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Plant protection

Patentability of products obtained by essentially biological processes in Europe

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1 Introduction

Patent protection of plants and processes to produce plants have been a matter of extensive discussion in European patent practice. With its decisions in the proceedings with case numbers **G 1/98**, **G 2/07**, **G 1/08**, **G 2/12** and **G 2/13**, the Enlarged Board of Appeal of the European Patent Office (EPO) provided its interpretation of different aspects of Article 53(b) of the European Patent Convention (EPC).

The conclusions reached by the Enlarged Board of Appeal are straightforward and provide a clear guidance as to how the exclusions from patentability defined in Article 53(b) EPC are to be understood in proceedings before the EPO.

Nevertheless, an applicant for a patent directed to plants again faces uncertainty as to the fate of its innovation. This uncertainty arises in view of a Notice from the European Commission on the exclusion from patentability of products obtained by essentially biological processes dated November 8, 2016 and the subsequent *ex officio* staying of proceedings before the EPO where the claimed subject-matter is directed to such products.

This Notice and the EPO's reaction to it is the latest twist in the seemingly never-ending story on patentability of biological products in Europe.

2 Legal background - Art. 53 EPC

In **Article 53**, the EPC determines which subject-matter is excluded from patentability, despite being subject-matter which could be considered as an invention:

> *European patents shall not be granted in respect of:*
> *(a) [...]*
> *(b)* ***plant or animal varieties or essentially biological processes*** *for the production of plants or animals; this provision shall not apply to microbiological processes or the products thereof;*
> *(c) [...]* (Emphasis added)

As explained in the Enlarged Board of Appeal's decision **G 1/98** [1] (reasons 3.4), the exclusion of plant varieties was introduced when drafting the EPC in consideration of Article 2(1) of the International Union for the Protection of New Varieties of Plants (UPOV) Convention 1961 and Article 2(b) of the Strasbourg Patent Convention (StrPC).

According to Article 2(1) of the UPOV Convention, the UPOV member states are allowed to grant either a special plant breeder's right or a patent, but simultaneous protection for the same botanical genus or species is not allowed. In view thereof, **Article 2(b)** of the StrPC stipulates the following:

> *The Contracting States shall not be bound to provide for the grant of patents in respect of (a) [...]; (b)* ***plant varieties or animal varieties or essentially biological processes for the production of plants or animals****; this provision does not apply to micro-biological processes and the products thereof.* (Emphasis added)

When drafting the EPC, it was decided to choose the option provided by the StrPC to exclude protection for plant and animal varieties since several EPC Contracting States provided plant breeder's rights for plant varieties. Interestingly, while IP systems to protect plant varieties have been developed, no such system has ever been conceived for animal breeds.

The drafters of the EPC considered that allowing patents directed to plant varieties under the EPC would have been contrary to the principle of uniform

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patent protection in all Contracting States.

The exclusion from patentability of essentially biological processes in the StrPC also originates from the ban on dual protection for plant species in the UPOV convention, as for example explained by the Enlarged Board of Appeal in decisions **G 2/07** [2] and **G 1/08** [3] (reasons 6.4.2.2). Why this consideration was extended to animal varieties, albeit no specific animal variety protection - similar to UPOV - was in place, with dual protection thus not being an issue, however remains a mystery.

As can be derived from the Enlarged Board of Appeal's analysis in **G 2/07** and **G 1/08**, the exclusion in the StrPC was originally directed to *"inventions relating to the production of or a process for producing a new plant variety or a new animal species"*, i.e. it was not directed to processes for the production of plants or animals in general.

Furthermore, the Board explains that during the drafting process, the term *"purely biological process"* was replaced by *"essentially biological process"* to extend the exclusion to processes where the fundamental character of the invention was not changed by the inclusion of a secondary, technical feature.

3 Legal background - Biotech Directive

The *"Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions"* [4] (the so-called *"Biotech Directive"*) was adopted in 1998 - after a decade of intensive discussions and negotiations as to its content and wording - with the aim of harmonizing national law on the patentability of inventions relating to biological material in all countries of the European Union. It has in the meantime been implemented in the legislation of all member states, though with slightly different wording and scope.

