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Financial pitfalls associated with an interim injunction

In *AstraZeneca v KRKA, d.d. Novo Mesto and Consilient Health Ltd.* ("KRKA"), the Mr Justice Sales of the UK High Court has considered the merits of arguments put forward when trying to recover damages following a cross-undertaking in respect of an interim injunction that was subsequently discharged.

Significantly, in awaiting damages in KRKA the Judge chose to rely on the evidence of medicine managers (experienced pharmacists employed by the National Health Service Primary Care Trusts) rather than that of expert economists when assessing the loss of "first mover" advantage.

Facts of the case

AstraZeneca owns a European (UK) patent that provides protection for Nexium®, which is the brand name for esomeprazole magnesium, a proton pump inhibitor that is used to treat a range of gastric conditions. Nexium® was launched in the UK in 2000 and was the only product of its kind on the market until 2011, during which period it commanded a high price.

In October 2010, AstraZeneca obtained an interim injunction in the UK that prevented KRKA from marketing Emozul®, a generic equivalent of Nexium®, in order to preserve the status quo pending a trial. KRKA claimed that Emozul® did not infringe AstraZeneca's patent.

At the time that AstraZeneca obtained its injunction against KRKA, the validity of AstraZeneca's patent for Nexium® was being challenged in the UK by Ranbaxy, who also sought to market a generic equivalent of Nexium® in the UK. A speedy trial concerning the issues of infringement found that Ranbaxy's product did not infringe AstraZeneca's patent.

Following the Ranbaxy judgment, AstraZeneca applied for the interim injunction against KRKA to be discharged because it recognised that its patent infringement claim could not succeed. The interim injunction against KRKA was finally discharged in July 2011.

Market activity

A number of generic equivalents of Nexium® were marketed in the UK following the Ranbaxy judgment: Ranbaxy marketed its equivalent in September 2011; Mylan in November 2011; and Teva in December 2011. AstraZeneca also teamed up with Arrow (another generics company) to sell a "branded generic" version of Nexium® in July 2011. The "branded generic" version was launched in the UK two days after the Ranbaxy judgment. AstraZeneca's market share for Nexium® fell following the arrival of several lower priced generic equivalents onto the marketplace.

Considerations for assessment of damages

In order to assess the damages payable by AstraZeneca under the cross-undertaking, the Court considered the commercial impact that the interim injunction had on KRKA by delaying its entry into the marketplace until after several other generic versions of Nexium® were available in the UK, referred to as the loss of "first mover" advantage. There was a significant divergence of opinion between AstraZeneca and KRKA as to the value of the loss of "first mover" advantage. AstraZeneca estimated the loss to be £6 million, whereas KRKA claimed it was £32 million.

There was universal agreement that the Court should apply the principles set out in *Les Laboratoires Servier v Apotex Inc.* [2008] EWHC 2347 when assessing damages and determining the loss that the injunction caused KRKA. Those principles are summarised as follows:

1. The approach is essentially compensatory and not punitive.

2. The assessment is made on the same basis on which damages for a breach of contract would be assessed.

3. The court should attempt a principled approach, even if it may not be possible to calculate the defendant's losses with certainty or precision.

4. The damages should be assessed on a particular hypothesis and then multiplied by the percentage chance of that hypothesis occurring.

The Court went on to clarify the approach in certain aspects, namely that:

1. So-called "restitutionary" damages could be considered if a wrongful extension of patent term results in benefit to the patent holder that exceeds and outstrips the loss to the generic company.

2. Damages are to be "liberally assessed". Although the party giving the cross undertaking of damages is not a wrongdoer, the approach to damages is the same as when considering damages against a wrongdoer.

In assessing damages, the Court needed to consider a complicated and highly regulated marketplace. The Court considered the premium price paid for patented drugs, where no generic equivalents are available, and the lower price paid for drugs when several alternative generic products are available. The Court also considered factors that influence switching patients to a new (less expensive) entrant into the marketplace.

In this case, KRKA argued that it would have been able to charge a higher price for Emozul® if it had benefitted from the "first mover" advantage in October 2010. KRKA also argued that it would have established and maintained some of its market share had it benefitted from the "first mover" advantage, because there would have been reluctance to switch patients to an alternative drug for a second time.

In response, AstraZeneca argued that it would have dropped the UK price for Nexium® following a loss of market share. However, if the price for Nexium® in the UK fell, then the prices in certain other European countries would also fall because the UK price for Nexium® was used as a reference point for the price payable in other countries.

Outcome

The court was not persuaded that AstraZeneca would have reduced the UK price for Nexium®.

The Judge concluded that if KRKA had been able to launch Emozul® in the UK in October 2010, then there would have been a substantial switch of patients from Nexium® to Emozul®. However, as the launch of Emozul® was delayed until September 2011, Emozul® was competing with Nexium® and five other generic products. The opportunity to charge a higher price and establish market share for Emozul® had been lost, because a competitive environment had developed. The Judge invited the parties to agree on the damages payable.

Conclusion

This case serves as a reminder that interim injunctions can be costly. It also presents an interesting insight into the commercial approach that the UK Courts might take in pharmaceutical cases when assessing damages for a defendant who seeks to benefit from a cross undertaking following an interim injunction.

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This briefing note was first published in the IAM IP Newsletter.