In a robust decision handed down by the English Court of Appeal\(^1\), Novartis has been awarded an interim injunction against Hospira to prevent sales of generic zoledronic acid in the UK despite Novartis’ patents having been declared invalid by the English High Court. The revocation proceedings are expected to reach the Court of Appeal some time in autumn 2013. Until then, Novartis is able to enjoy market exclusivity on its proprietary zoledronic acid product, Aclasta.

The Court of Appeal judgment represents a significant victory for Novartis and other innovators. In this eAlert, we discuss how this decision impacts innovators and generic companies alike, as well as the practical steps that parties should consider prior to the launch of a generic product.

\(^1\) Novartis AG v Hospira UK Limited [2013] EWCA Civ 583.
Sold under the brand name Aclasta, Novartis’ zoledronic acid is protected by two patents which cover the use of zoledronic acid for the treatment of osteoporosis. Until recently, Aclasta was also protected by an earlier compound patent and corresponding SPC.

Hospira planned to sell its generic version of zoledronic acid in the UK as soon as patent protection for the compound patent/SPC expired on 15th May 2013. In an attempt to “clear the way”, Hospira began revocation proceedings against Novartis’ two patents in December 2011, some 17 months before expiry of the compound patent/SPC, and some 11 months before Hospira had obtained a marketing authorisation for generic zoledronic acid.

Hospira obtained a marketing authorisation for zoledronic acid for osteoporosis in November 2012. When this came to Novartis’ attention, it sought and obtained undertakings that Hospira would not launch “at risk” prior to 15th May 2013. However, Novartis was not able to obtain from Hospira (i) an acknowledgement that Hospira’s generic zoledronic acid product infringed Novartis’ patents or (ii) an undertaking from Hospira that it would not launch generic zoledronic acid after 15th May 2013 (even if the use patents were found to be valid).

The revocation proceedings came before Mr Justice Arnold who, in February 2013, declared both of Novartis’ patents invalid on the grounds that the patents were not entitled to their claimed priority date and were therefore invalid for lack of novelty. The judge also held that some, although not all of the claims, were invalid for reasons of insufficiency.

Following Novartis’ appeal of the decision (“the invalidity appeal”), Hospira informed Novartis that it was Hospira’s intention to launch in the UK upon expiry of the compound patent/SPC on 15th May 2013. Two days later, Novartis commenced infringement proceedings and applied for an interim injunction against Hospira pending the invalidity appeal. On 14 May 2013, Birss J delivered his judgment, refusing to grant the injunction sought by Novartis.

Novartis’ appeal of Mr Justice Birss’ decision was unanimously overturned by the Court of Appeal only a few days later with an injunction being granted preventing Hospira’s launch of its generic product until final judgement in the invalidity appeal.

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2 Worldwide sales of Aclasta were some US$590 million in 2012, of which about GBP5.7 million represented UK sales.
3 EP (UK) Nos. 1296689 and 1591122. These patents cover the use of zoledronic acid, administered as a single intravenous injection half-yearly or annually. Other bisphosphonate compounds in this class are administered orally and hence subject to gastric intolerance and have to be taken more frequently.
Main points of interest arising out of the Court of Appeal

Novartis v Hospira Judgment

Patentees who are unsuccessful in asserting their rights at first instance may nevertheless be granted an interim injunction pending appeal.

Prior to the decision of Birss J, there had been no precedent for the grant of an interim injunction pending appeal when the patent had been found invalid. The Court of Appeal’s decision has now established precedent that it is open for the English courts to grant interim injunctions pending appeal even if the patent(s) at issue have been found invalid by the courts at first instance.

Patentees must prove the same factors in applying for an interim injunction pending appeal as they would for an interim injunction pending trial. These factors are that:

(i) The court must be satisfied that the appeal has “a real prospect of success”. If the court is satisfied that there are real prospects of success, it is not generally useful to form a view as to the prospects of appeal or give weight to that view in assessing the balance of convenience.

(ii) It does not automatically follow that if an interim injunction had, or would have, been granted pre-trial that an injunction pending appeal should also be granted. The court must address all relevant circumstances following the first instance judgment, including the period of time before the appeal is likely to be heard, and the balance of hardship to each party if an injunction is refused or granted.

(iii) The grant of an injunction pending appeal is not limited to the case where its refusal would effectively render the appeal nugatory or futile.

(iv) The court should endeavour to arrange matters so that the Court of Appeal is best able to deliver justice between the parties once the appeal has been heard.

Applying the principles to the facts before them, the Court of Appeal concluded that:

(i) Novartis’ appeal had a real prospect of success. The Court of Appeal acknowledged that both Arnold J and Birss J had concurred on this point.

(ii) This was a case where, had Hospira sought to launch before trial, it would have been subject to an injunction. Birss J had also concurred on this point.

(iii) The “unquantifiable damage” to Novartis outweighed that to Hospira. There would be an immediate downward price spiral if generic zoledronic acid were to be launched, “even between now and the hearing of the appeal”. The Court of Appeal recognised that Novartis would not be able to restore its pre-launch prices. The fact that Novartis could potentially divert its sales to its generic arm (Sandoz) was held to be irrelevant in this assessment. Furthermore, the Court was unconvinced that Hospira would lose its “first mover advantage” pending the invalidity appeal.

Generics must “clear the path” fully before their launch.

