Duncan Matthews, Paul Torremans

Introduction

Patent law in Europe is going through a period of significant change. After decades of often futile negotiations, the European Patent with unitary effect and the complementary Unified Patent Court (UPC) are finally materialising. The time is therefore right for patent scholars and practitioners to look in detail at the emerging landscape in European patent law from their unique legal perspectives. The new legal landscape shows a significant degree of complexity, as the new elements do not produce a tabula rasa effect. On the contrary, they build extensively on the existing system of European patent law and create new layers of complexity, new threats and new opportunities.

The Unitary Patent Package raises important questions about how the current system may evolve in the future, having due regard to its relationship to European Union (EU) law. In chapter 1 Jean-Christophe Galloux reflects on the role that the European Patent Office (EPO) Boards of Appeal have so far played in shaping European patent law as an independent and final appellate jurisdiction with no further mechanism for challenging their judgments by way of appeal. The Boards of Appeal not only construe and apply the European Patent Convention (EPC), but also interpret and adapt its spirit and intent to ever-changing legal and technical circumstances and, in this way, play a crucial role in the evolving European patent system.

In the context of the Unitary Patent Package, the interplay between the UPC, national courts and the EPO Boards of Appeal raises new possibilities for innovative patent filing and enforcement strategies. The Unitary Patent Package creates, by virtue of the European Patent with unitary effect, a third way to obtain patent protection in European countries alongside the existing national and 'classical' European Patent routes. In chapter 2 Heinz Goddar and Konstantin Werner highlight the strategic importance of filing and enforcement possibilities that lie ahead.

Cross-border patent litigation will also change as a result of the Unitary Patent Package. In chapter 3, Żaneta Zemła-Pacud, Tomasz Targosz explain why, despite the coming into force of the UPC Agreement, serious reform of the cross-border litigation system is still needed, since the existing system is characterised as being fragmented, expensive and complicated to navigate. Reform of cross-border litigation will be crucial for the enforcement of European patents for many coming years.

In European patent law the principle of plausibility requires that all valid patents must demonstrate that the technical problem underlying the invention was at least remove underlining solved at the filing date. In chapter 4 Alison Slade explains how, despite lacking direct acknowledgement by the EPO, plausibility appears aimed at addres-

Duncan Matthews, is Professor of Intellectual Property Law, Queen Mary University of London.
Paul Torremans, is Professor of Intellectual Property Law, University of Nottingham.

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sing deficiencies in the legal framework of the EPC that open the window to bad or unjustified patenting. Yet even plausibility seeks to uphold objectives that should be reflected in any well-functioning patent system, and uncertainties remain that may well be amplified by the new European patent system's legal architecture.

The relationship between EU procedural law, the EU Enforcement Directive and national procedural autonomy raises important questions in the context of patent litigation, particularly when defining what constitutes appropriate compensation and what should be considered 'abuse' of the injunction system. In chapter 5 Amandine Léonard assesses the scope for wrongful preliminary injunctions and EU procedural law, in a manner which is particularly timely given the arrival of the UPC.

The advent of the UPC has raised concerns that the issuance of final and preliminary injunctions may lead to undesirable outcomes. The UPC will be issuing injunctions covering the territories of all Contracting Member States of the EU and, in chapter 6, Maciej Padamczyk and Duncan Matthews assess how the concept of proportionality might be applied in such instances, based on the chapter's review of established practice in the United States (US), the United Kingdom (UK) and Germany.

The harmonisation of European patent law remains a work in progress and, as Frantzeska Papadopoulou explains in in chapter 7, the Unitary Patent Package creates a unique opportunity to reconsider the novelty and inventive step requirements in Europe. Significant differences exist when assessing novelty in the EPC member states, while the EPO approach to inventive step also differs from the various national approaches. The role of the UPC, and potentially an increased role for the Court of Justice of the European Union (CJEU) will be crucial in terms of how these patentability criteria are in the future defined.

The UPC Agreement for the first time establishes harmonised exceptions and limitations to patent rights in Europe. In chapter 8, Ana Nordberg analyses the exceptions and limitations established by Article 27 of the UPC Agreement. As Nordberg explains, the possibility remains for divergences and variations concerning applicable limitations depending on the type of patent and whether these are to be litigated under the jurisdiction of the UPC, and to some extent the approach taken will be difficult to predict.

Given the complexities and risks of litigation before national courts the advantages of alternative methods of dispute resolution help explain why arbitration is increasingly considered as an alternative. In chapter 9, Jacques de Werra assesses the patent arbitration arrangements set up under the Unified Patent Court Agreement, concluding that the success of the system will, ultimately, depend on the willingness of parties to use it.

