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), second sentence, of the Patent Act, Section 46 of the Patent Act (further examination, hearing, minutes) shall apply *mutatis mutandis* 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), second sentence, of the Patent Act shall apply *mutatis mutandis*). 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), fourth sentence, of the Patent Act shall apply *mutatis mutandis*). 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 shall apply *mutatis mutandis* (Sec. 49a(5), second sentence, Patent Act in conjunction with Sec. 46(2), second sentence, 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 *mutatis mutandis* 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 (Sec. 49a(5), second sentence, Patent Act in conjunction with Sec. 47(1), second sentence, 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 (cf. section 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 (cf. sections 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 (Sec. 49a(5), second sentence, Patent Act in conjunction with Sec. 47 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 (Sec. 49a(5), second sentence, in conjunction with Sec. 47(2) Patent Act).

The grant is published in the Patent Gazette (cf. section 2.4.).

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

3.7. Decision to reject the certificate

The patent division shall reject the application for a certificate pursuant to Section 49a(2), third sentence, 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 (cf. sections 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), second sentence, 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 (Sec. 73(2), first sentence, Patent Act in conjunction with Sec. 16a(2) 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 (Secs. 2, 3, 6 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 (Sec. 73(3) Patent Act in conjunction with Sec. 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, e.g. 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 (Sec. 73(3), second sentence, 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 (Sec. 73(3), third sentence, 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) no. 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, e.g. miscalculations or clerical errors, see section 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 sections 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 Sec. 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, Art. 8(4) MP-R in conjunction with Sec. 2(1) 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 (Art. 10(6) in conjunction with (3) MP-R in conjunction with Sec. 49a(2), second sentence, and (3) Patent Act). If the fee is not settled when the fixed period expires, the DPMA shall reject the application (Art. 10(6) in conjunction with (4) MP-R).

4.1.2. Written form

Applications for an extension shall be lodged in writing with the DPMA (cf. Art. 9(1), second sentence, 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 (Art. 8(2) 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 (Art. 8(3) MP-R).

4.1.4. Time limits for filing applications, Art. 7 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 (Art. 7(4) MP-R).

4.1.4.1. 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 (cf. Art. 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 (Art. 10(3), (6) 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.

<u>(b) Proof of marketing authorisation in the member states</u>

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

stated 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 section 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 (cf. Art. 36 paediatric MP-R).

4.2.2. Results of all paediatric studies contained in the application

Pursuant to Article 36(1), first sentence, 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 (cf. Art. 36(1), second sentence, 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 (cf. Art. 36(3) 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) no. 141/2000 (cf. Art. 36(4), second sentence, 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 (cf. Art. 36(5) 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 section 3.6. shall apply *mutatis mutandis* 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 (cf. sections 3.4. and 3.5.).

The guidelines mentioned in section 3.6. shall apply *mutatis mutandis* 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) no. 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) no. 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 *mutatis mutandis* 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 (e.g. 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 *mutatis mutandis*.

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 *mutatis mutandis*.

Reference is made to section 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 *mutatis mutandis* to supplementary protection certificates.