



# Examination Guidelines for Supplementary Protection Certificates

of 23 January 2015

	<b>Address</b>	<b>Telephone</b>	<b>Fax</b>
<b>Dienststelle München</b>	Central mailing address:	Customer Care and Services:	Central fax number:
<b>Dienststelle Jena</b>	80297 München	+49 89 2195-1000	+49 89 2195-2221
<b>Informations- und Dienstleistungszentrum Berlin</b>			

**Beneficiary:** Bundeskasse  
IBAN: DE84 7000 0000 0070 0010 54, BIC (SWIFT-Code): MARKDEF1700

**Address of the bank:** Bundesbankfiliale München, Leopoldstraße 234, 80807 München

**Internet:**  
<https://www.dpma.de>

## Contents

1. Preliminary remark .....	4
2. Introduction .....	4
2.1. Regulation (EC) number 469/2009 concerning the supplementary protection certificate for medicinal products .....	4
2.2. Regulation (EC) number 1610/96 concerning the creation of a supplementary protection certificate for plant protection products .....	4
2.3. Regulation (EC) number 1901/2006 on medicinal products for paediatric use which amended Regulation (EEC) number 1768/92, Directives 2001/20/EC and 2001/83/EC as well as Regulation (EC) number 726/2004 .....	4
2.4. Patent Act ( <i>Patentgesetz</i> ) .....	4
2.4.1. Section 16a of the Patent Act (supplementary protection certificate) .....	5
2.4.2. Section 49a of the Patent Act (examination regarding supplementary protection certificates) .....	5
2.4.3. Further provisions .....	5
2.5. Publication .....	5
3. Examination of the request for the grant of a certificate .....	5
3.1. Classification .....	6
3.2. Formal examination .....	6
3.2.1. Formal application requirements .....	6
3.2.1.1. Name and address of the applicant and – if a representative is appointed – of the representative, Article 8 (1) (a) (i), (ii) of the Regulations .....	6
3.2.1.2. Number of the basic patent, Article 8 (1) (a) (iii) of the Regulations .....	7
3.2.1.3. Number and date of the authorisation(s), Article 8 (1) (a) (iv) of the Regulations .....	7
3.2.1.4. Copies of authorisations, Article 8 (1) (b) and (c) of the Regulations .....	7
3.2.1.5. Title of the product for which protection is sought .....	8
3.2.1.6. Information explaining the protection afforded by the basic patent for the product .....	8
3.2.2. Application fee, Article 8 (2) of the PPP-R or Article 8 (4) of the MP-R in conjunction with section 2 (1) of the Patent Costs Act .....	8
3.2.3. Periods for lodging an application, Article 7 of the Regulations .....	9
3.2.4. Entitlement to file an application, Article 6 of the Regulations .....	9
3.3. Substantive examination .....	9
3.3.1. Examination of the furnished authorisation to place the product on the market .....	9
3.3.1.1. Authorisations according to the European Directives .....	9
3.3.1.2. Validity of the authorisation .....	10
3.3.1.3. First marketing authorisation .....	10
3.3.1.4. Identifying the product .....	11
3.3.2. Examining whether a certificate for the product has already been granted in Germany .....	12
3.3.3. Product protected by basic patent .....	12
3.3.4. Calculation of the duration .....	13
3.4. Intermediate reply .....	14
3.5. Hearing .....	14
3.6. The decision to grant the certificate .....	15
3.7. Decision to reject the certificate .....	15
3.8. Special legal remedies regarding supplementary protection certificates .....	15
3.8.1. Appeal/rectification .....	15
3.8.2. Rectifying the duration (after decision to grant) .....	16

4.	Examination of the application for an extension of the duration .....	16
4.1.	Formal examination .....	16
4.1.1.	Fee for the application, Article 8 (4) of the MP-R in conjunction with section 2 (1) Patent Costs Act .....	16
4.1.2.	Written form.....	16
4.1.3.	Reference to pending application or granted certificate .....	16
4.1.4.	Time limits for filing applications, Article 7 of the MP-R .....	16
4.1.5.	Supporting documents necessary when filing the application.....	17
4.2.	Substantive examination .....	18
4.2.1.	Entitlement to lodge an application for extension.....	18
4.2.2.	Results of all paediatric studies contained in the application .....	18
4.2.3.	Authorisation of the medicinal product in all EU member states .....	19
4.2.4.	No orphan medicinal product.....	19
4.2.5.	No one-year extension of the period of protection .....	19
4.3.	The decision to grant .....	19
4.4.	Decision to reject .....	19
4.5.	Special legal remedy: revocation of an extension of the duration .....	19
5.	General legal remedies .....	20
5.1.	Suspension .....	20
5.2.	Re-establishment of rights/further processing.....	20
5.3.	Correction of decisions .....	20
5.4.	Legal aid .....	20

## 1. Preliminary remark

These Guidelines shall supersede the Guidelines of 7 March 2011 (*Blatt für PMZ* [official gazette] 2011, page 121).

The Guidelines aim at ensuring the consistent and expeditious examination of applications for supplementary protection certificates (hereinafter also referred to as "certificate") at the German Patent and Trade Mark Office (DPMA). Equal treatment of all applicants is an obligation in accordance with the rule of law. Consequently, all members of the patent divisions are obligated to perform the examination of applications for supplementary protection certificates in accordance with the Guidelines below. It is understood that legislative amendments and developments of case law as well as special circumstances of each particular case shall also be considered.

The purpose of the publication of the Guidelines is to inform applicants on the examination practice of the patent divisions.

Words referring to persons in these Guidelines shall be understood to refer equally to women and men.

## 2. Introduction

New medicinal products or plant protection products often need to go through a lengthy approval process before authorisation to put these products on the market is obtained. This means that the time of use of patents is considerably reduced. The supplementary protection certificate was introduced to compensate for this loss of time. A supplementary protection certificate (hereinafter also referred to as "certificate") is a way to obtain extended protection for medicinal products and plant protection products. It is true that the supplementary protection certificate is a *sui generis* intellectual property right. However, since the certificate has the same effects during its lifetime as the patent on which it is based, the protection initially conferred by the patent is de facto extended by the certificate. However, the protection conferred by a certificate extends only to the product covered by the authorisation to place the corresponding medicinal or plant protection product on the market and, specifically, extends to any use of the product as a medicinal or plant protection product that has been authorised before the expiry of the certificate.

### 2.1. Regulation (EC) number 469/2009 concerning the supplementary protection certificate for medicinal products

Council Regulation (EEC) number 1768/92 of 18 June 1992, last amended by the Regulation (EC) number 1901/2006 of 12 December 2006, is replaced by Regulation (EC) number 469/2009 of 6 May 2009 (MP-R) pursuant to Article 22 of the MP-R. The MP-R forms the legal basis for supplementary protection

certificates for medicinal products. The Council Regulation (EEC) number 1768/92 of 18 June 1992, which entered into force on 2 January 1993 in the European Economic Community, created the option for holder of patents for medicinal products to obtain a supplementary protection certificate which provides protection after the end of the term of the patent.

### 2.2. Regulation (EC) number 1610/96 concerning the creation of a supplementary protection certificate for plant protection products

Regulation (EC) number 1610/96 of the European Parliament and of the Council of 23 July 1996 (hereinafter referred to as "PPP-R"), which entered into force on 8 February 1997, created the option for holders of patents for plant protection products to obtain a supplementary protection certificate which provides protection after the end of the term of the patent.

Hereinafter the two Regulations (MP-R and PPP-R) are also referred to as "Regulations". The two Regulations are applicable in all member states of the European Union (EU). However, the effects of the supplementary protection certificates only apply in the member state in which they are granted.

**The two Regulations have largely similar wording. Except for the cases, explicitly mentioned below, these Guidelines shall apply to both Regulations.**

### 2.3. Regulation (EC) number 1901/2006 on medicinal products for paediatric use which amended Regulation (EEC) number 1768/92, Directives 2001/20/EC and 2001/83/EC as well as Regulation (EC) number 726/2004

Regulation (EC) number 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use (paediatric MP-R), which amended Regulation (EEC) number 1768/92, Directives 2001/20/EC and 2001/83/EC as well as Regulation (EC) number 726/2004 and entered into force on 26 January 2007, gives the holder of a patent or a supplementary protection certificate for medicinal products a six-month extension of the duration of the certificate, provided certain conditions are fulfilled (see paragraph 4).

### 2.4. Patent Act (*Patentgesetz*)

The Regulations leave it to the discretion of the EU member states to require the payment of filing fees and annual fees for supplementary protection certificates and to lay down special procedural provisions for supplementary protection certificates. This option has been applied when sections 16a and 49a were included in the Patent Act.

