

Intellectual Property

This section is devoted to giving readers an inside view of the crossing point between intellectual property (IP) law and risk regulation. In addition to updating readers on the latest developments in IP law and policies in technological fields (including chemicals, pharmaceuticals, biotechnology, agriculture and foodstuffs), the section aims at verifying whether such laws and policies really stimulate scientific and technical progress and are capable of minimising the risks posed by on-going industrial developments to individuals' health and safety, inter alia.

The EU Embraces Enhanced Cooperation In Patent Matters: Towards A Unitary Patent Protection System

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I. Introduction

On 13 April 2011 the Commission tabled a package of two legislative proposals implementing enhanced cooperation in the field of unitary patent protection and translation arrangements. Such proposals have subsequently been agreed upon by the EU ministers in an Extraordinary Competitiveness Council on 27 June 2011. Patent protection is indeed key to the European Union (EU) and constitutes a priority in EU institutions' agenda, as it is capable of stimulating innovation and competitiveness.

The objective of this regulatory move is to offer innovators in Europe a unique patent right which can only be transferred, licensed, revoked or possibly lapse in all the Member States which participate in this enhanced cooperation. So far twenty-five Member States have joined the initiative, Spain and Italy having chosen to stay outside. This is the second time enhanced cooperation is sought at EU level, the first being in the area of the law applicable to divorce and legal separation and involving fourteen countries so far¹. The initiative was prompted by the acknowledgement that obtaining patent protection in all or most European countries by using the current procedure administered by the Munich-based European Patent Office (EPO) is too expensive. It has been estimated that protecting an invention using the current EPO procedure in all twenty-seven EU Member States would cost applicants roughly € 32,000, of which € 23,000 would be incurred for translation fees

alone. On the other hand, a US patent costs € 1,850 on average². This fact alone shows up the competitive disadvantage European technology-related businesses face in Europe and why the EU is lagging behind the US in the technological and R&D arena.

Why is the current EPO procedure so expensive?

It should be noted at the outset that EPO applications are filed under the rules set forth by the European Patent Convention (EPC), which is not an EU instrument. The EPC is an international treaty signed by thirty-eight European countries, *i.e.* the twenty-seven EU Member States plus eleven other European countries. The EPO examines patent applications and grants the applicant a bundle of national patent rights. In other words, what the EPO provides is a centralised examination procedure which ends up with the issuance of as many national patents as the countries designated in the application. Yet once the patent (*rectius*: the bundle of national patents) is granted by the EPO, the applicant is requested to validate it nationally in each state where protection is sought; a translation in most countries is also requested³. This multiplies administrative burdens and costs⁴ and particularly affects public research bodies, small and medium-sized enterprises and start-ups.

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- 1 Austria, Belgium, Bulgaria, France, Germany, Hungary, Italy, Latvia, Luxembourg, Malta, Portugal, Romania, Slovenia and Spain have joined the initiative so far. These states were authorised by the Council to proceed with enhanced cooperation on 12 July 2010. Subsequently, the Council Regulation 1259/2010 of 20 December 2010 implementing enhanced cooperation in the area of the law applicable to divorce and legal separation was adopted.
- 2 See the Commission's proposal for a Council Regulation implementing enhanced cooperation in the area of the creation of unitary patent protection with regard to the applicable translation arrangements, 13 April 2011, p. 2.
- 3 Thus the validation phase is necessary for the granted patent to be effective in any EPC Contracting State(s) where protection is sought. In order for the European Patent to be validated nationally, applicants must meet validation requirements in each designated state by a specific deadline, *i.e.* three months after the patent is granted by the EPO. The validation phase differs in each state, but generally requires the payment of a fee and the translation of either the claims or the entire patent specification.
- 4 The entry into force of the London Agreement was meant to reduce translation-related costs. This treaty was adopted in October 2000 by an Intergovernmental Conference of the EPC Contracting States. It sets forth an optional mechanism which aims to reduce the translation costs of European patents. Yet, even after the entry into force of this treaty on 1 May 2008 in fourteen EPC Contracting States (of which ten are also EU Member States), obtaining a European patent still remains several times more expensive than a US patent: see the Proposal for a Council Decision authorising enhanced cooperation in the area of the creation of unitary patent protection, 14 December 2010, p. 16.