In **Article 3** of the Biotech Directive, it is generally stated that inventions related to biological material are patentable:

> *1. For the purposes of this Directive, inventions which are new, which involve an inventive step and which are susceptible of industrial application shall be patentable even if they concern a product consisting of or containing **biological material** or a process by means of which biological material is produced, processed or used.*
>
> *2. **Biological material** which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention even if it previously occurred in nature.* (Emphasis added)

In **Article 4(1)** of the Biotech Directive, the exclusion from patentability of plant and animal varieties, as well as essentially biological processes, is defined. This exclusion complies with the provisions of Article 53(b) EPC. The limits to the exclusion from patentability are defined in **Article 4(2)** and **(3)** of the Biotech Directive:

> *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)

Although the EPO is not an institution of the European Union, the Administrative Council of the European Patent Organisation decided [5] to implement the Biotech Directive in the Implementing Regulations of the EPC as well. As stated in a corresponding Notice dated 1 July 1999 [6], this was done to **comply with the requirement for uniformity in harmonised European law**. The Notice also indicates that the principles in the Biotech Directive are based on the relevant provisions of the EPC and that they essentially reflect the practice as developed by the Office and its Boards of Appeal. Nevertheless, it was considered that some extensions and clarifications were required in the provisions of the EPC.

For example, definitions of terms were included in Rule 26 EPC (Rule 23b(5) EPC 1973), and the provisions of Article 3(2) and Article 4(2) and (3) of the Biotech Directive were included in **Rule 27 EPC** (Rule 23c EPC 1973), which reads as follows:

> *Biotechnological inventions **shall also be patentable** if they concern:*
> *(a) biological material which is isolated from its natural environment or produced by means of a technical process even if it previously occurred in nature;*
> *(b) plants or animals if the technical feasibility of the invention is not confined to a particular plant or animal variety;*
> *(c) a microbiological or other technical process, or a product obtained by means of such a process **other than a plant or animal variety**.* (Emphasis added)

In the Notice dated 1 July 1999 (see above), it is explained that Rule 27(b) EPC (Rule 23c(b) EPC 1973) *"indicates that a plant grouping characterised only by a particular gene – but not by its whole genome – […] is in principle patentable"* and that *"this also applies if such plant grouping comprises plant varieties"*.

In connection with Rule 27(c) EPC (Rule 23c(c) 1973 EPC), it is stated that the Rule affirms the principle laid down in Article 53(b) EPC and that it *"makes explicitly clear that product claims for plant or animal varieties cannot be granted even if the variety is produced by means of a microbiological process"*. We note that the explicit reference to plant or animal varieties is missing in corresponding Article 4(3) of the Biotech Directive.

4 Patentability of products obtained by essentially biological processes at the EPO

The term *"essentially biological process"* has been explicitly defined in **Rule 26(5) EPC** (Rule 23b(5) EPC 1973) following the implementation of the provisions of the Biotech Directive:

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

In the Notice dated 1 July 1999 (see above), it was stated that this Rule *"gives a more specific meaning to Article 53(b) EPC and establishes that only production processes based entirely on natural phenomena are excluded from patentability"*.

However, according to the Enlarged Board of Appeal in the consolidated proceedings leading to decisions **G 2/07** and **G 1/08**, the definition of essentially biological processes in the Biotech Directive (and consequently also in Rule 26(5) EPC) can be considered as being *ambiguous and contradictory*. This is due to the fact that crossing and selection are defined as examples of natural processes although they require human intervention (reasons 4.7).

Therefore, the Enlarged Board concluded that Rule 26(5) EPC **could not be used to interpret** the term *"essentially biological process"* defined in Article 53(b) EPC.

Considering the historical background of the StrPC and the EPC 1973, and particularly the replacement of the term *"purely"* by *"essentially"* when drafting the StrPC, the Enlarged Board then defined in decisions **G 2/07** and **G 1/08** that a process was to be considered as an *"essentially biological process"* and as excluded from patentability when the process is **mainly based on a conventional *"mixing"* of the genomes of plants**. Where an additional step introduces a trait into the genome or modifies a trait in the genome of the plant produced, the process is not excluded from patentability.

After the Enlarged Board had issued its decisions **G 2/07** and **G 1/08**, the cases were further considered by the Technical Board of Appeal. During this phase, the patent proprietors deleted the process claims and focused on product claims or product-by-process claims.

