Examples: Abstract Ideas

The following examples should be used in conjunction with the 2014 Interim Eligibility Guidance. As the examples are intended to be illustrative only, they should be interpreted based on the fact patterns set forth below. Other fact patterns may have different eligibility outcomes.

This set of examples is arranged into two parts. The first part includes four fact patterns with claims that are patent eligible, several of which draw from U.S. Court of Appeals for the Federal Circuit decisions, and the second part includes four fact patterns with claims that were found ineligible by the Federal Circuit. Each of the examples shows how claims should be analyzed under the 2014 Interim Eligibility Guidance. All of the claims are analyzed for eligibility in accordance with their broadest reasonable interpretation.

Part One

These examples show claims that would be patent **eligible** when analyzed under the 2014 Interim Eligibility Guidance. The first example is a hypothetical claim and fact pattern that illustrates an eligible software invention that is not directed to an abstract idea. The second example is a recent Federal Circuit decision. The third and fourth examples are informed by Federal Circuit decisions where claims were found eligible, but are drafted as hypothetical claims modified to prominently add an abstract idea for teaching purposes to facilitate analysis under the "significantly more" prong of the 2014 Interim Eligibility Guidance.

1. Isolating and Removing Malicious Code from Electronic Messages

Hypothetical claims 1 and 2 are not directed to an abstract idea.

Background

The invention relates to isolating and removing malicious code from electronic messages (*e.g.*, email) to prevent a computer from being compromised, for example by being infected with a computer virus. The specification explains the need for computer systems to scan electronic communications for malicious computer code and clean the electronic communication before it may initiate malicious acts. The disclosed invention operates by physically isolating a received electronic communication in a "quarantine" sector of the computer memory. A quarantine sector is a memory sector created by the computer's operating system such that files stored in that sector are not permitted to act on files outside that sector.

When a communication containing malicious code is stored in the quarantine sector, the data contained within the communication is compared to malicious code-indicative patterns stored within a signature database. The presence of a particular malicious code-indicative pattern indicates the nature of the malicious code. The signature database further includes code markers that represent the beginning and end points of the malicious code.

The malicious code is then extracted from malicious code-containing communication. An extraction routine is run by a file parsing component of the processing unit. The file parsing routine performs the following operations:

1. scan the communication for the identified beginning malicious code marker;

2. flag each scanned byte between the beginning marker and the successive end malicious code marker;

3. continue scanning until no further beginning malicious code marker is found; and

4. create a new data file by sequentially copying all non-flagged data bytes into the new file, which thus forms a sanitized communication file.

The new, sanitized communication is transferred to a non-quarantine sector of the computer memory. Subsequently, all data on the quarantine sector is erased.

Claims

1. A computer-implemented method for protecting a computer from an electronic communication containing malicious code, comprising executing on a processor the steps of:

receiving an electronic communication containing malicious code in a computer with a memory having a boot sector, a quarantine sector and a non-quarantine sector;

storing the communication in the quarantine sector of the memory of the computer, wherein the quarantine sector is isolated from the boot and the non-quarantine sector in the computer memory, where code in the quarantine sector is prevented from performing write actions on other memory sectors;

extracting, via file parsing, the malicious code from the electronic communication to create a sanitized electronic communication, wherein the extracting comprises

scanning the communication for an identified beginning malicious code marker,

flagging each scanned byte between the beginning marker and a successive end malicious code marker,

continuing scanning until no further beginning malicious code marker is found, and

creating a new data file by sequentially copying all non-flagged data bytes into a new file that forms a sanitized communication file;

transferring the sanitized electronic communication to the non-quarantine sector of the memory; and

deleting all data remaining in the quarantine sector.

2. A non-transitory computer-readable medium for protecting a computer from an electronic communication containing malicious code, comprising instructions stored thereon, that when executed on a processor, perform the steps of:

receiving an electronic communication containing malicious code in a computer with a memory having a boot sector, a quarantine sector and a non-quarantine sector;

storing the communication in the quarantine sector of the memory of the computer, wherein the quarantine sector is isolated from the boot and the non-quarantine sector in the computer memory, where code in the quarantine sector is prevented from performing write actions on other memory sectors;

extracting, via file parsing, the malicious code from the electronic communication to create a sanitized electronic communication, wherein the extracting comprises

scanning the communication for an identified beginning malicious code marker,

flagging each scanned byte between the beginning marker and a successive end malicious code marker,

continuing scanning until no further beginning malicious code marker is found, and

creating a new data file by sequentially copying all non-flagged data bytes into a new file that forms a sanitized communication file;

transferring the sanitized electronic communication to the non-quarantine sector of the memory; and

deleting all data remaining in the quarantine sector.

Analysis

Claim 1: Eligible.

The method claim recites a series of acts for protecting a computer from an electronic communication containing malicious code. Thus, the claim is directed to a process, which is one of the statutory categories of invention (*Step 1: YES*).

The claim is then analyzed to determine whether it is directed to any judicial exception. The claimed invention relates to software technology for isolation and extraction of malicious code contained in an electronic communication. The claim is directed towards physically isolating a received communication on a memory sector and extracting malicious code from that communication to create a sanitized communication in a new data file. Such action does not describe an abstract concept, or a concept similar to those found by the courts to be abstract, such as a fundamental economic practice, a method of organizing human activity, an idea itself (standing alone), or a mathematical relationship. In contrast, the invention claimed here is directed towards performing isolation and eradication of computer viruses, worms, and other malicious code, a concept inextricably tied to computer technology and distinct from the types of concepts found by the courts to be abstract. Accordingly, the claimed steps do not recite an abstract idea. Nor do they implicate any other judicial exception. Accordingly, the claim is not directed to any judicial exception (*Step 2A*: *NO*). The claim is eligible.

Claim 2: Eligible.

The claim is directed to a non-transitory computer-readable medium, which is a manufacture, and thus a statutory category of invention (*Step 1: YES*).

The claim recites the same steps as claim 1 stored on a non-transitory computer readable medium such that they are executable on a processor. The invention described by those steps is not directed towards an abstract idea, for the reasons explained above (*Step 2A*: *NO*). The claim is eligible.

2. E-Commerce Outsourcing System/Generating a Composite Web Page

The following claim was found eligible by the Federal Circuit in DDR Holdings, LLC v. Hotels.com et al., 113 USPQ2d 1097 (Fed. Cir. 2014) (DDR). The patent at issue was U.S. Patent No. 7,818,399.

Background

In affiliate commerce systems, website owners or hosts sell space on their web pages in the form of paid advertisements. Many of these advertisements are banner ads that include links to items offered for sale by third-party merchants. When a visitor activates (clicks on) a link, the visitor is instantly transported away from the host's web page to the merchant's web page so that she can purchase the item (a "commerce object", *e.g.*, a product or service) associated with the link. The merchant pays a commission on each such sale to the host of the web page displaying the link. While these advertising links function as a commission-based advertising program that provides the host additional revenues, they have the disadvantage of luring visitor traffic away from the host's web page, which results in the host losing control of potential customers.

The inventor has addressed this problem of retaining control over customers during affiliate purchase transactions, by creating a system for co-marketing the "look and feel" of the host web page with the product-related content information of the advertising merchant's web page. The system can be operated by a third-party outsource provider, who acts as a broker between multiple hosts and merchants. Prior to implementation, a host places links to a merchant's web page on the host's web page. The links are associated with product-related content on the merchant's web page. Additionally, the outsource provider system stores the "look and feel" information from each host's web pages in a computer data store, which is coupled to a computer server. The "look and feel" information includes visually perceptible elements such as logos, colors, page layout, navigation system, frames, mouse-over effects or other elements that are consistent through some or all of each host's respective web pages.

In the inventor's system, a customer who clicks on an advertising link is not transported from the host web page to the merchant's web page, but instead is re-directed to a composite web page that combines product information associated with the selected item and visually perceptible elements of the host web page. The outsource provider's server responds by first identifying the host web page where the link has been selected and retrieving the corresponding stored "look and feel" information. The server constructs a composite web page using the retrieved "look and feel" information of the host web page, with the product-related content embedded within it, so that the composite web page is visually perceived by the customer as associated with the host web page. The server then transmits and presents this composite web page to the customer so that she effectively remains on the host web page to purchase the item without being redirected to the third party merchant affiliate. Because such composite pages are visually perceived by the customer as associated with the host web page, they give the customer the impression that she is viewing pages served by the host. Further, the customer is able to purchase the item without being redirected to the third party merchant affiliate, thus allowing the host to retain control over the customer. This system enables the host to receive the same advertising revenue streams as before but without the loss of visitor traffic and potential customers.

Representative Claim

19. A system useful in an outsource provider serving web pages offering commercial opportunities, the system comprising:

(a) a computer store containing data, for each of a plurality of first web pages, defining a plurality of visually perceptible elements, which visually perceptible elements correspond to the plurality of first web pages;

(i) wherein each of the first web pages belongs to one of a plurality of web page owners;

(ii) wherein each of the first web pages displays at least one active link associated with a commerce object associated with a buying opportunity of a selected one of a plurality of merchants; and

(iii) wherein the selected merchant, the outsource provider, and the owner of the first web page displaying the associated link are each third parties with respect to one other;

(b) a computer server at the outsource provider, which computer server is coupled to the computer store and programmed to:

(i) receive from the web browser of a computer user a signal indicating activation of one of the links displayed by one of the first web pages;

(ii) automatically identify as the source page the one of the first web pages on which the link has been activated;

(iii) in response to identification of the source page, automatically retrieve the stored data corresponding to the source page; and

(iv) using the data retrieved, automatically generate and transmit to the web browser a second web page that displays: (A) information associated with the commerce object associated with the link that has been activated, and (B) the plurality of visually perceptible elements visually corresponding to the source page.

Analysis

Claim 19: Eligible.

The claim recites a system comprising a computer server and computer store. The system comprises a device or set of devices and, therefore, is directed to a machine which is a statutory category of invention (*Step 1: YES*).

Next, the claim is analyzed to determine whether it is directed to a judicial exception. This claim recites a system "useful in outsource provider serving web pages offering commercial opportunities," but is directed to automatically generating and transmitting a web page in response to activation of a link using data identified with a source web page having certain visually perceptible elements. The claim does not recite a mathematical algorithm; nor does it recite a fundamental economic or longstanding commercial practice. The claim addresses a business challenge (retaining website visitors) that is particular to the Internet. The claimed

invention differs from other claims found by the courts to recite abstract ideas in that it does not "merely recite the performance of some business practice known from the pre-Internet world along with the requirement to perform it on the Internet. Instead, the claimed solution is necessarily rooted in computer technology in order to overcome a problem specifically arising in the realm of computer networks." No idea similar to those previously found by the courts to be abstract has been identified in the claim. During examination, if the examiner does not identify an abstract idea recited in the claim, the claim should be deemed to be not directed to a judicial exception (*Step 2A*: *NO*). The claim is eligible.

Under the 2014 Interim Eligibility Guidance no further analysis would be necessary. In this decision, however, the court went on to point out certain features of the claim that amount to an inventive concept for resolving this particular Internet-centric problem, rendering the claims patent eligible. An excerpt of the court's discussion follows:

> In particular, the ′399 patent's claims address the problem of retaining website visitors that, if adhering to the routine, conventional functioning of Internet hyperlink protocol, would be instantly transported away from a host's website after "clicking" on an advertisement and activating a hyperlink. For example, asserted claim 19 recites a system that, among other things, 1) stores "visually perceptible elements" corresponding to numerous host websites in a database, with each of the host websites displaying at least one link associated with a product or service of a third-party merchant, 2) on activation of this link by a website visitor, automatically identifies the host, and 3) instructs an Internet web server of an "out-source provider" to construct and serve to the visitor a new, hybrid web page that merges content associated with the products of the third-party merchant with the stored "visually perceptible elements" from the identified host website. [ ]
>
> In more plain language, upon the click of an advertisement for a third-party product displayed on a host's website, the visitor is no longer transported to the third party's website. Instead, the patent claims call for an "outsource provider" having a web server which directs the visitor to an automatically-generated hybrid web page that combines visual "look and feel" elements from the host website and product information from the third-party merchant's website related to the clicked advertisement. [ ] In this way, rather than instantly losing visitors to the third-party's website, the host website can instead send its visitors to a web page on the outsource provider's server that 1) incorporates "look and feel" elements from the host website, and 2) provides visitors with the opportunity to purchase products from the third-party merchant without actually entering that merchant's website.

As the court cautioned, "not all claims purporting to address Internet-centric challenges are eligible," but in this case these additional limitations amount to more than simply stating "apply the abstract idea on the Internet." Therefore, when taken as a whole, the claimed invention has additional limitations that amount to significantly more than the abstract idea. Under this reasoning, the claim recites patent eligible subject matter (*Step 2B: YES*).

3. Digital Image Processing

The following hypothetical claims are modeled after the technology in Research Corporation Technologies Inc. v. Microsoft Corp., 627 F.3d 859 (Fed. Cir. 2010) (RCT). The patent at issue was U.S. Patent No. 5,111,310. Hypothetical claims 1-3 are directed to an abstract idea and have additional elements that amount to significantly more than the abstract idea because they show an improvement in the functioning of the computer itself and also show an improvement to another technology/technical field, either of which can show eligibility.

Background

A digital image generally consists of a discrete set of pixels arranged in columns and rows. In a gray scale image, the value of each pixel varies among shades of gray ranging from black at the weakest intensity to white at the strongest intensity. In contrast, a binary image includes pixels that can only have two values, black or white. Some printing devices such as facsimile machines and newspaper printers cannot reproduce gray scale images because they only print in black or white. Therefore, in order to convert a gray scale image into a binary image, halftoning techniques are used. Halftoning creates the illusion of various shades of gray in an image while only using the pixel colors black and white. Certain halftoning techniques involve the pixel-by-pixel comparison of the gray scale image to a two-dimensional array of threshold numbers, also known as a "mask." In digital implementation, the gray scale image to be halftoned is read into memory, and a computer processor compares each pixel of the image to a threshold number at the corresponding position of the mask stored in the computer's memory. Based on that comparison, a binary value representing black or white is output and these outputs are stored together in a binary array known as the dot profile. The dot profile is then converted to a binary display that is the halftoned image (the image for display).

In the instant application, the inventor has improved upon previous halftoning techniques by developing an improved mask called a "blue noise" mask. The blue noise mask requires less memory than previous masks and results in a faster computation time while improving image quality. The blue noise mask is produced through an iterative mathematical operation that begins with generating a dot profile with blue noise properties from an image at a 50% gray level using a blue noise filter. Subsequently, additional dot profiles are generated at differing gray levels. As pixels of the dot profile change across the gray levels, these changes are encoded in a cumulative array. Once all the dot profiles are built, the cumulative array becomes the blue noise mask.

Claims

1. A computer-implemented method for halftoning a gray scale image, comprising the steps of:

generating, with a processor, a blue noise mask by encoding changes in pixel values across a plurality of blue noise filtered dot profiles at varying gray levels;

storing the blue noise mask in a first memory location;

receiving a gray scale image and storing the gray scale image in a second memory location;

comparing, with a processor on a pixel-by-pixel basis, each pixel of the gray scale image to a threshold number in the corresponding position of the blue noise mask to produce a binary image array; and

converting the binary image array to a halftoned image.

2. A non-transitory computer-readable medium with instructions stored thereon, that when executed by a processor, perform the steps comprising:

generating a blue noise mask by encoding changes in pixel values across a plurality of blue noise filtered dot profiles at varying gray levels;

storing the blue noise mask in a first memory location;

receiving a gray scale image and storing the gray scale image in a second memory location;

comparing, on a pixel-by-pixel basis, each pixel of the gray scale image to a threshold number in the corresponding position of the blue noise mask to produce a binary image array; and

converting the binary image array to a halftoned image.

3. A system for halftoning a gray scale image, comprising:

a processor that generates a blue noise mask by encoding changes in pixel values across a plurality of blue noise filtered dot profiles at varying gray levels;

a first memory for storing the blue noise mask; and

a second memory for storing a received gray scale image;

wherein the processor further compares, on a pixel-by-pixel basis, each pixel of the gray scale image to a threshold number in the corresponding position of the blue noise mask to produce a binary image array and converts the binary image array to a halftoned image.

<u>Analysis</u>

<u>Claim 1: Eligible.</u>

The method claim recites a series of acts for generating a blue noise mask and using that blue noise mask to halftone a gray scale image. Thus, the claim is directed to a process, which is one of the statutory categories of invention (*Step 1: YES*).

The claim is then analyzed to determine whether it is directed to any judicial exception. The claim recites the step of generating a blue noise mask, which as defined in the background is produced through an iterative mathematical operation. The courts have found that mathematical relationships fall within the judicial exceptions, often labelled as "abstract ideas." Since the mathematical operation of generating a blue noise mask is recited in the claim, the claim is "directed to" a judicial exception (*Step 2A: YES*).

Next, the claim as a whole is analyzed to determine if there are additional limitations recited in the claim such that the claim amounts to significantly more than the mathematical operation. There are several additional limitations recited in the claim besides the mathematical operation of generating a blue noise mask. First, the claim recites using a processor to generate the blue

noise mask. The claim also recites the steps of storing the blue noise mask in a first memory location and receiving a gray scale image and storing the gray scale image in a second memory location. Thus, the claim uses a processor and memory to perform these steps of calculating a mathematical operation and receiving and storing data. The addition of general purpose computer components alone to perform such steps is not sufficient to transform a judicial exception into a patentable invention. The computer components are recited at a high level of generality and perform the basic functions of a computer (in this case, performing a mathematical operation and receiving and storing data) that would be needed to apply the abstract idea via computer. Merely using generic computer components to perform the above identified basic computer functions to practice or apply the judicial exception does not constitute a meaningful limitation that would amount to significantly more than the judicial exception, even though such operations could be performed faster than without a computer.

The claim also recites the additional steps of comparing the blue noise mask to a gray scale image to transform the gray scale image to a binary image array and converting the binary image array into a halftoned image. These additional steps tie the mathematical operation (the blue noise mask) to the processor's ability to process digital images. These steps add meaningful limitations to the abstract idea of generating the blue noise mask and therefore add significantly more to the abstract idea than mere computer implementation. The claim, when taken as a whole, does not simply describe the generation of a blue noise mask via a mathematical operation and receiving and storing data, but combines the steps of generating a blue noise mask with the steps for comparing the image to the blue noise mask and converting the resulting binary image array to a halftoned image. By this, the claim goes beyond the mere concept of simply retrieving and combining data using a computer.

Finally, viewing the claim elements as an ordered combination, the steps recited in addition to the blue noise mask improve the functioning of the claimed computer itself. In particular, as discussed above, the claimed process with the improved blue noise mask allows the computer to use to less memory than required for prior masks, results in faster computation time without sacrificing the quality of the resulting image as occurred in prior processes, and produces an improved digital image. These are also improvements in the technology of digital image processing. Unlike the invention in Alice Corp., the instant claim is not merely limiting the abstract idea to a computer environment by simply performing the idea via a computer (*i.e.*, not merely performing routine data receipt and storage or mathematical operations on a computer), but rather is an innovation in computer technology, namely digital image processing, which in this case reflects both an improvement in the functioning of the computer and an improvement in another technology. Taking all the additional claim elements individually, and in combination, the claim as a whole amounts to significantly more than the abstract idea of generating a blue noise mask (*Step 2B: YES*). The claim recites patent eligible subject matter.

Claim 2: Eligible.

The claim recites a non-transitory computer-readable medium with stored instructions. The term "non-transitory" ensures the claim does not encompass signals and other transitory forms of signal transmission. Therefore, the claim is directed to a manufacture (an article produced from materials), which is a statutory category of invention (*Step 1: YES*).

The claim recites the same steps as claim 1. Therefore, the claim is directed to the same abstract idea identified in claim 1 which is the mathematical operation of generating a blue noise mask

(*Step 2A: YES*). Similarly, the claim recites the same additional elements of comparing the blue noise mask to a gray scale image to transform the gray scale image to a binary image array and converting the binary image array into a halftoned image. These additional elements add significantly more to the abstract idea as evidenced by the improved functioning of the computer in halftoning a gray scale image and the improved digital image processing. For the same reasons set forth above, taking all the additional claim elements individually, and in combination, the claim as a whole amounts to significantly more than the abstract idea of generating a blue noise mask (*Step 2B: YES*). The claim recites patent eligible subject matter.

Claim 3: Eligible.

The claim recites a system comprising a processor, a first memory and a second memory. The claim is directed to statutory category of invention, *i.e.* a machine (a combination of devices) (*Step 1: YES*).

The claim recites the same abstract idea as identified with regard to claim 1, which is the mathematical operation of generating a blue noise mask, and thus is directed to the abstract idea (*Step 2A: YES*). Similarly, the claim recites the same additional elements that compare the blue noise mask to a gray scale image to transform the gray scale image to a binary image array and convert the binary image array into a halftoned image that add significantly more to the abstract idea. For the same reasons set forth above, taking all the additional claim elements individually, and in combination, the claim as a whole amounts to significantly more than the abstract idea of generating a blue noise mask (*Step 2B: YES*). The claim recites patent eligible subject matter.

4. Global Positioning System

The following hypothetical claims are modeled after the technology in SiRF Technology Inc. v. International Trade Commission, 601 F.3d 1319 (Fed. Cir. 2010) (SiRF Tech). The patent at issue was U.S. Patent No. 6,417,801. Hypothetical claims 1 and 2 are directed to an abstract idea and have additional elements that amount to significantly more than the abstract idea because they show an improvement to another technology or technical field.

Background

Global Positioning Systems (GPS) use signals from multiple satellites to calculate the position of a mobile GPS receiver on Earth. Each satellite transmits a signal containing unique pseudo-random noise (PN) codes, satellite positioning data and absolute time information. A mobile GPS receiver generally determines its position using the PN codes, satellite positioning data and the absolute time information from multiple satellite signals. In areas where signal levels are low, it is possible for the mobile GPS receiver to detect the PN codes, but is difficult to obtain the satellite positioning data and absolute time information from the satellite signals.

This application describes systems and methods in which a server wirelessly coupled to a mobile GPS receiver uses a mathematical model to solve for the mobile receiver position without receiving satellite positioning data or absolute time information from a satellite. These systems and methods improve GPS techniques by enabling the mobile GPS receiver to determine its position more accurately and improve its signal-acquisition sensitivity to operate even in weak-signal environments. In particular, the mobile GPS receiver is a mobile device that includes a

GPS antenna, a GPS receiver, a microprocessor, a display, and a wireless communication transceiver. Using mathematical formulas, the device calculates pseudo-ranges (estimated ranges from the GPS receiver to each satellite in view) based on PN codes received from the satellites, and the transceiver sends the pseudo-ranges to the server.

The server is a computer that uses the pseudo-ranges, along with an estimated position based on a known location of a wireless tower and time data from the server's own clock, in mathematical formulas to calculate the absolute time that the GPS receiver received the signals from the satellites. The server then creates a mathematical model that uses the pseudo-ranges and the calculated absolute time to solve for the mobile receiver position, which is transmitted to the mobile device for visual representation on a display. The components of the mobile device and the server (*e.g.*, central processing unit (CPU), clock, wireless tower location database, circuitry, and memory) are all well-known and routine computer components.

Claims

1. A system for calculating an absolute position of a GPS receiver and an absolute time of reception of satellite signals comprising:

a mobile device comprising a GPS receiver, a display, a microprocessor and a wireless communication transceiver coupled to the GPS receiver, the mobile device programmed to receive PN codes sent by a plurality of GPS satellites, calculate pseudo-ranges to the plurality of GPS satellites by averaging the received PN codes, and transmit the pseudo-ranges, and

a server comprising a central processing unit, a memory, a clock, and a server communication transceiver that receives pseudo-ranges from the wireless communication transceiver of the mobile device, the memory having location data stored therein for a plurality of wireless towers, and the central processing unit programmed to:

estimate a position of the GPS receiver based on location data for a wireless tower from the memory and time data from the clock,

calculate absolute time that the signals were sent from the GPS satellites using the pseudo-ranges from the mobile device and the position estimate,

create a mathematical model to calculate absolute position of the GPS receiver based on the pseudo-ranges and calculated absolute time,

calculate the absolute position of the GPS receiver using the mathematical model, and

transmit the absolute position of the GPS receiver to the mobile device, via the server communication transceiver, for visual representation on the display.

2. A method for calculating an absolute position of a GPS receiver and an absolute time of reception of satellite signals comprising:

calculating pseudo-ranges, at a mobile device comprising a GPS receiver, a microprocessor, a display, and a wireless communication transceiver, by averaging PN codes received by the GPS receiver from a plurality of GPS satellites;

wirelessly transmitting the calculated pseudo-ranges from the mobile device to a server, wherein the server comprises a central processing unit (CPU);

calculating, by the server CPU, absolute time that the PN codes were sent from the GPS satellites to the GPS receiver using the pseudo-ranges and an estimated position of the GPS receiver;

using a mathematical model to calculate, by the server CPU, absolute position of the GPS receiver based on the pseudo-ranges and calculated absolute time;

transmitting the absolute position from the server to the mobile device; and

displaying a visual representation of the absolute position on the display of the mobile device.

Analysis

Claim 1: Eligible.

The claim is directed to a statutory category, because a system including a mobile device and a server satisfies the requirements of a machine (as a combination of devices) (*Step 1: YES*).

The claim is then analyzed to determine whether it is directed to any judicial exception. The claim recites mathematical operations (*e.g.*, calculating pseudo-ranges and absolute times, and the mathematical model), which the courts have considered to fall within the judicial exceptions, e.g., as abstract ideas. Because these mathematical operations are recited in the claim, the claim is directed to a judicial exception (*Step 2A: YES*).

Next, the claim as a whole is analyzed to determine whether any element, or combination of elements, is sufficient to ensure that the claim amounts to significantly more than the exception. First, the claim recites using a central processing unit (CPU) for performing the mathematical operations of estimating position, calculating absolute time, and calculating absolute position using a mathematical model. The claim also recites using location data stored in a memory, and time data from a clock. These computer components are recited at a high level of generality and add no more to the claimed invention than the components that perform basic mathematical calculation functions routinely provided by a general purpose computer. Limiting performance of the mathematical calculations to a general purpose CPU, absent more, is not sufficient to transform the recited judicial exception into a patent-eligible invention.

However, the claim is further limited to a mobile device comprising a GPS receiver, microprocessor, wireless communication transceiver and a display that receives satellite data, calculates pseudo-ranges, wirelessly transmits the calculated pseudo-ranges to the server, receives location data from the server, and displays a visual representation of the received calculated absolute position from the server. The programmed CPU acts in concert with the recited features of the mobile device to enable the mobile device to determine and display its absolute position through interaction with a remote server and multiple remote satellites. The meaningful limitations placed upon the application of the claimed mathematical operations show that the claim is not directed to performing mathematical operations on a computer alone. Rather, the combination of elements impose meaningful limits in that the mathematical operations are applied to improve an existing technology (global positioning) by improving the signal-acquisition sensitivity of the receiver to extend the usefulness of the technology into

weak-signal environments and providing the location information for display on the mobile device. All of these features, especially when viewed in combination, amount to significantly more than the judicial exception (*Step 2B: YES*). The claim is eligible.

Claim 2: Eligible.

The claim is directed to a statutory category, because a series of steps including calculating pseudo-ranges and wirelessly transmitting those pseudo-ranges satisfies the requirements of a process (a series of acts) (*Step 1: YES*).

The claim recites the same abstract ideas identified with regard to claim 1, which are the mathematical operations of, *e.g.*, calculating pseudo-ranges and absolute times, and the mathematical model. Thus, this claim is also directed to a judicial exception (*Step 2A:* YES). Similarly, the claim recites the same additional elements of a server CPU estimating position, calculating absolute time, and calculating absolute position using a mathematical model, and a mobile device comprising a GPS receiver, microprocessor, wireless communication transceiver and a display receiving satellite data, calculating pseudo-ranges, wirelessly transmitting the calculated pseudo-ranges to the server, receiving a calculated absolute position from the server, and then displaying a visual representation of the received position. For the same reasons set forth above, taking all the additional claim elements individually, and in combination, the claim as a whole amounts to significantly more than the mathematical operations by themselves (*Step 2B: YES*). The claim is eligible.

Part Two

These examples show claims that were held **ineligible** by the Federal Circuit. The analysis sections are informed by the court decisions but offer exemplary hypothetical analyses under the 2014 Interim Eligibility Guidance.

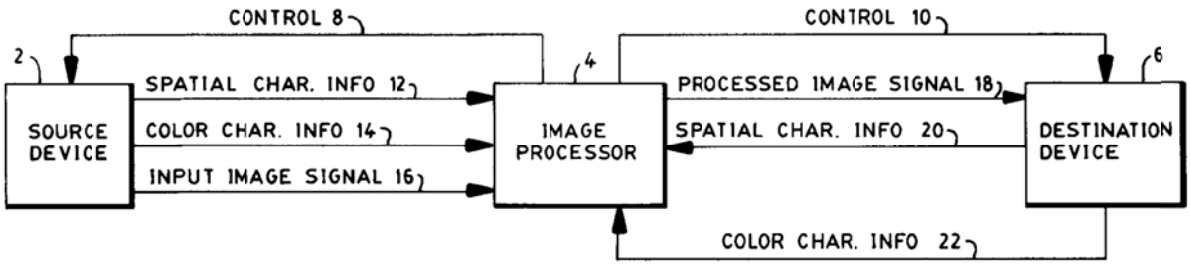
5. Digital Image Processing

The following claim was found ineligible by the Federal Circuit in Digitech Image Tech., LLC v. Electronics for Imaging, Inc., 758 F.3d 1344 (Fed. Cir. 2014). The patent at issue was U.S. Patent No. 6,128,415. The claim is directed to an abstract idea and does not have any additional elements that could amount to more than the abstract idea itself.

Background

In general, digital image processing involves the acquisition of an image at a source device (*e.g.*, digital camera, camcorder, scanner, etc.), processing the image in a desired fashion and outputting the processed image at a destination device (*e.g.*, monitor, printer, computer memory, etc.). However, all image devices, whether source devices or destination devices, impose some level of distortion of an image's color and spatial properties. Some past solutions to address the distortion have used a "device profile," which describes the color properties of both the source and destination devices, to enable a more accurate translation of the image's pixel data into the independent color space across the source and destination devices. The inventor has expanded upon the prior device profile to capture both spatial as well as the color properties of the devices.

In this invention, as seen in Fig. 1 reproduced below, a device profile is created based on information from a source device 2, such as a digital camera, and from a destination device 6, such as a printer. The device profile is used to produce the processed image signal 18 from the input image signal 16. Spatial characteristic information 12, 20 and color characteristic information 14, 22 are provided from each device to an image processor 4, along with the input image signal 16. This characteristic information is used to generate first data relating to color information content of the image and second data relating to spatial information content of the image using known mathematical techniques, such as Fourier analysis to yield a Wiener Noise Power Spectrum (mathematical processing techniques). The generated data is incorporated into the device profile.



Representative Claim

10. A method of generating a device profile that describes properties of a device in a digital image reproduction system for capturing, transforming or rendering an image, said method comprising:

generating first data for describing a device dependent transformation of color information content of the image to a device independent color space through use of measured chromatic stimuli and device response characteristic functions;

generating second data for describing a device dependent transformation of spatial information content of the image in said device independent color space through use of spatial stimuli and device response characteristic functions; and

combining said first and second data into the device profile.

Analysis

Claim 10: Ineligible.

The claim is directed to a statutory category, because a series of steps for generating data satisfies the requirements of a process (a series of acts) (*Step 1: YES*).

