

**An Chúirt Uachtarach****The Supreme Court**

O'Donnell CJ  
MacMenamin J  
Dunne J  
Charleton J  
Woulfe J

Supreme Court appeal number: S:AP:IE:2021:000052  
[2022] IESC 11  
Court of Appeal record number: 2020/94  
[2021] IECA 54  
High Court record number 2018/3485 P  
[2019] IEHC 814

**Between**

**Merck Sharp & Dohme Limited  
Plaintiff/Appellant**

**- and -**

**Clonmel Healthcare Limited  
Defendants/Respondents**

**UNAPPROVED JUDGMENT and DRAFT REFERENCE****Judgment of Mr Justice Peter Charleton delivered on Monday 21 February 2022**

1. Merck Sharp & Dohme have sought a reference to the Court of Justice of the European Union on the core issue in this appeal, namely, the appropriate interpretation and application of Articles 3(a) and 3(c) of Regulation (EC) 469/2009 concerning the supplementary protection certificate for medicinal products [2009] OJ L152/1. That application has been opposed by Clonmel Healthcare Limited, which contends that a reference is unnecessary because the law is already clear. In consequence of that disagreement, it is appropriate to indicate the nature of the controversy as between the parties and to explain why this Court is obligated to refer; the draft reference being appended hereto for circulation to the parties and amended, if necessary, the final form appearing on the approval of this judgment. First, the nature of what is a complex area of law should be set out.

## The issue

2. The human medication ezetimibe, while at this date out of patent, was the subject of a European Patent lasting 20 years. It was effective as and from the date of filing, 14 September 1994. Ezetimibe was subsequently granted a Supplementary Protection Certificate, an SPC. This medicinal therapy was marketed as Ezetrol upon the grant of a marketing authorisation. It is required for the patentee to apply within six months of such a marketing authorisation for an SPC; Article 7(1) of the Regulation. That SPC, which can endure for up to 15 years from grant, can give up to 5 years' protection post patent expiry; Recital 9 and Article 13 of the Regulation. The issue addressed by ezetimibe is excess cholesterol in the bloodstream leading to atherosclerosis. Prior to the marketing of ezetimibe, that condition was often treated by a statin. Statins enhance the liver's function with regard to reducing low density lipoproteins, LDL, in the blood. High concentrations of LDL are associated with an enhanced risk of atherosclerotic disease. A number of therapies have been developed for the treatment of LDL cholesterol. At the time of the priority date of this patent, statins were commonly used. Azetidinones such as ezetimibe operate, however, by inhibiting the absorption of cholesterol into the bloodstream at the borders of the intestinal villus in the small intestine. In the patent, the use of ezetimibe in combination with a statin, specifically mentioning simvastatin, is claimed. At all relevant times, simvastatin has been in the public domain.

3. In this instance, there is an SPC for the monotherapy of ezetimibe (SPC one for Ezetrol) and there is a second SPC for ezetimibe in an incipient combined with simvastatin (SPC two for Inegy). A common modern therapy for cholesterol would include a statin to decrease the natural production of cholesterol into the bloodstream. What is novel about ezetimibe is that it decreases absorption from the digestive system of cholesterol into the bloodstream. These two medicines were predicted to be mutually helpful to the health issue of atherosclerosis, a hardening or fogging of the arteries. Often a drug is prescribed for human or animal health with another or others and there may be additive or synergistic, meaning better than the sum of the parts, results. If a patented drug, ezetimibe marketed as Ezetrol, for which SPC 1 has been granted, is added to an existing drug in the public domain, simvastatin marketed as the single preparation Inegy, can a second SPC be granted? Is SPC 2 contrary to European law?

4. No drug can be sold, however, without marketing authorisation. A medicinal product for humans or animals cannot be placed on the market unless marketing authorisation has been granted in accordance with Directive 2001/83/EC or Directive 2001/82/EC. Obtaining such an authorisation takes time, because of clinical trials and other checks, and while seeking it the patent protection is running but without value being generated by the invention because it cannot be marketed. The undertaking does clinical trials and receives a marketing authorisation only in 2008. Thus the period of effective patent protection would be reduced to 12 years. Applying within 6 months of the marketing authorisation for an SPC, 15 years may be granted from 2008, meaning the patent protection may be extended to 2023; extending the protection for 3 years to make up for the 8 years lost in clinical trials and obtaining marketing authorisation. On the market, and in the public domain, there is another drug, drug B, which has either additive or synergistic effects on the human or animal patient's condition. The patent also claims the combination of drug A with drug B. The undertaking adds drug A in an appropriate incipient to drug B and does clinical trials lasting two years from 2008. A marketing authorisation is sought for the combination in 2012 and granted. An SPC is sought and granted for drug A plus B. This means that the patented drug A and the public domain drug B have, as a combination, protection up to 2025, since an SPC cannot be granted for more than 5 years beyond the patent term.

5. That exemplifies the situation here. Some may argue that this is in substance the grant of an SPC twice for the same drug; or at least in respect of the same invention. Others may reply that if an SPC is merely a measure to extend the life of a patented medicine that, in reality, this is no more than the extension of, what would be, ordinary patent protection. Hence, that argument would run: during the ordinary monopoly life of a patented drug A, where A is claimed to be therapeutic on its own and is also claimed in combination with drug B, during the 20 years of the patent, no one could manufacture or put on the market any product which was either the monotherapy A or any combination of A with B or C or any drug, whether in the public domain or not. Each product, it may be claimed, would have the period of effective protection of the patent and the SPC running in each case from the grant of the marketing authorisation for the monotherapy A or any combination therapy A+B or A+C; in the case of the first product comprising drug A from 2008 to 2023 (12 years patent and 3 SPC) and in the case of the combination from 2012 to 2025 (8 years under the patent and 5 years SPC). If the combination product A+B or A+C was protected as such by the patent before the expiry of the patent why should it not be protected by an SPC merely because a different SPC was earlier granted in respect of the single drug A? On the other hand, it is here argued that this would give monopoly protection by virtue of obtaining a patent for a total period of 17 years, and thus for more than either product, A or A+B or A+C, on its own if one of these is the first to be granted an SPC. Essentially, these are the key issues that the Court is obliged to address and to seek clarification on from the Court of Justice of the European Union.

6. The questions need to be asked in the context of patent law being domestic, although influenced by the European Patent Convention. The test for patentability requires a novel inventive step, sections 9 and 11 of the Patents Act 1992 and Article 54(1) EPC, meaning one which is not obvious and which does not form part of the state of the art as of the priority date, the day when the application for a patent is first filed, that step being a plausible contribution to a technical issue and thus which is capable of application in industry. National law conforms to the EPC; *Glaxo Group Limited v Patents Act* [2009] IEHC 277. What is inventive is judged from the point of view not of a reasonable and educated person but a skilled person or, most likely, a skilled team, who is or are acquainted with the prior art; Phillips and Firth, *Introduction to Intellectual Property Law* (4<sup>th</sup> edition, London 2001) chapter 5. What the patent, if granted, teaches is that which is set out in the claims and in the light of specifications and drawings elucidating the claims. Special Protection Certificates, SPCs, are a part of European law. Human and animal drugs may be potentially harmful or may have problematic side-effects or may not have any, or any beneficial, efficacy. Hence, before being introduced onto the market, pharmaceutical developments are assessed and trialled by undertakings and submitted for a marketing authorisation.

7. To maintain competitiveness with other countries or trading blocs extending protection to provide for delays in clinical trials, the EU responded; see Kur, Drier and Luginbuehl, *European Intellectual Property Law: Text, Cases and Materials* (2<sup>nd</sup> edition, Edward Elgar Publishing, 2019) 94-98. This situation of delay in exploitation of a patented medicine was first recognised in the USA in 1984 and in Japan in 1987 and, in the expectation that production and research would not flee European shores, the European Union introduced supplementary protection for up to 15 years from marketing authorisation, and up to 5 years post patent, in 1992. This is now Regulation (EC) No 469/2009. An SPC is granted by the relevant office dealing with intellectual property in Member States.

8. The grant of the SPC, it is contended, should not be dependent on any appraisal of the state of the art, of inventive step, or novelty, or plausibility, or industrial application but merely is a

step contingent on an undertaking having a patent and being thereby entitled to extra time by reason of clinical trials eating into patent protection before a marketing authorisation is achieved. If anyone has a problem with the patent as granted, they challenge the patent as being non-inventive, or already declared in the state of the art, or implausible, or other grounds existing in national law as influenced by the EPC. Although an SPC extends the life of the patent some may argue that an SPC is a legally different form of protection.

### Criteria for a Reference

9. The text of Article 267 of the Treaty on the Functioning of the European Union (Consolidated version) [2016] OJ C202/1, which sets out the preliminary reference procedure, provides at Article 267:

The Court of Justice of the European Union shall have jurisdiction to give preliminary rulings concerning:

- (a) the interpretation of the Treaties;
- (b) the validity and interpretation of acts of the institutions, bodies, offices or agencies of the Union;

Where such a question is raised before any court or tribunal of a Member State, that court or tribunal may, if it considers that a decision on the question is necessary to enable it to give judgment, request the Court to give a ruling thereon.

Where any such question is raised in a case pending before a court or tribunal of a Member State against whose decisions there is no judicial remedy under national law, that court or tribunal shall bring the matter before the Court.

If such a question is raised in a case pending before a court or tribunal of a Member State with regard to a person in custody, the Court of Justice of the European Union shall act with the minimum of delay.

10. As such, a national court of first instance has to assess on that basis whether or not to refer questions regarding the interpretation of European law to the CJEU. It cannot be compelled to do so by either the CJEU or the parties in question. However, if the national court is a court of final appeal it must make a preliminary reference unless the CJEU has already ruled on the point and the existing CJEU case-law is clearly applicable, or unless the law is *acte clair*, meaning the interpretation is obvious. Pursuant to the third paragraph of Article 267, where a question falling within the Article is raised in a case pending before a court or tribunal of a Member State against whose decisions there is no judicial remedy under national law, that court or tribunal must bring the matter before the Court. However, that obligation only arises where a ruling of the Court of Justice is truly necessary for the Court to reach its decision. There have emerged conditions to the obligation contained in Article 267(3) on a court or tribunal of a Member State against whose decisions there is no judicial remedy under national law to bring the matter before the CJEU. The decision of the European Court of Justice in Case C-283/81 *Srl CILFIT v Ministry of Health* [1982] ECR 3415 sets out these exceptions. At [16]-[17] of the judgment, the Court of Justice stated that:

... the correct application of Community law may be so obvious as to leave no scope for any reasonable doubt as to the manner in which the question raised is to be resolved.

