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Pepper plants lead to hot decisions and patentable subject matter

NLO

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Pepper plants lead to hot decisions and patentable subject matter

By Bart Swinkels and Stijn van Dongen, NLO

On 5 December 2018 the Boards of Appeal decided that Rule 28(2) of the European Patent Convention (EPC) is in conflict with Article 53(b) of the EPC and that the article prevails over the rule under Article 164(2) of the EPC. As a result, Rule 28(2) is to be considered void and should be ignored. This means that plants (or animals) obtained via essentially biological processes are not excluded from patentability – despite Rule 28(2) explicitly saying so.

The proceedings in Case T 1063/18 concerned the appeal of a patent applicant (Syngenta) against the decision of an examining division to refuse a European patent application (EP 2 753 168) for the sole reason that the claimed subject matter falls within the exception to patentability according to Article 53(b) and Rule 28(2) of the EPC (plants exclusively obtained by means of an essentially biological process). Public oral proceedings were arranged for 5 December 2018, where the rule was determined to conflict with Article 53(b) and was ruled to not be enforceable. The Board of Appeal, enlarged to five members, considered that this matter had already been settled by the Enlarged Board of Appeal in 2015 and that no new referral was required.

When the seed of discord was sown

Rule 28(2) at the centre of the issue is rather new. On 29 June 2017 the Administrative Council of the European Patent Office (EPO) amended the regulations pertaining to the patentability of plants. In the new rule, plants and animals exclusively obtained by an essentially biological breeding process were explicitly excluded from patentability. These rules originally came into being as an implementation into the EPC of the

EU Directive on Biotechnological Inventions (98/44/EC). This directive was issued to harmonise European law in a field that was newly emerging at the time.

The decision by the Administrative Council to change the rules was taken after a proposal by the EPO, which in turn was made after a notice of the European Commission was issued in November 2016. In this notice, the European Commission clarified that, in its view, it was never the intention of the original directive to allow patents on biological processes or products obtained by such processes. Delving further back in time, this notice was triggered by the *Tomato II* and *Broccoli II* cases from the EPO's Enlarged Board of Appeal.

In 2015 the *Tomato II* (G 2/12) and *Broccoli II* (G 2/13) cases reached decisions which held that “plants are patentable even if they are obtained through essentially biological breeding methods involving crossing and selection”. In other words, plants can be patented, even if they were the result of traditional breeding, as long as the usual criteria for patentability are met and the technical feasibility of the invention is not confined to a particular variety. These decisions caused some commotion, leading up to the short-lived implementation of Rule 28(2) of the EPC.

Legal perspective

The Boards of Appeal, which issued the *Broccoli* and *Tomato* decisions, are not formally bound by an amendment of the EPC Implementing Regulations if they perceive the rule to be in conflict with an article. This is because articles trump rules. Therefore, the boards can declare a rule invalid and non-enforceable under Article 164(2) of the EPC (which the Enlarged Board of Appeal in G 2/07

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already did with Rule 26(5) of the EPC, which deals with a sort of definition of what essentially biological processes would be). This prerogative of the boards also applies when there is a conflict of an EPC rule with the interpretation of an EPC article, wherein the interpretation is established by a ruling of the Enlarged Board of Appeal (eg, T 315/03, Point 5.7). In the present case, a board of appeal once again exercised this discretion by voiding Rule 28(2) of the EPC.

The Administrative Council, while competent to amend the rules of the EPC (Article 33(1)(c)), is not competent to amend the articles without meeting further requirements. In this light, the board in the present case, T 1063/18, reasoned that the Administrative Council overstepped its competence by implementing this new rule. The fact that Rule 28(2) would indirectly amend the scope of Article 53 could be seen as an indirect amendment of an article – one that was already clarified by authoritative Enlarged Board of Appeal decisions in the *Broccoli* and *Tomato* cases.

Thus, even though the rule change looked clear-cut when it was implemented, it did not actually achieve its intended effect. The patentability of plants obtained by means of an essentially biological process is still a fact.