Next, the claim is analyzed to determine whether it is directed to a judicial exception. The claim recites a method of generating first data and second data using mathematical techniques and combining the first and second data into a device profile. In other words, the claimed method simply describes the concept of gathering and combining data by reciting steps of organizing information through mathematical relationships. The gathering and combining merely employs mathematical relationships to manipulate existing information to generate additional information in the form of a 'device profile,' without limit to any use of the device profile. This idea is

similar to the basic concept of manipulating information using mathematical relationships (*e.g.*, converting numerical representation in Benson), which has been found by the courts to be an abstract idea. Therefore, the claim is directed to an abstract idea (*Step 2A:* YES).

The claim does not include additional elements beyond the abstract idea of gathering and combining data. Therefore, the claim does not amount to more than the abstract idea itself (*Step 2B: NO*). The claim is not patent eligible.

6. The Game of Bingo

The following claim was found ineligible by the Federal Circuit in Planet Bingo, LLC v. VKGS LLC, 576 Fed. Appx. 1005 (Fed. Cir. 2014). The patent at issue was U.S. Patent No. 6,398,646. The claim is directed to an abstract idea and has additional elements that do not amount to significantly more than the abstract idea.

Background

The invention relates to an automated Bingo system having the ability to print sets of numbers on tickets on site. The system uses a computer to print the tickets, track the sale of the tickets and to validate winning tickets. The computer stores the specific sets of Bingo numbers for a player and prints the tickets having the player's specific set of Bingo numbers to enable the player to play his specific Bingo numbers for various sessions of Bingo. The automated system allows for managing all aspects of a Bingo game, including solving tampering problems and minimizing other security risks during Bingo ticket purchases.

Representative Claim

Claim 1. A system for managing a game of Bingo which comprises:

(a) a computer with a central processing unit (CPU) and with a memory and with a printer connected to the CPU;

(b) an input and output terminal connected to the CPU and memory of the computer; and

(c) a program in the computer enabling:

(i) input of at least two sets of Bingo numbers which are preselected by a player to be played in at least one selected game of Bingo in a future period of time;

(ii) storage of the sets of Bingo numbers which are preselected by the player as a group in the memory of the computer;

(iii) assignment by the computer of a player identifier unique to the player for the group having the sets of Bingo numbers which are preselected by the player wherein the player identifier is assigned to the group for multiple sessions of Bingo;

(iv) retrieval of the group using the player identifier;

(v) selection from the group by the player of at least one of the sets of Bingo numbers preselected by the player and stored in the memory of the computer as the group for play in a selected game of Bingo in a specific session of Bingo wherein a number of sets of Bingo

numbers selected for play in the selected game of Bingo is less than a total number of sets of Bingo numbers in the group;

(vi) addition by the computer of a control number for each set of Bingo numbers selected for play in the selected game of Bingo;

(vii) output of a receipt with the control number, the set of Bingo numbers which is preselected and selected by the player, a price for the set of Bingo numbers which is preselected, a date of the game of Bingo and optionally a computer identification number; and

(viii) output for verification of a winning set of Bingo numbers by means of the control number which is input into the computer by a manager of the game of Bingo.

Analysis

Claim 1: Ineligible.

Claim 1 is directed to a system comprising a computer, an input and output terminal, and a program enabling management of the game of Bingo. The claimed system is therefore directed to a statutory category, *i.e.*, a machine (a combination of devices) (*Step 1: YES)*.

The claim is then analyzed to determine whether it is directed to any judicial exceptions. The claim recites program elements (i) through (viii) that describe the steps of managing a game of Bingo, including for example inputting and storing two sets of Bingo numbers, assigning a unique player identifier and control number, and verifying a winning set of Bingo numbers. Managing the game of Bingo as recited in the claim can be performed mentally or in a computer and is similar to the kind of 'organizing human activity' at issue in Alice Corp. Although the claims are not drawn to the same subject matter, the abstract idea of managing a game of Bingo is similar to the abstract ideas of managing risk (hedging) during consumer transactions (Bilski) and mitigating settlement risk in financial transactions (Alice Corp.) Claim 1 describes managing the game of Bingo and therefore is directed to an abstract idea (*Step 2A: YES*).

Next, the claim is analyzed to determine whether there are additional limitations recited that amount to significantly more than the abstract idea. The claim requires the additional limitations of a computer with a central processing unit (CPU), memory, a printer, an input and output terminal, and a program. These generic computer components are claimed to perform their basic functions of storing, retrieving and processing data through the program that enables the management of the game of Bingo. The recitation of the computer limitations amounts to mere instructions to implement the abstract idea on a computer. Taking the additional elements individually and in combination, the computer components at each step of the management process perform purely generic computer functions. As such, there is no inventive concept sufficient to transform the claimed subject matter into a patent-eligible application. The claim does not amount to significantly more than the abstract idea itself (*Step 2B: NO*). Accordingly, the claim is not patent eligible.

7. E-Commerce providing Transaction Performance Guaranty

The following claim was found ineligible by the Federal Circuit in buySAFE, Inc. v. Google, Inc., 765 F.3d 1350 (Fed. Cir. 2014). The patent at issue was U.S. Patent No. 7,644,019. The claim is directed to an abstract idea and has additional elements that do not amount to significantly more than the abstract idea.

Background

The invention relates to methods for conducting reliable transactions in an e-commerce environment. More specifically, the invention relates to methods providing a performance guaranty in a transaction. When a safe transaction service provider receives a request from a first party for obtaining a transaction performance guaranty service, the safe transaction service provider processes the request by underwriting the first party. If the underwriting is successful, the transaction performance guaranty service is provided to the first party, which binds a transaction performance guaranty to an online commercial transaction involving the first party and guarantees the first party's performance when the first party and second party enter the online transaction.

Representative Claim

1. A method, comprising:

receiving, by at least one computer application program running on a computer of a safe transaction service provider, a request from a first party for obtaining a transaction performance guaranty service with respect to an online commercial transaction following closing of the online commercial transaction;

processing, by at least one computer application program running on the safe transaction service provider computer, the request by underwriting the first party in order to provide the transaction performance guaranty service to the first party,

wherein the computer of the safe transaction service provider offers, via a computer network, the transaction performance guaranty service that binds a transaction performance guaranty to the online commercial transaction involving the first party to guarantee the performance of the first party following closing of the online commercial transaction.

Analysis

Claim 1: Ineligible.

The claim is directed to a process, *i.e.,* a series of steps or acts, for providing a performance guaranty. A process is one of the statutory categories of invention (*Step 1: YES*).

Next, the claim is analyzed to determine whether it is directed to a judicial exception. The claim recites the steps of creating a contract, including receiving a request for a performance guaranty (contract), processing the request by underwriting to provide a performance guaranty and offering the performance guaranty. This describes the creation of a contractual relationship, which is a commercial arrangement involving contractual relations similar to the fundamental economic practices found by the courts to be abstract ideas (*e.g.*, hedging in Bilski). It is also noted that narrowing the commercial transactions to particular types of relationships or particular

parts of that commercial transaction (*e.g.*, underwriting) would not render the concept less abstract. Thus, the claim is directed to an abstract idea (*Step 2A: YES*).

Analyzing the claim as whole for an inventive concept, the claim limitations in addition to the abstract idea include a computer application running on a computer and the computer network. This is simply a generic recitation of a computer and a computer network performing their basic functions. The claim amounts to no more than stating create a contract on a computer and send it over a network. These generic computing elements alone do not amount to significantly more than the judicial exception (*Step 2B: NO*). The claim is not patent eligible.

8. Distribution of Products over the Internet

The following claim was found ineligible by the Federal Circuit in Ultramercial v. Hulu and WildTangent, 2014 U.S. App. LEXIS 21633 (Fed. Cir. 2014). The patent at issue was U.S. Patent No. 7,346,545. The claim is directed to an abstract idea and has additional elements that do not amount to significantly more than the abstract idea.

Background

The invention addresses problems with piracy of digital copyrighted media (video, audio, etc.), especially among people who have limited access to cash and credit cards. The invention is directed to distributing products covered by intellectual property, such as copyright, over a telecommunications network by allowing a consumer to choose to view or interact with a sponsor's message in exchange for access to copyrighted material. The sponsor then pays the holder of the underlying intellectual property, thus allowing the consumer to obtain the product without paying with cash or credit. The invention uses a series of detailed steps that accomplish the exchange of products.

Representative Claim

1. A method for distribution of products over the Internet via a facilitator, said method comprising the steps of:

a first step of receiving, from a content provider, media products that are covered by intellectual property rights protection and are available for purchase, wherein each said media product being comprised of at least one of text data, music data, and video data;

a second step of selecting a sponsor message to be associated with the media product, said sponsor message being selected from a plurality of sponsor messages, said second step including accessing an activity log to verify that the total number of times which the sponsor message has been previously presented is less than the number of transaction cycles contracted by the sponsor of the sponsor message;

a third step of providing the media product for sale at an Internet website;

a fourth step of restricting general public access to said media product;

a fifth step of offering to a consumer access to the media product without charge to the consumer on the precondition that the consumer views the sponsor message;

a sixth step of receiving from the consumer a request to view the sponsor message, wherein the consumer submits said request in response to being offered access to the media product;

a seventh step of, in response to receiving the request from the consumer, facilitating the display of a sponsor message to the consumer;

an eighth step of, if the sponsor message is not an interactive message, allowing said consumer access to said media product after said step of facilitating the display of said sponsor message;

a ninth step of, if the sponsor message is an interactive message, presenting at least one query to the consumer and allowing said consumer access to said media product after receiving a response to said at least one query;

a tenth step of recording the transaction event to the activity log, said tenth step including updating the total number of times the sponsor message has been presented; and

an eleventh step of receiving payment from the sponsor of the sponsor message displayed.

Analysis

Claim 1: Ineligible.

The claim is directed to a process; *i.e.*, a series of steps or acts, for distributing media and advertisements over the Internet. A process is one of the statutory categories of invention (*Step 1: YES*).

The claim is then analyzed to determine whether it is directed to an exception. The claim recites an eleven step process for displaying an advertisement in exchange for access to copyrighted media. That is, the claim describes the concept of using advertising as an exchange or currency. This concept is similar to the concepts involving human activity relating to commercial practices (*e.g.*, hedging in Bilski) that have been found by the courts to be abstract ideas. The addition of limitations that narrow the idea, such as receiving copyrighted media, selecting an ad, offering the media in exchange for watching the selected ad, displaying the ad, allowing the consumer access to the media, and receiving payment from the sponsor of the ad, further describe the abstract idea, but do not make it less abstract. The claim is directed to an abstract idea (*Step 2A: YES*).

Next, the claim as a whole is analyzed to determine whether it amounts to significantly more than the concept of using advertising as an exchange or currency. The claim has additional limitations to the abstract idea such as accessing and updating an activity log, requiring a request from the consumer to view the advertising, restricting public access, and using the Internet as an information transmitting medium.

Viewing the limitations individually, the accessing and updating of an activity log are used only for data gathering and, as such, only represent insignificant pre-solution activity. Similarly, requiring a consumer request and restricting public access is insignificant pre-solution activity because such activity is necessary and routine in implementing the concept of using advertising as an exchange or currency; *i.e.*, currency must be tendered upon request in order for access to be

provided to a desired good. Furthermore, the Internet limitations do not add significantly more because they are simply an attempt to limit the abstract idea to a particular technological environment.

Viewing the limitations as a combination, the claim simply instructs the practitioner to implement the concept of using advertising as an exchange or currency with routine, conventional activity specified at a high level of generality in a particular technological environment. When viewed either as individual limitations or as an ordered combination, the claim as a whole does not add significantly more to the abstract idea of using advertising as an exchange or currency (*Step 2B: NO*). The claim is not patent eligible.

Nature-Based Products

The following examples should be used in conjunction with the 2014 Interim Eligibility Guidance. They replace the examples issued with the March 2014 Procedure For Subject Matter Eligibility Analysis Of Claims Reciting Or Involving Laws Of Nature/Natural Principles, Natural Phenomena, And/Or Natural Products and related training. As the examples are intended to be illustrative only, they should be interpreted based on fact patterns set forth below. Other fact patterns may have different eligibility outcomes.

1. Gunpowder and Fireworks: Product Claims That Are Not Directed To An Exception

This example illustrates the application of the markedly different characteristics analysis to a nature-based product produced by combining multiple components (claim 1), and also provides a sample of a claimed product that when viewed as a whole is not nature-based, and thus is not subjected to the markedly different characteristics analysis in order to determine that the claim is not directed to an exception (claim 2).

Claims:

1. Gunpowder comprising: an intimate finely-ground mixture of 75% potassium nitrate, 15% charcoal and 10% sulfur.
2. A fountain-style firework comprising: (a) a sparking composition, (b) calcium chloride, (c) the gunpowder of claim 1, (d) a cardboard body having a first compartment containing the sparking composition and the calcium chloride and a second compartment containing the gunpowder, and (e) a plastic ignition fuse having one end extending into the second compartment and the other end extending out of the cardboard body.

Analysis of Claims:

These claims are analyzed for eligibility in accordance with their broadest reasonable interpretation. Both claims are directed to a statutory category, *e.g.*, a composition of matter or manufacture (*Step 1: YES*).

Claim 1: Eligible. Because the claim is a nature-based product, *i.e.*, a combination of three naturally occurring substances (potassium nitrate, charcoal and sulfur), the nature-based product (the combination) is analyzed to determine whether it has markedly different characteristics from any naturally occurring counterpart(s) in their natural state. In this case, there is no naturally occurring counterpart to the claimed combination (the components do not occur together in nature), so the combination is compared to the individual components as they occur in nature. None of the three claimed substances are explosive in nature. When the substances are finely-ground and intimately mixed in the claimed ratio, however, the claimed combination is explosive upon ignition. This explosive property of the claimed combination is markedly different from the non-explosive properties of the substances by themselves in nature. Accordingly, the claimed combination has markedly different characteristics, and 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.

Claim 2: Eligible. Although the claim recites two nature-based products (calcium chloride and gunpowder), analysis of the claim as a whole indicates that the claim is focused on the assembly of components that together form the firework, and not the nature-based products. Thus, it is not necessary to apply the markedly different characteristics analysis in order to conclude that the claim is not directed to an exception (*Step 2A: NO)*. The claim qualifies as eligible subject matter.

2. Pomelo Juice: Process Claim That Is Directed To An Exception And Product Claim That Is Not Directed To An Exception

This example illustrates the eligibility analysis of a process (claim 1) that focuses on a nature-based product and a product (claim 2) that is nature-based but is not directed to an exception because it has markedly different characteristics from its naturally occurring counterpart.

Vervain Ex. 2008, p. 21 of 109
Vervain v. Phison
PGR2025-00010

Background: The pomelo tree (*Citrus maxima*) is a naturally occurring tree that is native to South and Southeast Asia. Pomelo fruit is often eaten raw or juiced, and has a mild grapefruit-like flavor. Naturally occurring pomelo juice spoils over the course of a few days even when refrigerated, due to the growth of bacteria that are naturally present in the juice. The specification indicates that suitable preservatives for fruit juices are known in the art, and include naturally occurring preservatives such as vitamin E, and non-naturally occurring preservatives such as preservative X. The specification defines an "effective amount" of these preservatives as an amount sufficient to prevent juice from spoiling for at least three weeks, *e.g.*, by retarding the growth of bacteria in the juice.

Claims:

1. A method comprising providing a pomelo fruit.
2. A beverage composition comprising pomelo juice and an effective amount of an added preservative.

Analysis of Claims:

These claims are analyzed for eligibility in accordance with their broadest reasonable interpretation. All of the claims are directed to a statutory category, *e.g.*, a process or composition of matter (*Step 1: YES*).

Claim 1: Ineligible. Although the claim is a process claim, it has been drafted such that there is no difference in substance from a product claim to the pomelo fruit itself. Accordingly, this process claim is focused on the pomelo fruit *per se* (a nature-based product), and must be analyzed for markedly different characteristics, to determine whether the claimed pomelo fruit is a "product of nature" exception. There is no indication in the specification that the claimed fruit has any characteristics (structural, functional, or otherwise) that are different from the naturally occurring fruit provided by pomelo trees. Thus, the claimed fruit does not have markedly different characteristics from what occurs in nature, and 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. Because the claim is a nature-based product, *i.e.*, a combination of a naturally occurring substance (pomelo juice) with an added preservative, the nature-based combination is analyzed to determine whether it has markedly different characteristics from any naturally occurring counterpart(s) in their natural state. In this case, there is no naturally occurring counterpart to the claimed combination, so the combination is compared to the individual components as they occur in nature. The specification indicates that the preservative can be natural or non-natural in origin, but that regardless of its origin, when an effective amount of preservative is mixed with the pomelo juice, the preservative affects the juice so that it spoils much more slowly (spoils in a few weeks) than the naturally occurring juice by itself (spoils in a few days). This property (slower spoiling) of the claimed combination is markedly different from properties of the juice by itself in nature. Accordingly, the claimed combination has markedly different characteristics, and 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.

3. Amazonic Acid, Pharmaceutical Compositions, & Methods of Treatment

This example illustrates the application of the markedly different characteristics analysis to single-element product claims (claims 1, 2 and 3) and to a product-by-process claim (claim 4). It also demonstrates that changes in chemical structure (claims 2 and 3), physical form (claim 5), or chemical/physical properties (claim 6), as compared to a product's natural counterpart can demonstrate markedly different characteristics. Additionally, this example provides samples of claimed processes that when viewed as a whole are not directed to a nature-based product, and thus are not subjected to the markedly different characteristics analysis in order to determine that the claim is not directed to an exception (claims 7 and 8).

Nature-Based Products

Background: The Amazonian cherry tree is a naturally occurring tree that grows wild in the Amazon basin region of Brazil. The leaves of the Amazonian cherry tree contain a chemical that is useful in treating breast and colon cancers. Many have tried and failed to isolate the cancer-fighting chemical from the leaves. Applicant has successfully purified the cancer-fighting chemical from the leaves and has named it amazonic acid. The purified amazonic acid is structurally and functionally identical to the amazonic acid in the leaves. Applicant has created two derivatives of amazonic acid in the laboratory. The first derivative (called 5-methyl amazonic acid), is structurally different from amazonic acid because a hydrogen has been replaced with a methyl group, and is functionally different because it stimulates the growth of hair in addition to treating cancer. The second derivative (called deoxyamazonic acid), was created by removing a hydroxyl group from amazonic acid and replacing it with a hydrogen. Applicant has not identified any functional difference between deoxyamazonic acid and amazonic acid.

Amazonic acid is absorbed through the lining of the human stomach and is rapidly metabolized by the body. It is also insoluble in water. Applicants disclose an example of a solid pharmaceutical composition demonstrating that when a core of amazonic acid is enveloped by a layer of a natural polymeric material, the resulting manufacture does not release the amazonic acid until it reaches the colon. This colonic release greatly improves the bioavailability of amazonic acid, and is particularly advantageous in the treatment of colon cancer. The specification defines "natural polymeric material" as being a naturally occurring polymer that is not easily digestible by human enzymes, so that it passes through most of the human digestive system intact until it reaches the colon. Specific disclosed examples are shellac and inulin. Applicants disclose an example of an aqueous composition, in which they were able to achieve a stable solution of amazonic acid in water by including a solubilizing agent in the solution. The solubilizing agent can be a naturally occurring product such as a sugar or polyol, or it can be a non-naturally occurring product such as a polysorbate surfactant.

Claims:

1. Purified amazonic acid.
2. Purified 5-methyl amazonic acid.
3. Deoxyamazonic acid.
4. A composition comprising an acid produced by a process which comprises: providing amazonic acid; and replacing the hydroxyl group of the amazonic acid with a hydrogen.
5. A pharmaceutical composition comprising: a core comprising amazonic acid; and a layer of natural polymeric material enveloping the core.
6. A stable aqueous composition comprising: amazonic acid; and a solubilizing agent.
7. A method of treating colon cancer, comprising: administering a daily dose of purified amazonic acid to a patient suffering from colon cancer for a period of time from 10 days to 20 days, wherein said daily dose comprises about 0.75 to about 1.25 teaspoons of amazonic acid.
8. A method of treating breast or colon cancer, comprising: administering an effective amount of purified amazonic acid to a patient suffering from breast or colon cancer.

Analysis of Claims:

These claims are analyzed for eligibility in accordance with their broadest reasonable interpretation. All of the claims are directed to a statutory category, *e.g.*, a composition of matter or process (*Step 1: YES*). Because claims 1-6 are nature-based products (*e.g.*, amazonic acid, 5-methyl amazonic acid, or deoxyamazonic acid), the markedly different characteristics analysis is used to determine if the nature-based products are exceptions. Although claims 7-8 recite nature-based products (amazonic acid), a full eligibility analysis of these claims is not needed because the claims clearly do not seek to tie up all practical uses of the nature-based products.

Nature-Based Products

Claim 1: Ineligible. Although applicant has discovered that amazonic acid naturally occurs in the leaves of the Amazonian cherry tree, this discovery does not, by itself, render amazonic acid patent eligible. *Association for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. __, 133 S. Ct. 2107, 2117 (2013) ("*Myriad*"). Instead, the claimed acid is analyzed to determine if separating the acid from its surrounding material in the leaf has resulted in the purified amazonic acid having markedly different characteristics from its naturally occurring counterpart. Based on the limited background information, there is no indication that purified amazonic acid has any characteristics (structural, functional, or otherwise) that are different from naturally occurring amazonic acid. The claim therefore encompasses amazonic acid that is structurally and functionally identical to naturally occurring amazonic acid. Because there is no difference between the claimed and naturally occurring acid, the claimed acid does not have markedly different characteristics from what occurs in nature, 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 5-methyl amazonic acid has a different structural characteristic than amazonic acid (its chemical structure is different due to the addition of the 5-methyl group). Because 5-methyl amazonic acid is a unique molecule that is distinct from, and does not prevent others from using, naturally occurring amazonic acid, its different structural characteristic rises to the level of a marked difference. Accordingly, the claimed 5-methyl amazonic acid is not a "product of nature" exception. This conclusion is bolstered by the fact that the different structural characteristic has resulted in a different functional characteristic (the stimulation of hair growth). Thus, the claim is not directed to an exception (*Step 2A: NO*), and qualifies as eligible subject matter.

Claim 3: Eligible. The claimed deoxyamazonic acid has a different structural characteristic from amazonic acid (its chemical structure is different due to the removal of a hydroxyl group). Based on the limited background information, this change in structure has not resulted in any different functional characteristics. However, because deoxyamazonic acid is a unique molecule that is distinct from, and does not prevent others from using, naturally occurring amazonic acid, its different structural characteristic rises to the level of a marked difference. Accordingly, the claimed deoxyamazonic acid 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.

Claim 4: Eligible. During examination, a product-by-process claim is not limited to manipulations of the recited steps, but instead is only limited to the structure implied by the steps. In this case, the specification describes that removing a hydroxyl group from amazonic acid and replacing it with a hydrogen results in deoxyamazonic acid. Thus, the acid produced by the claimed process steps is deoxyamazonic acid. As explained with respect to claim 3, deoxyamazonic acid has markedly different characteristics than naturally occurring amazonic acid, and 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.

Claim 5: Eligible. The claim is limited to a particular pharmaceutical composition having two naturally occurring substances physically joined together into a non-natural structure (core of amazonic acid surrounded by a layer of natural polymeric material). The claimed composition thus is structurally different from the naturally occurring substances, and this structural difference results in the claimed composition having different functional characteristics *in vivo* (*e.g.*, amazonic acid is not released until the composition reaches the colon, due to the relative indigestibility of the natural polymeric material, thus increasing the bioavailability of the amazonic acid) than the naturally occurring substances by themselves. These different structural and functional characteristics rise to the level of a marked difference, and accordingly the claimed composition 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.

Claim 6: Eligible. In nature, amazonic acid is insoluble in water. As explained in the specification, however, when amazonic acid is combined with a solubilizing agent, it becomes soluble in water and forms a stable solution. This changed property (solubility) between amazonic acid as a part of the claimed stable aqueous composition and amazonic acid in nature is a marked difference. Accordingly, the claimed composition has markedly different characteristics, and 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.

Claim 7: Eligible. Although the claim recites a nature-based product (amazonic acid), analysis of the claim as a whole indicates that the claim is focused on a process of practically applying the product to treat a particular disease (colon cancer), and not on the product *per se*. Thus, it is not necessary to apply the markedly different characteristics analysis in order to conclude that the claim is not directed to an exception (*Step 2A: NO)*. The claim qualifies as eligible subject matter.

Claim 8: Eligible. Although the claim recites a nature-based product (amazonic acid), analysis of the claim as a whole indicates that the claim is focused on a process of practically applying the product to treat a particular disease (breast or colon cancer), and not on the product *per se*. Thus, it is not necessary to apply the markedly different characteristics analysis in order to conclude that the claim is not directed to an exception (*Step 2A: NO)*. The claim qualifies as eligible subject matter.

4. Purified Proteins

This example illustrates that changes in physical/chemical structure (claims 2-5) as compared to a product's natural counterpart can demonstrate markedly different characteristics, whether or not accompanied by changes in biological/pharmacological function or chemical/physical properties.

Background: Newly discovered *Streptomyces arizoneus* bacteria produce Antibiotic L, which exhibits antibiotic activity in nature (*e.g.*, it kills other bacterial species in its natural environment). Naturally occurring Antibiotic L is a protein that occurs in the form of hexagonal-pyramidal crystals (each crystal has the shape of a six-sided pyramid) that are stored inside the bacteria. The specification describes several processes that yield Antibiotic L having the same hexagonal-pyramidal crystal form as naturally occurring Antibiotic L. The specification also discloses a process that yields purified Antibiotic L in the form of tetrahedral crystals (each crystal has the shape of a tetrahedron or triangular pyramid). The specification discloses that naturally occurring Antibiotic L has the amino acid sequence of SEQ ID NO: 2, and has a bacillosamine N-glycan on residue 49. In the specification, applicants describe recombinant yeast that are able to synthesize Antibiotic L (naturally occurring yeast cannot synthesize Antibiotic L or bacillosamine). Purified Antibiotic L expressed by these recombinant yeast has a high mannose (instead of a bacillosamine) N-glycan on residue 49, and has lower immunogenicity to humans and a different half-life *in vivo* than naturally occurring Antibiotic L. The specification defines "purified Antibiotic L" as only being either Antibiotic L in the tetrahedral crystal form or Antibiotic L having a high mannose N-glycan on residue 49.

Applicants disclose substitution modifications of Antibiotic L, *e.g.*, peptides having one or more amino acids substituted with different amino acids relative to SEQ ID NO: 2. No substitution modifications of Antibiotic L are known to occur in nature. Some of the modifications result in altering the function of the peptide, for example by increasing its ability to penetrate the cell membrane of a target organism. The modified peptides have 90% or greater identity to SEQ ID NO: 2.

Claims:

1. Antibiotic L.
2. Purified Antibiotic L.
3. The Antibiotic L of claim 1, which is in a tetrahedral crystal form.
4. The Antibiotic L of claim 1, which is expressed by recombinant yeast.

5. A purified antibiotic comprising an amino acid sequence that has at least 90% identity to SEQ ID NO: 2 and contains at least one substitution modification relative to SEQ ID NO: 2.

Analysis of Claims:

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

Claim 1: Ineligible. As described in the specification, some Antibiotic L produced by the applicants is in its naturally occurring hexagonal-pyramidal crystal form, while other Antibiotic L is in a non-natural form, *e.g.*, tetrahedral crystals. The claim thus encompasses antibiotic that is identical to the natural antibiotic, and antibiotic that is changed. Because there is no difference in characteristics (structural, functional, or otherwise) between the claimed and naturally occurring antibiotic for at least some of the embodiments encompassed by the claim, the claimed Antibiotic L does not have markedly different characteristics from what exists in nature, 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. Based on the specification's definition of purified Antibiotic L, the claim is limited to Antibiotic L in the form of tetrahedral crystals or having a high-mannose N-glycan on residue 49. The claim does not encompass naturally occurring Antibiotic L (which forms hexagonal-pyramidal crystals, and has a bacillosamine N-glycan on residue 49). The claimed antibiotic has particular structural/physical characteristics that are different from the naturally occurring antibiotic (*e.g.*, different crystalline form or different N-glycan). The person of ordinary skill in the art would understand that these structural differences may result in the claimed antibiotic having different functional characteristics (*e.g.*, different powder flow behavior or lower immunogenicity and different half-life) than the naturally occurring antibiotic. These differences 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.

Claim 3: Eligible. The claim is limited to Antibiotic L in the form of tetrahedral crystals, and does not encompass the naturally occurring hexagonal-pyramidal crystals. Although the claimed antibiotic is chemically unchanged from nature, the claimed antibiotic has particular structural/physical characteristics that are different from the naturally occurring antibiotic (*e.g.*, different crystalline form). The person of ordinary skill in the art would understand that these structural differences may result in the claimed antibiotic having different functional characteristics (*e.g.*, powder flow behavior) than the naturally occurring antibiotic. These differences 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.

Claim 4: Eligible. During examination, a product-by-process claim is not limited to manipulations of the recited steps, but instead is only limited to the structure implied by the steps. In this case, the specification describes that Antibiotic L produced by recombinant yeast has a different structure (high-mannose N-glycan) than the natural antibiotic (bacillosamine N-glycan). The claim is therefore limited to a structurally different Antibiotic L having a high-mannose N-glycan. This structural difference results in a change to the properties of the claimed antibiotic (lower immunogenicity and different half-life than the natural antibiotic). These differences 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.

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

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

bacteria. Thus, the mixture does not have markedly different characteristics from what occurs in nature, and 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.

The inoculant of claim 1 was held to be ineligible subject matter in *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 131 (1948):

> Discovery of the fact that certain strains of each species of these bacteria can be mixed without harmful effect to the properties of either is a discovery of their qualities of non-inhibition. It is no more than the discovery of some of the handiwork of nature and hence is not patentable. The aggregation of select strains of the several species into one product is an application of that newly-discovered natural principle. But however ingenious the discovery of that natural principle may have been, the application of it is hardly more than an advance in the packaging of the inoculants. Each of the species of root-nodule bacteria contained in the package infects the same group of leguminous plants which it always infected. No species acquires a different use. The combination of species produces no new bacteria, no change in the six species of bacteria, and no enlargement of the range of their utility. Each species has the same effect it always had. The bacteria perform in their natural way. Their use in combination does not improve in any way their natural functioning. They serve the ends nature originally provided and act quite independently of any effort of the patentee.

Recently, the Supreme Court looked back to this claim as an example of ineligible subject matter, stating that "the composition was not patent eligible because the patent holder did not alter the bacteria in any way." *Myriad*, 133 S. Ct. at 2117.

<u>Claim 2: Eligible</u>. In nature, *R. phaseoli* only infects garden beans, and *R. californiana* only infects lupine. When mixed together as claimed, the combination now infects a third species of plant: *R. californiana* infects both lupine and wild indigo, but *R. phaseoli* continues to only infect garden beans. The combination of species thus has changed *R. californiana* such that, when combined with *R. phaseoli*, it has a different characteristic (biological function) than it had in nature, *i.e.*, the claimed combination infects a new group of leguminous plants (wild indigo) as compared to the naturally occurring bacteria by themselves. This functional difference rises to the level of a marked difference, and accordingly the claimed mixture is not a "product of nature" exception. Note that unless the examiner can show that this particular mixture of bacteria exists in nature, this mere possibility does not bar the eligibility of this claim. *See, e.g.*, *Myriad*, 133 S. Ct. at 2119 n.8 ("The possibility that an unusual and rare phenomenon *might* randomly create a molecule similar to one created synthetically through human ingenuity does not render a composition of matter nonpatentable" (emphasis in original)). Thus, the claim is not directed to an exception (*Step 2A: NO*), and qualifies as eligible subject matter.

7. Nucleic Acids

This example illustrates that changes in genetic information/structure (claims 2 and 4), or physical structure (claim 3), as compared to a product's natural counterpart can demonstrate markedly different characteristics.

