrary to the principle of legal certainty if it relies, as regards the conditions for its implementation, on concepts known to the laws of the Member States, specifying, as here, their scope and limits and taking account, in order to do so, of the specific nature of the subject-matter.

41 Article 6 of the Directive is not therefore such as to exacerbate the legal uncertainty which the Directive seeks to alleviate.

42 Second, as regards the patentability of plant varieties, examination of the provisions mentioned in the application reveals no inconsistency.

43 As the Parliament and the Council explained in their defence, Article 4 of the Directive provides that a patent may not be granted for a plant variety but may be for an invention if its technical feasibility is not confined to a particular plant variety.

44 That distinction is made clear by the 29th to 32nd recitals of the preamble to the Directive, which indicate that plant varieties as such are covered by the legislation on protection of new plant varieties, but that the protection of new varieties applies only to varieties which are defined by their whole genome. For plant groupings of a higher taxonomic level than the variety, defined by a single gene and not by the whole genome, there is no risk of conflict between the legislation on new varieties and the legislation on patents. Thus, inventions which incorporate only one gene and concern a grouping wider than a single plant variety may be patented.

45 It follows that a genetic modification of a specific plant variety is not patentable but a modification of wider scope, concerning, for example, a species, may be.

- 46 Articles 8 and 9 of the Directive do not concern the principle of patentability but the scope of the protection conferred by the patent. According to those provisions, the protection extends to any biological material derived through propagation or multiplication from the biological material containing the patented information. The protection conferred by the patent may therefore cover a plant variety, without that variety being patentable in itself.
- 47 Finally, Article 12 covers, through a system of compulsory licences, cases where the exploitation of a patent issued for a biotechnological invention would infringe a prior plant patent, and vice versa.
- 48 Therefore, the two grounds relied on by the applicant to support its plea that the Directive gives rise to legal uncertainty do not justify its annulment.
- 49 The third plea must, therefore, be rejected.

The fourth plea

- 50 The applicant submits that the obligations created by the Directive for Member States are incompatible with those resulting from their international undertakings, even though, according to Article 1(2) of the Directive, it does not affect obligations under international agreements. In particular, the Directive breaches the Agreement on Trade-Related Aspects of Intellectual Property Rights (hereinafter 'TRIPs'), as set out in Annex 1 C to the Agreement establishing the World Trade Organisation (hereinafter 'the WTO Agreement'), approved on behalf of

the European Community, as regards matters within its competence, by Council Decision 94/800/EC of 22 December 1994 (OJ 1994 L 336, p. 1), the Agreement on Technical Barriers to Trade (hereinafter ‘the TBT Agreement’), the EPC and the Convention on Biological Diversity signed on 5 June 1992 in Rio de Janeiro (hereinafter ‘the CBD’), approved by the European Community by Council Decision 93/626/EEC of 25 October 1993 (OJ 1993 L 309, p. 1).

51 As their main argument, the Parliament and Council submit that the EPC does not create obligations for the Community, which is not a party to it. As regards the other three international legal instruments cited, the Council submits that the legality of a Community instrument can be called in question on grounds of breach of international agreements to which the Community is a party only if the provisions of those agreements have direct effect. That is not so in the present case.

52 It is common ground that, as a rule, the lawfulness of a Community instrument does not depend on its conformity with an international agreement to which the Community is not a party, such as the EPC. Nor can its lawfulness be assessed in the light of instruments of international law which, like the WTO agreement and the TRIPS and TBT agreements which are part of it, are not in principle, having regard to their nature and structure, among the rules in the light of which the Court is to review the lawfulness of measures adopted by the Community institutions (Case C-149/96 *Portugal v Council* [1999] ECR I-8395, paragraph 47).

53 However, such an exclusion cannot be applied to the CBD, which, unlike the WTO agreement, is not strictly based on reciprocal and mutually advantageous arrangements (see *Portugal v Council*, cited above, paragraphs 42 to 46).

- 54 Even if, as the Council maintains, the CBD contains provisions which do not have direct effect, in the sense that they do not create rights which individuals can rely on directly before the courts, that fact does not preclude review by the courts of compliance with the obligations incumbent on the Community as a party to that agreement (Case C-162/96 *Racke* [1998] ECR I-3655, paragraphs 45, 47 and 51).
- 55 Moreover, and in any event, this plea should be understood as being directed, not so much at a direct breach by the Community of its international obligations, as at an obligation imposed on the Member States by the Directive to breach their own obligations under international law, while the Directive itself claims not to affect those obligations.
- 56 For that reason at least, the plea is admissible.
- 57 The applicant argues essentially, first, that Article 27(3)(b) of the TRIPS Agreement allows Member States not to grant a patent for plants and animals other than micro-organisms, whereas the Directive does not allow Member States that possibility.
- 58 In that regard, suffice it to note that, while the Directive does deprive the Member States of the choice which the TRIPS Agreement offers the parties to that agreement as regards the patentability of plants and animals, the option taken in Article 4 of the Directive is in itself compatible with the Agreement, which, moreover, does not prevent certain party States adopting a common position with a view to its application. The joint selection of an option offered by an international instrument to which the Member States are parties is an act that falls within the approximation of laws provided for by Article 100a of the Treaty.

59 Second, it is claimed that the Directive contains technical regulations within the meaning of the TBT Agreement which should have been notified to the secretariat of the World Trade Organisation.

60 It is, however, established that the Directive does not in any event contain any technical regulations within the meaning of the TBT Agreement, such a regulation being defined in Annex I to the WTO Agreement as a document which lays down product characteristics or their related processes and production methods. It is therefore not necessary to rule on the extent to which the legal protection of biotechnological inventions might fall within the scope of the TBT Agreement.

61 The applicant submits, thirdly, that Article 6(1) of the Directive, which rules out the patentability of inventions ‘whose commercial exploitation would be contrary to *ordre public* or morality’, is incompatible with Article 53 of the EPC, which excludes from patentability ‘inventions the publication or exploitation of which would be contrary to *ordre public* or morality’. The difference in the terms used, it is argued, has an effect contrary to Article 1(2) of the Directive on the obligations which the EPC imposes on the Member States.

62 However, the applicant in no way indicates in what respect the slightly different wording used by the Directive on that point, inspired by the wording of Article 27(3) of the TRIPS Agreement, requires Member States to breach their obligations under the EPC in order to comply with their obligations under the Directive. In the absence of specific examples to the contrary, it seems reasonable to suppose that a breach of *ordre public* and morality as regards a specific invention could be equally well established by reference to its publication, exploitation or commercial exploitation.

- 63 Fourthly and finally, the applicant and, to a greater extent, the Norwegian Government intervening in its support submit that the very purpose of the Directive, which is to make biotechnological inventions patentable in all the Member States, runs counter to the principle of equitable sharing of the benefits arising out of the utilisation of genetic resources, which is one of the objectives of the CBD.
- 64 However, the risks described by the applicant and that intervener are expressed in hypothetical terms and are not derived directly from the provisions of the Directive but, at the very most, from the use which might be made of them.
- 65 It cannot be assumed, in the absence of evidence, which is lacking in this case, that the mere protection of biotechnological inventions by patent would result, as is argued, in depriving developing countries of the ability to monitor their biological resources and to make use of their traditional knowledge, any more than it would result in promoting single-crop farming or in discouraging national and international efforts to preserve biodiversity.
- 66 Moreover, while Article 1 of the CBD states that its objective is the fair and equitable sharing of the benefits arising out of the utilisation of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, it specifies that this must be done taking into account all rights over those resources and technologies. There is no provision of the CBD which requires that the conditions for the grant of a patent for biotechnological inventions should include the consideration of the interests of the country from which the genetic resource originates or the existence of measures for transferring technology.
- 67 Finally, as regards the possibility that the Directive might represent an obstacle in the context of the international cooperation necessary to achieve the objectives of

the CBD, it should be borne in mind that, under Article 1(2) of the Directive, the Member States are required to apply it in accordance with the obligations they have undertaken as regards *inter alia* biological diversity.

68 It follows from the foregoing that the fourth plea must be rejected.

The fifth plea

69 The applicant submits that the patentability of isolated parts of the human body provided for by Article 5(2) of the Directive reduces living human matter to a means to an end, undermining human dignity. Moreover, the absence of a provision requiring verification of the consent of the donor or recipient of products obtained by biotechnological means undermines the right to self-determination.

70 It is for the Court of Justice, in its review of the compatibility of acts of the institutions with the general principles of Community law, to ensure that the fundamental right to human dignity and integrity is observed.

71 As regards respect for human dignity, this is guaranteed in principle by Article 5(1) of the Directive which provides that the human body at the various stages of its formation and development cannot constitute a patentable invention.

- 72 Nor are the elements of the human body patentable in themselves and their discovery cannot be the subject of protection. Only inventions which combine a natural element with a technical process enabling it to be isolated or produced for an industrial application can be the subject of an application for a patent.
- 73 Thus, as is stated in the 20th and 21st recitals of the preamble to the Directive, an element of the human body may be part of a product which is patentable but it may not, in its natural environment, be appropriated.
- 74 That distinction applies to work on the sequence or partial sequence of human genes. The result of such work can give rise to the grant of a patent only if the application is accompanied by both a description of the original method of sequencing which led to the invention and an explanation of the industrial application to which the work is to lead, as required by Article 5(3) of the Directive. In the absence of an application in that form, there would be no invention, but rather the discovery of a DNA sequence, which would not be patentable as such.
- 75 Thus, the protection envisaged by the Directive covers only the result of inventive, scientific or technical work, and extends to biological data existing in their natural state in human beings only where necessary for the achievement and exploitation of a particular industrial application.
- 76 Additional security is offered by Article 6 of the Directive, which cites as contrary to *ordre public* and morality, and therefore excluded from patentability, processes for cloning human beings, processes for modifying the germ line genetic identity of human beings and uses of human embryos for industrial or commercial

purposes. The 38th recital of the preamble to the Directive states that this list is not exhaustive and that all processes the use of which offend against human dignity are also excluded from patentability.

- 77 It is clear from those provisions that, as regards living matter of human origin, the Directive frames the law on patents in a manner sufficiently rigorous to ensure that the human body effectively remains unavailable and inalienable and that human dignity is thus safeguarded.
- 78 The second part of the plea concerns the right to human integrity, in so far as it encompasses, in the context of medicine and biology, the free and informed consent of the donor and recipient.
- 79 Reliance on this fundamental right is, however, clearly misplaced as against a directive which concerns only the grant of patents and whose scope does not therefore extend to activities before and after that grant, whether they involve research or the use of the patented products.
- 80 The grant of a patent does not preclude legal limitations or prohibitions applying to research into patentable products or the exploitation of patented products, as the 14th recital of the preamble to the Directive points out. The purpose of the Directive is not to replace the restrictive provisions which guarantee, outside the scope of the Directive, compliance with certain ethical rules which include the right to self-determination by informed consent.

81 The fifth plea must, therefore, be rejected.

The sixth plea

82 Finally, the applicant argues that the Directive is vitiated by breach of procedural rules in that it gives no indication that the Commission's proposal was adopted by a college of members on the basis of a text available in all the official languages.

83 The Council takes the view that this plea is inadmissible in so far as the applicant does not make clear whether it relates to the original proposal or the amended proposal of the Commission and furnishes no evidence in support of its plea.

84 However, since the Directive states, in the preamble, that it concerns 'the Commission proposal', referring in a footnote to the editions of the *Official Journal of the European Communities* of 8 October 1996 and 11 October 1997, the plea must be taken to concern both the proposal for a directive 96/C 296/03 submitted by the Commission on 25 January 1996 (OJ 1996 C 296, p. 4), and the amended proposal for a directive 97/C 311/05 submitted by the Commission on 29 August 1997 (OJ 1997 C 311, p. 12). The plea is also sufficiently clear for the Court to be able to understand its scope.