#### **2.4.1. Section 16a of the Patent Act (supplementary protection certificate)**

By means of Article 1 number 1 of the Act Amending the Patent Act and other Acts (*Gesetz zur Änderung des Patentgesetzes und anderer Gesetze*) of 23 March 1993, section 16a of the Patent Act was included in the Patent Act with effect from 1 April 1993. The section was amended by the following legislative provisions: Article 2 number 2 of the Second Act Amending the Patent Act and other Acts (*Zweites Gesetz zur Änderung des Patentgesetzes und anderer Gesetze*) of 16 July 1998, Article 7 number 3 of the Act to Revise the Rules on Costs in the Field of Intellectual Property (*Gesetz zur Bereinigung von Kostenregelungen auf dem Gebiet des geistigen Eigentums*) of 13 December 2001, Article 4 (1) number 1 of the Transparency and Disclosure Act (*Transparenz- und Publizitätsgesetzes*) of 19 July 2002, Article 1 number 8 of the Act Implementing the Directive on the Legal Protection of Biotechnological Inventions (*Gesetz zur Umsetzung der Richtlinie über den rechtlichen Schutz biotechnologischer Erfindungen*) of 21 January 2005, Article 1 of the Act Amending Patent Opposition Proceedings and the Patent Costs Act (*Gesetz zur Änderung des patentrechtlichen Einspruchsverfahrens und des Patentkostengesetzes*) of 21 June 2006, Article 2 of the Act Improving the Enforcement of Intellectual Property Rights (*Gesetz zur Verbesserung der Durchsetzung von Rechten des geistigen Eigentums*) of 7 July 2008, Article 1 number 1 of the Patent Law Modernisation Act (*Gesetz zur Vereinfachung und Modernisierung des Patentrechts*) of 31 July 2009 and Article 1 of the Act Revising Certain Provisions of Patent Law and Other Acts in the Field of Industrial Property Protection (*Gesetz zur Novellierung patentrechtlicher Vorschriften und anderer Gesetze des gewerblichen Rechtsschutzes*) of 19 October 2013.

#### **2.4.2. Section 49a of the Patent Act (examination regarding supplementary protection certificates)**

By means of Article 1 number 4 of the Act Amending the Patent Act and other Acts of 23 March 1993, section 49a was included in the Patent Act with effect from 1 April 1993. That section was amended by the following legislative provisions: Article 2 number 19 of the Second Act Amending the Patent Act and other Acts of 16 July 1998, Article 7 number 22 of the Act to Revise the Rules on Costs in the Field of Intellectual Property of 13 December 2001, Article 40 of the Second Act to Revise Federal Law within the Remit of the Federal Ministry of Justice (*Zweites Gesetz über die Bereinigung von Bundesrecht im Zuständigkeitsbereich des Bundesministeriums der Justiz*) of 23 November 2007 and Article 1 number 4 of the Patent Law Modernisation Act of 31 July 2009.

#### **2.4.3. Further provisions**

Supplementary provisions can be found in sections 30 (1), 81 (1) sentences 1 and 3, 142 (1) of the Patent Act, sections 19 to 21 of the Patent Ordinance (*Patentverordnung*), sections 3 (2), 5 (2), 7 (1) of the Patent Costs Act (*Patentkostengesetz*), section 2 of the DPMA Ordinance (*DPMA-Verordnung*) and, for European patents, in Article II section 6a of the Act on International Patent Treaties (*Gesetz über internationale Patentübereinkommen*).

#### **2.5. Publication**

Information regarding the supplementary protection certificates required under the provisions of the Regulations (Article 9 and 11 of the Regulations and Article 17 of the MP-R or Article 16 PPP-R) or due to section 16a of the Patent Act in conjunction with the provisions mentioned therein, shall be published in part 7 of the Patent Gazette (*Patentblatt*) (application, application for an extension, withdrawal, grant, rejection, revocation, rectification, invalidity and lapse). Since there is no separate register for supplementary protection certificates, they are also recorded in the Patent Register (section 30 (1) of the Patent Act). These entries have the same extent as the entries for patents or patent applications. Thus, publication is ensured (section 32 (5) of the Patent Act).

The product protected by the basic patent is published in the Patent Gazette using the INID code (95) when the application is published or the certificate is granted. The designation of the product need not be identical to the product identified by the authorisation.

After the conclusion of the formal examination, the applications or the requests are published in the Patent Gazette. A certificate document similar to the first publication of the application (*Offenlegungsschrift*) or to the patent specification is not issued.

### **3. Examination of the request for the grant of a certificate**

The patent divisions are in charge of the procedure for the grant of a certificate under section 49a (1) of the Patent Act (section 27 (1) number 2 of the Patent Act). Which patent division is responsible depends on the IPC main class indicated in the basic patent on which the application for the certificate is based.

The patent division shall only constitute a quorum when at least three members are participating. Where the case presents particular legal difficulties, a legally qualified member of the patent division shall be involved in taking the decision pursuant to section 27 (3) sentence 2 of the Patent Act. Pursuant to section 27 (4) of the Patent Act, the chair of the patent division may act alone in handling all patent division matters, except for decisions or he may delegate these tasks to a technically qualified member of the division; this shall not apply to a hearing.

If the chair is unavailable due to illness, holidays or other factual or legal circumstances, if he is excluded or objected to successfully or if he resigns from service, the member of the patent division who was appointed his deputy shall act as chair. If no such member has been appointed or if the appointed member is also prevented from acting as chair, the group leader who is responsible according to the allocation of duties shall act as chair. The non-availability and the reason for it shall be documented in the files. Where the division has a temporary high workload with regard to procedures for the grant of a certificate, the chair or, in absence of the chair, his deputy may determine by a written order in the individual files that a group leader will act as chair in a selected number of pending procedures.

In the procedure before the patent division, the examiner shall do the reporting who is in charge of handling this IPC class according to the allocation of duties.

Applications for a certificate should – as far as possible – be handled in such a way that a possible intermediate office action or the decision on grant will be served on the applicant within eight months after receipt of the request for grant of a certificate. The decision on the request for grant of a supplementary protection certificate shall be taken – as far as possible – before the expiry of the basic patent to avoid a delay in the certificate becoming effective.

### 3.1. Classification

During the examination procedure, the examiner doing the reporting may, if necessary, initiate the assignment of an additional secondary class (refined classification) for the product (active ingredient or combination of active ingredients) protected by the certificate in that specific case.

### 3.2. Formal examination

In the procedure for the grant of a certificate it has to be initially examined whether all formal requirements of the request for the grant of a certificate are met.

Unless otherwise specified, staff of the upper grades of the civil service are responsible for the examination of the application as to (obvious) formal deficiencies, pursuant to the Administration Ordinance (*Wahrnehmungsverordnung*) (section 1 (3) in conjunction with (1) number 1 Administration Ordinance).

These staff can send a letter to the applicants inviting them to rectify the formal deficiency. In the case of extensive and complex deficiencies, the result of the preliminary formal examination will be forwarded to the patent division.

Within the scope of a substantive examination, the patent division must also examine compliance with formal requirements and object to existing deficiencies, if any.

The individual formal requirements of an application for a certificate are:

#### 3.2.1. Formal application requirements

Applications for certificates must be filed in writing at the DPMA (see Article 9 of the Regulations, section 19 in conjunction with section 4 (2) numbers 1, 4 and 5 of the Patent Ordinance). They cannot be validly filed at a patent information centre because sections 16a and 49a of the Patent Act do not contain a reference to section 34 (2) of the Patent Act (see also *Mitteilung des Präsidenten des DPMA* [Notice of the President of the DPMA] number 4/06, *Blatt für PMZ* 2006, pages 77 and the following). The form "*Antrag auf Erteilung eines ergänzenden Schutzzertifikats für Arzneimittel/ Arzneimittel einschließl. Verlängerung der Laufzeit/ Pflanzenschutzmittel*" (form P 2008) must be used for the request for the application.

The DPMA will send an acknowledgement of receipt to the applicant indicating the file number and the date of receipt and will also enclose a copy of the request; the date of receipt is printed on the copy or is shown on the data bar printed onto the bottom of the fax document by the DPMA.

The necessary content of an application for a certificate, which is described in detail in the following paragraphs, results from Article 8 of the Regulations.

##### 3.2.1.1. Name and address of the applicant and – if a representative is appointed – of the representative, Article 8 (1) (a) (i), (ii) of the Regulations

Pursuant to section 19 (1), second sentence 2 of the Patent Ordinance, in conjunction with section 4 (2), number 1 of the Patent Ordinance, the request for the grant of a certificate shall contain the name and full address of the applicant (form P 2008: field 4). It is not sufficient for large customers to indicate only a post office box or a postal code.

Where a representative has been appointed, the name and address of the representative must also be given in the request for grant (field 4). As a rule, a power of attorney must be attached (annex 7) to the request. However, where a lawyer or patent attorney acts as agent, the lack of a power of attorney or deficiencies in the power of attorney are irrelevant (see section 15 (4) of the DPMA Ordinance).

Applicants having neither their residence, principal place of business nor establishment in Germany must appoint a lawyer or patent attorney as their representative (section 16a (2) in conjunction with section 25 (1) of the Patent Act).

This representative may also be a national of a member state of the European Union or of another contracting party to the Agreement on the European Economic Area if he is entitled to use a professional title comparable to that of German lawyers or patent

attorneys (section 16a (2) in conjunction with section 25 (2) of the Patent Act).

### **3.2.1.2. Number of the basic patent, Article 8 (1) (a) (iii) of the Regulations**

The request for the grant of a certificate shall contain the title and the number of the basic patent (form P 2008: field 6). The application for a certificate may be based either on a German national patent or on a European patent taking effect in Germany. Where the basic patent is a European patent, the file number of the German translation, if any, must also be stated.

Staff of the upper grades of the civil service will check whether the basic patent, indicated in the request, was in force in Germany at the time when the application for the certificate was filed.

Within the framework of the substantive examination "Product protected by basic patent" (paragraph 3.3.3.), the status of the basic patent must again be examined by the patent division (see paragraph 3.3.3.).