In connection with these product claims, the Technical Boards of Appeal considered it necessary to refer - for the first time in the history of the EPO - a second question in the same proceedings to the Enlarged Board of Appeal. In particular, the Technical Boards of Appeal asked whether the exclusion of essentially biological processes had an **impact on the patentability of products which are directly obtained by such processes**. Although the questions differed slightly in both cases, the Enlarged Board again considered the referrals in consolidated proceedings, having case numbers **G 2/12** [7] and **G 2/13** [8].

In its first intermediate conclusions (reasons VII, 6), the Enlarged Board concluded that there were **no reasons** (based on conventional rules of interpretation) as to why the exclusion of essentially biological processes should extend to products obtainable by or explicitly defined as being obtained by such processes. According to the Enlarged Board, neither the context, the objective and purpose, and subsequent agreements, nor the historical background of Article 53(b) EPC provide an indication that it would have been the intention of the legislator to also exclude products obtained by essentially biological processes (reasons VII, 1 to 5). Interestingly, the Board explicitly states that also the Biotech Directive *"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"* (reasons VII, 4(3)).

Even when taking secondary aspects into consideration (reasons VIII), the Enlarged Board did not find any reasons to change its first intermediate conclusions. The Board noted that no dynamic interpretation was required since the legislator had not seen a need to revise the process exclusion in Article 53(b) EPC in view of the developments in the field under the EPC 2000 reform (Reasons VIII, 1). Also, the Enlarged Board noted that there was no legal erosion of the exception to patentability when allowing claims directed to products obtained by essentially biological processes since there was a distinction between the aspects of patentability and the (protective) effects of a European patent (Reasons VIII, 2(6)(b)).

The Enlarged Board further considered the various ethical, social and economic aspects in the debate and considered the changes of legislation in Germany and the Netherlands to explicitly exclude products obtained by essentially biological processes from patentability (cf. *infra*). In connection with these aspects, the Board pointed out that its role was to interpret the EPC but that it was not mandated to engage in legislative policy (Reasons VIII, 2(6)(c)).

On the basis of these considerations, the Enlarged Board of Appeal decided to answer the questions referred to it as follows (with the headnotes of decisions **G 1/12** and **G 2/13** being consolidated for the purpose of the present article):

> *1. 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** such as fruit* [**G 1/12**] */ plant parts* [**G 2/13**].
>
> *2. In particular, the fact that the only method available at the filing date for generating the claimed subject-matter is an essentially biological*

process for the production of plants disclosed in the patent application does not render a claim directed to plants or plant material other than a plant variety unallowable. [**G 1/12**]

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

(b) The fact that the only method available at the filing date for generating the claimed subject-matter is an essentially biological process for the production of plants disclosed in the patent application does not render a claim directed to plants or plant material other than a plant variety unallowable. [**G 2/13**]

3. In the circumstances, it is of no relevance that the protection conferred by the product claim encompasses the generation of the claimed product by means of an essentially biological process for the production of plants excluded as such under Article 53(b) EPC. [**G 1/12** and **G 2/13**] (Emphasis added)

In summary, products obtained by essentially biological processes are considered to be patentable under European (i.e. the EPO's) patent practice.

5 National regulations on products obtained by essentially biological processes

In most Member States of the European Union, the national provisions with respect to essentially biological processes and plants are largely identical to the provisions of the Biotech Directive [9]. However, as an exception, the provisions in the Netherlands, Germany, Austria and France explicitly exclude products obtained by essentially biological processes from patentability.

In the **Netherlands**, the Dutch Patent Act 1995 (Rijksoctrooiwet 1995) excludes in Article 3.1.d *"essentially biological processes, entirely consisting of natural phenomena such as crossings and selections, for the production of plants or animals, **as well as the products obtained as a result thereby**"* (emphasis added). The latter was already explicitly excluded from patentability in the Dutch Patent Act before implementation of the Biotech Directive. It is noted that for several reasons the Netherlands voted against the Biotech Directive and asked the Court of Justice of the EU (CJEU) to withdraw the Directive after its entry into force. The CJEU decided to reject the request, i.e. the Netherlands had to include the provisions of the Biotech Directive. However, in Article 3.1.d, only the definition of essentially biological processes as given in the Biotech Directive was included. Thus, the already existing exclusion of essentially biological processes, including the explicit exclusion of products obtained as a result thereby, was maintained.

