2023 – Study Question

Q 284 Doctrine of

equivalents

Q284 Dutch Group:

Tjibbe Douma (chairman; tjibbe.douma@twobirds.com), Bernard Ledeboer, Claudia Zeri, Jeroen Boelens, Wouter Pors, Erik Visscher, Bertrand ter Woort, Jasper Groot Koerkamp, Paul Reeskamp, Peter Van Schijndel, Michelle Simmen, Bart Trier, Arvid van Oorschot, Arjan Reijns, Rene Raggers, Marten Luten

Introduction

1) Several jurisdictions provide for patent protection of "equivalents", i.e. technical embodiments which are outside the scope of literal infringement of a patent's claims, but are still considered to be within the scope of protection/infringing, subject to additional requirements. Thus the "scope of claims" may not coincide with the "scope of protection."

2) In Europe, for example, Article 2 of the Protocol on the Interpretation of Art. 69 of the European Patent Convention (EPC) addresses the extent of protection conferred by a European patent; according to this provision, due account shall be taken of any element which is equivalent to an element specified in the claims. Further, under US law, equivalents are taken into account under the "function-way-result" or "insubstantial differences" tests, cf. *Mylan Institutional LLC v. Aurobindo Pharma Ltd.*, Fed. Cir., 2017 857 F.3d 858. Under Chinese law, the doctrine of equivalents was introduced by the Chinese Supreme Court in 2009. In the UK, *Actavis v Lilly* [2017] UKSC 48 introduced the doctrine of equivalents into national law in 2017 in place of a single purposive interpretation.

3) AIPPI's Resolution on Q175 – "The role of equivalents and prosecution history in defining the scope of patent protection" (Lucerne 2003) likely played a role in the process of this general degree of international harmonisation. However, detailed requirements and limitations of these doctrines may still vary quite significantly.

4) The focus of this Study Question is on important issues which haven not yet been covered by AIPPI's previous work and which have emerged in several cases before national courts, most prominently before the UK High Court in *Apple v Optis* [2021] EWHC 1739 (Pat), and before the Dutch Court of Appeals in *Fresenius Kabi Nederland B.V. v Eli Lilly & Company* (judgment 08.05.2018 –

ECLI:NL:GHA:2018:1105[1] confirmed by the Supreme Court on 12.06.2020 – ECLI:NL:HR:2020:1036), and before the German Federal Supreme Court (Judgment of 10.05.2011 - X ZR 16/09 – *Okklusionsvorrichtung*)[2].

5) One issue is the question whether equivalents should be considered as part of the scope of protection when discussing the validity and/or patentability of the patent, most importantly novelty/inventive step, but possibly also sufficiency of disclosure, plausibility and added matter. The aim is to study whether the enlargement of the scope of protection of the claim for the purposes of infringement also means that the scope of protection should be the same for the purpose of validity. For example, if the enlargement of the scope of protection results in prior art falling within the enlarged scope of protection, should the patent be considered anticipated and lacking in novelty?

6) Similarly, if the scope of protection of the patent-in-suit covers certain (equivalent) embodiments which are e.g. obvious over the prior art, or which lack plausibility in view of the original disclosure, can the validity of the patent be challenged on that basis? Depending on the answer to this question of principle, further procedural questions might need to be addressed.

7) As a second issue, the question is whether the patent owner is prevented or estopped from claiming equivalent infringement with regard to those embodiments which were known to the applicant (based on the contents of the specification) but which the applicant failed to claim literally. This 'disclosed but not claimed' question specifically arises if the specification lists a number of alternative embodiments, but the claims (based on their literal scope of protection) only cover a subset of these alternative embodiments.

Why AIPPI considers this an important area of study

8) In 2003, AIPPI studied the doctrine of equivalents in its Resolution on Q175 – "The role of equivalents and prosecution history in defining the scope of patent protection" (Lucerne 2003). This resolution focuses of the fundamental requirements for establishing equivalent infringement, as well as principal limitations of this doctrine. As for the limitations of the doctrine, the Resolution is generally inspired by the German "Formstein" doctrine (German Federal Supreme Court, judgement of 29.04.1986 - X ZR 28/85, GRUR 1986, 803 – *Formstein*). Since then, the doctrine of equivalents continuously developed in many jurisdictions, potentially deviating from the principles laid down in Q175 and also raising new legal issues, which merits further study.

9) Most importantly, the lack of symmetry between infringement and anticipation addressed by the UK High Court in *Apple v Optis* seems to be a legal issue which is not yet sufficiently studied in science and case law, although this issue touches upon

[1] Free English translation available at http://patentblog.kluweriplaw.com/wp-content/uploads/sites/52/2020/12/Court-of-Appeal-The-Hague-27-October-2020_Eli-Lilly-v-Fresenius_EN-translation.pdf.

