

4.5 Sequences and partial sequences of genes

Rule 27(1)(f)
Rule 23e(3)

In general it is required that the description of a European patent application should, where this is not self-evident, indicate the way in which the invention is capable of exploitation in industry. In relation to sequences and partial sequences of genes, this general requirement is given specific form in that the industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application. A mere nucleic acid sequence without indication of a function is not a patentable invention (EU Dir. 98/44/EC, rec. 23). In cases where a sequence or partial sequence of a gene is used to produce a protein or a part of a protein, it is necessary to specify which protein or part of a protein is produced and what function this protein or part of a protein performs. Alternatively, when a nucleotide sequence is not used to produce a protein or part of a protein, the function to be indicated could e.g. be that the sequence exhibits a certain transcription promoter activity.

5. State of the art

5.1 General remarks and definition

Art. 54(1)
Art. 54(2)

An invention is "considered to be new if it does not form part of the state of the art". The "state of the art" is defined as "everything made available to the public by means of a written or oral description, by use, or in any other way, before the date of filing of the European patent application". The width of this definition should be noted. There are no restrictions whatever as to the geographical location where or the language or manner in which the relevant information was made available to the public; also no age limit is stipulated for the documents or other sources of the information. There are, however, certain specific exclusions (see IV, 8). However, since the "state of the art" available to the examiner will mainly consist of the documents listed in the search report, this section 5 deals with the question of public availability only in relation to written description (either alone or in combination with an earlier oral description or use).

The principles to be applied in determining whether other kinds of prior art (which could be introduced into the proceedings e.g. by a third party under Art. 115) have been made available to the public are set out in D-V, 3.

Art. 52(1)

For the examination of the novelty of claimed subject-matter, see IV, 7.

A written description, i.e. a document, should be regarded as made available to the public if, at the relevant date, it was possible for members of the public to gain knowledge of the content of the document and there was no bar of confidentiality restricting the use or dissemination of such knowledge. For instance, German utility models ("Gebrauchsmuster") are already publicly available as of their date of entry in the Register of utility models ("Eintragungstag"), which precedes the date of announcement in the Patent Bulletin ("Bekanntmachung im Patentblatt"). The search report also cites documents in which doubts with regard to the fact of public availability and doubts concerning the precise date of publication of a document have not, or not fully, been removed (cf. B-VI, 7). If the applicant contests the public availability or assumed date of publication of the document, the examiner should consider whether to investigate the matter further or ask the Search Division so to do. If the applicant shows sound reasons for doubting whether the document forms part of the "state of the art" in relation to his application and any further investigation does not produce evidence sufficient to remove that doubt, the examiner should not pursue the matter further. The only other problem likely to arise for the examiner is where:

- (i) a document reproduces an oral description (e.g. a public lecture) or gives an account of a prior use (e.g. display at a public exhibition); and

- (ii) only the oral description or lecture was publicly available before the "date of filing" of the European application, the document itself being published on or after this date.

In such cases, the examiner should start with the assumption that the document gives a true account of the earlier lecture, display or other event and should therefore regard the earlier event as forming part of the "state of the art". If, however, the applicant gives sound reasons for contesting the truth of the account given in the document then again the examiner should not pursue the matter further.

5.2 Enabling disclosures

Subject-matter can only be regarded as having been made available to the public, and therefore as comprised in the state of the art pursuant to Art. 54(1), if the information given to the skilled person is sufficient to enable him, at the relevant date (see IV, 7.3), to practise the technical teaching which is the subject of the disclosure, taking into account also the general knowledge at that time in the field to be expected of him (see T 26/85, OJ 1-2/1990, 22, T 206/83, OJ 1/1987, 5 and T 491/99, not published in OJ).

5.3 Date of filing or priority date as effective date

Art. 89

It should be noted that "date of filing" in Art. 54(2) and 54(3) is to be interpreted as meaning the date of priority in appropriate cases (see Chapter V). It should be remembered that different claims, or different alternatives claimed in one claim, may have different effective dates, i.e. the date of filing or (one of) the claimed priority date(s). The question of novelty must be considered against each claim (or part of a claim where a claim specifies a number of alternatives) and the state of the art in relation to one claim or one part of a claim may include matter, e.g. an intermediate document (see B-X, 9.2(iv)), which cannot be cited against another claim or another alternative in the same claim because it has an earlier effective date.

