

A practical guide to interim injunctions

Fierce battles between branded and generic pharmaceutical companies have been played out in the English courts. **Brian Whitehead, Stuart Jackson and Richard Kempner** provide effective strategies for both obtaining and avoiding interim injunctions

Many generic pharmaceutical manufacturers have adopted a strategy of manufacturing and selling pharmaceutical products that are protected by a third party's patent. In addition to targeting and selling products protected only by formulation patents, which may be more vulnerable to attack than patents which protect the active ingredient itself, generic manufacturers are increasingly seeking to sell products in which the active compound is itself protected. Clearly, the success of such a strategy depends upon the generic manufacturer correctly identifying vulnerable patents. If the patentee is not confident of the strength of its patent, it may be willing to grant a licence on favourable

which lasts until the trial is heard (which may be many months later), does not generally depend on the strength of the patent. If the patentee can establish that there is a serious issue to be tried, the court may decide to grant an interim injunction. The proprietor of even a weak patent may therefore be able to delay the launch of a generic competing product for months, causing financial loss and inconvenience to the generic manufacturer. Once the generic manufacturer has been enjoined, the patentee can then look to license the generic manufacturer from a position of strength (because the generic product is off the market until trial).

Whether you are a patentee or a generic manufacturer, it is

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terms, rather than risk seeing its patent revoked, but if the patentee believes that it has a strong patent and chooses to bring a claim for infringement, the generic manufacturer will generally counterclaim for revocation, and the validity of the patent will then be determined at trial.

One powerful weapon in the hands of patentees is the availability of interim injunctions in patent actions. In recent years the English courts have been increasingly willing to grant interim injunctions, and as a result more patentees are applying for them. This is largely because the courts now recognize that infringement may lead to irrecoverable losses through permanent price reductions in the patentee's product.

The grant of an interim injunction,

Two case studies: advance evidence vital for invalidating patent

Company X supplied precursors and active pharmaceutical ingredients (APIs) to a wide range of pharmaceutical companies, including both major R&D-based and generic manufacturers. X had a successful process for manufacturing the API that was the basis of a major blockbuster product sold by a large pharmaceutical company, and a plant where it was scheduled to occupy a large proportion of manufacturing capacity. A number of generic manufacturers had marketing authorizations for products based upon X's API in the process of being granted in the UK and other countries in Europe. However, the particular form of the API was subject to a patent owned by the original approval holder. X's objectives were:

- to be able to assure its customers that they would not be prevented from launching products by the imposition of an interim injunction;
- to ensure that it was not itself prevented from manufacturing by the imposition of an interim injunction; and
- to obtain a judgment that would be highly persuasive in all jurisdictions.

Although X was a foreign company, its relevant manufacturing plant was in the UK. This, and the fact that there were pending marketing authorizations in the UK, were reasons for proceedings being brought in the English Patents Court. X also wanted to take action in England because the Patents Court can be one of the quickest in the world, and its decisions, recognized as being the result of particularly thorough investigations, are highly persuasive in other jurisdictions. In fact, X had already succeeded in revoking the equivalent German patent, and, while it did not feel that this would give it any advantage in actions elsewhere, it did mean that product manufactured in the UK could be exported to Germany for storage while the situation was resolved in the English courts, with relatively little risk of any injunction in the UK to stop the manufacture.

Some months before the expected grant of the first marketing authorization in the UK, X commenced proceedings for revocation of the UK patent. The patentee did not, in this case, attempt to counterclaim for infringement. The action was ordered to be heard as an expedited action, with a trial fixed for only three and a

desirable to be able quickly to assess the likelihood of an interim injunction being granted.

Basic principles

The basic principles governing the grant of interim injunctions in England and Wales are set out in *American Cyanamid Co v Ethicon Ltd* ([1975] RPC 513).

The claimant/applicant does not need to show that it is likely to win its case – if it can show that there is a serious issue to be tried, the court will generally go on to consider the balance of convenience between the parties. In doing so, the court first asks whether, if the injunction were refused, the claimant would suffer losses that could not be adequately compensated in damages following a successful trial. If so, it asks whether, if the injunction is granted but the claimant's action fails at trial, the defendant would suffer losses that could not be adequately compensated in damages. The balance-of-convenience test will generally favour the solution that causes the least injustice to the parties.

