News and Views

An unwelcome development for innovators in a key case on SPCs

Summary

On 25 April 2018, Advocate-General (A-G) Wathelet issued his opinion in C-121/17 (*Teva UK and Others*).

C-121/17 is one of three cases currently pending before the Court of Justice of the EU (CJEU) that poses questions regarding the interpretation of a key provision of the legislation governing Supplementary Protection Certificates (SPCs) for medicinal products (Article 3(a) of Regulation 469/2009).

Whilst the final judgement of the CJEU does not always follow the A-G's opinion, it does so in the majority of cases. In this respect, and for the reasons discussed below, the opinion of A-G Wathelet will represent an unwelcome development for innovators.

The Question Posed

The question posed to the CJEU (by the English High Court) in C-121/17 is:

> *What are the criteria for deciding whether "the product is protected by a basic patent in force" in Article 3(a) of Regulation No 469/2009?*

The A-G's Analysis and Conclusions

The A-G's preliminary analysis

A-G Wathelet started by reviewing the prior case law of the CJEU on Article 3(a). The key conclusions he drew from that case law can be summarised as follows.

(a) The CJEU has emphasised the key role played by the claims for the purposes of determining whether a product is "protected" according to Article 3(a).
(b) Protection in the sense of Article 3(a) should be determined by reference to the rules relating to extent of protection (as distinct from rules relating to infringement).
(c) Since patent law is not harmonised at EU level, the extent of protection can only be determined in the light of the non-EU rules governing patents (including Article 69 EPC).
(d) The CJEU has no jurisdiction to interpret Article 69 EPC and therefore cannot provide guidance to national courts on how to determine extent of protection for a patent issued by the EPO.

He then opined that:

- points (b) to (d) above create a tension between two separate legal regimes (i.e. on the one hand, the EU's SPC Regulations and, on the other hand, non-EU laws governing extent of protection); and
- this tension gives rise to difficulties in interpreting Article 3(a).

Assessment of the English court's proposals

The A-G agreed with the English High Court that the fact that a product falls within the extent of protection of a patent is a **necessary but not sufficient condition** for it to be considered "protected" by the patent within the meaning of Article 3(a). This was on the grounds that, in the A-G's view:

> "*merely because a substance might fall within the protection of the claims of a patent under Article 69 of the EPC and the Protocol on its interpretation and the provisions of relevant national law, such as Article 125 of the Patents Act 1977, does not necessarily imply that that substance is a product protected by a patent within the meaning of Article 3(a) of Regulation No 469/2009*".

However, the A-G disagreed with the English High Court on what more is required. That is, whilst the English High Court had proposed an additional step of assessing whether the product embodies *the inventive advance* of the basic patent, the A-G dismissed such a step as being

inconsistent with the CJEU's case law. In this respect, the A-G opined that:

> "*the only means of determining whether a basic patent protects an active ingredient within the meaning of Article 3(a) of Regulation No 469/2009 is to be found only in the wording, or interpretation of the wording, of the claims of the patent granted, and nowhere else*"; and
>
> "*Any other additional criterion, such as the requirement proposed by the referring court that the active ingredient embody 'the inventive advance of the patent' runs the risk, in my view, of giving rise to confusion with the criteria for determining whether an invention is patentable. The question whether a product is protected by a patent within the meaning of Article 3(a) of Regulation No 469/2009 is not the same as the question whether that product is patentable, which is a matter exclusively for national or treaty law*".

<u>The A-G's final conclusions</u>

The A-G identified the "*real question*" in C-121/17 as being:

> *with what degree of specificity or abstraction a product is 'specified' in the claims of the basic patent within the meaning of Article 3(a) of Regulation No 469/2009?*

His proposed answer to this question was:

> "*a product is protected by a patent within the meaning of Article 3(a) of Regulation No 469/2009 if, on the priority date of the patent, it would have been obvious to a person skilled in the art that the active ingredient in question was* ***specifically and precisely identifiable*** *in the wording of the patent claims. In the case of a combination of active ingredients, each active ingredient must be* ***specifically, precisely and individually identifiable*** *in the wording of the patent claims*" (emphasis added).

He also provided the following, additional commentary by way of "clarification":

> "*The name of the active ingredient or its chemical composition does not need to be referred to expressly in the claims, provided that the active ingredient is specifically and precisely identifiable as at the priority date of the patent*"; and
>
> "*If, for example, a substance claimed in a patent consists of several variants, the product protected by the patent within the meaning of Article 3(a) of Regulation No 469/2009 does not necessarily encompass all those variants. As at the priority date of the patent, a variant must be specifically and precisely identifiable in the wording of the patent claims in order for it to be 'a product protected by the patent' within the meaning of Article 3(a) of Regulation No 469/2009*".