85 After the Commission had provided, in its statement in intervention, information to establish that the principle of collegiality and the rules regarding languages applicable to its deliberations had been respected, the applicant explained that its plea did not allege breach of the principle of collegiality as such but the lack of any apparent proof, in the wording of the Directive, that the principle was respected.

- 86 In that regard, the obligation to state reasons for directives under Article 190 of the EC Treaty (now Article 253 EC) does not extend to a requirement that the signatures on proposals and opinions mentioned in that article must include a summary of the facts to establish that each of the institutions involved in the legislative procedure observed its procedural rules.
- 87 Furthermore, it is only where there is serious doubt as to whether the procedure prior to its intervention was followed properly that an institution is justified in investigating the matter. It has not been established, or even alleged, that the Parliament or the Council had valid reasons for believing that the Commission's examination of its proposal did not follow the proper procedures in this case.
- 88 The sixth plea, and the application in its entirety, must, therefore, be rejected.

Costs

- 89 Under Article 69(2) of the Rules of Procedure, the unsuccessful party is to be ordered to pay the costs if they have been applied for in the successful party's pleadings. Since the Parliament and the Council have applied for an order that the Kingdom of the Netherlands bear the costs and it has been unsuccessful, it must be ordered to pay the costs.
- 90 Pursuant to the first and second subparagraphs of Article 69(4) of those rules, the Italian Republic, the Kingdom of Norway and the Commission, which have intervened in the proceedings, are to bear their own costs.

On those grounds,

THE COURT

hereby:

1. Dismisses the application;
2. Orders the Kingdom of the Netherlands to bear the costs;
3. Orders the Italian Republic, the Kingdom of Norway and the Commission of the European Communities each to bear their own costs.

| | | | |
|--------------------|------------|-----------------|-------|
| Rodríguez Iglesias | Jann | Macken | |
| Colneric | von Bahr | Gulmann | |
| Edward | La Pergola | Puissochet | Sevón |
| Wathelet | Skouris | Cunha Rodrigues | |

Delivered in open court in Luxembourg on 9 October 2001.

R. Grass

Registrar

G.C. Rodríguez Iglesias

President



TEXTS ADOPTED

P8_TA(2015)0473

Patents and plant breeders' rights

European Parliament resolution of 17 December 2015 on patents and plant breeders' rights (2015/2981(RSP))

The European Parliament,

- having regard to its resolution of 10 May 2012 on the patenting of essential biological processes¹,
- having regard to Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions², in particular Article 4 thereof, which states that products obtained from essentially biological processes shall not be patentable,
- having regard to the European Patent Convention (EPC) of 5 October 1973, in particular Article 53(b) thereof,
- having regard to the decision of the Enlarged Board of Appeal of the European Patent Office (EPO) of 25 March 2015 in Cases G2/12 (on tomatoes) and G2/13 (on broccoli),
- having regard to the Implementing Regulations to the EPC, in particular Rule 26 thereof, which states that for European patent applications and patents concerning biotechnological inventions Directive 98/44/EC is to be used as a supplementary means of interpretation,
- having regard to the International Convention for the Protection of New Varieties of Plants of 2 December 1961, as revised at Geneva on 10 November 1972, 23 October 1978 and 19 March 1991 (hereinafter referred to as the 'UPOV Convention 1991'),
- having regard to Council Regulation (EC) No 2100/94 of 27 July 1994 on Community plant variety rights³ (hereinafter referred to as 'Council Regulation (EC) No 2100/94'), in particular Article 15(c) and (d) thereof,
- having regard to the Council Agreement on a Unified Patent Court of 19 February

¹ OJ C 261 E, 10.9.2013, p. 31.

² OJ L 213, 30.7.1998, p. 13.

³ OJ L 227, 1.9.1994, p. 1.

2013¹ (hereinafter referred to as ‘the UPC Agreement’), in particular Article 27(c) thereof,

- having regard to the Agreement on Trade Related Aspects of Intellectual Property Rights, Including Trade in Counterfeit Goods (TRIPS), in particular Article 27(3) thereof, which states that members may exclude essentially biological processes from patentability,
- having regard to Rules 128(5) and 123(4) of its Rules of Procedure,
- A. whereas access to biological plant material encompassing plant traits is absolutely necessary for boosting innovation and the development of new varieties in order to guarantee global food security, tackle climate change and prevent monopolies within the breeding sector, while at the same time providing more opportunities for SMEs;
- B. whereas intellectual property rights are important in order to safeguard economic incentives for developing new plant products and to deliver competitiveness;
- C. whereas patents on products derived from conventional breeding or on genetic material necessary for conventional breeding may undermine the exclusion established in Article 53(b) of the European Patent Convention and in Article 4 of Directive 98/44/EC;
- D. whereas products obtained from essentially biological processes, such as plants, seeds, native traits and genes, should be excluded from patentability;
- E. whereas plant breeding is an innovative process that has been practised by farmers and farming communities since the birth of agriculture, and whereas unpatented varieties and breeding methods are important for genetic diversity;
- F. whereas Directive 98/44/EC legislates for biotechnological inventions, in particular genetic engineering, but whereas – as indicated in recitals 52 and 53 thereof – it was not the legislator’s intention to allow the patentability of products obtained from essentially biological processes within the scope of the directive;
- G. whereas numerous applications concerning products obtained from essentially biological processes are currently awaiting a decision by the European Patent Office (EPO), and whereas there is therefore an urgent need to clarify the scope and interpretation of Directive 98/44/EC, in particular Article 4 thereof;
- H. whereas Directive 98/44/EC implicitly acknowledges the freedom to use material falling within the scope of a patent for experimental purposes, as follows from Articles 12(3)(b) and 13(3)(b);
- I. whereas the exemption for breeders provided for in Article 27(c) of the UPC Agreement will only be applicable to patents granted under the unitary patent system and will not automatically apply to national patents within the EU, which will result in a non-harmonised situation as regards the possibility of breeding with material obtained from essentially biological processes falling under the scope of a patent;
- J. whereas it is a fundamental principle of the international system of plant variety rights

¹ OJ C 175, 20.6.2013, p. 1.

based on the UPOV Convention 1991, and of the EU system based on Council Regulation (EC) No 2100/94, that the holder of a plant variety right cannot prevent others from using the protected plant for further breeding activities;

1. Expresses its concern that the recent decision of the Enlarged Board of Appeal of the EPO on Cases G2/12 (tomatoes) and G2/13 (broccoli) could lead to more patents being granted by the EPO in respect of natural traits introduced into new varieties by means of essentially biological processes such as crossing and selection;
2. Calls on the Commission, as a matter of urgency, to clarify the scope and interpretation of Directive 98/44/EC, and in particular Articles 4, 12(3)(b) and 13(3)(b) thereof, in order to ensure legal clarity regarding the prohibition of the patentability of products obtained from essentially biological processes, and to clarify that breeding with biological material falling under the scope of a patent is permitted;
3. Calls on the Commission to communicate its forthcoming clarification regarding the patentability of products obtained from essentially biological processes to the EPO so that it can be used as a supplementary means of interpretation;
4. Calls on the Commission and the Member States to ensure that the Union will safeguard guaranteed access to, and use of, material obtained from essentially biological processes for plant breeding, in order – where applicable – not to interfere with practices guaranteeing breeders' exemption;
5. Calls on the Commission to pursue the exclusion from patentability of essentially biological processes in the context of multilateral patent law harmonisation discussions;
6. Calls on the Commission to report on the development and implications of patent law in the field of biotechnology and genetic engineering, as required in Article 16(c) of Directive 98/44/EC and as requested by Parliament in its resolution of 10 May 2012 on the patenting of essential biological processes;
7. Instructs its President to forward this resolution to the Council, the Commission and the European Patent Office.



Plenary sitting

**B8-1394/2015 }
B8-1395/2015 }
B8-1399/2015 }
B8-1400/2015 } RC1**

15.12.2015

JOINT MOTION FOR A RESOLUTION

pursuant to Rules 128(5) and 123(4) of the Rules of Procedure

replacing the motions by the following groups:

PPE (B8-1394/2015)

S&D (B8-1395/2015)

ECR (B8-1399/2015)

ALDE (B8-1400/2015)

on patents and plant breeders' rights
(2015/2981(RSP))

Albert Deß, Tadeusz Zwiefka, Annie Schreijer-Pierik

on behalf of the PPE Group

Paolo De Castro, Evelyn Regner

on behalf of the S&D Group

James Nicholson, Bas Belder, Janusz Wojciechowski, Beata Gosiewska,

Zbigniew Kuźmiuk, Jadwiga Wiśniewska

on behalf of the ECR Group

Jan Huitema, Jean-Marie Cavada

on behalf of the ALDE Group

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PE574.464v01-00 }
PE574.465v01-00 }
PE574.469v01-00 }
PE574.470v01-00 } RC1

European Parliament resolution on patents and plant breeders' rights (2015/2981(RSP))

The European Parliament,

- having regard to its resolution of 10 May 2012 on the patenting of essential biological processes¹,
 - having regard to Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions², in particular Article 4 thereof, which states that products obtained from essentially biological processes shall not be patentable,
 - having regard to the European Patent Convention (EPC) of 5 October 1973, in particular Article 53(b) thereof,
 - having regard to the decision of the Enlarged Board of Appeal of the European Patent Office (EPO) of 25 March 2015 in Cases G2/12 (on tomatoes) and G2/13 (on broccoli),
 - having regard to the Implementing Regulations to the EPC, in particular Rule 26 thereof, which states that for European patent applications and patents concerning biotechnological inventions Directive 98/44/EC is to be used as a supplementary means of interpretation,
 - having regard to the International Convention for the Protection of New Varieties of Plants of 2 December 1961, as revised at Geneva on 10 November 1972, 23 October 1978 and 19 March 1991 (hereinafter referred to as the 'UPOV Convention 1991'),
 - having regard to Council Regulation (EC) No 2100/94 of 27 July 1994 on Community plant variety rights³ (hereinafter referred to as 'Council Regulation (EC) No 2100/94'), in particular Article 15(c) and (d) thereof,
 - having regard to the Council Agreement on a Unified Patent Court of 19 February 2013⁴ (hereinafter referred to as 'the UPC Agreement'), in particular Article 27(c) thereof,
 - having regard to the Agreement on Trade Related Aspects of Intellectual Property Rights, Including Trade in Counterfeit Goods (TRIPS), in particular Article 27(3) thereof, which states that members may exclude essentially biological processes from patentability,
 - having regard to Rules 128(5) and 123(4) of its Rules of Procedure,
- A. whereas access to biological plant material encompassing plant traits is absolutely necessary for boosting innovation and the development of new varieties in order to guarantee global food security, tackle climate change and prevent monopolies within the breeding sector, while at the same time providing more opportunities for SMEs;

¹ OJ C 261 E, 10.9.2013, p. 31.

² OJ L 213, 30.7.1998, p. 13.

³ OJ L 227, 1.9.1994, p. 1.

⁴ OJ C 175, 20.6.2013, p. 1.

