# Sufficiency and reach-through claims: Dutch Novozymes case

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Sufficiency of disclosure is one of the requirements for the grant of a European patent (Art. 83 EPC). The disclosure in a patent specification shall enable the skilled person to apply the invention, i.e. to make the claimed product or apply the claimed process. A claimed product or process is often defined in general terms and includes a number (a range) of embodiments. In principle the skilled person with the aid of his common general knowledge and the patent should be able to make or apply these embodiments. Insufficiency is a ground for revocation in opposition proceedings at the EPO and it is likewise a nullity ground under national patent laws, as it is under Dutch patent law.

*The case with the District Court: Novozymes v DSM*

Recently, the District Court of The Hague in a patent dispute between patentee Novozymes A/S and an alleged infringer, DSM, ruled that Novozyme's patent was insufficient. The patent at issue, EP 1131416, was – insofar as relevant for this case – for a method for producing dough, or bread from such dough, comprising the step of adding a lipolytic enzyme having a SLU/LU ratio of at least 3. The SLU/LU ratio appears to be a parameter that determines the relative amount of short chained organic compounds in the reaction product of the lipolytic enzyme. From the judgment it appears that the relative amount of short chained enzymatic reaction product should be small to prevent the bread baked with the dough referred to in the claim to have an "off" smell or taste. The way in which the SLU/LU ratio is determined is disclosed in the patent description, and it is also included in claim 1.

DSM argued that the scope of the claim was not commensurate with Novozyme's contribution to the art because the claim allegedly would cover an unknown amount of future enzymes having a SLU/LU ratio of at least 3, whereas the patent discloses the effect of only a few. According to DSM this claim would be a mere desideratum, a so-called *free beer* claim.

In a very brief paragraph the court confirms DSM's argument and explains why the patent is insufficient. The Court considers that the breadth of claim 1 is mainly determined by the properties of the lipolytic enzymes that must be added to the dough according to the claim. According to the Court, to apply the claim over its entire scope, it is therefore necessary that the patent teaches the skilled person how to obtain said enzymes. The patent merely describes the enzymes by their functional properties without disclosing a technical concept that teaches the skilled person how to obtain the enzymes. The examples in the patent disclosing specific enzymes having the appropriate SLU/LU ratio do not help the skilled person to obtain all other lipolytic enzymes with the same properties.

Novozymes' defenses, as apparent from the judgment, were that the patent discloses a screening method that teaches the skilled person how to obtain the enzymes within the claim, and that the patent does not claim enzymes as such, but a method for making dough or bread, using enzymes having certain properties. The Court does not honor these defences. As regards the first point, the screening method, the Court considers that this fact does not do away with the existence of very many lipolytic enzymes (DSM pointed to 746,495 variants that were in original claim 15 during prosecution) that would have the desired properties, and that screening all those would amount to undue burden because the patent would not give the skilled person any indications as how to select suitable candidates from such a large group. As regards the second point, the Court considers that although the patent is for a method, the 'core' of the invention is enzymes with certain functional properties. Because these properties are determinative for the scope of protection of the patent, the patent needs to sufficiently make clear how the skilled person can obtain these enzymes.

**COMMENT**

It is not easy to analyse the decisive part of the judgment (one paragraph) because it does not address any evidence, e.g. references or expert opinions. It also does not reflect in any detail the arguments of the parties, or the case law discussed. Nonetheless, some comments can be made about the Court's opinion on sufficiency.

*Contribution to the art*

In the first place the Court appears to make a comparison between the claim and the patentee's contribution to the art. The Court refers several times to this comparison within the framework of sufficiency. Such a comparison presupposes that the patentee's contribution to the art is determined. However, the judgment does not define that contribution. It can be inferred from the Court's considerations that it finds that the patentee's contribution is merely a number of examples of lipolytic examples disclosed in the specification, e.g. when the Court lays these few examples beside the huge amount of possible enzymes that may be within the claim. However, at the same time, in the introductory part, the Court seems to acknowledge that the patentee's contribution to the art is the proposition to use lipolytic enzymes with a SLU/LU ratio of at least 3 in the preparation of dough to improve the quality the ensuing bread, and the way determine this ratio.