Before it comes to the conclusion that such is the case, the national court or tribunal must be convinced that the matter is equally obvious to the courts of the other Member States and to the Court of Justice. Only if those conditions are satisfied, may the national court or tribunal refrain from submitting the question to the Court of Justice and take upon itself the responsibility for resolving it.

However, the existence of such a possibility must be assessed on the basis of the characteristic features of Community law and the particular difficulties to which its interpretation gives rise.

11. The Court also emphasised, at [19] of the judgment, that Community law uses language that is peculiar to it and that “legal concepts do not necessarily have the same meaning in Community law and in the law of the various Member States”. At [20], the Court stated that “every provision of Community Law must be placed in its context and interpreted in the light of the provisions of Community Law as a whole, regard being had to the objectives thereof and to its state of evolution at the date on which the provision in question is to be applied.” In light of all of the above considerations, the Court of Justice held that:

... the third paragraph of Article 177 of the EEC treaty [now Article 267 of the TEFU] is to be interpreted as meaning that a court or tribunal against whose decisions there is no judicial remedy under national law is required, where a question of Community law is raised before it, to comply with its obligation to bring the matter before the Court of Justice, unless it has established that the question raised is irrelevant or that the Community provision in question has already been interpreted by the Court of Justice or that the correct application of Community law is so obvious as to leave no scope for any reasonable doubt. The existence of such a possibility must be assessed in light of the specific characteristics of Community law, the particular difficulties to which its interpretation gives rise and the risk of divergences in judicial decisions within the Community.

12. The Court has spelled out the conditions required to be satisfied before a court of final appeal may find an issue to be already decided, or apparent from a legislative text; *acte clair*. Essentially, this means that the law is clear beyond a reasonable doubt. Critically, the national court: “must be convinced that the matter is equally obvious to the courts of the other Member States and to the Court of Justice”. In reaching its conclusion, the national court must bear in mind “the characteristic features of Community law and the particular difficulties to which its interpretation gives rise”. These include, at [19]-[20]:

- a. The need to compare the different language versions of Community legislation, each of which is equally authentic;
- b. The use of terminology which is peculiar to Community law, or which has a different meaning in Community law from its meaning in the law of the various Member States; and
- c. The need to place every provision of Community law in its context and to be interpreted in the light of the provisions of Community law as a whole, regard being had to the objectives of community law and to its data revolution at the date on which the provisions in question are to be applied.

13. The *CILFIT* elaboration of the doctrine remains the yardstick by which decisions to refer are measured, and neither of the major glosses provided by the CJEU since then (Case C-495/03 *Intermodal Transports BV v Staatssecretaris van Financiën* [2005] ECR I-08151 on the question of conflicting interpretations by non-judicial bodies, and Case C-461/03 *Gaston Schul Douane-expediteur BV v Minister van Landbouw, Natuur en Voedselkwaliteit* [2005] ECR I-10513 on the validity of Union Acts), have challenged this position. Commentators have remarked on this Court's "extremely punctilious attitude" to the question of making references; Anderson, *References to the European Court*, (Sweet and Maxwell, 1985) at p 168. These points were summed up in a reasonable way in the EU context in the recommendations to national courts and tribunals in relation to the initiation of preliminary ruling proceedings (2012/C 338/01), issued by the CJEU, in the following manner:

11. Article 267 TFEU provides that any court or tribunal may submit a request for a preliminary ruling to the Court of Justice on the interpretation of a rule of European Union law if it considers it necessary to do so in order to resolve the dispute brought before it.

12 However, courts or tribunals against whose decisions there is no judicial remedy under national law must bring such a request before the Court, unless the Court has already ruled on the point (and there is no new context that raises any serious doubt as to whether that case-law may be applied in that instance), or unless the correct interpretation of the rule of law in question is obvious.

13. Thus, a national court or tribunal may, in particular when it considers that sufficient guidance is given by the case-law of the Court of Justice, itself decide on the correct interpretation of European Union law and its application to the factual situation before it. However, a reference for a preliminary ruling may prove particularly useful when there is a new question of interpretation of general interest for the uniform application of European Union law, or where the existing case-law does not appear to be applicable to a new set of facts.

14. As has been emphasised in Case C-561/19 *Consorzio Italian Management, Catania Multiservizi SpA v Rete Ferroviaria Italiana SpA* [2021], a reference is not simply a matter of contention, being raised and ruled on in an adversarial context. Rather a reference is an obligation in European law which a court of final appeal should always bear in mind as its sole responsibility, whether contended for, mentioned, or opposed by the parties before that court in any relevant controversy. Furthermore, the form of the reference and the questions raised are a matter for the court holding that responsibility.

54. The system established by Article 267 TFEU therefore does not constitute a means of redress available to the parties to a case pending before a national court or tribunal. Thus, the mere fact that a party contends that the dispute gives rise to a question concerning the interpretation of EU law does not mean that the court or tribunal concerned is compelled to consider that such a question has been raised within the meaning of Article 267 TFEU (judgment of 6 October 1982, *Cilfit and Others*, 283/81, EU:C:1982:335, paragraph 9).

55. It follows that the determination and formulation of the questions to be put to the Court devolve upon the national court or tribunal alone and that the parties to the main proceedings may not change their tenor (see, to that effect, judgment of 18 July 2013, *Consiglio Nazionale dei Geologi*, C-136/12, EU:C:2013:489, paragraph 29 and the case-law cited).

56. Moreover, it is for the national court or tribunal alone to decide at what stage in the proceedings it is appropriate to refer a question to the Court of Justice for a preliminary ruling (see, to that effect, judgment of 17 July 2008, *Coleman*, C-303/06, EU:C:2008:415, paragraph 29 and the case-law cited), with the latter having no jurisdiction, however, to hear a reference for a preliminary ruling when, at the time it is made, the procedure before the referring court or tribunal has already been concluded (judgment of 13 April 2000, *Lehtonen and Castors Braine*, C-176/96, EU:C:2000:201, paragraph 19).

57. It follows from the foregoing that, where the case before it involves one of the situations set out in paragraph 33 above, a national court or tribunal against whose decisions there is no judicial remedy under national law is not required to bring the matter before the Court, within the meaning of the third paragraph of Article 267 TFEU, even when the question concerning the interpretation of EU law is raised by a party to the proceedings before it.

### **Importance of the issue**

15. A brief consideration of the controversy on appeal before this Court indicates the nature of the uncertainty prevailing as to the interpretation of the Regulation and as to whether it has imported into patent law new concepts or has required national intellectual property offices to consider: is something further required, beyond patent and marketing authorisation, before an SPC may be granted? Where there is a prior SPC for either a monotherapy of the patented drug, or a different combination therapy SPC for the patented drug in an incipient with a public domain drug, what is the situation in European Union law? As a matter of national law, patented drug A in combination with public domain drugs B, or C, or D, or any combination would prevent exploitation of any product containing patented drug A during the 20 year life of the patent. By what measure of law could that situation be changed consequent upon the grant of an SPC? Or, is there a further test that the intellectual property offices of Member States must consider when granting an SPC? Is this step not limited to having a patent and to getting a marketing authorisation?

### **The legislation**

16. Regulation (EC) No 469/2009 is the object of this reference. These are the definitions in Article 1:

- (a) ‘medicinal product’ means any substance or combination of substances presented for treating or preventing disease in human beings or animals and any substance or combination of substances which may be administered to human beings or animals with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in humans or in animals;
- (b) ‘product’ means the active ingredient or combination of active ingredients of a medicinal product;
- (c) ‘basic patent’ means a patent which protects a product as such, a process to obtain a product or an application of a product, and which is designated by its holder for the purpose of the procedure for grant of a certificate;
- (d) ‘certificate’ means the supplementary protection certificate;
- (e) ‘application for an extension of the duration’ means an application for an extension of the duration of the certificate pursuant to Article 13(3) of this Regulation and Article

36 of Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use (5).

17. A patent holder can get an extension beyond patent life of 20 years for up to 5 years by way of an SPC where the patentee has a patent for a medicine which has subsequently been granted marketing authorisation. That lasts 15 years, and may extend patent life for up to 5 years maximum. This is what Article 2 states:

Any product protected by a patent in the territory of a Member State and subject, prior to being placed on the market as a medicinal product, to an administrative authorisation procedure as laid down in Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use or Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products may, under the terms and conditions provided for in this Regulation, be the subject of a certificate.

18. Article 4 states:

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.

19. And the conditions are laid down in Article 3 thus:

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

- (a) the product is protected by a basic patent in force;
- (b) a valid authorisation to place the product on the market as a medicinal product has been granted in accordance with Directive 2001/83/EC or Directive 2001/82/EC, as appropriate;
- (c) the product has not already been the subject of a certificate;
- (d) the authorisation referred to in point (b) is the first authorisation to place the product on the market as a medicinal product.

### **The dispute**

20. At the heart of this dispute on this appeal is whether the combination product Inegy, A+B, which is the subject of the second SPC, is “protected by the basic patent in force” within the meaning of Article 3(a). If it is not, then the SPC is invalid. While a drug may be marketed as a monotherapy, a drug can also obtain a marketing authorisation as a combination therapy. On the one hand, MSD say that they should have two SPCs: one for ezetimibe on its own (Ezetrol), from 2003, and the other for ezetimibe combined with simvastatin (Inegy), from 2005. Is there some requirement that the combination of ezetimibe with simvastatin must be mentioned in the claims of the patent, in order to be covered by the patent? On the other hand, for a year, Clonmel marketed a combination therapy consisting of those drugs; it claims that the second SPC for Inegy is invalid on the basis that merely mentioning a product in the claims of the patent is not sufficient to qualify that product as being covered by the basic patent in force under Article 3(a) of the Regulation. Also at the heart of this case is Article 3(c) of the Regulation and



Clonmel's contention that MSD's disputed SPC is invalid under this provision because the product protected by the patent is ezetimibe and this has already been the subject of an SPC.

