PCT – Part G

Substantive requirements of the application

Contents

Chapter I – Patentability

1. General disclaimer

Under Art. 150(2) EPC, an international application filed under the PCT may be the subject of proceedings before the EPO. In such proceedings, the provisions of the PCT and its Regulations are applied, supplemented by the provisions of the EPC. In case of conflict, the provisions of the PCT and its Regulations prevail.

The EPO, acting as ISA or IPEA, has established practice on how the examiner assesses novelty and inventive step. For most subject-matter this practice is identical to that used in proceedings for European patent applications. However, for some subject-matter the ISPE Guidelines deviate from the practice in European proceedings, and for other subject-matter they recognise that different offices adopt different approaches. As a result of Art. 150(2) EPC, the EPO as ISA/IPEA will, for the assessment of novelty and inventive step, generally apply the provisions of the PCT and, where these are not sufficient, will base its assessment on its established practice. In the latter case, these Guidelines then state that "the principles as laid down in the corresponding section in the Guidelines for Examination in the EPO apply *mutatis mutandis*."

It should be borne in mind that when an international application validly enters the regional phase before the EPO, it is considered as a European patent application. Consequently, the EPO will apply its criteria for examination as laid down in the Guidelines for Examination in the EPO for any subject-matter.

2. General remarks

The aim of the PCT is to allow the applicant to obtain a preliminary and non-binding opinion on the patentability of the claimed subject-matter before entering the regional phase. The PCT procedure cannot serve the purpose of granting a patent as is the case for example under the EPC.

Art. 33(1)
Rule 43bis.1(a)

Chapter II – Inventions

1. General remarks

The objective of the international preliminary examination is to formulate a preliminary and non-binding opinion on the questions whether the claimed invention appears to be novel, to involve an inventive step and to be industrially applicable.

Art. 33(1)
Rule 43bis.1(a)

The PCT does not define what is meant by "invention", but Rules 39 and 67 contain a list of subject-matter for which the ISA or IPEA is not required to carry out an international search or an international preliminary examination, respectively (see also GL/PCT-EPO B-VIII, 2). The Agreement between the EPO and WIPO in relation to the functioning of the EPO as an International Authority under the PCT indicates the subject-matter which the EPO is not required to search or examine, and according to its Art. 4 and Annex C the discretion not to search or examine is exercised by the EPO as ISA and IPEA only to the extent that such subject-matter is not searched under the provisions of the EPC, specifically Art. 52(2), Art. 52(3), Art. 53(b) and Art. 53(c) EPC.

Art. 34(4)(a)(i)
GL/ISPE 9.02-9.15
OJ EPO 2017, A115
OJ EPO 2018, A24

2. Examination practice

Section GL/EPO G-II, 2 in the Guidelines for Examination in the EPO applies *mutatis mutandis*.

3. List of exclusions

See ISPE Guidelines 9.02 to ISPE Guidelines 9.15.

3.1 Discoveries

Rules 39.1 and 67.1 do not explicitly exclude an international search or international preliminary examination on discoveries from being carried out by the ISA or IPEA, respectively. However, under the Agreement between the EPO and WIPO these fall within the EPO's discretion to exclude matter which would be excluded under Art. 52(2)(a) and Art. 52(3) EPC. Section G-II, 3.1, in the Guidelines for Examination in the EPO applies *mutatis mutandis*.

Rules 39.1, 67.1
OJ EPO 2017, A115
OJ EPO 2018, A24

3.2 Scientific theories

See ISPE Guidelines 9.05. However, under the Agreement between the EPO and WIPO these fall within the EPO's discretion to exclude matter which would be excluded under Art. 52(2)(a) and Art. 52(3) EPC. Section G-II, 3.2, in the Guidelines for Examination in the EPO applies *mutatis mutandis*.

Rule 39.1(i),
Rule 67.1(i)
OJ EPO 2017, A115
OJ EPO 2018, A24

3.3 Mathematical theories

See ISPE Guidelines 9.05. However, under the Agreement between the EPO and WIPO these fall within the EPO's discretion to exclude matter which would be excluded under Art. 52(2)(a) and Art. 52(3) EPC. Section G-II, 3.3, in the Guidelines for Examination in the EPO applies *mutatis mutandis*.

Rule 39.1(i),
Rule 67.1(i)
OJ EPO 2017, A115
OJ EPO 2018, A24

3.4 Aesthetic creations

Rules 39.1 and 67.1 do not explicitly exclude an international search or international preliminary examination on aesthetic creations from being

OJ EPO 2017, A115
OJ EPO 2018, A24

carried out by the ISA or IPEA, respectively. However, under the Agreement between the EPO and WIPO these fall within the EPO's discretion to exclude matter which would be excluded under Art. 52(2)(b) and Art. 52(3) EPC. Section G-II, 3.4, in the Guidelines for Examination in the EPO applies *mutatis mutandis*.

