Unified Patent Court and the Implications for Pharma

Introduction

On 19 February 2013, 24 EU member states signed a supra-national agreement which is intended to bring into being a new court called the Uniform Patent Court[1]. This agreement together with two EU Regulations, the Unitary Patent Regulation (1257/2012) and the Translations Regulation (1260/2012), both of which had been adopted by the European Parliament the previous December, will finally bring into being something akin to a Community Patent and a Community Patent Court. **To appreciate the implications of this to industry and in particular the pharmaceutical industry, it is absolutely critical to understand the nature of both the new patent right and the new court.**

As regards the new patent known as the Unitary Patent, it is not a Community-wide right (as is the Community Trade Mark and the Community Design) insofar as the Regulation was enacted via a procedure known as the Enhanced Co-operation Procedure, and both Italy and Spain have decided not to participate in it.

As regards the new court known as the Unified Patents Court, it has been given not only exclusive jurisdiction over Unitary Patents but also exclusive jurisdiction over existing European Patents, subject to a transitional period where it may have either non-exclusive jurisdiction over European Patents or no jurisdiction at all depending upon the steps taken by patentees to opt their European Patents out of the new court system (and not opt them back in again).

Unitary Patents can start to be granted after 1 January 2014 or the date of entry into force of the UPC Agreement, whichever is the later. The UPC Agreement will come into force three months after 13 of the contracting states - including the UK, Germany and France - have ratified the UPC Agreement (or possibly the third month after the date of entry into force of the amendments to Regulation 1215/2012 (the Brussels Regulation) concerning its relationship with the Agreement, whichever is the later. It is anticipated that, because of the amount of work which needs to be done in order to set up the new court from scratch, the UPC Agreement will not come into force until early 2015. It remains to be seen how many of the remaining contracting states will have ratified the UPC Agreement at the point in time when it does come into force.

The Unitary Patent (UP)

The UP will be granted via an application for a European Patent (EP) to the EPO. On being notified of the intention to grant a patent by the EPO, applicants will have the option of obtaining a UP rather than a bundle of EPs if two conditions are satisfied: first, that the designated states include all of the member states who have participated in the UP Regulation (i.e., all of the EU member states other than Italy and Spain) and second, that the claims are the same for all those member states. If the applicant or prospective patentee decides that they want a UP then they have one month after the date of the publication of the mention of the grant of the EP to notify the EPO, and an entry is made by the EPO in the register of UP protection.

The option to obtain a UP will apply to all pending applications for patents in relation to which the mention of the grant of the patent has not been published prior to the entry into force of the UPC Agreement (subject to the above two conditions being satisfied).

The decision as to whether to obtain a UP or a bundle of EPs will therefore depend on several factors, but primarily translation costs, renewal fees and the effectiveness of the enforcement regime. The translation regime is known. During the transitional period of up to 12 years, if the patent is granted in French or German then a translation into English is required, and if the patent is granted in English then a translation into any other EU Official Language is required. The EPO will also provide free online access to automated translations of any European patent application and patent. Towards the end of the transitional period, the Commission will review the effectiveness of automated translations and, if shown to be effective, human translations will not be required at all on grant. At the moment, the level of renewal fees is not known. This is likely to be decided later this year. The expectation is that it will be comparable to the equivalent of four – six EPs. What the proprietor of a UP will lose, however, over that of the proprietor of a bundle of EPs is the flexibility to lower that cost over the lifetime of the patent by jettisoning the protection in one or more of the contracting states in which the EP is in force. At the moment, the effectiveness of the enforcement regime is also not known. As explained in more detail below, the rules of procedure for the UPC are still work in progress and the court fees are not known. Both the rules of procedure and the court fees are also likely to be finalised and decided respectively later this year. How effective the UPC proves to be in practice will obviously not become apparent until it actually starts to deal with cases.

