High Court decision in *Laboratoires Servier v Apotex* analysed

Jonathan Radcliffe and **Kieron Kelly** of Nabarro report on the UK's first damages enquiry following a cross-undertaking given on an injunction

Injunctions have long formed part of the strategic toolkit deployed by pharmaceutical companies to safeguard the market for their drugs until the courts have resolved any challenge to the legality of the patent protection for that drug. Originator companies frequently seek to preserve the monopoly status of their drug's market by asking the courts to restrain a generic competitor from launching an alternative formulation.

In the pharmaceutical industry, this often results in the patentee and the generic competitor giving cross-undertakings to one another. These undertakings will usually operate so that the generic company promises not to launch its competing product until any validity and infringement issues surrounding the patent have been properly considered by the court. In return, if the court decides either that the generic product does not infringe the patent or that the patent is invalid (so that the injunction should never have been granted in the first place), the patentee's cross-undertaking means that it has to pay damages to the generic competitor for the generic's loss of opportunity to enter the market at an earlier date.

In the first-ever UK damages enquiry under such a cross-undertaking, *Les Laboratoires Servier v Apotex Inc,*[1] the court was asked to grapple with this latter scenario. The generic, Apotex, was prepared to launch a new formulation of the hugely profitable drug, perindopril, 'at risk'. The patentee, Servier, obtained an injunction restraining Apotex from making sales until a full enquiry had taken place as to Servier's entitlement to a patent for the drug in question, and whether Apotex's alternative formulation was caught by Servier's patent protection. At trial, Apotex demonstrated that the patentee's monopoly was based on an invalid patent. The court decided that in the period between Apotex signalling its intention to launch and the enquiry taking place, Apotex had been prevented from lawfully entering the market because of the injunction obtained by Servier.

The case is the first example of UK courts having to quantify the loss to a generic company for being denied the opportunity of being the first generic product on what had previously been a monopoly market for the branded product. In a commercially focused judgment, the judge awarded £17.5m to Apotex.

The decision contains two unique insights. It provides valuable precedent for future courts to follow in how best to construct a model for the economic impact that a generic entrant has on a branded drug product market (as well as on some of the market dynamics when generics companies launch onto the market at risk and not at risk, such as market share, price, the operation of the NHS reimbursement market etc). It also lays bare the tactics that are deployed by patentees to protect the lucrative monopoly markets for premium branded drugs.

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When can a patentee obtain an injunction?

The legal threshold that a patentee must meet to obtain an injunction is set out in *American Cyanamid*.[2] The test is twofold. First, there must be a genuine issue that needs to be properly examined at trial. This limb is generally satisfied in pharmaceutical patent cases because of the complex and technical nature of the issues in dispute.

Second, the court must be satisfied that the party seeking the injunction will be injured or prejudiced in a way that cannot be adequately compensated by the payment of damages at a later date were the injunction to be refused. This requires the court to weigh up the effect that its decision may have on the parties. In the pharmaceutical context, if the injunction is refused the generic can launch its product and (potentially) irreparably destroy the premium price that the patentee had previously established.

On the other hand, if the injunction is granted, the generic is denied the opportunity of its product being the first alternative entrant to the market in what is commercially the most profitable period in the post-monopoly life of the drug.

The Court of Appeal looked at this 'balance of convenience' in *SmithKline Beecham v Apotex*.[3] It recognised that the decision was a finely-balanced one. It acknowledged that the patentee, SmithKline Beecham, would suffer unquantifiable and irreparable damage if the generic competitor were permitted to launch its product. It accepted that the introduction of generic alternatives to a market can have 'dire consequences' for the price of a branded product.

Conversely, the generic misses the opportunity to be the first alternative product on the market – missing out on the highly profitable post-launch period.

The Court of Appeal concluded that where the balance of convenience is evenly weighted, as was the case in *Servier*, courts are entitled to maintain the status quo by permitting the existing monopoly market to remain unchallenged. In underlining the importance of the doctrine of 'clearing the way', the Court of Appeal attached weight to the fact that the generic company had advance knowledge of its intentions to launch and could have resolved the infringement and validity issues well before the grant of its marketing authorisations and launch of product.