Of course, if all the matter in the state of the art was made available to the public before the date of the earliest priority document, the examiner need not (and should not) concern himself with the allocation of effective dates.

6. Conflict with other European applications

6.1 State of the art pursuant to Art. 54(3)

Art. 54(3), (4)
Art. 56
Art. 89
Art. 85

The state of the art also comprises the content of other European applications filed or validly claiming a priority date earlier than – but published under Art. 93 on or after – the date of filing or valid date of priority of the application being examined, to the extent that the earlier and later applications validly designate the same State or States. Such earlier applications are part of the state of the art only when considering novelty and not when considering inventive step. The "date of filing" referred to in Art. 54(2) and (3) is thus to be interpreted as meaning the date of priority in appropriate cases (see Chapter V). By the "content" of a European application is meant the whole disclosure, i.e. the description, drawings and claims, including:

- (i) any matter explicitly disclaimed (with the exception of disclaimers for unworkable embodiments);
- (ii) any matter for which an allowable reference (see II, 4.18, penultimate paragraph) to other documents is made; and
- (iii) prior art insofar as explicitly described.

However, the "content" does not include any priority document (the purpose of such document being merely to determine to what extent the priority date is valid for the disclosure of the European application (see V, 1.2)) nor, in view of Art. 85, the abstract (see B-XI, 2).

It is important to note that it is the content of the earlier application as filed which is to be considered when applying Art. 54(3). Where an application is filed in a non-official language as permitted by Art. 14(2) (see A-VIII, 1.1), it may happen that matter is erroneously omitted from the translation in the language of the proceedings and not published under Art. 93 in that language. Even in this case, it is the content of the original text which is relevant for the purposes of Art. 54(3).

6.1a Requirements

Whether a published European application can be a conflicting application under Art. 54(3) and (4) is determined firstly by its filing date and the date of its publication; the former must be before the filing or valid priority date of the application under examination, the latter must be on or after that date. If the published European application claims priority, the priority date replaces the filing date (Art. 89) for that subject-matter in the application which corresponds to the priority application. If a priority claim was abandoned or otherwise lost with effect from a date prior to publication, the filing date and not the priority date is relevant, irrespective of whether or not the priority claim might have conferred a valid priority right.

Further it is required that the conflicting application was still pending at its publication date (see J 5/81, OJ 4/1982, 155). If the application was withdrawn or otherwise lost before the date of publication, but published because the preparations for publication had been completed, the publication has no effect under Art. 54(3), but only under Art. 54(2). Art. 54(3) must be interpreted as referring to the publication of a "valid" application, i.e. a European patent application in existence at its publication date.

Rule 23a

Finally, as the designation fees can be paid up to 6 months after the mention of the publication of the search report (Art. 79(2)), extended where applicable by the grace period under Rule 85a, European applications are only comprised in the state of the art pursuant to Art. 54(3) for those Contracting States for which, at the expiry of the above mentioned period, the designation is definitive, i.e. the relevant designation fees have been paid.

Other changes taking effect after the date of publication (e.g. withdrawal of a designation or of the priority claim or loss of the priority right for other reasons) do not affect the application of Art. 54(3) and (4).

6.2 Euro-PCT applications

Art. 158(1), (2)

The above principles also apply to PCT applications designating EP, but with an important difference. Art. 158 makes it clear that a PCT application is not included in the state of the art for the purposes of Art. 54(3) unless the PCT applicant has paid the required national fee and has supplied the PCT application to the EPO in English, French or German (this means that a translation is required where the PCT application was published in Japanese, Chinese, Spanish or Russian). The national fee comprises the national basic fee (the amount being equal to the filing fee) and the designation fees (Rule 106).

6.3 Commonly designated States

Rule 87

Where an application designates some States which were designated in an earlier conflicting application and some which were not, there are several possibilities of amendment open to the applicant. Firstly, he may simply withdraw the designations common to his own and the earlier application. Secondly, he may file claims for such common States which are different from the claims for the other designated States. Where different claims are filed, the examiner should consider whether the retention of the same description and drawings throughout creates confusion. In such a case, Rule 87 permits the examiner to require the filing of a different description and drawings; the applicant himself has no right to request such amend-

ment (see also III, 8.1). Thirdly, the applicant can limit his existing set of claims in such a manner that the conflicting application is no longer relevant.

