



## 2019 Study Question

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Jonathan P. OSHA, Reporter General  
Ari LAAKKONEN and Anne Marie VERSCHUUR, Deputy Reporters General  
Guillaume HENRY, Ralph NACK and Lena SHEN, Assistants to the Reporter General

### Plausibility

Responsible Reporter(s): Ralph NACK

National/Regional Group	Germany
Contributors name(s)	Ina Bürck Heiko Dumlich Johannes Gierlich Robin Keulertz Simon Klopschinski Philipp Marchand Michael Schneider Stefan Schohe Michael Wallinger Thomas Wolter
e-Mail contact	keulertz@olbrichtpatent.de

### I. Current law and practice

**Please answer all questions in Part I on the basis of your Group's current law.**

#### 1 Does your law in general provide a plausibility requirement?

No

Please Explain

a) No Explicit 'Plausibility' Requirement under German Patent Law

German patent law does not decree an explicit 'plausibility' requirement, which comprehensively addresses the question whether there is sufficient evidence/disclosure that the purported technical effect of a claimed invention can be actually achieved, as opposed to mere 'speculative' patent applications.

In principle the German Patent Act (*Patentgesetz – PatG*) limits the conditions for patentability to the presence of a 'patentable invention', 'novelty', 'inventive step', 'industrial application', and 'sufficiency of disclosure'.

In addition, there is the unwritten concept of 'usability' (*Brauchbarkeit*) which originates from the time before the implementation of the European Patent Convention (EPC) into German law. An invention lacks 'usability' if the technical effect, which the invention aims to achieve, cannot be accomplished by using the means which are disclosed in the patent specification. [\[1\]](#)

b) German Court Practice

aa) Nowadays perpetual motion machines are for instance tested against the criterion of 'usability'. [2]

bb) In other technical fields the courts occasionally refer to the concept of 'speculative' patent applications when discussing the question whether the patent discloses reasons for expecting that the invention will actually work. [3]

c) European Patent Office (EPO) Practice

There is a 'plausibility' requirement in EPO practice, which is examined in the context of 'inventive step' pursuant to Article 56 EPC or 'sufficiency of disclosure' pursuant to Article 83 EPC. In Germany, EPO practice is of course relevant for patent prosecution. Furthermore, in German infringement proceedings the infringement court may have to consider EPO practice (including 'plausibility') when deciding the stay of infringement proceedings on the merits pending an EPO opposition, or in the context of provisional injunction proceedings. [4] With regard to EPO practice we refer to the comprehensive EPO case law compendium "Case Law of the Boards of Appeal of the European Patent Office" [5], in particular p. 181 ff., p. 344, p. 347 ff., p. 362 ff., and p. 696. In the following we will concentrate on German patent law.

## Footnotes

1. [^](#) Klaus Bacher, in: Georg Benkard et al., 'Patentgesetz' (11th ed., Verlag C.H. Beck, München, 2015) § 1 PatG para. 71 ff. and para. 74 f.
2. [^](#) BGH, 27.09.1984, X ZB 5/84, BeckRS 1984, 5234; BPatG, 28.10.1998, 9 W (pat) 3/98, GRUR 1999, 487 – Perpetuum mobile; BPatG, 18.04.2016, 9 W (pat) 1/13, BeckRS 2016, 10071.
3. [^](#) BGH, 25.02.2010, Xa ZR 100/05, GRUR 2010, 414 – Thermoplastische Zusammensetzung; BPatG, 22.05.2006, 21 W (pat) 42/04, GRUR 2006, 1015 – Neurodermitis-Behandlungsgerät; BPatG, 11.11.2008, 3 Ni 37/07 (EU), GRUR 2010, 50 – Cetirizin.
4. [^](#) Düsseldorf Higher Regional Court, 07.11.2013, I-2 U 94/12, GRUR-RS 2014, 04902.
5. [^](#) 8th ed., EPO, München, 2016.

**2** Is the plausibility requirement if any a stand-alone requirement or is it integrated into another requirement (e.g. inventive step)?

No

Please Explain

a) No Stand-alone 'Plausibility' Requirement

Under German patent law there exists no stand-alone 'plausibility' requirement. There is also no established practice to address 'plausibility' in the context of a specific patentability requirement, e.g. 'inventive step' or 'sufficiency of disclosure'. [1]

b) German Court Practice

In fact, the question whether a patent application ignores the laws of nature or is only of a speculative nature, is raised by the courts only from time to time and in connection with various patentability requirements, especially 'patentable invention' and 'sufficiency of disclosure'. [2]