If the parties' interests are evenly balanced, the court will generally take such measures as are necessary to preserve the status quo. This could mean, for example, granting an injunction to stop the proposed launch of an allegedly infringing generic product.

If one party's case is much stronger than the other, the strength of the patent may be considered at the interim stage.

The court should not however seek to carry out a mini-trial to assess the parties' strengths.

Clearing the way and other factors

Case law since *American Cyanamid* has shown the following to be the principal factors that are taken into account:

- 1) Whether the claimant would be likely to suffer losses that would be irrecoverable in damages following a successful trial. The courts often accept that the introduction of generic competitors to a market consisting of only one patented product may lead to an irreversible reduction in price of the patented product.
- 2) Conversely, the fact that a proposed generic drug will be likely to be sold at a lower price can be argued as a reason not to grant an interim injunction, because of the public interest of a saving in costs to a National Health Service struggling to cope with a large annual drugs bill.
- 3) Whether the defendant has taken steps to clear the way of

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half months after the case management conference.

Such a tight timetable is favourable to a generic manufacturer wishing to launch a new product, but is demanding in terms of generation of the expert evidence typically required in pharmaceutical patent actions. Nevertheless, if suitable potential expert witnesses are already known, or can quickly be identified, such a timetable is possible. As well as synthetic organic chemistry, a field that is frequently required in such actions is that of solid state techniques such as X-ray crystallography and solid-state NMR.

All of the product claims were revoked following the trial, and all that remained was one claim for a process that X did not use. X therefore achieved its objective of removing IP obstacles in the UK, leaving it free to manufacture the API and for customers to sell products based upon it. Furthermore this had been achieved within a remarkably short time, and the resulting judgment would help persuade other courts. Two further advantages of the English system is that invalidity and infringement are considered in the same proceedings, and the successful party can generally recover a significant proportion of its

legal costs from the other party. Accordingly, not only were X's legal costs little different from those it had incurred in Germany (where there had been separate invalidity and infringement actions), but it was able to recover a substantial proportion of its costs from the patentee.

In a second example, Y, one of the world's largest generic pharmaceutical companies, wanted to launch a generic alternative of a formulation of a drug that was patented in the UK and elsewhere. Y had already spent significant sums on developing its product, and did not wish to wait for the outcome of a revocation action before commencing its sales activities. Its objectives were:

- to do whatever was necessary to ensure that no interim injunction was awarded against it;
- if sued, to ensure it would be in the best position possible to defend the action; and
- to know where it stood as quickly as possible.

Accordingly, around three months before the expected launch of Y's drug, it started preparing evidence to defend a possible interim injunction application by the patentee. When the

application to the court for an interim injunction was made, Y had less than two working days before the hearing to put together all the evidence. However, having had so much time to prepare the evidence, Y had been able to prepare sufficient evidence to convince the judge that there was no particular matter of urgency justifying the court granting an interim injunction. In particular, Y demonstrated that there were no immediate prospects of permanent price depression, because the defendant's and claimant's products were in respect of different indications and were therefore not competing products. The interim injunction application was refused.

A speedy trial was ordered, and the trial was heard less than four months after the initial hearing. This was of significant benefit to Y, as it would know where it stood as soon as possible and, if it were ultimately to lose, the damages awarded against it would be kept to a minimum (Y was already selling its product at this point). At the trial, the patent was revoked, leaving Y free to continue selling its formulation. Y was also awarded a significant proportion of its costs back from the patentee.

