Neutral Citation Number: [2019] EWCA Civ 2272

Case No: A3 2018 2542

IN THE COURT OF APPEAL (CIVIL DIVISION)
ON APPEAL FROM THE HIGH COURT OF JUSTICE
CHANCERY DIVISION
PATENTS COURT
Mr Justice Arnold
[2017] EWHC 13 (Pat)

Royal Courts of Justice
Strand, London, WC2A 2LL
Date: 19/12/2019

Before:
LORD JUSTICE LEWISON
LORD JUSTICE FLOYD
and
LORD JUSTICE DINGEMANS

- -

Between:

TEVA UK LIMITED **ACCORD HEALTHCARE LIMITED** **LUPIN LIMITED** **LUPIN (EUROPE) LIMITED** **GENERICS (UK) LIMITED (TRADING AS MYLAN)**	**Respondents /Claimants**
- and -	
GILEAD SCIENCES, INC.	**Appellant/ Defendant**

- -
- -

Tom Mitcheson QC and **James Whyte** (instructed by **Simmons and Simmons LLP**) for the **Appellant**
Daniel Alexander QC and **Lindsay Lane QC** (instructed by **Pinsent Masons LLP**) for **Teva**
Daniel Alexander QC and **Kathryn Pickard** (instructed by **Taylor Wessing LLP**) for **Accord**
Daniel Alexander QC and **Joe Delaney** (instructed by **Taylor Wessing LLP**) for **Mylan**
Daniel Alexander QC and **Jaani Riordan** (instructed by **Mishcon de Reya LLP**) for **Lupin**

Hearing date: 10 December 2019

- -

Approved Judgment

Lord Justice Floyd:

Introduction

1. This appeal raises, yet again, the interpretation and application of European Parliament and Council Regulation 469/2009/EC of 6 May 2009 concerning the supplementary protection certificate for medicinal products ("the SPC Regulation"). Supplementary Protection Certificates ("SPCs") have the effect of extending the life of a patent for a medicinal product which has been granted a marketing authorisation for a period of up to 5 years beyond its normal expiry date, under the conditions laid down in the SPC Regulation. Their purpose is to compensate a patentee for the delay in bringing a medicinal product to market consequent on the need to obtain regulatory clearance in the form of a marketing authorisation.

2. In a set of proceedings which were all heard together, the various claimants all challenged the validity of the defendant's ("Gilead's") SPC numbered SPC/GB05/041 ("the SPC"). The SPC describes a product containing two ingredients, tenofovir disoproxil ("TD") in the form of its fumarate salt and emtricitabine. TD and emtricitabine are both inhibitors of reverse transcriptase. The SPC covers a product marketed by Gilead under the trade name Truvada. Truvada is used in the treatment of patients suffering from the effects of the human immunodeficiency virus, HIV.

3. In order for the SPC to be valid, Article 3(a) of the SPC Regulation states that the product described in the SPC must be "protected by a basic patent in force". Gilead contends that the product described in the SPC is protected by European Patent (UK) No 0 915 894 ("the patent"), because it has a claim (claim 27) to TD "and optionally other therapeutic ingredients". Emtricitabine, says Gilead, is another therapeutic ingredient. The claimants contend that claim 27 does not protect the combination in the manner required by the SPC Regulation. The judge, Arnold J as he then was, found in favour of the claimants, declaring the SPC to be invalid. Gilead appeals with permission which I granted on 15 January 2019.

4. Before us, Mr Tom Mitcheson QC and Mr James Whyte appeared for Gilead. Mr Daniel Alexander QC and Mr Joe Delaney appeared for all the claimants, although other counsel for the various claimants assisted with the written submissions.

The procedural history

5. The SPC in issue in this case has been extensively litigated. It was applied for on 1 August 2005. Its initial grant was refused by the UK Intellectual Property Office by a decision of Mr Howard, acting for the Comptroller General of Patents, dated 10 January 2008, but an appeal against that refusal was allowed by Kitchin J (as he then was) in a judgment dated 31 July 2008 ([2008] EWHC 1902 (Pat)). Given the developments in EU law which have taken place since that date, both sides recognise, as did Arnold J, that it was necessary to consider the matter afresh. The present actions came on for a trial lasting a total of one day, in December 2016. Arnold J considered that the case law of the CJEU on the interpretation of Article 3(a) of the SPC Regulation was not clear and so, following a judgment delivered on 13 January 2017 ([2017] EWHC 13 (Pat)) ("the First Judgment"), referred to the Court of Justice of the European Union ("CJEU") the following question for a preliminary ruling:

> "What are the criteria for deciding whether the 'product is protected by a basic patent in force' in Article 3(a) of the SPC Regulation?"

6. The Grand Chamber of the CJEU handed down its judgment on the reference in this case on 25 July 2018: Case C-121/17 [EU:C:2018:585]. As is not uncommon, each of the parties contended that it could yet be the successful party in the light of the CJEU's ruling. The claimants accordingly made an application to the judge for judgment to be entered in their favour, whilst Gilead made a cross-application for permission to rely on further expert evidence, and for the matter to be adjourned to a further hearing at which the evidence could be heard and the questions raised by the CJEU's ruling decided. In the judgment under appeal, handed down on 18 September 2018, Arnold J held that, in the light of the ruling of the Grand Chamber of the CJEU, the SPC was invalid. He refused the application to adduce expert evidence. I will refer to that judgment as the Second Judgment.

