THE COURT OF APPEAL

UNAPPROVED

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Costello J.
Haughton J.
Murray J.

BETWEEN

MERCK SHARP & DOHME CORP.

PLAINTIFF/
APPELLANT

- AND -

CLONMEL HEALTHCARE LIMITED

DEFENDANT/
RESPONDENT

JUDGMENT of Ms. Justice Costello delivered on the 24th day of February 2021

Introduction

1. This is an appeal against the decision of the High Court (McDonald J.) ([2019] IEHC 814). The defendant/respondent ("CHL") challenged the validity of a Supplementary Protection Certificate ("SPC") held by the plaintiff/appellant ("MSD") in respect of a cholesterol reducing medicinal product comprising a combination of two active ingredients, ezetimibe and simvastatin. The product is referred to as Ezetrol. CHL said that the SPC was invalid on three grounds:-

(i) it breached Article 3(a) of Regulation (EC) No. 469/2009 ("the SPC Regulation") on the ground that the combination of ezetimibe and simvastatin is not protected

by the underlying patent and/or was not the core inventive advance to which the patent pertained;

(ii) it breached Article 3(c) of the SPC Regulation as ezetimibe, which, according to CHL, was the only compound protected by the patent, was already the subject matter of an earlier SPC granted in 2003; and

(iii) the marketing authorisation for the combination was not the first marketing authorisation for such combination and that, in the circumstances, the SPC was granted contrary to the provisions of Article 3(d) of the SPC Regulation.

The trial judge held that the SPC was invalid as it breached Article 3(a) and (c). He rejected CHL's claim that the SPC had been granted contrary to the provisions of Article 3(d).

2. MSD appealed the findings in relation to Article 3(a) and (c). CHL appealed his finding in relation to Article 3(d).

Background

3. The trial judge sets out the facts in considerable detail and I do not propose to repeat his careful exposition. This judgment should be read together with that of the High Court. A summary of the facts found by the High Court is sufficient. MSD is the holder of Irish Patent 0 720 599 ("the patent") which was granted by the European Patent Office ("EPO") on 19 May 1999, with a priority date of 21 September 1993. The patent relates to a treatment for atherosclerosis. The patent covers a number of azetidinone compounds including ezetimibe. Ezetimibe inhibits the reabsorption of cholesterol which is a known cause of atherosclerosis. The mode of action of ezetimibe is different to that of other cholesterol lowering agents such as HMG-CoA reductase inhibitors, commonly known as statins. They act by increasing the breakdown of cholesterol in the liver.

4. In 2003, a marketing authorisation was granted in respect of a medicinal product under the trade name of Ezetrol which permitted the marketing of 10mg tablets of ezetimibe for three therapeutic indications as explained by the trial judge:-

> *"(a) In the case of primary hypercholesterolemia, the tablets were to be administered with an 'HMG-CoA reductase inhibitor (statin) or alone' as adjunctive therapy to diet for use in patients with primary (heterozygous familial and non-familial) hypercholesterolemia. It should be noted that heterozygous familial hypercholesterolemia occurs where the relevant gene is inherited from one parent alone.*
>
> *(b) For homozygous familial hypercholesterolemia, the tablets were to be administered with a statin and were indicated for use in patients with this condition. By way of explanation, homozygous hypercholesterolemia occurs where a child inherits the relevant gene from both parents.*
>
> *(c) For homozygous sitosterolemia, the tablet was indicated for use in patients with this condition. In other words, the tablet was to be administered alone for this condition. I should explain that homozygous sitosterolemia is an inherited disorder of sterol metabolism in which an excess of plant sterols is absorbed and not enough is excreted."*

5. MSD applied for, and was granted, an SPC based on the marketing authorisation granted for ezetimibe under the trade name Ezetrol.

6. In 2005, a new marketing authorisation was granted to MSD in respect of a medicinal product with the trade name Inegy. This was in respect of tablets containing a combination of ezetimibe and simvastatin. It was for four specific compositions, namely 10mg ezetimibe and 10mg simvastatin; 10mg ezetimibe and 20mg simvastatin; 10mg ezetimibe and 40mg

simvastatin and; 10mg ezetimibe and 80mg simvastatin. The therapeutic indications for the combination were:-

> *"(a) In the case of primary hypercholesterolemia, Inegy was indicated as adjunctive therapy to diet for use in patients with primary (heterozygous familial and nonfamilial) hypercholesterolemia or mixed hyperlipidaemia where use of a combination product is appropriate.*
>
> *(b) For homozygous familial hypercholesterolemia, Inegy was indicated as adjunctive therapy to diet for use in patients with this condition."*

7. The SPC, the subject matter of these proceedings, issued in 2005 in respect of ezetimibe or a pharmaceutically acceptable salt of ezetimibe in combination with *"a cholesterol biosynthesis inhibitor such as simvastatin".*

8. Simvastatin was the subject of a separate patent filed on 2 February 1981 and also had the benefit of an SPC. That SPC expired on 5 May 2003.

Atherosclerosis and its treatment

9. Atherosclerosis is a disease which arises as a consequence of the accumulation of atherosclerotic plaques in the inner layers of artery walls. This leads to the gradual narrowing of blood vessels. Atherosclerosis is typically asymptomatic especially in the early stages. Patients may only become aware of the condition after clinical complications. One of the risk factors for the development of atherosclerosis is the presence of low density lipoproteins ("LDL") in the blood. There are a number of reasons why LDL may be elevated. In circumstances where high concentrations of LDL are generally associated with an enhanced risk of atherosclerotic disease, attempts have been made over the years to develop treatments designed to reduce the LDL levels in a patient's blood. A number of monotherapies had been developed for the treatment of LDL cholesterol. Among these were statins (also known as HMG-CoA reductase inhibitors). These had been developed as a therapy in the early 1980s

and had been authorised for use in Ireland in January 1990. In November 1994, in the Scandinavian Simvastatin Survival Study, it was shown, in what was described as a landmark study, for the first time that statins could not only reduce cardiovascular events but also total mortality. The trial judge accepted that statins were already in use as a cholesterol treatment well in advance of the priority date of the patent and also well in advance of the Scandinavian Study referred to above. As of the priority date of the patent, several statins were already commercially available on the market including lovastatin and simvastatin, while others where in development.

10. By the priority date of the patent, combination therapy was both known and in use in the treatment of atherosclerosis. The advantage of two drugs with different modes of actions is that they may have an additive effect. In addition, where a combination of two inhibitors was used, the doses of the individual components of the combination could be lowered thereby reducing the risk of unwanted side effects. The trial judge considered a number of papers addressing these issues published in the 1980s and early 1990s. He concluded that the papers demonstrate that significant efforts were made in the period between 1988 and 1990 to educate general practitioners in Germany about the recommended treatment for hypercholesterolemia and to inform general practitioners of the treatment available, including combination therapy. He was of the opinion that the sheer extent of the guidance given to general practitioners in Germany supported the view that combination therapy was in use in Germany amongst general practitioners in 1992 and that it was also available in specialist clinics. This finding has potential implications for the outcome of the first issue, depending on the analysis of the argument in relation to Article 3(a) of the SPC Regulation.

