



## Parameters at the EPO - Issues Concerning Clarity and Sufficiency

Parameters are generally used in patent claims to define subject matter which cannot be expressed in terms of structural features. They are often relied upon for inventions in the chemical field, but can in fact be used in any technical area. Parameters can relate to features that can be measured directly, such as the density or melting point of a substance; measured indirectly, such as the tacticity of a polymer; or that can be calculated, such as the superficial velocity of a flow in a reactor. They can also be expressed in terms of relationships between such features.

Some interesting themes have developed from the decisions of the EPO's Technical Boards of Appeal for parameter cases, in particular in relation to the assessment of clarity and sufficiency. These are reflected in the Guidelines for Examination in the European Patent Office, Part F, Chapter IV, 4.11, which indicate that when inventions are characterised by parameters, it is necessary that *“those parameters can be clearly and reliably determined by objective procedures which are usual in the art”*. Further, in order to fulfil the requirements of clarity, the method for measuring the parameter, or at least a reference thereto, needs to appear completely in the claim. It is therefore important that a definition of any parameter is included in the specification at the time of drafting. Careful consideration needs to be given to ensure that any such definition will allow for the parameter to be determined accurately, since objections relating to this can prove problematic to overcome.

Issues of relevance to the clarity and sufficiency of parameters are discussed below. For completeness, we would mention that objections of lack of novelty often arise during prosecution if the Examiner cannot determine that a parameter differentiates the claimed subject matter from the prior art. The burden of proof then lies with the Applicant to show that the parameter acts as a distinguishing feature. Novelty can generally be established by providing a technical explanation of how fulfilment of the parameter acts to distance the claims from the prior art or through the provision of data.

### Clarity

According to Article 84 EPC, the claims define the matter for which protection is sought and they shall be clear and concise. Since it is important that the skilled person knows when they are working within the scope of the claims, issues concerning lack of clarity arise if the value of a parameter cannot be reliably determined.

Such a situation can occur when a patent specification does not specify how to determine a parameter. For example, in [T1851/06](#) the claims related to a composite material with a specified pore diameter but the specification did not indicate how

this was to be measured. In the absence of a standard method for the characterization of porous substances, the pore diameter was not considered to be clearly defined.

Objections can also arise when a protocol is provided in the specification but is found to be incomplete. Thus, [T955/07](#) related to a starch composition which was defined by reference to its extensional viscosity. The application described how the feature was to be determined. However, it did not specify the temperature of measurement which was found to affect the value obtained. The limits of the claim were thus uncertain and the requirements of clarity were not fulfilled.

Even when a full protocol is provided, problems can arise if the method does not produce a consistent result. This can be illustrated by reference to [T2086/11](#) where the mean aspect ratio determined from fifty particles was considered not to reliably characterize a product consisting of thousands of particles.

If there is only one way to determine a parameter, then it may not be necessary to include a detailed protocol in the specification as to the method of determination. The same applies if the feature is an invariant parameter and all methods of measurement would lead to the same value. However, even in these situations care needs to be taken - your scientists may always measure a feature in a given way, but that may not be the only way in which it can be determined. Similarly, even for well known parameters, there may be several ways in which a measurement can be taken. As an example, in [T307/06](#) the claim referred to a hydrophobic polymer with a glass transition temperature of less than 25°C. However, the method of measurement was not provided. The application was found to lack clarity since this feature could be determined by different methods yielding different results. A similar decision was reached in [T967/08](#) where the claim relied upon the average particle size.

In fact, even when an industrial standard is relied upon for the method of measurement, this may not necessarily be enough to properly define a particular feature. In [T1252/08](#) the through plane conductivity of an ovenware item was said to be measured using an ASTM standard. During examination, it was found that the value of the conductivity would be affected by features such as the temperature of measurement and the nature of the contact between the item and the measuring device. These were not specified in the standard nor the patent specification and the application was refused for lack of clarity.

### Sufficiency

According to Article 83 EPC, the European patent application shall disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art. When

sufficiency is assessed, consideration is given both to the teaching provided in the specification and to the common general knowledge of the skilled person at the time of the invention.

If a parameter is well known, it is often the case that omissions in the description of how the feature is to be measured can be overcome by relying upon common general knowledge or through the performance of simple tests. Thus, in [T148/91](#) the claim referred to the specific surface area of a particulate material measured by gas adsorption, but the specification did not contain any information concerning the method or conditions of measurement. However, the Board decided that specific surface area is an extremely well known concept in powder technology and that the skilled person could put a suitable method into practice. Similarly, in [T550/91](#) the claim referred to features such as the nickel surface area, average diameter of nickel crystallites and average pore size, but did not fully indicate the methods of determination. The Board found that such well known features could be measured by commonly applied methods and that any missing information could be determined without undue burden.

