

September 21<sup>st</sup>, 2018**Comments on the “Rule 28(2) disclaimer”**

The following comments refer to the proposed amendments to the Guidelines for Examination in the EPO compared to the previous version as of November 2017.

Many changes in the proposed guidelines relate to the need to introduce a disclaimer when claims are directed to plants characterized by a technical feature that may be the result either from a technical intervention or from an essentially biological process (EBP). The need for such a disclaimer seems to originate from the change to Rule 28(2) which now reads as follows:

*Rule 28 – Exceptions to Patentability*

...

*(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.*

The comments below are generally with regard to the disclaimer issue.

**1) The legal basis for a Rule 28(2) disclaimer should be clarified first**

Discussions about the need of a disclaimer seem to have started on the change to new Rule 28(2). However, it should be noted that the legality of that rule change is currently being challenged before the Technical Board of Appeal of the EPO in T1063/18 with requests to refer several questions to the Enlarged Board of Appeal (EBA). Third party observations addressing concerns with regard to the rule change were filed in that case<sup>1</sup>. It is therefore requested not to introduce changes in the guidelines during the pendency of T1063/18 and any potential referral to the EBA<sup>2</sup>, or in the alternative to clarify in

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<sup>1</sup> These can be accessed at the EPO register under the documents with respect to European Patent Application EP 12756468. Observations by e.g. Prof. Kirchberg concluded that: The amendment/supplementation of Rule 28 ...contradicts the primacy of the Convention over the Implementing Regulations (Art. 164 para. 2 EPC). It also infringes the legitimate expectations based on the existing legal and judicial practice as a generally accepted procedural principle in the EPC contracting states (Art. 125 EPC). This is because of the retrospective application of the amended Rules which has been ordered. Finally, it also unjustifiably intervenes with the proprietary right to the European patent under Art. 60 EPC guaranteed by Art. 1 of the Additional Protocol I of the ECHR.

<sup>2</sup> Before the change to Rule 28 (2) was introduced complaints were raised that claims directed to plants being issued in the plant breeding area might lack clarity and would somehow affect the freedom to operate of breeders. It should be pointed out that rather than applying the Rule 28(2), another option would be to ensure that claims to plants carrying a novel characteristic could only be granted when the genetic basis for such characteristic is clearly and unambiguously and reproducibly described in the specification. This would allow breeders to unequivocally determine whether any material in their possession would be infringing any such claim. Further, it would give legal certainty to all involved parties what is patentable subject matter or not. Any still remaining freedom to operate concerns could be addressed by other legal means such as by a breeder's exemption, or by the prior use exemption or by (to some extent already existing) facilitated licensing offerings. Raising the clarity requirements for plant based inventions is actually already an ongoing process as is shown by developing case law (T0967/10, T1988/12).

the guidelines that the requirement for removing subject matter pursuant to Rule 28 (2) – by disclaimer or otherwise - is contingent upon the applicability of Rule 28(2) as it currently exists.

## 2) There is no absolute requirement for a disclaimer

Even if the current Rule 28 (2) remains applicable this does not necessarily “mandate” or “require” a disclaimer. The proposed guidelines use wording like “a disclaimer is necessary to delimit the claimed subject matter...” and “A disclaimer is required in all cases and, in particular, even if the description only mentions a technical method of production and is silent on the use of an essentially biological process.”. In fact there does not seem to be a legal basis for doing so and the passages in the proposed guidelines that relate to the mandatory introduction of a disclaimer do not provide any legal authority by reference to standing case law of the EPO.

The EPC gives no basis for requiring introducing a disclaimer into any claim. To the contrary, it is standing case law of the Appeal Boards that the Applicant is solely responsible for wording of an application, including claims. Introducing the strict requirement of a disclaimer having no basis in the EPC in particular into claims of a specific technical field, drawn to a specific product by way of internal instructions is not in line with the provisions of the EPC<sup>3</sup>. Although nobody is legally bound by the Guidelines, the Examining and Opposition Divisions of the EPO are bound to comply with the Guidelines based on internal instructions. Examining and Opposition Divisions will therefore have no choice but to impose a disclaimer to applicants. The appeal boards of the EPO however are strictly and only bound by the EPC (Art 23 (3) EPC). Thus, introducing a disclaimer requirement for plants into the Guidelines will oblige Examination and Opposition Divisions bound to the Guidelines by EPO internal instructions to only propose that single unarguable solution, which applicants will have no choice but to appeal. Constantly having to appeal such decisions contradicts the principle of efficiency of proceedings and equity and good faith an applicant can rely on in a constitutional system.

