**WIPO Note C 8728:**

Pursuant to the decision of the *Standing Committee on the Law of Patents* (SCP), at its twenty-seventh session which was held in Geneva from December 11 to 15, 2017, (document SCP/27/9, paragraph 25), Member States and Regional Patent Offices are kindly invited to send to the International Bureau of the World Intellectual Property Organization (WIPO) the following information:

(i) any additional inputs for the preparation of the second draft reference document on exception regarding acts for obtaining regulatory approval from authorities. The inputs may relate to, for example, challenges faced by Member States in implementing the exception and the results of the national/regional implementation; and

(ii) examination guidelines/manuals and summary of the most important case law or interpretive decisions concerning the topics suggested, *inter alia*, in paragraph 8 of document SCP/24/3 (Proposal by the Delegation of Spain) for the preparation of a further study on inventive step. Please provide references to those materials and decisions for the Secretariat to access, if necessary.

**Ad (ii)**

Whether or not the invention involves an inventive step always depends on the specific individual case. In Germany, the assessment whether an invention is based on an inventive step as required under Sec. 4 Patent Act is guided by case law, that is, decisions by the Federal Court of Justice (Bundesgerichtshof, BGH), or the Federal Patent Court (Bundespatentgericht, BPatG). In the following, a non-exhaustive list of recent interpretive decisions by the BGH is given with respect to, *inter alia*, the topics suggested in paragraph 8 of document SCP/24/3, including a brief summary to each topic.

[Abbreviations used in references list: GRUR: Gewerblicher Rechtsschutz und Urheberrecht (journal); BlPMZ: Blatt für Patent-, Muster- und Zeichenwesen (journal); IBRRS: Case law database (available via beck-online: URL: https://beck-online.beck.de/Home)]

- General aspects: person skilled in the art, technical problem, obviousness, relevant state of the art

*Person skilled in the art, state of the art*: When assessing the inventive step, the evaluation of the development work to be carried out for a patentable invention depends on what knowledge and skills can be expected from an average skilled person entrusted with development work in the respective technical field. (1). In this respect, a skilled person must be expected to consider neighbouring technical fields, if necessary by consulting a skilled person in the other field. (2-5). This may even include a team of skilled persons whose joint

expertise is used as a basis. (6). The adoption of solutions in neighbouring fields is not jeopardised by considerable differences in detail if, in principle, solutions are to be expected (7).

*Technical problem of the invention*: The objective technical problem of the invention results from the state of the art known at the filing date or priority date. It must be formulated so neutrally that the question as to what suggestions the skilled person derived from prior art arises exclusively during the examination of the inventive step. (8). [cf. Problem inventions]

An invention may involve several different technical problems. In such constellations, the individual problems must first be considered separately during the examination of patentability. Patentability must possibly have to be denied if mastering one of these problems has been part of the tasks of the skilled person and, from this starting point, the claimed invention was obvious due to the state of the art. (9-11).

*Obviousness*: Finding a new technical teaching cannot be regarded as obvious merely because no obstacles arise when moving from what is known in prior art to the subject matter of this teaching. The skilled person must therefore not only be able (“could”) to apply a new path to a solution, but the skilled person must also have a concrete motivation ("would") to actually follow the new path to a solution. This evaluation requires that the known solutions gave the expert cause or prompting to arrive at the proposed teaching. In the absence of such motivation, the subject matter of the application must be considered to involve an inventive step (12-14).

An overall view of the individual case is required in order to answer the question as to what extent and with what level of concretisation the expert needs prior art suggestions in order to further develop a known solution in a certain way. In this context, the characteristics of the technical field in question, in particular with regard to the training of skilled persons may play a role as well as the usual approach to the development of innovations, technical needs arising from the construction or application of the subject matter in question and also non-technical specifications (14, 15).

*Starting point of the invention:* It does not necessarily always have to be just one alternative action that is obvious. Rather, depending on the circumstances of the field of technology concerned, there may be different options for the skilled person to proceed further and, accordingly, the pursuit of different paths to a solution may be obvious (8, 16).