The Unified Patent Court Agreement also impacts the regime of Supplementary Protection Certificates (SPCs) for patented medicinal products and plant protection products subject to additional regulatory requirements. In chapter 10 Justyna Ożegalska-Trybalska explains that the fact that the UPC has jurisdiction in SPC cases does not mean that unitary protection under the SPC will be available even after the unitary patent system is operational. While the logical next step would be to create a unitary SPC to sit

alongside the Unitary Patent, Justyna Ożegalska-Trybalska outlines the complexities and obstacles that may lie ahead.

The creation of the Unified Patent Court also raises important questions about proceedings which can be brought in the Court of Justice of the European Union (CJEU) against Contracting EU Member States where they have not complied with EU law. In chapter 11 Phillip Johnson explains that the UPCA includes rules that subject Contracting Member States to infraction proceedings before the CJEU. As Phillip Johnson points out, the fact that the UPC is not a Member State of the EU adds complexity to the task of ascertaining where liability should lie in such instances, but that the UPCA nonetheless includes various safety valves to ensure it was compatible with EU law and, in doing so, minimises such risks.

The creation of a new court that is operating as a court of the member states does of course raise the question of the jurisdiction of that court. On what basis can a defendant in cases that have by definition an international element to them be brought before the UPC? This issue is examined by Paul Torremans in chapter 12 on Regulation 542/2014. In order to comply with EU law the UPC Agreement does not deal with jurisdiction and reliance had to be placed on the Brussels I Regulation. The latter was amended to accommodate the special nature of the UPC by Regulation 542/2014.

In chapter 13 the book Paul Torremans looks at the internal division of labour in the UPC, i.e. the issue of competence. It does so against the backdrop of the particularly complex question of exclusive jurisdiction. For many years attempts to bring cross-border infringement cases in patent law before a single court have been frustrated by counterclaims on the basis of invalidity that led to the exclusive jurisdiction of the court of the state granting the patent. That made it impossible to continue with the infringement case in a single court. The chapter analyses whether the UPC has overcome this hurdle.

It is clear that the Unitary Patent Package (UPP) and the Unified Patent Court (UPC) are about to become part, not just of European patent law, but also of the European legal framework. But when looked at from a constitutional perspective question marks remain. In Chapter 14 Fernand de Vischer therefore looks at the debate on the legality of Regulation 1257/2012 and the even more controversial legality of the UPC Agreement and the UPC as a court it establishes.

In that controversial constitutional framework it will be of crucial importance for the UPC to build up trust. In Chapter 15 Esther van Zimmeren looks at this aspect from the perspective of the importance of the institutional design of the court and its judges. The one-of-its kind unique nature of the UPC is of course an important factor in this respect, but it is one that brings both risks and opportunities. The chapter therefore turns to the risk literature and asks the question how some of its key concepts can be translated to the UPC setting. One needs to define trust, identify the trust relationship and understanding the multilevel nature of trust within the context of the UPC. But trust also comes with an element of uncertainty about the trustee's future behaviour and that leap of faith needs to be given a place in the UPC context. Things are greatly helped if the

trustee is seen as trustworthy and the combination of ability, benevolence and integrity is crucial in this respect.

The new system will not depend solely on the UPC. There is also after all, aside from the infringement and validity litigation, the crucial element of the examination and the grant of the European Patent with unitary effect. This is where the EPO comes in and the organisation will play an important role in the shaping and the operation of the unitary patent system. In Chapter 16 Stefan Luginbuehl and Matilda Titeca look at the legislative framework before turning to the role of the EPO from a governance perspective. Attention then turns to the unitary patent procedure and the correlation of European Patent, Unitary Patent and national patent systems.

Much ink has been spilled on the role of the Court of Justice of the European Union in the process of enhanced cooperation in the area of patent law and lots of political capital has been invested in keeping that role as limited as possible. It is therefore important to take a step back and to look 'neutrally' at that role as it emerges from the agreed framework. In Chapter 17 Hanns Ullrich undertakes that crucial task by looking first of all at the role of the Court of Justice of the European Union in EU intellectual property matters in general. That analysis starts with the Treaty provisions and then compares the court's role under the EU intellectual property regulations with that under Regulation (EU) No 1257/2012 of the European Parliament and of the Council of 17 December 2012 implementing enhanced cooperation in the area of the creation of unitary patent protection. It is however equally important to analyse the role of the Court of Justice of the European Union in the interpretation of the rules of substantive law of the unitary patent and the European bundle patent.