3.5 Schemes, rules and methods of doing business, performing purely mental acts or playing games

Rule 39.1(iii), Rule 67.1(iii) OJ EPO 2017, A115 OJ EPO 2018, A24

See ISPE Guidelines 9.07, ISPE Guidelines A9.07 and ISPE Guidelines A9.07[2]. However, under the Agreement between the EPO and WIPO these fall within the EPO's discretion to exclude matter which would be excluded under Art. 52(2)(c) and Art. 52(3) EPC. Section G-II, 3.5, in the Guidelines for Examination in the EPO applies *mutatis mutandis*.

3.6 Programs for computers

Rule 39.1(vi), Rule 67.1(vi) OJ EPO 2017, A115 OJ EPO 2018, A24

See ISPE Guidelines 9.15, ISPE Guidelines A9.15 and ISPE Guidelines A9.15[2]. However, under the Agreement between the EPO and WIPO these fall within the EPO's discretion to exclude matter which would be excluded under Art. 52(2)(c) and Art. 52(3) EPC. Section G-II, 3.6, in the Guidelines for Examination in the EPO applies *mutatis mutandis* (cf. GL/PCT-EPO B-VIII, 2.2).

3.7 Presentations of information

Rule 39.1(v), Rule 67.1(v) OJ EPO 2017, A115 OJ EPO 2018, A24

See ISPE Guidelines 9.11 to ISPE Guidelines 9.14. However, under the Agreement between the EPO and WIPO these fall within the EPO's discretion to exclude matter which would be excluded under Art. 52(2)(d) and Art. 52(3) EPC. Section G-II, 3.7, in the Guidelines for Examination in the EPO applies *mutatis mutandis*.

4. Exceptions to patentability

4.1 Matter contrary to public order or morality

Art. 21(6) Rule 9 PCT AG I 5.175 OJ EPO 2017, A115 OJ EPO 2018, A24

Unlike the EPC, the PCT does not explicitly rule out the patentability of subject-matter for reasons of public order or morality. However, according to Rule 9, the application must not contain any expressions contrary to public order or morality, and under the Agreement between the EPO and WIPO the EPO may exclude matter which would be excluded under Art. 53(a) EPC. Generally, no search or preliminary examination is carried out on such matter by the EPO as ISA/IPEA. Section G-II, 4.1, in the Guidelines for Examination in the EPO applies *mutatis mutandis*.

4.2 Surgery, therapy and diagnostic methods

Rule 39.1(iv), Rule 67.1(iv) OJ EPO 2017, A115 OJ EPO 2018, A24

See ISPE Guidelines 9.08-9.10. However, under the Agreement between the EPO and WIPO these fall within the EPO's discretion to exclude matter which would be excluded under Art. 53(c) EPC. Generally, no search or preliminary examination is carried out on such matter by the EPO as ISA/IPEA. Section G-II, 4.2, in the Guidelines for Examination in the EPO applies *mutatis mutandis*.

5. Exclusions and exceptions for biotechnological inventions

5.1 General remarks and definitions

"Biotechnological inventions" are inventions which concern a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used. "Biological material" means any material containing genetic information and capable of reproducing itself or being reproduced in a biological system.

Rule 39.1(ii),
Rule 67.1(ii)
OJ EPO 2017, A115
OJ EPO 2018, A24

5.2 Biotechnological inventions

See ISPE Guidelines 9.06. However, under the Agreement between the EPO and WIPO these fall within the EPO's discretion to exclude matter which would be excluded under Art. 53(b) EPC. Generally, no search or preliminary examination is carried out on such matter by the EPO as ISA/IPEA. Section G-II, 5.2, in the Guidelines for Examination in the EPO applies *mutatis mutandis*.

OJ EPO 2017, A115
OJ EPO 2018, A24

5.3 Exceptions

The PCT, unlike the EPC, does not explicitly exclude carrying out an international search or an international preliminary examination on specific subject-matter related to biotechnological inventions. However, under the Agreement between the EPO and WIPO these fall within the EPO's discretion to exclude matter which would be excluded under Art. 53 EPC. Generally, no search or preliminary examination is carried out on such matter by the EPO as ISA/IPEA. Section G-II, 5.3, in the Guidelines for Examination in the EPO applies *mutatis mutandis*.

OJ EPO 2017, A115
OJ EPO 2018, A24

5.4 Plant and animal varieties, essentially biological processes for the production of plants or animals

See ISPE Guidelines 9.06. However, under the Agreement between the EPO and WIPO these fall within the EPO's discretion to exclude matter which would be excluded under Art. 53(b) EPC. Generally, no search or preliminary examination is carried out on such matter by the EPO as ISA/IPEA. Section G-II, 5.4 and subsections, in the Guidelines for Examination in the EPO applies *mutatis mutandis*.