The choice of a certain starting point (or even several starting points) requires a special justification, which is usually to be derived from the effort of the skilled person to find a better - or even only a different - solution for a certain purpose than the state of the art provides. For the assessment of the question whether a certain starting point was obvious for the skilled person, it is basically irrelevant whether other starting points might be considered as even more obvious. Therefore, when assessing the obviousness of a subject matter protected by a patent, it is not always possible to take the "closest" prior art as the sole starting point (17-20).

References: (1) BGH, X ZR 166/97 (2000) – Warenregal; (2) BGH, Ia ZR 34/63 (1963) – Wimpernfärbestift; (3) BGH, X ZR 60/75 (1977) – Börsenbügel, GRUR 1978, 37; (4) BGH (1988) – Gurtumlenkung, BlPMZ 1989, 133; (5) BGH, X ZR 169/07 (2009) – Diodenbeleuchtung, GRUR 2010, 41; (6) BGH X ZR 78/09 (2012) – Pfeffersäckchen, GRUR 2012, 482; (7) BGH, X ZR 49/09 (2010) – Ziehmaschinenzugeinheit II, GRUR 2010, 992; (8) BGH, X ZR 128/09 (2014) – Repaglinid, GRUR 2015, 356; (9) BGH, X ZR 72/08 (2011) – Kosmetisches Sonnenschutzmittel III, GRUR 2011, 607; (10) BGH, X ZR 200/99 (2003) – Hochdruckreiniger, GRUR 2003, 693; (11) BGH, X ZR 41/13 (2015) – Quetiapin, GRUR 2015, 352; (12) BGH, Xa ZR 92/05 (2009) – Betrieb einer Sicherheitseinrichtung, GRUR 2009, 746; (13) BGH, X ZR 65/05 (2009) – Einteilige Öse, GRUR 2009, 746; (14) BGH, X ZB 6/10 (2011) – Installiereinrichtung II, GRUR 2012, 378; (15) BGH, X ZR 10/10 (2012) – Kniehebelklemmvorrichtung, GRUR 2013, 160; (16) BGH, X ZR 56/03 (2007) – Injizierbarer Mikroschaum, GRUR 2008, 56; (17) BGH, X ZR 89/07 (2008), GRUR 2009, 382 – Olanzapin; (18) BGH, Xa ZR 138/05 (2009) – Fischbissanzeiger, GRUR 2009, 1039; (19) BGH, X ZR 78/14 (2016) – Opto-Bauelement, GRUR 2017, 148; (20) BGH, X ZR 109/15 (2017) – Spinfrequenz.

- Common general knowledge

The fact that knowledge of a technical fact is part of common general knowledge does not in itself mean that it was obvious for a skilled person to use this knowledge to solve a specific technical problem (1). As a rule, therefore, the application of a measure from the specialist knowledge also requires a motivation.

However, in the case of the application of a measure from the standard repertoire, which the skilled person would regularly consider in a large number of applications as a general means for the further development of existing systems, the existence of such a motivation can usually be assumed without further evidence. An average skilled person can also be

expected to geometrically design an object produced of a modified material to make optimum use of the properties of the chosen material. However, there must not be any obstacles (including difficulties) (2-6).

If the skilled person had to carry out several steps to find the subject matter of the invention for which he did not derive any prior art suggestion, it is also essential whether the whole work was routine or whether the skilled person had encountered difficulties, e.g. because alternatives existed to one or more steps, which lead to different results (7).

References: (1) BGH, Xa ZR 56/05 (2009) – Airbag-Auslösesteuerung, GRUR 2009, 743; (2) BGH X ZR 79/09 (2010) – Fugenglätter, GRUR 2010, 814; (3) BGH, X ZR 139/10 (2014) – Farbversorgungssystem, GRUR 2014, 647; (4) BGH, X ZB 5/13 (2014) – Kollagenase I, GRUR 2014, 461; (5) BGH, X ZB 6/13 (2014) – Kollagenase II, GRUR 2014, 464; (6) BGH, X ZR 109/15 (2017) – Spinfrequenz; (7) BGH, X ZR 24/03 (2006) – Mikrotom, GRUR 2006, 930.

- Combination: juxtaposition vs synergic effects

A combination of features does not involve an inventive step if the state of the art did not prompt the average skilled person to make precisely these features interact. The obviousness of individual features does not in itself substantiate the obviousness of their combination. (1-3). Therefore, the examination must refer to the obviousness of the proposed combination and must not be limited to the evaluation of the individual features or sub-combinations. (4-6).

