THE CJEU'S LATEST RULING ON ARTICLE 3(a): CASE CLOSED?

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This article discusses the hotly anticipated ruling from the Court of Justice of the EU (CJEU) in C–121/17 (*Teva UK and Others*),[1] as well as the subsequent judgment of the English High Court[2] that interpreted the CJEU's ruling and applied it to the facts of a dispute over the validity of an SPC directed towards a combination of active ingredients.

In addition to commenting upon the ruling, this article identifies a number of unresolved issues stemming from, and significant problems associated with, the Article 3(a) test established by the CJEU.

Background

The SPC Legislation

In Europe it is not possible for patentees to commercially exploit inventions relating to innovative active ingredients without first obtaining approval (in the form of one or more Marketing Authorisations, 'MAs') from EU and/or national regulatory bodies.

Considerable time and expense are required to obtain the data for, and then approval of, an MA application in Europe. One consequence of this is that, upon the commercialisation of a new medicinal product, the patents protecting the product are typically much closer to their maximum expiry date than are patents protecting newly marketed products in other technical fields. This means that the proprietors of patents protecting pharmaceutical products typically have a much shorter period of effective (that is, on-the-market) patent protection during which to recoup the investment made in bringing a new product to market.

Supplementary Protection Certificates (SPCs) for medicinal products are a form of intellectual property that first became available under EU law in 1993 and are now governed by Regulation 469/2009. In common with Patent Term Extensions (PTEs) in the United States, a key rationale for granting SPCs is to encourage investment in the development of innovative (combinations of) active ingredients by providing an additional period of exclusivity that at least partially offsets the loss of effective term for patents protecting such active ingredients. However, SPCs have a number of unique characteristics that distinguish them from PTEs.

For example, an SPC is not an extension of a patent. Instead, it represents a 'stand-alone' IP right that comes into force only once the patent upon which it is based has expired (at the end of its maximum term).

Further, as defined in Article 4 of Regulation 469/2009, the protection provided by an SPC is limited by all of the following:

(i) the scope of the claims of the patent upon which the SPC is based;

(ii) the active ingredient(s) to which the SPC is directed (that is, active ingredient(s) present in the medicinal product whose Marketing Authorisation supports the SPC); and

(iii) the uses of the specified active ingredient(s) that are authorised prior to expiry of the SPC.

The limited scope of SPC protection is one of the key features included by EU legislators with the aim of providing a balanced system, namely one that 'should be effective and

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1) Judgment issued on 25 July 2018 (see https://bit.ly/2RTSl6B).

2) *Teva UK Ltd and Others v Gilead Sciences Inc* [2018] EWHC 2416 (Pat) (18 September 2018), see https://bit.ly/2NPD2Zh.

appropriate for the industry's requirements without neglecting other substantial aspects of national and Community health policy' (see paragraphs 10 to 15 of the Explanatory Memorandum[3] to Regulation 1768/92).

Other features of the SPC legislation aimed at providing an appropriate balance of interests include:

– provisions aimed at ensuring that SPCs are granted only in respect of *new* medicinal products (for example, Articles 2, 3(c) and 3(d)), such that minor changes to medicinal products do not lead to the issue of a new SPC;[4] and

– Article 13(1), which ensures that all SPCs relating to any one (combination of) active ingredients have a harmonised/capped duration in all EU Member States, which duration is calculated by reference to the first authorisation 'in the Community' for a medicinal product containing the active ingredient(s) in question.[5]

Nevertheless, arguably the most important provision of the SPC legislation is Article 3(a), which neither has unique characteristics nor provides for a balance of interests. Instead, the purpose of that provision is to limit the types of patent that may serve as a basis for an SPC, namely those patents that 'protect' the innovative active ingredient(s) in question.[6]

Prior Case Law on Article 3(a)

Article 3(a) sets out one of the conditions that must be satisfied in order for an SPC to be granted. It requires that, in the country in question and on the date of application, the 'product' for the SPC application (that is, active ingredient(s) of the medicinal product whose authorisation is relied upon under Article 3(b)) must be 'protected by a basic patent in force'.

