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Report

Special Committee Q180

**Content and relevance of industrial applicability and/or
utility as requirements for patentability**

**Le contenu et la pertinence des critères de l'application
industrielle et/ou de l'utilité comme conditions de
brevetabilité**

**Inhalt und Bedeutung der gewerblichen Anwendbarkeit
und/oder Nützlichkeit („utility“) als
Patentierungsvoraussetzungen**

Report Q180

Content and Relevance of Industrial Applicability and/or Utility as Requirements for Patentability

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The need for an harmonized criterion, in addition to novelty and inventive step, and in replacement of industrial applicability and utility (hereinafter "*the third harmonized criterion*"), appeared more specifically in the framework of the work on the Substantive Patent Law Treaty (SPLT), which should not keep two criteria.

In the TRIPS, the difficulty of finding a new harmonized criterion was avoided by presenting the two current criteria as synonymous, in a footnote relating to Article 27.

With Q180, AIPPI decided to consider more thoroughly the similarities and differences of the two current criteria and to study whether it is possible to find a third harmonized criterion.

The Geneva Resolution of June 2004 confirmed the need for a third harmonized criterion, set some guidelines and concluded that further studies should be conducted for the purpose of defining the content of said third harmonized criterion.

The main difficulty of the work results from the fact that the definition of industrial applicability/utility varies from one country to another, as perfectly described in the informal paper "*The practical application of industrial applicability/utility requirements under national and regional laws*", prepared in April 2001 by the International Bureau of the Standing Committee of the Law of Patents (SCP) (paper provided by the Australian Member, quoted in the list below of the Members of the Special Committee).

The task is all the more challenging since the definition of industrial applicability/utility is not always perfectly clear-cut in each country, in particular in countries where the scope of this requirement has been affected over time by statutory or case law changes relating to other patentability requirements and, notably, the list of non patent eligible matters.

Lastly, the notions of industrial applicability and utility are closely interrelated to other substantive requirements of patentability, so that the definition of a third harmonized criterion should not be considered separately from the other patentability requirements taken as a whole.

All these factors mean that the definition of a third harmonized criterion requires a global and creative view.

The composition of the Special Committee was designed in order to include representatives of the main technical fields as well of the main legal systems.

The Special Committee is composed, by alphabetical order, as follows:

- Rob Aerts, from the Netherlands, in-house patent attorney within Solvay, specialised in biotechnology,
- Gunnar Baumgaertel, Secretary, from Germany, patent attorney,
- Richard Beem, from the US, patent attorney,
- Eiichiro Kubota, from Japan, Court attorney,
- Dr. Lulin Gao, from China, patent attorney and President of the patent attorneys association,
- Alexander Macklin, Co-Chairman, from Canada, Court attorney,

- Ross McFarlane, from Australia, patent attorney,
- Isabelle Romet, Chairman, from France, Court attorney,
- Jan Vleck, from the UK, patent attorney.

A Memorandum for the preparation of a Questionnaire was sent to the Members of the Special Committee on May 5, 2005.

This Memorandum invited the Members to give their opinion both as to the starting point of this work, i.e. the Geneva Resolution of June 2004, and on the subject matter of this work, i.e. the content and the title of the third harmonised criterion.

All the Members replied and provided most relevant comments or suggestions.

The purpose of this Report is to present the ideas exchanged by the Members about the definition of the third harmonized criterion and to show both the lines of consensus and the questions which remain to be discussed in Berlin, in September 2005, in order to continue the work of the Committee.

After a brief comment as to the starting point of this work (1.), this Report presents the various factors which can contribute to the definition of a third harmonized criterion.

In this respect, it considers the relevance of the reference to:

- the application or the use of the invention (2.),
- the manufacturing of a patented product (3.),
- a field of application or use, such as industry (4.),
- the identification of the required application (5.),
- the usefulness of the invention (6.),
- the economic value or interest of the invention (7.),
- the features of the required application (8.),
- the effect or the operability of the invention (9.).

The National Groups will be invited to consider the possible changes which the adoption of the third harmonized criterion would entail in their own country (10.).

Lastly, by way of example, this Report gives two possible definitions of the third harmonized criterion according to the options which are selected among the offered ones (11.).

1) Starting point of this work, i.e. the Geneva Resolution of June 2004

The starting point of this work, i.e. the Geneva Resolution of June 2004, is confirmed by a great majority of the Members.