In the light of these conclusions, the A-G unsurprisingly expressed the view that claim wording defining a composition "*comprising*" one active ingredient (tenofovir disoproxil, "TD") and "*optionally other therapeutic ingredients*":

- may mean that the combination of TD and another, specific active ingredient (emtricitabine) fell within the extent of protection provided by the claim in question; but
- did <u>not</u> "protect" (in the manner required by Article 3(a)) the combination of TD and emtricitabine.

Commentary

The SPC legislation is completely silent on the issue of how specific the claims of a patent must be in order to "protect" an active ingredient. Further, as is evident from points (b) to (d) above, the CJEU does not have jurisdiction to interpret the provisions that govern the subject matter that is protected by the claims of a patent.

In this context, a striking feature of the A-G's opinion is that none of his key conclusions appear to have basis in (an interpretation of) the wording of relevant legislation. Instead, those conclusions appear to derive solely from analyses of wording used in prior judgements of the CJEU. Whilst this is not necessarily problematic, it does mean that it is uncertain whether the A-G's conclusions are robust (i.e. consistent with the aims and objectives of the SPC legislation).

Aside from the issue of robustness (or otherwise) of the A-G's conclusions, it appears that interpreting Article 3(a) in the manner that he proposes would lead to the following outcomes:

(1) a more stringent "test" for Article 3(a) than is currently applied in many countries (including the UK); but

(2) no greater level of certainty regarding the precise circumstances under which the requirements of Article 3(a) are satisfied.

In other words, innovators would suffer (from the loss of SPC protection for some products) but it would still be difficult in many cases for users of the SPC system to predict with certainty whether Article 3(a) is satisfied.

Point (1)

As confirmed in the decision in *Sandoz v Searle* ([2017] EWHC 987 (Pat)), current practice in the UK deems Article 3(a) to be satisfied if the product for an SPC is "specified" in the claims of a basic patent by means of a Markush (i.e. generic) formula.

The A-G's conclusions, especially combined with his comments in various footnotes, cast doubt upon whether this practice can continue.

For example, as part of his justification for reaching the conclusion that the product must be "*specifically and precisely identifiable*" in the claims, the A-G:

- observes in paragraph 80 that "*It is common knowledge that claims are often (deliberately and ingeniously) drafted in broad, vague, generic and stereotypical terms so that they cover multiple substances*"; and
- in a footnote to that observation, indicates that Markush formulae (as well as functional formulae) provide examples of how claims can be "*broad*".

Further, in footnotes to paragraph 83, and in the context of claims covering several "variants" of a substance, the A-G opines that:

- "*a mere reference in the wording of the claims, such as a reference to a 'diuretic' or a 'non-steroidal anti-inflammatory' is* ***not*** *sufficient*"; and
- "*more than one variant of a chemical substance may be claimed* ***provided that, on the priority date of the patent, each variant is specifically and precisely identifiable***" (emphasis added).

Thus, it would seem that the A-G has in mind a test for satisfying Article 3(a) that is more stringent than that currently applied in the UK.

Point (2)

Whilst the Article 3(a) test proposed by the A-G appears to be relatively strict, it still leaves many questions unanswered. For example:

- If it is not necessary for the claims to identify an individual active ingredient (e.g. by name), what level of generality is permissible before that active ingredient can no longer be said to be "*specifically and precisely identifiable*" in the claims?
- What evidence can be relied upon to show that "*on the priority date of the patent, it would have been obvious to a person skilled in the art*" that the claims identify an active ingredient "*specifically and precisely*"?

In other words, whilst it may resolve the dispute in C-121/17, the test proposed by the A-G appears fundamentally incapable of providing clarity on the precise location of the boundary between those patent claims that satisfy Article 3(a) and those that do not. Indeed, the test proposed by the A-G appears to:

- merely place the boundary in the "grey zone" between two extremes (i.e. between a claim to a single active ingredient and a claim to a very broad genus of actives); but
- provide no hard and fast rules (or principles) that might help users of the SPC system to distinguish between the numerous different types of claim that exist in that "grey zone".

Action Required

It is possible that, in its final decision in C-121/17, the CJEU will not follow the A-G's opinion. In this respect, it is not necessary to take any action at this stage. However, as the A-G's opinion may lead to a significant shift in the manner in which SPC validity is assessed (under Article 3(a)) in many countries, anyone having an interest in specific SPCs (or SPC applications) should pay close attention to the judgement that the CJEU should issue in the next few months – especially in view of the threats and opportunities that it might generate.

Please contact Mike Snodin (at mike.snodin@parkgrove-ip.com) if you would like our advice on these or any other matters.