The patent

7. The judge summarised the relevant disclosure of the patent in the First Judgment at [8]-[15] in the following terms:

> "8. The Patent was applied for on 25 July 1997 with a claimed priority date of 26 July 1996 and granted on 14 May 2003. It is entitled "Nucleotide analogs". The specification states at [0001] that the invention relates to "intermediates for phosphonomethoxy nucleotide analogs, in particular intermediates suitable for use in the efficient oral delivery of such analogs."
>
> 9. In the "Summary of the Invention" at [0003]–[0006], the specification states that the invention provides compounds in accordance with two Markush formulae, formula (1a) and formula (1), and methods for preparing such compounds.
>
> 10. In the "Detailed Description of the Invention", the specification first defines the substituents in the two Markush formulae and then gives exemplary embodiments of the claimed compounds at [0007]-[0036]. At [0037] the specification discusses the chemical stability of the claimed compounds. The specification goes on to describe synthetic methods for the preparation of the claimed compounds at [0038]–[0043].
>
> 11. The specification then describes the utilities of the claimed compounds at [0044] and [0045]. In the first of these paragraphs it states:
>
> > "The compounds of this invention are useful in the treatment or prophylaxis of one or more viral infections in man or animals, including infections caused by DNA viruses, RNA viruses, herpesviruses (CMV, HSV 1, HSV 2,

> VZV, and the like), retroviruses, hepadnaviruses, (e.g. HBV), papillomavirus, hantavirus, adenoviruses and HIV. Other infections to be treated with the compounds herein include MSV, RSV, SIV, FIV, MuLV, and other retroviral infections of rodents and other animals…"

It can be seen from this that the Patent is directed to the treatment of viral infections generally, not just HIV, and to viral infections in both man and animals.

12. Next, the specification describes a wide range of potential pharmaceutical formulations of the claimed compounds at [0046]-[0065]. The description is very bland and general, rather than being specific to the particular compounds or the particular utilities of those compounds. Counsel for the Claimants aptly described this passage as "boilerplate". The range of potential formulations extends to (for example) formulations suitable for topical administration to the eye ([0056]) and veterinary compositions ([0063]).

13. Importantly for present purposes, the specification states at [0047]:

> "While it is possible for the active ingredients to be administered as pure compounds it is preferable to present them as pharmaceutical formulations. The formulations of the present invention comprise at least one active ingredient, as above defined, together with one or more acceptable carriers and optionally other therapeutic ingredients. The carrier(s) must be 'acceptable' in the sense of being compatible with the other ingredients of the formulation and not deleterious to the patient."

This is the only reference in the specification to the inclusion of "other therapeutic ingredients". The phrase "other therapeutic ingredients" is not defined or explained in the Patent in any way.

14. The specification goes on at [0068]-[0117] to describe various examples of the invention. Example 16, which is entitled "Antiviral Activity of PMPA and PMPA Carbonates in Tissue Culture", gives data showing antiviral activity of seven compounds in vitro against HIV-1. There is no example involving one of the claimed compounds in combination with any other therapeutic ingredient.

15. It is common ground that emtricitabine is not mentioned or referred to in the Patent."

8. Claims 1 and 2 are claims to classes of compounds defined by the Markush formulae 1(a) and 1 respectively, whilst claims 3-24 are dependent compound claims of increasingly narrow scope. Claim 25 is an independent compound claim specifically to TD, and claim 26 is to the use of any of the compounds of claims 1-25 for the treatment or prophylaxis of viral infections in man or animals. The debate centres on claim 27 which is in the following terms:

> "A pharmaceutical composition comprising a compound according to any one of claims 1-25 together with a pharmaceutically acceptable carrier and optionally other therapeutic ingredients."

9. As the judge pointed out, the words "comprising" and "optionally" in claim 27 mean that the claim permits, but does not require, the presence of other ingredients, both therapeutic and non-therapeutic. The presence of another pharmaceutical ingredient is irrelevant to whether a product falls within the scope of protection of the patent.

Therapeutic agents for the treatment of HIV at the priority date

10. At the claimed priority date of the patent a wide range of therapeutic agents was known for the treatment of viral infections including HIV. One known class was the class of anti-retroviral drugs known as nucleoside reverse transcriptase inhibitors or NRTIs. The judge found that, by that date, it was "increasingly common" to treat HIV using a combination of different NRTIs. Another approach was to combine a NRTI with a protease inhibitor or a non-nucleoside reverse transcriptase inhibitor (NNRTI), which are two other classes of anti-retroviral drugs.

11. TD and emtricitabine are both NRTIs. Emtricitabine was first described in an article by Schinazi *et al* published in November 1992: *Antimicrobial Agents and Chemotherapy*, 36(11), 2423-2431. The article reported *in vitro* studies of emtricitabine against HIV. The judge found at [7] of the First Judgment:

> "There is no evidence that it was known in July 1996 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. The European Medicines Agency first approved emtricitabine in October 2003, over seven years later."

12. Gilead does not seek to contradict this finding, but submits that emtricitabine was amongst a finite list of NRTIs known at the priority date as having potential for treating HIV. A non-exhaustive schedule compiled from journal articles available at the priority date was placed before the judge. It listed only 6 such NRTIs. Gilead asserts that emtricitabine was in clinical trials at the priority date, albeit that the results of those trials were not yet known. Clinical trials would not be permitted, Gilead infers, unless it had first been established that emtricitabine was tolerable by humans. It was to issues such as these that it wished to adduce further expert evidence.

