

# INJUNCTIONS IN PHARMACEUTICAL PATENT CASES: THE APPROACH OF THE ENGLISH COURTS AND THE LIKELY IMPACT OF THE UPC\*

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## Introduction

In English patent litigation an injunction is a 'formidable weapon'<sup>1</sup> for patentees and (usually) the principal remedy sought following a successful infringement action. Preliminary injunctions (that is, injunctions pending trial) are no less formidable and have been widely (and largely successfully) sought before the Patents Court in London in brand-generic pharmaceutical disputes going back to the early 2000s.

However, the injunction – both final and preliminary – and the role it plays in pharmaceutical patent disputes is not fixed; changes in both market conditions and the legal framework (not least with the advent of pan-EU remedies in the Unified Patent Court) are likely to impact on how and when injunctive relief is sought in future.

## Interim Injunctions

The basis upon which the English court exercises its discretion to grant interim injunctions pending trial is well established (under the *American Cyanamid*<sup>2</sup> principles): in short, the claimant must have an arguable case and if so – and assuming that damages would not be an adequate remedy to either party – one moves to consider the balance of convenience or balance of justice.<sup>3</sup>

In *SKB v Generics*<sup>4</sup> in 2001, the Patents Court (in the guise of Jacob J as he then was) held that, in brand-generic patent disputes, the court should, when considering the balance of convenience, take into account whether the generic has 'cleared the way' before launch. In his extempore judgment, Jacob J said this:

*... The defendants have known for a long time about this patent. You would have to be very naive in the pharmaceutical industry to think that the patentee, with a product as important as this, would not, if it had anything other than a frivolous chance of success, take action. So the defendants knew, when they set out upon this project in 1997 that if the patentees would cause trouble they would.*

*The defendants could, so soon as they settled upon the product they were intending to sell, have caused the litigation to start ...*

*I see no question of principle involved here of any sort. It is purely commercial common sense. If there may be an obstacle in your way, clear it out.<sup>5</sup> To my mind, this is a case where the retention of the status quo is a rational thing to do. It was something that could have been avoided by the defendants; they chose not to do it.*

Jacob J adopted the same reasoning in another case involving the same drug (paroxetine) a year later (*SKB v Apotex*);<sup>6</sup> on appeal the approach was endorsed by the Court of Appeal:<sup>7</sup>

\* This article assumes there will be no Brexit after the referendum on 23 June 2016. In the event of a vote to leave the EU, the UPC and Unitary Patent project is likely to be significantly delayed and may be at risk.

1) *Behrens v Richards* [1905] 2 Ch 614 (1 August 1905) (not an IP case).

2) *American Cyanamid v Ethicon Limited* [1975] 2 WLR 316 (5 February 1975).

3) If all factors are evenly balanced, the court will preserve the status quo, that is, usually the position before the conduct complained of, unless, for example, there has been significant delay.

4) 23 October 2001 (unreported).

5) According to the learned judge, by applying to revoke the patent, seeking a declaration of non-infringement and/or putting the patentee on notice.

6) *SmithKline Beecham Plc and Another v Apotex Europe Ltd and Others* [2002] EWHC 2556 (28 November 2002).

7) *SmithKline Beecham Plc and Another v Apotex Europe Ltd and Others* [2003] EWCA Civ 137 (14 February 2003).

*[The judge was] entitled to have in mind that Apotex could have resolved the question of infringement and validity if they had acted timeously as it was they that could have done that and not SB.*

*Apotex rightly submitted that there was no obligation on a potential defendant to start proceedings. However this was a case where Apotex intended to come on to the market with their product and they must have realised, back in November 2001, that SB would be likely to seek an interlocutory injunction if there was an arguable case of infringement. It was Apotex who knew the process that was to be used and when they intended to launch their product, but they refrained from telling SB until the late autumn of 2002. If they had wanted to they could have had the issue of infringement and validity decided before launch. They chose not to do so with the result that there was potential injustice whichever way the court decides.*

*... The judge was, in my view entitled to take into account when deciding to maintain the status quo that Apotex walked into the situation that they find themselves in with their eyes open to the risk that they were taking. They knew the risk and decided that it was best not to remove it.*