<u>Background</u>: Virginia nightshade is a naturally occurring plant that grows wild in the Shenandoah Valley of Virginia. When damaged, the leaves of Virginia nightshade produce a hormone called Protein W, which activates chemical defenses against herbivores. Protein W is naturally encoded by Gene W, which is part of chromosome 3 in Virginia nightshade and has the nucleic acid sequence disclosed as SEQ ID NO: 1. The specification also discloses substitution modifications of Gene W, *e.g.*, nucleic acids having one or more nucleotide bases that are substituted with different bases relative to SEQ ID NO: 1. For

example, one of the disclosed modifications changes a naturally occurring adenine to a guanine, *e.g.*, the first nine nucleotides are "TAC GGG AAA" in naturally occurring Gene L and "TAC GGG AAG" in the modified nucleic acid. Some of the modifications are silent, meaning that no change occurs in the encoded protein. It is known in the art that some silent modifications affect characteristics of nucleic acid such as transcription rate and splicing, and that some do not. No substitution modifications of Gene W are known to occur in nature. The modified nucleic acids have 90% or greater identity to SEQ ID NO: 1. The specification discloses labeling the nucleic acids, *e.g.*, with a fluorescent or radioactive label.

The specification discloses vectors comprising SEQ ID NO: 1 and a heterologous nucleic acid. The specification defines "heterologous" nucleic acid sequences as nucleic acid sequences that do not naturally occur in Virginia nightshade, *e.g.*, sequences from other plants, bacteria, viruses, or other organisms. Disclosed heterologous nucleic acids include plant viral vectors such as tobacco mosaic virus, and viral promoters such as the cauliflower mosaic virus (CaMV) 35S promoter. The viral promoters cause different expression of Gene W as compared to its natural expression levels in Virginia nightshade, *e.g.*, Gene W is expressed all the time (constitutively) as opposed to only in response to leaf damage.

Claims:

1. Isolated nucleic acid comprising SEQ ID NO: 1.
2. Isolated nucleic acid comprising a sequence that has at least 90% identity to SEQ ID NO: 1 and contains at least one substitution modification relative to SEQ ID NO: 1.
3. The isolated nucleic acid of claim 1, further comprising a fluorescent label attached to the nucleic acid.
4. A vector comprising the nucleic acid of claim 1 and a heterologous nucleic acid sequence.

Analysis of Claims:

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

Claim 1: Ineligible. The claimed nucleic acid has a different structural characteristic than naturally occurring Gene W, because the chemical bonds at each end were severed in order to isolate it from the chromosome on which it occurs in nature, but has the same nucleotide sequence as the natural gene. The claimed nucleic acid has no different functional characteristics, *i.e.*, it encodes the same protein as the natural gene. Under the holding of *Myriad*, this isolated but otherwise unchanged nucleic acid is not eligible because it is not different enough from what exists in nature to avoid improperly tying up the future use and study of naturally occurring Gene W. In other words, the claimed nucleic acid is different, but not markedly different, from its natural counterpart in its natural state (Gene W on chromosome 3), 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 claim is limited to nucleic acids in which the nucleotide sequence has been changed to contain at least one non-naturally occurring substitution modification relative to SEQ ID NO: 1. All of the claimed nucleic acids have different structural characteristics than the naturally occurring nucleic acid, *e.g.*, one or more nucleotides have been changed relative to the natural sequence. Some of the claimed nucleic acids may have different functional characteristics, *e.g.*, they may encode a different protein than the natural gene. Because the structural differences between the claimed nucleic acids and their natural counterparts are enough to ensure that the claim is not improperly tying up the future use of naturally occurring Gene W, they rise to the level of a marked difference, and so the claimed nucleic acids

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

Claim 3: Eligible. The claim is limited to a molecule that includes a nucleic acid and a fluorescent label, which combination does not occur in nature as a single molecule. The claimed molecule thus has different structural characteristics than the naturally occurring nucleic acid and label (single molecule vs. two separate molecules). It also has different functional characteristics (the labeled nucleic acid is now fluorescent, whereas the natural gene is not). These differences rise to the level of a marked difference, and so the claimed molecule 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.

Claim 4: Eligible. The claim is limited to vectors comprising a non-natural combination of Gene W (SEQ ID NO: 1) with a sequence from another organism, and thus does not read on the naturally occurring chromosome in Virginia nightshade. This non-natural combination results in the vectors having a different genetic structure and sequence than the naturally occurring nucleic acids, *i.e.*, different structural characteristics. Some of the claimed vectors may have different functional characteristics, depending on the selected heterologous sequence. These differences rise to the level of a marked difference, and so the claimed vector 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.

8. Antibodies

This example illustrates that products created by human manipulation of natural processes (claims 2 and 3), as well as products that are changed in structure as compared to a product's natural counterpart (claims 4 and 5), can have markedly different characteristics.

Background: Newly discovered *Staphylococcus texana* bacteria have an antigen called Protein S on their outer surface. The specification describes the discovery of naturally occurring antibodies to Protein S in mice and wild coyotes living in Texas. No human antibodies to Protein S are naturally occurring. Antibodies have two types of domains: (1) constant domains such as the Fc domain, which are unvarying in antibodies of a particular class (*e.g.*, IgA) within a species; and (2) variable domains comprising complementarity determining regions (CDRs) that bind to an antigen and that vary from antibody to antibody.

The specification describes multiple types of antibodies to Protein S, including:

- murine antibodies, that were created by injecting laboratory mice with Protein S;
- human antibodies, that were created by injecting transgenic mice with Protein S;
- chimeric antibodies (defined as antibodies that have murine variable domains and human constant domains);
- humanized antibodies (defined as antibodies having murine CDRs but are otherwise human); and
- antibodies with variant Fc domains (defined as antibodies having an Fc domain that is engineered to comprise at least one amino acid modification relative to a wild-type Fc domain).

It is well-known in the art that murine antibodies have different constant domains than human and coyote antibodies, and that murine antibodies may cause allergic reactions and anaphylactic shock when administered to humans or coyotes. The specification discloses a particular murine antibody created by applicants, comprising SEQ ID NOs: 7-12 as its six CDR sequences. There is no naturally occurring antibody that has this particular combination of CDR sequences. It is well-known in the art that chimeric and humanized antibodies are less immunogenic to humans than murine antibodies. It is also well-known that antibodies with variant Fc domains may exhibit different characteristics (*e.g.*, increased cytotoxicity and/or serum half-life) than antibodies with wild-type Fc domains.

Claims:

1. An antibody to Protein S.

2. The antibody of claim 1, wherein the antibody is a human antibody.
3. The antibody of claim 1, wherein the antibody is a murine antibody comprising complementarity determining region (CDR) sequences set forth as SEQ ID NOs: 7-12.
4. The antibody of claim 1, wherein the antibody is a chimeric or humanized antibody.
5. The antibody of claim 1, wherein the antibody comprises a variant Fc domain.

Analysis of Claims:

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

Claim 1: Ineligible. As described in the specification, some antibodies to Protein S are naturally occurring in mice and wild coyotes living in Texas, while other antibodies to Protein S (such as chimeric antibodies) have non-natural forms and may contain domains from multiple species. The claim thus encompasses antibodies that are structurally identical to naturally occurring antibodies, and antibodies that are structurally changed. Because there is no difference in characteristics (structural, functional, or otherwise) between the claimed and naturally occurring antibodies for at least some of the embodiments encompassed by the claim, the claimed antibodies do not have markedly different characteristics, and thus are 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 claim is limited to human antibodies to Protein S. No human antibodies to Protein S are naturally occurring. The claimed antibodies have different complementarity determining regions (CDRs) than what exists in nature, and therefore have different structural (*e.g.*, different amino acid sequences and three-dimensional structures) and functional (*e.g.*, bind to different antigens) characteristics. These differences rise to the level of a marked difference, and so the claimed antibodies are not "product of nature" exceptions. Thus, the claim is not directed to an exception (*Step 2A: NO*), and qualifies as eligible subject matter.

Claim 3: Eligible. The claim is limited to murine antibodies comprising complementarity determining region (CDR) sequences set forth as SEQ ID NOs: 7-12. Some murine antibodies to Protein S occur in nature, and it is possible that nature might randomly create a murine antibody having the CDR sequences of SEQ ID NOs: 7-12. But unless the examiner can show that this particular murine antibody exists in nature, this mere possibility does not bar the eligibility of this claim. *See, e.g., Myriad*, 133 S. Ct. at 2119 n.8 ("The possibility that an unusual and rare phenomenon *might* randomly create a molecule similar to one created synthetically through human ingenuity does not render a composition of matter nonpatentable" (emphasis in original)). Because the claimed antibodies have different CDRs than what exists in nature, they have different structural (*e.g.*, different amino acid sequences and three-dimensional structures) and functional (*e.g.*, bind to different antigens) characteristics. These differences rise to the level of a marked difference, and so the claimed antibodies are not "product of nature" exceptions. Thus, the claim is not directed to an exception (*Step 2A: NO*), and qualifies as eligible subject matter.

Claim 4: Eligible. The claim is limited to chimeric and humanized antibodies, which are defined as fusion proteins formed by physically fusing together part of a murine antibody (CDRs or variable domains) and part of a human antibody (constant domains). The claimed antibodies have different structural characteristics than natural antibodies, because the combination of murine and human antibody fragments into a single antibody molecule does not exist in nature. There may also be differences in functional characteristics, *e.g.*, chimeric antibodies are typically less immunogenic to humans than murine

antibodies. These differences rise to the level of a marked difference, and so the claimed antibodies are not "product of nature" exceptions. Thus, the claim is not directed to an exception (*Step 2A: NO*), and qualifies as eligible subject matter.

Claim 5: Eligible. The claim is limited to antibodies comprising a variant Fc domain, which is defined as an Fc domain that is engineered to comprise at least one amino acid modification relative to a wild-type Fc domain. The claimed antibodies have different structural characteristics (*e.g.*, different amino acid sequences and three-dimensional structures) than natural antibodies, and may also have different functional characteristics (*e.g.*, different cytotoxicity and/or serum half-life). These differences in characteristics rise to the level of a marked difference, and so the claimed antibodies are not "product of nature" exceptions. Thus, the claim is not directed to an exception (*Step 2A: NO*), and qualifies as eligible subject matter.

9. Cells

This example illustrates that a man-made product identical to a naturally occurring product does not have markedly different characteristics (claim 1), but that changes in phenotype caused by human manipulation can result in markedly different characteristics (claims 2 and 3). It also demonstrates the application of the "significantly more" analysis to claims directed to a "product of nature" exception (claims 4 and 5).

Background: Human stem cells are naturally occurring cells that can develop, through a process called differentiation, into many different types of cells, such as cardiac cells, skin cells, and so on. Stem cells have utility in regenerative medicine, which involves repairing diseased tissues or organs. One type of diseased tissue that often needs repair is the heart's pacemaker, which is formed from pacemaker cells that generate electrical impulses to control heart rate. In nature, pacemaker cells can be identified via a protein called marker P located on the cell surface. The pacemaker cells contain genes that are capable of expressing a protein called marker Z, but in nature these genes are never expressed (there are no naturally occurring pacemaker cells that have marker Z on their surface).

Applicant's specification discloses differentiating stem cells into pacemaker cells, for use in regenerating damaged heart tissue. Applicant discloses isolating stem cells from human volunteers, and then culturing those cells in a particular growth medium in the presence of growth factor A, at various temperatures. Isolation does not change the cells in any way, but applicant's culture conditions cause the stem cells to differentiate into pacemaker cells. Some of the man-made pacemaker cells produced by applicant are genetically and phenotypically identical (*e.g.*, express marker P) to naturally occurring pacemaker cells. Other man-made pacemaker cells produced by applicant are genetically identical, but have a different phenotype (*e.g.*, express marker Z and exhibit increased efficiency in utilizing oxygen) than naturally occurring pacemaker cells. Isolation of these man-made cells does not change them in any way.

The increased oxygen utilization efficiency of the pacemaker cells expressing marker Z is advantageous in the regeneration of heart tissue in patients who are recovering from damage to the heart, such as that caused by a myocardial infarction (heart attack). Applicant has discovered that a mixed population of pacemaker cells that is about 10-15% positive for marker Z (*i.e.*, about 10-15% of the cells in the population express marker Z), and about 85-90% positive for marker P (*i.e.*, about 85-90% of the cells in the population express marker P), can be injected into a patient's heart in order to regenerate a pacemaker *in vivo* (in a patient's body). This successful regeneration is possible because the cells interact with each other to affect their growth rates, *e.g.*, the cells expressing marker P grow faster in the mixed population than when they are by themselves. However, a cell population with fewer (or no) cells expressing marker Z is not capable of regenerating a pacemaker, because the cell population is starved of oxygen before it can become established in the patient.

The specification discloses compositions including populations of pacemaker cells in containers, such as flasks and petri dishes, which are routinely and conventionally used in laboratories to hold cells. Also

disclosed are compositions including populations of pacemaker cells in biocompatible three-dimensional scaffolds. The specification defines "biocompatible three-dimensional scaffolds" as being three-dimensional structures constructed of naturally occurring materials (such as polysaccharides or proteins) that are unchanged from their natural state, in which they are associated with non-cardiac cells, but that have been removed from their natural environment. The specification specifically excludes cardiac tissue from the definition of "biocompatible three-dimensional scaffolds". The specification also discloses that compositions including populations of pacemaker cells in the biocompatible three-dimensional scaffolds can be implanted directly into a patient, where they facilitate faster tissue regeneration than when pacemaker cells are implanted by themselves, because the scaffold provides mechanical support for the implanted cells to grow.

Claims:

1. An isolated man-made human pacemaker cell.
2. An isolated man-made human pacemaker cell expressing marker Z.
3. A population of human pacemaker cells, wherein the population is about 10-15% positive for marker Z, and 85-90% positive for marker P.
4. A composition comprising a population of isolated man-made human pacemaker cells in a container.
5. A composition comprising a population of isolated man-made human pacemaker cells in a biocompatible three-dimensional scaffold.

Analysis of Claims:

These claims are analyzed for eligibility in accordance with their broadest reasonable interpretation. All of the claims are directed to a statutory category, *e.g.*, a composition of matter (*Step 1: YES*).

Claim 1: Ineligible. Because the claim is a nature-based product, *i.e.*, a cell, the nature-based product is analyzed to determine whether it has markedly different characteristics from any naturally occurring counterpart(s) in their natural state. As described in the specification, some of the man-made cells are identical to what exists in nature (*e.g.*, same genotype and phenotype), while others are phenotypically different from what exists in nature (*e.g.*, express marker Z and have increased oxygen utilization), and these difference arose due to applicant's efforts. The claim thus encompasses cells that are identical (no difference in characteristics) to naturally occurring cells, and cells that are phenotypically different. Because there is no difference between the claimed and naturally occurring cells for at least some of the embodiments encompassed by the claim, the claimed cells do not have markedly different characteristics, and thus are a "product of nature" exception. *In re Roslin Institute (Edinburgh)*, 750 F.3d 1333, 1338-39 (Fed. Cir. 2014). 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 claim is limited to human pacemaker cells that express marker Z, which are nature-based products. No human pacemaker cells expressing marker Z are naturally occurring. As described in the specification, the claimed cells are exact genetic replicas of naturally occurring pacemaker cells, that were produced from naturally occurring stem cells. However, the claimed cells are phenotypically different than natural pacemaker cells, in that they express marker Z and have increased oxygen utilization efficiency. Further, these phenotypic differences were created by applicant's efforts (*e.g.*, by culturing the stem cells in a particular growth medium in the presence of growth factor A, at various temperatures), and were not the work of nature. These phenotypic differences rise to the level of a marked difference, and accordingly the claimed cell 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.

Claim 3: Eligible. The claim is limited to a population of human pacemaker cells, where about 10-15% of the cells express marker Z, and about 85-90% express marker P. Because the claim is a nature-based

product, *i.e.*, a combination of cells, the nature-based product (the population) is analyzed to determine whether it has markedly different characteristics from any naturally occurring counterpart(s) in their natural state. As discussed above with respect to claims 1 and 2, the cells expressing marker Z have markedly different characteristics than naturally occurring cardiac pacemaker cells because of their phenotypic differences, but the cells expressing marker P do not have markedly different characteristics because they are identical to naturally occurring pacemaker cells. However, as described in the specification, when these cells are mixed together in the claimed ratio to form the claimed population, the cells interact with each other to affect their growth rates, *e.g.*, the cells expressing marker P grow faster in the mixed population than when they are by themselves. Naturally occurring pacemaker cells do not grow at this rate in their natural state. This difference in biological properties (rate of cell growth) between the claimed cell population and naturally occurring human pacemaker cells rises to the level of a marked difference, and accordingly the claimed population 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.

Claim 4: Ineligible. Because the claim recites a nature-based product, *i.e.*, the population of cells, the nature-based product is analyzed to determine whether it has markedly different characteristics from any naturally occurring counterpart(s) in their natural state. As explained with respect to claim 1, isolated man-made pacemaker cells do not have markedly different characteristics due to their isolation or human manufacture. There is no indication in the specification that placing the cells in a generic container results in the cells having any characteristics (structural, functional, or otherwise) that are different from the naturally occurring cells in their natural state. Thus, the claimed population of cells does not have markedly different characteristics from what occurs in nature, and is a "product of nature" exception. Accordingly, the claim is directed to an exception (*Step 2A: YES*). Next, the claim as a whole is analyzed to determine whether any element, or combination of elements, is sufficient to ensure that the claim amounts to significantly more than the exception. Although the claim recites a container, use of a container to hold cells is not only well-understood, routine and conventional activity already engaged in by the scientific community, it is also required for growing and using the cells. Additionally, the claim recites the container at such a high level of generality that it merely tells a scientist to use whatever container she wishes to use. Therefore, the claim as a whole adds nothing significantly more to the "product of nature" itself. Thus, the claim does not amount to significantly more than the judicial exception itself (*Step 2B: NO*). The claim does not qualify as eligible subject matter, and should be rejected under 35 U.S.C. § 101.

Claim 5: Eligible. Because the claim is a nature-based product, *i.e.*, a combination of cells and a scaffold, the nature-based product (the combination) is analyzed to determine whether it has markedly different characteristics from any naturally occurring counterpart(s) in their natural state. As explained with respect to claim 1, isolated man-made pacemaker cells do not have markedly different characteristics due to their isolation or human manufacture. There is also no indication in the specification that placing the cells into a biocompatible three-dimensional scaffold results in the cells or the scaffold having any characteristics (structural, functional, or otherwise) that are different from the naturally occurring cells or scaffold in their natural state. Thus, the claimed population of cells, and the claimed scaffold, do not have markedly different characteristics from what occurs in nature, and are "product of nature" exceptions. Accordingly, the claim is directed to an exception (*Step 2A: YES*). Next, the claim as a whole is analyzed to determine whether any element, or combination of elements, is sufficient to ensure that the claim amounts to significantly more than the exception. The recitation of the biocompatible three-dimensional scaffold in combination with the pacemaker cells is not required for growing or using the cells, because the cells can be grown or used in other containers, and is not recited at a high level of generality. The addition of the pacemaker cells to the scaffold confines the claim to a particular useful application of the scaffold (repair of cardiac tissue), because the pacemaker cells are not routinely required for all practical uses of the scaffold. Further, the combination of these elements does more than generally link these two judicial exceptions together; as described in the specification, this combination improves the technology of regenerative medicine, by facilitating faster tissue regeneration than when pacemaker cells are implanted

by themselves. Thus, the claim amounts to significantly more than the judicial exception itself (*Step 2B: YES*), and qualifies as eligible subject matter.

10. Food

This example illustrates the difference between a nature-based product claim having multiple components that are unchanged because they are not combined (claim 1), and a nature-based product claim having multiple components that are changed by their combination (claim 2).

Background: Goats are naturally occurring animals that produce milk to feed their young. Humans have consumed goat milk and products made from goat milk (*e.g.*, cheese and yogurt) for centuries. One well-known method of making goat yogurt is to create a starter culture by mixing raw goat milk with bacteria, and then heating the starter culture to about 115 degrees Fahrenheit for several hours so that the bacteria can ferment the milk. The fermentation causes the conversion of lactose (milk sugar) in the goat milk into lactic acid, and this chemical change results in a physical change (the thickened consistency of the yogurt as compared to the goat milk). The lactic acid also makes the yogurt have a tangy flavor. Multiple species of bacteria are known as useful in making yogurt, including *Streptococcus thermophilus* (a naturally occurring bacterial species).

Applicant has discovered a new naturally occurring bacterial species that it named *Lactobacillus alexandrinus*. Goat milk yogurt made with *L. alexandrinus* has a pleasant tangy flavor. Neither *S. thermophilus* nor *L. alexandrinus* occur naturally in goat milk, and these bacteria do not occur together in nature. Applicant has also discovered that when mixed, *S. thermophilus* and *L. alexandrinus* have different properties than either bacteria has alone: (1) the mixed bacteria act synergistically to ferment goat milk at twice the speed than either bacteria can ferment by itself; and (2) the resultant goat yogurt is much lower in fat than either bacteria can produce when used by itself. Applicant discloses compositions comprising a goat milk starter comprising goat milk mixed with *S. thermophilus* and *L. alexandrinus*. Applicant also discloses kits for preparing goat milk yogurt. The kits comprise a separate packet of *S. thermophilus*, and a separate packet of *L. alexandrinus*, and may also comprise instructions for combining the two bacterial species with goat milk to make yogurt.

Claims:

1. A kit for preparing goat milk yogurt comprising: *Streptococcus thermophilus* and *Lactobacillus alexandrinus*.
2. A yogurt starter culture comprising: goat milk mixed with *Streptococcus thermophilus* and *Lactobacillus alexandrinus.*

Analysis of Claims:

These claims have been 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 (goat milk and/or bacteria), the markedly different characteristics analysis is used to determine if the nature-based products are exceptions.

Claim 1: Ineligible. As described in the specification, both *S. thermophilus* and *L. alexandrinus* are naturally occurring bacteria. There is no indication in the specification that the claimed bacteria have any characteristics (structural, functional, or otherwise) that are different from the naturally occurring bacteria. Because the bacterial species in the kit are not mixed, but instead are separate from each other, their inclusion in the same kit does not change their characteristics. Although the user of the kit may choose to mix the bacteria together at some time in the future, that mixture, which may or may not exist in the future is not a part of the claimed invention. *In re Venezia*, 530 F.2d 956, 958-59 (CCPA 1976). Thus, the bacterial species in the kit do not have markedly different characteristics from their natural counterparts in their natural state, and are "product of nature" exceptions. 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 exceptions (*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. As described in the specification, when *S. thermophilus* and *L. alexandrinus* are mixed, the two bacterial species have different characteristics than either species does on its own, *e.g.*, they act together to ferment milk into a lower fat yogurt than either bacteria can produce when individually mixed with the milk. Thus, the mixture of the bacteria and milk has different functional characteristics (lower fat content) than the naturally occurring bacteria (or milk) by itself. These differences rise to the level of a marked difference, and accordingly the claimed starter culture 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.

Streamlined Example 1

1. A hip prosthesis comprising:

   a femoral component and

   an acetabular cup,

   wherein the acetabular cup has an inner concave surface for engaging the femoral component, and an outer convex surface for engaging a patient's acetabulum, and

   wherein the outer convex surface is coated with hydroxyapatite.

- The claim recites a nature-based product (hydroxyapatite is a naturally occurring mineral).
- However, the claim <u>clearly</u> does not seek to tie up the mineral. Instead, the claim is focused on the assembly of the femoral component and the cup that together form the hip prosthesis.
- No need to perform the markedly different characteristics analysis on the mineral.

The claim qualifies as <u>eligible</u> subject matter without a full analysis.

Streamlined Example 2

2. A robotic arm assembly comprising:

a robotic arm having an end effector that is capable of movement along a predetermined motion path,

a sensor that obtains movement information about the end effector, and

a control system that uses the movement information from the sensor to adjust the velocity of the end effector in order to achieve a smooth motion along the predetermined motion path.

- The claim operates using certain mathematical relationships, *e.g.*, velocity is a relationship between the position of an object with respect to time.
- However, the claim <u>clearly</u> does not seek to tie up these mathematical relationships. For example, others are clearly free to use velocity in other applications such as in a radar gun.

The claim qualifies as <u>eligible</u> subject matter without a full analysis.

July 2015 Update Appendix 1: Examples

The following examples should be used in conjunction with the *2014 Interim Guidance on Subject Matter Eligibility* (2014 IEG). As the examples are intended to be illustrative only, they should be interpreted based on the fact patterns set forth below. Other fact patterns may have different eligibility outcomes. While some of the fact patterns draw from U.S. Supreme Court and U.S. Court of Appeals for the Federal Circuit decisions, each of the examples shows how claims should be analyzed under the 2014 IEG. All of the claims are analyzed for eligibility in accordance with their broadest reasonable interpretation.

Note that the examples herein are numbered consecutively beginning with number 21, because 20 examples were previously issued. A comprehensive index of all examples for use with the 2014 IEG is provided in Appendix 2 to the July 2015 Update.

21. Transmission Of Stock Quote Data

The following hypothetical claims and background are modeled after the technology in Google Inc. v. Simpleair, Inc., Covered Business Method Case No. CBM 2014-00170 (Jan. 22, 2015), but are revised to emphasize certain teaching points. The patent at issue was U.S. Patent No. 7,035,914 entitled "System and Method for Transmission of Data." Hypothetical claim 1 is directed to an abstract idea and does not have additional elements that amount to significantly more than the abstract idea. Hypothetical claim 2 also recites an abstract idea but does contain additional elements that amount to significantly more because there are meaningful limitations beyond generally linking the use of the abstract idea to a particular technological environment.

Background

The invention is directed to a stock quote alert subscription service where subscribers receive customizable stock quotes on their local computers from a remote data source. At the time of the invention, stock quote subscription services over the Internet were known in the art. However, existing services experienced challenges when attempting to notify a subscriber whose computer was offline (not connected to the Internet) at the time of the alert, since many stock quotes are time sensitive. Further, many previous subscription services simply transmitted all available stock quote information to the user at a given time, which required the subscriber to sort through large amounts of data to identify relevant stock quotes, and often sent information at an inconvenient time (*e.g.*, after the stock exchanges are closed). The stock quote alert subscription service of the present invention addresses these problems.

During enrollment to the subscription service, the subscriber provides preference information in the form of stocks of interest, stock price threshold (e.g., when the price reaches $100 per share), a destination address of a wireless device (e.g., a number for a cellular phone, pager or PDA), preferred format of the alert, and a transmission schedule indicating the time/date that alerts should be sent. The subscription service uses a transmission server to receive data from a data source and send selected data to subscribers. The transmission server includes a memory, a transmitter, and a microprocessor. The subscription service provides a stock viewer application to subscribers for installation on their individual computers. After a subscriber enrolls, the service receives stock quote information sent from a data source to the transmission

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server. The server filters the stock quote information based upon the subscriber preference information that is stored in memory on the server. That is, the server compares the received stock quote information to the stored stocks of interest and stock price threshold preferences to determine which stock quotes to drop and which to further process. Next, a stock quote alert is built containing the filtered stocks' name and price information and a universal resource locator (URL) to a web page at the data source which contains further information on the stock quote. The alert is then formatted into data blocks based upon the alert format preference information. Subsequently, the formatted data blocks are transmitted to the subscriber's wireless device in accordance with the transmission schedule. After receiving the alert, the subscriber can connect the wireless device to the subscriber's computer. The alert causes the subscriber's computer to auto-launch the stock viewer application provided by the service to display the alert. When connected to the Internet, the subscriber may then click on the URL in the alert to use the stock viewer application to access more detailed information about the stock quote from the data source.

Claims

1. A method of distributing stock quotes over a network to a remote subscriber computer, the method comprising:

receiving stock quotes at a transmission server sent from a data source over the Internet, the transmission server comprising a microprocessor and memory that stores the remote subscriber's preferences for information format, destination address, specified stock price values, and transmission schedule, wherein the microprocessor

filters the received stock quotes by comparing the received stock quotes to the specified stock price values;

generates a stock quote alert from the filtered stock quotes that contains a stock name, stock price and a universal resource locator (URL), which specifies the location of the data source;

formats the stock quote alert into data blocks according to said information format; and

transmits the formatted stock quote alert to a computer of the remote subscriber based upon the destination address and transmission schedule.

2. A method of distributing stock quotes over a network to a remote subscriber computer, the method comprising:

providing a stock viewer application to a subscriber for installation on the remote subscriber computer;

receiving stock quotes at a transmission server sent from a data source over the Internet, the transmission server comprising a microprocessor and a memory that stores

the remote subscriber's preferences for information format, destination address, specified stock price values, and transmission schedule, wherein the microprocessor

filters the received stock quotes by comparing the received stock quotes to the specified stock price values;

generates a stock quote alert from the filtered stock quotes that contains a stock name, stock price and a universal resource locator (URL), which specifies the location of the data source;

formats the stock quote alert into data blocks according to said information format; and

transmits the formatted stock quote alert over a wireless communication channel to a wireless device associated with a subscriber based upon the destination address and transmission schedule,

wherein the alert activates the stock viewer application to cause the stock quote alert to display on the remote subscriber computer and to enable connection via the URL to the data source over the Internet when the wireless device is locally connected to the remote subscriber computer and the remote subscriber computer comes online.

Analysis

Claim 1: Ineligible

The claim recites a series of acts for distributing stock quotes to selected remote devices. Thus, the claim is directed to a process, which is one of the statutory categories of invention (*Step 1: YES)*.

Next, the claim is analyzed to determine whether it is directed to a judicial exception. The claim recites the steps of receiving, filtering, formatting and transmitting stock quote information. In other words, the claim recites comparing and formatting information for transmission. This is simply the organization and comparison of data which can be performed mentally and is an idea of itself. It is similar to other concepts that have been identified as abstract by the courts, such as using categories to organize, store and transmit information in *Cyberfone*, or comparing new and stored information and using rules to identify options in *SmartGene*. Therefore, the claim is directed to an abstract idea (*Step 2A: YES*).

Next, the claim as a whole is analyzed to determine whether any element, or combination of elements, is sufficient to ensure that the claim amounts to significantly more than the exception. The claim recites the additional limitations of using a transmission server with a memory that stores subscriber preferences, a transmitter that receives and sends information over the Internet, and a microprocessor that performs the generic functions of comparing and formatting information. The transmission server is recited at a high level of generality and its broadest reasonable interpretation comprises only a microprocessor, memory and transmitter to simply perform the generic computer functions of receiving, processing and transmitting information. Generic computers performing generic computer functions, alone, do not amount to significantly more than the abstract idea. Finally, the

Internet limitations are simply a field of use that is an attempt to limit the abstract idea to a particular technological environment and, so do not add significantly more. Viewing the limitations as an ordered combination does not add anything further than looking at the limitations individually. When viewed either individually, or as an ordered combination, the additional limitations do not amount to a claim as a whole that is significantly more than the abstract idea (*Step 2B: NO*). The claim is not patent eligible.

A rejection of claim 1 should identify the exception by pointing to the filtering, generating and formatting steps and explain that the comparing and formatting of information is a mental process that is similar to the concepts that courts have previously found abstract. The rejection should also identify the additional limitations regarding the transmission server and explain why those limitations comprise only a generic computer performing generic computer functions that do not impose meaningful limits on the claimed method.

<u>Claim 2: Eligible</u>

The claim recites a series of acts for distributing stock quotes to selected remote devices. Thus, the claim is directed to a process, which is one of the statutory categories of invention (*Step 1: YES)*.

The claim is then analyzed to determine if the claim is directed to a judicial exception. As discussed above, the recited steps of comparing and organizing data for transmission are a mental process and similar to other concepts found to be abstract by the courts. The claim is directed to an abstract idea (*Step 2A: YES*).