The SPC Regulation

13. The recitals of the SPC Regulation which are material are the following:

> "[3] Medicinal products, especially those that are the result of long, costly research will not continue to be developed in the Community 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.
>
> [6] There exists a risk of research centres situated in the Member States relocating to countries that offer greater protection.
>
> [7] A uniform solution at Community 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 Community and thus directly affect the functioning of the internal market.
>
> [8] Therefore, the provision of a supplementary protection certificate granted, under the same conditions, by each of the Member States at the request of the holder of a national or European patent relating to a medicinal product for which marketing authorisation has been granted is necessary. A regulation is therefore the most appropriate legal instrument.
>
> …
>
> [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. …"

14. Articles 1, 3, 4 and 5 of the SPC Regulation provide, so far as relevant:

> "Article 1
>
> Definitions
>
> For the purpose 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 certificate;

…

Article 3

Conditions for obtaining a certificate

A certificate 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 in accordance with Directive 2001/83/EC or Directive 2001/82/EC, as appropriate;

(c) the product has not already been the subject of a certificate;

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

…

Article 4

Subject matter of protection

Within the limits of the protection conferred by the basic patent, the protection conferred by a certificate shall extend only to the product covered by the authorisation to place the corresponding medicinal product on the market and for any use of the product as a medicinal product that has been authorised before the expiry of the certificate.

Article 5

Effects of the certificate

> Subject to the provisions of Article 4, the certificate shall confer the same rights as conferred by the basic patent and shall be subject to the same limitations and the same obligations."

15. It is common ground in the present case that the SPC satisfies the conditions specified in Article 3 (b), (c) and (d). There is also no dispute that the patent was in force at the relevant date. The issue is whether the combination of TD and emtricitabine was protected by the patent, in accordance with Article 3(a).

Domestic law on the extent of protection afforded by a patent

16. The domestic rules on the extent of protection afforded by a patent are to be found in Article 69 of the European Patent Convention (EPC) as amplified in the Protocol on its interpretation. Article 69(1) provides that the extent of protection shall be determined by the claims, but that the description and drawings shall be used to interpret the claims. The Protocol explains that the correct approach to identifying the extent of protection is neither to take the "strict, literal meaning" of the claims nor to use the claims "only as a guideline", but a "position between these extremes which combines a fair protection for the patent proprietor with a reasonable degree of certainty for third parties".

17. Section 125 of the Patents Act 1977 is the domestic provision which gives effect to those provisions of the EPC and its Protocol. It provides so far as relevant:

> "(1) For the purposes of this Act an invention for a patent for which an application has been made or for which a patent has been granted shall, unless the context otherwise requires, be taken to be that specified in a claim of the specification of the application or patent, as the case may be, as interpreted by the description and any drawings contained in that specification, and the extent of the protection conferred by a patent or application for a patent shall be determined accordingly.
>
> …
>
> (3) The Protocol on the Interpretation of Article 69 of the European Patent Convention (which Article contains a provision corresponding to subsection (1) above) shall, as for the time being in force, apply for the purposes of subsection (1) above as it applies for the purposes of that Article."

The CJEU case law on Article 3(a)

18. There is no doubt that the CJEU has struggled with getting across to national courts its understanding of what is meant by a product being protected by a basic patent for the purposes of Article 3(a) of the SPC Regulation. The earliest case referred to the CJEU was Case C-392/97 *Farmitalia Carlo Erba Srl* [2000] RPC 580, when it was asked, not for the last time:

> "According to which criteria is it to be determined whether the product is protected by a basic patent within the meaning of Article 3(a)…"

19. The court's answer was that "…in the absence of Community harmonisation of patent law, the extent of patent protection can be determined only in the light of the non-Community rules which govern patents."

20. Had the matter been left there, one could have concluded that there was no further EU law component of the expression "protected by a basic patent". That, however, has subsequently proved not to be the case, although the nature of the additional component has proved somewhat elusive.

21. The court gave further guidance in Case C-322/10 *Medeva BV v Comptroller-General of Patents, Designs and Trade Marks* [2011] ECR 1-12051. At [25] of its judgment in that case it said that the SPC Regulation:

> "precludes the grant of a SPC relating to active ingredients which are not specified in the wording of the claims of the basic patent".

22. In other references the word "specified" is replaced by "identified", but no one suggests that any different meaning is conveyed. I think it is now clear that this means that a combination product of two active ingredients A and B, is not protected by a patent with claims to A, or a composition or formulation comprising A, even though the combination of A and B would, because of the presence of A, amount to infringement. There must be something in the claim which "identifies" or "specifies" the presence of B. The guidance nevertheless gives rise to the problem identified by the judge at [63] in the First Judgment, namely what is meant by "specified in the wording of the claims". Claims often define what is required to be present in functional terms. An example would be a claim that called for an antibody with a specific binding affinity. Such a claim would, as a matter of domestic law, include within the scope of protection any antibody which had the specified binding affinity. But does that mean the antibody is sufficiently specified or identified in the wording of the claims? The term "other therapeutic ingredients" used in claim 27 of the patent is of course very much more general: but where is the line to be drawn?

23. The next important case was Case C-493/12 *Eli Lilly & Co Ltd v Human Genome Sciences Inc* [2014] RPC 21. With the agreement of Lewison and Kitchin LJJ, I summarised the effect of that decision in *Sandoz Limited and another v G.D. Searle LLC and another* [2018] EWCA Civ 49 at [54], as follows:

> "i) The rules for determining whether the product is protected are those relating to the extent of the invention (in the case of a European patent, those defined by Article 69 and the Protocol): [32].
>
> ii) Recourse may not be had to the rules relating to infringement, such as those in section 60 of the Patents Act 1977: [33].