- B. whereas intellectual property rights are important in order to safeguard economic incentives for developing new plant products and to deliver competitiveness;
 - C. whereas patents on products derived from conventional breeding or on genetic material necessary for conventional breeding may undermine the exclusion established in Article 53(b) of the European Patent Convention and in Article 4 of Directive 98/44/EC;
 - D. whereas products obtained from essentially biological processes, such as plants, seeds, native traits and genes, should be excluded from patentability;
 - E. whereas plant breeding is an innovative process that has been practised by farmers and farming communities since the birth of agriculture, and whereas unpatented varieties and breeding methods are important for genetic diversity;
 - F. whereas Directive 98/44/EC legislates for biotechnological inventions, in particular genetic engineering, but whereas – as indicated in recitals 52 and 53 thereof – it was not the legislator’s intention to allow the patentability of products obtained from essentially biological processes within the scope of the directive;
 - G. whereas numerous applications concerning products obtained from essentially biological processes are currently awaiting a decision by the European Patent Office (EPO), and whereas there is therefore an urgent need to clarify the scope and interpretation of Directive 98/44/EC, in particular Article 4 thereof;
 - H. whereas Directive 98/44/EC implicitly acknowledges the freedom to use material falling within the scope of a patent for experimental purposes, as follows from Articles 12(3)(b) and 13(3)(b);
 - I. whereas the exemption for breeders provided for in Article 27(c) of the UPC Agreement will only be applicable to patents granted under the unitary patent system and will not automatically apply to national patents within the EU, which will result in a non-harmonised situation as regards the possibility of breeding with material obtained from essentially biological processes falling under the scope of a patent;
 - J. whereas it is a fundamental principle of the international system of plant variety rights based on the UPOV Convention 1991, and of the EU system based on Council Regulation (EC) No 2100/94, that the holder of a plant variety right cannot prevent others from using the protected plant for further breeding activities;
1. Expresses its concern that the recent decision of the Enlarged Board of Appeal of the EPO on Cases G2/12 (tomatoes) and G2/13 (broccoli) could lead to more patents being granted by the EPO in respect of natural traits introduced into new varieties by means of essentially biological processes such as crossing and selection;
 2. Calls on the Commission, as a matter of urgency, to clarify the scope and interpretation of Directive 98/44/EC, and in particular Articles 4, 12(3)(b) and 13(3)(b) thereof, in order to ensure legal clarity regarding the prohibition of the patentability of products obtained from essentially biological processes, and to clarify that breeding with biological material falling under the scope of a patent is permitted;

3. Calls on the Commission to communicate its forthcoming clarification regarding the patentability of products obtained from essentially biological processes to the EPO so that it can be used as a supplementary means of interpretation;
4. Calls on the Commission and the Member States to ensure that the Union will safeguard guaranteed access to, and use of, material obtained from essentially biological processes for plant breeding, in order – where applicable – not to interfere with practices guaranteeing breeders' exemption;
5. Calls on the Commission to pursue the exclusion from patentability of essentially biological processes in the context of multilateral patent law harmonisation discussions;
6. Calls on the Commission to report on the development and implications of patent law in the field of biotechnology and genetic engineering, as required in Article 16(c) of Directive 98/44/EC and as requested by Parliament in its resolution of 10 May 2012 on the patenting of essential biological processes;
7. Instructs its President to forward this resolution to the Council, the Commission and the European Patent Office.



EUROPEAN PARLIAMENT

2009 - 2014

Plenary sitting

2.5.2012

B7-0228/2012

MOTION FOR A RESOLUTION

to wind up the debate on the statement by the Commission

pursuant to Rule 110(2) of the Rules of Procedure

on the patenting of essential biological processes
(2012/2623(RSP))

Klaus-Heiner Lehne, Tadeusz Zwiefka, Martin Kastler, Peter Liese

on behalf of the PPE Group

Evelyne Gebhardt, Luigi Berlinguer, Sylvie Guillaume, Evelyn Regner,

Lidia Joanna Geringer de Oedenberg, Françoise Castex

on behalf of the S&D Group

Cecilia Wikström, Corinne Lepage

on behalf of the ALDE Group

Martin Häusling, Margrete Auken

on behalf of the Verts/ALE Group

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PE486.802v01-00

EN

United in diversity

EN

B7-0228/2012

**European Parliament resolution on the patenting of essential biological processes
(2012/2623(RSP))**

The European Parliament,

- having regard to Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions¹ (hereinafter referred to as ‘Directive 98/44’), and in particular Article 4 thereof, which states that plant and animal varieties and essentially biological processes for the production of plants or animals shall not be patentable,
- having regard to Article 2(2) and Recital 33 of Directive 98/44/EC, stating 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,
- having regard to the importance of the proper implementation of Article 11 of Directive 98/44, ensuring a farmer’s privilege,
- having regard to the Convention of 5 October 1973 on the Grant of European Patents (hereinafter referred to as the ‘European Patent Convention’) and Article 53(b) thereof,
- having regard to the decision of the Administrative Council of the European Patent Organisation of 16 June 1999 concerning the incorporation of Directive 98/44 into the Implementing Regulations to the European Patent Convention²,
- having regard to Decision G2/06 of the European Patent Office (EPO) and Decision C-34/10 of the European Court of Justice, establishing that when interpreting prohibitions in patent law one has to take into account the technical teaching of the application as a whole and not only the wording of the claims,
- having regard to Decisions G2/07 (on broccoli) and G1/08 (on tomatoes) of the Enlarged Board of Appeal of the EPO, which in principle exclude a breeding process from patentability,
- having regard to the patents granted by the EPO for the production of conventionally bred plants such as broccoli (EP 1069819), tomatoes (EP 1211926) and melons (EP 1962578),
- having regard to the patents granted by the EPO for the production of conventionally bred animals, such as sex selection and breeding material used in conventional breeding (EP 1263521, EP 1257168), selection of dairy cows (EP 1330552) and livestock production (EP 1506316),
- having regard to the International Treaty on Plant Genetic Resources for Food and Agriculture, to which the European Union adhered pursuant to Council

¹ OJ L 213, 30.7.1998, p. 13.

² Official Journal EPO 7/1999.

Decision 2004/869/EC³,

- having regard to the International Convention of 2 December 1961 for the Protection of New Varieties of Plants, as revised at Geneva on 10 November 1972, 23 October 1978 and 19 March 1991 (hereinafter referred to as the ‘UPOV Convention’),
 - having regard to Council Regulation (EC) No 2100/94 of 27 July 1994 on Community plant variety rights⁴ (hereinafter referred to as ‘Regulation (EC) No 2100/94’),
 - having regard to Rule 110(2) of its Rules of Procedure,
- A. whereas intellectual property rights are of importance for stimulating the development of new plant varieties and plant-related innovations, and are a necessary prerequisite for boosting growth and innovation and helping European business, in particular small and medium-sized enterprises (SMEs), to face the economic crisis and global competition;
- B. whereas, especially in the area of breeding, excessively broad patent protection can hamper innovation and progress and become detrimental to small and medium breeders by blocking access to animal and plant genetic resources;
- C. whereas the breeding of plants is an essential prerequisite for the security of the food supply and, to some extent, of the energy supply;
- D. whereas conventional breeding methods are of critical importance to modern plant and animal breeding;
- E. whereas it is a fundamental principle of the international system of plant variety rights based upon the UPOV Convention, and of the EU system based upon Council Regulation (EC) No 2100/94, that the holder of a plant variety cannot prevent others from using the protected plant to promote use of protected varieties for further breeding activities;
- F. whereas it is important that a similar privilege should exist within patent law throughout the European Union;
- G. whereas Article 4 of Directive 98/44/EC and Article 53(b) of the European Patent Convention establish that plant and animal varieties and essentially biological processes for the production of plants or animals shall not be patentable;
- H. whereas patents on products derived from conventional breeding or on genetic material necessary for conventional breeding can undermine the exclusion established in Article 4 of Directive 98/44 and Article 53(b) of the European Patent Convention;
- I. whereas, in the field of genetic engineering, patents can be granted but the prohibition of patents on plant and animal varieties has to be safeguarded;
- J. whereas, in the field of biotechnology, not only the wording of the claims, but the technical teaching of the invention as a whole should be taken into consideration when

³ OJ L 378, 23.12.2004, p. 1.

⁴ OJ L 227, 1.9.1994, p. 1.

deciding on patentability;

- K. whereas under Article 16(c) of Directive 98/44 the Commission is required to report annually ‘on the development and implications of patent law in the field of biotechnology and genetic engineering’;
- L. whereas the Commission has not published any such reports since 2005;
- M. whereas, in its resolution of 26 October 2005 on patents for biotechnological inventions⁵, Parliament called upon the Commission to address carefully in its next report the proper implementation of Article 4(1)(a) of Directive 98/44;
- N. whereas such Commission reports would serve the purpose of keeping the public fully informed, and whereas the European Union has to play a leading role in encouraging public debate;
1. Acknowledges the important role of the EPO in supporting innovation competitiveness and economic growth in Europe;
 2. Recognises that patents promote the dissemination of valuable technical information and are an important tool for the transfer of technology;
 3. Welcomes the decisions of the Enlarged Board of Appeal of the EPO in the so-called ‘broccoli’ (G 2/07) and ‘tomato’ (G 1/08) cases, dealing with the correct interpretation of the term ‘essentially biological processes for the production of plants (or animals)’ used in Directive 98/44 and the European Patent Convention to exclude such processes from patentability;
 4. Calls on the EPO also to exclude from patenting products derived from conventional breeding and all conventional breeding methods, including SMART breeding (precision breeding) and breeding material used for conventional breeding;
 5. Calls on the Commission to address in its forthcoming report the ‘broccoli and tomato decisions’ of the Enlarged Board of Appeal of the EPO;
 6. Calls on the Commission to address in its forthcoming report the potential implications of the patenting of breeding methods for plants and their impact on the breeding industry, agriculture, the food industry and food security;
 7. Calls on the Commission and the Member States to ensure that the EU will continue to apply a comprehensive breeders’ exemption in its patent law for plant and animal breeding;
 8. Instructs its President to forward this resolution to the Council, the Commission, the governments of the Member States and the EPO.

⁵ OJ C 272E, 9.11.2006, p. 440.

7.5.2012

B7-0228/3

Amendment 3

Tadeusz Zwiefka, Klaus-Heiner Lehne, Martin Kastler, Peter Liese

on behalf of the PPE Group

Evelyne Gebhardt

on behalf of the S&D Group

Martin Häusling, Margrete Auken

on behalf of the Verts/ALE Group

Motion for a resolution

B7-0228/2012

PPE, S&D, ALDE, Verts/ALE

Patenting of essential biological processes

Motion for a resolution

Recital J

Motion for a resolution

Amendment

J. whereas, in the field of biotechnology, not only the wording of the claims, but the technical teaching of the invention as a whole should be taken into consideration when deciding on patentability;

J. whereas, in the field of biotechnology, not only the wording of the claims, but the technical teaching of the invention as a whole should be taken into consideration when deciding on patentability, ***and this principle of whole content approach has been applied by the European Patent Office and the European Court of Justice in some of their recent decisions***¹;

Or. en

¹ *Enlarged Board of Appeal of the European Patent Office, decision of 25 November 2008, G 2/06 (“WARF”), and ECJ judgment C-34/10 (Greenpeace vs. Brüstle).*

7.5.2012

B7-0228/4

Amendment 4

Tadeusz Zwiefka, Klaus-Heiner Lehne, Martin Kastler, Peter Liese

on behalf of the PPE Group

Evelyne Gebhardt

on behalf of the S&D Group

Martin Häusling, Margrethe Auken

on behalf of the Verts/ALE Group

Motion for a resolution

PPE, S&D, ALDE, Verts/ALE

Patenting of essential biological processes

B7-0228/2012

Motion for a resolution

Paragraph 5 a (new)

Motion for a resolution

Amendment

*5a. Welcomes the recent decision of the European Patent Office in the WARF case¹ and of the European Court of Justice in the Brüstle case², as they **appropriately interpret Directive 98/44** and give important indications on the so-called **whole content approach**; calls on the European Commission to draw the appropriate consequences from these decisions also in other relevant policy areas in order to bring EU policy in line with these decisions;*

Or. en

¹ *Enlarged Board of Appeal of the European Patent Office, decision of 25 November 2008, G 2/06 (“WARF”).*

