On 29 June 2017, the Administrative Council (AC) of the European Patent Office (EPO) took the decision to amend Rules 27 and 28 of the Implementing Regulations to the European Patent Convention (EPC).

The amendments introduce a statutory interpretation of Article 53(b) EPC that excludes certain plants and animals from patentability. The stated intention of the amendments was to ensure that the EPO aligns its law and practice with an interpretation of the Biotech Directive (no 98/44/EC) set out in an EU Commission Notice, which Notice was stated to have been endorsed by both the Council of the EU and the European Parliament.

The amendments to the Implementing Regulations of the EPC mark the end of a chapter in an ongoing controversy surrounding the patentability of subject-matter covered by the Biotech Directive. Whilst that chapter began with rulings from the Enlarged Board of the EPO that were favourable to patentees, it has ended with a ‘win’ for those advocating that plants or animals that represent the products of conventional breeding methods (so-called ‘essentially biological processes’) should not represent patentable subject-matter in Europe.

This author does not have any strong views on whether, as a matter of policy, the products of conventional breeding methods should be patentable in Europe, at least in theory (that is, provided that they meet all of the standard requirements for patentability). Indeed, as Article 27.3 of TRIPs provides WTO Member States with the ability to exclude ‘plants and animals other than micro-organisms’ from patentability, the legislatures in Europe have considerable freedom with regard to policies that can be implemented in this area without contravening TRIPs.

However, mere compatibility with TRIPs does not mean that the amendments to EPC Rules 27 and 28 are compatible with all relevant laws (including EU law and human rights law), or even that those amendments will persuade the Boards of Appeal of the EPO (or national courts of the EU Member States) to overturn their previous conclusions on the interpretation of the exclusion from patentability defined in Article 53(b) EPC.

This article therefore investigates whether the amendments to EPC Rules 27 and 28 are ‘safe’ (that is, compliant with both EU law and human rights law) and whether they are likely to be effective in harmonising law and practice both within the EPO and across the EU Member States. In reaching negative conclusions on both points, this article further questions why the AC elected to take action that is likely to be ‘unsafe’ and/or ineffective, and whether the AC may ultimately have cause to regret taking that action.

The Amendments

Amended Rules 27 and 28 EPC entered into force on 1 July 2017.
The most important amendment was the introduction of new Rule 28(2) EPC, which provides a statutory interpretation of Article 53(b) EPC:

**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.**

For consistency, Rule 27(b) EPC (which provides for patentability of certain plants and animals) was amended to indicate that it is ‘without prejudice’ to new Rule 28(2).

The AC’s decision indicates that the amended rules will apply not only to applications filed on or after 1 July 2017, but also to all patents and patent applications that are subject to pending proceedings before the EPO. In other words, the new rules apply retroactively (within the EPO).

**EU Law and the EPC**

The amendments to Rules 27 and 28 EPC ‘read on’ to an area of patent law that, for EU Member States, is governed by Article 4(1)(b) of the Biotech Directive. Thus, it is important to establish whether the amendments comply with EU law. However, to do this, it is necessary to first outline a number of legal provisions and principles that are pertinent to the interrelationship between EU law and the EPC.

**No direct connections**

The principle of supremacy of EU laws means that national courts of EU Member States are obliged to afford individuals rights guaranteed under EU laws, regardless of whether provisions of national law afford those rights. Thus, for example, the courts of EU Member States are obliged to apply the provisions of the Biotech Directive when assessing the validity of national patents relating to plants or animals. This obligation extends to all forms of ‘national’ patents, that is, whether granted by a national patent office or by the EPO.6

However, the EPO (including its Boards of Appeal) is not subject to the same obligations. This is because the EPC is an international treaty that contains no provisions that explicitly subject the EPO to any obligations under EU law.

Thus, at least in theory, the AC is free to amend provisions of the EPC in any manner that it sees fit, regardless of whether those amendments are consistent with EU law. Also, the various divisions of the EPO are only bound by the provisions of the EPC (though they may consider other sources of law, including EU law, when interpreting provisions of the EPC in a ‘contextual’ or ‘dynamic’ manner).