Next, the claim as a whole is evaluated to determine if there are additional limitations that amount to significantly more than the abstract idea. The claim recites the additional limitations of using a transmission server with a microprocessor and a memory to store subscriber preferences, transmitting a stock quote alert from the transmission server over a data channel to a wireless device, and providing a stock viewer application that causes the stock quote alert to display on the subscriber computer and enables a connection from the subscriber computer to the data source over the Internet when the subscriber computer comes online. It is noted that, as discussed above, some of the limitations when viewed individually do not amount to significantly more than the abstract idea (such as storing subscriber preferences or transmitting an alert). However, when looking at the additional limitations as an ordered combination, the invention as a whole amounts to significantly more than simply organizing and comparing data. The claimed invention addresses the Internet-centric challenge of alerting a subscriber with time sensitive information when the subscriber's computer is offline. This is addressed by transmitting the alert over a wireless communication channel to activate the stock viewer application, which causes the alert to display and enables the connection of the remote subscriber computer to the data source over the Internet when the remote subscriber computer comes online. These are meaningful limitations that add more than generally linking the use of the abstract idea (the general concept of organizing and comparing data) to the Internet, because they solve an Internet-centric problem with a claimed solution that is necessarily rooted in computer technology, similar to the additional elements in *DDR Holdings*. These limitations, when taken as an ordered combination, provide

unconventional steps that confine the abstract idea to a particular useful application. Therefore, the claim recites patent eligible subject matter (*Step 2B: YES*).

If the examiner believes that the record would benefit from clarification, remarks could be added to an Office action or reasons for allowance indicating that the claim recites the abstract idea of comparing and organizing data for transmission. However, the claim is eligible because it recites additional limitations that when considered as an ordered combination demonstrates a technologically rooted solution to an Internet-centric problem and thus amounts to significantly more than comparing and organizing information for transmission.

22. Graphical User Interface For Meal Planning

The following claim was found ineligible by the Southern District of New York, and the judgment was affirmed by the Federal Circuit in Dietgoal Innovations LLC v. Bravo Media LLC, 599 Fed. Appx. 956 (Fed. Cir. Apr. 8, 2015). The patent at issue was U.S. Patent 6,585,516. The claim is directed to an abstract idea, and the additional elements do not amount to significantly more than the abstract idea, but merely implement the idea using generic computer technology. The exemplary analysis shows how an examiner would apply the 2014 IEG analysis to the claim when making a rejection.

Background

The invention addresses a way to solve the issue of obesity, specifically by using visuals to assist users to follow diet programs designed by health professionals for the purpose of modifying diet behavior. In particular, the invention is a computer system that "includes[s] a User Interface (UI), a Meal Database, a Food Database, Picture Menus and Meal Builder." The UI functions to receive commands from the user and display results to the user. The Food and Meal Databases are databases of food information and preselected combinations of foods that have been compiled into a single repository. The Picture Menus display pictures of meals on the UI so the user can make a plan by mixing and matching foods to meet customized eating goals. The Meal Builder permits the user to design meals and view the impact of the food choices on customized eating goals in real time. In practice, the invention permits a user to choose meals for a particular day, as well as modify one or more of the meals to create new meals, while seeing the impact on their dietary plan. The object of the invention is to influence a person's eating behavior.

Claim

2. A system of computerized meal planning, comprising:

a User Interface;

a Database of food objects; and

a Meal Builder, which displays on the User Interface meals from the Database and wherein a user can change content of said meals and view the resulting meals' impact on customized eating goals.

Analysis

Claim 2: Ineligible.

The broadest reasonable interpretation of the claim encompasses a computer system (*e.g.*, hardware such as a processor and memory) that implements a user interface, a database, and a food data selection program. The system comprises a device or set of devices and, therefore, is directed to a machine, which is a statutory category of invention (*Step 1: YES*).

The claim is then analyzed to determine if the claim is directed to a judicial exception. The claim recites a system for selecting and modifying meals based upon dietary goals. In other words, the claim describes a process of meal planning. Meal planning is the organization and comparison of information to develop a guideline for eating. It is a mental process of managing behavior that could be performed in the human mind, or by a human using a pen and paper. Such a basic concept is similar to other mental processes found abstract by the courts such as comparing new and stored information and using rules to identify options in *SmartGene*, and obtaining and comparing intangible data in *Cybersource*. Therefore, claim 2 is directed to an abstract idea *(Step 2A: YES).*

Next, the claim is analyzed to determine if there are additional claim limitations that individually, or as an ordered combination, ensure that the claim amounts to significantly more than the abstract idea. The only additional limitations in the claim relate to computerization of meal planning with an interface, a database of food objects, and a "meal builder," which is a computer program that allows selection and comparison of food data. The meal builder would require a processor and memory in order to perform basic computer functions of accepting user input, retrieving information from a database, manipulating that information and displaying the results. These components are not explicitly recited and therefore must be construed at the highest level of generality. The interface is also recited at a high level of generality with the only required function of displaying, which is a well-known routine function of interfaces. Further, the database performs only its basic function of storing information, which is common to all databases. Thus, the recited generic computer components perform no more than their basic computer functions. These additional elements are well-understood, routine and conventional limitations that amount to mere instructions to implement the abstract idea of meal planning on a computer. Taking these computer limitations as an ordered combination adds nothing that is not already present when the elements are taken individually. Therefore, the claim does not amount to significantly more than the recited abstract idea *(Step 2B: NO)*. The claim is not patent eligible.

A rejection of this claim should identify the abstract idea of selecting meals for a customized eating goal, which is similar to concepts of obtaining and comparing data that were found to be abstract by the courts. The rejection should also identify the additional elements and explain the reasons why they amount to no more than merely implementing the idea of meal planning using generic computer components.

23. Graphical User Interface For Relocating Obscured Textual Information

The following claims are hypothetical. Claim 1 demonstrates a claim that is not directed to an abstract idea. Claims 2 and 3 are directed to an abstract idea and do not recite significantly more. Claim 4 recites an abstract idea, but there are additional limitations in the claim that amount to significantly more than the abstract idea.

Background

The invention relates to a graphical user interface (GUI). A GUI manages the interaction between a computer system and a user through graphical elements such as windows on a display. Windows display various types of outputs for various computer processes and may contain controls to accept user input for those processes. In some instances, multiple windows are displayed at the same time; due to limited display space, however, the windows may overlap and obscure the content of underlying windows.

In the instant application, the inventor has improved upon previous GUIs by dynamically relocating obscured textual information of an underlying window to become automatically viewable to the user. In particular, in a graphical user interface that comprises multiple windows, the invention continuously monitors the boundaries of the windows to ascertain an overlap condition indicating that the windows overlap such that the textual information of an underlying window is obscured from a user's view by the overlapping window. Only when the textual information of the underlying window is detected to be obscured, the invention re-formats and moves the textual information in the underlying window to an unobscured portion of the underlying window so that the textual information is viewable by the user. When the overlap condition no longer exists, the textual information is returned to its original format and location.

The inventor's process is performed by modifying the vertical and horizontal margins of the underlying window in accordance with the overlap and utilizing a word wrap function to wrap the text around the obscured area based upon the new margins, and, where necessary, reducing the text size to permit the entirety of the textual information to be viewable in the unobscured portion. The textual information is scaled based upon a scaling factor that is calculated using a mathematical algorithm. First, an area of the underlying window and an area of the unobstructed portion of the underlying window are calculated. Next, the scaling factor is calculated which is proportional to the difference in area between the underlying window and the unobstructed portion of the underlying window. Finally, the font size of the textual information is changed in accordance with the scaling factor. The new scaled textual information is then moved as described above to the unobstructed portion of the underlying window. When the windows no longer overlap, the textual information is returned to its original format and location by resetting the vertical and horizontal margins of the window to their original values and no longer applying the scaling factor to the font size. By permitting textual information to be dynamically relocated based upon an overlap condition, the computer's ability to display information and interact with the user is improved.

Claims

1. A computer-implemented method for dynamically relocating textual information within an underlying window displayed in a graphical user interface, the method comprising:

displaying a first window containing textual information in a first format within a graphical user interface on a computer screen;

displaying a second window within the graphical user interface;

constantly monitoring the boundaries of the first window and the second window to detect an overlap condition where the second window overlaps the first window such that the textual information in the first window is obscured from a user's view;

automatically relocating the textual information, by a processor, to an unobscured portion of the first window in a second format during an overlap condition so that the textual information is viewable on the computer screen by the user; and

automatically returning the relocated textual information, by the processor, to the first format within the first window when the overlap condition no longer exists.

2. A computer-implemented method of resizing textual information within a window displayed in a graphical user interface, the method comprising:

generating first data for describing the area of a first graphical element;

generating second data for describing the area of a second graphical element containing textual information; and

calculating a scaling factor for the textual information which is proportional to the difference between the first data and second data.

3. A computer-implemented method of resizing textual information within a window displayed in a graphical user interface, the method comprising:

generating first data for describing the area of a first graphical element;

generating second data for describing the area of a second graphical element containing textual information; and

calculating, by the computer, a scaling factor for the textual information which is proportional to the difference between the first data and second data.

4. A computer-implemented method for dynamically relocating textual information within an underlying window displayed in a graphical user interface, the method comprising:

displaying a first window containing textual information in a first format within a graphical user interface on a computer screen;

displaying a second window within the graphical user interface;

constantly monitoring the boundaries of the first window and the second window to detect an overlap condition where the second window overlaps the first window such that the textual information in the first window is obscured from a user's view;

determining the textual information would not be completely viewable if relocated to an unobstructed portion of the first window;

calculating a first measure of the area of the first window and a second measure of the area of the unobstructed portion of the first window;

calculating a scaling factor which is proportional to the difference between the first measure and the second measure;

scaling the textual information based upon the scaling factor;

automatically relocating the scaled textual information, by a processor, to the unobscured portion of the first window in a second format during an overlap condition so that the entire scaled textual information is viewable on the computer screen by the user; and

automatically returning the relocated scaled textual information, by the processor, to the first format within the first window when the overlap condition no longer exists.

Analysis

Claim 1: Eligible.

The claim recites a series of steps for relocating textual information in an underlying window to an unobscured portion of the underlying window. Thus, the claim is directed to a process, which is one of the statutory categories of invention (*Step 1: YES*).

Next, the claim must be analyzed to determine whether it is directed to a judicial exception. Here, the claimed method relates to addressing a problem with overlapping windows within a graphical user interface. In particular, the claim recites dynamically relocating textual information within a window displayed in a graphical user interface based upon a detected overlap condition. When the windows overlap, textual information is reformatted and relocated to an unobscured portion of the underlying window; when the windows no longer overlap, the textual information is returned to its original format and location. The claim does not recite a basic concept that is similar to any abstract idea previously identified by the courts. For example, the claim does not recite any mathematical concept or a mental process such as comparing or categorizing information that can be performed in the human mind, or by a human using a pen and paper. Accordingly, the claim does not set forth or describe an abstract idea. Instead, the claimed method is necessarily rooted in computer technology to overcome a problem specifically arising in graphical user interfaces. Additionally, the claim does not recite any other judicial exception. Therefore, the claim is not directed to a judicial exception *(Step 2A: NO)*. The claim is patent eligible.

If the examiner believes that the record would benefit from clarification, remarks could be added to an Office action or reasons for allowance indicating that the claim is not directed to any judicial exception.

Claim 2: Ineligible.

The claim is directed to a series of steps for calculating a scaling factor, and thus is a process which is a statutory category of invention (*Step 1: YES*).

The claim is then analyzed to determine whether it is directed to any judicial exceptions. The claim recites the steps of calculating a first area and a second area and using the areas to calculate a scaling factor. This concept is similar to the other types of basic concepts that have been found by the courts to be abstract. In particular, the courts have found mathematical algorithms to be abstract ideas (*e.g.*, a mathematical procedure for converting one form of numerical representation to another in *Benson*, or an algorithm for calculating parameters indicating an abnormal condition in *Grams*). Therefore, the claim is directed to an abstract idea *(Step 2A: YES)*.

Next, the claim is analyzed to determine whether there are additional limitations recited in the claim that amount to significantly more than the abstract idea, either individually or as an ordered combination. The body of the claim does not recite any additional limitations besides the mathematical algorithm for calculating a scaling factor. However, the preamble of the claim does provide the additional limitations that the process is computer-implemented and textual information is contained in a window in a graphical user interface. These limitations indicate the claimed process is used in a graphical user interface environment. Where the preamble only states the purpose or the field of use of an invention, the preamble does not limit the scope of the claim. Such a limitation does not give "life, meaning and vitality to the claim." (*See MPEP 2111.02.)* Therefore, the limitations in the preamble do not limit the claim and there are no additional limitations beyond the mathematical algorithm. Therefore, the claim does not amount to significantly more than the abstract idea itself *(Step 2B: NO).* The claim is not patent eligible.

A rejection of claim 2 should identify the exception by pointing to the generating and scaling steps and explain that the steps are a mathematical algorithm similar to those found by the courts to be abstract. The rejection should also note that the preamble does not limit the scope of the claim and, therefore, there are no additional limitations in the claim besides the abstract idea.

Claim 3: Ineligible.

The claim is directed to a series of steps for calculating a scaling factor, and thus is a process which is a statutory category of invention (*Step 1: YES*).

The claim is then analyzed to determine whether it is directed to any judicial exceptions. The claim recites the steps of calculating a first area and a second area and using the areas to calculate a scaling factor. As discussed above, these steps describe a mathematical algorithm which has been found by the courts to be an abstract idea. Therefore, the claim is directed to an abstract idea *(Step 2A: YES)*.

The claim is then analyzed to determine whether it is directed to any judicial exceptions. The claim recites that the step of calculating a scaling factor is performed by "the computer" (referencing the computer recited in the preamble). Such a limitation gives "life, meaning and vitality" to the preamble and, therefore, the preamble is construed to further limit the claim. (*See MPEP 2111.02.)* Thus, the claim recites the additional limitations that

the mathematical algorithm is implemented by a computer in a graphical user interface environment. However, the mere recitation of "computer-implemented" is akin to adding the words "apply it" in conjunction with the abstract idea. Such a limitation is not enough to qualify as significantly more. With regards to the graphical user interface limitation, the courts have found that simply limiting the use of the abstract idea to a particular technological environment is not significantly more. *(See, e.g., Flook.*) Even though the disclosed invention may improve computer technology, the claimed invention provides no meaningful limitations such that this improvement is realized. Therefore, the claim does not amount to significantly more than the abstract idea itself *(Step 2B: NO).* The claim is not patent eligible.

A rejection of claim 3 should identify the exception by pointing to the generating and scaling steps and explain that the steps are a mathematical algorithm similar to those found by the courts to be abstract. The rejection should also note that the preamble is limiting on the scope of the claim, but the additional limitations do not amount to significantly more because they merely require the abstract idea to be performed by a computer and in a particular technological environment.

<u>Claim 4: Eligible.</u>

As discussed above, the claim recites a series of acts and thus is a process *(Step 1: YES).*

Next, the claim is evaluated to determine if the claim is directed to a judicial exception. The claim recites similar steps to those recited in claim 2; notably calculating a first measure of the area of a first window and a second measure of the area of the unobstructed portion of the first window and calculating a scaling factor that is proportional to the difference between the first and second measure. As explained with regards to claim 2, the courts have previously found mathematical algorithms to be abstract ideas. Therefore, the claim is directed to an abstract idea *(Step 2A: YES).*

The claim must be analyzed to determine if the claim recites additional limitations that amount to significantly more than the abstract idea. The claim recites the additional limitations of a computer screen and processor. The recitation of the computer screen for displaying and the processor for moving data is not enough by itself to transform the exception into a patentable invention, because these limitations are generic computer components performing generic computer functions at a high level of generality. Merely using these generic computer components to perform the identified basic functions does not constitute meaningful limitations that would amount to significantly more than the abstract idea.

However, when viewing these computer limitations as an ordered combination with the remaining limitations, the claim amounts to significantly more than the abstract idea. The claim further recites the limitations of displaying a first and second window, detecting an overlap condition indicating the windows overlap such that textual information in the first window is obscured from view, determining the textual information is too large to fit in an unobstructed portion of the first window, scaling the textual information based upon the calculated scale factor, automatically relocating the scaled textual information to an unobstructed portion of the first window so that it is viewable by the user, and automatically returning the textual information to its original format when the overlap

condition no longer exists. These limitations are not merely attempting to limit the mathematical algorithm to a particular technological environment. Instead, these claim limitations recite a specific application of the mathematical algorithm that improves the functioning of the basic display function of the computer itself. As discussed above, the scaling and relocating the textual information in overlapping windows improves the ability of the computer to display information and interact with the user.

Taking all the claim elements both individually and as an ordered combination, the claim as a whole amounts to significantly more than the mathematical algorithm of calculating a scaling factor *(Step 2B: YES)*. Thus, the claim recites patent eligible subject matter.

If the examiner believes that the record would benefit from clarification, remarks could be added to an Office action or reasons for allowance indicating that the claim recites a mathematical algorithm which is an abstract idea. However, the claim is eligible because it recites additional limitations that when considered as an ordered combination demonstrate an improvement to the computer's basic ability to display information and interact with the user.

24. Updating Alarm Limits

The following claim was held ineligible by the Supreme Court in Parker v. Flook, 437 U.S. 584 (1978) (Flook). The claim is directed to an abstract idea, and has additional elements that do not amount to significantly more than the abstract idea. This exemplary analysis illustrates a rejection of the claim using the 2014 IEG analysis.

Background

Applicant has invented a method for updating alarm limits using mathematical formulae. An "alarm limit" is a number. During catalytic conversion processes, operating conditions such as temperature, pressure, and flow rates are constantly monitored. When any of these "process variables" exceeds a predetermined alarm limit, an alarm may signal the presence of an abnormal condition indicating either inefficiency or perhaps danger. At certain points in the catalytic conversion processes, it may be necessary to update the alarm limits periodically.

Applicant's patent application describes a method of updating alarm limits consisting of three steps that are known in the art: an initial step which merely measures the present value of the process variable (*e.g.*, the temperature); an intermediate step which calculates an updated alarm-limit value; and a final step in which the actual alarm limit is adjusted to the updated value. Applicant also describes mathematical formulae used to calculate the updated alarm-limit value in the second step, which were discovered by applicant and are expressed as

> $B_1 = B_0(1.0-F) + PVL(F)$, where B_1 is the new alarm base, B_0 is the current alarm base, F is a weighting factor greater than zero and less than 1.0, and PVL is the present value of a process variable (*e.g.*, temperature); and
>
> $UAV = B_1 + K$, where UAV is the updated alarm limit, and K is a predetermined alarm offset that represents a margin of safety.

Using the formulae, an operator can calculate an updated alarm limit once he knows the original alarm base, the appropriate margin of safety, the time interval that should elapse between each updating, the current temperature (or other process variable), and the appropriate weighting factor to be used to average the original alarm base and the current temperature. The formulae for updating alarm limits are used in a catalytic conversion processing system; however, applicant's specification contains no disclosure relating to that system, such as the chemical processes at work, the monitoring of process conditions, the determination of variables in the formulae from process conditions, or the means of setting off an alarm or adjusting an alarm system. Applicant's specification makes it clear that the method is implemented on a computer for automatic adjustment of alarm settings.

Claim

1. A method for updating the value of at least one alarm limit on at least one process variable involved in a process comprising the catalytic chemical conversion of hydrocarbons wherein said alarm limit has a current value of B_0+K wherein B_0 is the current alarm base and K is a predetermined alarm offset which comprises:

(1) Determining the present value of said process variable, said present value being defined as PVL;

(2) Determining a new alarm base B_1, using the following equation:

$B_1 = B_0(1.0-F) + PVL(F)$

where F is a predetermined number greater than zero and less than 1.0;

(3) Determining an updated alarm limit which is defined as B_1+K; and thereafter

(4) Adjusting said alarm limit to said updated alarm limit value.

Analysis

Claim 1: Ineligible.

The claim is analyzed for eligibility in accordance with its broadest reasonable interpretation, which here covers performance of the method by hand or by a computer.

The claim recites a series of acts including determining the value of a process variable, calculating a new alarm base and an updated alarm limit, and adjusting the alarm limit to the updated alarm limit value. Thus, the claim is directed to a process, which is one of the statutory categories of invention (*Step 1: YES*).

The claim is then analyzed to determine whether it is directed to any judicial exception. The claim recites a formula for updating alarm limits that comprises the limitations of calculating the alarm base using the mathematical formula $B_1 = B_0(1.0-F) + PVL(F)$, and then calculating the updated alarm limit (UAV) using the mathematical formula $UAV=B_1+K$. These limitations set forth a judicial exception, because mathematical relationships have been characterized by the courts as abstract ideas (*e.g.,* the mathematical formula in

Mackay Radio). It should be noted that in this case, the formula is novel, yet is an abstract idea. Thus, the claim is directed to an exception (*Step 2A: YES*).

Next, the claim as a whole is analyzed to determine whether any element, or combination of elements, is sufficient to ensure that the claim amounts to significantly more than the exception. The claim recites additional elements/steps of determining the value of an unspecified process variable involved in catalytic chemical conversion of hydrocarbons and adjusting the alarm limit to the calculated updated alarm limit value. The preamble specifies the field of use, which is catalytic conversion of hydrocarbons, but in this case imposes no limits on the process of calculating an alarm limit value using the specified equation.

Taken alone, none of the additional elements amounts to significantly more than the exception. Determining the value of an unspecified process variable is mere data gathering and the claimed adjusting the alarm limit to an updated limit is mere post-solution activity that could be attached to almost any formula. By failing to explain how the process variable is selected, integrate the formula into any specified chemical processes at work in the catalytic conversion, or specify the means of setting off an alarm or adjusting the alarm limit, the claim fails to improve the recited technological field. The steps merely calculate a result using a novel equation and do not add any meaningful limits on use of the equation. Taken alone or as an ordered combination, these additional elements do not amount to a claim as a whole that is significantly more than the exception. (*Step 2B: NO*). The claim is not eligible.

For purposes of discussion, it is noted that if the broadest reasonable interpretation of this claim were limited to a computer implementation, adding a generic computer to perform generic functions that are well-understood, routine and conventional, such as gathering data, performing calculations, and outputting a result would not transform the claim into eligible subject matter. Generic computer-implementation of the method is not a meaningful limitation that alone can amount to significantly more than the exception. Moreover, when viewed as a whole with such additional elements considered as an ordered combination, the claim modified by adding a generic computer would be nothing more than a purely conventional computerized implementation of applicant's formula in the general field of industrial chemical processing and would not provide significantly more than the judicial exception itself.

A rejection of claim 1 should identify the exception by pointing to the formula in the claim and explain that the formula is a mathematical relationship similar to those found by the courts to be abstract. The rejection should also identify the additional elements in the claim and explain why they do not amount to significantly more, in this case, because they merely add data gathering and a field of use.

25. Rubber Manufacturing

The following illustrates an exemplary analysis using the 2014 IEG for actual and hypothetical claims modeled after the technology in Diamond v. Diehr, 450 U.S. 175 (1981) (Diehr). As the claims in this example are eligible, no written analysis would be provided in an Office action. The application at issue was granted as U.S. Patent No. 4,344,142. Actual claim

1 recites a method that is directed to a mathematical relationship and steps that could be performed mentally and has additional elements/steps that amount to significantly more than the abstract ideas because as a whole they transform a particular article to a different state or thing and use the abstract ideas to improve another technology/technical field, either of which can show eligibility. Claim 2 is a hypothetical claim in the form of computerized instructions. Claim 2, which also is directed to the mathematical relationship and steps that could be performed mentally, is eligible due to the additional elements/steps that use the abstract ideas to improve another technology/technical field.

Background

Applicant has invented a process of controlling a rubber molding press with a computer to precisely shape uncured material under heat and pressure and then cure the synthetic rubber in the mold to obtain a product that retains its shape. Raw (uncured) synthetic rubber comprises independent polymeric chains, *e.g.,* a mixture of isobutylene and isoprene polymers. Curing cross-links the polymeric chains together, thereby changing the rubber from its raw state into a more durable form that will retain a molded shape. Proper curing depends upon several factors including the thickness of the article to be molded, the temperature of the molding process, and the amount of time that the article is allowed to remain in the press.

At the time of applicant's invention, the usual way of operating rubber-molding presses is for the operator to load and close the press manually. Closure of the press operates a timer that is preset for an estimated cure time. Due to the manual operation, the actual mold temperature may vary, and result in overcured or undercured rubber because the preset time is not equivalent to the actual time required for proper curing.

In the instant application, applicant's process improves upon conventional molding processes by constantly measuring the actual temperature inside the mold using a thermocouple, and automatically feeding these temperature measurements into a standard digital computer that repeatedly recalculates the cure time by use of the Arrhenius equation. The Arrhenius equation has long been used to calculate the cure time in rubber-molding processes, and can be expressed as $\ln v = CZ+x$, where ln is natural logarithm conversion data, v is the total required cure time, C is the activation energy constant unique to each batch of said compound being molded, Z is the temperature of the mold, and x is a constant dependent upon the geometry of the particular mold of the press. When the recalculated time equals the actual time that has elapsed since the press was closed, the computer signals a device to open the press. Applicant's process obtains uniformly accurate cures, which results in substantially reducing the number of defectively cured batches that must be discarded. The improved process also substantially reduces the amount of time in which the presses are closed unnecessarily, thereby resulting in more efficient employment of the mold and operator.

Claims

1. A method of operating a rubber-molding press for precision molded compounds with the aid of a digital computer, comprising:

providing said computer with a data base for said press including at least, natural logarithm conversion data (ln), the activation energy constant (C) unique to each batch of

said compound being molded, and a constant (x) dependent upon the geometry of the particular mold of the press,

initiating an interval timer in said computer upon the closure of the press for monitoring the elapsed time of said closure,

constantly determining the temperature (Z) of the mold at a location closely adjacent to the mold cavity in the press during molding,

constantly providing the computer with the temperature (Z),

repetitively calculating in the computer, at frequent intervals during each cure, the Arrhenius equation for reaction time during the cure, which is $\ln v = CZ+x$, where v is the total required cure time,

repetitively comparing in the computer at said frequent intervals during the cure each said calculation of the total required cure time calculated with the Arrhenius equation and said elapsed time, and

opening the press automatically when a said comparison indicates equivalence.

2. A non-transitory computer readable medium with computer executable instructions stored thereon executed by a processor to perform the method of controlling a rubber-molding press having a mold with a cavity for precision molded compounds, the method comprising:

accessing a data base in the computer including at least, natural logarithm conversion data (ln), the activation energy constant (C) unique to each batch of said compound being molded, and a constant (x) dependent upon the geometry of the particular mold of the press,

initiating an interval timer in the computer upon the closure of the press for monitoring the elapsed time of the closure,

constantly receiving data relating to the temperature (Z) of the mold at a location closely adjacent to the mold cavity in the press during molding,

repetitively calculating in the computer, at frequent intervals during each cure, the Arrhenius equation for reaction time during the cure, which is $\ln v = CZ + x$ where v is the total required cure time,

repetitively comparing in the computer at the frequent intervals during the cure each calculation of the total required cure time calculated with the Arrhenius equation and the elapsed time, and

initiating a signal that controls the press to open when the comparison indicates equivalence, meaning that the molded product is cured.

Analysis

Claim 1: Eligible.

The claim recites a series of acts including determining the temperature of the mold and providing that temperature to the computer. Thus, the claim is directed to a process, which is one of the statutory categories of invention (*Step 1: YES*).

The claim is then analyzed to determine whether it is directed to any judicial exception. The claim recites a limitation of repetitively calculating the Arrhenius equation (the mathematical formula: ln v = CZ+x) for reaction time during the cure. This limitation sets forth a judicial exception, because calculating the reaction time using the Arrhenius equation is a mathematical relationship that the courts have held is representative of a law of nature (*e.g.*, the mathematical formula in *Flook*). Mathematical relationships such as this have also been characterized by the courts as abstract ideas. Additionally, the claim limitations of performing repetitive calculations and comparisons between the calculated time and the elapsed time could be performed by a human using mental steps or basic critical thinking, which are types of activities that have also been found by the courts to represent abstract ideas (*e.g.*, the mental comparison in *Ambry Genetics*). Thus, the claim is directed to at least one exception (*Step 2A: YES*).

Next, the claim as a whole is analyzed to determine whether any additional element, or combination of elements, is sufficient to ensure that the claim amounts to significantly more than the exceptions (the mathematical relationship and the critical thinking steps of calculating and comparing). Since there are multiple abstract ideas recited in the claim, the Step 2B analysis needs to be conducted for each abstract idea individually, until the analysis shows ineligibility for one or eligibility for all.

The Step 2B analysis is first conducted for the mathematical relationship. Besides the mathematical relationship, the claim recites additional elements of providing a digital computer with a data base of values, initiating an interval timer, constantly determining the temperature of the mold, constantly providing the computer with the temperature, using the computer to perform the calculations and comparisons, and opening the press automatically when the comparison indicates equivalence. Some of the additional elements/steps, such as accessing a database and using a computer to perform calculations and comparisons, are routine computer activities or generic functions performed by a computer that taken alone do not add significantly more to the process instructions in the claim. By themselves, these limitations are recited at a high level of generality and perform the basic functions of a computer that are well-understood, routine and conventional (*e.g.*, accessing a data base to receive and store data, and performing mathematical operations on a computer). Likewise, initiating a timer and determining a temperature, taken alone, are mere data gathering steps to obtain data necessary to calculate the time using the Arrhenius equation.

However, when viewing the claim as a whole, the combination of all these steps taken together, including the constant determination of the temperature of the mold, the repetitive calculations and comparisons, and the opening of the press based on the calculations, amount to significantly more than simply calculating the mold time using the Arrhenius equation because they add meaningful limits on use of the equation. The claim

does not merely recite the equation in isolation, but integrates these ideas into the molding process. The additional steps specifically relate to the particular variables used, how the variables are gathered, the process by which the rubber is molded and cured, and how the result of the cure time calculation is used. The totality of the steps act in concert to improve another technical field, specifically the field of precision rubber molding, by controlling the operation of the mold. In addition, the claimed steps taken as a combination effect a transformation of the raw, uncured synthetic rubber into a different state or thing, *i.e.*, a cured and molded rubber product. Thus, the claim amounts to significantly more than the mathematical relationship (*i.e.*, the abstract idea of the Arrhenius equation).

Because the claim is eligible with respect to the first abstract idea, it is expected that the additional limitations will amount to significantly more than the second abstract idea (the critical thinking steps of calculating and comparing). This is true in this example. The additional limitations discussed above are significantly more than the critical thinking skills of calculating and comparing results. As previously stated, evaluating the additional limitations both individually and as an ordered combination demonstrates that the claim improves the technical field of precision rubber molding and transforms the raw, uncured synthetic rubber into a different state or thing. Taking all the claim elements both individually and as an ordered combination, the claim as a whole amounts to significantly more than the abstract ideas (*Step 2B: YES*). The claim recites patent eligible subject matter.

If the examiner believes that the record would benefit from clarification, remarks could be added to an Office action or reasons for allowance indicating that the claim recites exceptions including the Arrhenius equation, which is a law of nature or abstract idea. However, the claim is eligible because it recites additional limitations that when considered as an ordered combination provide meaningful limits on the use of the equation and improve the technical field of precision rubber molding.

<u>Claim 2: Eligible.</u>

The claim recites a non-transitory computer-readable medium with stored instructions that are used to control a rubber molding press. The claim is directed to a manufacture (an article produced from materials), which is a statutory category of invention (*Step 1: YES*). Note that the term "non-transitory" ensures the claim does not encompass signals and other non-statutory transitory forms of signal transmission.