The Uniform Patent Court (UPC) – Jurisdiction over UPs and EPs

As mentioned above, although the intention is for the UPC to have exclusive jurisdiction over both UPs and EPs, this will not happen in respect of EPs in the short to medium term, mainly because of the transitional provisions. The transitional provisions have two dimensions to them. First of all, they provide that for a period of seven years (which in fact is likely to be extended to 14 and even up to 21 years), the UPC only has non-exclusive jurisdiction over EPs (both those that were granted before as well as those granted after the UPC Agreement comes into force). This means that a patentee contemplating an action for infringement or a third party contemplating an action for revocation or a declaration of non-infringement will have a choice as to whether to commence the action in a national court of a member state in which the EP is in force, or the UPC. Once an action in respect of an EP has been started in the

courts of one system, then the courts of the other system will no longer have jurisdiction over the EP. Second, they also provide that the proprietor of an EP can choose at any time during the transitional period (seven/14/21 years) to opt the EP out of the UPC system altogether by notifying the UPC Registry of that fact. Although it is not clear on the face of the Agreement itself, it is understood that once an EP has been opted out then it remains opted out for the remainder of its life. If an EP is opted out then a third party who wishes to commence an action for revocation or a declaration of non-infringement has no option but to start the action in one or more of the national courts of a member state in which the EP is in force. The patentee however is in a more advantageous position in that (subject to an action for revocation or a declaration of non-infringement already having been started in a national court) they can decide to opt the EP back into the UPC system again and having done so, commence an action for infringement in the UPC.

The upshot of the rather complicated position under the transitional provisions is that proprietors of both existing and future EPs need to take a positive decision whether to opt one or more or all of their EPs out of the UPC system. Given the ability to opt back into the UPC system, EPs that had previously been opted out, coupled with the fact that the jurisdiction of the UPC over EPs which have not been opted out is in any event non-exclusive, there would appear to be no good reason for proprietors of EPs not to opt all of their EPs out of the UPC system[2].

There is one further (mainly short term) complication for EPs and that is that as and when the Agreement is brought into force, it will not apply to EPs in force in Spain and possibly Poland, because Spain and as yet Poland have not signed the Agreement and it will not apply to EPs in force in those EU member states which have signed but not ratified the Agreement[3]. As regards the non-ratifying EU member states, they will presumably ratify the Agreement in the fulness of time and as and when they do, the UPC will then start to have non-exclusive jurisdiction over the EPs in force in those member states (unless in the meantime the EPs have been opted out).

The Uniform Patent Court – Structure, Language and Composition of Judicial Panels

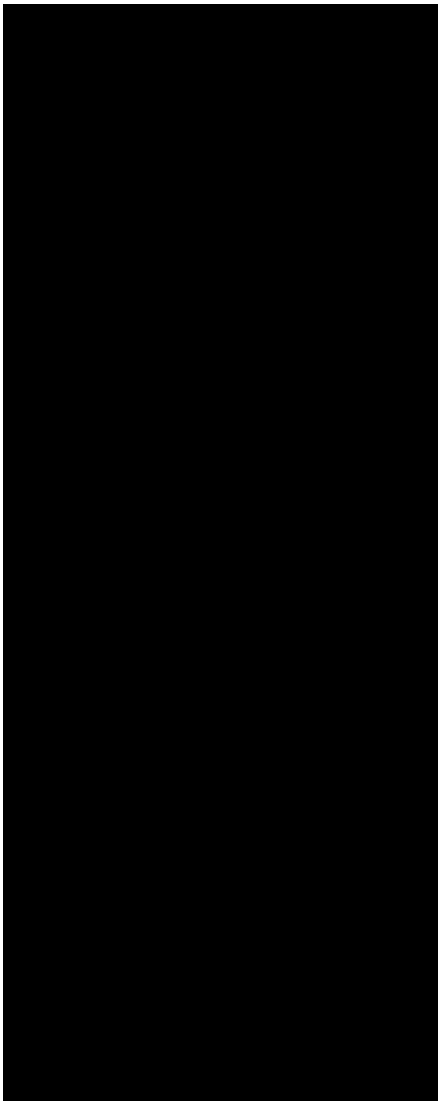
National patent enforcement systems around the world fall into one of two categories: those in which the issues of infringement and validity are heard by the same court, and those in which the issues of infringement are heard by one court and the issue of validity is heard by a different court. In Europe, most member states operate a unified system. Germany stands out as a European member state which operates a bifurcated system. The UPC has not adopted either the one or the other system but rather a hybrid version of the bifurcated system.