> iii) The fact that the product infringes is not, therefore, "a crucial" factor: [37].
>
> iv) The claims have a key role for the purpose of determining whether a product is protected by a basic patent within the meaning of Article 3(a): [34].
>
> v) An active ingredient which is not identified in the claims by any means (i.e. either a structural or functional definition) is not protected: [38].
>
> vi) It is not necessary for the active ingredient to be identified in the claims of the patent by a structural formula: a "functional formula" will do as well: [39], but:
>
> vii) It must be possible to reach the conclusion on the basis of the claims, interpreted inter alia in the light of the description of the invention, that the claims relate, implicitly but necessarily and specifically, to the active ingredient in question: [39], [44].
>
> viii) It is for the national court to determine the application of this test: [40], [44]."

24. The court has thus explained further the concept of "protected by" in the case where the product is not expressly specified or identified in the claims. The claims must "relate, implicitly but necessarily and specifically, to the active ingredient in question." That was the position which the case law had reached by the time of the First Judgment of Arnold J in this case.

The First Judgment

25. Having reviewed the case law of the CJEU, the judge concluded at [91] of the First Judgment that the test to be applied to determine whether a product is protected by a basic patent within the meaning of Article 3(a) of the SPC Regulation remained unclear. It was a necessary condition that dealings in the product fall within at least one claim of the patent applying the extent of protection rules, but it was not clear whether that condition was sufficient. If more was required, it was not clear what.

26. The judge proffered his provisional view that, in addition to a requirement that the product fall within at least one claim of the patent there should be a further requirement that the product should embody the inventive advance (or technical contribution) of the patent. Where the product was a combination of active ingredients, the combination, as distinct from one of them, must embody the inventive advance of the basic patent.

The Opinion of Advocate General Wathelet

27. Gilead's argument before the CJEU was, to quote Advocate General Wathelet at [37]:

> "… that a product is protected by a basic patent in force, in accordance with Article 3(a) of [the SPC Regulation] if the product falls within the scope of protection of a claim of the

> basic patent in force, as determined in accordance with Article 69 of the EPC or national legislation derived from that article. Gilead submits that there is no further or other additional requirement under EU law."

28. In giving his opinion, the Advocate General dismissed the judge's "inventive advance" approach, notwithstanding that it had by then gained support from the intervening governments of a number of Member States. His view was that the "only means of determining whether a basic patent protects an active ingredient … was to be found only in the wording, or interpretation of the wording, of the claims of the patent granted". He considered that "any other additional criterion", such as the "core inventive advance" approach, ran the risk of giving rise to confusion with the criteria for determining whether an invention is patentable: see [72] to [73].

29. At this point in the Advocate General's Opinion, Gilead might have been forgiven for thinking that their submissions were on the verge of being accepted. It is clear however that the Advocate General was not ruling out all additional criteria, merely those which risked confusion with the rules relating to determining whether an invention was patentable. This is clear from what he went to say at [74]:

> "Nevertheless, merely because a substance might fall within the protection of the claims of a patent under Article 69 of the EPC and the Protocol on its interpretation and the provisions of relevant national law, such as [section] 125 of the Patents Act 1977, does not necessarily imply that that substance is a product protected by a patent within the meaning of Article 3(a) of [the SPC Regulation]."

30. At [75] the Advocate General confirmed that, in his opinion, compliance with the extent of protection rules was a necessary but not a sufficient condition.

31. The key point for the Advocate General, discussed at paragraphs [76] to [84] was the degree of specificity or abstraction of the claims. To deal with the claims which were drafted in broad general terms, he proposed the following test:

> "81. …a product is protected by a patent within the meaning of Article 3(a) … if, on the priority date of the patent, it would have been obvious to a person skilled in the art that the active ingredient in question was specifically and precisely identifiable in the wording of the patent claims. In the case of a combination of active ingredients, each active ingredient must be specifically, precisely and individually identifiable in the wording of the patent claims.
>
> 82. The name of the active ingredient does not need to be referred to expressly in the claims, provided that the active ingredient is specifically and precisely identifiable as at the priority date of the patent."

32. The Advocate General also expressed a view on the application of this test to the facts of the present case, whilst recognising that this was ultimately not a task for the court itself:

> "87. To my mind, and subject to verification by the referring court, as the active ingredient emtricitabine is claimed solely through the use of completely indeterminate expressions such as 'comprising' and 'optionally other therapeutic ingredients', terms which may cover multiple substances that are not specifically and precisely identifiable on the priority date of the patent, the combination containing the active ingredients TD and emtricitabine, that is to say, the medicinal product marketed under the name Truvada, is not protected by the basic patent within the meaning of Article 3(a) of Regulation No 469/2009, even though that combination may fall within the protection of claim 27 of the patent at issue in the main proceedings under Article 69 of the EPC and the Protocol on its interpretation and section 125 of the Patents Act 1977.
>
> 88. It would appear, subject once again to verification by the referring court, that, on 26 July 1996, the claimed priority date of the patent at issue in the main proceedings, it would not have been obvious to a person skilled in the art that the active ingredient emtricitabine was specifically and precisely identifiable in the wording of the claims of that patent."

The judgment of the Court of Justice

33. That brings me to the judgment of the CJEU in the present case. At [31] to [35] the court (a) reiterates that, according to its settled case law, and since no harmonised EU rules are applicable, the extent of protection conferred by a basic patent can be determined only in the light of the non-EU rules governing patents, i.e. Article 69 EPC and the Protocol; (b) that the court cannot take account of the rules governing infringement proceedings (such as those contained in our section 60 Patents Act 1977); and (c) applying those rules, the key role is played by the claims.