### Guidance from the existing decisions

21. In joined cases C-650/17 and C-114/18 *Royalty Pharma Collection Trust v GD Searle LLC, Sandoz Ltd v GD Searle LLC* [2020], the issue concerned whether a patent protecting a particular medicine could be granted an SPC in combination with another drug which was not part of the teaching on the patent. While this case turned on what could be identified from the claims on the patent, the Opinion of Advocate General Hogan [2019] referred to the prior legal controversy which had brought the issue about:

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

22. The necessity to refer to this concept of "core inventive advance" arises as to construing Article 3(a) and the wording thereof requiring a marketing authorisation of a "product protected by a basic patent in force". There is no wording referring to any requirement for any inventive advance to be demonstrated to national intellectual property offices in the grant of an SPC. As Advocate General Hogan stated:

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

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

48. In my view, that doubt can be swiftly and definitively resolved by a reading of paragraphs 52 and 53 of the judgment of 25 July 2018, *Teva UK and Others* (C-121/17, EU:C:2018:585). In paragraph 52 of that judgment, the Court indicated when a product is 'protected by a basic patent in force' and then in paragraph 53 it stated that 'such an interpretation of Article 3(a) of Regulation No 469/2009 must *also* be upheld in a situation, such as that at issue in the case in the main proceedings, where the products which are the subject of a SCP are composed of several active ingredients which have a combined effect.' It is therefore clear from the very language utilised by the Court that the test referred to in paragraph 57 of the judgment of 25 July 2018, *Teva UK*

*and Others* (C-121/17, EU:C:2018:585) and in the operative part of that judgment, applies *both* to products consisting of a single active ingredient and products composed of several active ingredients. In any event, for my part, I fail to see why, as a matter of principle, the *Teva* test should apply to combination products with several active ingredients while not also applying to a product with one single active ingredient.

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

23. Advocate General Hogan referenced the earlier opinion to the same effect by Advocate General Wathelet in Case C-121/17 *Teva UK and Others v Gilead Sciences Inc* [2018], in a consideration of whether there were criteria unstated in the Regulation which would lead to enquiries by national intellectual property agencies beyond the existence of a patent and the grant of a marketing authorisation:

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

51. In that regard, Advocate General Wathelet noted that that concept was referred to in paragraph 41 of the judgment of 12 December 2013, *Actavis Group PTC and Actavis UK* (C-443/12, EU:C:2013:833) in relation to a different provision of Regulation No 469/2009, namely Article 3(c). He proceeded to state that ‘the only means of determining whether a basic patent protects an active ingredient within the meaning of Article 3(a) of Regulation No 469/2009 is to be found only in the wording, or interpretation of the wording, of the claims of the patent granted, and nowhere else. ... Any other additional criterion, such as the requirement proposed by the referring court that the active ingredient embody “the inventive advance of the patent” runs the risk, in my view, of giving rise to confusion with the criteria for determining whether an invention is patentable. The question whether a product is protected by a patent within the meaning of Article 3(a) of Regulation No 469/2009 is not the same as the question whether that product is patentable, which is a matter exclusively for national or treaty law.’

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

53. It must be noted that, at no point in its consideration of the question referred or the operative part of the judgment of 25 July 2018, *Teva UK and Others* (C-121/17, EU:C:2018:585) did the Court refer to the concept of ‘core inventive advance’. Rather,

the Court laid down in paragraph 57 and in the operative part of that judgment an entirely different and unrelated two-part test for the interpretation of Article 3(a) of Regulation No 469/2009.

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

24. In *Teva UK and Others v Gilead Sciences Inc*, a medicine against HIV had been patented but an SPC had been granted in respect of that medicine in combination with another drug not stated in the patent’s claims. The High Court of England and Wales asked as to the “criteria for deciding” whether “the product is protected by a basic patent in force” in Article 3(a) of the Regulation. While the answer to the question posed was that a combination SPC could be granted for a patented medicine combined with another active ingredient not expressly mentioned in the claims of the patent, where those claims necessarily and specifically must be taken to refer to that combination, the Court is here – as is argued by Clonmel - contended to have stated that where an SPC had been granted for a monotherapy, a second SPC at a later date might not be granted for that patented medicine combined with any drug in the public domain. Does that include drugs to be combined with the patented drug as taught in the claims of the patent? The wording of the claims in a patent, including elucidation by drawings and specifications, was examined to discover for what an SPC could be granted. But, in national patent law, by reason of an advance in the state of the art, that was at the priority date an inventive step and of industrial application, any use of a new patented medicine, alone or in combination with any medicine in the public domain, was protected for 20 years. There is, however, no requirement in patent law to identify the core inventive advance and protection of the monopoly of exploitation is not limited to that. Rather, every valid claim in the patent is protected. What may be argued by Clonmel to have emerged, and in the light of the opinions of Advocate General Hogan and Advocate General Wathelet this is uncertain, is a change in patent law whereby for an SPC only a core inventive advance is to be protected and then protected only once. Hence:

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.

39. That requirement is in line with the objective of the SPC, which is to re-establish a sufficient period of effective protection of the basic patent by permitting the holder to enjoy an additional period of exclusivity on the expiry of that patent, which is intended to compensate, at least in part, for the delay to the commercial exploitation of his invention by reason of the time which has elapsed between the date on which the application for the patent was filed and the date on which the first MA in the European Union was granted. As indicated in recital 4 of Regulation No 469/2009, the purpose of that additional period of exclusivity is to encourage research and, to that end, it is designed to ensure that the investments put into such research are covered (see, to that effect, judgment of 12 December 2013, *Eli Lilly and Company*, C-493/12, EU:C:2013:835, paragraphs 41 and 42 and the case-law cited).

40. 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 Regulation No 469/2009, reiterated in the preceding paragraph, to grant an SPC for a product which does not fall under the invention covered by the basic patent, inasmuch as such an SPC would not relate to the results of the research claimed under that patent.

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

43. Accordingly, having regard to the objectives pursued by Regulation No 469/2009, the claims cannot allow the holder of the basic patent to enjoy, by obtaining an SPC, protection which goes beyond that granted for the invention covered by that patent. Thus for the purposes of the application of Article 3(a) of that regulation, the claims of the basic patent must be construed in the light of the limits of that invention, as it appears from the description and the drawings of that patent.

44. That interpretation is borne out by Article 4 of Regulation No 469/2009, which provides that the protection granted by the SPC extends only to the product covered by the MA granted for the corresponding medicinal product and for any use of the product as a medicinal product that has been authorised before the expiry of the SPC, exclusively '[w]ithin the limits of the protection conferred by the basic patent'.

45. The same is true regarding Article 5 of that regulation, under which the SPC confers the same rights as conferred by the basic patent and is subject to the same obligations. Accordingly, if, during the period in which the patent was valid, the patent holder could oppose, on the basis of his patent, all use or certain uses of his product in the form of a medicinal product consisting of such a product or containing it, the SPC granted in relation to that product would confer on the holder the same rights for all uses of the product, as a medicinal product, which were authorised before the expiry of the certificate (judgments of 24 November 2011, *Medeva*, C-322/10, EU:C:2011:773, paragraph 39, and of 24 November 2011, *Georgetown University and Others*, C-422/10, EU:C:2011:776, paragraph 32).

46. It follows from the above that the subject matter of the protection conferred by an SPC must be restricted to the technical specifications of the invention covered by the basic patent, such as claimed in that patent.

47. With regard to the implementation of that rule, it must in the first place be stated that, in accordance with a principle shared by the patent laws of the Member States and reflected in Article 1 of the Protocol on the Interpretation of Article 69 of the EPC, the claims of a patent are to be interpreted from the perspective of a person skilled in the art and, therefore, the issue whether the product which is the subject of the SPC necessarily falls under the invention covered by that patent must be assessed from that perspective.

48. To that end, it is necessary to ascertain whether a person skilled in the art can understand without any doubt, on the basis of their general knowledge and in the light of the description and drawings of the invention in the basic patent, that the product to which the claims of the basic patent relate is a specification required for the solution of the technical problem disclosed by that patent.

25. Since Case C-577/13 *Actavis Group PTC EHV v Boehringer Ingelheim Pharma GmbH* [2015] was about a patent amended after grant, the point at issue on this appeal has not been decided on actual facts requiring such a decision. In *Boehringer*, there were two SPCs, the first, SPC1, for a monotherapy and the second, SPC2, for the monotherapy combined with an ingredient only added to the claims by reason of an amendment. While the High Court of England and Wales had stated, correctly as a matter of national law, that amendments were normal course for a patent, [2013] EWHC 2927 (Pat) per Birss J at [10], and while the decision of the CJEU may be confined to amended patents, there are indications that, on the one hand, a claim in a patent for an invention as a monotherapy may give rise to an SPC, so also may that medicine combined with other public domain medicines, meaning more than one SPC, and, on the other hand, that this may not occur. The answer is needed in order to establish legal certainty in an area of law of key economic importance; see also Case C-433/12 *Actavis Group PTC and Actavis UK Ltd v Sanofi* [2013]. This quote from the CJEU's judgment in *Boehringer* sets out the situation as a matter of patent law, under the EPC, and then states an ostensibly different test where an SPC is to be granted following marketing authorisation:

33. It should be recalled in that regard, first, that it is possible, in principle, on the basis of a patent which protects several different 'products', to obtain several SPCs in relation to each of those different products, provided, inter alia, that each of those products is 'protected' as such by that 'basic patent' within the meaning of Article 3(a) of Regulation No 469/2009, in conjunction with Article 1(b) and (c) of that regulation (see, to that effect, judgments in *Actavis Group PTC and Actavis UK*, C-443/12, EU:C:2013:833, paragraph 29, and *Georgetown University*, C-484/12, EU:C:2013:828, paragraph 30).

34. Second, it should be noted that, according to recitals 4, 5 and 9 in the preamble to Directive No 469/2009, the SPC is designed to re-establish a sufficient period of effective protection of a basic patent by permitting the holder to enjoy an additional period of exclusivity on the expiry of his patent, which is intended to compensate, at least in part, for the delay to the commercial exploitation of his invention by reason of the time which has elapsed between the date on which the application for that patent was filed and the date on which the first marketing authorisation in the European Union was granted (see, to that effect, judgment in *Actavis Group PTC and Actavis UK*, C-443/12, EU:C:2013:833, paragraph 31 and the case-law cited).

35. However, the Court has also held that the objective pursued by Regulation No 469/2009 is not to compensate the holder fully for the delay to the marketing of his invention or to compensate for such delay in connection with the marketing of that invention in all its possible commercial forms, including in the form of combinations based on the same active ingredient (see, to that effect, judgment in *Actavis Group PTC and Actavis UK*, EU:C:2013:833, paragraph 40).

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.