Chapter 18 Sam Granata offers a judge's perspective to the rules of procedure of the UPC. It is important to note that there are different levels in those rules of procedure and with that comes a certain hierarchy. At the top of this hierarchy one finds the procedural rules contained in the UPC Agreement itself. These are then in the first place supplemented by the procedural rules in the Statute of the Court, as that is defined in Article 2 UPC Agreement. And then there are the rule of procedure themselves. The rules give the UPC judge a relatively high level of discretion and trust that his or her decisions will be based on standards of fairness and proportionality. The whole framework also takes a very pragmatic approach.

The creation of the UPC rather inevitably puts the focus of the debate on the court, its structure and functioning. That does not detract from the fact that the success or the failure of the UPC will depend on how well it serves or rather is able to serve its users. In Chapter 19 Guillaume Dubos, Thomas Leconte and Stéphanie Rollin de Chambonas look therefore at the UPC through the eyes of the users. Such an analysis cannot avoid starting by noting the complexities and the confusion that arise from the opportunity for the users to opt in and out. There is a risk of torpedoes here. Leaving these temporary concerns to one side, there is also the introduction of a new procedural framework and as always the devil will be in the details and undue reliance on previous national habits may prove risky. On the other hand there is the attraction of being able to use

the UPC as a one-stop shop. National courts are however not yet out of the picture and there are therefore issues of forum shopping to be contended with. Evidence and the availability and format of procedural tools are, of course, also of crucial importance to the users.

The introduction of the UPC brings with it the challenge to build a new international court. Public international law provides the backdrop for such an exercise and, in chapter 20, Klara Polackova Van der Ploeg turns attention to that aspect of the creation of the UPC. She looks at the status of the UPC as an international court and at international law as the UPC's governing law. Against that backdrop it is critical to examine how much interpretative autonomy the UPC will have. The UPC may, however, be required under international law to consider or even apply international legal rules beyond those that may have traditionally been viewed as 'patent law', which bring us to the issue of regime interplay. Narrow subject matter and the specialisation of its staff may in this context turn out to involve risks for the UPC, but the topic will need to be addressed as modern public international law puts obligations on the shoulders of commercial patentees and other businesses.

They may not be monopolies properly speaking, but as exclusive rights patents do have an impact on competition. They affect and regulate competition at a structural level. The introduction of the European Patent with unitary effect will have an impact in this respect, as a single right is stronger and more effective than a bundle of national rights (or a bundle of the equivalents of national rights). Competition law on the other hands deals with behavioural aspects of the operation of exclusive rights. They can be used in unacceptable ways, turning such use into an abuse (of rights). In chapter 21 Miłosz Malaga looks at the impact of the introduction of European Patents with unitary effect on the operation of competition law in the European Union and pays particular attention, not only to the impact of the translation regime, but also to the potential redefinition of the geographical market.

A patent system can only be justified if it supports and encourages innovation. That raises the intriguing question of when a patent system is fit for innovation. Therefore, against the background that the key objective of patent regulation is to encourage investments in innovation in an optimal and functional manner, in chapters 22 and 23 Thomas Jaeger and Johannes Lukan make the argument that a balance must be struck between two main interests in order to attain this goal: on the one hand, easy, fast, legally secure and inexpensive access to patent protection and to a solid substantive, territorial and temporal scope of patent protection will provide incentives for investment in R&D. On the other hand, access to patentable knowledge for follow-on research also needs to be ensured within a patent system. The first part of this bipartite contribution will therefore be dedicated to an analysis of the incentives and obstacles the UP legal framework provides in this respect. The second Jaeger and Lukan chapter deals with the second question and concludes with an overall assessment of whether the UP and its surrounding legal framework succeed in striking a fair balance between these two interests, ie a balance between protect-

ing a patented 'senior' invention on the one hand and facilitating a 'junior' invention on the other.

The emergence of the European Patent with unitary effect has directed a lot of attention to the UPC and the idea of streamlining patent litigation in Europe. That should however not obscure the increasingly important role that is played by mediation in the patent arena. Guided by principles such as confidentiality, voluntariness and openness it is easy to see why certain types of conflict are better addressed in this way and away from the open courts and the conflictual approach and why certain parties prefer mediation. Licence agreements and SEP/FRAND disputes are obvious examples that come to mind. But international and complex disputes are maybe also better served by mediation, rather than risk potentially conflicting proceedings in national courts and/or the UPC. In chapter 24 Maximilian Haedicke examines the rise and potential of patent mediation in full detail.

