Review of EPO Parameter Decisions in 2022

Before the EPO, parameters can be used to define a claim scope which appropriately captures an invention. Parameters are based on measurable values and can relate to any property of a product or a process. They are often used in the chemical sphere and are particularly useful in situations where it is not possible to reflect the characteristics of an invention by relying upon structural features alone.

Since parameters are commonly used in the claims of EP patents, a large body of case law provides insights into the approaches adopted by the Boards of Appeal when considering issues that arise when relying upon such features. The present review highlights some of the issues that can be faced by parameter inventions as illustrated by cases which were published during 2022.

Clarity (Article 84 EPC) – formal requirements

According to the Guidelines for Examination in the European Patent Office, when a claim relies upon parameters the method for measuring the parameter, or a reference thereto, must appear fully in the claims. The only time that such a method does not need to be recited in the claims is where the measurement method belongs to the skilled person's common general knowledge, for example if there was only one method or one which is commonly used, or where all measurement methods yield the same result within the appropriate limits of accuracy.

T 1320/20 (Cytosorbents) related to a polymer system with restrictions to the pore diameter and pore volume. The claims were held to be unclear by the Examining Division since they did not define the method of measurement of these features. The Board was not convinced by the applicant's arguments that the pore diameter was an intrinsic material property that was independent of the method of measurement. This was particularly the case since there was evidence that even if gas adsorption was used on a specific machine, the result would depend on a calculation which included a user-defined option.

The requirement relating to the inclusion of a measurement method in the claims has been present in the Guidelines for some time. However, the language used in the relevant sections was strengthened in the revisions of 2018 and 2019 and it has subsequently been enforced more strictly by examiners. In fact, it has been notable that in 2022 there have been fewer cases coming before the Boards which contain parameters that are undefined.

Clarity (Article 84 EPC) – substantive requirements

In assessing clarity, it needs to be considered as to whether a given feature can be accurately and reliably measured. If the method provided in the specification does not allow for unambiguous determination, then the claims can be found not to comply with the requirements of Article 84 EPC.

These issues can be illustrated by reference to T 735/20 (Authentix). This application concerned a fuel marker of a given formula and which had an ion in GC-MS analysis with a molecular weight of over 1000. It was recognised that the claim did not cover all of the identified compounds, but only those that fulfilled the GC-MS requirement. However, the claim did not specify the conditions under which the GC-MS was carried out and it was not clear whether the ion was the heaviest one produced or just an arbitrary one. A lack of clarity thus arose. Deletion of the GC-MS feature from the claims and its replacement with a requirement that compounds had a specified molecular weight resulted in the application being found to be allowable.

It is also important that the method provided to determine a feature will not alter over time. T 3037/19 (Chugai) concerned a method for controlling the plasma pharmacokinetics of an IgC antibody which included modifying the theoretical isoelectric point when determined using "software GENETYX". An issue was raised as to whether such software could appropriately be relied upon. A declaration was provided to show that there had been no changes in the way the software calculated the relevant value since its implementation in 1996. However, the Board considered that there was no evidence that changes affecting the calculation would not occur in the future. On the basis that the reference to that particular software had no precise and invariable meaning, the claims were found not to satisfy the requirements of Article 84 EPC.

Sufficiency (Article 83 EPC)

In considering sufficiency, the question to be asked is whether the skilled person is able to conduct a measurement to determine a value for the feature, relying on both the specification and common general knowledge. If the parameter is insufficient, it will automatically lack clarity. However, the converse is not necessarily true. Thus, if a value can be determined but without accuracy, the feature can be sufficient but lacking in clarity. Such a distinction can be particularly important after grant since although lack of sufficiency is a ground for opposition, lack of clarity is not. If a feature appears in the claims as granted, it cannot be attacked for lack of clarity in accordance with G3/14.

The relevant issues and approach taken by the Boards can be seen from numerous opposition appeal decisions.

T1243/19 (Philip Morris) related to an aerosol-generating system and specified the relative permeability of an element. An objection was raised that the relative permeability varied with changes in flux density and temperature and no information was provided for the values of these in the patent. This was considered to be an issue of clarity rather than of sufficiency of disclosure, so the objection failed.

