A>method for claim - when is the recited purpose limiting?

The tug-of-war between Patent Proprietors and Opponents in EPO Opposition proceedings



There has been a recent surge in the biosimilars market in Germany. According to Horizon Grand View Research's >Germany Biosimilars Market Size & Outlook 2020-2027<, the biosimilars market in Germany is expected to reach a projected revenue of US\$ 3,347.3 million by 2027. A compound annual growth rate of 12.6% is expected from 2021 to 2027. This has also led to a surge of Oppositions against European Patents pertaining to methods of manufacturing pharmaceutical products. Therefore, claims to a method and their correct legal interpretation has become increasingly important for Patent Proprietors, Opponents, and their representatives.

While there is a common understanding that a product for claim reciting a purpose is only limited to the extent that the product is merely suitable for that purpose, it is often a point of debate in EPO Opposition proceedings whether a method for claim reciting a purpose is strictly limited by the purpose when it comes to assessment of novelty.

The Opponents usually argue that a prior art document does not have to disclose the purpose to be novelty-destroying when the actual method steps are disclosed in that prior art document. The Patent Proprietors usually respond by asserting that a method for claim reciting a purpose is not equivalent to a product for claim reciting a purpose and that a higher legal standard needs to be applied. This higher standard for method claims under the EPC, according to Patent Proprietors, allows for reading the defined purpose as a hard limitation on the method claims, such that a prior art document would have to also disclose this purpose

We herewith review the legal standard for interpreting a method for claim reciting a purpose and provide examples of recent cases.

in order to be novelty-destroying.

Not limiting!



The established legal standard for interpreting method for claims under the EPC

Indeed, the Guidelines for Examination at the EPO outline a legal assessment of a higher standard that is to be applied for a method claim as compared to a product claim reciting a purpose, however, only in certain cases (Guidelines for Examination at F.IV.4.13.3). According to the Guidelines, in view of the landmark Decision T 1931/14, there are two types of method claims that often lead to different interpretations:.

- Methods where the stated purpose is a **specific application** of the method and the recited steps of
 the method would not inevitably result in that stated
 purpose. Thus, said stated purpose should be construed
 as a **functional feature** and, hence, **limiting feature** of
 the claim (such as, e.g., a method for remelting of the
 galvanic layer in which additional steps not implied
 by or inherent in the recited steps are necessary to
 achieve remelting, T 848/93), and
- Methods where the stated purpose is an intended technical effect which inevitably arises when carrying out the remaining steps of the claimed method and is thus inherent in those steps. This stated purpose should not be construed as a limiting feature of the claim (such as, e.g., a method for reducing malodor is anticipated by a prior-art document describing a method having such suitability for reducing malodor although not mentioning the technical effect, T 304/08).

One of the major points of discussion in EPO Opposition proceedings pertaining to method claims reciting a purpose ensues from the Patent Proprietors' stance that, **even though the stated purpose is a technical effect** and not an application, if it does not inevitably result from the recited method steps, **it should be construed a limiting feature** of the claim when assessing novelty of the method claim.

The question to be asked is whether this is the right approach.

Genentech's EP Patent 2 188 302 -Purpose considered a non-limiting technical effect

An example of how Patent Proprietors often seek to use the higher standard for method for claims reciting a purpose to their advantage when establishing novelty of the claim can be taken from a recent, heavily publicized EPO Opposition case against European Patent 2 188 302 granted to Genentech, Inc. Granted claim 1 was on a method of manufacturing an antibody and recited: >A method for the prevention of the reduction of a disulfide bond in a polypeptide (...).

Initially, ten Oppositions were filed against the grant of EP 2 188 302, with an 11th Opposition from an Intervener in the Opposition proceedings. Oral proceedings in the first instance were initially scheduled for **five days** and were extended by three more days leading to a total of **eight days** of oral proceedings concluding the first instance Opposition proceedings.

The Patent Proprietor argued that the recited technical effect of prevention of disulfide bond reduction is not inherent or implied in the recited steps and therefore, it is not inevitably achieved when the recited steps are performed. They argued that, since it is not inevitably achieved, this effect should be considered a limiting feature when assessing novelty of the claim. According to them, it is the recitation of the effect that ensures that only such methods in which the recited steps do lead to the recited technical effect are encompassed by the claim. The Patent Proprietor also argued that a method for claim reciting a purpose is to be construed such that the purpose is necessarily achieved, and since it is necessarily achieved, that purpose needs to be disclosed in a prior art document for it to be considered novelty-destroying.

All Opponents argued that the feature sfor the prevention of the reduction of a disulfide bond in a polypeptide (...) reflects a technical effect inevitably resulting from the recited method steps and, therefore, a novelty-destroying document disclosing these steps need not acknowledge that prevention of disulfide bond reduction had occurred.

