# Neurim wins the battle but not (yet) the war for innovators

*Mike Snodin* and *Michael Pears* argue that while the EU decision on supplementary protection certificates might be good news for drug companies that find new uses for "old" active ingredients, it raises more questions than it answers and leaves lingering uncertainty for many other companies.

On 19 July, the Court of Justice of the EU issued a hotly anticipated decision on supplementary protection certificates (SPCs) in *Neurim Pharmaceuticals* (C-130/11)[1,2].

In what marked a new and more flexible interpretation of the SPC legislation, the CJEU effectively ruled that a new use of an "old" active ingredient can be eligible for an SPC.

The high level of interest in the decision had been due to an earlier opinion from the advocate general in the same case that, unexpectedly, proposed a profound liberalisation of the system of supplementary protection in Europe.

Whilst the innovative pharmaceutical industry will have been delighted that the CJEU's decision does appear to provide a more liberal interpretation of the legislation, there will nevertheless be a lingering sense of frustration and disappointment at the lack of clarity in that decision. This is because, although interpreting the legislation in a way that seems likely to result in the grant of an SPC to Neurim, the decision will still leave many companies completely in the dark in relation to whether SPCs can be granted for their new products that contain previously authorised active ingredients.

With a great deal of uncertainty remaining in connection with how broadly (and to whom) the decision can be applied, there are certain to be many further questions asked of the CJEU in the near future. One of the hardest of these to answer will be whether it will be possible for the CJEU to square the circle between *Neurim* and apparently contradictory earlier case law of that court.

Thus, there are likely to be many further battles before the war is won in relation to arriving at an interpretation of the SPC legislation that is clear and consistent and that provides an appropriate reward for those that experience substantial regulatory delay in getting their patented medicinal products to market in Europe.

## Background

Neurim had obtained a patent for the use of melatonin in the treatment of insomnia. It also obtained a marketing authorisation for the product Circadin, which contains melatonin as the sole active ingredient and which is authorised for the short-term treatment of primary insomnia in certain individuals.

With both a patent "protecting" the active ingredient melatonin and an authorisation for a medicinal product containing that active ingredient, Neurim applied for an SPC in the UK that would enable it to block generic competition for Circadin for up to five years after patent expiry.

In arguing that its SPC should be granted, Neurim pointed to the regulatory delay (over 15 years from the filing date of their patent) that it had experienced in bringing Circadin to the market. It also pointed to statements of principle made in connection with the original SPC legislation that it believed supported its view that Circadin was precisely the kind of product that should benefit from supplementary protection.

The difficulty for Neurim was that there were two veterinary medicinal products that had been authorised in Europe (including one in the UK) that contained melatonin as the sole active ingredient. Although those products were authorised for uses that were unrelated to insomnia, the SPC legislation, as interpreted by the earlier case law of the CJEU (which was at that time called the European Court of Justice), appeared to lead to the inevitable conclusion that Neurim would not be entitled to obtain an SPC (or at least not an SPC having a useful term).

For this reason, the UK Intellectual Property Office rejected Neurim's SPC application, as did the UK High Court (upon appeal from the UKIPO). However, Neurim's arguments had a more sympathetic hearing at the Court of Appeal, where Lord Justice Jacob felt that a system that denied Neurim an SPC would not be fit for purpose.

The Court of Appeal therefore needed the CJEU to clarify:

(a) whether Neurim could be granted an SPC in the UK regardless of the existence of an earlier UK authorisation for the same active ingredient for a different use (which earlier use does not fall within the scope of Neurim's patent); and, if it could,
(b) whether earlier UK and European authorisations could be ignored for the purposes of calculating the term of that SPC.

A total of five questions were submitted to the CJEU, with at least the first two being drafted in such a way as to not rely upon the specific factual situation in Neurim (where there were earlier authorisations of veterinary medicinal products followed by a later authorisation for a human medicinal product for a different use).

## The highlights

From the point of view of the innovative pharmaceutical industry, there are two main positive aspects to the CJEU's decision.

Firstly, it appears that Neurim will be granted an SPC. This represents a new (and more liberal) interpretation of the SPC legislation and gives fresh hope to at least those companies that find new uses for previously authorised active ingredients.

Secondly, the decision significantly diverges from the opinion of the advocate general in a way that, through (arguably) focusing upon the need for a new therapeutic application/indication of an active substance, may just avoid some of the undesirable side-effects that could have arisen from strict adherence to the proposals in that opinion[3].

## To be continued...

Despite the positive aspects mentioned above, there will nevertheless be some who will be disappointed that the CJEU did not answer Neurim's broadest question. For the reasons discussed below, this leaves open a number of important questions that are likely to be referred to the CJEU in future cases.

### How broadly will *Neurim* be applied?

Instead of answering the question asked by the UK Court of Appeal, the CJEU answered its own, reformulated question (which was an amended version of a combination of two of Neurim's questions). Importantly, this reformulation excluded a key consideration in Neurim's question (the earlier use not falling within the scope of protection of the patent relied upon) but included other considerations that are specific to the factual scenario in the Neurim case.

The general stipulations that can be deduced from CJEU's first answer are that, where there is an earlier authorisation for the same active ingredient, an SPC can be granted if:

(i) the marketing authorisation relied upon in the SPC application is for a *"different application"* of the active ingredient; and
(ii) that *"different application"* falls within the limits of protection conferred by the patent relied upon in the SPC application.

However, for various reasons, it is difficult to know how broadly these general stipulations can be applied.