### **The arguments for the appellant MSD**

26. The submissions for MSD set out three approaches to deciding whether an active ingredient is "protected by a basic patent in force" within the meaning of Article 3(a) of the Regulation. The first approach is that it suffices that the product in the SPC simply falls within the extent of protection of the claims of the patent. The second is the identificatory approach in which the active ingredient present in the product in the SPC needs to be identified in the wording of the claims of the patent either expressly, or, if not identified expressly, to the requisite degree of specificity. The third approach is a qualitative test requiring consideration of whether the skilled person would have understood, at the priority date, that the active ingredient of the SPC represented an "inventive advance" or "independent innovation" of the patent. MSD's submissions argue that the second, identificatory, approach is the correct one to be applied. MSD submits that Clonmel's case rests on the third approach being followed; this was, in MSD's view, erroneously applied by the Court of Appeal and the trial judge through a misreading of the relevant case law.

27. MSD argues that the Court of Appeal erred in its reading of the case law from the CJEU. By concluding that some consideration of inventiveness was required, so that even where the product was specifically identified in the claims included in the patent, a product might not be considered to fall within the basic patent in force, the Court had, in essence, retained the "core

inventive advance” test. In MSD’s submission, the CJEU in *Teva UK Ltd and Royalty Pharma Collection Trust* rejected the “core inventive advance” approach to Article 3(a) and instead outlined an identificatory test whereby it is sufficient for the ingredient to be referred to in the claims. MSD relies on the opinion of Advocate General Wathelet in *Teva* where, at [72], he outlines that, in order to determine whether a basic patent protects an active ingredient, the answer is “to be found only in the wording, or interpretation of the wording, of the claims of the patent granted, and nowhere else.” Advocate General Wathelet found, at [82], that what was required for an active ingredient to be “specified” in the claims is that it is “specifically and precisely identifiable as at the priority date”. MSD’s submissions then consider the judgment of the Grand Chamber in *Teva*. In its interpretation, the judgment, at [37], requires that, for a product to be protected by the basic patent, it must be “either expressly mentioned in the claims of that patent or those claims [must] relate to that product necessarily and specifically.” In MSD’s view, only where the active ingredients are not expressly identified in the claims must the description and drawings relating to the ingredient be taken into account. In summary, MSD argues that in *Teva* the Grand Chamber set out that, in order for an ingredient to be covered by the basic patent, it must be expressly identified in the claims or one of those claims must relate to it necessarily and specifically; only in the latter scenario should the skilled person have regard to information beyond the claims.

28. MSD’s submissions further rely on *Royalty Pharma*, claiming that the Court in that case affirmed that, in following *Teva*, the “core inventive advance” approach is not relevant for the interpretation of Article 3(a). The CJEU in MSD’s view reinforced the primacy of the claims and confirmed that the other limbs of the *Teva* test, “necessarily” and “specifically”, only arise if the claims do not explicitly refer to the product. No further enquiry is necessary by a national court if an active ingredient is expressly mentioned in the claim; the result is that the ingredient is covered by the patent. This case also makes clear, in MSD’s submission, that the test in *Teva* does not involve examining the innovative quality of the combination; the test requires a consideration of whether the ingredients have been expressly or implicitly claimed.

29. MSD avers that the Court of Appeal erroneously applied this line of case law. It is submitted by MSD that the Court of Appeal wrongly understood its argument to be that it was enough that the active ingredients merely “fall within the protection of the claims”. MSD accepts that this would be insufficient and instead argues that where the active ingredient is expressly mentioned in the claims of the patent or are otherwise identified with a sufficient level of particularity then it is covered by the patent. MSD also submits that the Court of Appeal misunderstood the opinion of Advocate General Hogan in *Royalty Pharma* [2019]; the Court read it as requiring that the test in *Teva* be applied whether or not one of the active ingredients is expressly mentioned in the claims of the basic patent. Rather, in MSD’s view, Advocate General Hogan was stating that the test of whether the claims related necessarily and specifically to the active ingredient in question had to be applied where the active ingredient is not expressly mentioned.

30. MSD argues that the CJEU judgment in *Boehringer* was wrongly interpreted by the Court of Appeal as being fatal to their argument. In MSD’s submission, *Boehringer* did not endorse an inventive advance test. *Boehringer* was addressing a situation where a claim was introduced subsequently for a combination, when at the grant date there was never any claim for a combination at all. On this basis, its facts are distinguishable from the present case. It was also argued that the decision had been superseded by *Teva* and by *Royalty Pharma*.

31. By virtue of the, in MSD’s view, erroneous approach of the Court of Appeal to Article 3(a), this led to them reaching the wrong conclusion under Article 3(c). Accordingly, MSD submits that “the product” in Article 3(a) is the ezetimibe/simvastatin combination. Accordingly, for the

purposes of the Article 3(c) analysis, the “product” is in fact the ezetimibe/simvastatin combination.

32. In the event that the Court concludes that consideration has to be given to the quality of inventiveness of the combination, then MSD submits that, on the evidence before the trial judge and the Court of Appeal, the requisite degree of inventiveness has been proven.

### **The arguments for the respondent Clonmel**

33. Clonmel’s submissions refer also to *Boehringer*, claiming that this is the case that most closely aligns with the facts in the present case. *Boehringer* similarly involved the pairing of a non-novel compound with a patented compound as a basis for obtaining an SPC additional to the SPC obtained for a product in which the patented compound was the sole active ingredient. It is not, in Clonmel’s view, possible to distinguish *Boehringer* on the basis that the patent in question had been amended following grant in order to introduce the claim for the combination, as MSD submits it is. This aspect of the case did not have influence over the CJEU’s analysis. The judgment in *Boehringer* was referred to with approval by the CJEU in *Teva* without any qualification by reference to post-grant amendment of the patent. The argument made by MSD in the present case was, in Clonmel’s submission, made and rejected by the court in *Boehringer*. The Court of Appeal was correct in deciding that *Boehringer* had not been overruled.

34. Clonmel’s submissions outline its understanding of [42]-[43] of the Grand Chamber judgment in *Teva*. For ease, the judgment is quoted:

37. ... a product cannot be considered to be protected by a basic patent in force within the meaning of Article 3(a) of Regulation No 469/2009 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.

35. Clonmel asserts that the phrase “for that purpose” is a reference back to the issue as to whether a product can be considered to be protected by a basic patent in force within the meaning of Article 3(a). It concerns both of the alternatives mentioned in [37]. Clonmel agrees with the Court of Appeal’s assessment at [59] that the court’s investigation “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”.

36. With regard to *Royalty Pharma*, Clonmel also submits that this contains no statement to the effect that any express reference to two active ingredients in a patent claim is enough to satisfy Article 3(a). *Royalty Pharma*, Clonmel outlines, did not involve a combination product and thus there is no discussion of the decision in *Boehringer*. Clonmel disputes MSD’s claim that *Royalty Pharma* supports the contention that whatever is said in the claim is to be taken to be “the invention covered by the basic patent”. This results from an interpretation of [31]-[32] of the judgment:



31. In this regard, it should be observed that, in its reply to the question raised in the case which gave rise to the judgment of 25 July 2018, *Teva UK and Others* (C-121/17, EU:C:2018:585, paragraphs 34 and 35), the Court did not employ the concept of 'core inventive advance', even though the referring court called on it to do so in its request for a preliminary ruling. 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 (judgment of 25 July 2018, *Teva UK and Others*, C-121/17, EU:C:2018:585, paragraph 46), and not extend to the 'core inventive advance'.

32. In so doing, the Court clearly relied on an interpretation of Article 3(a) of Regulation No 469/2009, in the context of which the concept of 'core inventive advance' is not relevant."

37. According to Clonmel, the CJEU clearly perceived "core inventive advance" as being a concept that is different to "the technical specifications of the invention covered by the basic patent." Clonmel, however, submits that the succeeding phrase "such as claimed in that patent" is merely an add-on to the reference to "the technical specifications of the invention covered by the basic patent". It cannot be segregated out as MSD attempts to do in support of its argument that whatever is said in the claim is the invention covered by the basic patent. There is no statement in *Royalty Pharma* that an express reference to a product in a claim is conclusive. Clonmel submits that the very fact that there is a further test beyond the claims indicates that the claims are not conclusive of the Article 3(a) issue. A skilled person reads more than the claims to find out whether the product comes within the scope of protection afforded by the patent.

38. On the contingent ground of appeal, Clonmel submits that it comes down to MSD trying to claim that the trial judge should have seen the evidence in their favour. In any event, the trial judge issued a 67 page judgment which comprehensively, in Clonmel's submission, reviewed the arguments of the parties and the evidence in support of the claims. The trial judge's decision was then affirmed by the Court of Appeal. Clonmel submits that there is therefore no substance to MSD's criticism of the trial judge's approach to the evidence.

### **The ruling of the High Court on the issues**

39. The High Court decision of McDonald J analysed in great detail the scientific basis of the patent and the products contended to be covered by it. It received expert opinions and examined the historical development of both monotherapy and combination treatments for atherosclerosis; [15]-[37]. The knowledgeable analysis evident in the judgment has been valuable to this Court in navigating this complex area. McDonald J held that the SPC for Inegy was invalid on the basis of Article 3(a) of the Regulation. He interpreted the Grand Chamber's judgment in *Teva* to mean that a court must look beyond the claims when determining what is covered by a patent:

68. ... I cannot see any basis in the judgment to suggest that the CJEU intended that all of its judgment from para. 38 onwards is confined to cases where the relevant combination is not expressly mentioned in the claims of a patent. On the contrary, para. 38 of the judgment commences with the words "*For that purpose ...*". Those words seem to me to refer back to the entire of what was said in the preceding paragraph (i.e. para. 37). I can see nothing in the language used in para. 38 of the judgment to support the

suggestion that the CJEU only intended to refer back to the second part of para. 37 (i.e. the part dealing with cases where the relevant combination is not expressly mentioned in the claims of a patent)

... In my view, it is critically important, to have regard to the rationale expressed by the CJEU in paras. 38-43 of its judgment. 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. If the plaintiff's interpretation of the judgment is correct, it would have the bizarre consequence that the concerns expressed by the CJEU in those paragraphs could be readily sidestepped by those patentees who had taken the course of assiduously listing expressly in the claims of the relevant patent a large range of products or combinations of products even where those claims went beyond the limits of the underlying invention. In my view, the approach suggested by the plaintiff would subvert the rationale expressed by the CJEU in its judgment in *Teva v. Gilead*. I therefore cannot accept the approach which the plaintiff suggests.

40. While McDonald J did see it as necessary that the product, in order for it to be covered by the patent, be within the limits of the patent's invention, he did not think that any test of core inventive advance was relevant; [101]. He concluded as to the patent's validity under Article 3(a) thus:

89. ... Having regard to the approach taken by the CJEU in *Teva v. Gilead*, a product will only be protected by a basic patent for the purposes of the SPC Regulation where the product falls within the limits of the invention, the subject of the patent in issue.