The terms of the patent

11. The trial judge analysed the relevant terms of the patent in paras. 45-60 of his judgment. The invention relates to hydroxy-substituted azetidinones used as

hypocholesterolemic agents in the treatment and prevention of atherosclerosis and also to *"the combination of a hydroxy-substituted azetidinone of this invention and a cholesterol biosynthesis inhibitor for the treatment and prevention of Atherosclerosis*."

12. Paragraphs 0009 to 0019 contain a summary of the invention. The novel compound of the invention represented by Formula 1 or pharmaceutically acceptable salts of such compounds are set out in para. 0009. Paragraph 0028 reads:-

> *"Cholesterol biosynthesis inhibitors for use in the combination of the present invention include HMG CoA reductase inhibitors such as lovastatin, pravastatin, fluvastatin, simvastatin and CI-981".*

13. Thus, the possibility of a combination of the inventive compound with simvastatin is expressly described. Details for the preparations of Formula 1 are set out in para. 0029. No equivalent information is provided in relation to the preparation of any combination of any of the Formula 1 compounds with a statin.

14. The claim in relation to ezetimibe is covered in Claim 8. Claim 9 refers to combinations as follows:-

> *"A pharmaceutical composition for the treatment or prevention of Atherosclerosis, or for the reduction of plasma cholesterol levels, comprising an effective amount of a compound as claimed in any one of claims 1 to 8 alone or in combination with a cholesterol biosynthesis inhibitor, in a pharmaceutically acceptable carrier."*

15. The trial judge held that it was clear from Claim 16 that when the patent speaks of cholesterol biosynthesis inhibitors, it is not confining itself to statins. Claim 16 reads:-

> *"A pharmaceutical composition of any of claims 9, 12 or 15 wherein the cholesterol biosynthesis inhibitor is selected from the group comprising of HMG CoA reductase inhibitors, squalene synthesis inhibitor and squalene epoxidase inhibitors."*

16. Claim 17 contains a list of named biosynthesis inhibitors which includes simvastatin:-

"A pharmaceutical composition of Claim 16 wherein the cholesterol biosynthesis inhibitor is selected from the group consisting of lovastatin, pravastin, fluvastatin, simvastatin, CI-981, DMP-565, L-659, 699, squalestatin 1 and NB-598."

The trial judge describes NB-598 not as a statin but as a squalene epoxidase inhibitor.

17. It is thus clear that the combination of ezetimibe and simvastatin has been the subject of a specific claim in the patent. In light of these findings of fact, it is necessary to consider the SPC Regulation itself and the various decisions of the Court of Justice of the European Union ("CJEU") addressing the proper interpretation of Article 3 of the SPC Regulation.

The SPC Regulation

18. Regulation (EC) 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products establishes the SPC regime. It arises from the recognition that there is a sometimes very lengthy delay between the date on which the application for a patent is filed in respect of an invention and the commercial exploitation of that invention when the first marketing authorisation in the European Union in respect of the invention is granted. The SPC is designed to afford the owner of the basic patent an opportunity to enjoy an additional period of exclusivity on the expiration of the patent in order to compensate in part for that delay. That this requires a balancing of potentially conflicting interests is reflected in the 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.

…

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

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

19. In order to obtain an SPC in respect of a product, that product first must benefit from a marketing authorisation enabling the placing of the product on the market as a medicinal product in accordance with Directive 2001/83/EC or Directive 2001/82/EC (Article 3(b)). The authorisation must be the first authorisation to place *"the product"* on the market. Just as there should be only one marketing authorisation, the product may not obtain an SPC if it has already been the subject of a certificate (Article 3(c)). The condition which is central to these proceedings is Article 3(a) which requires that the product must be *"protected by a basic patent in force"*.

20. Article 1(b) defines product to mean *"the active ingredient or combination of active ingredients of a medicinal product"*. Article 1(c) defines basic patent as *"a patent which protects a product as such ..."*.

21. The SPC Regulation is a measure of EU law which must be applied harmoniously throughout the member states and the concepts underlying must be afforded an autonomous meaning. However, patent laws have not been harmonised and the European Patent Convention (EPC) is not a measure of EU law. The construction of a patent is a matter of national law and the EPC, as interpreted in light of the Protocol on the Interpretation of the EPC. Article 69 of the EPC deals with the extent of protection of a patent. It provides:-

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

22. The Protocol on the Interpretation of Article 69 of the EPC is an integral part of the EPC, pursuant to Article 164(1). Article 1 of the Protocol sets out the general principles in the following terms:-

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

23. Section 45 of the Patents Act 1992 (as amended) governs the extent of protection and precisely mirrors the provisions of Article 69 of the EPC save for the omission of a reference to European patents or European applications. Subsection (3) provides that the court shall have regard to the directions contained in the Protocol on the Interpretation of Article 69 of the EPC.

24. Article 3(a) of the SPC Regulation establishes that an SPC may be granted in respect of a *"product protected by a basic patent as such"*. However, the interpretation of this requirement has given rise to considerable difficulty in member states. The provision is one of EU law which must be given an autonomous interpretation, while the construction of the patent is a matter of national law, interpreted in light of the EPC and the Protocol. There have been several references to the CJEU seeking guidance in relation to the interpretation of Article 3.

The decisions of the CJEU interpreting Article 3 of the SPC Regulation

25. In Case C-322/10 *Medeva BV v. Comptroller General of Patents, Designs and Trade Marks*, the CJEU held at para. 25 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."*

26. As is common with judgments of the court, it is expressed in a negative fashion. The judgment does not state that an SPC must be granted in respect of a product containing active ingredients which are specified in the wording of the claims of the basic patent.

27. In Case C-443/12 *Actavis Group PTC EHF and Actavis UK Ltd v. Sanofi Pharma Bristol-Myers Squibb SNC ("Sanofi")*, the English High Court requested a preliminary ruling on the interpretation of Article 3 in respect of a combination product. Sanofi was the proprietor of a European patent in respect of a family of compounds which included the antihypertensive active ingredient, irbesartan. Claims 1 to 7 of the basic patent were based

on irbesartan, or one of its salts. Claim 20 related to a pharmaceutical composition containing irbesartan in association with "a diuretic". No specific diuretic was named in Claim 20 nor in the description of the basic patent. Sanofi obtained two marketing authorisations in respect of the patent. The first was for the medicinal product, Aprovel, which contained irbesartan as its single active ingredient. The second was in respect of a medicinal product, CoAprovel, which comprised a combination of irbesartan and a diuretic, namely hydrochlorothiazide. Sanofi obtained an SPC in respect of the product Aprovel and it obtained a second SPC in respect of the product CoAprovel. Actavis challenged the validity of the second SPC. It argued that the combination of irbesartan and hydrochlorothiazide was not protected by the basic patent within the meaning of Article 3(a) of the SPC Regulation as that combination of active ingredients was not expressly specified or identified in the wording of any of the claims of the patent. Secondly, it argued that the second SPC was invalid in light of Article 3(c) of the SPC Regulation as the *"product"*, within the meaning of Article 3(c), had already been the subject of an initial SPC.