Despite the apparent simplicity of this requirement, by early 2018:

– the CJEU had 'clarified' the meaning of Article 3(a) in no fewer than five full judgments[7] and three reasoned orders;[8] and

– a further three preliminary references[9] were pending before the CJEU that posed questions relating to the interpretation of Article 3(a).

Consistent themes emerging from the CJEU's prior rulings are as follows.

– The claims of the basic patent play a key role in determining whether a product is 'protected' according to Article 3(a), including in the sense that the product must be 'specified' or 'identified' in the claims.[10]

– 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).[11]

– 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).[12]

– 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.[13]

– An active ingredient which is not identified in the claims by any means (that is, either a structural or functional definition) is not protected.[14]

Nevertheless, as evidenced by the three further references pending by early 2018, such guidance from the CJEU did not enable national courts and patent offices to reach definitive conclusions on how Article 3(a) should be interpreted when applied to cases having different fact patterns.

3) COM(90) 101 final – SYN 255 (Brussels,11 April 1990).

4) Explanatory Memorandum paragraphs 11 and 35.

5) Ibid., paragraphs 14 and 50 to 53.

6) Ibid., paragraphs 29 and 33.

7) C–392/97 (*Farmitalia*), C–322/10 (*Medeva*), C–493/12 (*Eli Lilly and Company*), C–577/13 (*Actavis v Boehringer*) and C–631/13 (*Forsgren*).

8) C–518/10 (*Yeda Research and Development Company and Aventis Holdings*), C–630/10 (*University of Queensland and CSL*) and C–6/11 (*Daiichi Sankyo*).

9) C–121/17 (*Teva UK and Others*), C–650/17 (*Royalty Pharma Collection Trust*) and C–114/18 (*Sandoz and Hexal*).

10) See paragraphs 54 to 57 of the Opinion of Advocate-General Wathelet in C–121/17 and the cited case law.

11) See, for example, paragraph 33 of the CJEU's judgment in C–493/12.

12) See, for example: point 2 and paragraph 27 of the CJEU's judgment in C–392/97; paragraphs 22 and 23 of the CJEU's judgment in C–322/10; paragraphs 31 and 32 of the CJEU's judgment in C–493/12.

13) See, for example, paragraph 40 of the CJEU's judgment in C–493/12.

14) See paragraph 38 of the CJEU's judgment in C–493/12.

The Dispute Underlying C–121/17

One of the cases that was pending before the CJEU in early 2018 related to a dispute over the validity of a UK SPC granted to Gilead (SPC/GB05/041, which was originally granted on 9 October 2008). Gilead's SPC was directed to the combination of tenofovir disoproxil (TD) and emtricitabine (E) and was supported by:

– a Marketing Authorisation (EU/1/04/305) for the medicinal product Truvada®, the active ingredients of which are TD and E; and

– a basic patent (EP 0 915 894 B1), claim 27 of which was directed to a pharmaceutical composition comprising TD 'together with a pharmaceutically acceptable carrier and optionally other therapeutic ingredients'.

Teva UK and others sought to invalidate Gilead's SPC on the grounds that, in their view, the phrase 'other therapeutic ingredients' in claim 27 did not provide sufficient basis to conclude that the basic patent 'protects' the combination of TD and E in the manner required by Article 3(a).

The judge at the English High Court (Arnold J) expressed the view that it was clear from the case law of the CJEU 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). However, Arnold J held that it was not clear from that case law what more was required. Therefore, in order to settle the dispute, he referred the following question to the CJEU (in Case C–121/17):

> *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 CJEU's Ruling

After having heard the parties at an oral hearing and having considered the opinion of Advocate-General Wathelet,[15] the CJEU ruled as follows.

