

Prof. Dr. Rudolf Kraßer

***Ordinary Professor (em.) for Private Law
and Patent Law
at the Munich University of Technology***

***External Academic member of the
Max Planck Institute for Intellectual
Property Law and Competition Law***

**Effects of an inclusion of regulations concerning the content and limits of
the patent holder's rights to prohibit in an EU regulation for the creation of
unitary European patent protection**

I. Occasion for the study

1. Pursuant to Art 20 (2) of the TEU, the Council can in accordance with the principles and in the procedures laid down in Arts. 326 to 334 of the TFEU authorise enhanced cooperation limited to some of the Member States by finding that the objectives pursued by the cooperation cannot be achieved by the Union as a whole within a reasonable period. The Council has issued such an authorisation by ruling dated 10 March 2011¹ for the field of the creation of unitary European patent protection.

The European Commission then submitted a proposal for a corresponding Regulation. In its current wording, the latter also contains provisions on the patent holder's rights to prohibit direct use and indirect use of the patented invention and on the restriction of the effect of the unitary patent to be created pursuant to the Regulation. This concerns a core area of substantive patent law. If the Regulation in its present proposed wording were to enter into effect, it would become an integral part of the law of the European Union. What would not become European law, on the other hand, would be the rules contained in the European Patent Convention (EPC) concerning the substantive preconditions for the grant of a patent and on the corresponding grounds for which a granted patent can be revoked or declared null and void. This would not lead to any changes for the Member States participating in the enhanced cooperation. The same also applies to the determination of the scope of protection. According to the proposed Regulation, Art. 69 of the EPC and the corresponding Protocol to be issued by the European Patent Office would also determine the scope of protection for the patent with unitary effect.

¹ No. 2011/167/EU, OJ L 76 of 22. 3. 2011, p. 53.

2. The creation of the possibility of European patents with unitary effect for the Member States of the EU participating in the enhanced cooperation is intended to achieve substantial savings in costs and effort for enterprises that desire patent protection in all these countries.² The same objective is also pursued at the level of the enforcement of unitary patent protection and the subsequent review of the legal validity of patents with unitary effect (as also for the European "bundle" patent) by means of a European patent litigation system,³ for which preliminary work began roughly 10 years ago and for which today fully developed proposals are available. At the moment, the objective is to reconcile these proposals with Union law according to Opinion 1/09 dated 8 March 2011 of the European Court of Justice.⁴

3. The following considerations address the question whether for the objectives that are aimed at by a patent with unitary effect for the Member States participating in enhanced cooperation and by the establishment of a European patent litigation system, it is of advantage or more of a disadvantage to include provisions concerning the content and limitations of the substantive law effects of the patent in the Regulation on the patent with unitary effect. Of importance here is in particular the jurisdiction of the Court of Justice of the European Union to issue preliminary rulings on the construction of the treaties and the acts of the bodies, institutions and other agencies of the Union regulated in Art. 267 of the TFEU. Within the scope of this jurisdiction, courts of the Member State can submit questions of interpretation to the Court of Justice (Art. 267 Para. 2, TFEU); courts against whose decisions there is no judicial remedy under national law are obliged to bring the matter before the Court (Art. 267 Para. 3, TFEU). The following examines a number of important provisions of Articles 6 to 8 of the proposed Regulation for the problems they contain that might give rise to an occasion or an obligation to submit the matter to the Court of Justice of the European Union.

II. Problems in the interpretation of the provisions concerning the content and limitation of the effects of unitary patents contained in the proposed Regulation

1. Uses with respect to a product which is the subject matter of a patent (Art. 6 a of the proposed Regulation)

² Communication from the Commission to the European Parliament, The Council, the European Economic and Social Committee and the Committee of the regions: A single market for intellectual property rights ... (provisional version, COM (2011)xxx), No. 3.1.1.

³ No. 3.1.2 loc. cit.

⁴ GRUR Int. 2011, 309.

a) Manufacture

The factual requirements are satisfied by the creation of a product that contains identically or in equivalent modification all the technical features designated in a claim of the patent asserted. Whether this is the case is to be determined by the rules concerning the determination of the scope of protection, which are not part of EU law (see above I.1). It would on the other hand be necessary to interpret the Regulation concerning manufacture contained in the proposed Regulation if a user only carries out a part of the production process, which is then completed by another person. The question then arises whether under certain circumstances the completion is to be attributed to the person who began the manufacture, who would hence be guilty of a (direct) patent infringement.