If, however, litigation is the preferred option, the topic of litigation strategies surfaces immediately. In chapter 25 Alan Johnson looks at these strategies in the light of the additional options that the emergence of the UPC offers. The key idea is centralisation, but that also raises the stakes. Much more depends potentially on the outcome of a single case. There are forum shopping options within the UPC and these require careful consideration. And there is still a role for bifurcation, but is it an option worth considering? The transitional period comes with its own forum shopping problems, this time between the UPC and the national courts. In that context, but also in the relationship with the courts of third countries the potential for anti-suit injunctions also needs to be taken into account and it further adds to the creation of what looks at least for the initial period like a more uncertain world for European patent litigation.

The creation of the UPC as a single court system obviously required the contracting parties to take a view on the concept of bifurcation. The German approach on this point was often a topic for discussion, as it differed significantly from the approach in most other contracting states. In chapter 26 Matthias Lamping & Christoph Rademacher therefore look in depth at bifurcation in the context of litigation strategies. The chapter first of all analyses the German approach in depth and then goes into the place and role of bifurcation in the new UPC approach. The balance between the divisions of the court of first instance on the one hand and the central division on the other hand takes centre stage in this debate and it will be interesting to see how this unfolds over the coming years.

Leaving litigation strategies to one side, the creation of the UPC and European Patents with unitary effect adds another layer of complexity. Indeed, national and (traditional) European Patents remain an option and will still be the preferred option in a number of scenarios. That complexity of the European patent framework at large is expressed through various forms of fragmentation. This fragmentation occurs within the applicable legal rules, but also will be seen along territorial and institutional lines and moreover within that of markets in Europe. The key issue here is the co-existence between the EPC and its (traditional) European Patents on the one hand and European Pa-

tents with unitary effect of the other hand. In chapter 27 Mark Mimler examines the rules in this respect and tries to clarify some of the complexity.

Co-existence issues arise in a sense also inside the added layer of the European Patent with unitary effect and the UPC. The latter is after all made up of many different divisions. There exists therefore a necessity of judicial dialogue and cooperation in the UPC. In chapter 28 Karen Walsh focusses mainly on post-grant matters, and particularly on the functioning of the UPC, and argues that the post-grant harmonisation of patent law in Europe, to the extent that this is possible and desirable, cannot rely solely on the EU unitary patent system. To assist with the development of a consistent system overall, communication between divisions within the UPC, and between the UPC and external institutions will be key. Judicial dialogue and cooperation, that is, the process of judges considering or discussing relevant decisions and interpretations of other courts, and taking a coordinated approach where possible, will be essential in achieving this goal.

In the arduous process that eventually led to the creation of the European Patent with unitary effect and the UPC the role of the Court of Justice of the European Union was often seen as a major stumbling block. In chapter 29 Tamar Khuchua therefore looks in detail at the role of the Court of Justice of the European Union in the area of patent law. She does so from a procedural point of view, as in the almost complete absence of substantive patent law at EU level the enforcement directive and its various measures takes centre stage. Preliminary measures, the reimbursement of legal costs and final injunctions will of course also remain important in the UPC era and that will in practice require a smooth and fruitful cooperation between the two courts.

Gene patents are a fascinating topic, but also one of considerable complexity. In chapter 30 Naomi Hawkins examines the concept of gene patents in depth and looks at the way the EPC and the national legal systems and courts have dealt with them. It is fair to say that a certain form of divergence in approach to key questions around gene patent eligibility and scope has opened up in recent years. The chapter then turns to the UPC and asks the question whether it may arguably provide scope for this divergence to be explored, and for some degree of consistency and coherence in approach to be developed.

Taking a small step back from the practical issues involving gene patents, it becomes clear rather easily that ethical issues remain important in the context of the patenting of biotechnological inventions in Europe. In chapter 31 Aisling McMahon explains how ethical considerations play a role in patent decision-making for biotechnological inventions in Europe and that is reflected in legislative instruments such as the biotech directive and an additional layer of complexity is added by the fact that multiple adjudicative bodies are involved in the interpretation of these ethical provisions across the EU, European Patent Organisation (EPOrg), and now the UPC contexts. The addition of the latter creates the need for a proper discussion all the more urgent, as it re-enforces the need for a single harmonised approach.

Not only ethical harmonisation may end up on the UPC's plate. The Court may also soon be asked to deal with the FRAND issue. In chapter 32 Gail Evans therefore examines on the basis of recent case law in the UK and Germany whether and how the UPC

may determine whether a SEP holder, who has undertaken to grant licences on FRAND terms, is entitled to a prohibitory injunction. The analysis shows that despite the courts having some discretion in the grant of an injunction, once there is a finding of patent infringement, the court is unlikely to refuse a FRAND injunction.

We hope that our team of contributors has been able to offer a comprehensive and in depth analysis of patent law in Europe at this historical point in its development. The future will of course tell us if all of this was worth the decades of waiting and whether the European patent system will really emerge in far better shape from all of this.