No inventive step is involved if the average skilled person too would have combined the features. However, an inventive step is involved if the skilled person would only potentially have arrived at the invention. Inventive step was thus confirmed when a combination of two different solutions, which have proved effective in practice, is proposed and a particular advantage is achieved through it. However, an inventive step cannot be assumed if the invention merely consists of the expert addition of the effects of the features. (7). Likewise, an arbitrary, mosaic-like composition of features is generally regarded as obvious to the skilled person. (8).

References: (1) BGH, X ZR 87/65 (1968) – Betondosierer, GRUR 1969, 182; (2) BGH, X ZR 62/79 (1981) – Kautschukrohlinge, GRUR 1981, 736; (3) BGH, X ZR 115/96 (1998) – Stoßwellen-Lithotripter, GRUR 1999, 145; (4) BGH, X ZB 9/79 (1980) – Tomograph, GRUR

1980, 984; (5) BGH, X ZR 46/78 (1981) – piezoelektrisches Feuerzeug, GRUR 1981, 341; (6) BGH, X ZR 19/79 (1981) – First- und Gratabdeckung, GRUR 1981, 732; (7) BGH, I ZR 117/54 (1956) – Wasch- und Bleichmittel, GRUR 1956, 317; (8) BGH (1963) – Schutzkontaktstecker, BlPMZ 1963, 365.

- The danger of hindsight analysis

Only the level of knowledge at the filing date or priority date relevant as the date of comparison can be attributed to the skilled person. All specialist knowledge that was only created after that date must be disregarded. A retrospective analysis of the state of the art from the viewpoint of the invention (ex-poste analysis) is not permitted. In a comparison with the state of the arte, knowledge gained from the invention must not be interpreted as part of the state of the art. (1-3).

References: (1) BGH, X ZR 14/77 (1979) – Bodenkehrmaschine, GRUR 1980, 100; (2) BGH, X ZR 95/87 (1989) – Sauerteig, GRUR 1989, 899; (3) BGH, X ZR 107/12 (2014) – Kommunikationskanal, GRUR 2014, 542.

- Secondary indicia

General: Secondary indicia themselves can neither establish nor replace an inventive step. (1, 2). Only in individual cases can they give cause for an assessment of solutions known in prior art to determine whether, against the background of the common general knowledge, they actually provide sufficient evidence of the obviousness of the subject matter of the invention or whether it is only in an ex post view that they seem to contain a suggestion leading to the invention. (3).

*Technical progress*: The patentability of the subject matter does not depend on whether it entails technical progress or offers a discernible advantage. It is sufficient if it describes another (non-obvious) path in comparison to the state of the art (4). However, if technical progress is to be used as an indication of inventive step, only such progress can be considered for assessment which promotes technology in a particular way. If the teaching as such was obvious, then a great technical progress achieved by it is also obvious (5, 6).

*Prejudices, vain attempts*: If, in view of the many and varied previous efforts in a narrow technical field, only limited progress was to be expected at the time of filing the application, a considerable improvement in the state of the art may indicate the non-obviousness of the

invention (7). However, this is not the case if the inventor has just encountered a negative attitude when introducing his teaching into practice, but it is the case if the prejudice was general (8).

*Expectation of success*: Patentability must be denied not only for the "closest" approach to solve a problem, but for any solution to a technical problem that is obvious to a skilled person and which he at least considers on the basis of a reasonable expectation of success. (9, 10).

It does not depend solely on the probability of success whether a prospect of success can be regarded as sufficient for regarding the pursuit of a certain path to a solution as obvious. The urgency of resolving the technical problem and its expected technical or economic benefit must be taken into account, as must the time, cost and effort of the work required, the lack of alternatives, the nature, scope and effects of difficulties which may arise along the path to the solution to be followed and, finally, the risk that such difficulties make attaining the goal considerably more difficult or the goal unattainable (11-13).

*Economic success*: A great market success may be a secondary consideration to be included in the assessment of inventive step if it is based on a sudden major enhancement of the state of the art, but not if it is due to successful marketing (1). The economic success of a product can only be used as an indication of inventive step to the extent that it is based on technical causes (3, 14).

