2019 Study Question

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Plausibility

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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?**

Yes

Please Explain

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

Plausibility is not a stand-alone requirement, but both the District Court and Court of Appeal have integrated it into other requirements, in particular inventive step, but also priority, novelty and enablement (see discussion of case law below).

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

No

Please Explain

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.**

As indicated above, the plausibility requirement has been integrated by both the District Court and Court of Appeal into other requirements, in particular inventive step, but also priority, novelty and enablement (see discussion of case law below).

In the context of inventive step, there is consistent case law (though not confirmed by the Supreme Court) that only effects that have been made plausible by the patent at the priority date can be taken into account when assessing inventive step. The Court of Appeal has held in the context of priority that in order for a priority document to have an enabling disclosure, it has to plausibly demonstrate that the invention works. Moreover, there is a decision of the District Court of The Hague in which it was held that for prior art to be novelty destroying it should be enabled as well and that therefore the same plausibility requirement should be applied to the prior art when assessing novelty. In the context of enablement there is case law that suggests that a patent could be held invalid if a claimed effect was not made plausible at the priority date.

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**

Yes

Please Explain

In general the Dutch courts seem to take a similar approach to the Boards of Appeal of the European Patent Office ("EPO").

In the context of inventive step it is established case law that only those effects that are made "plausible" can be taken into account when assessing inventive step. See for example the Court of Appeal of The Hague in the *calcipotriol* case between Leo Pharma and Sandoz (Court of Appeal of The Hague 7 November 2017, ECLI:NL:GHDHA:2017:4029, *Leo Pharma/Sandoz; calcipotriol*, para. 4.17) or Court of Appeal, 25-10-2016 (Teva / Synthon), District Court of The Hague, 17 January 2007 (Conor/Angiotech), Court of Appeal of The Hague, 27 September 2011 (Eli Lilly/Ratiopharm), District Court of The Hague, 11 May 2016 (Leo Pharma/Sandoz).

In the context of enablement, there is also case law in which it is stated that if the therapeutic effect is part of the claim, a patent can be held invalid for a lack of enablement if the application does not render the effect plausible (e.g. Court of Appeal, 27-1-2015 (Novartis / Sun). However, in Ajinimoto / GBT (26-4-2016) the Court of Appeal seemed to take an approach which differs from the EPO approach with respect to "post-published evidence". It indicated firstly that the admissibility of post-published evidence in national invalidity proceedings is a matter of the Dutch law of evidence and that there is thus no reason to not consider such evidence. The Court held that the test for admissibility of post-published-evidence was whether it was not "immediately implausible" that the claimed effect occurred across the whole breadth of the claim. This application of the plausibility requirement seems at odds with other case law from the Court of Appeal.

In the context of novelty, there are two decisions by the District Court of The Hague in which it held that for a prior art reference to be novelty destroying it should be enabled and thus a therapeutic effect should be made plausible as well (District Court of The Hague, 29 June 2016 (MSD/Ono) and 27 July 2016 (Astrazeneca/Sandoz)).

As regards priority, unlike the Boards of Appeal (T 0903/05 (Telomerasepeptides/GEMVAX) –2007), the Court of Appeal of The Hague has suggested that the priority document needs to make the therapeutic effect claimed in the patent plausible in order for the patent to be able to claim priority (Court of Appeal of The Hague, 27 January 2015, (Novartis/Sun)).

There is no Dutch case law on industrial applicability and thus there is also no case law on plausibility in this context.

To date the Dutch Supreme Court has not yet ruled on the concept of plausibility.

We are not aware of any deviating administrative practice before the Dutch Patent Office.

6 **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.**

Inventive step

The plausibility requirement was first applied by the Dutch courts in the context of the problem solution approach (PSA). [1] More specifically, it was applied in the second stage of the PSA (formulation of the objective technical problem), when identifying the technical effect resulting from the distinguishing features. In *Conor/Angiotech,* the District Court of The Hague considered that for the more general claim 1 no specific and surprising technical effect of a combination of known elements was credibly shown in the patent application nor at the date of the litigation for that matter. On the other hand the court did find that for the more specific application in claim 12 the skilled person would understand from the patent that the claimed effect would occur. Therefore claim 12 of the patent showed the benefits of the claimed effect sufficiently to take the effect into account when applying the PSA.