[2] Free English translation available at https://www.bgh-entscheidungen-patentrecht.de/fileadmin/user_files/ptdc_db/en/BGH_X_ZR_16_09_-_Okklusionsvorrichtung_EN.pdf

the fundamental justification of the doctrine of equivalence, as further discussed below. Likewise, the question raised by the German Federal Supreme Court in *Okklusionsvorrichtung* whether (unclaimed) alternative embodiments disclosed in the specification are excluded from infringement by equivalence requires study of a fair balance between legal certainty and an appropriate scope of protection.

Relevant treaty provisions

10) Art. 69 EPC states:

(1) The extent of the protection conferred by a European patent or a European patent application shall be determined by the claims. Nevertheless, the description and drawings shall be used to interpret the claims.

(2) For the period up to grant of the European patent, the extent of the protection conferred by the European patent application shall be determined by the claims contained in the application as published. However, the European patent as granted or as amended in opposition, limitation or revocation proceedings shall determine retroactively the protection conferred by the application, in so far as such protection is not thereby extended.

11) Article 1 of the Protocol on the Interpretation of Art. 69 EPC states:

Article 69 should not be interpreted as meaning that the extent of the protection conferred by European patent is to be understood as that defined by the strict, literal meaning of the wording used in the claims, the description and drawings being employed only for the purpose of resolving an ambiguity found in the claims. Nor should it be taken to mean that the claims serve only as a guideline and that the actual protection conferred may extend to what, from a consideration of the description and drawings by a person skilled in the art, the patent proprietor has contemplated. On the contrary, it is to be interpreted as defining a position between these extremes which combines a fair protection for the patent proprietor with a reasonable degree of legal certainty for third parties.

12) Article 2 of the Protocol on the Interpretation of Art. 69 EPC states:

For the purpose of determining the extent of protection conferred by a European patent, due account shall be taken of any element which is equivalent to an element specified in the claims.

Scope of this Study Question

13) The objective of this Study Question is to revisit whether, in principle, refinements, amendments or changes need to be made to the rationale of the Q175 Resolution. Further, from the various additional issues related to the doctrine of equivalence, this Study Question aims to focus on the following two issues:

- the lack of symmetry between infringement and validity/patentability
- whether (unclaimed) alternative embodiments disclosed in the specification should be excluded from infringement by equivalence

14) The above questions would become significantly more complex if covering both patents and utility models, as utility models are unexamined right. Therefore, equivalent infringement of utility models is out of scope.

Previous work of AIPPI

15) The role of equivalents in relation to claim construction was addressed by AIPPI in the Resolution Q126 – "Methods and principles of novelty evaluation in patent law" (Montréal 1995). AIPPI resolved that "*the interpretation of a disclosure must take into account the understanding of a person skilled in the art. Such interpretation should extend to what the person skilled in the art, on considering the disclosure, would understand as implicitly or inherently disclosed. It should not extend to technical equivalents not covered by such an interpretation, nor should it extend to the realm of inventive activity*."

16) In the Resolution on Q175 – "The role of equivalents and prosecution history in defining the scope of patent protection" (Lucerne 2003), AIPPI noted that a*n "element shall be regarded as equivalent to an element in a claim, if: 4.a) the element under consideration performs substantially the same function to produce substantially the same result as the claimed element; and 4.b) the difference between the claimed element and the element under consideration is not substantial according to the understanding of the claim by a person skilled in the art at the time of the infringement."*

17) In contrast, an element shall not be regarded as equivalent to an element in a claim, if *5.a) "a person skilled in the art would at the filing date have understood it to be excluded from the scope of protection, or 5.b) as a result the claim covers the prior art or that which is obvious over the prior art, or 5.c) the patentee expressly and unambiguously excluded it from the claim during prosecution of that patent to overcome a prior art objection."*

18) Furthermore, AIPPI concluded that an equivalent infringement must be denied if the claim would otherwise cover "*the prior art or that which is obvious over the prior art*". Thus, AIPPI's position as expressed in Q175 reflects the core of the so-called Formstein defense.

19) In the Resolution on Q229 – "The use of prosecution history in post-grant patent proceedings" (Seoul 2012), AIPPI resolved that "*where the prosecution history*

contains a clear and unambiguous statement made (and not withdrawn before the grant of the patent) by or on behalf of the applicant, from which it must be concluded that the applicant disclaims or abandons part of the scope of protection that would otherwise be included, the scope of protection shall be limited accordingly in post- grant proceedings."

20) Finally, the 2021 World Congress (Online) featured a panel session "Doctrine of equivalents: Can prior art infringe?"

Discussion

Lack of symmetry between infringement and validity/patentability

21) In the UK, prior to *Actavis v Lilly*, following the approach set out by the House of Lords in *Kirin-Amgen v Hoechst* [2004] UKHL 46, the meaning of a claim was considered functionally in the context of the teaching of the patent as a whole and the question was asked how a skilled person would have understood the patentee if he had used the language of the claim. If a claim was infringed by the prior art, it was anticipated. However, post-*Actavis* it would be possible in theory for a prior art device to fall within the scope of protection but outside the literal scope of the claims.