Therefore, from the small acorn of Jacob J's extempore judgment in 2001, clearing the way has evolved into a 'well established'<sup>8</sup> and critical factor in brand-generic disputes: whether by motivating generic firms to initiate proceedings well in advance of their proposed launch or by the court imposing injunctions if they have not.<sup>9</sup> The long arm of the clearing the way doctrine<sup>10</sup> has even extended to the grant of an injunction where a generic firm refused to disclose whether or when it intended to launch an approved product; according to the court, silence, coupled with the securing of a

marketing authorisation nearly two years in advance of SPC expiry, sufficed to give rise to a threat of infringement for which the generic firm was enjoined.<sup>11</sup>

It will be interesting to see whether and to what extent 'clearing the way' maintains a hold over generic firms and their future UK product launches. Certainly, the Patents Court's willingness to grant injunctions at the interim stage (and even pending appeal – see below) has led to fewer at risk launches relative to the number of clearing the way actions. However, there may be other factors at play. First, it is quite possible that generic firms, inured to the dangers of an injunction should they launch at risk, have embraced the idea that knowing where they stand before liability for (monopoly) damages kicks in has a degree of commercial benefit. Second, where the generic firm has undertaken not to launch during clearing the way proceedings (as is often the case) they will typically have the benefit of a cross-undertaking in damages which, in light of the decision in *AstraZeneca v KRKA*<sup>12</sup> can have real teeth.<sup>13</sup> Third, even if the generic wins at trial the possibility of being enjoined pending the appeal is very real. In *Novartis v Hospira*,<sup>14</sup> the Court of Appeal confirmed that the criteria that apply when determining whether to award an interim injunction pre-trial apply equally pending any appeal. As the Court of Appeal ominously put it: a generic manufacturer should not consider the way to market clear until all of a patentee's arguable objections have been 'eliminated'. Therefore, if a generic manufacturer 'allows the trial ... to coincide with the intended launch date', it runs the risk of a successful appeal getting in the way, even if it wins at trial. A further factor which may become influential is that, in December 2015, the UK Patents Court committed to cases coming on for trial within 12 months.<sup>15</sup> This commitment may give some comfort to patent challengers who were previously uncertain as to when their case would be heard.<sup>16</sup>

8) Arnold J in *Actavis UK Ltd and Others v Eli Lilly & Co* [2016] EWHC 234 (Pat) (12 February 2016) at paragraph 179.

9) A rare exception being in *Cephalon, Inc and Others v Orchid Europe Ltd and Another* [2010] EWHC 2945 (Pat) (19 November 2010).

10) Floyd J in *Cephalon v Orchid* suggested there was a danger in treating the clearing the way factor as a principle of law. More recently, Arnold J considered the failure to clear the way as a tie breaker consideration when deciding to grant an interim injunction: '... it is well established, not least by the decision of the Court of Appeal in *SKB v Apotex*, that the principle that, in cases of doubt the court should maintain the status quo, applies with particular force. That leads to the conclusion that the better course is to grant the injunction as sought' (*Teva Pharmaceutical Industries Limited v Actavis UK Limited* [2015] EWHC 2604 (Pat) (9 September 2015)).

11) *Merck Sharp Dohme Corp. and Another v Teva Pharma BV* [2012] EWHC 627 (Pat) (15 March 2012). It did not assist the defendant that it had previous 'form' for launching without notice.

12) *AstraZeneca AB v KRKA dd Novo Mesto* [2015] EWCA Civ 484 (21 May 2015).

13) The Court of Appeal upheld an award of £27 million under a cross-undertaking given to the generic firms by AstraZeneca. However, in practice proving loss under a cross-undertaking is time consuming and expensive, and many generic manufacturers would prefer to be on the market with immediate financial benefits.

14) *Novartis AG v Hospira UK Limited* [2013] EWCA Civ 583 (22 May 2013).

15) Practice Statement: Listing of Trials in the Patents Court, 10 December 2015.

16) However, the comfort may be limited: the Practice Direction does not demand that judgment be handed down within a particular time frame and there is no time limit as to when an appeal must be heard.

Patentees are not without challenges of their own on the question of interim relief pending trial. In particular, the ongoing pregabalin litigation in the United Kingdom has highlighted the difficulty of securing interim remedies in relation to the marketing of products under a 'skinny label'.<sup>17</sup> In *Warner-Lambert I*,<sup>18</sup> Arnold J refused Warner-Lambert's application for an interim mandatory injunction requiring Actavis to take positive steps to prevent its skinny labelled product being dispensed for a patented indication (the patentee accepted that the defendant was entitled to market pregabalin for off-label indications). Whilst the Court of Appeal disagreed with Arnold J on the question of whether there was a serious issue to be tried, it upheld his refusal to grant interim relief.<sup>19</sup> As discussed further below, the position of final injunctive relief in the context of infringement of second medical use patents is also likely to be a subject for further consideration.