In *Accord/Medac* the District Court held that improved patient compliance as such could not be qualified as a technical effect and also considered that such improved patient compliance had not been made plausible in the patent (the patent merely mentioned that such improved patient compliance was envisaged). Moreover, the court held that a reduced specific side effect had not been mentioned at all in the patent, and it had not been made sufficiently plausible and hence post-published evidence was not allowed to further substantiate this improvement.[2] The Court of Appeal of The Hague, although it held that some steps should have been taken differently, concurred with the main conclusions of the decision of the District Court. [3]

In *Eli Lilly/Ratiopharm* the Court of Appeal of The Hague used the plausibility requirement to answer the question which experimental material in the patent application should be present in the application to substantiate the technical effect claimed therein. [4] The Court of Appeal considered that 'in vitro' experiments were sufficient to make the claimed technical effect plausible. Moreover, the court considered that post-published evidence including information on marketing authorisations could then be used to further substantiate that the product was in fact better than two alternatives.

The District Court of The Hague considered in *Teva/Sanofi* that it is established case law that research data submitted later than the date of the patent application cannot be taken into account when assessing inventive step, if the claimed technical effect has not already been made plausible in the original patent application. [5] If, hence, the application merely mentions an effect but does not make plausible that this is an improved effect, such an improved effect is not taken into account for inventive step.

In *Teva/Boehringer[6]*, the District Court of The Hague reaffirmed it to be established case law that technical effects attributed to the distinguishing feature, which are described and made plausible in the patent application can serve as a basis for formulating the objective technical problem. According to the Court, plausibility can be based on experiments, a causal explanation of the effect, reference to (publications) in the state of the art and common general knowledge.

In appeal in *Teva/Boehringer*[7] and in *Teva/Synthon*[8] the Court of Appeal of The Hague also noted that it was established case law that only claimed technical effects that are mentioned and have been made plausible in the patent (application) can serve as a basis for the formulation of the objective technical problem. The Court of Appeal in the *Boehringer* case concluded that since the claimed technical effects had not been made plausible, as a result – and in line with EPO case law –the technical effect may not be taken into account when formulating the objective technical problem, which meant in this case that the objective technical problem should be characterised as merely providing an alternative (which the person skilled in the art would in this case have arrived at without any inventive step). The Court of Appeal in the *Synthon* case noted that the plausibility requirement is a low threshold which in that case had been met (however, the claims were in the end found not to pass the *Agrevo* test, as the technical effect was not achieved across the full breadth of the claim). In *Leo Pharma/Sandoz*[9] the Court of Appeal explained the plausibility requirement as an embodiment of the principle that the scope of the patent monopoly must correspond to the contribution of the patent to the state of the art. The contribution to the state of the art is determined on the application date from the perspective of the person skilled in the art. This means that effects that were not made plausible in the patent specification on that date must be disregarded when assessing inventive step. The court considered that on the one hand plausibility is referred to as a low threshold because the applicant does not need to provide complete evidence of the claimed effect in the application, but that on the other hand the threshold should be high enough to avoid that inventive step is determined based on an invention made or disclosed after the priority date (and the application thus contained mere speculation). If the effect is a surprising effect (not expected by the person skilled in the art) it means, according to the Court, that the threshold is higher for establishing that the skilled person would understand from the patent that the effect would occur.

