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EXPERT OPINION

Preliminary injunctions in generic and branded patent litigation

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1. Introduction

Patents are rights entitling their owner or an exclusive licensee to 20 years right to exclude others from the sale of a product or the use of a process protected by the patent. In the pharmaceutical sector this right can be very valuable – blockbuster drugs, in particular, can bring in annual revenues of several billion US dollars. Much of this value is owed to the premium price that can be applied to drugs when competition is excluded by patent protection. Such lucrative markets nonetheless attract competition from generic companies willing to test the validity of the patent protection and the ability of the manufacturer to enforce their patent right. For this reason, the patent owners for branded products, or their exclusive licensees, often need to enforce their patent rights in court. One very powerful tool that may be at their disposal for this purpose is the preliminary injunction. Obtaining a preliminary injunction at the first sign that a generic has infringed can swiftly bring the allegedly infringing activity to an end, until the issues of validity and infringement have been determined at trial.

However, obtaining a preliminary injunction is not a formality, and even though the European Enforcement Directive [1] makes preliminary injunctions available across the European Union (EU), the circumstances in which they may be obtained and the arguments that must be made to obtain one, vary from one country to another in Europe. Preliminary injunctions are discretionary and determined by questions of national law. This will remain the case until such time as the Unitary Patent and Unified Patent Court (UPC) becomes effective. Here, we briefly discuss the key requirements for a preliminary injunction in England and Wales, Germany, France and the Netherlands.

2. England and Wales

In the English courts, preliminary injunctions are not uncommon, particularly in the pharmaceutical sector, less so in other sectors, so long as the defendant is financially secure. The criteria for obtaining a preliminary injunction are i) there is a serious question in issue (meaning that on the face of the evidence the court is satisfied there may be an infringement – infringement does not need to be proved as it would be at trial); ii) damages are not an adequate remedy for the patentee such that, without the injunction, irreparable harm will be caused; and iii) taking all the circumstances into account, the balance of convenience lies in favour of granting the preliminary injunction. Together, these criteria are frequently difficult to satisfy.

However, pharmaceutical patent cases involving branded originator patents and generic competitors are arguably a special case in which the criteria are more easily met. This is because the Patents Court has previously stated that alleged infringers in the pharmaceutical sector should 'clear the way' of any blocking patents before

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attempting to enter the market [2]. The received wisdom is that entry onto the market by an infringing generic product will irreparably damage the branded market by forcing down the price due to exclusive presence on the market through competition. The brand companies argue that the exclusive price may subsequently never be recovered (even were the generic company to withdraw from the market) and therefore damages are an inadequate remedy. Instead, immediate measures are needed to cease the infringing activity.

However, this view has not gone unchallenged. In litigation concerning a generic of the hypersomnia and narcolepsy drug modafinil [3] where the defendant did not 'clear the way' of patent protection, arguments put forward by the claimant (Cephalon) about irreparable damage to their market share did not convince the court that an injunction was appropriate.

In contrast, the Patents Court ordered an injunction in favour of Merck Sharp Dohme and Bristol-Myers Squibb to prevent the sale of generic efavirenz (an anti-retroviral used in the treatment of HIV/AIDS) before it entered the market [4]. However, the circumstances were unusual. First, suspicions arose because the marketing authorisation was obtained for the generic a full two years before patent expiry. The defendant also refused to disclose its marketing intentions. The court also noted that the defendant had marketed another drug at risk of injunction not long before.

Most recently (on 22 May 2013), the Court of Appeal has allowed an injunction to prevent the marketing of generic zolendronate [5] after the two Novartis patents protecting it were found invalid at first instance, pending appeal. The court held that the price erosion and loss of market share that would be suffered by the patentee outweighed the potential loss of a first mover advantage by the defendant. These cases confirm that preliminary injunctions are alive and well in pharmaceutical cases in the UK.

3. Germany [6]

In general, in Germany, the courts will grant preliminary injunctions only if the patent infringement is clear (and can be shown without the need for additional expert evidence). Secondly, the patents at issue should be considered clearly valid (and, ideally, tested in opposition or nullity proceedings) [7]. Additionally, the patentee must act without undue delay. Thus, the German approach is concerned more with the merits of the case than it is with its commercial impact.

However, approach to generic launches in Germany may be more favourable for patentees. The Düsseldorf court has recently indicated that, even if the validity of the patent is unclear, interim injunctions may be granted if the balance of convenience is in favour of the patentee (looking at commercial factors, for example, price erosion); this is usually assumed in cases of a generic launch [8].

A further problem faced by generics in Germany is the system of 'bifurcation'. This means that the full hearings of infringement and validity are dealt with in separate proceedings in different courts. In this system, infringement and validity proceed with different timescales, with a final infringement decision usually about one year in advance of a final determination of validity (the so-called 'injunction gap'). The result is that even *final* injunctions can be granted some time before the defendant has a chance to argue that the patent in question should not have been granted. Whilst infringement courts have a discretion to await the outcome of validity proceedings they rarely do so.