The claim recites the same steps of performing repetitive calculations of the reaction time using the Arrhenius equation and comparing the results as claim 1, albeit in the form of computer executable instructions. Therefore, the claim is directed to the same abstract ideas identified in claim 1 (*Step 2A: YES*).

Conducting the Step 2B analysis for the first abstract idea (the Arrhenius equation), the claim recites additional elements including computer instructions to access a database, initiate an interval timer, constantly receive data, and initiate a signal to control the press. The steps also include computer instructions to implement the equation. While some of the elements taken alone are well-understood, routine and conventional use of a computer, or mere data gathering, the combination of the additional elements when the claim is viewed as a whole amounts to significantly more than simply calculating the mold time using the

Arrhenius equation. The totality of the steps governed by the claimed instructions provides software that improves another technical field, specifically the field of precision rubber molding, through controlling the operation of the mold by initiating a signal to control the press to open when the comparison indicates equivalence and the molded product is cured. This software enhances the ability of a specific rubber molding device to open the press at the optimal time for curing the rubber therein. This process does not merely link the Arrhenius equation to a technical field, but adds meaningful limitations on the use of the mathematical relationship by specifying the types of variables used (temperature and time), how they are selected (their relationship to the reaction time), how the process uses the variables in rubber molding, and how the result is employed to improve the operation of the press. For at least these reasons, the elements/steps recited in addition to the mathematical formula, particularly taken in combination, show that claim 2 is not directed to instructions to use the formula in isolation, but rather integrate the concept into an eligible control scheme to improve another technological process.

Similarly, the claim recites additional limitations that when viewed as an ordered combination amount to significantly more than the second abstract idea (the critical thinking steps of calculating and comparing the timing data). As already discussed, these additional limitations demonstrate an improvement in the field of precision rubber molding technology and amount to more than simple instructions to perform the calculating/comparing steps in isolation. Thus, the claim amounts to significantly more than the judicial exceptions (*Step 2B: YES*). The claim recites patent eligible subject matter.

If the examiner believes that the record would benefit from clarification, remarks could be added to an Office action or reasons for allowance indicating that the claim recites exceptions including the Arrhenius equation, which is a law of nature or abstract idea. However, the claim is eligible because it recites additional limitations that when considered as an ordered combination provide meaningful limits on the use of the equation and improve the technical field of precision rubber molding.

26. Internal Combustion Engine

This hypothetical example demonstrates the use of the streamlined analysis. The claim below is based on the technology from U.S. Pat. 5,533,489. As a streamlined analysis would not result in a written rejection, the discussion sets forth exemplary reasoning an examiner might use in drawing a conclusion of eligibility.

<u>Background</u>

Nitrogen oxides are constituents of exhaust gas that are produced during the operation of an internal combustion engine. It is generally understood that nitrogen oxides are harmful to our atmosphere and cause air pollution. The amount of nitrogen oxides produced in the exhaust gas is relative to the temperature that the fuel and air mixture burns in the engine. Therefore, exhaust gas recirculation (EGR) has been developed to recirculate the exhaust gas back to the air intake, which reduces the amount of oxygen in the combustion mixture and causes it to burn at a lower temperature, thereby reducing the amount of nitrogen oxides produced. However, as the amount of EGR increases there may be a resulting decline in engine performance (*e.g.*, a decrease in power output).

The invention is an internal combustion engine that solves this problem by automatically modifying the amount of EGR based upon current engine operations. In particular, the inventor has discovered that engine performance can be optimized by turning off the EGR during acceleration, which permits the engine to operate at maximum power output while retaining the reduction in nitrogen oxides. Therefore, the invention uses a control system to control the opening and closing of an exhaust gas recirculation valve based upon a rate of change of the engine throttle, in order to modify the amount of EGR.

Claim

1. An internal combustion engine providing exhaust gas recirculation comprising:

an air intake manifold;

an exhaust manifold;

a combustion chamber to receive air from the air intake manifold, combust a combination of the received air and fuel to turn a drive shaft, and output resulting exhaust gas to the exhaust manifold;

a throttle position sensor to detect the position of an engine throttle;

an exhaust gas recirculation valve to regulate the flow of exhaust gas from the exhaust manifold to the air intake manifold; and

a control system, comprising a processor and memory, to receive the engine throttle position from the throttle position sensor, calculate a position of the exhaust gas recirculation valve based upon the rate of change of the engine throttle position and change the position of the exhaust gas recirculation valve to the calculated position.

Analysis

Claim 1: Eligible.

The claim recites an internal combustion engine with an intake manifold, exhaust manifold, combustion chamber, throttle position sensor, exhaust gas recirculation valve and a control system comprising a processor and memory. Thus, the claim is directed to a machine (a combination of mechanical parts), which is one of the statutory categories of invention (*Step 1: YES*).

Next, the claim must be evaluated to determine if the claim is directed to a law of nature, natural phenomenon or abstract idea. But when the claim is reviewed, it is immediately evident that although the claim operates by calculating the rate of change, which is a mathematical relationship describing how a variable changes over a specific period of time, the claim clearly does not seek to tie up this mathematical relationship so that others cannot practice it. In particular, the claim's description of an internal combustion engine having manifolds, valves, and sensors forming a specific structure that uses the control system to optimize exhaust gas recirculation makes it clear that the claim as a whole would clearly amount to significantly more than any recited exception. The claim as a whole adds meaningful limitations to the use of the mathematical relationship. Additionally, use of the mathematical relationship improves engine technology. Thus, eligibility of the claim is self-

evident, and there is no need to perform the full eligibility analysis (*e.g.*, Steps 2A and 2B). The claim is patent eligible.

If the examiner believes that the record would benefit from clarification, remarks could be added to an Office action or reasons for allowance indicating that while the claim may recite a mathematical relationship, the claim clearly amounts to significantly more than the rate of change by providing meaningful limitations to the mathematical relationship and improving engine technology.

27. System Software - BIOS

This example demonstrates the use of the streamlined analysis. The claim below is taken from U.S. Pat. 5,230,052 and was suggested as an example by comments received in response to the June 2014 Preliminary Examination Instructions. As a streamlined analysis would not result in a written rejection, the discussion sets forth exemplary reasoning an examiner might use in drawing a conclusion of eligibility.

Background

BIOS is an acronym that stands for Basic Input/Output System. When a computer is powered on, BIOS code runs to initialize and test the hardware components. BIOS also acts as an insulation layer between the hardware and software of a computer, by providing an interface between the application program/operating system and the hardware devices. At the time of the invention, conventional computers stored BIOS code in non-volatile read only memory (ROM) on the computer's motherboard. However, as computers have grown more sophisticated, two disadvantages have arisen. First, the size of the BIOS code has increased such that it exceeds the memory space in ROM. Second, storing BIOS code in ROM also makes it difficult to modify or rewrite the code as new input/output devices are added.

In order to overcome these disadvantages, the inventors utilize a local area network (LAN) to store the BIOS code remotely from the computer. Upon startup, a computer connected to the LAN loads code to initialize and test only those system components and functions necessary to load the BIOS from a remote computer. Subsequently, the computer requests a remote memory location, which is also connected to the LAN, for the BIOS code. In response to the request, the remote system builds the appropriate BIOS for that computer including a master boot record and transmits the BIOS to the local computer system. The local computer system stores the received BIOS code in random access memory (RAM), and uses the master boot record to load and execute the BIOS.

Claim

15. A method for loading BIOS into a local computer system which has a system processor and volatile memory and non-volatile memory, the method comprising the steps of:

(a) responding to powering up of the local computer system by requesting from a memory location remote from the local computer system the transfer to and storage in the

volatile memory of the local computer system of BIOS configured for effective use of the local computer system,

(b) transferring and storing such BIOS, and

(c) transferring control of the local computer system to such BIOS.

Analysis

Claim 15: Eligible.

The claim recites a series of steps for loading BIOS on a local computer system from a remote storage location. Thus, the claim is directed to a process, which is one of the statutory categories of invention (*Step 1: YES*).

Next, the claim must be evaluated to determine if the claim is directed to a law of nature, natural phenomenon or abstract idea. But when the claim is reviewed, it is immediately evident that even if the claim did recite a judicial exception, the claim is not attempting to tie up any such exception so that others cannot practice it. In particular, the claim's description of initializing a local computer system using BIOS code stored at a remote memory location, by triggering the processor to transfer BIOS code between two memory locations upon a powering up of the computer and transferring control of the processor operations to that BIOS code, makes it clear that the claim as a whole would clearly amount to significantly more than any potential recited exception. Thus, eligibility of the claim is self-evident in the streamlined analysis, without needing to perform the full eligibility analysis (*e.g.*, Steps 2A and 2B). The claim is patent eligible.

It is important to point out as well that there is no apparent exception recited in the claim, which alone would be sufficient for eligibility. While computers operate on mathematical theory, that underlying operation should not trigger an eligibility analysis – computers and computer operations are not automatically subjected to an eligibility analysis. The cases in which courts find mathematical relationships to represent abstract ideas (thus raising eligibility issues) are those in which the mathematical relationship is recited in the claim as part of the invention, such as a method of performing a mathematical calculation to obtain a result. Courts have found computers and computer implemented processes to be ineligible when generic computer functions are merely used to implement an abstract idea, such as an idea that could be done by human analog (*i.e.*, by hand or by merely thinking).

If the examiner believes that the record would benefit from clarification, remarks could be added to an Office action or reasons for allowance, indicating that the claim is not directed to any judicial exception.

The following examples should be used in conjunction with the *2014 Interim Guidance on Subject Matter Eligibility* (2014 IEG). As the examples are intended to be illustrative only, they should be interpreted based on the fact patterns set forth below. Other fact patterns may have different eligibility outcomes. While some of the fact patterns draw from U.S. Supreme Court or U.S. Court of Appeals for the Federal Circuit decisions, each of the examples shows how claims should be analyzed under the 2014 IEG. All of the claims are analyzed for eligibility in accordance with their broadest reasonable interpretation.

Note that the examples herein are numbered consecutively beginning with number 28, because 27 examples were previously issued. A comprehensive index of all examples for use with the 2014 IEG is provided in the attached appendix (which is an updated version of Appendix 2 to the July 2015 Update).

28. Vaccines

This example illustrates the application of the markedly different characteristics and significantly more analyses to claims reciting hypothetical nature-based products. It also illustrates the importance of applying the broadest reasonable interpretation in the eligibility analysis, and how that interpretation assists in the identification of appropriate naturally occurring counterparts of claimed nature-based products. Hypothetical claims 1, 2 and 4-6 are eligible in Step 2A, because the claimed nature-based products have markedly different characteristics from what exists in nature. Hypothetical claim 3 is ineligible, because the claimed nature-based product lacks markedly different characteristics from what exists in nature, and the claim fails to amount to significantly more than the exceptions. Hypothetical claim 7 is eligible in Step 2B, because although the claim is directed to an exception, it recites a particular and unconventional device that amounts to significantly more than the exception.

Background

Applicant discloses an influenza A viral strain, which was named the "Pigeon flu" because it was discovered in pigeons. Applicant filed an application disclosing several types of Pigeon flu vaccines, and evaluating their functional characteristics (such as immunogenicity) in terms of their seroprotection rate, *i.e.*, the percentage of vaccinated patients who developed immunity to the Pigeon flu. The disclosed vaccines include:

- Vaccines comprising "live attenuated Pigeon flu virus", which the specification defines as a live mutant virus that has been attenuated so that it has at least one mutation (*i.e.*, a change in the nucleotide sequence) of its polymerase gene, which reduces its virulence as compared to naturally occurring Pigeon flu virus. No mutations of this polymerase gene are known to occur in nature. Applicant created this mutant attenuated virus by isolating Pigeon flu virus from infected pigeons, and passaging the isolated virus through a cell culture at least 50 times until the desired mutation occurred. The live attenuated Pigeon flu virus is safe (unable to cause disease in pigeons or other test animals) and strongly immunogenic, *e.g.*, it has a high seroprotection rate of about 85%.
- Vaccines comprising "inactivated Pigeon flu virus", which the specification defines as a dead virus that is formalin-inactivated, *i.e.*, the naturally occurring Pigeon flu virus was contacted with a chemical solution called formalin that causes structural changes to the virus (*e.g.*, it chemically modifies the viral nucleic acids in a manner that does not occur in nature) so that it can no longer reproduce. Because the inactivated virus can no longer replicate, it is unable to cause disease in pigeons or other test animals, but it is still strongly immunogenic, *e.g.*, it has a high seroprotection rate of about 75%.

- Vaccines comprising Peptide F (a naturally occurring peptide isolated from the Pigeon flu virus) either alone or mixed with a pharmaceutically acceptable carrier such as water. Prior to applicant's invention, and at the time of filing the application, water was routinely and conventionally used as a carrier for peptide vaccines. Isolation does not change any structural or functional characteristics of Peptide F. Applicant discloses vaccines where the suitable pharmaceutically acceptable carrier is selected from a group consisting of a cream, emulsion, gel, liposome, nanoparticle, or ointment. Applicant discloses that although the carriers in this group comprise naturally occurring components (such as water and oil), when the components are assembled into the carrier form, the carrier has changed structural and physical characteristics that distinguish it from the closest counterpart in nature. *E.g.*, a pharmaceutically acceptable cream comprising water and vegetable oil has a form (a semi-solid homogeneous emulsion) that is structurally and physically distinct from the water and oil in nature. These vaccines are weakly immunogenic, *e.g.*, they have a low seroprotection rate of about 30%, meaning that many people who are vaccinated with these vaccines will not develop immunity to the Pigeon flu.
- Vaccines comprising Peptide F mixed with aluminum salt adjuvants (a well-known class of adjuvants) such as aluminum phosphate ($AlPO_4$). While many of these adjuvants including aluminum phosphate are naturally occurring, none of them occur together with Peptide F in nature. Adjuvants are commonly added to vaccines in order to improve their functional characteristics, *e.g.*, by increasing the strength of the immune response that the vaccines produce (immunogenicity). The amount of adjuvant sufficient to increase a vaccine's immunogenicity to a level high enough to effectively vaccinate a typical patient is called the "immuno-effective amount", and those skilled in the art understand that this amount may vary depending on the particular adjuvant and formulation selected. Adjuvants can increase immunogenicity in several ways, such as by slowing the release of Peptide F to tissue around the injection site, and/or by improving the delivery of Peptide F to the patient's lymph nodes. On their own or combined with water or other common carriers, Peptide F induces only a weak protective immune response to Pigeon flu virus (seroprotection rate of 30%), and the adjuvants do not induce any protective immune response to Pigeon flu virus (seroprotection rate of 0%). When immuno-effective amounts of the disclosed adjuvants are combined with Peptide F, however, the combined vaccine induces a strong immune response to Pigeon flu virus (seroprotection rate of 80%).

Applicant also discloses vaccine delivery devices comprising coated microneedle arrays for delivery of a vaccine comprising Peptide F. Prior to applicant's invention, and at the time the application was filed, it was routine and conventional in the field to use syringes, but not coated microneedle arrays, for vaccine delivery. A pre-filled syringe is a tube that has been loaded with a vaccine dose prior to distribution of the vaccine to health professionals. The syringe can be fitted with a hollow needle about 5/8" to 1.5" long to administer the vaccine subcutaneously or intramuscularly. A coated microneedle array comprises a plurality of very small solid needles (e.g., less than 0.05" long) that are coated with a vaccine formulation, which is placed against a patient's skin to administer the vaccine into the skin (transcutaneously). Because the microneedles are very small, administration of a vaccine with a microneedle array is virtually painless.

<u>Claims</u>

1. A vaccine comprising live attenuated Pigeon flu virus.

2. A vaccine comprising inactivated Pigeon flu virus.

3. A vaccine comprising:
   Peptide F; and
   a pharmaceutically acceptable carrier.

4. A vaccine comprising:
   Peptide F; and
   a pharmaceutically acceptable carrier selected from the group consisting of a cream, emulsion, gel, liposome, nanoparticle, or ointment.

5. A vaccine comprising:
   Peptide F; and
   an immuno-effective amount of an aluminum salt adjuvant.

6. A vaccine comprising:
   Peptide F;
   an immuno-effective amount of an aluminum salt adjuvant; and
   a pharmaceutically acceptable carrier.

7. A vaccine delivery device comprising a microneedle array that is coated with a vaccine comprising Peptide F.

Analysis

Claim 1: Eligible.

The claim recites a vaccine comprising live attenuated Pigeon flu virus. Based on the plain meaning of "vaccine", and the specification's definition of "live attenuated Pigeon flu virus", the broadest reasonable interpretation of the claim is live mutant Pigeon flu virus that has been attenuated so that it has at least one mutation (*i.e.*, a change in its nucleotide sequence) that reduces its virulence as compared to naturally occurring Pigeon flu virus, in an amount sufficient to produce an immunogenic response in a typical patient. Because viruses are composed of matter, the claim is directed to a statutory category, *e.g.*, a composition of matter (*Step 1: YES*).

The claim is then analyzed to determine whether it is directed to any judicial exception. The recited live attenuated virus is a nature-based product that must be compared to its naturally occurring counterpart to determine if it has markedly different characteristics than the counterpart. Here, the closest natural counterpart is the naturally occurring Pigeon flu virus from which the live attenuated virus was mutated. When the live attenuated virus is compared to this counterpart, the comparison indicates that the live attenuated virus has a different structural characteristic (the nucleotide sequence of its polymerase gene was changed due to the mutation), which has resulted in the live attenuated virus having a different functional characteristic (reduced virulence). No mutations of this gene are known to occur in nature. Thus, under the holding in Myriad, this structural difference is a markedly different characteristic, because it causes the claimed virus to have a nucleotide sequence that is different from anything found in nature. Association for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107, 2119 (2013). While in other fact patterns, a functional change may be enough by itself to confer eligibility, for this claim the functional change is a result of the structural change and thus is inseparable from it. Because the live attenuated virus has markedly different characteristics from what exists in nature, it 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.

Note that because the analysis of this claim ends at Step 2A, the Step 2B analysis is not performed. Thus, the examiner would not need to evaluate the significantly more considerations for this claim.

If the examiner believes that the record would benefit from clarification, remarks could be added to an Office action or reasons for allowance, indicating that the claim is not directed to any judicial exception.

Claim 2: Eligible.

The claim recites a vaccine comprising inactivated Pigeon flu virus. Based on the plain meaning of "vaccine", and the specification's definition of "inactivated Pigeon flu virus", the broadest reasonable interpretation of the claim is dead Pigeon flu virus that has been structurally altered by contacting it with formalin so that its nucleic acids are chemically modified in a manner that does not occur in nature and it can no longer reproduce, in an amount sufficient to produce an immunogenic response in a typical patient. Because viruses are composed of matter, the claim is directed to a statutory category, *e.g.*, a composition of matter (*Step 1: YES*).

The claim is then analyzed to determine whether it is directed to any judicial exception. The recited inactivated virus is a nature-based product that must be compared to its naturally occurring counterpart to determine if it has markedly different characteristics than the counterpart. Here, the closest natural counterpart is the naturally occurring Pigeon flu virus. When the inactivated virus is compared to this counterpart, the comparison indicates that the inactivated virus has a different structural characteristic (its exposure to formalin has chemically modified its nucleic acids in a manner that does not occur in nature), which has resulted in the inactivated virus having different functional characteristics (inability to replicate or cause disease). Like the Chakrabarty bacterium, which had markedly different characteristics "due to the additional plasmids and resultant 'capacity for degrading oil,'" Myriad, 133 S. Ct. at 2117, the inactivated virus has markedly different characteristics, due to the non-natural chemical modification of its nucleic acids and the resultant change in the virus's ability to replicate or cause disease. While in other fact patterns, a functional change may be enough by itself to confer eligibility, for this claim the functional change is a result of the structural change and thus is inseparable from it. Because the inactivated virus has markedly different characteristics from what exists in nature, it 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.

Note that because the analysis of this claim ends at Step 2A, the Step 2B analysis is not performed. Thus, the examiner would not need to evaluate the significantly more considerations for this claim. If the examiner believes that the record would benefit from clarification, remarks could be added to an Office action or reasons for allowance, indicating that the claim is not directed to any judicial exception.

Claim 3: Ineligible.

The claim recites a vaccine comprising Peptide F and a pharmaceutically acceptable carrier. Based on the plain meaning of "vaccine" and "pharmaceutically acceptable carrier", the broadest reasonable interpretation (BRI) of the claim is a sufficient amount of Peptide F to produce an immunogenic response in a typical patient, which is mixed with a pharmaceutically sufficient amount of a carrier such as water. Thus, one embodiment within the BRI is a mixture of Peptide F and water. Because the peptide and carrier are composed of matter, the claim is directed to a statutory category, *e.g.*, a composition of matter (*Step 1: YES*).

The claim is then analyzed to determine whether it is directed to any judicial exception. The recited mixture of Peptide F and water is a nature-based product that must be compared to its closest naturally occurring counterpart to determine if it has markedly different characteristics than the counterpart. Because Peptide F and water do not occur together in nature, there is no naturally occurring counterpart mixture for comparison, and so the claimed mixture is compared to its naturally occurring components, *i.e.*, Peptide F, and water. Peptide F is naturally occurring, and water

is naturally occurring, so neither would be eligible as claimed on their own. While the mixture of these two naturally occurring components is novel and does not occur in nature, there is no indication that mixing these components changes the structure, function, or other properties of the peptide or water. For example, the claim encompasses a mixture where the peptide is heterogeneously dispersed in the water, but such heterogeneous mixing does not change the structure, function, or other properties of the peptide or the water in any marked way. Instead, the peptide retains its naturally occurring structure and function, and is merely dispersed in the water, which also retains its naturally occurring structure and function. Thus, for at least one embodiment within the broadest reasonable interpretation, the claimed mixture as a whole does not display markedly different characteristics compared to the naturally occurring counterparts. Accordingly, each component (the peptide and the carrier) is a "product of nature" exception, and the claim is directed to at least one exception (*Step 2A: YES*).

Next, the claim as a whole is analyzed to determine whether any additional element, or combination of elements, is sufficient to ensure that the claim amounts to significantly more than the exceptions. Because the component elements (the peptide and carrier "product of nature" exceptions) do not occur together in nature and are not markedly changed by their combination into a mixture, each is considered as an additional element to the other. This consideration provides an opportunity to explore whether this combination of "products of nature" amounts to significantly more than the products themselves. As discussed above, mixing the peptide with a carrier such as water does not markedly change the characteristics of either component, because each component continues to have the same properties in the mixture as it had alone. In addition, using a carrier in a peptide vaccine was well-understood, routine & conventional prior to applicant's invention and at the time of filing the application, so the mixing of the peptide and carrier, when recited at this high level of generality, does not meaningfully limit the claim. Thus, the claim as a whole does not amount to significantly more than each "product of nature" by itself (*Step 2B: NO*). The claim does not qualify as eligible subject matter.

A rejection of claim 3 should identify the exceptions by pointing to the nature-based products in the claim (the peptide and carrier) and explaining why they lack markedly different characteristics from their naturally occurring counterparts, *e.g.*, because there are no changes in structure, function, or other characteristics. The rejection should also explain that combining the peptide and carrier does not amount to significantly more than the exceptions, because their combination is well-understood, routine and conventional in the field.

If the examiner believes that it would be helpful to cite an analogous court decision, the rejection could include an explanation of how the claimed mixture is like the novel bacterial mixture of Funk Brothers, which was held ineligible because each species of bacteria in the mixture (like each component in the peptide-carrier mixture) continued to have "the same effect it always had", *i.e.*, it lacked markedly different characteristics. Funk Brothers Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 131 (1948), discussed in Myriad Genetics, 133 S. Ct. at 2117 (explaining that the bacterial mixture of Funk Brothers "was not patent eligible because the patent holder did not alter the bacteria in any way").

Claim 4: Eligible.

The claim recites a vaccine comprising Peptide F in a pharmaceutically acceptable carrier selected from the group consisting of a cream, emulsion, gel, liposome, nanoparticle, or ointment. Based on the plain meaning of "vaccine" and "pharmaceutically acceptable carrier", the broadest reasonable interpretation (BRI) of the claim is a sufficient amount of Peptide F to produce an immunogenic response in a typical patient, which is mixed with a sufficient amount of other substances to produce a carrier form suitable for administration to a patient. The BRI thus encompasses, for example, a

vaccine comprising Peptide F in a carrier that is a cream. Because the plain meaning of a "cream" in the pharmaceutical arts is a semi-solid homogeneous emulsion comprising water and oil, the recitation of a cream necessarily requires (i) the presence of water and an oil (such as naturally occurring cottonseed oil) in addition to Peptide F, and (ii) that the water and oil be structurally arranged into a homogenous emulsion to produce a semi-solid form. Thus, one embodiment within the BRI is an emulsion comprising Peptide F mixed with small uniform droplets of cottonseed oil that are homogenously dispersed in water. Because the peptide and the carrier are composed of matter, the claim is directed to a statutory category, *e.g.*, a composition of matter (*Step 1: YES*).

The claim is then analyzed to determine whether it is directed to any judicial exception. The claimed cream containing Peptide F, cottonseed oil, and water is a nature-based product that must be compared to its closest naturally occurring counterpart to determine if it has markedly different characteristics than the counterpart. Here, all three substances (the peptide, cottonseed oil, and water) do not occur together in nature, so there is no naturally occurring counterpart mixture for comparison. The mixture is therefore compared to its naturally occurring components, *i.e.*, Peptide F, cottonseed oil, and water. The claimed cream has different structural and physical characteristics than its naturally occurring components, for example the oil droplets are small, uniform in size, and homogenously dispersed in the water, which causes the resultant cream to have a semi-solid and non-flowable form at room temperature as compared to the oil and water, which are both flowable liquids at room temperature in nature. Because the oil and water are emulsified, the cream will also adhere to a patient's skin or mucous membranes much longer than oil or water in their natural non-emulsified form, thus permitting a sufficient amount of peptide to transfer from the cream into the patient's tissues where it will then stimulate an immune response. In contrast, the oil or water, if used in their natural state, would simply slide off the patient's skin after a short time. The cream's changed form and adherence are marked differences in structural and physical characteristics as compared to the natural counterparts, and therefore the cream 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.

Note that because the analysis of this claim ends at Step 2A, the Step 2B analysis is not performed. Thus, the examiner would not need to evaluate the significantly more considerations for this claim. If the examiner believes that the record would benefit from clarification, remarks could be added to an Office action or reasons for allowance, indicating that the claim is not directed to any judicial exception.

Practice Note: The BRI of claim 4 also encompasses cream embodiments in which the oil is a non-naturally occurring oil, or is a naturally occurring oil other than cottonseed oil, or in which the homogenous emulsion is a water-in-oil emulsion instead of an oil-in-water emulsion, as well as embodiments in which the carrier is something other than a cream, *e.g.*, a liposome or nanoparticle carrier. If the examiner were to analyze such embodiments for markedly different characteristics, the analysis may differ slightly due to the choice of different counterparts, but the same result of eligibility would be achieved because in every embodiment, the plain meaning of each carrier recited in the claim requires that the carrier have structural and physical characteristics that distinguish it from the closest counterpart in nature.

Claim 5: Eligible.

The claim recites a vaccine comprising Peptide F and an immuno-effective amount of an aluminum salt adjuvant. Based on the plain meaning of "vaccine" and "immuno-effective amount", the broadest reasonable interpretation (BRI) of the claim is a mixture of (i) a sufficient amount of Peptide F to produce an immunogenic response in a typical patient, and (ii) a sufficient amount of an aluminum salt adjuvant (*e.g.*, aluminum phosphate; $AlPO_4$) to increase the vaccine's immunogenicity (measured here by seroprotection rate) to a level high enough to effectively vaccinate a typical patient. Thus,

one embodiment within the BRI is a mixture of Peptide F with a sufficient amount of aluminum phosphate to increase the vaccine's immunogenicity. Because the peptide and adjuvant are composed of matter, the claim is directed to a statutory category, *e.g.*, a composition of matter (*Step 1: YES*).

The claim is then analyzed to determine whether it is directed to any judicial exception. The claimed mixture of Peptide F and aluminum phosphate is a nature-based product that must be compared to its closest naturally occurring counterpart to determine if it has markedly different characteristics than the counterpart. Because Peptide F and aluminum phosphate do not occur together in nature, there is no naturally occurring counterpart mixture for comparison, and so the claimed mixture is compared to its naturally occurring components, *i.e.*, Peptide F, and the adjuvant (*e.g.*, aluminum phosphate). There is no indication that mixing these components changes the structure of the peptide or aluminum phosphate. However, the mixture has a changed functional property, in that the immunogenicity of the mixture is different (higher) than the mere "sum" of the immunogenicity of the individual components. In other words, the peptide by itself has poor immunogenicity (30% seroprotection rate) and the adjuvant by itself has no immunogenicity (0% seroprotection rate) with respect to Pigeon flu virus, but when combined, the resultant mixture has a greatly enhanced immunogenicity (80% seroprotection rate) with respect to Pigeon flu virus. The mixture's changed immunogenicity is a marked difference in functional characteristics as compared to the natural counterparts, and therefore the mixture 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.

Note that because the analysis of this claim ends at Step 2A, the Step 2B analysis is not performed. Thus, the examiner would not need to evaluate the significantly more considerations for this claim. If the examiner believes that the record would benefit from clarification, remarks could be added to an Office action or reasons for allowance, indicating that the claim is not directed to any judicial exception.

Practice Note: The BRI of claim 5 also encompasses embodiments in which the adjuvant is a non-naturally occurring aluminum salt, or is a naturally occurring aluminum salt other than aluminum phosphate. If the examiner were to analyze such an embodiment for markedly different characteristics, the analysis may differ slightly due to the choice of different counterparts, but the same result of eligibility would be achieved because in every embodiment, the immuno-effective amount of the adjuvant will result in the claimed mixture exhibiting the same marked difference in immunogenicity described in the preceding analysis.

Claim 6: Eligible.

The claim recites a vaccine comprising Peptide F, an immuno-effective amount of an aluminum salt adjuvant, and a pharmaceutically acceptable carrier. Based on the plain meaning of "vaccine", "immuno-effective amount", and "pharmaceutically acceptable carrier", the broadest reasonable interpretation of the claim is a mixture of (i) a sufficient amount of Peptide F to produce an immunogenic response in a typical patient, (ii) a sufficient amount of an aluminum salt adjuvant (*e.g.*, aluminum phosphate; $AlPO_4$) to increase the vaccine's immunogenicity (measured here by seroprotection rate) to a level high enough to effectively vaccinate a typical patient, and (iii) a pharmaceutically sufficient amount of a carrier such as water. Thus, one embodiment within the BRI is a mixture of Peptide F, a sufficient amount of aluminum phosphate to increase the vaccine's immunogenicity, and water. Because the peptide, adjuvant, and carrier are composed of matter, the claim is directed to a statutory category, *e.g.*, a composition of matter (*Step 1: YES*).

The claim is then analyzed to determine whether it is directed to any judicial exception. The claimed mixture of Peptide F, aluminum phosphate, and water is a nature-based product that must be

compared to its closest naturally occurring counterpart to determine if it has markedly different characteristics than the counterpart. Here, all three substances (the peptide, aluminum phosphate, and water) do not occur together in nature, so there is no naturally occurring counterpart mixture for comparison. However, aluminum phosphate does occur naturally in combination with water (*e.g.*, in soil). Accordingly, the closest naturally occurring counterparts to which the claimed mixture is compared are Peptide F, and the naturally occurring water/aluminum phosphate combination. There is no indication that mixing the peptide with the water/aluminum phosphate combination changes the structure of either component, but the mixture does have a changed functional property, in that the immunogenicity of the mixture is different (higher) than the mere "sum" of the immunogenicity of the individual components. In other words, the peptide by itself has poor immunogenicity (30% seroprotection rate), and the water/aluminum phosphate combination by itself has no immunogenicity (0% seroprotection rate) with respect to Pigeon flu virus, but when combined, the resultant mixture has a greatly enhanced immunogenicity (80% seroprotection rate) with respect to Pigeon flu virus. The mixture's changed immunogenicity is a marked difference in functional characteristics as compared to the natural counterparts, and therefore the mixture 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.