Only the UK remains sceptical about the principle of a third harmonised criterion:

"The UK Group is not convinced that there is any need for a third harmonised criterion. As was elegantly put in Trevor Cook's submission on the First Draft Resolution:

"Internationally we have a requirement of "capable of industrial application" which can be deemed synonymous with "utility". There is complex case law in most countries on industrial applicability and/or utility but in practice the debates do not lead to unreasonable restriction or expansion of what can be patented. Any attempt to codify in another way or to attempt to clarify perceived or actual differences between the two terms will cause confusion and further the dangerous tendency to use the requirement of industrial applicability or utility to introduce new exclusions from patentability."

Actually, the UK reserve should mainly lead to reassert that a third harmonised criterion should not result in any additional requirement, nor to bring significant changes in any country regarding the definition of patentable inventions as it results from all its current provisions taken all together.

In other words, the third harmonized criterion should not lead to find that an invention which was formerly patentable in a country is no longer patentable in the same country, or *vice versa*.

The purpose of the third harmonised criterion is to help the progress of the SPLT, as well as to simplify the obtention and enforcement of patent rights in the various countries of the world by providing an additional common requirement, besides novelty and inventive step, even though this new common requirement would lead some countries to adopt further provisions in order to maintain some specificities such as the non patentability of certain types of inventions, e.g. therapeutical methods, or genes.

In other words, the purpose is to have domestic patentability requirements which match better with one another from one country to another.

Regarding the issues to be covered by the third harmonised criterion, only item 6 of the noting part of the Geneva Resolution of June 2004 was not unanimously confirmed.

Said item 6 reads as follows:

6) This criterion is not intended to address any requirement of technical content.

The Chinese Member expressed the view that the requirement of technical content should not be independent from the third harmonized criterion.

However, the search for a consensus leads to consider that, for the time being, it is wise to address separately the definition of a third harmonized criterion and the requirement of technical content, even though it may appear both appropriate and possible, in the future, to study whether these two requirements should be merged.

2) Relevance of a reference to the application or the use of the invention

All the Members who agree with the principle of a third harmonized criterion consider that its essence is to assure the implementation of the invention in practice.

This view is stated by the Chinese Member in these terms:

"The essence of either the "industrial applicability" criterion applied in Europe or the "utility" criterion in the US is to assure the implementation of the inventions in practice."

This idea was expressed by various wordings: the third harmonized criteria requires that the invention can be *"implemented"*, *"used in practice"*, *"realized in practice"*, *"applied in practice"*, *"put in effect"*, and that it *"achieves a positive result"*.

Therefore, it can be concluded that the third harmonized criterion requires that the invention has a practical application, or use, in contrast with abstract ideas or fine arts.

The choice of the best language can be further discussed.

3) Relevance of the manufacturing of a patented product

Industrial application requires that the invention can be *"made or used"* in the industry, the term *"industry"* having the broadest possible meaning and covering all sectors of economic activities.

With this definition, a product which cannot be used in the industry meets the industrial applicability requirement provided it can be made in the industry, as it is the case of a surgical knife in countries where the therapeutical field is not included in the industry.

Likewise, a molecule satisfies the industrial applicability requirement as soon as it can be obtained, even though it does not have any known use (this point is discussed more thoroughly in section 6).

The reference to the manufacturing of a product, in addition to its application or use, should be discussed further in order to decide whether it should be kept.

4) Relevance of a reference to a field of application or use, such as industry

In the countries using the industrial applicability requirement, the term "industry" covers more than traditional industry.

As indicated in paragraph g) of the Geneva Resolution of June 2004, the term "industry" is so broad that it excludes no more than the inventions which can be implemented only in the private sphere:

"In most countries, the specific feature of industrial applicability lies in the fact that it excludes from patentability inventions which can be made and used only in the private or non commercial sphere (like a contraceptive method which can be used only in the private sphere)."

The first consequence of the above remark is that the term "industry" seems, in any case, inappropriate because it sounds narrow while it should be understood as broad and as meaning "any economic sector".

The second question is whether there is a real need for excluding the patentability of inventions which can be implemented only in the private sphere.

In particular, it is not essential to exclude the patentability of this type of inventions if other legal requirements deprive patents covering such inventions of any effect.

