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## 2016 – Study Question (Patents)

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### Added matter: the standard for determining adequate support for amendments

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## I. Current law and practice

You are reminded that a reference to patent in the following questions refers to both a granted patent and an application for a patent.

If your answer differs depending on the distinction between a granted patent and an application for a patent, please answer the questions for each, as applicable.

1) Under your Group's current law, are amendments to the description and/or figures of a patent possible?

### Introductory remarks

Swedish patent law is based on international agreements, such as the Paris Convention for the Protection of Industrial Property (Paris Convention), the Patent Cooperation Treaty (PCT), the European Patent Convention (EPC), the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), and the Patent Law Treaty (PLT). To that effect, patents valid in Sweden may have either been granted by the Swedish Patent and Registration Office or by the European Patent Office (EPO).

Sweden became a party to the EPC in 1978 and consequently the Patents Act is highly harmonized with it. Practice in Sweden has developed in conformity with the EPC as interpreted by the EPO Boards of Appeal. Accordingly, the provisions and principles under Swedish law are intended to be interpreted in a way consistent with the EPO's practice. This has further been confirmed by the weight the Swedish Supreme Administrative Court and the Swedish Supreme Court gives to the EPC and the development within the EPO.

Yes, amendments to the description and/or figures of a patent are possible under Swedish law (see Chapter 2 Section 13 of the Patents Act and Section 19 the Swedish Patent Decree), insofar the amendment is necessary to fulfil the requirements set out in Chapter 2 Section 8 of the Patents Act, i.e.

to ensure that the description is sufficiently clear to enable a person skilled in the art to carry out the invention with guidance from the description.

It is generally permitted to make changes to the description for clarification and/or correction of errors, and to add new references to known prior art that has been discovered during the prosecution.

Further restrictions of making amendments to the description and figures corresponds to amendments to claims, see Question 2.

2) Under your Group's current law, are amendments to the claims of a patent possible?

Yes, amendments to the claims of a patent are possible under Swedish law, both during prosecution and after grant, whether it be in an administrative proceeding or in an invalidity proceeding. In order to be permissible, amendments must have support in the patent application as filed and, if requested after grant of the patent, may not increase the scope of protection of the patent (see Chapter 2 Sections 13 and 20 and Chapter 4a Section 40a of the Patents Act). Corrections of pure clerical errors in the translations of a claim which also could qualify as a sort of amendment, however not further addressed in this report on added matter, may also be permitted (see Section 40 of the Swedish Patent Office Regulations).

It should be noted that the basis in Swedish law for the assessment of amendments is the so called "original file", (sw. "grundhandlingar", see Section 21 of the Patents Decree) which is defined as the description, figures and the patent claims filed in a language accepted by the Swedish Patent and Registration Office ("PRV"). Due to the language requirement, resulting in the translation of the patent application for a national/European patent or an international application, the "original file" may differ from the "application as filed" (cf. art. 123 of the EPC). In the present draft of a new Swedish Patents Act, it has been suggested that the term "original file" is removed. In the following, the term "application as filed" will refer to the Swedish definition of "original file".

3) Further to your answers to questions 1) and 2), please indicate:

a) the standard for determining whether such amendments are permissible and indicate whether this standard exists in statutes, regulations, patent office guidelines, and/or in case law.

The standard for assessing permissible amendments is not explicitly stated in the Patents Act. It has instead been determined by administrative case law and preparatory works with influence from the EPO's Guidelines for Examination and case law from the EPO's Boards of Appeal. For the amendment to be permissible, the person skilled in the art, using common general knowledge, must be able to directly and unambiguously derive the added subject matter from the application as filed, i.e. the added subject matter must implicitly or explicitly be disclosed in the application as filed (cf. the EPO Guidelines for Examination, Art. 123 (2) EPC).

The standard is presented in PRV's guidelines for amendments made during examination/prosecution and post-grant assessment in administrative proceedings.

b) whether there are the differences between the substantive standards for amendments under 1) and 2) above. If so, what?

The standard for assessing whether the amendments have support in the application as filed is the same for amendments of the description and/or figures and the patent claims.

- 4) To the extent your answer to question 3) depends on timing (e.g. after filing but before examination, after allowance but before grant, and after grant), please explain how the standard changes and during which time periods.

Even though the standard for assessing impermissible added matter is not dependent on timing, there are practical differences in the possibilities to make amendments prior to the grant of the patent and after grant.