Rule 39.1(ii),
Rule 67.1(ii)
OJ EPO 2017, A115
OJ EPO 2018, A24

5.5 Microbiological processes

See ISPE Guidelines 9.06. GL/EPO G-II, 5.5, applies *mutatis mutandis*.

Rule 39.1(ii),
Rule 67.1(ii)
OJ EPO 2017, A115
OJ EPO 2018, A24

Chapter III – Industrial application

1. General remarks

See ISPE Guidelines 14.01 to ISPE Guidelines 14.03. *Art. 33(4)*

2. Methodology

See ISPE Guidelines 14.04 to ISPE Guidelines 14.06.

3. Industrial applicability

See ISPE Guidelines A14.01[2].1.

Chapter IV – Prior art

1. General remarks and definition

An invention is to be "considered novel if it is not anticipated by the prior art". The "prior art shall consist of everything which has been made available to the public anywhere in the world by means of written disclosure (including drawings and other illustrations) and which is capable of being of assistance in determining that the claimed invention is or is not new and that it does or does not involve an inventive step (i.e., that it is or is not obvious), provided that the making available to the public occurred prior to the international filing date". The scope of this definition should be noted. There are no restrictions whatsoever as to the geographical location where or the language 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.

Art. 33(2), (3)
Rules 33.1(a), (b)
Rule 64.1

See also ISPE Guidelines 11.01 and ISPE Guidelines 11.12.

The principles to be applied in determining whether other kinds of prior art, e.g. relating to use (which could be introduced e.g. by a third party, see GL/PCT-EPO E-II, ISPE Guidelines 16.57 and PCT/AI section 801), have been made available to the public are governed by Rules 33.1(b) and 64.2.

For the examination of the novelty of claimed subject-matter, see GL/PCT-EPO G-VI.

Art. 33(2)

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").

2. Enabling disclosures

The principles as laid down in section G-IV, 2, in the Guidelines for Examination in the EPO apply *mutatis mutandis*.

3. Date of filing or priority date as effective date

It should be noted that for the purpose of international preliminary examination all prior art is taken into account which was publicly available before the international filing date or, where a priority has been validly claimed, before the date of priority. 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 prior art in relation to one claim or one part of a claim may include matter, e.g. an intermediate document (see GL/PCT-EPO B-X, 9.2.4), which cannot be cited against another claim or another alternative in the same claim because it has an earlier effective date.

Rule 64.1(a), (b)
GL/ISPE 11.24-11.26

Rule 20.5

If the applicant subsequently furnishes missing parts of the description, parts of the claims or all or parts of the drawings under Rule 20.5, the international filing date is the date on which the purported international application is completed by the furnishing of the missing parts, unless the missing parts are completely contained in the priority document and the requirements given in Rule 20.6 are satisfied, in which case the original filing date is maintained. The date of the application as a whole is thus either the date on which the missing parts are received or the original filing date (see GL/PCT-EPO C-III, 2, and GL/PCT-EPO H-II, 2.2.2).

Rule 20.5bis

If the applicant subsequently furnishes (a) correct element(s) (an element being the description or the claims) or correct parts of the description, parts of the claims or all or parts of the drawings under Rule 20.5*bis*, the international filing date is the date on which the purported international application is corrected by the furnishing of the correct elements or parts, unless the correct elements or parts are completely contained in the priority document and the requirements given in Rule 20.6 are satisfied, in which case the original filing date is maintained. The date of the application as a whole is thus either the date on which the correct elements or parts are received or the original filing date (see GL/PCT-EPO C-III, 2, and GL/PCT-EPO H-II, 2.2.2).

4. Documents in a non-official language of the (S)ISA or IPEA

Where applicants

(i) dispute the relevance of a document in a non-official language cited in the search report (for procedure at the search stage, see GL/PCT-EPO B-X, 9.1.2 and 9.1.3), and

(ii) give specific reasons,

examiners should consider whether, in the light of these reasons and of the other prior art available to them, they are justified in pursuing the matter. If so, they should obtain a translation of the document (or merely the relevant part of it if that can be easily identified). If they remain of the view that the document is relevant, they should send a copy of the translation to the applicant with the next communication in the PCT Chapter II phase.

4.1 Machine translations

In order to overcome the language barrier constituted by a document in an unfamiliar non-official language, it might be appropriate for the examiner to rely on a machine translation of the document, which should be sent to the applicant. If only part of the translated document is relevant, the particular passage relied upon should be identified. A translation has to serve the purpose of rendering the meaning of the text in a familiar language. Therefore mere grammatical or syntactical errors which have no impact on the possibility of understanding the content do not hinder its qualification as a translation.

A general statement that machine translations as such cannot be trusted is not sufficient to contest the value of the translation. If the applicant objects to the use of a specific machine translation, the applicant bears the burden of

adducing evidence (in the form of, for instance, an improved translation of the whole or salient parts of the document) showing the extent to which the quality of the machine translation is defective and should therefore not be relied upon.

