

Legal developments on the patentability of biotech inventions

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After the European Patent Office (EPO) Enlarged Board of Appeal (EBoA) issued Decisions G1/08 and G2/07, it appeared that ambiguities in interpreting Article 53(b) of the European Patent Convention (EPC) had been clarified and that there was finally legal certainty about what is excluded from patentability according to Article 53(b). As a result of these decisions, the EPO's examining divisions allowed claims directed to a process for the production of a plant that contains within it the steps of sexually crossing and selecting an additional step of technical nature, which introduces a trait into the genome or modifies a trait in the genome of a plant. However, the situation changed yet again when both technical boards of appeal (TBoA) in charge of the underlying Cases T1242/06 (*Tomato*) and T83/05 (*Broccoli*) again decided to refer questions of law to the EBoA concerning the possible impact of the process exclusion set out in Article 53(b) on the allowability of claims to products resulting from such excluded processes.

Background

The issue emerged as a result of the EBoA's decision in G1/08, which gave the process exclusion a broad reading. In Decisions G1/08 and G2/07 the EBoA considered how an essentially biological process for the production of plants and animals should be defined within the meaning of Article 53(b) of the EPC. The EBoA decided to define an 'essentially biological process' within the meaning of Article 53(b) as referring to a "non-microbiological process for the

production of plants which contains or consists of the steps of sexually crossing the whole genomes of plants and of subsequently selecting plants". It further clarified that such a process is still considered 'essentially biological' within the meaning of Article 53(b) and is therefore excluded from patentability if it contains as a further step – or as any of the steps of crossing and selection – a step of a technical nature which serves to enable or to assist the performance of the steps of sexually crossing the whole genomes of plants or of subsequently selecting plants. Only if this technical step by itself introduces a trait into the genome or modifies a trait in the genome of the plant produced, and this introduction or modification is not the result of mixing the genes of plants chosen for sexual crossing, will the process not be considered 'essentially biological' within the meaning of Article 53(b) of the EPC.

As reasoned reaction to the answers given by the EBoA in G1/08, Appellant I (the rights holder) of the appeal procedure T1242/06, which underlay G1/08, amended its claim requests by restricting all of the process claims to product claims. Appellant II pointed out that allowing claims to products resulting from excluded essentially biological processes would nullify the effect of the process exclusion set out in Article 53(b) of the EPC and the EBoA's interpretation in Decision G1/08.

Appellant I responded by arguing that both the product and method aspects of the exception to patentability pursuant to Article 53(b) of the EPC had been dealt with

already by the EBoA in Decisions G1/98 and G1/08 respectively.

In Decision G1/98 the EBoA ruled that a claim in which specific plant varieties are not individually claimed is not excluded from patentability, even though it may embrace plant varieties. Consequently, it followed from the principles laid down in G1/98 that the product claims should be allowed.

TBoA's interlocutory decision

In its reasons for the interlocutory decision, the TBoA mentioned that if it only had to consider the exclusion of plant varieties in Article 53(b) of the EPC, the subject matter of the claims of Appellant I's Auxiliary Request would not be excluded from patentability. However, it reasoned that this would lead to an inconsistent legal framework, which would exclude essentially biological processes for the production of plants from patentability while allowing patents on plants produced by an excluded process. The legislature's reasons for excluding these processes had to be respected and necessarily implied the exclusion of plants or plant parts that are produced by essentially biological processes. The TBoA further underpinned this reasoning by considering the different scope of protection conferred by product and process claims.

According to the TBoA, it is an established principle of patent law that the protection conferred by a product claim is absolute (see Decision G2/88, OJ EPO 1990, 93, point 5 of the reasons) and gives the patent owner the right to exclude others from making or using the patented product (see Decisions G2/06, OJ EPO 2009, 306, point 25 of the reasons; Article 28.1(a) of the Agreement on Trade-Related Aspects of Intellectual Property (TRIPs) and the corresponding provisions of the national laws of contracting states). In contrast, the protection conferred by a process claim for making a product is narrower, since it basically covers only the use of the process and the products directly obtained by it (see Article 64(2) of the EPC and Article 28.1 (b) of TRIPs). Hence, the TBoA concluded that a claim to a product provides the patent owner with protection for the process of making that product.