Prior to grant, an amendment may extend the scope of protection as long as it has support in – is directly and unambiguously derived from – the application as filed. Such pre-grant amendments may be accepted during the entire period of examination by PRV. However, after novelty search and receipt of a corresponding notice from PRV, the claims may not be amended to relate to an invention independent of the invention defined by the patent claims in the application as filed (see Section 19 of the Patent Decree).

During post-grant opposition (i.e. administrative proceedings), the patentee's freedom to make amendments is slightly restricted. Such amendments may only be made insofar as they relate to, and are intended to overcome, the grounds on which the opposition is based.

After grant of the patent, the patentee is only allowed to make amendments to the patent claims and/or, where necessary, the description (only possible in administrative proceedings), that result in a limitation of the scope of protection awarded by the claims (cf. Chapter 2 Section 20, third paragraph, Chapter 4a Section 40a and Chapter 7 Section 52 of the Patents Act).

Amendments post-grant may be made (i) upon request by the patentee before PRV; and (ii) upon request by the patentee during invalidity proceedings before the Stockholm District Court. Amendments made in an effort to delimit remaining valid claims in an invalidity proceeding must, to be permissible, be of immediate relevance with respect to the grounds invoked for invalidity *i.e.* it is not possible to use the fact that the patent is under attack to "fix" other identified issues with the patent. This in effect corresponds to the restriction during post-grant opposition proceedings.

- 5) Further to your answer to question 3), if impermissible added matter is a ground for refusing an amendment, please explain how impermissible added matter is defined.

Impermissible added matter as such is not defined under Swedish law. Instead, the distinction of impermissible added matter is indirectly derived from Chapter 2 Section 13 of the Patents Act which marks the scope of a permissible amendment, *i.e.* it is impermissible to add subject matter beyond that disclosed in the patent application as filed. The demarcation of impermissible added matter – in reality a review of the application as filed and amendment– requires flexibility due to the varying complexity of patent applications and technical fields and therefore an assessment is made on a case by case basis. For each case, the relevant invention must be individually identified and also, for each individual assessment, the relevant skilled person in the art.

However, as a general rule, an amendment is considered to add impermissible matter if the person skilled in the art cannot directly and unambiguously derive the amendment from the original application as filed. Therefore, the literal wording of the application as filed will be the starting point for every assessment of added matter. If the added matter cannot be found in the literal wording, a subsequent assessment will be made if the added matter could be "implicitly derived" from the application. If both assessments give the answer no, the added matter is impermissible. The criteria for implicit disclosure is strict. The Swedish Court of Patent Appeals has established that in order for an implicit feature to be allowed, it is not sufficient that the added feature is deemed as a feasible or a reasonable option to the skilled person. Instead, the skilled person must realize that the added feature is an inevitable result, *i.e.* unambiguously derivable, of what is disclosed in the application as filed.

A more complex situation is when the added matter actually could be found in the literal wording of the patent application as filed but, the added matter nevertheless fall outside of the scope of the invention i.e. is something new in relation to the subject matter as filed, and therefore is considered impermissible added matter.

Furthermore amendments that result in intermediate generalizations of a feature in the application as filed have also been rejected on grounds of impermissible added matter. The Swedish Court of Patent Appeals has established that generalizations, for example when adding only a few features of several features that together distinguish a specific embodiment found in the application as filed, is only permitted if the specific generalization was - to the skilled person - directly and unambiguously derivable from the application as filed.

6) In any assessment of impermissible added matter under your Group's current law, please explain:

a) how the patent application as filed is interpreted;

The patent application as filed (see Question 2 above regarding the distinction of the application as filed) is interpreted as the literal disclosure of the application as filed, including patent claims, description and drawings, supplemented with all matters that the skilled person, using his common general knowledge, can derive directly and unambiguously, also taking into account any implicit features, from it.

b) if interpreted as the notional skilled person would understand the patent application as filed, what is the relevant date of knowledge of the notional skilled person?

The relevant date of knowledge for the skilled person regarding amendments is the date of filing or priority date when applicable. This corresponds to the date of knowledge of the same skilled person when assessing for example patentability.

7) If an amendment that was made to a patent application prior to grant is later reviewed by your patent office or a court in a post-grant proceeding and determined to contain impermissible added matter, is there a mechanism for the patentee to remedy the defect, for example by removing portions of the amendment found to be impermissible?

no

Please explain:

No, there is no specific mechanism for the patentee to remedy impermissible added matter during prosecution. However, the possibilities available for the patentee to make amendments as described under Question 4 above are equally applicable in this situation. Naturally, such an amendment must also comply with the requirements as set out in Questions 1 - 5.