When the applicant provides substantiated reasoning for questioning the objections raised based on the translated text, the examiner will have to take these reasons into account, similarly to when the publication date is questioned.

5. Conflict with other applications

5.1 Prior art pursuant to Rules 33.1(c) and 64.3

Under the PCT, the prior art does not comprise the content of other applications filed or validly claiming a priority date earlier than – but published on or after – the date of filing or valid date of priority of the application being examined. However, attention must be drawn to such applications in the international search report and, where applicable, the preliminary examination report, as they may become relevant under Article 54(3) EPC (see also GL/PCT-EPO B-XI, 4.3). By the "content" of an application is meant the whole disclosure, i.e. the description, drawings and claims, including:

GL/ISPE 11.07-11.09
Rule 33.1(c),
Rule 64.3,
Rule 70.10

(i) any matter explicitly disclaimed (with the exception of disclaimers for unworkable embodiments);

(ii) any matter for which an allowable reference (see GL/EPO F-III, 8, 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 international application).

5.2 Co-pending applications

The PCT does not deal explicitly with the case of co-pending international applications of the same applicant of the same effective date, see ISPE Guidelines 11.10.

6. Prior art made available to the public anywhere in the world by non-written disclosure

A non-written disclosure is not considered part of the prior art for the purposes of Art. 33(2) and (3) if the date of that non-written disclosure is indicated in a written disclosure which has been made available to the public on or after the relevant date of the application (i.e. on or after the international filing date or, if a priority has been validly claimed, the earliest priority date).

Rule 33.1(b),
Rule 64.2
GL/ISPE 11.22

6.1 Types of non-written disclosure, in particular use, and instances of prior art made available in any other way

Making available to the public may occur by means of an oral disclosure, use, exhibition or other non-written means. Use may be constituted by producing, offering, marketing or otherwise exploiting a product, or by

Rule 33.1(b),
Rule 64.2

offering or marketing a process or its application or by applying the process. Marketing may be effected, for example, by sale or exchange.

Prior art may also be made available to the public in other ways, as for example by demonstrating an object or process in specialist training courses or on television.

Availability to the public in any other way also includes all possibilities which technological progress may subsequently offer of making available the aspect of the prior art concerned.

It should be borne in mind that for the purposes of the international search and the international preliminary examination a non-written disclosure is to be considered part of the prior art for the purposes of Art. 33(2) and (3) only if its content is confirmed by a written disclosure that was made available to the public earlier than the relevant date as defined by Rule 64.1(b).

6.2 Matters to be determined as regards use

Rule 33.1(b), Rule 64.2

When the ISA or the IPEA has gained knowledge of an object or process that has been used in such a way that it is comprised in the prior art (e.g. by a third party, see GL/PCT-EPO E-II, ISPE Guidelines 16.57 and PCT/AI section 801), the following details have to be determined:

(i) whether there is a written disclosure that was made available to the public earlier than the relevant date as defined by Rule 64.1(b) which confirms the use of the object or the process;

(ii) the date on which an alleged use occurred, i.e. whether there was any instance of use before the relevant date (prior use);

(iii) what has been used, in order to determine the degree of similarity between the object used and the subject-matter of the application; and

(iv) all the circumstances relating to the use, in order to determine whether and to what extent it was made available to the public, as for example the place of use and the form of use. These factors are important in that, for example, the details of a demonstration of a manufacturing process in a factory or of the delivery and sale of a product may well provide information as regards the possibility of the subject-matter having become available to the public.

6.2.1 General principles

Subject-matter should be regarded as made available to the public by use or in any other way if, at the relevant date, it was possible for members of the public to gain knowledge of the subject-matter and there was no bar of confidentiality restricting the use or dissemination of such knowledge. This may, for example, arise if an object is unconditionally sold to a member of the public, since the buyer thereby acquires unlimited possession of any knowledge which may be obtained from the object. Even where in such cases the specific features of the object may not be ascertained from an external examination, but only by further analysis, those features are nevertheless to be considered as having been made available to the public.

This is irrespective of whether or not particular reasons can be identified for analysing the composition or internal structure of the object. These specific features only relate to the intrinsic features. Extrinsic characteristics, which are only revealed when the product is exposed to interaction with specifically chosen outside conditions, e.g. reactants or the like, in order to provide a particular effect or result or to discover potential results or capabilities, therefore point beyond the product *per se* as they are dependent on deliberate choices being made. Typical examples are the first or further application as a pharmaceutical product of a known substance or composition and the use of a known compound for a particular purpose, based on a new technical effect. Thus, such characteristics cannot be considered as already having been made available to the public.

If, on the other hand, an object could be seen in a given place (a factory, for example) to which members of the public not bound to secrecy, including persons with sufficient technical knowledge to ascertain the specific features of the object, had access, all knowledge which an expert was able to gain from a purely external examination is to be regarded as having been made available to the public. In such cases, however, all concealed features which could be ascertained only by dismantling or destroying the object will not be deemed to have been made available to the public.

