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Case Nos: HP-2016-000004/00023/000032/000034

IN THE HIGH COURT OF JUSTICE

**CHANCERY DIVISION**

**PATENTS COURT**

Rolls Building

Fetter Lane, London EC4A 1NL

Date: 13 January 2017

**Before** :

MR JUSTICE ARNOLD

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**Between :**

|  |  |  |
| --- | --- | --- |
|  | **TEVA UK LIMITED****ACCORD HEALTHCARE LIMITED****LUPIN LIMITED and LUPIN EUROPE LIMITED****GENERICS (UK) LIMITED trading as MYLAN** | Claimants |
|  | **- and -** |  |
|  | **GILEAD SCIENCES INC** | Defendant |

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**Daniel Alexander QC** and **Lindsay Lane** (instructed by **Pinsent Mason LLP**) for **Teva**

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**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**

**Thomas Mitcheson QC** and **James Whyte** (instructed by **Herbert Smith Freehills LLP**) for **Gilead**

Hearing dates: 15-16 December 2016

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Approved Judgment

I direct that pursuant to CPR PD 39A para 6.1 no official shorthand note shall be taken of this Judgment and that copies of this version as handed down may be treated as authentic.

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MR JUSTICE ARNOLD

**MR JUSTICE ARNOLD :**

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Introduction

1. In these proceedings the Claimants challenge the validity of the Defendant’s (“Gilead’s”) supplementary protection certificate SPC/GB05/041 (“the SPC”) for a product described in the SPC as “Composition containing both Tenofovir disoproxil, optionally in the form of a pharmaceutically acceptable salt, hydrate, tautomer or solvate, together with Emtricitabine”. The SPC covers a product which is marketed by Gilead under the trade mark Truvada. Truvada is an anti-retroviral medication used in the treatment of human immunodeficiency virus (HIV). It is a combination product consisting of two active ingredients, namely (i) 245 mg tenofovir disoproxil (“TD”) in the form of 300 mg of the fumarate (“TDF”) and (ii) 200 mg emtricitabine (also known as FTC) in a single, fixed dose tablet. TD and emtricitabine are both inhibitors of a viral enzyme known as reverse transcriptase. Gilead contends that the product described in the SPC is protected by European Patent (UK) No. 0 915 894 (“the Patent”), but the Claimants dispute this. Accordingly, the Claimants contend that the SPC does not comply with Article 3(a) of European Parliament and Council Regulation 469/2009/EC of 6 May 2009 concerning the supplementary protection certificate for medicinal products (codified version) (“the SPC Regulation”).
2. It should be noted at the outset that Gilead’s application for the SPC was originally rejected by the Comptroller-General of Patents, but Gilead’s appeal against that refusal was allowed by Kitchin J (as he then was) for the reasons he gave in a judgment dated 31 July 2008 ([2008] EWHC 1902 (Pat)). Since then, however, there have been a number of judgments of the Court of Justice of the European Union which are relevant to the issue raised by the Claimants. Furthermore, Kitchin J did not have the benefit of the Claimants’ arguments or of the evidence adduced by the parties before me. Accordingly, I must consider the matter afresh. As explained below, the Claimants contend that it is clear from the case law of the CJEU that the SPC does not comply with Article 3(a) of the SPC Regulation, while Gilead contends that it is clear that it does comply, but in the alternative contends that, if this is not clear, the question of interpretation of Article 3(a) should be referred to the CJEU.

The evidence

1. The parties in this case adopted slightly odd procedures to adduce evidence of the technical background. Gilead served a witness statement of Professor Brian Gazzard CBE, who is Professor of HIV Medicine, Consultant Physician and Research Director for HIV and Genitourinary Medicine at Chelsea and Westminster Hospital. Prof Gazzard is, and has been for many years, a well-known and eminent expert in the field of HIV treatment. He stated in his witness statement that he had been asked to give evidence “as an independent fact witness”. In reality, Prof Gazzard’s evidence is, at least in part, expert evidence which Gilead did not obtain the permission of the Court to adduce. The fact that his statement was, commendably, quite brief and drafted so as to be uncontroversial does not alter this. Sensibly, however, the Claimants did not object to the admission of this evidence. They did, however, point out that some of it was of no relevance since it related to the position well after the priority date of the Patent.
2. For their part, the Claimants served hearsay notices in respect of a number of scientific papers. This was another device for adducing what in substance amounted to expert evidence without obtaining the Court’s permission, and an even less satisfactory one. The general rule in English law is that a scientific textbook or article is not in itself admissible evidence: see *Phipson on Evidence* (18th ed) at §32-20. The reason for this rule is that it cannot generally be assumed that the court has sufficient expertise to understand and assess such materials without the assistance of an expert. It is, of course, entirely proper both for expert witnesses to refer to such materials in their evidence, and for cross-examiners to test the evidence of such witnesses by reference to such materials, but that does not alter the fact that the primary evidence is that of the expert witnesses. Again, however, Gilead sensibly did not object to the admission of this evidence. It is again uncontroversial and I was able to understand it to the extent necessary.

Technical background

1. A wide range of therapeutic agents was known for the treatment of viral infections, including HIV, in July 1996. These included a class of anti-retroviral drugs called nucleoside reverse transcriptase inhibitors or NRTIs. By July 1996, it was increasingly common to treat HIV using a combination of different NRTIs, and in particular zidovudine (also known as AZT) and didanosine (also known as ddI). Other combinations which were used to treat HIV included AZT and zalcitabine (also known as ddC) and AZT and lamivudine (also known as 3TC). Another approach which was used in some cases was to combine a NRTI with a protease inhibitor or a non-nucleoside reverse transcriptase inhibitor or NNRTI, two other classes of anti-retroviral drugs.
2. Emtricitabine appears to have been first described in an article by Raymond Schinazi *et al*, “Selective inhibition of human immunodeficiency viruses by racemates and enantiomers of cis-5-fluoro-1-[2-(hydroxymethyl)-1,3-oxathiolan-5-yl]cytosine”, *Antimicrobial Agents and Chemotherapy*, 36(11), 2423-2431 (November 1992). This article reported, inter alia, data for emtricitabine from *in vitro* anti-HIV studies.
3. 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.

The Patent

1. 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.”
2. 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.
3. 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].
4. 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.

1. 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]).
2. 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.

1. 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.
2. It is common ground that emtricitabine is not mentioned or referred to in the Patent.

The claims of the Patent

1. Claim 1 is a claim to compounds of formula (1a) and claim 2 is a claim to compounds of formula (1). Claims 3-24 are dependent compound claims which get progressively narrower in scope. Claim 25 is an independent compound claim to TD.
2. Claim 26 is a claim in Swiss form to the use of any of the compounds of claims 1-25 for the treatment or prophylaxis of viral infections in man or animals.
3. Claim 27 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.”

1. Claims 28-33 are method claims.
2. It should be appreciated that the decision whether to include claims like claims 26 and 27 at all in a patent of this nature, and if so how to draft such claims, are matters for the choice of the patent proprietor. In practice, the decision will be taken by the patent attorney who drafts the patent application based on legal, rather than scientific or technical, considerations.

Interpretation of claim 27

1. The claims of a patent are to be interpreted in accordance with the principles stated by Lord Hoffmann in *Kirin-Amgen Inc v Hoechst Marion Roussel Ltd* [2004] UKHL 46, [2005] RPC 9 and summarised by Jacob LJ in *Virgin Atlantic Airways Ltd v Premium Aircraft Interiors UK Ltd* [2009] EWCA Civ 1062, [2010] RPC 8 at [5]. These principles give effect to Article 69 of the European Patent Convention and the Protocol on the Interpretation of Article 69 (as to which, see below).
2. Claim 27 requires the presence in the pharmaceutical composition of a compound falling within any of claims 1-25 together with a pharmaceutically acceptable carrier. The significance of the words “comprising” and “optionally” is that claim 27 permits, but does not require, the presence of other ingredients, both therapeutic and non-therapeutic. Thus the scope of protection of claim 27 is not limited to a pharmaceutical composition containing two (or more) therapeutic ingredients, but extends to a pharmaceutical composition containing a single therapeutic ingredient consisting of a compound falling within claims 1-25. It follows that the presence or absence of another therapeutic ingredient is irrelevant to any assessment of whether a pharmaceutical composition falls within claim 27, and thus to whether dealings in such a pharmaceutical composition infringe that claim of the Patent.