T1543/19 (Borealis) concerned a polymer film which was defined

by amongst others the comonomer content. An argument was raised that there were different measurement methods for this feature and that no test method was disclosed in the patent-in-suit. The Board considered that any ambiguity arising from the lack of an indication of a test method might render the scope of the claim unclear but does not render it insufficiently disclosed. It was also commented that if various methods of different accuracy existed, a skilled person would employ the more accurate method when needed and less accurate ones for routine measurements. For example, if an exact value was required for the ethylene content, an absolute test method such as NMR spectroscopy would be used.

T3192/19 (Nutricia) was directed to a powdered nutritional composition with restrictions to the D90 particle size, but a method for measuring this was not provided. The opponent was unsuccessful with an objection of lack of sufficiency on the basis that the criticality of an exact determination of this feature for carrying out the invention had not been demonstrated. It was recognised that differences of up to about 23% could be observed using different methods of measurement. However, it was not shown or rendered plausible that such levels of fluctuation would prevent the invention from being carried out.

A similar approach to this issue was adopted in a number of other cases including T586/19 (Chevron) [comonomer distribution], T464/18 (Koito) [illuminance], T1818/18 (GlaxoSmithKline) [relative humidity], T769/18 (Nestle) [average size of oil droplets], T2152/18 (Nutricia) [particle size], T711/17 (UACJ) [fluidization temperatures] and T467/20 (Philips Image) [pressure differential].

Unusual Parameters

The above decisions relate to parameters based on features which are familiar to the skilled person. The situation is different for unusual parameters, these relating to properties for which another parameter is generally used or to features that have not been measured before in the relevant field. In such a case, the unusual parameter is often the feature differentiating the invention from the prior art and there is a higher standard to provide a full description of its determination. A deficiency here can lead to a finding of lack of sufficiency.

Such a situation arose in T2920/18 (Ineos) where a dependent claim provided for a relationship involving the transverse direction tear strength of a 15 mm film (TTD in g/25mm). The patent did not provide any information to convert between these values and it was found that there was no direct, linear relationship between tearing force and specimen thickness. On the basis that essential information was missing in relation to an unusual parameter, the claim lacked sufficiency. The patent was maintained on the basis of a claim set in which this feature had been cancelled.

An interesting issue concerning the burden of proof in a case involving unusual parameters arose in T555/18 (Cryovac). The claim concerned a multilayer, heat-shrinkable film which differed from the prior art due to a feature relating to an absorbance ratio. The Board stated that:

If the only feature that distinguishes a claim from the closest prior art is a range of an unusual parameter and it is concluded that it would be obvious for the skilled person to solve the underlying technical problem in ways that can be presumed to inherently lead to values within or close to the claimed range, it is the proprietor who should bear the burden of proof to demonstrate that implementing such solutions would not lead to the claimed parametrical range.

Standards

A common way of providing the method to determine a parameter is to rely upon a published standard. However, it is important that the standard is referred to in such a way as to allow for the feature to be determined unambiguously. Thus, the version of the standard should be cited. It is also advisable to review the standard and provide values for any variable feature associated with the method.

Problems with not correctly identifying an appropriate standard arose in T1556/19 (Micro Motion). The patent related to a flameproof housing wherein "*the flameproof gap limit is determined by applying an applicable flameproof standard*". Such a feature was rejected by the Board as lacking clarity. Although the skilled person could measure the values of the "*face gap*" and "*perimeter gap*" of a product according to the invention, there was no indication of which "*flameproof standard*" they have to "*apply*" to determine a gap limit. It was also commented that even the indication of a specific standard in claim 1 would not provide the appropriate clarification because such standards were typically revised over time, and the possibility of substantial changes could not be ruled out.

The following opposition appeal cases highlight issues that can arise when relying on standards. Since the relevant methods were mentioned in the granted claims, only compliance with the requirements of sufficiency could be considered.

T1114/19 (Nano Cleantech) provided for an anticorrosion paint which was defined by its rotational viscosity measured according to ASTM D4212. Unfortunately, ASTM D 4212 did not relate to a rotational viscosity measurement, although a suitable test method was mentioned in section 2 of the standard. The Board found that the skilled person would understand that they were not meant to use a measurement involving dip-type viscosity cups as provided by the original standard, but would instead use the referenced method since it was well known in the field of paints.

T914/17 (Evonik) concerned a polymer powder which had a specified melting enthalpy measured according to DIN 53765. A point that arose concerned whether the measurement was determined on the 1st or 2nd heating run. In this regard, the standard stated that the determination took place after the 2nd run unless something else was expressly agreed. It was not mentioned in the patent that the 1st run was to be used. However, the relevant material property related to a powder and it was recognised the material would become solidified after the initial heating and cooling step such that it would no longer be in powder form. On this basis, the Board decided that the determination of the enthalpy of fusion according to DIN 53765 as covered by the patent would relate to the 1st run.