In the first instance Decision, the Opposition Division sided with the Patent Proprietor. They decided that the purpose is a limiting feature of the claim because there are additional steps that need to be taken that are neither implied nor inherent in the explicitly mentioned method steps to achieve the recited purpose. They eventually decided that the claim was novel due to the recited purpose and maintained the Patent with minimal amendments.

Seven of the eleven Opponents appealed the Decision of the Opposition Division and one of the main arguments in their Grounds of Appeal was that the purpose was a mere technical effect inevitably arising from the method steps and, thus, should not be considered a limiting feature of the claim when assessing its novelty, in line with the Guidelines.

The Preliminary Opinion of the Board was issued on 12 September 2024. In it, the Board applied the legal standard established in the Guidelines for method for claims reciting a purpose and preliminarily concluded that the purpose of the prevention of the reduction of a disulfide bond in a polypeptide (...) cannot be considered a limiting feature of the claim and thus, cannot confer novelty on the claim over a prior art document reciting all other method steps.

The Board considered that the recited purpose was a technical effect that is a mere verbal description of a mechanism inevitably taking place when carrying out the step(s) defined in the claim or as the mechanistic explanation of an effect inherently arising during the use of certain compounds in a method for antibody production (see point 33 of the Preliminary Opinion of the Board).

The Board reminded the parties in point 36 of its Preliminary Opinion:

>This view is consistent with the general principle of the EPC that patents are granted for contributions to the state of the art which allow new technical applications, but not for the discovery of a previously unknown property of a compound already known to be used in the same process (see Case Law of the Boards of Appeal of the EPO, 10th edition 2022, I. C. 8.1.3.(e)).<

The Board concluded in point 40 of its Preliminary Opinion:

»The board therefore considers the stated purpose of the method of preventing reduction of a disulfide bond only limiting on the claim as far as the corresponding effect has to be inherently achieved when carrying out the method. For a method of the prior art to anticipate the claimed subject matter it is not necessary that achieving this effect was intended or recognised.

The Patent Proprietor withdrew all Auxiliary Requests on file and their request for oral proceedings. Also, the Patent Proprietor indicated their understanding that the Patent would be revoked for lack of novelty of claim 1 of the Main Request. The Board cancelled the oral proceedings that were scheduled for 12-14 February 2025.

The Board's Decision was issued on 4 March 2025 as T 2695/22, and the Patent was revoked for added subject matter under Art. 123(2) EPC without touching upon novelty.

Nevertheless, this case shows that, while there are settings in which a method for claim reciting a purpose does enjoy a higher standard when it comes to interpreting the purpose as a limiting feature, such a standard can only be applied under certain circumstances, i.e. when the purpose is an application, which tends to be quite rare.

Cambridge Enterprise Limited's EP Patent 3 545 079 - Purpose considered a limiting application

In Opposition proceedings concerning Cambridge Enterprise Limited's EP 3 545 079, the Opposition Division decided that the purpose of a method for feature that defines a specific application is a limitation when assessing the claim's novelty.

The method recited, in a wherein clause, that the method is of or forward programming of pluripotent stem cells. The Opposition Division preliminarily sided with the Opponent and opined that this purpose was not a limiting feature of the claim and, therefore, the claim lacked novelty over a prior art document that was focussed on reprogramming specialized cells.

The Patent Proprietor in turn argued that the claim must be interpreted such that the feature **for forward programming of pluripotent stem cells* is the **specific application** of the method that provides an actual technical limitation in view of the Guidelines F.IV.4.13.3 and established Case Law of the Boards of Appeal, T 1931/14.

The Opposition Division changed their preliminary opinion on the day of the oral proceedings and maintained the Patent in amended form. The Decision was issued on 24 October 2024. In points 83 to 88 of the Grounds for the Decision, the Opposition Division applied the legal standard for interpreting method for claims established by the Guidelines and concluded that the purpose of forward programming of pluripotent stem cells represents a limiting feature of the claim when assessing novelty.

This Decision shows that, though rare, in certain circumstances, when adhering to the legal standard established by the Guidelines F.IV.4.13.3, it is possible to successfully argue that a method claim reciting a purpose is to be considered its limiting feature for the assessment of novelty. There is no pending appeal proceedings and the Opposition Division's decision has become final.

Discussion

While it is somewhat concerning that the Opposition Divisions at the EPO appear to differ in their interpretation and application of the legal standard (e.g. as laid out in the Guidelines) compared to the Boards of Appeal, it nevertheless seems that careful argumentation that adheres to the established legal standard for interpretation of method claims under the EPC may succeed in unifying the resulting decisions.



Asim Akbani

/ Patent Engineer

/ M.Sc. Forensic Epigenetics and
Molecular Biology



Dr. Regina Neuefeind
/ Partner
/ German Patent Attorney
/ European Patent Attorney
/ UPC Representative
/ Biologist
/ LL.M.>European Intellectual

Property Law