In other words, it is possible (in theory) for the EPO to assess the validity of claims directed towards ‘biotech’ subject-matter by using standards that diverge from those mandated (for the patent offices and courts of the EU Member States) under the Biotech Directive.

**Relevant, indirect connections?**

While there may not be any direct connections between EU law and the EPC, there are indirect connections.

Contracting States to the EPC (including all EU Member States) are obliged to ensure equivalence between national patents and European patents with respect to:

- the effect of a patent and the conditions to which it is subject (Article 2(2) EPC); and
- the grounds upon which a patent can be revoked (Article 138 EPC).

Thus, EU Member States are obliged to assess validity of national patents in accordance with the Biotech Directive and to ensure that the same standards are applied to European patents.

When it comes to the rules governing the activities of the EPO (as opposed to the rules governing national courts and patent offices), the significance of these combined obligations is open to debate. Nevertheless, it is clear that the EU legislator intended to rely upon Articles 2(2) and 138 EPC in order to achieve ‘harmonisation’ between the provisions of the EPC (and their interpretation) and those of the Biotech Directive. This is most evident from paragraph 15 of the Explanatory Memorandum to the original proposal for a Biotech Directive,7 which:

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6) This is confirmed by the CJEU’s decision in C-428/08 (Monsanto; http://bit.ly/2iCvoKa), where the CJEU ruled that the extent of protection provided the patent in question (which was granted by the EPO) was subject to the constraints imposed by Article 9 of the Biotech Directive.
7) COM/95/0661 final – COD 95/0330 (see also OJ EU 1996/C-296/04).
states that ‘a directive harmonising Member States’ legislation may not directly influence the EPC and the European Patent Office’s rulings’ (emphasis added); and

– subsequently references indirect connections provided by Articles 2(2) and 138 EPC.

In other words, it appears that the EU legislator expected the EU Member States to use their status as EPC Contracting States to ensure that the provisions of the EPC (and their interpretation) are ‘harmonised’ with the Biotech Directive.

**Overriding obligations on EU Member States**

EU Member States are obliged to respect not only the provisions of specific legislation (EU Treaties, Regulations and Directives) but also interpretations of those provisions set out in rulings of the Court of Justice of the EU (CJEU).

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 purpose of that procedure 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’.8

According to case law of the CJEU,9 any ‘court or tribunal against whose decisions there is no judicial remedy under national law’ must use the preliminary reference procedure in circumstances where interpretation of a provision of EU law is relevant to national proceedings and the interpretation is neither:

– acte éclairé (that is, already the subject of a ruling from the CJEU); nor
– acte clair (that is, so obvious that no reasonable doubt is left).

The Boards of Appeal of the EPO are clearly a ‘court or tribunal against whose decisions there is no judicial remedy under national law’. However, because they are established under an international treaty, they fall outside the institutional and judicial framework of the European Union and are therefore unable to participate in the preliminary reference procedure under Article 267 TFEU.

Nevertheless, participation of the EU Member States in the EPC may well not remove their obligations under Article 267 TFEU.

This is, first, because the relevant provisions of Article 267 TFEU originate in Article 177 of the EEC Treaty, which was concluded in 1957. Thus, EU Member States’ obligations in connection with the preliminary reference procedure predate even the original version of the EPC10 by over 15 years.

Perhaps more importantly, the Biotech Directive not only predates all incarnations of Rules 27 and 28 EPC (including previous versions of those rules11) but also the current version of the EPC.12 This is significant because it means that EU Member States’ obligations to interpret the provisions of the Biotech Directive using the preliminary reference procedure predate all (potentially contrary) obligations of those Member States under Rules 27 and 28 EPC.

**Do the Amendments Comply With EU Law?**

With the above background in mind, it is now possible to answer the question of whether the amendments to Rules 27 and 28 comply with EU law.