- IP obstacles (for example, by applying to revoke a patent) before launching a new product. If such an exercise is not undertaken, the chances of an interim injunction being granted may be substantially increased.
- 4) An infringer will not be permitted to gain an unfair advantage by entering the market shortly before the expiry of the patent (springboard argument).
 - 5) Whether there are likely to be difficulties in calculating the damage suffered by the claimant, if successful at trial, or in calculating the defendant's losses if the interim injunction is shown to have been wrongly granted.
 - 6) The likelihood of job losses and/or adverse effects on the claimant's research and development programme.
 - 7) Whether it is likely that other infringers may subsequently appear unless prompt action is taken against the first infringer to appear on the market (snowball effect).
 - 8) Whether the claimant is in the process of establishing its business in the UK, and the entry of the defendants into the market may damage that exercise.
 - 9) Undue delay in bringing proceedings is generally detrimental to a claimant's prospects of obtaining an interim injunction, and may influence the court's view of which date should be used when assessing the status quo. The date of the application may be used instead of the date of issue of the claim.
 - 10) Whether the financial circumstances of the defendant are such that it may be unable to pay any damages and costs awarded following trial. The defendant may be able to avoid an interim injunction in such circumstances if it undertakes to make a payment into a nominated bank account of a reasonable sum to cover part or all of the likely sums that would be awarded following trial.

Early preparation of evidence, prior to commencement of proceedings, is vitally important

Case study: timing is vital

In this case, a company, Z, had a substantial business in branded agricultural products, the active ingredients of which, being the results of its own R&D, were protected by patents.

Z expected its best-selling product to be the one most likely to be infringed, and from past experience predicted that this would take place in April/May. The timing was predictable because sales of agricultural products are dictated by the growing seasons, and are therefore highly seasonal. At the expected time, it became apparent that distributors were being offered large volumes of a product for which a company, B, had a marketing authorization to sell rebranded and repackaged parallel imports of Z's product. Z was immediately ready to obtain samples of B's product, and analysis of those samples showed that, although the product contained the active ingredient covered by Z's patent, the profile of excipients and manufacturing impurities was different from that of Z's product. The product being offered for sale by B was therefore infringing. An application to the court by Z for an interim injunction was supported by an analytical report which showed conclusively that B's product infringed, but the question remained whether an interim injunction would be granted.

Z prepared three pieces of evidence in support of its application. The principal evidence was a comparison of the prices at which product containing the relevant active ingredient had been offered to distributors over the previous two years. This showed a marked reduction following the importation of B's infringing product. Due to the way in which prices in the agricultural chemicals industry are negotiated between supplier and distributor, the reduction in prices directly affected the price that Z could obtain for its own product. Also relevant was the fact that B's infringing product was significantly inferior to Z's, and had caused problems for a number of farmers. Z argued that this damaged the reputation of Z's own product, because customers, knowing that B sold its product under a parallel import licence, believed that when they bought B's product, they would in fact be receiving a product manufactured by Z. Finally, B's published accounts showed that it would be unlikely to be good for the payment of substantial damages if ultimately granted. In the words of the judge, if the matter were to be left until trial, and B were to lose and be held liable to pay damages and costs, the likelihood would be that B would disappear "like snow on a hot summer's day".

Strategies for obtaining/avoiding interim injunctions

Given that the hearing to determine whether an interim injunction should be granted can take place within days of the claimant issuing its application, it is desirable for the claimant to prepare its evidence well in advance of making its application. However, it is likely that the first knowledge it will have of the defendant's activities is when the defendant commences marketing and/or sales of its product, leaving little time to prepare evidence. Equally, it is desirable for the defendant to assemble its evidence to defend the application at an early stage, but unless adequate preparatory steps have been taken, the first knowledge the defendant will have of the hearing is upon service of the claimant's application, again leaving little time to prepare. We set out below some steps that a potential claimant/defendant can take to maximize its chances of successfully obtaining/resisting an interim injunction.

Strategies for generic manufacturers

Bringing an action for revocation of the patent

If a generic manufacturer suspects that its new product may infringe a granted but potentially invalid patent, preparatory steps should be taken quickly, and preferably before significant sums are invested in marketing and obtaining regulatory approval. There are three main options: (1) apply to revoke the patent; (2) apply for a declaration of non-infringement; and (3) do nothing and wait to see if the patentee sues for infringement (whether or not including an application for an interim injunction).