What is the inventive advance (or technical contribution) of the Patent?

1. In my judgment it is clear that the inventive advance (or the technical contribution, to use the language used in the jurisprudence of the Boards of Appeal of the European Patent Office) of the Patent lies in the disclosure of the new compounds of formulae (1a) and (1), including TD, as claimed in claims 1-25. It is also clear that, given that invention, claim 27 does not reflect any further inventive advance (or technical contribution). In the jargon of patent lawyers, claim 27 is not independently valid over claims 1-25.

Gilead’s marketing authorisations and patents for TD

1. In addition to Truvada, Gilead markets a monotherapy for the treatment of HIV under the trade mark Viread which has only TDF as the active ingredient. Gilead obtained the first marketing authorisation for Viread on 5 February 2002 via the centralised procedure. Gilead has not obtained an SPC for Viread, presumably because the period which elapsed between the date of filing of the application for the Patent and the date of that marketing authorisation was less than five years (so that the term of any SPC would have been negative).
2. Gilead obtained a marketing authorisation for Truvada on 21 November 2005, again by the centralised procedure. It is this marketing authorisation which Gilead designated as the basis for the SPC.
3. Gilead applied for and was granted a patent for the combination product, European Patent No 1 583 542, but that patent was revoked by the Opposition Division of the European Patent Office for lack of inventive step (although that decision is presently under appeal).

The SPC Regulation

1. The SPC Regulation enables the proprietor of a patent for a medicinal product to obtain an SPC which extends the duration of the patent with respect to that product so as to compensate the proprietor for the effective loss of patent term caused by the need to obtain a marketing authorisation before the product can be marketed.
2. The SPC Regulation includes the following recitals:

“[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 establishment and the functioning of the internal market.

[8] Therefore, the creation 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.”

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

“*Article 1*

**Definitions**

For the purpose of this Regulation:

(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 defined in (b) 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;

…

*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.”

Interpretation of the SPC Regulation

1. As is common ground, it is well established that the correct approach to the interpretation of the SPC Regulation is that stated by the CJEU in Case C-482/07 *AHP Manufacturing v Bureau voor de Industriele Eigendom* [2009] ECR I-7295 at [27]:

“Next, the Court observes that the second sentence of Article 3(2) of Regulation No 1610/96 must be interpreted not solely on the basis of its wording, but also in the light of the overall scheme and objectives of the system of which it is a part (see, by analogy, Case C-292/00 *Davidoff* [2003] ECR I-389, paragraph 24).”

1. As is also common ground, the SPC Regulation pursues a number of different objectives and aims to strike a balance between them. This was well described by Advocate General Trstenjak in her opinion in Case C-130/11 *Neurim Pharmaceuticals (1991) Ltd v Comptroller-General of Patents* [EU:C:2012:268], [2013] RPC 23:

“41. Those rules are intended to achieve a balance between the various interests at stake in the pharmaceutical sector. Those interests include, on the one hand, the interests of the undertakings and institutions, some of which pursue very cost-intensive research in the pharmaceutical sector and therefore favour an extension of the term of protection for their inventions in order to be able to balance out the investment costs. On the other hand, there are the interests of the producers of generic medicines who, as a consequence of the extension of the term of protection of the active ingredients under patent protection, are precluded from producing and marketing generic medicines. It is also relevant in this connection that, in general, the marketing of generic medicinal products has the effect of lowering the prices of the relevant medicinal products. Against that background, the interests of patients lie between the interests of the undertakings and institutions conducting research and those of the producers of generic medicines. That is because patients have an interest, on the one hand, in the development of new active ingredients for medicinal products, but, on the other, they also have an interest in those products then being offered for sale as cheaply as possible. The same applies to State health systems in general which, in addition, have a particular interest in preventing old active ingredients from being brought onto the market in slightly modified form under the protection of certificates but without genuine innovation and thereby artificially driving up expenditure in the health section.

42. Against the background of that complex situation as regards interests, Regulation 1768/92 sought to achieve a balanced solution taking due account of the interests of all parties. In view of the complexity of that balance of interests, it is necessary to proceed with great caution when making a teleological interpretation of the individual provisions of the regulation.”

Interpretation of Article 3(a): the problem

1. The interpretation of Article 3(a) of the SPC Regulation (and its predecessor, Council Regulation 1768/92/EEC) has caused great difficulty over the years, as is illustrated by the successive judgments of the CJEU discussed below. It may be helpful if I attempt to explain the problem before turning to consider the case law. Article 3(a) requires that “the product is protected by a basic patent in force”. The term “product” is defined in Article 1(b) and the term “basic patent” is defined in Article 1(c). The question is what is meant by the term “protected” in this context.
2. There is very little in the SPC Regulation which sheds any light on this issue. The most one can say is that the SPC Regulation appears to draw a distinction between the *protection* conferred by a basic patent (and a certificate) and the *rights* conferred (subject to limitations and obligations) by the basic patent (and the certificate): see Articles 4 and 5.
3. Approaching the issue from first principles, however, I would suggest that what is tolerably clear is that the product must at least be “protected” by the basic patent applying the applicable rules of patent law in the country where the SPC has been applied for. But less clear are the answers to the following questions: first, what the applicable rules of patent law are for this purpose; and secondly, whether satisfaction of that test is sufficient to establish that a product is protected by a basic patent for the purposes of the SPC Regulation or whether something more is required, and if so what. As I will explain, it is the second of these questions which is particularly difficult to answer.
4. So far as the first question is concerned, there are two sets of rules which might be relevant in a case such as the present, which concerns a European patent. The first set, which I shall call the “Extent of Protection Rules”, consists of national laws which implement Article 69 EPC, of which all Member States of the European Union are Contracting States. Article 69 concerns the extent of protection of a European patent. Article 69(1) provides that:

“The extent of the protection conferred by a European patent … shall be determined by the claims. Nevertheless, the description and drawings shall be used to interpret the claims.”

Article 69 is supplemented by the Protocol on the Interpretation of Article 69, which concerns the manner in which the claims are to be interpreted. Article 69 and the Protocol are given effect to in the UK by section 125(1) and (3) of the Patents Act 1977 and by the case law referred to above.

1. The second set of rules, which I shall call the “Infringing Act Rules”, consists of national laws which define what acts amount to an infringement of a patent. In many, but not all, Member States of the EU, including the United Kingdom, the relevant laws were intended to implement Articles 25 and 26 of the Community Patent Convention (as revised in 1989), which never came into force. These provide for a patent to “confer on its proprietor the right to prevent all third parties not having his consent” from committing certain acts. Some acts amount to direct use of the invention (and hence direct infringement of the patent) and other acts amount to indirect use of the invention (and hence indirect infringement of the patent). In the UK, Articles 25 and 26 CPC are implemented by sections 60(1) and (2) of the 1977 Act respectively. There are similar kinds of laws in countries which did not implement the CPC.
2. Bearing in mind (i) the apparent distinction drawn by the SPC Regulation between the protection conferred by a basic patent and the rights conferred by that patent, (ii) the fact that the extent of protection conferred by a European patent is governed by the Extent of Protection Rules while the rights conferred by a patent are governed by the Infringing Act Rules, and (iii) the fact it is not a product which infringes a patent, but an act performed by a person in relation to a product which infringes a patent, then one might conclude that the answer to the first question posed in paragraph 34 above was that the applicable rules are the Extent of Protection Rules, and not the Infringing Act Rules.
3. It is possible to arrive at a similar conclusion in relation to national patents. It is not necessary for present purposes to spell out the details of the route to this conclusion.
4. Turning to the second question posed in paragraph 34 above, it might be suggested that it was both necessary and sufficient that a product fell within the scope of protection of the basic patent applying the Extent of Protection Rules. The problem with this suggestion was identified by Jacob J (as he then was) in *Takeda Chemical Industries Ltd’s SPC Applications (No 3)* [2003] EWHC 649 (Pat), [2004] RPC 3.
5. In that case Takeda had obtained a patent, a marketing authorisation and an SPC for the anti-ulcer agent lansoprazole. Subsequently Takeda obtained a patent for the use of lansoprazole for the manufacture of a medicament for preventing or treating infectious diseases caused by Helicobacter pylori. It also obtained a variation to the marketing authorisation adding the eradication of Helicobacter pylori as a new therapeutic indication for lansoprazole when used in combination with appropriate antibiotics. It filed six applications for SPCs for combinations of lansoprazole with two antibiotics selected from clarithromycin, amoxycillin and metronidazole. Three of the applications designated the first patent, and the other three the second patent. The hearing officer refused all the applications for non-compliance with Article 3(a) and (b) of Regulation 1769/92/EEC. Takeda appealed to the Patents Court. Jacob J dismissed the appeal.
6. In relation to Article 3(a) Jacob J held as follows:

“7. Mr Alexander, for Takeda, submits that the combination of lansoprazole with an antibiotic, if sold, would infringe the patent (and for this purpose it matters not which). So, the combination is protected by a basic patent which is in force. So, Takeda comply with condition 3(a). Moreover, he submits, definition (b) specifically contemplates that ‘product’ may be a combination of active ingredients. So it is clear that condition 3(a) contemplates protection of a combination.

…

10. Mr Birss, for the Comptroller, submits Mr Alexander's argument is flawed. I agree. The so-called ‘combination’ of lansoprazole and an antibiotic would only infringe because of the presence of the lansoprazole. In truth, the combination is not as such ‘protected by a basic patent in force’. What is protected is only the lansoprazole element of that combination. It is sleight-of-hand to say that the combination is protected by the patent. The sleight-of-hand is exposed when one realises that any patent in Mr Alexander's sense protects the product of the patent with anything else in the world. But the patent is not of course for any such ‘combination’.

…

12. … The SPC system is to provide supplementary protection to that provided by the patent—to extend the relevant part of the patent monopoly. It is not a system for providing protection for different monopolies. Here, Takeda's monopoly is in lansoprazole. The monopoly which they seek is a combination of lansoprazole and an antibiotic. The fact that that combination might infringe the monopoly given by the patent simply because one component infringes is irrelevant. Accordingly, I uphold Mr Walker's decision in relation to Art.3(a).”

1. Three points should be noted about this reasoning. First, at [10] Jacob J used the expression “as such”. This expression is not contained in Article 3(a), but it is contained in Article 1(c). This tells us that the basic patent must protect the product “as such”. It is not clear what is meant by this, but it does suggest that some degree of specificity is required. Secondly, Jacob J spoke in terms of infringement of the basic patent, that is to say, the Infringing Act Rules. But his reasoning is equally applicable to the Extent of Protection Rules. Dealings in the combination of lansoprazole and an antibiotic would have infringed the basic patent because the combination of lansoprazole and an antibiotic fell within the scope of protection of the basic patent, not because of any peculiarity in the Infringing Act Rules applicable in the UK. The combination of lansoprazole and an antibiotic only fell within the scope of protection of the basic patent because of the presence of lansoprazole, however. Thirdly, Jacob J referred at [12] to an SPC extending “the relevant part of the patent monopoly”. This is an important point: an SPC does not extend the term of an entire patent, it provides a limited extension for the part of the patent which protects the medicinal product which has been granted a marketing authorisation.
2. These considerations suggest that it is not sufficient for the product in question to fall within the scope of protection of the basic patent applying the Extent of Protection Rules. Something more is required. But what? I shall return to this question after considering the case law.

Case law of the CJEU on the interpretation of Article 3(a)

*Farmitalia*

1. In Case C-392/97 *Farmitalia Carlo Erba Srl* [1999] ECR I-5553 Farmitalia had obtained a German patent for idarubicin. The claims specifically covered idarubicin hydrochloride. Farmitalia had also obtained a marketing authorisation for idarubicin hydrochloride. Farmitalia applied for an SPC for “idarubicin and salts thereof including idarubicin hydrochloride”. The German Patent Office granted an SPC for idarubicin hydrochloride, but refused to grant one for “idarubicin and salts thereof including idarubicin hydrochloride”. Farmitalia appealed first to the Bundespatentsgericht (German Federal Patent Court) and then the Bundesgerichtshof (German Federal Court of Justice). The latter court referred two questions concerning the interpretation of Article 3(b) and (a) respectively of what was then Council Regulation 1768/92/EEC to the Court of Justice. The second question was as follows:

“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), where the grant of a protection certificate is sought for the free base of an active ingredient including any of its salts, but the basic patent in its patent claims mentions only the free base of this substance and, moreover, mentions only a single salt of this free base? Is the wording of the claim for the basic patent or the latter's scope of protection the determining criterion?”

1. Advocate General Fennelly recommended in his opinion that the Court of Justice should answer the second question by holding that the product “should be deemed to be protected by a basic patent in force when it comes within the terms of the claims of the relevant patent”. He nevertheless observed at [31] that “there are no grounds for concluding that the Regulation requires a uniform approach to the question of the extent of the protection conferred by an SPC”, and read in context it seems clear that this observation was also applicable to the basic patent.
2. The Court held as follows:

“23. By its second question, the Bundesgerichtshof is, in substance, asking what are the criteria, according to Regulation No 1768/92, and in particular Article 3(a) thereof, for determining whether or not a product is protected by a basic patent.

…

26. As Community law now stands, the provisions concerning patents have not yet been made the subject of harmonisation at Community level or of an approximation of laws.

27. Accordingly, 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.

…

29. The answer to be given to the second question must therefore be that, in order to determine, in connection with the application of Regulation No 1768/92 and, in particular, Article 3(a) thereof, whether a product is protected by a basic patent, reference must be made to the rules which govern that patent.”

1. So far as it went, this reasoning is unquestionably correct. Since there is no EU legislation determining the extent of patent protection, then reference must be made to the rules laid down by national law. But the Court’s answer was incomplete because it did not address either of the questions identified in paragraph 34 above.

*Medeva and its progeny: the references*

1. In Case C-322/10 *Medeva BV v Comptroller-General of Patents, Designs and Trade Marks* [2011] ECR I-12051 Medeva was the proprietor of a patent the specification of which disclosed that a combination of two antigens known as pertactin and filamentous haemagglutinin (or FHA) produced a synergistic effect such that a third antigen called pertussis toxin (or LPF) was not required to produce a vaccine against *Bordella pertussis* (which causes whooping cough). The claims covered the combination of pertactin and FHA. Medeva obtained four marketing authorisations in respect of vaccines each of which was for immunisation against a number of diseases in addition to pertussis and contained between 8 and 11 different antigens. Each of these included pertactin, FHA and pertussis toxin. Medeva filed five applications for SPCs in respect of the medicinal products the subject of the authorisations. The Comptroller-General of Patents refused four of the applications on the ground that they did not comply with Article 3(a) since the patent did not protect the combinations of antigens which were the subject of the authorisations and were specified in the applications. He also refused a fifth application on the ground that it did not comply with Article 3(b).
2. Medeva appealed to the Patents Court, but its appeal was dismissed by Kitchin J ([2010] EWHC 68 (Pat), [2010] RPC 20). Medeva appealed to the Court of Appeal, which referred the following five questions concerning Article 3(a) to the CJEU ([2010] EWCA Civ 700, [2010] RPC 27) together with a sixth question concerning Article 3(b):

“1. Regulation 469/2009 (‘the Regulation’) recognises amongst the other purposes identified in the recitals, the need for the grant of an SPC by each of the Member States of the Community to holders of national or European patents to be under the same conditions, as indicated in recitals 7 and 8. In the absence of Community harmonisation of patent law, what is meant in Article 3(a) of the Regulation by ‘the product is protected by a basic patent in force’ and what are the criteria for deciding this?

2. In a case like the present one involving a medicinal product comprising more than one active ingredient, are there further or different criteria for determining whether or not ‘the product is protected by a basic patent’ according to Article 3(a) of the Regulation and, if so, what are those further or different criteria?