² *ECJ judgement C-34/10.*

Amendment 1**Sajjad Karim**

on behalf of the ECR Group

Motion for a resolution**PPE, S&D, ALDE, Verts/ALE**

Patenting of essential biological processes

B7-0228/2012**Motion for a resolution****Paragraph 3***Motion for a resolution*

3. Welcomes the decisions of the Enlarged Board of Appeal of the EPO in the so-called ‘broccoli’ (G 2/07) and ‘tomato’ (G 1/08) cases, *dealing with the correct interpretation of* the term ‘essentially biological processes for the production of plants (or animals)’ used in Directive 98/44 and the European Patent Convention *to exclude such processes from patentability*;

Amendment

3. Welcomes the decisions of the Enlarged Board of Appeal of the EPO in the so-called ‘broccoli’ (G 2/07) and ‘tomato’ (G 1/08) cases, *concerning* the term ‘essentially biological processes for the production of plants (or animals)’ used in Directive 98/44 and the European Patent Convention, *and notes the need to ensure that an appropriate balance is found between patentability of innovative processes and access to genetic resources*;

Or. en

7.5.2012

B7-0228/2

Amendment 2

Sajjad Karim

on behalf of the ECR Group

Motion for a resolution

PPE, S&D, ALDE, Verts/ALE

Patenting of essential biological processes

B7-0228/2012

Motion for a resolution

Paragraph 3

Motion for a resolution

Amendment

4. *Calls on the EPO* also to exclude from patenting products derived from conventional breeding and all conventional breeding methods, including SMART breeding (precision breeding) and breeding material used for conventional breeding;

deleted

Or. en

Unterrichtung

durch die Bundesregierung

Zweiter Bericht der Bundesregierung über die Auswirkungen des Patentrechts im Bereich der Biotechnologie unter anderem hinsichtlich ausreichender Technizität sowie Auswirkungen im Bereich der Pflanzen- und Tierzüchtung

Inhaltsverzeichnis

| | Seite |
|---|-------|
| 1. Berichtsauftrag und Ergebnis | 2 |
| 2. Die Rechtslage zur Patentierung biotechnologischer Erfindungen | 3 |
| 2.1. Die Rechtslage in der Bundesrepublik Deutschland | 3 |
| 2.2. Die Rechtslage nach dem Europäischen Patentübereinkommen..... | 4 |
| 2.3. Der Rechtsrahmen der Europäischen Union | 4 |
| 2.4. Maßnahmen der Bundesregierung, Einschätzung der Entwicklung auf europäischer Ebene und weitere Schritte..... | 5 |
| 3. Das Biopatent-Monitoring des Bundesministeriums für Ernährung und Landwirtschaft (BMEL) | 6 |
| 3.1. Aufbau und Methode des Biopatent-Monitorings..... | 6 |
| 3.2. Beobachtungswürdige Biopatente..... | 6 |
| 3.3. Ergebnisse | 6 |
| 3.3.1 Zusammenfassung der Ergebnisse des Biopatent-Monitorings des BMEL in den Jahren 2014 und 2015 | 6 |
| 3.3.2 Entwicklungen im Bereich Nutzpflanzen | 7 |
| 3.3.3 Entwicklungen im Bereich Nutztiere | 7 |
| 3.3.4 Statistischer Überblick | 8 |

1. Berichtsauftrag und Ergebnis

Mit dem Beschluss „Keine Patentierung von konventionell gezüchteten landwirtschaftlichen Nutztieren und Nutzpflanzen“ vom 9. Februar 2012 hat der Deutsche Bundestag die Bundesregierung in Ziffer II.5. (siehe Plenarprotokoll 17/158, S. 18979) unter anderem aufgefordert, „ein staatliches Biopatent-Monitoring aufzubauen, um Entwicklungen frühzeitig erkennen zu können, und in diesem Zusammenhang alle zwei Jahre einen Bericht über die Auswirkungen des Patentrechts im Bereich der Biotechnologie unter anderem hinsichtlich ausreichender Technizität sowie Auswirkungen im Bereich der Pflanzen- und Tierzüchtung vorzulegen“. Dieser Beschluss ist auf einen Entschließungsantrag der Fraktionen CDU/CSU, FDP, SPD und BÜNDNIS 90/DIE GRÜNEN vom 17. Januar 2012 (Bundestagsdrucksache 17/8344) hin ergangen.

Am 9. Juli 2014 hat die Bundesregierung den Bericht für den Beobachtungszeitraum 2013 erstmals vorgelegt (Bundestagsdrucksache 18/2119). Hiermit wird der zweite Bericht für den Beobachtungszeitraum 2014 bis 2015 vorgelegt. Wie schon der erste Bericht stellt auch der zweite Bericht die Ergebnisse des vom Bundesministerium für Ernährung und Landwirtschaft (BMEL) in Kooperation mit der Bundesanstalt für Landwirtschaft und Ernährung (BLE) und dem Bundessortenamt (BSA) aufgebauten und durchgeführten Biopatent-Monitorings dar. Das Monitoring erfasst die beim Deutschen Patent- und Markenamt (DPMA) und beim Europäischen Patentamt (EPA) eingegangenen Patentanmeldungen und von diesen Ämtern erteilten Patente.

Der Bericht stellt zur besseren Verständlichkeit des Gesamtzusammenhangs einleitend die Rechtslage für Biopatente nach dem deutschen Patentgesetz sowie nach den geltenden europäischen Rechtsgrundlagen dar, das heißt nach der Richtlinie 98/44/EG des Europäischen Parlaments und des Rates vom 6. Juli 1998 über den rechtlichen Schutz biotechnologischer Erfindungen (Biopatent-Richtlinie; ABl. L 213 vom 6. Juli 1998, S. 13) und nach dem Europäischen Patentübereinkommen (EPÜ) (Abschnitt 2). Darüber hinaus werden die Maßnahmen der Bundesregierung dargestellt und neue Entwicklungen auf europäischer Ebene gewürdigt. So wird insbesondere auf die Entscheidungen der Großen Beschwerdekammer des EPA vom 25. März 2015 zur Patentierbarkeit von aus im Wesentlichen biologischen Verfahren gewonnenen Pflanzen und Tieren (G 2/12 Tomate II und G 2/13 Brokkoli II) eingegangen. Schließlich wird der aktuelle Stand der Aktivitäten auf Ebene der Europäischen Union für eine Klarstellung der Biopatent-Richtlinie dargestellt.

In Abschnitt 3 folgen die zahlenmäßigen Ergebnisse des Monitorings des BMEL für den Beobachtungszeitraum 2014/2015.

Für das Verständnis der vorliegenden Darstellung ist zu berücksichtigen, dass Patentanmeldungen grundsätzlich erst 18 Monate nach ihrer Einreichung bzw. ihrem Prioritätstag von den Patentämtern veröffentlicht und damit erfasst werden können. Dementsprechend werden im Jahr 2015 eingegangene Patentanträge erst von 2016 bis Mitte 2017 veröffentlicht werden.

Es lässt sich festhalten, dass das Aufkommen der vom Monitoring erfassten, für die Landwirtschaft relevanten Biopatente eher gering ist, wenn man die Zahlen des Biopatent-Monitorings in Relation zu der Gesamtzahl der Patentanmeldungen bzw. der Patenterteilungen setzt. Laut den jeweiligen Jahresberichten wurden beim DPMA im Jahr 2014 insgesamt 65 951 Patente angemeldet und 15 317 Patente erteilt. Im Jahr 2015 wurden 66 889 Patente angemeldet und 14 795 Patente erteilt. Beim EPA wurden im Jahr 2014 274 174 Patente angemeldet und 64 613 Patente erteilt. Im Jahr 2015 wurden 278 867 Patente angemeldet und 68 421 Patente erteilt.

Die Zahl der erfassten landwirtschaftlich relevanten erteilten Patente im Berichtszeitraum beträgt für das Jahr 2014 190 und für das Jahr 2015 244. Im Jahr 2013 waren es 208 Patente. Die Zahl der veröffentlichten landwirtschaftlich relevanten Patentanmeldungen betrug im Jahr 2014 391 und im Jahr 2015 375. Im Jahr 2013 waren es 490 Patentanmeldungen.

Im Jahr 2014 wurden im Bereich Nutzpflanzen 142 erteilte Patente und 289 Patentanmeldungen und im Jahr 2015 160 erteilte Patente und 233 Patentanmeldungen identifiziert. Im Jahr 2013 waren es 158 erteilte Patente und 372 Patentanmeldungen. Von den erfassten Patenten und Patentanmeldungen für den Bereich Nutzpflanzen wurden im Jahr 2014 88 Veröffentlichungen als beobachtungswürdig eingestuft, in 2015 waren es 81 Veröffentlichungen. Dies ist ein Rückgang gegenüber dem Jahr 2013, in dem 96 erteilte Patente und Patentanmeldungen als beobachtungswürdig eingestuft wurden (vgl. zum Kriterium „beobachtungswürdig“ unten 3.2.). Im Bereich Nutztiere wurden im Jahr 2014 71 erteilte Patente und 126 Patentanmeldungen und im Jahr 2015 94 erteilte Patente und 159 Patentanmeldungen veröffentlicht. Im Jahr 2013 waren es 63 erteilte Patente und 135 Patentanmeldungen. Im Jahr 2014 wurden im Bereich Nutztiere zwölf erteilte Patente und Patentanmeldungen und im Jahr 2015 acht erteilte Patente und Patentanmeldungen als beobachtungswürdig eingestuft. Im Jahr 2013 waren es sieben erteilte Patente und Patentanmeldungen.

Aus diesen Zahlen, die das Biopatent-Monitoring für die Jahre 2013 bis 2015 ergeben hat, werden bemerkenswerte Entwicklungen nicht ersichtlich. Politischer Handlungsbedarf hat sich jedoch aus den Grundsatzentscheidungen der Großen Beschwerdekammer des Europäischen Patentamtes vom 25. März 2015 in den Verfahren G 2/12 (Tomate II) und G 2/13 (Brokkoli II) ergeben. Die Große Beschwerdekammer hat für den Geltungsbereich des EPÜ einen Patentschutz auch für solche Pflanzen und Tiere bejaht, die durch im Wesentlichen biologische Verfahren gewonnen worden sind. Sie hat damit anders als der deutsche Gesetzgeber im Jahr 2013 entschieden, der mit § 2a des Patentgesetzes (PatG) insoweit einen Patentschutz ausgeschlossen hat. EPÜ und Biopatent-Richtlinie regeln die von der Großen Beschwerdekammer entschiedene Frage nicht ausdrücklich. Die Bundesregierung unterstützt deshalb die am 18. Mai 2016 in Brüssel von der zuständigen EU-Kommissarin Elzbieta Bienkowska verkündete Absicht, baldmöglichst eine „clarifying notice“ zu veröffentlichen. In dieser soll die Intention des europäischen Gesetzgebers im Hinblick auf die Patentierbarkeit von Produkten im Wesentlichen biologischer Züchtungsverfahren erläutert werden. Die Bundesregierung erachtet eine solche Erklärung der Europäischen Kommission – nach Möglichkeit gemeinsam mit dem Europäischen Rat und dem Europäischen Parlament – zur genaueren Auslegung der Patentierungsausnahmen in der Biopatent-Richtlinie für eine geeignete und sinnvolle Maßnahme. Die Bundesregierung wird sich dafür einsetzen, dass die „Notice“ so formuliert wird, wie es der Deutsche Bundestag mit § 2a PatG getan hat, so dass keine Patente auf Pflanzen und Tiere als Produkte im Wesentlichen biologischer Verfahren erteilt werden können. Parallel wird sich die Bundesregierung weiter dafür einsetzen, dass der Patentrechtsausschuss der Europäischen Patentorganisation die Auslegung des EPÜ zur Frage der Erteilung von Patenten auf Pflanzen in weiteren Sitzungen berät, und darauf hinwirken, dass ein abgestimmtes Vorgehen von Europäischer Patentorganisation einerseits sowie der Mitgliedstaaten der Europäischen Union und der Europäischen Kommission andererseits gewährleistet ist

2. Die Rechtslage zur Patentierung biotechnologischer Erfindungen

2.1. Die Rechtslage in der Bundesrepublik Deutschland

Grundsätzlich sind Erfindungen, die sich auf biologisches Material beziehen, patentierbar. Biologisches Material ist jedes Material, das genetische Informationen enthält und sich entweder selbst reproduzieren oder in einem biologischen System reproduziert werden kann (§ 2a Absatz 3 Nummer 1 PatG). Patentrechtlich zulässig ist auch die Patentierung von Pflanzen oder Tieren mit durch Gentechnik oder sonstige technische Verfahren veränderten Eigenschaften. Auch die Früchte bzw. die Folgegenerationen von Tieren können von dem Patentschutz erfasst werden (§ 9a PatG) und entsprechend Lizenzzahlungsverpflichtungen auslösen.

