Reports of Cases

OPINION OF ADVOCATE GENERAL
HOGAN
delivered on 11 September 2019[1]

Joined Cases C-650/17 and C-114/18

Royalty Pharma Collection Trust
joined party
Deutsches Patent- und Markenamt
(Request for a preliminary ruling from the Bundespatentgericht (Germany))
and
Sandoz Ltd,
Hexal AG
v
G.D. Searle LLC,
Janssen Sciences Ireland

(Request for a preliminary ruling from the Court of Appeal (England & Wales) (Civil Division))

(Reference for a preliminary ruling — Medicinal products for human use — Supplementary protection certificate — Regulation (EC) No 469/2009 — Article 3(a) — Conditions for obtaining — Concept of a 'product protected by a basic patent in force' — Criteria for assessment — Functional claims — *Markush* formulae)

I. Introduction

1. These requests for a preliminary ruling once again raise the issue of the interpretation of Article 3(a) of Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products and more specifically the meaning of the terms 'the product is protected by a basic patent in force' contained in that provision.[2]

2. A supplementary protection certificate ('SPC') is designed to re-establish a sufficient period of effective protection of the basic patent by permitting the holder to enjoy an additional period of exclusivity on the expiry of that patent, which is intended to compensate, at least in part, for the delay to the commercial exploitation of his or her invention by reason of the time which has elapsed between the date on which the application for the patent was filed and the date on which the first marketing authorisation ('MA') in the European Union was granted.[3]

1 Original language: English.

2 OJ 2009 L 152, p. 1.

3 Judgment of 12 December 2013, *Eli Lilly and Company* (C-493/12, EU:C:2013:835, paragraph 41). See also judgment of 25 July 2018, *Teva UK and Others* (C-121/17, EU:C:2018:585, paragraph 39).

3. The request in case C-650/17, which was lodged at the registry of the Court on 21 November 2017, has been made in proceedings between Royalty Pharma Collection Trust ('Royalty Pharma') and Deutsches Patent- und Markenamt (German Patent and Trade Marks Office) ('DPMA') in relation to the latter's refusal to grant an SPC for Sitagliptin, a medicinal product for the treatment of diabetes mellitus.

4. The request in Case C-114/18, which was lodged at the registry of the Court on 14 February 2018, has been made in proceedings between Sandoz Ltd ('Sandoz') and Hexal AG ('Hexal'), on the one hand, and G.D. Searle LLC ('Searle') and Janssen Sciences Ireland ('JSI'), on the other, concerning the validity of an SPC granted to Searle for Darunavir, a medicinal product for the treatment of human immunodeficiency virus ('HIV').

5. While I do not feel called upon either by the referring courts or, indeed, for that matter by the parties who lodged pleadings in the present cases to revisit the general principles referred to by the Grand Chamber of the Court in the judgment of 25 July 2018, *Teva UK and Others* (C-121/17, EU:C:2018:585), these cases nonetheless provide the Court with a further opportunity to clarify aspects of Article 3(a) of Regulation No 469/2009 in the wake of that judgment. This is particularly true in relation to patent claims which either are functional in nature or in the form of what are sometimes described as *Markush* formulae.

6. These cases will also enable the Court to indicate whether the concept of 'core inventive advance' is a relevant and applicable concept in this context and whether the judgment of 25 July 2018, *Teva UK and Others* (C-121/17, EU:C:2018:585) is specific to combination products comprised of a number of active ingredients and thus may or may not also be applied to products consisting of a single active ingredient. The Court, moreover, may consider it appropriate to clarify further the question as to what is the relevant date for assessing whether a product is protected by a basic patent in force pursuant to Article 3(a) of Regulation No 469/2009.

7. Before examining these issues it is necessary first to set out the relevant legislative provisions.

II. Legal context

A. European Patent Convention

8. Under the heading 'Extent of protection', Article 69 of the Convention on the Grant of European Patents, signed in Munich on 5 October 1973, in the version applicable at the material time in the main proceedings ('the EPC'), stipulates as follows:

'(1) The extent of the protection conferred by a European patent or a European patent application shall be determined by the claims. Nevertheless, the description and drawings shall be used to interpret the claims.

(2) For the period up to grant of the European patent, the extent of the protection conferred by the European patent application shall be determined by the claims contained in the application as published. However, the European patent as granted or as amended in opposition, limitation or revocation proceedings shall determine retroactively the protection conferred by the application, in so far as such protection is not thereby extended.'

9. Article 1 of the Protocol on the Interpretation of Article 69 of the EPC, which forms an integral part of the convention pursuant to Article 164(1) thereof, provides as follows:

'Article 69 should not be interpreted as meaning that the extent of the protection conferred by a European patent is to be understood as that defined by the strict, literal meaning of the wording used in the claims, the description and drawings being employed only for the purpose of resolving an ambiguity found in the claims. Nor should it be taken to mean that the claims serve only as a guideline and that the actual protection conferred may extend to what, from a consideration of the description and drawings by a person skilled in the art, the patent proprietor has contemplated. On the contrary, it is to be interpreted as defining a position between these extremes which combines a fair protection for the patent proprietor with a reasonable degree of legal certainty for third parties.'

B. European Union law

10. Recitals 3 to 5, 7, 9 and 10 of Regulation No 469/2009 state as follows:

'(3) Medicinal products, especially those that are the result of long, costly research will not continue to be developed in the [Union] and in Europe unless they are covered by favourable rules that provide for sufficient protection to encourage such research.

(4) At the moment the period that elapses between the filing of an application for a patent for a new medicinal product and authorisation to place the medicinal product on the market makes the period of effective protection under the patent insufficient to cover the investment put into the research.

(5) This situation leads to a lack of protection which penalises pharmaceutical research.

…

(7) A uniform solution at [Union] level should be provided for, thereby preventing the heterogeneous development of national laws leading to further disparities which would be likely to create obstacles to the free movement of medicinal products within the [Union] and thus directly affect the functioning of the internal market.

…

(9) The duration of the protection granted by the [SPC] should be such as to provide adequate effective protection. For this purpose, the holder of both a patent and a[n SPC] should be able to enjoy an overall maximum of 15 years of exclusivity from the time the medicinal product in question first obtains authorisation to be placed on the market in the [Union].