28. At para. 41 the court held:-

> *"It should be recalled that the basic objective of [the SPC Regulation] 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."* (emphasis added)

29. The court held that the basic objective of the SPC Regulation was to compensate for the delay to the marketing of what constituted *"the core inventive advance that is the subject of the basic patent"*. It identified this as being irbesartan, the novel compound. It did not consider the combination of irbesartan and hydrochlorothiazide to be protected by the basic patent as such simply because a diuretic was referred to in the wording of the claims of the patent in conjunction with the novel compound. The court considered each of the two active ingredients in the combination product to ascertain whether each active ingredient was protected by the basic patent. As hydrochlorothiazide was not protected by the basic patent as such the court held that the combination product was not protected by the basic patent as such.

30. It is clear that this analysis differs from that undertaken as a matter of domestic law when seeking to ascertain whether a product is protected by the patent. Under domestic rules of extent of protection, a combination of A+B is protected by a patent, even though only A is a novel active ingredient invented by the patentee and B is an active ingredient not invented by the patentee, and in respect of which it can make no monopoly claim. However, such a combination does not meet the autonomous test of protection by the basic patent as such laid down in Article 3(a).

31. The CJEU had to consider the provisions of Article 3(a) again in the case of C-577/13 *Actavis Group PTC EHF and Actavis UK Ltd v. Boehringer Ingelheim Pharma GmbH & Co. KG ("Boehringer").* Boehringer obtained a patent in respect of numerous

molecules, one of which was telmisartan, an active ingredient used in the treatment of hypertension, and the reduction of cardiovascular morbidity in adults. It obtained a marketing authorisation for the medicinal product, Micardis, which contained telmisartan as the sole active ingredient. It obtained an SPC in respect of that active ingredient. Subsequently, one of the Boehringer group of companies was granted a marketing authorisation for a combination of telmisartan and hydrochlorothiazide – coincidently the same diuretic as was referred to in *Sanofi* – called MicardisPlus. Hydrochlorothiazide had been known to exist since 1958 and was in the public domain. Boehringer filed an application for an SPC for the combination product. The UK IPO suggested that Boehringer should apply to amend the basic patent to assert a claim to the combination of telmisartan and the hydrochlorothiazide. In due course, the basic patent was amended to include such a claim. Under s. 27 of the UK Patents Act 1977, the amendment to Boehringer's basic patent is deemed always to have had effect from the date that the patent was granted, namely 20 May 1998. In due course, an SPC in respect of the combination was granted.

32. Actavis challenged the validity of the SPC for the combination product and the High Court referred a series of questions to the CJEU for a preliminary ruling. The court noted that it was common case that telmisartan was the innovative active ingredient in Boehringer's basic patent and was the sole subject matter of the invention. It stated that Boehringer did not *"in any event, contribute to the discovery of hydrochlorothiazide … and the claim relating to that substance does not constitute the subject-matter of the invention"*. At paras. 36-39 the court held as follows:-

> *"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).*

*37. Accordingly, in view of the interests referred to in recitals 4, 5, 9 and 10 in the preamble to [the SPC Regulation]****, 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 [the SPC Regulation], ***that active ingredient must constitute the subject-matter of the invention covered by that patent****.*

39. In the light of the foregoing considerations, the answer to Questions 2 and 3 is that Article 3(a) and (c) of [the SPC Regulation] must be interpreted as meaning that, where a basic patent includes a claim to a product comprising an active ingredient which constitutes the sole subject-matter of the invention, for which the holder of that patent has already obtained an SPC, as well as a subsequent claim to a product comprising a

combination of that active ingredient and another substance, that provision precludes the holder from obtaining a second SPC for that combination." (emphasis added)

33. In para. 36 of its judgment, the court explained that it would be contrary to the requirement to balance the interests of the pharmaceutical industry and those of public health, as set out in Recital 10, if the marketing of an active ingredient, which was the subject matter of the invention covered by the basic patent, in conjunction with an unlimited number of active ingredients which were not, entitled the patent holder to an SPC in respect of each such combination product. In para. 37, the court made clear that it was not permissible to obtain multiple SPCs in respect of different combinations of the active ingredient protected as such by the basic patent and constituting the subject-matter of the invention covered by the patent *"and another substance which does not constitute the subject-matter of the invention covered by the basic patent."* It is to be recalled that, following the amendment to Boehringer's patent, each of the active ingredients and the specific combination were expressly mentioned in the claims. However, this did not satisfy the requirements of Article 3(a) as the second active ingredient, hydrochlorothiazide, a diuretic known to exist since 1958, was not the subject matter of the invention covered by the patent.

34. Issues still remained regarding the application of Article 3(a) and a further reference was made to the court by the High Court in England in *Case C-121/17 Teva UK Ltd. v. Gilead Sciences Inc. ("Teva").* The Grand Chamber of the court met to consider:-

"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]?"

Gilead had obtained a marketing authorisation in respect of a medicinal product named TRUVADA which contained two active ingredients, tenofovir disoproxil ("TD") and emtricitabine ("FTC") which had a combined effect on treatment of persons infected with HIV. Gilead was the holder of a patent which contained descriptions of a series of

pharmaceutical formulae, one of which was for the active ingredient TD. Claim 27 of the basic patent was for *"[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".* Gilead obtained an SPC based on Claim 27 of the basic patent and the marketing authorisation in respect of TRUVADA, the combination product TD and FTC.

35. At para. 30 of the judgment, the court recast the question of the referring court regarding the conditions which must be satisfied in order to comply with Article 3(a) of the Regulation as:-

> *"[W]hether ... it is sufficient that the active ingredients of the product which is the subject matter of the SPC are mentioned in the claims in the basic patent in force or that those claims relate to the active ingredients implicitly but necessarily, or whether an additional criterion must be applied."*

36. At para. 37, the court held:-

> *"... a product cannot be considered to be protected by a basic patent in force within the meaning of Article 3(a)... unless the product which is the subject of the SPC is* ***either expressly mentioned in the claims of that patent*** *or those claims relate to that product necessarily and specifically."* (emphasis added)

37. MSD argues that this is clear authority for the proposition that the test in *Boehringer* and *Sanofi* no longer applies, and that a product will be protected by the basic patent in force as such within the meaning of Article 3(a) if the combination of the two active ingredients comprising the product is expressly mentioned in the claims, as in this case. It argues that the balance of the judgment in *Teva* only concerns combination products where the second active ingredient is not expressly mentioned in the claims of the basic patent. It argues that this is confirmed in para. 52 of the judgment:-

"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."*

And in para. 57:-

"57. Having regard to all the foregoing considerations, the answer to the question referred is that 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."* (emphasis added)

