Review of Recent SPC Case Law in the UK – Little Appetite for Divergence from the EU

The UK courts have been reasonably active in the SPC field recently, with two cases in particular catching our attention.

In the first case, the High Court of England and Wales heard an appeal from a decision of the UKIPO to refuse Merck Serono's SPC application for cladribine, which turned on the applicability in the UK of the CJEU judgment in *Santen* (C-673/18). As is explained in more detail below, the Court held as expected that *Santen* applies in the UK *ex tunc*. Although a further appeal to a higher court is possible in principle, it is difficult to see how the Court of Appeal or Supreme Court would find differently, unless they choose to exercise their authority to deviate from CJEU case law established pre-Brexit. Certain judicial comments in the following case suggests that they may be unwilling to do so.

In the second case, the Court of Appeal heard an appeal from a decision of the High Court affirming the UKIPO's refusal of Newron's SPC application for a so-called "loose" combination of safinamide, levodopa and a peripheral decarboxylase inhibitor (PDI). The Court of Appeal confirmed the earlier refusals on the basis that only safinamide is the authorised product within the meaning of the SPC regulation. This is consistent with the approach to "loose" combinations that has been taken in the UK to date, based on earlier UK and CJEU case law. Given that the CJEU case law was quoted with approval, this may suggest a relatively small appetite on the part of the UK courts to deviate from established EU law.

Merck Serono v Comptroller General of Patents – [2023] EWHC 3240 (Ch)

This case concerns Article 3(d) of the SPC Regulation, which requires an application for SPC to be based on the first authorisation to place a drug on the market as a medicinal product (the earliest marketing authorisation). On 9 July 2020, the CJEU issued its landmark judgment in *Santen* (C-673/18 – discussed in detail in our briefing note here), in which the court concluded that:

"*Article 3(d) … must be interpreted as meaning that a marketing authorisation cannot be considered to be the first marketing authorisation, for the purpose of that provision, where it covers a new therapeutic application of an active ingredient, or of a combination of active ingredients, and that active ingredient or combination has already been the subject of a marketing authorisation for a different therapeutic application.*"

The *Santen* decision therefore effectively prohibits grant of SPCs in the EU based on a marketing authorisation for a new medical use or new formulation of an active ingredient (or combination of active ingredients) that has previously been authorised for other therapeutic applications. *Santen* explicitly overturned the earlier decision of the CJEU in *Neurim* (C-130/11), which had held that SPCs may be based on a subsequent marketing authorisation provided there was a suitably limited patent claim.

The SPC application (SPC/GB18/007) at issue in this case was filed by Merck Serono (Merck) for the product cladribine, based on the authorisation of MAVENCLAD® for treatment of highly active relapsing multiple sclerosis. The application was refused based on *Santen* because the authorisation of MAVENCLAD® was not the first for the active ingredient, cladribine. The medicinal products LEUSTAT® and LITAK® containing cladribine had already been authorised in 1995 and 2004 for the treatment of hairy cell leukaemia. However, because the SPC application was filed after *Neurim*, but before *Santen*, Merck argued that compliance with Article 3(d) should be assessed based on *Neurim* and not *Santen*.

In the hearing before the UKIPO, Merck argued that the *Santen* should be applied *ex nunc*, and therefore the SPC application should be allowable in light of Neurim. Merck cited *Denkavit Italiana* (C-61/79) and *Dansk Industri* (C-441/14) in an attempt to demonstrate that in exceptional circumstances a temporal restriction can be applied to a CJEU judgment such that it applies *ex nunc*, which circumstances may include the legitimate expectations of a party and a need for legal certainty. Merck argued that their decision to revive a costly clinical development programme of MAVENCLAD® was a direct consequence of their legitimate expectation following *Neurim* that they would be entitled to an SPC.

The Hearing Officer disagreed, deciding that *Santen* applies *ex tunc* because the CJEU made no mention of a temporal restriction in *Santen*, nor is there any CJEU case law relevant to SPCs for establishing such a restriction. The Hearing Officer noted that according to *Denkavit Italiana* it is for the CJEU alone to decide whether its judgments are subject to temporal restriction, and it is clear that they did not do so in *Santen*. Rather, it was deemed clear that the CJEU explicitly intended to overrule *Neurim* in its entirety. The Hearing Officer also expressed doubts that Merck's decision to pursue clinical development of MAVENCLAD® was a consequence of any expectation arising from *Neurim*, given phase III clinical trials had begun prior to *Neurim*.

Merck appealed this decision to the Patents Court on three grounds. The second and third grounds of appeal were addressed first to simplify proceedings. We have followed the same approach below.

