Current Developments – Europe

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Introduction

Last December, the Technical Board of Appeal ("TBA") of the European Patent Office ("EPO") held that the recently amended Rule 28(2) of the *Implementing Regulations to the Convention on the Grant of European Patents* (the "Implementing Regulations") which excludes plants or animals exclusively obtained by means of an essentially biological process would conflict with Article 53(b) of the *Convention on the Grant of European Patents* ("EPC") as interpreted by the Enlarged Board of Appeal Decision ("EBoA") in the *Broccoli/Tomatoes II* decision[1]. Pursuant to Article 164(2) of the EPC which governs conflicts between the provisions of the EPC with those of the Implementing Regulations, the TBA held that Article 53(b) of the EPC would prevail and would render Rule 28(2) void. This decision is yet another piece in the ongoing saga whether plant products produced by essential biological processes could be protected under the provisions of the EPC. In addition, it highlights the sometimes complicated relationship between two major institutions in European patent law - the EPO and the European Union ("EU").

Background

The scope of the subject matter which may be patented in Europe is ex ante quite broad. Article 52 (1) of the EPC states that "European patents shall be granted for any inventions, in all fields of technology." However, subsection 2 of Article 52 of the EPC declares certain subject matter not to be inventions. The excluded subject matter ranges from discoveries, scientific theories, business methods to computer programs. Importantly, this exclusion only applies where the "subject-matter or activities referred to therein only to the extent to which a European patent application or European patent relates to such subject-matter or activities as such". In addition, Article 53 of the EPC provides for exceptions to patentability and excludes invention which would be contrary to "ordre public" or morality as well as "methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body". Finally, Article 53b) of the EPC states that patents should not be granted for "plant or animal varieties or essentially biological processes for the production of plants or animals."

[1] *State of Israel/Tomatoes II*, G 2/12 [2016] OJ EPO A27 and *Plant Bioscience/Broccoli II,* G 2/13 [2016] OJ EPO A28.

The regulatory framework of the EU has had lesser impact on the law of patents in comparison to other fields of intellectual property. However, the Biotech Directive (the "Directive")[2] has had substantial influence of the laws of EU Member States. The Directive regulates issues such as the patentability, the scope of protection of biotechnological patents as well as excluded subject matter. Its rules were also adopted within the framework of the EPC.[3] All EU Member States are also Contracting Member States of the European Patent Organisation. The Directive's rules were therefore adopted in order to avoid discrepancies between the law of the EPC and that of EU Member States who were obliged to implement these rules. Article 4 of the Directive corresponds to Article 53(b) of the EPC and excludes essentially biological processes for producing plants and animals from patentability. However, products produced by such processes are not explicitly excluded.

The *Broccoli/Tomato* I and II decisions by the EBoA of the EPO

The scope of the exclusion within Article 53(b) of the EPC has been the subject of two important decisions by the EBoA of the EPO. The consolidated decision *Broccoli I/ Tomato I*[4] was based on the referral in T 83/05[5] which related to a method of obtaining particular broccoli lines and on the referral within T 1242/06[6] relating to a method of breeding tomato plants which produce tomatoes with reduced fruit water content. The EBoA held that essentially biological processes which would make use of gene markers for selection could not be patented.

This decision was followed by the *Broccoli/Tomatoes II* decision on 25 March 2015. Again, the EBoA decided to elaborate on the points of law within one consolidated decision. It provided a lengthy discussion on the rules of interpretation with respect to Article 53(b) of the EPC stating that while "there is no general notion of an obligatorily restrictive construction of exceptions to patentability,"[7] it held that the exclusion of Article 53(b) of the EPC would need to be interpreted narrowly. Consequently, the EBoA held that "the process exclusion of Article 53(b) of the EPC does not extend directly to a product claim or a product-by-process claim directed to plants or plant material such as a fruit, or to plant parts other than a plant variety."[8]