> *Article 3(a) of Regulation No 469/2009 of the European Parliament and of the Council of 6 May 2009, concerning the supplementary protection certificate for medicinal products, must be interpreted as meaning that a product composed of several active ingredients with a combined effect is 'protected by a basic patent in force' within the meaning of that provision where, even if the combination of active ingredients of which that product is composed is not expressly mentioned in the claims of the basic patent, those claims relate necessarily and specifically to that combination. For that purpose, from the point of view of a person skilled in the art and on the basis of the prior art at the filing date or priority date of the basic patent:*
>
> *– the combination of those active ingredients must necessarily, in the light of the description and drawings of that patent, fall under the invention covered by that patent, and*
>
> *– each of those active ingredients must be specifically identifiable, in the light of all the information disclosed by that patent.*

In non-binding comments, the CJEU also stated the following with regard to applying their interpretation of Article 3(a) to the facts of the specific case.

> *54. Thus, as regards the issue whether a claim such as claim 27 of the basic patent in fact covers a combination such as the TD/emtricitabine combination which is the subject of the SPC at issue, it falls to the referring court to determine whether the general expression 'other therapeutic ingredients', associated with the term 'optionally', satisfies the requirement that the claims of the basic patent must relate necessarily and specifically to the product.*
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> *55. In particular, it is for the referring court to ascertain, in accordance with the considerations in paragraphs 47 to 51 above, whether, from the point of*

15) Opinion issued on 25 April 2018 (see https://bit.ly/2QW6peu).

> *view of a person skilled in the art, the combination of active ingredients of which the product which is the subject of the SPC at issue consists necessarily falls under the invention covered by that patent, and whether each of those active ingredients is specifically identifiable on the basis of the prior art at the filing date or priority date of that patent.*
>
> *56. In the present case it is apparent, first, from the information in the order for reference that the description of the basic patent at issue contains no information as to the possibility that the invention covered by that patent could relate specifically to a combined effect of TD and emtricitabine for the purposes of the treatment of HIV. Consequently, it does not seem possible that a person skilled in the art, on the basis of the prior art at the filing date or priority date of that patent, would be able to understand how emtricitabine, in combination with TD, necessarily falls under the invention covered by that patent. The onus is nevertheless on the referring court to check whether such is indeed the case. Secondly, it is also for that court to establish whether emtricitabine is specifically identifiable by that person skilled in the art in the light of all the information contained in that patent, on the basis of the prior art at the filing date or priority date of the patent in question.*

Interpretation by the English High Court

In the light of the 'clarification' provided by the CJEU's judgment, the English High Court resumed its assessment of the validity of Gilead's SPC. In a judgment issued on 18 September 2018, Arnold J interpreted the CJEU's ruling as follows.

– By way of paragraphs 39 to 42 of their ruling, the CJEU 'is saying is that the purpose of the SPC Regulation is to enable the holder of the basic patent to obtain supplementary protection for what the patentee actually invented and not for what the patentee did not invent'.

– The CJEU's key conclusions are set out in paragraphs 43 and 46 of their judgment:

> *… having regard to the objectives pursued by Regulation No 469/2009, the claims cannot allow the holder of the basic patent to enjoy, by obtaining an SPC, protection which goes beyond that granted for the invention covered by that patent. Thus for the purposes of the application of Article 3(a) of that regulation, the claims of the basic patent must be construed in the light of the limits of that invention, as it appears from the description and the drawings of that patent; […]*
>
> *It follows from the above that the subject matter of the protection conferred by an SPC must be restricted to the technical specifications of the invention covered by the basic patent, such as claimed in that patent.*

– The CJEU's conclusions mean that Article 3(a) requires two tests to be satisfied, the first of which (that outlined in paragraphs 47 and 48 of the CJEU's judgment) Arnold J interpreted as meaning that:

> *the product must be one that the skilled person would understand, on the basis of the description and drawings and their common general knowledge, as embodying the technical contribution made by the patent.*

– Further, Arnold J's view was that the second test (that described in paragraphs 49 to 51 of the CJEU's judgment) demanded that:

> *the product must be specifically identifiable by the person skilled in the art in the light of the description and drawings and the prior art, which must mean their common general knowledge, as at the filing date or priority date of the patent, and not merely in the light of information which becomes available later.*

– In Arnold's view, the Article 3(a) test set out in the CJEU's judgment 'represents an elaboration and elucidation of the test which the CJEU propounded in the *Eli Lilly* case'.