Ausgenommen von der Patentierung sind unter anderem Pflanzensorten und Tierrassen sowie im Wesentlichen biologische Verfahren zur Züchtung von Pflanzen und Tieren und die ausschließlich durch solche Verfahren gewonnenen Pflanzen und Tiere (§ 2a Absatz 1 Nummer 1 PatG, „Patentierungsverbote“). Diese Patentierungsverbote haben folgenden Hintergrund: Es soll grundsätzlich vermieden werden, dass Pflanzensorten als solche durch Sortenschutz und gleichzeitig durch Patentschutz geschützt werden. In der Praxis kann es allerdings durchaus vorkommen, dass Erfindungen an Pflanzen (z. B. Pflanzen mit verbesserten Eigenschaften) patentierbar sind und als Sorte Sortenschutz erhalten können. Ernährungssicherung ist auf steten Zugang zu einem breiten Genpool angewiesen, der auch durch Patente möglichst wenig eingeschränkt werden soll. Patentrechtlich werden Besonderheiten im Bereich der Pflanzenzüchtung durch § 11 Nummer 2a PatG berücksichtigt. Diese Vorschrift erlaubt die Nutzung biologischen Materials zu Züchtungszwecken trotz etwaig bestehender Patente. Lediglich bei der Verwertung der Erzeugnisse der Weiterzüchtung muss das Patentrecht des Erstzüchters berücksichtigt werden.

Bereits nach der früheren Rechtslage war gemäß § 2a Absatz 1 Nummer 1 PatG die Erteilung von Patenten durch das DPMA für „Pflanzensorten, Tierrassen sowie im Wesentlichen biologische Verfahren zur Züchtung von Pflanzen und Tieren“ verboten. Diese Norm wurde in wörtlicher Umsetzung von Artikel 4 Absatz 1 der Biopatent-Richtlinie in das deutsche Patentgesetz aufgenommen.

Der Biopatent-Richtlinie ist nicht eindeutig zu entnehmen, ob auch Pflanzen und Tiere, die ausschließlich durch „im Wesentlichen biologische Verfahren“ gewonnen werden, als Erzeugnisse ebenfalls von der Patentierung ausgenommen sind. Um dem Sinn und Zweck der Biopatent-Richtlinie, herkömmliche Züchtungsverfahren von der Patentierbarkeit auszuschließen, in vollem Umfang Geltung zu verleihen und eine Gesetzesumgehung zum Nachteil der Züchter und Landwirte zu verhindern, hat der Deutsche Bundestag am Ende der letzten Legislaturperiode das deutsche Patentgesetz ergänzt (vgl. BGBl. I 2013, S. 3830). Im Wege einer klarstellenden Konkretisierung der Biopatent-Richtlinie wurde § 2a Absatz 1 Nummer 1 PatG durch das Gesetz zur Novellierung

patentrechtlicher Vorschriften und anderer Gesetze des gewerblichen Rechtsschutzes 2013 dahingehend erweitert, dass auch „die ausschließlich durch solche (im Wesentlichen biologischen) Verfahren gewonnenen Tiere und Pflanzen“ nicht patentiert werden können.

2.2. Die Rechtslage nach dem Europäischen Patentübereinkommen

Für beim EPA eingereichte Patentanmeldungen gilt Artikel 53 Buchstabe b EPÜ, der – wörtlich aus der Biopatent-Richtlinie übernommen – ebenfalls Pflanzensorten, Tierrassen sowie im Wesentlichen biologische Verfahren zur Züchtung von Pflanzen und Tieren von der Patentierbarkeit ausnimmt. Zu der Frage, was genau unter einem nicht patentierbaren „im Wesentlichen biologischen Verfahren“ in Abgrenzung zu patentierbaren technischen Verfahren zu verstehen ist, verkündete die Große Beschwerdekammer des EPA am 9. Dezember 2010 in ihren beiden Leitentscheidungen G 1/08 (Tomate I) und G 2/07 (Brokkoli I), dass die bloße Verwendung technischer Verfahrensschritte zur Durchführung bzw. Unterstützung im Wesentlichen biologischer Verfahren diese nicht patentierbar macht.

Einen ausdrücklichen Patentierungsausschluss von Pflanzen und Tieren, die durch im Wesentlichen biologische Verfahren erzeugt werden, also eine Regelung, die dem ergänzten § 2a PatG entspricht, gibt es im EPÜ nicht. Mit der Frage, wie das EPÜ im Hinblick auf seine Regelungen der Patentierbarkeit von Pflanzen auszulegen ist, hat sich die Große Beschwerdekammer des EPA in den Folgeentscheidungen G 2/12 (Tomate II) und G 2/13 (Brokkoli II) vom 25. März 2015 befasst. Sie entschied anders als der deutsche Gesetzgeber im Jahr 2013 und bejahte im Ergebnis die Möglichkeit eines Patentschutzes auch für solche Pflanzen und Tiere, die durch im Wesentlichen biologische Verfahren gewonnen worden sind. Die Große Beschwerdekammer setzte sich mit allen Argumenten der Verfahrensbeteiligten und auch mit den Argumenten der Verbände und der Vertreter der Zivilgesellschaft auseinander, die als *amicus curiae* zu dem Verfahren Stellung genommen hatten.

Die Große Beschwerdekammer erwähnte auch den ersten Biopatent-Bericht der Bundesregierung, ferner die Entschließung des Europäischen Parlaments zur Patentierung von im Wesentlichen biologischen Verfahren aus dem Jahr 2012 (2012/2623[RSP]), die das EPA aufgefordert hatte, alle Erzeugnisse aus konventioneller Zucht und alle herkömmlichen Zuchtverfahren von der Patentierbarkeit auszuschließen. Hierzu führte die Große Beschwerdekammer aus, die ethischen, sozialen und wirtschaftlichen Argumente des Europäischen Parlaments fielen nicht in die judizielle Entscheidungsgewalt der Großen Beschwerdekammer. Hier sei vielmehr der Gesetzgeber gefordert. Als Beispiele für entsprechende legislatorische Entscheidungen auf nationaler Ebene verwies die Große Beschwerdekammer auf die Rechtslage in Deutschland und in den Niederlanden.

Beim EPA waren 125 Anmelde- bzw. Einspruchsverfahren im Hinblick auf die Entscheidungen der Großen Beschwerdekammer ausgesetzt worden. Diese wurden wieder aufgenommen und werden, sofern noch nicht geschehen, unter Berücksichtigung der von der Großen Beschwerdekammer getroffenen Entscheidungen bearbeitet werden.

2.3. Der Rechtsrahmen der Europäischen Union

Die Biopatent-Richtlinie der Europäischen Union (ABl. L 213 vom 6. Juli 1998, S. 13) gilt unverändert seit 1998. Nach ihrem Artikel 16 Buchstabe c war die Europäische Kommission verpflichtet, ab 2000 jährlich einen Bericht über die Entwicklung und die Auswirkungen des Patentrechts im Bereich der Biotechnologie und der Gentechnik vorzulegen. Mit diesem Bericht soll die Grundlage für eine sachgerechte Beurteilung sowohl von positiven Patentierungseffekten in der Biotechnologie und der Gentechnik als auch von Fehlentwicklungen und einem möglichen gesetzgeberischen Korrekturbedarf geschaffen werden. Dieser Verpflichtung ist die Europäische Kommission jedoch in den letzten Jahren nicht nachgekommen. Ihr zweiter Bericht stammt aus dem Jahr 2005.

Mit Beschluss von 7. November 2012 hat die Europäische Kommission allerdings eine Sachverständigengruppe für die Entwicklungen und Auswirkungen des Patentrechts im Bereich der Bio- und Gentechnologie eingerichtet. Der Bericht der Expertengruppe, der neben dem EPA 14 Experten angehören, darunter die deutsche Professorin Dr. Ingrid Schneider (Universität Hamburg) und Dr. Christoph Then (No Patents on Seeds), ist am 17. Mai 2016 vorgelegt worden und im Internet unter folgendem Link verfügbar:

<http://ec.europa.eu/transparency/regexpert/index.cfm?do=groupDetail.groupDetailDoc&id=23442&no=1>.

Das Europäische Parlament hat die Europäische Kommission in einer im Anschluss an eine erste Entschließung vom 10. Mai 2012 gefassten fraktionsübergreifenden zweiten Entschließung vom 17. Dezember 2015 aufgefor-

dert, als Reaktion auf die Entscheidungen der Großen Beschwerdekammer den Geltungsbereich und die Auslegung der Biopatent-Richtlinie dringend klarzustellen, und diese Klarstellung dem EPA mitzuteilen, damit diese Klarstellung als ergänzendes Auslegungsmittel herangezogen werden kann.

Auf Antrag der Niederlande ist die Patentierung von Pflanzen in den Sitzungen des Europäischen Rats für Landwirtschaft und Fischerei am 13. Juli 2015 und am 22. Oktober 2015 thematisiert worden. Am 18. Mai 2016 hat die niederländische Ratspräsidentschaft in Zusammenarbeit mit der Europäischen Kommission ein Symposium veranstaltet zu Fragen, die durch die Entscheidungen der Großen Beschwerdekammer aufgeworfen werden.

Die zuständige Kommissarin für Binnenmarkt, Industrie, Unternehmertum und KMU, Frau Elżbieta Bieńkowska, fasste in einem Schlusswort das Ergebnis der Konferenz zusammen und erklärte, die Europäische Kommission beabsichtige, als kurzfristig zu realisierende Maßnahme im 4. Quartal 2016 eine „clarifying notice“ zu veröffentlichen, in der die Intention des europäischen Gesetzgebers im Hinblick auf die Patentierbarkeit von Produkten im Wesentlichen biologischer Züchtungsverfahren erläutert werden soll. Sie machte deutlich, dass die Europäische Kommission entsprechend der Mehrheit der Stellungnahmen bei der Konferenz nicht beabsichtige, die Biopatent-Richtlinie zu ändern. Die Europäische Kommission werde darüber hinaus weitere Maßnahmen zur Verbesserung der Transparenz bei der Lizenzierung von Patenten im Biotechnologie-Sektor ergreifen. Darüber hinaus befürwortete sie eine engere Zusammenarbeit und einen intensiveren Austausch zwischen Europäischem Patentamt und dem Europäischen Sortenamts (Community Plant Variety Office).

Im Internet sind weitere Informationen zu dieser Konferenz unter dem Titel „Finding the Balance – Die Suche nach einer ausgewogenen Lösung in der Debatte über das Patent- und Sortenschutzrecht“ unter folgendem Link verfügbar:

<http://deutsch.eu2016.nl/kalender/2016/05/18/finding-the-balance-%E2%80%93-die-suche-nach-einer-ausgewogenen-losung-in-der-debatte-uber-das-patent--und-sortenschutzrecht>.