22) The "traditional" approach in some jurisdictions to address this lack of symmetry is to apply the Formstein defense according to which a claim construction is adopted such that an (otherwise equivalent) embodiment does not constitute patent infringement if this embodiment either anticipated by prior art or obvious over prior art. This basic doctrine has been widely adopted in various jurisdictions, albeit with some nuances.

23) As an example of such "modified implementation" of the Formstein doctrine, one may refer to the UK High Court stating in *Facebook v Voxer* (2021, EWHC 1377 (Pat)) that if the equivalent device would have lacked novelty, or would have been obvious, the scope of protection must be confined to its normal/purposive construction in that respect. In *Vernacare Limited v Moulded Fibre Products Limited* (2022: EWHC 2197: IPEC), the UK High Court agreed with the approach set out in *Facebook v Voxer,* saying that the *"skilled person is unlikely to construe a claim as applying to a variant (an equivalent) to the inventive concept of that claim where that variant was not inventive but was, rather, a part of that skilled person's common general knowledge."*

24) As an example of the more "traditional implementation" of the Formstein doctrine, one may refer to the Dutch Court of Appeal in *Eli Lilly v Fresenius* (ECLI:NL:GHDHA:2020:2052).

25) However, in *Apple v Optis* the UK High Court raised the question whether equivalents should be considered as part of the scope of protection when discussing the novelty/inventive step in order to broaden a claim as the target for an anticipation attack ("anticipation by prior art or its equivalents"). The rationale behind this approach is that a patent which is held to be infringed must be also valid, i.e. there must be symmetry between infringement and validity/patentability. If one develops this idea further, also the question of added matter, plausibility and sufficiency of disclosure could be examined taking into account the equivalent scope of protection.

26) While this basic rationale seems to be quite compelling as a starting point, both policy considerations and practical considerations may raise questions as to whether fu**ll** symmetry is actually a desired or even achievable goal.

27) As a policy consideration, one may argue that there is actually no such thing as an abstract "equivalent scope of protection": Contrary to the normal/non-equivalent scope of protection which can be defined in the abstract by interpreting the claim language, no such abstract definition of all equivalent means might be possible (other than just reciting the generally applicable test for equivalent infringement), because equivalent infringement is always tied to a specific embodiment and/or specific prior art under a Formstein approach. Consequently, one might take the position that the normal scope of protection has an *erga omnes* effect, while equivalent infringement is always tied to an *inter partes* relation and a specific case. At the same time, it seems to be generally accepted that the question of validity has an *erga omnes* nature, as in most jurisdictions the validity can be challenged by anyone at any time, and an invalidation has an *ex tunc* and *erga omnes* effect. In contrast, most defences (estoppels) against patent infringement claims are limited to a concrete *inter partes* relation. Taking into consideration these general principles, one may then conclude that validity and normal infringement indeed require a full symmetry, while no such symmetry is required regarding equivalent infringement. An *inter partes* defence against an equivalent infringement by prior art might be viewed as appropriate given the limited nature of equivalent infringement.

28) As a practical consideration, if one considered the equivalent scope of protection when assessing validity and/or patentability, the question is whether the relevant embodiments should be limited to those embodiments which are attacked as "equivalent infringement" in a specific case, or whether also merely "potential" or "likely" embodiments might be considered (which would then require a test to determine what a "potential" or "likely" embodiment is). Further, the question is whether such invalidity argument should be available only in post-grant proceedings, or also during prosecution. All these considerations might lead to the conclusion that full symmetry might cause a significant degree of legal uncertainty and various practical complications, and might not even be an achievable goal.

29) However, if full symmetry is not achievable, is it legitimate to continue to apply a Formstein-type approach, and exclude anticipating prior art from the scope of protection? Alternatively, should the doctrine of equivalents not cause the scope of protection to be extended to cover prior art or obvious extensions of the prior art?

<u>Whether (unclaimed) alternative embodiments disclosed in the specification should be excluded from infringement by equivalence</u>

30) As mentioned above, the German Federal Supreme Court held in *Okklusionsvorrichtung* that alternative embodiments of the claimed invention disclosed in the patent application (but not covered by the literal scope of protection) cannot be claimed as equivalent infringement. The German Federal Supreme Court

further developed this doctrine in *Pemetrexed*[3] (14. 06. 2016) X ZR 29 / 15) and *V-förmige Führungsanordung"*[4] (23. 08. 2016, X ZR 76 / 14), holding that it only applies if at least one of several embodiments explicitly mentioned in the specification is actually subject matter of a granted claim. In contrast, the fact that other embodiments are merely generally mentioned in the specification, e.g. by using generic terms, does not result in a categorical denial of equivalent patent infringement.