(10) All the interests at stake, including those of public health, in a sector as complex and sensitive as the pharmaceutical sector should nevertheless be taken into account. For this purpose, the [SPC] cannot be granted for a period exceeding five years. The protection granted should furthermore be strictly confined to the product which obtained authorisation to be placed on the market as a medicinal product.'

11. Article 1 of that Regulation provides:

'For the purposes of this Regulation, the following definitions shall apply:

(a) "medicinal product" means any substance or combination of substances presented for treating or preventing disease in human beings or animals and any substance or combination of substances which may be administered to human beings or animals with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in humans or in animals;

(b) "product" means the active ingredient or combination of active ingredients of a medicinal product;

(c) "basic patent" means a patent which protects a product as such, a process to obtain a product or an application of a product, and which is designated by its holder for the purpose of the procedure for grant of a[n SPC];

…'

12. Article 3 of that Regulation, entitled 'Conditions for obtaining a[n SPC]', provides as follows:

'A[n SPC] shall be granted if, in the Member State in which the application referred to in Article 7 is submitted and at the date of that application:

(a) the product is protected by a basic patent in force;

(b) a valid authorisation to place the product on the market as a medicinal product has been granted …;

(c) the product has not already been the subject of a[n SPC];

(d) the authorisation referred to in point (b) is the first authorisation to place the product on the market as a medicinal product.'

III. The main proceedings and the questions referred for a preliminary reference

A. Case C-650/17

13. Royalty Pharma is the proprietor of European Patent EP 1 084 705 (DE 597 13 097), which was filed on 24 April 1997 and granted on 25 June 2014 and has now lapsed. The patent concerns a method for lowering blood glucose levels in mammals through the administration of 'DP IV inhibitors'. The use of this group of active ingredients is intended to inhibit the enzyme dipeptidyl peptidase IV, as a result of which it is possible to regulate the blood sugar levels of diabetes mellitus patients. Sitagliptin, which belongs to this class of active ingredients, was developed after the filing date of the basic patent by a licensee which obtained a patent for it, on the basis of which it was granted an SPC. [4]

4 See in that regard, judgment of 8 December 2011, *Merck Sharp & Dohme Corporation* (C-125/10, EU:C:2011:812).

14. On 17 December 2014, Royalty Pharma applied to the DPMA, on the basis of the patent in question in judgment of 8 December 2011, *Merck Sharp & Dohme Corporation* (C-125/10, EU:C:2011:812), for the grant of an SPC for the product '*sitagliptin in all forms protected by the basic patent*', and in the alternative for '*sitagliptin, in particular sitagliptin phosphate monohydrate*'. In that regard, Royalty Pharma relied on the authorisation to place a medicinal product on the market granted for the medicinal product Januvia (EU/1/07/383/001-018) by the European Medicines Agency (EMA) on 21 March 2007.

15. By decision of 12 April 2017, the DPMA rejected that application on the basis that Article 3(a) of Regulation No 469/2009 was not fulfilled. The DPMA stated that although the product satisfied the functional definition of the basic patent as a DP IV inhibitor, the basic patent did not contain any specific disclosure of sitagliptin, with the result that the precise active ingredient was not provided to the expert. According to the DPMA, the subject matter of protection of the basic patent did not correspond to the subsequently developed medicinal product which was granted authorisation to be placed on the market, on which the contested application for the grant of an SPC was based. The DPMA thus considered that it would be contrary to the objectives of Regulation No 469/2009 to grant an SPC for a product which was not provided for in the basic patent.

16. Royalty Pharma lodged an appeal against that decision before the Bundespatentgericht (Federal Patent Court, Germany). It claims in particular that the contested decision of the DPMA does not take sufficient account of the fact that the contribution and the core of the patented invention does not consist in the use of specific compounds, but in the utilisation of DP IV inhibitors to treat diabetes mellitus in general. Sitagliptin is one such DP IV inhibitor and it therefore satisfies the functional definition of the class of active ingredients in claim 2 of the basic patent. The active ingredient sitagliptin is also authorised for the treatment of diabetes mellitus. Royalty Pharma accepts that it is true that the product was not disclosed in individualised form in the basic patent, but was developed only after the filing date of the basic patent. However, it considers that the requirements set out by the Court regarding the conditions for the grant of an SPC under Article 3(a) of Regulation No 469/2009 should be considered as having been met. The judgment of 24 November 2011, *Medeva* (C-322/10, EU:C:2011:773) does not suggest that the Court considers it necessary, in respect of Article 3(a) of Regulation No 469/2009, for the active ingredient in question to have been indicated in individualised form in the claim, for example by giving the chemical name or the structure of the substance. When the Court held in its judgment of 12 December 2013, *Eli Lilly and Company* (C-493/12, EU:C:2013:835) that the use of a functional characterisation of the authorised product in the claim of a basic patent was possible in principle and that a structural definition was not necessary, it also made clear that it was not necessary to mention the product in individualised form in the claims of the basic patent.

17. Furthermore, Royalty Pharma maintains that in the judgments of 12 December 2013, *Actavis Group PTC and Actavis UK* (C-443/12, EU:C:2013:833) and of 12 March 2015, *Actavis Group PTC and Actavis UK* (C-577/13, EU:C:2015:165), the Court stressed the importance of the core of the inventive conception. Adopting this approach, the concept of 'inventive advance' was applied, for example, by the High Court of Justice (England and Wales), Chancery Division (patents court) when examining Article 3(a) of Regulation No 469/2009, the decisive factor being whether the product in question embodied the inventive conception of the basic patent or whether the product utilised the core of the invention in respect of the market authorisation. According to Royalty Pharma, these conditions are met in the present case. The level of abstraction of the functionally defined generic term 'DP IV inhibitor' should be regarded as sufficiently specific, especially in combination with the category of the claim and the other characteristics, as that generic term covers only active ingredients with the same medical or medicinal properties. The claims therefore relate 'implicitly, necessarily and specifically' to the active ingredient sitagliptin.

