



Preliminary injunctions alive and well – a view from Europe

How do European IPR holders prevent key competitors from launching or selling their products in valuable markets in Europe? The answer is simple: obtain a preliminary injunction (PI), also known as an interim or interlocutory injunction, to put a stop to the competition at an early stage. It worked for Pfizer in the UK, where the sale of generic Lipitor® was recently halted within a matter of hours. Similarly, within 24 hours, Novartis stopped Sanofi's at-risk launch of generic CoDiovan® in France. PIs have also recently been obtained by Apple against Samsung in respect of products in both the Netherlands and Germany.

Perhaps the reality for many companies is that life is not quite so simple. However, PIs are a very serious business and it looks as though they may be coming back into fashion. What is more, a number of courts across Europe seem to be showing signs of a greater willingness to grant them in the context of commercially important, high-value IP disputes.

Historically, PIs were developed by European national courts in order to provide fast and effective relief to IPR holders pending a full hearing on the merits, which could take several weeks or months. Today, the grant of PIs by European courts (now enshrined in Article 9 of the IP Enforcement Directive (2004/48/EC)) can provide an immensely powerful tool for companies who are under increasing pressure to stave off fierce competition from third parties in over-crowded market spaces.

Consider, for example, a company who succeeds in obtaining a PI against its competitor who is about to launch, the result being that the competing product is kept off key European markets for 6 to 9 months (the time it may take for a full hearing on the merits). Even if the company loses the case at the full hearing in its entirety (either because the IP right is not valid and/or not infringed), the company might still be financially better off as a result of keeping the competing product off the market for many months - despite the potentially high costs of damages payable to the competitor and legal costs if it turns out the PI is lifted at trial. There may be further benefits to the company which are associated with extended market exclusivity - for example, the company may continue to enjoy brand development and brand loyalty during the life of the PI. The company may also have bought itself enough time to take other protective measures (legal or otherwise) to deal with the consequences of the eventual launch of the competing product.

The potential harm which can be caused to businesses by the launch of rival products is in some cases too grave to ignore. The result is that companies need to be adequately prepared and need to be able to move quickly, be it in making PI applications or responding to PIs. It is also of course important to note that PIs, if successfully secured, can very quickly trigger a rather different settlement between the parties than the sort of settlement agreement which had been previously envisaged by the parties (e.g. because of the nature of the ramifications imposed on the alleged infringer).

UK

In the UK, if the case is urgent, PIs can usually be obtained very quickly (e.g. within 1 month of the application). It is also possible to obtain a "temporary" PI (without the other party being heard) very quickly, pending a PI hearing between the parties. For example, in the case involving the launch of generic Lipitor® by Teva almost 1 year before expiry of the SPC protecting Lipitor®, a PI was granted by Mr Justice Floyd against Teva and a number of its wholesalers within hours of the application being made, on the very day of product launch (*Warner-Lambert Co LLC v Teva UK Ltd* (unreported, 20 June 2011)). The applica-

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tion was made within hours of the discovery of Teva's "surreptitious" launch. Thus one of the advantages of the English courts is that they are able to act very fast to provide temporary relief in urgent cases. It is also possible, for example, to make out-of-hours applications and applications by telephone. Another advantage for PI applicants is that there is usually a very limited assessment of infringement or validity in the UK; the applicant only needs to show that there is a serious question to be tried.