However, even for very well known parameters, there are limits to the extent that common general knowledge can be relied upon to overcome any deficiencies in the disclosure of the measuring method. Thus, in [T466/05](#) the claim referred to polysaccharides which were characterized by their molecular weight, but the specification did not specify the type of molecular weight nor the method of measurement. It was found that different methods could provide values for the molecular weight which differed by up to 280%. The Board decided that this level of uncertainty was such that the patent lacked sufficiency.

If the parameter is unusual i.e. one where there is not a commonly used and reliable method for its determination, the burden lies with the Applicant to provide a full disclosure of how the parameter is to be determined. Difficulties on this point have arisen in a number of cases. [T484/05](#) was concerned with a process for producing a lubricating base stock and referred to the free carbon index of a paraffin fraction. Since the free carbon index was an unusual parameter, the Board indicated that the description must contain sufficient information as to how it was to be measured in order for the invention to be enabled. A full protocol was not provided and so the patent was found to lack sufficiency. In [T288/06](#) the claim referred to an interlayer film with a specified haze, the haze being determined using a particular type of machine. However, the specification did not teach how the sample should be prepared and this was found to affect the measured value. The patent was found to lack sufficiency since the method provided did not disclose all of the details which critically influenced the measured value. Further, there were no technical standards to which the skilled person could resort to fill any gaps in the information.

## Overlap between Clarity and Sufficiency

From the discussion above, it can be seen that there is a close relationship between the requirements which need to be fulfilled in relation to clarity and sufficiency. In fact, [T593/09](#) indicated that when a disclosure is insufficient due to the presence of an ill-defined parameter, claims defined by reference to this parameter would lack clarity under Art. 84 EPC since establishing the exact scope of the claim would then be impossible. However, it does not follow that there is necessarily insufficient disclosure whenever the scope of the claims is unclear. During examination, the

distinction between the different grounds may not be of great relevance since any claim must fulfil the requirements of both sufficiency and clarity. However, it can be particularly important post-grant, for example in EPO Opposition proceedings where lack of sufficiency is a ground of Opposition, but lack of clarity is not.

## Opposition

During an Opposition, whenever objections are raised concerning the determination of a parameter, the Opposition Division have to assess whether the issue relates to clarity or sufficiency. They thus have to determine whether any omission in the determination of a parameter only affects the reliability of the measurement in which case it may just be a point of clarity. Alternatively, if the omission is more fundamental and the feature cannot be appropriately determined, there can instead be problems relating to sufficiency. For example, in [T943/00](#) the weight average molecular weight of a series of polymers was said to be measured by gel permeation chromatography, but the exact measurement conditions were not provided. The missing details were found to affect the determination of the limits of protection rather than making it impossible for the skilled person to carry out the process. The point at issue therefore related to clarity rather than sufficiency.

When objections are raised concerning the manner in which a parameter is to be determined, it is sometimes possible to have them dismissed on the basis that the objection is simply a disguised attack of lack of clarity and cannot therefore be used as a ground of Opposition. In that case, the parameter is considered to be appropriately disclosed. The parameter can then be relied upon to support the novelty and inventive step of the claims.

However, if there are issues concerning clarity, it may be possible for an Opponent to make use of this when attacking novelty and inventive step. Thus, if it can successfully be argued that the skilled person is unable to determine the exact value of a given parameter, the claims could then be construed in a broader manner which may increase the relevance of the prior art. For example, in [T59/08](#) the claim referred to a polyethylene composition which was defined by features which related to the molecular weight, but no indication of the method of determination was provided. It was found that alternative methods were available in the art which would provide different values for the parameters. The uncertainty regarding the method to be used was not found adequate to make a case against sufficiency. However, it did affect the boundaries of the claim since any method that could be considered to be standard in the art could be used.

Although lack of clarity cannot be used to attack a patent as granted, clarity can be considered if the claims are amended during the Opposition. This can occur if an in clarity is introduced into the claims by the inclusion of a feature from the description.

## Third Party Observations

The fact that lack of clarity is not a ground for Opposition means that there are issues which could cause serious difficulties during examination that cannot be raised after the patent has granted. In fact, if an unreliable parameter is an essential feature of an invention, it could prove impossible to overcome an objection of lack of clarity raised during examination. Thus, if there is a third party application which relies upon a parameter that does not fulfil the requirements of clarity, it may be advantageous to file third party observations during examination to explain the

deficiencies to the Examiner, rather than waiting until the patent has granted and filing an Opposition. Third party observations can be filed anonymously and Examiners are required to seriously consider the content of any such submissions.

## Summary

It is important that the application as originally filed provides the appropriate information to enable any parameter to be measured in a reliable manner.

- Particular care is needed when there is a method which is always employed within a given company. If the method is not

a recognised standard or if it, for example, is performed on a machine where there are a number of variable settings, the relevant information may not be part of the skilled person's common general knowledge.

- An incomplete disclosure of how to determine a given parameter can cause difficulties in relation to clarity and sufficiency. However, only lack of sufficiency is a Ground for Opposition.
- If a third party's application relies upon parameters, rather than waiting to file an Opposition, it may be advantageous to file third party observations during examination to raise objections of lack of clarity.

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