34. At [36] the court explains that Article 3(a):

> " … does not, in principle, preclude an active ingredient which is given a functional definition in the claims of a basic patent issued by the EPO being regarded as protected by the patent, <u>on condition that</u> it is possible, on the basis of those claims as interpreted inter alia in the light of the description of the invention, as required under Article 69 of the EPC and Protocol on the Interpretation of that provision, to conclude that the claims relate implicitly but necessarily and specifically to the active ingredient in question (see judgment of 12 December 2013, *Eli Lilly and Company*, C-493/12, EU:C:2013:835, paragraph 39)." (emphasis supplied).

35. This meant (see the judgment at [37]) that a product cannot be considered to be protected by a basic patent unless the product "is either expressly mentioned in the claims of the patent or those claims relate to that product necessarily and specifically". The court continues:

> "38. For that purpose, in accordance with the case-law cited in paragraph 36 above, the description and drawings of the basic patent must be taken into account, as stipulated in Article 69 of the EPC read in the light of the Protocol on the Interpretation of that provision, where that material shows whether the claims of the basic patent relate to the product which is the subject of the SPC and whether that product in fact falls under the invention covered by that patent."

36. The parties take different views as to whether the court is doing more in paragraph [38] than explaining in its own words the way in which Article 69 and the Protocol delineate the scope of protection. Gilead submits that the court is doing just that, whilst the claimants contend that this is the first occasion on which the court focuses on the limits of the actual invention as opposed to the scope of protection. This, they contend is what the requirement that the product "fall[s] under the invention covered by the patent" is getting at.

37. Paragraph [38] is explained further in [39] as being in line with the objective of the SPC, which is to re-establish protection to compensate at least in part for the delay to the commercial exploitation of the invention by reason of the time which has elapsed between the application for the patent and the grant of the marketing authorisation, thus encouraging research and innovation. This paragraph, however, does not throw light on which party's contention is correct.

38. Paragraphs [40] to [42] are directed to the question of whether an SPC "can extend the protection conferred by a patent beyond the invention that the patent covers". It was not, of course, the contention of either party that the SPC could extend more widely than the extent of protection (in the domestic law sense) conferred by the claims: the question was whether the extent of protection was in any respect narrower, or subject to additional tests. These paragraphs lend some support to the claimants' case that the requirement that the product "falls under the invention" is more specific than one which only requires it to be within the scope of protection (in the domestic law sense). Thus at [40] the court says:

> "However, it is not the purpose of the SPC to extend the protection conferred by that patent <u>beyond the invention which the patent covers</u>. It would be contrary to the objective of [the SPC Regulation], reiterated in the preceding paragraph, to grant an SPC for a product which does not fall under the invention covered by the basic patent, inasmuch as such an SPC would not <u>relate to the results of the research claimed under that patent</u>" (emphasis supplied).

39. Likewise, at [41]:

> "In the light of the need, referred to inter alia in recital 10 of the preamble to [the SPC Regulation], to take into account all the interests at stake, including those of public health, to accept that an SPC could grant to the holder of the basic patent protection which goes beyond the protection guaranteed by that patent in connection with the invention it covers would be contrary to the requirement to balance the interests of the pharmaceutical industry and those of public health as regards the encouragement of research within the European Union by the use of SPCs (see, by analogy, judgment of 12 March 2015, *Actavis Group PTC and Actavis UK*, C-577/13, EU:C:2015:165, paragraph 36 and the case-law cited)." (emphasis supplied).

40. The reference to paragraph [36] of the judgment of the CJEU in *Actavis Group* requires explanation. In that case, Boehringer had a patent which claimed numerous molecules, including telmisartan and one of its salts. Telmisartan was an antihypertensive agent marketed by Boehringer and for which they obtained a SPC for "telmisartan optionally in the form of one of its salts". Boehringer also later obtained a SPC for the combination of telmisartan and hydrochlorothiazide. In order to obtain this second SPC it had amended the basic patent to include a claim for telmisartan and hydrochlorothiazide. The court held that Articles 3(a) and 3(c) precluded the grant of a second SPC to Boehringer for the combination:

> "36. In the light of the need, referred to, inter alia, in recital 10 in the preamble to [the SPC Regulation], to take into account all the interests at stake, including those of public health, if it were accepted that all subsequent marketing of an active ingredient in conjunction with an unlimited number of other active ingredients which do not constitute the subject-matter of the invention covered by the basic patent would confer entitlement to multiple SPCs, that would be contrary to the requirement to balance the interests of the pharmaceutical industry and those of public health as regards the encouragement of research within the European Union by the use of SPCs (see, to that effect, judgment in *Actavis Group PTC and Actavis UK, EU:C:2013:833*, paragraph 41)." (emphasis supplied).

41. The court in the present case refers again to "the subject matter of the invention covered by the patent" at [42], before saying at [43]:

> "Accordingly, having regard to the objectives pursued by [the SPC Regulation], 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."

42. It is, again, difficult to understand this paragraph if the court intended to say no more than "apply Article 69 and the Protocol". As I have said, it was not being contended that the product defined by the SPC lay outside the protection conferred by the claims, applying those provisions.

43. In [44] and [45] the court derived support for what it was saying from Articles 4 and 5 of the Regulation. Article 4 states that, within the limits of the protection conferred by the basic patent, the protection conferred by a SPC shall extend only to the product covered by the authorisation. It might be said, however, that that provision is consistent with whatever interpretation one arrives at for the term "protected by a basic patent". Article 5 states that the certificate shall confer the same rights as conferred by the basic patent and shall be subject to the same limitations and the same obligations. It is difficult to see how these provisions do any more than support the proposition that "protected by a basic patent" has the same meaning in each of the three articles.