As with many European jurisdictions (with the exception of France, as explained below), the English courts apply the "balance of convenience" test in considering whether to grant a PI, i.e. what is the potential harm to one party compared to the other (assuming a "loss" at the PI hearing but a "win" on the merits) and whether that harm is capable of being compensated. For example, in the generic Lipitor® case, Mr Justice Floyd stated: *"It does seem to me that, even over a relatively short period until the application can be heard, there is a real risk of damage being caused to the market in this product.... The launch is obviously on a very large scale, involving at least two pharmaceutical retailers and millions of tablets.... Given those considerations, in my view, the balance of convenience over the very short period until the effective hearing of the application is in favour of [Pfizer]. I bear in mind that [Teva and its wholesalers] have not been notified, but it is not as if atorvastatin is not available from other sources"*. In a further hearing, Mr Justice Floyd refused to grant the same relief against retail pharmacies who had already been sold the generic drug but continued to dispense the drug (*Warner-Lambert Co LLC v Teva UK Ltd* [2011] EWHC 1691). In coming to this decision, Mr Justice Floyd stated, *"It seems to me that once the product has found its way into retail pharmacies and is being dispensed then that is a situation which is not capable of remedy by virtue of injunction. The actual dispensing of the product is not the basis of the harm to [Pfizer]. It is the sales of the products by the wholesalers which is the source of the damage."* (This position with respect to pharmacies is to be contrasted with the French CoDiovan® case referred to below.)

In reaching his decision Mr Justice Floyd was clearly influenced by the fact that Teva had not tried to clear the way and, in previous correspondence with Pfizer, had indicated that it would not launch ahead of the SPC expiry. However, the decision was made on the basis that Pfizer would suffer irreparable harm by the Teva launch, in particular there would be massive price erosion from which Pfizer would be unable to recover. This case can be contrasted with the position of Cephalon when it tried and failed to obtain a PI against Orchid to prevent Orchid from dealing in generic modafinil (*Cephalon Inc v Orchid Europe Ltd* [2010] EWHC 2945). Importantly, in the Cephalon case, Mr Justice Floyd noted that Orchid had failed to make any attempt to clear the path. However, on the evidence Cephalon would not suffer irreparable harm by a PI not being granted but that Orchid would. The reasoning being that Cephalon would be able to reinstate its full pricing following a successful outcome on the merits but Orchid would not ever be able to recover the position it had as the first generic to market.

France

In France, the courts can also act on a speedy basis to grant wide relief to applicants. For example, in the generic CoDiovan® case, following request by Novartis, the President of the Paris First Instance Court granted an injunction against Sanofi at 1 p.m. on the day after the generic product was launched. Sanofi was further ordered to recall its generic products from its distribution channels, including from pharmacies. In coming to its decision, the French court stated that, *"Novartis sufficiently evidenced that the premature launch of a generic product on the market, even during a relatively short period of time, is of a nature to create a severe harm through the loss of clientele and the decrease in prices it necessarily leads to."*

Another significant advantage for PI applicants in France is that there is no real requirement of urgency (unlike most of the key European jurisdictions) and the French courts generally do not apply the "balance of convenience" test. Hence the fact that an infringing activity may have continued for many months to the knowledge of the applicant will not of itself deprive an IPR holder from obtaining a PI. However, applicants should also be aware that they are required to demonstrate a strong case on its merits; and in practice this usually means a relatively detailed assessment of infringement and validity.

Germany

In Germany, although it is possible to obtain a speedy PI without the other party being heard, the court must first be persuaded that an oral hearing, where both sides are represented, is not necessary (an oral hearing could delay matters by 20-40 days). Interestingly, the German courts have in the past tended to order an oral hearing where there was doubt as to whether infringement and/or validity of the IPR was sufficiently certain - for example, in complex patent actions, or in cases where the alleged infringer had filed protective writs in the relevant German courts (alleging invalidity of the IPR in case a PI action was initiated). However Apple was recently able to secure a PI against Samsung in the courts of Düsseldorf. Notwithstanding Samsung's protective measures, Apple was still able to quickly and successfully secure a PI without Samsung being present on the basis that infringement and validity of the IP right was adequately demonstrated. As the court put it, "*The preliminary injunction is admissible. The application for preliminary injunction is at any rate sufficiently definite to the extent that claims under Design Protection Law are asserted.*"

Netherlands

In the Netherlands, PIs may be obtained provided the applicant shows there is real urgency and the matter requires an immediate remedy. One advantage for the PI applicant is that it is not strictly required to give any form of bond or undertaking to the alleged infringer. However, in practice, there are not that many examples of PIs being granted by the Dutch courts in complex cases, especially complex patent cases. Furthermore, hearings without one of the parties have only recent come about in the Netherlands as a result of the IP Enforcement Directive. To date, there has been only one patent case (dated 8 January 2010) in which PI has been granted on this basis.