There are pros and cons to each of the above courses of action. The best course of action will vary from case to case. Option (1) carries the advantage of

certainty of outcome – either the patent is invalid, in which case the generic manufacturer is free to sell its product, or it is valid, in which case the manufacturer will be unable to sell without infringing. The principal disadvantage is that this option may lead the parties into litigation which would not otherwise have occurred – the patentee may defend its patent against an attack on its validity, whereas it may not have issued infringement proceedings had the manufacturer simply gone ahead and marketed its infringing product. It is therefore generally advisable to write to the patentee prior to issuing proceedings, setting out the reasons why the patent is invalid. However, care should be taken to ensure that such a letter does not provide detailed information as to the patentee's intention to sell an infringing product, as such information could be relied upon by the patentee to bring a *quia timet* infringement action, including an application for an interim injunction. An alternative is to send a without prejudice letter informing the patentee of the manufacturer's intentions, and inviting the patentee to grant a licence. A recent English court decision confirmed that such a letter may not be relied upon by a patentee in any subsequent proceedings as evidence of intention to infringe, provided the letter can reasonably be regarded as constituting an invitation by the defendant to negotiate (*Schering Corp v Cipla Ltd* [2005] FSR 25).

Option (2) can either be brought as a free-standing application (which may be appropriate in circumstances where the patent is thought to be valid, but the manufacturer believes that its proposed product does not infringe), or in conjunction with an application to revoke the patent. This option carries similar advantages and disadvantages to option (1). One important difference, however, is that revocation proceedings may be brought by any person, whereas a declaration of non-infringement in respect of any proposed act may be granted only if the requirements set out in § 71(1) of the Patents Act 1977 are satisfied:

- the person applying for the declaration has applied in writing to the proprietor for an acknowledgement that its proposed act does not infringe;
- the above written application provides the patentee with full particulars of the proposed act in question; and
- the proprietor has refused or failed to give any such acknowledgment.

The drawback is that the written application will inevitably contain sufficient information to allow the proprietor to issue proceedings in respect of the proposed act. The manufacturer may therefore find itself as the defendant in a patent litigation action. Such an outcome can be avoided if the manufacturer issues and serves its application for a declaration of non-infringement at the same time as writing to the proprietor, although this may simply provoke the patentee into defending the application.

Option (3) would generally only be best in circumstances where the patentee does not object to the generic manufacturer's activities, which most manufacturers cannot know, and consequently this option is best characterised as the "gambler's" option. Even in a scenario where the patentee is unlikely to obtain an interim injunction (for example where there is no prospect of irreversible price depression) it is advisable to

prepare evidence in advance to defend a possible interim injunction application, as there may be insufficient time to prepare such evidence once an application has been served (see case studies pages 62-3).

Strategies for patentees

Anticipatory preparation

It is clearly impossible for a company holding a large number of patents to predict precisely which patents will be infringed, but it may be possible to identify those that are vulnerable to infringement by generic manufacturers. Patents protecting products with high volume sales, approaching the end of their validity period, or in respect of products for which the data exclusivity period has expired, may be particularly likely to attract generic competition.

If a patent is thought to be likely to be infringed, anticipatory steps can be taken

If a patent is thought to be likely to be infringed, anticipatory steps can be taken. Such steps need not entail preparation of evidence in the actual form in which it will be used in court, as this may be prohibitively expensive, but as a minimum the following could be done:

- Identify what evidence may be required for the interim injunction application. The requirements for evidence will be far less than at a full trial, but analytical evidence, and/or expert evidence to explain why the defendant's activities are infringing, will generally be required.
- Identify suitable expert witnesses and/or analytical facilities able to provide the above evidence.
- Provide evidence of the likelihood of price reduction – this will require evidence as to the market, the existence of legitimate competing products, the activities of competitor companies etc.

Summary: prepare evidence early

Early preparation of evidence, prior to commencement of proceedings, is vitally important both for the claimant and the defendant. A generic manufacturer may decide to issue proceedings seeking revocation of patents that it believes are invalid and/or a declaration of non-infringement. If this is not done, it is generally advisable for a generic manufacturer to prepare evidence in anticipation of an application for an interim injunction. Similarly, for a patentee, anticipating which patents may be infringed, and preparing initial evidence in advance of the commencement of infringing activities, will substantially enhance the likelihood of its success in any litigation.



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