In **Germany**, the provisions with respect to essentially biological processes were taken literally from Article 4 of the Biotech Directive. However, after the issuance of decisions **G 2/07** and **G 1/08** by the EPO's Enlarged Board of Appeal, the German legislator considered it necessary to clarify in the German Patent Act (Patentgesetz) that **products** immediately obtained from essentially biological processes were **excluded from patentability**. According to the reasoning of the German legislator, the object and purpose of Article 4 of the Biotech Directive require that such products be excluded from patentability since otherwise the exclusion of essentially biological processes could be easily circumvented [10].

In view thereof, § 2 a (1)1 of the German Patent Act has been amended and now reads *"plant or animal varieties or essentially biological processes for the production of plants or animals **and plants and animals exclusively obtained by such processes**"* (emphasis added, with the part in bold having been added). The amended Patent Act entered into force on 25 October 2013.

In 2016, also **Austria** decided to change its Patent Act (Patentgesetz) in this respect. In § 2(2) it is now explicitly defined that *"**plants or animals obtained exclusively by such** [essentially biological] **processes**"* are excluded from patentability. According to a press release from the responsible Austrian ministry dated July 8, 2016 [11] on the decision to change the Patent Act in this respect, it is indicated that Austria would prefer the exclusion of patentability of plants and animals on a European level.

Very recently, also **France** changed its Intellectual Property Code (Code de la propriété intellectuelle) in this respect by inserting Article L 611-19 I.3° bis which excludes *"**products obtained exclusively by essentially biological processes** defined in 3°, including the elements constituting these products and the genetic information they contain"* (emphasis added). This amendment is based on a law adopted on 8 August 2016 for the recovery of the biodiversity, of nature and landscapes [12] and is included in a version of the Intellectual Property Code consolidated on 17 March 2017.

Until now, the national restrictions in connection with products obtained by essentially biological processes in the Netherlands, Germany, Austria and France did not have an influence on the protection conferred by the national parts of a European patent in these countries. Patents originating from a European patent may, in national proceedings, only be revoked for the reasons mentioned in Article 138 EPC, in which national restrictions with respect to subject-matter excluded from patentability are not mentioned.

The understanding that patent protection can be obtained via a European patent irrespective of any exclusion of the claimed subject-matter on a national level, has been corroborated by a decision issued by the District Court of The Hague on 8 May 2013 [13] in a nullification procedure related to a European patent directed to plant products. In its decision, the Court makes abundantly clear that the argument, as brought forward by the alleged infringer, that the Dutch Patent Act explicitly excludes products obtained by essentially biological processes from patentability **is not relevant** since the validity of the patent must be evaluated in line with the provisions of the EPC and not with the provisions of the national patent law (point 5.10 of the decision).

6 Interpretation of patentability exclusions by the European Commission

Following the Enlarged Board of Appeal's decisions **G 2/12** and **G 2/13**, the European Parliament asked the European Commission to evaluate the patentability of products obtained by essentially biological processes. In the Resolution of 17 December 2015 [14], the European Parliament expressed its concern that these decisions might lead to more patents in respect of natural traits introduced into new varieties by means of essentially biological processes. It asked for clarification of the scope and interpretation of the Biotech Directive, as a supplementary means of interpretation thereof.

In the resulting Commission Notice dated November 8, 2016 [15], the Commission emphasized the fact that the Enlarged Board's decisions **G 2/12** and **G 2/13** were mainly confined by considerations on the EPC and the guiding principle that exclusions from patentability have to be interpreted narrowly. Upon an interpretation of the provisions of the Biotech Directive in their entirety a different conclusion had to be drawn.

The Commission further noted that a specific reference to the non-patentability of plants and animals obtained by an essentially biological process was originally included but removed during drafting of the Biotech Directive since the drafts stated that biological material being isolated from its natural environment or produced by means of a technical process was explicitly defined as being patentable subject-matter. Also, the Commission referred to a statement of the Rapporteur on amendments proposed by the Parliament, where it is stated that

patent protection is not appropriate for essentially biological procedures *"and their products"* in view of their lack of reproducibility.