### **3.2.1.3. Number and date of the authorisation(s), Article 8 (1) (a) (iv) of the Regulations**

The application must also contain the number, the date and the validity of the first authorisation to place the product on the market (hereinafter referred to as "authorisation") in Germany (form P 2008: field 8). Pursuant to applicable case law, the date when the authorisation is issued shall be considered the relevant date (Federal Patent Court 15 W (pat) 50/95, *Blatt für PMZ* 1997, pages 61 and the following – *Ceftibuten*; last confirmed by the Federal Patent Court 15 W (pat) 59/03, BPatGE<sup>1</sup> 49, pages 113 and the following – *Porfimer*).

The first authorisation may also be a central authorisation granted on the basis of Regulation (EC) number 726/2004. Central authorisations are valid in every member state of the European Union or European Economic Area (EEA) and therefore replace national authorisations.

If an authorisation for placing the product on the market was already granted in an EU or EEA member state before the first authorisation in Germany, the number and the date of the first authorisation in the EU or the EEA must be given (form P 2008: field 9). Furthermore, information regarding the identity of the product thus authorised and the legal provision under which the authorisation procedure took place must be stated (see form P 2008: annexes 2 and 3 in field 12). On the basis of the Agreement on the European Economic Area, authorisations from Norway, Iceland, Liechtenstein and indirectly also Switzerland (recognition of the Swiss authorisations in Liechtenstein) must also be taken into account.

### **3.2.1.4. Copies of authorisations, Article 8 (1) (b) and (c) of the Regulations**

As proof of the authorisations mentioned in paragraph 3.2.1.3. the applicant must file certain copies as annex to the request for the grant.

A copy of the authorisation to place the product on the market in Germany must be filed (form P 2008: annex 1 in field 12). However, the copy does not have to reproduce the complete authorisation; it is sufficient where it provides the following information: information identifying the product, the number of the authorisation, the date when the authorisation has been issued, the validity period and the summary of the product characteristics of the medicinal product pursuant to the annex to the official communication on the authorisation including the "qualitative and quantitative composition" as well as the therapeutic indications (see Article 8 (1) (b) of the Regulations; see also *Mitteilung des Präsidenten des DPMA* number 19/96 in *Blatt für PMZ* 1996, page 425).

For authorisations for medicinal products of the European Commission, a copy of "Annex 1 – Summary of the product characteristics" of the marketing authorisation for the medicinal product should also be filed including the "qualitative and quantitative composition" as well as the therapeutic indications.

In the case of plant protection products, copies of provisional and/or definitive marketing authorisations must be filed (form P 2008: annex 1 in field 12). Where a provisional authorisation for placing the plant protection product on the market in Germany is directly followed by a definitive marketing authorisation for the plant protection product, copies must be furnished of the provisional authorisation as well as of the definitive marketing authorisation to prove that there are no gaps.

However, if no definitive marketing authorisation has been issued, a copy of the provisional authorisation/s is sufficient (see Court of Justice of the European Union [CJEU], C-229/09, GRUR<sup>2</sup> 2011, pages 213 and the following – *Lovells/Bayer*).

The holder of the authorisation who is not identical with the holder of the basic patent is not obliged to make a copy of that authorisation available to the patent holder. Where, due to that reason, a patent holder cannot furnish the copy, the application should not be rejected, but the DPMA must get a copy from the authority which issued the marketing authorisation (see CJEU, C-181/95, GRUR Int.<sup>2</sup> 97, pages 363 and the following – *Biogen/Smithkline*).

For an authorisation for the identical product in a member state of the EU or EEA that was granted earlier than the German authorisation, only a copy of the notice publishing the authorisation in the appropriate official publication must be filed under Article 8 (1) (c)

<sup>1</sup> *Entscheidungen des Bundespatentgerichts* (decisions of the Federal Patent Court)

<sup>2</sup> Publication of the German Association for the Protection of Intellectual Property (GRUR)

of the Regulations (form P 2008: annex 4 in field 12). Failing such notice, any other document will be recognised, pursuant to Article 8 (1) (c), last semi-clause of the PPP-R, which provides proof that the authorisation has been issued, the date on which it was issued and the identity of the product authorised. According to recital 17 of the PPP-R, this applies accordingly to supplementary protection certificates for medicinal products.

Translations of foreign-language copies of the above mentioned documents must only be provided where the individual data mentioned and required in Article 8 (1) (b) of the Regulations (such as the product identified, the number and date of the authorisation, the summary of the product characteristics) are not identifiable without further explanation (form P 2008: annex 5 in field 12).

### **3.2.1.5. Title of the product for which protection is sought**

In the request form the applicant must indicate the product for which the grant of the supplementary protection certificate is sought (form P 2008: field 7).

"Product" is defined in Article 1(b) of the MP-R as "the active ingredient or combination of active ingredients of a medicinal product" and in Article 1 number 8 of the PPP-R as "the active substance or combination of active substances of a plant protection product". In Article 1 number 3 of the PPP-R, active substances are defined as "substances and microorganisms including viruses, having general or specific action: (a) against harmful organisms, or (b) on plants, parts of plants or plant products".

Under Article 3 (b) of the MP-R or Article 3 (1) (b) of the PPP-R, a valid authorisation to place the product on the market as a medicinal product or plant protection product must have been granted. Accordingly, under Article 4 of the Regulations, the protection conferred by a certificate shall extend only to the product covered by the authorisation to place the corresponding product on the market and for any use of the product as a medicinal product or plant protection product that has been authorised before the expiry of the certificate. Therefore, the title of the product should be directed at the name of the active ingredient or combination of active ingredients resulting from the valid authorisation to place the product on the market. Combinations of active ingredients should be phrased as "component 1 with component 2". The German names of active ingredients/substances shall be indicated for medicinal products as well as for plant protection products.

The name of the active ingredient or names of the active ingredients in the German authorisation to place the medicinal product on the market is/are usually indicated under "*arzneilich wirksame Bestandteile*" or "*qualitative und quantitative Zusammensetzung*" according to the annex to the marketing authorisation and in a European authorisation under "qualitative and

quantitative composition" in annex I (Summary of product characteristics). If the name of the active substance of the plant protection product cannot be derived from the text of the authorisation, the text of the Register of Plant Protection Products (*Pflanzenschutzmittelverzeichnis*, published by the Federal Office of Consumer Protection and Food Safety) can be used alternatively.

It should be kept in mind that the supplementary protection certificate can also be granted for a product that covers the active ingredient as such as well as its various derived (chemical) forms (for example salts and esters) where only one of its possible forms is covered by the marketing authorisation provided that these forms too are protected by the basic patent (see CJEU, C-392/97, GRUR Int. 2000, pages 69 and the following – *Farmitalia* and Federal Court of Justice, NJW 2000, pages 1723 and the following – *Idarubicin II*).

### **3.2.1.6. Information explaining the protection afforded by the basic patent for the product**

Since the product has to be protected by a basic patent that is in force at the time of filing the application for a certificate pursuant to Article 3(a) of the MP-R or Article 3 (1) (a) of the PPP-R, a seamless documentation explaining the correlation between the authorised product and the text passage in the patent specification must be furnished as annex to the request for the grant of a supplementary protection certificate (annex 6 in field 12) showing the protection afforded by the patent for this product (see section 19 (2) of the Patent Ordinance). Typically, it is useful and necessary to furnish copies of documents, namely

- from chemical or pharmaceutical standard works showing the relationship between the chemical and the biological structure and the international non-proprietary name (INN) or the "common name",
- from official works or documents clearly identifying the product covered by the authorisation (for plant protection products, for example, an excerpt from the Register of Plant Protection Products published by the Federal Office of Consumer Protection and Food Safety),
- a copy of the relevant passages of the granted basic patent.

### **3.2.2. Application fee, Article 8 (2) of the PPP-R or Article 8 (4) of the MP-R in conjunction with section 2 (1) of Patent Costs Act**

Pursuant to Article 8 (2) of the PPP-R or Article 8 (4) of the MP-R in conjunction with section 2 (1) of the Patent Costs Act, the request for the grant of a supplementary protection certificate is subject to an application fee, according to the schedule of fees annexed to the Patent Costs Act.

The fee payment can be made by SEPA mandate under the core direct debit scheme or by credit transfer (after receiving the acknowledgement of receipt), indicating the complete file number and the purpose of use.

Where the application fee is not paid upon filing the application, the DPMA will set a time limit for payment of the fee. This time limit shall be at least two months (Article 10 (3) of the Regulations in conjunction with section 49a (2) sentence 2 of the Patent Act). If the time limit expires without result, the DPMA will reject the application (Article 10 (4) Regulations).

### **3.2.3. Periods for lodging an application, Article 7 of the Regulations**

Article 7 of the Regulations prescribes periods for lodging an application for a certificate. The time limits must be monitored.

In this respect, two cases must be distinguished:

- a) Where the basic patent is granted before the authorisation to place the product on the market, the period for lodging an application for a certificate is six months from the date of the authorisation in Germany.
- b) Where the authorisation to place the product on the market in Germany is granted before the grant of the patent, the period for lodging an application for a certificate is six months from the date of the grant of the patent.

Pursuant to applicable case law, with regard to case (a), the date when the authorisation is issued, as shown in the official communication on the authorisation, is considered the date from which the period starts to run (see paragraph 3.2.1.3.).

According to the office's current practice with regard to case (b), the publication date of the grant in the German Patent Gazette or the European Patent Bulletin is considered the date from which the period starts to run. Usually, this date is printed on the first page of the patent specification following the INID code (45).