Note that because the analysis of this claim ends at Step 2A, the Step 2B analysis is not performed. Thus, the examiner would not need to evaluate the significantly more considerations for this claim. If the examiner believes that the record would benefit from clarification, remarks could be added to an Office action or reasons for allowance, indicating that the claim is not directed to any judicial exception.

Practice Note: The BRI of claim 6 also encompasses embodiments in which the adjuvant is a non-naturally occurring aluminum salt, or is a naturally occurring aluminum salt other than aluminum phosphate, and embodiments in which the carrier is something other than water. If the examiner were to analyze such an embodiment for markedly different characteristics, the analysis may differ slightly due to the choice of different counterparts, but the same result of eligibility would be achieved because in every embodiment, the immuno-effective amount of the adjuvant will result in the claimed mixture exhibiting the same marked difference in immunogenicity described in the preceding analysis.

Claim 7: Eligible.

The claim recites a vaccine delivery device comprising a microneedle array that is coated with a vaccine comprising Peptide F. Based on the plain meaning of "microneedle array" and "vaccine", the broadest reasonable interpretation (BRI) of the claim is an array of small solid needles coated with a sufficient amount of Peptide F to produce an immunogenic response in a typical patient. Thus, one embodiment within the BRI is an array of small solid needles (the microneedle array) coated with Peptide F. The microneedle array is a manufacture and the peptide is composed of matter; thus, the claim is directed to at least one statutory category, *e.g.*, a manufacture and/or a composition of matter (*Step 1: YES*).

The claim is then analyzed to determine whether it is directed to any judicial exception. The microneedle array is not a nature-based product, but the Peptide F is a nature-based product that must be compared to its closest naturally occurring counterpart (naturally occurring Peptide F) to determine if it has markedly different characteristics than the counterpart in its natural state as part of the virus. There is no indication in the specification that isolation changes any structural or functional characteristics of Peptide F, or that coating the needles in the array with Peptide F results in the peptide having any characteristics (structural, functional, or otherwise) that are different from the naturally occurring peptide in its natural state. Thus, the claimed peptide does not display

markedly different characteristics compared to the naturally occurring counterpart. Accordingly, the peptide is a "product of nature" exception, and the claim is directed to at least one exception (*Step 2A: YES*).

Next, the claim as a whole is analyzed to determine whether any additional element, or combination of elements, is sufficient to ensure that the claim amounts to significantly more than the exception. Besides the exception, the claim recites an additional element of the microneedle array, which is coated with the peptide. Prior to applicant's invention, and at the time the application was filed, coated microneedle arrays were known to most scientists in the field, but were not routinely or conventionally used to administer vaccines. The conventional delivery device was a syringe that was routinely pre-filled with the vaccine. Thus, the claim's recitation of a microneedle array coated with the peptide is an application of the exception with a particular manufacture that is not a conventional delivery device, and thus is more than a mere instruction to "apply" the peptide (the exception) using a well-understood, routine or conventional device in the field. It is an unconventional limitation that confines the exception to a particular useful application of the exception. Thus, the recitation of the coated microneedle array yields a claim as a whole that amounts to significantly more than the "product of nature" exception itself (*Step 2B: YES*). The claim is eligible.

If the examiner believes that the record would benefit from clarification, remarks could be added to an Office action or reasons for allowance indicating that the peptide is a "product of nature" exception because it lacks markedly different characteristics from its naturally occurring counterpart, *e.g.*, because there are no changes in structure, function, or other characteristics. However, the claim is eligible because it recites a particular, unconventional limitation (the coated microneedle array) that confines the exception to a particular useful application, and that is more than a mere instruction to "apply" the exception using a well-understood, routine or conventional device in the field.

29. Diagnosing and Treating Julitis

This hypothetical example illustrates the application of the significantly more analysis to diagnostic and treatment claims using a hypothetical disease. Claims 1 and 7 are eligible in Step 2A, because they are not directed to any judicial exception. Claim 2 is ineligible, because it is directed to a judicial exception that could be termed either a law of nature or an abstract idea, and the recited additional elements do not amount to significantly more than the exception. Claims 3-6 are directed to the same exception, but are eligible in Step 2B because they recite specific and unconventional reagents and/or treatments that amount to significantly more than the exception.

<u>Background</u>

"Julitis" is an autoimmune disease affecting more than 17 million people in North America, which develops when the immune system mistakes normal skin cells for pathogens. Julitis causes chronic inflammation of the skin that results in an itchy and extremely painful rash on the face, hands, and feet. Conventionally, julitis is diagnosed by a physical examination of the characteristic rash. However, because the rash caused by julitis looks similar to rashes caused by rosacea, doctors often misdiagnosed people as having rosacea when they actually had julitis.

Applicant has discovered that the presence of a protein known as "JUL-1" in a person's body is indicative that the person has julitis. All julitis patients have JUL-1 in their plasma, skin, hair and nails, but this protein is not found in persons who do not have julitis (*e.g.*, patients with rosacea). Applicant discloses detecting JUL-1 by routine and conventional methods such as (i) physical biopsies of skin, hair or nails, or (ii) immunoassays in which a sample from a patient (*e.g.*, a plasma or skin sample) is contacted with an antibody to the protein being detected, and then binding between the antibody and the protein is detected using a laboratory technique such as fluoroscopy. In particular, applicant

discloses detecting JUL-1 using anti-JUL-1 antibodies that may be naturally occurring (*e.g.*, a human anti-JUL-1 antibody isolated from a patient known to have julitis), or non-naturally occurring (*e.g.*, a porcine anti-JUL-1 antibody created by injecting pigs with JUL-1, or a specific monoclonal antibody named "mAb-D33" that was created by applicant). Prior to applicant's invention, and at the time the application was filed, the use of porcine antibodies in veterinary therapeutics was known to most scientists in the field, but these antibodies were not routinely or conventionally used to detect human proteins such as JUL-1.

Prior to applicant's invention, and at the time the application was filed, julitis was conventionally treated with anti-tumor necrosis factor (TNF) antibodies, but for unknown reasons, some patients do not respond well to this conventional treatment. Because rosacea treatments (*e.g.*, antibiotics) are not effective against julitis, julitis patients who were misdiagnosed as having rosacea also did not respond well to the treatments they were given. Some anti-TNF antibodies are naturally occurring in patients with other autoimmune diseases such as lupus. Applicant has successfully treated julitis patients (even those who are non-responsive to anti-TNF antibodies) with topical vitamin D. Prior to applicant's invention, and at the time the application was filed, vitamin D was commonly used as an oral supplement to maintain bone health (*e.g.*, in fortified dairy products), but doctors were not commonly or routinely administering topical vitamin D to patients with julitis or other diseases.

<u>Claims</u>

1. A method of detecting JUL-1 in a patient, said method comprising:
   a. obtaining a plasma sample from a human patient; and
   b. detecting whether JUL-1 is present in the plasma sample by contacting the plasma sample with an anti-JUL-1 antibody and detecting binding between JUL-1 and the antibody.

2. A method of diagnosing julitis in a patient, said method comprising:
   a. obtaining a plasma sample from a human patient;
   b. detecting whether JUL-1 is present in the plasma sample by contacting the plasma sample with an anti-JUL-1 antibody and detecting binding between JUL-1 and the antibody; and
   c. diagnosing the patient with julitis when the presence of JUL-1 in the plasma sample is detected.

3. A method of diagnosing julitis in a patient, said method comprising:
   a. obtaining a plasma sample from a human patient;
   b. detecting whether JUL-1 is present in the plasma sample by contacting the plasma sample with a porcine anti-JUL-1 antibody and detecting binding between JUL-1 and the porcine antibody; and
   c. diagnosing the patient with julitis when the presence of JUL-1 in the plasma sample is detected.

4. A method of diagnosing julitis in a patient, said method comprising:
   a. obtaining a plasma sample from a human patient;
   b. detecting whether JUL-1 is present in the plasma sample by contacting the plasma sample with antibody mAb-D33 and detecting binding between JUL-1 and antibody mAb-D33; and
   c. diagnosing the patient with julitis when the presence of JUL-1 in the plasma sample is detected.

5. A method of diagnosing and treating julitis in a patient, said method comprising:
   a. obtaining a plasma sample from a human patient;

b. detecting whether JUL-1 is present in the plasma sample;
c. diagnosing the patient with julitis when the presence of JUL-1 in the plasma sample is detected; and
d. administering an effective amount of topical vitamin D to the diagnosed patient.

6. A method of diagnosing and treating julitis in a patient, said method comprising:
   a. obtaining a plasma sample from a human patient;
   b. detecting whether JUL-1 is present in the plasma sample;
   c. diagnosing the patient with julitis when the presence of JUL-1 in the plasma sample is detected; and
   d. administering an effective amount of anti-tumor necrosis factor (TNF) antibodies to the diagnosed patient.

7. A method of treating a patient with julitis, the method comprising administering an effective amount of anti-TNF antibodies to a patient suffering from julitis.

Analysis

Claim 1: Eligible.

The claim recites a series of steps or acts, including detecting the presence of JUL-1 in a plasma sample. Thus, the claim is directed to a process, which is one of the statutory categories of invention (*Step 1: YES*).

The claim is then analyzed to determine whether it is directed to any judicial exception. The claim recites steps of obtaining a plasma sample from a patient (step a) and detecting whether JUL-1 is present in the plasma sample by contacting the plasma sample with an anti-JUL-1 antibody and detecting resultant binding between JUL-1 and the antibody (step b). These steps do not recite or describe any recognized exception. *See, e.g.*, Mayo Collaborative Svcs. v. Prometheus Labs., 566 U.S. __, 132 S. Ct. 1289, 1297 (2012) (recited steps of administering a drug to a patient and determining the resultant level of 6-thioguanine in the patient "are not themselves natural laws"). Accordingly, the claim is not directed to an exception (*Step 2A: NO*), and is eligible.

Note that although nature-based product limitations are recited in the claim (*e.g.*, the plasma sample and JUL-1), analysis of the claim as a whole indicates that the claim is focused on a process of detecting whether JUL-1 is present in a plasma sample, and is not focused on the products *per se*. Thus, there is no need to perform the markedly different characteristics analysis on the recited nature-based product limitations. In addition, note that because the analysis of this claim ends with eligibility at Step 2A, the Step 2B analysis does not need to be performed. Thus, the examiner would not need to evaluate the significantly more considerations for this claim.

If the examiner believes that the record would benefit from clarification, remarks could be added to an Office action or reasons for allowance, indicating that the claim is not directed to any judicial exception.

Claim 2: Ineligible.

The claim recites a series of steps or acts, including detecting the presence of JUL-1 in a plasma sample. Thus, the claim is directed to a process, which is one of the statutory categories of invention (*Step 1: YES*).

The claim is then analyzed to determine whether it is directed to any judicial exception. In step c, the claim recites diagnosing the patient with julitis when the presence of JUL-1 in the plasma sample is detected, which describes a correlation or relationship between the presence of JUL-1 in a patient's

plasma and the presence of julitis in the patient. This limitation sets forth a judicial exception, because this type of correlation is a consequence of natural processes, similar to the naturally occurring correlation found to be a law of nature by the Supreme Court in Mayo). Additionally, step c could be performed by a human using mental steps or basic critical thinking, which are types of activities that have been found by the courts to represent abstract ideas (*e.g.*, the mental comparison in Ambry Genetics, or the diagnosing an abnormal condition by performing clinical tests and thinking about the results in Grams). Thus, the claim is directed to at least one exception (*Step 2A: YES*), which may be termed a law of nature, an abstract idea, or both. Note that although the claim recites several nature-based product limitations (*e.g.*, the plasma sample and JUL-1), the claim as a whole is focused on a process of detecting whether JUL-1 is present in a plasma sample, and is not focused on the products *per se*. Thus, there is no need to perform the markedly different characteristics analysis on the recited nature-based product limitations.

Next, the claim as a whole is analyzed to determine whether any element, or combination of elements, is sufficient to ensure that the claim amounts to significantly more than the exception. Besides the law of nature, the claim recites additional steps of obtaining a plasma sample from a human patient (step a), and detecting whether JUL-1 is present in the plasma sample by contacting the plasma sample with an anti-JUL-1 antibody and detecting resultant binding between JUL-1 and the antibody (step b). Obtaining a sample in order to perform tests is well-understood, routine and conventional activity for those in the field of diagnostics. Further, the step is recited at a high level of generality such that it amounts to insignificant presolution activity, *e.g.*, a mere data gathering step necessary to use the correlation. Detecting whether JUL-1 is present in the plasma sample merely instructs a scientist to use any detection technique with any generic anti-JUL-1 antibody. When recited at this high level of generality, there is no meaningful limitation, such as a particular or unconventional machine or a transformation of a particular article, in this step that distinguishes it from well-understood, routine, and conventional data gathering activity engaged in by scientists prior to applicant's invention, and at the time the application was filed, *e.g.*, the routine and conventional techniques of detecting a protein using an antibody to that protein. Further, it is well established that the mere physical or tangible nature of additional elements such as the obtaining and detecting steps does not automatically confer eligibility on a claim directed to an abstract idea (*see*, *e.g.*, Alice Corp. v. CLS Bank Int'l, 134 S.Ct. 2347, 2358-59 (2014)).

Consideration of the additional elements as a combination also adds no other meaningful limitations to the exception not already present when the elements are considered separately. Unlike the eligible claim in Diehr in which the elements limiting the exception are individually conventional, but taken together act in concert to improve a technical field, the claim here does not invoke any of the considerations that courts have identified as providing significantly more than an exception. Even when viewed as a combination, the additional elements fail to transform the exception into a patent-eligible application of that exception. Thus, the claim as a whole does not amount to significantly more than the exception itself *(Step 2B: NO).* The claim is not eligible.

A rejection of claim 2 should identify step c as an exception by pointing to it in the claim and explaining why it is an exception, *e.g.*, that the recited correlation is a law of nature because it is a consequence of a natural process in the body, and/or that the critical thinking step is an abstract idea similar to those found by the courts to be an exception. The rejection should also identify the additional elements in the claim and explain why they do not amount to significantly more, in this case, because they merely add data gathering and well-understood, routine and conventional activities that do not impose meaningful limits on the law of nature.

Claim 3: Eligible.

The claim recites a series of steps or acts, including detecting the presence of JUL-1 in a plasma sample. Thus, the claim is directed to a process, which is one of the statutory categories of invention (*Step 1: YES*). Because claim 3 recites the same correlation and critical thinking step (step c) as claim 2, which as explained above is a law of nature and/or an abstract idea, the claim is directed to a judicial exception (*Step 2A: YES*). Although this claim recites several nature-based product limitations (the plasma sample, JUL-1, and the antibody), there is no need to perform the markedly different characteristics analysis on them, for the reasons discussed above for claim 2.

Next, the claim as a whole is analyzed to determine whether any element, or combination of elements, is sufficient to ensure that the claim amounts to significantly more than the exception. Besides the exception, the claim recites additional steps of obtaining a plasma sample from a human patient (step a), and detecting whether JUL-1 is present in the plasma sample by contacting the plasma sample with a porcine anti-JUL-1 antibody and detecting resultant binding between JUL-1 and the antibody (step b). The additional element of obtaining a plasma sample (step a) does not by itself add significantly more, for the reasons discussed above for claim 2. Step b, however, also requires detecting using a porcine anti-JUL-1 antibody. Prior to applicant's invention, and at the time the application was filed, the use of porcine antibodies in veterinary therapeutics was known to most scientists in the field. But significantly, there is no evidence that porcine antibodies were routinely or conventionally used to detect human proteins such as JUL-1. Thus, the claim's recitation of detecting JUL-1 using a porcine antibody is an unconventional step that is more than a mere instruction to "apply" the correlation and critical thinking step (the exception) using well-understood, routine or conventional techniques in the field. Whether taken alone or as a combination with the other additional elements, the recitation of detecting JUL-1 using a porcine anti-JUL-1 antibody yields a claim as a whole that amounts to significantly more than the exception itself (*Step 2B: YES*). The claim is eligible.

If the examiner believes that the record would benefit from clarification, remarks could be added to an Office action or reasons for allowance indicating that the correlation and critical thinking step (step c) is a law of nature and/or an abstract idea. However, the claim is eligible because it recites additional limitations that when considered as a combination are unconventional steps that are more than a mere instruction to "apply" the exception using well-understood, routine or conventional techniques in the field.

Claim 4: Eligible.

The claim recites a series of steps or acts, including detecting the presence of JUL-1 in a plasma sample. Thus, the claim is directed to a process, which is one of the statutory categories of invention (*Step 1: YES*). Because claim 4 recites the same correlation and critical thinking step (step c) as claim 2, which as explained above is a law of nature and/or an abstract idea, the claim is directed to a judicial exception (*Step 2A: YES*). Although this claim recites several nature-based product limitations (the plasma sample, JUL-1, and the antibody), there is no need to perform the markedly different characteristics analysis on them, for the reasons discussed above for claim 2.

Next, the claim as a whole is analyzed to determine whether any element, or combination of elements, is sufficient to ensure that the claim amounts to significantly more than the exception. Besides the exception, the claim recites the additional elements of obtaining a plasma sample from a human patient (step a) and detecting the presence of JUL-1 in the sample by contacting the plasma sample with antibody mAb-D33 and detecting resultant binding between the antibody and JUL-1 (step b). The additional element of obtaining a plasma sample (step a) does not add significantly more by itself, for the reasons discussed above for claim 2. Step b, however, requires detecting using a specific anti-

JUL-1 antibody (mAb-D33). Prior to applicant's invention, and at the time the application was filed, antibody mAb-D33 was not routinely or conventionally used to detect human proteins such as JUL-1. Thus, the claim's recitation of detecting JUL-1 using mAb-D33 is an unconventional step that is more than a mere instruction to "apply" the correlation and critical thinking step (the exception) using well-understood, routine or conventional techniques in the field. Whether taken alone or as a combination with the other additional elements, the recitation of detecting JUL-1 using mAb-D33 yields a claim as a whole that amounts to significantly more than the exception itself (*Step 2B: YES*). The claim is eligible.

If the examiner believes that the record would benefit from clarification, remarks could be added to an Office action or reasons for allowance indicating that the correlation and critical thinking step (step c) is a law of nature and/or an abstract idea. However, the claim is eligible because it recites additional limitations that when considered as a combination are unconventional steps that are more than a mere instruction to "apply" the exception using well-understood, routine or conventional techniques in the field.

<u>Claim 5: Eligible.</u>

The claim recites a series of steps or acts, including detecting the presence of JUL-1 in a plasma sample. Thus, the claim is directed to a process, which is one of the statutory categories of invention (*Step 1: YES*). Because claim 5 recites the same correlation and critical thinking step (step c) as claim 2, which as explained above is a law of nature and/or an abstract idea, the claim is directed to a judicial exception (*Step 2A: YES*). Although the claim recites several nature-based product limitations (the plasma sample, JUL-1, and vitamin D), there is no need to perform the markedly different characteristics analysis on them, for the reasons discussed above for claim 2.

Next, the claim as a whole is analyzed to determine whether any element, or combination of elements, is sufficient to ensure that the claim amounts to significantly more than the exception. Besides the exception, the claim recites the additional elements of obtaining a plasma sample from a human patient (step a) and detecting the presence of JUL-1 in the sample (step b). When considered individually, steps a and b by themselves do not add significantly more to the exception for the reasons discussed above for claim 2 (*e.g.,* step b in this claim is recited at an even higher level of generality than in claim 2, that encompasses any protein detection method, whether or not it uses antibodies). However, this claim further recites an additional element of administering an effective amount of topical vitamin D to the diagnosed patient (step d). Vitamin D was known to doctors, and was routinely and conventionally used as an oral supplement to maintain bone health prior to applicant's invention, and at the time the application was filed. However, mere knowledge of vitamin D or its use in other ways to treat other medical conditions does not make the administration of topical vitamin D to treat julitis a conventional step that those in this field would routinely practice. The evaluation turns on whether the use of topical vitamin D was widely prevalent in the field at the time the invention was made and the application was filed. Because it was not, the recitation of administering topical vitamin D is an unconventional step that is more than a mere instruction to "apply" the correlation and critical thinking step (the exception) using well-understood, routine or conventional techniques in the field. Whether taken alone or as a combination with the other additional elements, the recitation of administering topical vitamin D yields a claim as a whole that amounts to significantly more than the exception itself (*Step 2B: YES*). The claim is thus eligible.

If the examiner believes that the record would benefit from clarification, remarks could be added to an Office action or reasons for allowance indicating that the correlation and critical thinking step (step c) is a law of nature and/or an abstract idea. However, the claim is eligible because it recites additional limitations that when considered as a combination are unconventional steps that are more

than a mere instruction to "apply" the exception using well-understood, routine or conventional techniques in the field.

Claim 6: Eligible.

The claim recites a series of steps or acts, including detecting the presence of JUL-1 in a plasma sample. Thus, the claim is directed to a process, which is one of the statutory categories of invention (*Step 1: YES*). Because claim 6 recites the same correlation and critical thinking step (step c) as claim 2, which as explained above is a law of nature and/or an abstract idea, the claim is directed to a judicial exception (*Step 2A: YES*). Although the claim recites several nature-based product limitations (the plasma sample, JUL-1, and the anti-TNF antibodies), there is no need to perform the markedly different characteristics analysis on them, for the reasons discussed above for claim 2.

Next, the claim as a whole is analyzed to determine whether any element, or combination of elements, is sufficient to ensure that the claim amounts to significantly more than the exception. Besides the exception, the claim recites the same additional elements of obtaining a plasma sample from a human patient (step a) and detecting the presence of JUL-1 in the sample (step b) as claim 5. When considered individually, steps a and b do not by themselves add significantly more to the exception for the reasons discussed above for claims 2 and 5. This claim further recites an additional element of administering an effective amount of anti-TNF antibodies to the diagnosed patient (step d). Prior to applicant's invention, and at the time the application was filed, however, administering these antibodies to treat a patient diagnosed with julitis was well-understood, routine and conventional activity engaged in by doctors in the field. Further, it is well established that the mere physical or tangible nature of additional elements such as the obtaining, detecting, and administering steps does not automatically confer eligibility on a claim directed to an exception (*see*, *e.g.*, Alice Corp., 134 S.Ct. at 2358-59).

When the additional elements are viewed as a combination, however, the additional elements (steps a, b and d) amount to a claim as a whole that adds meaningful limits on the use of the exception (the correlation and critical thinking step). The totality of these steps including the recitation of a particular treatment (administration of an effective amount of anti-TNF antibodies) in step d integrate the exception into the diagnostic and treatment process, and amount to more than merely diagnosing a patient with julitis and instructing a doctor to generically "treat it." Further, the combination of steps, which is not routine and conventional, ensures that patients who have julitis will be accurately diagnosed (due to the detection of JUL-1 in their plasma) and properly treated with anti-TNF antibodies, as opposed to being misdiagnosed as having rosacea as was previously commonplace. *See* Diamond v. Diehr, 450 U.S. 175, 188 (1981) ("a new combination of steps in a process may be patentable even though all the constituents of the combination were well known and in common use before the combination was made"). Thus, the administration of anti-TNF antibodies, when considered as a combination with the other additional elements, yields a claim as a whole that amounts to significantly more than the exception itself (*Step 2B: YES*). The claim is eligible.

If the examiner believes that the record would benefit from clarification, remarks could be added to an Office action or reasons for allowance indicating that the correlation and critical thinking step (step c) is a law of nature and/or an abstract idea. However, the claim is eligible because it recites additional limitations that when considered as a combination are a meaningful way of applying the exception that is more than a mere instruction to "apply" the exception.

Claim 7: Eligible.

The claim recites at least one step or act, *e.g.*, administering an effective amount of anti-TNF antibodies to a patient suffering from julitis. Thus, the claim is directed to a process, which is one of the statutory categories of invention (*Step 1: YES*).

The claim is then analyzed to determine whether it is directed to any judicial exception. Although the claim recites a nature-based product limitation (the anti-TNF antibodies), analysis of the claim as a whole indicates that the claim is focused on a process of practically applying the product to treat a particular disease (julitis), and not on the product *per se*. Accordingly, it is not necessary to perform the markedly different characteristics analysis on the antibodies. The recited step of administering antibodies to a patient suffering from julitis does not recite or describe any recognized exception. *See, e.g.*, Mayo, 132 S. Ct. at 1297 (recited steps of administering a drug to a patient and determining the resultant level of 6-thioguanine in the patient "are not themselves natural laws"). Thus, the claim is not directed to an exception (*Step 2A: NO*). The claim is eligible.

Note that because the analysis of this claim ends in eligibility at Step 2A, the Step 2B analysis does not need to be performed. Thus, the examiner would not need to evaluate the significantly more considerations for this claim.

If the examiner believes that the record would benefit from clarification, remarks could be added to an Office action or reasons for allowance, indicating that the claim is not directed to any judicial exception.

30. Dietary Sweeteners

This example illustrates the application of the markedly different characteristics and significantly more analyses to claims reciting hypothetical nature-based products including mixtures. It also illustrates the importance of applying the broadest reasonable interpretation in the eligibility analysis, and how that interpretation assists in the identification of appropriate naturally occurring counterparts of claimed nature-based products. Hypothetical claims 1 and 2 are ineligible, because the claimed nature-based products lack markedly different characteristics from what exists in nature, and the claims fail to amount to significantly more than the exceptions (even though claim 2 recites specific amounts of the components in the nature-based product). Hypothetical claims 3-6 are eligible in Step 2A, because the claimed nature-based products have markedly different characteristics from what exists in nature.

Background

The "Texas mint" plant is a relative of stevia, which has a thin liquid sap containing about 10% texiol (a newly discovered glycoside similar to rebaudioside A). When the Texas mint plant is damaged, *e.g.*, by a leaf or stem breaking, sap is released from the injury site, and over time dries to form irregular crystals of texiol. Texiol is lower in calories and tastes sweeter than table sugar, but it has a bitter aftertaste. Texiol can be used as crystals or as a powder, and is soluble in water at various concentrations. Applicant filed an application defining a "dietary sweetener" as one of the following formulations, noting that all percentages are by weight:

- A dietary sweetener comprising texiol mixed with other components such as water to form a heterogeneous or homogenous mixture, *e.g.*, a solution or suspension. Applicant discloses that trained sensory panels reviewed formulations having varying concentrations of texiol in water, and found that the sensory perceptions of texiol's sweetness and bitter aftertaste both increased with concentration, *e.g.*, higher concentrations of texiol were perceived as having stronger sweet and bitter tastes. Based on the panel's review, and from a consumer's perspective, applicant discloses a preferred dietary sweetener comprising 1-5% texiol and at least 90% water. This preferred sweetener retains the naturally occurring texiol's sweetness and bitter aftertaste.
- A dietary sweetener comprising texiol mixed with water and Compound N (a natural flavor excreted from mushrooms and having a mild umami taste). Applicant discloses that when combined with texiol in particular amounts, Compound N neutralizes the bitter aftertaste of

texiol. Applicant discloses that this neutralization does not involve a chemical reaction. The same sensory panel tasted mixtures having various concentrations of Compound N and texiol, and found that a formulation comprising 1-5% texiol, 1-2% Compound N, and the balance water produced the most palatable results for a dietary sweetener with no bitter aftertaste. When Compound N is added in the specified amount, the changed taste perception occurs whether or not the texiol is fully dissolved, *e.g*., even when large crystals of texiol are used.

- A dietary sweetener solid gel formulation comprising 5% texiol mixed with water and/or fruit juice and sufficient pectin to provide a solid gel. The Texas mint plant does not contain pectin in nature. Solid gel formulations are useful commercial sweeteners because their solid, jelly-like consistency makes them spreadable onto other foods, such as bread, cake layers, or pastry dough. Solid gels can also be formed into candies such as jellybeans. Applicant discloses that the same sensory panel tasted the gel formulation and found that it had improved organoleptic properties (*e.g.*, a more pleasant mouthfeel) and a solid but easily-spreadable consistency as compared to naturally occurring texiol (either in the sap or crystallized).
- A dietary sweetener comprising texiol in granular form for use by consumers. Naturally occurring texiol forms irregular crystals that aggregate into large chunks of varying size and shape. Due to this variation, sweeteners formed from these irregular crystals do not have consistent and commercially acceptable dissolution rates. For example, a consumer attempting to sweeten iced tea with irregular texiol crystals will typically experience a need to add more than the expected amount of texiol in order to obtain the desired level of sweetness, because the larger particles of texiol dissolve more slowly (if at all) than the smaller particles even with vigorous stirring. The presence of these undissolved crystals may also cause an undesirable gritty mouth feel as the sweetened tea is consumed. To solve the problem of inconsistent and slow dissolution rates, applicant has produced granulated texiol formulations having even and regular particle size distributions, *e.g*., by grinding or milling coarse texiol crystals into an even and regular powder, or by crystallizing texiol in a controlled manner that forms regularly sized and shaped crystals. Granular texiol having a particle size of X10 of 80 microns and X90 of 300 microns is preferred, because this particle size distribution results in a greatly increased (and consistent) dissolution rate in water-based liquids as compared to naturally occurring texiol crystals. The terms "X10" and "X90" refer to the median diameter of the particles, as measured on a volume basis by a laser diffraction particle sizing system. For "X10", 10 percent of the particles have a diameter smaller than the specified size, and 90 percent of the particles have a larger diameter, and for "X90", 90 percent of the particles have a diameter smaller than the specified size, and 10 percent of the particles have a larger diameter.
- A dietary sweetener comprising texiol in a controlled release formulation. Applicant discloses that the same sensory panel, upon tasting naturally occurring texiol, reported perceiving an immediate burst of sweetness that rapidly dissipated. Applicant discloses formulations that achieve controlled release (*e.g.*, release of specific amounts of texiol from the formulation at specific time intervals, or over a prolonged period of time) by mixing the texiol with other substances such as polymers and/or changing the form of the texiol so that a controlled perception of sweetness is achieved. For example, in one such formulation, texiol particles are encapsulated in a polymer-emulsifier mixture that delays release of the texiol as compared to unencapsulated (*e.g*., naturally occurring) texiol particles. These controlled release formulations prolong enjoyment of a texiol-sweetened product such as chewing gum, by altering the time over which texiol's sweetness is perceived.

Claims

1. A dietary sweetener comprising:
   texiol; and
   water.

2. A dietary sweetener comprising:
   1-5 percent texiol; and
   at least 90 percent water.

3. A dietary sweetener comprising:
   1-5 percent texiol;
   at least 90 percent water; and
   1-2 percent Compound N.

4. A dietary sweetener comprising:
   5 percent texiol;
   water, fruit juice, or a combination of water and fruit juice; and
   sufficient amounts of pectin to provide a solid gel.

5. A dietary sweetener comprising:
   granular particles of texiol having a particle diameter of X10 of 80 microns and X90 of 300 microns.

6. A dietary sweetener comprising texiol in a controlled release formulation.

Analysis

Claim 1: Ineligible

The claim recites a dietary sweetener comprising texiol and water. Based on the specification's definition of "dietary sweetener", the broadest reasonable interpretation (BRI) of the claim is a mixture of texiol and water in any amount that will be understood as a sweetener to those of ordinary skill in the art. Thus, the BRI covers the naturally occurring sap of the Texas mint plant, which contains texiol and water. Because texiol and water are composed of matter, the claim is directed to a statutory category, *e.g.*, a composition of matter (*Step 1*: *YES*).