3. In a case like the present one involving a multi-disease vaccine, are there further or different criteria for determining whether or not ‘the product is protected by a basic patent’ according to Article 3(a) of the Regulation and, if so, what are those further or different criteria?

4. For the purposes of Article 3(a), is a multi-disease vaccine comprising multiple antigens ‘protected by a basic patent’ if one antigen of the vaccine is ‘protected by the basic patent in force’?

5. For the purposes of Article 3(a), is a multi-disease vaccine comprising multiple antigens ‘protected by a basic patent’ if all antigens directed against one disease are ‘protected by the basic patent in force’?”

1. In Case C-518/10 *Yeda Research and Development v Comptroller-General of Patents, Designs and Trade Marks* [2011] ECR I-12209 Yeda was the proprietor of a patent, claim 1 of which was as follows:

“A therapeutic composition comprising:

(a)       a monoclonal antibody which inhibits the growth of human tumour cells by said antibody binding to the extra‑cellular domain of the human EGF receptors of said tumour cells in an antigen‑antibody complex, said tumour cells being characterised by their expression of human EGF receptors and mitogenic stimulation by human EGF; and

(b)       an anti‑neoplastic agent

wherein the antibody is not antibody 108 produced by hybridoma cell line ATCC HB 9764 or antibody 96 produced by hybridoma cell line ATCC HB 9763.”

1. Yeda obtained a marketing authorisation for cetuximab (a monoclonal antibody specific for the receptor of epidermal growth factor or EGF) authorising its use in combination with irinotecan (an anti-neoplastic agent). Yeda applied for an SPC for cetuximab. The Comptroller-General of Patents refused the application on the ground that it did not comply with Article 3(a). Yeda appealed to the Patents Court, arguing that cetuximab was protected by the basic patent because sales of cetuximab would infringe pursuant to section 60(2) of the 1977 Act. Lewison J (as he then was) dismissed the appeal ([2010] EWHC 1733 (Pat), [2010] RPC 29). Yeda appealed to the Court of Appeal which referred the following question to the CJEU:

“If the criteria for deciding that a product is ‘protected by a basic patent in force’ under Article 3(a) of the Regulation include or consist of an assessment of whether the supply of the product would infringe the basic patent, does it make any difference to the analysis if infringement is by way of indirect or contributory infringement based on Article 26 of the Community Patent Convention, enacted as s60(2) of the Patents Act 1977 in the UK, and the corresponding provisions in the laws of other Member States of the Community?”

1. In Case C-630/10 *University of Queensland v Comptroller-General of Patents, Designs and Trade Marks* [2011] ECR I-12231 Queensland was the proprietor of three patents, 935, 211 and 156. 211 and 156 were divisionals from 935. 935 covered vaccines made from HPV type 6 or 11 L1 protein, 211 covered vaccines made from HPV type 18 L1 protein and 156 covered vaccines made from HPV type 16 L1 protein. Claim 1 of 935 was a method claim. GSK had a marketing authorisation for Cervarix vaccine which contained a combination of HPV type 16 and type 18 L1 proteins. Sanofi Pasteur had a marketing authorisation for Gardasil/Silgard which contained a combination of HPV type 6, 11, 16 and 18 LI proteins. Queensland applied for SPCs, filing applications both for the two combination products and for various products defined as single active ingredients. The Comptroller-General of Patents refused the combination applications on the ground that they did not comply with Article 3(a) and the single active ingredient applications on the ground that they did not comply with Article 3(b). Queensland appealed to the Patents Court. I referred the following questions concerning Article 3(a) to the CJEU together with two further question concerning Article 3(b):

“1. Regulation 469/2009 (the Regulation) recognises amongst the other purposes identified in the recitals, the need for the grant of an SPC by each of the Member States of the Community to holders of national or European patents to be under the same conditions, as indicated in recitals 7 and 8. In the absence of Community harmonisation of patent law, what is meant in Article 3(a) of the Regulation by ‘the product is protected by a basic patent in force’ and what are the criteria for deciding this?

2. In a case like the present one involving a medicinal product comprising more than one active ingredient, are there further or different criteria for determining whether or not ‘the product is protected by a basic patent’ according to Article 3(a) of the Regulation and, if so, what are those further or different criteria?

3. Is one of these further or different criteria whether the active ingredients are admixed together rather than being delivered in separate formulations but at the same time?

4. For the purposes of Article 3(a), is a multi-disease vaccine comprising multiple antigens ‘protected by a basic patent’ if one antigen of the vaccine is ‘protected by the basic patent in force’?

5. In a case like the present one involving a medicinal product comprising more than one active ingredient, is it relevant to the assessment of whether or not ‘the product is protected by a basic patent’ according to Article 3(a) that the basic patent is one of a family of patents based on the same original patent application and comprising a parent patent and two divisional patents which between them protect all the active ingredients in the medicinal product?

6. In a case like the present one involving a basic patent with claims to ‘a process to obtain a product’ in the sense of Article 1(c), does the ‘product’ of Article 3(a) have to be obtained directly by means of that process?”

1. In Case C-6/11 *Daiichi Sankyo Co v Comptroller-General of Patents, Designs and Trade Marks* [2011] ECR I-12255Daiichi was the proprietor of a patent, claim 5 of which was for:

“A pharmaceutical composition for the treatment or prophylaxis of hypertension which comprises an anti-hypertensive agent in admixture with a pharmaceutically acceptable carrier or diluent, in which the anti-hypertensive agent is at least one compound of formula (I) or a pharmaceutically acceptable salt or ester thereof, as claimed in any one of claims 1 to 4.”

1. Daiichi had obtained a marketing authorisation for a combination of olmesartan medoxomil, an anti-hypertensive agent of formula I, and hydrochlorothiazide, a different type of anti-hypertensive agent. Daiichi applied for an SPC for a combination of olmesartan medoxomil and
hydrochlorothiazide. The Comptroller-General of Patents refused the application on the ground that it did not comply with Article 3(a). Daiichi appealed to the Patents Court. Floyd J (as he then was) held that claim 5 only covered a combination of olmesartan medoxomil with another hypertensive agent where the other agent was also a compound of formula I ([2010] EWHC 2897 (Pat)). He nevertheless referred the following questions to the CJEU:

“1. Regulation 469/2009(the Regulation) recognises amongst the other purposes identified in the recitals, the need for the grant of an SPC by each of the Member States of the Community to holders of national or European patents to be under the same conditions, as indicated in recitals 7 and 8. In the absence of Community harmonisation of patent law, what is meant in Article 3(a) of the Regulation by ‘the product is protected by a basic patent in force’ and what are the criteria for deciding this?

2. In a case like the present one involving a medicinal product comprising more than one active ingredient, are there further or different criteria for determining whether or not ‘the product is protected by a basic patent’ according to Art 3(a) of the Regulation and, if so, what are those further or different criteria?

3. In order for a combination of active ingredients cited in an authorisation for placing a medicinal product on the market to be the subject of an SPC, and having regard to the wording to Article 4 of the Regulation, is the condition that the product be ‘protected by a basic patent’ within the meaning of Articles 1 and 3 of the Regulation satisfied if the product infringes the basic patent under national law?

4. In order for a combination of active ingredients cited in an authorisation for placing a medicinal product on the market to be the subject of an SPC, and having regard to the wording to Article 4 of the Regulation, does satisfaction of the condition that the product be ‘protected by a basic patent’ within the meaning of Articles 1 and 3 of the Regulation depend upon whether the basic patent contains one (or more) claims which specifically mention a combination of (1) a class of compounds which includes one of the active ingredients in the said product and (2) a class of further active ingredients which may be unspecified but which includes the other active ingredient in the said product; or is it sufficient that the basic patent contains one (or more) claims which (1) claim a class of compounds which includes one of the active ingredients in the said product and (2) use specific language which as a matter of national law extends the scope of protection to include the presence of further other unspecified active ingredients including the other active ingredient in the said product?”

