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European Patent Office
D-80298 München
GERMANY

For the attention of: **The Registrar, The Enlarged Board of Appeal**

By facsimile and courier

Dear Sirs

Amicus curiae brief on questions referred by the Board 3.3.04 in case T83/05 to the Enlarged Board of Appeal – pending as G2/07

A Background & Summary

The Chartered Institute of Patent Attorneys (CIPA) has considered the questions referred to the Enlarged Board of Appeal in case G2/07. CIPA is the professional and examining body for patent attorneys (also known as patent agents) in the United Kingdom. The Institute was founded in 1882 and was incorporated by Royal Charter in 1891. It represents virtually all of the 1,700 registered patent attorneys in the United Kingdom, whether they practice in industry or private practice. The total membership is over 3,000 and includes trainee patent attorneys and other professionals with an interest in intellectual property matters. CIPA maintains the Register of Patent Agents under statutory authority on behalf of the Department of Trade and Industry and reports to the Comptroller-General of Patents, Trade Marks and Designs at the UK Intellectual Property Office. Nearly all registered patent attorneys in the UK are also professional representatives before the EPO (i.e. they are European Patent Attorneys as well).

CIPA's written comments to the Enlarged Board of Appeal are set out below. They are submitted in respect of the questions referred to the Enlarged Board of Appeal in case G2/07.

We submit that the exclusion of Article 53(b) EPC should be construed narrowly, in line with the EPO Enlarged Board of Appeal decision in G5/83, for consistency with Rule 23b(5) EPC and also to uphold current case law regarding exclusion for patentability in other fields of technology. This means that a non-microbiological process for the production of plants including the steps of crossing and selection should escape the exclusion of Article 53(b) EPC if the process contains a further step of a technical nature. Such non-excluded processes would then be assessed, just like any other invention, against the standard EPC patentability requirements (to ensure that they are industrially applicable, new and involve an inventive step). If the latter requirements are correctly applied, the EPO will be able to ensure that patents are awarded only in cases where the resulting limited monopoly is appropriate.

B The Questions

Question 1

1. Does a non-microbiological process for the production of plants which contains the steps of crossing and selecting plants escape the exclusion of Article 53(b) EPC merely because it contains, as a further step or as part of any of the steps of crossing and selection, an additional feature of a technical nature?

Article 53(b) EPC specifies that European patents shall not be granted in respect of "essentially biological processes for the production of plants or animals". An essentially biological process is defined in Rule 23b(5) EPC as one which "consists entirely of natural phenomena such as crossing or selection".

It is therefore appropriate that the answer to question 1 is "yes": if a process for the production of plants comprises a technical step, in addition to or as a part of crossing and selection steps, such that the process no longer consists entirely of natural phenomena, then the process should escape the exclusion of Article 53(b) EPC.

By way of technical background, it is observed that the biological processes of crossing and selection to produce new plants are embodied in conventional plant breeding. A breeding programme commences with the crossing of two parent plants, each comprising one or more desirable traits that the breeder wishes to combine in a new distinct, stable and uniform plant variety. Such conventional plant breeding relies on natural re-combination of the genes of the parent plants in their offspring. Although natural recombination results in a large diversity of new gene combinations, most of the first filial generation (F1) offspring will include non-desirable combinations but these (and desirable) combinations will be apparent only when the offspring are crossed again to produce a second (F2) generation. Plants need to be carefully selected for the desired traits and the best plants crossed again, often for many generations, until the final end product is obtained. It is commonly estimated that it will take 6-10 years to produce a new plant variety using traditional plant breeding techniques.

It is now well known to use scientific advances such as genetic modification, marker assisted breeding and other techniques to speed up and improve the efficiency of the production of new plant varieties. Marker assisted breeding, for example, may rely on molecular markers developed from genomic studies, linking one or more markers to genes or traits. It is therefore possible to determine the presence or absence of a trait in a plant before it is tested for expression in the breeding programme. Such non-natural techniques are thus used in combination with essentially biological processes such as crossing and selection, but are distinct from the biological processes *per se*.