The Court of Appeal's justification for maintaining the status quo is well known. After examination of the infringement and validity issues it may be clear that the injunction should never have been granted in the first place, and consequently that the generic was wrongly denied the opportunity to launch. If so, by the time that the court is asked to quantify the loss of opportunity to the generic, the market will have been generally open to generic competitors, and factors such as market pricing and NHS reimbursement costs will have adjusted accordingly (often permanently, and at a far lower rate, to the detriment of the injuncted generic). Therefore, the effect that an entrant has on the price of a particular drug can in principle be determined. In arriving at a figure for this loss of opportunity, evidence should be available to assist in assessing how the market responded to generic entrants and the assessment would not be proceeded on a speculative basis.

Les Laboratoires Servier v Apotex

Servier is the first decision to carry out this assessment set out in *SmithKline Beecham v Apotex*. It underlines some of the peculiarities of the pharmaceutical market, such as the way that a patentee can use the patent system and marketing regime to control a market in which it no longer has a monopoly to maintain a prominent position.

Background

The drug in question was perindopril, a product developed by Servier and sold under the branded name Coversyl. Perindopril is an ACE inhibitor used for the treatment of hypertension.

Servier secured a patent for the original compound of Coversyl and the industrial synthesis process to create the compound in the early 1980s. With its original protection due to expire, Servier applied for a patent to protect a new formulation of the drug in July 2000. Once the original patent protection expired, Servier relied on this second formulation patent to defend its perindopril market.

Apotex firmly believed that this second formulation patent was invalid (on the basis that it merely claimed the product obtained by following the process described in the original patent). It decided to manufacture a formulation of perindopril that it was confident fell outside the scope of the original process patent, and decided to launch its new product 'at risk' in spite of the second generation patent.

Having obtained its marketing authorisation on 28 July 2006, Apotex began to sell the product. Unbeknown to Apotex, on 27 July 2006 the EPO had upheld the validity of the formulation patent. Servier became aware that Apotex had obtained marketing authorisation and it applied to the courts for an immediate interim injunction preventing the sale of Apotex's generic alternative.

Relying on the *SmithKline Beecham v Apotex* decision, Servier secured the injunction on the basis that if Apotex entered the perindopril market, Servier would suffer 'irreparable and unquantifiable harm'. The injunction was awarded on the basis that Apotex's damages were more easily capable of calculation than Servier's. It prevented Apotex from selling perindopril until the validity and infringement issues had been decided at trial.

On 6 July 2007 the Patents Court held the second generation patent to be invalid for lack of novelty and obviousness. Servier quickly signalled its intention to appeal the decision. It requested that the injunction be extended until the appeal had been decided. This request was first rejected by the trial judge, and then by the Court of Appeal. The appeal was robustly dismissed, with Lord Justice Jacob describing the formulation patent as one 'which can give the patent system a bad name'.

Assessment of Apotex's damages under the cross-undertaking

Apotex set about enforcing the cross-undertaking given by Servier when it first obtained the injunction. Apotex estimated its loss of profits due to the injunction at £27m, whereas Servier assessed these damages at only £400,000.

The judge identified his task as assessing the compensation Apotex was entitled to for having been denied the opportunity to be the first supplier of a generic perindopril product on the market. He decided that the purpose of the damages was to compensate Apotex by awarding compensation in line with contractual damages, rather than punitive tortious damages. It was therefore a compensatory rather than a punitive approach, and followed the *obiter* observation of Lord Diplock in *Hoffman-La Roche v Secretary of State for Trade*[4] that it should be seen as a notional contract between Servier and Apotex that Servier would not prevent Apotex from selling perindopril in the UK. The judge treated Servier not as a 'wrongdoer', but instead as a party that had 'obtained an advantage upon consideration of a necessarily incomplete picture'.

The judge held that there were a number of competing scenarios that could have arisen had there been no injunction. He therefore had to apply percentage probability chances to these scenarios:

• *Launch of perindopril by third parties during the period of the injunction*

The judge held that the probability of this happening was completely speculative, and so ignored it.

• *A Servier and Apotex duopoly*

This scenario (referred to as 'Scenario 1') involved only Servier and Apotex on the market. Both would compete on price, thereby driving the price down from the monopoly price, and each would secure an approximately 50% market share. The judge calculated that in Scenario 1 Apotex would have earned £23.4m but as this scenario only had a 67% probability Apotex's damages were therefore £15.075m.