18. The Bundespatentgericht (Federal Patent Court) considers that contrary to Royalty Pharma's observations, the 'core inventive advance' is not the relevant test under Article 3(a) of Regulation No 469/2009. It considers that the Court made clear that the active ingredient in question must be specifically identifiable as forming part of the subject matter of protection of the basic patent.[5] Accordingly, the Court also did not adopt the concept of 'inventive advance', which had been proposed by the High Court of Justice (England and Wales), Chancery Division (patents court) in the companion case[6] as a test for the application of Article 3(a) of Regulation No 469/2009 when interpreting that provision, but instead took it into consideration in connection with the interpretation of Article 3(c) of Regulation No 469/2009.[7]

19. In those circumstances, the Bundespatentgericht (Federal Patent Court) decided to stay proceedings and refer the following questions to the Court for a preliminary ruling:

'1. Is a product protected by a basic patent in force pursuant to Article 3(a) of Regulation (EC) No 469/2009 only if it forms part of the subject matter of protection defined by the claims and is thus provided to the expert as a specific embodiment?

2. Is it not therefore sufficient for the requirements of Article 3(a) of Regulation (EC) No 469/2009 if the product in question satisfies the general functional definition of a class of active ingredients in the claims, but is not otherwise indicated in individualised form as a specific embodiment of the method protected by the basic patent?

3. Is a product not protected by a basic patent in force under Article 3(a) of Regulation (EC) No 469/2009 if it is covered by the functional definition in the claims, but was developed only after the filing date of the basic patent as a result of an independent inventive step?'

B. Case C-114/18

20. Searle is the proprietor and JSI is the exclusive licensee of SPC/GB07/038 for a product described in the SPC as 'Darunavir or the pharmaceutically acceptable salt, ester, or prodrug thereof'. The SPC covers a product marketed in Europe under the trade mark 'Prezista'. It is a protease inhibitor used in an anti-retroviral medication for the treatment of the HIV virus and AIDS. The product described in the SPC was protected by European Patent (UK) No 0810 209.

21. The patent is entitled 'Alpha- beta-amino acid hydroxyethylamino sulphonamides useful as retroviral protease inhibitors'. It claims a priority date of 25 August 1992. The specification begins by stating that the invention relates to such inhibitors, and in particular to 'sulfonamide-containing hydroxyethylamine protease inhibitor compounds, a composition and the use thereof for preparing a medicament for inhibiting retroviral proteases such as human immunodeficiency virus (HIV) protease and for treating a retroviral infection e.g. an HIV infection'.

22. The detailed description of the invention, includes a series of paragraphs corresponding to the claims. The form of claim adopted in the present case is based on a structural formula having a fixed element with variable substituents to be chosen from amongst a defined class. Such a formula is known as a *Markush* formula.

5 See judgment of 12 December 2013, *Eli Lilly and Company* (C-493/12, EU:C:2013:835, paragraph 35).

6 *Sandoz Ltd. v. GD Searle LLC* [2017] EWHC 1987 (Pat) at para. 65 (Mr. Justice Arnold).

7 See judgment of 12 December 2013, *Actavis Group PTC and Actavis UK* (C-443/12, EU:C:2013:833, paragraphs 41 et seq.).

23. According to the referring court 'the *Markush* formula enables a large class of compounds to be claimed without the necessity of writing out every single chemical entity. The use of a *Markush* formula in a claim is an appropriate means of claiming an invention where the patentee's invention has involved the discovery of a new technical effect which he predicts will be common to all members of the claimed class provided they share a common structural element … . Claims relying on a *Markush* formula to define their scope are referred to as *Markush* claims. They avoid the necessity of writing out *in extenso* every possible member of the claimed class. A danger with such claims is that they may cover compounds which do not show the claimed activity, and so result in insufficiency under Article 83 of the European Patent Convention (EPC), or equivalent national laws'. … 'The practice of permitting the use of a *Markush* formula in a patent claim had been followed by patent offices worldwide, and in particular by the United Kingdom and the EPO.'

24. The referring court noted that, according to the expert chemist of Sandoz and Hexal, the estimated number of compounds covered by claim 1 of the patent in question in Case C-114/18 was somewhere between 7×10^{135} and 1×10^{377}. By contrast the number of compounds specifically disclosed was approximately 100. It is common ground that there is no reference to Darunavir anywhere in the specification.

25. The SPC expired on 23 February 2019.

26. Sandoz and Hexal brought proceedings before the High Court of Justice (England & Wales), Chancery Division (Patents Court) in order to clear the way for the marketing of a generic Darunavir product prior to the expiry of the SPC. It is common ground, at least for the purposes of these proceedings, that the marketing of Searle's and JSI's product would infringe the SPC, assuming, that is, that the SPC was valid. Sandoz and Hexal contend that it is invalid because, on the true construction of Article 3(a) of Regulation No 469/2009, Darunavir is not a product 'protected' by the patent. There is no challenge to the validity of the patent itself.

27. In a decision dated 3 May 2017, the High Court of Justice (England &Wales), Chancery Division (Patents Court) dismissed those proceedings and decided that Darunavir was a product protected by the patent. Sandoz and Hexal brought an appeal before the Court of Appeal (England & Wales) (Civil Division) [8] in which they contend that for the product to be protected by a basic patent for the purposes of Article 3(a) of Regulation No 469/2009 it must be shown that 'the skilled team would recognise the product as forming a part of the subject matter of the patent by reference to a careful reading of the patent based on the common general knowledge at the priority date.' They submit that, given the large number of compounds covered by the claim that test is not satisfied in the present case. Searle and JSI disagree and contend that Darunavir will be protected by the patent if it is one of the class of products defined and claimed in the claims of the patent by reference to the *Markush* formulae.

28. The Court of Appeal (England & Wales) (Civil Division) observes that in its judgment of 12 December 2013, *Eli Lilly and Company* (C-493/12, EU:C:2013:835, paragraph 39), the Court stated that Article 3(a) of Regulation No 469/2009 does not, in principle, preclude an active ingredient which is given a functional definition in the claims of a patent being regarded as protected by the patent, on condition that it is possible to reach the conclusion on the basis of those claims, interpreted, inter alia, in the light of the description of the invention, as required by Article 69 of the EPC and Protocol on the interpretation of that provision, that the claims *relate, implicitly but necessarily and specifically, to the active ingredient in question*.

8 [2018] EWCA Civ 49.