44. The court expresses its interim conclusion at [46]:

> "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."

45. Both sides seek to draw support from this formulation. The claimants stress the expression "the technical specifications of the invention covered by the basic patent" as indicating that it is directed at the invention as opposed to the scope of the monopoly, whereas Gilead point to the words "such as claimed in that patent", as indicating that it is no more than an extent of protection test.

46. Next, at [47], the court explains that, when implementing this rule, in accordance with a principle shared by the patent laws of Member States, and reflected in the Protocol, the claims are to be interpreted from the perspective of a person skilled in the art and therefore:

> "… the issue whether the product which is the subject of the SPC necessarily falls under the invention covered by that patent must be assessed from that perspective.
>
> 48. To that end, it is necessary to ascertain whether a person skilled in the art can understand without any doubt, on the basis of their general knowledge and in the light of the description and drawings of the invention in the basic patent, that 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."

47. As was pointed out by Lewison LJ in the course of the hearing, as a matter of grammar the words "the product … is a specification required for the solution of the

technical problem" are not clear. Presumably what is meant is that "the product … is specified as required for the solution of the technical problem". Paragraph [48] has been referred to as the "first limb" of the CJEU's test, and I will adopt that convention.

48. Paragraph [49] sets out what I shall call the second limb:

> "In the second place, having regard to the objective of [the SPC Regulation], recalled in paragraph 39 above, for the purposes of assessing whether a product falls under the invention covered by a basic patent, account must be taken exclusively of the prior art at the filing date or priority date of that patent, such that the product must be specifically identifiable by a person skilled in the art in the light of all the information disclosed by that patent."

49. The limitation to reliance on "the prior art at the filing date or priority date of that patent" is explained in [50] and [51] as being justified by the considerations in paragraphs [40] and [41] of the judgment. In paragraph [40] the court had explained that it would "extend the protection conferred by the patent" if an SPC were granted which "does not fall under the invention covered by the basic patent, inasmuch as such an SPC would not relate to the results of the research claimed under the patent".

50. Gilead contends that the purpose of the second limb is simply to "stop the clock" in relation to the materials which may be used to identify an active ingredient which is not specified in the claims. Gilead accepts that this is a limitation to the normal domestic extent of protection rules. If a claim is defined by a functional term, a subsequently invented product may infringe if it satisfies the functional terms. Under the second limb of the court's rule, however, it would be excluded, because it could not be identified on the basis of the information in the patent and the prior art at the priority date.

51. The court's test is then expressed again at paragraph [52]:

> "Having regard to all the foregoing considerations, a product is 'protected by a basic patent in force' within the meaning of Article 3(a) of [the SPC Regulation] in so far as, if that product is not expressly mentioned in the claims of the basic patent, one of those claims relates to it necessarily and specifically. For that purpose, that product must, from the point of view of a person skilled in the art and in the light of the description and drawings of the basic patent, necessarily fall under the invention covered by that patent. The person skilled in the art must be able to identify that product specifically in the light of all the information disclosed by that patent, on the basis of the prior art at the filing date or priority date of the patent concerned."

52. The court then goes on to indicate how these principles might be applied in the present case, whilst at the same time making it clear that their application to the facts was a matter for the national court:

> "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.
>
> 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 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."

53. Finally there is the operative part of the judgment or *dispositif*:

> "Article 3(a) of [the SPC Regulation] 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."

54. It will be noted that both limbs of the two-part test are to be answered "on the basis of the prior art at the priority date" in contrast to their original expression in paragraphs [48] and [49] where "common general knowledge" was referred to for the first limb of the test and "prior art" for the second.

The Second Judgment

55. In the Second Judgment, the judge reviewed the judgment of the CJEU in the course of which he reached a number of conclusions. Thus, having set out paragraphs [39] to [42] of the court's judgment, he said at [10]:

> "In a nutshell, what the Court 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."

56. The judge then moved on to paragraphs [43] to [46]. As to [46] he said:

> "Taken in isolation, it is unclear what the Court means by "the technical specifications of the invention covered by the basic patent". The Court is using terminology derived from patent law, but not in accordance with its meaning in that field."

57. The judge thought this did not matter greatly, however, as what the court had in mind was made clear by what followed. Having set out [47] to [48] of the court's judgment he said:

> "Counsel for Gilead submitted that this test was a pure extent of protection test. I do not accept that submission. The Court is clearly saying that more is required than that the product should fall within the scope of the claim: the skilled person must understand that the product is "a specification required for the solution of the technical problem". Again, this is not as pellucid as one would hope, because the Court is again using terminology derived from patent law inaccurately. Nevertheless, the sense is tolerably clear: the product must be one that the skilled person would understand, on the basis of the description and drawings and their common general knowledge, <u>as embodying the technical contribution made by the patent</u>. This is confirmed by what the Court says later in the judgment at [56]." (emphasis added).

58. Turning to the second limb, and having set out paragraphs [49] to [51] of the court's judgment, the judge said:

> "Thus 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."

59. As I have said, it is accepted that it is correct to exclude information which becomes available after the priority date. Nevertheless, there is a dispute about whether the judge was justified in equating the court's reference to the prior art as meaning the common general knowledge.

60. The judge went on to deal with the court's indication as to how these principles would apply to the facts of this case. He rejected a submission by Gilead that the court had exceeded its jurisdiction by setting out these views. He also rejected Gilead's submission that the court had misapplied the extent of protection test.