41. As McDonald J held the second SPC for Inegy to be invalid on the basis of Article 3(a), he did not see it as necessary to discuss Article 3(c). However, he did conclude that because the product protected by the patent was ezetimibe, Clonmel was successful in its counterclaim on the basis of Article 3(c), which requires that there cannot be more than one SPC per product.

### **The ruling of the Court of Appeal on the issues**

42. The Court of Appeal, in its judgment delivered by Costello J, assessed the effect of the *Teva* and *Royalty Pharma* case law from the CJEU. It held that the ECJ did not overrule its decision in *Boehringer* in its subsequent decision of *Teva*; [57]. The Grand Chamber had expressly approved of [36]-[37] of *Boehringer*, in [41]-[42] of *Teva*, and did not indicate that it was departing from that decision. In its assessment of [43] of the Grand Chamber's decision in *Teva*, the Court of Appeal stated the following:

59. ... 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.

43. Thus, the Court of Appeal did not agree with MSD's contention that, if a product is mentioned in the claims of the patent, this means that it is covered by the patent with no further enquiry being necessary. The Court read the judgment in *Teva* as requiring that a Court look beyond the claims, taking account of the description and drawings in the patent to determine whether the invention covered the product for the purposes of Article 3(a). For this reason, the Court of Appeal expressed its disagreement with the approach adopted by the Court of Appeal of England and Wales in *Teva UK Ltd & Ors v Gilead Sciences Inc* [2019] EWCA Civ 2272, made after its receipt of the CJEU's decision.

81. ... [Floyd LJ] was of the view that para. 37 [of the CJEU decision in *Teva*] 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.

44. The Court of Appeal agreed with McDonald J's conclusion that the patent did not cover the combination product, Inegy, on the basis that "the product did not fall under the invention covered by the patent", [82].

45. As the Court had found that MSD failed on Article 3(a), its consideration of the second SPC's validity under Article 3(c) was understandably less detailed. The Court agreed with McDonald J's conclusion that, because the product protected by the patent was ezetimibe, the 'product' for the purposes of Article 3(c) must be ezetimibe. As this had already been the subject of the first SPC, the second SPC failed on the basis of Article 3(c), [83].

### **Impact of interpretation on other Member States**

46. To the best of available research and as of the date hereof, the position on this controversy in other Member States should be mentioned. The courts of two European countries, Belgium (in the Brussels Enterprise Court) and Portugal (in, most recently, the Supreme Court of Justice), have deemed MSD's disputed SPC to be valid. In the Czech Republic, proceedings in the City Court in Prague regarding the infringement of the SPC are pending but the Intellectual Property Office and the Industrial Property Office have deemed the SPC valid on the basis of their interpretation of Articles 3(a) and 3(c). The two SPCs which are the subject of the dispute in the Czech Republic are different from those at issue in the present proceedings in Ireland. In Greece, in a first-instance decision from the Athens court, MSD was successful in infringement proceedings brought on the basis of the disputed SPC, but the validity of the SPC was not in fact addressed in the proceedings. In Italy, a decision as to the validity of the disputed SPC is

pending, but there have been four opinions issued by court appointed experts to the effect that the SPC is valid under Articles 3(a), 3(c), and 3(d). In France, in the Cour d'appel de Paris, the disputed SPC was deemed invalid on the basis of both Articles 3(a) and 3(c). There the Court interpreted the patent as containing only one invention; the combination with simvastatin could not be regarded as another invention covered by the patent. With regards Article 3(c), the Court held that where the holder of the patent has already obtained an SPC for an active ingredient entitling them to oppose the use of that active ingredient, alone or in combination, this article must preclude them from getting another SPC in respect of the combination. There is an appeal pending in the Cour de cassation on this matter. In Germany's Federal Patent Court, and in Spain, the disputed SPC was deemed invalid on the basis of Article 3(c), with no decision given as to its validity under Article 3(a). In Austria, a decision on the validity of the SPC is pending before the Commercial Court of Vienna.

47. In its appeal to the French Cour de cassation, MSD contends that a reference to the CJEU is necessary on the question of whether its SPC for the combination product is valid. The opposing party in that case, Teva, argues that a reference is unnecessary. In the event that the Court decides that the issue is to be referred, both parties have submitted questions which, in their view, should form the content of the reference. MSD proposes a total of five questions, which cover whether explicit mention of a product in the claims is enough for it be protected by the patent; if the response to the first answer is in the negative, what criteria must be met for the product to be covered; should the same or a different definition of product be used for the purposes of Articles 3(a) and 3(c); if the definition is the same, is it possible to obtain the issuance of an SPC for the combination; and finally, does the issuance of an SPC for the combination depend on whether or not the second active ingredient is the first compound in its therapeutic class for which a marketing authorisation was obtained, for instance, would it be relevant to the validity of the second SPC, where the second SPC concerned the combination of drug A with simvastatin, that that was the first SPC for a combination of drug A with any statin? Teva, the opposing party, proposes two questions: the first relates to Article 3(c) and whether or not MSD can obtain an SPC for drug A, the patented drug, on its own as well as an SPC for A, the patented drug, combined with B, a drug in the public domain; are those the same invention for the purposes of this article? The second question relates to Article 3(d), which is not in issue in these proceedings.

48. The Market Court of Finland has similarly submitted a reference to the CJEU regarding the validity of SPCs, although it concerns a patent and SPCs for different products. The Market Court has drafted questions but these cannot be disclosed at the present time. MSD submitted a question concerning whether the meaning of 'product' is the same for each of the conditions for obtaining an SPC under Article 3. Teva, the opposing party, submitted a suggested question concerning Article 3(c) and whether an SPC for a combination of products A and B can be valid where there has already been an SPC for product A as a monotherapy.

## **Result**

49. In the result, a set of issues has arisen concerning the interpretation of Article 3 of the Regulation which cannot be said to be *acte clair*. Hence, this Court is compelled to make a reference. The text is appended hereto.

**Request for a preliminary ruling by the Court of Justice of the European Union under Article 267 of the Treaty of the Functioning of the European Union from the Supreme Court of Ireland made by decision of February 2022**

1. Under national law, where an undertaking is granted a patent, the protection extends for a period of 20 years from “the date of filing of the patent application”; s 27 and s 36 of the Patents Act 1992. The state of the art is assessed as to novelty as of the date of filing, as is inventiveness and practical application. The relevant provisions follow:

9 (1). An invention shall be patentable under this Part if it is susceptible of industrial application, is new and involves an inventive step.

11 (1) An invention shall be considered to be new if it does not form part of the state of the art.

(2) The state of the art shall be held to comprise everything made available to the public (whether in the State or elsewhere) by means of a written or oral description, by use, or in any other way, before the date of filing of the patent application.

(3) Additionally, the content of a patent application as filed, of which the date of filing is prior to the date referred to in subsection (2) and which was published under this Act on or after that date, shall be considered as comprised in the state of the art.

(4) The provisions of subsections (1), (2) and (3) shall not exclude the patentability of any substance or composition, comprised in the state of the art, for use in a method referred to in subsection (4) of section 9 provided that its use for any method referred to in the said subsection (4) is not comprised in the state of the art.

2. Regulation (EC) No 469/2009 concerning the supplementary protection certificate for medicinal products [2009] OJ L152/1 is the object of this reference and the relevant text is set out below. Under the Regulation, a patented product, having received marketing authorisation for use in human or animal medicine, may be granted an SPC for a term of up to 15 years, which cannot extend the patent protection for more than 5 years. While national patent law has to a degree been harmonised by the European Patent Convention through the adaptation or influencing of core concepts in Member States as derived from the EPC, the SPC system is an entirely new system of patent extension which cannot be said to be subject to concepts derived from patent law or subject to any interpretation through those concepts.

**Necessity for a reference**

3. The Supreme Court considers that a reference under Article 267 of the TFEU is required in this case because the interpretation of Regulation EC 469/2009 is unclear despite a number of decisions of the CJEU on the application and interpretation of the Regulation, particularly in circumstances where two or more SPCs have been granted in respect of products covered by a single national patent.

**Outline Facts**

4. In these proceedings, Merck Sharp and Dohme, MSD, sought an injunction and damages for infringement of an SPC granted by the Patent Office in Ireland in respect of an anti-cholesterol product, marketed as “Inegy”. This is a combination product combining an azetidinone, called

ezetimibe, with a statin, in this case simvastatin. The defendant, Clonmel Healthcare Limited, Clonmel, a pharmaceutical firm which produces generic medicines, launched a competing product during the lifetime of the SPC, contending that the SPC was invalid having regard to the provisions of Regulation 469/2009 as interpreted in the decisions of the CJEU.

5. In consequence, the core issue in the proceedings is as to the validity of the SPC for Inegy; the combination of ezetimibe and simvastatin. This, in turn, depends on the true interpretation of the Supplementary Protection Certificate Regulation, and the clarification of the decisions of the CJEU on this issue. The Irish High Court, [2019] IEHC 814, concluded that the SPC was invalid under Article 4(a) of the Regulation and, consequently, Article 4(c), and thus made an order revoking the SPC. That decision was upheld by the Court of Appeal by judgment delivered on 24th February 2021, [2021] IECA 54. Leave to appeal to this Court was sought by MSD and granted by order of this Court on 4th August, 2021 [2021] IESCDET 92. The appeal was heard on 8 and 9 December, 2021.

6. Inegy is a preparation used in the treatment of atherosclerosis. This is a disease involving a hardening of the arteries, which arises as a consequence of the accumulation of atherosclerotic plaques in the inner layers of artery walls. One of the risk factors for the development of atherosclerosis is the presence of low density lipoproteins, LDL, in the blood. High concentrations of LDL are associated with an enhanced risk of atherosclerotic disease. A number of monotherapies have been developed for the treatment of LDL cholesterol. At the time of the priority date of the patent, statins were commonly used. Statins operate by promoting the breakdown of cholesterol in the liver. Azetidinones operate, however, by inhibiting the absorption of cholesterol into the bloodstream at the borders of the intestinal villus in the small intestine. It was not in dispute that, at the time of the priority date of the Irish patent, ezetimibe was the first known azetidinone to demonstrate cholesterol inhibition but, at all material times, the anti-cholesterol quality of the statins were well known. It was also clear that while ezetimibe would be used as a monotherapy, it was also likely to be used in combination with other drugs known or believed to be efficacious in the treatment of cholesterol, including statins. Such combinations were claimed in the patent. The patent specifically claimed a combination of azetidinone and a statin, and in particular, in Claim 17, a combination of ezetimibe and one of a number of statins, including simvastatin.

