



## Review of EPO Parameter Decisions in 2020

Before the EPO parameters are defined as features which are based on directly measurable properties or combinations of several variables in the form of formulae. This might be a claim defined by the viscosity of a composition, or the particle size of a powder, for example. Relying on such features to define an invention is commonplace within the chemical sphere and can be very useful. However, their utility is not limited to such subject matter and they could be used to define characteristic features in a broad range of technologies.

The EPO has developed a large amount of case law which relates specifically to the use of parameters in the claims, in particular whether these claims fulfil the requirements for clarity and sufficiency. Here we review the cases in this area which have issued during 2020. The majority of cases before the Boards of Appeal this year where parameters have been at issue have been appeals from decisions of the Opposition Division. Since lack of clarity is not a ground for opposition, the bulk of the case law from 2020 has focused upon whether particular parameters fulfil the requirements of sufficiency. For such cases, a significant amount of effort has also been devoted to determining whether the relevant issues do in fact relate to sufficiency or are instead objections of lack of clarity in disguise.

### Introduction

When a claim includes a parameter, the skilled person needs to be able to appropriately determine a value for the feature in question. This can be of relevance to determining whether the claim fulfils the requirements of clarity and sufficiency. Which ground an objection relates to can often be of importance, in particular since lack of clarity is not a ground for opposition. However, the general principles applied by the EPO in this regard are well established. In essence, for a well-known parameter any defects in the protocol which mean that the feature cannot be accurately determined are likely to relate to matters of clarity, unless the feature is so ill-defined that the skilled person is unable to carry out the invention. For an unusual parameter the situation is somewhat different and any defect in the measurement method which causes variation in results obtained can lead to problems for both sufficiency and clarity.

The recent case law illustrates the approach taken by the Boards in assessing such matters and provides guidance to both patentees and opponents on how to achieve success.

### Clarity - Article 84 EPC

Claims including parameters can be vulnerable to objections of lack of clarity if it is found that the method of measurement does not lead to accurate or consistent results. In light of the fact that lack of clarity is not a ground for opposition, such objections are more likely to arise in cases which are appealed from the Examining Division although they can become of relevance if

amendments are made to claims post-grant.

If the claims rely upon a parameter for which an appropriate protocol is provided or where the feature is common in the art, then the relevant requirements should be recognised as being fulfilled. This was the case in [T 2519/17 \(COLGATE-PALMOLIVE\)](#) which defined an oral composition containing an abrasive silica defined by its average particle size, Einlehner hardness, oil absorption, d<sub>10</sub>, pellicle cleaning ratio and radioactive dentin abrasion. The Board commented that all of these parameters are known and usual in the field of dentifrice and that methods for the measurement of all of the parameters were provided in the description. [T 911/16 \(ALBEMARLE\)](#) concerned a process for hydroprocessing a heavy hydrocarbon oil using a catalyst defined by its pore volume. The claims were found to be allowable once they had been amended to specify that the relevant feature was the total pore volume and to include the method for its determination.

However, defects in the method or variability in the results obtained are likely to result in difficulties. [T 277/17 \(PAR PHARMACEUTICAL\)](#) related to a pharmaceutical aqueous solution having a viscosity less than about 1000 cPs. It is known that viscosity is dependent upon temperature and the Board commented that without specifying a temperature of measurement reference to the viscosity makes little sense. Nor was it accepted that in the absence of a specific temperature being provided, the skilled person would understand the measurements to be taken at 20°C. A similar conclusion was reached in [T 5/17 \(DESPHARMA\)](#) which described a composition comprising clinoptilolite with a mean particle size between 100 nm and 20 µm. Neither the claims nor the description specified a method for determining this feature. The applicant suggested that the skilled person was not a producer of raw materials but was instead a pharmacist who would simply buy a product with the appropriate particle size. The Board did not accept this argument and instead indicated that to satisfy the relevant requirements, physical characterization must be unambiguous.