## Footnotes

1. <sup>^</sup> Unlike EPO practice: EPO, 28.06.2005, T 1329/04, BeckRS 2005, 30690092 – Factor 9/JOHN HOPKINS; EPO, 01.02.2017, T 488/16, BeckRS 2017, 119725 – Dasatinib/BRISTOL-MYERS SQUIB; EPO, 08.07.2011, T 578/06 – Pancreatic cells/IPSEN; EPO, 16.02.2005, T 609/02 – AP-1 complex/SALT INSTITUTE; EPO, 19.02.2010, T 1437/07 – Botulinum toxin for treating smooth muscle spasm/ALLERGAN; EPO, 03.02.2017, T 950/13, BeckRS 2017, 138817 – CYCLIC PROTEIN TYROSINE KINASE INHIBITORS.
2. <sup>^</sup> BGH, 27.09.1984, X ZB 5/84, BeckRS 1984, 5234; BGH, 25.02.2010, Xa ZR 100/05, GRUR 2010, 414 – Thermoplastische Zusammensetzung; BPatG, 28.10.1998, 9 W (pat) 3/98, GRUR 1999, 487 – Perpetuum mobile; BPatG, 22.05.2006, 21 W (pat) 42/04, GRUR 2006, 1015 – Neurodermitis-Behandlungsgerät; BPatG, 11.11.2008, 3 Ni 37/07 (EU), GRUR 2010, 50 – Cetirizin; BPatG, 18.04.2016, 9 W (pat) 1/13, BeckRS 2016, 10071.

**3 Are there any statutory provisions that specifically apply to plausibility? If yes, please briefly explain.**

No

Please Explain

The Patent Act as well as statutory instruments like the Patent Ordinance ( *Patentverordnung – PatV*) do not contain statutory provisions that specifically apply to 'plausibility'.

**4 Please briefly describe the general patentability requirements in the statutory law of your jurisdiction that are or would be relevant to the issue of plausibility.**

a) General Remarks

The courts have discussed 'plausibility' issues in the context of 'patentable invention' and 'sufficiency of disclosure'. Here are the respective statutory provisions:

b) 'Patentable Invention' – Section 1(1) Patent Act

'Patents shall be granted for any inventions, in all fields of technology, provided that they are new, involve an inventive step and are susceptible of industrial application.'

The Patent Act does not provide a positive definition of the concept of a 'patentable invention' but only excludes certain subject matter from patentability (see divs 1 [3], 1a [1], 2 and 2a of the Patent Act). Furthermore, the wording of div 1(1) Patent Act does not address 'plausibility'. The statute leaves it to the courts to define what constitutes a 'patentable invention', having regard to the progress of science and technology.

c) 'Sufficiency of Disclosure' – Section 34(4) Patent Act

'The application shall disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.'

The 'sufficiency of disclosure' requirement is at the heart of the so-called 'patent bargain'. The inventor obtains an exclusive right in its invention in exchange for disclosing the invention and dedicating it to the public for use after the patent has expired. However, div 34(1) of the Patent Act primarily deals with the question whether the person skilled in the art is able to perform the invention from the invention disclosed in the specification, whereas the issue of 'plausibility' is not directly mentioned.

**5 Under the case law or judicial or administrative practice in your jurisdiction, are there decisions or rules that specifically apply to plausibility? If yes, please briefly explain**

No

Please Explain

a) General Remarks

The few existing court decisions that refer to the concepts of 'usability' as well as 'speculative' patent applications do not display a developed approach towards 'plausibility'. On the one hand, there are cases involving non-feasible inventions, e.g. perpetual motion machines which ignore the laws of nature. Those cases are discussed under the heading of 'usability' in the context of 'patentable invention' pursuant to div 1(1) Patent Act. On the other hand, the courts have treated 'speculative' patent applications in the context of 'sufficiency of disclosure' pursuant to div 34(4) Patent Act. [1]

b) 'Patentable Invention' – Section 1(1) Patent Act (Article 52[1] EPC)

Every once in a while, the Federal Supreme Court (*Bundesgerichtshof – BGH*) and the Federal Patent Court (*Bundespatentgericht – BPatG*) have to decide cases involving patents on perpetual motion machines. In those instances where the inventions mistakenly claim to have overcome the law of conservation of energy the courts regard the invention to be 'unusable' and therefore deny a 'patentable invention' within the meaning of div 1(1) Patent Act. [2]

c) 'Sufficiency of Disclosure' – Section 34(4) Patent Act (Article 83 EPC)

In the majority of cases, considerations of plausibility are made in the context of 'sufficiency of disclosure'.

aa) In the 'Cetirizin' case the Federal Patent Court held that in a case where the patent claims the use of a known compound for the treatment of a specific illness, the question whether or not the invention is speculative can arise when the claimed therapeutic effect of the compound is not substantiated by any experimental data in the application as filed. [3] The 'Cetirizin' case leads to the follow-up question what constitutes sufficient disclosure of the therapeutic effect of a compound. Disclosure of in-vitro tests or in-vivo tests can be sufficient, whereas disclosure of clinical trials is normally not necessary. [4]

bb) In the 'Thermoplastic Composition' case the Federal Supreme Court decided that patent protection must be limited to the contribution of the invention to the art, in order to avoid speculatively broad claims. Since the claimed composition was not limited to the technical contribution that was disclosed in an enabling manner in the patent specification, the Federal Supreme Court held the invention to be insufficiently disclosed. [5]