29. The Court of Appeal (England & Wales) (Civil Division) is unclear in the light of the judgments of 24 November 2011, *Medeva* (C-322/10, EU:C:2011:773) and of 12 December 2013, *Eli Lilly and Company* (C-493/12, EU:C:2013:835) how specifically the claims must focus on the active ingredient. That court considers that in the case of a product with a single active ingredient and a patent with a claim which identifies a number of compounds by means of a *Markush* formula, all of which compounds embody the core inventive technical advance of the patent, the test should be whether the skilled person, considering the claims of the patent on the one hand and the structure of the product in question on the other, would immediately recognise that the active ingredient in question is one of those specified by the formula. That court considered that on the facts of Case C-114/18, the test advanced by it is satisfied.

30. In those circumstances, the Court of Appeal (England & Wales) (Civil Division) decided to stay the proceedings and refer the following question to the Court for a preliminary ruling:

'Where the sole active ingredient the subject of a [SPC issued under Regulation No 469/2009] is a member of a class of compounds which fall within a *Markush* definition in a claim of the patent, all of which class members embody the core inventive technical advance of the patent, is it sufficient for the purposes of Article 3(a) of [Regulation No 469/2009] that the compound would, upon examination of its structure, immediately be recognised as one which falls within the class (and therefore would be protected by the patent as a matter of national patent law) or must the specific substituents necessary to form the active ingredient be amongst those which the skilled person could derive, based on their common general knowledge, from a reading of the patent claims?'

IV. Procedure before the Court

31. By decision of 20 December 2017, Case C-650/17 was suspended until the judgment of 25 July 2018, *Teva UK and Others* (C-121/17, EU:C:2018:585) was delivered.

32. By decision of 1 March 2018, Case C-114/18 was suspended until the judgment of 25 July 2018, *Teva UK and Others* (C-121/17, EU:C:2018:585) was delivered.

33. Following the judgment of 25 July 2018, *Teva UK and Others* (C-121/17, EU:C:2018:585), the Court by letters dated 26 July 2018 asked the Bundespatentgericht (Federal Patent Court) and the Court of Appeal (England & Wales) (Civil Division) whether they wished to maintain their requests for a preliminary ruling in Case C-650/17 and Case C-114/18 respectively.

34. In Case C-650/17, the Bundespatentgericht (Federal Patent Court), by letter dated 21 August 2018, stated that it wished to maintain its request for a preliminary ruling. That court noted that it was not clear whether the concept of 'core inventive advance' was still relevant given that the Court did not adopt the criticism of that concept made by Advocate General Wathelet in his Opinion of 25 April 2018 in *Teva UK and Others* (C-121/17, EU:C:2018:278, point 73).[9]

35. In Case C-114/18, the Court of Appeal (England & Wales) (Civil Division), by letter dated 3 October 2018, stated that it wished to maintain its request for a preliminary ruling. That court noted that the answer given by the Court in its judgment of 25 July 2018, *Teva UK and Others* (C-121/17, EU:C:2018:585) is specific to combination products. The question of that court in case

9 I would note that while the Court of Appeal (England & Wales) (Civil Division) specifically mentions the concept of 'core inventive advance' in the question it referred to this Court, the Bundespatentgericht (Federal Patent Court) did not refer to that concept in its three questions. The latter court, however, referred to that test on a number of occasions in its order of reference.

C-114/18 relates to a basic patent which protects products consisting of a single active ingredient by means of a class formula where all members of the class embody the core inventive concept of the patent. The Court of Appeal (England & Wales) (Civil Division) thus considered that the preliminary reference remains necessary to resolve the dispute in the main proceedings.

36. In Case C-650/17, written observations were submitted by Royalty Pharma, the French and Netherland Governments and the Commission.

37. In Case C-114/18, written observations were submitted by Searle and JSI, Sandoz and Hexal and the Commission.

38. By decision of the President of the Court dated 7 May 2019, Case C-650/117 and Case C-114/18 were joined for the purposes of the hearing and the judgment.

39. Royalty Pharma, Sandoz and Hexal, Searle and JSI, the French Government and the Commission submitted oral observations at the hearing of 27 June 2019.

V. Analysis

40. At paragraph 57 and the operative part of the judgment of 25 July 2018, *Teva UK and Others* (C-121/17, EU:C:2018:585), the Court held that 'Article 3(a) of Regulation No 469/2009 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.'[10]

41. Thus where an active ingredient is not expressly mentioned in the claims of a basic patent, the judgment of 25 July 2018, *Teva UK and Others* (C-121/17, EU:C:2018:585) lays down a test comprising two parts, both of which must be satisfied. Moreover, in its judgment, the Court made it clear that while the objective of the SPC is to re-establish a sufficient period of effective protection of the basic patent by permitting the holder to enjoy an additional period of exclusivity on the expiry of that patentit is not the purpose of the SPC to extend the protection conferred by that patent beyond the invention which the patent covers.[11]

10 Emphasis added. It is settled case-law that for the purpose of determining whether a product is 'protected by a basic patent in force' within the meaning of Article 3(a) of Regulation No 469/2009, recourse may only be had to the rules relating to the extent of the invention covered by such a patent and not to the rules governing infringement proceedings. See in particular, judgment of 12 December 2013, *Eli Lilly and Company* (C-493/12, EU:C:2013:835, paragraphs 32 and 33).

11 See, the judgment of 25 July 2018, *Teva UK and Others* (C-121/17, EU:C:2018:585, paragraph 40). At paragraph 43 of that judgment, the Court restated that '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 [Regulation No 469/2009], 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.' See also paragraph 46 of that judgment.

42. I consider that the judgment of 25 July 2018, *Teva UK and Others* (C-121/17, EU:C:2018:585) lays down a definitive test for the interpretation of Article 3(a) of Regulation No 469/2009 which must be applied by national courts in concrete cases. In that regard, it is not the role of the Court to step into the shoes of the national court — which alone has full knowledge of the undoubtedly complex facts of the case before it — in order to apply the principles enunciated in that judgment to those particular facts.

43. The Bundespatentgericht (Federal Patent Court) and the Court of Appeal (England & Wales) (Civil Division) have nonetheless indicated to the Court that a number of questions concerning the interpretation of Article 3(a) of Regulation No 469/2009 still remain unclear despite the judgment of 25 July 2018, *Teva UK and Others* (C-121/17, EU:C:2018:585).