31) As a legal certainty consideration, one might argue that the public understands that the applicant wanted to disclaim all embodiments which are explicitly mentioned in the specification but not in one of the claims. However, one might equally argue that the public more likely understand that all alternative embodiments mentioned in specification are actually clearly "marked" as potential equivalent embodiments so that legal certainty is actually not an issue at all. If the latter conclusion was more convincing, excluding such embodiments from equivalency might even viewed as quite significant interference with the underlying principle of the doctrine of equivalence "to temper unsparing logic and prevent an infringer from stealing the benefit of the invention" (*Royal Typewriter Co. v. Remington Rand, Inc.*, 168 F.2d 691, 692 (2d. Cir. 1948). As a third approach, one may apply the general position taken by AIPPI in Q175 also to this particular question, i.e. unclaimed alternative embodiments disclosed in the specification should only be excluded from infringement by equivalence if the patentee expressly and unambiguously excluded them from the claim during prosecution of that patent to overcome a prior art objection.

You are invited to submit a Report addressing the questions below.

Questions

I) Current law and practice

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

In the questions below:

"4a function test" means that the element under consideration in the allegedly infringing product performs substantially the same function to produce substantially the same result as the corresponding claim element,

"4b difference test" means that the difference between the claimed element and the element under consideration is not substantial according to the understanding of the claim by a person skilled in the art at the time of the infringement,

[3] Free English translation available at https://www.bgh-entscheidungen-patentrecht.de/fileadmin/user_files/ptdc_db/en/BGH_X_ZR_29_15_ -_Pemetrexed_I_EN.pdf

[4] Free English translation available at https://www.bgh-entscheidungen-patentrecht.de/fileadmin/user_files/ptdc_db/en/BGH_X_ZR_76_14_ -_V-foermige_Fuehrungsanordnung_EN.pdf

"5a exclusion" means that a person skilled in the art would at the filing date have understood an element to be excluded from the equivalent scope of protection,

"5b exclusion" means that as a result of adopting the equivalent scope of protection, the scope of protection covers the prior art or that which is obvious over the prior art,

"**5c exclusion**" means the patentee expressly and unambiguously excluded an element from the claim during prosecution of that patent to overcome a prior art objection, and

The **"Q175 Approach"** means that the scope of protection shall include those elements that meet the 4a function test and 4b difference test, provided that they are not excluded under the 5a, 5b or 5c exclusions.

1) Is the current law and practice in your jurisdiction generally in line with the Q175 Approach?

Albeit not identical, current Dutch law and practice is considered to be generally in line with the Q175 Approach. The Dutch Group wishes to mention that the tradition of Dutch case law shows that the Dutch patent courts have a highly casuistic, hands-on approach, where much depends on the concrete circumstances of the case at hand.

a) Is there a distinction between the scope of protection and the scope of claims? Please answer YES or NO and you may add a brief explanation.

YES, reading the scope of protection and the scope of claims in the way explained under par 1 above. In the Netherlands, Article 69 European Patent Convention ("EPC") and the Protocol on the Interpretation of Article 69 EPC ("Protocol") are applicable. In interpreting said statutory provisions, a twostep test has most recently been applied in Dutch case law (Court of Appeal of The Hague, 27 October 2020, ECLI:NL:GHDHA:2020:2052 (*Fresenius/Lilly,* hereafter *"Fresenius/Lilly"*)).

Consistent with the two sections of the Protocol, the first step of the twostep test considers infringement based purely on the scope of claims, while the second step considers equivalent infringement, amounting to establishment of the scope of protection (i.e. "literal" plus equivalent infringement).

b) Is the current law and practice in your jurisdiction following the 4a function test? Please answer YES or NO and you may add a brief explanation.

YES. The first question in assessing equivalent infringement in accordance with the second step of the above twostep test relates to so-called "technical equivalence". This involves assessing whether the variant element under consideration is equivalent to the element as claimed from a technical point of view. That requirement is satisfied if the product or process containing the element under consideration also solves the problem that the patent solves and, in that context, the element under consideration performs the same function as the element as claimed (*Fresenius/Lilly*, para. 4.7).

c) Is the current law and practice in your jurisdiction following the 4b difference test? Please answer YES or NO and you may add a brief explanation.

NO. The twostep test does not literally address the *substantiality* of the differences between the claimed element and the element under consideration in an isolated manner.

The differences between the claimed element and the element under consideration will, however, in practice be reviewed when assessing equivalence using the second step of the two-step approach. For instance, the second question to be answered in assessing equivalent infringement in accordance with the second step of the above-mentioned twostep test, is whether extending the scope of protection of a particular patent to encompass a certain variant does not extend the protection of the patentee beyond a fair one. Such fair protection of the patentee requires the scope of protection to commensurate with the patent's contribution to the prior art (*Fresenius/Lilly*, para. 4.8). In that light, it has been considered that a high degree of innovation may fairly deserve a broader protection. In that case a wider variation of equivalents may still be considered to fall under the scope of protection than if a patent only embodies a low degree innovation.

d) Is the current law and practice in your jurisdiction following the 5a exclusion? Please answer YES or NO and you may add a brief explanation.