This recent approach to preliminary injunctions in Germany and the bifurcation problem also militate towards a strategy for generics of clearing the way of blocking patents first.

4. France [9]

Generally, in France, preliminary injunctions may be granted if there is evidence of infringement or that the infringement is imminent [10]. However, in respect of generic pharmaceuticals it has been held that merely doing acts in preparation for a post-patent expiry launch (for example, obtaining regulatory approval before patent expiry) is not sufficient to show that there is an intention to infringe during the patent term.

In addition to assessing infringement the French courts will also conduct a preliminary assessment of the validity of the patent, taking into account any serious arguments raised by the parties on this issue. The degree of assessment of both infringement and validity issues for a preliminary injunction in France is closer to a hearing on the merits than is the case, for example, in England and Wales [11].

5. The Netherlands

The Dutch court will also need prima facie evidence of infringement, and will come to a provisional view about the patent's validity [12]. Like the German courts, unless new evidence of invalidity, such as new prior art, that was not available on prosecution is produced the court will assume validity. This is particularly the case where the patent has been contested through an opposition, and even appeal.

Urgency must again be shown to obtain preliminary relief – patentees must act quickly to obtain relief as soon as the infringement has come to their attention. The Dutch courts generally consider a continuing infringement as inherently urgent [13], but urgency may also be made out if there is evidence of a risk of irreparable damage if preliminary relief is not granted [14].

In the Netherlands an order for injunctive relief will usually contain obligations on the infringer to give details of the number of infringing products sold or the use of a process; give

details of the customers supplied with infringing product; and inform those customers of the infringement. In other jurisdictions this information would normally be gathered by separate procedures [15].

The Dutch courts are also prepared to grant preliminary cross-border injunctions [16]. As a result of a CJEU ruling permitting the Dutch court's order for one such injunction we may now see these being considered in other EU countries, in similar circumstances [17]. In this case, Solvay applied for a cross-border injunction in the Dutch court to prevent infringement by Honeywell of a European patent that was in force in various European member states. Honeywell said that the various national parts of the European patent were invalid. Under article 22(4) of European Regulation 44/2001, validity is a question that may only be addressed by the courts of the member state in which the patent is granted. Honeywell said that the Dutch court should therefore have stayed the case as it did not have jurisdiction to decide on the validity of those parts of the patent concerning countries other than the Netherlands.

However, in this case, the CJEU ruled that it is open to a court to grant a cross-border injunction when defendants domiciled in more than one country are infringing two or more national counterparts of a European patent by the same product. This is even when validity is raised as a defence to the injunction. However, there must be a risk that, unless the case is heard by a single court, irreconcilable judgements (that is, contradictory decisions) on the infringement will issue from national courts as a result of parallel national actions being brought in the countries affected, further to Article 6(1) of the Brussels Regulation [18].

As explained, the approach to injunctions varies across Europe and even cross-border injunctions are confined to certain circumstances. A fully cross-border approach to injunctions will only come when the "UPC" enters into being.

6. The UPC

The UPC [19] will have jurisdiction to grant both final and preliminary injunctions to prevent patent infringement of the new Unitary Patent [20] (which has pan-European effect), as well as existing European patents that have not opted out of the UPC system. Injunctions based on a Unitary Patent will have effect over all EU member states except Spain and Italy (which are not currently participating in the Unitary Patent). Injunctions based on non-opted-out European patents will have effect in all the countries designated that are also signatories to the UPC. However, the UPC will not have jurisdiction over European patents that do opt out of the UPC system and national patents.

The UPC will operate according to rules of procedure that are currently still in draft form [21]. Therefore, it remains to be seen exactly how preliminary injunctions will be approached by the UPC until the rules are finalised and the court is in operation and granting them (not expected to be until 2015/2016). Until then obtaining preliminary injunctions are granted very much a country-by-country basis.

Declaration of interest

S Cohen is a partner and P England a professional support lawyer in the Taylor Wessing Patents Group. S Cohen has acted as a solicitor for Teva. The authors state no conflict of interest and have received no payment in preparation of this manuscript.

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14. Meijn Food Processing Technology v Tieleman Food Equipment et al., Hague District Court, 1 April 2008, KG RK 08-0517
15. For example, in France, the saisie contrefaçon would be the appropriate means to gather such evidence of infringement and in Germany by pre-action search order. In English proceedings, such matters are typically dealt with in general disclosure
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17. Solvay SA v Honeywell Fluorine Products Europe BV and Others, Case C-616/10

18. Council Regulation (EC) No 44/2001 of 22 December 2000 on jurisdiction and the recognition and enforcement of judgments in civil and commercial matters

19. See the Agreement on a Unified Patent Court, signed on 19 February 2013

20. 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

21. Currently the 15th draft Rules of Procedure, dated 31 January 2013

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