Objections Raised in Due Time

According to Article 12(2) of the Rules of Procedure of the Boards of Appeal, "*a party's appeal case shall be directed to the requests, facts, objections, arguments and evidence on which the decision under appeal was based*". Any part of a party's appeal which does not meet such requirements is considered to be an amendment and may be admitted only at the discretion of the Board. It is therefore important to ensure that any challenge to a feature is properly raised before the Opposition Division. If objections are raised for the first time during the appeal, there is

a high probability that they will not be admitted. Objections relating to parameters can often require experimental support to succeed, and so if such an objection is being raised in an opposition it is always advisable to file suitable evidence as early as possible in the procedure.

In T2341/17 (Arkema), the claimed method involved laser sintering a thermoplastic composition which was defined by properties including a d90 value. An objection concerning this feature was raised by the opponent for the first time during the oral proceedings before the Opposition Division. During the appeal, the patentee requested that such issues not be admitted since they had only arisen in a late stage of the opposition. However, since the issue was raised in the opposition proceedings and specifically addressed in the decision under appeal, the Board found there was no legal basis in the EPC to disregard it. Since no suitable method for measuring this feature was provided in the specification and in light of evidence that different determinations could differ by more than the size of the range, the invention was found not to meet the requirements of Article 83 EPC.

T1455/19 (Tokuyama Dental) was concerned with an organic-inorganic composite filler defined by features including a pore volume. With their Grounds of Appeal, the appellant filed an experimental report reworking an example from the prior art and providing a determination of the pore volume. The Board commented that the primary object of opposition-appeal proceedings is to obtain a judicial review of the opposition decision. Since the relevant feature was in the claims as granted and this matter should have been addressed earlier, the document was deemed to be inadmissible. In their response to the Grounds of Appeal, the respondent also filed an experimental report reworking the same examples. This was found to be inadmissible using the same reasoning.

Classical Sufficiency

As well as being able to determine a parameter, it is also important that the skilled person can work the invention across the scope of the claims. Difficulties in this regard can arise particularly when a claim contains a number of parameters which have to be simultaneously fulfilled.

T373/17 (Borealis) related to a cable comprising a conductor and a polymer which was defined in terms of its constituents and a combination of parameters relating to flexural modulus, strain at break and environmental stress crack resistance. On the basis that there was a lack of information on how to select an appropriate polymer component and ensure that the parametrical features were satisfied, the ground of lack of sufficiency was found to prejudice the maintenance of the patent.

T1335/19 (Olam) concerned a method of alkalizing cocoa beans in such a way that the resulting product, when processed into a cocoa powder, satisfied requirements relating to its colour and pH. The Board found that there was a plethora of factors which would influence the product properties, such as the alkalisation temperature and time, amount of water and base added, type of cocoa beans, air flow and production scale. The skilled person would therefore have to undertake a multi-parametric research programme to determine suitable parameter combinations to obtain a such a product. This was considered to be an undue burden such that the claimed subject matter was insufficiently disclosed.

Impact upon Further Issues

When objections are raised during an opposition against features defined by parameters, often the only issues which are considered relate to sufficiency. However, if it is found that a parameter is sufficient but the features cannot accurately be determined, this can have an effect upon the claim scope and the assessment of novelty and inventive step.

In T691/20 (Carl Freudenberg) a filter medium was defined by the thickness and porosity of various layers, but the patent did not contain any information on how to measure these. It was found that the person skilled in the art was aware of how to determine such features such that there was a clarity issue which did not call into question the workability of the invention. However, since the relevant features were not clearly defined, there was a problem with the interpretation of the claims which would be taken into account in the discussion of novelty and inventive step.

T1543/19 (Borealis) concerned a polymer film defined by having a sealing initiation temperature SIT of Tm -33°C or less, this being the temperature at which a fixed seal strength is reached. A method for the determination of this parameter was not provided and it was found that seal strength was dependent on the application area of the film which was not specified. The SIT was the only feature which distinguished the claims from the prior art. The uncertainty associated with this feature meant it could not be relied upon to delimit the claims and they were found to lack novelty.