Having interpreted the CJEU's judgment in this manner, Arnold J concluded that neither of the tests laid down by the CJEU was satisfied for the SPC in question, which was therefore invalid for not complying with Article 3(a). The grounds for this conclusion were that:

> *the Patent says nothing about the possibility that TD and emtricitabine may be combined to treat HIV. Indeed, it does not even mention emtricitabine. All it says at [0047] is that the claimed compounds may be administered as pharmaceutical formulations with optionally other therapeutic ingredients. Accordingly, as the Court rightly indicates, there is no basis for the skilled person to understand that the combination embodies the technical contribution of the patent; […]*
>
> *In my view it is clear that emtricitabine is not specifically identifiable. Once again, it is not mentioned in the Patent. It is not even a member of a specific class of compounds mentioned in the Patent, whether by reference to their structure or activity, as being suitable for combination with the compounds of the invention. Furthermore, although emtricitabine was known at the priority date, there is no evidence that it was known that emtricitabine was an effective agent for the treatment of HIV in humans, still less that this was common general knowledge to the person skilled in the art to whom the Patent is addressed.*

Commentary

In addition to being the CJEU's ninth ruling on Article 3(a), the judgment in C–121/17 represents the CJEU's second answer to the same question. This is because an *identical* question was posed in C–493/12, *Eli Lilly* (the same question was also posed in C–433/12, *Actavis v Sanofi*, though the CJEU declined to answer it on that occasion).

It is perhaps surprising that the answer provided by the CJEU in C–121/17 differs significantly from its previous answer in C–493/12. However, this merely reflects the tendency of the CJEU to provide 'narrow' answers to questions on SPC law, that is, answers that are closely confined to the facts of each case and that therefore often do not fully clarify matters for cases having materially different facts.

Nevertheless, as suggested by Arnold J, it is arguable that the CJEU's answer in C–121/17 merely represents an 'elaboration and elucidation' of their answer in C–433/12. For example, the two parts of the Article 3(a) test identified by Arnold J in the CJEU's judgment in C–121/17 (see above) could be viewed as a mere 'fleshing out' of the requirement from C–443/12 for the claims to 'relate, implicitly but necessarily and specifically, to the active ingredient in question'.

On the other hand, whilst the benefit of hindsight makes it possible to identify commonalities between the Article 3(a) tests outlined in C–433/12 and C–121/17, the CJEU's ruling in the latter case is likely to lead to changes in practice on Article 3(a) before many national patent offices and courts. This is because the CJEU's ruling in C–433/12 did not result in complete harmonisation of national practices on Article 3(a). Moreover, that ruling was interpreted by at least the English High Court[16] as merely requiring a product comprising a combination of active ingredients to fall within both the extent of protection of the claims and the *focus* of the claims.

Thus, for example, assessments of compliance with Article 3(a) in the United Kingdom for combination products will now need to be adjusted[17] in order to account for the more stringent test established in C–121/17. Expressed in simple terms, that test appears to mean that, for a product composed of several active ingredients with a combined effect, the claims of the basic patent must either expressly mention that product or 'relate necessarily and specifically' to that combination of active ingredients. Further, from the point of view of a person skilled in the art and on the basis of the prior art at the filing date or priority date of the basic patent:

(i) the combination of active ingredients must necessarily, in the light of the description and drawings of that patent, fall under the invention covered by that patent, and

(ii) each of those active ingredients must be specifically identifiable, in the light of all the information disclosed by that patent.