2.4. Maßnahmen der Bundesregierung, Einschätzung der Entwicklung auf europäischer Ebene und weitere Schritte

Angesichts des klaren Votums der Großen Beschwerdekammer des Europäischen Patentamtes ist es keine einfache Aufgabe für die Bundesregierung, entsprechend der Koalitionsvereinbarung auf eine Präzisierung des europäischen Rechtsrahmens in dem Sinne hinzuwirken, wie dies der deutsche Gesetzgeber im Jahr 2013 geregelt hat. Das Bundesministerium der Justiz und für Verbraucherschutz (BMJV) und das BMEL haben im Berichtszeitraum in zahlreichen Gesprächen mit beteiligten Kreisen, Sachverständigen und mit Vertretern anderer Mitgliedstaaten der Europäischen Union Gestaltungsspielräume ausgelotet. In den Gesprächen befürwortete keiner der Vertreter oder Sachverständigen eine Änderung der Biopatent-Richtlinie. Vielmehr wurde einvernehmlich als nächster Schritt eine Maßnahme unterhalb der Schwelle einer legislativen Intervention befürwortet. Dementsprechend hat das BMJV auch in bilateralen Gesprächen mit der Europäischen Kommission für eine entsprechende Lösung geworben. Vor diesem Hintergrund ist das weitere Vorgehen, das die Europäische Kommission auf dem Symposium der niederländischen Ratspräsidentschaft angekündigt hat, aus Sicht der Bundesregierung grundsätzlich zu begrüßen. Das BMJV und das BMEL werden sich in weiteren bilateralen Gesprächen mit der Europäischen Kommission dafür einsetzen, dass in der angekündigten „clarifying notice“ der Europäischen Kommission, die nach Auffassung der Bundesregierung auch vom Europäischen Rat und dem Europäischen Parlament mitgetragen werden sollte, ein Verständnis der Biopatent-Richtlinie in dem Sinne formuliert wird, wie es der Deutsche Bundestag mit § 2a PatG zum Ausdruck gebracht hat, das heißt, dass keine Patente auf Pflanzen und Tiere als Produkte im Wesentlichen biologischer Verfahren erteilt werden können. Das BMJV wird sich für dieses Ziel auch im Rahmen der neu eingerichteten Arbeitsgruppe von Experten der Mitgliedstaaten im Bereich des gewerblichen Rechtsschutzes (Expert Group on Industrial Property Policy – GIPP) einsetzen, die die Europäische Kommission vor Kurzem eingerichtet hat.

Parallel wird sich die Bundesregierung weiter dafür einsetzen, dass der Patentrechtsausschuss der Europäischen Patentorganisation die Auslegung des EPÜ zur Frage der Erteilung von Patenten auf Pflanzen im Anschluss an eine erste Sitzung im Mai 2016 in weiteren Sitzungen berät, und darauf hinwirken, dass ein abgestimmtes Vorgehen von Europäischer Patentorganisation einerseits sowie der Mitgliedstaaten der Europäischen Union und der Europäischen Kommission andererseits gewährleistet ist.

3. Das Biopatent-Monitoring des Bundesministeriums für Ernährung und Landwirtschaft (BMEL)

3.1. Aufbau und Methode des Biopatent-Monitorings

Das BMEL beauftragte die BLE und das BSA mit der Durchführung des Biopatent-Monitorings für den Bereich Landwirtschaft. Für die Patentrecherchen im Bereich Nutzpflanzen ist das BSA zuständig. Die BLE führt Patentrecherchen für den Bereich Nutztiere durch. Der BLE obliegt zudem die Koordination der Rechercheergebnisse.

Das Biopatent-Monitoring erfolgt in folgenden Arbeitsschritten:

a) Erfassung der für die Landwirtschaft relevanten Patente und Patentanmeldungen

Vom Biopatent-Monitoring erfasst werden die veröffentlichten erteilten Patente und Patentanmeldungen, die in Deutschland wirksam sind oder werden können. Diese werden beim DPMA, weit überwiegend jedoch beim EPA eingereicht und entsprechend von diesen Ämtern erteilt. Die Patentrecherche erfolgt auf Basis der von den Patentämtern veröffentlichten Patent- und Offenlegungsschriften. Hierzu nutzt das BSA die Rechercheoberfläche der Patentdatenbank Thomson Innovation, die BLE die Rechercheoberflächen von DEPATISnet und Espacenet.

Der Schwerpunkt der Beobachtung liegt bei erteilten Patenten, da Auswirkungen auf Landwirtschaft und Züchtung lediglich von erteilten Biopatenten ausgehen können. Eine Einflussnahme auf einzelne Patenterteilungsverfahren erfolgt nicht.

Geprüft werden soll, ob aufgrund von Entwicklungen in längeren Zeiträumen gesetzgeberischer Handlungsbedarf für weitere Beschränkungen der Patentierbarkeit besteht. Der Zugang von Züchtern zu genetischen Ressourcen im Hinblick auf die konsequent erforderliche züchterische Weiterentwicklung von Pflanzensorten und Tierrassen ist für die Landwirtschaft außerordentlich wichtig. Wichtig ist allerdings auch, dass innovative Forscher und Züchter und entsprechende Unternehmen ihre Erfindungen auch auf diesem Gebiet angemessen schützen können.

b) Charakterisierung der relevanten Biopatente und Eingabe in eine Datenbank

Es wurde eine Datenbank aufgebaut, in der die Daten der aus dem Blickwinkel von Landwirtschaft und Züchtungswesen relevanten und von der BLE und dem BSA als einschlägig charakterisierten Biopatente und Biopatentanmeldungen nach festgelegten Kriterien gespeichert werden. Neben patentrechtlich einschlägigen Kriterien (Anspruchskategorien) werden beim Monitoring erfasste Patente und Patentanmeldungen hinsichtlich landwirtschaftlich-fachlicher Kriterien zugeordnet. So werden bei Nutztieren die Bereiche Tierzüchtung, Tiergesundheit, Tierernährung und Tierhaltung unterschieden. Die Datenbank soll auch Auswertungen zur Darstellung von Entwicklungen über einen mehrjährigen Zeitraum hinweg ermöglichen.

3.2 Beobachtungswürdige Biopatente

Patentanmeldungen und erteilte Patente wurden als beobachtungswürdig eingestuft, wenn die Möglichkeit eines Patentierungsverbots gemäß Patentgesetz besteht.

Dies ist der Fall, wenn im Wesentlichen biologische Verfahren oder hierdurch gewonnene Erzeugnisse beansprucht werden und umfasst auch die (Züchtungs-)Verfahren Heterosis-/ Hybridzüchtung, auf Marker-gestützter Selektion aufbauende Präzisionszüchtung und auf Mutagenese basierende Mutationszüchtung, da diese vollständig oder zum Teil auf den im Wesentlichen biologischen Verfahrensschritten der Kreuzung und der Selektion beruhen.

3.3. Ergebnisse

3.3.1 Zusammenfassung der Ergebnisse des Biopatent-Monitorings des BMEL in den Jahren 2014 und 2015

Im Jahr 2014 erteilte das EPA im Bereich Nutzpflanzen 142 Biopatente und im Bereich Nutztiere 71 Biopatente. Im Jahr 2015 waren es 160 Biopatente im Bereich Nutzpflanzen und 94 Biopatente im Bereich Nutztiere. Dies liegt in der Größenordnung des Jahres 2013, in dem 158 Biopatente im Bereich Nutzpflanzen und 62 Biopatente im Bereich Nutztiere vom EPA erteilt wurden. Das DPMA erteilte im Berichtszeitraum 2014/2015 lediglich ein Biopatent im Jahr 2014 für den Bereich Nutzpflanzen und keines für den Bereich Nutztiere. Im Jahr 2013 hatte das DPMA kein Biopatent im Bereich Nutzpflanzen und ein Biopatent im Bereich Nutztiere erteilt. Im Jahr

2015 erteilte das DPMA kein Biopatent mit landwirtschaftlicher Relevanz. 286 Patentanmeldungen im Bereich Nutzpflanzen und 119 Patentanmeldungen im Bereich Nutztiere wurden vom EPA im Jahr 2014 bzw. 229 Patentanmeldungen im Bereich Nutzpflanzen und 156 Patentanmeldungen im Bereich Nutztiere im Jahr 2015 veröffentlicht. Im Jahr 2013 wurden 369 Patentanmeldungen im Bereich Nutzpflanzen und 125 Patentanmeldungen im Bereich Nutztiere beim EPA veröffentlicht. Beim DPMA waren es drei Patentanmeldungen im Bereich Nutzpflanzen und sieben Patentanmeldungen im Bereich Nutztiere im Jahr 2014 und vier im Bereich Nutzpflanzen und drei im Bereich Nutztiere im Jahr 2015. Im Jahr 2013 betrug die Anzahl landwirtschaftlich relevanter Biopatentanmeldungen beim DPMA drei im Bereich Nutzpflanzen und zehn im Bereich Nutztiere.

Der überwiegende Anteil der vom Biopatent-Monitoring erfassten Patente und Patentanmeldungen beim EPA und beim DPMA betrifft die Herstellung oder Verwendung von gentechnisch veränderten Organismen (GVO). Im Bereich Nutzpflanzen sind dies knapp 90 Prozent der erteilten Patente und knapp 80 Prozent der Patentanmeldungen (Abbildung 3). Im Bereich Nutztiere beruhen knapp 50 Prozent sowohl der Patentanmeldungen als auch der erteilten Patente auf GVO (Abbildung 4).

3.3.2 Entwicklungen im Bereich Nutzpflanzen

Im Jahr 2014 wurden im Bereich Nutzpflanzen 142 erteilte Patente (141 beim EPA, 1 beim DPMA) und 289 Patentanmeldungen (286 beim EPA, 3 beim DPMA) identifiziert, im Jahr 2015 waren es 160 erteilte Patente (160 beim EPA, 0 beim DPMA) und 233 Patentanmeldungen (229 beim EPA, 4 beim DPMA) (Tabelle 1). Damit sind die Zahlen im Vergleich zum ersten Berichtszeitraum vor allem bei den Patentanmeldungen leicht gesunken. Im Jahr 2013 waren es noch 158 erteilte Patente (158 beim EPA, 0 beim DPMA) und 372 Patentanmeldungen (369 beim EPA, 3 beim DPMA) (Abbildung 1).

Von den erfassten Patenten und Patentanmeldungen für den Bereich Nutzpflanzen wurden im Jahr 2014 5 erteilte Patente (5 beim EPA, 0 beim DPMA) und 83 Patentanmeldungen (82 beim EPA, 1 beim DPMA) als beobachtungswürdig eingestuft, in 2015 waren es 12 erteilte Patente (12 beim EPA, 0 beim DPMA) und 69 Patentanmeldungen (68 beim EPA, 1 beim DPMA). Dies entspricht in etwa den Zahlen des Jahres 2013, in dem 17 erteilte Patente (17 beim EPA, 0 beim DPMA) und 79 Patentanmeldungen (79 beim EPA, 0 beim DPMA) als beobachtungswürdig eingestuft wurden (Abbildung 5).

Maßgeblich für die Beobachtung ist der Sachverhalt, dass konventionelle Züchtungsmethodik basierend auf den „im Wesentlichen biologischen Verfahren“ der Kreuzung und der Selektion gegebenenfalls in Kombination mit labortechnischen Schritten zur Beschleunigung des Züchtungsfortschritts direkt oder indirekt beansprucht wird (vgl. Kapitel 2.3 und 3.2).

3.3.3 Entwicklungen im Bereich Nutztiere

Im Jahr 2014 wurden im Bereich Nutztiere 71 Patente (71 beim EPA, 0 beim DPMA) erteilt und 126 Patentanmeldungen (119 beim EPA, 7 beim DPMA) veröffentlicht. Im Jahr 2015 waren es 94 erteilte Patente (94 beim EPA, 0 beim DPMA) und 159 Patentanmeldungen (156 beim EPA, 3 beim DPMA) (Tabelle 2). Im Jahr 2013 wurden 63 erteilte Patente (62 beim EPA, 1 beim DPMA) und 135 Patentanmeldungen (125 beim EPA, 10 beim DPMA) veröffentlicht (Abbildung 2).

