Contents

1. Introduction

The following comments are provided by the Chartered Institute of Patent Attorneys (CIPA) to alert the IPO (as well as the heads of the delegations to the Administrative Council from other EU Member States) to a grave risk of EU Member States obligations under a fundamental provision of EU law (Article 267 TFEU) being contravened if Rules 27 and 28 EPC are amended in accordance with the proposal of the President of the European Patent Office as set out in CA/56/17.

CIPA also wish to draw attention to financial liabilities on EU Member States and/or their delegates to the Administrative Council that may arise if the amendments to Rules 27 and 28 EPC are successful in achieving their intended purpose.

CIPA is the professional and examining body for patent attorneys 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. Most registered patent attorneys in the UK are also professional representatives before the European Patent Office (EPO; i.e. they are also European patent attorneys)

2. Background

2.1 The primacy of EU law

As explained, for example, in paragraph 65 of the CJEU's Opinion 1/09, a particular characteristic of EU law is its primacy:

> "*It is apparent from the Court's settled case-law that the founding treaties of the European Union, unlike ordinary international treaties, established a new legal order, possessing its own institutions, for the benefit of which the States have limited their sovereign rights, in ever wider fields, and the subjects of which comprise not only Member States but also their nationals (see, inter alia, Case 26/62 van Gend & Loos [1963] ECR 1, 12 and Case 6/64 Costa [1964] ECR 585, 593).* ***The essential characteristics of the European Union legal order thus constituted are in particular its primacy over the laws of the Member***

> ***States and the direct effect of a whole series of provisions which are applicable to their nationals and to the Member States themselves*** *(see Opinion 1/91 [1991] ECR I-6079, paragraph 21)*" (emphasis added).

The primacy of EU law has the consequence that EU Member States' obligations under that law cannot be overridden (e.g. by contrary provisions in national laws of EU Member States, or in international agreements to which those Member States are a party).

2.2 Article 267 TFEU

One of the cornerstones of EU law is the preliminary reference procedure set out in Article 267 of the Treaty on the Functioning of the European Union (TFEU):

> "*The Court of Justice of the European Union shall have jurisdiction to give preliminary rulings concerning:*
> *(a) the interpretation of the Treaties;*
> *(b) the validity and interpretation of acts of the institutions, bodies, offices or agencies of the Union;*
>
> *Where such a question is raised before any court or tribunal of a Member State, that court or tribunal may, if it considers that a decision on the question is necessary to enable it to give judgment, request the Court to give a ruling thereon.*
>
> *Where any such question is raised in a case pending before a court or tribunal of a Member State against whose decisions there is no judicial remedy under national law, that court or tribunal shall bring the matter before the Court.*
>
> *If such a question is raised in a case pending before a court or tribunal of a Member State with regard to a person in custody, the Court of Justice of the European Union shall act with the minimum of delay*".

The case law of the CJEU, such as *Cilfit* (C-283/81), has clarified that the obligation under Article 267 TFEU to refer questions to the CJEU is **mandatory** for "*any court or tribunal against whose decisions there is no judicial remedy under national law*" when:
(I) interpretation of a provision of EU law is relevant to national proceedings;
(II) the interpretation is not *acte éclairé*; and
(III) the interpretation is not *acte clair*.

2.3 Interpretation of Article 4(1)(b) of the Biotech Directive

Article 4(1)(b) of the Biotech Directive excludes from patentability "*essentially biological processes for the production of plants*". However, there is nothing in the Biotech Directive to indicate that the *products* of such (excluded) processes are also excluded from patentability.

The provisions of Article 4(1)(b) of the Biotech Directive have been interpreted by a judicial authority of an EU Member State. Unsurprisingly, the decision of that judicial authority (the Court of Appeal of The Hague; 28 May 2013, *Cresco v Taste of Nature*; http://bit.ly/2rH5S80) was that the products of essentially biological processes for the production of plants are **not** excluded from patentability.