**General principles**

It is not necessary for the EPO to ensure that the EPC complies with EU law. This is because of the absence of any direct connections between the two legal systems.

However, this is not the end of the matter. Whilst it may be perfectly ‘legal’ for the EPO to amend the EPC without regard to EU law, this does not mean that there are no consequences for the EU Member States that consent to such amendments.
The reason for this emerges from case law of the CJEU on the subject of the interplay between EU law and international treaties to which EU Member States are signatories. Thus, for example, paragraph 60 of the CJEU’s judgment in C–124/95\(^{13}\) neatly summarises the principle that EU Member States cannot voluntarily consent to adoption of measures under an international treaty that are contrary to EU law:

> It should, in any event, be remembered that, when an international agreement allows, but does not require, a Member State to adopt a measure which appears to be contrary to Community law, the Member State must refrain from adopting such a measure. (emphasis added)

It is certainly true that the EPC requires EU Member States to recognise decisions of the EPO, including unappealable rulings from EPO Boards of Appeal in connection with grant and opposition proceedings. However, there are no provisions of the EPC that both predate the Biotech Directive and require the Boards of Appeal of the EPO to provide rulings that are in any way inconsistent with EU law.

Thus, it appears that EU law obliges EU Member States to refrain from consenting to any amendments to the EPC\(^{14}\) that are liable to lead to decisions of the EPO that are irreconcilable with either the Biotech Directive or Article 267 TFEU.

**Detailed analysis**

In the light of the general principles outlined above, the view of this author is that the amendments to Rules 27 and 28 will contravene EU law if they achieve the stated objective of aligning the law and practice of the EPO with the interpretation of the Biotech Directive that is set out in the Commission’s Notice.

This conclusion has nothing to do with the persuasiveness (or otherwise) of the Commission’s reasons for interpreting the Biotech Directive in a manner that excludes from patentability the products of ‘essentially biological processes’. Instead, the conclusion stems from the following observations:\(^{15}\)

1. The EU Commission is an executive and not a judicial body.
2. As acknowledged in the Commission’s Notice, only the CJEU is competent to interpret EU law.
3. To date, the CJEU has not provided a ruling on the interpretation of the exclusion from patentability that is set out in Article 4(1)(b) of the Biotech Directive.
4. The Court of Appeal of The Hague (that is, a national court of an EU Member State) has interpreted that exclusion and found that it does not preclude the grant of patents to the products of ‘essentially biological processes’.
5. In view of points (3) and (4) above, the interpretation of Article 4(1)(b) of the Biotech Directive set out in the Commission’s Notice is neither acte éclairé nor acte clair.
6. In the light of point (5) above and Article 267 TFEU, any ‘court or tribunal against whose decisions there is no judicial remedy under national law’ intending to provide a ruling based upon the Commission’s interpretation of Article 4(1)(b) of the Biotech Directive cannot do so without first using the preliminary reference procedure to obtain the CJEU views on the interpretation of that provision.

In other words, EU law now requires the Member States of the EU to ensure that all final instance courts or tribunals either:

(a) continue to grant (or uphold) patents to the products of ‘essentially biological processes’ in accordance with the Dutch court ruling mentioned in point (4) above; or

(b) invoke the preliminary reference procedure to obtain a ruling from the CJEU on the interpretation of Article 4(1)(b) of the Biotech Directive.

However, if the amendments to EPC Rules 27 and 28 achieve their stated objective, then they will produce results that are contrary to both options (a) and (b) above. That is, they will

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\(^{13}\) C–124/95 (Centro-Com; http://bit.ly/2v88Eo2).

\(^{14}\) Or at least amendments subsequent to entry into force of the Biotech Directive on 30 July 1998.

\(^{15}\) Further commentary on these points can be found in the observations of CIPA on proposals to exclude organisms produced by biological processes from patentability (http://bit.ly/2tksnPc).

lead to EPO Boards of Appeal revoking or refusing relevant patent rights, without any possibility for the proprietors or applicants to invoke their right to obtain a preliminary reference to the CJEU.