## Footnotes

1. [^](#) BPatG, 22.05.2006, 21 W (pat) 43/04, GRUR 2006, 1015 – Neurodermitis-Behandlungsgerät.
2. [^](#) BGH, 27.09.1984, X ZB 5/84, BeckRS 1984, 5234; BPatG, 28.10.1998, 9 W (pat) 3/98, GRUR 1999, 487 – Perpetuum mobile; BPatG, 18.04.2016, 9 W (pat) 1/13, BeckRS 2016, 10071.
3. [^](#) BPatG, 11.11.2008, 3 Ni 37/07 (EU), GRUR 2010, 50 – Cetirizin.
4. [^](#) Eva-Maria Scherner, 'Die Offenbarung der therapeutischen Wirkung des Stoffs bei der zweiten medizinischen Indikation'; GRUR 2009, 349; BPatG, 07.02.2017, 3 Ni 20/15 Erlotinib-Hydrochlorid.
5. [^](#) BGH, 25.02.2010, Xa ZR 100/05, GRUR 2010, 414 – Thermoplastische Zusammensetzung.

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**Please briefly describe the general patentability requirements under the case law or judicial or administrative practice of your jurisdiction that are or would be relevant to the issue of plausibility. If there is no explicit or implied plausibility requirement in the law or under the judicial or administrative practice in your jurisdiction, please skip the below questions and proceed directly to question 15.**

a) General Remarks

The courts have discussed 'plausibility' under various headings, in particular 'patentable invention' and 'sufficiency of disclosure'. Here are some general remarks on the case law regarding these patentability requirements.

b) 'Patentable Invention' – Section 1(1) Patent Act

aa) The concept of 'patentable invention' is an open legal term which has to be brought to life by the courts. In the seminal 'Red Dove' decision of 1969 the Federal Supreme Court held that a 'patentable invention' is a teaching to methodically utilize controllable forces of nature to achieve a causal, perceivable result. [1]

bb) Since non-feasible inventions like perpetual motion machines neglect the laws of nature, it is arguable to deny that they are 'patentable inventions' within the meaning of the 'Red Dove' decision.

c) 'Sufficiency of Disclosure' – Section 34(4) Patent Act

aa) An invention is sufficiently disclosed if the information revealed in the patent provides the person skilled in the art with enough information that he can carry out the invention, using his technical knowledge and skill. It is not necessary to disclose at least one practicable embodiment of the invention. [2] Furthermore, 'sufficiency of disclosure' only requires disclosure of one way to carry out the invention. [3] It is also not necessary that all possible embodiments, which fall within the scope of the claim, are disclosed in the patent specification. [4] Even if the person skilled in the art has to undertake experiments for carrying out the invention, the invention is sufficiently disclosed, as long as these experiments are within the normal limits and do not require inventive considerations. [5]

bb) By contrast, if the patent specification does not disclose any information that the claimed therapeutic effect of a compound is actually achieved, it can justifiably be argued that the person skilled in the art will regard the invention as mere speculation and not workable. In case of other types of claims the person skilled in the art will only in exceptional circumstances regard the claimed invention as speculation. This is evidenced by the absence of a significant amount of case law.

**Footnotes**

1. [^ BGH, 27.03.1969, X ZB 15/67, GRUR 1969, 672 – Rote Taube.](#)
2. [^ BGH, 13.07.2010, Xa ZR 126/07, GRUR 2010, 916 – Klammernahtgerät.](#)
3. [^ BGH, 03.05.2001, X ZB 168/97, GRUR 2001, 813 – Taxol.](#)
4. [^ BGH, 11.05.2010, X ZR 51/06, GRUR 2010, 901 – Polymerisierbare Zementmischung.](#)
5. [^ BGH, 24.03.1998, X ZR 39/95, GRUR 1998, 1003 – Leuchtstoff.](#)

**7** Can the plausibility requirement be regarded primarily as a “credibility” requirement, i.e., a requirement applying to patent applications that describe a technical effect that appears non-credible, e.g., because the described effect contradicts the common perception of in the relevant technical field, and/or is a surprising effect?

Yes

Please Explain

Whereas in the case law of the European Patent Office the plausibility requirement indeed appears to be regarded as a 'credibility' requirement, "credibility" German courts do not appear to equate plausibility with credibility.

**7.a** If yes, is the credibility determined from the perspective of a person having ordinary skill in the art, or from the perspective of an expert in the field?