The first instance courts of the UPC comprise two types of court division: the local or regional divisions which are primarily the infringement courts, and the central division which is primarily the validity court. Any contracting state can set up its own local division. A member state having more than 100 patent cases a year for each of the three years preceding the Agreement coming into force can set up additional local divisions (and indeed more than one for each additional 100 patent cases up to a maximum of four). In addition, any member state can join forces with one or more other member states and set up a regional division. The central division has its seat in Paris but also a section in London and a section in Munich. Cases are allocated to one of three locations depending on the subject matter of the patent being litigated – life sciences to London, electrical to Paris and mechanical to Munich.

There is a detailed set of provisions governing the language of the proceedings before any given first instance court. In the central division, it is the EPO Official Language in which the patent was granted i.e., English, French or German. The local or regional divisions can choose whether, in the first instance, the language of the proceedings in their division is the OL (or one of the OLs of the country) or countries hosting the local or regional division respectively or one of the EPO OLs (i.e., English, French or German). The parties and the court are also given the right to propose the EPO OL in which the patent was granted and, failing agreement on the matter, a party is given the right to have the issue referred to the President of the Court.

As matters stand at present, it seems that there will be four local divisions set up in Germany, at least one local in each of the UK, Holland, France and Italy, and a regional division in Scandinavia (Sweden, Denmark and Finland). There are also indications that the language chosen by the Dutch local division and the Scandinavian regional division may be English rather than Dutch or Swedish/Finnish/Danish respectively.

Again, there is a detailed set of provisions governing the composition of the Judges in the first instance divisions. There will be a pool of both legal and technical Judges used to staff the central division as well as supply additional foreign legal and technical Judges to the local and regional divisions. The judicial panels have to be multinational. In the case of local divisions, if they have had more than 50 cases in each of the three years preceding the UPC Agreement coming into force, they are entitled to two local Judges and one foreign Judge from the pool, otherwise they are entitled to only



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one local Judge and two Judges from the pool, of which at least one would need to be foreign. The regional divisions are entitled to two Judges from the countries making up the region and one foreign Judge from the pool. If validity is put in issue by way of a counterclaim and the local or regional court decides to hear the validity counterclaim (rather than transfer it to the central court) then a(n additional) technical Judge must be appointed from the pool.

The Uniform Patent Court – Jurisdiction for Actions for Infringement, Revocation and Declarations of Non-Infringement

The forum shopping opportunities within the UPC system are very much biased in favour of the patentee.

An action for infringement may be brought in (1) any of the jurisdictions in which an act of infringement has taken place or (2) the jurisdiction of the principal place of business (PPOB) of the defendant, or failing that the place of business (POB) of the defendant or (3) if there is no PPOB or POB or the infringement is taking place in a jurisdiction which does not have a local or regional division, or a revocation action has already been started in the central division.

If a revocation action is pending in the central division then although an infringement action may be started in a local or regional division, the local or regional division has to decide whether to do one of three things: (1) hear both the infringement action and revocation counterclaim, in which case it has to request the appointment of a technical Judge from the pool; (2) transfer only the revocation counterclaim to the central division and either suspend or proceed with the infringement action; and (3) with the agreement of the parties, transfer the infringement action and the revocation counterclaim to the central division.