In fact when looking at the notice on introduction of Rule 28 (2) (CA56/17 point 41) seems, when faced with claims including both natural and artificial mutant plants, to direct the practice in the opposite directions:

*Some forms of mutagenesis occur in nature (usually called spontaneous mutagenesis). However, whether a specific mutation indeed would occur as the result of spontaneous mutagenesis is entirely speculative. Application of an exception to patentability cannot depend on hypothetical considerations and on whether specific process elements are traceable in the claimed product, in particular when taking into account the considerable developments in the technical field of plant breeding in the past and the unpredictable nature of future developments. (emphasis added)*

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<sup>3</sup> There is precedent for not requiring a disclaimer even though the claims may encompass embodiments excluded from patentability (G1/98). Indeed plant varieties are clearly not patentable under Art 53 (b) EPC but there is no requirement for applicants to disclaim plant varieties from claims directed to plants. In this regard it may be important to note that Art 53 (b) and Rule 28(2) in defining exceptions to patentability use similar wording : “European patents shall not be granted in respect of...”.

Furthermore, in a comparable situation, the European Patent Office now routinely grants claims directed to (human) stem cells without requiring a disclaimer to exclude stem cells obtained by a method which involves destruction of a human embryo although such methods excluded from patentability under Art 53(a) and Rule 28(1) (see e.g. EP 2455452, EP 2548950 or EP 2611910).

Furthermore in notice CA56/17 there is an entire section about use of disclaimers but this only generally points to the case law of disclaimers. Nowhere is there any suggestion that any disclaimer should be mandatory. Even in the proposed guidelines Part H, the use of a disclaimer and its form is left completely at the discretion of the applicant.

### **3) There is no need for a disclaimer – other options are available**

If at all, applicants should be able to remove any subject matter from the claims by other means. In fact at least one example of permitted claim language in the proposed guidelines seems to make this possible without the need for a disclaimer.

*A mutant of a plant carrying a heritable exchange in a nucleotide sequence effected by technical means, e.g. UV mutagenesis or CRISPR/Cas*

If Rule 28(2) remains applicable, it should be clarified that there are multiple ways in which the claims can comply with it and that the applicant is free to choose the wording of the claims.

In this case, other guidance with regard to acceptable claim language should be included. For instance, it is suggested - in the spirit of the above-cited example - to clarify that a claim reciting “a mutated gene” (rather than “a mutant gene”) implies an active mutation step so that the requirements of Rule 28(2) are implicitly complied with. Other suggested alternative to comply with Rule 28 (2) could be “human created mutant gene”, “manufactured” or “artificially induced mutant gene” or similar wording . In this respect, it may even be provided that the adjectives “mutated”, “human created” or “artificially induced” would not necessarily have to find support in the specification to allow compliance with both R. 28(2) and Art. 123(2) EPC.

### **4) Introduction of “Rule 28(2) disclaimers” provides legal uncertainty**

The proposed guidelines indicate that the disclaimer is required to exclude subject matter that is not patentable pursuant to Rule 28 (2) and seem to suggest that the disclaimer should be in the form of

*“ A plant ... provided that the plant is not exclusively produced by means of an essentially biological process”.*

In fact, in many applications applicants will have no choice but to use such wording because they have no support for other claim language that would effectively exclude subject matter that is not patentable pursuant to Rule 28 (2) and would run into restrictions with regard to the use of undisclosed disclaimers (as set forth in proposed guidelines Part H).

However it is submitted that a disclaimer in the form specified above is unclear and would introduce legal uncertainty both for applicants and third parties as it would be based on unclear terms (see below).

The term “essentially biological processes”

Rule 28(2) refers to processes by which the claimed plant product is obtained (i.e. essentially-biological processes). However the definition of essentially biological processes is not at all clear.

Rule 26(5) provides 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.<sup>4</sup>*

This definition was taken over from the Biotech Patent Directive EC 98/44/EC and was necessarily the one used by the European commission in drafting their 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 (the “Commission Notice”). Indeed, the Commission Notice took the view 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”*. In addition the Commission Notice links the technical character of the invention to reproducibility.

However the EPO, in G2/07 deviated from the principle of alignment with 98/44/EC in adopting a broader definition of an EBP and furthermore defines processes comprising steps of crossing and selection as non-technical, irrespective of their reproducibility and technical character. This definition is reflected in the Guidelines Part G 5.4 and is used also for purposes of Rule 28(2) :

*“Thus the exclusion extends to plants and animals exclusively obtained by means of an essentially biological process where no direct technical intervention in the genome of the plants or animals takes place, as the relevant parental plants or animals are merely crossed and the desired offspring is selected for. This is the case even if technical means are provided serving to enable or assist the performance of the essentially biological steps. In contrast, plants or animals produced by a technical process which modifies the genetic characteristics of the plant or animal are patentable.”*

*“Determining whether a plant or animal is obtained by exclusively biological means entails examining whether there is a change in a heritable characteristic of the claimed organism which is the result of a technical process exceeding mere crossing and selection, i.e. not merely serving to enable or assist the performance of the essentially biological process steps.”*

Therefore it remains unclear what is actually disclaimed with a disclaimer in the form set forth above since the scope of the disclaimer will depend on the definition of EBP that is adopted. It will be up to the Boards of Appeal of the EPO and/or the National courts to determine which definition is appropriate in the context of Rule 28(2).

