**Reply from the Norwegian Industrial Property Office on WIPO C.8728**

## (i) Additional inputs regarding acts for obtaining regulatory approvals from authorities

In 2009 Norway implemented an exemption regarding acts for obtaining regulatory approval from authorities, cf. Norwegian Patent Act section 3, last paragraph no 5. The exception applies only to patented medicines, and for such tests and experiments that are necessary in order to obtain regulatory approval from authorities in a WTO-country. We have not experienced any specific challenges with this implementation.

## (ii) Inventive step

"Common general knowledge"

The Norwegian examination guidelines presumes to be in aligned with the EPC examination guidelines, consequently the guidelines refers to EPO decisions.

The Norwegian guideline states:

Common general knowledge may come from different sources and may not necessarily depend on the publication of a special document on a particular date. An assertion that something is common knowledge only needs to be supported by documentable evidence (such as a textbook) if this is contested.

A single publication (such as a patent document or the content of a technical journal) can not normally be regarded as general knowledge (cf. T 475/88). In special cases, articles in technical journals may represent general knowledge (cf. T 595/90). This is especially true for articles that provide a broad overview or examination of a subject (cf. T 309/88). For the skilled perseon who faces the problem of bringing together certain starting materials, the conclusions of research on these materials carried out by only a small number of manufacturers will form part of the relevant general knowledge, although the relevant studies have only been published in technical journals (cf. T 676/94). Another exception is that general knowledge may also be the information in a patent or scientific publication if the invention is within a field of research that is so new that the relevant technical knowledge is not yet available from textbooks (cf. T 51/87).

Basic textbooks and monographs can be considered to represent common knowledge (cf. T 171/84); and if they contain references that direct the reader to additional articles dealing with particular issues, these articles may also be included as part of such knowledge (cf. T 206/83). It should be remembered that information will not become general knowledge simply because it has been published in a particular textbook, reference work, etc .; rather, it appears in this type of books because it is already common knowledge (cf. T 766/91). This means that the information in such a publication must already have been part of general knowledge at some point before the publication date.

Furthermore, it is obvious to combine the teaching of one or more documents with prior art with the common general knowledge in the art.

“Combination”

The invention claimed must normally be considered as a whole. When a claim consists of a "combination of features", it is not correct to argue that the separate features of the combination taken by themselves are known or obvious and that "therefore" the whole subject-matter claimed is obvious.

However, where the claim is merely an aggregation or juxtaposition of features and not a real combination, it is only necessary to show that the individual features are obvious to prove that the aggregation of features does not involve an inventive step. A set of technical features are considered as a combination of features if the functional interaction between the features achieves a combined effect that differs from, e.g. greater than, the sum of the technical effects of the individual features. In other words, the interaction of the individual features must produce a synergistic effect.

“Danger of hindsight analysis”

Regarding danger of hindsight analysis the examination guidelines states that: One should, however, be careful about such analysis based on hindsight ("ex post facto" analysis). It should be remembered that the documents produced in the search have been obtained with foreknowledge of what matter constitutes the alleged invention. In all cases one should attempt to visualize the overall state of the art confronting the skilled person before the applicant`s contribution and seek to make a real life assessment of this and other relevant factors.

“Secondary indicia”

- Predictable disadvantage; non-functional modification; arbitrary choice

If the invention is the result of a foreseeable disadvantageous modification of the closest prior art, which the skilled person could clearly predict, and if this predictable disadvantage is not accompanied by an unexpected technical advantage, then the claimed invention does not involve an inventive step (see T 119/82 and T 155/85). In other words, a mere foreseeable worsening of the prior art does not involve an inventive step. However, if this worsening is accompanied by an unexpected technical advantage, an inventive step might be present. Similar considerations apply to the case where an invention is merely the result of an arbitrary non-functional modification of a prior-art device or of a mere arbitrary choice from a host of possible solutions (see T 72/95 and T 939/92).