To give an example, a patent covering an invention which can be implemented only in the private sphere has no effect in legal systems providing that the use of a non commercial and/or private use is not infringing.

The National Groups should discuss further whether they agree that the issues relating to the private or non commercial use of an invention should be dealt with only by the provisions defining infringement (the National Groups are invited to take into account not only the provisions which already exist in their own legal system in this respect but also those which may be added in the future if necessary due to the adoption of the third harmonized criterion).

If it is concluded that there is no need for excluding the patentability of inventions which can be implemented only in the private or non commercial use, the reference to "industry" or any other equivalent term may be found as no longer relevant.

This issue should be further discussed.

5) Identification of the required application

It seems clear for everybody that the required application is that of the subject matter of the claims.

In the Memorandum circulated on May 5, 2005, it was suggested that "the application should be described in the specification if such application does not derive obviously for the skilled person from the specification or the nature of the invention".

The Canadian Member, approved by the US Member, observed that the term “obviously” may create confusion because usually reserved to the definition of inventive step.

The US Member suggested that the term “apparently” would avoid the risk of ambiguity.

The Dutch Member suggested that the application should be “self-evident” to the skilled person.

The ambiguity would also be avoided by providing that the required application “shall be identified by the skilled person either in the light of the specification or the nature of the invention”.

It is necessary to have the opinion of the National Groups in this respect.

6) Relevance of a reference to the usefulness of the invention

Paragraph f) of the considering part of the Resolution of June 2004 holds that:

“The specific feature of the utility criterion lies in the fact that it requires that the invention provides a benefit to the public, which, for example, excludes from patentability a product having no specific, substantial and credible use (while such a product would meet the requirement of industrial application provided it can be manufactured by industry).”

As a result, the utility requirement excludes the patentability of a molecule without any identified or identifiable use while such a molecule would satisfy the requirement of industrial applicability provided it can be manufactured in the industry.

However, in the countries applying the industrial applicability requirement, such a molecule is unlikely to meet the requirement of inventive step because, in the absence of any identified or identifiable use, it does not solve any technical problem.

As a result, it appears that both systems lead to find that such a molecule is not patentable.

In addition, the Dutch Member pointed that, at least in the field of biotechnology, the European Patent Office becomes more reluctant to acknowledge industrial applicability to a molecule which can be manufactured in the industry but which does not have yet any known use:

“In the Trilateral Project B3b (ex-24.1) (1998–2002), the US Patent and Trademark Office (USPTO), European Patent Office (EPO) and Japanese Patent Office (JPO) conducted comparative investigations with respect to the patenting of biotechnological inventions. In one hypothetical case the patentability was discussed of a probe to be used in order to isolate a full-length DNA without known function or biological activity.

Here, it is interesting to note what the EPO remarked about the industrial applicability/ utility requirement with respect to such an ‘invention’:

This requirement normally does not cause a problem for the EPO since an invention shall be considered as susceptible of industrial application if it can be made or used in any kind of industry (Article 57 EPC). In following the conventional interpretation of Article 57 EPC one could take the position that the claimed polynucleotides of 500 bp in length clearly can be made and therefore the requirement of industrial application is fulfilled. However, Article 57 EPC could also be interpreted differently by putting more weight on the “industrial” aspect thereof. Along these lines it could be argued that the right question to ask under this provision is whether “one would indeed make ESTs in any kind of industry if a specific usefulness is not known for them and therefore there is no motivation at all to make them”.

Thus, I suppose this illustrates nicely the moving away by a major jurisdiction like the European Patent Convention (EPC) from the mere "make or use in industry" approach to a "specific usefulness" approach, in support of "practical applicability".

If the National Groups confirm that both systems lead (or should lead) to the same result, they only need to agree on a common ground for unpatentability, i.e. the third harmonized criterion or a lack of inventive step.

Beyond the meaning of the utility requirement, the National Groups should also discuss the choice of the language.

In this respect, the term "*utility*" may introduce some construction difficulties in the systems using the industrial applicability requirement.

In particular, the terms "*utility*" and "*useful*" (for example, a "*useful application*") can sound as most subjective.

It may be better to adopt a term new for all countries and as self explanatory as possible.

In this respect, the term "*practical*" (for example in the expression "*practical application*") may be a good candidate, instead of the term "*useful*" (for example in the expression "*useful application*").

The issue should be further discussed.

