

Kluwer Patent Blog

The Recurring Dream

Chloe Dickson (Bristows) · Monday, February 7th, 2022

On 15 to 17 December 2021 a three-day trial took place to determine preliminary issues in a second action brought by Neurim against Mylan in relation to patents protecting the product Circadin (“**Neurim v Mylan 2021**”). Meade J’s judgment (*Neurim Pharmaceutical (1991) Limited and Anor v Generics (UK) Limited t/a Viartis and Anor* [2022] EWHC 109 (Pat)), which can be found [here](#), was handed down on 24 January 2022.

In the earlier patent infringement action (“**Neurim v Mylan 2020**”), Neurim asserted EP 1 441 702 (“**EP 702**”), a patent that protected the use of melatonin for treating a certain type of insomnia. Marcus Smith J’s main judgment was handed down on 4 December 2020 and a detailed look at it can be found [here](#). By way of background, readers might also recall that earlier in the *Neurim v Mylan 2020* action, Marcus Smith J refused Neurim’s application for a preliminary injunction (reported [here](#)), which was subsequently upheld by the Court of Appeal (reported [here](#)).

When the first instance decision in *Neurim v Mylan 2020* was issued, proceedings before the Technical Board of Appeal of the EPO were pending. Shortly after Marcus Smith J’s decision, the TBA issued an oral opinion during day one of the hearing that EP 702 was invalid for insufficiency. One day two of the hearing, Neurim withdrew its appeal of the EPO Opposition Division’s decision that had found EP 702 invalid for lack of novelty and the patent was revoked *ab initio*. This prompted a further hearing in the English Patents Court to deal with a number of consequential matters, including an unusual order for Neurim, originally the winning party, to pay Mylan’s costs (reported [here](#)).

Neurim v Mylan 2021

Mylan faced the familiar sight that a divisional of the EP 702 parent patent, EP 3 103 443 (“**EP 443**”), was pending during the *Neurim v Mylan 2020* action. This divisional was granted by the EPO on 30 June 2021 (i.e., after the appeal on the parent patent had been withdrawn). After EP 443 had granted, Neurim issued the second set of infringement proceedings against Mylan before the English Patents Court. Mylan responded with a counterclaim for revocation. Neurim applied to amend the claims of EP 443 into a form identical to the claims of EP 702 that had been found to be valid and infringed in *Neurim v Mylan 2020*.

In an effort to achieve a quicker win (EP 443 expires in August of this year), Neurim sought to argue that, as a result of the decision in *Neurim v Mylan 2020*, an issue estoppel arose that prevented Mylan from pursuing its invalidity counterclaim. In response, Mylan argued that Neurim’s conduct in amending EP 443 to match the claims of EP 702 that had been found valid by

Marcus Smith J was an abuse of process. Mylan also argued that, by seeking to shut out its validity challenge, Neurim's conduct amounted to an abuse of a dominant position under s.18 of the Competition Act 1998[1].

Issue estoppel

The basic principles to consider when assessing whether issue estoppel arises were not in dispute:

- issue estoppel arises where there is a decision on an issue in a cause of action as an essential step in the reasoning.
- issue estoppel can also arise in relation to issues which were not raised in an earlier proceeding, but could and should have been. It is necessary that if raised and decided, the issue would have been essential.
- The determination of the decision must have been fundamental, not collateral.
- The effect of issue estoppel is subject to an exception for special circumstances, if fresh material comes to light, because the doctrine is intended to do justice and might not do so in such circumstances.

The question of whether the party alleged to be estopped could effectively appeal is “a useful test” going to the question of whether a determination is fundamental (point (iii)). Having reviewed the case law, the key issues for Meade J to assess were the proper characterisation of the result of the proceedings before Marcus Smith J, the reasons for the result, who was the “winner”, and when. The relevant time to conduct the assessment was, in the judge's view, only after the TBA had revoked EP 702. At this point, the patent no longer existed, since the TBA's decision had “trumped” Marcus Smith J's validity judgment. Mylan was therefore the winner and thus there was no possibility for Mylan to file an appeal. There could be no issue estoppel.

Neurim argued as a fall-back that Mylan could and should have appealed Marcus Smith J's decision in *Neurim v Mylan 2020* when it became apparent that the EP 443 divisional was going to be granted. However, the fundamental outcome remained that EP 702 had been revoked by the EPO centrally. Marcus Smith J's reasons and findings in upholding EP 702 as valid played no role in (and therefore could not be fundamental to) that outcome. There was therefore no decision or finding that Mylan could have appealed and, again, no issue estoppel arose.

Abuse of process

Mylan alleged that Neurim's conduct in withdrawing the appeal before the TBA to avoid a written decision finding EP 702 invalid and subsequently pursuing the same claims in the UK action was an abuse of process. In support, Mylan further alleged that by withdrawing its appeal before the TBA, Neurim had accepted that the claims it now sought to pursue were invalid.

Meade J's judgment notes that the use of divisionals is a well-established practice. It was not argued that this practice, by itself, was abusive. Furthermore, in the peculiar circumstances of the present case, Neurim was not trying to use a divisional to have “*another bite of the cherry*” after losing on the merits in the UK. EP 702 had been held to be valid by the English Patents Court. Mylan had long been aware that Neurim was prosecuting divisional applications and would be likely to use them as backups, if necessary. This leads to litigation uncertainty and for a period that might be longer than usual in English patent litigation, but this was inherent where divisionals are in play. There was always a risk the validity decision in *Neurim v Mylan 2020* might go to the Court of Appeal, which would have increased the length of the dispute too.

Mylan's case on abuse of process was founded on the fact that the form of the amended claims was identical to those pursued for EP 702 in *Neurim v Mylan 2020*. It was "implicit in that that Mylan's argument could not run if Neurim had put forward claims for [EP 443] which were more different from the Patent, but which ... still gave Neurim another opportunity to succeed in the UK, yet required a fuller trial and a greater burden on the parties". The abuse of process arguments therefore failed.

The competition law argument

Meade J declined to rule on the competition aspects of the hearing as the arguments, in a complicated and developing area of the law, were of no greater significance than the issue estoppel arguments that had been rejected by the judge.

Don't nod off yet

The judgment also includes a reminder to practitioners of the need to cooperate with each other and the Court where there are parallel proceedings at the EPO. In this case, the judge commented that much "complexity and confusion" had arisen that could have been avoided. The judge acknowledged that the parties might have their own goals when it comes to scheduling but stated that parties to such patent cases should regard themselves "as under a duty to inform the Court about of scheduling issues".

The case has been referred back to Marcus Smith J to deal with the substantive trial in relation to infringement and validity of EP 443, on the basis of the materials and arguments that were before the judge in *Neurim v Mylan 2020*, as well as limited additional submissions from the parties.

[1] The equivalent of Art. 102 TFEU.

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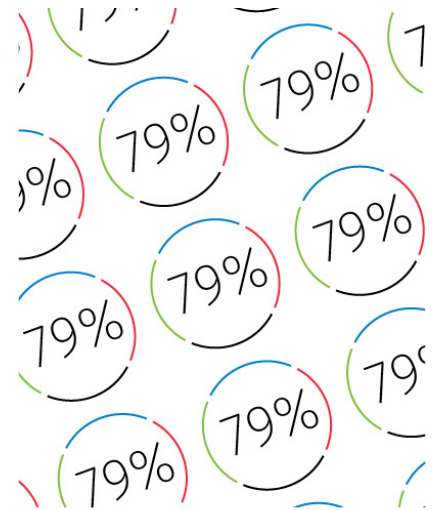
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