6.2.2 Agreement on secrecy

GL/EPO G-IV, 7.2.2

The basic principle to be adopted is that subject-matter has not been made available to the public by use or in any other way if there is an express or tacit agreement on secrecy which has not been broken, or if the circumstances of the case are such that such secrecy derives from a relationship of good faith or trust. Good faith and trust are factors which may occur in contractual or commercial relationships.

6.2.3 Use on non-public property

As a general rule, use on non-public property, for example in factories and barracks, is not considered as use made available to the public, because company employees and soldiers are usually bound to secrecy, save in cases where the objects or processes used are exhibited, explained or shown to the public in such places, or where specialists not bound to secrecy are able to recognise their essential features from the outside. Clearly the above-mentioned "non-public property" does not refer to the premises of a third party to whom the object in question was unconditionally sold or the place where the public could see the object in question or ascertain features of it.

6.2.4 Example of the accessibility of objects used

A press for producing light building (hard fibre) boards was installed in a factory shed. Although the door bore the notice "Unauthorised persons not admitted", customers (in particular dealers in building materials and clients who were interested in purchasing light building boards) were given the opportunity of seeing the press although no form of demonstration or explanation was given. An obligation to secrecy was not imposed as, according to witnesses, the company did not consider such visitors as a possible source of competition. These visitors were not genuine specialists, i.e. they did not manufacture such boards or presses, but were not entirely

laymen either. In view of the simple construction of the press, the essential features of the invention concerned were bound to be evident to anyone observing it. There was therefore a possibility that these customers, and in particular the dealers in building materials, would recognise these essential features of the press and, as they were not bound to secrecy, they would be free to communicate this information to others.

6.2.5 Example of the inaccessibility of a process

The subject of the patent concerns a process for the manufacture of a product. As proof that this process had been made available to the public by use, a similar already known product was asserted to have been produced by the process claimed. However, it could not be clearly ascertained, even after an exhaustive examination, by which process it had been produced.

6.3 Prior art made available by means of oral description

Rule 33.1(b), Rule 64.2, Rule 70.9 GL/ISPE 11.22

If the prior art was made available to the public by an oral description before the relevant date (i.e. the date of filing of the application or, if applicable, the date of the earliest validly claimed priority) but a document which reproduces the oral description was only published on or after that relevant date, the ISR and the IPER draw attention to this non-written disclosure in the manner provided for in Rule 70.9 (Rules 33.1(b) and 64.2).

6.4 Internet disclosures

GL/ISPE 11.13-11.20

As a matter of principle, disclosures on the internet form part of the prior art. Information disclosed on the internet or in online databases is considered to be publicly available as of the date the information was publicly posted. Internet websites often contain highly relevant technical information. Certain information may even be available only on the internet from such websites. This includes, for example, online manuals and tutorials for software products (such as video games) or other products with a short life cycle.

As regards establishing the publication date and the standard and burden of proof, in particular with technical journals or "print equivalent" publications, the principles as laid down in the Guidelines for Examination in the EPO (GL/EPO G-IV, 7.5.1-7.5.6) apply *mutatis mutandis*.

6.5 Standards and standard preparatory documents

The principles as laid down in the Guidelines for Examination in the EPO (GL/EPO G-IV, 7.6) apply *mutatis mutandis*.

7. Cross-references between prior-art documents

If a document (the "primary" document) refers explicitly to another document (the "secondary" document) as providing more detailed information on certain features, the teaching of the latter is to be regarded as incorporated into the primary document if the document was available to the public on the publication date of the primary document. The relevant date for novelty purposes, however, is always the date of the primary document.

8. Errors in prior-art documents

~~Errors may exist in prior-art documents.~~

~~When a potential error is detected, three situations may arise depending on whether the skilled person, using general knowledge,~~

~~(i) can immediately see that the document contains an error and immediately identify what the only possible correction should be;~~

~~(ii) can immediately see that the document contains an error, but is able to identify more than one possible correction; or~~

~~(iii) cannot immediately recognise that an error has occurred.~~

~~When assessing the relevance of a document to patentability,~~

~~in case (i), the disclosure is considered to contain the correction;~~

~~in case (ii), the disclosure of the passage containing the error is not taken into account;~~

~~in case (iii), the disclosure is taken into account as is.~~The principles as laid down in the Guidelines for Examination in the EPO (GL/EPO G-IV, 9) apply *mutatis mutandis*.

Chapter V – Non-prejudicial disclosures

1. General

GL/ISPE 16.76
PCT/AI Section 215
Rule 4.17(v)

The PCT acknowledges that in certain cases the invention may have been disclosed before the relevant date for the purposes of the PCT in such a way that it is not considered to form part of the prior art in accordance with the national law of one or more designated Offices (Rule 51*bis*.1(a)(v)).