• *An oligopoly*

This scenario (referred to as 'Scenario 2') involved Servier supplying two authorised generic companies with Servier's own perindopril and all four companies (the authorised generics plus Servier and

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Apotex) competed on the market throughout the injunction period. The judge calculated that in Scenario 2 Apotex would have won a 28% market share but at a lower price than in Scenario 1. The judge calculated that in Scenario 2 Apotex would have earned £7.9m, but as this scenario only had a 33% probability Apotex's damages were therefore £2.607m.

In calculating the final figure for Apotex's damages the judge added the results from Scenarios 1 and 2 together and then rounded it down from £17.682m to £17.5m. This is a large sum, but nonetheless significantly smaller than the £27m originally claimed by Apotex.

The judge's methodology was to reconstruct a scenario under which Apotex would have exploited its unique position of being the first generic entrant to the perindopril market. He attempted to analyse characteristics of the pharmaceutical market by identifying certain commercial practices, accepting that the artificial nature of this exercise was unsatisfactory but necessary in the circumstances. Having heard extensive evidence to establish these commercial principles, this approach is likely to provide a model that can be followed in future enquiries of this kind.

The judgment also impacts upon the way in which injunctive relief is sought. To secure the injunction, Servier had made representations to the court that limited some of the arguments it could use in the damages enquiry.

The impact of entering 'at risk'

Having had the benefit of substantial expert evidence, the judge mapped out the way in which the market would respond to a generic entrant. As the market for a particular drug flows from a state of monopoly of the patent holder to one in which there is a market open to all competitors, there is not a conversion. Instead, there are periods in which the price of the drug changes quickly as the market responds to new entrants tempting to gain market share by offering the drug at a lower price. In between these transitional periods there are periods of relative stability in which competitors are content that each is earning satisfactory profits. Typically, the transition from an inclusive branded product to an entirely open market takes three to four years.

A critical reason for Apotex receiving a large costs award is that it was prepared to launch 'at risk'. In doing so, a generic takes a huge commercial risk. As the seller of the only product on the market, the patentee stands to make a large profit on each sale.

Any generic that enters the market 'at risk' must be confident that its assessment of the strength of the patent is correct. If it miscalculates this judgment, the potential losses could be far greater than the potential profits. Once a cheaper generic product has entered the market, the lucrative premium that the patentee is able to charge will be lost once the NHS adjusts its reimbursement price to reflect the competition on the market.

In this case, Servier was selling Coversyl for roughly £11 per unit during its monopoly. In the open market, the current price (which has settled following the entrants of generic products) is approximately £1.50 per unit.

In attempting to reconstruct this scenario in relation to perindopril, the steps that the patentee itself can take to maintain a price had to be factored in.

What steps can a patentee take to maintain the price of its product?

Where a patentee suspects that the patent on which its monopoly is based is weak, there are steps it can take to minimise the impact of generics by playing a role in the generic market itself.

The evidence revealed that patentees commonly manufacture and distribute products to potential generic competitors. The patentee can do this by supplying the original product to a generic, for sale under a new name and repackaged in different livery. The generic purchaser sells the patentee's product on the market under a different guise, and secures a proportion of the generic market for the patentee. The purchasers of products such as this from patentees are known as 'authorised generics'. These differ from 'true generics', who are independent competitors that manufacture and supply their own alternative formulation of a particular drug.

From the perspective of the patentee, supplying authorised generics provides numerous benefits. The patentee can still maintain its established branded product, often at a higher price than the generic alternative. This maintains the cache of its premium market. The sales of this branded product are supplemented by the patentee's sale of products to the authorised generics. The patentee can therefore continue to exert an influence on the volume and price of generic products, thereby enabling the patentee to create a 'false' commercial environment in which generics are competing.

The EU Commission's final report on the pharmaceutical sector enquiry is due to be published in Easter 2009. It should be expected that practices such as those in this case will come under scrutiny. This may (potentially) limit the long-term utility of this judgment as an aide in calculating the costs and benefits of interim injunctions in the pharmaceutical sector.

1 [2008] EWHC (Ch) 2347
2 [1975] All ER 504
3 [2003] EWCA Civ 137
4 [1975] AC 295

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