The situation described in the question may lead to a dilemma commonly referred to as “the fox leg-hold trap” or “the inescapable trap”, where a patentee, when forced to remove the impermissible added matter, as a result extends the scope of protection afforded by the patent beyond the scope of protection of the patent as granted. In these situations, patent limitation is generally not possible since all limitations would encompass the impermissible added matter, albeit in a more narrow form.

## II. Policy considerations and possible improvements to your current law

8) How does your Group's current law strike a balance between allowing a patent applicant to make

appropriate amendments during the examination process and preventing the applicant from adding impermissible matter?

When considering the possibilities to make amendments the Sweden Group finds it important to recognise that a certain amount of flexibility is required during the examination process, in particular in relation to applicants that are individual inventors. However this flexibility must be weighed against third party interests for legal certainty of the scope of the subject matter in a patent application filed and foreseeability as to the patent possibly later granted.

As described above, Swedish law does not have a definition of impermissible added matter. Instead it provides the outer boundaries for amendments within which the applicant may freely operate to make required amendments. Beyond this limit, added matter will be considered impermissible. The standard for determining impermissible added matter is in general applied strictly by Swedish courts and the PRV. In practice, this will often lead to a search for literal proof of the amendment in the application as filed, and the room for implicit disclosure is, as described in Question 5, limited. As a result of this strict approach, especially in certain technical areas, the Swedish Group acknowledges that it may be difficult for the applicant to amend the application, for example in relation to selection inventions related to the biomedical area. However, it should be noted that there are no substantive limitations in relation to how many times an applicant may request to make amendments. In reality, the applicant may submit an indefinite number of requests, and each request is to be assessed. Hereby, the applicant is in practice free to try to adapt the application, and the subject matter, in relation to information disclosed during examination and could through “trial and error” achieve an amendment insofar it can be directly and unambiguously derived from the application as filed.

In light of this, the Swedish Group is of the opinion that Swedish law provides satisfactory possibilities for the applicant to make amendments. To further avoid impermissible added matter, Swedish law requires, in relation to any amendment, that the patent applicant shows where in the application as filed the added matter (for example new features to the patent claims) is directly or indirectly disclosed (see Section 19 of the Patents Decree). If the patentee cannot prove where the added matter is explicitly or implicitly disclosed in the application as filed, the amendment will not be allowed. Even though this procedure still requires that the examiner assesses whether the amendment is permissible under the conditions mentioned under Questions 1 – 5 above, the risk that impermissible added matter is included in the patent by mistake is reduced, since the basis for the assessment will be the arguments on which the patent applicant relies.

The Swedish Group is therefore of the opinion that the Swedish patent legislation and practice do strike a fair balance between allowing a patent applicant freedom to make appropriate amendments during the examination process and at the same time preventing impermissible added matter.

9) Are there aspects of these laws that could be improved?

yes

Please explain:

In general, the Swedish Group is of the opinion that a strict approach to amendments is to be preferred. It reduces the risk of impermissible added matter, and consequently also the risk of a later revocation of the granted patent and third party uncertainty on the scope of protection of the patent. Hence, the current legislation and practice provides an appropriate balance between the applicants’ right to amend the application and third party’s interest in not being put at risk of infringing a patent due to unforeseeable added matter after the filing date.

As the standard for assessing impermissible added matter according to Swedish practice gives room for interpretation it is also adaptive and will allow the needed flexibility in relation to the assessment of amendments made during different stages of the life of a patent. On this ground, the Swedish Group is

of the opinion that “directly and unambiguously” will give a correct indication on the limits for amendments and clarity as to what will be considered impermissible matter i.e. to fall outside the boundaries for amendments.

A possible improvement discussed by the Swedish Group, which would furthermore simplify the determination of the permissibility of amendments during examination but also post-grant, is that the applicant should not only be obligated to refer to relevant parts of the application as filed to prove support for the amendments, but he/she should rather be obligated to explain explicitly and in detail how the patent claims, as they are finalized after all amendments, are disclosed in the application as filed. Possibly, such an obligation on the applicant will result in a more exhaustive assessment of whether or not the added matter is permissible. However, at the same time, it may lead to increased costs and delays.

10) Does your Group’s current law allow amendments post grant? If so, how does your Group's current law strike a balance between allowing a patentee to make appropriate amendments to a granted patent (such as amendments necessary to sustain its validity) and preventing the patentee adding impermissible matter?