Therefore, it should be borne in mind that, upon validly entering the regional phase before the EPO, the standards for non-prejudicial disclosures as laid down in Article 55(1) EPC will be applied.

Consequently, the principles as laid down in Chapter G-V of the Guidelines for Examination in the EPO apply *mutatis mutandis*.

Chapter VI – Novelty

1. Prior art pursuant to Art. 33(2)

Under the PCT, an invention is considered to be novel if it is not anticipated by the prior art. Everything which is made available to the public anywhere in the world by means of a written disclosure is considered prior art provided that such making available occurred prior to the relevant date. In cases where the making available to the public occurred by non-written means, it constitutes prior art only if a written disclosure that occurred before the relevant date confirms the non-written disclosure. The relevant date is the international filing date or, where at least one priority has been validly claimed, the date of the earliest priority. It should be noted that in considering novelty (as distinct from inventive step), 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, see also ISPE Guidelines 12.06.

Art. 33(2)
Rule 43bis.1(a)(i),
Rule 64.1, Rule 64.2
GL/ISPE 12.01, 12.02

For the specific case of selection inventions see ISPE Guidelines 12.10.

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.

GL/ISPE 12.06

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 inventive step.

GL/ISPE 12.04

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. For the purpose of assessing novelty the "relevant" date for written disclosures is the date as defined by Rule 64.1(b), i.e. either the international filing date of the application under consideration or, if a priority has been validly claimed, the application date of that earlier application (if the filing date of the application is within the two-month period after the expiry of the priority period of the earlier application, the relevant date is also the application date of that earlier application); for non-written disclosures see Rules 33.1(b) and 64.2.

Rule 64.1, Rule 64.2,
Rule 33.1(b)

4. Enabling disclosure of a prior document

Rule 33, Rule 64
GL/ISPE 12.02

Subject-matter described in a document can only be regarded as having been made available to the public, and therefore as comprised in the prior art pursuant to Rules 33 and 64, if the information given therein to the skilled person is sufficient to enable them, at the relevant date of the document, 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 them.

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.

The EPO applies option A12.02[1] of the Appendix to Chapter 12 of the ISPE Guidelines.

5. Generic disclosure and specific examples

GL/ISPE 12.08, 12.09

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.

6. Implicit disclosure and parameters

GL/ISPE 12.04

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. Situations of this kind may also occur when the claims define the invention, or a feature thereof, by parameters. 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. The burden of proof for an alleged distinguishing feature lies with the applicant. No benefit of doubt can be accorded if the applicant does not provide evidence in support of the allegations. If, on the other hand, 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. 5).

7. Examination of novelty

GL/ISPE 12.05

In determining novelty of the subject-matter of claims, the examiner should remember that, particularly for claims directed to a physical entity, non-distinctive characteristics of a particular intended use should be disregarded. 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.

A known compound is not rendered novel merely because it is available with a different degree of purity if the purity can be achieved by conventional means.

7.1 Second or further medical use of known pharmaceutical products

How the novelty of second or further medical use claims is assessed depends on the IPEA. The examiner at the EPO as IPEA examines the novelty of the subject-matter in view of the entry into the regional phase before the EPO and therefore will apply the principles as laid down in GL/EPO G-VI, 7.1 and subsections. See GL/PCT-EPO B-VIII, 2.1, for the treatment of medical use claims by the EPO as ISA.

7.2 Second non-medical use

A claim to the use of a known compound for a particular purpose (second non-medical use) which is based on a technical effect will be interpreted by the EPO examiner as including that technical effect as a functional technical feature. The novelty of the use of the known compound for the known production of a known product cannot be deduced from a new property of the produced product. In such a case, the use of a compound for the production of a product will be interpreted as a process for production of the product with the compound. Therefore, it can be regarded as novel only if the process of production as such is novel.

8. Selection inventions

GL/ISPE 12.10

Selection inventions deal with the selection of individual elements, subsets, or subranges, which have not been explicitly mentioned, within a larger known set or range. The examiner of the EPO as IPEA will assess the novelty of the subject-matter according to the principles laid down in GL/EPO G-VI, 8 and subsection.

9. Novelty of "reach-through" claims

"Reach-through" claims are defined as claims attempting to obtain protection for a chemical product (and also uses thereof, compositions thereof, etc.) by defining that product functionally in terms of its action (e.g. agonist, antagonist) on a biological target such as an enzyme or receptor. In many such cases, the applicant functionally defines chemical compounds in this way by reference to a newly identified biological target. However, compounds which bind to and exercise this action on that biological target are not necessarily novel compounds simply because the biological target which they act on is new. Indeed in many cases, applicants themselves provide test results in the application whereby known compounds are shown to exert this

action on the new biological target, thus demonstrating that compounds falling within the functional definition of the "reach-through" claim are known in the prior art and so establishing that a reach-through claim relating to compounds defined in this way lacks novelty.