Turning to the legal issues, options for determining whether or not a process for the production of plants or animals should be excluded under Article 53(b) have been outlined by the Board of Appeal in T1054/96. They said:

"25. To decide whether a process can be defined as an 'essentially biological process' requires a value judgment of the extent to which it should be non-biological before it loses the status of 'essentially biological process', which value judgement can be arrived at by different approaches.

26. One approach is analogous to that used under Article 52(4) EPC relating to methods of treatment by surgery and therapy. As stated for example in decision T 820/92 (OJ EPO 1995, 113) 'in the case of a method involving administration of two or more substances, the question for the

purposes of Article 52(4) EPC is not whether the main or even the only reason for carrying out the whole of the claimed method is non-therapeutic. Rather, a method claim falls under the prohibition of Article 52(4) EPC if the administration of one of the substances is a treatment by therapy, and the administration of this substance is a feature of the claim.'

27. The consequences of such an approach would be that to be considered as 'non essentially biological', the claimed process for producing plants should only comprise clearly identified non-biological process steps and no 'essentially biological' steps (whatever uncertainties may be attached to the term). A process involving the crossing of two existing plants such as in claim 24 would not be allowable. This approach would have the advantage that it would be clear to applicants what steps to mention in a claim.

28. A second approach would be that adopted in decision T 320/87 (OJ EPO 1990, 71) where it was held that whether or not a process is to be considered as 'essentially biological' has to be judged on the basis of the essence of the invention taking into account the totality of human intervention and its impact on the result achieved (see point 6 of the reasons). The consequences of such an approach, as discussed in T 356/93 (*loc. cit.*, see point 28 of the reasons), would be that 'a process for the production of plants comprising at least one essential technical step, which cannot be carried out without human intervention and which has a decisive impact on the final result does not fall under the exceptions to patentability under Article 53(b) EPC first half sentence.' Following such an approach leaves it to the instances of the EPO to assess whether a claim as a whole is directed to an 'essentially biological process for the production of plants'. Its outcome could be relatively uncertain.

29. Yet another approach would require, for a process for the production of plants to escape the prohibition of Article 53(b) EPC with regard to essentially biological processes, at least one clearly identified "non-biological" process step but allow any number of additional 'essentially biological steps' which would be carried into allowability by the 'non-biological' process step. The definition given in the proposed EU directive Article 2 No. 2 adopts this approach. The definition is 'A process for the production of plants or animals is essentially biological if it consists entirely of natural phenomena such as crossing or selection'. This approach would be that most favourable to applicants. It is not the approach so far adopted by the boards of appeal."

We submit that the third option outlined in Reasons 29 of T1054/96 quoted above is the correct approach for determining whether or not a non-microbiological process for the production of plants falls under the Article 53(b) exclusion. Although it may appear in some ways to be most favourable to applicants, as suggested in T1054/96, this is only in the assessment of whether the claimed subject-matter is allowable under Article 53(b) – if yes, then the applicant should be subjected to the usual rigorous EPO examination procedure to ensure the claims satisfy other patentability requirements.

In comparison, by placing too much emphasis on value or subjective judgements such as whether a technical feature "has a decisive impact on the final result" or "on the basis of the essence of the invention taking into account the totality of human intervention and its impact on the result achieved" (see Reasons 28 in T1054/96 above), the second option noted above introduces legal uncertainty for the applicant as well as third parties. Such issues regarding contribution of the invention to the art should, we submit, be assigned to the investigation of other patentability criteria such as novelty and inventive step.

The Guidelines for Examination in the EPO (Updated 12 December 2007) gives examples at C-IV, 4.6.2, of which processes for the production of plants or animals may be considered to be excluded from patentability under Article 53(b) EPC as impacted by Rule 26(5) EPC. Methods that are deemed to be allowable include a process of treating a plant or animal to improve its properties or yield,

because "although a biological process is involved the essence of the invention is technical". We submit that although the Guidelines here follow the Board of Appeal in T320/87 and similar decisions, they suggest that in order to determine whether or not a process falls under the Article 53(b) EPC exclusion there must be a consideration of further criteria other than simply ascertaining whether or not the process is essentially biological or not. Our view is that this is not the correct approach.