Moreover, the maintenance of an EPO-granted patent requires the payment of annual renewal fees in every country where it is validated, as well as the registration of any transfers, licences and other rights related to the title (the relevant costs to be paid by right owners). Further costs are to be borne by patentees for entrusting in each designated state their local representatives (*e.g.* patent attorneys) to take care of the national patent procedures: this is necessary for compliance with all the bureaucratic steps requested locally⁵.

Such complexities and costs often prompt European innovators to limit their patent protection to only a few EPO Contracting States. On average, patent seekers protect their inventions and thus validate their EPO-granted patents in only five of the EU's twenty-seven Member States. This situation inevitably makes inventions less valuable, as the lack of protection in many EU countries permits them to be imitated and boosts the trade of patent-infringing products. For example, under the above circumstances it is impossible to make seizures at EU customs pursuant to Customs Regulation 1383/2003⁶ because infringing products are able to enter the EU via Member States where the patentee has not validated his patent. And such infringing products can then freely circulate in the EU and be imported into those countries where the invention is protected⁷.

In the last few years there have been several attempts – unsuccessful so far – to introduce changes with a view to creating a unique patent title along the lines of the Community trademark and design rights granted by the Alicante-based Office for Harmonisation in the Internal Market (OHIM). The pursuit

of enhanced cooperation in the EU twenty-five participating countries is the latest attempt (this kind of procedure allows a minimum of nine Member States to set up an “inner circle” that pursues cooperation in an area covered by EU treaties but without the other countries being involved). This latter attempt may turn out to be successful, also because of the legal basis chosen by the EU institutions. Indeed, the Lisbon Treaty introduced an *ad hoc* legal basis, *i.e.* Article 118 of the Treaty on the Functioning of the European Union (TFEU), which allows the introduction of specific measures for the creation of uniform patent protection and the establishment of a centralised EU-wide authorisation, coordination and supervision arrangements.

The enhanced cooperation has been authorised by a Council Decision of 10 March 2011 pursuant to Article 329(2) TFEU⁸. According to Article 20 of the Treaty on the European Union (TEU) this procedure can only be used as a last resort, *i.e.* when the targets pursued by the cooperation cannot be met within reasonable time by the EU as a whole. It seems that this condition is met here. This would be buttressed by the many (unsuccessful) efforts made by EU institutions to create the unique rights in question, most recently by the failure to reach an unanimous agreement on applicable translation arrangements: indeed on 30 June 2010 the Commission had tabled a proposal for a Regulation on such arrangements, but the proposal has remained a dead letter. Thus there have been insurmountable difficulties to reach the target in question by the EU as a whole, making unanimity impossible⁹. Furthermore, as shown above, measures for the creation of European IPRs are expressly referred to in Article 118 TFEU and therefore the condition set forth in Article 329(1) TFEU that enhanced cooperation can be established “*in one of the areas covered by the Treaties*” is met.

II. The proposed regulations

Two draft regulations have been tabled by the Commission. In addition to a regulation related to the unique title *per se* (to be introduced by following an ordinary legislative procedure) a further instrument has been proposed: a regulation related to the applicable translation arrangements. The adoption of this additional instrument has been found necessary as the translation arrangements must be established under an autonomous and special legislative

5 Under the current system, the maintenance of a patent in all the twenty-seven Member States for all the twenty years of protection would reach an estimated sum of Euro 200,000: see the Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee of the Regions, 24 May 2011, p. 7, available on the Internet at <http://ec.europa.eu/internal_market/copyright/docs/ipr_strategy/COM_2011_287_en.pdf> (last accessed on 3 June 2011).