*Medeva and its progeny: the opinion, the judgment and the reasoned orders*

1. *Medeva* was the subject of an Advocate General’s opinion and a judgment of the Court of Justice, whereas *Queensland*, *Daiichi* and *Yeda* were disposed of by reasoned orders.
2. In her opinion in *Medeva* Advocate General Trstenjak considered questions 1 to 5 together at [51]-[116]. She distinguished between what she called the “subject matter – or extent of protection” of the basic patent and what she called the “protective effect” of the patent: see in particular [68]-[72]. This is the same as the distinction between the Extent of Protection Rules and the Infringing Act Rules that I have discussed above. She concluded, in essence, that a product was “protected” by a basic patent within the meaning of Article 3(a) if it formed the subject-matter of the patent, meaning that it fell within the scope of protection of the patent applying the Extent of Protection Rules, but was not “protected” if it did not form the subject-matter of the patent, but dealings in the product would infringe applying the Infringing Act Rules: see [70], [72], [101], [110] and [112]-[113]. She also expressed the view that this resulted in a narrow interpretation of Article 3(a) which should be balanced by a broad interpretation of Article 3(b).
3. The Court of Justice also considered questions 1 to 5 together, beginning as follows:

“19. By its first five questions, which it is appropriate to examine together, the Court of Appeal asks, in essence, whether Article 3(a) of Regulation No 469/2009 must be interpreted as precluding the competent industrial property office of a Member State from granting a SPC where the active ingredients specified in the application include active ingredients not mentioned in the wording of the claims of the basic patent relied on in support of such an application.

20.       While the Latvian, Lithuanian and Portuguese Governments submit that only the wording of the claims is relevant 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, Medeva and the United Kingdom Government maintain that the concept of a ‘product … protected by a basic patent in force’ within the meaning of that provision corresponds to any combination of substances of a medicinal product directly infringing the patent.”

1. The Court then repeated what it had said in *Farmitalia* at [26]-[27] and continued:

“24. It should be noted that Regulation No 469/2009 establishes a uniform solution at European Union level by creating a SPC which may be obtained by the holder of a national or European patent under the same conditions in each Member State. It thus aims to prevent 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 European Union and thus directly affect the establishment and functioning of the internal market (see Case C‑350/92 *Spain* v *Council* [1995] ECR I‑1985, paragraphs 34 and 35; Case C‑127/00 *Hässle* [2003] ECR I‑14781, paragraph 37; and Case C‑482/07 *AHP Manufacturing* [2009] ECR I‑7295, paragraph 35).

25.       Moreover, it should be recalled that Article 5 of Regulation No 469/2009 provides that any SPC confers the same rights as conferred by the basic patent and is subject to the same limitations and the same obligations. It follows that Article 3(a) of the 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.

26.       Similarly, if a patent claims that a product is composed of two active ingredients but does not make any claim in relation to one of those active ingredients individually, a SPC cannot be granted on the basis of such a patent for the one active ingredient considered in isolation.

27.       That approach is also borne out by the second subparagraph of paragraph 20 of the explanatory memorandum to the proposal for Council Regulation (EEC) of 11 April 1990 concerning the creation of a supplementary protection certificate for medicinal products (COM(90) 101 final) (‘the explanatory memorandum’), which, in so far as concerns what is ‘protected by the basic patent’, refers expressly and solely to the wording of the claims of the basic patent. That interpretation also accords with that given in recital 14 in the preamble to Regulation (EC) No 1610/96 of the European Parliament and of the Council of 23 July 1996 concerning the creation of a supplementary protection certificate for plant protection products (OJ 1996 L 198, p. 30), which refers to the need for ‘products’ to be ‘the subject of patents specifically covering them’.

28.       The answer to the first five questions is, therefore, that Article 3(a) of Regulation No 469/2009 must be interpreted as precluding the competent industrial property office of a Member State from granting a SPC relating to active ingredients which are not specified in the wording of the claims of the basic patent relied on in support of the SPC application.”

1. In *Yeda* the Court of Justice began by saying at [30]-[32] that the question referred in this case was, for all essential purposes, similar to those referred in *Medeva*, and accordingly could be dealt with by way of reasoned order. It then stated at [33]:

“By its question, the Court of Appeal asks, in essence, whether Article 3(a) of Regulation No 469/2009 must be interpreted as precluding the competent industrial property office of a Member State from granting a SPC where the active ingredient specified in the application, even though identified in the wording of the claims of the basic patent as an active ingredient forming part of a combination in conjunction with another active ingredient, is not the subject of any claim relating to that active ingredient alone.”

1. The Court went on at [34]-[38] to repeat its reasoning in *Medeva* at [22]-[26]. It concluded at [39]:

“In view of the foregoing considerations, the answer to the question referred is that Article 3(a) of Regulation No 469/2009 must be interpreted as precluding the competent industrial property office of a Member State from granting a SPC where the active ingredient specified in the application, even though identified in the wording of the claims of the basic patent as an active ingredient forming part of a combination in conjunction with another active ingredient, is not the subject of any claim relating to that active ingredient alone.”

1. In *Queensland* the Court of Justice began by saying at [23]-[24] that the questions referred in this case were, for all essential purposes, similar to those referred in *Medeva*, and accordingly could be dealt with by way of reasoned order. It then repeated both its reasoning in *Medeva* and its answers to questions 1-5 in answer to questions 1-5 of *Queensland*, except that its answer used the word “identified” rather than the word “specified”.
2. In *Daichii* the Court of Justice again began by saying at [21]-[24] that the questions referred in this case were, for all essential purposes, similar to those referred in *Medeva*, and accordingly could be dealt with by way of reasoned order. It then repeated both its reasoning in *Medeva* and its ruling, except that its answer again used the word “identified” rather than the word “specified”.
3. As I have stated in previous judgments, I find the reasoning of the Court of Justice in *Medeva* difficult to follow. The core of the difficulty is at [25]. The Court states that “It follows that Article 3(a) … precludes the grant of a SPC relating to active ingredients which are not specified in the wording of the claims of the basic patent”. I cannot see how this conclusion follows from the preceding reasoning. Moreover, it substitutes one problem for another. In place of the problem of what is meant by the word “protected” in Article 3(a), we are faced with the problem of what is meant by “specified in the wording of the claims”. Moreover, the Court does not explicitly address either of the questions identified in paragraph 34 above.
4. On the other hand, as the Court of Appeal held when the matter returned to the national court ([2012] EWCA Civ 523, [2012] RPC 26 at [32] (Sir Andrew Morritt C)) and as is common ground between the parties in the present case, what does seem clear from the Court’s answer and reasoning in *Medeva*, particularly at [26], and from its answer in *Yeda*, is that it is not sufficient that dealings in the product in question would infringe the basic patent applying the Infringing Act Rules. Thus the minimum requirement is that the product should fall within the claims of the basic patent applying the Extent of Protection Rules. But it is unclear from *Medeva* and its progeny whether this is sufficient. The judgment suggests that something more is required, but it is not clear whether this is so, or if so what that something more is: see my comments in *Novartis Pharmaceuticals UK Ltd v MedImmune Ltd* [2012] EWHC 181 (Pat), [2012] FSR 23 at [53] and [56].

 *Actavis v Sanofi*

1. In Case C-443/12 *Actavis Group PTC ehf v Sanofi* [EU:C:2013:833], [2014] RPC 20 Sanofi was the proprietor of a patent that covered an antihypertensive drug called irbesartan which expired on 20 March 2011. Irbesartan was marketed by Sanofi under the trade mark Aprovel. Sanofi obtained an SPC for “[irbesartan] optionally in the form of one of its salts” (“the Irbesartan SPC”) based on the patent and marketing authorisations for irbesartan. The Irbesartan SPC expired on 14 August 2012. Sanofi also obtained an SPC for “[irbesartan] optionally in the form of one of its salts and hydrochlorothiazide” (“the Combination SPC”) based on the patent and marketing authorisations for a fixed dose combination of irbesartan and hydrochlorothiazide which was marketed by Sanofi under the trade mark CoAprovel. The Combination SPC was due to expire on 14 October 2013. Actavis intended to market generic versions of both Aprovel and CoAprovel. It was common ground that the latter would infringe the Combination SPC if the Combination SPC was valid. Actavis contended that it was invalid on the grounds that (i) the Combination SPC was not protected by the patent within the meaning of Article 3(a) of the SPC Regulation and (ii) the product had already been the subject of an SPC (namely the Irbesartan SPC) contrary to Article 3(c) of the SPC Regulation or because the product had already been the subject of a marketing authorisation (namely the authorisations for Aprovel) contrary to Article 3(d) of the SPC Regulation.
2. For the reasons given in my judgment following the trial of Actavis’ claim ([2012] EWHC 2545 (Pat), [2013] RPC 24), I referred questions to the CJEU concerning the interpretation of Article 3(a) and Article 3(c). Question 1 was as follows:

“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]?”

