EuGH Urteil vom 9.2.2012, C-442/11– *Novartis I*

**Fundstellen**: GRUR Int 2012, 523 (*Brückner/Teschemacher/Hartmann*) = GRUR-Prax 2012, 284 (*Künzel*)

**1. Aufgrund eines Grundpatents für einen Wirkstoff kann kein ergänzendes Schutzrechtszertifikat (SPC) für eine diesen Wirkstoff enthaltende Kombination erteilt werden.**
**2. Art 4 und 5 der Schutzzertifikat-VO Arzneimittel sind aber dahin auszulegen, dass der Inhaber eines Schutzzertifikats für einen Wirkstoff (als Erzeugnis), der den Vertrieb einer Wirkstoffkombination mit diesem Erzeugnis nach dem Recht aus dem Grundpatent untersagen konnte, auch den Vertrieb für eine Wirkstoffkombination mit diesem Erzeugnis durch das Schutzzertifikat verbieten kann.**

Leitsätze verfasst von Dr. *Clemens Thiele*, LL.M.

In Case C-442/11, REFERENCE for a preliminary ruling under Article 267 TFEU from the High Court of Justice (England & Wales), Chancery Division (Patents Court) (United Kingdom), made by decision of 12 July 2011, received at the Court on 26 August 2011, in the proceedings **Novartis AG v Actavis UK Ltd,** THE COURT (Eighth Chamber), composed of A. Prechal, President of the Chamber, L. Bay Larsen and C. Toader (Rapporteur), Judges,
Advocate General: V. Trstenjak, Registrar: A. Calot Escobar, the Court, proposing to give its decision by reasoned order in accordance with the first subparagraph of Article 104(3) of its Rules of Procedure, after hearing the Advocate General, makes the following

## Order

1 This reference for a preliminary ruling concerns the interpretation of Articles 4 and 5 of Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products (OJ 2009 L 152, p. 1).
2 The reference has been made in proceedings between Novartis AG (‘Novartis’) and Actavis UK Ltd (‘Actavis’) concerning the scope of the protection conferred by the supplementary protection certificate (‘SPC’) which Novartis holds for the active ingredient valsartan.

**Legal context**

*European Union law*

3 Article 1 of Regulation No 469/2009, entitled ‘Definitions’, provides:
‘For the purposes of this Regulation, the following definitions shall apply:
(a) “medicinal product” means any substance or combination of substances presented for treating or preventing disease in human beings …;
(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 [SPC];
…’
4 Under the title ‘Scope’, Article 2 of that regulation provides:
‘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 [OJ 2001 L 311, p. 67] 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 [OJ 2001 L 311, p. l] may, under the terms and conditions provided for in this Regulation, be the subject of a certificate.'

5 Article 3 of Regulation No 469/2009, entitled 'Conditions for obtaining a certificate', provides as follows:

'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.'

6 Article 4 of the same regulation, entitled 'Subject matter of protection', is worded as follows:

'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.'

7 Article 5 of Regulation No 469/2009, concerning '[e]ffects of the certificate', provides that 'subject to Article 4, the certificate is to confer the same rights as conferred by the basic patent and to be subject to the same limitations and the same obligations'.

*National law*

8 Section 60 of the UK Patents Act 1977, entitled 'Meaning of infringement', provides as follows:

'(1) Subject to the provisions of this section, a person infringes a patent for an invention if, but only if, while the patent is in force, he does any of the following things in the United Kingdom in relation to the invention without the consent of the proprietor of the patent, that is to say:

(a) where the invention is a product, he makes, disposes of, offers to dispose of, uses or imports the product or keeps it whether for disposal or otherwise;

…

2) Subject to the following provisions of this section, a person (other than the proprietor of the patent) also infringes a patent for an invention if, while the patent is in force and without the consent of the proprietor, he supplies or offers to supply in the United Kingdom a person other than a licensee or other person entitled to work the invention with any of the means, relating to an essential element of the invention, for putting the invention into effect when he knows, or it is obvious to a reasonable person in the circumstances, that those means are suitable for putting, and are intended to put, the invention into effect in the United Kingdom.

…'

**The dispute in the main proceedings and the question referred for a preliminary ruling**

9 Valsartan is an active ingredient which acts as an angiotensin II receptor blocker. It is primarily used in the treatment of high blood pressure (hypertension), but is also recommended for the treatment of congestive heart failure and post-myocardial infarction.