Further, as will be evident from points (1) and (2) above, the interpretation of Article 4(1)(b) of the Biotech Directive set out in the Commission's Notice is non-binding. This means that there was simply no need for the EPC to be amended in the light of the Commission's Notice.

It therefore follows that not only are the amendments to EPC Rules 27 and 28 designed to achieve a result that contravenes EU law but that the delegations to the AC from EU Member States were under no obligation to consent to those amendments. In the view of this author, this represents a clear violation of the principle, as set out in C–124/95, that EU Member States cannot voluntarily consent to adoption of measures under an international treaty that are contrary to EU law. As such, it is arguable that the EU Member States (or at least those that supported the amendments to EPC Rules 27 and 28) will be financially liable for failing to ensure that patent applicants and proprietors are afforded rights guaranteed under EU law.

Will the Amendments be Effective?

Whilst the amendments to EPC Rules 27 and 28 may not be entirely ‘safe’ for the EU Member States, the above-mentioned problems under EU law might only arise if those amendments are effective in aligning the law and practice of the EPO with the amended rules (that is, in ensuring that the EPO no longer follows the interpretation of Article 53(b) EPC set out in G2/12 and G13).

However, there are good reasons to doubt whether the amendments will be suitably effective. This is because, whilst first instance departments of the EPO (Examining and Opposition Divisions) may well provide rulings in accordance with the amended rules, it is doubtful that any Board of Appeal of the EPO (that is, any ‘tribunal against whose decisions there is no judicial remedy’) will be persuaded to do the same.

The potential divergence of views between first and second instance departments of the EPO is based upon Articles 23(3) and 164(2) EPC. Article 164(2) EPC indicates that Articles of the EPC prevail if any conflict arises between those Articles and the Implementing Regulations. Whilst first instance departments of the EPO may nevertheless feel ‘pressured’ by internal instructions to follow the amended rules, Article 23(3) EPC ensures that the Boards of Appeal are not bound by any such instructions. Thus, the Boards of Appeal will be obliged to ignore Rules 27 and 28 as amended if they believe that those rules conflict with Article 53(b) EPC.

The key question for the Boards of Appeal will therefore be whether the amended rules (and/or the Commission Notice upon which they are based) provide sufficient legal basis to diverge from the Enlarged Board of Appeal’s prior interpretation of Article 53(b) EPC.

In G2/12 and G2/13, the Enlarged Board of Appeal was careful to adopt ‘a methodical interpretation of Article 53(b) EPC in respect of, primarily, its wording and, secondarily, considering also the legislator’s intention and the aspects of systematic and historical interpretation’. In this respect, it is striking that the Enlarged Board’s view was that:

(A) none of the primary or secondary considerations support the contention that Article 53(b) excludes from patentability the products of essentially biological processes; but

(B) at least systematic, historical and dynamic interpretations, as well as consideration of the Biotech Directive, support the opposite contention.

Whilst it is true that the Notice issued by the EU Commission will now also need to be considered, it must be remembered that the Notice is non-binding and was issued by a non-judicial body. As mentioned above, the EPO, therefore, has no obligation to align its law and practice with that Notice. By way of contrast, the Enlarged Board of Appeal’s decision in G5/8318 makes it clear that the EPO is obliged to give full consideration to decisions of national courts of the EPC Contracting States (which, in this instance,
include the above-mentioned decision of the Court of Appeal of The Hague:  

The establishment of harmonised patent legislation in the Contracting States must necessarily be accompanied by harmonised interpretation. For this reason, it is incumbent upon the European Patent Office, and particularly its Boards of Appeal, to take into consideration the decisions and expressions of opinion of courts and industrial property offices in the Contracting States. (emphasis added)

In combination with other considerations (including both (A) and (B) above), the Dutch court decision, therefore, bolsters the Enlarged Board's interpretation of Article 53(b) EPC to such an extent that it seems highly improbable that the mere issuance of Notice from the Commission could possibly challenge the validity of that interpretation.