Pan-European measures

Given the subtle differences in each of these national courts, European IPR holders may be asking themselves, would it not be simpler and easier just to approach one national court and obtain a pan-European PI to cover a number of jurisdictions? The answer is yes, and pan-European injunctions are in fact possible where the relevant IPR is a community trade mark (CTM) or a registered community design (RCD). This approach makes sense as CTMs and RCDs are, after all, unitary rights which ought to be protectable in such a way so as to afford temporary relief to IPR holders simultaneously across a number of European jurisdictions.

The position is, however, quite different for patents: as companies are only too painfully aware, European patents are bundles of national rights. The result is that obtaining a pan-European PI for infringement of patent rights is much more difficult. In the past, the Dutch courts have shown an ambitious willingness to grant pan-European injunctions in patent cases, although this was later somewhat restricted by introducing the "spider in the web" doctrine (which effectively said the Dutch courts would only assume jurisdiction and grant pan-European injunctions in cases where the primary defendant was domiciled in the Netherlands). In contrast, the English courts have shown a real reluctance to assume jurisdiction over matters involving foreign patents. The position was eventually clarified in the judgment of the Court of Justice of the European Union in *Roche v Primus* (C-539/03), which held that if patent validity was in issue (either by way of an action or a plea in response to infringement), then the courts of the country where the patent is registered have exclusive jurisdiction (under Article 22(2) of the Brussels Regulation (44/2001)). In practice, alleged patent infringers will almost always raise patent validity as an issue and therefore the possibility of pan-European PIs is now severely limited for patents.

Conclusions

Whatever the approach taken by PI applicants, there are some "golden rules" which a company should try to follow if it finds itself seeking a PI in a jurisdiction (or a number of jurisdictions). First, it is important to gather as much evidence and information to support the PI application as quickly as possible. For example, if the infringing product is about to be launched, the applicant should speak directly to the sales and business teams "on the ground" to gather evidence of the suspected launch, as well as constantly monitor the

situation with the business right up until the PI hearing. Secondly, the company must fully understand all of the ramifications of any “cross-undertaking” or security given to the alleged infringer in order to compensate that alleged infringer if a PI granted is subsequently lifted at trial because of non infringement or invalidity of the underlying right. If the company ultimately loses on the merits, then the financial consequences of having successfully obtained a PI could be significant. Finally, the company must be adequately prepared for the result of the application - a loss could be very costly due to entry of the competing product on the market.

For those companies who fear a PI application made be made against them, it is advisable to take protective measures where possible. For example, the practice of filing protective writs in Germany and the Netherlands could prevent a PI without being heard (but of course may not always succeed - it did not in *Apple v Samsung*). In France and Belgium, where there may also be a risk of the IPR holder obtaining a *saisie contrefaçon* (seizure of infringing goods), steps can be taken by the relevant employees in their dealings with the bailiff so as to minimise any damage to the infringer’s case (for example, asking the bailiff to refrain from carrying out any searches until their instructed lawyer arrives at the premises, and asking for any confidential documents to be shielded from the other party). Other protective steps include gathering evidence on why the PI application should be refused (which could include, for example, allegations of delay and reasons why damages alone would be adequate remedy). On a practical level it is important that the business understands the full impact of a PI so that they are able to deploy a contingency plan if a PI is granted.

Finally, the role of publicity should not be underestimated. A party who succeeds in obtaining a PI will be inclined to spread the word about their victory. Against that positive PR will be the fact that a competing product is kept off the market which of course gives consumers less choice and which may not be viewed favourably by the market as a whole.

In the end, being adequately prepared is the best advice for any party involved in a PI application - because in practice, events usually unfold very quickly. And as demonstrated by the examples of recent cases above, some European courts are certainly not shy about granting PIs having a wide scope. So it seems PIs are alive and well at least in parts of Europe.

Huw Evans and Pam Taak, 16 December 2011