Chapter VII – Inventive step

1. General

An invention is considered to involve an inventive step if, having regard to the prior the art, it is not obvious to a person skilled in the art. Novelty and inventive step are different criteria. The question of whether there is inventive step only arises if the invention is novel.

Art. 33(3)
GL/ISPE 13.01

2. Prior art; date of filing, date of priority

The "prior art" for the purposes of considering inventive step is as defined in Art. 33(3).

GL/ISPE 13.02

In determining what is to be considered prior art, the principles laid down in GL/PCT-EPO G-IV apply.

3. Person skilled in the art

The "person skilled in the art" should be presumed to be a skilled practitioner in the relevant field of technology, who possesses average knowledge and ability and is aware of what was common general knowledge in the art at the relevant date. They should also be presumed to have had access to everything in the "prior art", in particular the documents cited in the search report, and to have had at their disposal the means and capacity for routine work and experimentation which are normal for the field of technology in question. If the problem prompts the person skilled in the art to seek its solution in another technical field, the specialist in that field is the person qualified to solve the problem. The skilled person is involved in constant development in their technical field.

GL/ISPE 13.11

3.1 Common general knowledge of the skilled person

Section G-VII, 3.1, in the Guidelines for Examination in the EPO applies *mutatis mutandis*.

4. Obviousness

Thus the question to consider, in relation to any claim defining the invention, is whether before the filing or priority date valid for that claim, having regard to the art known at the time, it would have been obvious to the person skilled in the art to arrive at something falling within the terms of the claim. If so, the claim is not allowable for lack of inventive step. The term "obvious" means that which does not go beyond the normal progress of technology but merely follows plainly or logically from the prior art, i.e. something which does not involve the exercise of any skill or ability beyond that to be expected of the person skilled in the art. In considering inventive step, as distinct from novelty, it is fair to construe any published document in the light of knowledge up to and including the day before the relevant date according to Rule 65.2 for the claimed invention and to have regard to all the knowledge generally available to the person skilled in the art up to and including that day.

Rule 65.1
GL/ISPE 13.03,
GL/ISPE 13.09,
GL/ISPE 13.10

5. Problem-solution approach

In order to render the assessment of inventive step more objective, the EPO applies the so-called **"problem-solution approach"**, which should be applied consistently.

GL/ISPE 13.08,
GL/ISPE A13.08.1-
GL/ISPE A13.08.9

In the problem-solution approach, there are three main stages:

(i) determining the "closest prior art",

(ii) establishing the "objective technical problem" to be solved, and

(iii) considering whether or not the claimed invention, starting from the closest prior art and the objective technical problem, would have been obvious to the skilled person.

The EPO applies option A13.08.1 of the Appendix to Chapter 13 of the ISPE Guidelines.

5.1 Determination of the closest prior art

GL/ISPE 13.10, GL/ISPE A13.08.2

Generally, the principles laid down in section G-VII, 5.1, in the Guidelines for Examination in the EPO apply *mutatis mutandis*. The closest prior art is that which in one single reference discloses the combination of features which constitutes the most promising starting point for a development leading to the invention. In selecting the closest prior art, the first consideration is that it should be directed to a similar purpose or effect as the invention or at least belong to the same or a closely related technical field as the claimed invention. In practice, the closest prior art is generally that which corresponds to a similar use and requires the minimum of structural and functional modifications to arrive at the claimed invention.

5.2 Formulation of the objective technical problem

GL/ISPE A13.08.3-GL/ISPE A13.08.7

In the second stage, the examiner establishes in an objective way the **technical problem** to be solved. The method to do so is to study the application (or the patent), the closest prior art and the difference (also called "the **distinguishing feature(s)**" of the claimed invention) in terms of features (either structural or functional) between the claimed invention and the closest prior art, identify the technical effect resulting from the distinguishing features, and then formulate the technical problem.

The objective technical problem derived in this way may not be what the applicant presented as "the problem" in the application. The latter may require reformulation, since the objective technical problem is based on objectively established facts, in particular appearing in the prior art revealed in the course of the proceedings, which may be different from the prior art of which the applicant was actually aware at the time the application was filed. In particular, the prior art cited in the search report may put the invention in an entirely different perspective from that apparent from reading the application only. Reformulation might lead to the objective technical problem being less ambitious than originally envisaged by the application.

Section G-VII, 5.2, in the Guidelines for Examination in the EPO applies *mutatis mutandis*.

5.3 Could-would approach

GL/ISPE A13.08.8, GL/ISPE A13.08.9

In the third stage the question to be answered is whether there is any teaching in the prior art as a whole that **would** (not simply could, but would) have prompted the skilled person, faced with the objective technical problem,

to modify or adapt the closest prior art while taking account of that teaching, thereby arriving at something falling within the terms of the claims, and thus achieving what the invention achieves.