(As an aside, we also note that the above-mentioned decision of the Dutch court arrived at an interpretation of Article 4(1)(b) of the Biotech Directive that is wholly consistent with the interpretation of Article 53(b) EPC arrived at by the EPO Enlarged Board of Appeal in decisions G2/12 and G2/13).

By way of contrast, Notice C/2016/6997 from the EU Commission (OJ EU 2016/C 411/03) reaches a completely different conclusion on the interpretation of Article 4(1)(b) of the Biotech Directive.

Irrespective of the persuasiveness (or otherwise) of the reasoning used to arrive at the conclusions in Notice C/2016/6997, it is important to note that:

- the EU Commission is an executive and not a judicial body;
- to date, the CJEU has not provided a ruling on the interpretation of Article 4(1)(b) of the Biotech Directive; and
- in the introduction to the above-mentioned Notice, the Commission acknowledges that "*Only the Court of Justice of the European Union is competent to interpret Union law*".

In the light of the above, it is possible to reach the following conclusions.

(1) Due to the issuance of Notice C/2016/6997, there is an ongoing (and, as yet, unresolved) dispute over the interpretation of the exclusion of Article 4(1)(b) of the Biotech Directive.

(2) There has been no relevant CJEU ruling, and so the matter is **not** *acte éclairé*.

(3) In the light of the divergence of opinion between the Court of Appeal of The Hague and the EU Commission, the interpretation of Article 4(1)(b) of the Biotech Directive proposed Notice C/2016/6997 is **not** *acte clair*.

As will be evident from conclusions (2) and (3) above, this means that any dispute regarding the interpretation of Article 4(1)(b) of the Biotech Directive **must** (in the light of Article 267 TFEU and the interpretation of that provision in *Cilfit*) now be settled either by:

- confirmation of the prior judicial interpretation; or
- a reference to the CJEU, seeking a ruling on the interpretation of Article 4(1)(b).

2.4 EU law vs. the European Patent Convention

There is nothing in decisions such as *Cilfit* to suggest that the delegation of certain tasks to an international organisation (such as the EPO) is capable of relieving EU Member States of their obligations under Article 267 TFEU. Indeed, we submit that opinions provided by the CJEU make it clear that not only do those obligations persist (in keeping with the principle of primacy of EU law), but also that any attempts to dispense with them will call into question the compatibility of the international organisation with EU law.

Firstly, the CJEU's Opinion 1/09 (relating to the proposal to create a European and Community Patents Court) held as follows:

> "*68. It should also be observed that the Member States are obliged, by reason, inter alia, of the principle of sincere cooperation, set out in the first subparagraph of Article 4(3) TEU, to ensure, in their respective territories, the application of and respect for European Union law (see, to that effect, Case C 298/96 Oelmühle and Schmidt Söhne [1998] ECR I 4767, paragraph 23). Further, pursuant to the second subparagraph of Article 4(3) TEU, the Member States are to take any appropriate measure, general or particular, to ensure fulfilment of the obligations arising out of the Treaties or resulting from the acts of the institutions of the European Union. In that context,* ***it is for the national courts and tribunals and for the Court of Justice to ensure the full application of European Union law in all Member States and to ensure judicial protection of an individual's rights under that law*** *(see, to that*

> *effect, Case C 432/05 Unibet [2007] ECR I 2271, paragraph 38 and case-law cited).*
> *...*
>
> *80. While it is true that the Court has no jurisdiction to rule on direct actions between individuals in the field of patents, since that jurisdiction is held by the courts of the Member States, nonetheless* ***the Member States cannot confer the jurisdiction to resolve such disputes on a court created by an international agreement which would deprive those courts of their task, as 'ordinary' courts within the European Union legal order, to implement European Union law and, thereby, of the power provided for in Article 267 TFEU, or, as the case may be, the obligation, to refer questions for a preliminary ruling in the field concerned***" (emphasis added).