44. In my view, the questions originally raised by the referring courts in these joined cases have, in large part, been superseded by the judgment of 25 July 2018, *Teva UK and Others* (C-121/17, EU:C:2018:585). In this Opinion, however, I propose to provide some insight into how that judgment might be applied by answering a number of specific questions raised by the referring courts in the light of the judgment in question without unduly usurping their role. This is a rather delicate exercise as any minor or even inadvertent departure from the wording used in that judgment could be perceived as a new or different test, thereby reopening a debate which I believe was finally settled by that judgment.[12]

45. I wish to stress that my intention is not to depart in any manner whatsoever from the ruling in the judgment of 25 July 2018, *Teva UK and Others* (C-121/17, EU:C:2018:585) or attempt to graft further conditions onto the two-part test referred to in that case. I merely wish to elucidate that test having regard to the circumstances of the present referred cases. It is to these issues which I now turn.

A. Application of the judgment of 25 July 2018, Teva UK and Others (C-121/17, EU:C:2018:585) where a basic patent protects a product consisting of a single active ingredient

46. The dispute in the case which gave rise to the judgment of 25 July 2018, *Teva UK and Others* (C-121/17, EU:C:2018:585) concerned a medicinal product indicated for the treatment of persons infected with HIV, under the name TRUVADA. That medicinal product contains two active ingredients, tenofovir disoproxil ('TD') and emtricitabine, which have a combined effect for that treatment.

47. Given that the operative part of the judgment of 25 July 2018, *Teva UK and Others* (C-121/17, EU:C:2018:585) provides an interpretation of Article 3(a) of Regulation No 469/2009 which referred, in accordance which the specific facts of that case, to a medicinal product composed of *several* active ingredients, doubt has arisen[13] as to whether the test or interpretation referred to therein is applicable to medicinal products composed of a single active ingredient.[14]

48. In my view, that doubt can be swiftly and definitively resolved by a reading of paragraphs 52 and 53 of the judgment of 25 July 2018, *Teva UK and Others* (C-121/17, EU:C:2018:585). In paragraph 52 of that judgment, the Court indicated when a product is 'protected by a basic patent in force' and then in paragraph 53 it stated that 'such an interpretation of Article 3(a) of Regulation No 469/2009 must *also* be upheld in a situation, such as that at issue in the case in the main proceedings, where the products which are the subject of a SCP are composed of several active

12 I would note that the Bundespatentgericht refers to the concepts of 'specific embodiment' and 'independent inventive step'. As these terms are not found in the judgment of 25 July 2018, *Teva UK and Others* (C-121/17, EU:C:2018:585), I propose, for the avoidance of doubt, not to employ them in this Opinion.

13 See point 35 of this Opinion.

14 According to Searle and JSI, the judgment of 25 July 2018, *Teva UK and Others* (C-121/17, EU:C:2018:585) was expressly limited to combination products where one of the members of the combination was not expressly mentioned in the claims.

ingredients which have a combined effect.'[15] It is therefore clear from the very language utilised by the Court that the test referred to in paragraph 57 of the judgment of 25 July 2018, *Teva UK and Others* (C-121/17, EU:C:2018:585) and in the operative part of that judgment, applies *both* to products consisting of a single active ingredient and products composed of several active ingredients.[16] In any event, for my part, I fail to see why, as a matter of principle, the *Teva* test should apply to combination products with several active ingredients while not also applying to a product with one single active ingredient.

49. In this context any distinction between a product consisting of a single active ingredient and a combination of active ingredients is not material for the purposes of this test and any suggested distinction between the two types of products would not be a meaningful one. What matters instead is that, as the Court said at paragraph 57 and the operative part of the judgment of 25 July 2018, *Teva UK and Others* (C-121/17, EU:C:2018:585), where the ingredient(s) of the product is or, as the case may be, are not expressly mentioned in the claims of the basic patent, 'those claims relate necessarily and specifically' either to that active ingredient or, in the case of a multiplicity of active ingredients to that combination This is so even if the Court was in terms considering only the position with regard to several active ingredients.

B. Relevance of the concept of 'core inventive advance' in the wake of the judgment of 25 July 2018, Teva UK and Others (C-121/17, EU:C:2018:585)

50. It is clear from points 64 to 75 of the Opinion of Advocate General Wathelet in *Teva UK and Others* (C-121/17, EU:C:2018:278) that he considered that the concept of 'core inventive advance' was wholly inapplicable in relation to Article 3(a) of Regulation No 469/2009.

51. In that regard, Advocate General Wathelet noted that that concept was referred to in paragraph 41 of the judgment of 12 December 2013, *Actavis Group PTC and Actavis UK* (C-443/12, EU:C:2013:833) in relation to a different provision of Regulation No 469/2009, namely Article 3(c).[17] He proceeded to state 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. … 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.'[18]

52. In its request for a preliminary ruling, the High Court of Justice (England and Wales), Chancery Division (Patents Court) , in the case giving rise to the judgment of 25 July 2018, *Teva UK and Others* (C-121/17, EU:C:2018:585), asked the Court whether it is necessary to take into account, inter alia, the 'core inventive advance' of the patent.[19]

15 Emphasis added.

16 See also Article 1(b) of Regulation No 469/2009 which states that '"product" means *the active ingredient or combination of active ingredients* of a medicinal product.' Emphasis added.

17 See point 67 of the Opinion of Advocate General Wathelet in *Teva UK and Others* (C-121/17, EU:C:2018:278).

18 See points 72 and 73 of the Opinion of Advocate General Wathelet in *Teva UK and Others* (C-121/17, EU:C:2018:278).

19 See paragraph 26 of that judgment.

53. It must be noted that, at no point in its consideration of the question referred or the operative part of the judgment of 25 July 2018, *Teva UK and Others* (C-121/17, EU:C:2018:585) did the Court refer to the concept of 'core inventive advance'. Rather, the Court laid down in paragraph 57 and in the operative part of that judgment an entirely different and unrelated two-part test for the interpretation of Article 3(a) of Regulation No 469/2009.

54. For the avoidance of any possible doubt, I consider that in the light of the judgment of 25 July 2018, *Teva UK and Others* (C-121/17, EU:C:2018:585) the concept of the 'core inventive advance' of the patent does not apply and is of no relevance in the context of Article 3(a) of Regulation No 469/2009.