In case it assisted the Court of Justice, I also offered my own suggested answer to this question at [75]-[77].

1. The Court of Justice gave judgment without an Advocate General’s opinion. In its judgment the Court answered the second question by holding that Article 3(c) should be interpreted as precluding the grant of a second SPC to Sanofi for the combination of irbesartan and hydrochlorothiazide. It therefore did not answer question 1, since it was not necessary to do so.
2. I must nevertheless refer to what the Court said in two passages. The first is at [38]:

“Similarly, if, in circumstances such as those in the main proceedings, the medicinal product CoAprovel had obtained MA before Aprovel, which would have enabled its proprietor to obtain an SPC either, in the light of paragraph 34 of *Medeva*, for irbesartan alone, or for the irbesartan-hydrochlorothiazide combination, and MA had subsequently been obtained for Aprovel, that could not have secured a second SPC for irbesartan, in view of the condition laid down in Article 3(c) of Regulation No 469/2009.”

1. This statement was relied upon by counsel for Gilead as showing that the Court considered that the Combination SPC did comply with Article 3(a). As counsel for the Claimants submitted, however, it is not possible to draw that conclusion given that the Court did not answer question 1.
2. The second passage is at [41]:

“It should be recalled that the basic objective of Regulation No 469/2009 is to compensate for the delay to the marketing of what constitutes the core inventive advance that is the subject of the basic patent, namely, in the main proceedings, irbesartan. In the light of the need, referred to in recital 10 in the preamble to that regulation, to take into account all the interests at stake, including those of public health, if it were accepted that all subsequent marketing of that active ingredient in conjunction with an unlimited number of other active ingredients, not protected as such by the basic patent but simply referred to in the wording of the claims of the patent in general terms, such as, in the case of the patent in the main proceedings, ‘beta-blocking compound’, ‘calcium antagonist’, ‘diuretic’, ‘non-steroidal anti-inflammatory’ or ‘tranquilizer’, conferred 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.”

1. It can be seen that, in this passage, the Court draws a contrast, albeit in the context of Article 3(c), between an active ingredient which represents “the core inventive advance that is the subject of the basic patent” and “other active ingredients, not protected as such by the basic patent but simply referred to in the wording of the claims of the patent in general terms”. In my view this lends some support to the proposition that question 1 should be answered in the manner I suggested in my judgment when making the reference. I recognise, however, that such support is limited, because the Court had already made it clear (at [30]) that this concern applied even if Article 3(a) was satisfied.

*Lilly*

1. In Case C-493/12 *Eli Lilly & Co Ltd v Human Genome Sciences Inc* [EU:C:2013:835], [2014] RPC 21 HGS was the proprietor of a patent which disclosed the existence of a novel member of the TNF ligand superfamily of cytokines (being proteins which act as intercellular mediators in inflammation and other immune responses) called Neutrokine-α. The patent also disclosed the structure of Neutrokine-α, the sequence of its encoding DNA, its tissue distribution, its expression and its membership of the TNF ligand superfamily. HGS had found Neutrokine-α not by traditional laboratory techniques, but by computer-assisted sequence homology studies. Consequently, the description in the patent specification was not supported by any data obtained from *in vitro* or *in vivo* studies, but was essentially a prediction based upon what was known about other members of the TNF superfamily.
2. Claim 13 of the patent effectively covered any antibody that bound specifically to Neutrokine-α, of which there were potentially many thousands, if not millions. It was in the following terms:

“An isolated antibody or portion thereof that binds specifically to:

(a) the full length Neutrokine-α polypeptide (amino acid sequence of residues 1 to 285 of SEQ ID No: 2); or

(b) the extracellular domain of the Neutrokine-α polypeptide (amino acid sequence of residues 73 to 285 of SEQ ID No: 2).”

1. At the date of the patent neither HGS nor anyone else knew whether Neutrokine-α or any of its antibodies would be valuable products. Subsequently, further research work by HGS and others had led to the identification of specific antibodies to Neutrokine-α which were promising, particularly in the context of the treatment of lupus, rheumatoid arthritis and multiple myeloma.
2. Lilly sought a declaration that any SPC which HGS might be granted in respect of the patent and based upon any marketing authorisation which Lilly had obtained for its own antibody product for use in the treatment of autoimmune diseases, LY2127399, would be invalid. LY2127399 contained as its active ingredient an antibody which bound specifically to Neutrokine-α. Although it was not expressly mentioned in the patent, Lilly accepted that LY2127399 would fall within claim 13 of the patent. Lilly nevertheless contended that LY2127399 was not protected by the patent within the meaning of Article 3(a) of the SPC Regulation since it was not specified in the wording of Claim 13.
3. Warren J referred the following questions to the CJEU:

“1. 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]?

2. Are the criteria different where the product is not a combination product, and if so, what are the criteria?

3. In the case of a claim to an antibody or class of antibodies, is it sufficient that the antibody or antibodies are defined in terms of their binding characteristics to a target protein, or is it necessary to provide a structural definition for the antibody or antibodies, and if so, how much?”

1. The case was dealt with by the same Chamber of the CJEU and the same rapporteur as *Actavis v Sanofi*. The Court gave its judgment on the same date as it gave judgment in *Actavis v Sanofi* and again without an Advocate General’s opinion. It dealt with all three questions together, which it reformulated as follows at [24]:

“By its three questions, which it is appropriate to consider together, the referring court asks, in essence, 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.”

1. Having summarised the arguments of the parties and interveners, and noting once again the absence of any EU harmonisation of patent law, the Court continued:

“32.     It must be borne in mind that the rules for determining what is protected by a basic patent for the purpose of Article 3(a) of Regulation No 469/2009 are those relating to the extent of the invention covered by such a patent, such as the rules laid down in the main proceedings in section 125 of the UK Patents Act 1977. Where the patent in question has been granted by the EPO, those rules are also the rules laid down in the EPC and Protocol on the Interpretation of Article 69 of that convention.

33.       On the other hand, as is apparent from the response given by the Court to questions 1 to 5 in the case which gave rise to the judgment in *Medeva*, 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 not be had to the rules governing infringement proceedings, such as, in the main proceedings, those laid down in section 60 of the UK Patents Act 1977.

34.       By finding that Article 3(a) of Regulation No 469/2009 precludes the grant of an SPC relating to active ingredients which are not specified in the claims of a basic patent (see *Medeva*, paragraph 25, and the orders in Case C-630/10 *University of Queensland and CSL* [2011] ECR I‑12231, paragraph 31, and Case C-6/11 *Daiichi Sankyo* [2011] ECR I‑12255, paragraph 30), the Court emphasised the key role played by the claims for the purpose of determining whether a product is protected by a basic patent within the meaning of that provision.”

1. Thus far, the judgment is clear: the answer to the first question identified in paragraph 34 above is that the relevant rules are the Extent of Protection Rules and not the Infringing Act Rules. Moreover, it follows that the claims play a key role in determining whether a product is protected by a basic patent. Counsel for Gilead pointed out that the Court referred at [34] to what was “specified in the claims” and not to what was “specified in the wording of the claims”, as in *Medeva*. There is nothing in its judgment in *Lilly* to suggest that the Court intended this difference in language to be significant, however.
2. The Court went on to consider the significance of the fact that LY2127399 was not mentioned in the patent, and said:

“38. It should be recalled that, in accordance with the case-law cited at paragraph 34 above, an active ingredient which is not identified in the claims of a basic patent by means of a structural, or indeed a functional definition cannot, in any event, be considered to be protected within the meaning of Article 3(a) of Regulation No 469/2009.