In other words, the CJEU held that, where the (national courts of) EU Member States have obligations under EU law, those obligations cannot be delegated to a body that is unable to make preliminary references under Article 267 TFEU.

The purpose of Article 267 TFEU is to provide "*a fundamental mechanism of European Union law aimed at enabling the courts and tribunals of the Member States to ensure uniform interpretation and application of that law within the European Union*" (see the CJEU's "Recommendations to national courts and tribunals in relation to the initiation of preliminary ruling proceedings", OJ EU 2012/C 338/01). In this respect, the importance of preliminary references under Article 267 TFEU to ensuring judicial protection of rights under EU law cannot be overstated. Indeed, this very point was central to the CJEU's Opinion 2/13 (which ruled the proposed accession of the EU to the European Convention on Human Rights to be incompatible with EU law):

> "*176. In particular, the judicial system as thus conceived* ***has as its keystone the preliminary ruling procedure provided for in Article 267 TFEU, which, by setting up a dialogue between one court and another, specifically between the Court of Justice and the courts and tribunals of the Member States, has the object of securing uniform interpretation of EU law*** *(see, to that effect, judgment in van Gend & Loos, EU:C:1963:1, p. 12), thereby serving to ensure its consistency, its full effect and its autonomy as well as, ultimately, the particular nature of the law established by the Treaties (see, to that effect, Opinion 1/09, EU:C:2011:123, paragraphs 67 and 83)*".

These principles of EU laws are neatly summed up in the comments of the CJEU judge Allan Rosas (in his article "The National Judge as EU Judge: Opinion 1/09" in the book "Constitutionalising the EU Judicial System"):

> "*The added value of Opinion 1/09 lies undoubtedly in its emphasis of the essential role played by national courts as integral parts of the Union judicial system. Just as the tasks of Union Courts cannot be transferred to non-EU bodies,* ***the national courts of EU Member States have a constitutional mandate which cannot, in principle, be outsourced****. Both Union Courts and national courts fulfil a 'duty entrusted to them both' of ensuring that in the interpretation and application of the Treaties law is observed*".

Thus, regardless of their participation in the EPC, we submit that the EU Member States are still obliged to ensure that all patents filed in or in respect of those States are handled in accordance with relevant EU legislation (such as the Biotech Directive).

2.5 Obligations of EU Member States regarding the EPC

When examining patent applications filed in respect of EPC Contracting States, the EPO (including its Boards of Appeal) is bound only by provisions the provisions of the EPC.

Further, despite being a "*court or tribunal against whose decisions there is no judicial remedy under national law*" for patent applications filed in respect of (i.e. designating) EU Member States, the Boards of Appeal of the EPO (in common with the Enlarged Board of Appeal) are unable to refer questions to the Court of Justice of the EU (a conclusion confirmed in G2/06).

This places the EU Member States in a delicate position with regard to patent applications filed in respect of those States where:
- examination is effectively "outsourced" to the EPO; and
- patentability (in EU Member States) of claimed subject matter must be determined by interpretation of provisions covered by EU law (such as the Biotech Directive).

This is because the EU Member States' obligations under Article 267 TFEU will be contravened if such patent applications are refused by the EPO in circumstances where the applicant is entitled to obtain a preliminary reference to the CJEU regarding the interpretation of relevant provisions of EU law.

Thus, the EU Member States' obligations under Article 267 TFEU will only ever be satisfied if the Boards of Appeal of the EPO, when dealing with provisions of the EPC that overlap with provisions of EU law, interpret those provisions in a manner that:
(A) is *acte éclairé* under EU law (i.e. in accordance with a CJEU judgement);
(B) is *acte clair* under EU law (i.e. based upon an interpretation that is so obvious that no reasonable doubt is left); or
(C) affords the benefit of the doubt to the patent applicant (i.e. allows for the grant of a patent that, if necessary, can give rise to preliminary references to the CJEU *via* legal actions before national courts).

