

Nature-Based Products

Claim 5: Eligible. The claim is limited to peptides in which the amino acid sequence has at least 90% identity to SEQ ID NO: 2, but has been changed to contain at least one non-naturally occurring substitution modification relative to SEQ ID NO: 2. All of the claimed peptides have different structural characteristics (*e.g.*, one or more amino acids have been changed relative to the natural sequence). Some of the claimed peptides may have different functional characteristics, but at least for some conservative modifications there may be no observable functional difference. Because the structural differences between the claimed peptides and their natural counterparts are enough to ensure that the claim is not improperly tying up the future use of naturally occurring Antibiotic L, they rise to the level of a marked difference, and thus the claimed antibiotic is not a “product of nature” exception. Thus, the claim is not directed to an exception (*Step 2A: NO*), and qualifies as eligible subject matter.

5. Genetically Modified Bacterium

This example illustrates that a naturally occurring product that is unchanged from its natural state does not have markedly different characteristics (claim 1), but that changes in biological function between a claimed product and its natural counterpart can demonstrate markedly different characteristics (claim 2).

Background: Stable energy-generating plasmids that provide hydrocarbon degradative pathways exist within certain bacteria in nature. Different plasmids provide the ability to degrade different hydrocarbons, *e.g.*, one plasmid provides the ability to degrade camphor, and a different plasmid provides the ability to degrade octane. *Pseudomonas* bacteria are naturally occurring bacteria. Naturally occurring *Pseudomonas* bacteria containing one stable energy-generating plasmid and capable of degrading a single type of hydrocarbon are known. There are no known *Pseudomonas* bacteria in nature that contain more than one stable energy-generating plasmid. In the specification, applicant discloses genetically modifying a *Pseudomonas* bacterium to include more plasmids than are found in a single naturally occurring *Pseudomonas* bacterium.

Claims:

1. A stable energy-generating plasmid, which provides a hydrocarbon degradative pathway.
2. A bacterium from the genus *Pseudomonas* containing therein at least two stable energy-generating plasmids, each of said plasmids providing a separate hydrocarbon degradative pathway.

Analysis of Claims:

These claims are analyzed for eligibility in accordance with their broadest reasonable interpretation. Because both claims are directed to a statutory category, *e.g.*, a manufacture or composition of matter (*Step 1: YES*), and are nature-based products (plasmid or bacterium), the markedly different characteristics analysis is used to determine if the nature-based products are exceptions.

Claim 1: Ineligible. Based on the limited background information, there is no indication that the claimed plasmid has any characteristics (structural, functional, or otherwise) that are different from naturally occurring energy-generating plasmids. Because there is no difference between the claimed and naturally occurring plasmid, the claimed plasmid does not have markedly different characteristics, and thus is a “product of nature” exception. Accordingly, the claim is directed to an exception (*Step 2A: YES*). Because the claim does not include any additional features that could add significantly more to the exception (*Step 2B: NO*), the claim does not qualify as eligible subject matter, and should be rejected under 35 U.S.C. § 101.

Claim 2: Eligible. The claimed bacterium has a different functional characteristic from naturally occurring *Pseudomonas* bacteria, *i.e.*, it is able to degrade at least two different hydrocarbons as compared to naturally occurring *Pseudomonas* bacteria that can only degrade a single hydrocarbon. The claimed bacterium also has a different structural characteristic, *i.e.*, it was genetically modified to include more plasmids than are found in a single naturally occurring *Pseudomonas* bacterium. The different functional and structural characteristics rise to the level of a marked difference, and accordingly the

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claimed bacterium is not a “product of nature” exception. Thus, the claim is not directed to an exception (*Step 2A: NO*), and qualifies as eligible subject matter.

The bacterium of claim 2 was held to be patent-eligible subject matter in *Diamond v. Chakrabarty*, 447 U.S. 303 (1980). Recently, the Supreme Court looked back to this claim as an example of a nature-based product that is patent-eligible because it has markedly different characteristics than naturally occurring bacteria, as explained in *Myriad*, 133 S. Ct. at 2116-17:

In *Chakrabarty*, scientists added four plasmids to a bacterium, which enabled it to break down various components of crude oil. 447 U. S., at 305, 100 S. Ct. 2204, 65 L. Ed. 2d 144, and n. 1. The Court held that the modified bacterium was patentable. It explained that the patent claim was “not to a hitherto unknown natural phenomenon, but to a nonnaturally occurring manufacture or composition of matter--a product of human ingenuity ‘having a distinctive name, character [and] use.’” *Id.*, at 309-310, 100 S. Ct. 2204, 65 L. Ed. 2d 144 (quoting *Hartranft v. Wiegmann*, 121 U. S. 609, 615, 7 S. Ct. 1240, 30 L. Ed. 1012 (1887); alteration in original). The *Chakrabarty* bacterium was new “with markedly different characteristics from any found in nature,” 447 U. S., at 310, 100 S. Ct. 2204, 65 L. Ed. 2d 144, due to the additional plasmids and resultant “capacity for degrading oil.”

6. Bacterial Mixtures

This example illustrates the application of the markedly different characteristics analysis to nature-based product claims produced by combining multiple components.

Background: *Rhizobium* bacteria are naturally occurring bacteria that infect leguminous plants such as clover, alfalfa, beans and soy. Each species of bacteria will only infect certain types of plants, for example *R. meliloti* will only infect alfalfa and sweet clover, and *R. phaseoli* will only infect garden beans. It was assumed in the prior art that all *Rhizobium* species were mutually inhibitive, because prior art combinations of different bacterial species produced an inhibitory effect on each other when mixed together, with the result that their efficiency was reduced. Applicant has discovered that there are particular strains of each *Rhizobium* species that do not exert a mutually inhibitive effect on each other, and that these strains can be isolated and used in mixed cultures. Applicant has also discovered that certain *Rhizobium* species, when mixed together, exhibit biological properties that are different than in nature. For example, in nature or by itself, *R. californiana* will only infect lupine. When mixed with *R. phaseoli*, however, *R. californiana* will infect both lupine and wild indigo. *R. californiana* and *R. phaseoli* are not known to occur together in nature.

Claims:

1. An inoculant for leguminous plants comprising a plurality of selected mutually non-inhibitive strains of different species of bacteria of the genus *Rhizobium*, said strains being unaffected by each other in respect to their ability to fix nitrogen in the leguminous plant for which they are specific.
2. An inoculant for leguminous plants comprising a mixture of *Rhizobium californiana* and *Rhizobium phaseoli*.

Analysis of Claims:

These claims are analyzed for eligibility in accordance with their broadest reasonable interpretation. Because both claims are directed to a statutory category, e.g., a composition of matter (*Step 1: YES*), and are nature-based products (a mixture of bacteria), the markedly different characteristics analysis is used to determine if the nature-based products are exceptions.

Claim 1: Ineligible. There is no indication in the specification that the claimed mixture of bacteria has any characteristics (structural, functional, or otherwise) that are different from the naturally occurring