It is also noteworthy that, in the pregabalin litigation, the Department of Health took an especially active role in the litigation (in particular the Secretary of State was represented throughout the proceedings and, at trial, counsel for the Secretary of State made submissions which, on any analysis, favoured the position adopted by the generic defendant firms). We will have to wait and see whether the pregabalin litigation represents a new, more interventionist, approach by the UK Government. If so, that could cause some concern amongst the brand-patentee community, not least because exposure under any cross-undertaking in damages is significantly greater where the NHS is a beneficiary under the undertaking.<sup>20</sup>

## Provisional Injunctions in the Unified Patent Court (UPC)

The UPC will have exclusive jurisdiction over Unitary Patents. During a transitional period of seven years (which may at a

later date be extended by a further seven years), the UPC and national courts will have shared jurisdiction over infringement and revocation actions relating to standard European patents that have not been opted out of the UPC<sup>21</sup> (following the end of the transitional period, all non-opted out standard European patents will be under the exclusive jurisdiction of the UPC). The provisions relating to the opt-out of standard European patents (and withdrawal of the opt-out), and the jurisdictional questions that arise during the transitional period are complex and beyond the scope of this article.

The UPC Agreement provides that an injunction may be granted against an alleged infringer on a provisional basis to prohibit any infringement or 'imminent infringement'.<sup>22</sup> The decision to award a provisional injunction is discretionary but the Agreement gives some (albeit limited) guidance to UPC panels: in exercising their discretion, they must weigh up the parties' interests and, in particular, take into account the potential harm for either party resulting from the grant or refusal of the injunction.<sup>23</sup> The panel may also require the applicant to provide any reasonable evidence to satisfy it with a sufficient degree of certainty that it is the right holder and that its right is being infringed, or that such infringement is imminent.<sup>24</sup>

However, otherwise, the Agreement is silent as to how panels should exercise their discretion to award provisional injunctions. During the consultation process on the Rules of Procedure this has been a significant concern: given that different judicial traditions mean that courts across the EU currently take significantly divergent approaches to awards of interim injunctions, many are concerned that this largely unfettered discretion will lead to inconsistent decision-making between UPC panels, and therefore facilitate forum shopping.

17) Skinny label patent litigation has – perhaps inevitably – become increasingly common in pharmaceutical patent litigation as patents for basic compounds and first medical use patents expire whilst follow on use patents for new indications remain extant.

18) *Warner-Lambert Company LLC v Actavis Group PTC EHf and Others* [2015] EWHC 72 (Pat) (21 January 2015).

19) [2015] EWCA Civ 556 (28 May 2015).

20) There is an understanding (as discussed by Jacob LJ in *SmithKline Beecham Plc v Apotex Europe Ltd* [2006] EWCA Civ 658) that parties to a pharmaceutical injunction are obliged to notify the Department of Health in advance of any injunction hearing (in case the Secretary of State decides to make representations and/or apply to be a party to the cross-undertaking). In

the pregabalin litigation, Warner-Lambert accepted that cross-undertakings should, where granted, be for the benefit of the Department of Health and NHS also.

21) Article 83(1), 83(3) of the Unified Patent Court Agreement 16351/12. References in this article are to Articles of the UPC Agreement unless indicated.

22) Article 62(1).

23) Article 62(2).

24) Article 62(4) UPCA, Rule 211.2 Rules of Procedure. References to the Rules of Procedure are to the 18th draft of the Rules of Procedure which, subject to inclusion of the rules relating to fees and recoverable costs, was adopted as the final approved version in October 2015.

Later versions of the Rules of Procedure have sought to mitigate this concern, by incorporating<sup>25</sup> the text from the UPC Agreement and also requiring panels to have regard to any unreasonable delay in seeking provisional measures. However, the main message is that there should be no further guidance in the Agreement or Rules, as this would be an inappropriate fetter on the panels' discretion, which would negate the flexible framework in place.

