There is currently a significant divergence in practice between Europe and the United States when considering the patentability of naturally-occurring products. Since the *Myriad* decision of the U.S. Supreme Court, the USPTO has started to reject claims directed to naturally-occurring products under 35 USC §101. In the European Patent Office (EPO), such objections do not generally arise.

The EPO’s position is that merely finding a previously unrecognised substance occurring in nature is an unpatentable discovery. However, if that substance can be shown to produce a technical effect, then the naturally-occurring substance may be patentable (*EPO Guidelines for Examination G-II, 3.1*).

This ability to patent natural products derives from the rules of the European Patent Convention (EPC), which explicitly state that biological material which is isolated from its natural environment or produced by means of a technical process can be patented, even if it has previously occurred in nature (*Rule 27(a) EPC*). Similarly, although the human body itself cannot be patented at the EPO, elements isolated from the human body, including gene sequences, can form patentable inventions, even if they are structurally identical to a natural element (*Rule 29(1) and (2) EPC*).

In order to obtain a patent at the EPO to a product that occurs in nature, the claim must specify that the product is isolated from its natural environment, or it must make it clear that the product as claimed was produced by a non-natural process.

In addition, in order to be considered patentable at the EPO, the patent application must identify some kind of technical effect or purpose for the natural product. That effect must be disclosed in the patent application, but does not need to be specified in the claim (and preferably should not be specified in the claim unless needed to address some other provision of the EPC). For example:

- if a substance that occurs in nature is found to have an antibiotic effect, then a claim to the isolated substance may be patentable in Europe;
- if a naturally-occurring microorganism is found to produce an antibiotic substance, then a claim to the isolated microorganism may be patentable in Europe.

This requirement is set out more specifically in relation to nucleic acid sequences. A nucleic acid sequence is not considered patentable if the patent application gives no indication of its function (*Rule 29(3) EPC*). This means that claims based on ESTs or other uncharacterised sequences are unlikely to be allowed under the EPC. However, if the application shows that a sequence encodes a useful protein, or part of such a protein, then a claim to that nucleic acid sequence may be patentable, even if it occurs in nature. Similarly, claims to vectors or plasmids containing that sequence, or to cells capable of expressing the sequence may be patentable, again even if they exist in nature. If the application shows that a nucleic acid
sequence has another useful function, for example activity as a transcription promoter or enhancer, then a claim to that nucleic acid sequence, or to products comprising that sequence, may be patentable.

Contrary to current practice at the USPTO, newly-discovered natural products may therefore still be patented in the EPO, as long as the patent application makes it clear that they have a utility. The EPO’s position is consistent with the European Union (EU) Directive 98/44/EC on the legal protection of biotechnological inventions. That Directive is binding on the EPO member states that are also EU member states and should therefore also be reflected in the national patent laws of those states. EPO member states that are not members of the EU may or may not follow this directive.

For more information on patent eligible subject matter in the United States and Europe, please see our webinar on Drafting the “Global” Patent Application.

Tags

European Patent Office (EPO), natural products, biologics, Association for Molecular Pathology v. Myriad Genetics Inc., Life Sciences, gene sequences, naturally occurring, Patentability, patent eligibility

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