Yes

Please Explain

In the EPO, credibility and thus plausibility is determined from the perspective of a person having ordinary skill in the art, rather than from the perspective of an expert in the field. [1]

Where German Courts dealt with technical effects which appeared to be "incredible", they did so by reference to the commonly

known and accepted natural laws [2] or to the accepted understanding in the prior art [3]. When an invention directly contradicts physical laws or the like (e.g. perpetual motion machine), it is examined if the claimed subject-matter is technically feasible (“technische Realisierbarkeit”). This leads to an objection that the claimed invention is technically not useable, since the proposed effect is not achieved. [4]

### Footnotes

1. [^](#), EPO, 01.02.2017, T 488/16, BeckRS 2017, 119725 – Dasatinib/BRISTOL-MYERS SQUIB.
2. [^](#) BPatG, 17.07.2017, 9 W (pat) 29/14.
3. [^](#) BPatG, 22.05.2006, 21 W (pat) 42/04.
4. [^](#) BGH, 27.09.1984, X ZB 5/84; BPatG, 17.07.2017, 9 W (pat) 29/14.

7.b

**If the relevant perspective is the person having ordinary skill in the art, why is a “credible” technical effect not also obvious at the same time?**

Yes

Please Explain

German courts tend to use a rather holistic approach to assess the inventive step requirement, which is less effect-centered than the EPO's problem-solution approach. Therefore, the question as to whether or not a particular technical effect appears to be plausible in light of the disclosure of the invention is rather dealt with in the context of sufficiency of disclosure (if the technical effect is recited in the claim at stake such as in medical use claims). The German Group notes that even under EPO standards, non-obviousness is not equated with implausibility. [1]

### Footnotes

1. [^](#) EPO, 03.02.2017, T 950/13, BeckRS 2017, 138817 – CYCLIC PROTEIN TYROSINE KINASE INHIBITORS.

7.c

**Do all the promises of the patent description have to seem achievable for the person skilled in the art?**

No

Please Explain

No, only the technical teaching as claimed in the patent claims is relevant. Even though the description can be used to interpret the claims, objectives of the invention, which are mentioned in the description, are only relevant to the extent they are reflected in the patent claims. [1] In case of chemical reactions it can be sufficient if one way to carry out the invention is disclosed. [2]

### Footnotes

1. [^](#) BPatG, 22.05.2006, 21 W (pat) 42/04 Neurodermitis-Behandlungsgerät.
2. [^](#) BGH, 22.05.2001, X ZR 168/97, Taxol.

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**Can the plausibility requirement be regarded primarily as a prohibition of “speculative” patent applications which do not (expressly) disclose a technical effect or concrete use, e.g., of a chemical substance (the potential technical effect or concrete use rather remains speculative)?**

Yes

Please Explain

Yes, the plausibility requirement appears to reflect a desire to prevent grant of speculative inventions in particular in the biotech field.

**8.a** If yes, which standard does apply to determine a speculative filing? Which requirements does the applicant have to meet in order to reach a non-speculative filing?

Under EPO standards, a technical effect which is not (expressly) disclosed in a patent application can be taken into account if it is implied by or at least related to the technical problem initially suggested in the originally filed application. [1] However, supplementary post-published evidence may not serve as the sole basis to establish, that the application solves indeed the problem it purports to solve. [2]

Under German standards, an invention will be considered speculative if it turns out to be unusable, i.e., if the person of ordinary skill in the art is not able to obtain the described technical effect or is not able to solve the problem put forward with the means disclosed in the patent. According to the competent senate of the Federal Patent Court it is therefore to be investigated whether the claimed technical effect is achieved by a feature of the claim and whether the effect can be obtained following the technical teaching. [3] Regarding a therapeutic effect it can be sufficient that the person skilled in the art would not find it purely speculative. [4] In specific cases it was sufficient to refer to *in vitro* and *in vivo* data in the prior art for the claimed group of compounds. But in such a case methods to test the relevant compounds for the specific technical effect have to be disclosed and the technical effect, e.g. inhibition of a particular enzyme, is very specific. [5]

It has to be decided on a case by case basis what the contribution of an invention is and whether a broadening over the concrete examples named in the patent is allowable. This may be e.g. the case if the invention opens a new field of research. [6]

#### Footnotes

1. [^ EPO, 24.03.1992, T 0386/89.](#)
2. [^ EPO, 28.06.2005, T 1329/04, reasons 12.; EPO, 01.02.2017, T 488/16, point 4.2 of the Reasons.](#)
3. [^ BPatG, 22.05.2006, 21 W \(pat\) 42/04.](#)
4. [^ BPatG, 11.11.2008, 3 Ni 37/07 Cetririzin; BPatG, 04.06.2007 3 Ni 21/04 \(EU\).](#)
5. [^ BPatG, 07.02.2017, 3 Ni 20/15 Erlotinib-Hydrochlorid.](#)
6. [^ BGH, 11.09.2013, X ZB 8/12 Dipeptidyl-Peptidase-Inhibitoren.](#)

**8.b** If a technical effect (which is not expressly described in the specification) is nonetheless plausible because the skilled person would understand that the technical effect was, at the priority date, implied or self-evident from the specification, why was the technical effect not obvious at the priority date?