It seems inevitable, therefore, that there will be significant differences between different UPC panels as to how they approach applications for provisional measures. This will especially be the case in the early years of the UPC, although it is hoped that these will be 'ironed out' by the Court of Appeal (and by the multinational judicial make-up of panels). For example, there is likely to be divergence as to whether an infringement is *imminent*: as noted above, the Patents Court has accepted that an MA application some 22 months before expiry of the relevant patent rights is an imminent threat to infringe. However, the District Court in the Hague, just a few weeks later in a dispute between the same parties and on the same patent, said the MA application was not sufficient. Other areas of potential variation include the weight to be given to 'unreasonable delay' and whether there will be any requirement to 'clear the way'. As discussed above, the Patents Court requires generic entrants to 'clear the way' before launch. Whilst (and not surprisingly) there is no reference to 'clearing the way' in the UPC Rules (and similarly, there is no reference to the adequacy of damages for either party), it can be assumed that, for the UK-based local division panel, this will remain a relevant factor in the exercise of its discretion.

Most interim injunction applications in the UPC will be 'on notice' but provisional measures may be ordered on a without notice basis,<sup>26</sup> particularly where delay is likely to cause the applicant irreparable harm (given the potentially wide scope of an injunction in the UPC, the possibility of without notice applications will be a significant concern for potential defendants). One interesting aspect is the availability of German-style protective letters.<sup>27</sup> If a party entitled to bring UPC proceedings considers it likely that an application for provisional relief will be made against it in the near future, it may file a protective letter (which will become publicly

available on the UPC register should an application for provisional measures subsequently be lodged) in which it may challenge the facts the presumed applicant is expected to rely on, and assert invalidity or why an interim injunction application should be refused. By lodging the protective letter, the potential respondent will hope to ensure that its arguments are put before the panel on any subsequent application for provisional relief (albeit the rule merely provides that the panel shall consider summoning the parties to an oral hearing if a protective letter has been filed).<sup>28</sup> If no interim injunction application is issued within six months, the protective letter will be removed from the register, unless an extension is sought (subject to payment of a further fee).

The court may order<sup>29</sup> an applicant to provide security for appropriate compensation for any injury which is likely to be caused to the defendant (and shall do so where interim measures are ordered on a without notice basis, unless there are special circumstances). The court may, if appropriate, order security by deposit or bank guarantee.

The risk that the court may order security against the patent holder will be a very significant factor, given the potentially sizeable scale of compensation which might be awarded to a defendant as a result of the broad geographical scope of the injunction. During the consultation on the Rules, the British Generic Manufacturers Association submitted that the Rules should also provide for the possibility of security for compensation to third parties, such as national health authorities. However, the commentary to the 16th draft of the Rules stated in response: 'in a civil procedure only the interests of the parties are at stake'. Whilst this tends to suggest that it is anticipated that compensation will not be available for the losses suffered by third parties such as the NHS, this cannot be assumed, and ultimately will need to be resolved by the court.

## Final Injunctions in the Patents Court

Once patent infringement is established (and provided it has not ceased by trial), a final injunction will usually be granted. However, whilst infringement is taken to imply an intention to continue the relevant infringing activity, an injunction does

25) Rules 211.3 and 211.4.

26) Article 60(5) and Rule 212.

27) Rule 207. There will be a fee of €200 to lodge a protective letter.

28) Rule 209.2(d).

29) Rule 211.5.

not automatically follow. It remains a discretionary remedy and one only awarded for a preventive purpose (so, an injunction may be refused where the infringement is historic and further infringement is unlikely).<sup>30</sup>

The IP Enforcement Directive<sup>31</sup> requires Member States to provide necessary remedies to ensure the enforcement of IP rights, which are fair and equitable, and not unnecessarily complicated. Further, such remedies must be effective, proportionate and dissuasive, and be applied in such a manner as to avoid the creation of barriers to legitimate trade and to provide for safeguards against their abuse. Further, Article 12 of the Directive provides that Member States may, in certain circumstances, provide for alternative measures, namely damages, instead of an injunction.<sup>32</sup>

The IP Enforcement Directive factors are clearly important considerations for a court when deciding whether to grant an injunction, but there is little consistency between Member States' courts as to how they are applied (with some courts granting an injunction automatically, with little, or no, consideration of, for example, proportionality). The Patents Court is well versed in considering such issues. For example, in *HTC v Nokia*,<sup>33</sup> HTC argued that the court should exercise its discretion to award damages in lieu of an injunction.<sup>34</sup> Arnold J refused but, in doing so, reiterated that the IP Enforcement Directive criteria were central to the decision as to whether to grant an injunction. However, much also depended on the rights in play; in particular, in patent cases, the court should be very cautious before ordering something tantamount to a compulsory licence in circumstances where one would not be available.