### Sufficiency - Article 83 EPC

#### *General Considerations*

If a patent relies upon a parameter and the specification sets out an appropriate protocol for its accurate determination or if suitable measurement methods are commonly known in the art, then objections relating to the sufficiency can generally be dealt with relatively easily. [T 113/19 \(RHODIA\)](#) related to a zirconium oxide catalyst defined by features including its specific surface area. The Board commented that the method to be used was indicated in the patent, was commonly employed in the field and the skilled person could determine the relevant feature accordingly. [T 217/17 \(L'ORÉAL\)](#) concerned a composition which

was defined by its solidification point determined by differential scanning calorimetry (DSC). The patent indicated the apparatus to be used and it was found that DSC is a well-established technology for determining physical characteristics. In the absence of any evidence to raise serious reservations, the Board found the relevant requirements to be fulfilled.

### ***Possible Variation in Results***

If a measurement method is not fully defined, opportunities arise for opponents to argue that the claims lack sufficiency. However, the Boards are very conscious to differentiate between objections of lack of sufficiency and lack of clarity in such situations. Sufficiency will generally be decided in favour of the patentee if the skilled person is aware of one or more methods to determine the relevant feature. If the objection in fact concerns the accuracy of determination and whether the claim has a clear boundary, this is more likely to be considered to relate to clarity.

T 2319/14 (COVESTRO) was concerned with a process for producing nitrobenzene which relied upon features such as percentages of weight, volume and conversion without defining the basis on which such features were determined. The Board commented that these features were well-known to the person skilled in the art and that a possible lack of clarity in the definition of the scope of the claims does not automatically lead to a lack of disclosure of the invention. T 1224/15 (ARKEMA) concerned a multi-layer structure based on polyamides and included features relating to the melting or glass transition temperature. The Board acknowledged that different measuring methods were available and could be used by the skilled person. Arguments relating to variations in the results obtained were considered to relate to clarity since they concerned the precise identification of the boundaries of the claims. Similar conclusions were reached in T 1049/17 (JOHNSON MATTHEY) with regard to the mean crystallite size, T 524/17 (ARCONIC) in relation to texture intensities and T 1399/16 (HYDRO ALUMINIUM) which concerned peak heights in topography.

T 552/18 (SUMITOMO) defined an alumina powder by the maximum peak of particle size. Different passages in the description referred to the use of two different mesh sizes for determining this feature. It was decided that the skilled person could use either of the methods provided and that the claims covered both possibilities. Any difference resulting from the use of the different methods were considered to be an ambiguity and so not a problem for sufficiency.

### ***The Approach of the Boards***

The Boards will take a practical approach in determining the effects of any defect since the patent is directed to the skilled person and it is their approach to the matter that should be determinative. For example, in T 709/17 (MEDICHEM) the claims referred to an average particle size D90 but were not limited to this feature being determined “by volume”. However, the description indicated that the values were derived from volume distributions and the measurement method used laser diffraction which gives volume-weighted distributions. T 2450/17 (HENKEL) concerned a filler which was defined as containing an aggregate that was “non-porous”. It was established that there are different types of porosity, but the Board decided that the skilled person would understand that this should be determined in the context of the use of the invention.

Further examples of this pragmatic approach are found in T

942/17 (AGC) and T 1279/15 (DOUWE EGBERTS). T 942/17 (AGC) defined a claim by reference to the reactivity ratio  $r_{TFE}$ , the value of which can depend upon the temperature and pressure of measurement which were not defined. The Board decided that the skilled person would make use of the conditions employed in the process of the patent. T 1279/15 (DOUWE EGBERTS) related to a capsule for preparing a beverage which comprised a product satisfying a particular particle size distribution. The method for measurement was disclosed in the patent, but it was shown that changes to the conditions would lead to different measured values. However, on the basis that the skilled person would take a sensible approach to this matter, the requirements of sufficiency were found to be fulfilled. A similar conclusion was reached in T 786/15 (NITTO KASEI) in relation to the glass transition temperature.