Im Jahr 2014 wurde kein erteiltes Patent nach den in Abschnitt 3.2 beschriebenen Kriterien als beobachtungswürdig eingestuft, jedoch 12 Patentanmeldungen (12 beim EPA, 0 beim DPMA) und im Jahr 2015 1 erteiltes Patent (1 beim EPA, 0 beim DPMA) sowie sieben Patentanmeldungen (7 beim EPA, 0 beim DPMA). Im Jahr 2013 waren es 4 erteilte Patente (4 beim EPA, 0 beim DPMA) und 3 Patentanmeldungen (3 beim EPA, 0 beim DPMA) (Abbildung 6).

Der überwiegende Teil der identifizierten erteilten Patente und Patentanmeldungen im Bereich Nutztiere betraf veterinärmedizinische Anwendungen, wie z. B. Nachweisverfahren für Krankheitserreger oder die Entwicklung von Impfstoffen. Diesem Anwendungsgebiet wurden in den Jahren 2014 und 2015 36 erteilte Patente (36 beim EPA, 0 beim DPMA) und 64 Patentanmeldungen (62 beim EPA, 2 beim DPMA) bzw. 45 erteilte Patente (45 beim EPA, 0 beim DPMA) und 82 Patentanmeldungen (81 beim EPA, 1 beim DPMA) zugeordnet. Im Jahr 2013 waren es 34 erteilte Patente (34 beim EPA, 0 beim DPMA) und 82 Patentanmeldungen (78 beim EPA, 4 beim DPMA). Auf die Tierzucht im engeren Sinne entfielen im Jahr 2014 6 erteilte Patente (6 beim EPA, 0 beim DPMA) und 16 Patentanmeldungen (14 beim EPA, 2 beim DPMA) und im Jahr 2015 30 erteilte Patente (30 beim EPA, 0 beim DPMA) und 41 Patentanmeldungen (40 beim EPA, 1 beim DPMA). Im Jahr 2013 waren es 14 erteilte Patente (14 beim EPA, 0 beim DPMA) und 25 Patentanmeldungen (22 beim EPA, 3 beim DPMA).

Auch das Anwendungsgebiet Tierernährung, bei dem vorherrschend Verfahren zur Herstellung von überwiegend pflanzlichen Futtermitteln Gegenstand der Erfindung waren, nahm noch einen größeren Anteil ein. Im Jahr 2014 wurden hier 21 erteilte Patente (21 beim EPA, 0 beim DPMA) sowie 26 Patentanmeldungen (25 beim EPA, 1 beim DPMA) und im Jahr 2015 6 erteilte Patente (6 beim EPA, 0 beim DPMA) und 23 Patentanmeldungen (23 beim EPA, 0 beim DPMA) veröffentlicht. Zuvor waren es 13 erteilte Patente (13 beim EPA, 0 beim DPMA) und 21 Patentanmeldungen (19 beim EPA, 2 beim DPMA) im Jahr 2013. Im Anwendungsgebiet Tierhaltung (einschließlich Aquakultur und nicht-aquatische Wirbellose, z. B. Bestäuber) werden nur sehr wenige Patente angemeldet und erteilt. (Abbildungen 7 und 8).

3.3.4 Statistischer Überblick

Tabelle 1

Anzahl der im Biopatent-Monitoring für den Bereich Nutzpflanzen erfassten Patente und Patentanmeldungen

| Merkmal | Anzahl Patentveröffentlichungen im Bereich Pflanze | | | |
|---------------------------|--|-------------------|------------------|-------------------|
| | 2014 | | 2015 | |
| | Erteilte Patente | Patentanmeldungen | Erteilte Patente | Patentanmeldungen |
| Gesamt | 142 | 289 | 160 | 233 |
| dav. beim DPMA angemeldet | 1 | 3 | 0 | 4 |
| dav. beim EPA angemeldet | 141 | 286 | 160 | 229 |

Tabelle 2

Anzahl der im Biopatent-Monitoring für den Bereich Nutztiere erfassten Patente und Patentanmeldungen

| Merkmal | Anzahl Patentveröffentlichungen im Bereich Tier | | | |
|---------------------------|---|-------------------|------------------|-------------------|
| | 2014 | | 2015 | |
| | Erteilte Patente | Patentanmeldungen | Erteilte Patente | Patentanmeldungen |
| Gesamt | 71 | 126 | 94 | 159 |
| dav. beim DPMA angemeldet | 0 | 7 | 0 | 3 |
| dav. beim EPA angemeldet | 71 | 119 | 94 | 156 |

Abbildung 1

Anzahl der im Biopatent-Monitoring für den Bereich Nutzpflanzen erfassten Patente und Patentanmeldungen

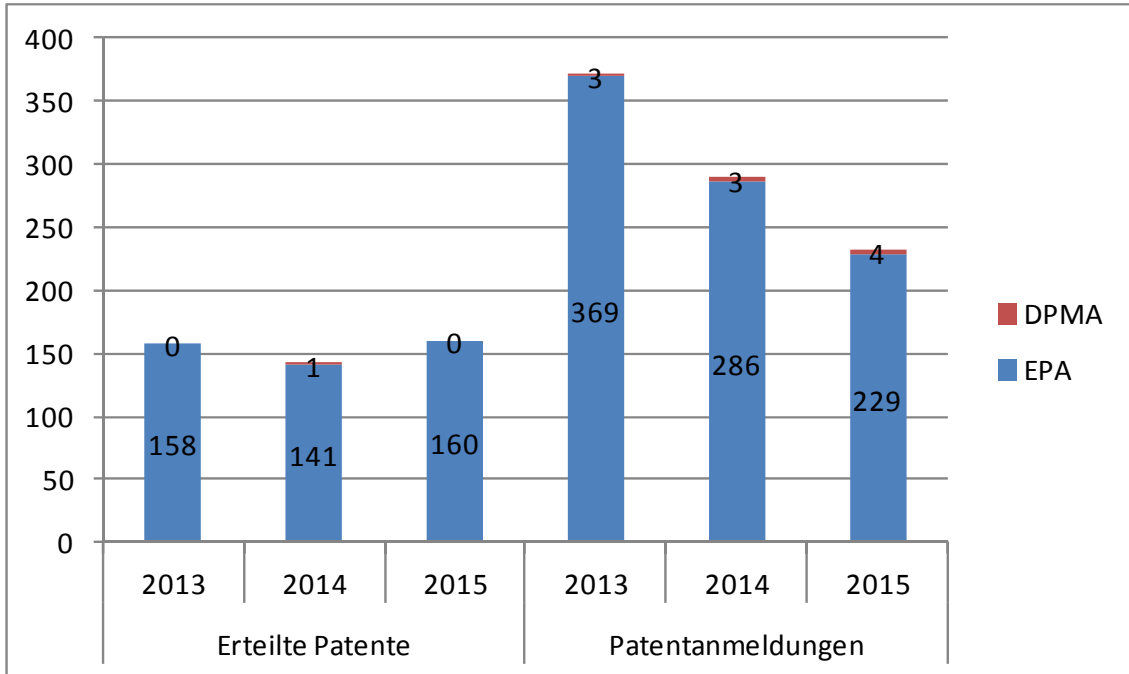


Abbildung 2

Anzahl der im Biopatent-Monitoring für den Bereich Nutztiere erfassten Patente und Patentanmeldungen

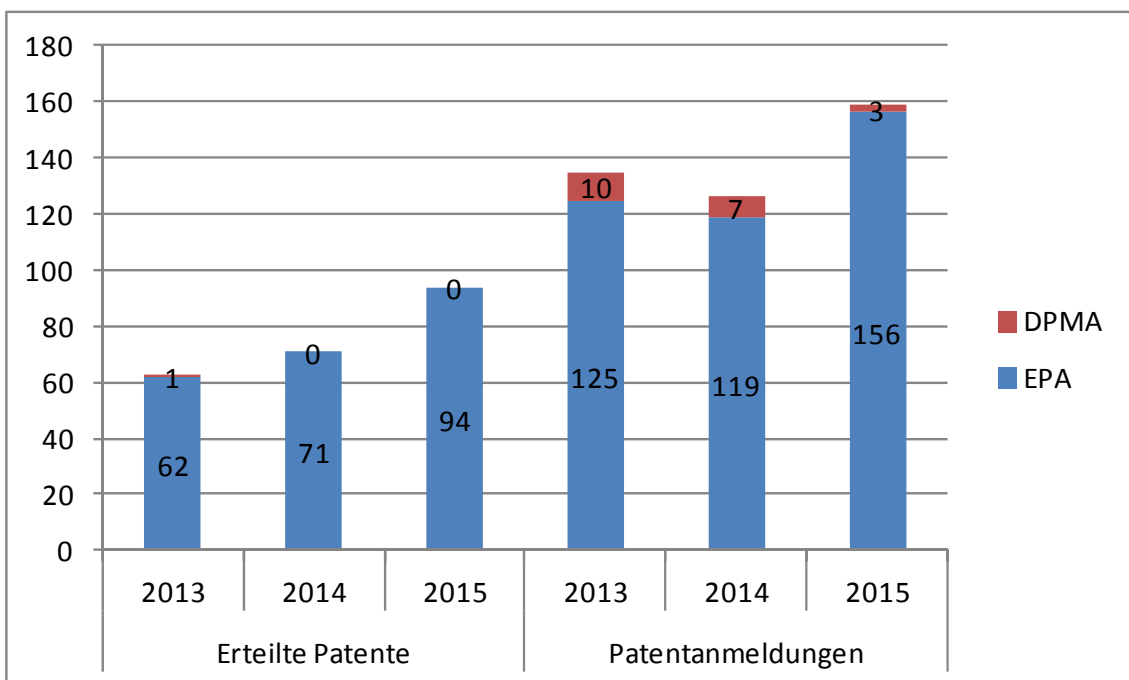


Abbildung 3

Anteil der veröffentlichten erteilten Patente und Patentanmeldungen zur Herstellung und Verwendung von GVO und Nicht-GVO im Bereich Nutzpflanzen

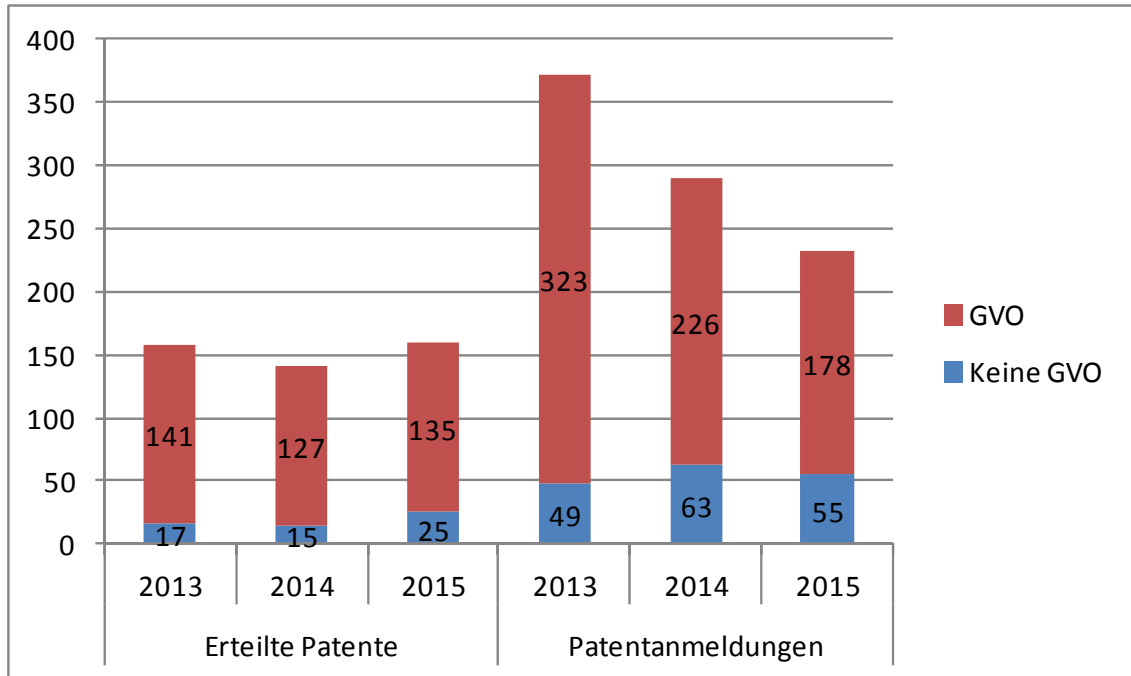


Abbildung 4

Anteil der veröffentlichten erteilten Patente und Patentanmeldungen zur Herstellung und Verwendung von GVO und Nicht-GVO im Bereich Nutztiere