The TBoA further remarked that in

Tomato (T1242/06), this would mean that if the product claims of Appellant I's Auxiliary Request I directed to a naturally dehydrated raisin-type tomato fruit of the species *Lycopersicon esculentum* were allowed, any act of making and using the claimed dehydrated tomato fruits would in principle fall under the prerogative of the rights holder. According to the description of the patent, the claimed dehydrated tomato fruits were obtainable only using an essentially biological process excluded from patentability within the meaning of Article 53(b) of the EPC, which would mean that the rights holder could prevent others from using this essentially biological plant breeding method.

As demonstrative examples that situations exist where an exclusion referring to specific processes may negatively affect the allowability of product claims, the TBoA referred to Decision G2/06 of the EBoA and to the European Court of Justice's (ECJ) decision in *Oliver Brüstle v Greenpeace eV* (C-34/10), while being aware that, due to the different legislative purposes of the patentability exceptions under Articles 53(a) and (b) of the EPC, the following considerations do not necessarily apply to the interpretation of the process exclusion set out in Article 53(b).

In G2/06 it was concluded that Rule 28(c) of the EPC prohibits the patenting of claims directed to products which at the date of filing could be prepared exclusively by a method necessarily involving the destruction of human embryos from which said products are derived – even if the said method is not part of the claims.

In Decision C-34/10 the ECJ concluded that the corresponding provision (ie, Article 6(2) (c) of the EU Biotech Directive) excludes an invention from patentability where the technical teaching requires the prior destruction of human embryos or their use as base material – regardless of the stage at which this took place and even if the description of the technical teaching claimed did not refer to the use of human embryos. The ECJ argued that otherwise this provision would be redundant if applicants could circumvent refusal by skilful drafting of the claim.

In its reasons for the interlocutory

decision, the TBoA also considered arguments against extending the effect of the process exclusion in Article 53(b) of the EPC to product claims. In particular, it addressed the following interrelated lines of argument:

- Issues of patentability (including the applicability of an exclusionary provision) should be determined strictly in relation to the subject matter of the claim to be examined.
- The subject matter of product claims is different from that of process claims, so their different treatment is justified when trying to determine what is patentable and what is not.
- The difference in subject matter should not be smoothed out by taking into account the scope of protection or the rights holder's prerogatives conferred by the claims, since this would amount to an impermissible mixing of two bodies of rules (ie, those concerned with the patentability of inventions and those concerned with patent infringement).

The TBoA considered the issue dealt with by the EBoA in G1/98 to be the obverse of the present core issue – namely, the analysis of a possible impact of the product exclusion in Article 53(b) of the EPC on the examination of process claims. In particular, in G1/98 the EBoA had to consider whether, in view of Article 64(2) of the EPC, the exclusion of plant varieties should be a bar to process claims when the products directly obtained by such processes are or cover plant varieties. As mentioned above, this question was answered in the negative. The EBoA decided that during the examination of a claim to a process for the production of a plant variety, Article 64(2) of the EPC should not be taken into consideration.

According to the TBoA, it is apparent that the protection conferred by Article 64(2) of the EPC on any process for the production of a plant variety is considerably narrower (ie, limited to the variety directly obtained by the process) than the protection which would be conferred by a product claim to the variety. The TBoA inferred from this that a legal framework does not lack consistency if it disallows the broader protection conferred by

product claims while allowing the narrower protection conferred by process claims.

However, the TBoA did note that the core issue of the present case was quite different, since not taking into account the process exclusion of Article 53(b) of the EPC when examining product claims may lead to a situation where the legal framework disallows the narrower protection conferred by the claims on essentially biological plant production processes while allowing the generally broader protection conferred by product claims. For this reason the TBoA was of the opinion that, in contrast to Appellant I's argument, the EBoA's abovementioned finding in Decision G1/98 could not simply be extrapolated to the present case.

The TBoA further noted that the patenting of products which are used in an excluded process was already recognised and accepted at an early stage in the legislative history of Article 2(b) of the Strasbourg Convention and Article 53(b) of the EPC (eg, a particular type of instrument for use in a surgical grafting process, a special greenhouse for growing a plant or substances and compositions for use in therapeutic and diagnostic methods). The legislature apparently saw no inconsistency in allowing patent protection for these devices, notwithstanding that the rights holder's prerogatives might then encompass the use of the patented devices in an excluded process.

The TBoA concluded that a process exclusion cannot have the general effect of precluding patents on any product that can be used in the excluded process.