YES. The third question of the second step of the twostep test deals with the protection of the reasonable degree of legal certainty for third parties.

There is deemed to be a sufficient degree of legal certainty if (i) the skilled person would understand that the claims leave room for equivalents because the teaching of the patent is clearly broader than the wording of those claims, and (ii) limiting the scope of protection to the element mentioned in the claims has no justifiable basis. Such justifiable basis exists if the skilled person has reasons to assume that part of the protection has been waived by the patentee, even though the subjective will or intent of the patentee does not play a decisive role in determining the scope of protection (*Fresenius/Lilly*, para. 4.48).

e) Is the current law and practice in your jurisdiction following the 5b exclusion? Please answer YES or NO and you may add a brief explanation.

YES. The fourth question of the second step of the twostep test may be (if such is argued) whether the equivalent element is novel and inventive over the prior art (*Fresenius/Lilly*, para. 4.11). If such is not the case (i.e. the variant is not new or inventive over the state of the art on the priority date or date of application of the patent), a device/process containing such element is deemed not to infringe, as a patent should not protect non-patentable subject matter.

f) Is the current law and practice in your jurisdiction following the 5c exclusion? Please answer YES or NO and you may add a brief explanation.

YES. In establishing whether there exists a justifiable basis for limiting the scope of protection, the skilled person may review the prosecution file. If the prosecution file shows that the patentee has limited its patent to overcome a prior art objection, such limitation may be held against the patentee in establishing the scope of protection (Court of Appeal of The Hague, 20 September 2022, ECLI:NL:GHDHA:2022:1802 (*Tinnus/Koopman*), paras. 6.11-6.12).

2) Whether (unclaimed) alternative embodiments disclosed in the specification should be excluded from infringement by equivalence

a) Under the current law and practice in your jurisdiction, does equivalent infringement categorically exclude those embodiments which are disclosed in the patent specification as possible alternatives of the means literally mentioned in the granted claims, i.e. are such alternative embodiments implicitly disclaimed from the equivalent scope of protection?

Please answer YES or NO and you may add a brief explanation.

NO. As explained above under 1d), the requirement of a sufficient degree of legal certainty for third parties prescribes that (i) if the skilled person understands that the claims leave room for equivalents because the teaching of the patent is clearly broader than the wording of those claims, but (ii) also understands that part of protection has been waived by the patentee, such third party may – under circumstances – presume that the limiting waiver takes precedence over the broader disclosure.
Taking into account the full context in which the claims have been worded (i.e. the contents of the description and the drawings, his/her common general knowledge and the prosecution file), the skilled person may – under circumstances – conclude that, if embodiments have been disclosed in the specification but have, despite their disclosure, not been claimed by the patentee (without a justifiable basis (e.g. to overcome an added matter objection), no protection was sought for these embodiments in that patent. In such a case, the requirement of a sufficient degree of legal certainty will require a restrictive claim interpretation in the context of equivalent infringement.

However, a general "disclosed but not claimed is disclaimed" rule has not been established under Dutch law and practice (Pleadings Advocate-General Supreme Court Supreme Court, ECLI:NL:HR:2020:1036 (*Fresenius/Lilly*), par. 2.66), and embodiments that have been disclosed in the specification but are not claimed are not "categorically" excluded from the equivalent scope of protection. The court will consider all circumstances of the case, which consideration will always include the assessment of the reason(s) why a certain element was left out of the claims of a patent.

b) Under the current law and practice in your jurisdiction, does equivalent infringement exclude those embodiments which are disclosed in the patent specification as possible alternatives of the means literally mentioned in the granted claims if the patentee excluded them from the claim during prosecution of that patent to overcome a prior art objection?

Please answer YES or NO and you may add a brief explanation.

YES. In the Netherlands, equivalent infringement generally excludes embodiments which are disclosed in the patent specification as possible alternatives of the means literally mentioned in the granted claims, but were excluded from the claim during prosecution to overcome a prior art objection.

The Dutch courts assess such embodiments by analysing whether or not the skilled person deems there to have been a justifiable basis ("goede grond" in Dutch) for limiting the patent's scope of protection to the application of the feature included in the patent claim(s), notwithstanding the fact that the disclosure in the patent appears to be broader than what is specifically claimed (Supreme Court, ECLI:NL:HR:2016:196 (*Bayer/Sandoz*), under 3.4.1-3.4.2). Limitation to overcome a prior art objection would generally be perceived as such justifiable basis (see also question 1f).

