

## Preliminary injunctions available in the UK despite first instance invalidity finding

The UK Court of Appeal (CoA) has reversed an earlier decision of the High Court and granted Novartis a preliminary injunction (PI) against Hospira, preventing sales of generic zoledronic acid for treating osteoporosis.

The decision provides precedent for the granting of a PI in respect of a UK patent which is under appeal, notwithstanding the patent previously being held invalid in first instance proceedings. This most recent development will therefore be welcomed by pharmaceutical innovators. [2013] EWCA Civ 583

### The facts

- Two Novartis patents relating to the use of the bisphosphonate osteoporosis drug zoledronic acid (Aclasta®) were invalidated by the High Court during revocation proceedings in February 2013.
- At the end of April 2013, after having obtained permission to appeal the decision of invalidity, Novartis brought infringement proceedings and applied for a PI against Hospira.
- The PI application was initially dismissed by the High Court but this decision was reversed a few days later on 22nd May 2013 by the CoA, despite the decision of invalidity on the patents.

- Hospira is enjoined from launching its generic zoledronic acid product at least until a final decision on the validity of the patents is handed down by the CoA.

### First instance decision on validity

Hospira's attempt to clear the way showed early promise at the High Court which held that both Novartis' patents were not entitled to priority and that they therefore lacked novelty over an intervening disclosure. The patents were also held to be invalid for insufficiency. The judgement contains reasoning on the interpretation and validity of medical use claims which have come as a surprise to some observers. Practitioners will be eagerly awaiting the views of the CoA on the High Court judgment.

### First instance PI decision

Despite the invalidity decision, it was possible for Novartis to apply for a PI because it had started appeal proceedings to reverse the decision of the High Court. The possibility that Novartis

would prevail on appeal and that the patents would ultimately be held valid was sufficient basis for the PI application.

However, Hospira received more good news when the High Court refused to grant the PI. Hospira successfully argued that the earlier invalidity decision represented a "clear view on the merits" which should be taken into account in deciding that the balance of justice was in its favour (i.e. that it would suffer greater unquantifiable damage if the PI was granted than Novartis would suffer if it was not granted).

The High Court agreed, considering that the position before the invalidity trial could not be equated to that after it. Now that the patents had been held invalid, Novartis should face a higher threshold on the prospects of it succeeding on appeal. The court appears to have considered that it counted against Novartis that it could not show anything more than a "real prospect of success" on appeal, as underlined by the judge's view that he would probably have granted the PI had Novartis applied for it before the invalidity trial.

## The CoA's view

The CoA disagreed with the High Court holding that Novartis should not have been penalised by the earlier invalidity decision. According to the CoA, once it had been established that Novartis's appeal had at least a "real prospect of success", it was not useful to quantify that prospect and attempt to give weight to it in assessing the balance of justice.

In finding for Novartis, the CoA agreed with the statement of the High Court judge that, had Hospira tried to launch its product before the invalidity trial, Novartis would have likely been granted the PI. However, the situation was held by the CoA to be the same after the invalidity trial because the unquantifiable damage to Novartis (the immediate downward price erosion in the period until the appeal trial) outweighed the damage to Hospira (loss of "first mover" advantage).

Interestingly, Hospira's argument that Novartis could avoid loss of market share without cutting the price of its branded product, by diverting sales to its generics arm, Sandoz, was not considered persuasive by the CoA. The fact was that the market would become accustomed to lower prices (whether as a result of generic sales by Sandoz or by third parties such as Hospira) and restoring the monopoly position would, if possible at all, be accompanied by harm of other kinds for Novartis (e.g. loss of reputation).

A further argument by Hospira that it was unreasonable for generic manufacturers to start proceedings so far in advance of intended launch as to be able to obtain a final judgement (including any appeal) was not accepted by the CoA. According to the court, it was not unreasonable to expect generics manufacturers to plan on the basis that there will be an appeal, as appeals were the norm, rather than the exception, in disputes between pharmaceutical companies.

## Conclusions

Innovators will be encouraged by this ruling, which shows that PIs in the UK are not barred solely by an adverse finding in first instance proceedings on validity. The decision highlights that the onus still firmly remains with generic manufacturers to clear the way before launching their products. The CoA sounds this warning: *"the way to market for a generic manufacturer is not clear until all arguable objections from the patentee have been eliminated. If the generic manufacturer allows the trial of the action at first instance to coincide with the intended launch date, he runs the risk that a successful appeal could get in the way, even if judgement at first instance is given in his favour"*.

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## Need advice?

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