Although there is no explicit exclusion from patentability for products obtained by essentially biological processes in the Biotech Directive, the Commission concluded that **this must have been the intention of the EU legislator**. In the Commission's opinion, this is particularly true since certain provisions are only consistent if products obtained by essentially biological processes are understood as being excluded from the scope of the Directive. According to the Commission, such products are implicitly excluded from patentability on the basis of the provisions of Article 3(2) of the Directive, which provides a positive definition of patentable biological material (being material isolated from its natural environment or produced by means of a technical process). The Commission considered that plant and animal products obtained by essentially biological processes did not fulfill the criteria defined therein. Also, the provisions of Article 4 were analyzed to support the Commission's opinion that products obtained by essentially biological processes should be excluded from patentability. In connection with Article 4(2), the Commission stated that the exception provided therein did not nullify the exclusion in Article 4(1). Furthermore, the explicit reference to Article 4(1)(b) in Article 4(3) supports, according to the Commission, that it was the legislator's intention to exclude from patentability products that are obtained by essentially biological processes.

The Commission concluded that *"the EU legislator's intention when adopting Directive 98/44/EC was to exclude from patentability products (plants/animals and plant/animal parts) that are obtained by means of essentially biological processes"*.

7 Stay of proceedings at the EPO

The Commission's Notice does not have a legally binding character and the EPO is not an institution of the European Union. Thus, the Commission's Notice does not have an immediate or direct effect on the patent granting practice at the EPO. Also, certain contracting states of the EPC are not member states of the European Union, i.e. for those countries, the Commission's Notice does not have any legal value.

Nevertheless, the President of the EPO has now decided [16] to stay *"all proceedings before EPO examining and opposition divisions in which the decision depends entirely on the patentability of a plant or animal obtained by an essentially biological process in view of the potential impact of the Commission Notice"*.

This is the first time in the history of the EPO that proceedings relating to a certain matter have been stayed *ex officio* for reasons other than that proceedings in connection with that matter are pending with the Enlarged Board of Appeal.

In the Notice from the EPO, it is indicated that the intention of introducing the provisions of the Biotech Directive in the Implementing Regulations was to comply with the requirement for uniformity in harmonized European patent law. It is also noted that the Directive was used at the EPO as supplementary means of interpretation when examining European patent applications and European patents for compliance with the relevant provisions of the EPC. According to the Notice, *"the effect of the Commission Notice for the EPO's examination practice including any necessary follow-up measures is currently under discussion with the representatives of the member states of the European Patent Organisation"*.

The follow-up measures being considered can be derived from reports [17] on the meeting of the Committee on Patent Law held at the EPO on November 21, 2016 where the EPO decided to stay the proceedings after the discussion of the topic with the Contracting States.

According to a presentation by the EPO at the *"Hearing on the implementation of the Biotech Directive"* of the Committee on Legal Affairs of the European Parliament on November 29, 2016, a significant number of delegations from the EPO Contracting States indicated at the meeting on November 21, 2016 that they were **in favor of the Commission's interpretation**. Also, several delegations indicated that they were **in favor of an amendment to the EPC Implementing Regulations**. The presentation also indicates that the EPO *"intends to submit to its governing bodies, early in 2017, a discussion paper setting out options, including a proposal for an amendment of the Implementing Regulations"*.

8 Comments

The history of the relevant provisions relating to essentially biological processes teaches that slight differences in the wording of the provisions can have a tremendous impact on their interpretation. Intriguingly, the provisions excluding plant and animal varieties and essentially biological processes from patentability were all based on the initial intention to exclude plant varieties from patentability in view of plant breeder's rights available for plant varieties (without actually taking into account that no corresponding rights existed for animal breeders). In addition to the message that subtle differences and nuances in legal texts may have far-reaching practical consequences, the present situation also provides us with interesting insights into in the political arena and shows which instruments and strategies the Commission is willing to use in order to change an apparently unpleasant *status quo*.

Despite the fact that plant breeder's rights for plant varieties seem to have been the reason for the exclusions defined in Article 2(b) StrPC (from which Article 53(b) EPC was derived, and which in turn was considered when drafting Article 4 of the Biotech Directive), the original exclusion of essentially biological processes for the production of new plant or animal varieties in the draft StrPC was amended during the drafting process to the exclusion of essentially biological processes for the production of plants or animals as such. This resulted in a different scope of the product exclusion (restricted to varieties) and the process exclusion (directed to material which is not restricted to varieties).