The Commission's Notice

In the aftermath of the *Broccoli/Tomatoes II* decision, the European Parliament asked the European Commission (the "Commission") to review the patentability of products derived from essentially biological processes. The Commission issued a Notice[9] which outlined its

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[2] *Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions* [1998] OJ L213/13.
[3] *Administrative Council Decision*, OJ EPO 7/1999, 437–440.
[4] *Plant Bioscience/Broccoli*, G 2/07 [2012] OJ EPO, 130 and *State of Israel/Tomatoes*, G 1/08 [2012] OJ EPO, 20.
[5] *Plant Bioscience/Broccoli*, T 83/05 [2007] OJ EPO 644.
[6] *State of Israel/Tomatoes,* T 1242/06 [2008] OJ EPO 523.
[7] *State of Israel/Tomatoes II,* G 2/12 [2016] OJ EPO A27, 37.
[8] *State of Israel/Tomatoes II,* G 2/12 [2016] OJ EPO A27, 49.
[9] *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) OJ C411/3 (8 November 2016).

view on the law on this issue. It referred to Articles 4 and 2 of the Directive and noted that the Directive was silent as to whether plants or plant material (e.g. fruits or seeds), or animals/animal material obtained through essentially biological processes, could be subject to patent protection.

As to the impact of the decision by the EBoA on its analysis of the issue at hand, the Commission provided following interesting statement:

> *While these decisions of March 2015 are in line with the intentions of the drafters of the EPC, it is questionable whether the same result would have been reached in the EU context. Directive 98/44/EC does not distinguish between different layers of provisions, and its provisions should be interpreted together in their entirety. When trying to assess the intentions of the EU legislator when adopting the Directive, the relevant preparatory work to be taken into consideration is not the work which preceded the signature of the EPC in 1973, but that which relates to the adoption of the Directive.*[10]

After a lengthy deliberation on the negotiation history and of the provisions of the Directive, the Commission found that the Directive would foresee that plants and animals derived from essentially biological processes should not be considered patentable. It stated "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."[11] This finding consequently conflicts with the views of the EBoA in *Broccoli/Tomatoes II*.

Amendments to the Implementing Regulations

Following the Commission's Notice, the Administrative Council of the European Patent Organisation (the "Administrative Council"), which acts as the supervisory body of the EPO, amended Rule 28 of the Implementing Regulations in summer 2017.[12] It added the following subsection to Rule 28:

(*2) Under Article 53(b), European patents shall not be granted in respect of plants or animals exclusively obtained by means of an essentially biological process.*

Decision T 1063/18

The TBA was called to decide on the appeal against the decision of the Examining Division to refuse Syngenta's patent application. The invention in suit related to European patent application No. 12 756 468.0 called" New pepper plants and fruits with improved nutritional value". Claim 1 was directed to a "cultivated blocky fruit type pepper plant, bearing extreme

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[10] *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) OJ C411/3 (8 November 2016) 5.
[11] *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) OJ C411/3 (8 November 2016) 7.
[12] *Decision of the Administrative Council of 29 June 2017 amending Rules 27 and 28 of the Implementing Regulations to the European Patent Convention* (CA/D 6/17), Official Journal EPO, 2017, A56 <https://www.epo.org/law-practice/legal-texts/official-journal/2017/07/a56.html> .

dark green color at immature harvestable stage". The Examining Division, however, concluded that claims 1 and 2 would fall within the exception to patentability Article 53(b) of the EPC and Rule 28(2) of the EPC and consequently refused the application.