39.       With regard to the question whether the use of a functional definition may alone be sufficient, it should be noted 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 issued by the EPO 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.

40.       With regard to the requirements laid down by the EPC, it should, however, be noted that the Court does not have jurisdiction to interpret the provisions of that convention, since, unlike the Member States, the European Union has not acceded to the convention. The Court cannot, therefore, provide further guidance to the referring court concerning the manner in which it is determine the extent of the claims of a patent issued by the EPO.

…

43. In the light of the objective of Regulation No 469/2009, the refusal of an SPC application for an active ingredient which is not specifically referred to by a patent issued by the EPO relied on in support of such an application may be justified – in circumstances such as those in the main proceedings and as observed by Eli Lilly – where the holder of the patent in question has failed to take any steps to carry out more in-depth research and identify his invention specifically, making it possible to ascertain clearly the active ingredient which may be commercially exploited in a medicinal product corresponding to the needs of certain patients. In such a situation, if an SPC were granted to the patent holder, even though – since he was not the holder of the MA granted for the medicinal product developed from the specifications of the source patent – that patent holder had not made any investment in research relating to that aspect of his original invention, that would undermine the objective of Regulation No 469/2009, as referred to in recital 4 in the preamble thereto.

44.       In the light of the foregoing considerations, the answer to the questions referred is that 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, it is not necessary for the active ingredient to be identified in the claims of the patent by a structural formula. Where the active ingredient is covered by a functional formula in the claims of a patent issued by the EPO, Article 3(a) of that regulation does not, in principle, preclude the grant of an SPC for that active ingredient, 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 the Protocol on the interpretation of that provision, that the claims relate, implicitly but necessarily and specifically, to the active ingredient in question, which is a matter to be determined by the referring court.”

1. I am bound to say that, in this passage, the Court of Justice has once again failed to give national authorities clear guidance as to the proper interpretation of Article 3(a). Although the Court does clearly state that Article 3(a) does not preclude a product being protected by a basic patent by virtue of a functional definition, it then says that this is only permitted where the claims “relate, implicitly but necessarily and specifically” to the product in question. What does this mean? How are national authorities supposed to apply this test? The Court does not explain. All that can be said with confidence is that, once again, the Court appears to be suggesting that something more is required than the product falls within the scope of the basic patent applying the Extent of Protection Rules, but without making it clear what more.
2. I would add that what the Court says at [43] is relevant to a question which was not before the Court, which is whether the proprietor of a patent can obtain an SPC based on a marketing authorisation obtained by a third party as a result of clinical trials and other investigations carried out by the third party rather than by the patent proprietor (as to which, see *Novartis* at [61]).
3. When the case returned to the national court, Warren J struggled at some length to make sense of the guidance given by the Court ([2014] EWHC 2404 (Pat), [2015] RPC 8) which, like me, he regarded as unclear: see [4] and [63]. I note, however, that he did not refer to the judgment of the Court in *Actavis v Sanofi*. Notwithstanding what the Court had said in *Lilly* at [43], Warren J dismissed Lilly’s claim for a declaration. His primary reason for doing so was that he held that claim 13 did “relate, implicitly but necessarily and specifically” to LY2127399 (now known as tabalumab). If I have understood his reasoning correctly, which I am not sure that I have, he did so because he interpreted the test laid down by the Court as requiring the application of no more than the Extent of Protection Rules (see in particular [40], [43], [54], [58], [65], [70], [73] and [76]), save that he considered that it was not sufficient for a combination product to fall within the scope of a claim due to the presence in the claim of open-ended words such as “comprising” (see [66]). If that was his reasoning, I regret to say that I respectfully disagree with it. If the Court had meant to say that Article 3(a) simply required the application of the Extent of Protection Rules, it could have stopped the judgment after the words “as required by Article 69 of the EPC and the Protocol on the interpretation of that provision” in [39]. The Court did not stop there, however. Moreover, Warren J’s own qualification recognises that more is required at least in cases involving claims containing words like “comprising” and combination products. But why should such cases be treated differently? This is not to say that Warren J’s conclusion on this issue was wrong, however.

*Actavis v Boehringer*

1. In Case C-577/13 *Actavis Group PTC ehf v Boerhinger Ingelheim Pharma GmbH & Co KG* [EU:C:2015:165] Boehringer was the proprietor of a patent two of the claims of which covered telmisartan and one of its salts respectively. The patent expired on 31 January 2012. Boehringer marketed telmisartan under the trade mark Micardis. Boehringer obtained an SPC for telmisartan optionally in the form of a pharmaceutically acceptable salt (“the Telmisartan SPC”) on the basis of the patent and a marketing authorisation for telmisartan. The Telmisartan SPC expired on 10 December 2013. Boehringer also obtained an SPC in respect of the combination of telmisartan and hydrochlorothiazide (“the Combination SPC”) based on the patent and a marketing authorisation it had obtained for that combination. During the course of the application for the Combination SPC Boehringer amended the patent to insert a new claim to the combination of telmisartan and hydrochlorothiazide. The Combination SPC was due to expire on 30 January 2017. Actavis contended that the Combination SPC was invalid on similar grounds to those raised in *Actavis v Sanofi* and also on grounds relating to the amendment of the patent.
2. Birss J referred four questions to the CJEU, questions 1 and 2 of which were as follows:

“‘1.(a) If a patent does not, upon grant, contain a claim that explicitly identifies two active ingredients in combination, but the patent could be amended so as to include such a claim, could this patent, whether or not such an amendment is made, be relied upon as a ‘a basic patent in force’ for a product comprising those ingredients in combination pursuant to Article 3(a) of [the SPC Regulation]?

(b)       Can a patent that has been amended after the grant of the patent and either (i) before and/or (ii) after the grant of the SPC be relied upon as the ‘basic patent in force’ for the purposes of fulfilling the conditions set out in Article 3(a) of Regulation No 469/2009?

(c)       Where an applicant applies for an SPC for a product comprised of active ingredients A and B in circumstances where:

(i)       after the date of application for the SPC but before the grant of the SPC, the basic patent in force, being a European Patent (UK) is amended so as to include a claim which explicitly identifies A and B;

and

(ii)       the amendment is deemed, as a matter of national law, always to have had effect from the grant of the patent;

is the applicant for the SPC entitled to rely upon the patent in its amended form for the purposes of fulfilling the Article 3(a) condition?

2.       For the purposes of determining whether the conditions in Article 3 [of the SPC Regulation] are made out at the date of the application for an SPC for a product comprised of the combination of active ingredients A and B, where:

(a)       the basic patent in force includes a claim to a product comprising active ingredient A and a further claim to a product comprising the combination of active ingredients A and B, and

(b)       there is already an SPC for a product comprising active ingredient A (‘Product X’),

is it necessary to consider whether the combination of active ingredients A and B is a distinct and separate invention from that of A alone?”

1. The case was dealt with by a three-judge Chamber of the Court of Justice, all of whom had been members of the five-judge Chamber which had heard *Actavis v Sanofi* and *Lilly*, and by the same rapporteur, again without an Advocate General’s opinion. In its judgment the Court answered the second and third questions by holding that Articles 3(a) and (c) should be interpreted as precluding the grant of a second SPC to Boehringer for the combination of telmisartan and hydrochlorothiazide. It therefore did not answer either the first question or the second question to the extent that it went further than this, since it was not necessary to do so.
2. I must nevertheless refer to what the Court said in the following passage:

“36. In the light of the need, referred to, inter alia, in recital 10 in the preamble to Regulation No 469/2009, 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).

37.       Accordingly, in view of the interests referred to in recitals 4, 5, 9 and 10 in the preamble to Directive 469/2009, it cannot be accepted that the holder of a basic patent in force may obtain a new SPC, potentially for a longer period of protection, each time he places on the market in a Member State a medicinal product containing, on the one hand, an active ingredient, protected as such by the holder’s basic patent and constituting the subject-matter of the invention covered by that patent, and, on the other, another substance which does not constitute the subject-matter of the invention covered by the basic patent (see, to that effect, judgment in *Actavis Group PTC and Actavis UK*, EU:C:2013:833, paragraph 30).