61. At [36] to [40] the judge explained why he considered that neither of the limbs of the CJEU's test were satisfied in the present case. As to the first limb he phrased the test as whether the combination of TD and emtricitabine was one that the skilled person would understand, on the basis of the description and drawings, and their common general knowledge, to embody the technical contribution of the patent. His answer, at [38] was:

> "As the Court of Justice rightly says at [56], 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. TD embodies the technical contribution of the Patent, but that is a different matter."

62. As to the second limb of the test, the judge expressed this as being whether, from the point of view of the person skilled in the art and on the basis of the prior art at the priority date, each of the active ingredients was specifically identifiable. He concluded:

> "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."

63. At paragraph [40] the judge referred to certain other matters, as being "perfectly consistent" with his conclusion. Although Mr Mitcheson sought to make something of these points, they were far from being central to the judge's reasoning, and I say no more about them.

The Advocate General in *Sandoz v Searle*

64. Since the second judgment, the CJEU has held a hearing on the reference from this court in *Sandoz v Searle*. That reference was joined with a reference from Germany entitled *Royalty Pharma Collection Trust* and an Opinion in conjoined cases C-650/17 and C-114/18 was issued by Advocate General Hogan on 11 September 2019. The court has not yet delivered its judgment, however. For present purposes it is worth noting a number of points from the Opinion. First, the Advocate General expressed the view, at [53] to [54] of his Opinion, that the court in the reference in the present case had not adopted the "inventive advance" approach either in its reasoning or in the operative part of its judgment. In his view:

> "…the 'core inventive advance' of the patent does not apply and is of no relevance in the context of Article 3(a)."

65. Secondly, the Advocate General expressed a view on the difference between "prior art" to which the court had referred in paragraph [50] of the reference in the present case in its exposition of the second limb of the test. He considered that the suggestion that the reference to prior art should be substituted by a reference to the common general knowledge should be rejected "as it is in direct conflict with the unambiguous wording of the operative part of the ruling of the court". The only substantive reasoning given by the Advocate General is that the assessment must exclude results from research which took place after the priority date: see [68] to [69]. This deals only with the temporal limit on what is to be taken into account. It does not deal with the well known patent law distinction between what is known at the priority date and what is common general knowledge.

66. Thirdly, the Advocate General makes some observations on the two limbs of the test at [73] to [77]. At [73], whilst repeating that the core inventive advance test is not applicable, he recited the first limb of the test as being that the product "*necessarily* falls under the invention covered by the patent", and at [74] as being that "the product … is a specification *required* for the solution of the technical problem", the words "necessarily" and "required" being emphasised in the original. He continued:

> "It follows that if, from the point of view of the 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 for the solution of the technical problem disclosed by a patent, the first part of the test in that judgment is not satisfied…"

67. As to the second limb, the Advocate General said at [77] that it:

> "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 the priority date."

The appeal

68. Mr Mitcheson submitted that the test for what is protected by a basic patent for the purposes of Article 3(a) of the SPC regulation remained an extent of protection test subject only to the two provisos contained in the respective limbs of the test explained by the CJEU in the reference in this case. The judge had gone wrong in failing to find that the two limbs of the CJEU's test were satisfied in this case. The first limb excluded cases where the claim contained no reference to the other ingredients: as exemplified by a claim which only said that it "comprised" ingredient A but was said to protect a combined product A+B. That was not this case, however, because the claim did refer to other therapeutic ingredients. The "other therapeutic ingredients" were part of the subject matter of the claims. The second limb was intended to "stop the clock" in relation to what knowledge could be deployed to determine whether the ingredient was identifiable. That limb was also satisfied here because emtricitabine was identifiable based on the prior art at the priority date.

69. Mr Mitcheson submitted that the judge had gone wrong in law in two ways. First, he had applied the "inventive advance" or "technical contribution" test. Secondly, he had assessed compliance with the second limb by reference to the common general knowledge when the court had expressly ruled that all the prior art formed the relevant pool of knowledge.

70. Finally, Mr Mitcheson submitted that the judge had been plainly wrong to refuse to admit the fresh evidence to make good Gilead's case under the second limb. The CJEU's test was new, and Gilead could not have anticipated the need for expert evidence as to the prior art and common general knowledge to the extent which the new test required.

71. Mr Alexander supported the judge's reasoning. The judge's use of the "technical contribution" test was not in the objectionable sense identified by the Advocate General (leading to confusion with patentability and inventive step), but in the sense meant by the court, namely whether it was the actual subject matter of the patent. He submitted that if the CJEU was really intending to revert to a simple extent of protection test, subject to only minor provisos, it would have said so. The first limb of the test could not possibly be satisfied, when the claims made the "other therapeutic ingredient" optional.

72. Mr Alexander further submitted that the language of claim 27 was far too general to make emtricitabine specifically identifiable in accordance with the second limb.

Discussion

73. The question raised by the first limb of the CJEU's test is whether the combination of the active ingredients TD and emtricitabine must necessarily, in the light of the description and drawings of that patent, fall under the invention covered by the patent.

74. I do not think that by using the term "fall under the invention covered by the patent" the court is intending to refer to the inventive advance or technical contribution of the patent. The court has definitely set its face against the introduction of such a test. Although there is no reference to it in the reasoning of the court in the reference in this case, the retention of such a test would be inconsistent with the proposition in paragraph [37] of the court's judgment. That paragraph states that express mention of the active ingredient in the claim is enough. Express mention in a claim says nothing about whether the added ingredient forms part of the inventive advance. Moreover, the opinion of Advocate General Wathelet in that case and (since the Second Judgment) that of Advocate General Hogan in *Sandoz v Searle*, both roundly reject such a test. Whatever might be said for it from a policy point of view, it must now be regarded as wrong.