C. Application of judgment of 25 July 2018, Teva UK and Others (C-121/17, EU:C:2018:585) to functional claims and claims using Markush formulae

1. Technological neutrality

55. It is clear from paragraph 57 and the operative part of the judgment of 25 July 2018, *Teva UK and Others* (C-121/17, EU:C:2018:585)[20] that an active ingredient or a combination of active ingredients of a medicinal product does not have to be expressly mentioned in the claims of the basic patent, provided those claims relate necessarily and specifically to that active ingredient or combination of active ingredients and could be so ascertained by a person skilled in the art.

56. Considerable differences have arisen between the parties as to how the two-part test in the judgment of 25 July 2018, *Teva UK and Others* (C-121/17, EU:C:2018:585) applies in a given case involving functional claims and claims using a *Markush* formula.

57. In their reasoned request to the Court for a hearing in accordance with Article 76 of the Rules of Procedure of the Court, Sandoz and Hexal claimed that it is unclear whether the interpretation of Article 3(a) of Regulation No 469/2009 referred to in judgment of 25 July 2018, *Teva UK and Others* (C-121/17, EU:C:2018:585) applies to *Markush* claims and moreover that further guidance is required in the application of the interpretation of Article 3(a) of Regulation No 469/2009 to such claims.[21]

58. Searle and JSI consider, in the first place, that a *Markush* definition/formula constitutes an express mention of the active ingredient(s) of a product[22]. They also accept, but only in the alternative, the application of the two-part test in the judgment of 25 July 2018, *Teva UK and Others* (C-121/17, EU:C:2018:585) in relation to a *Markush* definition/formula.[23]

20 See also paragraph 52 of that judgment.

21 At paragraphs 30 and 31 of their written observations, Sandoz and Hexal stated that 'in the case of a *Markush* claim, it may be possible for the claim to specify or identify a product expressly. … Alternatively, the *Markush* claim may define the substituent groups in broad terms only, by reference to a class or group that encompasses a range of different chemical moieties. In this situation, the claim clearly does not expressly mention any particular product that falls within the scope of the *Markush* formula, although it may relate to that product necessarily and specifically.' Sandoz and Hexal indicated in their reasoned request to the Court for a hearing in accordance with Article 76 of the Rules of Procedure of the Court, that the Commission erred in suggesting that structural formulae and *Markush* formulae are interchangeable terms. They consider that a *Markush* formula covers a range of compounds while a structural formula only covers one compound. As would appear from paragraph 22 of this Opinion, Court of Appeal (England & Wales)(Civil Division) considered that a *Markush* formula is a structural formula. This is however a question of fact which lies within the competence of the referring court to determine.

22 They consider that a *Markush* claim is a shorthand way of expressly writing out each member of the defined class of compounds. Thus their primary position is that it is not necessary to apply the test set out by the Court in the judgment of 25 July 2018, *Teva UK and Others* (C-121/17, EU:C:2018:585) in the context of a sole active ingredient that is a member of a class of compounds defined by a *Markush* claim.

23 At paragraph 6(i) and (ii) of their written observations, Searle and JSI stated that 'a *Markush* definition (also known as a *Markush* formula) in a claim of a patent amounts to a shorthand way of expressly writing out each of the defined class of compounds. On the basis that an express disclosure is all that is needed for the grant of an SPC, then Article 3(a) is satisfied ….. In the alternative, the approach suggested by the Referring Court is correct: where the skilled person, considering the claims of the patent on the one hand and the structure of the active ingredient in question on the other, would immediately recognise that the active ingredient is one of the class of compounds specified by a *Markush* formula in a claim of the basic patent, then that active ingredient is "specified or identified in the wording of the claims" of that basic patent, so that the requirement of Article 3(a) of the SPC Regulation is met.'

59. Royalty Pharma stated in its written observations that 'often, the structural definition takes the form of a generic formula called *Markush's* formula. These formulas define the relationship groups by means of a structural element common to all relationships, and show positions of this element with variable substituents. The permutation of these variable substituents generally allows these *Markush* formulas to cover several million individual relationships.'

60. Given the fact that a *Markush* formula may potentially cover millions of compounds, some known and some hitherto unknown, I cannot accept that each and every *Markush* formula constitutes, per se and without further examination, an express mention of the active ingredient(s) of a product. Whether it does or not will depend on the individual facts of a case, which the national courts alone are competent to assess. Moreover, I do not agree with the argument of Searle and JSI that, by not accepting that every *Markush* formula constitutes an express mention of the active ingredient(s) of a product, this ensures that form prevails over substance.

61. Rather, I consider that ultimately what is fundamental is that where a claim in a patent uses either a functional definition or a *Markush* formula, the two-part test in the judgment of 25 July 2018, *Teva UK and Others* (C-121/17, EU:C:2018:585) is nonetheless satisfied.

62. In my view, the two-part test in the judgment of 25 July 2018, *Teva UK and Others* (C-121/17, EU:C:2018:585) is technologically neutral in nature. It thus applies to active ingredients which fall under the invention covered by the patent and which are specifically identifiable in the claims of a patent by means, inter alia, of a structural definition/formula, including a *Markush* formula [24], and a functional definition/formula. [25] I consider therefore that the form of a claim — as opposed to its substance or content — is not, in any sense, decisive, *provided* it satisfies the test in question.

63. In the case which gave rise to the judgment of 12 December 2013, *Eli Lilly and Company* (C-493/12, EU:C:2013:835), the Court was asked whether Article 3(a) of Regulation No 469/2009 must be interpreted as meaning that, in order for an active ingredient to be regarded as 'protected by a basic patent in force' within the meaning of that provision, the active ingredient must be identified in the claims of the patent by a structural formula, or whether the active ingredient may also be considered to be protected where it is covered by a functional formula in the patent claims.

64. The Court considered that Article 3(a) of Regulation No 469/2009 does not, in principle, preclude an active ingredient which is given a functional definition in the claims of a patent being regarded as protected by the patent. [26]

24 Sandoz and Hexal indicated in their reasoned request to the Court for a hearing in accordance with Article 76 of the Rules of Procedure of the Court, that the Commission erred in suggesting that structural formulae and *Markush* formulae are interchangeable terms. They consider that a *Markush* formula covers a range of compounds while a structural formula only covers one compound. As would appear from paragraph 22 of this Opinion, the Court of Appeal (England & Wales) (Civil Division) considered that a *Markush* formula is a structural formula. This is, however, a question of fact which alone lies within the competence of the referring court to determine.