3) Under the current law and practice in your jurisdiction, does one consider the equivalent scope of protection conferred by a patent when assessing validity and/or patentability of that patent? In other words, is it possible that, considering the equivalent scope of protection of a particular patent, this patent is deemed to

[the question continues in subquestions below]

NO. For the interpretation, we have assumed that this question related specifically to the "anticipation by equivalence" doctrine as addressed in Apple v. Optics.

In the Netherlands, equivalents as part of the scope of protection are, up to now, not considered when assessing lack of novelty, lack of inventive step or other grounds for non-patentability (in the context of anticipation by equivalence) during prosecution or validity assessment in court (see *Fresenius/Lilly,* para 4.11 and 4.45.2.).

Gillette-style defenses, where the equivalent under discussion in a specific case is argued to be non-patentable in light of the prior art of the patent, form part of the equivalent *infringement* assessment of the court. If a variant device or process is found to lack novelty or inventive step over the prior art of the patent, extending the scope of protection of a patent to such an equivalent is deemed to go beyond what justifies fair protection for the patentee. Thus, such variants cannot be deemed infringing on such patent (see *Fresenius/Lilly,* para 4.11, the fourth question of the second step of the twostep test, also cited under the answer to Question 1).

a) lack novelty, and/or

Please answer YES or NO and you may add a brief explanation.

NO, see answer above.

b) lack inventive step (non-obviousness), and/or

Please answer YES or NO and you may add a brief explanation.

NO, see answer above.

c) lack sufficiency of disclosure, and/or

Please answer YES or NO and you may add a brief explanation.

NO, see answer above.

d) lack plausibility, and/or

Please answer YES or NO and you may add a brief explanation.

NO, see answer above.

e) claim added matter?

Please answer YES or NO and you may add a brief explanation.

NO, see answer above.

If your answer to any of the questions 3 a) to e) is YES, please address the following questions:

4) When assessing validity and/or patentability against the equivalent scope of protection, are the relevant embodiments limited to those embodiments which are attacked as "equivalent infringement" in a specific case by the patent owner (or an otherwise entitled person)?

Please answer YES or NO and you may add a brief explanation.

N/A, see answer to Question 3.

5) If the answer to question 4 is YES, is anyone be entitled to attack the validity and/or patentability of the patent based on such argument, or only the alleged infringer?

Please answer YES or NO and you may add a brief explanation.

N/A, see answer to Question 3.

6) If the answer to question 4 is NO, what is the appropriate approach to identify the relevant equivalent embodiments when assessing validity and/or patentability? Is there, for example, a requirement that relevant equivalent embodiments must be likely being used in practice?

Please answer YES or NO and you may add a brief explanation.

N/A, see answer to Question 3.

7) If the answer to question 4 is NO, does the patent office consider the equivalent scope of protection when assessing validity and/or patentability,

or is such discussion limited to post-grant proceedings?

Please answer YES or NO and you may add a brief explanation.

N/A, see answer to Question 3.

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

8) According to the opinion of your Group, is your current law regarding the doctrine of equivalents adequate and/or sufficient? Please answer YES or NO and you may add a brief explanation.

YES. In general it holds a fair balance between a reasonable scope of protection and a reasonable degree of legal certainty.

9) According to the opinion of your group, is there (still) a need for a doctrine of equivalents under your law, i.e. in that there needs to be a distinction between the scope of protection and the scope of claims? Please answer YES or NO and you may add a brief explanation.

YES. There is a need for a doctrine of equivalents which is present in the Netherlands (we refer to our answer to question 1a, displayed again here).

In the Netherlands, Article 69 European Patent Convention ("EPC") and the Protocol on the Interpretation of Article 69 EPC ("Protocol") are applicable. In interpreting said statutory provisions, a twostep test has most recently been applied in Dutch case law (Court of Appeal of The Hague, 27 October 2020, ECLI:NL:GHDHA:2020:2052 (*Fresenius/Lilly,* hereafter *"Fresenius/Lilly"*)).

Consistent with the two sections of the Protocol, the first step of the twostep test considers infringement based purely on the scope of claims, while the second step considers equivalent infringement, amounting to establishment of the scope of protection (i.e. "literal" plus equivalent infringement).

We further refer to our answer to Question 10 for the reasons for the need according to our Group.

10) According to the opinion of your group, what is the principal justification of the doctrine of equivalents? What factor does legal certainty for third parties play in this regard?

The principal justification is to extend the scope of protection to methods and products that embody the inventive concept of the patent, in particular including equivalents which could not have been reasonably foreseen by the patentee at the priority date. If third parties were justified to believe that the patentee intended not to claim certain embodiments, (we refer to our answer to Question 1d, 1f and 2) the patentee should not be allowed to extend the scope of protection through relying on the doctrine of equivalents.

11) Are there any other policy considerations and/or proposals for improvement to your Group's current law falling within the scope of this Study Question?