38. MSD says that its interpretation of the effect of the decision in *Teva* is confirmed by the decision of the court in the subsequent case of Case C-650/17 *Royalty Pharma Collection Trust v. Deutsches Patent - und Markenamt* (*"Royalty Pharma"*). At para. 37 of the decision in *Royalty Pharma*, the court referred to the decision of the court in *Teva* in the following terms:-

> *"The Court inferred from this that, in order to ascertain whether a particular product is protected by a basic patent in force, within the meaning of Article 3(a) of [the SPC Regulation], it is necessary to ascertain,* ***where that product is not expressly mentioned in the claims of that patent****, whether that product is necessarily and specifically covered by one of those claims. To that end, two cumulative conditions must be satisfied. First, the 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 come under the invention covered by that patent. Second, 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 (see, to that effect, judgment of 25 July 2018, Teva UK and Others, C-121/17, EU:C:2018:585, paragraph 52)."* (emphasis added)

39. It also refers to para. 42 of the judgment in *Teva* as follows:-

> *"Insofar as,* ***where the product is not explicitly disclosed by the claims of the basic patent****, but is covered by a general functional definition, such as that used by the basic patent at issue in the main proceedings, a person skilled in the art must be able to infer directly and unambiguously from the specification of the patent as filed that the product which is the subject of the SPC comes within the scope of the protection afforded by that patent."* (emphasis added)

40. The observations of the court reflect those of Advocate General Hogan at para. 41 of his opinion where he says that:-

> *"**where an active ingredient is not expressly mentioned in the claims of a basic patent**, the judgment [in Teva] lays down a test comprising two parts, both of which must be satisfied."* (emphasis added)

41. MSD submits that the two-limb test established in *Teva* only applies to those combination products where one of the active ingredients is not expressly mentioned in one of the claims of the basic patent. It argues that a product is protected by the basic patent as such if the second active ingredient, which was not the subject of the invention of the patent, is expressly mentioned in the claims of the patent in combination with the novel ingredient. This is not merely necessary but is sufficient to satisfy the requirement of Article 3(a).

42. MSD's arguments to this court were in substance identical to those advanced by Boehringer and the Government of Portugal in *Boehringer*. The CJEU rejected those arguments in that case. Thus, MSD can only succeed on this aspect of its claim if the court in *Teva* overruled the earlier rejection of those arguments in *Boehringer.*

43. CHL argues that express reference to the second active ingredient in the claims is a necessary but not a sufficient condition in order to satisfy the requirements of Article 3(a) of the SPC Regulation. It points to the fact that there is no decision of the CJEU which states that express mention of the active ingredients in the claim satisfies the requirements of Article 3(a). It points to the fact that in *Teva* the court quoted from *Boehringer* with approval and did not overrule *Boehringer*.

44. The trial judge was of the view that the decision in *Teva* sought to clarify the law in relation to the meaning and effect of Article 3(a) and was not solely confined to circumstances where the second active ingredient in a combination product was not expressly mentioned in the claims of the basic patent in force for the purposes of Article 3(a). The trial

judge reached this conclusion on the basis that the court assembled a Grand Chamber in order to provide definitive guidelines. He saw no reason to suggest that the CJEU intended that all of its judgment from para. 38 onwards was confined to cases where the relevant combination was not expressly mentioned in the claims of the patent. He noted that the CJEU was mindful of the requirements of Article 69 of the EPC that the description and drawings of the basic patent must be taken into account and one does not look solely at the claims in the patent. Most importantly the CJEU, in paras. 39-41 of its judgment, emphasised the underlying objective of the SPC Regulation which is to compensate for the delay in the commercial exploitation of an invention. The CJEU highlighted, in stark terms, that it would be contrary to the objective of that Regulation to grant an SPC for a product which does not fall under the invention covered by the patent. Having invoked Recital 10 of the SPC Regulation, which refers to the need to take into account all the interests at stake, including those of public health, at para. 43 of the judgment it held:-

> *"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."*

45. The trial judge was of the view that it was critically important to have regard to the rationale expressed by the CJEU in paras. 38-43 of its judgment. He held that:-

> *"Those paragraphs illustrate the concern of the CJEU to ensure that an SPC should not be granted for a product which does not fall within the invention covered by the patent. The paragraphs also stress that the claims of the basic patent must be construed*

in the light of the limits of that invention. That rationale and concern are equally applicable whether or not a product is expressly mentioned in the claims of the patent."

46. Advocate General Wathelet, in *Teva*, likewise did not accept the current arguments of MSD. He expressed the opinion at para. 74 that:-

"… 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 … 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]."

Did the court overturn *Boehringer*?

47. In *Teva*, the court reiterated that since there is no harmonisation of EU patent rules, the extent of the protection conferred by a basic patent can be determined only in the light of non-EU rules governing patents. The position in relation to the rules for determining what is protected by a basic patent in force within the meaning of Article 3(a) of the SPC Regulations is different, as this is a matter of EU law. At para. 32 of the judgment the court says that those rules are those relating to the extent of the invention covered by such a patent. The patent must be interpreted in accordance with Article 69 of the EPC and the Protocol on the interpretation of the provision, and the relevant domestic legislation. At para. 34 the court again referred to:-

"… 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 [Article 3(a)]."

48. It then stated that, pursuant to Article 69, the extent of the protection conferred by such a patent is determined by the claims. It reiterated, in light of Article 1 of the Protocol that:-

"… those claims must ensure both a fair protection for the patent proprietor and a reasonable degree of legal certainty for third parties. Thus, they are not to serve only

as a guideline, nor can they be interpreted as meaning that the extent of the protection conferred by a patent is that defined by the narrow, literal meaning of the wording used in the claims."

49. CHL argues that if MSD is correct, and it is sufficient for a product to satisfy the requirements of Article 3(a) if the active ingredients are listed in the claims, then there is no scope for the court to have regard to Article 69 in interpreting the extent of the protection conferred by the basic patent for the purposes of Article 3(a), as it is required by the CJEU to do.

50. Further, CHL argues that para. 37 should not be read in isolation but rather that paras. 36, 37 and 38 should be read together. For ease of reference, I cite all three of them here:-

"36. In this respect, the Court has held that Article 3(a) of [the SPC Regulation] 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, on condition that it is possible, on the basis of those claims as interpreted inter alia in the light of the description of the invention, 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).

37. Therefore, a product cannot be considered to be protected by a basic patent in force within the meaning of Article 3(a) of [the SPC Regulation] unless the product which is the subject of the SPC is either expressly mentioned in the claims of that patent or those claims relate to that product necessarily and specifically.

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."

51. CHL argues that para. 36 addresses the conditions upon which an active ingredient, which is given a functional definition in the claims of the basic patent, may satisfy the requirement of Article 3(a). It is expressed, as is common with the court, in the negative: *"Article 3(a)… does not, in principle, preclude …"*.