There is no case law, where no technical effect is disclosed in the specification. In such a case the application will not provide a solution to a problem and would therefore be regarded as not inventive.

**9** Can the plausibility requirement be regarded primarily as specific prohibition against “prophetic” examples (or embodiments) in the specification in support of the technical solution purported by the claimed invention, e.g., the description merely “predicts” that a specific experiment “will” prove a special property of the claimed compound?

No

Please Explain

9.a If yes, which standard does apply to identify a prophetic example? Must the applicant submit test data etc. to support examples (unless self-evident)?

9.b Do all examples (or embodiments) need to pass this plausibility test? What is the consequence if only some examples (or embodiments) do not pass the test?

No

Please Explain

10 Is it possible to make a clear distinction between the above-mentioned aspects (as set out in the questions 7-9 above) or do they merge into each another?

No

Please Explain

No, despite the case where the invention contradicts physical laws of nature, the aspects of questions 8 and 9 merge into each other.

11 What is the relevant point in time for the plausibility test?

According to the current practice of the European Patent Office, the purported technical effect of the claimed invention needs to be plausible at the effective filing date (application date or priority date, if a priority is claimed). [1] Supplementary post-published evidence may in the proper circumstances be taken into consideration, however, it may not serve as the sole basis to establish that the application solves indeed the problem it purports to solve. [2]

According to the current practice in Germany the purported technical effect of the claimed invention needs to be plausible at the effective filing date. [3] The German Patent and Trademark Office (GPTO) is less strict than the EPO when considering whether the claimed invention was plausible at the effective filing date. [4] There are no decisions of German courts related to the question of a technical effect of an invention appearing to be plausible at the effective filing date that later proves wrong or vice versa. The invention, however, will not meet the sufficiency of disclosure requirement if the technical effect cannot be achieved such that the invention provides no contribution to the art. [5]

## Footnotes

1. <sup>△</sup> EPO, 27.10.2004, [T 609/02](#), point 9 of the Reasons; EPO, 28.06.2005, [T 1329/04](#), point 12 of the Reasons; EPO, 01.02.2017, [T 488/16](#), point 4.2 of the Reasons; Case Law of the Boards of Appeal of the European Patent Office, 8th edition, [I.D.4.6](#).



2. [EPO, 28.06.2005, T 1329/04](#), point 12 of the Reasons; [EPO, 01.02.2017, T 488/16](#), point 4.2 of the Reasons.
3. [BPatG, 11.11.2008, 3 Ni 37/07 \(EU\)](#), point III.1 of the Reasons.
4. [BPatG, 11.11.2008, 3 Ni 37/07 \(EU\)](#), point III.1 of the Reasons.
5. [BPatG, 11.11.2008, 3 Ni 37/07 \(EU\)](#), point III.1 of the Reasons.

**What if for example the technical effect of an invention appears plausible at the priority date, but later proves to be wrong, or vice versa?**

If the purported technical effect of the claimed invention appeared to be plausible at the effective filing date, but later proves wrong, the invention is not a successful solution to the technical problem it wants to solve. Hence, the claimed improvement cannot be taken into account for assessing inventive step and the objective technical problem has to be reformulated. [1] If the purported technical effect of the claimed invention was not made plausible at the effective filing date, but later proves to be plausible, the claimed invention is not patentable as it was not disclosed that the application indeed solves the problem it purports to solve at the effective filing date, i.e., the application was rather speculative. [2]

#### Footnotes

1. [Case Law of the Boards of Appeal of the European Patent Office, 8th edition, I.D.4.6.](#)
2. [EPO, 28.06.2005, T 1329/04](#), point 12 of the Reasons.

**12 Are there different plausibility tests for different types of claims (e.g. pure product/compound claims without a functional feature, product claims including a functional feature, second medical use claims, etc.)?**

Yes

Please Explain

According to European case law, the plausibility test is applied in a different manner for claims that recite a technical effect as a functional technical feature compared to claims that do not recite the technical effect as a functional technical feature. [1]

In particular, different plausibility tests are applied for product claims and second medical use claims for the purpose of assessing whether the application discloses the invention in a manner sufficiently clear and complete for it to be carried out by the skilled person. [2] For product claims, not restricted to any specific therapeutic effect it is in principle sufficient that the application provides information which allows the skilled person to produce the product and that there are no substantiated doubts that it could indeed be used in therapy. [3] For second medical-use claims, i.e., claims for which a therapeutic effect is claimed as a functional technical feature, it is required not only that the composition itself is disclosed in an enabling way but also that its suitability for the claimed treatment is plausibly disclosed in the application. [4]

Furthermore, the European Patent Office assesses inventive step based on the problem-solution approach in which an objective technical problem is formulated based on the technical effect resulting from the distinguishing features over the closest prior art. [5] The technical effect on which the objective technical problem is based has to be made plausible for all types of claims. [6]

The current practice in Germany in contrast does not appear to make the same distinction as the EPO for different types of claims.