Usually, compliance with these time limits is monitored through staff of the upper grades of the civil service.

Before the examination procedure is concluded, the patent division is responsible for the monitoring.

### **3.2.4. Entitlement to file an application, Article 6 of the Regulations**

Pursuant to Article 6 of the Regulations, only the holder/s of the basic patent or their successor/s in title can file an application for a certificate, because only this/these person/s has/have the right to the supplementary protection certificate.

Staff of the upper grades of the civil service also examine whether this formal requirement for an application for a certificate is met and in case of failure

to meet this requirement, a deficiency letter is sent to the applicant.

Before the examination procedure is concluded, the patent division must carry out a respective review.

## **3.3. Substantive examination**

During the examination of the application for a certificate, it must also be verified whether the substantive requirements for granting a certificate are met in addition to the formal requirements mentioned above (see also paragraph 3.2.).

### **3.3.1. Examination of the furnished authorisation to place the product on the market**

Pursuant to Article 3 (b) of the MP-R or Article 3 (1) (b) of the PPP-R, as appropriate, an authorisation to place the product on the market, valid in Germany at the time of filing the application for a certificate, must have been granted for the product on which the application for the certificate is based.

The application for a supplementary protection certificate can validly be made only after a valid marketing authorisation has come into being CJEU, C-210/12, GRUR Int. 2013, pages 1129 and the following – *Sumitomo Chemical/DPMA*).

#### **3.3.1.1. Authorisations according to the European Directives**

During examination of the furnished authorisations it must be seen to it that these authorisations were granted according to the European Directives mentioned in Article 3 (b) of the MP-R or Article 3 (1) (b) of the PPP-R (Directive 65/65/EEC for medicinal products, meanwhile replaced by Directive 2001/83/EC; Directive 81/851/EEC for veterinary medicinal products, meanwhile replaced by Directive 2001/82/EC; Directive 91/414/EEC for plant protection products, meanwhile replaced by Regulation (EC) number 1107/2009).

Provisional authorisations to place plant protection products on the market, which were granted pursuant to Article 8 (1) of the Directive 91/414/EEC (implemented in section 15c of the Plant Protection Act [*Pflanzenschutzgesetz*]), are recognised as valid first marketing authorisations (see CJEU, C-229/09, GRUR 2011, pages 213 and the following – *Lovells/Bayer*). However, this is not applicable to emergency authorisations to place a product on the market granted under Article 8 (4) of the Directive 91/414/EEC (implemented in section 11 (2) of the Plant Protection Act; cf. CJEU, C-210/12, GRUR Int. 2013, pages 1129 and the following – *Sumitomo Chemical/DPMA*).

Pursuant to Article 13(3) of the PPP-R, for the purposes of calculating the duration of the certificate, provisional marketing authorisations are taken into account as first authorisations to place a product on the market in the Community only if they are directly followed by a

definitive authorisation concerning the same product. Where no definite marketing authorisation has been furnished, making it impossible to assess whether authorisations seamlessly followed each other, the provisional authorisation shall nevertheless be taken into account for calculating the duration of the certificate in order to take into account the judgment *Lovells/Bayer* of the CJEU (CJEU, C-229/09, GRUR 2011, pages 213 and the following – *Lovells/Bayer*).

The central marketing authorisations, available for medicinal products, granted pursuant to Regulation (EEC) number 2309/93 or Regulation (EC) number 726/2004, and hence also valid in Germany must be considered as first marketing authorisations pursuant to Article 3(b) of the MP-R.

### 3.3.1.2. Validity of the authorisation

Article 3 (b) of the MP-R or Article 3 (1) (b) of the PPP-R, as appropriate, stipulates as condition for obtaining a certificate that a valid authorisation to place the product on the market in Germany has been granted at the date of the filing the application. According to the office's current practice, this condition is interpreted to mean that the authorisation actually is in force at the date of filing the application for the certificate and, in particular, has not lost validity by revocation, withdrawal or expiry of the term of the authorisation.

With regard to the reason for the lapse of a certificate, mentioned in Article 14 (d) of the Regulations, it must be ensured that the furnished authorisation to place the product on the market in Germany has not been revoked or withdrawn at the date of the grant of the certificate. Otherwise, the application must be rejected. However, the application will not be rejected for the reason that the duration of the authorisation expires after the date of filing the application.

### 3.3.1.3. First marketing authorisation

Pursuant to Article 3(d) of the MP-R or Article 3 (1) (d) of the PPP-R, a certificate shall be granted only if the furnished authorisation to place the product on the market in Germany is the first authorisation for this product in Germany.

The DPMA does not have the verification and search options required for a comprehensive verification of this condition. Since it is not possible in Germany to waive the verification of this condition, as laid down in Article 10 (5) of the Regulations, a verification has at least to be carried out as far as it is feasible. In view of the applicant's obligation to tell the truth it is generally assumed that the respective statements of the applicant are accurate.

However, if any evidence or information is found that challenges the statements of the applicant, it has to be considered and clarified during the course of the procedure. Information on an earlier first marketing authorisation of the product is available in the relevant authorisation lists (for example, Rote Liste<sup>®</sup>, website of the European Medicines Agency [EMA], website of the Federal Institute for Drugs and Medical Devices, website of Paul-Ehrlich-Institut, website of the Federal Office of Consumer Protection and Food Safety, Register of Plant Protection Products).

Similar considerations apply when verifying whether the first authorisation to place the product on the market in the European Community, indicated by the applicant for the purpose of calculating the duration, actually is the first marketing authorisation for this product in the European Community.

Due to the special characteristics of the national authorisation procedures, different opinions may initially arise about which marketing authorisation is the first marketing authorisation.

According to current case law, marketing authorisations which were issued in Switzerland have to be considered as the first marketing authorisations in the Community upon recognition of the Swiss authorisations in Liechtenstein (CJEU, C-207/03, *MitttschPatAnw*<sup>3</sup> 2005, pages 261 and the following – *Novartis*). In this context, the circumstances of the grant of the Swiss marketing authorisation and its later fate are irrelevant (CJEU, C-617/12, *GRUR-Prax*<sup>4</sup> 2014, page 13 – *Astrazeneca/Comptroller General*). Until 1 June 2005, the marketing authorisations granted in Switzerland were automatically recognised in Liechtenstein at that date so that in those cases the date of the grant of the Swiss authorisation has to be regarded as the date of the first marketing authorisation in the Community. Since 1 June 2005, the Swiss marketing authorisations have usually been recognised in Liechtenstein only after a certain time delay so that, in those cases, the date of the recognition of the marketing authorisation in Liechtenstein must be regarded the date of the first marketing authorisation in the Community.

The authorisations required under pricing legislation in some countries (for example, Luxembourg, Spain), which are usually granted only after conclusion of the preceding actual marketing authorisation procedure, do not constitute a first marketing authorisation in the Community (CJEU, C-127/00, *GRUR* 2004, pages 225 and the following – *Hässle*).

In practice, different interpretations regarding the identity of the product (see also paragraph 3.3.1.4.) may give rise to different opinions about which authorisation constitutes the first marketing authorisation for the product on which the certificate is based.

<sup>3</sup> *Mitteilungen der deutschen Patentanwälte* (publication of the German chamber of patent attorneys [*Patentanwaltsskammer*])

<sup>4</sup> *GRUR* publication

According to current case law (see also paragraph 3.3.1.4.), products containing identical active substances and which only differ with regard to the additional adjuvants or the content of active substances should be regarded as identical products within the meaning of the Regulations. Therefore the respective authorisations for these products shall be taken into account as first marketing authorisations.

According to the former office's practice, it was irrelevant for which use of a product the first marketing authorisation was granted (for example, medicinal product for human use or as a veterinary medicinal product; second medical uses) (CJEU, C-31/03, GRUR 2005, pages 139 and the following – *Dostinex*). However the CJEU (CJEU, C-130/11, GRUR Int. 2012, pages 910 and the following – *Neurim*) stated that "the mere existence of an earlier marketing authorisation obtained for a veterinary medicinal product does not preclude the grant of a supplementary protection certificate for a different application of the same product for which a marketing authorisation has been granted, provided that the application is within the limits of the protection conferred by the basic patent relied upon for the purposes of the application for the supplementary protection certificate".

Pursuant to the *Neurim* judgment, Article 13 (1) of the MP-R must be construed as meaning that it relates to the authorisation of a product which falls within the scope of protection of the basic patent to which the application for the supplementary protection certificate refers.

#### 3.3.1.4. Identifying the product

Pursuant to Article 1 of the Regulations, a product means an active ingredient/substance or combination of active ingredients/substances of a medicinal product or a plant protection product.

In the case of applications for supplementary protection certificates for medicinal products, the therapeutically effective components define the active ingredient or combination of active ingredients of the product. Other components without any therapeutic effect of their own do not constitute active ingredients or a part of a combination of active ingredients (CJEU, C-210/13, GRUR-Prax 2014, page 14 – *Adjuvant*; CJEU, C-431/04, GRUR 2006, pages 694 and the following – *Polifeprosan*).

In the case of applications for supplementary protection certificates for plant protection products, active substances or combinations of active substances are "substances and microorganisms including viruses, having general or specific action: (a) against harmful organisms; (b) on plants, parts of plants or plant products". In this context, the term "active substance" may cover a substance intended to be used as a safener, where that substance has a toxic, phytotoxic or plant protection action of its own (CJEU, C-11/13, GRUR 2014, page 756 – *Bayer CropScience/DPMA*).