Problems have also arisen in cases involving the repair of patented products. Admittedly, as a rule, the principle of exhaustion means that the purchaser is free to do what he likes once a product has been put into circulation with the patent holder's consent, but under certain circumstances this can be interpreted as the making of a new product, which is reserved to the patent holder. Of practical importance in more recent decisions by German courts is the distinction between a mere repair and the making of a new product in the event of the replacement of wear-and-tear parts which are of essence for the functioning of the patented product but which of themselves are not protected because they do not have all the features listed in the relevant patent claim. If repair in such cases is interpreted as the making of a new product infringing the patent, not only can the user of the complete product be prohibited from making such a repair as being a direct infringement, but the supply by the supplier of the spare parts can also be prohibited as an indirect infringement.

b) Putting into circulation

Areas of doubt with respect to this factual element can arise in cases of export from and transit through the geographical scope of application of the patent. Can the patent holder forbid such acts even if the products do not enter into the power of disposal of a third party in the said area?

c) Import, possession

If a person has imported or possesses patented products without yet having offered them for sale, put them into circulation or used them, there may be doubt as to the conditions under which it can be assumed that the import or possession is for the purpose of offering a product

for sale, putting it into circulation or using it. Is it sufficient that objective circumstances clearly indicate such a purpose, or must the importer or possessor be proven to have a (subjective) intention to this effect?

2. Using or offering for use a process that is the subject matter of a patent (Art. 6 b of the proposed Regulation)

a) Where a process is used, preparatory acts such as the making or supplying of means for the use of the process are to be distinguished from this use itself, although of course supplying can be an indirect use. Doubt may arise as to whether the testing of means for the use of the process within certain limits without the consent of the holder of the process patent is permissible, even if it completely implements the method.

b) If means for the use of the process have been put into circulation with the consent of the process patent holder, the question arises whether, in accordance with the exhaustion principle, they can be applied to use the process without further requirements or – because the exhaustion principle does not apply here – only with the specific consent of the patent holder. If the latter is to be assumed, and if express consent has not been issued, it is necessary to examine whether this can be regarded as having been granted implicitly in the light of the circumstances of the case.

c) The question of when the offering of a process for use can be regarded as an infringement of a patent has as yet not been clarified beyond doubt in the literature, but has, as far as can be seen, acquired hardly any practical significance. Nevertheless, it cannot be excluded that in an individual case a party to the litigation may rely on an opinion in the literature that appears to support its view and thus give occasion for a submission to the Court of Justice of the European Union.

3. Acts with respect to a product obtained directly from a process that is the subject matter of the patent (Art. 6 c of the proposed Regulation)

a) In this area, doubt may already arise with the definition of the term product: are only physical objects covered, or might the term also include intangible process results such as sound, light, heat or electrical energy?

b) From experience, it is often difficult to distinguish between a process used to make a product and mere "working methods" that only change the condition of a product, or merely check it for specific qualities, without substantially changing the product itself. Thus for instance degassed tubes have been regarded as products of the degassing process, while a similar result was denied for impregnated drive belts as products of the impregnation process; nor were motor blocks repaired using a patented metal injection process regarded as a product of this process.

According to the prevailing opinion in Europe, products that have been found by means of the use of DNA sections for test purposes are not products of any patented test process. However, it cannot be excluded that in individual cases such an extension of patent protection will be requested in infringement litigation, as has occasionally been attempted in patent applications by including "reach-through" claims. Many courts might take this as an occasion for submitting the matter to the Court of Justice of the European Union.

c) The question whether a product has been *directly* obtained by means of a protected process has been addressed by judicial practice, specifically in cases in which the first result of the process has been further processed with or without chemical conversion or has been included as a dependent element in a complex object. Since such procedures do not necessarily interrupt the direct connection with the protected process, criteria need to be developed for an intelligent delimitation of the effects of a patent.

4. Indirect use (Art. 7 of the proposed Regulation)

a) The central objective element of the factual constellation is that the means the supply of which might be an indirect use relate to an essential element of the invention. The requirement for this cannot be that it has all the features of a patent claim. Whether a factual requirement is nevertheless satisfied depends on technical conditions, the assessment of which may cause considerable difficulties in the individual case and require corresponding special technical knowledge.

b) The supply of means that while relating to an essential element of the invention are staple commercial products does not constitute indirect use. The supplier is only liable under patent law if he deliberately induces the person supplied to perform a direct patent infringement.