Unresolved Issues

Whilst the CJEU's test has settled the dispute over the validity of Gilead's SPC, many issues remain unresolved. The questions and commentary below illustrate a number of such issues.

16) *Eli Lilly and Co v Human Genome Sciences Inc* [2014] EWHC 2404 (Pat) (18 July 2014).

17) Indeed, the UK Intellectual Property Office has already updated section SPM 3.02.6 of the *Manual of Patent Practice* in view of the test set in C–121/17 (see https://bit.ly/2ylaaDt).

(1) Does the new Article 3(a) test only apply to products 'composed of several active ingredients with a combined effect' ?

The CJEU's tendency to provide narrow rulings makes it difficult determine how much weight to place upon the fact that the binding part of the judgment in C–121/17 is confined to combination products. However, it is noteworthy that the English High Court has previously interpreted[18] the CJEU's ruling in C–433/12 as setting a two-step test for combination products but only one, simple (extent of protection) test for products consisting of a single active ingredient.

(2) How robust is Arnold J's interpretation of the test(s) set by C–121/17?

In Arnold J's view, the (combination) product must both embody 'the technical contribution made by the patent' *and* be 'specifically identifiable by the person skilled in the art … as at the filing date or priority date of the patent'. Whilst the second of these criteria closely mirrors relevant wording from the binding part of the CJEU's judgment, the same is not true for the first. It is therefore possible that other (national) courts will arrive at different interpretations of the CJEU's judgment, in particular the requirement for the claims to relate 'necessarily and specifically' to product.

(3)In cases where the product is not expressly mentioned in the claims, will evidence from persons of ordinary skill in the art be required in order to determine compliance with Article 3(a)?

Given that the test set by the CJEU makes specific reference to 'the point of view of a person skilled in the art', it seems that at least some Article 3(a) disputes before national courts will only be settled through the provision of 'expert' evidence. (Whilst Arnold J did not admit such evidence in the *Teva* case subsequent to the CJEU's ruling, his grounds for doing so were largely procedural.) However, it remains to be seen how this issue will be handled by national patent offices, and especially whether, and to what extent, examiners will feel empowered to challenge evidence submitted by applicants.

(4) How should Article 3(a) now be assessed for claims directed to methods for producing active ingredients?

For claims in process format, a prior ruling from the CJEU[19] indicates that compliance with Article 3(a) requires the product to be 'identified in the wording of the claims' of the basic patent, but that it is irrelevant whether it is possible to obtain the product directly as a result of the claimed process.

The CJEU's prior ruling has been interpreted by some national patent offices[20] to mean that Article 3(a) is satisfied if a product is merely 'identified' in a process claim, and that it is not necessary to additionally determine whether the claimed process is actually capable of producing the product. This interpretation is controversial on two grounds. First, it does not address the question of whether Article 3(a) can be satisfied where the product is defined in generic terms (for example encompassing both embodiments which can be prepared by the claimed process and those, potentially including the authorised active ingredient(s), which cannot). Secondly, it seemingly ignores the fact that the protection conferred by a patent to a process extends only the process itself and the product(s) '*obtained directly*' by that process.[21]

The CJEU has now ruled that a product comprising a combination of active ingredients should '*fall under the invention covered by that patent*'. This stems from the CJEU's conclusion (as set out in paragraph 43 of the judgment) that 'having regard to the objectives pursued by Regulation No 469/2009, the claims cannot allow the holder of the basic patent to enjoy, by obtaining an SPC, protection which goes beyond that granted for the invention covered by that patent'.

As it derives from objectives pursued by the SPC legislation that are broadly applicable, it is clear that this conclusion is intended to apply to all products and all categories of patent claims, *including* claims in process format. In this respect, for patents directed towards processes, it is currently unclear whether the CJEU's ruling in C–121/17 will prompt national patent offices and courts to seek evidence confirming that a product falls 'under the invention' of the patent in question, in the sense of representing a product that can be 'obtained directly' by the claimed process.