- Unexpected technical effect; bonus effect

An unexpected technical effect can be seen as an indication of inventive step. However, it must derive from the subject-matter as claimed not only from some additional features mentioned only in the description. The effect must be based on the characterizing features of the invention, in combination with the known features of the claim, and not only on features already comprised in the prior art.

However, if, having regard to the state of the art, it would already have been obvious for a skilled person to arrive at something falling within the terms of a claim, for example due to a lack of alternatives thereby creating a "one-way street" situation, the unexpected effect is merely a bonus effect which does not confer inventiveness on the claimed subject-matter. Similarly, as long as the skilled person solves a known problem with a known means, the unexpected additional technical effect would have to be considered a "bonus effect" that does not warrant patent protection, (see T 231/97 and T 192/82, as well as the Norwegian Board of Appeal for Industrial Property Rights (KFIR) Case No. 7066). If the skilled person would have to choose from a range of possibilities, there is no one-way street situation and the unexpected effect will lead to recognition of inventive step.

The unexpected property or effect must be described in precise terms. A vague formulation, such as "The new compounds have shown unexpectedly good pharmaceutical properties", can not support the presence of an inventive step.

However, the product or process does not have to be "better" than known products or processes. It is sufficient that the property or effect would not have been expected.

- Long felt need; commercial success

If the invention solves a technical problem which workers in that art have been attempting to solve for a long time, or otherwise fulfils a long felt need, this can be seen as an indication of inventive step.

Commercial success alone should not be considered as an indication of inventive step. However, evidence of immediate commercial success coupled with evidence of fulfillment of a long felt need is relevant, provided that the success can be derived from the technical features of the invention and not from any other influences (e.g., sales techniques or advertising).

- Overcome technical prejudice

As a general rule, there is an inventive step if the prior art leads the skilled person away from the procedure proposed by the invention. This applies in particular when the skilled person would note even consider carrying out experiments to determine if these were alternatives to the known way of overcoming a real or imagined technical obstacle.

In order for a technical prejudice to exist, it is required that the prejudice is well known and documented and that it is the current perception of experts in the field, cf. T119 / 82 and T48 / 86. Furthermore, the burden of proof lies with the person who claims that there is a technical prejudice, cf. T60 / 82, T631 / 89, T695 / 90 and T1212 / 01.

It would normally not be sufficient to base an assertion of technical prejudice on a single document; in any case not a patent application, cf. T19 /81.

“Selection inventions”

The subject-matter of selection inventions differs from the closest prior art in that it represents selected sub-sets or sub-ranges. If this selection is connected to a particular technical effect, and if no hints exist leading the skilled person to the selection, then an inventive step is accepted. This technical effect occurring within the selected range may also be the same effect as attained with the broader known range, but to an unexpected degree.

The criterion of "seriously contemplating" mentioned in connection with the test for novelty of overlapping ranges should not be confused with the assessment of inventive step. For inventive step, it has to be considered whether the skilled person would have made the selection or would have chosen the overlapping range in the hope of solving the underlying technical problem or in expectation of some improvement or advantage. If the answer is negative, then the claimed matter involves an inventive step.

The unexpected technical effect must apply to the entire range as claimed. If it occurs in only part of the claimed range, the claimed subject-matter does not solve the specific problem to which the effect relates, but only the more general problem of obtaining, for example, "a further product X" or "a further process Y" (see T 939/92).

“The assessment of inventive step in the chemical sector”

- Biotechnological inventions

Norwegian practice for the assessment of the inventive step of naturally occurring biological material shall be within our EEA legal obligations and in line with the most restrictive EU countries, in accordance with the Act on Amendments to the Patent Act of 2004.02.01.

Example:
Product patents may be given to naturally occurring gene sequences if the sequences can not be isolated using routine methods, or if the gene sequences or proteins they encode have unexpected properties that lead to inventive step in relation to the state of the art.