38.       It follows that, in order for a basic patent to protect ‘as such’ an active ingredient within the meaning of Articles 1(c) and 3(a) of Regulation No 469/2009, that active ingredient must constitute the subject-matter of the invention covered by that patent.”

1. I would make four comments about this passage. First, as in *Actavis v Sanofi*, the Court places emphasis upon what is protected “as such” by the basic patent. Secondly, the Court uses the expression “the subject-matter of the invention covered by the basic patent”, which is not an expression which it used in the cited paragraphs of *Actavis v Sanofi*. Thirdly, despite this difference in language, it seems to me that this passage reinforces the message conveyed by *Actavis v Sanofi* at [41] and that what matters is whether the product constitutes what is described here as “the subject-matter of the invention covered by the basic patent”. Fourthly, it nevertheless remains unclear what is required in order for Article 3(a) to be satisfied.

Summary of the Claimants’ contentions

1. The Claimants contend in summary as follows:
	1. In order for Article 3(a) to be satisfied, the product in question must be “specified in the wording of the claims” to use the language of the CJEU in *Medeva*, and where the claim contains a functional definition it must “relate, implicitly but necessarily and specifically” to that product to use the language of the CJEU in *Lilly*.
	2. In the present case, emtricitabine is not specified in the wording of claim 27 in any way. The words “other therapeutic ingredients” do not specify any active ingredient, whether structurally, functionally or otherwise. On the contrary, they cover a virtually unlimited range of active ingredients for the treatment of many diseases. Indeed, emtricitabine was not approved for clinical use until seven years after the priority date of the Patent and there is no evidence that it was known to be efficacious at that date.
	3. Furthermore, claim 27 does not require the presence of any “other therapeutic ingredients” since they are only “optionally” present. It is clear from the case law of the CJEU that it is not enough that a claim to “A composition comprising compound A” would be infringed due to the presence of A in a combination product consisting of A and B. There is no distinction between such a claim and a claim to “A composition consisting of compound A and optionally other active ingredients”.
	4. The “core inventive advance” of the Patent to use the language of the CJEU in *Actavis v Sanofi*, or the “subject-matter of the invention covered by” the Patent to use the language of the CJEU in *Actavis v Boehringer*, is TD (or, more broadly, the class of compounds covered by formulae (1) and (1a) of which TD is a member).
	5. So far as is relevant to the present case, the law is now clear and no reference to the CJEU is required.

Summary of Gilead’s contentions

1. Gilead contends in summary as follows:
	1. In order for Article 3(a) to be satisfied, it is necessary and sufficient that the product in question falls within the scope of protection of at least one claim of the basic patent applying the Extent of Protection Rules. In support of this contention, Gilead particularly relies upon *Lilly* at [32] and [39].
	2. In the present case, the combination of TD and emtricitabine does fall within the scope of protection of claim 27 of the Patent applying Article 69 EPC and the Protocol which are given effect in the UK by section 125 of the 1977 Act and the case law referred to in paragraph 21 above.
	3. Consideration of the “core inventive advance” of, or the “subject-matter of the invention covered by”, the basic patent is only relevant to Article 3(c), and not to Article 3(a). It is Article 3(c), and not Article 3(a), which prevents patent proprietors from obtaining repeat protection by way of SPCs.
	4. The law is now clear and no reference to the CJEU is required. In the alternative, if the law is not clear, there should be a reference to the CJEU.

Conclusion

1. In my judgment the test to be applied in order to determine whether a product is “protected” by a basic patent within the meaning of Article 3(a) remains unclear. It is clear that it is not sufficient that dealings in the product would infringe a claim applying the Infringing Act Rules. It is also clear that it is necessary that the product falls within at least one claim of the basic patent applying the Extent of Protection Rules. But it is not clear whether that is sufficient. It appears from the case law of the CJEU that it is not sufficient, and that more is required; but it is not clear what more is required. Accordingly, it is necessary to refer the question once more to the Court of Justice in the hope that finally a clear answer will be given. Although counsel for the Claimants submitted that there was no reason to think that a further reference would result in a different answer being given by the Court to the answers which it had previously given in *Medeva* and *Lilly*, I am encouraged by what the Court said in *Actavis v Sanofi* and *Actavis v Boehringer* to believe that there is a realistic prospect of the Court providing further and better guidance to that which it has hitherto provided.
2. If confirmation that a reference is necessary, it can be found in the divergent decisions that have been reached around Europe as to the availability of an SPC on the facts of the present case and in the differing interpretations of Article 3(a) that have been adopted in the case law of the national courts.
3. So far as the first point is concerned, applications for an SPC for the combination of TD and emtricitabine have been rejected by the Swedish patent office and Patent Appeals Court, albeit prior to *Medeva*, by the Dutch Patent Office and the Greek Patent Office, but in Spain the application was granted following a decision of the Madrid Administrative Court. An application was also granted in Germany following a decision of the Federal Patent Court, again prior to *Medeva*. But more recently the German Patent Office refused an application by Gilead for an SPC for a triple combination of TD, emtricitabine and efavirenz.
4. As for the second point, I referred to a number of decisions in my judgment in *Actavis v Sanofi* at [73]. Since then national courts have continued to interpret Article 3(a) in different ways. In Spain, it appears that the Madrid Administrative Court has interpreted Article 3(a) in a judgment *Merck & Co* dated 15 December 2014, which it followed in its decision on the facts of the present case, as requiring little if anything more than that the product falls within at least one claim of the basic patent applying the Extent of Protection Rules. To similar effect is a decision of the Lisbon Court of Appeal in a judgment *BASF AG* dated 7 May 2014. On the other hand, it appears that in Germany Article 3(a) is interpreted more strictly, although it is fair to say that I was not shown any court (as opposed to patent office) decision which confirms this.
5. I shall therefore ask question 1 in *Actavis v Sanofi* again:

“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?”

1. In the hope that it will assist the Court of Justice to provide a clear answer this time, I will again offer my own suggested answer to this question. As discussed above, it is now clear that it is not sufficient that dealings in the product would infringe a claim applying the Infringing Act Rules. It is also clear that it is necessary that the product falls within at least one claim of the basic patent applying the Extent of Protection Rules. In my view, however, it is not sufficient that the product falls within at least one claim of the basic patent applying the Extent of Protection Rules. As explained in paragraphs 39-43 above, and as the facts of the present case illustrate, the scope of protection test proves too much in this context. Accordingly, more is required.
2. What more is required? In my view, the answer is that the product must infringe because it contains an active ingredient, or a combination of active ingredients, which embodies the inventive advance (or technical contribution) of the basic patent. Where the product is a combination of active ingredients, the combination, as distinct from one of them, must embody the inventive advance of the basic patent. Thus in a case such as the present, where the inventive advance of the Patent consists generally of the compounds of formulae (1) and (1a), including specifically TD, a medicinal product whose active ingredient is TD is protected by the Patent within the meaning of Article 3(a) because it embodies the inventive advance of the Patent. A medicinal product whose active ingredients are TD and another therapeutic agent such as emtricitabine in combination is not protected by the Patent within the meaning of Article 3(a) because the combination, as distinct from TD, does not embody the inventive advance of the Patent. This is not a question of the wording of the claims of the basic patent, which as discussed above can be manipulated by the patent attorney who drafts it, but of its substance. By contrast, if Gilead (or another inventor) were to obtain a patent for an invention consisting of a combination of TD and substance X which surprisingly had a synergistic effect in treating HIV, then a medicinal product whose active ingredients were TD and X would be protected by that patent since it would embody the inventive advance of that patent. In my view, this interpretation of Article 3(a) would accord with the object of the SPC Regulation, which is to encourage invention in the field of medicinal products by compensating inventors for the delay in exploiting their inventions due to the need to obtain regulatory approval, and not to confer unjustified monopolies.
3. For the avoidance of doubt, this interpretation of Article 3(a) would not prevent a patentee from obtaining an SPC in circumstances where the patent protected a single active ingredient A, but the patentee had only obtained a marketing authorisation for that active ingredient in combination with another active ingredient B. In those circumstances, as the Court of Justice held in *Medeva*, the patentee could obtain an SPC for product A.