7. In due course, separate marketing authorisations were obtained in respect of a product consisting of ezetimibe alone, Ezetrol, and the combination product, Inegy, and SPCs were obtained in respect of each product; first the monotherapy, Ezetrol, and then the combination therapy, Inegy. It is not suggested that the patent for ezetimibe is or was invalid, or did not, during its lifetime, cover the two products. It is, however, contended that the second SPC in respect of the combination product Inegy is invalid. The High Court and Court of Appeal agreed and struck down the SPC.

## **Background**

8. The pharmaceutical preparation ezetimibe was the subject of Irish patent 0 720 599 granted by the European Patent Office on 19th May 1999, with a priority date of 21 September 1993; the 599 patent. A marketing authorisation for ezetimibe alone under the product name Ezetrol was granted in 2003 and a Supplementary Protection Certificate (SPC 2003/014) for Ezetrol was granted by the Irish Patent Office in the same year. No issue is raised as to the validity of the SPC 2003/014 for Ezetrol.

9. Claims 1 to 8 of the patent for ezetimibe related to single molecules. However, claims 9, 12, 15 and 16 of the 599 patent address uses of ezetimibe in combination with other molecules, including statins. Paragraph 0028 of the patent referred to “[c]holesterol 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”. Claim 17 specifically identified the combination of a pharmaceutical composition of Claim 16 “wherein the cholesterol biosynthesis inhibitor is selected from the group consisting of lovastatin, pravastatin, fluvastatin, simvastatin, CI-981, DMP-565, L-659, 699, squalestatin 1 and NB-598”. Thus, it is not in dispute that the 599 patent specifically identifies and claims the combination of ezetimibe and simvastatin.

10. In 2004, MSD obtained a marketing authorisation for a combination product Inegy which combined ezetimibe and simvastatin in a single medicine, and in 2005 obtained an SPC (SPC 2005/01) in respect of the product, and which is the subject matter of these proceedings.

### **The SPC Regulation**

11. A key point for the interpretation of the SPC Regulation is the fact that patent law is not harmonised by the law of the European Union and that the European Patents Convention is not a measure of European law. The need for a measure such as the SPC Regulation is explained in the recital to the Regulation and follows from the requirements of Union law and, in particular, the requirement that a medicinal product for humans or animals cannot be placed on the market unless marketing authorisation has been granted in accordance with Directive 2001/83/EC or Directive 2001/82/EC. Obtaining such an authorisation takes time, because of clinical trials and other checks, and while seeking it the patent protection is running but without value being generated by the invention because it cannot be marketed.

12. Thus, Recital 3 of the Regulation records the fact that medicinal products are the result of long and costly research and will not continue to be developed in the community and in Europe unless they are covered by favourable rules providing sufficient protection to encourage such research. Recital 4 records that:

[a]t the moment, the period that elapses between the filing of an application for a patent for a new medicinal product and the 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.

13. The Regulation continues by noting that there is, therefore, a risk of research centres situated in Member States relocating to countries that offer greater protection and an SPC should be available for products for which marketing authorisation has been granted. Such a certificate is limited to an overall maximum of 15 years of exclusivity from the time of the grant of the marketing authorisation and extending no more than 5 years after expiry of the patent.

14. Recital 10 recognises other interests and provides that:

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.

15. Thus, while patents may provide protection under national law for inventions which may or may not be the subject of consequent development, an SPC is confined to the product which, moreover, must be one which has obtained a marketing authorisation, is limited to the use for which such authorisation was granted and cannot extend protection of the product for more than five years beyond the life of the patent. These are the definitions in Article 1:

- (a) ‘medicinal product’ means any substance or combination of substances presented for treating or preventing disease in human beings or animals and any substance or combination of substances which may be administered to human beings or animals with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in humans or in animals;
- (b) ‘product’ means the active ingredient or combination of active ingredients of a medicinal product;
- (c) ‘basic patent’ means a patent which protects a product as such, a process to obtain a product or an application of a product, and which is designated by its holder for the purpose of the procedure for grant of a certificate;
- (d) ‘certificate’ means the supplementary protection certificate;
- (e) ‘application for an extension of the duration’ means an application for an extension of the duration of the certificate pursuant to Article 13(3) of this Regulation and Article 36 of Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use (5).

16. Article 3 sets out the conditions for obtaining a certificate and provides:

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

- (a) the product is protected by a basic patent in force;
- (b) a valid authorisation to place the product on the market as a medicinal product has been granted in accordance with Directive 2001/83/EC or Directive 2001/82/EC, as appropriate;
- (c) the product has not already been the subject of a certificate;
- (d) the authorisation referred to in point (b) is the first authorisation to place the product on the market as a medicinal product.

17. The “product” referred to at Article 3(a) and Article 3(c) was defined in Article 1(b) as being “the active ingredient or combination of active ingredients of a medicinal product”. Under Article 4 of the Regulation, the protection is limited to the product covered by the authorisation and for the use of the product authorised by it. Under Article 5, an SPC confers the same rights conferred by the basic patent and is subject to the same limitations and same obligations. Article 15 of the Regulation provides for invalidity of the certificate and provides that the certificate shall be invalid if:

- (a) it was granted contrary to the provisions of Article 3;
- (b) the basic patent has lapsed before its lawful term expires;
- (c) the basic patent is revoked or limited to the extent that the product for which the patent was granted would no longer be protected by the claims of the basic patent or, after the basic patent has expired, grounds for revocation exist which would have justified such revocation or limitation.



## Observations on the Regulation

18. A number of observations may be made about the terms of the Regulation.

- First, the claim of invalidity made by Clonmel against the combination ezetimibe-simvastatin product Inegy is made under Article 15(a) and is that the conditions for a grant of a valid SPC under Article 3 were not met: Article 15(c) is not relied upon. Accordingly it is not suggested the patent or any component part of it was or ought to be revoked.
- Second, the Regulation does not say anything expressly or otherwise about the number of SPCs that may be granted in respect of products covered by a patent so long as those products have been the subject of marketing authorisations, or any limitation on such SPCs. If such a limitation is to be found in the Regulation, the Regulation itself does not explain how it is to be defined and applied; such as, for example, limiting the number of SPCs, and if so how, and by reference to what criteria.
- Third, the Regulation does not itself contain any requirement or reference to inventiveness, innovation or any inventive step. That is a matter for national patent law. The requirements of Article 3 are, on their face, simple: the product must be one which has been the subject of a first marketing authorisation under Directives 2001/83/EC or 2001/82/EC must be protected by a basic patent in force and have not already been the subject of an SPC.

19. It may also be observed, in the light of the findings of the High Court, that the dispute in this case is a relatively narrow one dependent on a resolution of a single issue of interpretation. There is no doubt, that the significant innovation and, in that sense invention, disclosed by the 599 patent for ezetimibe, is the teaching that ezetimibe inhibits the absorption of cholesterol and thus could be useful in the treatment of atherosclerosis. It is not suggested that any of the molecules or classes of molecules with which it was suggested ezetimibe could be combined were themselves novel. Any novelty lies only in their use in combination with the new molecule ezetimibe.

20. Equally, there is – and can be – no dispute that the combination of ezetimibe and simvastatin is expressly covered by the patent and, in particular, by Claim 17. It was not suggested that Claim 17 was invalid. Thus this case must proceed on the basis that the claim is valid and in force, and protected the combination product Inegy in terms during the lifetime of the 599 patent. If the requirement in Article 3(a) that the product “is protected by a basic patent in force” requires merely that the product be the subject of the SPC and marketing authorisation be identified or identifiable in a valid patent and covered by it, and therefore protected by the patent as a matter of national law, then the SPC is valid, since it was not suggested that the patent or any aspect of it is invalid, has been revoked, or that grounds exist for revocation. If, however, the requirement that the product be protected by a basic patent in force involves some further consideration above and beyond protection by the patent as a matter of patent law and, in particular, entails a further criterion of separate inventiveness or novelty, or a demonstration that the product falls within a narrower concept described as “the invention covered by the patent”, then the findings of the High Court on the evidence would, it appears, lead to the invalidity of the SPC.

## The issue and the interpretation

21. The issue of interpretation which requires resolution in this case can be understood best by considering the development of the case law of the CJEU, including, where relevant, the opinions of the Advocates General, and also the manner in which such decisions and opinions

have been understood in the decisions of national courts. It is also important to recognise that this is a developing area and therefore some of the decisions were not available at the time of delivery of the judgments of the High Court and Court of Appeal, respectively.

22. In Case 322/10 *Medeva BV v Comptroller General of Patents, Designs and Trade Marks* [2011] I-12051 (at [25]) in Case C-6/11 *Daiichi Sankyo Company v Comptroller General of Patents, Designs and Trade Marks* [2011] I-12255 (at [28]), the ECJ observed that Article 3(a) of the SPC regulation precluded the grant of an SPC relating to an active ingredient not specified in the wording of the claims of the basic patent. This, so far as it goes, would suggest that the question under Article 3(a) is one of identification or specification within the wording of the claims.

23. An important decision in the context of this case is the decision of the Eighth Chamber of the ECJ in C-577/13 *Actavis Group v Boehringer* [2015], hereafter *Boehringer*. The Court had to consider the position where Boehringer had obtained a patent for telmisartan, used in the treatment of high blood pressure and the reduction of cardiovascular morbidity in adults. Boehringer obtained a marketing authorisation for a medicinal product, Micardis, containing telmisartan as the sole active ingredient, and accordingly obtained an SPC in 1999, expiring in December 2013. In April 2002, one of the Boehringer Group companies obtained a marketing authorisation for a product which was a combination of telmisartan and hydrochlorothiazide and sold under the name MicardisPlus. The UK Intellectual Property Office indicated that for combination products, the combination must be clearly claimed in the patent, and suggested that Boehringer apply to amend the patent to insert a claim to the combination of telmisartan and hydrochlorothiazide. In due course, the amendment was granted and the SPC later granted in 2005, with an expiry date of January 2017. Actavis, seeking to market a combination product containing telmisartan and hydrochlorothiazide, contended that the SPC granted to Boehringer for the combination product was invalid. The Eighth Chamber of the ECJ found that Articles 3(a) and 3(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 a supplementary protection certificate, 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 supplementary protection certificate for that combination.