Rooting through the decision

The following are some relevant excerpts from the written decision, which illustrate the discussion above:

23. In the decision under appeal, the examining division reasoned that Rule 28(2) EPC constitutes a “clarification of the scope of Article 53(b) EPC”. The board however cannot 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. Since Rule 28(2) EPC excludes plants or animals exclusively obtained by means of an essentially biological process from patentability, its meaning is in conflict with the meaning of Article 53(b) EPC as interpreted by the EBA.

24... in the present case, Rule 28(2) EPC in fact reverses the meaning of Article 53(b) EPC, as interpreted by the EBA. In view of this direct contradiction, interpreting Rule 28(2) EPC in such a way that no contradiction exists is not possible.

25. The board therefore concurs with the appellant’s view... that Rule 28(2) EPC is in conflict with Article 53(b) EPC as interpreted by the EBA...

34... the Administrative Council is not... competent to amend the Convention, here Article 53(b) EPC, by amendment of the Implementing Regulations, here Rule 28(2) EPC...

43. The view that Rule 28(2) EPC served to ensure consistency between the Biotech Directive and the EPC and with that legal certainty, is based on the presumption that the Biotech Directive has to be interpreted as set out in the Notice. As explained under point 29 above, such a presumption is not valid unless the CJEU has decided on the matter, which it has not. In fact, adopting the interpretation of the Notice in the absence of a decision of the CJEU on the matter, creates a risk of misaligning the provisions of the EPC with the Biotech Directive, should the CJEU later concur with the analysis of the EBA...

46. Having established that Rule 28(2) EPC is in conflict with Article 53(b) EPC as interpreted by the EBA and in view of Article 164(2) EPC, it must be concluded that the provisions of the Convention prevail.

Culturing the future

If it is still the intention of the legislature that plants obtained by means of an essentially biological process are to be excluded from patentability, then a few possibilities remain.

One option is that Article 53(b) of the Convention could be changed via a direct process. However, this would not be a short-term exercise because it requires the unanimity of all the contracting states at a diplomatic conference. Moreover, such a change in law would require appropriate transitional provisions to take account of existing rights of patentees and applicants. A

further point that would need to be considered is that the exclusion of plants produced by essentially biological processes creates additional legal uncertainty because such plants are nowadays no longer clearly distinguishable from plants produced by new gene-editing technologies such as CRISPR-Cas.

Another possibility is that the European Court of Justice (ECJ) would have to deal with the patentability of plants obtained by means of an essentially biological process under the EU Biotech Directive. While the ECJ is not formally bound by decisions of the EPO's Enlarged Board of Appeal (and *vice versa*), the ECJ would be wise not to ignore such well-reasoned and authoritative decisions as the *Broccoli* and *Tomato* cases. After all, not only does the Enlarged Board of Appeal have final competence in interpretation of the EPC, its decisions are reached only after exhaustively applying established international provisions on the interpretation of treaties, and

after considering facts from all available sources. In *Tomato II* (G 2/12) and *Broccoli II* (G 2/13) the Enlarged Board of Appeal already considered the relevant provisions of the EU Biotech Directive (Articles 2, 3 and 4) and concluded that an exception of plants (and animals) is not supported by the directive. The more recent notice of the European Commission is not legally binding and could be seen as merely reflecting the current political climate. The notice itself mentions its own non-binding nature. In light of this, it would not be unexpected if the ECJ were to come to a conclusion in line with that of the Enlarged Board of Appeal.

As a third option, the Enlarged Board of Appeal could come to a new point of view on Article 53. However, this is unlikely for multiple reasons – the first of which is that *Tomato II* (G 2/12) and *Broccoli II* (G 2/13) are already a second consideration of the subject matter, confirming the earlier point of view. A third consideration



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Bart Swinkels has more than 25 years' experience in patenting in the life sciences area. His strength is that he is passionate about finding creative solutions in complex IP situations to help clients bring their innovative products to market with robust protection, free of competitor patents. Mr Swinkels specialises in the areas of genomics, genome editing, gene therapy, immunology (antibodies and vaccines), metabolic engineering, microbiology and the breeding of plants and animals. He has gained extensive experience in handling adversarial proceedings before the national courts, as well as in European opposition proceedings up to the Boards of Appeal.