Interpretation of Features

The Boards will often adopt a constructive approach in considering the way that the claims will be interpreted by the skilled person, particularly if the only objections on this issue relate to sufficiency.

T1738/17 (Ethicon) related to a barbed suture. An objection was raised that the invention could not be carried out for various combinations of the claimed parameters. However, any incompatibilities were considered to arise only at the edges of the claim. The Board further commented that "*specific combinations of the geometric parameters that do not work would be immediately ruled out by the person skilled in the art as being outside the scope of practical application of the claimed subject-matter, so their existence does not justify an objection of insufficiency of disclosure*".

A similar approach was taken in T2220/18 (Kone) where a claim to a rope of a lifting device such as an elevator was amended during opposition to include a reference to the proportion by volume of reinforcements being at least 60 percent. An objection was raised that it would be impossible to find a meaningful upper limit such that the claims lacked clarity and sufficiency. The Board disagreed and considered that the upper limit would be defined by the maximum fibre content that is practically applicable.

End Points of Ranges

Parametric features are often specified in the claims to fall within a particular numerical range. However, it is important the end points of the ranges are clearly defined. In T2100/18 (Hemanext), an issue was raised concerning a feature referring to an "*acidified additive solution having a pH of between 5.5 and 7.0*" The question was raised as to whether the term "*acidified*" was compatible with the reference to a pH of 7.0. The Board found that they did not need to consider whether the term "*between*"

included the limits of the range on the basis that the term does not appear in the claim in isolation but instead is combined with the feature that the solution is acidified. The value of 7.0 which implied a neutral rather than acid pH was therefore excluded from the range.

It is generally advisable to avoid relying upon relative or indefinite terms to define the limits of a range. In T1254/17 (GE Oil & Gas) the claim involved a flexible pipe which was amended during opposition to specify a layup angle close to 90°. The Opposition Division interpreted this as meaning "*as close as technically possible to 90°*". However, this was not accepted by the Board since such wording did not appear in the claim. Instead, the phrase "*close to 90°*" was considered to be vague and undefined such that it did not comply with Art 84 EPC. The Board were not convinced by an argument that the same language was used in a standard. It is commented in the decision that "*a definition in a standard document did not have to fulfil the requirements of Art 84 EPC. It is rather unrealistic to assume that each and every word used in the 32 page document D13 has been chosen with the diligence required for clear claim drafting*".

Further problems were encountered in T2503/18 (Vallourec) where a claim to a threaded connection was amended during opposition to specify that one component had an axial length that was "*slightly longer*" than that of another. It was recognised that the claim required this feature to be longer, but the word "*slightly*" was taken to suggest that there was an upper limit which was not defined and hence the claim was found to be unclear.

Amendments during Examination

Care should be taken if any amendments are made to parameters and their definitions during examination. If the parameter is changed in some way that is not appropriately based on the teaching of the original text, an added matter objection can arise which can in some cases not be possible to overcome.

An objection along such lines was raised in T574/17 (Rockwool) where it was argued that amendments to a sound absorption coefficient changed the understanding of this feature and the way it was measured. In this case the objection failed. Whilst it was recognised that there was a slight ambiguity in the wording used in the specification when different parts of the apparatus were referenced, this did not change what the skilled person, using their common general knowledge, clearly and unambiguously understood from the application as a whole.

The patentee was not so successful before the Opposition Division in EP Application No. 15850818.1 (Godo). The patent claimed a lactase solution comprising sugar in an amount of 0.1 to 50 mg/g on the basis of the total mass of the lactase solution and wherein the amount of reducing sugar contained in the lactase solution was 2.0 mg/g on the basis of the total mass of the lactase solution. The reference to the amount of reducing sugar being determined relative to the total mass of the lactase solution was added to the claim during examination. However, the Opposition Division found that the specification suggested that the amounts of reducing sugar were calculated based on the total amount of sugar not on the basis of the lactase composition. Since there was no basis to define the amount of reducing sugar relative to the total mass of lactase solution, the claims were found to add matter and the patent was revoked.

Conclusion

Reliance on parameters remains a very effective way to define claims in order to provide a suitable claims scope to capture an inventor's contribution. However, care does need to be taken at time of drafting an application to ensure that any feature is fully defined such that it can be accurately measured and that the invention can be properly worked. Provided that the relevant aspects are given due consideration, then they remain a valuable way of defining the characteristics of a product or process.

For more information, please contact:

Stuart Raynor — sraynor@jakemp.com