

EIP

Déjà vu in melatonin rematch as Neurim v Mylan (Take II) marches on in the UK

With a back catalogue to rival Bob Dylan, the latest development in the Neurim – Mylan battle over Mylan’s generic melatonin product saw Mr Justice Meade referee the trial of preliminary issues in December 2021.

In relation to earlier decisions involving the parties, we previously reported on Marcus Smith J’s Consequential Judgment concerning the “Parent Patent” which formed the basis of the first round of litigation (the “2020 Action”) and also then reported on Neurim’s successful application for an expedited preliminary issue trial concerning a divisional patent (the “Divisional”) which now forms the basis of the second round of litigation.

Background and Preliminary Issues To Be Determined

This second round of litigation is so entwined with the first round, that the Judge spent almost half his judgment setting out a detailed account of the history of the proceedings between the two parties. Of importance to note was that the 2020 Action resulted in a detailed judgment (the “Main Judgment”) finding the Parent Patent valid and infringed. On 16 December 2020 Marcus Smith J made various orders at a hearing which were never formalised in writing due to disagreements between the parties. On 18 December 2020 following withdrawal of its appeal by Neurim, the Technical Board of Appeal (“TBA”)

found the Parent Patent to be revoked ab initio for the UK (and all other designated member states).

Fast forward through the Consequentials Hearing, the grant of the Divisional (due to expire in August 2022), commencement of proceedings involving the Divisional, Mellor J's Order for an expedited trial of certain preliminary issues and the parties find themselves in the Preliminary Issues Trial. Here, the Judge was to determine:

- i) Whether Mylan was issue-estopped from challenging the validity of the Divisional in the light of the 2020 Action.
- ii) Whether Neurim's conduct in amending the Divisional was an abuse.
- iii) Whether Neurim's conduct amounted to an abuse of a dominant position (on the assumption of dominance and market definition).

Issue Estoppel

The Judge was taken through a plethora of material involving case law, statute and legal literature. The Judge surmised that there was no issue estoppel on the basis that the reasons and findings in the Main Judgment were not fundamental to the overall, eventual result.

Mylan's Abuse Argument

Mylan contended that Neurim's application to amend the Divisional was an abuse of process. The amendment application was unconditional, so if it was not allowed then the Divisional would be revoked.

Mylan's made oral submissions which had not been pleaded. The Judge limited himself to what Mylan had pleaded, which was an objection to the form of the amendment, the proposed amended claims being effectively identical to those of the Parent Patent that the TBA had revoked. The Judge did not believe this led to an abuse and rejected Mylan's argument.

The Competition Issues

The Judge felt that given how matters had developed thus far, it was not suitable to deal with competition issues as preliminary issues and declined to decide them.

Case Management

The Judge decided that the most efficient and correct procedural way forward for this case was that the presiding Judge would deal with the trial of this action (a) on the basis only of the materials and arguments before Marcus Smith J from the 2020 Action (agreed by both parties); (b) by adopting and giving effect to the Main Judgment, and (c) by refusing permission to appeal just as Marcus Smith J did on 16 December 2020. Mylan had objected to (b) and (c).

Upon further written submissions, the Judge reconsidered the permission to appeal ((c)) and thought it at least should now be considered even if the result was simply that permission to appeal was, again, refused.

On (b), although the Judge was comfortable in adopting and giving effect to the Main Judgement, he took Mylan's concerns seriously and proposed that the best way to solve this conundrum was for the case to go back before Marcus Smith J. The Judge considered this was a fair, proportionate and judicially appropriate way to proceed because if Marcus Smith J decides, it being a decision for him after he has received submissions, to adopt what he did before, he will be adopting his own findings, his own words and his own judgment. This would eliminate the possibility of another judge having to deal with something uncomfortably halfway between an appeal and a fresh trial. And as Mylan wished to rely on evidence from the 2020 Action, Marcus Smith J was in the position of having heard that given at the first trial.

Take Away Points

Two points can be taken from the Neurim v Mylan litigation, the first is that it is clear from the judges that have heard the various hearings that the Court is willing to adapt its procedures flexibly to deal justly with unusual situations that arise from collisions between national and EPO proceedings. The Courts also look to be willing to consider commercial factors that may affect the parties.

Secondly and more important to remember is that, as a party to litigation where parallel proceedings are in play, one should keep the Court actively and fully informed. It is not enough to put in a sentence in the middle of a skeleton argument. Meade J actively agreed with Marcus Smith J on this point and highlighted that it was an important lesson for the future. Parties in litigation in the Patents Court where there are parallel EPO proceedings should regard themselves as under a duty to inform the Court about scheduling issues and scheduling changes, whether or not they intend to make a case

management application themselves and whether or not it suits their strategy.

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The judgment is available [here](#).