At first, it has to be examined whether these products can actually be chemically identified from the submitted application documents with regard to their therapeutically effective components.

A clear identification by means of the chemical structure of this product is necessary in order to verify whether the product – as prescribed in Article 3(a) of the MP-R and Article 3(1)(a) of the PPP-R – falls within the scope of the basic patent in force (see also paragraph 3.3.3.).

Hence, the relevant information on the active ingredients contained in the authorised commercial product which is mentioned in the submitted copies of the marketing authorisations should be examined to ensure that the active ingredients or combinations of active ingredients indicated therein correspond to the names of the active ingredients listed in the request for grant (see form P 2008: field 7).

Frequently, it is impossible to clearly compare the trade names of the authorised medicinal or plant protection products. Therefore, attention should be paid during this examination to the international non-proprietary names (INN) of active ingredients for medicinal products and the standardised names of plant protection products (common names), usually given in the marketing authorisations, since it is usually possible to clearly attribute these names to a definite chemical structure.

If the pages indicating the active ingredients and the uses are missing from the copies of the marketing authorisations filed, the applicant should be invited to subsequently furnish these pages. It may also be possible to conduct a search in the standard lists of medicinal products or plant protection products to explicitly clarify which active ingredients are contained in the authorised commercial product. In the latter case, it is not necessary to subsequently file the missing parts of the marketing authorisation, mentioned above.

A frequent problem with central marketing authorisations granted by EMA, pursuant to Regulation (EEC) number 2309/93 or Regulation (EC) number 726/2004, is that the active ingredients stated in the actual single marketing authorisation (particularly in the title) differ from the information in annex I of the single marketing authorisation ("Summary of the product characteristics" in the item "Qualitative and quantitative composition"). Therefore, in most cases, a copy of annex 1 of the single marketing authorisation in German is indispensable.

With regard to authorisations for plant protection products, too, it may occur that the active substances or combinations of active substances contained in the authorised plant protection product are not separately stated in the marketing authorisation.

If the office cannot clarify matters, for example, by using the Register of Plant Protection Products of the Federal Office of Consumer Protection and Food Safety, the applicant of the certificate should be invited to

subsequently file copies of the relevant pages of the marketing authorisation documents.

### 3.3.2. Examining whether a certificate for the product has already been granted in Germany

Pursuant to Article 3 (2), first sentence, of the PPP-R and recital 17 as well as Article 3 (c) of the MP-R or Article 3 (1) (c) of the PPP-R, a certificate for the identical product must not have already been granted in Germany to the same applicant. If the same applicant applies for several certificates for the same product, he can only receive one certificate even though he possesses and indicates various patents as basic patents (Article 3 (2) sentence 1 of the PPP-R and recital 17).

However, where two or more applications concerning the same product and emanating from two or more holders of different basic patents are pending, one certificate for this product may be issued to each of these holders (Article 3 (2) sentence 2 of the PPP-R) even though a certificate for that product has already been granted (see CJEU, C-482/07, GRUR Int. 2010, pages 41 and the following – *AHP Manufacturing*).

It is possible, on the basis of a patent which protects several different products, to obtain several supplementary protection certificates in relation to each of those different products, provided that each of those products is protected as such by that basic patent (CJEU, C-484/12, GRUR 2014, pages 160 and the following – *Georgetown University/Octrooicentrum Nederland*; CJEU, C-443/12, GRUR 2014, pages 157 and the following – *Actavis/Sanofi*).

For example, on the basis of this patent and the marketing authorisation for a medicinal product which is a combination of active ingredients, the holder of a basic patent may be granted a supplementary protection certificate for this combination of active ingredients as well as for one of those active ingredients which, individually, is also protected as such by the that patent (CJEU, C-484/12, GRUR 2014, pages 160 and the following – *Georgetown University/Octrooicentrum Nederland*).

In contrast, where, on the basis of a patent protecting an innovative active ingredient and a marketing authorisation for a medicinal product containing that ingredient as the single active ingredient, the holder of that patent has already obtained a supplementary protection certificate for an innovative active ingredient, this holder may not be granted a second supplementary protection certificate on the basis of that same patent but a subsequent marketing authorisation for a different medicinal product containing that active ingredient in combination with another active ingredient which is not protected as such by the patent (see CJEU, C-443/12, GRUR 2014, pages 157 and the following – *Actavis/Sanofi*; Federal Patent Court 3 Ni 5/13, GRUR 2014, pages 1073 and the following – *Telmisartan*).

For identification, the definitions of the product stated in Article 1 of the Regulations must be taken into account (see also paragraph 3.3.1.4.).

A search for certificates that have already been granted must be conducted at least in the special internal DPMA database of supplementary protection certificates for medicinal and plant protection products (*Fachdatenbank für Arzneimittel- und Pflanzenschutzmittelzertifikate [SPC]*). Alternatively, a search may be carried out in INPADOC and INPAFAM databases of STN.

According to the office's current practice, the date stated in the decision on grant by the patent division is deemed the day of the grant of the certificate.

### 3.3.3. Product protected by basic patent

Pursuant to Article 3(a) of the MP-R or Article 3 (1) (a) of the PPP-R, the product for which an application for the grant of a certificate is filed, must be protected by a basic patent in force at the date of filing the application for a certificate. That means that the basic patent must not have lapsed, withdrawn or declared invalid at the time of filing the application for the certificate. Even where the marketing authorisation has been granted only after the lapse of the basic patent, an application for a certificate cannot be filed. Usually, the staff of the upper grades of the civil service in charge of the matter will check whether the basic patent indicated in the application for the certificate was in force in Germany, at the time of filing the application for the certificate.

The patent division must perform an additional examination of the legal status or procedural status of the basic patent concerned by inspecting the respective patent registers (DPMAregister; European patent register).

At the time of the grant of the certificate, it should be considered and verified, with regard to the grounds of invalidity stated in Article 15 (1) (b) of the Regulations, that the basic patent has not lapsed before its lawful term expires. In that case, the application must be rejected.

However, if, after the regular expiry of the term of the patent, the basic patent is no longer in force at the date of the grant of the certificate, it is nevertheless possible to grant a certificate.

If the outcome of pending opposition, limitation or revocation proceedings, if any, in respect of the basic patent is known when the certificate is granted this shall also be taken into consideration. Because this may retroactively affect the scope of protection of the basic patent to such extent that the scope of protection no longer covers the authorised product. In that case, the application for the certificate shall be rejected due to non-compliance with the requirement of Article 3 (a) of the MP-R or Article 3 (1) (a) of the PPP-R, as the case may be. The same applies in case of the revocation of the basic patent. A certificate may be granted in spite

of opposition, limitation and revocation proceedings if these proceedings have not yet been completed.

Where the product is protected by several patents (for example, product patent or process patent) the applicant himself may decide which patent to choose as the basic patent.

The basic patent on which protection is based, may be a process patent, use patent or product patent (substance patent or product patent).

For the examination of the requirement of Article 3 (a) of the MP-R or Article 3 (1) (a) of the PPP-R, the extent of protection in accordance with Section 14 of the Patent Act shall be taken into consideration for German basic patents and the extent of protection in accordance with Article 69 of the European Patent Convention (EPC) in conjunction with the Protocol on the Interpretation of Article 69 of the EPC shall be taken into consideration for European patents taking effect in the territory of the Federal Republic of Germany.

In its decisions in the cases *Medeva* (CJEU, C-322/10, GRUR Int. 2012, pages 140 and the following – *Medeva*) and *Georgetown* (CJEU, C-484, 12, GRUR 2014, pages 160 and the following – *Georgetown*) the CJEU has clarified that a supplementary protection certificate in accordance with Article 3(a) of the MP-R can be granted only for those active ingredients which are specified in the wording of the claims of the basic patent.

In order to fulfil this requirement it is not necessary for the active ingredient to be identified in the claims of the patent by a structural formula (CJEU, C-493/12, GRUR Int. 2014, pages 145 and the following – *Eli Lilly/Human Genome Sciences*). On condition that it is possible to reach the conclusion on the basis of the claims, interpreted inter alia in the light of the description of the invention, that the claims relate, implicitly but necessarily and specifically, to the active ingredient in question, it suffices where the active ingredient is covered by a functional formula in the claims.

It should be recalled that, in accordance with the case law cited at paragraph 34 of the mentioned judgment, an active ingredient which is not identified in the claims of a basic patent by means of a structural, or indeed a functional definition cannot, in any event, be considered to be protected within the meaning of Article 3 (a) of Regulation (EC) no 469/2009 (CJEU, C-493/12, GRUR Int. 2014, pages 145 and the following paragraph 38 – *Eli Lilly/Human Genome Sciences*).

#### 3.3.4. Calculation of the duration

Pursuant to Article 13 of the Regulations, the certificate takes effect at the end of the lawful term of the basic patent for a period equal to the period which elapsed between the date on which the application for a basic patent was lodged and the date of the first authorisation to place the product on the market in the Community, reduced by a period of five years. The maximum duration of the certificate may not exceed five years.