52. CHL says that para. 37 is dealing with a situation of either a product which is expressly mentioned in the claims or a claim which relates necessarily and specifically to that product. It argues that para. 37 establishes a necessary but not sufficient pre-condition for Article 3(a). Crucially, para. 38 commences *"For that purpose"*. CHL argues that this must refer to the two alternatives identified in para. 37. Therefore, the requirement to take into account the description and drawings of the basic patent, as stipulated in Article 69 of the EPC is not confined to patents with a functional definition; it also applies to patents where an ingredient is expressly mentioned in the claims. This is because, while the claims play a key role in determining whether a product is protected by a basic patent, they must be construed in the light of Article 69 of the EPC and Article 1 of the Protocol. This enjoins the court to look at the description and drawings in the patent. This direction is superfluous if a simple listing of active ingredients in the claims satisfies the requirements of Article 3(a).

53. Paragraph 38 requires the national court to determine two matters, in the light of that interpretative exercise:

1. whether the claims of the basic patent relate to the product which is the subject of the SPC; and
2. whether that product in fact falls under the invention covered by that patent.

The fact that an active ingredient is expressly listed in the claims of a patent may mean that it satisfies the first of these tests, but it does not indicate whether the product falls under the invention covered by that patent. CHL, therefore, submits that by implication this paragraph answers the first question raised in para. 30 of the judgment in the negative, *i.e.* it is not sufficient that the active ingredients of the product, which is the subject of the SPC, are mentioned in the claims in the basic patent in force in order to satisfy the conditions laid down in Article 3(a). It argues that, in addition, the product must fall under the invention covered by the patent in force.

54. CHL highlights the fact that the court repeatedly refers to the invention covered by the patent and that this cannot be satisfied by simply listing known ingredients or substances in conjunction with the novel ingredient in the claims. In this regard, it refers to para. 40 which provides:-

> *"However, it is not the purpose of the SPC to extend the protection conferred by that patent beyond the invention which the patent covers. It would be contrary to the objective of [the SPC Regulation]… 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 relate to the results of the research claimed under that patent."*

55. An SPC cannot extend the protection conferred by the patent beyond the claims in the patent. It follows that this passage simply does not make sense if *"the invention which the patent covers"* is to be equated with *"the claims"* as MSD contends, according to CHL. CHL asks rhetorically: if a mere listing of ingredients in the claims is sufficient to meet the requirements of Article 3(a), what does this passage mean?

56. At paras. 41 and 42 of the judgment the court said:-

"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).

42. It must be added that, in view of the interests referred to in recitals 4, 5, 9 and 10 of [the SPC Regulation], it cannot be accepted that the holder of a basic patent in force may obtain an SPC 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 of 12 March 2015, Actavis Group PTC and Actavis UK, C-577/13, EU:C:2015:165, paragraph 37 and the case-law cited)."

57. At para. 41, the court expressly endorses para. 36 of *Boehringer* and in para. 42 it expressly endorses para. 37 of *Boehringer*. In those circumstances, I do not accept that the court in *Teva* can be said to be overruling *Boehringer*. In my judgment, it is simply inconceivable that the Grand Chamber of the court would have expressly endorsed these two paragraphs and not indicated that it was departing from that decision, if that were indeed the

intention of the court in *Teva*. In *Boehringer*, both active ingredients were expressly mentioned in the claims but only one constituted *"the subject matter of the invention covered by the patent"*. The court in *Teva* reiterated that the holder of a basic patent in force may not obtain an SPC each time it places on the market a medicinal product containing two active ingredients, one of which is protected as such by the holder's basic patent and constituting the subject matter of the invention covered by the patent, and the other which does not constitute the subject matter of the invention covered by the basic patent. To my mind, there is no reason to read this paragraph as accepting a situation where that second substance, which does not constitute the subject matter of the invention covered by the basic patent, but which is listed in the basic patent, does not also conflict with the balance referred to in Recital 10 and in *Boehringer* and *Sanofi*.

58. Immediately following these two paragraphs which endorse the two paragraphs in *Beohringer,* the court continues in para. 43:-

> *"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."*

59. The phrase *"protection … granted for the invention covered by [the] patent"* cannot be equated with the claims of the patent, as this would render the first sentence in para. 43 meaningless. It follows that the court is not saying that it is sufficient simply to consider the claims of the patent where ingredients are mentioned in the patent. The protection granted by an SPC is limited to that granted for the invention covered by the patent. The court must make an assessment of what is the invention covered by the patent in order to ascertain

whether or not the SPC at issue affords protection which goes beyond that granted for the invention covered by the patent, and thus is impermissible. The court emphasises that for the purposes of the application of Article 3(a), the claims of the basic patent must be construed in the light of the limits of the invention as it appears from the description and the drawings of the patent. It is therefore clear from para. 43 that the investigation to be undertaken by the court cannot be limited to the claims and cannot stop with the claims; the court must have regard to the description and the drawings of the patent in order to ascertain what are the limits of the invention in the basic patent.

60. The court concludes this section of the judgment at para. 46 stating:-

> *"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."*

61. It is the role of the claims to set out technical specifications of the invention. In the first part of the sentence the court is establishing a limits of the invention test, while the second part appears to refer to the claims in the patent. In light of the paragraphs preceding para. 46, I do not believe the court was stating that the protection conferred by an SPC must be restricted to the claims such as claimed in the patent. The court was not ruling out the interpretation of the patent by reference to Article 69 and the description and drawings of the patent which it previously discussed in the judgment.

62. Paragraph 47 immediately continues "*[w]ith regard to the implementation of [the] rule*" that the claims of the patent are to be interpreted from the perspective of a person skilled in the art in accordance with Article 69 of the EPC and Article 1 of the Protocol, whether the product which is the subject of the SPC necessarily *"falls under the invention covered by that patent"* must be assessed from the perspective of a person skilled in the art in light of these principles.

63. In my judgment, the court requires the national court to make this assessment in light of the description and drawings, and not confine itself to the wording of the claims. It must assess the invention of the patent in order to determine whether a product, the subject of an SPC, is protected by the basic patent as such. The mention of a non-novel ingredient in the claims in conjunction with the novel active ingredient does not thereby mean that the combination of the novel active ingredient with the non-novel active ingredient falls under the invention covered by the basic patent.

64. At paras. 48-51, the court considers the necessarily and specifically test it lays down in respect of a second active ingredient and then it continues in para. 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 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."*

65. As discussed above, MSD argues that the first sentence of this paragraph supports the proposition that if the product is expressly mentioned in the claims of the basic patent then it is protected by a basic patent in force. I do not accept that this a correct reading of either this paragraph nor the judgment.

66. The second sentence commences *"[f]or that purpose"*. That purpose must refer to the issue whether a product is protected by a basic patent in force. There is nothing to suggest that the purpose varies depending on whether a product is expressly mentioned in the claims

or is necessarily and specifically related to one of the claims. The second sentence clearly requires that in order that a product be protected by a basic patent in force it necessarily falls under the invention covered by that patent. To my mind, this is consistent with the earlier analysis undertaken by the court.