24. The reasoning of the Court was, firstly at [32], that the reference in Article 1(c) of the Regulation to “as such” must be given an autonomous interpretation in the light of the objectives pursued by the regulation and the scheme of which the expression forms part. Furthermore, the Court observed:

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 ...

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...

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.

25. It is accepted that if the conclusion of the Eighth Chamber in *Boehringer* is to be treated as a statement of general application which remains applicable, this provides strong support for the argument made by Clonmel in these proceedings; since that conclusion appears to require the Court to identify the "sole subject matter of the invention" or "the subject matter of the invention covered by the patent" and, once so identified, to preclude the grant of a subsequent SPC for a combination of that active ingredient and another substance, even if that other substance had been specified and identified in a claim in the patent. Indeed, the respective treatment of the decision in that case neatly highlights the rival contentions of the parties. Clonmel maintains that the decision not only remains authoritative, but also can be applied more generally outside the exceptional facts of the case. In particular, a court considering the validity of a second or later SPC, where a prior SPC has been granted in respect of a product involving the same patent, must identify the subject matter of the invention and only if it can be said that the product comes within that invention and, further, that invention has not already been the subject of an SPC, can the SPC be granted and, if granted, be valid. MSD, on the contrary, contends that the subsequent case law of the ECJ makes it very clear that the Court has repudiated any separate test of inventiveness as a condition of an SPC's validity. For MSD, the question is whether the product is identified or clearly identifiable in a valid patent and satisfies the other requirements of Article 3 of the Regulation.

26. Since the treatment of this decision is an important touchstone for the resolution of this case, some observations on that decision are merited. It is not clear whether the reference to a "subsequent claim to a product comprising a combination" refers simply to a claim coming later in the patent (and, if so, what relevance this could have) or to the facts of that case where, as it happened, the combination claim was made later in time as a result of an amendment application. More importantly, it is not at all clear that, even if "as such" is to be given an autonomous interpretation, it can support the quite elaborate edifice sought to be constructed on those two words. On its face, it should be remembered that Article 1(c) refers to at least three types of things that can be covered by a basic patent, namely: firstly, a process to obtain a product; secondly, an application of a product; or, as the Article says, thirdly, "a product as such". Nor is Recital 10 easily understood as mandating an exercise of balancing competing interests by defining some narrower area of patent protection which may be the subject of an SPC. While the recital clearly recognises that there are other interests "at stake", that is in the context of explaining the limitations on the SPC, that is, that it is limited to the product that obtained a marketing authorisation and is, moreover, strictly limited in time by reference to the life of the patent. It is difficult, therefore, to read this Recital as requiring an additional limitation on the grant of an SPC not contemplated or referred to in the Regulation.

27. In Case C-121/17 *Teva UK Limited v Gilead Sciences Inc* [2018], a Grand Chamber of the ECJ considered a challenge to the validity of an SPC for a product for treatment of persons infected with HIV, named Truvada, and made up of two active ingredients, tenofovir disoproxil (TD)

and emtricitabine. It was contended that this was protected by claim 27 of the basic patent, which covered “a pharmaceutical composition comprising a compound according to any one of claims 1-25 [and which included TD] together with a pharmaceutically acceptable carrier and optionally other therapeutic ingredients”. It was contended that emtricitabine was covered by the language “optionally other therapeutic ingredients”. The High Court of England and Wales referred to the ECJ this question: “[w]hat are the criteria for deciding whether “the product is protected by a basic patent in force” in Article 3(a) of Regulation No 469/2009”, and the High Court suggested that it was not sufficient that the product fall within at least one claim, but that it must also embody the “core inventive advance” of the patent.

28. Advocate General Wathelet delivered an opinion which clearly rejected this approach:

72. To my mind, it is clear from the Court’s case-law, in particular the judgments of 24 November 2011, *Medeva* (C-322/10, EU:C:2011:773), of 12 December 2013, *Eli Lilly and Company* (C-493/12, EU:C:2013:835), and of 12 March 2015, *Actavis Group PTC and Actavis UK* (C-577/13, EU:C:2015:165), that the only means of determining whether a basic patent protects an active ingredient within the meaning of Article 3(a) of Regulation No 469/2009 is to be found only in the wording, or interpretation of the wording, of the claims of the patent granted, and nowhere else.

73. Any other additional criterion, such as the requirement proposed by the referring court that the active ingredient embody ‘the inventive advance of the patent’ runs the risk, in my view, of giving rise to confusion with the criteria for determining whether an invention is patentable. The question whether a product is protected by a patent within the meaning of Article 3(a) of Regulation No 469/2009 is not the same as the question whether that product is patentable, which is a matter exclusively for national or treaty law.

29. At [78] of his opinion, Advocate General Wathelet referred to the decision in *Boehringer* and the conclusion that the fact that a basic patent contains a claim relating to a specifically named active ingredient may in certain circumstances not be sufficient. He stated, however, that the judgment should be read with caution given the singular facts it dealt with. The amendment to the patent had been sought with the intention, in his view, of obtaining an SPC. He considered that it was not sufficient merely that a product falls within the scope of the protection of a patent for it to be regarded as a protected product within the meaning of Article 3(a) of the Regulation. Protection by a patent within the meaning of Article 3(a) would be established, however, if on the priority date of the patent:

it would have been obvious to a person skilled in the art that the active ingredient in question was specifically and precisely identifiable in the wording of the patent claims. In the case of a combination of active ingredients, each active ingredient must be specifically, precisely and individually identifiable in the wording of the patent claims.

30. Hence, the name of the active ingredient did not need to be referred to expressly in the claims, provided the active ingredient was specifically and precisely identifiable as at the priority date of the patent.

31. It is apparent that if this opinion was adopted by the Court, it in turn would provide decisive support for MSD’s claim, since it makes it clear that the issue under Article 3(a) is simply identification of the product or the ingredients of the product in the patent. In this case, that is beyond doubt: ezetimibe and simvastatin are specifically claimed in combination in the patent.

However, Clonmel contends on this appeal that the decision of the Grand Chamber did not endorse the views of the Advocate General, did not cast any doubt on *Boehringer* as a correct general statement and rather repeated some of the key paragraphs in judgment in *Boehringer*. It is necessary, therefore, to consider with some care some paragraphs in the Court's decision and in respect of which each party advances a differing interpretation. The Court said first:

37. Therefore, a product cannot be considered to be protected by a basic patent in force within the meaning of Article 3(a) of Regulation No. 469/2009 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 the 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.

32. These paragraphs appear to adopt the same approach as that contained in the opinion of the Advocate General and also to suggest that the test under Article 3(a) is one of identification and a requirement that any such identification, if not express, must necessarily and specifically follow from the terms of the claim.

33. Clonmel, however, point out that at [41] the Court, secondly, refers to the decision in *Boehringer*, and at [40]-[42] repeats much of the language of [35]-[37] of that judgment, albeit with some differences which MSD assert are significant. The Court concluded:

57. Having regard to all of the foregoing considerations, the answer to the question referred is that Article 3(a) of Regulation no 469/2009 must be interpreted as meaning that a product composed of several active ingredients with a combined effect is 'protected by a basic patent in force' within the meaning of that provision where, even if the combination of active ingredients of which that product is composed is not expressly mentioned in the claims of the basic patent, those claims relate necessarily and specifically to that combination. For that purpose, from the point of view of a person skilled in the art and on the basis of the prior art at the filing date or priority date of the basic patent:

- the combination of those active ingredients must necessarily, in the light of the description and drawings of that patent, fall under the invention covered by that patent, and
- each of those active ingredients must be specifically identifiable, in the light of all the information disclosed by that patent.

34. Clonmel maintains that it remains the case that it is necessary to establish more than express reference or necessary identification in the claims of the patent. Clonmel argues that it is necessary to also show that the product falls under the invention covered by the patent, which in turn requires the Court to consider the nature of the invention protected by the patent, and, on this argument, limits an SPC to what can be said to be within such invention. MSD counter-argues that it is sufficient if a product is expressly mentioned in the claims. If, however, a product is not expressly mentioned, then it is necessary to consider if the claims relate necessarily and specifically to the combination. There is no warrant, on this argument, for reading this

paragraph as establishing a separate test of inventiveness to be applied even where the combination is expressly mentioned in the claims in the patent.

35. In joined cases C-650/17 and C-114/18 *Royalty Pharma Collection Trust v GD Searle LLC, Sandoz Ltd v GD Searle LLC* [2020], the German Federal Patent Court had made a reference to the CJEU on the interpretation of Article 3(a) and expressed the view that it was not clear from the judgment of Case C-121/17 *Teva UK & ors* [2018], read in the light of earlier case law of the Court in the opinion of the Advocate General in that case, “whether the concept of ‘core inventive advance’” was still relevant, given that the Court did not adopt the criticism of that concept made by the Advocate General in his opinion.

36. Advocate General Hogan expressed the view that the test in *Teva UK* was clear, and that where an active ingredient was not expressly mentioned in the claims of a basic patent, then Teva laid down a test comprising two parts, both of which must be satisfied. From the point of view of a person skilled in the art as of the priority date of the basic patent, the combination of the active ingredients must necessarily in the light of the descriptions and drawings of that patent fall under the invention covered by that patent, and that each of those active ingredients must be specifically identifiable in the light of all the information disclosed by that patent. Advocate General Hogan noted, at [53]-[54], that at no point in its consideration of the question referred to in the operative part of the judgment of 25 July 2018, *Teva UK & ors*, did the Court refer to the concept of “core inventive advance”. Rather, the Court laid down at [57] in the operative part of the judgment an entirely different and unrelated two part test for the interpretation of Article 3(a) of Regulation No. 469/2009. He continued:

54. For the avoidance of any possible doubt I consider that in the light of the judgment of 25 July 2018, *Teva UK & ors* ... the concept of the ‘core inventive advance’ of the patent does not apply and is of no relevance in the context of Article 3(a) of Regulation No 469/2009.

37. In its judgment, the Court adopted a similar approach. At [42], it observed that in:

so far as, where the product is not explicitly disclosed by the claims of the basic patent, but is covered by a general functional definition... 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.

38. At [32], the Court made it clear that in its decision in *Teva UK* it had clearly relied on an interpretation of Article 3(a) of Regulation No. 469/2009 in the context which the concept of “core inventive advance” was not relevant. However, at [46] of the judgment, the Court repeated the language of [39]-[40] of *Teva UK*, themselves repeating the language contained in *Boehringer*.