For calculating the duration, the period between the filing date of the basic patent and the date of issuance of the grant of the first marketing authorisation in the Community is calculated first. This period is reduced by a period of five years resulting in the residual period pursuant to Article 13 (1) of the Regulations. Then the duration that may be granted for the certificate can be calculated, bearing in mind that the maximum duration is five years (Article 13 (2) Regulations). For the calculation, the years will always be determined first, then the months and at last the days. Years and months are to be understood as whole units regardless of the actual number of days. In contrast, the calculation at day level must be based on the actual number of days of the respective month. The beginning of the duration of the certificate is always the first day after the end of the lawful term of the basic patent.

In its *Merck* judgment the CJEU clarified that the grant of a certificate cannot be rejected by reason only of the fact that the duration determined in accordance with the calculation rules laid down in Article 13(1) of the MP-R is not positive (CJEU, C-125/10, GRUR Int 2012, pages 146 and the following – *Merck*). The reason for this is a possible paediatric extension pursuant to Article 13 (3) of the MP-R. The period of the paediatric extension starts to run from the date determined by deducting from the patent expiry date the difference between five years and the duration of the period which elapsed between lodging the patent application and obtaining the first marketing authorisation (CJEU, C-125/10, GRUR Int. 2012, pages 146 and the following – *Merck*).

All authorisations granted in the member states of the EU or in a state party to the Agreement on the European Economic Area, Norway, Iceland or Liechtenstein, are regarded as a first authorisation to place the product on the market in the Community. This also applies to Swiss authorisations due to their recognition in Liechtenstein (see also paragraph 3.3.1.3.). The transitional provisions of Articles 19 to 22 of the MP-R or Articles 19 and 20 of the PPP-R, as appropriate, apply to the first authorisations to place a product on the market in the Community in the new EU member states before their accession to the EU.

Provisional authorisations to place a product on the market as a plant protection product, granted under Article 8 (1) of the Directive 91/414/EEC (implemented in section 15c of the Plant Protection Act), are recognised as valid first authorisations within the meaning of Article 3 (1) (b) of the PPP-R (CJEU, C-229/09, GRUR 2011, pages 213 and the following – *Lovells/Bayer*). To take account of this judgement, a certificate must be granted even where a definite authorisation has not yet been issued. In that case, the calculation of the duration must be based on the provisional marketing authorisation.

If a request for the extension of the period has been received together with the request for the grant of a certificate for a medicinal product, the former has to be considered for calculating the duration. The periods

laid down in Article 13 (1) and (2) of the MP-R will be extended by six months in the case where Article 36 of the paediatric MP-R applies. The months are treated as whole units. If, for example, the certificate ends on 31 August it will be extended by six months to 28/29 February of the following year. However, the period laid down in Article 13 (1) of the MP-R may be extended only once.

The conditions for the extension of the period must be examined using the explanations stated in paragraph 4.

The beginning and the end of the term must be indicated in the decision to grant the certificate pursuant to section 49a (2) sentence 1 of the Patent Act.

### **3.4. Intermediate reply**

If the application for a certificate does not meet the requirements of the MP-R/PPP-R and section 16a of the Patent Act (see paragraphs 3.2. and 3.3.), the patent division shall invite the applicant, pursuant to section 49a (2) sentence 2 of the Patent Act, to correct any deficiencies within a time limit of at least two months to be set by it. The period may be extended upon a request by the applicant stating the reasons.

For reasons of legal certainty, this must be done in writing. Hence, an intermediate reply must be issued.

The number of intermediate replies is determined by the obligation to clarify the facts, to grant the right to be heard and the special circumstances of each individual case.

The intermediate replies must be drafted in a neutral and clear style. The formal and substantive deficiencies must be noted so concretely that the applicant is not left guessing as to what kind of deficiency has been noted.

The intermediate replies serve to prepare the grant of a certificate or the rejection of the application for a certificate pursuant to section 49a of the Patent Act. In case that the rejection of the application for a certificate is intended, this possibility will be pointed out in the intermediate reply.

The intermediate reply can also be issued by the reporting examiner alone. In this case, this must be noted in the records.

### **3.5. Hearing**

Pursuant to section 49a (5) sentence 2 of the Patent Act, section 46 of the Patent Act (further examination, hearing, minutes) shall apply accordingly to the examination procedure for certificates before the patent division. The patent division may summon and hear the parties at any time, may examine witnesses, experts and parties and may undertake further examination as necessary to examine the matter.

Generally, a hearing can be expedient for conducting the procedure speedily. However, deficiencies regarding the application requirements and conditions for the grant of a certificate may as a rule be noted and rectified in the procedure conducted in writing.

The hearing is chaired by the head of the patent division; the hearing is not public. Third parties may only attend the hearing with the consent of the applicant.

The applicant shall be heard upon request (section 46 (1) sentence 2 of the Patent Act shall apply accordingly). The request must be submitted in writing. If the request is not submitted in the requisite form, the request will be refused (section 46 (1) sentence 4 of the Patent Act applies accordingly). The decision to refuse the request is not independently contestable.

Minutes shall be drawn up of the hearings (and taking of evidence, if any) by a member of the patent division or a recording clerk. The minutes contain the essentials of the proceedings and the relevant statements made by the parties. Sections 160a, 162 and 163 of the Code of Civil Procedure apply accordingly (section 49a (5) sentence 2 of the Patent Act in conjunction with section 46 (2) sentence 2 of the Patent Act). The following, *inter alia*, shall be included in the minutes: place, date, persons attending, course of the hearing, new circumstances and aspects as far as necessary to understand the course of the hearing or are conducive to the grant of the right to be heard and the relevant statements made by the parties. The latter comprises everything substantively altering the subject matter of the application (for example, the product) or affecting the procedure, for example, all requests, amendments to requests and withdrawals of requests.

The provisions of the guidelines of the opposition proceedings shall apply accordingly to the minutes.

As a rule, the decision of the patent division on the application should be delivered at the end of the hearing. The delivery as well as the operative part of the delivered decision shall be included in the minutes of the hearing.

When delivering the decision, it is sufficient to announce the operative part of the decision and to refer to the written statement of grounds (section 49a (5) sentence 2 of the Patent Act in conjunction with section 47 (1) sentence 2 of the Patent Act). If the chair considers it appropriate, he may also give an oral statement on the essential contents of the grounds. Any inconsistencies between the written statement of grounds and the orally communicated grounds are non-prejudicial, but should be avoided, if possible.

The written statement of grounds shall be executed without delay and the complete decision shall be served in an execution copy.

The DPMA is bound by the decision delivered. Written pleadings received after the decision was delivered must not be taken into consideration – except later, in the case that an appeal is allowed (see paragraph 3.8.).

### 3.6. The decision to grant the certificate

If the application for the certificate complies with the MP-R/PPP-R as well as section 16a of the Patent Act (see paragraphs 3.2. and 3.3.), the patent division shall decide to grant the certificate for the duration of its term and, if appropriate, its extension pursuant to section 49a of the Patent Act.

In analogy to opposition proceedings, the decision shall be taken in a session or in lieu of a session by way of a written procedure. If a session is held, the form P 2543 "Sitzungsprotokoll" (minutes of session) shall be completed.

The decision need not be reasoned if the single request or the main request of the applicant is granted. However, a decision shall be reasoned if it falls short of the request of the applicant, for example, if only a subsidiary request is allowed. A statement of grounds is required, in particular, where the certificate is granted according to the request, but an extension of the duration applied for, if any, is not granted.

The decision must be executed in writing and served on the applicant (section 49a (5) sentence 2 of the Patent Act in conjunction with section 47 of the Patent Act).

The decision to grant a supplementary protection certificate shall contain: the product (active ingredient/substance or combination of active ingredients/substances) identified by the marketing authorisation pursuant to the MP-R/PPP-R, the name of the holder of the certificate, the file number of the basic patent, number and date of the above-mentioned marketing authorisation as well as the first authorisation to place the product on the market in the Community as well as the duration of the certificate and the period of extension of the duration, if any.

Furthermore, a declaration instructing the applicant on the possibility to appeal shall be attached (section 49a (5) sentence 2 in conjunction with section 47 (2) of the Patent Act).

The grant is published in the Patent Gazette (see paragraph 2.4.).

Details regarding the applications for the extension of the duration of supplementary protection certificates for medicinal products see paragraph 4.

### 3.7. Decision to reject the certificate

The patent division shall reject the application for a certificate pursuant to section 49a (2) sentence 3 of the Patent Act, if the application does not comply with the MP-R/PPP-R as well as section 16a of the Patent Act. The applicant shall be given sufficient opportunity to be heard (see paragraphs 3.4. and 3.5.).

In analogy to opposition proceedings, the decision shall be taken in a session or in lieu of a session by way of a written procedure. If a session is held, the form P 2543 shall be completed.

The decision to reject the certificate shall be reasoned, executed in writing and served on the applicant ex officio, pursuant to section 49a (5) sentence 2 in conjunction with section 47 (1) of the Patent Act. In accordance with section 47 (2) of the Patent Act, the written execution copy shall be accompanied by a declaration instructing the applicant about the possibility to appeal.

In case that decisions must be taken on several requests (main request and subsidiary requests) in an application for a certificate, one decision on all requests shall be taken in analogy to the patent examination procedure and the opposition proceedings. This decision shall contain the rejection of the main request and the subsidiary requests as well as, if appropriate, the grant pursuant to a subsidiary request.

### 3.8. Special legal remedies regarding supplementary protection certificates

#### 3.8.1. Appeal/rectification

Pursuant to section 73 (1) of the Patent Act in conjunction with section 16a (2) of the Patent Act, the decisions of the patent divisions may be appealed.

