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OBTAINING PATENTS FOR MANUFACTURED PRODUCTS OF NATURALLY OCCURRING SUBSTANCES

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Many of the products which are produced by biotechnology, such as recombinant DNA technology, are products which also occur naturally. Obtaining patent protection for such products which exist in nature is difficult because the products may not be novel, and therefore the invention may not meet the novelty requirements for patentability.

1. SYNTHETIC PRODUCTS

A manufactured product which differs from one that is naturally occurring only because it is artificially made is not novel and thus is not patentable. However, the process by which it is manufactured may be novel and unobvious, and therefore patentable.

A Supreme Court case addressing whether a synthetic product is patentable is Funk Bros. Co. v. Kalo Co.. The claimed invention was directed to a naturally occurring strain of bacteria which enabled different species of leguminous plants like clover and alfalfa to take nitrogen from the air and fix it to the roots of the plants. No species of bacteria acquired a different use. The Supreme Court held that:

"The qualities of bacteria, like the heat of the sun, electricity, or the qualities of metals, are part of the storehouse of knowledge of all men. They are manifestations of laws of nature, free to all men and reserved exclusively to none. He who discovers a hitherto unknown phenomenon of nature has no claim to a monopoly of it which the law recognizes. If there is to be invention from such a discovery, it must come from the application of the law of nature to a new and useful end."

A different result is achieved in the case of genetically altered bacteria where the end product is a bacterium that possesses properties unknown to any other living organism. The bacterium itself would be patentable because it is unique and novel. However, any product produced by the metabolic activity of the bacterium would only be patentable if it too were unique, novel and unobvious. The case establishing the patentability of a human-made, genetically engineered bacterium is Diamond v. Chakrabarty. In 1972, Chakrabarty, a microbiologist working for General Electric, asserted claims for the invention of a bacterium that was capable of breaking down multiple components of crude oil. This property was not possessed by any bacterium known to exist in nature. The significant value of the invention was in the treatment of crude oil spills. This case was distinguished from Funk Bros. because "the patentee produced a new bacterium with markedly different characteristics from any found in nature".

2. PURITY LIMITATIONS

Is a replica of a naturally occurring substance which is of higher purity patentable? This was addressed by the Court of Customs and Patent Appeals in *In re Merz*.

"While appellant may be entitled to a patent on a method for purifying an ultramarine either artificial or natural, he is not entitled to a patent on the article which after being produced has a greater degree of purity than the product produced by former methods. This general rule is a well-settled one, but like all other rules it has an exception. The exception is that if the process produces an article of such purity that it differs not only in degree but in kind it may be patentable."

The exception to the rule was addressed in *Merck & Co. v. Olin Mathieson Chemical Corp.*. The court held that the product claims to a bacterially produced vitamin B12 protein, although known in nature,

were patentable because the claims recited a specific purity limitation. The claim stated:

"A vitamin B12 active composition comprising recovered elaboration products of the fermentation of a vitamin B12 activity producing strain of Fungi selected from the class consisting of Schizomycetes, Torula, and Eremothecium, the L.L.D. activity of said composition being at least 440 L.L.D. units per milligram and less than 11 million L.L.D. units per milligram."

In *In re Bergstrom*, an often-cited case, the claims related to the prostaglandins PGE and PGF, natural substances extracted from sources such as the human prostate gland. The C.C.P.A. held that the pure prostaglandin substance is not naturally occurring and that the applicant had not merely claimed that which had previously existed in nature, albeit unknown. "Whether the claimed pure materials are novel as compared with the less pure materials of the reference," the Court stated:

"...pure materials necessarily differ from less pure or impure materials and, if the latter are the only ones existing and available as a standard of reference, as seems to be the situation here, the "pure" materials are "new" with respect to them."

Similarly, in *In re Bergy*, the C.C.P.A. held that a biologically pure culture of the *Streptomyces* microorganism was not a "product of nature". It was therefore patentable over the microorganism as it existed in nature.

5. RECOMBINANT PRODUCTS

1. Claims to a Purified and Isolated Product

While the U.S. Patent Office often rejects claims for a recombinantly produced product which exists in a natural form, it has become common practice to distinguish the recombinant product from the natural product by stipulating that the new recombinant product exists in a "purified or isolated" form.

Claims to recombinantly produced proteins or DNA sequences have been allowed relying on the levels of purity as the distinguishing feature of the claim. In U.S. Patent Number 4,703,008, the Amgen EPO patent, there is a claim to:

A purified and isolated DNA sequence consisting essentially of a DNA sequence encoding human erythropoietin.

Rejections based on the DNA sequence being a "product of nature" were overcome by the addition of the words "purified and isolated" to the claim.

A Court has stated that this claim was not to the DNA sequence encoding human EPO because that is a "nonpatentable naturally occurring phenomenon 'free to all men and reserved exclusively to no-one'" It was the "purified and isolated" DNA sequence encoding EPO.

Also, in *Scripps v. Genentech*, it was stated:

"There is no dispute over the patentability of a Factor VIII:C preparation. Although Factor VIII:C molecules occur in nature, a purified and concentrated preparation of Factor VIII:C as claimed in the patent constitutes a new form or combination not existing in nature, and hence is patentable under 35 U.S.C. 101. (ii) Claims to a Recombinant Product

In *Ex Parte Gray* the Patent Board of Appeals rejected a claim to recombinantly produced nerve growth factor identified by the particular amino acid sequence and being free from other proteins of human origin. The prior art disclosed the material isolated from human placental tissue. The difference between the claimed material and the prior art was primarily that the claimed material was produced by recombinant technology. The Board, however, stated that the applicant needed to establish unexpected properties for the claimed recombinant product over the prior art. The mere presence of a single methionyl moiety on the recombinant protein not present on the natural protein would not in itself render the claim patentable.

This is a new development in patents directed to recombinant products. This means that claims are not allowable merely to recombinantly produced products simply because they are produced

by recombinant DNA techniques. Increased purity of biological activity or other property not found in the natural, known product or other properties will need to be shown to overcome an unobviousness rejection.

Thus, the current standard in the United States is that a recombinant product will be patentable if it is in a more highly purified or isolated form than the product can be found in nature. If the purified and isolated natural product is previously known, some other evidence of novelty and nonobviousness is required.

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