6 Customs Regulation 1383/2003, the full title of which is Regulation concerning customs action against goods suspected of infringing certain intellectual property rights and the measures to be taken against goods found to have infringed such rights.

7 See the Proposal for a Council decision, *supra* note 4, pp. 11 and 15.

8 Article 329(1) TFEU provides *inter alia* that it is the Commission that may submit a proposal of enhanced cooperation to the Council in one of the areas covered by the Treaties.

9 See Recital 4 of the Council Decision of 10 March 2011 authorising enhanced cooperation in the area of the creation of unitary patent protection.

procedure by the Council acting unanimously after consulting the European Parliament, as envisaged by Article 118(2) TFEU.

(i) The first draft Regulation provides the terms and conditions for obtaining a unitary patent right and its legal effects. This instrument constitutes a special agreement within the meaning of Article 142 EPC that states that “*Any group of [EPC] Contracting States, which has provided by a special agreement that a European patent granted for those States has a unitary character throughout their territories, may provide that a European patent may only be granted jointly in respect of all those States*”. The unique patent right would be granted by the EPO and would have equal effect in all participating countries without any need for carrying out validation requirements – and it would coexist with both national and European patents. Thus, a single examination procedure would be carried out by the EPO and, until the European patent has been granted, applicants will have the possibility to choose between the following options: (a) requesting a European patent right valid in all the participating States as unique title¹⁰; (b) requesting a European patent valid in the territories of the participating countries as unique title, but also designating other selected Contracting States of the EPC (including EU countries which do not participate in the enhanced cooperation system); (c) the old solution, *i.e.* a European Patent designating specific countries parties to the EPC.

The owners of a European patent granted by the EPO may thus choose to follow the route of the unitary protection by filing a specific request with the above office within one month after the mention of the grant is published in the European Patent Bulletin¹¹. The protection however would take effect retroactively in the territories of the participating Member States as of the date of the publication of the mention of the grant in the European Patent Bulletin¹². The substantive provisions regulating the unique title are similar to those set out in several national patent laws: see for example the provisions on scope of protection (Articles 6 and 7), limitations (Article 8) and exhaustion of rights (Article 9).

Article 5 of the proposed Regulation contains an important exception. If the unitary patent is limited or revoked on the ground of lack of novelty (pursuant to Article 54(3) EPC), the limitation or revocation of a European patent with unitary effect should be effective only in the participating State(s) designated

in the earlier European patent application. In other words, if someone has filed a European patent application (regarding a similar invention) in a participating State on a date prior to the filing of the European patent application which has given rise to the unitary patent (and accordingly the latter patent has been limited or revoked), the limitation or revocation of such a patent would be effective in that Member State only. This would mean that the scope of protection or even the availability of protection would be either reduced or excluded in certain EU countries but not in others. This aspect of the system has already been criticised, as it does not guarantee a uniform patent protection in all the participating Member States. It therefore seems that the ensuing scenario resembles the opposite of a unitary patent, and indeed goes against the very objective that the envisaged system pursues, *i.e.* legal certainty.

(ii) The second proposed Regulation deals with translation arrangements. It is envisaged that the current EPO translation system – which is based on the three official languages, *i.e.* English, French and German – will apply. Thus, applicants will file the patent application in any language, but those not made in English, French or German should be translated into one of the above three languages and (in the post-grant phase) the patent claims should be translated into the other two EPO official languages. However, these translation costs will be reimbursed up to a certain ceiling¹³ and no additional translations will be needed. This is the gist of the proposed Regulation, which aims to cut the costs of patent protection in the EU by simplifying the translation system.

Yet a transitional period of twelve years maximum has been foreseen. During this period, European patents with unitary effect which have been granted in French and German should be translated into English. And the patents granted in English should be translated into any official language of the participating Member State that is an EU official language.