Syngenta appealed against the decision of the Examining Division and based its appeal on the fact "that Rule 28(2) EPC was in contradiction to Article 53(b) EPC as interpreted by the Enlarged Board of Appeal in its decisions G 2/12 and G 2/13."[13] The TBA agreed since it could not "deduce from decisions G 2/12 and G 2/13 any other interpretation of Article 53(b) EPC than that plants are not excluded from patentability, even if they can only be obtained by an essentially biological process."[14] Pursuant to Article 164(2) of the EPC,[15] which regulates conflicting interpretations, this would mean that text of the EPC would prevail over that of the Implementing Regulations which would make the newly amended Rule void. The TBA found that the Administrative Council would not have the legal power to amend the text of the EPC through the Implementing Rules:

> *the Administrative Council is not, in the light of Articles 33(1)(b) and 35(3) EPC, competent to amend the Convention, here Article 53(b) EPC, by amendment of the Implementing Regulations, here Rule 28(2) EPC.*[16]

Furthermore, the interpretation given by the EBoA of the EPC would be de facto binding on the TBA.[17] Where a Board of Appeal would consider it necessary to deviate from the EBoA's interpretation provided in an earlier decision, it should refer the question to the EBoA pursuant to Article 21 of the *Rules of Procedure of the Boards of Appeal*. Indeed, Article 112 (1)(a) of the EPC permits this where there is doubt on "a point of law of fundamental importance" or where there is need to ensure the uniform application of the law. With regards to the Commission's Notice, the Board noted that it would have no legal authority. Within the EU framework a binding interpretation on provisions of EU law such as the as the Directive would have to be decided in the last instance by the Court of Justice of the European Union ("CJEU").[18]

Referral to the EBoA

In its 159th meeting in March 2019, the Administrative Council decided that decision T 1063/18 should be referred to the EBoA in order to end the uncertainty raised. This should be conducted by means of a referral by the EPO President pursuant to Article 112(1)(b) of the EPC.

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[13] T 1063/18 (5 December 2018), 1.
[14] T 1063/18 (5 December 2018), 19.
[15] Article 164 EPC:
Implementing Regulations and Protocols
1. *The Implementing Regulations, the Protocol on Recognition, the Protocol on Privileges and Immunities, the Protocol on Centralisation, the Protocol on the Interpretation of Article 69 and the Protocol on Staff Complement shall be integral parts of this Convention.*
2. *In case of conflict between the provisions of this Convention and those of the Implementing Regulations, the provisions of this Convention shall prevail.*

[16] T 1063/18 (5 December 2018), 22.
[17] T 1063/18 (5 December 2018), 20.
[18] T 1063/18 (5 December 2018), 21.

A press release issued by the EPO stated:

> *The Contracting States expressed their concerns with regard to the legal uncertainty caused by decision T 1063/18. The President of the EPO expressed his view that a President's referral of the case to the Enlarged Board of Appeal is justified and necessary. The aim is to obtain an opinion from the Enlarged Board of Appeal on the patentability of plants exclusively obtained by essentially biological processes, hereby considering recent legal developments (interpretations and statements of the European Commission, the EU Council, European Parliament and EPO's Administrative Council on the interpretation of the European Patent Convention and the EU Bio-Directive, all of them concluding that there should be no patentability in these cases).*[19]

On 5 April 2019, the President of the EPO, António Campinos, submitted questions to the EBoA aiming to clarify the situation in relation to the patentability of plants exclusively obtained by essentially biological processes.[20]

Comment

The decision highlights the tricky relationship between the two major institutional players in European patent law. In addition, the stakes are high for the industry in this field of technology on whether patent protection may be available or not. It remains to be seen whether the EBoA will actually permit the EPO President's question pursuant to Article 112 (1)(b) of the EPC. This is only possible where "two Boards of Appeal have given different decisions on that question." It needs to be borne in mind that the *Broccoli/ Tomatoes II* decision which held that Article 53(b) of the EPC should not prevent claims in relation to plants or plant products produced by essentially biological processes was handed down by the EBoA. A decision by the CJEU would provide more legal certainty as the Commission's Notice was not deemed to be legally binding – an issue referred to in the Notice itself. .[21]

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[19] <https://www.epo.org/news-issues/news/2019/20190329.html>

[20] <https://www.epo.org/news-issues/news/2019/20190405.html>

[21] *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) OJ C411/3 (8 November 2016) 5.