However, it noted that in *Tomato* a product was being claimed which was being made (ie, not only used) when an excluded process was performed, as the breeding method disclosed in the patent necessarily implied the production of the claimed tomatoes. According to the TBoA, this would lead to a situation whereby plant breeders performing the essentially biological process disclosed in Appellant I's patent would directly fall under its scope and in addition be prevented from commercialising tomatoes obtained through the breeding method without being able to invoke the doctrine of

exhaustion. Thus, the TBoA concluded that by allowing the product claims of Appellant I, plant breeders would be more severely restricted in performing essentially biological processes than in the above-mentioned situation, where a product to be used in the course of an excluded process was patented.

Hence, the TBoA remarked that serious concerns remained that allowing claims to plant material which – according to the disclosure of the patent – was obtained by means of an essentially biological breeding process would *de facto* frustrate the legislature's intentions in framing the process exclusion. These concerns were emphasised in Decision G1/08 and make circumvention of the exclusion in many cases a matter of skilful claim drafting, thus diminishing the consistency and persuasiveness of the EPC's legislative framework with regard to patentable subject matter.

Supplementary questions

Similar to the proceedings in *Tomato*, the respondent rights holder in *Broccoli* (T83/05) decided to submit new requests that contained no method claims in response to Decision G2/07 of the EBoA. In view of Referral G2/12, which resulted from the related Case T1242/06, all parties to Case T83/05 requested that additional questions be referred to the EBoA.

The TBoA decided that the pending claim requests of the respondent to *Broccoli* contained relevant additional aspects which could be integrated into Referral G2/12 by formulating supplementary questions of law. Further, it was concerned that the withdrawal of its opposition by Appellant II in Case T1242/06 and the repeated requests by Appellant I for termination of the proceedings might mean that the case could end without a decision on the merits.

Therefore, the questions of pending Referral G2/12 were modified slightly and supplemented by Referral G2/13, which referred the following questions to the EBoA:

- Can the exclusion of essentially biological processes for the production of plants in Article 53(b) of the EPC have a negative effect on the allowability of a product

claim directed to plants or plant material such as plant parts?

- Is a product-by-process claim directed to plants or plant material other than a plant variety allowable if its process features define an essentially biological process for the production of plants?
- Is a claim directed to plants or plant material other than a plant variety allowable even if the only method available at the filing date for generating the claimed subject matter is an essentially biological process for the production of plants disclosed in the patent application?
- Is it relevant in the context of the above questions 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) of the EPC?

Contributing profiles



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- If a claim directed to plants or plant material other than a plant variety is considered not allowable because the plant product claim encompasses the generation of the claimed product by means of a process excluded from patentability under Article 53(b) EPC, is it possible to waive the protection for such generation by disclaiming the excluded process?

In comparison to the questions set out in Referral G2/12, the first question was modified to read “plant material such as plant parts” instead of “plant material such as fruits”. The third and fourth questions were adopted without amendments, while the fifth was a new question, which specifically took account of the fact that Auxiliary Request I submitted by the respondent during oral proceedings on March 1 2013 contained as a disclaimer the following wording at the end

of each claim: “wherein the claim does not encompass an essentially biological process for producing.” That is, the respondent appeared to be seeking to waive a part of the prerogatives of the owner of a product patent which encompass the right to prohibit others from producing the claimed product in any manner. According to the TBoA, the positive effect of the respondent’s proposed disclaimer was that producing the claimed product by an essentially biological process could no longer be prohibited.

Waiting on the EBoA

The *amiciae curiae* briefs received so far in both Referrals G2/12 and G2/13 – which are accessible via the EPO website – are approximately balanced between those in favour and those against the process exclusion of Article 53(b) of the EPC on claims to products produced by such processes.



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Supporters mostly argue in line with the arguments in favour raised by the TBoA in its interlocutory decision in Case T1246/06, while opponents rely mostly on the arguments put forward by the TBoA in the same case against such an extension of the process exclusion to product claims. In addition, opponents argue that since the purpose of excluding essentially biological processes for the production of plants from patentability was to give full effect to the ban on dual protection under the International Convention for the Protection of New Varieties of Plants, the term 'plant' in Article 53(b) of the EPC should be read as meaning that the exclusion is limited to processes for the production of plant varieties. In its reasons for Decisions G1/08 and G2/07, the EBoA had ruled out the interpretation of the term 'plant' as meaning 'plant variety'. Therefore, opponents require the EBoA to revise the broad definition given to an essentially

biological process in Decisions G1/08 and G2/07.

Oral proceedings in Cases G2/12 and G2/13 have been scheduled for October 27 2014. While it remains ambiguous what answers the EBoA will give to the referred questions, it is certain that the eventual decision will have a significant impact on the patent protection available to plant-related inventions. **iam**

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