10 The EPO would then be entrusted with (i) handling patentees’ requests for EU unitary effects, (ii) carrying out the relevant entries and (iii) collecting the relevant fees.

11 See Article 12 of the proposed Regulation for unitary patent protection.

12 See also Article 4(1) of the proposed Regulation for unitary patent protection.

13 See Article 5 of the proposed Regulation related to translations arrangements and Article 12(f) of the proposed Regulation on unitary patent protection.

Such arrangements would make sure that during the transitional period all European patents with unitary effect are made available in English, which is the language used in the field of international technological research and publications¹⁴. These translations would be paid by patentees but they would only be required for a limited period of time, *i.e.* until translation machines of high quality become available and anyway not more than the transitional period of twelve-years.

Specific provisions have also been made to facilitate the handling of litigation involving unitary patents by both alleged infringers and judges. In the case of a dispute relating to a European patent with unitary effect, the patentee (if requested) should provide the alleged infringer with a full translation into the official language of the participating state in which either the alleged infringement took place or in which the supposed infringer is domiciled. Patentees should also provide courts with a translation of the litigated unitary patent into the language of the proceedings of that specific court. The costs of all the above translation should be borne by the patentee¹⁵.

III. Alleged advantages of the proposed system and critical points

The Commission is convinced that the costs (that will be) required for obtaining the unique patent title will be far lower than what is now required for the current EPO procedure, especially due to the elimination of national validation requirements and in particular to the simplified translation requirements. It is envisaged that the cost for a unique European patent in the twenty-five participating Member States would be €680. During the above-mentioned transitional period of twelve years maximum, the costs would be a bit higher, *i.e.* not more than €2,500 for twenty-five countries, but this would still cost less than what is needed on average for the current EPO procedure¹⁶.

This considerable reduction of the total costs for and difficulties in obtaining patent protection in the EU – as the Commission stresses – could have important ‘spill-over’ effects: as a matter of fact, it is expected that companies and innovators in general would have increased financial resources as a consequence of the reduced costs and thus be more willing to protect their inventions by means of the traditional EPO route also in non-participating countries¹⁷.

However, both Member States (Spain and Italy) that have elected to remain outside the enhanced cooperation system point out that applicants coming from EU English-, French- or German-speaking countries would be at an advantage. They argue that this would lead to a distortion of competition across the EU, meaning that companies and individuals coming from countries whose official languages are not the above ones would be discriminated against. Indeed, as we have seen, the current EPO translation system requires that the applications filed in a language different from English, French and German should be translated into one of these three languages, the relevant costs to be borne by applicants. This system would therefore be contrary to the provisions of the TFEU devoted to enhanced cooperation, *e.g.* Article 326 which states that the cooperation “*shall not constitute a barrier to or discrimination in trade between Member States, nor shall it distort competition between them.*” It is also in light of the above that on 30 May 2011 Italy and Spain lodged a complaint before the EU Court of Justice (ECJ) challenging the Council Decision of 10 March 2011 authorising enhanced cooperation.

On the other hand, the twenty-five participating Member States believe that the requirements for adopting enhanced cooperation are already met. In particular, it is argued that companies and individuals that will have to carry out the translations in question would be reimbursed for most of the costs incurred – and therefore the system would not discriminate against companies and countries whose official language is not English, French or German. Furthermore, according to Recital 14 of the Council Decision authorising enhanced cooperation, the system in question would respect the competences, rights and obligations of non participating countries, as requested by Article 327 TFEU: indeed, such system would not affect the availability of patent protection in the non participating States by means of either a traditional EPO route or a fully national patent procedure.

14 See Recital 11 of the proposed Regulation related to translation arrangements.

15 See Article 4 of the proposed Regulation related to translation arrangements.

16 See the FAQ document drafted by the European Commission and available on the Internet at <<http://europa.eu/rapid/pressReleases-Action.do?reference=MEMO/11/240&format=HTML&aged=0&language=EN&guiLanguage=en>> (last accessed on 11 May 2011).