As described under Question 7, amendments post-grant are allowed under Swedish law upon request by the patentee, both through an administrative procedure and in connection with invalidity proceedings (see Sections 40a and 52 of the Patents Act), under the added condition that the amendment limits the scope of protection of the patent. The provisions are relatively new, introduced as a consequence of the implementation of EPC 2000, and were inter alia motivated by the need to provide the patentee with a quick, simple and inexpensive way to limit the scope of protection of its patent to overcome barring prior art which could lead to revocation of the patent. However, a pre-condition, due to the more limited assessment of novelty and inventive step in these proceedings, was that only limitations would be allowed. The standard for determining the permissibility of a limitation is however the same that i.e. that it can be directly and unambiguously derived from the application as filed. For sake of clarity, we will in the following text refer to amendments post-grant as “limitations”.

One aspect setting the proceedings pre-grant apart from proceedings post-grant is that in the latter an opposing party is present. Consequently, the opposing party will usually dispute any proposed limitation on grounds of impermissible added matter and hence force the patentee to present arguments proving the admissibility of the limitation. Furthermore, the patentee is seldom free in post-grant proceedings to propose any limitation just to improve the patent. The limitation must correspond to the grounds for invalidity invoked by the opposing party and should in reality be intended to remedy any deficiency that may render the patent invalid.

Overall, the Swedish Group is of the opinion that the possibilities for a patentee to achieve a limitation post-grant are appropriate. Within the boundaries of a requested limitation, the Court applies the standard for determining impermissible added matter strictly. Due to the evidentiary difficulty showing implicit support in the application as filed the Court is often inclined to only allow amendments where a dependent feature is added to a prevailing independent claim or minor changes of wording. However, considering the importance to the patent system that a third party is able to rely on the validity and scope of a granted patent, the Swedish Group finds that Swedish law strikes a fair balance between allowing the patentee to make limitations and avoiding impermissible added matter.

11) Are there aspects of these laws that could be improved?

yes

Please explain:

In order to establish legal certainty in this field and to sufficiently weigh in the rights of parties other

than the patentee, the Swedish Group is of the opinion that there should be a limit to the number of times amendments are allowed to be put forward. This could be achieved by introducing a prerequisite similar to that found in the EPC, *i.e.* that PRV or the Court must give its consent to further amendments and that such a consent should be based on a proportionality assessment between the patentee's right to a fair proceeding or trial and third party interests of certainty of the scope of protection of the patent. This would for example allow PRV or the Court to stop additional amendments when the patent claims have already been amended several times.

12) If your Group's current law uses, at least in part, the notional person skilled in the art to determine the permissibility of amendments, is this approach effective? Are there aspects of this that could be improved?

Swedish law uses the notion of person skilled in the art, as stated above (cf. Question 6), to determine the permissibility of amendments. In the Swedish Group's report on an earlier Study Question (Q213), the use of the notional person skilled in the art in Sweden has been described in relation to the inventive step requirement. The same characteristics of the person skilled in the art apply in relation to the assessment of impermissible added matter.

Overall, the Swedish Group deems that the use of the notional person skilled in the art is an effective approach in determining questions regarding added matter. However, there are certain difficulties in relation to the use of a notional skilled person, such as defining who this person is and what knowledge may be attributable to such person. These issues arise in all areas of use of the skilled person and are not specifically connected to the issues in this Study Question and will for this reason not be further developed.

The Swedish Group would however like to stress that the person skilled in the art in this context is only to be used to determine what is directly and unambiguously disclosed in the patent application and not confused with the unrelated assessment of obviousness. For example, there is a risk that the use of the skilled person in determining whether an amendment is permissible makes the assessment more subjective, as compared to an approach where amendments are only allowed if there is literal support in the application as filed.

The "skilled person approach" could in some cases make it easier for the applicant to argue for the permissibility of added matter during examination pre-grant and during administrative limitation procedures post-grant, *i.e.* instances where there is only one party. The Swedish Group recognizes that this may lead to a higher acceptance of impermissible added matter during the examination process. However, this risk must be weighed against excessive descriptions that would be required by the applicant if a requirement for explicit literal support in the application were to be applied instead of the skilled person approach.

### III. Proposals for harmonisation

13) Is harmonisation of the definition of impermissible added matter 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 laws could be improved.

yes

Please explain:

14) If yes, please propose a definition of impermissible added matter that you believe is appropriate.

