

THE FIRST ASSESSMENT OF DAMAGES CAUSED BY AN INJUNCTION ON A PATENT LATER FOUND TO BE INVALID

Les Laboratoires Servier v Apotex [2008] EWHC (Ch) 2347

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Introduction

Judgment on the damages enquiry in *Les Laboratoires Servier v Apotex* was handed down in the Patents Court of the High Court on 9 October 2008 by Mr Justice Norris. Apotex were awarded £17.5m together with a later award of interest of £2.11m.

It is the first time the court has adjudicated on the measure of damages due under the cross-undertaking given by a patentee in respect of an injunction, when the patent on which the injunction was based is subsequently found to have been invalid.

Background

Apotex had been subject to an injunction for almost a year in respect of Servier's patent, EP 1 296 947 for heart drug, perindopril, brand name Coversyl, which was subsequently found invalid by the High Court and by the Court of Appeal. The patent for the ACE inhibitor used to treat hypertension was for a particular crystalline form of perindopril.

Generic companies other than Apotex, had obtained UK marketing authorisations and were also involved in infringement and/or validity proceedings with Servier concerning this patent but these actions settled before trial. An application by one of those companies, Krka to have the patent found invalid upon summary judgment was unsuccessful. The European Patent Office, in opposition proceedings brought by a number of generic companies, found the patent valid (subject to appeal). The finding of invalidity by the Court at trial was based on the evidence given by the results of full experiments put forward by Apotex that carrying out a process set out in Servier's own earlier patent produced the claimed crystal form.

Of the patent, Lord Justice Jacob of the Court of Appeal said:

"It is the sort of patent which can give the patent system a bad name... The only solution to this type of undesirable patent is a rapid and efficient method for obtaining its revocation. Then it can be got rid of before it does too much harm to the public interest... It is right to observe that nothing Servier did was unlawful. It is the court's job to see that try-ons such as the present patent get nowhere."

Jacob L J made reference to this case in his speech upon the launch of the European Commission's Pharmaceutical Sector Inquiry Preliminary Report on 28 November 2008.

Executive Summary

The Judge took the view that Servier obtained the injunction on the basis that Servier believed its patent to be valid and infringed. The Judge concluded that belief would be consistent with maintaining a duopoly with Apotex in order to maximise Servier's profits both before trial with Apotex on the market, and after trial when their monopoly could be reinstated. The Judge put the likelihood of a duopoly at 67%. Servier sought to argue that Apotex's profits would have been considerably lower as Servier said that they would have authorised generics to compete with Apotex if Apotex had not been enjoined. The Judge assessed the likelihood of this scenario at 33%.

The Judge calculated the damages by adding 67% of Apotex's estimated loss in a duopoly scenario to 33% of Apotex's estimated loss in a market with competing authorised generics.

The Law

The legal principles given in the judgment in assessing damages caused by an interim injunction in order to preserve a patent monopoly pending trial can be summarised as:

1. The question to be answered by the enquiry is what loss did the Order for an injunction cause Apotex?
2. The approach is compensatory rather than punitive.
3. Damages are assessed on the basis of breach of contract, on a contract that the claimant would not prevent the defendant from doing that which the injunction restrained. See *Smith v Day* [1882] 21ChD 421 per Brett LJ at page 427 and the obiter observations of Lord Diplock in *Hoffmann-La Roche v Secretary of State for Trade* [1975] AC 295 at 361E.
4. Damages are assessable but incapable of certainty or precision (see *Chaplin v Hicks* [1911] 2 KB 786 at 791).
5. Apotex had to establish on the balance of probabilities that the chance of making a profit was real and not fanciful. The Judge then had to evaluate that substantial chance. See *Allied Maples v Simmons & Simmons* [1995] 1 WLR 1602 and *Mallett v McMonagle* [1970] AC 166 at 176 E-G.
6. Damages on a particular hypothesis are assessed and the award then adjusted by reference to the percentage chance of that hypothesis occurring. Where more than one scenario is possible, the award can be made by multiplying the damages on each hypothesis by the percentage chance of that scenario occurring, and adding the figures together. See *Earl of Malmesbury v Strutt and Parker* [2007] PNLR 570.
7. The award is of equitable compensation, not of damages strictly speaking.
8. Whilst it was for Apotex to establish its loss, the Judge said he should not be over eager in scrutiny of that evidence or too ready to subject Apotex's methodology to minute criticism. The Judge gave two reasons for this, apart from the reality that the nature of exercise renders precision impossible. Firstly, Servier had had to persuade the Judge when obtaining an interim injunction that Apotex's loss was easier to assess than their own. Servier could not now say that the task was one of extreme complexity, i.e. having emphasised the ease at the interlocutory stage, they could not

