Novartis owns two European patents (which cover the use of zolendronic acid for the treatment of osteoporosis) (“the Use Patents”). These Patents have a number of years left to run and cover Novartis’ marketed drug Aclasta. Novartis also owns the basic zolendronic acid compound patent and its corresponding SPC which expired on 15 May 2013.

Hospira initiated revocation proceedings against the Use Patents in December 2011. The revocation proceedings were not expedited. In November 2012, Hospira obtained its marketing authorisation for zolendronic acid for use in the treatment of osteoporosis and Paget’s disease and Novartis’ solicitors requested an undertaking from Hospira not to sell zolendronic acid prior to the SPC expiry and not to infringe the Use Patents until handing down of the judgment in the revocation proceedings and also an acknowledgment that Hospira’s zolendronic acid formulation covered by the marketing authorisation would infringe the Use Patents. Novartis’ request did not address what would happen if the Use Patents were held invalid.

The Use Patents were found to be invalid at first instance on the grounds that they were not entitled to their claimed priority date and were thus rendered invalid by an intervening prior publication. The judge also held that some of the claims were invalid for insufficiency.

Novartis sought to appeal and permission was granted on the basis that the appeal would have a real as opposed to a fanciful, prospect of success. Hospira then told Novartis that they intended to launch their zolendronic acid product in the UK following expiry of the SPC and Novartis issued infringement proceedings and applied for an interim injunction. The injunction was refused at first instance and Novartis appealed.

The Court of Appeal considered the principles for the grant of interim relief pending appeal and in particular the case of Servier v Apotex (unreported, 6 July 2007). In that case, following revocation of the patent at first instance, an interim injunction which had been in place pending trial was not extended pending the outcome of the appeal. Notwithstanding the first instance judge granting the patentee permission to appeal, the judge considered that the normal American Cyanamid principles applied and that the injunction should be refused on the ground that the appeal had no real prospect of success. Jacob LJ agreed that the appeal had no real prospect of success and refused the injunction on that basis.

However, in the present case, the Court of Appeal held that once the court was satisfied that the appeal had a real prospect of success, it would not normally be useful to try to form a view as to how much stronger the prospects of appeal were, or to try and give weight to that view in assessing the balance of convenience. In this case, the best way of holding the ring pending the appeal (as would have been the case pending trial) was to grant an injunction.

Implications

As ever in interim injunction applications, the court has sought to balance the interests of both parties; on the one hand a competitor; in this case a generic, trying to seek a first to market position and on the other, the patentee who is looking to protect their position. The fact that obviousness was not in play in the case clearly impacted on that assessment.

The other broader implication is one of timing. Where a party is seeking to clear the way for a competitor product launch, timing has always been hard to judge, and requires, amongst other things, an understanding of when trials (and appeals) are likely to be heard by the English Court. This case underlines that, when making such assessment, it is important to evaluate the prospects and likely timing of appeal or, indeed references to the Court of Justice of the EU (CJEU) where they might be applicable. That is not to say that this is a one size fits all approach and it is to be expected (and has already been seen) that the lower court will pay attention to this decision when making assessments around granting of injunctions and permission to appeal, but ultimately it will all still be dealt with on a case by case basis.

1 http://www.bailii.org/ew/cases/EWCA/Civ/2013/583.html

This note does not constitute legal advice. Specific legal advice should be taken before acting on any of the topics covered.

Pinsent Masons LLP is a limited liability partnership registered in England & Wales (registered number: OC333653) authorised and regulated by the Solicitors Regulation Authority and the appropriate regulatory body in the other jurisdictions in which it operates. The word ‘partner’, used in relation to the LLP, refers to a member of the LLP or an employee or consultant of the LLP or any affiliated firm of equivalent standing. A list of the members of the LLP, and of those non-members who are designated as partners, is displayed at the LLP’s registered office: 30 Crown Place, London EC2A 4ES, United Kingdom. We use ‘Pinsent Masons’ to refer to Pinsent Masons LLP and affiliated entities that practise under the name ‘Pinsent Masons’ or a name that incorporates those words. Reference to ‘Pinsent Masons’ is to Pinsent Masons LLP and/or one or more of those affiliated entities as the context requires.

© Pinsent Masons LLP 2013.

For a full list of our locations around the globe please visit our website: www.pinsentmasons.com