17 See the Proposal for a Council decision, *supra* note 4, p. 10.

Moreover, as the Commission put it, companies and individuals originating from non-participating countries will have the right to obtain the unique title valid in the participating countries under the same conditions as the companies and individuals coming from those countries. They would therefore benefit from the envisaged scheme and this would stimulate R&D investments in all EU and boost the functioning of the internal market and economic cohesion. The conditions set forth in Article 326 TFEU (e.g. maintenance of economic cohesion in EU) and the targets pursued by Article 3(3) TEU – i.e. the establishment of an internal market and the promotion of scientific and technological advance – would therefore be met¹⁸.

IV. Where do we stand today?

Another centralized patent litigation system soon?

What are the next steps to be taken for the enhanced cooperation to be finalised? The proposed regulations have been transferred to the Council and European Parliament for adoption. A qualified majority of the twenty-five Member States and the favourable vote of the European Parliament are required for adopting the Regulation introducing the unique title (this is the ordinary legislative procedure envisaged by Article 118(1) TFEU). On the other hand, as shown above, for adopting the Regulation relating to the translation arrangements the twenty-five Member States must act unanimously after consulting the European Parliament (this is the special legislative procedure envisaged by Article 118(2) TFEU).

But the above system is just a first step towards a unified EU patent system. The creation of a unique title should be coupled with adequate jurisdictional arrangements allowing unitary patents to be enforced and revoked throughout the territory of the participating countries.

Such a second step is not an easy one, however, especially after the ECJ opinion of 8 March 2011 on a proposed European and European Union Patents Court (EEUPC). This proposal would have entailed the accession of the EU to the EPC thus triggering the adoption of an international treaty between the EU, its Member States and the non-EU Contracting States of EPC. It would have given EEUPC exclusive jurisdic-

tion over infringement and validity issues concerning European patents. In its opinion the ECJ held that the Member States cannot confer the jurisdiction to resolve patent-related disputes on a court created by an international agreement which would deprive national courts of their task to implement EU law and therefore of the power provided for in Article 267 TFEU on preliminary ruling procedures. In particular the ECJ stressed that, by providing for a preliminary ruling mechanism which would reserve the power to refer questions for such ruling to the EEUPC, the draft agreement would divest that power from the national courts. As such, this agreement would alter the essential character of the powers conferred on the institutions of the European Union and on the Member States which are indispensable to the preservation of the very nature of European Union law. The proposal was therefore held not to be compatible with EU law¹⁹.

The Commission is currently assessing the above ECJ opinion of 8 March 2011 in order to address the concerns raised. The target of this move is to finally overcome all the hurdles and come up with a fresh patent litigation-related proposal. In particular, at the end of May 2011 in a non-paper of the Commission services it was noted that a unified patent court can only be instituted by EU Member States, and the participation of third countries should be excluded²⁰. As said above, the final goal is to couple the unique patent protection (substantive part) with a system permitting such patents to be litigated in all the EU countries participating in the enhanced cooperation (enforcement part). The latter step is also urgent as the current enforcement system obliges owners of European patents to fight infringement in the courts of every European state in which infringement occurs. This multiplies the costs for patentees, who often decide not to enforce their exclusive rights in several European countries, and this in turn encourages infringement activities.

18 See the Proposal for a Council decision, *supra* note 4, p. 8.

19 For a brief comment of Advocate General's opinion in this case see Enrico Bonadio, "ECJ Advocate General Rejects EU Patent Litigation Scheme", 5(12) *Journal of Intellectual Property Law & Practice* (2010), pp. 286–287.

20 See Annex II "Solutions for a unified patent litigation system – The way forward after the opinion 1/09 of the ECJ – Non-paper of the Commission Services" to Document 10630/11 of the Council of the European Union of 26 May 2011, available on the Internet at <<http://register.consilium.europa.eu/pdf/en/11/st10/st10630.en11.pdf>> (last accessed on 2 June 2011).