In *AstraZeneca/Sandoz* the District Court of The Hague in the proceedings on the merits held that if a prior art document provides more details on the effects than the patent itself, it can be taken into account for inventive step and cannot be dismissed on the ground that the prior art document would not have made the technical effect sufficiently plausible. [10]

Novelty

The District Court of The Hague has first applied the plausibility requirement in the assessment of novelty in *MSD/Ono*[11]. According to the Court, a prior art document is only novelty destroying for a patent containing medical use claims if the therapeutic effect has been disclosed and made plausible in the prior art document, which would follow from EPO case law. [12]

In *AstraZeneca/Sandoz*[13] the District Court in the preliminary injunction proceedings considered that the prior art document did not show the claimed technical therapeutic effect, and the skilled person would not have considered it plausible that the claimed effect would occur. Therefore the prior art document did not pass the threshold and was deemed not novelty destroying for the patent. In appeal in the preliminary injunction proceedings, this consideration was upheld by the Court of Appeal. [14]

Sufficiency (and priority)

The Court of Appeal considered in *Novartis/Sun* that it was up to Sun to make it plausible that the claimed invention was not sufficiently disclosed in the priority document. The Court also considered that the claimed invention needs to be disclosed in an enabling manner in the priority document, in the sense that it needs to be plausible that the claimed invention works. It is not necessary to make it plausible that the

claimed invention is safe.[15]

In *MSD/Ono* the Court of Appeal considered that the therapeutic effect had been made sufficiently plausible by two examples that were part of the priority application as well. It was up to MSD to show that insufficiency of disclosure would apply. [16]

In *Ajinomoto/Global* the Court of Appeal considered that it was undisputed that the patent works for at least two of the amino acids falling within the claim and therefore it was not implausible in advance that the patent works for the other amino acids as well. [17]

In *AstraZeneca/Sandoz* the Court of Appeal found that when a prior art document is considered not to be novelty destroying because that document has not made the claimed technical effect plausible, it does not automatically also mean that the claimed invention is not sufficiently disclosed or not inventive because the claimed technical effect has not been made plausible in the patent application. The Court of Appeal emphasized that the standard for assessment of sufficiency and inventive step is different than the one for novelty. [18] In the appeal of the proceedings on the merits, the Court of Appeal held that the animal tests in the prior art document did not predict the effect in humans while the different animal tests in the patent did and thus did make the effect plausible. [19] Since the plausibility of the effect was based on different animal tests, the court considered it did not have to go into the “squeeze” argument.

Industrial applicability

There is no Dutch case law yet on plausibility in the context of industrial applicability.

Footnotes

1. ^ *District Court The Hague, 17 January 2007, IEPT20070117, (Conor/Angiotech).*
2. ^ *District Court The Hague, 27 July 2016, ECLI:NL:RBDHA:2016:8596, (Accord/Medac).*
3. ^ *Court of Appeal The Hague, 27 March 2018, IEF 177736, (Accord/Medac).*
4. ^ *Court of Appeal The Hague, 27 September 2011, ECLI:NL:GHSGR:2011:BT6897, (Eli Lilly/Ratiopharm).*
5. ^ *District Court The Hague, 2 October 2013, ECLI:NL:RBDHA:2013:15067, (Teva/Sanofi).*
6. ^ *District Court The Hague, 7 September 2016, ECLI:NL:RBDHA:2016:10815, (Teva / Boehringer).*
7. ^ *Court of Appeal The Hague, 11 December 2018, IEPT20181211 (Teva/Boehringer).*
8. ^ *Court of Appeal The Hague, 25 October 2016, ECLI:NL:GHDHA:2016:3368, (Teva/Synthon).*
9. ^ *Court of Appeal The Hague, 7 November 2017, IEF 17255, LS&R 1535, (Leo Pharma/Sandoz).*
10. ^ *District Court The Hague, 11 April 2018, ECLI:NL:RBDHA:2018:4127, (AstraZeneca/Sandoz).*
11. ^ *District Court The Hague, 29 June 2016, ECLI:NL:RBDHA:2016:7363, (MSD/Ono).*
12. ^ *Court follows the EPO, see T 1437/07.*
13. ^ *District Court The Hague, 27 July 2016, ECLI:NL:RBDHA:2016:8700, (AstraZeneca/Sandoz).*
14. ^ *Court of Appeal The Hague, 31 October 2017, IEPT20171031 (AstraZeneca/Sandoz).*
15. ^ *Court of Appeal The Hague, 27 January 2015, ECLI:NL:GHDHA:2015:1769, (Novartis/Sun).*
16. ^ *District Court The Hague, 29 June 2016, ECLI:NL:RBDHA:2016:7363, (MSD/Ono).*
17. ^ *Court of Appeal The Hague, 26 April 2016, IEPT20160426, (Ajinomoto/Global).*
18. ^ *Court of Appeal The Hague, 31 October 2017, IEPT20171031, (AstraZeneca/Sandoz).*
19. ^ *Court of Appeal The Hague, 27 November 2018, IEF 18122 (AstraZeneca/Sandoz).*