3. Relevance to the proposed amendments of Rules 27 and 28 EPC

The proposed amendments to Rules 27 and 28 EPC do not fall under any of categories (A) to (C) above. This is not least because they are intended to produce a result (rejection of patent applications directed towards the products of essentially biological processes) that directly contradicts the interpretation of Article 4(1)(b) of the Biotech Directive arrived at by the Court of Appeal of The Hague (see section 1.3 above).

Therefore, if implemented, the above-mentioned amendments would give rise to a grave risk of EU Member States contravening their obligations under EU law, and in particular their obligations under Article 267 TFEU.

That is, if implemented, the proposed amendments would inevitably give rise to the situation where a Board of Appeal of the EPO (or the Enlarged Board of Appeal) is faced with a decision to either:
(i) provide a ruling in accordance with Rules 27 and 28 EPC as amended; or
(ii) reaffirm the decision in G2/12 and G2/13 on the grounds that Rules 27 and 28 EPC as amended are invalid (due to inconsistency with Article 53(b) EPC).

In that situation, the obligations of EU Member States under Article 267 TFEU would only be satisfied if the (Enlarged) Board of Appeal proceeded in accordance with option (ii), i.e. by effectively nullifying the amendments to Rules 27 and 28 EPC. On the other hand, if any such Board of Appeal instead elected to proceed in accordance with option (i), this would lead to a contravention of Article 267 TFEU. This is because:

- for the reasons outlined in section 1.3 above, a reference to the CJEU is now **mandatory** under Article 267 TFEU if a final rejection of a patent application in (or in respect of) an EU Member State is contemplated, based upon any interpretation of Article 4(1)(b) of the Biotech Directive that diverges from that arrived at by the Court of Appeal of The Hague; but
- the Board in question would be incapable making the reference to the CJEU that would be required in order to ensure that the EU Member States obligations under Article 267 TFEU are fulfilled.

4. Conclusion

We believe that, to the extent that the proposed amendments to Rules 27 and 28 EPC are effective in denying patentability to the products of essentially biological processes, those amendments would contravene the obligations of EU Member States under Article 267 TFEU.

This contravention of EU Member States' obligations under EU law would persist unless and until the CJEU interprets Article 4(1)(b) of the Biotech Directive in accordance with the proposed amendments to Rules 27 and 28 EPC. (Though we note that one effect of the proposed rule changes would be to reduce the number of granted patents that could give rise to cases in which a national court might seek a preliminary reference from the CJEU – which could, in turn, have the effect of prolonging the period during which the contravention of Article 267 TFEU persists.)

5. Possible Consequences

With regard to possible consequences of the above-mentioned contravention of EU law, we note that these might include the following.

5.1 Constitutional law

Contravention of Article 267 TFEU would, we believe, represent the removal of a fundamental right (to a preliminary reference) that is guaranteed under a founding treaty of the EU. As such, that contravention may also have repercussions under the constitutional laws of those countries whose constitutions incorporate the provisions of the TFEU.

5.2 Financial liabilities

The case law of the CJEU has established that the failure of Member States to honour their obligations under EU law can give rise to financial liability for either a Member State (e.g. as in the joined cases of C-46/93 (*Brasserie du Pêcheur*) and C-48/93 (*Factortame*)) or an individual official of the State (e.g. as in as C-470/03 (*A.G.M.-COS.MET*)).

We therefore believe that any contravention of EU law (such as Article 267 TFEU) that arises due to adoption of the proposed amendments to Rules 27 and 28 EPC could give rise to financial liability for:
- EU Member States; and/or
- individual officials (AC delegates) of such Member States.

Further, even if the CJEU ultimately interprets of Article 4(1)(b) of the Biotech Directive in accordance with Rules 27 and 28 EPC as amended, we note that it is far from certain that this would eliminate the liability of Member States for prior infractions of the fundamental right (enshrined in Article 267 TFEU) of patent applicants to obtain a preliminary reference to the CJEU, e.g. according to the CJEU's ruling in *Cilfit*.