10 Valsartan was protected by patent EP (UK) 0 443 983, which expired on 12 February 2011, Claim 1 of which was to a general chemical formula which comprised thousands of compounds including valsartan, whilst Claim 26 was specifically directed to that active ingredient.

11 On the basis of that patent and the marketing authorisation granted on 16 October 1996 for Diovan, a medicinal product having valsartan as its sole active ingredient, on 22 August 1997 Novartis was granted an SPC for that active ingredient, which expired, following a six-month extension pursuant to the Paediatric Regulation, on 12 November 2011.

12 Novartis also markets and sells Co-Diovan, a medicinal product which contains valsartan in combination with another active ingredient, hydrochlorothiazide, a diuretic which also has blood pressure reducing properties. Novartis did not, however, apply in the United Kingdom for an SPC for valsartan in combination with hydrochlorothiazide, and so it does not have such a certificate.

13 On 30 November 2010, Actavis indicated its intention to market a generic medicinal product comprising valsartan in combination with hydrochlorothiazide, after the expiry of the patent EP (UK) 0 443 983.

14 Novartis then brought an action against Actavis before the referring court, claiming that the marketing of such a medicinal product would infringe the rights conferred by the SPC it holds for valsartan.

15 Novartis argues that the marketing of valsartan in combination with another active ingredient would have infringed its patent whilst it was still in force. Accordingly, since the SPC granted for valsartan confers on Novartis the same protection as it enjoyed under that patent, the marketing of valsartan after the patent expired would similarly infringe the SPC which it holds. In Novartis's submission, any other interpretation of Regulation No 469/2009 as regards the scope of the protection of such an SPC would enable a third party to circumvent the protection conferred by a certificate for a particular product, since in order to avoid such protection it would simply be necessary for the third party to market a medicinal product combining that product with another active ingredient.

16 Actavis, however, argues, in essence, that the SPC held by Novartis is only for valsartan as a sole active ingredient. Therefore, the marketing of a medicinal product containing valsartan in combination with another active ingredient amounts to the marketing of a different product from the product protected by the SPC and, hence, the marketing of that different product would not infringe the rights of the holder of that SPC.

17 Against that background, the High Court of Justice (England & Wales), Chancery Division (Patents Court) decided to stay the proceedings and to refer the following question to the Court of Justice for a preliminary ruling:

'Where a supplementary protection certificate has been granted for a product as defined by Regulation … No 469/2009 for an active ingredient, are the rights conferred by that certificate pursuant to Article 5 of the Regulation in respect of the subject matter as defined in Article 4 of the Regulation infringed:

(a) by a medicinal product that contains that active ingredient (in this case valsartan) in combination with one or more other active ingredients (in this case hydrochlorothiazide); or

(b) only by a medicinal product that contains that active ingredient (in this case valsartan) as the sole active ingredient?'

**The question referred for a preliminary ruling**

18 In accordance with the first subparagraph of Article 104(3) of its Rules of Procedure, where the answer to a question may be clearly deduced from existing case-law, the Court may, after hearing the Advocate General, at any time give its decision by reasoned order in which reference is made to the relevant case-law. The Court considers that that is so in the present case.

19 By its question, the referring court asks, in essence, whether Articles 4 and 5 of Regulation No 469/2009 must be interpreted as meaning that, where a 'product' consisting of an active ingredient was protected by a basic patent and the holder of that patent was able to rely on the protection conferred by that patent for that 'product' in order to oppose the marketing of a medicinal product containing that same active ingredient in combination with

one or more other active ingredients, an SPC granted for that product enables its holder to oppose such marketing after that patent has expired.

20 It should be noted in that regard that, in accordance with Article 5 of Regulation No 469/2009, an SPC granted in connection with such a product confers, upon the expiry of the patent, the same rights as were conferred by the basic patent in relation to that product, within the limits of the protection conferred by that patent, as provided for in Article 4 of that regulation. 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 (Case C-322/10 *Medeva* [2011] ECR I-0000, paragraph 39; Case C-422/10 *Georgetown University and Others* [2011] ECR I-0000, paragraph 32; and orders of 25 November 2011 in Case C-630/10 *University of Queensland and CSL* [2011] ECR I-0000, paragraph 34, and Case C-6/11 *Daiichi Sankyo* [2011] ECR I-0000, paragraph 29).