#### Footnotes

1. [EPO, 28.06.2005, T 1329/04](#), point 12 of the Reasons; [EPO, 27.10.2004, T 609/02](#), point 9 of the Reasons; [EPO, 27.08.2014, T 1616/09](#), point 6 of the Reasons; [Case Law of the Boards of Appeal of the European Patent Office, 8th edition, II.C.6.2.](#)
2. [EPO, 27.08.2014, T 1616/09](#), point 6 of the Reasons.

3. [EPO, 27.08.2014, T 1616/09](#), point 6 of the Reasons.
4. [EPO, 27.08.2014, T 1616/09](#), point 6 of the Reasons; [EPO, 27.10.2004, T 609/02](#), point 9 of the Reasons.
5. [Guidelines for Examination in the European Patent Office November 2018 edition, G-VII, 5](#).
6. [EPO, 27.08.2014, T 1616/09](#), point 6 of the Reasons; [EPO, 02.12.2010, T 1642/07](#), points 14 to 23 of the Reasons; [EPO, 28.06.2005, T 1329/04](#), point 12 of the Reasons.

13

**Who has the burden of proof for (lack of) plausibility (patentee/applicant or patent office/opponent)?**

In European and German examination proceedings, while the burden of proof of sufficiency of disclosure generally lies with the patent office, the applicant has to show that the purported technical effect of the claimed invention can actually be achieved, i.e., by providing one or more examples or technical information. [1]

In opposition and nullity proceedings, generally the burden of proof for lack of plausibility lies with the opponent. This principle, however, does not apply to cases, where the application does not provide a single example or other technical information from which it is plausible that the claimed invention can be carried out. [2] In these cases the patentee has to show that the invention can achieve the purported technical effect. Furthermore, if the opponent through own experiments shows that the purported technical effect cannot be achieved by the claimed invention, the patentee has to show that the claimed invention can achieve the purported technical effect. [3]

**Footnotes**

1. [Guidelines for Examination in the European Patent Office November 2018 edition, F-III, 4](#); [BPatG, 11.11.2008, 3 Ni 37/07 \(EU\)](#), point III.1 of the Reasons.
2. [EPO, 19.11.2015, T 1329/11](#), point 3.9 of the Reasons; [Guidelines for Examination in the European Patent Office November 2018 edition, F-III, 4](#); [BPatG, 03.07.2008, 3 Ni 45/06 \(EU\)](#), point II.2.b) of the Reasons.
3. [Guidelines for Examination in the European Patent Office November 2018 edition, F-III, 4](#).

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**Please comment on any additional issues concerning any aspect of plausibility that is being regulated by your Group's law/practice you consider relevant to this Study Question, having regard to the scope of this Study Question as set out above.**

There are no additional issues concerning any aspect of plausibility that is being regulated by our Group's law/practice we consider relevant to this Study Question.

**II. Policy considerations and proposals for improvements of your Group's current law**

15

**Are there aspects of your Group's current law relating to plausibility that could be improved? If YES, please explain.**

Yes

Please Explain

While there is no stand-alone 'plausibility' requirement under EPO or German patent law and practice, the German group notes a

tendency in the case law of the European Patent Office to treat plausibility as a de facto requirement in the sense that a patent application may be refused or a patent revoked, e.g., for lack of sufficiency of disclosure or lack of inventive step, because effects that the applicant asserts or relies on were not made plausible in the patent application as originally filed.

The German group notes that establishing the patentability requirements at the inception of the EPC, the legislator discarded requirements that previously existed under national law, such as the requirements of technical progress and usability ( *Brauchbarkeit*) that were previously applied under German law. The Diplomatic Conference for the revision of the European Patent Convention of 2000 saw no need to amend the selection made at the time of the inception of the EPC. The current list of patentability requirements in the European Patent Convention is therefore the result of a conscious decision of the legislator, which the adjudicating bodies are not entitled to question or to amend, and to be considered exhaustive.

The above applies mutatis mutandis to German law, which was amended to comprise the same requirements as the EPC, when the EPC was established.

The German group furthermore notes that R. 42 of the EPC requires that the technical problem, which does not need to be expressly stated as such, and its solution can be understood from the description, but to this end does not require any evidence or explanation in terms of cause and effect. The German group also notes standing case law that the problem underlying an invention is to be established on an objective basis<sup>[1]</sup> and hence the consequence of not establishing that an invention solves a problem stated in the application is the reformulation of the problem, rather than a lack of inventive step.

The German group also notes that this approach of the European Patent Office is not followed by the German courts.

Treating plausibility as de facto requirement for patentability therefore does not seem to be in line with the EPC or German patent law and with general principles of patent law.