If the search report on the conflicting application has been published, but the time limit for validly paying the designation fees has not yet expired, the applicant is informed that the examination cannot be concluded until such time as the situation regarding the designations has been clarified for the prior application, unless the applicant – irrespective of the confirmation of the designations by valid payment – limits his claims in such a manner that the conflicting application is no longer relevant for novelty. If the search report has not yet been published (the conflicting application having been published as an "A2" publication), the examiner will invite the competent Search Division to perform the search at its earliest convenience. In the meantime, the examination rests.

For the rare case where the application is ready for grant before the search for conflicting applications can be performed (e.g. request for accelerated prosecution of an application filed without priority), see VI, 8.4.

6.4 Double patenting

The EPC does not deal explicitly with the case of co-pending European applications of the same effective date. However, it is an accepted principle in most patent systems that two patents cannot be granted to the same applicant for one invention. It is permissible to allow an applicant to proceed with two applications having the same description where the claims are quite distinct in scope and directed to different inventions. However, in the rare case in which there are two or more European applications from the same applicant definitively designating the same State or States (by confirming the designation through payment of the relevant designation fees) and the claims of those applications have the same filing or priority date and relate to the same invention (the claims conflicting in the manner explained in VI, 9.1.6), the applicant should be told that he must either amend one or more of the applications in such a manner that they no longer claim the same invention, or choose which one of those applications he wishes to proceed to grant. Should two applications of the same effective date be received from two different applicants, each must be allowed to proceed as though the other did not exist.

6a. Conflict with national rights of earlier date

Where a national right of an earlier date exists in a Contracting State designated in the application, the applicant has the same possibilities of amendment as mentioned in IV, 6.3, first paragraph, above, for conflicting European applications. Amendment of the application to take account of prior national rights should, however, be neither required nor suggested (see also III, 8.4).

7. Novelty

7.1 State of the art pursuant to Art. 54(2)

Art. 54(1)

An invention is considered to be new if it does not form part of the state of the art. For a definition of "state of the art", see IV, 5. It should be noted that in considering novelty (as distinct from inventive step, see IV, 9.9), it is not permissible to combine separate items of prior art together. It is also not permissible to combine separate items belonging to different embodiments described in one and the same document, unless such combination has specifically been suggested (T 305/87, OJ 8/1991, 429).

However, if a document (the "primary" document) refers explicitly to another document as providing more detailed information on certain features, the teaching of the latter is to be regarded as incorporated into the document containing the reference, if the document referred to was available to the public on the publication date of the document containing the reference

(see T 153/85, OJ 1-2/1988, 1) (For the state of the art pursuant to Art. 54(3), see IV, 6.1, and II, 4.18, penultimate paragraph). The relevant date for novelty purposes, however, is always the date of the primary document (see IV, 7.3).

Furthermore, any matter explicitly disclaimed (with the exception of disclaimers which exclude unworkable embodiments) and prior art acknowledged in a document, insofar as explicitly described therein, are to be regarded as incorporated in the document.

It is further permissible to use a dictionary or similar document of reference in order to interpret a special term used in a document.

7.2 Implicit features or well-known equivalents

A document takes away the novelty of any claimed subject-matter derivable directly and unambiguously from that document including any features implicit to a person skilled in the art in what is expressly mentioned in the document, e.g. a disclosure of the use of rubber in circumstances where clearly its elastic properties are used even if this is not explicitly stated takes away the novelty of the use of an elastic material. The limitation to subject-matter "derivable directly and unambiguously" from the document is important. Thus, when considering novelty, it is not correct to interpret the teaching of a document as embracing well-known equivalents which are not disclosed in the documents; this is a matter of obviousness.

7.3 Relevant date of a prior document

In determining novelty, a prior document should be read as it would have been read by a person skilled in the art on the relevant date of the document. By "relevant" date is meant the publication date in the case of a previously published document and the date of filing (or priority date, where appropriate) in the case of a document according to Art. 54(3) (see IV, 6.1).