67. I also believe that MSD's reliance upon para. 57 of the judgment is misplaced. It provides:-

> *"57. Having regard to all the foregoing considerations, the answer to the question referred is that 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."* (emphasis added)

68. The fact that the court says *"even if"* the combination of active ingredients of which the product is composed is not expressly mentioned in the claims, shows that the test established in *Teva* applies to cases where the second active ingredient is expressly mentioned as well as to those where the second active ingredient is implicitly referred to. In other words, even if the combination of active ingredients of which the product is composed

are expressly mentioned in the claims of the basic patent, nonetheless it must be shown that the combination of the active ingredients falls under the invention covered by the patent.

69. As discussed above, MSD says that the court in *Royalty Pharma* endorsed its interpretation of the decision in *Teva* at paras. 37 and 42, as does AG Hogan at para. 41 of his opinion.

70. *Royalty Pharma* concerned a product with one active ingredient, sitagliptin. The claims in the patent were set out in functional definitions. Sitagliptin met the functional definition used in one of the claims of the patent, but it was not individually identified in the specification of the basic patent in issue. It was developed after the filing date of the application for the basic patent following an independent inventive step. Before giving judgment in respect of the request for a preliminary reference by the German Federal Patent Court, the court delivered judgment in *Teva*. The court asked the Federal Patent Court whether it wished to maintain its request for a preliminary ruling. The Federal Patent Court indicated that it did because it was still unclear whether the concept of *"core inventive advance"* was of any relevance for the purposes of interpreting Article 3(a) of the SPC Regulation.

71. The CJEU said that it did not employ that concept and that the concept is not relevant to an interpretation of Article 3(a). It said at para. 31:-

> *"On the contrary, in that judgment, the Court recalled the key role played by the claims, under Article 69 of the EPC and Article 1 of the Protocol on the Interpretation of Article 69, thus confirming 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."*

72. The court did not purport to alter the test set out in para. 42 and the dispositif of the judgment in *Teva*. This means that a court faced with a challenge to the validity of an SPC

must ascertain whether the product, the subject of the SPC, falls under the invention of the basic patent, but not whether it is the core inventive advance of the patent. This is clear from para. 37 of the judgment in *Royalty Pharma* which cites para. 52 of the judgment in *Teva*. At para. 43, the court posited the question whether the product corresponds to a general functional definition used by one of the claims of the basic patent and necessarily comes within the *"scope of the invention covered by that patent"* when applying the first limb of the test in *Teva*. Thus, while ruling out a core inventive advance assessment, it still requires the national court to assess whether the product necessarily falls under the invention covered by the basic patent. As the case concerned a mono-product rather than a combination product, it did not address the issue of whether a listing or mention of a non-novel active ingredient in one of the claims of the basic patent sufficed for the purposes of Article 3(a) of the SPC Regulation.

73. The third question raised by the referring court in *Royalty Pharma* was whether Article 3(a) of the SPC Regulation must be interpreted as meaning that a product is not protected by the basic patent in force, within the meaning of that provision, if, although covered by the functional definition in the claims of the patent, it was developed after the filing date of the application for the basic patent following an independent inventive step. The court re-emphasised that it is not permissible to have regard to results from research occurring after the filing date or priority date. At para. 46 it said that:-

> *"... it is not the purpose of the SPC to extend the protection conferred by the basic patent beyond the invention which that patent covers. It would be contrary to the objective of [the SPC Regulation], according to which the grant of the additional period of exclusivity by the use of SPCs is intended to encourage research and, to that end, to ensure that the investments made in such research are covered, to grant an SPC for a product which is not covered by the invention which is the subject of the basic*

patent, inasmuch as such an SPC would not relate to the results of the research claimed under that patent (see, to that effect, judgment of 25 July 2018, Teva UK and Others, C-121/17, EU:C:2018:585, paragraphs 39 and 40)."

74. The court ruled at para. 47 that a product which is the subject of an SPC which was developed after the filing date or priority date of the basic patent, following an independent inventive step, cannot be regarded as coming within the scope of the subject matter of the protection conferred by that patent. CHL says that this approach is inconsistent with the identification test contended for by MSD. It argues that it is simply not possible to determine whether a product is the result of an independent inventive step if the court does not identify the invention in the basic patent.

75. I agree with the submissions of CHL and I do not accept that *Royalty Pharma* excludes assessing whether the product comes under the invention covered by the basic patent.

76. The opinion of the Advocate General in *Royalty Pharma* commences the 'Analysis' by quoting para. 57 from the judgment in *Teva*. At para. 41, the Advocate General says:-

"Thus where an active ingredient is not expressly mentioned in the claims of a basic patent, the judgment [in Teva] lays down a test comprising two parts, both of which must be satisfied."

77. He was not saying that *Teva* established that express mention of the active ingredients suffices to satisfy the requirements of Article 3(a). At para. 45, he stresses that his intention was not to depart in any manner whatsoever from the ruling in *Teva* or to attempt to graft any further conditions onto the two-part test referred to in that case. At para. 49, he dismissed as irrelevant any distinction between a product consisting of a single active ingredient and a combination of active ingredients. He said:-

"What matters instead is that, as the Court said at paragraph 57 and the operative part of the judgment [in Teva], where the ingredient(s) of the product is or, as the case may

be, are not expressly mentioned in the claims of the basic patent, 'those claims relate necessarily and specifically' either to that active ingredient or, in the case of a multiplicity of active ingredients to that combination. This is so even if the Court was in terms considering only the position with regard to several active ingredients."

78. This suggests that the Advocate General was of the view that the test in *Teva* applies whether or not one, or more, active ingredient(s) is, or are, expressly mentioned in the claims of the basic patent, contrary to MSD's contention.

79. There is nothing in the opinion of the Advocate General which supports the proposition that in *Teva* the court overruled *Boehringer*, nor that the court rejected the test whether the product *"falls under the invention covered by the basic patent"*, while ruling out a core inventive advance test.

The Court of Appeal decision in *Teva v. Gilead*

80. Upon receipt of the decision of the CJEU in *Teva,* Arnold J. in the High Court in England ruled that the SPC granted to Gilead in respect of the combination product TD and Emtricitabine (FTC) was invalid. Gilead appealed to the Court of Appeal and the judgment was delivered by Floyd L.J. (*Teva UK Ltd. & Ors. v. Gilead Sciences Inc.* [2019] EWCA Civ. 2272). He carefully considered the relevant provisions of the SPC Regulation and reviewed the judgments of the CJEU commencing with *Medeva, Eli Lilly*, the opinion of Advocate General Wathelet in *Teva* and the decision of the court in *Teva.* He also considered the decision of Advocate General Hogan in *Royalty Pharma*. At paras. 73 and 74, he stated as follows:-

"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 [Royalty Pharma], 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."