*Proof of insufficiency*

Second, according to standing EPO case law, a finding of insufficiency requires 'serious doubts, substantiated by verifiable facts' that the skilled person cannot work the claimed invention. As a granted European patent is presumed to be valid (and therefore also sufficient), it is also standing case law that the burden of proof is upon the third party alleging insufficiency of disclosure. The judgment does not refer to any evidence that would have been brought forward by DSM. Therefore it can neither be inferred from the judgment what the 'serious doubts' are, nor by what 'verifiable facts' they are supported. More specifically, it is not argued why screening the more than 700,000 possible candidates as alleged by DSM, would constitute undue burden. After all, it is not merely the amount of work that constitutes undue burden, as long as it is routine work and as long as it is clear what needs to be done. In this case, no doubts were apparently cast on the clarity and reproducibility of the screening method of claim 1 as such. Nor was it, insofar as the judgment informs us, alleged by DSM that using the screening method as such would amount to undue burden. It appears that the Court found the "indefinite-ness" of the group of enzymes having a SLU/LU ratio of above 3, a decisive factor.

What is commonly done by opponents raising an insufficiency case against a range of compounds (e.g. claimed by a Markush formula) having a specified technical effect is to establish that certain compounds within the claimed range do not have this effect. This would then cast serious doubts on the claim's sufficiency. In the case at hand, serious doubts would for example have been cast by the existence of enzymes having a SLU/LU ratio of at least 3, which do not have the desired effect (i.e. improving smell/taste of the bread). However, the judgment does not address such evidence.

*Reach-through claims?*

Third, the Court appears to lean heavily on *Bayer* (T 1063/06). *Bayer* was about the use of certain compounds in cardiovascular disease, the compounds defined and selected by their ability to stimulate a certain enzyme (heme-independent guanlyate cyclase activation), and this activity to be established by the screening method disclosed in the patent. The Board held that such claim constitutes a "reach-through"- claim (a claim which is also directed to future inventions based on the one now being disclosed). The Court in the case at hand appears to consider that Novozyme's claim would also cover many future inventions, i.e. many enzymes to be discovered having the SLU/LU ratio of at least 3.

Is the claim at hand a reach-through claim in the sense of *Bayer*? This can be questioned. In *Bayer* the claim would, according to the Board, encompass 'future inventions', and this term is also used by the Court in this case. However, the claim at issue merely describes how existing fungal lipolytic enzymes should be tested as regards their SLU/LU ratio. It is at first sight difficult to see how any invention could lie in determining the SLU/LU ratio of existing fungal lipolytic enzymes.

Regardless of the above, the case law of the Boards of Appeal is not principally adverse to reach through-claims. Although in *Bayer* (Board 3.3.10) the patent was revoked under 83 EPC, in *Hoffmann-La Roche* (T 216/96, Board 3.3.4) a similar claim was found sufficient, although the claimed method of detecting nucleic acid sequences made use of primers complimentary to the sequence to be detected, which is arguably a group of molecules as open-ended and infinite as the sequences to be determined by the method (they can be any sequence). The Board in *Bayer* distinguished over *Hoffmann* by considering that the primers in *Hoffmann* were not an "innumerable host of alternatives", but a finite number, narrowed down by their function of primer, and defined by the nucleic acid sequence (because they are complimentary thereto). In *Bayer* the compounds referred to in claim 1 were not defined in terms of chemical structure, composition or other verifiable parameters.

Regardless of whether there is merit in the distinction made by the *Bayer* board, we can take from these two cases that the EPO appears adverse against reach trough claims by novel screening methods if the group of compounds to be tested is truly unlimited (like in *Bayer*), but that they may be allowed when enough limitations are disclosed to allow the skilled person to embark upon a (routine) test program.

In the case at hand, the compounds referred to in claim 1 are, according to the introductory part of the judgment, characterized by several limitations. Claim 1 recites that it regards a "fungal lipolytic enzyme", i.e. a protein taken from a fungus, that catalyzes biological reactions, and that the compounds have "hydrolytic activity towards digalactosyl diglyceride and a phospholipid". This appears at first sight to narrow down the group considerably in comparison to *Bayer*, and could give the skilled person appropriate guidance as to which group of enzymes he should test with the assay described in claim 1. More so, claim 2 limits the options to enzymes from the *Humicola* family. In this respect the facts of this case – insofar as apparent from the judgment – resemble more the *Hoffmann* case than the *Bayer* case.