21 In the case before the national court, it is common ground that the marketing of a medicinal product containing valsartan in combination with hydrochlorothiazide for use in the treatment of high blood pressure would infringe the rights conferred by the patent for valsartan.

22 It is also common ground that the use of that active ingredient as an angiotensin II receptor blocker, inter alia, was authorised under the marketing authorisation granted for Diovan, that medicinal product being authorised for the therapeutic indications of high blood pressure, congestive heart failure and post-myocardial infarction.

23 Consequently, the answer to the question referred is that Articles 4 and 5 of Regulation No 469/2009 must be interpreted as meaning that, where a ‘product’ consisting of an active ingredient was protected by a basic patent and the holder of that patent was able to rely on the protection conferred by that patent for that ‘product’ in order to oppose the marketing of a medicinal product containing that active ingredient in combination with one or more other active ingredients, an SPC granted for that ‘product’ allows its holder, after the basic patent has expired, to oppose the marketing by a third party of a medicinal product containing that product for a use of the ‘product’, as a medicinal product, which was authorised before that certificate expired.

**Costs**

24 Since these proceedings are, for the parties to the main proceedings, a step in the action pending before the national court, the decision on costs is a matter for that court. Costs incurred in submitting observations to the Court, other than the costs of those parties, are not recoverable.

On those grounds, the Court (Eighth Chamber) hereby rules:

Articles 4 and 5 of Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products must be interpreted as meaning that, where a ‘product’ consisting of an active ingredient was protected by a basic patent and the holder of that patent was able to rely on the protection conferred by that patent for that ‘product’ in order to oppose the marketing of a medicinal product containing that active ingredient in combination with one or more other active ingredients, a supplementary protection certificate granted for that ‘product’ enables its holder, after the basic patent has expired, to oppose the marketing by a third party of a medicinal product containing that product for a use of the ‘product’, as a medicinal product, which was authorised before that certificate expired.

# *Anmerkung*[*]

## I. Das Problem

Im englischen Ausgangsverfahren stritten (zunächst) die klagende Novartis AG und die beklagte Actavis UK Ltd. bzw. Actavis Deutschland GmbH & Co KG um den Umfang des Schutzes aus einem ergänzenden Schutzzertifikat (SRC) für Arzneimittel, das den Wirkstoff „Valsartan" betraf. Dieser Wirkstoff war Gegenstand eines der Klägerin erteilten Europäischen Patents, das am 12.02.2011 abgelaufen war. Auf der Grundlage dieses Patents und der Zulassung für ein Arzneimittel, das als einzigen Wirkstoff „Valsartan" enthielt, hatte die Klägerin im Vereinigten Königreich ein ergänzendes Schutzzertifikat für diesen Wirkstoff erhalten.
Die klagende Partei vertrieb ein weiteres Arzneimittel, das „Valsartan" in Kombination mit einem weiteren Wirkstoff enthielt. Für diese Wirkstoffkombination verfügte sie jedoch nicht über ein SRC. Nachdem die beklagte Partei angekündigt hatte, ein generisches Arzneimittel mit „Valsartan" in Kombination mit einem weiteren Wirkstoff auf den Markt bringen zu wollen, ging die Klägerin in die Offensive und verklagte die Actavis UK Ltd wegen Verletzung ihrer Rechte aus dem SRC vor englischen Patentgerichten. Der Englische High Court legte dem EuGH die Frage vor, ob ein ergänzendes Schutzzertifikat, das für einen Einzelwirkstoff erteilt war, auch dann verletzt wurde, wenn ein Arzneimittel diesen Wirkstoff in Kombination mit einem oder mehreren weiteren Wirkstoffen enthielt.
Der EuGH musste letztlich über den Schutzumfang des SRC im Verhältnis zum Grundpatent Stellung beziehen.