The reason for not referring to varieties when excluding essentially biological processes from patentability is suggested to originate from the fact that at the time of drafting the relevant provisions such processes commonly resulted in varieties. In decisions **G 2/12** and **G 2/13**, the Enlarged Board of Appeal pointed out that the legislative purpose of Article 53(b) EPC, as far as the process exclusion is concerned, was to exclude processes which, at the time of drafting, commonly resulted in plant varieties for which protection under the UPOV Convention could be sought (reasons VIII, 1). In line with this consideration, the European Commission suggests in its Notice of 2016 that products obtained from essentially biological processes were **not explicitly mentioned** in Article 4(1) of the Biotech Directive since it was not considered possible to obtain products other than varieties when applying such processes.

Departing from this *"common ground"*, the Enlarged Board of Appeal notes that despite the fact that nowadays new breeding techniques, which are still to be considered as essentially biological, might result in plants or plant materials other than varieties, the legislator **did not see a need to** extend the process exclusion to the products obtained by such (new) essentially biological processes (e.g. in the course of the EPC 2000 reform) (reasons VIII, 1). Accordingly, plant products which are not varieties and which are obtained by essentially biological processes were considered patentable under the EPC.

The Commission, on the other hand, provides arguments as to why products which are not restricted to varieties and which are obtained by essentially biological processes would be **excluded from patentability** under Article 4 of the Directive, the main argument being an implicit exclusion on the basis of Article 3(2), which offers a positive definition of patentable biological material not including products obtained from essentially biological processes.

However, questions may be raised as to the conclusiveness and consistency of the Commission's analysis.

Firstly, the Commission concludes from the positive definition of patentability of inventions which concern plants or animals in Article 4(2) of the Biotech Directive that, the other way around, plants and animals are not patentable if the technical feasibility of the invention is confined to a particular plant or animal variety (seventh paragraph of point 1.3). This seems obvious since, in our opinion, a product claim would be directed to a variety if the technical feasibility of an invention is confined to a plant or animal variety. Such products are explicitly excluded from patentability in Article 4(1). However, the Commission focusses on process aspects, which are in our opinion not necessarily applicable to the product part of the relevant articles. A conclusion as to the patentability of products which are not varieties and which are obtained by essentially biological processes seems missing in the Commission's analysis.

Secondly, the Commission states at point 1.3 of the Notice that recital 32 of the Biotech Directive indicates that both plant varieties which are the result *"not of an essentially biological process"* (as recited in the recital) and plant varieties which are the result of essentially biological processes are excluded from patentability. Indeed, recital 32 seems to indicate explicitly that a plant variety is also excluded from patentability when it is **obtained by a technical (patentable) process**, i.e. that the exclusion of plant varieties from patentability is **independent of the technicality of the process**. However, the Commission concludes from this recital that the technicality of the process determines whether products of the process are patentable or not. In our opinion, this circular reasoning leads to a conclusion which is not commensurate with the rather straightforward meaning of recital 32.

Finally, the Commission also concludes from Article 4(3) of the Biotech Directive that it must have been the legislator's intention to exclude from patentability products that are obtained by essentially biological processes. Apparently, the Commission considers the explicit mentioning of the patentability of products obtained by patentable microbiological processes as an indication that products obtained by non-patentable processes (as mentioned in Article 4(1)(b)) cannot be considered as being patentable. Certainly, this is a questionable line of argumentation. According to the Commission, the explicit mentioning of the patentability of microbiological processes shows that the products obtained thereby were considered patentable subject-matter. Since microbiological processes are mentioned as an exception of the processes excluded from patentability, the Commission seems to conclude that also the products obtained by microbiological processes must be seen as an exception of products which are excluded from patentability. One issue with this argument is that Article 4(1)(b) does not mention products, in contrast to Article 4(3). In connection with Article 4(3), it is interesting to note the different focus of the EPO's interpretation when discussing the introduction of corresponding Rule 27 EPC (see Notice dated 1 July 1999 discussed above).