75. In my judgment, the first limb is simply a more elaborate exposition of the "necessarily" part of the test first advanced in *Eli Lilly*, namely that "the claims relate … necessarily … to the active ingredient in question". I agree with Mr Mitcheson that this limb means that a claim to "a formulation comprising compound A" does not protect a combination of A and B. That is because the presence of B is not a necessary part of the invention claimed. It follows that, to protect a combination product, a claim must require the presence of two compounds, not just one.

76. This is not what a domestic patent lawyer would call a simple extent of protection test, applying Article 69 and the Protocol. Rather it is a test which examines whether *each* component of the combination product is *required* by the claim. A domestic extent of protection test would only ask whether that which is claimed is present anywhere in the product, which is a quite different question.

77. I do not accept, however, that the first limb of the test, so understood, is met in the present case. The addition of "other therapeutic ingredients" to TD in claim 27 is expressly made optional. That is no different in principle to a claim which "comprises" TD, which we know is not good enough to protect a combination. Mr Mitcheson strove valiantly to explain why the court should nevertheless find that claim 27 necessarily relates to a combination of TD and other therapeutic ingredients. He submitted, first, that the claim was merely a convenient way of avoiding having to write out separate claims to (a) a pharmaceutical composition comprising TD and (b) such a composition containing TD plus other therapeutic ingredients. He submitted that reliance on the word "optionally" would mean that a claim to "A in combination with X or Y" could never support an SPC, because both X and Y are optional. Secondly, he submitted that if the answer to the case was so straightforward, the CJEU would have said so, rather than saying that the national court needed to consider the matter further. Thirdly, he submitted that the skilled person would know that, on the basis of the common general knowledge at the priority date, monotherapy of patients with HIV was likely to be insufficient, and that combination therapy, ideally with another antiviral, was likely to be necessary to prevent the patient dying.

78. I cannot accept these submissions. As to the wording of the claim, it is not possible to understand claim 27 as requiring the presence of another therapeutic ingredient when it expressly states that it is optional. The fact that the claims might have been drafted differently does not assist. It is clear that claim drafting is of importance in this area, as cases such as C-577/13 *Actavis* (cited above) make clear. It did not assist Actavis to say that it could have had a claim to the combination. The claims which it had were all that mattered. The same applies here.

79. Mr Mitcheson's example of a claim to "A in combination with X or Y" is, moreover, not a true analogy, because combinations are expressly claimed, and a second ingredient is required. The true analogy is a claim "A, optionally combined with X or Y", which requires only A.

80. It is correct that the CJEU did not decide that the word "optionally" was fatal to Gilead's case. Nevertheless, the CJEU drew specific attention to the use of the word "optionally" at [54], and then applied appropriate restraint by not venturing further than it did into the resolution of the issue, which is for the national court alone. I do not infer anything from this failure to venture further.

81. Finally, it is by a focus on the claims and the description that the skilled person (albeit with the benefit of his common general knowledge) decides what the claims necessarily relate to. Although the patent contains lengthy, standard form, material as to how the compounds of the invention can be formulated, there is nothing to suggest to the skilled person that claim 27 requires the presence of another ingredient. Everything points the other way. The skilled person might well know from the common general knowledge that other anti-viral agents would be useful in practice in the treatment of HIV, but he would not therefore assume that the presence of such an agent was required by the claim.

82. In any event, Mr Mitcheson's argument appears to assume that claim 27 is limited to a pharmaceutical composition containing TD for the treatment of HIV. It is not so limited, and the phrase "other therapeutic ingredients" is not limited to anti-viral agents either. The breadth of the claim is a further reason for not reading it as requiring the presence of a second anti-viral agent known to have potential for HIV.

83. To put it another way, drawing on paragraph [48] of the court's judgment, there is no basis for the skilled person to conclude that "the product [i.e. TD plus another therapeutic ingredient] is specified as required for the solution of the technical problem disclosed by the patent".

84. Those reasons are sufficient to result in the appeal being dismissed. It is not therefore necessary for me to go on to consider the application of the second limb of the CJEU's test. There is a difficult question as to whether the second limb merely stops the clock as regards the pool of prior art material which can be called upon to satisfy the test, or whether it extends further by imposing a qualitative restriction on the type of knowledge which can be relied on, such as that it must form part of the common general knowledge. There is a further question as to whether the breadth of a functional definition such as "other therapeutic agents" is itself fatal to the specific identification test, or whether it is permissible to consider evidence as to what other therapeutic agents would be brought to mind, or existed in the prior art for combination with TD, which is, after all, specifically claimed, and exemplified in the

patent in a test against HIV. Finally, there is a question of whether the fact that it was not yet known that emtricitabine was effective in humans against HIV, or approved for human use, would exclude it from consideration as a "therapeutic ingredient". I would prefer to leave those issues to a case in which their resolution affected the result. I would only add that I would not wish to endorse the view, implicit in the judge's paragraph [39], that if emtricitabine was otherwise sufficiently identified, it would be necessary to show that it was known at the priority date to be an effective agent for the treatment of HIV in humans, or approved for such use, or that these facts were by then, common general knowledge. Given that none of this was known for TD at the priority date, it may be that this is to impose too high a standard.

85. It also follows that there is no need to consider the challenge to the exclusion of expert evidence, as this was only asserted to be relevant to limb 2.

86. For the above reasons I would dismiss the appeal.

Lord Justice Dingemans:

87. I agree.

Lord Justice Lewison:

88. I also agree.