We believe that the doctrine of equivalents is valuable, but should not become a cure for sloppy drafting. In addition, if one is to support the 'disclosed but not claimed is disclaimed' doctrine, it is difficult to see why this should be applied only to embodiments disclosed in the specification but not to embodiments that are part of the CGK (at the priority date).

III) Proposals for harmonisation

12) Do you consider harmonisation regarding the doctrine of equivalents as desirable in general? Please answer YES or NO and you may add a brief explanation

YES. The Dutch Group sees free worldwide trade with low boundaries between jurisdiction as desirable to bolster worldwide prosperity. Furthermore, good patent law is considered to incentivize innovation. Harmonisation of legislation in general in patent legislation in particular supports this. Therefore, the Dutch Group considers harmonisation regarding any doctrine of equivalents as desirable.

13) Do you see any need to amend and/or change the Q175 Approach?

a) Is there (still) a need for doctrine of equivalents, i.e should there be a distinction between the scope of protection and the scope of claims? Please answer YES or NO and you may add a brief explanation.

YES. The Dutch Group does see a difference between the scope of protection, which seems to be determined by Article 2 of the Protocol on the Interpretation of Article 69 EPC, and the scope of the claims, which seems to be determined by Article 1 of the Protocol on the Interpretation of Article 69 EPC. Following thereon, the Dutch Group considers the question to be whether there should be any difference between the "literal" wording of the claims and the scope of protection. The answer to that is a firm yes.

Firstly, with a still growing pace of innovation, it cannot be expected that a patentee is able to look fifteen years ahead and for that reason, it cannot be expected that in the drafting of a patent application, wording is always to be used that literally covers equivalents of a claimed element that do not exist at the time of drafting and may exist fifteen years later (in particular where they relate to elements that do not lie at the core of the invention).

Second, an invention and understanding thereof may develop over the years after a patent application has been filed, which makes equivalents not logical at the time of filing of a patent application while it may be obvious after for example nine years after filing. It would be unjust for the patentee who has made a contribution to the state of the art that such new insights based on the initial invention would not be covered by the patent granted. Those standing on the shoulders of a giant should pay tribute to those giants.

Thirdly, if it would be fair to award a patentee a broader scope of protection than the "literal" wording then there should be room for that. If for example a competitor takes the benefit of the invention, but uses a variant of a claimed element that is not essential to the invention, then it may – under circumstances – be fair to award the patentee a scope of protection that includes such a variant.

I.e. the Dutch Group believes that also in case of foreseeable minor modifications to (especially non-essential) elements there should be room for infringement by equivalence. Otherwise, there would exist a need for a practice of listing all such foreseeable variants of non-essential elements in a patent application, which is considered not desirable.

Thus, there is still a need for doctrine of equivalents.

b) Alternatively, instead of a doctrine of equivalents, would it better to require more comprehensive claim drafting, or would you prefer any other alternative approaches to address the material issues underlying the doctrine of equivalence, such as e.g. an exhaustive list of equivalents set forth in the specification? Please answer YES or NO; in particular if answering YES, please add a brief explanation.

NO. An approach alternative to a doctrine of equivalents, like different claim drafting or solely relying on limitation in the description is all but preferred by the Dutch Group. Firstly, such approaches would be at odds with the arguments provided above. Second, such approach would require more information to be provided in patent applications, which would result in larger and longer specifications and claim sets. This would, in turn result in increased cost for right holders, both for drafting and storage space of documents.

c) Do you see any need to amend and/or change the 4a function test in Q175? Please answer YES or NO and you may add a brief explanation.

YES. The Dutch Group would prefer 4a of resolution Q175 to be amended to state that if an equivalent element of a claim element is by an alleged infringer implemented such that it has substantially the same function and achieves substantially the same result in substantially the same way, the element implemented by the alleged infringer is considered to be equivalent to the claimed feature.

d) Do you see any need to amend and/or change the 4b difference test in Q175? Please answer YES or NO and you may add a brief explanation.

NO. The difference test of 4b of A175 is in view of the Dutch Group too vague to be practical. It is not clear how the difference is to be assessed, for example from a constructional or functional point of view? Therefore, the Dutch Group prefers the approach of Question 13(c).

e) Do you see any need to amend and/or change the 5a exclusion in Q175? Please answer YES or NO and you may add a brief explanation.

YES. Free trade is served by legal certainty. If it is clear to the skilled person, at the date of filing of an application, that a particular equivalent would not fall within the scope of protection of a patent, such element is not to contribute to infringement.
Such understanding may arise from the application as filed as a whole or from the prosecution history before a patent authority.
Alternatively, or additionally, if it is clear that any acts of an alleged infringer are

not novel or obvious when assessed at the effective date of an application for the patent in suit, such acts are not to be held infringing. An important reason for this is that patents are to protect subject-matter only if such subject-matter is novel and not to be obvious at the effective date of the patent.

f) Do you see any need to amend and/or change the 5b exclusion in Q175? Please answer YES or NO and you may add a brief explanation.