Since the EPO's Enlarged Board of Appeal used the Biotech Directive as supplementary means of interpretation in the proceedings leading to decisions **G 2/12** and **G 3/13**, but arrived at an entirely different conclusion compared with the European Commission, the Enlarged Board thus seems **not to understand** the provisions of the Biotech Directive **in the same manner** as the European Commission. This is a quite surprising finding, given the Enlarged Board's earlier efforts to come to a well-founded decision.

Thus, there is a clear perception that the Commission's notice was rather produced on purpose - while neglecting several contradictions and plausibility flaws - in order to serve the greater good of political harmonization without essentially touching the Biotech Directive's substance, than with the aim of a thorough juridical analysis. This understanding is largely in line with material presented by Jean Bergevin, Head of the IP unit of the European Commission in a Symposium held in May 2016 [18], in which a reopening and renegotiation of the Biotech Directive was considered as *"opening Pandora's box"* since other sensitive issues such as patentability of human stem cells could arise.

Mr. Bergevin, instead, suggested the provision of a Commission's clarifying notice regarding the scope of Article 4(2) of the Biotech Directive. While such a notice was considered by him as having *"a non-binding legal effect"* it was still seen as offering a *"satisfactory solution in terms of interpreting the scope of the Biotech Directive"*.

The Commission's notice of November 2016 perfectly fulfils these requirements. Moreover it has resulted in a further, quite surprising effect, namely the EPO's unprecedented reaction to it in the form of a staying of all corresponding proceedings before it. Further given the EPC Contracting States' apparent positive feedback on the Commission's notice, it is considered not unlikely that the next chapter in this narrative could be an **amendment to the implementing regulations of the EPC**. By merely changing some (or one) of the EPC Rules an opening of *"Pandora's box"*, i.e. of the Biotech Directive, could be prevented, while largely providing a similar effect, namely to provide statutory guidance which would render the central stipulations of **G 2/12** and **G 2/13** obsolete and at the same time would bring the EPO's approach in alignment with an increasing number of national laws.

It is still unclear when the proceedings before the EPO will be resumed. Apparently, the resumption of the proceedings will depend on the outcome of the discussions of the EPO's proposals and, should it be decided that an amendment of the Regulations is necessary, the time required to implement any such amendments.

9 Conclusion

After the Enlarged Board of Appeal issued its decisions **G 1/12** and **G 2/13**, it was clear that a European patent could be granted for products obtained via essentially biological processes at the European Patent Office. The national part of a European patent is considered valid even in countries which have restrictions on patentability of such products in their Patent Acts (the Netherlands, Germany, Austria and France). However, the Notice regarding the staying of proceedings before the EPO following the diverging opinion put forward in the Notice issued by the European Commission, and following the EPO's decision to work out a discussion paper, including a proposal for an amendment of the Implementing Regulations, shows that the EPO evaluates whether it should and/or could change the practice recently established by the Enlarged Board of Appeal.

Thus, ten years after the Enlarged Board of Appeal started interpreting Article 53(b) EPC, and almost 20 years after the Biotech Directive came into force, it is once again uncertain which biological products can be patented in Europe.

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1 OJ EPO 2012, 206
2 OJ EPO 2012, 130; also referred to as *"Broccoli I"*
3 OJ EPO 2012, 206; also referred to as *"Tomato I"*
4 OJ of the European Union, L 213, 30.7.1998, p. 13
5 Decision of the Administrative Council of 16 June 1999 amending the Implementing Regulations to the European Patent Convention; OJ 1999, 437
6 OJ EPO 1999, 573
7 OJ EPO 2016, A27; also referred to as *"Tomato II"*
8 OJ EPO 2016, A28; also referred to as *"Broccoli II"*
9 Committee on Biotechnological Inventions of the European Patent Institute (epi), *"Patentability on Plants"*, epi Information 4/2015, pp 156-168
10 Bundestagsdrucksache 17/14222 (26.06.2013): *"Entwurf eines Gesetzes zur Novellierung patentrechtlicher Vorschriften und anderer Gesetze des gewerblichen Rechtsschutzes"*
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15 Commission Notice on certain articles of Directive 98/44/EC of the European Parliament and of the Council on the legal protection of biotechnological inventions (2016/C 411/03, OJ of the European Union)
16 Notice from the European Patent Office dated November 24, 2016 concerning the staying of proceedings due to the Commission Notice on certain articles 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 2016, A104)
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