The applicant for a certificate or the holder of the certificate shall be entitled to appeal.

The appeal shall be filed in writing with the DPMA within one month of service of the decision (section 73 (2) sentence 1 of the Patent Act in conjunction with section 16a (2) of the Patent Act). An appeal fee pursuant to the Patent Costs Act is due upon filing the appeal. If the appeal fee is not paid within the time limit for filing an appeal, the appeal is deemed not to have been filed (sections 2, 3, 6 of the Patent Costs Act).

The patent division shall examine whether an appeal received is admissible (filing in the due form and within the prescribed time limit) and well-founded. If it regards the appeal as well-founded, it shall rectify the decision (section 73 (3) of the Patent Act in conjunction with section 16a (2) Patent Act).

A decision can be rectified only if the grounds for the rejection outlined by the patent division do no longer exist, for example because the reasons provided in support of the appeal convinced the patent division of the other opinion or because the requested amendments have been made. If the decision is rectified, the patent division may order that the appeal fee be reimbursed (section 73 (3) sentence 2 of the Patent Act).

Reimbursement of the appeal fee shall be ordered if, due to particular circumstances, it would not be equitable to retain the fee. This is the case, if an obvious error of the DPMA prompted the appellant to file an appeal.

If the appeal is not allowed, it shall be remitted to the Federal Patent Court within one month and without comment as to its merits (section 73 (3) sentence 3 of the Patent Act), even if the submission of further documents has been announced.

### **3.8.2. Rectifying the duration (after decision to grant)**

Pursuant to Article 17 (2) and recital 17 of the PPP-R the decisions to grant the certificate are open to an appeal aimed at rectifying the duration of the certificate (of the certificate for a medicinal product extended by six months, if appropriate) if the date, which is indicated in the application for a certificate pursuant to Article 8 of the MP-R/PPP-R, of the first authorisation to place the product on the market in the Community is incorrect.

Section 49a(4) number 1 of the Patent Act prescribes that, for Germany, the decision on the request to correct the duration of a supplementary protection certificate shall be taken by the patent division. The request may be filed any time and by any person. The proceedings may be conducted in an adversarial manner.

For rectification of obvious errors in calculating the duration, for example miscalculations or clerical errors, see paragraph 5.3.

## **4. Examination of the application for an extension of the duration**

For supplementary protection certificates for medicinal products, there is an option to extend the duration of the certificate by a further six months under the conditions provided in paragraphs 4.1. and 4.2.

The patent divisions shall decide on the application for an extension of the duration of a supplementary protection certificate for medicinal products pursuant to section 49a (3) in conjunction with (2) of the Patent Act.

If possible, the examination of applications for an extension of the duration of certificates should be carried out in such a way that an interim reply, if any, or a decision to grant will be served on the applicant within eight months after the receipt of the application. In this context, it should be noted that the decision on the application for an extension of the duration of the certificate is taken, if possible, before the expiry of the certificate on which it is based.

### **4.1. Formal examination**

First, it must be examined whether all formal requirements of the application for an extension are complied with.

The formal requirements of an application for an extension are in detail:

#### **4.1.1. Fee for the application, Article 8 (4) of the MP-R in conjunction with section 2 (1) of the Patent Costs Act**

Pursuant to Article 8 (4) of the MP-R in conjunction with section 2 (1) of the Patent Costs Act, a fee is payable upon application according to the Schedule of Fees of the annex to section 2 (1) of the Patent Costs Act.

The fee payment can be made by using a SEPA core direct debit mandate or by bank transfer (after receiving the acknowledgement of receipt), indicating the complete file number and the purpose of payment.

If the application fee is not paid upon filing the application, the DPMA will fix a time limit for payment of the fee, which shall be two months minimum (Article 10 (6) in conjunction with (3) of the MP-R in conjunction with section 49a (2) sentence 2 and (3) of the Patent Act). If the fee is not settled when the fixed period expires, the DPMA shall reject the application (Article 10 (6) in conjunction with (4) of the MP-R).

#### **4.1.2. Written form**

Applications for an extension shall be lodged in writing with the DPMA (see Article 9 (1) sentence 2 of the MP-R). A patent information centre cannot validly accept such applications because there is no reference to section 34 (2) of the Patent Act in the sections 16a and 49a of the Patent Act.

The form "*Antrag auf Verlängerung der Laufzeit eines ergänzenden Schutzzertifikats*" (P 2040) shall be used for the application for an extension of the duration of a certificate if the certificate has already been granted or its grant has already been requested separately. If the extension is requested together with the application for the grant of the certificate, the respective box on the form "*Antrag auf Erteilung eines ergänzenden Schutzzertifikats*" (P 2008) may be ticked.

The DPMA will send the applicant an acknowledgement of receipt.

#### **4.1.3. Reference to pending application or granted certificate**

Where an application for a certificate is pending, an application for an extended duration shall include a reference to the pending application for a certificate (Article 8 (2) of the MP-R).

Where a certificate has already been granted, the application for an extension of the duration of a certificate shall contain a copy of the decision of the certificate already granted (Article 8 (3) of the MP-R).

#### **4.1.4. Time limits for filing applications, Article 7 of the MP-R**

The observance of the time limits for filing applications for an extension, set in Article 7 (4) and (5) of the MP-R, shall be checked.

The application for an extension of the duration of the certificate may be made, pursuant to Article 7 (3) of the MP-R, when lodging the application for a certificate or when the application for the certificate is pending and the appropriate requirements of Article 8 (1)(d) or Article 8 (2) of the MP-R, respectively, are fulfilled.

Where a certificate has already been granted, the application for an extension of the duration of a certificate already granted shall be lodged not later than two years before the expiry of the certificate (Article 7 (4) of the MP-R).

#### Calculation of periods

The earliest date for filing the application for an extension of the duration is upon lodging the application for the grant of a certificate (see Article 7 (3) MP-R).

The latest date for filing the application for an extension of the duration is two years before expiry of the certificate. The period has to be calculated backwards. It ends at the beginning (0:00) of the day of the year before the previous year whose date is equivalent to the day when the certificate expires.

#### Example:

If the duration of the certificate ends on 14 September 2025, the application for an extension must have been lodged by 0:00 on 14 September 2023.

#### 4.1.5. Supporting documents necessary when filing the application

The following documents must be attached to the application for the extension:

##### **(a) Copy of the statement indicating compliance**

Pursuant to Article 8 (1) (d) (i) of the MP-R, the request for an extension of the duration shall include a copy of the statement indicating compliance with an agreed completed paediatric investigation plan as referred to in Article 36 (1) of the paediatric MP-R. The statement indicating compliance cannot be replaced by an opinion of the Paediatric Committee pursuant to Article 23 (2) of the paediatric MP-R.

The competent authority shall include within the marketing authorisation such a statement, pursuant to Article 28 (3) of the paediatric MP-R, if the application for authorisation complies with all the measures contained in the agreed completed paediatric investigation plan and if the summary of product characteristics reflects the results of studies conducted in compliance with that agreed paediatric investigation plan. If the new indication applied for (field 4) is not authorised, the competent authority issues upon rejection of the authorisation an official communication on varying the existing marketing authorisation of the product. The official communication on varying the marketing authorisation contains a statement on the above compliance (annex

1) and the results of studies in the summary of characteristics of the medicinal product.

If the copy of the statement of compliance is not submitted upon filing the application, it shall be proceeded as follows:

##### (1) Failure to provide a statement of compliance

If the applicant cannot provide a copy of the statement of compliance, because the statement of compliance has not yet been issued, a period shall be fixed for subsequently filing the missing documents (Article 10 (3), (6) of the MP-R). Where the documents are submitted within the fixed period, the application shall not be treated as having been filed after expiry of the period.

- If the applicant proves upon filing the application that he has made every effort to file the statement of compliance before the expiry of the period for filing the application and that he was justified to believe that in the case of proper conduct of procedures for the marketing authorisation of medicinal products he would have obtained the statement of compliance in time, the application shall be admissible.

The applicant shall be invited to submit a copy within a period of one month (two months for applicants from abroad). Upon request this period may be extended by further periods of one month. The grace period shall be given on condition that the applicant continues his efforts to obtain the missing documents. For reasons of legal certainty, the last grace period shall be given in a way to ensure that a decision on the extension of the duration of the certificate can be taken at the latest upon expiry of the certificate. If the statement of compliance has not been submitted when the decision is taken, the application for the extension of the duration of the certificate shall be rejected on substantive grounds (see below). The applicant should be advised of this possible consequence at least when the period is extended for the last time.

It is considered that the applicant has made every effort in his power if he would have been able to submit all documents before the expiry of the period on condition that the authorisation authorities concerned had granted the marketing authorisations within the periods prescribed by the relevant directives and regulations. For example, the authorities responsible for granting authorisations of the member states concerned are obligated, pursuant to Article 34 (3) of the Directive 2001/83/EC, to grant the national marketing authorisations or variations of the marketing authorisation within 30 days after conclusion of the European part of the decentralised

authorisation procedure, pursuant to Article 28 of the Directive 2001/83/EC.

- If the applicant does not provide proof upon filing the application that he has made every effort in his power and that he was justified to believe that in the case of proper conduct of procedures he would have obtained the documents in time, the applicant shall be invited to submit proof before the expiry of the period for filing the application. If the applicant cannot, before the expiry of the period for filing the application, prove that he has made every effort in his power and that he was justified to believe that in the case of proper conduct of procedures he would have obtained the documents in time, the application for extension shall be rejected as inadmissible after the expiry of the period for filing the application.