The German Group considers plausibility as an evidentiary standard with lower requirements than full evidence, which may be appropriate for reasons of procedural efficiency or where full evidence cannot be readily provided.

In particular, a requirement of plausibility may be appropriate

- where full evidence cannot be provided at the time of filing or during prosecution, e.g. in cases where trials to confirm the effects of an invention will take several years,
- where full evidence to remove remaining doubts about the properties of an invention during the application phase would unduly delay the examination procedure,
- where the patent office or an opponent prima facie has reasonable doubts about properties of an invention claimed or relied on by the applicant or patentee and under standard procedural rules neither the patent office nor the opponent can be expected to provide evidence that such properties actually existed at the effective filing date.

Plausibility is not to replace the provisions on evidence of the EPC or of national law. If existence or non-existence of a property of the invention is plausible, it must be possible for the affected party to provide evidence that the contrary actually is the case. In particular, where it is found plausible that a patentability requirement is not met, the applicant must be provided with a reasonable and fair opportunity to prove the contrary, which may include the suspension of the proceedings, when evidence cannot or cannot reasonably be expected to be provided on a short-term basis.

On a legislative level, the German group does not recognize a need for an additional patentability requirement beyond those already codified in the EPC and in German law.

## Footnotes

1. <sup>^</sup> cf. *Case Law of the Boards of Appeal at the European Patent Office, 8th edition, div I.D.4., 4.1.*

16

**Under your Group's current law, does the availability of patent protection aim to incentivize an early disclosure of technical achievements, or rather the disclosure of "completed" inventions (which may involve a mandatory disclosure of a "best mode")?**

Yes

**Please Explain**

While both the EPC and German law require a complete invention at the effective filing date, German courts have repeatedly emphasized that disclosure of one way (which does not have to be the best mode) how to put a claimed invention into practice is sufficient in order to meet the requirements of sufficiency of disclosure. [\[1\]](#) Moreover, German law and the European Patent Convention do not contain a requirement that evidence of a completed invention, at any standard, be provided or even being available at the effective filing date. Thus, evidence of a completed invention can, in the opinion of the German Group, be provided after the effective filing date.

For the sake of clarity, such evidence must be directed to proving that the respective patentability requirements were met at the effective filing date, respectively, with the average person skilled in the art as the relevant standard. Evaluating the evidence, special attention is required, whether the evidence provided relies on knowledge or information from after the effective filing date and/or on knowledge or skills that cannot be attributed to an average person skilled in the art (as to the requirements on disclosure by prior art at the priority date, see the decision of the Federal Court of Justice Xa ZR 100/05 – Thermoplastische Zusammensetzung (Thermoplastic Composition) of February 25, 2010, div 29 et seq.).

In many cases, it may be difficult or impossible to prove that later experiments were not influenced by later knowledge and, accordingly, a certain property of the invention cannot be proven to have been implied in the application at the effective filing date, unless the essential information was already comprised in the application. Thus, plausibility from the application may be needed to prove such a property, but it should not be a requirement in its own right.

The German group notes that the case law of the European Patent Office does not admit later evidence for properties of an invention, unless such properties are already plausible from the application as filed, but, for the reasons set out in the answer to question 15, does not consider this as the right approach, also considering that the same requirement would necessarily have to apply to the disclosure of the prior art, but such a requirement is not raised under the current practice. Actually, contrary to the Technical Boards of Appeal of the EPO, the German courts do not appear to have ruled on the issue of admissibility of post-filed evidence based on the presence or absence of a plausible disclosure. Where the EPO applies a strict standard, generally arguing that post-filed evidence cannot be taken into account to support a particular technical effect if the technical effect was not at least made plausible in the original filing [\[2\]](#), it is believed within the German group that a more lenient approach is applied by German courts, leading to a further incentivization of an early disclosure.

**Footnotes**

1. [^](#) *BGH, 03.05.2001, X ZR 168/97 – Taxol.*
2. [^](#) *see e.g. EPO, 28.06.2005, T1329/04.*

**17 Under your Group's current law, does the plausibility requirement, if any, interfere with the incentive for an early disclosure provided by the first-to-file system?**

No

Please Explain

No. If a finding of lack of plausibility can be refuted by full evidence, an applicant can prove the properties claimed or relied on after filing, although at the risk that the evidence provided by it will be found to be influenced by information, knowledge or skills not available to an average person skilled in the art at the effective filing date.

It is and should be the responsibility of an applicant to decide whether to delay filing and collect evidence in the meantime or to file an application without having such evidence available, it being understood that failure to provide such evidence can be to the detriment of the applicant or the patentee.

### III. Proposals for harmonization

**Please consult with relevant in-house / industry members of your Group in responding to Part III.**

**18 Do you consider that harmonization regarding plausibility is desirable? If YES, please respond to the following questions without regard to your Group's current law. Even if NO, please address the following questions to the extent your Group considers your Group's current law could be improved.**

Yes

Please Explain

Considering plausibility as an evidentiary standard, it is, of course, desirable that all patent offices use similar evidentiary standards.