## II. Die Entscheidung des Gerichts

Der EuGH antwortete in beiden Fällen,[1] dass der Inhaber eines SRC für ein „Erzeugnis", das aus einem Wirkstoff besteht, gegen den Vertrieb eines Arzneimittels, das diesen Wirkstoff in Kombination mit anderen Wirkstoffen enthält, dann nach Laufzeitende des Grundpatents vorgehen kann, wenn das Grundpatent dieses „Erzeugnis" schützte und der Inhaber aus dem Patent während dessen Laufzeit gegen ein Arzneimittel vorgehen konnte, das den geschützten Wirkstoff in Kombination mit einem oder mehreren anderen Wirkstoffen enthält.
Der EuGH machte auch für das aus Deutschland stammende Verfahren klar, dass das ergänzende Schutzzertifikat für ein „Erzeugnis", nicht für ein Arzneimittel erteilt wird und de facto eine Verlängerung des Patentschutzes bewirken soll.

## III. Kritische Würdigung und Ausblick

Der vorliegende Richterspruch aus Luxemburg sagt nicht mehr, aber auch nicht weniger als, dass der Inhaber SPC aufgrund seines ergänzenden Schutzrechtszertifikats auch verbieten kann, was er aufgrund seines Grundpatents verbieten könnte, wäre dessen Schutzdauer nicht abgelaufen. Dies führt letztlich zu einem inhaltlichen Gleichlauf des Schutzes bei Wirkstoffkombinationen.
Der EuGH führt nunmehr konsequent seine jüngste Rsp[2] zum ergänzenden Schutzzertifikat fort. Darin hatte er bereits entschieden, dass aus einem ergänzenden Schutzzertifikat für ein

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[1] Im deutschen Vorabentscheidungsverfahren genügte ein Beschluss nach Art 104 § 3 Abs 1 der Verfahrensordnung des Gerichtshofes ohne Anhörung der Generalanwaltschaft.

[2] EuGH 24.11.2011, C-322/10 – *Medeva/ Kombinationsimpfstoff I*, GRUR 2012, 257 = GRUR-Prax 2011, 555 (*von Zumbusch*).

Einzelwirkstoff-„Erzeugnis“ dieselben Rechte wie aus dem Grundpatent gegen ein Arzneimittel geltend gemacht werden können, das diesen Wirkstoff mit anderen kombiniert. Weil im Ausgangsverfahren vor dem High Court unstreitig geblieben war, dass aus dem Grundpatent auch gegen Arzneimittel mit dieser Wirkstoffkombination vorgegangen werden konnte, ergab sich die Antwort auf die Vorlagefrage bereits aus der „Medeva“-Entscheidung. [3]
**Ausblick**: Die vorliegenden Entscheidungen bedienen ein Praxisbedürfnis der Pharmaindustrie. Oftmals entwickelt diese Industrie neue Arzneimittel zunächst als Monopräparate. Erst später wird festgestellt, dass der Wirkstoff mit einem anderen Wirkstoff oder in einer anderen Dosierung vorteilhafter ist. Würde das für einen Wirkstoff erteilte SPC nicht gegen diesen Wirkstoff enthaltende Kombipräparate schützen, müsste man bei jedem Präparat prüfen, ob es sich um eine neues Produkt handelt oder nicht. Dies wäre sehr zeitaufwendig und würde Mitbewerbern die Umgehung des SPC erleichtern. Die Lösung des EuGH bringt Unternehmen wie Novartis Rechtssicherheit, sodass ein Ausweichen auf das sog. „Evergreening von Arzneimittelpatenten“, d.h. schutzverlängernde Patentstrategien, entbehrlich sein dürfte.[4]

## IV. Zusammenfassung

Nach der nunmehr wohl gefestigten Unionsrechtsprechung sind Artt. 4 und 5 der Schutzzertifikat-VO Arzneimittel dahingehend auszulegen, dass der Inhaber eines Schutzzertifikats für einen Wirkstoff (als Erzeugnis), der den Vertrieb einer Wirkstoffkombination mit diesem Erzeugnis nach dem Recht aus dem Grundpatent untersagen konnte, auch den Vertrieb für eine Wirkstoffkombination mit diesem Erzeugnis durch das Schutzzertifikat verbieten kann.

[3] Dazu bereits *Thiele*, Patentrecht in *Staudegger/Thiele* (Hrsg), Jahrbuch Geistiges Eigentum 2012, 103, 146 f mwN.
[4] Grundlegend zu diesem Pharma-Phänomen *Berthold*, Evergreening von Arzneimittelpatenten (2011).