A pre-emptive revocation action can only be brought in the central division. Otherwise, if an action for infringement is already pending in a local or regional division then the defendant can only put the validity of the patent in issue by way of a counterclaim. However, as noted above, the local or regional division has to decide whether to transfer the revocation counterclaim to the central division or not and, if it is to be transferred, whether to stay the infringement action pending the outcome of the revocation action or proceed to hear it.

A pre-emptive action for a declaration of non-infringement can also only be brought in the central division. However, if the patentee starts an infringement action in a local or regional division within three months, the infringement action takes precedence and the action for a declaration of non-infringement is automatically transferred to that local or regional division.

As mentioned above, most of the national courts of the EU member states hear both the infringement and validity issues. The UPC Agreement allows for but does not mandate bifurcation as is the case currently in Germany. It seems unlikely that the local and regional divisions (including for that matter the German local divisions), if given the choice to bifurcate, will in practice decide to do so and deprive themselves of the ability to determine both the infringement action and the revocation counterclaim. If this does turn out to be the case then the central division is likely to have a lighter than anticipated workload. The only cases that will remain in the central division will be pre-emptive actions for revocation or pre-emptive actions for declarations of non-infringement where the patentee has been unable or unwilling to commence an infringement action in a local or regional division within three months or infringement actions where the defendant has no PPOB or POB or there is no act of infringement taking place, in a jurisdiction having a local or regional division.

Costs

As mentioned above, the court fees for initiating an action have yet to be decided. Given the need for the court to be self-financing coupled with the perceived benefit of obtaining a decision in one action which will have effects on a pan-European basis, it is to be assumed that the court fees will not be insignificant.

The legal fees for running an action in the UPC are likely in most cases to be considerably greater than those for running an action in a national court, especially in the early years, given the uncertainties inherent in a new court system with a new set of rules of procedure. Given how much will be at stake in a UPC action, one would expect the parties to throw everything at the litigation in order to secure a successful outcome. Overall, therefore, the parties to a UPC action cannot expect it to be a cheap exercise. Whether it proves to be cost-effective compared to the alternative of litigating national patents or opted out EPs before the national courts remains to be seen.

The UPC Agreement provides that the winning party shall, as a general rule, be entitled to reimbursement of its reasonable and proportionate legal costs and other expenses (up to a ceiling yet to be decided). Interestingly, there is also a provision (familiar to English practitioners where the costs follows the event rule has been the norm) giving a defendant the right to apply to the Court for an order for security for costs.

The Uniform Patent Court - Procedure

The UPC Agreement sets out a number of (somewhat conflicting) general principles as to how cases should be tried and decisions taken – decisions should be of high quality, a fair balance should be reached between the legitimate interests of the parties, the courts are to be allowed a certain degree of judicial discretion although the exercise of that discretion should not impair predictability, the rules should be applied in a proportionate but also a fair manner, and the court should exercise active management of cases but without impairing the freedom of the parties to determine the evidence needed to decide their case.

The UPC Agreement also sets out in broad terms the way in which an action is to proceed to trial with a first written stage for the pleadings, a second interim stage with a Case Management Conference, and then a third oral stage involving the trial or hearing. It also contains a mixed bag of procedural tools to enable the parties to gather or test the evidence needed to decide their case. These tools include the production of documents (akin to disclosure in the English system), the preservation of evidence (akin to a saisi in the French or Belgium system or a descrizione in the Italian system), the appointment of an expert (akin to that employed occasionally in the German system and to a greater extent in the Italian system), and cross-examination of expert witnesses (as used in the English system).

The more detailed aspects of the procedure before the UPC are to be contained in the rules of procedure of the court. These however are still in draft – draft 14 to be exact. It is understood that draft 16 will be published later this year for public consultation.