Anyone who deliberately induces another to infringe a patent is, however, already liable on the grounds of inducement to unlawful conduct according to general principles that are no doubt be found in the national laws of all the countries participating in enhanced cooperation. The provision in the proposed Regulation that makes this liability an integral part of EU law in cases where the inducement is related to the supply of means generally available in commerce, is preparing the way for submissions to the Court that might lead to the development of EU-specific rules for part of the field of application of the said general principles, and for this reason is systematically inappropriate.

c) Doubts may also arise when determining whether a supply has been made for the use of the protected invention. This feature of the factual element is in connection with the one that requires that the supplier knows or ought to have known that the means supplied are capable and intended to be applied for the use of the invention. In practical terms, the decisive factor will in the final analysis mostly be whether the supplier at least should have had this knowledge. If this is the case, it can also be assumed that the means were supplied for the use of the invention. The decisive aspect will be what objective circumstances are regarded as the reasons for the supplier being reproached for the ignorance on which he might attempt to rely. Even though it will depend essentially on the individual case, it cannot be excluded that this will be used as the basis for a question to be submitted to the Court of Justice of the European Union.

5. Limitation of the effects of the patent (Art: 8 of the proposed Regulation)

a) The exception proposed for acts done privately for non-commercial purposes can give rise to doubts as to interpretation concerning the distinction between the private sphere and in particular the commercial nature of the purpose pursued by the use of the invention. Should any activity whose objective is gain be sufficient, even if the activity is carried out as part of dependent employment, or must it be a self-employed activity? In the latter case, should members of the liberal professions be treated as equivalent to persons pursuing a trade in the narrower sense or not?

b) Within the framework of the exception proposed for the use of the invention for experimental purposes, it may in the individual case be doubtful whether the subject matter of

the invention is (merely) the object of the experiment or (possibly also) an aid to the conduct of the experiment.

III. Conclusion

1. The above – by no means exhaustive – summary shows that the inclusion of provisions concerning the content and limitations of the effects of the patent with unitary effect for the EU Member States participating in the proposed enhanced cooperation in the Regulation serving to create this patent opens up a broad field of opportunities and in many cases also obligations to submit questions on the interpretation of these provisions to the Court of Justice of the European Union pursuant to Art. 267 of the TFEU. National courts involved in the application of these provisions can be expected in many cases to see an occasion or an obligation to submit the matter to the Court, in particular if they have still little experience in patent law. The provisions of Art. 267 concerning preliminary rulings by the Court of Justice and the corresponding questions for submission would, however – as follows from the Court's Opinion (see above I.2) – also have to be taken into account by the courts that will be responsible within the framework of a future European patent litigation system.

The court of justice would no doubt be capable of replying to the questions submitted with leading decisions. However, the court would be overstretched by the expected quantity of questions submitted. As the "constitutional court" of the EU, it should not be obliged to address individual issues in a specialised field. Of significance is also the fact that questions submitted on patent law can frequently only be answered with the assistance of technical experts. The objective of offering protection in the form of the unitary patent that has considerable cost advantages and perceptibly reduces the working effort of its users would be defeated by the possibility and obligation to submit preliminary questions, if only because of the large additional time involved that each preliminary question requires. In the field of patent law, this can be significantly more if the consultation of technical experts is necessary.

2. The need to develop principles for the effect of the planned unitary patent that would apply equally in all participating Member States is primarily to be taken into account by harmonising the corresponding national provisions (which of course should not be by means of a European Directive, for the reasons already stated). The 1975 Community Patent Agreement, which never entered into effect, had a not inconsiderable harmonisation effect.

There would be an opportunity to continue this development if the urgently needed creation of a European Patent Court were implemented. That should not be by means of the adoption of European legislation but instead by means of a separate agreement. According to the overwhelming view, the Opinion of the Court of Justice (see above, I.2) allows scope of this if no states from outside the EU participate. The supreme European patent instance would be able to ensure a uniform construction of the identical national substantive patent law provisions, as well as those contained in the EPA and possibly in a patent jurisdiction agreement that are not part of European law, without a greater workload being imposed on the Court of Justice of the European Union than required by its constitutional court function.

3. The models for the current versions of Arts. 6 to 8 of the proposed Regulation were essentially Articles 29 to 31 of the 1975 Community Patent Agreement (Articles 25 to 27 of the version according to the 1989 Agreement on the Community Patent). However, these provisions did not become an element of Community law and for this reason their interpretation does not fall within the preliminary ruling jurisdiction of the Court of Justice. Instead, according to the Dispute Settlement Protocol drawn up in 1985, a Common Patent Appeal Court (COPAC) was intended to ensure the uniform handling of substantive patent law in proceedings concerning the infringement and the validity of Community patents.