In the light of the above, this author's view is that there are no valid grounds upon which a Board of Appeal of the EPO could accept the interpretation of Article 53(b) EPC as set out in EPC Rules 27 and 28 in preference to the Enlarged Board's interpretation as set out in G2/12 and G2/13.

Finally, it is worth noting that there are separate grounds for questioning whether Boards of Appeal at the EPO will condone the application of amended Rules 27 and 28 to cases filed before 1 July 2017. This is because the case law of the EPO recognises and protects legitimate expectations based upon established practices. Indeed, it affords particular prominence to expectations based upon decisions of the Enlarged Board of Appeal (such as G2/12 and G2/13). As explained in Legal Board of Appeal decision J25/95:  

The users’ confidence in the continuity of a practice based on a decision of the Enlarged Board may be considered particularly legitimate since all Boards of Appeal are expected to follow the Enlarged Board’s interpretation of the EPC.

**Other Considerations**

Setting aside the issues of compliance with EU law and effectiveness (within the EPO), there are still further reasons to question the AC’s decision to amend Rules 27 and 28 EPC. These reasons relate to harmonisation of the law across the EU Member States and to principles of the European Convention on Human Rights (ECHR).

**Harmonisation of the law**

Whilst presented as a means to ‘safeguard … the uniformity in harmonised European patent law’, it is far from certain that the amendments to Rules 27 and 28 EPC will have the effect of harmonising the law across the EU Member States. This is because the (potentially conflicting) views of the CJEU may need to be taken into account.

The CJEU has not yet been asked for its views on the interpretation of Article 4(1)(b) of the Biotech Directive. However, if and when a preliminary reference to the CJEU is made on this point, which is still perfectly possible, the resulting ruling from the CJEU will be binding upon all EU Member States.

It is of course impossible to be certain which interpretation the CJEU will favour. However, given the decisions of the Court of Appeal of The Hague and the Enlarged Board of Appeal of the EPO, it would not be unreasonable to expect the CJEU to disagree with the Commission and rule that the products of ‘essentially biological processes’ are not excluded from patentability. If that happens, then the amendments to Rules 27 and 28 EPC will have achieved the exact opposite of their stated objective, namely disharmony with the laws of the EU Member States.

In this context, the AC’s decision to amend Rules 27 and 28 EPC seems somewhat premature, as the EPO will have little choice but to reverse those amendments if the CJEU disagrees with the Commission’s interpretation of the Biotech Directive. Moreover, the AC’s decision appears to risk irreversible refusal or revocation (by the EPO) of patent rights that could ultimately prove to have been valid under the CJEU’s interpretation of the Biotech Directive.

There would of course have been a ‘risk’ to maintaining Rules 27 and 28 EPC in their previous form. That is, the EPO may have granted or maintained patents that could ultimately...
have proved to be invalid under the CJEU’s interpretation of the Biotech Directive. However, in that instance there would be no irreversible loss of rights. This is because grant or maintenance of a patent by the EPO does not preclude third parties from seeking invalidation of that patent before the national courts.

The ECHR

All EPC Contracting States are signatories to the ECHR. Amongst other rights of individuals that are protected by the ECHR is the right to peaceful enjoyment of property defined in Article 1 of Protocol 1 to the Convention. In its case law, the European Court of Human Rights (ECtHR) has established that this right:

- applies to the protection of intellectual property, including in circumstances where there is merely a legitimate expectation of obtaining an IP right;
- can be violated if property is taken without payment of an amount ‘reasonably related to its value’.

Of perhaps more immediate concern for the national delegations to the AC is that the ECtHR has established a precedent for holding an individual state responsible for entering into treaty commitments that violate the ECHR. An important point in this context is that Article 53(b) EPC has not been amended, and that the exclusion from patentability defined in that Article has consistently been interpreted by judicial authorities to not preclude the patenting of the products of ‘essentially biological processes’. This is likely to mean that proprietors of, or applicants for, patents filed before the entry into force of amended Rules 27 and 28 EPC will have little difficulty in demonstrating a legitimate expectation of securing patent rights in respect of (novel, inventive and sufficiently disclosed) products not excluded from patentability under the prior, judicial interpretation of Article 53(b) EPC.