NO, see e)

g) Do you see any need to amend and/or change the 5c exclusion in Q175? Please answer YES or NO and you may add a brief explanation.

NO, see e)

14) Whether (unclaimed) alternative embodiments disclosed in the specification should be excluded from infringement by equivalence

a) Should equivalent infringement categorically exclude those embodiments which are disclosed in the patent specification as possible alternatives of the means literally mentioned in the granted claims, i.e. are such alternative embodiments implicitly disclaimed from the equivalent scope of protection? Please answer YES or NO and you may add a brief explanation.

NO, equivalent infringement should exclude those embodiments which are disclosed in the patent specification as possible alternatives of the means literally mentioned in the granted claims unless there is a justifiable basis for such limited claim. Hence, there should not be a categorical exclusion under all circumstances. We refer to the answers to Questions 1d, 1f and 2 but also Question 14 (b).

The Dutch Group had a discussion about whether obvious alternative embodiments not disclosed in the application for the patent in suit at the filing thereof should be excluded from infringement by equivalence. In line with the answer under Question 13e), the Dutch Group notes that if it is clear that any alternative embodiment provided by an alleged infringer is not novel or obvious when assessed at the effective date of an application for the patent in suit, such alternative embodiments are not to be held infringing.

b) Should equivalent infringement exclude those embodiments which are disclosed in the patent specification as possible alternatives of the means literally mentioned in the granted claims if the patentee excluded them from the claim during prosecution of that patent to overcome a prior art objection? Please answer YES or NO and you may add a brief explanation.

YES, equivalent infringement should exclude those embodiments which are disclosed in the patent specification as possible alternatives of the means literally mentioned in the granted claims if the patentee excluded them from the claim during prosecution of that patent to overcome a prior art objection. Arguments are provided under 13(e).

15) Should one consider the equivalent scope of protection conferred by a patent when assessing validity and/or patentability of that patent? In other words, should it be possible that, considering the equivalent scope of protection of a particular patent, this patent is deemed to

a) lack novelty, and/or
b) lack inventive step (non-obviousness), and/or
c) lack sufficiency of disclosure, and/or
d) lack plausibility, and/or
e) claim added matter?

NO. The Dutch Group considers it improper to take equivalents into account when considering patentability of the subject-matter of the claims or any other question of compliance of claims with applicable legislation. Certain parts of the doctrine of equivalents are to be applied using knowledge at the moment of infringement, whereas validity is always to be assessed using knowledge at the effective date of the patent. The Dutch Group considers it to be sufficient to hold any equivalents that would not be patentable at the effective date of the patent to be non-infringing (see our answer to Questions 3 and 14 (b).

Even if your answer to question 15 is NO, please address the following questions:

16) When assessing validity and/or patentability against the equivalent scope of protection, should the relevant embodiments be limited to those embodiments which are attacked as “equivalent infringement” in a specific case by the patent owner (or an otherwise entitled person)?

Please answer YES or NO and you may add a brief explanation.

NO. When assessing validity and/or patentability against the equivalent scope of protection, the relevant embodiments should not be limited to those embodiments which are attacked as "equivalent infringement" in a specific case by the patent owner per se. Circumstances may arise under which a broader application would be justified. The Dutch Group refers to arguments provided under answer 15.

17) If the answer to question 16 is YES, should anyone be entitled to attack the validity and/or patentability of the patent based on such argument, or only the alleged infringer?

Please answer YES or NO and you may add a brief explanation.

This question is not relevant in this case.

18) If the answer to question 16 is NO, what should be the appropriate approach to identify the relevant equivalent embodiments when assessing validity and/or patentability? Should there be, for example, a requirement that relevant equivalent embodiments must be likely being used in practice?

Please answer YES or NO and you may add a brief explanation.

NO. According to the Dutch Group, there is no appropriate approach to identify the relevant equivalent embodiments when assessing validity and/or patentability other

than the literal approach; the Dutch Group refers to arguments provided under answer 15.

19) If the answer to question 16 is NO, should the patent office consider the equivalent scope of protection when assessing validity and/or patentability, or should such discussion be limited to post-grant proceedings?

Please answer YES or NO and you may add a brief explanation.

NO. The Dutch Group holds application of any doctrine of equivalents to be a privilege of courts. Firstly, the doctrine of equivalents is relevant in case of infringement, not in case of patentability. Second, such assessment requires a substantial amount of legal acumen, whereas most examiners of patent offices only have a science or engineering degree, complemented with knowledge of patent law on patentability at the date of filing.

20) Please comment on any additional issues concerning any aspect of equivalents that you consider relevant to this Study Question.

The Dutch Group has no further comments on this matter.

21) Please indicate which industry sector views provided by in-house counsels are included in your Group's answers to Part III.

No in-house counsels were involved in providing answers to this section of the study question.