(2) Failure to file the copy of the statement of compliance

If the application is merely formally deficient because only the copy of the (already issued) statement of compliance has not been attached to the application, section 49a (2), (3) of the Patent Act shall be applicable.

**(b) Proof of marketing authorisation in the member states**

Pursuant to Article 8 (1) (d) (ii) of the MP-R, proof shall be filed of possession of authorisations to place the product on the market in all other member states, as referred to in Article 36 (3) of the paediatric MP-R.

The following cases shall be distinguished:

**(1) New active ingredient**

If a new active ingredient is placed on the market, a marketing authorisation for the new medicinal product must be granted by all member states. No previous marketing authorisation exist so that it is clear which marketing authorisation is meant. Where the marketing authorisation is granted by the central European agency EMA for all member states of the EU, this marketing authorisation is sufficient as proof. However, if the medicinal product was granted in a decentralised procedure, proof of possession of authorisations to place the medicinal product on the market in all member states shall be filed.

**(2) New use (also paediatric) of the active ingredient**

If a medicinal product which has been authorised previously is placed on the market for a new use, a marketing authorisation for this new use shall be granted in all member states and a corresponding proof shall be filed.

**(3) No new use**

Where a marketing authorisation was sought for a new use of a medicinal product previously authorised and the authorisation for the new use was rejected, an

official communication to vary the previous marketing authorisation shall be issued together with the rejection. This official communication on the variation of the marketing authorisation shall be issued in all member states to ensure that information on the paediatric studies are available in all member states.

Documents may be submitted as proof of the grant of the marketing authorisation, of the date of the marketing authorisation and of the identity of the authorised product in each individual EU member state.

Where the copies of the official communications have not been submitted before the expiry of the period for filing the application, it shall be proceeded as prescribed in paragraph 4.1.5. (a).

**4.2. Substantive examination**

When an application for extension of the duration is scrutinised, it must also be examined whether the substantive requirements for an extension of the duration are met in addition to the above-indicated formal requirements.

**4.2.1. Entitlement to lodge an application for extension**

Only the applicant/s or the holder/s of the supplementary protection certificate may apply for an extension of the period (see Article 36 of the paediatric MP-R).

**4.2.2. Results of all paediatric studies contained in the application**

Pursuant to Article 36 (1) sentence 1 of the paediatric MP-R, the application for marketing authorisation of a medicinal product or of the new indication, of the new pharmaceutical forms and of the new routes of administration shall contain the results of all paediatric studies conducted in compliance with an agreed paediatric investigation plan.

The DPMA will accept as proof a copy of the statement of compliance, which is attached to the marketing authorisation in the event that an authorisation to place the product on the market is granted. In the event that the application for authorisation is rejected, the statement of compliance is issued separately.

If no authorisation of a paediatric indication is granted, the results of the studies conducted must be reflected in the summary of product characteristics of the medicinal product and, if appropriate, in the package leaflet of the medicinal product concerned (see Article 36 (1) sentence 2 of the paediatric MP-R). If no authorisation of a new indication applied for is granted, the summary of product characteristics of the already authorised medicinal product must be amended.

The DPMA will accept as proof a copy of the statement of compliance which includes a declaration to this effect.

#### **4.2.3. Authorisation of the medicinal product in all EU member states**

The medicinal product must be authorised in all EU member states (see Article 36 (3) of the paediatric MP-R).

If an authorisation of a new medicinal product or a new indication was granted, this new medicinal product or new indication must be authorised in all member states. If the new indication was not authorised, at least the old indication of the medicinal product must be authorised in all member states and this authorisation must have been varied in accordance with the findings of the paediatric studies.

The DPMA will accept as proof a copy of the EU-wide authorisation or copies of the respective national authorisations.

#### **4.2.4. No orphan medicinal product**

The medicinal product shall not be designated as an orphan medicinal product pursuant to Regulation (EC) number 141/2000 (see Article 36 (4) sentence 2 of the paediatric MP-R).

If a corresponding self-declaration by the applicant is ticked on the form, this will be accepted as proof by the DPMA.

#### **4.2.5. No one-year extension of the period of protection**

If an application leads to the authorisation of a new paediatric indication, the applicant must not have applied for, nor obtained, a one-year extension of the period of marketing protection for the medicinal product concerned (see Article 36 (5) of the paediatric MP-R).

If a corresponding self-declaration by the applicant is ticked on the form, this will be accepted as proof by the DPMA.

#### **4.3. The decision to grant**

If the application for the extension of the duration complies with the indicated provision, the patent division shall decide to extend the duration of the supplementary protection certificate.

- If the application for extension was filed together with the application for the grant of the supplementary protection certificate, a uniform decision on the grant of the certificate shall be taken and the duration of the certificate shall be calculated taking into account the extension.

- If the application for extension was filed after the application for the grant of the supplementary protection certificate, a separate decision on the extension of the duration shall be taken.

The guidelines mentioned in paragraph 3.6. apply accordingly to the decisions.

The subsequent extension of the duration shall be entered in the patent register and published in the Patent Gazette.

#### **4.4. Decision to reject**

If the requirements for an extension of the duration are not met, the patent division shall decide to reject the application for extension of the duration.

- If the application for extension was filed together with the application for the grant of the supplementary protection certificate or while the application for the grant of the supplementary protection certificate was pending, a uniform decision on the grant of the certificate shall be taken. If the certificate is granted but the extension cannot be granted, the duration shall be calculated accordingly and an explanation why an extension of the duration is not granted shall be given in the statement of reasons. If the certificate is not granted, it is not necessary to address the extension of the duration.
- If the supplementary protection certificate has already been granted at the time of filing the application for the extension of the duration, a separate decision on the application for the extension of the duration shall be taken. In this case, the patent division shall reject the application for the extension of the duration pursuant to Article 10(3) in conjunction with (6) of the MP-R in conjunction with section 49a (3) in conjunction with (2) of the Patent Act if the application does not comply with the requirements of the paediatric MP-R and of the MP-R.

The applicant must be given sufficient opportunity to be heard (see paragraphs 3.4. and 3.5.).

The guidelines mentioned in paragraph 3.6. apply accordingly to the decisions.

The decision shall be entered in the patent register and published in the Patent Gazette.

#### **4.5. Special legal remedy: revocation of an extension of the duration**

Pursuant to Article 16 of the MP-R in conjunction with section 49a (4) number 2 of the Patent Act the extension of the duration may be revoked if it was granted contrary to the provisions of Article 36 of the paediatric MP-R.

Pursuant to section 49a (4) number 2 of the Patent Act, the patent division will decide on the revocation.

Pursuant to Article 16(2) of the MP-R, any person is entitled to submit an application for revocation. The application for revocation of the extension of the duration must be submitted in writing at the DPMA. It may be submitted any time.

The patent division shall examine whether the application for revocation of the extension of the duration is admissible and justified. If the patent division finds that the application is admissible and justified, it shall revoke the extension of the duration. The proceedings may be conducted in an adversarial manner.

The revocation of the extension of the duration shall be entered in the Patent Register and published in the Patent Gazette.

## **5. General legal remedies**

### **5.1. Suspension**

It is possible to suspend proceedings for the grant of a supplementary protection certificate by applying accordingly section 148 of the Code of Civil Procedure (*Zivilprozessordnung*). The purpose of the suspension is to avoid contradictory decisions in parallel proceedings. This means that proceedings to grant a certificate may be suspended at the request of the applicant or ex officio if a decision in another matter is anticipated. This is the case where the decision on the grant of a supplementary protection certificate depends on the question of whether or not a legal relationship exists, and this relationship forms the preliminary issue of the suspended proceedings and the subject matter of other pending proceedings (for example, in case a preliminary ruling by the CJEU is necessary to interpret EU law). Suspension should be inadmissible if the issue at dispute in the other proceedings may be left undecided or if there is a mere possibility of contradictory decisions or the mere prospect that the proceedings might be deprived of their purpose by other proceedings.

The ordering of a suspension is at the discretion of the patent division. The decision to suspend proceedings shall be taken ex officio for the whole of the proceedings. The right to be heard shall be granted. The decision shall provide verifiable facts to prove that the suspension is justified, in particular, that discretion has been properly exercised. Suspension shall be terminated by completion of the other proceedings whose decision was anticipated or by a decision to lift suspension. The parties shall be notified that proceedings will be continued. The decision to suspend proceedings may be appealed.

### **5.2. Re-establishment of rights/further processing**

The re-establishment of rights (for example in respect of the six-month period for filing the application or in respect of the period for payment of the annual fee) is possible pursuant to sections 16a (2) and 123 of the Patent Act under the conditions mentioned in these provisions.

Although section 16a (2) of the Patent Act lacks a corresponding reference, further processing is possible due to legal similarity by applying section 123a of the Patent Act accordingly.

### **5.3. Correction of decisions**

In the case of obvious mistakes, decisions of the patent division in procedures regarding supplementary protection certificates may be corrected, pursuant to section 16a (2) of the Patent Act, by applying section 95 of the Patent Act accordingly.

Reference is made to paragraph 3.8.2. with regard to the correction of the term pursuant to section 49a (4) of the Patent Act.

### **5.4. Legal aid**

Section 16a of the Patent Act does not provide for applying sections 129 to 138 of the Patent Act on legal aid accordingly to supplementary protection certificates.