*Simplification, cost reduction*: The fact that, before the filing date or priority date, no skilled person found the solution, which is disclosed in an application, for producing a (known) mass article in a new, simpler and cheaper way, although there has long been a need for it, justifies the assumption that an inventive step is involved. (15).

*Legal provisions*: Legal provisions may provide a motivation to apply a particular measure. For example, if the relevant legal provisions explicitly emphasise an individual measure and declare it admissible, there is, as a rule, a motivation for a skilled person to consider this measure in the case of related problems (16).

*Technical standards*: When a data structure provided for in an international standard is selectively improved, the skilled person has usually been prompted to resort to mechanisms already provided for in the standard in order to solve the technical problem (17). A motivation for the further development of a technical standard can also arise, in particular, from the gaps it contains that have to be filled in (18). On the other hand, the fact that a path to a solution

was only given in an earlier version of a technical standard, but was not pursued further in a later version, does not automatically lead to the assumption that this path to the solution is to be regarded as non-obvious. (19).

*Lapse of time*: If a long period of time has passed up to the invention and the expert community has already been trying to find a solution for a long time or has accepted disadvantages that the invention avoids, this circumstance may be indicative of inventive step. The fact that the skilled person considered a certain citation as a possible starting point for a further development must therefore not be concluded solely from the technical closeness to the inventive solution, especially in the case of the very old state of the art at the time of priority. However, if a technical solution known for many years already contains all the essential elements of the invention, it can be assumed that the skilled person also would have considered them on the filing date or priority date (15, 20-22).

If a citation is old, but the need to solve the problem of the invention is recent, then only the time period from the emergence of the need can be taken into account in the assessment. This is also the case if the conditions for solving the problem were only met shortly before the filing date or priority date (e.g. availability of materials or a necessary process). The skilled person must be allowed a normal period of time for solving a new problem, which may vary from one field to another (23-27).

References: (1) BGH, X ZR 29/89 (1990) – Elastische Bandage, GRUR 1991, 120; BGH, X ZB 15/06 (2007) – Wellnessgerät, GRUR 2007, 997; (3) BGH, Xa ZR 22/06 (2009) – Dreinahtschlauchfolienbeutel, GRUR 2010, 44; (4) BGH, X ZB 1/15 (2015) – Flugzeugzustand, GRUR 2015, 983; (5) BGH, X ZR 104/90 – Messventil, GRUR 1994, 36; (6) BGH, X ZR 129/92 (1995) – Triarylphosphite; (7) BGH, X ZR 15/66 (1969) – Dia-Rähmchen IV, GRUR 1970, 289; (8) BGH, I ZR 135/55 (1956), GRUR 1957, 212 – Karbidofen; (9) BGH X, ZR 50/09 (2012) – Ebastin, IBRRS 2012, 1491; (10) BGH, X ZR 98/09 (2012) – Calcipotriol-Monohydrat, GRUR 2012, 803; (11) BGH, X ZR 27/04 (2007) – Stahlblech, GRUR 2008, 145; (12) BGH, X ZR 141/10 (2013) - PNGase F, IBRRS 2014, 0612; (13) BGH, X ZR 148/11 (2016) – Zöliakiediagnoseverfahren, GRUR 2016, 1027; (14) BGH, X ZR 104/90 (1993) – Meßventil, GRUR 1994, 36; (15) BGH, I ZR 156/54 (1957) – Polstersessel, GRUR 1957, 543; (16) BGH, X ZR 4/11 (2013) – Anthocyanverbindung, GRUR 2014, 349; (17) BGH, X ZR 58/10 (2011) – E-Mail via SMS, GRUR 2012, 261; (18) BGH, X ZR 5/14 (2016) – Anrufroutingverfahren, GRUR 16, 1023; (19) BGH, X ZR 35/11 (2014) – Zugriffsrechte, GRUR 2015, 159; (20) BGH, I ZR 21/55 (1957) – Schleudergardine, GRUR 57, 488; (21) BGH, I ZR 146/59 (1961) – Brieftauben-Reisekabine, GRUR 62, 290;

(22) BGH, X ZR 119/14 (2017) – Gestricktes Schuhoberteil, GRUR 2017, 498; (23) BGH, I ZR 33/52 (1954) - Holzschutzmittel, GRUR 1954, 584; (24) BGH, I ZR 59/57 (1959) – Verbindungsklemme, GRUR 1960, 27; (25) BGH I ZR 130/57 (1961) – Einlegesohle, GRUR 1962, 83 (26) BGH, X ZR 49/94 (1996) – Rauchgasklappe, GRUR 1996, 857; (27) BGH X ZR 17/83 (1986) - Abfördereinrichtung für Schüttgut, GRUR 1986, 798.