now emphasise the difficulty. Secondly, by analogy to damages for patent infringement, damages should be “liberally assessed” as per *Lord Wilberforce in General Tyre [1976] RPC 197 at 212*. Liberal assessment was appropriate since it provided a “degree of symmetry” between the process of obtaining interim relief (an approximation with limited considerations of the merits) and compensating the subject of the injunction. The Judge noted that this was especially so where the paying party had declined to provide full details of sales and profits.

Findings of hypothetical fact

The court had to decide the likely loss of profit to Apotex in being kept out of the market for 11 months. It therefore had to consider what market share and price Apotex would have achieved and how that would have changed over the duration of the injunction period. Central to this was the number of possible competitors in the market and their ability to take market share and compete upon price.

On the evidence, there were two possible hypothetical factual scenarios:

1. A duopoly – only Servier and Apotex would have been on the market during the period the injunction ran; or
2. Servier would have supplied perindopril to authorised generic companies and the four companies would have competed throughout the period.

The court considered that evidence from Servier in respect of third parties possibly also launching before trial, at risk of patent infringement, was speculative since there was no evidence given by the third parties themselves, and evidence of objective factors suggested it was unlikely.

The unchallenged accounting evidence was that Servier would have stood to make greater profits in the duopoly scenario than had they authorised generic companies to compete.

The Judge decided that had Apotex not been subjected to an injunction over the period to trial, Scenario 1, i.e. a duopoly, was twice as likely as Scenario 2 where authorised generics would have been supplied. Key to this was that Servier obtained the interim injunction on the basis that Servier believed its patent to be valid and infringed. If there had been no interim injunction then in this belief Servier would expect their monopoly to be reinstated by an injunction against Apotex after trial. The Judge concluded that belief in the patent’s validity was consistent with maintaining a duopoly with Apotex to maximise Servier’s profits. Servier’s witness could not offer an explanation as to why Servier would vigorously pursue its claim to patent infringement in order to retain (or regain) its monopoly and at the same time supply authorised generics thereby destroying the market it was protecting.

The Judge calculated the total damages of £17.5m by adding 67% of Apotex’s estimated loss in a duopoly scenario (67% of £22.5m) to 33% of Apotex’s estimated loss in a market competing with authorised generics (33% of £7.9m).

Implications of the case for future litigation and patent law

Those seeking an interim injunction should be aware that, and those looking to the courts to assess damages caused by an injunction in respect of a patent which is later found not infringed and/or invalid can expect that:

1. Damages will be “liberally assessed”.

2. Where there are number of possible factual scenarios, the assessed damages on each scenario will be multiplied by the percentage likelihood of that scenario, and those figures added together.
3. Evidence given at the hearing for an interim injunction as to the likely effect on the patentee of there being no injunction will be relevant on the enquiry. Evidence later on at the enquiry which then seeks to suggest that the penetration of the potential infringer would have been more minimal, which is inconsistent with previous evidence is unlikely to be entertained.
4. Any request by a patentee for an interim injunction is made with the belief that the patent is valid and infringed. A patentee is unlikely to convince the Court of a hypothetical factual scenario that would be inconsistent with that belief.