 

Firstly, stipulations (i) and (ii) above are only mentioned in the context of there being an earlier authorisation for a *veterinary* medicinal product. Thus, it is not completely clear how the ruling should be applied in situations where there is an earlier authorisation for a human medicinal product (although a paragraph in the CJEU's reasoning for the decision could be argued to suggest that the result should be no different).

Moreover, stipulation (ii) above is something that will *always* be the case if any SPC that is granted is to have a useful protective scope. Thus, only stipulation (i) above would appear to have any teeth.

This could imply that an SPC will now always be granted if there is a new authorisation for a new, patent-protected *"application"* of an active ingredient. However, it is not yet certain if there are other factors that are not explicitly stated in the CJEU's answer that could make it more difficult than this to obtain a further SPC for a previously authorised active ingredient. For example, some comments in the CJEU's decision could be argued to imply that the patent relied upon in the SPC application must be *"new"* (though what this could mean is also open to interpretation).

### Does *Neurim* overrule certain earlier decisions?

The CJEU's first answer raises some important questions in connection with whether certain of the CJEU's earlier decisions are still valid. This applies particularly to the CJEU's decisions in *Pharmacia Italia* (C-31/03) and *Yissum* (C-202/05), which were two of the three key cases that caused the UKIPO and the UK High Court to refuse Neurim's SPC application.

In common with the earlier opinion of the advocate general, the CJEU's decision in *Neurim* does not mention either *Pharmacia Italia* or *Yissum*. Moreover, although the CJEU's decisions in *Pharmacia Italia* and *Yissum* led to SPC applications being refused, there now appear to be clear reasons to believe that those SPC applications might have been found allowable under the logic of the *Neurim* decision. The same applies to decisions in two further cases, namely *Synthon v Merz* (C-195/09) and *Generics v Synaptech* (C-427/09), which led to the invalidation of certain SPCs.

The CJEU could perhaps point out that *Pharmacia Italia*, *Yissum*, *Synthon v Merz* and *Generics v Synaptech* were decisions on different provisions of the SPC legislation. Although this is true, it is also true that all of those cases might have reached different conclusions if the logic of *Neurim* were applied.

For example, the facts in *Yissum* differ from those in *Neurim* in only one relevant respect, namely that there were earlier authorisations for human (as opposed to veterinary) medicinal products. As discussed above, there is reason to believe that this would have made no difference to the conclusion reached in *Neurim*.

Thus, whilst the decision in *Neurim* neatly side-steps the earlier case law of the CJEU, it is nevertheless extremely difficult to make sense of the decision in the context of that earlier case law (and the general aims and objectives of the SPC legislation).

### Does *Neurim* change the interpretation of other provisions?

The decision in *Neurim* relates specifically to the interpretation of provisions of the SPC legislation (Articles 3(d) and 13(1)) where it is important to determine what the *"first authorisation"* is of an active ingredient.

However, there is another provision of the legislation (Article 3(c)) that prevents multiple SPCs for the same active ingredient being awarded to the same applicant. Although the CJEU has ruled that an earlier marketing authorisation can sometimes be ignored, the same does not necessarily hold true for an earlier SPC based upon that authorisation.

Answering the question of whether an earlier SPC can also be ignored is particularly tricky in view of the fact that the CJEU has not explicitly overruled the decision in *Yissum*. This has the consequence that the logic of the CJEU's decision in *Neurim* cannot automatically be applied to the interpretation of Article 3(c).

Thus, not only is it unclear how broadly the decision in *Neurim* can be applied, but it is also unclear to whom it applies.

### What term will be granted to a *Neurim*-type SPC?

In interpreting Article 13(1) of the SPC legislation (the provision that governs the term of an SPC), the CJEU decided that the term of an SPC is set by:

> *the marketing authorisation of* ***a product*** *which comes within the limits of protection of the protection conferred by the basic patent relied upon (emphasis added).*

This answer is hard to understand for various reasons, but primarily because it seems to be inconsistent with the CJEU's own reasoning.

The SPC legislation states that the term *"product"* means *"the active ingredient or combination of active ingredients of a medicinal product"*. However, inserting this definition into the CJEU's second answer leads to a statement that is at odds with the CJEU's reasoning. That is, it would lead to the same term *("first authorisation")* being interpreted differently in different provisions of the legislation. In its reasoning, the CJEU is at pains to point out that this should not happen.

Of course, the CJEU could have chosen to explain that the relevant authorisation under Article 13(1) is the first authorisation (in the European Economic Area) for the *application* of the *"product"* (active ingredient) that falls within the scope of the patent relied upon for the SPC application.

However, it did not do this, and so it would be dangerous to assume that this is what the CJEU actually meant.

A degree of clarification on this issue will hopefully be gained when the UK Court of Appeal issues its decision based upon the CJEU's judgement.

## The future

Various further questions from national courts are now almost certain to be referred to the CJEU, if only to obtain clarification as to what the decision in *Neurim* actually means. In this respect, although the *Neurim* decision has improved the situation for the innovative pharmaceutical industry, the war is still far from won.

The hardest battle yet to be faced relates to how to the CJEU can reach a clear and consistent interpretation of the SPC legislation that provides an appropriate reward for innovators.

Although the current SPC legislation has survived the battle in *Neurim*, it is still perfectly possible that the legislation itself may become a casualty of future battles, especially if the CJEU fails to square the circle between *Neurim* and earlier case law such as *Yissum*.



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