The claim is then analyzed in Step 2A to determine whether it is directed to any judicial exception. As noted above, the BRI of this claim encompasses the naturally occurring sap. Because the sap is naturally occurring, it cannot have markedly different characteristics from how it exists in nature, and therefore the claimed mixture of texiol and water (*i.e.*, the sap) is a "product of nature" exception. Association for Molecular Pathology v. Myriad Genetics, 133 S. Ct. 2107, 2116 (2013) (naturally occurring things are "products of nature" which cannot be patented). Thus, the claim is directed to at least one exception (*Step 2A: YES*).

Next, the claim as a whole is analyzed to determine whether any additional element, or combination of elements, is sufficient to ensure that the claim amounts to significantly more than the exception. In this case, the combination as claimed occurs in nature (as sap) so there are no additional elements to the claimed combination. The claim is to a "product of nature" exception with nothing that adds significantly more (*Step 2B: NO*). Claim 1 is not eligible.

A rejection of claim 1 should identify the exception(s) by pointing to the nature-based product in the claim (the combination of texiol-water) and explaining that it is a "product of nature" exception

because it is naturally occurring. The rejection should also explain that because the combination of the texiol and water is the exception, there are no additional elements in the claim that could amount to significantly more than the exception.

If the examiner believes that it would be helpful to cite an analogous court decision, the rejection could include an explanation of how the claimed mixture is like the cloned mammals of Roslin, which were held ineligible because, as claimed, the cloned mammals lacked markedly different characteristics from their naturally occurring counterparts. In re Roslin Institute (Edinburgh), 750 F.3d 1333, 1339 (2014).

Claim 2: Ineligible

The claim recites a dietary sweetener comprising 1-5 percent texiol and at least 90 percent water. Based on the specification's definition of "dietary sweetener", the broadest reasonable interpretation (BRI) of the claim is a mixture of texiol and water in the specified amounts. In this case, the BRI does not cover the naturally occurring sap of the Texas mint plant, which contains a different amount of texiol. Because texiol and water are composed of matter, the claim is directed to a statutory category, *e.g.*, a composition of matter (*Step 1*: *YES*).

The claim is then analyzed in Step 2A to determine whether it is directed to any judicial exception. The claimed mixture is a nature-based product that is compared to its closest naturally occurring counterpart, in order to determine if it has markedly different characteristics from this counterpart. As noted above, the BRI of this claim is limited to the recited percentages and thus does not encompass the naturally occurring sap of the Texas mint plant. Accordingly, the closest naturally occurring counterpart is not the sap, but the naturally occurring texiol-water mixture in the sap. By comparing the claimed mixture and its component parts to the naturally occurring texiol-water mixture in the sap, all potential changes in characteristics can be investigated.

Texiol is naturally occurring, and water is naturally occurring, so neither would be eligible as claimed on its own. Although the combination as claimed is novel and does not occur in nature, there is no indication that mixing them in the recited amounts (*i.e.*, 1-5 percent texiol and at least 90 percent water) changes the structure, function, or other properties of the texiol or water in any marked way. Instead, the texiol retains its naturally occurring structure and properties (*e.g.*, its sweetness and bitter aftertaste), and is merely located in water, which also retains its naturally occurring structure and properties (*e.g.*, its liquid form at room temperature). These characteristics are also the same as the naturally occurring texiol and water in the sap, which is also a sweet liquid at room temperature. Thus, the claimed mixture as a whole does not display markedly different characteristics compared to the closest naturally occurring counterpart. Accordingly, each component (the texiol and the water) is a "product of nature" exception, and the claim is directed to at least one exception (*Step 2A: YES*).

Next, the claim as a whole is analyzed to determine whether any additional element, or combination of elements, is sufficient to ensure that the claim amounts to significantly more than the exceptions. Because the component elements (the texiol and water "product of nature" exceptions) do not occur together in nature as claimed (*i.e.*, in the recited amounts) and are not markedly changed by their combination into a mixture, each component is considered as an additional element to the other to determine whether their combination results in significantly more than the products of nature. This consideration of the texiol as an additional element to the water, and vice-versa, provides an opportunity to explore whether this combination of "products of nature" amounts to significantly more than the products themselves. As discussed above, mixing the sweetener with water does not markedly change the characteristics of either component, because each component continues to have the same properties in the mixture as it had alone. Prior to applicant's invention and at the time of

filing the application, mixing a sweetener with water (or vice-versa) was well-understood, routine and conventional in the field, as evidenced by, *e.g.*, the ubiquity of simple syrup and stevia-based liquid sweeteners. The recitation of specific amounts of texiol and water does not affect this analysis, because it was also well-understood, routine and conventional at the time to mix specific amounts of sweeteners with water (or vice-versa) and to vary the amounts of the combination, *e.g.*, to achieve commercially acceptable sweetness levels and provide sweeteners for different purposes. Thus, the mixing of texiol and water, when recited at this high level of generality, does not meaningfully limit the claim, and the claim as a whole does not amount to significantly more than each "product of nature" by itself (*Step 2B: NO*). The claim does not qualify as eligible subject matter.

A rejection of claim 2 should identify the exceptions by pointing to the nature-based product limitations in the claim (texiol and water) and explaining why they lack markedly different characteristics from their naturally occurring counterparts, *e.g.*, because there are no marked changes in structure, function or other characteristics. The rejection also should explain that mixing texiol and water does not amount to significantly more than the exceptions, because mixtures of sweeteners and water are well-understood, routine and conventional in the field.

If the examiner believes that it would be helpful to cite an analogous court decision, the rejection could include an explanation of how the claimed mixture is like the novel bacterial mixture of Funk Brothers, which was held ineligible because each species of bacteria in the mixture (like each component in the texiol mixture) continued to have "the same effect it always had", *i.e.*, it lacked markedly different characteristics. Funk Brothers Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 131 (1948), discussed in Myriad Genetics, 133 S. Ct. at 2117 (explaining that the bacterial mixture of Funk Brothers "was not patent eligible because the patent holder did not alter the bacteria in any way"). While not discussed in the opinion, it is noted that several of the claims held ineligible in Funk Brothers recited specific amounts of the bacterial species in the mixture, *e.g.*, claims 6, 7 and 13. Funk Brothers, 333 U.S. at 128 n.1.

Practice Note: In this set of facts, the specificity of the amounts of each component in this mixture did not result in markedly different characteristics of the sweetener. However, under different facts, other mixtures or combinations with specific amounts may result in markedly different characteristics or, when viewed as a whole, may result in adding significantly more to the claimed product of nature. If that is the case, it would be a best practice to indicate why the claim is eligible by explaining which characteristics are markedly different, and not simply noting that the percentages or ratios do not occur in nature.

Claim 3: Eligible

The claim recites a dietary sweetener comprising 1-5 percent texiol, at least 90 percent water, and 1-2 percent Compound N. Based on the specification's definition of "dietary sweetener", the broadest reasonable interpretation (BRI) of the claim is a mixture of texiol, water, and Compound N in the specified amounts. Because texiol, water, and Compound N are composed of matter, the claim is directed to a statutory category, *e.g.*, a composition of matter (*Step 1*: *YES*).

The claim is then analyzed in Step 2A to determine whether it is directed to any judicial exception. The claimed mixture is a nature-based product that must be compared to its closest naturally occurring counterpart to determine if it has markedly different characteristics than the counterpart. Because texiol, water and Compound N do not occur together in nature, there is no naturally occurring counterpart mixture for comparison. However, texiol does occur naturally in combination with water, in the sap of the Texas mint plant. Accordingly, the closest naturally occurring counterparts to which the claimed mixture is compared are Compound N, and the naturally occurring texiol-water combination. Each of these components is naturally occurring, so none would be eligible

as claimed on its own. There is no indication that mixing these components changes the structure of the components, and no chemical reaction occurs between or among the components. However, the mixture has a changed organoleptic property (*e.g.*, taste), because its flavor profile (sweet and lacking bitterness) is different than the mere sum of the flavors of the individual components, *e.g.*, texiol's sweetness and bitter aftertaste, and Compound N's mild umami flavor. This altered property is a marked difference in characteristics, because it results in the claimed mixture being distinct from its natural counterparts in a way that is relevant to the nature of the invention as a dietary sweetener, *e.g.*, because the taster no longer perceives the bitter aftertaste of naturally occurring texiol. *Cf.* In re Roslin Institute (Edinburgh), 750 F.3d 1333, 1339 (2014) (claimed cloned mammals do not have markedly different characteristics from their naturally occurring counterparts). Thus, the claimed dietary sweetener has markedly different characteristics as compared to its natural counterparts, and is not a "product of nature" exception. Accordingly, the claim is not directed to an exception (*Step 2A: NO*), and qualifies as eligible subject matter.

Note that because the analysis of this claim ends in eligibility at Step 2A, the Step 2B analysis is not performed. Thus, the examiner would not need to evaluate the significantly more considerations for this claim. If the examiner believes that the record would benefit from clarification, remarks could be added to an Office action or reasons for allowance, indicating that the claim is not directed to any judicial exception.

Claim 4: Eligible

The claim recites a dietary sweetener comprising 5 percent texiol, water and/or fruit juice, and sufficient amounts of pectin to provide a solid gel. Based on the specification's definition of "dietary sweetener" and the plain meaning of "solid gel", the broadest reasonable interpretation of the claim is a mixture of texiol, pectin, and water that has the form of a solid gel (*i.e.*, has a jelly-like spreadable consistency). Because the gel is composed of matter, the claim is directed to a statutory category, *e.g.*, a composition of matter (*Step 1*: *YES*).

The claim is then analyzed to determine whether it is directed to any judicial exception. The claimed gel is a nature-based product that must be compared to its closest naturally occurring counterpart to determine if it has markedly different characteristics than the counterpart. Because texiol, pectin, and water do not occur together in nature (the Texas mint plant does not contain any pectin), there is no naturally occurring counterpart mixture for comparison. However, pectin does occur naturally in combination with water (*e.g.*, in apples), and texiol occurs naturally in combination with water in the thin liquid sap of the Texas mint plant. Accordingly, the closest naturally occurring counterparts to which the claimed gel is compared are the naturally occurring water-pectin and texiol-water combinations. There is no indication that mixing the texiol-water combination with the water-pectin combination changes the structure of the water or pectin. However, the texiol in the claimed mixture does have changed properties as compared to naturally occurring texiol in the plant sap, in that the claimed texiol is present in a solid yet spreadable gel form and has improved organoleptic properties (*e.g.*, a more pleasant mouthfeel). These altered properties are a marked difference in characteristics, because they result in the claimed formulation being distinct from its natural counterparts in a way (jelly-like spreadable consistency and more pleasant mouthfeel) that is relevant to the nature of the invention as a dietary sweetener, *e.g.*, because the claimed formulation can be spread onto other foods such as pastry dough, or formed into candies such as jellybeans. *Cf.* Roslin, 750 F.3d at 1339 (claimed cloned mammals do not have markedly different characteristics from their naturally occurring counterparts). Because the claimed dietary sweetener formulation thus has markedly different characteristics as compared to its natural counterpart, it is not a "product of nature" exception. Accordingly, the claim is not directed to an exception (*Step 2A: NO*), and qualifies as eligible subject matter.

Note that because the analysis of this claim ends in eligibility at Step 2A, the Step 2B analysis is not performed. Thus, the examiner would not need to evaluate the significantly more considerations for this claim. If the examiner believes that the record would benefit from clarification, remarks could be added to an Office action or reasons for allowance, indicating that the claim is not directed to any judicial exception.

Claim 5: Eligible

The claim recites a dietary sweetener comprising granular particles of texiol having a specific particle size distribution, where X10 is 80 microns and X90 is 300 microns. Based on the specification's definition of "dietary sweetener" and the plain meaning of "X10" and "X90", the broadest reasonable interpretation of the claim is a texiol formulation having a specific particle size distribution, *i.e.*, 10 percent of the particles have a diameter smaller than 80 microns, 10 percent of the particles have a diameter greater than 300 microns, and the remaining 80 percent have a diameter between 80 and 300 microns. Because texiol is composed of matter, the claim is directed to a statutory category, *e.g.*, a composition of matter (*Step 1*: *YES*).

The claim is then analyzed to determine whether it is directed to any judicial exception. The claimed texiol formulation having a specific particle size distribution is a nature-based product that must be compared to its closest naturally occurring counterpart (texiol in its natural irregular crystal state) to determine if it has markedly different characteristics than the counterpart. As disclosed by applicant, the specific particle size distribution results in the claimed texiol formulation having a changed property, *i.e.*, an increased (and consistent) dissolution rate, as opposed to the slow and inconsistent dissolution rate of naturally occurring texiol. This altered property is a marked difference in characteristics, because it results in the claimed formulation being distinct from its natural counterpart in a way (release of sweetness over time) that is relevant to the nature of the invention as a dietary sweetener, *e.g.*, because the claimed formulation will dissolve evenly and rapidly in a cool liquid. *Cf.* Roslin, 750 F.3d at 1339 (claimed cloned mammals do not have markedly different characteristics from their naturally occurring counterparts). Because it has markedly different characteristics as compared to its natural counterpart, the claimed formulation 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.

Note that because the analysis of this claim ends in eligibility at Step 2A, the Step 2B analysis is not performed. Thus, the examiner would not need to evaluate the significantly more considerations for this claim. If the examiner believes that the record would benefit from clarification, remarks could be added to an Office action or reasons for allowance, indicating that the claim is not directed to any judicial exception.

Claim 6: Eligible

The claim recites a dietary sweetener comprising texiol in a controlled release formulation. Based on the specification's definition of "dietary sweetener" and the plain meaning of "controlled release formulation", the broadest reasonable interpretation of the claim is a texiol formulation that has altered time release properties so that its sweetness is now released in a controlled manner over time due to (a) a change in form or structure or (b) being mixed with other substances (*e.g.*, by being encapsulated in a polymer-emulsifier mixture). In either case, the texiol formulation is composed of matter, and thus the claim is directed to a statutory category, *e.g.*, a composition of matter (*Step 1*: *YES*).

The claim is then analyzed to determine whether it is directed to any judicial exception. The claimed formulation is a nature-based product that must be compared to its closest naturally occurring counterpart to determine if it has markedly different characteristics than the counterpart. There is

no naturally occurring mixture for comparison, and so the claimed formulation is compared to naturally occurring texiol in its natural state. As disclosed by applicant, the claimed formulation has altered time release properties, in that it releases the sweetness of texiol in a controlled manner over time, as opposed to the naturally occurring texiol, which releases all of its sweetness at one point in time. These altered properties are a marked difference in characteristics, because they result in the claimed formulation being distinct from its natural counterpart in a way (release of sweetness over time) that is relevant to the nature of the invention as a dietary sweetener. *Cf.* Roslin, 750 F.3d at 1339 (claimed cloned mammals do not have markedly different characteristics from their naturally occurring counterparts). Because it has markedly different characteristics as compared to its natural counterpart, the claimed formulation 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.

Note that because the analysis of this claim ends in eligibility at Step 2A, the Step 2B analysis is not performed. Thus, the examiner would not need to evaluate the significantly more considerations for this claim. If the examiner believes that the record would benefit from clarification, remarks could be added to an Office action or reasons for allowance, indicating that the claim is not directed to any judicial exception.

31. Screening For Gene Alterations

The following illustrates an exemplary analysis using the 2014 IEG for actual claim 1 and hypothetical claims 70, 75, 80, and 85 modeled after the technology in U.S. Patent 5,753,441. Actual claim 1 was held ineligible by the Federal Circuit as directed to an abstract idea without additional elements that amount to significantly more than the abstract idea in Association for Molecular Pathology v. U.S. Patent and Trademark Office, 689 F.3d 1303 (Fed. Cir. 2012) ("Myriad CAFC"), aff'd in part and rev'd in part on other grounds, Association for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107 (2013). (It is noted that claims 7 and 8 of the same patent were held ineligible in University of Utah Research Foundation v. Ambry Genetics Corp., 774 F.3d 755 (Fed. Cir. 2014).) Hypothetical claims 70 and 80 are eligible in Step 2B, because they recite specific and unconventional ways of gathering data that amount to significantly more than the abstract idea, e.g., amplifying nucleic acids via a hypothetical technique known as "Cool-Melt PCR." Hypothetical claims 75 and 85 are eligible in Step 2A, because they are not directed to any judicial exception.

Background

Applicant discovered the "wild-type" sequence of the human BRCA1 gene (*i.e.*, the typical sequence of the gene in humans), and has also discovered naturally occurring alterations from the wild-type sequence that are correlated with an increased likelihood of developing breast or ovarian cancer. Applicant's disclosure provides methods of screening patients for alterations in the BRCA1 gene by comparing a patient's BRCA1 sequence with the wild-type BRCA1 sequence. The compared sequences can be germline (genomic) DNA sequences, RNA sequences, or cDNA sequences.

At the time the invention was made and the application was filed, scientists routinely compared DNA sequences using two data-gathering techniques. The first technique seeks to hybridize two different DNA molecules (*e.g.*, a probe and DNA isolated from a patient sample), and detects whether the molecules bind to each other and form a hybridization product. The second technique amplifies (makes copies of) at least part of a DNA molecule such as DNA isolated from a patient sample, by using a set of primers to produce amplified nucleic acids, and then sequences the amplified nucleic acids. The probes and primers used in these techniques are short single-stranded DNA molecules that typically have a naturally occurring nucleotide sequence, for example a probe to the BRCA1 gene

may have a nucleotide sequence that is identical to a portion of the germline sequence of the wild-type BRCA1 gene.

In one embodiment, applicant discloses using a computer-implemented micromechanical method known as Scanning Near-field Optical Microscopy (SNOM) to detect hybridization of a single probe to its target. SNOM is a technique that achieves high spatial resolution of a nanometric sample, using a laser and optical microscope that are controlled by a computer. At the time the invention was made and the application was filed, the use of SNOM to study DNA hybridization had been discussed in several articles in widely-read scientific journals. However, scientists were not commonly or routinely using SNOM to study DNA hybridization at the time the invention was made and the application was filed. Instead, scientists at the time typically used autoradiography to detect hybridization products.

In another embodiment, applicant discloses using Cool-Melt polymerase chain reaction (Cool-Melt PCR) to amplify BRCA1 DNA from the patient sample. Cool-Melt PCR uses lower melting and annealing temperatures than conventional PCR. Because these lower temperatures result in preferential amplification of mutant nucleic acids as compared to wild-type nucleic acids, Cool-Melt PCR has a 20-fold higher sensitivity of mutation detection than conventional PCR. At the time the invention was made and the application was filed, Cool-Melt PCR was known and used by a few scientists in the field. Several years after filing the application, Cool-Melt PCR became a standard laboratory technique that appeared in virtually every laboratory manual and was conventionally used by most scientists in the field to amplify mutant nucleic acids.

<u>Claims</u>

1. A method for screening germline of a human subject for an alteration of a BRCA1 gene which comprises comparing germline sequence of a BRCA1 gene or BRCA1 RNA from a tissue sample from said subject or a sequence of BRCA1 cDNA made from mRNA from said sample with germline sequences of wild-type BRCA1 gene, wild-type BRCA1 RNA or wild-type BRCA1 cDNA, wherein a difference in the sequence of the BRCA1 gene, BRCA1 RNA or BRCA1 cDNA of the subject from wild-type indicates an alteration in the BRCA1 gene in said subject.

70. The method of claim 1, wherein said comparing BRCA1 sequences further comprises:

    hybridizing a wild-type probe to a BRCA1 gene isolated from said sample; and

    detecting the presence of a hybridization product by measuring conformational changes in the probe that are indicative of hybridization to the BRCA1 gene with scanning near-field optical microscopy.

75. A method for hybridizing BRCA1 sequences comprising:

    hybridizing a wild-type probe to a BRCA1 gene isolated from a tissue sample from a human subject; and

    detecting the presence of a hybridization product by measuring conformational changes in the probe that are indicative of hybridization to the BRCA1 gene with scanning near-field optical microscopy.

80. The method of claim 1, wherein said comparing BRCA1 sequences further comprises:

    amplifying by Cool-Melt PCR all or part of a BRCA1 gene from said sample using a set of primers to produce amplified nucleic acids; and

sequencing the amplified nucleic acids.

85. A method for amplifying BRCA1 sequences comprising:

amplifying by Cool-Melt PCR all or part of a BRCA1 gene from a tissue sample from a human subject using a set of primers to produce amplified nucleic acids; and

sequencing the amplified nucleic acids.

Analysis

Claim 1: Ineligible.

The claim recites a step or act, *i.e.*, comparing the patient's genetic sequence with wild type genetic sequences. Thus, the claim is directed to a process, which is one of the statutory categories of invention (*Step 1: YES*).

The claim is then analyzed to determine whether it is directed to any judicial exception. The claim recites a step of comparing the patient's BRCA1 sequence with wild-type BRCA1 sequences, and a wherein clause stating the result of the comparison, which is that a difference in the compared sequences indicates that the patient has an alteration in the BRCA1 gene. This step of comparing is recited at a high level of generality that merely requires a comparison of two pieces of information and imposes no limits on how the comparison is performed. In *Myriad CAFC*, the court found this step of comparing to be an abstract idea.

When applying the 2014 IEG and interpreting the claim during examination, it is apparent that the step of comparing could be performed by a human using mental steps or basic critical thinking. Similar mental processes have been held by the courts to be abstract ideas, *e.g.*, collecting and comparing known information in Classen, or comparing information regarding a sample or test subject to a control or target data in Ambry and Myriad CAFC. The specific information that is being compared (sequences of a BRCA1 gene, BRCA1 RNA, or BRCA1 cDNA with wild-type sequences) merely narrows the abstract idea, which does not make the comparison step less abstract and is not sufficient to provide eligibility on its own. Thus, the claim is directed to an abstract idea (*Step 2A: YES*).

Note that although nature-based product limitations are recited in the claim (*e.g.*, genes), analysis of the claim as a whole indicates that this claim is focused on a process of comparing information about the products, and is not focused on the products *per se*. Thus, there is no need to perform the markedly different characteristics analysis on the recited nature-based product limitations in this claim.

Next, the claim as a whole is analyzed to determine whether any additional element, or combination of elements, is sufficient to ensure that the claim amounts to significantly more than the abstract idea. The claim recites a single step of comparing, along with a wherein clause, all of which were identified as the abstract idea explained above. There are no other elements/steps recited in the claim. Accordingly, the claim as a whole does not amount to significantly more than the abstract idea of comparing information (*Step 2B: NO*). The claim is not patent eligible.

A rejection of claim 1 should identify the exception by pointing to the comparison of sequences in the claim and explain that this type of comparison of information has been held by the courts to be an abstract idea and that limits on the type of information being compared merely narrow the abstract idea. The rejection should also identify that there are no additional elements/steps in the claim. For clarity, the rejection can explain why the wherein clause does not impose any additional limitations on the claimed method, but merely breathes meaning into the comparison step by stating the result of the comparison.

Claim 70: Eligible

Claim 70 depends from claim 1 and recites at least one step or act, *e.g.*, comparing the patient's genetic sequence with wild type genetic sequences. Thus, the claim is directed to a statutory category of invention (a process; *Step 1: YES*). As a dependent claim, claim 70 incorporates the comparing step of claim 1, which as explained above is an abstract idea. Therefore, the claim is directed to a judicial exception (*Step 2A: YES*).

Next, the claim as a whole is analyzed to determine whether any additional element, or combination of elements, is sufficient to ensure that the claim amounts to significantly more than the exception. Claim 70 recites two additional elements, *i.e.*, that the comparing of claim 1 further comprises a hybridizing step and a detecting step.

The step of hybridizing a wild-type probe to a BRCA1 gene isolated from a sample is recited at a high level of generality, and merely instructs a scientist performing the process to use any hybridization techniques with any probe that she wishes to use to detect any alteration. When recited at this high level of generality, there is nothing in this step that distinguishes it from well-understood, routine and conventional activity engaged in by scientists at the time the invention was made and the application was filed. While this step specifies that the compared sequences are of a probe and a gene, limiting the comparison in this way imposes no limits on how the comparison is performed. Further, it is well established that the mere physical or tangible nature of additional elements such as the hybridizing step does not automatically confer eligibility on a claim directed to an abstract idea (*see*, *e.g.*, Alice Corp. v. CLS Bank Int'l, 134 S.Ct. 2347, 2358-59 (2014)). Thus, taken alone, the hybridizing step does not amount to significantly more.

Claim 70, however, further recites a detecting step in which conformational changes in the gene probe that are indicative of hybridization with the patient's BRCA1 gene are measured by scanning near-field optical microscopy (SNOM). Although SNOM was known to scientists at the time the invention was made and the application was filed, *e.g.*, because it had been discussed in several widely-read scientific journals, mere knowledge of this technique does not make the use of SNOM to detect DNA hybridization routine or conventional in this field. Instead, the evaluation turns on whether the use of SNOM to detect DNA hybridization was actually routinely or conventionally used by scientists at the time the invention was made and the application was filed. Because it was not, the recitation of SNOM to detect DNA hybridization distinguishes claim 70 from well-understood, routine and conventional methods of detecting DNA hybridization such as autoradiography. Thus, the claim's recitation of using SNOM is more than a mere instruction to "apply" the abstract idea using well-understood, routine or conventional techniques in the field. Whether taken alone or as a combination with the other additional elements, the recitation of detecting hybridization using SNOM yields a claim as a whole that is significantly more than the judicial exception itself (*Step 2B: YES*). The claim recites patent eligible subject matter.

If the examiner believes that the record would benefit from clarification, remarks could be added to an Office action or reasons for allowance indicating that the claim recites the abstract idea of comparing sequence information. However, the claim is eligible because it recites additional limitations that when considered as a combination are more than a mere instruction to "apply" the abstract idea using well-understood, routine or conventional techniques in the field.

Claim 75: Eligible

Claim 75 recites at least one step or act, *e.g.*, hybridizing a wild-type probe to a BRCA1 gene isolated from a sample. Thus, the claim is directed to a statutory category of invention (a process; *Step 1: YES*).

The claim is then analyzed to determine whether it is directed to any judicial exception. The claim recites a step of hybridizing a wild-type probe to a BRCA1 gene isolated from a sample and a detecting

step in which conformational changes in the gene probe that are indicative of hybridization with the patient's BRCA1 gene are measured by scanning near-field optical microscopy (SNOM). These steps do not recite or describe any recognized exception. *See, e.g.*, Mayo Collaborative Svcs. v. Prometheus Labs., 566 U.S. __, 132 S. Ct. 1289, 1297 (2012) (recited steps of administering a drug to a patient and determining the resultant level of 6-thioguanine in the patient "are not themselves natural laws"). Accordingly, the claim is not directed to an exception (*Step 2A: NO*), and is eligible.

Note that although nature-based product limitations are recited in the claim (*e.g.*, the probe and BRCA1 gene), analysis of the claim as a whole indicates that the claim is focused on a process of detecting whether the probe has hybridized to the BRCA1 gene, and is not focused on the products *per se*. Thus, there is no need to perform the markedly different characteristics analysis on the recited nature-based product limitations. In addition, note that because the analysis of this claim ends with eligibility at Step 2A, the Step 2B analysis does not need to be performed. Thus, the examiner would not need to evaluate the significantly more considerations for this claim.

If the examiner believes that the record would benefit from clarification, remarks could be added to an Office action or reasons for allowance, indicating that the claim is not directed to any judicial exception.

Claim 80: Eligible

Claim 80 depends from claim 1 and recites at least one step or act, *e.g.*, comparing the patient's genetic sequence with wild type genetic sequences. Thus, the claim is directed to a statutory category of invention (a process; *Step 1: YES*). As a dependent claim, claim 80 incorporates the comparing step of claim 1, which as explained above is an abstract idea. Therefore, the claim is directed to a judicial exception (*Step 2A: YES*).

Next, the claim as a whole is analyzed to determine whether any additional element, or combination of elements, is sufficient to ensure that the claim amounts to significantly more than the exception. Claim 80 recites two additional elements, *i.e.*, that the comparing of claim 1 further comprises an amplifying by Cool-Melt PCR step, and a sequencing step.

The step of sequencing the amplified nucleic acids is recited at a high level of generality, and merely instructs a scientist performing the process to use any sequencing technique that she wishes to use. When recited at this high level of generality, there is nothing in this step that distinguishes it from well-understood, routine and conventional activities previously engaged in by scientists in the field at the time the invention was made and the application was filed. Further, it is well established that the mere physical or tangible nature of an additional element such as the sequencing step does not automatically confer eligibility on a claim directed to an abstract idea (*see*, *e.g.*, Alice Corp., 134 S.Ct. at 2358-59).

Claim 80, however, further recites a step in which Cool-Melt PCR is used to amplify the patient's BRCA1 gene. Although Cool-Melt PCR was used by a few scientists in the field to amplify nucleic acids at the time the invention was made and the application was filed, use by only a few scientists does not make the technique routine or conventional in the field as a whole. Nor does it matter that at a later time, Cool-Melt PCR became a routine and conventional technique. Instead, the evaluation turns on whether the use of Cool-Melt PCR to amplify nucleic acids was actually routinely or conventionally used by scientists in this field at the time the invention was made and the application was filed. Because it was not, the recitation of amplification using Cool-Melt PCR distinguishes claim 80 from well-understood, routine and conventional methods of amplification such as standard PCR. Thus, the claim's recitation of amplifying nucleic acids using Cool-Melt PCR is more than a mere instruction to "apply" the abstract idea using well-understood, routine or conventional techniques in the field. Whether taken alone or as a combination with the other additional elements, the recitation of

amplifying using Cool-Melt PCR yields a claim as a whole that is significantly more than the judicial exception itself (*Step 2B: YES*). The claim recites patent eligible subject matter.

If the examiner believes that the record would benefit from clarification, remarks could be added to an Office action or reasons for allowance indicating that the claim recites the abstract idea of comparing sequence information. However, the claim is eligible because it recites additional limitations that when considered as a combination are more than a mere instruction to "apply" the abstract idea using well-understood, routine or conventional techniques in the field.

Claim 85: Eligible

Claim 85 recites at least one step or act, *e.g.*, amplifying nucleic acids using Cool-Melt PCR. Thus, the claim is directed to a statutory category of invention (a process; *Step 1: YES*).

The claim is then analyzed to determine whether it is directed to any judicial exception. The claim recites a step of amplifying nucleic acids (all or part of a human subject's BRCA1 gene) using Cool-Melt PCR and a step of sequencing the amplified nucleic acids. These steps do not recite or describe any recognized exception. *See, e.g.*, Mayo Collaborative Svcs. v. Prometheus Labs., 566 U.S. __, 132 S. Ct. 1289, 1297 (2012) (recited steps of administering a drug to a patient and determining the resultant level of 6-thioguanine in the patient "are not themselves natural laws"). Accordingly, the claim is not directed to an exception (*Step 2A: NO*), and is eligible.

Note that although nature-based product limitations are recited in the claim (*e.g.*, the primers and BRCA1 gene), analysis of the claim as a whole indicates that the claim is focused on a process of amplifying and sequencing a BRCA1 gene, and is not focused on the products *per se*. Thus, there is no need to perform the markedly different characteristics analysis on the recited nature-based product limitations. In addition, note that because the analysis of this claim ends with eligibility at Step 2A, the Step 2B analysis does not need to be performed. Thus, the examiner would not need to evaluate the significantly more considerations for this claim.

If the examiner believes that the record would benefit from clarification, remarks could be added to an Office action or reasons for allowance, indicating that the claim is not directed to any judicial exception.

32. Paper-Making Machine

This hypothetical example demonstrates the use of the streamlined analysis. The claim below is based on the technology from U.S. Patent 845,224, which was upheld by the Supreme Court in Eibel Process Co. v. Minnesota & Ontario Paper Co., 261 U.S. 45 (1923). As a streamlined analysis would not result in a written rejection, the discussion sets forth exemplary reasoning an examiner might use in drawing a conclusion of eligibility.