- Selection inventions

A selection invention is a teaching that specifically selects a not explicitly mentioned sub-range or an individual from a larger range for which special effects, characteristics or advantages are claimed in comparison to the larger range.

First of all, the novelty of the selection must be examined in this context. It depends on what the state of the art has made accessible to a skilled person. It does not require the prior art document to explicitly state the subject matter of the selection, but rather whether the skilled person considers the subject matter of the selection to be also disclosed in the citation. For example, in the case of ranges precisely numerically defined by a start point and an end point (closed numerical parameters), the values between these points as well as all possible variations and intermediate values within the specified limits and all sub-sets randomly formed from them, as a rule, are also disclosed, because the stating of a quantity range merely represents a simplified notation of the intermediate values between the lower limit value and upper limit value (1-3).

The novelty of a use of a sub-range that has to be regarded as known, although it itself is not mentioned in the citation, does not make this sub-range new: it itself must be new. An exception to this principle applies to the first and further medical use of known substances (Sec.3 (3) Patent Act).

If a particular selection is new, an inventive step of the selection may be that a specifically selected range has valuable characteristics in comparison to the known range, e.g. has a previously unknown or superior effect which the skilled person would not have expected. On the other hand, an arbitrary choice made at will cannot as a rule substantiate an inventive step (4). This applies both to the selection from a larger range and to the selection of one of several alternatives (5). Nor – conversely – can the (generalising) indication of a range of values be regarded as inventive if the selection of individual values from the uniformly claimed range were obvious to the skilled person through prior art. (6).

If the skilled person considers a large number of alternatives, also several (possibly all) may be obvious. There is no legal rule that only the alternative solution, which the skilled person would probably try first, is obvious. (4; 7-9). Furthermore, the selection of one of several alternatives to the solution of the technical problem, which are recognisable to the skilled person due to the state of the art, cannot be regarded as being based on an inventive step merely because, from the point of view of the average skilled person, other solutions appear more suitable or advantageous (10).

As in the case of measures from the standard repertoire, obstacles or difficulties arising in connection with a certain alternative may confer an inventive step. Then an inventive step may be involved even with a limited number of alternatives (11).

For the question of obviousness of alternative solutions, the secondary criterion of an "appropriate expectation of success" can be used (8, 12). [cf. secondary indicia]

References: (1) BGH, X ZB 10/88 (1990) – Crackkatalysator, GRUR 1990, 510; (2) BGH, X ZR 40/95 (1999) – Inkrustierungsinhibitoren, GRUR 2000, 591; (3) BGH, X ZB 11/90 (1992) – Chrom-Nickel-Legierung, GRUR 1992, 842; (4) BGH, X ZR 56/03 (2007) – Injizierbarer Mikroschaum, GRUR 2008, 56; (5) BGH, X ZR 7/00 (2003) – Blasenfreie Gummibahn I, GRUR 2004, 47; (6) BGH, X ZR 100/10 (2013) – Laser-Feinabtastung, IBRRS 2014, 0122; (7) BGH, X ZR 58/10 (2011) – E-Mail via SMS, GRUR 2012, 261; (8) BGH X, ZR 50/09 (2012) – Ebastin, IBRRS 2012, 1491; (9) BGH, X ZR 5/14 (2016) – Anrufroutingverfahren, GRUR 16, 1023; (10) BGH, X ZR 49/94 (1996) – Rauchgasklappe, GRUR 1996, 857; (11) BGH, X ZR 173/07 (2010) – Walzgerüst II, GRUR 2011, 37; (12) BGH, X ZR 98/09 (2012) – Calcipotriol-Monohydrat, GRUR 2012, 803.

