Novelty of biotechnological inventions and further therapeutic use in Europe

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This article analyses recent European case law and changes following the entry into force of the European Patent Convention (EPC) 2000 in relation to the assessment of the novelty of certain biotechnological inventions, including claims to products and method/use claims.

Concept of novelty as applied to biological inventions

According to Article 54 of the EPC 2000, an invention shall be considered novel if it does not form part of the state of the art.

A certain level of complexity was introduced by the case law of the European Patent Office Boards of Appeal (T677/91, T465/92), which held that a product or a method will be considered to form part of the state of the art (ie, will not be considered novel) if all features of the product or method may be inferred directly and unambiguously from the state of the art – including inherent features, as long as these have already been made available to the skilled person.

Furthermore, features which are revealed only when the product is exposed to interaction under specific conditions in order to create a technical effect or result (so-called "extrinsic" features) point beyond the product *per se*, as they depend on deliberate choices being made (Enlarged Board Decision G01/92).

The question has thus arisen as to when a product or method is considered to have been made available to form part of the state of the art. Several examples of the assessment of the novelty of biotechnological inventions are examined below.

Vaccine

In Case T977/93, a coronavirus vaccine was commercially available before the priority date of a patent also claiming a coronavirus vaccine. Two features of this claimed vaccine (one inherent feature concerning the target cells of the vaccine and one extrinsic feature concerning the mode of administration) were held not to have been disclosed in the prior art vaccine. As a consequence, the claimed corona virus *per se* was held novel in view of the prior art vaccine.

Glycoprotein

In Case T277/95, the patent claimed that recombinant erythropoietin (rEPO) having O-linked glycosylation could be obtained by culturing CHO cells transformed with the nucleic acid sequence coding for rEPO and isolating the rEPO produced. The priority document said nothing about the presence and pattern of glycosylation of rEPO. The Board was unable to accept that the glycosylation pattern referred to in the claims at issue (O-glycosylation) was inherent when using the CHO cell line as submitted in the priority document. Inherency must be established on the basis of certainty, not probability or possibility. The priority right was held invalid.

Nucleic acid sequence

In Case T179/01, a nucleic acid sequence coding for a specific protein was claimed. The prior art was directed to a nucleic acid sequence that, in theory, could encode this specific protein. According to the Board, an inherent feature of a nucleic acid sequence is its sequence. This sequence is "reflected" in the sequence of the protein it encodes, which in turn is responsible for the biological properties of the protein. Therefore, the inherent property of a nucleic acid molecule is deducible from that of another molecule, which is the encoded protein – leading to the concept of "indirect proof of inherency". In order for the prior art to destroy the novelty of the claimed nucleic acid sequence, the prior art document must also disclose this "indirect proof of inherency": it must provide clear, unambiguous

and enabling disclosure leading to the inherent properties. The prior art was considered as failing to provide an enabling disclosure which would permit testing of the "indirect proof of inherency". The submission of post-published evidence did not change this situation and the prior art document thus did not destroy the novelty of the claimed nucleic acid sequence.

Conclusions

Features of a product that have allegedly been inherently disclosed in a prior art document will be considered as having been disclosed only on the basis of certainty, not probability or possibility. An inherent feature of a product will be considered to have been made available to the public if this feature *per se* has become part of the prior art and/or could be derived by the skilled person using common knowledge.

Novelty of medicament and its therapeutic use

Purpose-related product protection for further therapeutic use

Following the entry into force of the EPC 2000 on 13th December 2007, an additional level of product protection has been granted to pharmaceutical companies.

Under the previous EPC (Article 54.5 of the EPC 1973), only the first medical use of a medicament could be protected as a broad product claim covering all potential therapeutic uses of that medicament. Such a claim would read as follows: "Product X for use as a medicament."

Further therapeutic uses were protected only by a use claim, also called a "second medical use" or "Swiss-type" claim (Enlarged Board G5/83). Such a claim would read as follows: "Use of product X for the manufacture of a medicament for a specified new and inventive therapeutic application."

Under Article 54.4 of the EPC 2000, purpose-related product protection is now granted for any further medical use of a known medicament. Such a claim would read as follows: "Product X for use as a medicament for a specified new and inventive therapeutic application."

Therefore, under the EPC 2000, a known medicament may still be protected as a product for each new and inventive therapeutic application that is discovered.

Second and further therapeutical use

Under the EPC 2000, a known medicament may be further protected via the so-called "second medical use" claim, as outlined above.

Recent case law (T1020/03) has additionally established that where a medicament is already known to be used for a given therapeutic application, and a new and inventive particular dosage regimen (specific cyclic administration regime) of the same medicament is found to treat the same therapeutic application, this new and inventive particular dosage regimen is to be seen as a further therapeutic application and can therefore be protected as a second further medical use.

Under the EPC 2000, this further medical use based on a new and inventive particular dosage regimen can therefore be protected both as a further purpose-related product protection as outlined above and as a further medical use claim.

Conclusions

The novelty of a medicament as a purpose-related product has been further extended by the EPC 2000. It is now possible to claim each additional new and inventive therapeutic application of a known medicament as a product claim limited to this specific therapeutic application.

The concept of new and inventive therapeutic application seems to have been broadly interpreted by the European Patent Office, since a new and inventive mode of administration may also be considered as a new and inventive therapeutic application.

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