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?**

No

Please Explain

No, see our answer to Q 10.

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?**

No

Please Explain

Under Dutch law, plausibility is assessed from the perspective of a person having ordinary skill in the art.

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?**

No

Please Explain

The fact that a technical effect is credible, does not necessarily mean that the claimed invention is obvious. A claimed invention is obvious when the combination of (technical) features as claimed is arrived at without inventive step by the skilled person at the relevant date. Facts and arguments in support of the position that an effect is credible or obvious if the skilled person looks at the claim or specification might play a role, but the only relevant question is whether the skilled person would have arrived at the claimed subject matter in an obvious way. In answering this question care must be taken to avoid hindsight.

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, but if the inventive step of a claimed invention is based on a given technical effect, the latter should be achievable over substantially the whole area claimed.

8 **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)?**

No

Please Explain

No, see our answer to Q 10.

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?**

The applicant does not need to provide complete evidence of the alleged effect in the application. However, the statements regarding the effect should not be merely speculative. If the effect is evident for the person having ordinary skill in the art when reading the patent, taking into account his common general knowledge, it is not necessary to disclose and substantiate the technical effect in the application. However, if the effect is not evident for the person having ordinary skill in the art, the threshold for disclosing the effect is higher (see *Leo Pharma / Sandoz* discussed in Q 6).

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?**

If a technical effect is plausible (implied or evident from the specification), the technical effect is also obvious, but this does not necessarily mean that the claimed invention is obvious (see above Q7 (b))

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)?**

The applicant is not obliged to submit test data to support examples.

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

No, not all examples need to pass the plausibility test. It is of note that substantially all embodiments falling within the scope of a claim do need to pass the test, failing which there may be an enablement and/or inventive step problem.

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

In Dutch case law, plausibility is not considered primarily as a credibility requirement or a prohibition against speculative patent applications.

Furthermore, it is not prohibited to include prophetic examples. The plausibility requirement is regarded by Dutch Courts as an embodiment of the principle that the scope of the patent monopoly must correspond to the contribution of the patent to the state of the art (*Leo Pharma / Sandoz*). The latter is determined from the perspective of the person having ordinary skill in the art at the application date. Reference is made to the case law discussed in Q 6.

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

See above. Plausibility of the effect must be assessed at the application date or, if priority is claimed, the effect should be made plausible (explicitly or implicitly) in the priority document.

If a technical effect that is part of a claim later proves to be wrong or not there for substantially the whole scope of the claim, the patent is likely to be invalid for a lack of enablement.

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 technical effect later proves to be right, but is not rendered plausible in the priority document / application, the Dutch case law suggests that the patent should be held invalid for a lack of enablement (if the effect is a feature of the claim) and/or the effect should not be taken into account when assessing inventive step () which often leads to a finding of invalidity as well.

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.)?**

No

Please Explain

There is no case law dealing with the question whether the threshold would differ if plausibility comes up in a different context. The question is simply always referred to as whether a certain technical effect is "plausible", suggesting that the test is the same in each context.

In addition, it is noted that lack of plausibility arguments can only be made in the context of enablement if the (therapeutic or other type of) effect is part of the claim. In the context of inventive step, an effect that has not been made plausible by the priority document / application cannot be taken into account when assessing inventive step. So if the effect (also) forms the only basis for the inventive step of the patent, lack of plausibility of such effect (also) leads to a finding of obviousness.