7) Relevance of a reference to the economic value or interest of the invention

The German Member suggested that the third harmonized criterion should require, among other things, that the invention is susceptible of economic exploitation, in order to exclude abstract ideas which have no economic relevance.

However, such a requirement would significantly change the requirements currently in force, at least in the countries applying industrial applicability requirement.

In this respect, the Canadian Member expresses the following view:

"Under Canadian jurisprudence, it is unnecessary for a patented invention to have commercial utility so long as the invention has practical utility, that is, the promised results are obtained even though it may provide no commercial benefit. The non-patentability of abstract concepts, etc. as listed in item e), in Canada at least, would be excluded from patentability by the lack of utility"

In addition, such a requirement seems to introduce a great uncertainty since the economic relevance of an invention does not seem easy to assess, notably because it may significantly change according to the way, where and when the invention is exploited.

Therefore, it seems dangerous to introduce a reference to the economic relevance of the invention.

However, this point can be discussed further.

8) Features of the required application

The German and the Dutch Members suggested that the required application should be "*specific and substantial*".

In some of the countries applying the utility requirement, an invention shall have a "*specific, substantial and credible*" utility.

The term “specific” notably implies that it is not sufficient to indicate that a compound may be useful in treating unspecified disorders, or that the compound has useful properties: it is necessary to describe a specific use.

The Dutch Member provided the Committee with interesting remarks about the evolution of the approach of the European Patent Office:

“Here again it is interesting to note how the approach of a major jurisdiction like the EPC is developing. In the famous ‘Icos’ case (Decision of the Opposition Division of the EPO dated 20 June 2001, Official Journal EPO 6/2002, 293–308), the Opposition Division of the EPO found that uses of an invention disclosed in a patent application are not considered industrially applicable if such uses:

“ ... are speculative, i.e. are not specific, substantial and credible ... ”

Thus, here it would seem that the EPO is seeking support for its industrial applicability test by using the ‘specific, substantial and credible’ means of interpretation according to the U.S. Utility Examination Guidelines”.

It will be necessary to decide whether some of these features (specific, substantial and credible) should be introduced in the definition of the third harmonized criterion.

Regarding the choice of the language, it is recommended to avoid terms which may raise some difficulties regarding their construction by the Courts of the countries which apply the industrial applicability requirement and which are not familiar with the utility requirement terminology.

9) Relevance of a reference to the effect or the operability of the invention

The Canadian and Chinese Members suggested that it would be useful to refer to the workability of the invention.

In this respect, the Chinese Member stated:

“Practical applicability requests that an invention should be implemented in industry or repeatedly used in practice, and achieves a positive effect. As mentioned in our answer to Item 3, abstract idea should be excluded from patentability. An invention contrary to the laws of nature, such as a perpetual motion machines, at least from our current view, cannot be realized and implemented in practice and therefore cannot satisfy the requirement of practical applicability. Similarly, inventions that do not provide the effects or results disclosed in the patent cannot satisfy the requirement of applicability either.”

Several wordings were suggested:

- the subject matter of the claims works as described in the specification,
- the invention can be repeatedly implemented and provide the effects disclosed in the patents (or the expected effects).

It should be discussed further whether this requirement is appropriate, although it is already included in most patent systems, at least through the requirement of an enabling description, instead of that of industrial applicability.

10) Possible incidence of a third harmonized criterion

The adoption of a third harmonized criterion is likely to lead at least some countries to modify other patentability requirements.

For example, the countries which consider that the industrial applicability excludes the patentability of therapeutic methods will be led to adopt separate provisions for the same purpose.

More generally, the adoption of a third harmonized criterion may lead some countries to modify their list of non patent eligible subject matters or to create such a list if they do not have any yet.

The National Groups are invited to think of the changes which the adoption of a third harmonized criterion would entail in their own country.

11) Possible definition

By way of example, the third criterion might be entitled "practical applicability" and defined as follows according to the options which are selected among those offered above:

- *"the subject matter of a claim is applicable in practice if at least one practical application can be identified by the skilled person in the light of the specification or the nature of the invention"*
- *"the subject matter of a claim is applicable in practice if it can be used in practice at least in one economic sector for producing the specific effects which the skill person can reasonably expect in light of the specification of the patent or the nature of the invention".*

Other proposals of definition and title for the third harmonized criterion are welcome.