Thus, patent proprietors or applicants adversely affected by retroactive imposition of amended Rules 27 and 28 EPC may well be able to seek compensation from EPC Contracting States on the grounds that those amended rules violate the principles of Article 1 of Protocol 1 to the ECHR.

Summary and Conclusions

In the light of the above, this author believes that the following conclusions can be reached in connection with the amendments to Rules 27 and 28 EPC.

- If the amendments are effective in changing EPO law and practice, at least those EU Member States that supported them could accrue financial liability for taking action that denies patent applicants and proprietors the ability to exercise rights guaranteed under EU law.
- There are good reasons to doubt that the amendments will be effective in changing the law applied by the EPO Boards of Appeal.
- Legitimate expectations based upon Enlarged Board of Appeal Decisions G2/12 and G2/13 may in any event prevent the amended rules being applied to cases filed before 1 July 2017.
- It is perfectly possible that, if asked to interpret Article 4(3)(b) of the Biotech Directive, the CJEU will issue a ruling that will effectively force the EPO to reverse the amendments to Rules 27 and 28 EPC.
- The amendments to Rules 27 and 28 EPC give rise to the risk that patent applicants and proprietors will suffer serious injustices (that is, irreversible and unjust loss of rights), whereas maintaining the status quo would have posed little or no risk of injustice towards third parties.
- EPC Contracting States may be liable to pay compensation to patent proprietors or applicants adversely affected by the imposition of amended Rules 27 and 28 EPC to cases filed before 1 July 2017, on the grounds that the retroactive application of those rules violates the principles of Article 1 of Protocol 1 to the ECHR.

Thus, not only are there serious doubts surrounding the legitimacy and/or likely efficacy of the amendments to Rules

20) Smith Kline and French Laboratories Ltd v The Netherlands (1990) 66 DR 70.
23) Matthews v United Kingdom (application no 24833/94), http://www.webcitation.org/5Wx37oMR.
27 and 28 EPC, but it could also be argued that those amendments give rise to a significant risk of disharmony and/or injustices (towards rights holders). In short, based upon legal considerations alone, this author is unable to explain why the AC embarked upon such a legally dubious and risky course of action.

Nevertheless, it is perhaps possible to make sense of the AC’s actions, but only if one considers motivations outside of the legal sphere (that is, political considerations). In this respect, this author is aware that the AC faced significant political pressure (from certain EU Member States, the European Parliament and the European Commission) as a result of lobbying by parties that were alarmed by the EPO’s rulings in G2/12 and G2/13. From this perspective, the AC’s actions can perhaps be understood as a means of dissipating that political pressure by applying a ‘quick fix’ solution intended to limit the ‘damage’ to the patent system to only a small category of biotechnological inventions.

However, by placing political considerations ahead of legal constraints, it appears to this author that the AC has established a number of potentially dangerous precedents. These precedents include:

– approval of amendments to the EPC that effectively circumvent EU law (that is, that prevent patent applicants and proprietors from exercising rights guaranteed under EU law) and that contravene a principle enshrined in the ECHR; and

– failure to withstand political pressure despite the existence of firm, legal grounds upon which that pressure could and should have been resisted.

Of course, it will be difficult to uphold public confidence in the patent system in Europe if such precedents are allowed to stand (or, worse still, if future actions of the AC follow such precedents). Thus, ironically, actions of the AC that were perhaps intended to limit damage to the patent system in Europe could end up undermining public confidence in that system.

In this respect, whilst it is perhaps possible to understand why the AC was tempted to ‘take the easy way out’ by amending Rules 27 and 28 EPC, the view of this author is that there are many reasons why the AC may well yet regret giving in to that temptation.