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

As a general remark, the party invoking the nullity of a patent bears the onus of proof under Dutch law (Supreme Court of The Netherlands 7 June 2013, ECLI:NL:HR:2013:BZ4115, *Lundbeck/Tiefenbacher; escitalopram*, para. 4.5.2).

A party invoking nullity for lack of inventive step is required to establish and substantiate that an effect disclosed (expressly or implicitly) in the patent should not be taken into account in the formulation of the objective technical problem (Court of Appeal of The Hague 7 November 2017 (Leo Pharma/Sandoz). However, if the patentee wishes to rely on the contested technical effect, it is not sufficient for the patentee to merely assert that the effect is "from the outset not implausible" (District Court of The Hague, 7 September 2016, ECLI:NL:RBDHA:2016:10815 *, Teva/Boehringer; tiotropiumbromide*, para. 4.12)

In the context of enablement, the burden of proof that the claims are not enabled (and thus not made plausible) lies with the party invoking the nullity of the patent (Court of Appeal, 26-4-2016 (Ajinimoto / GBT).

In the context of a lack of novelty, the burden of proof also that the prior art document is enabled and thus makes the effect relied upon plausible, lies with the party invoking the invalidity (District Court of The Hague, 29-6-2016 (MSD / Ono).

14 **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.**

N/A

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

Currently, the doctrine of plausibility in the Netherlands has solely been developed in case law of the District Court and the Court of Appeal in The Hague. In these decisions, which turn on the facts of the matter at hand, relatively little guidance is provided on how to determine whether or not a certain effect has been made plausible, what level of evidence is required under which circumstances etc. In the Dutch Group's view, in the absence – thus far - of an authoritative Supreme Court decision it would be beneficial if guidance would be provided by the EPO on the scope, the threshold, and whether the threshold is the same for different situations / different concepts of patent law (inventive step, enablement, novelty, etc.) or different types of patents and claims.

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

The availability of patent protection aims to incentivize disclosure of technical achievements to the public in such a way, that after patent expiry these technical achievements can be used and further developed by others. It has never been confirmed in Dutch (case) law that the availability of patent protection would aim to incentivize either an early disclosure of technical achievements or rather the disclosure of "completed" inventions. In our Group's view, the test as applied in Dutch case law most likely aims to find a balance between the two aforementioned aims. An application may already be filed when the effect has not been definitively been proven, as long as it is plausible that the effect will occur. The invention need not be completed in that sense. At the same time, the test is designed to avoid that a patent granted based on theoretical assumption/speculation at the priority date, whilst the invention that the effect actually occurred was made after that date.

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

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

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.**

Yes

Please Explain

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, such a requirement puts the standard too low. After all, if this would be the requirement, a described and/or claimed effect would already be plausible if it does not look "incredible". This opens the door to speculative or wide-ranging unsubstantiated claims. After all, unless these claims would be *prima facie* incredible, they would meet the requirement. In our view, the standard should be higher than that. The case law from the Boards of Appeal confirms this.

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?**

N/A

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

Yes

Please Explain

If the inventive step of a claimed invention is based on a given technical effect, the latter should be achievable over substantially the whole area claimed. If the inventive step is based on a number of different effects, the patentee can only rely on those effects that have been made plausible. The applicant should in any case not be able to rely solely on an embodiment disclosing an effect that is not made plausible.

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)?**

Yes

Please Explain

The plausibility test should avoid that a patent is granted based on theoretical assumptions or speculation at the priority date, whilst the invention that the effect was actually obtained was made only after that date. In that sense, plausibility should be a prohibition of 'speculative' patent applications.

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?**

a) On the one hand, it is important that the inventor cannot be expected to provide full proof of an effect by the date of application. On the other hand, the plausibility threshold must be sufficiently high to prevent applications for an invention that was not made or disclosed until after the application date.

