Missed opportunity

Following an English Court of Appeal decision in Novartis v Hospira, Gareth Morgan and Phil Carey question whether the American Cyanamid criteria remain valid in patent interim injunction hearings.

Novartis is the proprietor of a series of patent rights covering in various ways the pharmaceutically active product zoledronic acid. Hospira is a generic pharmaceutical company and it challenged two of Novartis’ “use” patents relating to this product. During those proceedings, infringement of the “use” patents was not an issue the court needed to consider. Hospira prevailed at trial with Arnold J ruling in March 2013 both use patents were invalid. The SPC on the “product” patent held by Novartis also expired on 15 May 2013. Hence, after 15 May, Hospira was free to launch its generic product only subject to Novartis’ appeal relating to the findings of the Patents Court on its “use” patents.

The parties entered into extensive correspondence on the intentions of Hospira to launch its product after the expiry of the SPC on the “product” patent, and one letter assumed significance after Novartis sued Hospira for infringement and applied for an interim injunction on the recently invalidated “use” patents pending the determination of the validity of its rights on appeal.

At first instance Birss J refused Novartis an injunction, holding that, although he would have granted an interim injunction had the parties come before him at interim stage in the usual manner, Hospira had gone to the trouble of invalidating the Novartis “use” patents at trial. Also, the Judge held that Novartis, as soon as it became clear Hospira had the wherewithal and intention to launch its product after expiry of the SPC on the Novartis “product” patent, should have made efforts to ensure the question of infringement was resolved and/or the appeal of the invalidity decision to the court of Appeal expedited.

Novartis then appealed Birss J’s refusal to the Court of Appeal, and that court overturned the lower court, granting the injunction sought by Novartis. In reaching their decision they held that the Judge had been wrong to approach the matter in any other manner than that endorsed by the House of Lords in American Cyanamid. After deciding that there was a serious issue to be tried on appeal and finding the balance of convenience lay in favour of granting the interim injunction, the Court of Appeal held the first instance Judge should not have indulged in any further analysis. The case has been seen as a stark reminder that the UK, courts will almost never entertain defences to applications for interim injunctions based on the strengths of the parties’ respective cases on the merits, and also that the “clearing the way” obligation placed on generic pharmaceutical companies extends to the determination of the validity of the relevant patent rights after the patentee has exhausted the possibilities of the appellate system. In many ways there are no surprises in the judgment, merely the Court of Appeal rigidly following the American Cyanamid criteria by which it is bound.

American Cyanamid and UK interim injunctions

Interim injunctions are not available as of right, but are granted at the absolute discretion of the court under criteria set out by the House of Lords case of American Cyanamid v Ethicon Ltd ([1975] AC 396). In summary, the House of Lords considered that courts should ask the following questions:

- Is there a serious issue to be tried in relation to the patentee’s claim that the patent in suit is valid and infringed? This is a low threshold a patentee has to overcome.
- If so, would damages be an adequate remedy for the patentee should the interim injunction not be granted but the patentee found to be ultimately right in its claim of infringement (of a valid patent) at trial?

If the answer to that question is “yes”, then ordinarily no injunction should be granted, irrespective of the apparent strength of the patentee’s case.

If the answer to that question is “no”, then the adequacy of damages for the alleged infringer in circumstances where the injunction is granted wrongly, should be considered.

- If there is doubt as to the adequacy of damages available to either party or both, other factors which go to the balance of convenience fall to be assessed.
- Where other factors appear to be evenly balanced, it is a counsel of prudence to take such measures as are calculated to preserve the status quo.

In American Cyanamid the court explained that the reason for introducing cross-undertakings in damages permitted the courts to abstain from expressing views on the strengths and weaknesses of the parties’ cases. There are good reasons to suggest that this position should be reviewed:

- First, the number of trials in the last few decades where a patentee in this sector is successful in defending validity attacks against its patents from generic pharmaceutical companies is low. It is
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• Third, the period of time during which the patentee challenges the patent (i.e. time between
  application for and grant of
  an interim injunction). Taking the perindopril litigation as an example, the Court was
  granted an interim injunction for around 18 months on a product market
  worth over £70m per annum. When the
  patent was ultimately found invalid, it was
  ordered to pay just over £17m in damages
  on the cross-undertaking.

However, in addition to the above American Cyanamid criteria, the failure of a new market entrant “to clear the way” in advance of launch, has in many cases been a significant (if not decisive) factor in the decision to grant an interim injunction.

The combined effect of these practices is to create significant disincentives for companies to challenge patents in the pharmaceutical sector if they are seeking to bring generic products to the market. Far better to monitor your competitors’ litigation behaviour and ensure you have product ready to go when you have invalidated the patent.

This is an important policy question with which the courts are unwilling to grapple (see paragraph 64 of the Court of Appeal judgment in this case). The Court held that the requirement for strict compliance with “clearing the way” was an overriding concern to any recoverable losses that might be incurred by the NHS in paying monopoly rights on a potentially invalid patent monopoly.

Conclusions

For the reasons highlighted above, the American Cyanamid rules should be modified for the pharmaceutical industry sector even if they remain appropriate to be used in other industry sectors. The public policy case for incentivising the removal of unmeritorious patent monopolies should override the UK court’s desire not to express views on the merits of the case until trial. This is particularly so where it is the public purse that is picking up the majority of the cost of interim injunctions being granted on patents that prove to be invalid.

We now also consider whether the impending introduction of the Unified Patents Court (UPC) in Europe should also now drive UK court behaviour to modify the American Cyanamid criteria.

Will American Cyanamid rules be relevant in the UPC?

The starting point for the UPC is the Agreement that created it. While the UPC Agreement does address provisional measures, it (and the Rules of Procedure that accompany the Agreement) says very little as to how the various judges should approach interim injunctions.

Article 62 of the Agreement says:

“The Court shall have the discretion to weigh up the interests of the parties and in particular to take into account the potential harm for either of the parties resulting from the granting or the refusal of the injunction.” (emphasis added)

The Rules of Procedure add:

“…the Court shall be satisfied with a sufficient degree of certainty that…”

permit the option to arise. Where next?

The Court of Appeal decision in this case was arguably a missed opportunity both to endorse what was a brave decision by the first instance judge in trying to provide some reward to the generic pharmaceutical company that had successfully invalidated the patents in suit at the trial. It would also have brought the American Cyanamid criteria into line with 21st Century civil procedure for patent litigation in the UK. American Cyanamid was that English procedural practice was moving towards lengthy interim injunction applications. This will not be a concern in the UPC.

Hence, assuming in the UPC American Cyanamid will be modified, taking a more continental approach to interim injunctive relief, might result in, “clearing the way” also being discarded.

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