In practice, it is likely only to be in exceptional cases that the Patents Court will, following a finding of patent infringement, not award a final injunction, or that it will decide to award damages in lieu of an injunction. However, the Patents Court is already willing to impose conditions on a final injunction in appropriate cases, and the courts' approach to the question of injunctive relief may become even more flexible in the

future. Indeed, the Supreme Court recently suggested in *Coventry v Lawrence*<sup>35</sup> (a non-IP case) that a re-evaluation of this question, leading to a more flexible approach, may be appropriate in future cases.

One area where the scope of injunctive relief is under particular scrutiny is where there has been a finding of infringement of a second medical use patent by a skinny labelled product. In his *Pregabalin* trial decision,<sup>36</sup> Arnold J accepted that it was, in general, for the defendant to decide what to do to avoid infringement, but he reiterated that the court must (as he had explained in *HTC v Nokia* and in accordance with the requirements of the IP Enforcement Directive) ensure that an injunction was proportionate and did not create barriers to legitimate trade. Accordingly, this could mean that the form of injunction should be more specific than the conventional general form,<sup>37</sup> not least given that a general injunction would be likely to leave the generic manufacturer in a 'state of considerable uncertainty' as to what it must do to comply. The grant of an unqualified injunction in general form in such a case was, he said, arguably disproportionate and/or would create barriers to legitimate trade, as it would force the generic manufacturer to withdraw from the lawful market for the non-patented indications. Floyd LJ in the Court of Appeal<sup>38</sup> had earlier also noted that there were potential 'hard cases' where the court could restrict the scope of an injunction so that it did not prevent sale of the product itself, or even refuse an injunction altogether.

## Stays of Injunctions Pending Appeal

The decision to grant a stay of a final injunction pending appeal is also an exercise of discretion, intended to ensure that loss and inconvenience for the ultimately successful party on appeal is kept to a minimum. The court will not assess the respective merits of the parties' positions (provided the appeal has a real prospect of success). It instead focuses on the effect a stay would have on the parties, the guiding principle being to ensure that the appeal court

30) See, for example, *Stretchline Intellectual Properties Limited v H & M Hennes & Mauritz UK Limited* [2016] EWHC 162 (Pat) (21 January 2016).

31) 2004/48/EC; Article 3(1) and (2).

32) Article 12 of the IP Enforcement Directive is not specifically implemented in UK law.

33) *HTC Corporation v Nokia Corporation* [2013] EWHC 3778 (Pat) (3 December 2013).

34) Under section 50 Senior Courts Act 1981; and the key cases of *Jaggard v Sawyer* [1995] 1 WLR 269 and *Shelfer v City of London Lighting Co Ltd* [1895] 1 WLR 287.

35) *Coventry v Lawrence* [2015] UKSC 50 (22 July 2015).

36) [2015] EWHC 2548 (Pat) (10 September 2015). The patent was held invalid. At the time of writing, the decision was under appeal.

37) *Oracle America Inc v M-Tech Data Ltd* [2012] UKSC 27 (27 June 2012).

38) [2015] EWCA Civ 556.

can do justice between them, whatever the outcome.<sup>39</sup> Clearly, in many cases, the grant of a final injunction will have very severe consequences for the enjoined party, both practically and economically, and in terms of its market reputation (if the injunction is not stayed, the court may require a cross-undertaking).

As the Court of Appeal noted in *HTC v Nokia*<sup>40</sup> (where the final injunction was stayed, given the disastrous and potentially irrecoverable impact it would have on HTC's business):<sup>41</sup>

*Perfect justice is rarely obtainable and the uncertainty of the eventual outcome inevitably dictates that the court may be able to do no more than to opt for the lesser of two evils. It is essentially about minimising risk. Where the potentially adverse consequences are relatively evenly balanced, the court can probably do no better than to maintain the status quo ...*

The courts have also considered whether a stay should be granted pending a further appeal to the Supreme Court, or the outcome of EPO opposition proceedings. In *ASSIA v BT*<sup>42</sup> the injunction was stayed for a short period to allow BT to make potentially non-infringing alterations to its system. However, the Court of Appeal refused its application for a cross-undertaking in damages to deal with the possibility that the EPO might revoke or substantially amend ASSIA's patent:

