

Injunctions Pending Appeal



By **Simon Cohen** (top) and **Matthew Royle***

Les Laboratoires Servier ('Servier') markets perindopril, an ACE inhibitor (blood pressure controller) which has an annual turnover of approximately £70m in the UK, and owns a number of patents protecting its monopoly over the drug. In late July 2006, Apotex launched its generic perindopril product in the UK. Servier issued proceedings against Apotex on 1 August 2006 for infringement of its patent, **EP (UK) 1 296 947**, which relates to a novel crystalline form of perindopril erbumine and applied to Court for an interim injunction pending trial.

On 8 August 2007, **Mann J** ordered¹ an interim injunction following the principles of *American Cyanamid*² and recent jurisprudence in this area.

With Apotex enjoined, a speedy trial was ordered. Leading up to the trial a number of other generic companies joined the proceedings. 'Krka' were sued by Servier for infringement of the patent on the same day as Apotex but were not enjoined until 3 October 2006 when **Kitchin J** also refused a cross-application by Krka for summary judgment alleging that the patent was invalid. 'Lupin' brought an action for revocation of the patent against Servier on 17 October 2006. Both Krka and Lupin, however, settled with Servier before the trial which was heard by **Pumfrey J** between 13 and 20 March 2007. On 6 July 2007 **Pumfrey J** handed down judgment and held that the patent was invalid and should be revoked as it was anticipated and obvious in light of a prior art patent, **EP 0 308 341**, which was also owned by Servier³.

Until this point, of course, this is a typical story that is played out in any number of pharma patent disputes. However, in the face of a High Court decision invalidating its patent, Servier made an application *to continue the injunction pending an appeal*. This is the first time that such an application has been made and the very fact of the application raised a number of issues.

At the time of the application Apotex were the only company still enjoined from selling perindopril and, should other generic companies become aware that the patent was to be revoked, what was there to stop them launching while Apotex were still enjoined? Moreover, should the injunction be continued pending an appeal, would Servier be able to use its (now invalid) patent to prevent third parties from launching? As a result of this uncertainty, Servier's application was heard in private and **Pumfrey J**'s decision invalidating the patent was embargoed until after the hearing.

Leave to Appeal

Obviously, in order to have an injunction pending appeal there must be an appeal pending. The first issue to be resolved was, therefore, whether Servier would be given permission to appeal **Pumfrey J**'s decision. In deciding whether to grant leave to appeal, the Court must consider whether:

- (1) the appeal would have a real prospect of success; or
- (2) there is some other compelling reason why the appeal should be heard.⁴

During submissions, Servier's Counsel argued that the appeal had a real prospect of success but, in any event, directed the judge to the recent decision of the Court of Appeal in *Pozzoli v BDMO*⁵ where guidance is given on granting permission to appeal. In that case, **Jacob LJ** says:

10. I would add this about permission to appeal in patent cases generally. Unless the case is very clear and can be understood sufficiently readily in an hour or so, the better course is normally for permission to be granted by the trial judge. For, unlike the trial judge, the Court of Appeal judge(s) who have to decide whether or not permission should be granted (where the trial judge has refused it) will not be immersed in the technology and evidence in the same way as the trial judge. Faced with an incomplete understanding and a plausible skeleton argument seeking permission, the Court of Appeal will generally be likely to grant permission, even if later it discerns that the case is indeed clear.

Apotex's Counsel requested that, if the guidance in *Pozzoli* was the only reason that **Pumfrey J** was giving leave to appeal, then he should make it clear in his judgment as it might have an effect on the continuation of the injunction. This is ultimately what he did, deciding that Servier had no real prospect of

1. *Les Laboratoires Servier v Apotex Inc* [2006] EWHC 2137 (Pat)
2. *American Cyanamid Co (No. 1) v Ethicon Ltd* [1975] RPC 513
3. *Les Laboratoires Servier v Apotex Inc* [2007] EWHC 1538 (Pat)
4. CPR 52.3(6)
5. [2007] EWCA Civ 588

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success on appeal but following the guidance given by **Jacob LJ** in *Pozzoli* and stating that ‘for that reason only, I am going to grant permission to appeal.’

In fact, the Court of Appeal had little trouble in deciding that there was no prospect of success on appeal and at least implied that the judge’s interpretation of *Pozzoli* may have been erroneous, saying:

The judge indicated that he did not think the appeal would have a reasonable prospect of success but following the guidance which **he understood to have come** from the recent *Pozzoli* case granted permission nonetheless [emphasis added].

If the Court of Appeal did not intend *Pozzoli* to have this meaning, it is difficult to see what other interpretation can be given to it. It appears to be very clear and, in effect, means that appeals will be available in all but the simplest patent cases. Patent cases often require the judge to consider a huge amount of evidence before coming to a decision and to expect the Court of Appeal to assimilate this information ‘in an hour or so’ is unlikely in most cases. If the Court of Appeal meant the passage to have some other effect, further guidance will be necessary to prevent permission to appeal being granted almost automatically. Such guidance was not given here.

Injunction pending appeal

Since neither counsel nor the Court was aware of an application previously having been made for the continuation of an injunction pending appeal on a patent that had been invalidated at first instance, it was not clear on what basis the application should be considered. Servier’s counsel argued that *American Cyanamid* should apply, albeit modified to take account of the fact that this was an application for an injunction pending appeal rather than pending trial. Apotex’s counsel, on the other hand, argued that the most relevant test was whether lifting the injunction would make the outcome of the appeal nugatory, following *Ketchum*.⁶

American Cyanamid will, no doubt, be familiar whereas *Ketchum* might need some introduction. *Ketchum* is a case relating to damages for breach of a share agreement. The issue was whether an injunction should be granted to prevent the successful party at first instance dealing with the proceeds of the sale of shares pending the appeal. The approach taken by the court in *Ketchum* was to ask

(1) whether there are reasonable grounds of appeal;

(2) would the appeal be rendered nugatory should the relief not be granted and the appeal were ultimately successful; and
(3) where did the balance of convenience lie?