5.4 Claims comprising technical and non-technical features

Section G-VII, 5.4, in the Guidelines for Examination in the EPO applies *mutatis mutandis*.

5.4.1 Formulation of the objective technical problem for claims comprising technical and non-technical features

Section G-VII, 5.4.1, in the Guidelines for Examination in the EPO applies *mutatis mutandis*.

5.4.2 Examples of applying the steps listed in GL/EPO G-VII, 5.4

Illustrative examples can be found in section G-VII, 5.4.2, and subsections G-VII, 5.4.2.1 to G-VII, 5.4.2.5, in the Guidelines for Examination in the EPO.

6. Combining pieces of prior art

In the context of the problem-solution approach, it is permissible to combine the disclosure of one or more documents, parts of documents or other pieces of prior art (e.g. a public prior use or unwritten general technical knowledge) with the closest prior art. However, the fact that more than one disclosure must be combined with the closest prior art in order to arrive at a combination of features may be an indication of the presence of an inventive step, e.g. if the claimed invention is not a mere aggregation of features.

Rule 65.1
GL/ISPE 13.12,
GL/ISPE 13.13

Section G-VII, 6, in the Guidelines for Examination in the EPO applies *mutatis mutandis*.

7. Combination vs. juxtaposition or aggregation

The invention claimed must normally be considered as a whole. When a claim consists of a "combination of features", it is not correct to argue that the separate features of the combination taken by themselves are known or obvious and that "therefore" the whole subject-matter claimed is obvious. However, where the claim is merely an "aggregation or juxtaposition of features" and not a true combination, it is enough to show that the individual features are obvious to prove that the aggregation of features does not involve an inventive step.

GL/ISPE 13.05,
GL/ISPE 13.14(c), (d)

8. *Ex post facto* analysis

It should be remembered that an invention which at first sight appears obvious might in fact involve an inventive step. Once a new idea has been formulated, it can often be shown theoretically how it might be arrived at, starting from something known, by a series of apparently easy steps. Examiners should be wary of *ex post facto* analysis of this kind. When combining documents cited in the search report, they should always bear in mind that the documents produced in the search have, of necessity, been obtained with foreknowledge of what matter constitutes the alleged invention. In all cases they should attempt to visualise the overall state of the art confronting the skilled person before the applicant's contribution, and should seek to make a "real-life" assessment of this and other relevant factors. They

GL/ISPE 13.15

should take into account all that is known concerning the background of the invention and give fair weight to relevant arguments or evidence submitted by the applicant, without the benefit of hindsight.

9. Origin of an invention

While the claim should in each case be directed to technical features (and not, for example, merely to an idea), in order to assess whether an inventive step is present it is important for the examiner to bear in mind that an invention may, for example, be based on the following:

(i) the devising of a solution to a known problem;

(ii) the arrival at an insight into the cause of an observed phenomenon (the practical use of this phenomenon then being obvious).

Many inventions are of course based on a combination of the above possibilities - e.g. the arrival at an insight and the technical application of that insight may both involve the use of the inventive faculty.

10. Secondary indicators

10.1 Predictable disadvantage; non-functional modification; arbitrary choice

Section G-VII, 10.1, in the Guidelines for Examination in the EPO applies *mutatis mutandis*.

10.2 Unexpected technical effect; bonus effect

Section G-VII, 10.2, in the Guidelines for Examination in the EPO applies *mutatis mutandis*.

10.3 Long felt need; commercial success

See ISPE Guidelines 13.16-13.18.

11. Arguments and evidence submitted by the applicant

Section G-VII, 11, in the Guidelines for Examination in the EPO applies *mutatis mutandis*.

12. Selection inventions

Generally, the principles laid down in section G-VII, 12, in the Guidelines for Examination in the EPO apply *mutatis mutandis*. The subject-matter of selection inventions differs from the closest prior art in that it represents selected sub-sets or sub-ranges. If this selection is connected to a particular technical effect, and if no hints exist leading the skilled person to the selection, then an inventive step is accepted (this technical effect occurring within the selected range may also be the same effect as attained with the broader known range, but to an unexpected degree). The criterion of "seriously contemplating" mentioned in connection with the test for novelty of overlapping ranges should not be confused with the assessment of inventive step. For inventive step, it has to be considered whether the skilled person would have made the selection or would have chosen the overlapping range in the hope of solving the underlying technical problem or in expectation of

some improvement or advantage. If the answer is negative, then the claimed matter involves an inventive step.

The unexpected technical effect must apply to the entire range as claimed. If it occurs in only part of the claimed range, the claimed subject-matter does not solve the specific problem to which the effect relates, but only the more general problem of obtaining, for example, "a further product X" or "a further process Y".

13. Dependent claims; claims in different categories

See ISPE Guidelines 13.19.

14. Examples

See ISPE Guidelines 13.14.