- Problem invention

What is known as “problem invention” does not occur in German practice, because the “objective” technical problem must be formulated in such a general and neutral manner that the question of what suggestions the skilled person received from the prior art arises exclusively during the examination of the inventive step. Advantages of the invention, which the skilled person would not have focused his efforts on to further develop the state of the art because they have only been shown to be achievable through the invention, thus cannot determine the technical problem underlying the invention (the problem of the invention) (1, 2).

Therefore, there can be no inventive merit in the mere problem. Rather, it lies in solving the problem. It is therefore redundant to examine whether the problem alone constitutes an inventive achievement (3).

References: (1) BGH X ZR 128/09 (2014) – Repaglinid, GRUR 2015, 356; (2) BGH X ZR 41/13 (2015) – Quetiapin, GRUR 2015, 352; (3) BGH, X ZR 27/82 (1983) – Kreiselegge, GRUR 84, 194.

- Chemical sector

The inventive step of chemical substances or natural substances is generally based on the surprising properties and effects which the new substance possesses compared to comparable known substances and which the skilled person could not have expected (1, 2). The absence of those can be an obstacle to the grant of a patent. (3).

The production process of a substance that is as such new and inventive need not be inventive in itself, it can be a customary method of isolation and synthesis. In special cases, however, the inventive step can also result from the fact that, although the existence of a substance (e. g. an enantiomer) was obvious to the skilled person, he could not produce it without major difficulties (4).

Similarly, the invention of a medicinal product may involve an inventive step if a skilled person would not have created the new medicinal product or other medicinal substance because he would not have expected its beneficial effects. However, for the skilled person wishing to provide a composition with beneficial effects on health risk factors, it is generally obvious to first give attention to compositions known for these effects, to identify their active substances and to charge them, in particular where there is evidence of an improvement of the effect through a higher dose of the active substance (5). Thus, even a surprising synergy effect cannot confer inventive step if the measures resulting in this effect were themselves obvious (6).

When examining whether a specific application of a medicinal product involves an inventive step, those ways of acting must also be considered which were obvious to the skilled person because they were part of the standard repertoire of doctors on the priority date (7). [cf. Standard measures]

Some of the rulings mentioned in the context of the above principles, in particular with regard to selection inventions, also concern the chemical sector. These are shown again in the following list of references (8-20).

References: (1) BGH, X ZB 11/68 (1969) – Disiloxan, GRUR 1969, 265; (2) BGH, X ZB 3/69 (1970) – Anthradipyrazol, GRUR 1970, 408; (3) BGH, X ZR 2/66 (1969) – Geflügelfutter, GRUR 1969, 531; (4) BGH, Xa ZR 130/07 (2009) – Escitalopram, GRUR 2010, 123; (5) BGH, Xa ZR 28/08 (2010) – Fettsäurezusammensetzung, GRUR 2010, 607; (6) BGH X, ZR 50/09 (2012) – Ebastin, IBRRS 2012; (7) BGH, X ZB 6/13 (2014) – Kollagenase II, GRUR 2014, 464; (8) BGH X ZR 128/09 (2014) – Repaglinid, GRUR 2015, 356; (9) BGH, X ZR 41/13 (2015) – Quetiapin, GRUR 2015, 352; (10) BGH, X ZR 89/07 (2008) – Olanzapin, GRUR 2009, 382; (11) BGH, X ZB 5/13 (2014) – Kollagenase I; (12) BGH, I ZR 117/54 (1956) – Wasch- und Bleichmittel, GRUR 1956, 317; (13) BGH, X ZR 129/92 (1995) – Triarylphosphite; (14) BGH, X ZR 98/09 (2012) – Calcipotriol-Monohydrat, GRUR 2012, 803; (15) BGH, X ZR 148/11 (2016) – Zöliakiediagnoseverfahren, GRUR 16, 1027; (16) BGH, X ZR 4/11 (2013) – Anthocyanverbindung, GRUR 2014, 349; (17) BGH, I ZR 33/52 (1954) - Holzschutzmittel, GRUR 1954, 584; (18) BGH, X ZB 10/88 (1990) – Crackkatalysator, GRUR 1990, 510; (19) BGH, X ZR 40/95 (1999) – Inkrustierungsinhibitoren, GRUR 2000, 591; (20) BGH, X ZB 11/90 (1992) – Chrom-Nickel-Legierung, GRUR 1992, 842.