This fundamental question is also raised in T1063/18 where one of the questions requested for referral to the ELBA is :

*“What is the applicable definition for an essentially biological process in the context of Rule 28(2) EPC?”*

Consequently, in line with the definition in the commission notice, the term essentially biological processes should be clarified first before any disclaimer requirement based on such term should be considered to be introduced.

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<sup>4</sup> The Administrative Council when introducing the amendments to Rule 28 did not amend Rule 26(5), which consequently stays in place.

The scope of removal of Rule 28(2) subject matter (by disclaimer or otherwise)

The Guidelines in Section F IV 4.24 provide that :

*“Claims defining plants or animals produced by a method including a technical step which imparts of technical feature to a product constitute an exception in so far as the requirements of Art 53 (b) are concerned”*

This provision is not based on any precedent and is not binding on the Boards of Appeal of the EPO or on National Courts. It is however contrary to existing product-by-process EPO case law which consistently equates “obtained” as meaning “obtainable”. It is therefore not certain how this would be decided in the end. Nevertheless, the outcome of such interpretation is especially important with regard to claims in the form *“a plant obtained by a technical process”* (which is a form of claim explicitly endorsed in the guidelines (see examples in Part G II 5.4.2.1) as well as to claims with a disclaimer which amount to “plants not obtained (exclusively) by an essentially biological process”.

The term “exclusively obtained”

In principle offspring of a mutated plant that carry the mutation would be obtained by processes that involve only crossing and selection and could be regarded as plants exclusively produced by EBP. Although the guidelines provide that

*“When looking at the offspring of transgenic organisms or mutants, if the mutation or transgene is present in said offspring it is not produced exclusively by an essentially biological method and is thus patentable”*

it remains to be seen how the disclaimer would be interpreted with regard to offspring, especially in the case of potential infringers who have developed varieties based (unknowingly perhaps) on the basis of plants originally produced by a technical process. Such potential infringers may argue, that since “plants obtained exclusively by an essentially-biological process” have been disclaimed from the patent scope, offspring of the claimed plants, which are obtained only by crossing and selection, are part of the disclaimed subject-matter and are therefore not infringing the patent, even though such claimed plants and their offspring originate from a process having created or modified a trait in their genome. Although this may not have been the intent of the legislator having created Rule 28(2), the consequence may well be for patentees that their technically-obtained plant inventions become so easily copied that applicants may consider not to file such applications any more- this solely because of having been forced to introduce a disclaimer.

**5) The introduction of a disclaimer aggravates undesired consequences of Rule 28(2)**

As discussed above in section 4) the use of the disclaimer in the form set forth there results in legal uncertainty. It is simply not clear what subject matter is covered by a claim that has such a disclaimer. This is true from the perspective of both patentee and for the potential infringer<sup>5</sup>.

An undesired effect of the new Rule 28 (2) seems to be that it allows that use is made of the information provided by a published patent application disclosing a trait that is introduced into a plant by technical

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<sup>5</sup> In this respect it should not be forgotten that, since the guidelines are not binding on the boards of appeal of the EPO and on national courts, neither party will necessarily be able to rely on the guidelines for interpretation of a disclaimer.

means, to “copy” the invention by using “essentially biological processes”. Indeed, the fact that it was technically created means that it is likely to be genetically characterized at DNA level in the patent application. As soon as the application is published the disclosed genetic information can be used in combination with current technologies to screen large plant populations to identify plants with the similar genetic change (which would then have occurred naturally). Plants obtained in such way would however then not necessarily be covered by claims of the patent under Rule 28 (2). Apparently, this seems to create a loophole for potential infringers to benefit from the teaching of a patent application and create products that would be non-infringing<sup>6</sup>.

From a patentee’s position the generation of such product obtained by EBP using the technical information of a patent should be equivalent with having made such product by technical means and should therefore not fall under any disclaimed subject matter. Obviously the presence of a disclaimer in the form set forth above makes this problem even more visible.

## 6) Conclusions

The following comments should be taken into account when revising the proposed Guidelines:

- The introduction of the need to remove subject matter in accordance with Rule 28 (2) - by disclaimer or otherwise - should await resolution of cases such as T1063/18.
- There is no overall need to remove subject matter - by disclaimer or otherwise -solely on the ground of Rule 28 (2). It is well accepted that claims can cover subject matter that is not patentable on its own (G1/98)..
- The introduction of a disclaimer would introduce legal uncertainty for all involved parties. If Rule 28(2) remains applicable in its current form, guidance should rather be provided on various other ways of claim construction, including by way of examples.

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<sup>6</sup> In this regard – as discussed above - the discussion resulting in the new Rule 28(2) seemed to have been primarily arising from the concern of breeders that they may be prevented from using traits that are subject of patents but that they had independently developed prior to patent publication. However, if Rule 28(2) remained applicable in its current form, breeders could also independently develop patented traits after patent publication even making use of the teaching of the patent.