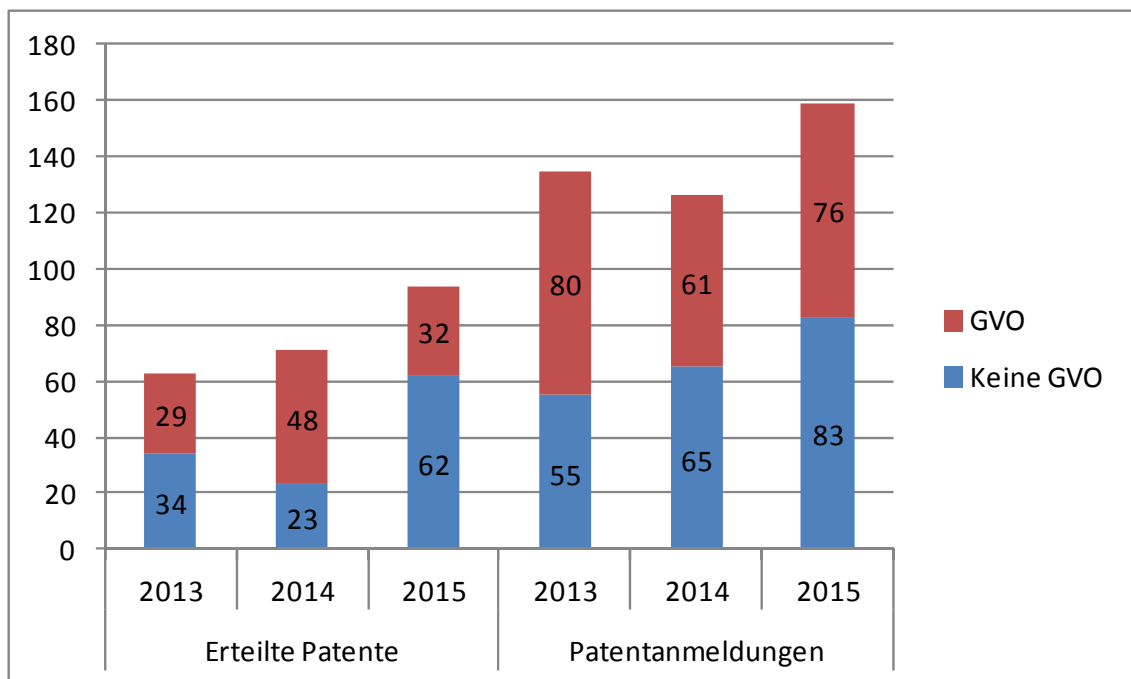


Abbildung 5

Anzahl beobachtungswürdiger erteilter Patente und Patentanmeldungen im Bereich Nutzpflanzen

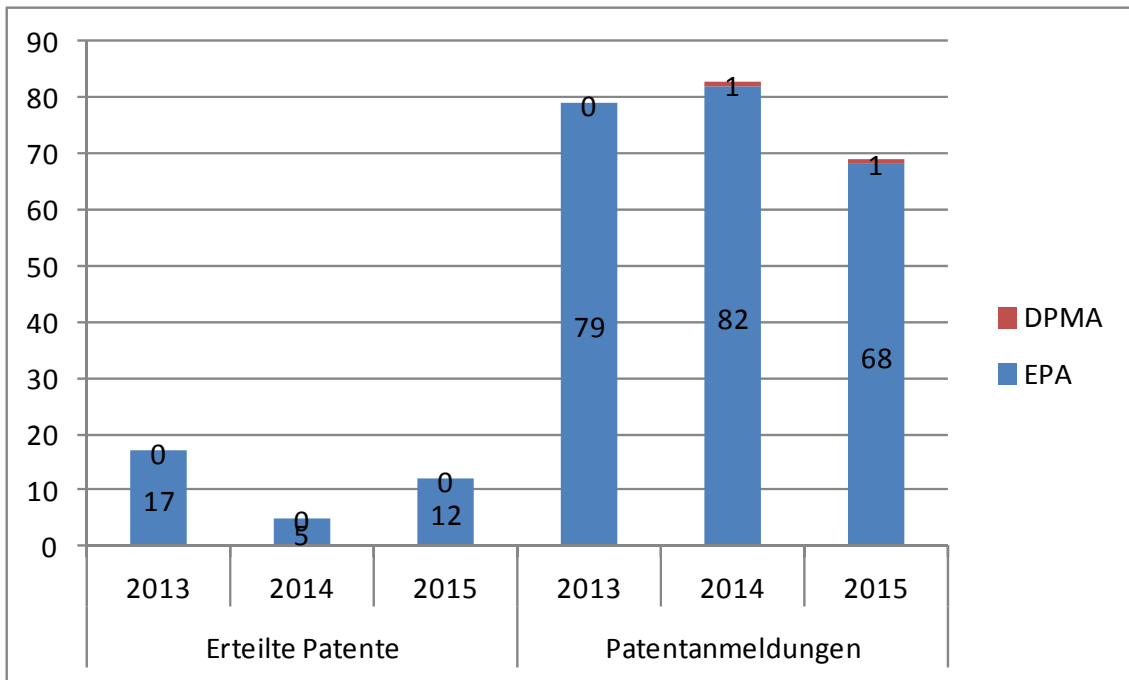


Abbildung 6

Anzahl beobachtungswürdiger erteilter Patente und Patentanmeldungen beim EPA im Bereich Nutztiere (Für den Bereich Nutztiere wurden keine beobachtungswürdigen Veröffentlichungen beim DPMA festgestellt.)

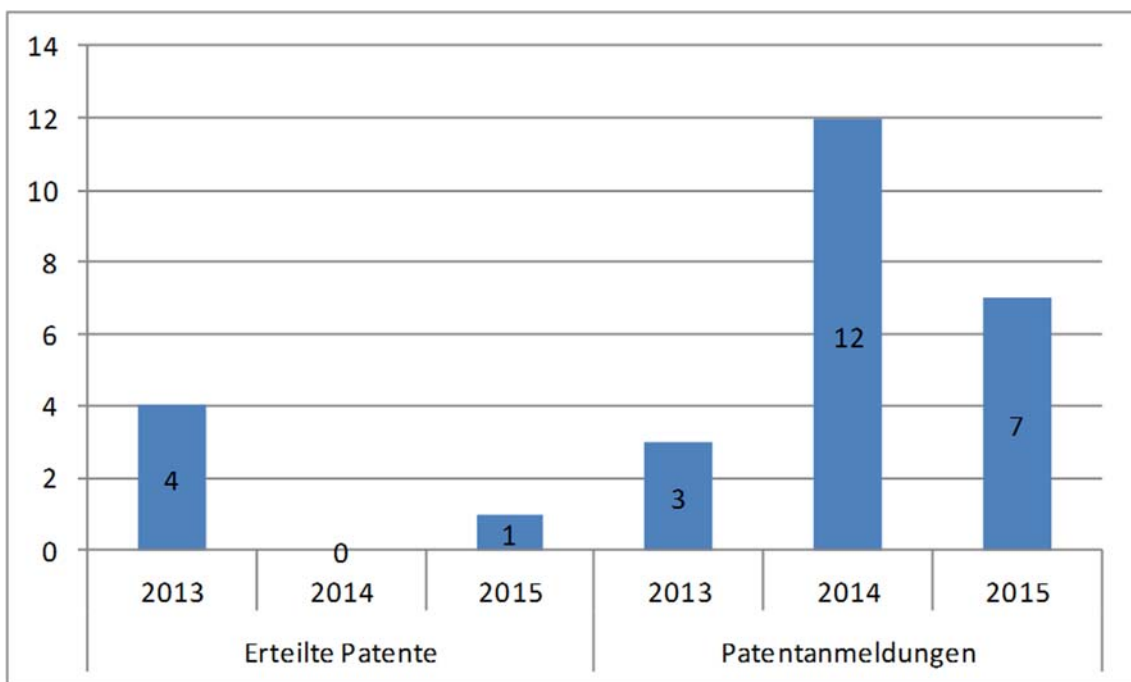


Abbildung 7

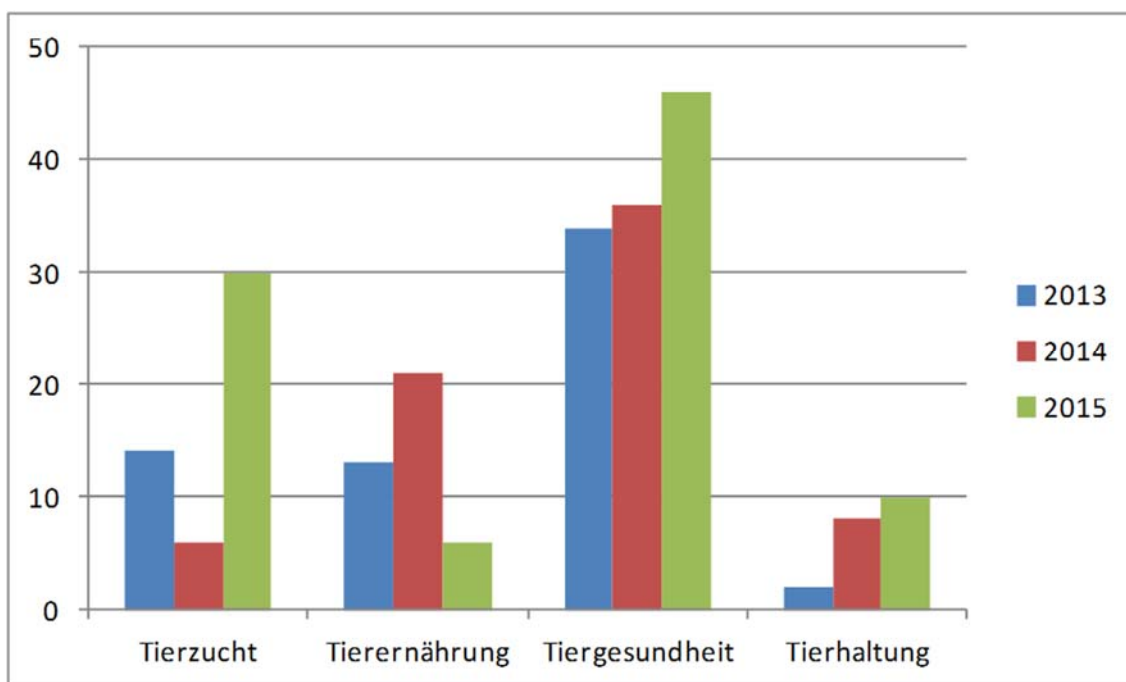
Anteil der erteilten Patente im Bereich Nutztiere bezogen auf Anwendungsgebiete

Abbildung 8

Anteil der Patentanmeldungen im Bereich Nutztiere bezogen auf Anwendungsgebiete