T 1372/16 (EVONIK) provides a good example of the level of detail in which the Boards will consider the relevant issues. The invention related to an oil-in-water emulsion which had restrictions on the droplet size distribution, this being indicted in the patent to be determined using a Coulter® LS particle size analyser. The manual for the LS series of analysers was assessed during the appeal, it was decided which optical model would be suited for samples of the invention, and it was further considered how the skilled person would approach the determination of both the real and imaginary parts of the refractive index and the nature of the results that would be obtained using this type of instrument. It was decided that the patent, together with the common general knowledge, provided sufficient information to verify whether or not an emulsion is according to the claims of the patent.

### ***The Degree of Variation***

A patent may face more difficulties in relation to a sufficiency objection if it can be established that the level of variability associated with a given parameter is such that the skilled person is prevented from being able to carry out the invention. The burden to demonstrate that this is the case will generally lie with the opponent.

Examples of three cases from 2020 where the Boards found that the opponent had not met this burden are summarised here: T 1627/17 (BOREALIS) related to propylene-ethylene copolymers defined by their ethylene content and xylene solubles content. It was established during the proceedings that the parameters were ambiguous due to a lack of a definition of the methods, measuring conditions and calculation methods for their determination. However, it was not shown that this would prevent the skilled person from working the invention. T 122/18 (STO SE) concerned a coating compound defined by features including the maximum grain size. No method for measurement was provided and it was submitted that the different known sieving or laser diffractometry methods would provide different results. However, it was not demonstrated that the results of such methods would vary to an extent to affect not only the clarity but also the feasibility of the invention. T 1728/16 (ABBOTT) concerned a solid pharmaceutical dosage form which specified the presence of a water-soluble polymer with a specified  $T_g$ . Again, it was established that there was a lack of clarity since no measuring method was provided and it was also found that different methods would lead to different values. Nevertheless, the Board decided that the glass transition temperature was a well-known parameter and the known methods for its measurement did not result in arbitrary values such that there would be no problem in carrying out the invention.

However, a number of successful attacks based on such an approach have also appeared in the case law this year. [T 1657/15 \(TOYO KOHAN\)](#) concerned a metal plate coated with polyester which was defined by the half crystallisation time of a resin layer. No indication was provided in the patent for the method of measurement and evidence was presented to show that the crystallisation temperature and heating rate strongly influenced the results obtained. On this basis, it was found that the skilled person was unable to carry out the invention and the patent was found not to be sufficient. [T 218/17 \(KALLE\)](#) described a food casing defined by features including the porosity of the inner layers. It was established in the proceedings that there were two common methods employed for determining porosity - SEM and mercury pressure penetration. The Board decided that for the products in question the skilled person would make use of SEM. However, it was found that such a method could only measure pores within a specific size range and was not suitable for determining total porosity. In [T 2288/15 \(3M\)](#) the claim related to a fastening film which was defined by the maximum density in particular directions. It was found problems would be encountered if the adhesive strip was not continuous and the skilled person would then not be in a position to determine the density of the film. The Board acknowledged that such a situation may have been an embodiment that was not considered at the time of drafting.

### ***The Nature of the Invention***

It is important that any parameter is considered in the context of the invention. Even features which at first glance would seem to be reasonably commonplace can result in difficulties when a detailed assessment is made of the relevant subject matter. This can be illustrated by [T 292/18 \(KERR\)](#) which concerned a dental composite defined by features including the % by volume of particular components. The method of measurement for this was not provided in the patent nor was there any indication that the skilled person in the relevant field would be aware of a suitable method of calculation or conversion from the different types of known density measurements. On this basis, it was found that the skilled person would not know how to put the invention into effect and the patent was revoked for lack of sufficiency.