25 See the judgment of 25 July 2018, *Teva UK and Others* (C-121/17, EU:C:2018:585, paragraph 36). According to point 6.5 of the EPO's guidelines for examination 'a claim may broadly define a feature in terms of its function, i.e., as a functional feature, even where only one example of the feature has been given in the description, if the skilled person would appreciate that other means could be used for the same function …'.
See https://www.epo.org/law-practice/legal-exts/html/guidelines/e/f_iv_6_5.htm

26 See, the judgment of 12 December 2013, *Eli Lilly and Company* (C-493/12, EU:C:2013:835, paragraph 39).

65. I see no reason that the Court should depart from the technologically neutral position adopted by the Court in its judgment of 12 December 2013, *Eli Lilly and Company* (C-493/12, EU:C:2013:835) and confirmed by the Court in the judgment of 25 July 2018, *Teva UK and Others* (C-121/17, EU:C:2018:585).[27] Moreover, I consider that the Court should extend that approach to the use of *Markush* formulae in patent claims given their widespread and accepted use in the Member States and the EPO.[28]

66. I therefore consider that Article 3(a) of Regulation No 469/2009 does not preclude the grant of an SPC for an active ingredient which is covered by a functional definition or a *Markush* formula provided, however, that the two-part test set out in the judgment of 25 July 2018, *Teva UK and Others* (C-121/17, EU:C:2018:585) is satisfied.

2. Point of view of a person skilled in the art at the filing date or priority date

67. The assessment of whether a 'product is protected by a basic patent in force' in accordance with Article 3(a) of Regulation No 469/2009 is carried out, in principle, on the date of application for an SPC. Given that many years may have elapsed since the filing of the patent and the SPC application, that assessment undoubtedly requires a degree of retrospection[29] as, in accordance with the judgment of 25 July 2018, *Teva UK and Others* (C-121/17, EU:C:2018:585), a person who is skilled in the art must assess whether, on the basis of the prior art at the filing date or priority date, the two-part test referred to in that judgment is satisfied.[30]

68. In that regard, at paragraph 50 of that judgment the Court clearly emphasised that such an assessment *may not* take into account results from research which took place *after* the filing date or priority date in order not to extend unduly the scope of protection.

69. It is therefore inappropriate to examine the claims in the patent in the light of the state of the prior art at, inter alia, the date of application for the SPC.[31]

70. The question of who is 'a person skilled in the art' and what is 'the prior art' are matters of national law as these concepts are not harmonised by European Union law. In their written observations and at the hearing, Sandoz and Hexal considered that the basis of assessment of the claim should be 'the common general knowledge'[32] rather than the prior art. At the hearing, Searle and JSI pointed out that there is a very significant difference for patent practitioners between 'prior art' and 'the common general knowledge'.[33]

27 The Court stated at paragraph 36 of judgment of 25 July 2018, *Teva UK and Others* (C-121/17, EU:C:2018:585), that Article 3(a) of Regulation No 469/2009 does not, in principle, preclude an active ingredient which is given a functional definition in the claims of a basic patent being regarded as protected by the patent, on condition that it is possible, on the basis of those claims as interpreted, inter alia, in the light of the description of the invention to conclude that the claims relate in accordance with the two-part test referred to in that judgment to the active ingredient in question.

28 It must be recalled that while Regulation No 469/2009 establishes a uniform solution at European Union level by creating an SPC which may be obtained by the holder of a national or European patent under the same conditions in each Member State, in the absence of European Union harmonisation of patent law, the extent of patent protection can be determined only in the light of the non-European Union rules governing patents. See, judgment of 24 November 2011, *Medeva* (C-322/10, EU:C:2011:773, paragraphs 23 and 24).

29 Requiring the production of expert evidence.

30 The Commission noted in Case C-114/18 that this requirement 'to look back in time' may leave the procedure for an application for an SPC vulnerable to abuse and even fraud.In that regard, it cited as an example of circumstances in which such abuse arose in the judgment of 6 December 2012, *AstraZeneca v Commisson* (C-457/10 P, EU:C:2012:770). I do not see the relevance of that case, which involved highly misleading representations to national patent offices, in the context of the present proceedings. The fact that parties may have diverging views on the state of the prior art at the priority date or the date of filing is, in my view, legitimate and patent offices and/or national courts are competent to deal with such disputes.

31 I therefore agree with the written observations of Sandoz and Hexal that it is not sufficient for the purposes of Article 3(a) of Regulation No 469/2009 'for the person skilled in the art immediately to recognise that the product falls within the scope of the *Markush* formula *once that product is known and presented to them*. The product must fall under the invention covered by the basic patent as assessed by the person skilled in the art at the priority date or filing date of the basic patent and not at a later date.' Emphasis added.

32 In Case C-114/18, Sandoz and Hexal claimed that this consists of the general knowledge of the person skilled in the art and the prior art.

33 In my view, there is, undoubtedly, considerable overlap between these two distinct sources of information.

71. For my part, I consider that reference to 'the common general knowledge' for the purposes of applying the test in question should be rejected as it is in direct conflict with the unambiguous wording of the operative part of the ruling of the Court in the judgment of 25 July 2018, *Teva UK and Others* (C-121/17, EU:C:2018:585) which refers to the prior art. [34]

72. The two-part test referred to in paragraph 57 of the judgment of 25 July 2018, *Teva UK and Others* (C-121/17, EU:C:2018:585) and in the operative part of that judgment must, accordingly, be applied 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.

3. The requirements that the product must 'necessarily' fall under the invention covered by the patent and be 'specifically identifiable'

73. As I indicated at paragraph 54 of this Opinion, the concept of the 'core inventive advance' of the patent does not apply and is of no relevance in the context of Article 3(a) of Regulation No 469/2009. The first part of the test referred to in the judgment of 25 July 2018, *Teva UK and Others* (C-121/17, EU:C:2018:585) which states that the product which is subject to the SPC *necessarily* falls under the invention covered by that patent and therefore does not require that the product embody the 'core inventive advance' of the patent.