(5) Has the CJEU overruled its prior case law indicating that protection in the sense of Article 3(a) should be determined by reference to the rules governing the extent of protection?

Extent of protection does form a (relatively small) part of the Article 3(a) test derived by the CJEU, in the sense that the

18) *Eli Lilly and Co v Human Genome Sciences Inc*, Note 16 above.

19) C–630/10 (*University of Queensland and CSL*).

20) See, for example, the decision of the Hearing Officer at the UK IPO in BL O/552/14 (*Icahn School of Medicine at Mount Sinai*).

21) See, for example, Article 64(2) EPC.

combination of active ingredients must 'fall under the invention covered by that patent'. However, the CJEU has imposed limits on how that test must be performed. For example, consideration of information emerging only after the filing date of the patent is forbidden. Also, the test requires the ingredients not only to fall under the invention but to *necessarily* do so. Thus, there is no part of the test derived by the CJEU that involves determination of extent of protection according to the (non-EU) rules normally applied by national courts.

One example of how extent of protection is determined differently by national courts is provided by the ruling of UK Supreme Court in *Actavis v Eli Lilly*.[22] In that case, the Supreme Court held that 'when considering the extent of such protection, equivalents must be taken into account'. It also devised a test that explicitly considers *post-filing* information in order to determine equivalency.

By its own admission, the CJEU is not competent to interpret the rules governing extent of protection. Therefore, as the Article 3(a) test in C–121/17 does not appear to include any 'normal' determination of extent of protection, it remains to be seen whether the CJEU has overruled its previous conclusion that 'protection' in the sense of Article 3(a) can only be determined by reference to *non*-EU rules.

On the Right Path?

For this author, the ruling in C–121/17 raises a much more fundamental question. That is, in cases having significantly different underlying facts, is the approach adopted by the CJEU capable of providing results that satisfy the objectives of the SPC legislation?

As illustrated by paragraph 29 of the Explanatory Memorandum to the original SPC Regulation, Article 3(a) was intended by the legislators to serve a straightforward purpose, namely to ensure that SPCs are only granted based upon patents that protect innovative active ingredients:

> *The purpose of the expression ' product protected by a patent' is to specify what types of invention may serve as a basis for a certificate.*
>
> *The proposal does not provide for any exclusions. In other words, all pharmaceutical research, provided that it leads to a new invention that can be patented, whether it concerns a new product, a new process for obtaining a new or known product, a new application of a new or known product or a new combination of substances containing a new or known product, must be encouraged, without any discrimination, and must be able to be given a supplementary certificate of protection provided that all of the conditions governing the application of the proposal for a Regulation are fulfilled.*

Conspicuously absent from this explanation of the purpose of Article 3(a) is any indication that the claims of the patent must relate to the product with any particular degree of specificity. To the contrary, it indicates that SPCs based upon patents to new inventions should be available *without discrimination*.

In this author's view, such observations undermine the basis for the CJEU's conclusion that the (components of the) product must be *specifically* identifiable in the light of the information disclosed by the patent.

The differences between the precise technical features of an active ingredient and the terms used to describe those features in (the claims of) a basic patent can vary enormously. This makes it hard, if not impossible, to provide a simple (and broadly applicable) set of rules for determining whether the protection provided by the patent is sufficiently focused to meet the criterion of *specifically* identifying the active ingredient(s). Whilst the CJEU has endeavoured to devise a test on this point, that test appears to contravene key objectives of the SPC legislation.

First, the test is far from simple. This is because it requires consideration of:

(a) the claims of the patent;

(b) all other disclosures of the patent;

(c) the effective date(s) of the claims that encompass the product (that is, the earliest dates to which those claims are entitled);

(d) all relevant prior art and common general knowledge at the effective date(s); and

(e) the point of view of a person skilled in the art in the light of all of (a) to (d) above.

22) *Actavis UK Limited and others v Eli Lilly and Company* [2017] UKSC 48.