[T 1050/16 \(SCA\)](#) related to an absorbent article defined by the length of the crotch portion relative to the entire length of the article in an extended state. In the absence of a teaching how to establish the boundaries of the crotch portion, it was decided that any limits imposed by the skilled person would be nothing but entirely arbitrary.

### ***Consider the Whole Case***

In opposition proceedings before the EPO, it is becoming increasingly important for an opponent to raise all of the objections on which they wish to rely at an early stage of the proceedings. There are therefore situations where a parameter is objected to as lacking sufficiency to ensure that this line of argumentation is available, even though it is not the main focus of the case. In [T 381/15 \(MEIJI\)](#) it was objected that a method for establishing the content ratio of free fat was not sufficiently described. The Board rejected this, pointing out that a method was provided in the patent and that the opponents had been able to perform tests and measure this feature.

### ***Specific Machine***

Decision [T 1293/13 \(NIKE\)](#) issued in 2017 and considered the

situation where a feature in a claim was specified to be determined by a machine that was possibly not ever, and certainly no longer, publically available. The patent was found to be insufficient.

We are not aware of this matter being considered again until it was revisited this year in [T 1714/15 \(KUREHA\)](#). This case concerned a polyamide-based stretch-oriented multilayer film and the claims defined the impact energy as being measured using a Drop-Weight Tester RTD-5000 available from Rheometrics, Inc. The actual machine to be used has the designation RDT-5000 and the Board accepted that this apparatus was available at the effective date of the patent such that the invention was enabled at that time. However, they went on to state that an invention has to be enabled throughout the lifetime of the patent. With the patentee confirming that an apparatus with the correct designation was no longer available, the patent was revoked for lack of sufficiency.

It may be that these decisions result from very specific and unusual sets of facts. In this regard, it may prove difficult in practice to demonstrate that a particular machine identified in a claim is no longer in existence. However, these decisions perhaps open up another avenue for attack against claims which define a parameter by referring to the use of a specific measuring apparatus.

### ***Classical Insufficiency***

It is also worth noting that even when parameters are properly defined, issues relating to sufficiency can still arise if it is found that the skilled person is unable to manipulate the invention across the claim scope. In [T 2039/16 \(NESTLÉ\)](#) a range of infant food products were specified to have below a certain level of furan, but the patent was found not to teach the skilled person how to achieve appropriately low levels. In [T 1296/15 \(GIESECKE+DEVRIENT\)](#) the claims related to a security feature containing a luminescent pigment. Restrictions were provided for the luminophore together with a parametric definition of the luminescence behaviour. However, it was considered that the skilled person was not aware how to select suitable materials to ensure that the required properties were fulfilled. Similar problems were encountered in [T298/17 \(NOURYON\)](#) relating to emulsions, [T 2219/16 \(FITT\)](#) relating to flexible hoses and [T 1171/16 \(JOHNSON & JOHNSON\)](#) concerning an absorbent article.

### **Summary**

Parameters remain a very effective way of defining claim scope and in some instances they are the only way in which particular inventions can be properly characterised. The case law from 2020 re-enforces that which has previously been established and confirms that issues relating to sufficiency and clarity have to be assessed and that it needs to be properly determined under which banner an objection falls.

The cases also demonstrate that the relevant issues will be considered by the Boards in great detail and that complexity in either the nature of the feature or the relationship provided in a claim does not represent a bar on relying on such features to define an invention. This latter point can be illustrated by [T 2670/18 \(JFE STEEL\)](#) where the characterising feature was the size of a seal point defined by:

[Equation 1]  $x_p = \frac{\int_{x_1}^{x_2} p(x)x dx}{F}$ , where  $F = \int_{x_1}^{x_2} p(x) dx$

The claims were found to satisfy the requirements of clarity, once they had been amended to introduce definitions of  $x_1$  and  $x_2$ , and were also sufficient since the skilled person could calculate  $p(x)$ ,  $x_1$ ,  $x_2$  and thus  $x_p$  using the guidance in the application and common general knowledge.

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