### **Conflict in interpretation in national courts**

39. It may now be of assistance to the CJEU to refer to the decision of the High Court and the Court of Appeal of England and Wales in the decision in *Teva UK Limited v Gilead Sciences Inc* when that case returned to the courts of that jurisdiction subsequent to the decision of the CJEU. In the High Court, [2018] EWHC 2416 (Pat), Arnold J at [37] expressed some difficulty in interpreting the judgment of the CJEU but concluded that the “the combination must be one that the skilled person would understand, on the basis of the description and drawings and their common general knowledge, to embody the technical contribution made by the patent”. On

appeal, [2019] EWCA Civ 2272, and while upholding the decision of the High Court judge, Floyd LJ, with whom Lewison and Dingemans LJJs agreed, came to a different conclusion on this issue. At [74], he stated:

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 judgment of the High Court of England & Wales]) that of Advocate General Hogan in *Sandoz v. Searle*, both roundly reject such a test. Whatever might be said for it from a policy point of view, it must now be regarded as wrong.

40. That observation was itself the subject of consideration in the judgment of the Court of Appeal in present case. At [81] of the judgment, Costello J observed that:

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.

41. There is a conflict on these interpretations. It is thus apparent that the High Court of England and Wales, the Court of Appeal of England and Wales and the Court of Appeal of Ireland have all taken differing views as to the interpretation of the judgment of the ECJ in *Teva v Gilead*. MSD contend that [57] of the judgment of *Teva*, read in the light of the entire judgment, means that Article 3(a) is satisfied in the case of a combination product where that product is expressly mentioned in the claims of the basic patent, or if not expressly mentioned, the claims relate necessarily and specifically to that combination. For that purpose, viz considering whether claims necessarily and specifically relate to a combination itself not expressly mentioned in the claims, it is necessary to establish that the combination of the active ingredients must necessarily in the light of the descriptions and drawings of the patent fall under the invention covered by that patent, and each of the active ingredients must be specifically identifiable in the light of all the information disclosed by that patent. Thus, on this interpretation, the reference to "fall under the invention covered by that patent" does not involve any consideration of inventiveness but, rather, is merely a way of considering whether, if there is in an application for an SPC, any

combination of active ingredients not expressly mentioned in the claims is nevertheless necessarily and specifically covered and protected by the patent. On the other hand, Clonmel maintain that [57] establishes a general test requiring a court to consider in any case whether the combination product falls under the invention covered by the patent, which in turn requires an assessment of the invention covered by the patent.

### Observation on the issues

42. In this case, the resolution of that dispute will determine the case. On the facts as found by the High Court judge, the combination product ezetimibe and simvastatin, marketed as Inegy, is clearly and expressly mentioned in the claims of the basic patent. However, on the facts as found by the trial judge, if “the invention covered by the patent” must be considered to be narrower than the claims of the patent, and involve some assessment of the invention or inventive advance taught by the patent, and limiting the grant of an SPC to what is considered that invention, then it would appear that the combination product would not fall under the invention of the patent and only ezetimibe would; that is the product Ezetrol. It is thus necessary to refer to the CJEU the question of the true interpretation of Article 3(a) of the SPC Regulation in the case of a combination product where the ingredients of that product are specifically mentioned in the claims of the basic patent.

43. In the event that the interpretation advanced by MSD is correct, it will also be necessary to obtain the assistance of the CJEU in relation to the true interpretation of Article 3(c) in such circumstances. Both the High Court and the Court of Appeal considered that the conclusion under Article 3(c) followed from the determinations made by those courts under Article 3(a), and that is entirely understandable. The “product” referred to in Article 3(a) and Article 3(c) must be the same product. It must also be the product in respect of which the marketing authorisation has been granted. It would seem, therefore, that if the product in this case satisfies the requirement of Article 3(a), the only question under Article 3(c) is whether the combination product has already been the subject of the certificate, which in this case is clearly not so. However, some of the case law of the CJEU (Case C-443/12 *Actavis Group v Sanofi* [2013]) appears to suggest that it is possible to satisfy Article 3(a) but fail to satisfy Article 3(c). Thus, at [30] of that judgment it was stated that:

even if the condition laid down in Article 3(a) of Regulation No 469/2009 were satisfied, for the purpose of the application of Article 3(c) of that 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, the principle active ingredient, protected as such by the holder’s basic patent and constituting, according to the statements of the referring court, the core inventive advance of that patent, and, on the other, another active ingredient which is not protected as such by that patent.

44. It is not clear what is meant by another active ingredient “which is not protected as such by the patent in question”, as in this case both ezetimibe on its own and combining ezetimibe with simvastatin are part of the claims in the patent, but in the event that the Court adopts the interpretation of Article 3(a) advanced by MSD in this case, or some similar interpretation, then it would also be necessary to clarify the true interpretation of Article 3(c) and whether it is sufficient to establish that the combination product has not itself been the subject of an earlier SPC, or whether the existence of the SPC in respect of Ezetrol, ezetimibe alone, in this case is to be treated as an earlier SPC for the product so that the SPC for Inegy, ezetimibe and simvastatin, could not be granted pursuant to Article 3(c).



## Other Member States

45. We now set out, to the best of our knowledge and as of the date hereof, the position on this controversy in other Member States. The courts of two European countries, Belgium (in the Brussels Enterprise Court) and Portugal (in, most recently, the Supreme Court of Justice), have deemed MSD's disputed SPC to be valid. In the Czech Republic, proceedings in the City Court in Prague regarding the infringement of the SPC are pending but the Intellectual Property Office and the Industrial Property Office have deemed the SPC valid on the basis of their interpretation of Articles 3(a) and 3(c). The two SPCs which are the subject of the dispute in the Czech Republic are different from those at issue in the present proceedings in Ireland. In Greece, in a first-instance decision from the Athens court, MSD was successful in infringement proceedings brought on the basis of the disputed SPC, but the validity of the SPC was not in fact addressed in the proceedings. In Italy, a decision as to the validity of the disputed SPC is pending, but there have been four opinions issued by court appointed experts to the effect that the SPC is valid under Articles 3(a), 3(c), and 3(d). In France, in the Cour d'appel de Paris, the disputed SPC was deemed invalid on the basis of both Articles 3(a) and 3(c). There the Court interpreted the patent as containing only one invention; the combination with simvastatin could not be regarded as another invention covered by the patent. With regards Article 3(c), the Court held that where the holder of the patent has already obtained an SPC for an active ingredient entitling them to oppose the use of that active ingredient, alone or in combination, this article must preclude them from obtaining another SPC in respect of the combination. There is an appeal pending in the Cour de cassation on this matter. In Germany's Federal Patent Court, and in Spain, the disputed SPC was deemed invalid on the basis of Article 3(c), with no decision given as to its validity under Article 3(a). In Austria, a decision on the validity of the SPC is pending before the Commercial Court of Vienna.

46. In its appeal to the French Cour de cassation, MSD contends that a reference to the CJEU is necessary on the question of whether its SPC for the combination product is valid. The opposing party in that case, Teva, argues that a reference is unnecessary. In the event that the Court decides that the issue is to be referred, both parties have submitted questions which, in their view, should form the content of the reference. MSD proposes a total of five questions, which cover whether explicit mention of a product in the claims is enough for it to be protected by the patent; if the response to the first answer is in the negative, what criteria must be met for the product to be covered; should the same or a different definition of product be used for the purposes of Articles 3(a) and 3(c); if the definition is the same, is it possible to obtain the issuance of an SPC for the combination; and finally, does the issuance of an SPC for the combination depend on whether or not the second active ingredient is the first compound in its therapeutic class for which a marketing authorisation was obtained, for instance, would it be relevant to the validity of the second SPC, where the second SPC concerned the combination of drug A with simvastatin, that that was the first SPC for a combination of drug A with any statin? Teva, the opposing party, proposes two questions: the first relates to Article 3(c) and whether or not MSD can obtain an SPC for drug A, the patented drug, on its own as well as an SPC for A, the patented drug, combined with B, a drug in the public domain; are those the same invention for the purposes of this article? The second question relates to Article 3(d), which is not in issue in these proceedings.

47. The Market Court of Finland has similarly submitted a reference to the CJEU regarding the validity of SPCs, although it concerns a patent and SPCs for different products. The Market Court has drafted questions but these cannot be disclosed at the present time. MSD submitted a question concerning whether the meaning of 'product' is the same for each of the conditions for

obtaining an SPC under Article 3. Teva, the opposing party, submitted a suggested question concerning Article 3(c) and whether an SPC for a combination of products A and B can be valid where there has already been an SPC for product A as a monotherapy.

## Questions

48. The Supreme Court of Ireland therefore requests a ruling of the Court of Justice of the European Union on the following questions:

1. (a) For the purpose of the grant of a supplementary protection certificate, and for the validity of that SPC in law, under Article 3(a) of Regulation (EC) No 469/2009 concerning the supplementary protection certificate for medicinal products [2009] OJ L152/1, does it suffice that the product for which the SPC is granted is expressly identified in the patent claims, and covered by it; or is it necessary for the grant of an SPC that the patent holder, who has been granted a marketing authorisation, also demonstrate novelty or inventiveness or that the product falls within a narrower concept described as the invention covered by the patent?

1. (b) If the latter, the invention covered by the patent, what must be established by the patent holder and marketing authorisation holder to obtain a valid SPC ?

2. Where, as in this case, the patent is for a particular drug, ezetimibe, and the claims in the patent teach that the application in human medicine may be for the use of that drug alone or in combination with another drug, here, simvastatin, a drug in the public domain, can an SPC be granted under Article 3(a) of the Regulation only for a product comprising ezetimibe, a monotherapy, or can an SPC also be granted for any or all of the combination products identified in the claims in the patent?

3. Where a monotherapy, drug A, in this case ezetimibe, is granted an SPC, or any combination therapy is first granted an SPC for drugs A and B as a combination therapy, which are part of the claims in the patent, though only drug A is itself novel and thus patented, with other drugs being already known or in the public domain; is the grant of an SPC limited to the first marketing of either that monotherapy of drug A or that first combination therapy granted an SPC, A+B, so that, following that first grant, there cannot be a second or third grant of an SPC for the monotherapy or any combination therapy apart from that first combination granted an SPC?

4. If the claims of a patent cover both a single novel molecule and a combination of that molecule with an existing and known drug, perhaps in the public domain, or several such claims for a combination, does Article 3(c) of the Regulation limit the grant of an SPC;

(a) only to the single molecule if marketed as a product ;

(b) the first marketing of a product covered by the patent whether this is the monotherapy of the drug covered by the basic patent in force or the first combination therapy, or

(c) either (a) or (b) at the election of the patentee irrespective of the date of market authorisation?

And if any of the above, why?