

Has the leopard changed its spots? Hold your horses.

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A judgment from Henry Carr J refusing an interim injunction to Abbott against Edwards Lifesciences was released to the public on 24 May 2019. The application related to Edwards' PASCAL medical device to treat mitral regurgitation in the heart. PASCAL is implanted in the mitral valve via a catheter by a procedure known as TMVr.

The facts of the application were somewhat unusual. The UK market for TMVr products is small because the procedure is not funded by the NHS although the NHS is currently considering whether to provide such funding. Edwards' evidence to the Court was that a controlled roll-out of a small number PASCAL devices was planned for the autumn and winter of 2019 and into 2020. This pilot launch was to obtain feedback and plan for a fuller roll-out as and when NHS funding became available. Another important fact was that Abbott had sought and obtained an Order for an expedited trial to be heard in December 2019 with judgment expected by the end of January 2020.

When deciding whether to grant the injunction, Henry Carr J made reference to the American Cyanamid principles which have governed this area since the 1970s. American Cyanamid requires that after establishing that there is a serious issue to be tried in the merits, the Court should next consider whether either side will be likely to suffer irreparable harm if the injunction were or were not granted. Following that, the Court should assess the multifactorial "balance of convenience" and decide whether the interests of justice would be better served by granting or not granting the injunction.

Importantly, the Judge held that before looking at the respondent's position on irreparable harm, it was necessary for the Court to be satisfied that the applicant would suffer irreparable harm if the interim injunction were not granted. In light of Edwards' undertaking not to exceed 10 implantations in 2 hospitals until judgment on the merits without permission of the Court, it was held that damages would be an adequate remedy for Abbott.

The important points of principle emerging from this interesting decision are as follows:

- The decision confirms that the American Cyanamid questions are a series of gates to be passed through sequentially. If any gate is not passed through, the application will fail.
- The second question - irreparable harm consists of considering sequentially the position of the applicant and the respondent. Here Abbott failed to convince the Judge that it would suffer irreparable harm in light of this, a consideration of Edwards' position was unnecessary.
- Henry Carr J was clear that the failure of Edwards to clear the way in respect of Abbott's patents was a factor to be weighed in the balance of convenience if the other factors in the case were evenly balanced. Accordingly, attempting to clear the way or not so attempting to do so is just one part of one stage of a multi-stage analysis.
- The Judge noted in his ruling, presumably because he had a bee in his bonnet about it, that Abbott had characterised the PASCAL device as a "copycat" product which was "piggybacking" on the investment and training carried out by Abbott. Henry Carr J considered that "this type of advocacy relied on too many animal analogies. The allegations that PASCAL was a copycat product should never have been made." Future applicants should be careful not to get the judge's goat and it may be a case of softly softly catchy monkey.

Does this decision represent a fundamental change to the approach of the English Patents Court to the granting of interim injunctions? We do not consider that it does and that in a more typical situation where the applicant patentee can point to a substantial loss of market share and/or indeterminate collapse in the price for its medicine in the face of generic competition, the Courts will, subject to the satisfaction of the American Cyanamid questions, listen with sympathy to applications to hold the ring pending trial, particularly if the patentee will do all it can to allow a consideration of the merits at the earliest opportunity. The authors will continue to watch developments in this area like hawks.