It is important that the definition of impermissible added matter balances the applicant's interest of amending a patent following filing of the application, to third parties interests of legal certainty of the scope of the subject matter in a patent application as filed and foreseeability as to the patent possibly later granted. Furthermore, the definition must correspond to the standard for assessing the subject matter contained in a patent application under all circumstances where this is relevant (i.e. also when discussing novelty and priority).

The Swedish Group suggests that impermissible added matter should be defined as *"added matter that the person skilled in the art, using common general knowledge, cannot directly and unambiguously derive from the patent application as filed; amendments should be impermissible if there is no disclosure of the added subject matter either implicitly or explicitly in the application as filed."*

15) Should this definition depend on when an amendment is made (for example, after filing but before examination, after allowance but before grant, and after grant)?

no

Please explain:

No, the definition should be the same regardless of when the amendment is made. However, post-grant of a patent, extension of the scope of protection of the patent as granted must not be permissible.

16) Should rules against impermissible added matter prohibit the addition of claims per se, as opposed to adding limitations to claims?

No, the Swedish Group does not find that such restrictions should apply. The structure chosen for the set of patent claims is not a factor when assessing the subject-matter protected by the patent.

17) Should rules against impermissible added matter prohibit the removal of claims per se, as opposed to removing limitations from claims?

no

Please explain:

No, the Swedish Group does not find that this distinction is appropriate. In practice, an amendment – either through full removal of a claim or through removing a limiting feature in a claim – will not be allowed (unless under particular circumstances during examination; see Question 4 above) as it will generally lead to an increase of the scope of protection conferred by the patent. The Swedish Group does not find that the structure chosen for the set of patent claims as such should be a factor when assessing the subject-matter protected by the patent.

18) Should the definition of impermissible added matter be the same when applied by a patent office as when applied by a court?

yes

Please explain:

Yes. However, post-grant of a patent, extension of the scope of protection of the patent as granted must not be permissible.

19) If your proposed definition refers to the notional skilled person, what should be the relevant date of



knowledge for the notional skilled person in evaluating the permissibility of an amendment?

The relevant date of knowledge for the skilled person regarding amendments should be the date of filing (or date of priority where applicable), since this is the date used to define the skilled person and the common general knowledge that person possesses, for the application at hand (cf. Question 6 above). If the relevant date were to be taken as a later date, this could result in an extension of the scope of protection by amendments, which is not – and should not be – allowed post-grant.

20) If the deletion of impermissible added matter by amendment would result in an impermissible extension of scope, how should the impermissible added matter defect be remedied in these circumstances?

As described under Question 7 the problem of the so called “inescapable trap” is a well known phenomenon that may not in all cases be remedied. The patentee is faced with the problem that if he/she erases the impermissible feature, the scope of protection is (likely) extended. The patentee may furthermore be unable to insert another limiting feature, as no such feature is disclosed in the application as filed.

The Swedish Group suggests that it should be permissible to limit another aspect of the claim in order to “escape” the inescapable trap. However, this should only be allowed if this limitation neutralizes the impermissible matter in such way that it no longer is of relevance for the scope of protection.

21) Please comment on any additional issues concerning any aspect of impermissible added matter you consider relevant to this Study Question.

N/A.

Please indicate which industry sector views are included in part “**III. Proposals for harmonization**” of this form:

The Swedish Group has consisted of lawyers, patent attorneys and engineers; its members representing the industry (Biotech), lawfirms, PRV and patent attorney firm. This report is a joint work where the point of view on the question of impermissible added matter of all members has been considered.

## Summary

Swedish law lacks a definition on impermissible added matter. Instead the possibility to make an amendment - pre-grant or post-grant - is defined by addressing the outer boundary *i.e.* an amendment is allowed as long it could be directly and unambiguously derived, explicitly or implicitly, from the application as filed. The standard for determining “directly and unambiguously” is strictly applied whereby the patentee may find it difficult to make an amendment. In particular the room for implicitly derivable amendments is restricted. However, as a result the risk of allowing impermissible added matter is reduced. Overall the Swedish Group has found the standard to be proportionate with consideration of third party interest.

The Swedish Group suggests the following harmonized definition of impermissible added matter:

*“Added matter that the person skilled in the art, using common general knowledge, cannot directly and unambiguously derive from the patent application as filed; amendments should be impermissible if*

*there is no disclosure of the added subject matter either implicitly or explicitly in the application as filed."*