The second ground argued that Merck's application could be distinguished on its facts compared to *Santen* and hence that *Santen* should be ignored. The case heard in *Santen* concerned a further authorisation of a new dosage form for the same

therapeutic use of the same active ingredient as had already been authorised. Merck argued that their application differed in that it concerned an entirely new therapeutic use. The Court dismissed this argument, noting that the *Santen* judgment is expressed as general guidance for the interpretation of Article 3(d) and so its application is not dependent on the facts.

The third ground was that *Santen* was wrongly decided and should be set aside. Merck acknowledged, and the Court confirmed, that under the EU Withdrawal Act 2018 only the Court of Appeal or Supreme Court are permitted to depart from a CJEU judgment established pre-Brexit. Merck therefore reserved this ground for a possible appeal to higher court.

Returning to the first ground of appeal, Merck submitted two strands of argument. Firstly, Merck argued that *Santen* should have an *ex nunc* effect rather than *ex tunc*. Secondly, its own alleged legitimate expectations at the time of filing the SPC application constitute exceptional circumstances, such that the present application should be assessed in light of *Neurim* rather than *Santen*.

The first strand was rejected for essentially the same reasons as decided by the Hearing Officer. For the second strand, referring to *Dansk Industri*, the judge confirmed that a legitimate expectation cannot override the *ex tunc* effect of a judgment. Furthermore, by referring to *Denkavit Italiana*, the judge highlighted that when a judgment would have *"serious effects…, as regards the past, on legal relationships established in good faith"*, it is for the deciding Court alone to decide whether an *ex nunc* effect (or any other temporal restriction) should be imposed. The judge deemed it clear that the CJEU had not intended to impose any such temporal restriction in *Santen*. Thus Merck's second strand of argument was not found persuasive and Merck's first ground of appeal was dismissed.

Notably, the judge also envisaged issues with examining SPC applications if Merck were correct, since it would require any assessment of validity to consider at least to some degree the legitimate expectations of the applicant, as opposed to the statutory provisions of the SPC Regulation interpreted through established case law. The Court concluded by dismissing all of Merck's grounds of appeal, agreeing with the Hearing Officer that Merck's SPC application does not satisfy the requirements of Article 3(d) of the SPC Regulation.

In our view, the conclusions reached by the UKIPO and the Patents Court are not surprising. It had been generally accepted that *Santen* was intended to overrule *Neurim* in its entirety with no temporal restriction, and therefore it must have an *ex tunc* effect. Given this context it will be interesting to see whether this case is appealed to a higher court, particularly given Merck's reservation of its third ground of appeal. However, we feel that the second case discussed below suggests that the Court of Appeal and Supreme Court may be unwilling to exercise their authority to deviate from the established CJEU case law on this point.

Newron v Comptroller General of Patents – [2024] EWCA Civ 128

SPCs directed to combinations of active ingredients are currently a hot topic in SPC law with referrals pending before the CJEU under Articles 3(a) and 3(c) of the SPC regulation. See our news items on these referrals here, here and here for more detail.

We also reported last year on the UKIPO decision in O/711/22 (*Roche Glycart*), in which an application for a combination SPC was refused for failure to comply with Article 3(b) of the SPC regulation. Article 3(b) of the regulation requires that *"a valid authorisation to place the product on the market as a medicinal product has been granted"*. In O/711/22, the marketing authorisation in question was held not to "place the combination therapy on the market". See our discussion of this case here for more detail.

The present case concerns Newron's SPC application for a combination of safinamide, levodopa and a peripheral decarboxylase inhibitor (PDI), based on the marketing authorisation for XADAGO®. The definition of the authorised product XADAGO® is provided in Section 2 of the SmPC as "safinamide methanesulfonate" equivalent to either 50 mg or 100 mg safinamide. No other active ingredients are explicitly recited in the product definition. However, section 4 of the SmPC (which relates to the "clinical particulars" of use of the product) discusses add-on therapy of safinamide and levodopa. It does not reference PDI explicitly, but references to a PDI can be found elsewhere in the marketing authorisation documents.

This fact pattern is similar to that in the *Roche Glycart* decision, and therefore the UKIPO hearing officer refused the application under Article 3(b) for similar reasons (decision O/1053/22). Specifically, the hearing officer held that:

- The authorisation for XADAGO® was for safinamide alone, and not a combination product; and
- In any event, the MA does not relate at all to a combination of safinamide with *both* levodopa *and*

Newron appealed the refusal first to the High Court, which concurred with the Hearing Officer ([2023] EWHC 1471 (Ch), and subsequently to the Court of Appeal. The Court of Appeal rejected Newron's appeal and upheld the refusal of the SPC application under Article 3(b).