For a provision as fundamental as Article 3(a), establishing such a complex test may well contravene the objective of the SPC legislation to provide 'a simple, transparent system which can easily be applied by the parties concerned'.[23]

Secondly, discounting knowledge gained after the effective date of the claim(s) in question appears to breach the objective to reward, *without any discrimination*, pharmaceutical research that leads to a patented invention.

For example, inventions relating to combinations of active ingredients are often patentable due to surprising effects that arise when ingredients having different modes of action are administered in combination. For such inventions, any combination of ingredients having the appropriate modes of action would embody the inventive concept of the patent. However, because it explicitly forbids consideration of information emerging only after the effective date of the relevant patent claims, the Article 3(a) test formulated by the CJEU would discriminate between:

– those commercial embodiments of the invention that contain only active ingredients known at the effective date of the patent; and

– other commercial embodiments of the invention that, whilst not separately patentable, include an ingredient not known at the effective date of the patent.

Moreover, denying supplementary protection for the latter commercial embodiments could discourage innovators from seeking authorisation for combination products in which an ingredient known at the effective date of the patent is replaced with an improved variant developed only after that date. In other words, the test developed by the CJEU could discourage development of the most effective treatment options, which is a result that could be seen to run counter to the core purpose of the legislation.

From this author's perspective, the above considerations point to the conclusion that the CJEU has gone down the wrong path in arriving at the Article 3(a) test set out in C–121/17. This conclusion is reinforced by pointers in the paragraph 40 of the UK decision regarding factors that may have motivated the courts to arrive at the conclusion that Gilead's SPC was invalid.

> *… Gilead obtained a marketing authorisation in respect of Viread, which contains TDF, on 5 February 2002, less than five years after the application for the Patent was filed. Thus Gilead did not suffer sufficient regulatory delay in exploiting the Patent to warrant the grant of an SPC in respect of Viread. Moreover, although Gilead applied for and was granted a patent for the combination in Truvada, that patent was revoked by the Opposition Division of the European Patent Office and Gilead's appeal against that decision was dismissed. Thus Gilead made no invention in devising the combination which warranted the grant of a patent, let alone an SPC.*

In essence, it appears that the main motivating factor was the court's view that the combination of TD and E:

– did not represent an independent invention over TD alone; and therefore

– was not entitled to supplementary protection having a longer duration than the (zero) term to which TD alone would have been entitled (based upon the same patent).

In this context, it is important to note that these motivations have *nothing whatsoever* to do with the issue of whether the claims of Gilead's patent 'protected' the combination of TD and E, in the sense of *specifically* identifying the components of that combination. Put another way, Gilead's SPC appears to have been invalidated on grounds that:

– are inappropriate, that is, do not bear any relation to the underlying reasons for objection; and

– could have easily been circumvented (for example by specifically identifying TD and E in the patent claims) in a manner that would not have removed those underlying reasons.

23) See paragraph 16 of the Explanatory Memorandum to Regulation 1768/92.

What Next?

At the time of writing, two further cases on Article 3(a) remain pending before the CJEU. In both cases, C–650/17 (*Royalty Pharma Collection Trust*)[24] and C–114/18 (*Sandoz and Hexal*),[25] each of the SPCs involved is directed towards an individual active ingredient. Thus, the rulings in those cases are likely to provide more insights with respect to at least question (1) above.

However, it remains to be seen whether concerns such as those outlined above will prompt the CJEU to change course, for example by identifying a different solution that does not contravene key objectives of the SPC legislation (and that might provide a more appropriate and effective solution to any perceived problems of 'unjustified' SPC term).

On the other hand, one thing seems certain, namely that it will be some time yet before the CJEU receives its last ever preliminary reference posing questions on the interpretation of Article 3(a). This means that the answer to the question posed in the title of this article is a firm 'no'.

24) See https://bit.ly/2PgSwdT.

25) See https://bit.ly/2R2RZcE.