Some clarification may be helpful as to what is meant in Question 1 referred by T83/05 by "an additional feature of a technical nature". It is self-evident that the technical feature must be more than simply a commonplace technical device (for example, a magnifying glass or a pair of forceps) for use in an essentially biological process such as crossing or selecting. Rather, the technical feature must be one which characterises the step in which the feature is involved, and hence the process, as being one which does not consist entirely of natural phenomena such as crossing or selection. As noted above, this does not require an assessment of whether the technical feature contributes something beyond a trivial level but merely whether it makes the process non-natural. Deciding whether the resulting process is trivial in comparison with the prior art would be undertaken when inventive step is considered using established procedures.

A "yes" answer to Question 1 correct is also consistent with current EPO case law in other areas of technology. For example, computer program-related subject-matter may be barred from patentability if its falls under the exclusion of Article 52(2)(c) EPC which states that programs for computers (as such) shall not be regarded as inventions. Previously, various Boards of Appeal had deemed that in assessing whether such subject matter was patentable, it was necessary to determine not only whether the subject-matter was of a technical nature but also whether a technical contribution to the art had been made. This so-called "technical contribution approach" has in more recent years been discounted by the Boards of Appeal. As stated in T1173/97 (reasons 8):

"Determining the technical contribution an invention achieves with respect to the prior art is therefore more appropriate for the purpose of examining novelty and inventive step than for deciding on possible exclusion under Article 52(2) and (3)".

Furthermore, in T931/95 (Headnote 4), it was noted that:

"There is no basis in the EPC for distinguishing between 'new features' of an invention and features of that invention which are known from the prior art when examining whether the invention concerned may be considered to be an invention within the meaning of Article 52(1) EPC. Thus there is no basis in the EPC for applying this so-called contribution approach for this purpose".

Both of the above decisions have been approved by various other Boards, for example in T258/03 (reasons 3.3).

We consider that there is similarly no basis in the EPC for assessing the Article 53(b) EPC exclusion by adopting an equivalent "contribution approach" which has been deemed unsound in the computer program-related field of technology.

If the Enlarged Board in the present case deems that additional criteria other than the inclusion of a technical step in an otherwise biological process for the production of plants are required for assessing the Article 53(b) EPC exclusion, then this will be inconsistent with the comparable current EPO practice in the filed of computer-program-related inventions.

We submit in conclusion that a clear, practical and objective approach to assessing whether or not a non-microbiological process for the production of plants (and equally, animals) falls under the Article 53(b) should involve a simple determination of whether the process comprises at least one

identifiable non-biological process step, i.e. a step of a technical nature. The answer to Question 1 should accordingly be "yes".

Question 2


2. If question 1 is answered in the negative, what are the relevant criteria for distinguishing non-microbiological plant production processes excluded from patent protection under Article 53(b) EPC from non-excluded ones? In particular, is it relevant where the essence of the claimed invention lies and/or whether the additional feature of a technical nature contributes something to the claimed invention beyond a trivial level?

We consider that the answer to question 1 should be positive. As discussed above, the issues raised in Question 2 regarding the contribution of the claimed invention to the state of the art should be considered under novelty (Article 54) and inventive step (Article 56 EPC) and not under Article 53(b) EPC.

C Conclusions

We consider that a narrow interpretation of the exclusion in Article 53(b) EPC is correct, and submit that the Enlarged Board should accordingly answer "yes" to Question 1, leaving determination of contribution to the art highlighted in Question 2 to the assessment of other patentability requirements such as novelty and inventive step.

Yours faithfully



On behalf of the Chartered Institute of Patent Attorneys (CIPA)