Considered as a patentability requirement, it is desirable that patentability requirements are harmonized.

**19 Should there be a plausibility requirement? If no, please briefly explain why and then please also answer the following questions assuming there is a plausibility requirement.**

No

Please Explain

In terms of an additional patentability requirement, no. The German group considers the patentability requirements currently codified in the law sufficient and appropriate

**20 Should plausibility be a "credibility" requirement that excludes patent applications describing a technical effect of the claimed invention which however looks "incredible", e.g. because the described effect contradicts the common perception of in the relevant technical field, and/or is a surprising effect?**

No

Please Explain

No, an applicant should be able to prove its case by the usual means of evidence provided under the applicable procedural law.

**20.a** If yes, which standard should apply to determine the credibility of the invention? Is the credibility determined from the perspective of a person having ordinary skills in the art, or from the perspective of an expert in the field?

Not applicable. In as much as evidence is concerned the proper standard is the average person skilled in the art, as with other issues in patent law.

**20.b** Should all the promises of the patent description have to seem achievable for the person skilled in the art?

Yes

Please Explain

A patent application should be examined under objective standards as to what the contribution to the art is. Accordingly, promises that cannot be verified are to be disregarded. If, for reasons of procedural expedience, the patent office decides to accept plausibility as a lesser standard of proof (subject to verification by full evidence in a post-grant procedure), the "promises" must appear achievable for a person skilled in the art to the extent they are relevant for a codified patentability requirement, such as non-obviousness/inventive step.

**21** Should plausibility be a prohibition of "speculative" patent applications which do not (expressly) disclose a technical effect or concrete use e.g. of a chemical substance (the potential technical effect or concrete use rather remains speculative)?

No

Please Explain

No. If the application can be proven to have implied the technical effect or the suitability for the concrete use for an average person skilled in the art at the effective filing date, the application cannot be refused under a lesser standard of evidence, i.e. plausibility.

**21.a** If yes, which standard should apply to determine a speculative filing? Which requirements should the applicant have to meet in order to reach a non-speculative filing?

The normal evidentiary standards provided under the applicable procedural law.

**21.b** What should be the consequence if a technical effect which is not expressly described in the specification is nonetheless plausible because the skilled person would understand that the technical effect was, at the priority date, implied or self-evident from the specification?

The question is unrelated to the question of plausibility. If a technical effect is implied or self-evident for a person skilled in the art, it is disclosed according to the standards of the EPC and of German law. This is in fact the basis for examination in most fields of technology.

**22** Should plausibility be a specific prohibition to refer to “prophetic” examples (or embodiments) in the specification in support of the technical solution purported by the claimed invention, e.g. the description “predicts” that a specific experiment “will” prove a special property of the claimed compound?

Yes

Please Explain

If it is alleged that the experiment proves the property, this needs to be verified. If it is verified, this has to be treated as a fact, if not, the prophetic example is to be disregarded. If, during the examination phase, the patent office chooses to apply plausibility as an evidentiary standard for reasons of procedural expedience, it must, of course, be plausible that the experiment will confirm the allegation for it to be considered.

**22.a** If yes, which standard should apply to identify a prophetic examples?

As long as a proposed experiment has not been carried out, it should not be considered. The underlying explanation why the experiment will show the alleged property, may, however, contribute to plausibility.

**22.b** Should all examples (or embodiments) need to pass this plausibility test? What should be the consequence if only some examples (or embodiments) do not pass the test?

Yes

What should be the consequence if only some examples (or embodiments) do not pass the test?

See answer to questions 22 and 22 a)

**23** What should be the relevant point in time for the plausibility test? What if for example the technical effect of an invention appears plausible at the priority date, but later proves to be wrong, or vice versa?

The patentability requirements need to be met at the effective filing date. Hence, when plausibility is used as the evidentiary standard, it must be plausible that the patentability requirements were met at the effective filing date.

The second question is unrelated to the relevant point in time, but relates to the relation between lesser and higher standards of evidence. If, under a higher standard of evidence, a fact is not proven, this invalidates the assessment under a lesser standard.

**24** Should there be different plausibility tests for different types of claims (e. g. pure product/compound claims without functional feature, product claims including functional feature, second medical use claims, etc.)?

No

Please Explain

-

**25** Who should have the burden of proof for (lack of) plausibility (patentee/applicant or patent office/opponent)?

The burden of proof should be the burden of proof under the rules of evidence of the applicable procedural law.

**26** Please comment on any additional issues concerning any aspect of plausibility you consider relevant to this Study Question, having regard to the scope of this Study Question as set out above.

None.

**27** Please indicate which industry sector views provided by in-house counsel are included in your Group's answers to Part III.

None.