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would therefore be highly unlikely. In addition, to even bring a case before the Enlarged Board of Appeal, certain conditions must be met. For example, a board of appeal needs to make a referral. This is virtually out of the question, as the only board which deals with this subject matter has just explicitly stated that referral to the Enlarged Board of Appeal is not required. Referral can also be made by the president of the EPO, but this can be done only when conflicting decisions from the Board of Appeal exist; this is not the case, at least explicitly. The president might try and find a conflicting opinion to justify a new referral to the Enlarged Board of Appeal. For example, in T 297/88 the board found that a board of appeal should refer a question that has already been decided by the Enlarged Board of Appeal to that enlarged board again if, weighing all circumstances, it considers that legal developments which have occurred since the earlier decision let it appear desirable in the public interest to have the issue re-assessed by the Enlarged Board of Appeal. It remains to be seen whether this can be construed as actually conflicting with the present decision. Also, it is not a given that T 297/88 also applies when a case has already been decided more than once with consistent outcome.

As a fourth option, the European Commission could amend the provisions of the biotech directive corresponding to the relevant EPC articles. Article 33(1)(b) allows the Administrative Council to amend the EPC articles if the amendment brings the articles in line with an international treaty relating to patents, or with European Community legislation relating to patents. Faced with changed international law, the competency of the Administrative Council would in such a case expand to a direct amendment of Article 53. If the article itself were to be amended, the Boards of Appeal would be unable to rely on the present argument that the rule conflicts with an article. Moreover, the G 2/12 and G 2/13 Enlarged Board of Appeal decisions would no longer apply

to the latest wording of Article 53, meriting new consideration from the Enlarged Board of Appeal as well. Thus far, it appears as if the commission has been reluctant to open up the biotech directive, as it may well open a can of worms that could also affect the patentability of biotechnological inventions outside the realm of plant breeding. Nonetheless, if the commission does go forward with amending the biotech directive, good governance, as well as the European Convention on Human Rights, would require the commission to legislate proper transitional provisions to take account of existing rights of patentees and applicants.

A final consideration is that the decision formally binds other cases only ‘where the facts are the same’. This technicality does not seem very hopeful for limiting the reach of this decision: when Rule 28(2) becomes relevant, it can only be expected that the facts relating to patentability will be substantially the same.

Which plans might bear fruit?

In a 20 February 2019 meeting of the Committee on Patent Law, the EPO and representatives of all the contracting states discussed Decision T 1063/18. This discussion was also attended by representatives from the European Commission as observers. The committee addressed different potential options for the way forward, and were particularly interested in options for obtaining a new opinion from the Enlarged Board of Appeal. However, this would require an unconventional approach, because the EPC does not allow for a referral to the Enlarged Board of Appeal in the present circumstances. Moreover, whether the Enlarged Board of Appeal has at present any reason to deviate from its well-reasoned earlier decisions in G 2/12 and G 2/13 is under serious doubt. All parties present at the committee meeting expressed the intention to find a solution in the short term, but a diplomatic conference between 38 states is not generally seen as a short-term undertaking.

Judging by Point 43 of the decision, it can be concluded that the board might expect consideration of the situation by the ECJ. This, or the amendment of the biotech directive, might be the only ways forward for those wishing to reinstate Rule 28(2) (or its effect) to its short-lived glory. Then again, the president might try to refer the case based on the allegedly conflicting decisions. One thing that is certain is that there is not much certainty at the moment.

The little plant that persisted

The patent application at issue related to “a cultivated blocky fruit type pepper plant” wherein several genetic markers associated with an extreme dark green colour in the fruit were to be present. The refusal by the Examining Division has been overturned in appeal, and the Examining Division is now bound by this decision. The appeal was not a solitary affair – there were various third-party observations and interested members of the public present at the oral proceedings. Given this interest, it is probably a safe bet that notices of opposition are already being drafted.

Latest developments

At the time of writing, the president of the EPO has expressed his view that a president’s referral

of the case to the Enlarged Board of Appeal is justified and necessary. Whether this will lead to a decision is uncertain; the Enlarged Board considers presidential referrals inadmissible if they are not based on conflicting board decisions (see G4/98, reason 1.1), and has dismissed earlier presidential referrals even when *prima facie* conflicting decisions existed (see G3/08, headnote 6) because the conflict was seen as “a legitimate development of the case law”. As the Dutch say, developments in this case ‘grow as fast as cabbage’. *iam*



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