*A cross-undertaking is appropriate to take account of the possibility that the earlier judgment is wrong (e.g., an interim injunction or an injunction pending appeal). In the present case, revocation by the EPO would not show our judgment to be wrong, or the injunction to have been wrongly granted ... There is no reason for ASSIA to pay for the harm during the period when the injunction was rightly granted.*

In *Smith & Nephew v ConvaTec*<sup>43</sup> (parties that have been involved in significant patent litigation relating to wound dressings), the Court of Appeal granted a stay of the final

injunction pending Smith & Nephew's application to the Supreme Court for permission to appeal. The consequences of the injunction for Smith & Nephew were likely to be severe and irreparable, whereas ConvaTec could recover its monopoly in the market following the short period of the suspension. Significantly, the injunction was also stayed pending the EPO TBA proceedings but the court recognised there were unusual circumstances which meant that to refuse a stay would be disproportionate: the Opposition Division had revoked the patent, and the TBA decision would be only a few months after the Supreme Court's decision on permission to appeal.

## Springboard Injunctions

A springboard injunction is intended to deprive a defendant of any unwarranted benefit it obtains as a result of gaining a springboard into a particular market through its infringing activities. Importantly, this may include restraining otherwise lawful activity, such as selling a product for a limited period after patent expiry. Springboard injunctions have been granted in a small number of patent cases<sup>44</sup> and were considered in detail by Birss J in *Smith & Nephew v ConvaTec*<sup>45</sup> where he said that, provided that the Article 3 requirements are met, such an order will comply with the IP Enforcement Directive. However, the court must be careful not to put the claimant in a better position than if there had been no infringement, especially if it means that otherwise lawful competitive activity will be restrained (a springboard injunction was refused in this case).

## Final Injunctions in the UPC

As has been noted, one of the UPC's selling points is the potential ability to obtain (for Unitary Patents and European Patents that are not opted out during the transitional period) in one action injunctive relief across the EU (or, more accurately, in those Member States that ratify the UPC Agreement).

39) *Minnesota Mining & Manufacturing Co v Johnson & Johnson* (No 3) [1976] RPC 671 (23 January 1976).

40) [2013] EWCA Civ 1759 (12 December 2013).

41) Arnold J had only ordered a stay of the injunction in respect of HTC's flagship One device, but the Court of Appeal extended it to the One Mini as the impact of an injunction applied across the entire range.

42) *Adaptive Spectrum and Signal Alignment Inc v British Telecommunications plc* [2014] EWCA Civ 1513 (21 November 2014).

43) *Smith & Nephew plc v ConvaTec Technologies Inc and Others* [2015] EWCA Civ 803 (30 July 2015).

44) For example, *Generics v Smith Kline & French C-316/95* (a reference from the Dutch court) (where an injunction was granted to restrain sales of a generic product for 14 months); *Union Carbide v BP Chemicals* [1998] FSR 1; *Dyson Appliances Ltd v Hoover Ltd (No 2)* [2001] RPC 27 (where a 12-month injunction was granted).

45) *Smith & Nephew v ConvaTec Technologies Inc and Others* [2013] EWHC 3955 (Pat) (12 December 2013).

Where there is an infringement finding, the UPC Agreement provides that a UPC panel *may* grant a final injunction against the infringer.<sup>46</sup> Whilst the use of 'may' confirms a final injunction is discretionary, concerns have been expressed<sup>47</sup> that panels will tend to grant injunctions automatically, leading to fears of substantial activity by non-practising entities in the EU patent litigation market. Many have called for an *eBay*<sup>48</sup> type provision, whereby a successful claimant must demonstrate certain factors have been met before an injunction will be awarded. However, these calls have gone unheeded.

Indeed, the 17th edition of the draft Rules of Procedure saw deletion of a provision which had provided that, in appropriate (limited) cases, a panel could order damages or compensation instead of an injunction.<sup>49</sup> The following reasons were given by the UPC Preparatory Committee for its deletion:

*Where the Court finds an infringement of a patent it will under Article 63 of the Agreement give order of injunctive relief. Only under very exceptional circumstances it will use its discretion and not give such an order. This follows from Article 25 of the Agreement which recognizes the right to prevent the use of the invention without the consent of the patent proprietor as the core right of the patentee. When exercising this discretion the Court can also consider the use of alternative measures.*

It is not yet clear to what extent these 'explanatory remarks' may end up effectively operating as a fetter on a panel's discretion to grant a final injunction (that is, that final injunctions will be granted in all but 'very exceptional circumstances') or to consider alternative measures.