81. Floyd L.J. was of the view that the term *"fall under the invention covered by the patent"* rules out any consideration of the *"inventive advance"* in the patent as the CJEU rejected the core inventive advance test and any such consideration is inconsistent with the express wording in para. 37 of the court's judgment. He was of the view that para. 37 states that express mention of the active ingredient in the claim is sufficient to satisfy the requirements of Article 3(a). As I have sought to illustrate above, I do not believe that this is, in fact, the case. I read the judgment of the CJEU in the opposite sense. In my judgment, the court establishes a *"fall under the invention covered by the patent test"* and it requires the national court to assess the invention of the patent by reference to the description and drawings of the basic patent. I agree with Floyd L.J. that express mention in a claim says nothing about whether the added ingredient formed part of the inventive advance. It is precisely because I agree with him on this point and I disagree that the CJEU has ruled out any assessment of the invention covered by the patent, that I disagree with his conclusion that para. 37 results in the conclusion that the phrase *"falling under the invention covered by the*

patent" prohibits the national court from engaging in an assessment of the invention covered by the patent. It must be borne in mind that the Court of Appeal was not specifically addressing the question at issue in this appeal: whether the express mention of a non-novel ingredient in combination with a novel ingredient in one of the claims of the basic patent satisfies the requirements of Article 3(a). For these reasons, I respectfully decline to follow his judgment on this point.

Conclusion on Article 3(a)

82. The judgments of the CJEU require the national court to assess whether the product the subject of an SPC falls under the invention covered by the basic patent. In this case, ezetimibe falls under the invention covered by the patent as it is one of the novel compounds invented by the patent and is claimed in Claim 8. At the priority date, simvastatin was a known ingredient and had been the subject of a different patent, and a different SPC, and so cannot be considered to fall under the invention covered by the basic patent. The combination of ezetimibe and simvastatin is expressly claimed in Claim 9 of MSD's basic patent. The trial judge rejected MSD's argument that it was sufficient for the purposes of Article 3(a) that the two ingredients were expressly mentioned in the claims of the patent and that no assessment of the invention of the patent was either required or permitted. At para. 89, McDonald J. held that:-

> *"... the addition of an existing compound to a novel compound cannot, without more, make the combination an invention in itself. If that was all that was required, it would mean that an SPC would automatically be available for any combination product containing a combination of a novel product disclosed in a patent and a pre-existing product available off the shelf."*

For this reason, he held that the product did not fall under the invention covered by the patent and therefore it was not protected by the basic patent, and he revoked the SPC. In my

judgment, he was correct in his approach and his assessment, and I agree with his conclusion. I would refuse the appeal on this point.

Article 3(c)

83. Article 3(c) requires that the product, the subject of the SPC, has not already been the subject of a certificate. MSD argued that when considering whether the product satisfied the provisions of Article 3(c), the trial judge applied the same incorrect definition of *"the product"* that he applied in respect of Article 3(a) and therefore the error, it alleged, carried through into his analysis of its case in relation to Article 3(c) also. The parties agreed that *"the product"* identified for the purposes of Article 3(c) had to be the same as that found to be protected by the basic patent further to Article 3(a). In my judgment, the trial judge correctly held that the product protected by the patent was ezetimibe, the mono-product, and not the combination of ezetimibe and simvastatin. It was accepted that ezetimibe had been the subject of an earlier SPC in respect of Ezetrol. It follows that MSD's appeal in relation to Article 3(c) also must fail.

Article 3(d)

84. CHL appealed the refusal of the High Court to find that the SPC was invalid pursuant to Article 3(d) of the SPC Regulation. It will be recalled that Article 3 provides that an SPC shall be granted to a product if it satisfies the four requirements of the article. Article 3(b) and (d) provide:-

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

CHL says that Article 3(d) of the SPC Regulation requires that the authorisation referred to in Article 3(b) is the first authorisation to place the product on the market as a medicinal product.

85. The SPC was granted in respect of the marketing authorisation for Inegy. MSD says the authorisation satisfies Article 3(b). The product identified in the SPC is:-

> *"Ezetimibe, or a pharmaceutically acceptable salt thereof, in combination with a cholesterol biosynthesis inhibitor such as simvastatin."*

CHL's case is that the Inegy marketing authorisation was not the first marketing authorisation that authorised the placing of a combination of ezetimibe and simvastatin on the market *"as a medicinal product"*. The first such marketing authorisation was, according to CHL, in fact, for Ezetrol. Ezetrol specifically mandated that, in respect of one of the permitted indications, ezetimibe was required to be used with a statin, and simvastatin was expressly identified as one of four such specific statins. It follows, according to CHL, that the marketing authorisation for Ezetrol was the first marketing authorisation for ezetimibe in combination with simvastatin and so the Inegy marketing authorisation could not be relied upon by MSD as satisfying Article 3(d) of the SPC Regulation.

86. MSD emphasised the distinction between the co-administration of two products and a combination product. It argued that the co-administration of two products cannot be equated to a medicinal product authorised by Directive 2001/83/EC ("the Medicinal Products Directive) and that, as a consequence, the Ezetrol authorisation could not constitute the first authorisation to place the combination of ezetimibe and simvastatin on the market for the purposes of Article 3(d).

87. The key issue for resolution is whether the marketing authorisation for Ezetrol authorises the placement of the combination product of two active ingredients, ezetimibe and simvastatin, on the market as a medicinal product.

The decision of the High Court

88. The trial judge rejected the argument of CHL. He relied upon the analysis of Lewison J. (as he then was) in *Yeda Research and Development Company Ltd. v. Comptroller General of Patents* [2010] EWHC 1733 (Pat) and held that the manner in which a medicinal product is used does not form part of the identification of the product itself. McDonald J. held at para. 121 of his judgment:-

> *"The decision in Yeda Research is a useful illustration of the application of the principles laid down in the case law of the CJEU. There is a very clear parallel between the facts in Yeda Research and the facts in issue in these proceedings. In Yeda Research, the use of Erbitux in combination with irinotecan was expressly indicated for the treatment of patients with a particular form of cancer after failure of irinotecan as a monotherapy. Similarly, in the case of the Ezetrol marketing authorisation, the co-administration was indicated for use in patients with homozygous familial hypercholesterolemia. I cannot see any distinction, in substance, between the therapeutic indication in Yeda Research and the therapeutic indication for homozygous familial hypercholesterolemia under the Ezetrol marketing authorisation. What the latter does is to require that a statin should be co-administered with the ezetimibe product. That clearly relates to the manner in which ezetimibe is to be used in such cases. It is to be used in conjunction with a statin. It therefore seems to me to fall squarely within the principle laid down in Pharmacia Italia and in Yissum Research. Just as in Yeda Research, the product is identified in the SmPC as Ezetrol. That product comprises ezetimibe exclusively. The statin is not part of the product authorised. Any such statin required its own authorisation with its own SmPC. The qualitative and quantitative composition of the product authorised by the authorisation refers only to ezetimibe and the various excipients. The pharmaceutical form relates*

only to the Ezetrol tablet. The fact that, in the case of homozygous familial hypercholesterolemia, the Ezetrol product was to be used in conjunction with a statin does not make that combination the subject of the authorisation for the purposes of the SPC Regulation. While Prof. Salvatore accepted that there was "no doubt" that the authorisation was to use Ezetrol with a statin in such cases, use is not sufficient in itself to bring the relevant statin within the ambit of the product authorised by the marketing authorisation. The case law of the CJEU makes that clear."

