Study Guidelines

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2023 – Study Question

Doctrine of equivalents

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 full 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

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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.

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?

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. The scope of claims does not include equivalents, but the scope of protection does.

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.

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. However, our response is based on the date at which the assessment is conducted. In accordance with Finnish practice, the assessment should be conducted in light of the priority date.

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.

NO. See answer to c) above. The test is worded differently, i.e. the test looks at what is included under equivalence, and not what is excluded. A requirement for infringement under equivalence is that the equivalent solution was an obvious alternative to the skilled person at the priority date of the patent.

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. It is a well-established principle that the scope of protection may not ensnare prior art. However, there is no exclusion in relation to that which is obvious over prior art.

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.

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.

YES. Cf. 1(f) above.

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. See our response to question 2(a) above.

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

a) lack novelty, and/or

NO.

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

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

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

NO.

c) lack sufficiency of disclosure, and/or

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

NO.

d) lack plausibility, and/or

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

NO.

e) claim added matter?

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

NO.

If your answer to any of the questions 3 a) to e) is YES, please address the following questions: ***N/A; answers to questions 3(a) to (e) is NO.***

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.

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.

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.

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.

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.

NO. The current law is unclear as to a precise legal test for determining infringement under the doctrine of equivalence.

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. The purpose of the doctrine of equivalence is to prevent the circumvention of the norms of literal infringement.

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 purpose of the doctrine of equivalence is to prevent the circumvention of the norms of literal infringement. However, there should also be a reasonable degree of legal certainty, allowing a *bona fide* third party to ensure its freedom of operation.

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?

A precise legal test should be adopted for the doctrine of equivalence. There should also be more certainty on the exclusions and limitations of the doctrine of equivalence.

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. For example, the scope of protection of European patents and unitary patents should not be construed differently depending on the jurisdiction in which the patent is enforced.

If YES, please respond to the following questions without regard to your Group's current law or practice.

Even if NO, please address the following questions to the extent your Group considers your Group's current law or practice could be improved.

13) Do you see any need to amend and/or change the Q 175 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**. **There is a need for the doctrine of equivalence. However, there is no need to change the Q 175 Approach.**

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**.

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. **NO. The Finnish Group finds that the 4a function test is still a working test, but there is always room for adjustment/improvement.**

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 Finnish Group finds that the 4a difference test is still a working test, but there is always room for adjustment/improvement**

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. **NO**.

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**.

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**.

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

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**.

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**. **However, only insofar as the patentee has been required to restrict the scope of claims to overcome prior-art objections.**

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

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

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

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

c) lack sufficiency of disclosure, and/or

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

d) lack plausibility, and/or

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

e) claim added matter?

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

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. **YES**.

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. **YES**. **Subject to a sufficient declaratory interest.**

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. **N/A**.

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. **N/A**.

20) Please comment on any additional issues concerning any aspect of equivalents that you consider relevant to this Study Question. **NO**.

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