The amount of information that needs to be included in the application to support an effect should differ depending on how obvious the effect is that is described and/or claimed in the application for the average skilled person who reads the application with his common general knowledge.

An effect and the substantiation thereof need for example not be explicitly mentioned in the patent specification if the effect and the achievement of this effect by the claimed subject matter is plausible to the average skilled person on the application date on the basis of his common general knowledge.

However, stricter requirements must be set to the substantiation of an effect in the patent specification in the situation that an effect for the average skilled person reading the patent is not plausible on the basis of his common general knowledge on the application date. In that case, the application must contain some evidence that the effect in fact occurs. A way to prove this – and the preferred way in life sciences and chemistry - is by including data from experiments in the application. However, depending on the circumstances and the common general knowledge, a convincing scientific theoretical explanation in the application as to why the effect occurs may be sufficient to render it plausible.

Finally, any effect relied upon for the assessment of the validity of the patent should be made plausible. Thus, a patent application that mentions various (advantageous) effects, should render each of these effects individually plausible. An effect that is not made plausible, cannot be taken into account when formulating the objective technical problem in the context of inventive step. There is no consensus in the Dutch Group whether the patent should be held invalid for insufficiency of disclosure if the effect is a functional feature of the claim. Plausibility of the effect can be based on experimental data included in the application.

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?**

Applying the standard explained above, an effect and its substantiation need not be explicitly mentioned in the patent specification if the effect and its occurrence when applying the teaching of the patent were plausible to the skilled person on the application date on the basis of his common general knowledge. This would be the case if the effect is implied or self-evident from the specification. However, this should not necessarily render the claimed subject matter obvious.

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?**

No

Please Explain

The plausibility requirement should not be a *specific* measure to prevent prophetic examples. Whether a prophetic example can contribute to the plausibility of an invention, must thus be assessed on a case-by-case basis

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

N/A

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?

No

Please Explain

For an advantageous effect associated with the technical differences between the claim and the closest prior art to be taken into account when formulating the objective technical problem in the context of inventive step, that effect must be rendered plausible. This is also the case for any effect that is claimed, with a view of passing the test for sufficiency. Examples therefore do not need to pass the plausibility test – they can be relied upon to render an effect plausible. To the extent that the Examples are incredible or purely speculative, they cannot be used to render the effect plausible. This must be assessed on a case-by-case basis

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 relevant point of time should be the application date, or - if priority is claimed - the priority date. If the technical effect claimed appears to be wrong later on, the patent should be vulnerable to nullification by a third party on the ground of lack of enablement or may be vulnerable to a lack of inventive step attack.

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

The test should not be – and based on Dutch case law at this moment in time is not - different. Lack of plausibility of the effect leads to different consequences, depending on whether the effect is a functional feature of the claim. If it is, Dutch case law suggests that the claim will be insufficiently disclosed. If the effect is not a functional claim feature but it is (part of) the solution to the technical problem allegedly solved by the patent, the lack of plausibility leads to a reformulation of the technical problem to a (less ambitious) problem.

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

The party invoking the nullity of the patent should establish and, if sufficiently disputed, prove that the technical effect at issue is not plausible to the skilled person reading the patent. If he achieves this, the burden of proof that the effect is plausible should be on the patentee/applicant, regardless whether lack of plausibility is argued in the context of lack of enablement or lack of inventive step. In both instances the issue is essentially whether the skilled person reading the patent finds it plausible that the invention that is claimed actually works.

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.

There are a couple of issues we believe are important to sort out in particular:

- We believe that as a starter the three big patent offices (USPTO, EPO, JPO) should agree on the basic principles regarding the plausibility requirement and the burden of proof
- Like the Enlarged Board of the EPO has done (see G 1/03, G 2/03, and G 2/10) with the so called "gold standard" (i.e. the test for both novelty, priority, and added matter) , we believe a similar standard should be developed for the plausibility requirement for a patent (application) and for prior art to be novelty destroying.

When answering these questions it became increasingly clear to us that one cannot properly deal with the issue of plausibility without taking the factor of post published evidence into account.

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