Given the array of procedural options made available to the first instance divisions, coupled with the likelihood that the judicial panels of most local and regional divisions will be staffed by a majority of local Judges, it seems likely that at least in the early years of operation the local and regional divisions are likely to be more amenable to doing things in the same way as their national courts have done them, i.e., they will show their couleur locale. For instance, one would imagine that the Italian local division would be more likely to grant a PI or order a court expert to be appointed, whereas the English local division would be more likely to order cross-examination of expert witnesses. At the same time, however, there will also be an opportunity for the local and regional divisions to do things differently to their corresponding national courts.

Appeals to the Court of Appeal and the Role of the CoJ

The Court of Appeal will be based in Luxembourg along with the Registry. No permission will be needed to appeal against a final decision in the action itself, nor will permission be required against orders made on certain interim applications, e.g., language, preliminary injunction. For all other orders made by a Court of First Instance, permission will be required to appeal immediately. Otherwise, the appeal has to be made at the same time as the appeal from the decision.

On an appeal, the Court of Appeal is free to review matters of fact as well as law, which would suggest that the appeal may tend more towards a rehearing than a judicial review. There is also a provision prohibiting the use of fresh evidence unless the party wishing to file it can show that it could not have been obtained before the first instance decision.

One of the issues which had prevented agreement on the UP being reached before now was the role of the Court of Justice of the EU as the ultimate arbiter of infringement. The experience of the CJEU in other areas of IP (especially trade marks and SPCs) has been seen by many to leave much to be desired. To avoid this outcome in the UP, the infringement provisions were removed from the UPC Agreement and the UP Regulation provides that infringement of a UP is deemed to be a matter of the national law of the EU member state where the patent proprietor had its PoP at the time of filing the UP (or if none then Germany). It remains to be seen whether in fact these provisions will achieve the desired effect and preclude the jurisdiction of CJEU on issues concerned with the infringement of a UP.

Implications for the Pharmaceutical Industry

There is no question that the opportunity in the UPC system for patentees to obtain pan-European injunctive relief and for third parties to invalidate weak patents for the whole of Europe will provide, in many cases, a significant advantage over the existing regime.

Inevitably for a new court system, it will take time before the effectiveness of the new enforcement regime as compared to the existing regime will become known. Speed and a rational decision-making process are two of the most important prerequisites to a successful enforcement regime. The preamble to the rules states that the aim of the Court would be to make a decision within one year of an action being commenced. Other than in the most straightforward of cases, this seems optimistic. Much will depend upon the quality of the Judges and their ability to manage cases effectively. Much may also depend upon the ability of the Court of Appeal to impose its will on the first instance divisions.

The pharmaceutical industry is different to many other industries in two important respects: first, drugs are most often protected by only one patent and if that patent is invalidated then the market is lost; second, geographical coverage is needed to protect the market in each country. Obtaining and maintaining EU-wide patent protection is intended to be cheaper with a UP than a bundle of EPs. However, when it comes to enforcement, a finding of invalidity by the UPC will result in the entire EU market being lost.

The decision at the outset to obtain only a UP for a pharmaceutical product for which a UP can only therefore be enforced in the UPC system is one that should not be taken lightly. Furthermore, there seems no question that patentees should opt their existing and future EPs for pharmaceutical products out of the UPC system, bearing in mind that the jurisdiction of the UPC over EPs in the transitional period is non-exclusive, and a decision can always be made to opt them back in again.

Despite the uncertainties, the fact that the UPC is due to open for business in early 2015 and has jurisdiction over existing EPs from the outset (unless steps are taken by patentees to opt their patents out) is something that both patentees and third parties need to take into account in their current litigation strategies.

References

1. Bulgaria added its name on 5 March 2013, leaving only Poland and Spain outside the Agreement, although it is expected that at least Poland will sign in due course.
2. One possible reason may be the cost of opting a patent out of the UPC system. It is not known whether a fee will be charged for the privilege of opting out and opting back in again and if so, how much the fee will be per patent.
3. Even though Spain is currently challenging the basis on which UP and the Translation Regulations were made before the Court of Justice, it is certainly possible that it will eventually decide to sign up to both the UP and the UPC.

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