Another controversial topic has been the risk of bifurcation of validity and infringement proceedings within UPC divisions and the consequences for forum shopping: a Local/Regional Division panel may decide to bifurcate proceedings and refer

a revocation counterclaim to the Central Division, and continue the infringement proceedings.<sup>50</sup> The concern is that bifurcation will allow patent holders (particularly of weaker patents) to obtain a decision on infringement, including an injunction, before the validity decision (the so-called 'injunction gap'). Rule 118.2 provides that, where proceedings are bifurcated (or where there are opposition proceedings before the EPO), the panel hearing the infringement claim: (1) may render its decision on the merits of the infringement action and issue an injunction; (2) may make its decision and order subject to the condition subsequent that the patent is not held wholly/partially invalid in the revocation proceedings or before the EPO; or (3) *may* stay the infringement proceedings pending the revocation/EPO proceedings and *shall* stay the infringement proceedings where it is of the view that there is a high likelihood that the relevant claims will be held invalid in the revocation proceedings or the EPO, where the EPO decision is expected to be given rapidly.

Whether bifurcation will occur much in practice remains to be seen, with many commentators suggesting that UPC panels (even those with a tradition of bifurcation) will only rarely bifurcate. Further, the Rules of Procedure now also include case management provisions which deal with the injunction gap risk to some extent:<sup>51</sup> where proceedings are bifurcated and the infringement action is not stayed, the Judge-Rapporteur at the Central Division is required to accelerate the revocation proceedings and 'shall endeavour' to set an early date for the oral hearing, taking into account information received from the Local/Regional Division about the dates set for the interim conference and oral hearing of the infringement action. It remains to be seen how effectively Judge-Rapporteurs will exercise their discretion in synchronising the respective panels' calendars.

Finally, whilst it is anticipated that injunctions in the UPC will have effect across all relevant Member States, considerations of proportionality may still impact on the scope of an injunction.

46) Article 63(1); non-compliance may, where appropriate, be subject to a recurring penalty payment.

47) For example, The Industry Coalition in its Comments on the Rules of Procedure dated 26 November 2014.

48) In *eBay v MercExchange* 547 US 388 (2006) the US Supreme Court said that a claimant seeking an injunction must show that (1) it has suffered irreparable injury; (2) remedies, such as damages, are inadequate to

compensate it for that injury; (3) considering the balance of hardships, a remedy in equity is warranted; (4) the public interest would not be disserved by a permanent injunction.

49) The provision was based on the wording in Article 12 of the IP Enforcement Directive.

50) Article 33(3).

51) Rule 37.5, Rule 40b.

## Conclusion

The availability of both provisional and final injunctive relief across (in time) potentially most of the EU (for both Unitary Patents and standard European patents, assuming they have not been opted out of the UPC's jurisdiction) is an extremely significant weapon in the hands of a patent holder. It does, of course, come with the corresponding significant risk that the patent may be revoked across the same wide geographical area. The availability of pan-EU relief under the UPC is particularly significant given that the scope for cross-border injunctive relief has been minimised in recent years by the CJEU's decisions in *GAT v Luk*<sup>52</sup> and *Roche v Primus*<sup>53</sup> (subject, of course, to its later decision in *Solvay v Honeywell*<sup>54</sup> that a cross-border

provisional injunction may still be available even where invalidity is raised as a defence).

As far as the United Kingdom is concerned, a sort of equilibrium has been reached: the Patents Court's approach to questions of clearing the way and balance of convenience arguments are well settled and understood by both patentees and patent challengers (subject to factual nuances in a particular case). In the early years of the UPC, despite the fact that panels will apply a common set of rules, they may well adopt divergent approaches to the exercise of their discretion to grant injunctive relief, based on their existing legal traditions. However, given the multi-national judicial make-up of panels, it must be anticipated that judicial traditions will become blended over time, with much hoped-for consistency coming down from the Court of Appeal.

52) *GAT v Luk* C-4/03 (13 July 2006).

53) *Roche Nederland BV and Others v Primus* C-539/03 (13 July 2006).

54) *Solvay SA v Honeywell Fluorine Products Europe BV* C-616/10 (xx).