The Court of Appeal acknowledged that “it is purely common sense” that generic manufacturers who plan to launch a generic product must take steps to effectively clear obstacles facing its manufacture/sale before launch. The burden is on the generic manufacturer to do so. Birss J had noted that “the generic knows more about
its plans than the innovator, so the generic ought to arrange things to have the merits tried before it launches”.

Hospira, however, argued that they had carried out all the necessary “clearing” steps; in particular, they had sought to revoke Novartis’ patents well before 15th May 2013.

The Court of Appeal held that Hospira’s action was insufficient. Both parties know that litigation is not finally concluded until all appeals are disposed of. In an industry where appeals are the “norm”, it is not unreasonable to expect generics (not the innovator) to plan to “clear the way” on the assumption that there will be an appeal. The Court of Appeal said that the generics would therefore have to:

(i) Disclose their intentions to the innovator in time for the appeal to take place; or
(ii) Seek an appropriately expeditious hearing to take into account any appeal.

The inability of the UK’s National Health Service (NHS) to achieve 100% recovery in a cross-undertaking in damages is not a sufficient public interest argument to justify the refusal of an injunction.

In the event that Birss J had granted the injunction in favour of Novartis, the Secretary of State for Health had written to Birss J requesting that the Court require that any cross-undertaking given by Novartis be extended to cover the losses by the NHS in the interim. Novartis was willing to give this undertaking.

The Court of Appeal recognised that, although the NHS was unlikely to achieve 100% recovery under the cross-undertaking, this was not of sufficient weight to justify refusing an injunction.

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6 The first mover advantage is the advantage that the first generic to market enjoys when it enters the market at a price near the monopoly price in the absence of other generic competition. In such circumstances it can reap far greater rewards than second and subsequent companies who would be likely to cause uncontrolled downward price spiral. The Court of Appeal had evidence before it that at least one, and probably two, other generic companies were in a position to market products with market authorisations, hence eroding Hospira’s first mover advantage.
7 Quoting Jacob J in Smithkline Beecham v Apotex (unreported Court of Appeal 23 October 2001).
8 Novartis AG v Hospira UK Limited [2013] EWHC 1285 (Pat), Birss J., Para 36.
9 Wake Forest University Health Services & Ors v Smith & Nephew plc [2009] EWCH 45 pat, established that innovators’ customers can also claim retrospectively under cross-undertakings, the underlying rationale being that that they are entitled to be compensated if it turns out that they have paid too much for the innovator’s drugs during the pendency of the injunction.

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Top tips for innovators and Generics following Novartis v Hospira

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INNOVATORS

Innovators should be bolstered by the fact that as long as they can show that there is a real prospect of success on appeal, a finding of invalidity of a patent at first instance is not a bar to obtaining an injunction pending appeal. This is the case irrespective of whether an innovator sought a preliminary injunction prior to the first instance hearing.

The “balance of unquantifiable harm” remains weighted in innovators’ favour.
Innovators must remember however that an interim injunction pending appeal may come with the price of a cross-undertaking in damages. The potential financial exposure under the cross-undertaking can be extensive if it covers loss to third parties such as the NHS. There are tactical advantages for generics to alert third parties, such as the NHS, of an innovator’s application for a preliminary injunction. Although the generic may not directly benefit from the cross-undertaking, this increased exposure will force innovators to consider very carefully whether the risk of having to pay damages under such a wide cross-undertaking is worth the benefit of obtaining an injunction.

Innovators need to be prepared for applications made by generic companies for expedited trials. If granted, innovators will find that they need to prepare themselves for a hearing on the merits within relatively short time-frames.

**GENERICS**

Generics bear the burden of “clearing the way” in advance of the expiration of the innovator’s patent. This “clearing” should take account of potential appeal hearings. In order to achieve this, it may be necessary to apply for expedited hearings.

Generics will have to be transparent about their launch plans. The Court of Appeal emphasised that generics should disclose their intentions to the innovator in time for an appeal to take place, as one option of “clearing the way”. This appears to run contrary to the generics’ argument that their launch plans are “confidential/a commercial secret”. The latter has previously not found favour before the English Courts’ ears. In *BMS v Teva* [2012]10 Birss J held that a generic’s launch date could only be a valuable commercial secret if the launch date was scheduled to be prior to expiry the innovator’s patent/SPC. This sentiment continues to pervade the courts’ current views on the matter. Generics are encouraged to take comfort in a “confidentiality club” system that would be able to preserve the confidentiality of the detailed launch date.

Generics must be conscious that the English courts will take into account past surreptitious behaviour, even if unconnected to the current launch plans. A generic’s prior conduct may just sway the court in granting an injunction in favour of the innovator. In *BMS v Teva*, Birss J was much influenced by Teva’s previous launch “at risk” of very large quantities of generic atorvastatin in advance of the expiry of Pfizer’s drug, when he granted a *qua timet* injunction against Teva in respect of its generic form of efavirenz, “Efavirenz Teva”.

Generics must be cautious about refusing to provide responses as to their launch plans and/or in providing appropriate undertakings as such conduct may result in the English courts granting an injunction against them at a later date.

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10 (1) *Merck Sharp Dohme Corp.* (2) *Bristol-Myers Squibb Pharmaceuticals Limited v (1) Teva Pharma B.V.* (2) *Teva UK Limited* [2012] EWCH 627 (Pat).
Key contacts

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