On appeal, Newron had submitted that a teleological approach should be taken to the definition of "product" and to the effect of Article 3(b), so as not to unfairly prejudice research into so-called "loose" combination products. These are products where two or more drugs are developed for use together in therapy, but are administered (and typically authorised) separately, as opposed to a "fixed" combination product such as a vaccine, where a single authorised product typically contains several active ingredients.

The CJEU decisions in *Medeva* (C-322/10) and *Georgetown* (C-422/10) established that an applicant's SPC application for compound A only is allowable if based on (i) a basic patent directed to compound A, and (ii) an authorisation for a "fixed" combination of A with other active substances, B, C, D etc. If not, the CJEU held that this would be contrary to the principles behind the SPC Regulation of encouraging research into new medicines, because the relevant health authorities often require that a new vaccine product be authorised as a multivalent product (i.e. as A+B+C+D).

The present case in effect represents the inverse situation to *Medeva* and *Georgetown*, with the applicant's SPC application directed to a combination A+B+C based on authorisation of the single ingredient A, which authorisation further identifies that A is to be used in combination with B and C. Newron argued that it would be contrary to the purpose of the SPC Regulation to deny an SPC simply because the product is authorised as a "loose" combination product rather than a "fixed" combination product.

The Court of Appeal disagreed, noting that conceptually the SPC Regulation must provide a balance between various stakeholders, and also that it was intended to be a simple and transparent system to administer. In particular, a "product" is defined in Article 1(b) of the SPC Regulation as *"the active ingredient or combination of active ingredients of a medicinal product"*. The Court noted that the case law of the CJEU speaks to a strict interpretation of this concept, with reference made to *Pharmacia Italia* (C-31/03), *Yissum* (C-202/05) and *Santen* (C-673/18). In particular, it was noted that *Santen* explicitly indicates (at para. 44) that the term "product" is not dependent on the manner in which the product is used, and that the intended use of the medicinal product does not constitute a decisive factor for the grant of the SPC.

The Court of Appeal also observed that this line of CJEU case law is consistent with UK case law, in particular the Patents Court decision in *Yeda v Comptroller General of Patents* ([2010] RPC 29), in which an appeal from the UKIPO's refusal to grant an SPC under similar circumstances to the present case was refused.

The Court of Appeal further observed that examination of SPC applications ought not to require a minute analysis of the authorisation documents in order to determine the identity of the "product". Thus, the fact that the Commission Decision authorising XADAGO® refers only to safinamide, and that the first two sections of the SmPC also only refer to safinamide, should be determinative. Although the only therapeutic use of safinamide that is described in the SmPC is combination therapy with levodopa, that information was held to relate only to the *use* of the product, and not its identity.

An alternative way to approach the problem, which the Court felt put the matter beyond doubt, was to appreciate that the authorisation of XADAGO® authorises the holder (Newron) to market XADAGO®, i.e. safinamide. It does not authorise the holder to market any other active ingredient on the market, including levodopa or a PDI. To market those active ingredients would require separate authorisation(s).

The appeal was therefore dismissed on the grounds that the authorisation of XADAGO® is solely for safinamide as a "product" within the meaning of the SPC Regulation. Accordingly, it was not necessary for the Court to also reach a decision on the second issue, i.e. whether the authorisation properly referred to a combination therapy involving PDI.

In our view, the outcome here was not particularly surprising given the established UK and EU case law on the topic. However, it is perhaps a little disappointing given that an increasing number of combinations are only available as "loose" rather than "fixed" embodiments, and this does not necessarily reduce the amount of work required for their development. Denying SPC coverage for such combinations may not be entirely consistent with the aims of the SPC Regulation to reward medical research. That being the case, it is interesting to note that not all patent offices around Europe have reached the same conclusion as the UK when examining corresponding SPC applications filed by Newron. Although the Swedish patent office refused Newron's SPC application, the French, Danish, Dutch and Spanish patent offices have all granted SPCs. Given that Newron still has pending SPC applications in other EU member states, it is possible that we may see a referral to the CJEU to settle the inconsistency in approach. Other applicants pursuing SPCs for "loose" combinations may also seek referral to the CJEU.

Should such a CJEU referral arise, it will be interesting to see how much weight may be given to the resulting judgment by the UK Courts, particularly if the CJEU are more favourable to "loose" combinations. In the present case, the Court of Appeal could in principle have chosen to deviate from the established CJEU case law in such a fashion, but its references to that case law instead largely indicated approval. In particular, the CJEU's earlier *Neurim* judgement is described as containing "difficulties" (para. 21) and it is concluded that "orthodoxy was restored" by *Santen*. Whilst such remarks may indicate only approval of the clarity provided by *Santen*, nonetheless it seems that the Court of Appeal will not go out of its way to deviate from established CJEU case law.

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