The inclusion of substantive law provisions concerning the content and limitations of the effects of a unitary patent for the Member States participating in enhanced cooperation would, on the other hand, subject an important element of substantive patent law to the preliminary ruling jurisdiction of the Court of Justice of the European Union, which in many cases would lead to delays in the proceedings as well as additional cost and effort for the parties involved, thereby seriously counteracting the objectives of the enhanced cooperation. Similarly, the effects on the field of patent law would run contrary to the objective aimed at by a separate Directive⁵ of the rapid and effective enforcement of intellectual property rights.

IV. Supplementary comments on Art. 118 Para. 1, TFEU

1. The discussion on the proposed regulation has raised the question whether Art. 118 Para. 1 of the TFEU requires the Regulation to at least regulate the patent holder's claim to a cease-and-desist order against unauthorised users of the patented invention. If this were the case, it

⁵ Directive No. 2004/48/EC of the European Parliament and the Council on the enforcement of intellectual property rights of 29. 4. 2004, OJ L 157/45, 195/16 and 351/44.

would also be necessary to define in the Regulation the acts that the patent holder can forbid third parties from carrying out without his consent.

2. Art. 118 Para.1 of the TFEU authorises the European Parliament and the Council to establish measures for the creation of European intellectual property rights to provide uniform protection of intellectual property rights throughout the Union. This authorisation permits the extensive harmonisation of the regulations concerning intellectual property rights to which the measures are related. However, it covers not only a comprehensive harmonisation. On the contrary, the extent of harmonisation – depending on the right and the measure concerned – is a question of expediency. If harmonisation is not expedient or not achievable, the detailed form of the right to which the measures under Union law relate remains the responsibility of the national laws of the Member States – in the case of enhanced cooperation, the participating Member States – or a contractual agreement between the (participating) Member States, such as would also be necessary with respect to the rights of continued use (in particular those created on the basis of prior use) and with respect to compulsory licences if the proposed regulation including its Arts. 6 to 8 were to be adopted.

3. The minimum requirement for the application of the authorisation is, according to Art. 118 Para. 1 of the TFEU, merely that an intellectual property right *is created by Union law*. This itself achieves the necessary minimum harmonisation at least if the subject matter and core effect of the right in question is established identically in the law of the (participating) Member States. In the case of patents, the subject matter of the law consists of a technical invention, the core effect in the fact that the invention is exclusively attributed to a specific legal subject and accordingly this legal subject can forbid the use of the subject matter of the right without his consent. For this reason, the proposed Regulation can be restricted to creating the basis for the grant of unitary patents for the participating Member States. Thanks to the granting act under Union law, which is unitary for all participating states, a bond based on Union law is established with respect to the invention – as defined in the patent claims – to which it relates, which is closer than in the case of the grant of a ("bundle") patent based only on the European Patent Convention (EPC). This is reflected in the fact that the patent can only be limited, licensed or transferred or can only be cancelled uniformly for all participating states, as laid down in Art. 3 (2) of the proposed Regulation. As we have already said, it is sufficient for the uniform protection required by Art. 118 Para. 1 of the TFEU and the "same effect" of Art. 3 (2) of the proposed Regulation that the aforesaid core effect is unitary. In

addition, in most of the (expected) participating states the details of the patent are approximated to the relevant provisions of the Community Patent Agreement, and are thus largely harmonised. Should this harmonisation proved insufficient, a remedy could be found by means of convention and national law.

4. Certainly, the authorisation contained in Art. 118 Para. 1 of the TFEU would permit the more detailed regulation of the effects of the unitary patent under Union law. However, for the reasons set out above under II and III, this would be prejudicial to the proposed enhanced cooperation's objective of simplifying, accelerating and reducing the costs not only of the proceedings for the grant of the unitary patents but also of those intended for their enforcement.

5. To date, it is undisputed that Art. 118 Para. 1 of the TFEU, in the event that a unitary patent under Union law is created, does not require the preconditions for the grant to be regulated under Union law. On the contrary, the provisions of the EPC will continue to apply, and the EPC is not part of Union law,. The courts that will have to decide on the validity of unitary patents under Union law, including within the framework of the future European patent court system, are for this reason neither obliged nor entitled to submit questions of the interpretation of the EPC to the Court of Justice of the European Union for a preliminary ruling. It would be logical to word the Regulation to implement the enhanced cooperation in such a way that questions of the content and limits on the effect of such patents cannot give rise to a submission to the Court of Justice.

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Professor Dr. Rudolf Kraßer