74. Rather, in accordance with paragraph 48 of the judgment of 25 July 2018, *Teva UK and Others* (C-121/17, EU:C:2018:585), that part of the test is satisfied if the product to which the claims of the basic patent relate is a specification *required* for the solution of the technical problem disclosed by that patent. It follows that if, 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 claims in a patent in relation to a product are not required [35] for the solution of the technical problem disclosed by a patent, the first part of the test in that judgment is not satisfied and an SPC may not be granted in respect of that product.

75. As regards the second part of the test and the requirement that the active ingredient(s) be 'specifically identifiable', in the light of all the information disclosed in the patent, this question has given rise to considerable debate in the written observations and at the hearing. In effect, what is at stake is to what extent the product must be identifiable at the filing date or priority date.

34 Moreover, while the 'prior art' is referred to on numerous occasions in the judgment of 25 July 2018, *Teva UK and Others* (C-121/17, EU:C:2018:585) and in its operative part, 'general knowledge', rather than 'common general knowledge' is only referred to once at paragraph 48 of that judgment.

35 While the matter was ultimately left to the referring court to decide, I believe that the Court at paragraph 54 of the judgment of 25 July 2018, *Teva UK and Others* (C-121/17, EU:C:2018:585) showed considerable scepticism as to whether a combination such as TD (which was specifically mentioned in the patent claims) and emtricitabine (which was allegedly covered by the general expression 'other therapeutic ingredients' and associated with the term 'optionally') satisfied the two-part test referred to in that judgment.

76. It is clear from the judgment of 25 July 2018, *Teva UK and Others* (C-121/17, EU:C:2018:585) that while a product does not have to be expressly mentioned [36] in the claims of the basic patent, it must nonetheless be 'specifically identifiable' by a person skilled in the art in the light of all the information disclosed by the basic patent and of the prior art at the filing date or priority date of that patent. [37] The Court stressed in that regard that account must be taken exclusively of the prior art at the filing date or priority date of that patent and that results from later research must not be taken into account. [38]

77. I consider that the second part of the test in the judgment of 25 July 2018, *Teva UK and Others* (C-121/17, EU:C:2018:585) requires that it be established that a person skilled in the art would have been able, in the light of all the information contained in a patent, on the basis of the prior art at the filing date or priority date of the patent in question, to derive the product in question. This is not the case where, in the light of all the information contained in a patent, a product or constituent element of the product remains unknown to a person skilled in the art on the basis of the prior art at the filing date or priority date of the patent in question.

VI. Conclusion

78. In view of all the foregoing considerations, I consider that the Court should answer the questions referred by the Bundespatentgericht (Federal Patent Court, Germany) and the Court of Appeal (England & Wales) (Civil Division) as follows:

The two-part test referred to in paragraph 57 of the judgment of 25 July 2018, *Teva UK and Others* (C-121/17, EU:C:2018:585) and in the operative part of that judgment applies *both* to products consisting of a single active ingredient and products composed of several active ingredients;

The concept of the 'core inventive advance' of the patent does not apply and is of no relevance in the context of Article 3(a) of Regulation No 469/2009;

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 does not preclude the grant of a supplementary protection certificate for an active ingredient which is covered by a functional definition or a *Markush* formula provided, however, that the two-part test set out in paragraph 57 of the judgment of 25 July 2018, *Teva UK and Others* (C-121/17, EU:C:2018:585) and in the operative part of that judgment is satisfied;

36 See paragraph 52 of this judgment.

37 See, in particular, paragraph 51 of the judgment of 25 July 2018, *Teva UK and Others* (C-121/17, EU:C:2018:585). In Case C-650/17, the French and Netherlands Governments and the Commission observed that a product, which falls within the functional definition contained in the claims of a patent, but, which was developed after the lodging of the patent, cannot be considered as protected by the basic patent in accordance with Article 3(a) of Regulation No 469/2009. Royalty Pharma considers that no specific weight can be attributed to the fact that the licensee Merck obtained a product patent and a SPC for sitagliptin. It claims that this does not preclude the granting of an SPC for sitagliptin on the basis of the basic patent. According to Royalty Pharma, the mere fact that a product has only been made available after the filing date of the basic patent does not prevent that product from being covered by the basic patent in accordance with Article 3(a) of Regulation No 469/2009. This also applies to products whose availability requires an inventive activity.

38 According to Sandoz and Hexal in Case C-114/18, 'the P1 substituent group of Darunavir was not part of the common general knowledge or prior art available to the skilled person at the priority date or filing date of the basic patent. It was not even published until after the priority date of the basic patent.' Searle and JSI in Case C-114/18 consider that 'a Markush formula specifies each of its members. It defines a precise and closed group, so whatever the number of members in the class, the skilled person can "*immediately recognise*" that a given molecule is a member of it. Where the skilled person can immediately recognise that a given compound is within the claimed group, s/he would necessarily learn nothing more about it if all the group's members were listed individually. In the present case, it has been found as a fact that the skilled person would immediately recognise that Darunavir was a compound of the claimed formula. There is therefore no room for dispute as to exactly what compounds the Markush formula of the Patent specifies.' According to Searle and JSI, a Markush formula must be understood as a shorthand way of denoting each of its members.

The two-part test referred to in paragraph 57 of the judgment of 25 July 2018, *Teva UK and Others* (C-121/17, EU:C:2018:585) and in the operative part of that judgment must be applied 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 first part of the two-part test referred to in paragraph 57 of the judgment of 25 July 2018, *Teva UK and Others* (C-121/17, EU:C:2018:585) and the operative part of that judgment is not satisfied and an SPC may not be granted in respect of a product if, 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 claims in a patent in relation to that product are not required for the solution of the technical problem disclosed by a patent;

The second part of the two-part test referred to in paragraph 57 of the judgment of 25 July 2018, *Teva UK and Others* (C-121/17, EU:C:2018:585) and the operative part of that judgment requires that it be established that a person skilled in the art would have been able, in the light of all the information contained in a patent, on the basis of the prior art at the filing date or priority date of the patent in question, to derive the product in question. This is not the case where, in the light of all the information contained in a patent, a product or constituent element of the product remains unknown to a person skilled in the art on the basis of the prior art at the filing date or priority date of the patent in question.