7.3a Enabling disclosure of a prior document

Subject-matter described in a document can only be regarded as having been made available to the public, and therefore as comprised in the state of the art pursuant to Art. 54(1), if the information given therein to the skilled person is sufficient to enable him, at the relevant date of the document (see IV, 7.3), to practise the technical teaching which is the subject of the document, taking into account also the general knowledge at that time in the field to be expected of him (see T 26/85, OJ 1-2/1990, 22, T 206/83, OJ 1/1987, 5 and T 491/99, not published in OJ).

Similarly, it should be noted that a chemical compound, the name or formula of which is mentioned in a prior-art document, is not thereby considered as known, unless the information in the document, together, where appropriate, with knowledge generally available on the relevant date of the document, enables it to be prepared and separated or, for instance in the case of a product of nature, only to be separated.

7.4 Generic disclosure and specific examples

In considering novelty, it should be borne in mind that a generic disclosure does not usually take away the novelty of any specific example falling within the terms of that disclosure, but that a specific disclosure does take away the novelty of a generic claim embracing that disclosure, e.g. a disclosure of copper takes away the novelty of metal as a generic concept, but not the novelty of any metal other than copper, and one of rivets takes away the novelty of fastening means as a generic concept, but not the novelty of any fastening other than rivets.

7.5 Implicit disclosure and parameters

In the case of a prior document, the lack of novelty may be apparent from what is explicitly stated in the document itself. Alternatively, it may be implicit in the sense that, in carrying out the teaching of the prior document, the skilled person would inevitably arrive at a result falling within the terms of the claim. An objection of lack of novelty of this kind should be raised by the examiner only where there can be no reasonable doubt as to the practical effect of the prior teaching (for a second non-medical use, however, see IV, 7.6). Situations of this kind may also occur when the claims define the invention, or a feature thereof, by parameters (see III, 4.7a). It may happen that in the relevant prior art a different parameter, or no parameter at all, is mentioned. If the known and the claimed products are identical in all other respects (which is to be expected if, for example, the starting products and the manufacturing processes are identical), then in the first place an objection of lack of novelty arises. If the applicant is able to show, e.g. by appropriate comparison tests, that differences do exist with respect to the parameters, it is questionable whether the application discloses all the features essential to manufacture products having the parameters specified in the claims (Art. 83).

7.6 Examination of novelty

In determining novelty of the subject-matter of claims, the examiner should have regard to the guidance given in III, 4.4 - 4.13. He should remember that, particularly for claims directed to a physical entity, non-distinctive characteristics of a particular intended use should be disregarded (see III, 4.8). For example, a claim to a substance X for use as a catalyst would not be considered to be novel over the same substance known as a dye, unless the use referred to implies a particular form of the substance (e.g. the presence of certain additives) which distinguishes it from the known form of the substance. That is to say, characteristics not explicitly stated, but implied by the particular use, should be taken into account (see the example of a "mold for molten steel" in III, 4.8). For claims to a first medical use, see IV, 4.2.

It should further be borne in mind that a claim to the use of a known compound for a particular purpose (second non-medical use) which is based on a technical effect should be interpreted as including that technical effect as a functional technical feature, and is accordingly not open to objection under Art. 54(1), provided that such technical feature has not previously been made available to the public (G 2/88, OJ 4/1990, 93, and G 6/88, OJ 4/1990, 114). For claims to a second or further medical use, see IV, 4.2.

8. Non-prejudicial disclosures

8.1 General

- Art. 55(1) There are two specific instances (and these are the only two) in which a prior disclosure of the invention is not taken into consideration as part of the state of the art, viz. where the disclosure was due to, or in consequence of:
- Art. 55(1)(a) (i) an evident abuse in relation to the applicant or his legal predecessor – e.g. the invention was derived from the applicant and disclosed against his wish; or
- Art. 55(1)(b) (ii) the display of the invention by the applicant or his legal predecessor at an officially recognised international exhibition as defined in Art. 55(1)(b).

8.2 Time limit

An essential condition, in both instances (i) and (ii), is that the disclosure in point must have taken place not earlier than six months preceding the filing