Pumfrey J was ‘very doubtful’ that the jurisdiction of the Court is circumscribed by *Ketchum*. On the other hand, he saw no reason why the ‘familiar principles of *American Cyanamid v Ethicon*, with necessary qualification’ should not apply and so proceeded on that basis, applying the modified *American Cyanamid* criteria.

The questions to be addressed were, therefore,

(1) was there an arguable appeal;
(2) were damages an adequate remedy to the patentee and to the enjoined party; and
(3) balance of convenience.

Having already decided that Servier had no reasonable prospect of success on appeal, it followed that the application fell at the first hurdle. However, had there been a reasonable prospect of success on appeal, **Pumfrey J** indicated that he would not have reconsidered the arguments on the balance of convenience and, instead, would have granted interim relief.

As this was the first time that such an application had been considered, **Pumfrey J** continued the injunction for a short time to allow Servier to ask the Court of Appeal for permission to appeal the decision to lift the injunction. On 9 July 2007 (the following working day), **Jacob LJ** and **Keene LJ** decided that the injunction should not be continued pending appeal and upheld **Pumfrey J**’s decision.⁷ This decision was also based on the *American Cyanamid* criteria and **Jacob LJ**, giving judgment concluded that there was no prospect of success on appeal so the first hurdle was not passed.

Would applying *Ketchum* have made a difference?

Following the criteria from *Ketchum*, Servier’s application would still have fallen at the first hurdle. Thereafter, however, an injunction would only be continued if the effect of granting one would be to render the appeal ‘nugatory’. Lifting an injunction would be nugatory if, as described by **Stuart-Smith LJ** in *Ketchum*, it ‘would deprive the appellant, if successful, of the results of the appeal’. Instead, ‘the Court should be able to take steps to ensure that their judgments are not rendered valueless’. An example of a nugatory appeal would be if an order preserving a tree were

6. *Ketchum International PLC v Group Public Relations Holdings Ltd & ors* [1997] 1 WLR 4 (CA)

7. [2007] EWCA Civ 783

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lifted pending appeal and the tree was then felled before the appeal was heard. An appeal decision reversing the first instance decision and saving the tree would be nugatory because the tree would no longer exist.

Whether lifting an injunction in the pharmaceutical market will render an appeal nugatory depends on the facts of the case. The patentee would, of course, lose its monopoly and it could be argued that if the monopoly cannot be re-instated following a successful appeal, any appeal would be nugatory as the monopoly, like the tree, would be irretrievably lost. As the monopoly only protects a financial interest, though, would damages be adequate enough to avoid the appeal being nugatory? If so, the presumption would be that, where damages were available, the appeal would not be nugatory and the injunction would be lifted. However, if not, there would be little difference in the results of applying *Ketchum* compared to *American Cyanamid* as everything would come down to the balance of convenience in both cases.

Going forward

This decision means that if there is an arguable appeal and the balance of convenience is not altered by the judgment, then any injunction may be maintained pending appeal irrespective of the decision of the court at first instance. There will be an arguable appeal in the majority of pharmaceutical cases and obviously in almost every case that goes to appeal (unless *Pozzoli* is to be used as a ground for appeal regularly), which means that the injunction could be continued in an overwhelming majority of cases that proceed to appeal.

Would, however, maintaining the injunction against one company protect the patentee's market in any event? With a High Court decision invalidating the patent, it is likely that a number of other companies might prepare to launch and the patentee would have to apply to the High Court, the same court that had just invalidated its patent, for an injunction preventing these third parties from infringing its patent.

Whilst any order for revocation is normally stayed pending appeal, it is a moot point whether a patentee could actually enforce against third parties a patent that has been held invalid at first instance. Assuming that such a patent was not enforceable, the only party that would be prevented from selling the patented product would be the enjoined party who sought to 'clear the way'. Such an outcome

would appear to favour a third party and swing the balance of convenience towards not continuing the injunction.

What effect would the first instance judgment have on the balance of convenience? In this case, counsel for Apotex argued that the balance of convenience in previous cases had been decided by the failure of the generic company to bring proceedings to clear the way, as the Court requires following *SmithKline Beecham v Apotex*.⁸ But here the balance of convenience should favour Apotex as they had done what was required of them: they had 'cleared the way'. **Pumfrey J** recognised the force of this submission but did not

find it helpful to re-exercise existing discretions on the hypothesis that one and one only of the relevant factors has changed in a material respect.

However, because the balance of convenience looks at the relative injustice to each party, altering one factor could tip the balance in the other direction and lead to a different result. Whilst it did not affect the decision in the present case, it seems wrong not to reassess the balance of convenience following a judgment invalidating the patent. Only one factor may have changed (as long as Apotex having cleared the way and the patent being invalid are taken to be the same factor) but it has been the deciding factor in a number of recent cases.

If a positive first instance decision is not enough to clear the way and prevent an injunction, generic companies will have to review their strategies in the future and aim to bring proceedings against a patentee up to two years before a planned launch to allow time for the decision of the Court of Appeal as well as that of the High Court. Meanwhile, based on the decision in this case, patentees who have lost at first instance should always apply for an injunction. It seems that on occasions they will be successful and potentially extend their valuable monopolies for another nine months or so until the appeal.

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8. As per **Jacob J** in paragraphs 65 to 68 of *SB v Apotex* [2002] EWHC 2556 (Pat) and approved by **Aldous LJ** in paragraphs 39 to 40 of *SB v Apotex* [2003] EWCA Civ 137.