Discussion

89. The Medicinal Product Directive requires that an application for a marketing authorisation set out a summary of the product characteristics, the SmPC. A marketing authorisation is granted in respect of the product. Article 1 defines a medicinal product as:-

"Any substance or combination of substances presented for treating or preventing disease in human beings.

Any substance or combination of substances which may be administered to human beings with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in human beings is likewise considered a medicinal product."

Thus, a product may be a mono-product or a combination product. It is the product which is authorised.

90. In Article 1 of the SPC Regulation a medicinal product is defined as:-

"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 medicinal diagnosis or to restoring, correcting or modifying physiological functions in humans or in animals."

91. A product means *"the active ingredient or combination of active ingredients of a medicinal product."* A product is defined by reference to the active ingredient(s) and may be mono or combination.

92. The Ezetrol authorisation was granted for three indications:

(a) primary hypercholesterolemia;

(b) homozygous familial hypercholesterolemia; and

(c) homozygous sitosterolaemia.

93. In the case of homozygous familial hypercholesterolemia (HoFH), the SmPC for Ezetrol reads as follows:-

"Homozygous familial hypercholesterolemia (HoFH)

EZETROL 10 mg Tablets, administered with a statin, are indicated for use in patients with HoFH. Patients may also receive adjunctive treatments (e.g. LDL apheresis).

94. The second indication in the SmPC links ezetimibe to statins. The SmPC later refers to clinical trials with simvastatin. Where a clinician is treating a patient for HoFH, the quality and quantity of ezetimibe is fixed at 10mg, but the particular statin and the dosage of the statin is a matter for the clinician. The clinician is specifically directed to consult the product specification for the *statin* as regard to the dosage of the statin. The active ingredient of the product Ezetrol is ezetimibe. A product for the purposes of the SPC Regulation refers to the active ingredient or combination of active ingredients. The product Ezetrol is not a combination of active ingredients. While the co-administration of ezetimibe with a statin is mandatory when treating HoFH, co-administration of two products is not to be equated with a combination product.

95. The arguments of CHL are very similar to those which were rejected by Lewison J. in *Yeda*. The language in the SmPC for Ezetrol is very similar to that in *Yeda*. The relevant extract read:-

"Erbitux in combination with irinotecan is indicated for the treatment of patients with epidermal growth factor."

96. In *Yeda*, the phrase was *"in combination with"* whereas in this case the phrase is *"administered with"*. In *Yeda*, the additional active ingredient was specially identified as irinotecan, whereas in this case it is merely a statin, and later four statins are mentioned, including simvastatin. In *Yeda*, the clinician was directed to consult the medical authorisation for the dosages of irinotecan. Similarly, as regards the co-administration of Ezetrol with a statin, the clinician is directed to look to the relevant statin marketing authorisation for the appropriate dosage. At para. 19 of the judgment, Lewison J. held:-

"To my mind it is clear from recital (10) and from the case law that what constitutes a "product" is to be strictly construed: Generics (UK) Ltd v Daiichi Pharmaceutical Co Ltd [2009] EWCA Civ 646. In deciding what is a "product" one must focus, as the Hearing Officer put it, "on what the product is, rather than what it does". As the ECJ said in Case C-202/05 Yissum Research and Development Co v Comptroller-General (§ 18):

'It follows that the concept of "product" cannot include the therapeutic use of an active ingredient protected by a basic patent.'"

97. He continued at paras. 26 and 27 as follows:-

"26. ... But as the case law shows, how a medicinal product is used does not form part of the identification of the product itself. In my judgment the brief references to irinotecan in explaining how cetuximab is used are wholly insufficient to amount to a marketing authorisation of a product consisting of both cetuximab and irinotecan ...

27. So far as the second point is concerned, in the first place I am not convinced that the Swiss authorities gave a marketing authorisation for a combined <u>product</u>, as opposed to a combined <u>use</u> (or, to put the point another way, they attached a condition about use to

their approval of cetuximab as a product). In the second place what is important for present purposes is not what the Swiss regulators have authorised but what the Community regulators have authorised. If they have authorised different things, so be it. Third, it may well have been open to the patentee to frame its application to the Community regulator for marketing authorisation in such a way as would have resulted in an authorisation for a combination of cetuximab and irinotecan. But it did not." (emphasis added)

98. In *Yeda*, Lewison J. said that the court must focus on what the product is rather than what it does. The concept of the product cannot include the therapeutic use of an active ingredient protected by a basic patent. Therefore, the fact that there are far more references to a statin, or even simvastatin, in the SmPC for Ezetrol compared to the references to irinotecan in the SmPC for Erbitux does not alter the principle and is not a reason, as CHL contended, for distinguishing *Yeda*.

99. This statement of the law gives effect to the decisions of the CJEU in Case C-31/03 *Pharmacia Italia SpA* and again in Case C-202/05 *Yissum Research and Development v. Comptroller-General of Patents* that the decisive factor, in the words of the trial judge, *"is not the intended use of a medicinal product but the product itself"*. Recital 10 of the SPC Regulation says that the protection granted should be *"strictly confined to the product"* which obtained the marketing authorisation. Article 4 of the SPC Regulation extends the protection of the SPC only to the product covered by the marketing authorisation.

100. In my opinion, the analysis of Lewison J. and subsequently McDonald J. is correct. I agree with the reasoning and conclusions of the High Court. The essential flaw in the submission of CHL is the argument that the authorisation of the product Ezetrol was for a combination of active ingredients. To my mind, it is inescapable that the product related to one active ingredient; albeit that its therapeutic use to treat HoFH required that it be co-

administered with a stain. This central plank of CHL's case must be rejected and it, therefore, follows that Inegy was the first marketing authorisation of the combination product comprising ezetimibe and simvastatin, and the trial judge was correct to refuse to invalidate the SPC on the grounds that it breached Article 3(d) of the SPC Regulation.

Conclusion on Article 3(d)

101. The marketing authorisation to place a medicinal product on the market as a medicinal product must be the first such authorisation to place the product on the market. The marketing authorisation to place the product Inegy on the market was for a combination product comprising two active ingredients, ezetimibe and simvastatin. Previously, MSD had obtained an SPC in respect of Ezetrol. This product comprised one active ingredient, ezetimibe, but for one indication in the authorisation it was required to be co-administered with a statin. The SmPC referred to clinical trials co-administering ezetimibe with simvastatin in specific dosages which were subsequently reproduced in the SmPC for Inegy. This did not amount to a marketing authorisation of a combination product comprising ezetimibe and simvastatin. This combination product, therefore, had not been the subject of a previous SPC. It follows that the marketing authorisation of Inegy was the first authorisation to place the product on the market as a medicinal product in accordance with Article 3(d) of the SPC Regulation. The trial judge was correct to hold that the SPC was not invalid on the basis of the alleged breach of Article 3(d). For these reasons, I would reject the appeal of CHL.

102. As this judgment is being delivered electronically, Haughton and Murray JJ. have indicated their agreement with this judgment. The case will be listed for a short hearing on the costs of the two appeals at a date to be notified to the parties.