Background

Fourdrinier machines are used to make paper from a slurry of wood pulp mixed with water (called "stock"). The paper-forming section of the machines typically comprises a headbox that feeds the stock onto one end of a conveyor belt called a "paper-making wire", which is passed over a series of rolls at a constant speed. The belt carries the stock from the headbox end of the machine (called the "breast-roll end") to the other end (called the "couch-roll end"), while simultaneously draining and shaking the stock to form a continuous paper web. The paper web is then passed into the press section of the machine for further processing.

At the time applicant made the invention and filed the application, it was routine and conventional to arrange the paper-making wire so that the breast-roll end was at the same or a lower height than the couch-roll end, and to feed the stock from the headbox onto the paper-making wire at a speed substantially slower than the wire speed. However, this arrangement necessitated running the machine at an overall slow speed (less than 500 feet/minute) in order to avoid undesirable effects (*e.g*., waves, wrinkles and ripples) on the quality of the paper web.

Applicant's invention is a Fourdrinier machine that solves the problem of running the process at a slow speed by raising the breast-roll end of the paper-making wire to a height substantially above the couch-roll end, and by using gravity to feed the stock into the machine at a speed approximately equal to the wire speed. This gravity-fed arrangement permits applicant's machine to be run at an overall speed that is much higher (*e.g.*, more than 700 feet/minute) than conventional machines, without producing undesirable effects on the quality of the paper web.

Hypothetical Claim

1. A Fourdrinier machine having a breast-roll end of a paper-making wire maintained at a substantial elevation above level, whereby stock is caused to travel by gravity, rapidly, in the direction of movement of the paper-making wire, and at a speed approximately equal to the speed of the paper-making wire.

Analysis

Claim 1: Eligible.

The claim recites a Fourdrinier machine with a paper-making wire (conveyor belt) that is passed over a breast-roll. The claim is directed to a machine (a combination of mechanical parts), which is one of the statutory categories of invention (*Step 1: YES*).

Next, the claim must be evaluated to determine if the claim is directed to a judicial exception. But when the claim is reviewed, it is immediately evident that although the claimed machine operates using gravity, which is a law of nature, the claim clearly does not seek to tie up this law of nature so that others cannot utilize it. In particular, the claim's recitation of a Fourdrinier machine (which is understood in the art to have a specific structure comprising a headbox, a paper-making wire, and a series of rolls) that is arranged in a particular way to optimize the speed of the machine while maintaining quality of the formed paper web makes it clear that the claim as a whole would clearly amount to significantly more than any recited exception. The claim as a whole adds meaningful limitations to the use of the law of nature (gravity). Additionally, use of the law of nature improves paper-making technology. Thus, eligibility of the claim is self-evident for these reasons, and there is no need to perform the full eligibility analysis (*e.g.*, Steps 2A and 2B). The claim is patent eligible.

If the examiner believes that the record would benefit from clarification, remarks could be added to an Office action or reasons for allowance indicating that while the claim recites gravity - a law of nature - the claim clearly amounts to significantly more than the mere use of gravity by providing meaningful limitations to the law of nature and additionally improving paper-making technology.

It is noted that although Eibel Process Co. was decided prior to the 1952 Patent Act, the Supreme Court has subsequently described the decision as upholding the eligibility of process claims containing a law of nature. *See, e.g*., Diamond v. Diehr, 450 U.S. 175, 187-88 (1981); Parker v. Flook, 437 U.S. 584, 590-91 and n.12 (1978).

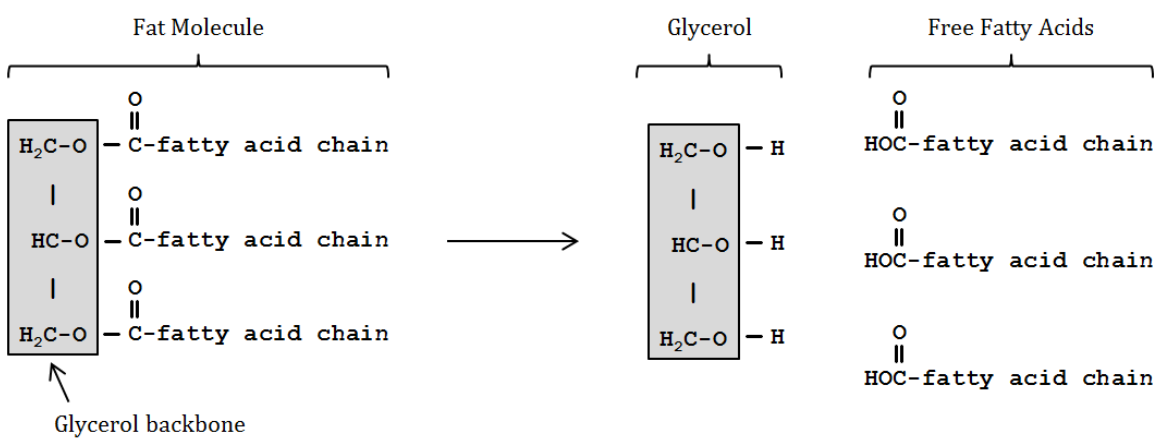
33. Hydrolysis of Fat

This hypothetical example demonstrates the use of the streamlined analysis. The claim below is based on the technology from U.S. Patent 11,766, which was upheld by the Supreme Court in Tilghman v. Proctor, 102 U.S. 707 (1881). As a streamlined analysis would not result in a written rejection, the discussion sets forth exemplary reasoning an examiner might use in drawing a conclusion of eligibility.

Background

Fats are naturally occurring chemicals that are found in many plants and animals, *e.g.*, in tree nuts such as walnuts. As shown in Figure 1, each fat molecule comprises a glycerol backbone to which three fatty acid chains are bound.

Figure 1



As also shown in Figure 1, fat molecules can be broken down into free fatty acids and glycerol (also called glycerine) via a chemical reaction. At the time applicant made the invention and filed the application, it was routine and conventional to carry out this chemical reaction using either the alkaline saponification process, or the sulphuric-acid distillation process. Both of these conventional processes required the use of a steam distillation step in order to produce free fatty acids, and also required the fat to be mixed with either lye or sulphuric acid.

Applicant invented a process of hydrolyzing fat molecules into free fatty acids and glycerol without steam distillation, and using only water as opposed to lye or sulphuric acid. This hydrolysis process begins with a mixture of substantially equal quantities of fat and water in a vessel that is closed and strong enough to resist the effort of the mixture to convert itself into steam. The mixture is then gradually heated to a high temperature (at least 600 degrees Fahrenheit) and kept at that temperature for at least 10 minutes, so that a chemical reaction takes place between the water and fat. While it is heated, the mixture is also subjected to sufficient pressure to prevent the water-fat mixture from forming steam inside the closed vessel.

Hypothetical Claim

1. A process for obtaining free fatty acids and glycerol from fat comprising:

   mixing substantially equal quantities of fat and water in a closed vessel; and

heating the mixture to an elevated temperature of at least 600 degrees Fahrenheit under sufficient pressure to prevent the formation of steam in the closed vessel; and

maintaining the elevated temperature for at least 10 minutes so that the fat and water react with each other to form free fatty acids and glycerol.

Analysis

Claim 1: Eligible.

The claim recites a series of steps for mixing and heating fat and water. Thus, the claim is directed to a process, which is one of the statutory categories of invention (*Step 1: YES*).

Next, the claim must be evaluated to determine if the claim is directed to a judicial exception. But when the claim is reviewed, it is immediately evident that although the claim is founded upon a chemical principle relating to neutral fats, it is not attempting to tie up any judicial exception so that others cannot practice it. In particular, the claim's description of mixing substantially equal quantities of fat and water, heating the mixture to an elevated temperature of at least 600 degrees Fahrenheit under sufficient pressure to prevent the formation of steam in the closed vessel, and maintaining the elevated temperature for at least 10 minutes so that the fat and water react with each other to form free fatty acids and glycerol, makes it clear that the claim as a whole would clearly amount to significantly more than any potential recited exception. For example, the claim as a whole effects a transformation of the fat and water into different chemicals, *i.e.*, from fat and water into the fatty acids and glycerol, by means of specific and unconventional steps. Thus, eligibility of the claim is self-evident in the streamlined analysis, without needing to perform the full eligibility analysis (*e.g.*, Steps 2A and 2B). The claim is patent eligible.

It is important to point out as well that there is no apparent exception recited in the claim, which alone would be sufficient for eligibility. Although the claim is clearly based upon a law of nature (the chemical principle or scientific fact that the elements of neutral fat require that they be severally united with an atomic equivalent of water in order to separate from each other and become free), the law of nature is not recited in the claim. The cases in which courts found claims directed to laws of nature are those in which the law is recited in the claim as part of the invention, such as when the claim sets forth or describes a naturally occurring principle.

If the examiner believes that the record would benefit from clarification, remarks could be added to an Office action or reasons for allowance, indicating that the claim is not directed to any judicial exception.

It is noted that although Tilghman was decided prior to the 1952 Patent Act, the Supreme Court has subsequently described the decision as upholding the eligibility of process claims containing a law of nature. *See, e.g.*, Parker v. Flook, 437 U.S. 584, 590-91 and n.12 (1978); Gottschalk v. Benson, 409 U.S. 63, 70 (1972).

The following examples should be used in conjunction with the *2014 Interim Guidance on Subject Matter Eligibility* (2014 IEG) and the follow-on guidance. As the examples are intended to be illustrative only, they should be interpreted based on the fact patterns set forth below. Other fact patterns may have different eligibility outcomes. While some of the fact patterns draw from U.S. Supreme Court or U.S. Court of Appeals for the Federal Circuit decisions, each of the examples shows how claims should be analyzed under the 2014 IEG. All of the claims are analyzed for eligibility in accordance with their broadest reasonable interpretation. Citations for the cases discussed in these examples are provided in the chart of court decisions available on the Office's website.

Note that the examples herein are numbered consecutively beginning with number 34, because 33 examples were previously issued.

34. System for Filtering Internet Content

The following was a claim found eligible by the Federal Circuit in BASCOM Global Internet v. AT&T Mobility LLC, 119 USPQ2d 1236 (Fed. Cir. 2016) (BASCOM). The patent at issue is U.S. Patent No. 5,987,606. As the claim in this example is eligible, no written analysis would be provided in an Office action. Claim 1 is directed to an abstract idea and has additional elements that amount to significantly more than the abstract idea because they add specific limitations other than what are well-understood, routine, conventional activities in the field and result in an improvement to the technology of filtering content on the Internet. The court's rationale for eligibility is explained below in the context of the 2014 IEG.

Background

Applicant has invented a system for filtering content from an Internet computer network by an Internet Service Provider (ISP) server using individual controlled access network accounts. At the time of applicant's invention in 1997, there was a need to block access to certain web sites for certain end users. For example, a corporation may want to allow access to certain technical or business sites, while blocking access to certain entertainment sites, and a parent may seek to block access by their children to certain objectionable sites.

Previous systems controlled access to content received by client machines over the Internet by filtering the information available using "black-listing" (*i.e.*, preventing access to all web sites on a predetermined list of web sites), "white-listing" (*i.e.*, allowing access to all web sites that are on a predetermined list of web sites), or word-screening or phrase-screening (*i.e.*, preventing access to a web page that contains any word or phrase on a predetermined list). Initially, the filtering software was placed on a client computer. However, this configuration suffered from several disadvantages because the end user could modify or work around the filtering software, the difficulty and time to install on each client computer was great, each client computer required configuration of the software based on its hardware and operating system, and a database storing the allowed or disallowed websites needed to be frequently updated. To overcome the disadvantages of installing the filtering software on a client computer, the filtering software was placed on a local server. In this configuration, client computers on a local area network connected to the Internet through a local server. If an end user on a client computer requested a website on the Internet, the local server would filter all requests for Internet content. This approach suffered from similar disadvantages including being limited to one set of filtering criteria, time-consuming installation and maintenance, and the filtering software being tied to one local area network or local server platform. Finally, ISPs used a server-based configuration in which a filter was installed on their remote servers to prevent

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subscribers from accessing certain websites. However, this configuration only allowed for a single set of filtering criteria for all of the subscriber's end users.

In the instant application, applicant's system improves upon the prior art filtering systems by providing a system for filtering Internet content by subscribers on an individually customizable basis. An ISP server stores a filtering scheme in memory and a database of a plurality of sets of filtering elements associated with individual end users. The filtering scheme is executable code, including object code, interpreted code (*e.g.*, Java™ or Javascript™), other high-level code, or a combination thereof. The ISP server associates an end user account with a set of filtering elements from a plurality of filtering elements (*e.g.*, a master list of words or phrases that are not allowed) and one or more filtering schemes (*e.g.*, a word-screening type or phrase-screening type filtering scheme).

In applicant's system, the ISP server receives a log-in request from an end user. After verifying the identity of the end user, the ISP server determines the filtering scheme and filtering elements associated with the end user based on the end user account. The ISP server then receives a request to access a website from the end user and identifies the particular website requested. The ISP server implements the filtering scheme associated with the end user account utilizing the customized filtering elements that are associated with the end user account. The ISP server then determines whether the filtering scheme authorizes the request. If the request is authorized, it is processed and forwarded to the Internet. If it is not authorized, the ISP server provides a rejection notice to the end user.

In one embodiment, a request to access the Internet from an end user is partially processed while the ISP server monitors the content for certain words or phrases using the filtering scheme (*e.g.*, a word-screening or phrase-screening scheme). In this embodiment, the ISP server stores a table of logged-in end users associated with the filtering scheme. The request for Internet access is forwarded directly to the Internet. The ISP server then monitors all data packets transmitted to the ISP server to determine which packets will be forwarded to the end users stored in the table. If a data packet is being sent to a user stored in the table, the ISP server screens the packet based on the filtering scheme and filtering elements associated with that end user's account. If the data packet(s) match the filtering elements of the filtering scheme, such as by containing specific words or phrases, the transmission of the data packet(s) to the user is terminated.

<u>Representative Claim</u>

1. A content filtering system for filtering content retrieved from an Internet computer network by individual controlled access network accounts, said filtering system comprising:

a local client computer generating network access requests for said individual controlled access network accounts;

at least one filtering scheme;

a plurality of sets of logical filtering elements; and

a remote ISP server coupled to said client computer and said Internet computer network, said ISP server associating each said network account to at least one filtering scheme and at least one set of filtering elements, said ISP server further receiving said network access requests from said client computer and executing said associated filtering scheme utilizing said associated set of logical filtering elements.

Analysis

Claim 1: Eligible

The claim recites a local client computer and a remote ISP server that implements at least one filtering scheme and a plurality of sets of logical filtering elements. The system comprises a device or set of devices and, therefore, is a machine, which is a statutory category of invention (*Step 1: YES*).

The claim is then analyzed to determine if the claim is directed to a judicial exception. The claim recites a system for filtering content retrieved from an Internet computer network, which generates access requests for individual accounts, associates each account with at least one filtering scheme and at least one set of filtering elements from a plurality of sets of filtering elements, receives the access requests, and executes the associated filtering scheme utilizing the associated set of filtering elements. Thus, the focus of the claim and its character as a whole is on the idea of filtering content, which is implemented by a system that uses computer and networking components.

Filtering content is according to the court a "method of organizing human behavior" that is similar to other concepts that have been identified as abstract by the courts, such as tracking financial transactions to determine whether they exceed a pre-set spending limit in *Intellectual Ventures I v. Capital One Bank;* 1) collecting data, 2) recognizing certain data within the collected data set, and 3) storing that recognized data in a memory in *Content Extraction;* and organizing information through mathematical correlations in *Digitech*. Therefore, it is reasonable to conclude based on the similarity of the idea described in this claim to several abstract ideas found by the courts that claim 1 is directed to an abstract idea (*Step 2A: Yes*).

This conclusion is not altered by *Enfish*, where the Federal Circuit stated that certain claims directed to improvements in computer-related technology, including claims directed to software, are not necessarily abstract (*Step 2A*). Unlike the claims in *Enfish*, claim 1 is not clearly directed to an improvement in computer-related technology (*e.g.*, computer functionality). Thus, because it is not readily apparent that claim 1 is directed to a non-abstract idea under *Step 2A*, it is necessary to analyze the additional elements in claim 1 under *Step 2B*.

It is noted, however, that the Federal Circuit in BASCOM described claim 1 as presenting a "close call" as to what it is directed to. Thus, if an examiner skilled in this art recognizes that the claim is directed to an Internet-centric problem, for example, or clearly to an improvement in the computer technology of filtering, it would be appropriate to find that the claim, while "involving" an abstract idea is not "directed" to that idea standing alone, thus ending the analysis with a finding of eligibility at Step 2A.

Under *Step 2B*, the claim as a whole is analyzed to determine whether any element, or combination of elements, is sufficient to ensure the claim amounts to significantly more than the abstract idea. The claim recites the additional limitations of 1) controlled access network accounts, 2) a local client computer to generate network access requests for the controlled access network accounts, 3) an Internet computer network, and 4) a remote ISP server coupled to the client computer and the Internet computer network. The remote ISP server associates each account with at least one filtering scheme and at least one set of filtering elements from a plurality of sets of filtering elements, receives the access requests, and executes the associated filtering scheme utilizing the associated set of filtering elements. The local computer, ISP server, Internet computer network, and controlled access network account are generic computer and networking components performing generic computer and networking functions at a high level of generality. As the Federal Circuit determined, these limitations do not amount to significantly more when "taken individually, [because they] recite generic computer, network and Internet components, none of which is inventive by itself."

However, the analysis under *Step 2B* (also called the "inventive concept inquiry") requires more than determining that each additional claim element – the controlled access network accounts, a local

client computer, an Internet computer network, and a remote ISP server – is well known by itself. Here, an inventive concept can be found in the unconventional and non-generic ***combination*** of known elements, and more specifically "the installation of a filtering tool at a specific location, remote from the end-users, with customizable filtering features specific to each end user" where the filtering tool at the ISP is able to "identify individual accounts that communicate with the ISP server, and to associate a request for Internet content with a specific individual account." The Federal Circuit also determined that the claimed arrangement of elements in the system results in an improvement in the technology of filtering content on the Internet, because it offers "both the benefits of a filter on the local computer, and the benefits of a filter on the ISP server."

Further, these limitations confine the abstract idea to a particular, practical application of the abstract idea and, as explained in the specification, this combination of limitations is not well-understood, routine or conventional activity. Unlike the claimed system, previous content filtering systems were able to be modified by end users when the systems were located on local client computers rather than on the ISP server and were dependent on hardware and software on the local computer, or limited to a configuration based on the particular local client computer, local server, or ISP server. In addition, these limitations do not simply recite an instruction to apply the abstract idea of filtering content on the Internet or to perform the abstract idea on a generic set of computers. Instead, the claim recites a "technology-based solution" of filtering content on the Internet that overcomes the disadvantages of prior art filtering systems. Thus, when viewed as an ordered combination, the claim limitations amount to significantly more than the abstract idea of content filtering (*Step 2B: Yes*). The claim is patent eligible.

In practice, if an examiner believes the record would benefit from clarification, remarks could be added to the Office action or reasons for allowance indicating that the claim recites the abstract idea of filtering content. However, the claim is eligible because analyzing the claim limitations as an ordered combination demonstrates that the claim is a particular application of and an improvement to the technology of filtering content on the Internet, rather than well-understood, routine, conventional activity or a simple instruction to apply the abstract idea of filtering content on the Internet or to perform the abstract idea on a generic set of computers.

<u>Additional explanation of prior decisions from *BASCOM*</u>

The following discussion of case law is informative regarding the reasoning that led the court in *BASCOM* to hold claim 1 patent-eligible. It may be useful to examiners to recognize the similarities and differences as identified by the Federal Circuit between claim 1 and the claims at issue in *DDR*, *OIP, Intellectual Ventures I*, *Content Extraction*, *Ultramercial*, and *Accenture*. A discussion of the case law to this extent is not required during examination.

In *DDR*, the claimed invention solved the problem of retaining potential customers on a website by "sending the viewer to a hybrid webpage that combined visual elements of the first website with the desired content from the second website that the viewer wished to access." The claimed invention in *DDR* was not a "business method *per se*." Similarly, even though claim 1 in *BASCOM* was "engineered in the context of filtering content," claim 1 is not simply directed to the abstract idea of filtering content applied to the Internet, *i.e.*, abstract idea + "apply it". Instead, claim 1 recites a "technology-based solution" of filtering content on the Internet that overcomes the problems in the prior art with other Internet content filtering systems rather than "an abstract-idea-based solution" (*i.e.*, a solution "implemented with generic technical components in a conventional way").

In contrast, in *OIP*, the claims were directed to the performance of the abstract idea of price optimization on generic computer components using conventional computer functions. In other words, the claimed invention was "simply the generic automation of traditional price-optimization

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techniques" and was not a "technology-based solution" of the abstract idea. Claim 1 of *BASCOM* presents a "technology-based solution" of filtering content on the Internet that overcomes the problems in the prior art with other Internet content filtering systems as discussed above.

Finally, the claims in *Intellectual Ventures I*, *Content Extraction*, *Ultramercial*, and *Accenture* are directed to an abstract idea performed on generic computer components, "without providing a specific technical solution beyond simply using generic computer concepts in a conventional way." In *Intellectual Ventures I*, the claims were directed to the abstract idea of tracking financial transactions to determine whether they exceed a pre-set spending limit simply implemented on a generic computer and the Internet. In *Content Extraction*, the claims were directed to the abstract idea of collecting data, recognizing certain data within the collected data set, and storing that recognized data in a memory performed on generic scanning devices and computers. In *Ultramercial*, the claims were directed to the abstract idea of using advertising as an exchange or currency on the Internet. And finally, the claims in *Accenture* were directed to the abstract idea of generating rule-based tasks for processing an insurance claim using generic computer components performing conventional activities. Unlike the claims in *Intellectual Ventures I*, *Content Extraction*, *Ultramercial*, and *Accenture*, claim 1 of *BASCOM* is not simply directed to the abstract idea of filtering content on the Internet or on generic computer components performing conventional activities. Instead, claim 1 "carve[s] out a specific location for the filtering system (a remote ISP server) and require the filtering system to give users the ability to customize filtering for their individual network accounts."

35. Verifying A Bank Customer's Identity To Permit An ATM Transaction

The following fact pattern and claims are hypothetical. Assume that the claims are presented in a recently filed application that is under examination and thus each claim is given its broadest reasonable interpretation in view of the specification as it would be understood by one of ordinary skill in the art. In this example, the terms in the claim are given their plain meaning in the art because no special definitions have been set forth in the specification. An abbreviated version of the hypothetical specification is provided below. Claim 1 is ineligible, because it is directed to an abstract idea and does not recite additional elements that amount to significantly more. Claims 2 and 3 are directed to the same abstract idea, but are eligible because they have additional elements that amount to significantly more than the abstract idea (i.e., provide an inventive concept) because they implement the abstract idea with specific meaningful limitations.

Background

Financial institutions routinely provide automated teller machines (ATMs) for customers to conduct banking transactions at convenient locations other than brick-and-mortar banks, and without the need to interact with a bank teller. Typical ATMs include a customer interface with a keypad, function key, display, outlet slot for statements or other information, cash dispenser slot, deposit inlet, and often a speaker to provide customer voice guidance and a camera to monitor transactions. A reader is provided for customers to present data bearing records, which can include data corresponding to the customer, financial accounts, or other data, and are commonly embodied as a bank card with a magnetic strip or a contactless card with a radio frequency identification (RFID) tag. Other input devices, such as a biometric reader to receive customer identifying inputs such as fingerprints, iris scans, and face topography data, a camera, or speech recognition device, used to identify a user can be provided as well. The customer interface is coupled to a controller with a processor and memory and a network communicator to enable communication between the controller and a financial institution to exchange information about the transactions. To conduct a transaction, a customer typically inserts a bank card into the appropriate slot in the ATM and inputs a personal identification

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number (PIN) that verifies that the user is an authorized user for the bank account associated with the bank card. The account data is read from the card using the reader in the ATM and the PIN associated with the card. The network communicator transmits the read data and PIN to a remote computer at the financial institution, which then transmits instructions back to the ATM regarding authorization to carry out the requested transaction.

Due to its speed and convenience, the use of ATMs to conduct banking business has become ubiquitous, but so have problems with theft and fraud. For example, if another person illegally or fraudulently obtains a user's PIN, that person can gain access to funds in the account. Another problem associated with ATMs is "skimming" where a false card reader that appears to be a legitimate reader is affixed to an ATM to obtain an authorized user's account information and PIN. In skimming operations, an authorized user unwittingly presents their bank card to the skimming device on the ATM and enters their PIN, which is then captured and stored for subsequent fraudulent activity.

There have been various solutions attempting to reduce the instance of fraud associated with ATMs and to improve security when verifying an authorized user. For example, some bank cards are provided with chips that interact with a special reader to generate a unique transaction number each time a transaction is conducted to reduce the chance that a user's account information and PIN can be stolen for later use (so-called "chip and pin" cards). Bank cards have also been outfitted with RFID tags or "smart labels" (non-contact transponders) that allow account information to be transmitted to an ATM without inserting the card into the machine, and thus exposing it to theft or skimming. The smart label can contain various types of customer information, including profile data, preferences, and unique customer identification data. To conduct a transaction using such a contactless card, the customer brings the card into range of an ATM reader, which uses radio frequencies to interrogate the smart label to receive information about the customer. The interrogation can be encrypted to provide additional security. The customer can then start a transaction, *e.g.*, by pressing an enter key on the ATM. While such cards can prevent fraud based on skimming, these non-contact cards have given rise to other security issues, such as allowing a malicious person to obtain card information by use of an unauthorized RFID reader.

Applicant has invented a method of ensuring secure transmission of data from a card using a smart label and encryption techniques. The invention leverages the wide-spread use of mobile personal communication devices (smart phones) to facilitate the secure transmission. When a customer is issued a bank card with a smart label, the financial institution also provides a downloadable software application to the customer to install on their mobile communication device. The software application is designed to assist communication with a specially outfitted ATM.

The ATM in accordance with this invention includes a controller that is programmed with a time-variant random code generator. The code generator generates a random code when activated in response to the reader receiving data from the customer's bank card. In other words, when the customer is within a certain range of the ATM with their bank card, the smart label is read from the RFID reader in the ATM, which signals the code generator to generate a time-variant random code, which can be a plurality of digits, numbers and/or letters. The ATM then provides the random code to the customer. In one embodiment, the ATM provides the random code by displaying it. The customer is prompted to enter the displayed code into their mobile device, which already has the institutional software installed. In another embodiment, the random code is transmitted by the ATM to the customer's mobile device, *e.g.*, by a near-field communication or Bluetooth link, if the customer has installed the institutional software on their mobile device and registered their mobile device with the institution.

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The software provided by the institution generates data in response to the random code, which may be, *e.g.*, a customer confirmation code or an encryption that includes the code data and the card's data. The software then causes the mobile device to communicate the responsive data to the ATM. In one embodiment, the mobile device displays the encrypted data as an image on its display screen. The image can be machine readable data in the form of a bar code or an image such as a colored pattern. The customer is prompted to allow the ATM to scan the image displayed by the mobile device. The reader of the ATM reads the encrypted image and verifies that it is authentic by, for example, determining if it is readable, recognizable, or properly formatted. Once verified, the processor in the ATM decrypts the data and confirms that the decrypted code matches the random code that was generated for the current transaction session. In another embodiment, the customer confirmation code is obtained by the ATM (*e.g.*, by transmission over near-field communication or Bluetooth link), and the ATM then confirms that the customer confirmation code matches the random code. The outcome of the comparison between the responsive code data (*e.g.*, the decrypted code or the customer confirmation code) and the random code is used to control access to the keypad. In particular, if the responsive code data and the generated code match and the elapsed time is within a certain time frame, the transaction is continued in conventional fashion with the customer entering a PIN using the keypad. If the responsive code data and generated code do not match or the elapsed time exceeds the time frame, a signal is sent to lock the keypad so that any attempts at entering a PIN will be futile.

Applicant's method allows the ATM to receive user card data in a more secure and efficient manner. Customer card data entry begins before PIN entry and verification, so if the ATM user is not the authorized customer and does not have the appropriate verification software on their mobile device, the transaction is concluded before entry of the PIN. This method prevents skimming and other techniques to fraudulently obtain a customer's PIN and even theft of the card since the downloaded software can authenticate the user and likewise authenticate the ATM before the PIN is produced.

<u>Claims</u>

1. A method of conducting a secure automated teller transaction with a financial institution by authenticating a customer's identity, comprising the steps of:

obtaining customer-specific information from a bank card,

comparing, by a processor, the obtained customer-specific information with customer information from the financial institution to verify the customer's identity, and

determining whether the transaction should proceed when a match from the comparison verifies the authenticity of the customer's identity.

2. A method of conducting a secure automated teller transaction with a financial institution by authenticating a customer's identity, comprising the steps of:

obtaining customer-specific information from a bank card,

comparing, by a processor, the obtained customer-specific information with customer information from the financial institution to verify the customer's identity, by

generating a random code and transmitting it to a mobile communication device that is registered to the customer associated with the bank card,

reading, by the automated teller machine, an image from the customer's mobile communication device that is generated in response to receipt of the random code, wherein the image includes encrypted code data,

decrypting the code data from the read image, and

analyzing the decrypted code data from the read image and the generated code to determine if the decrypted code data from the read image matches the generated code data, and

determining whether the transaction should proceed when a match from the analysis verifies the authenticity of the customer's identity.

3. A method of conducting a secure automated teller transaction with a financial institution by authenticating a customer's identity, comprising the steps of:

obtaining customer-specific information from a bank card,

comparing, by a processor, the obtained customer-specific information with customer information from the financial institution to verify the customer's identity, by

generating a random code and visibly displaying it on a customer interface of the automated teller machine,

obtaining, by the automated teller machine, a customer confirmation code from the customer's mobile communication device that is generated in response to the random code, and

determining whether the customer confirmation code matches the random code, and

automatically sending a control signal to an input for the automated teller machine to provide access to a keypad when a match from the analysis verifies the authenticity of the customer's identity, and to deny access to a keypad so that the transaction is terminated when the comparison results in no match.

Analysis

Claim 1: Ineligible

The claim recites a method of conducting a secure automated teller transaction comprising a series of steps. Thus, the claim is directed to a process, which is a statutory category of invention (*Step 1: Yes*).

The claim is then analyzed to determine if the claim is directed to a judicial exception. The claim recites the steps of obtaining customer-specific information, comparing the obtained customer-specific information with customer information from the financial institution to authenticate the customer's identity, and determining whether the transaction should proceed when a match from the comparison verifies the authenticity of the customer's identity. These steps describe a method of fraud prevention by verifying the authenticity of the customer's identity prior to proceeding with a banking transaction, which is a "long prevalent" business practice that bank tellers have used for many years. Fraud prevention by verifying the identity of the customer is as fundamental to business as the economic concepts that were identified as abstract ideas by the Supreme Court, such as intermediated settlement (*Alice Corp.*) and risk hedging (*Bilski*). The claim as a whole is also similar to the claimed invention in *CyberSource*, which the Federal Circuit described as directed to an abstract mental process for detecting fraud by obtaining and comparing intangible data pertinent to business risks. The method of claim 1 similarly recites steps of obtaining and comparing data pertinent to business risks. More particularly, it describes a method of fraud prevention by authenticating a customer's identity. Therefore, claim 1 is directed to an abstract idea (*Step 2A: Yes*).

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Next, the claim as a whole is analyzed to determine whether any element, or combination of elements, is sufficient to ensure the claim amounts to significantly more than the abstract idea. In addition to the steps that describe the abstract idea of preventing fraud through verifying a customer's identity, the claim recites the additional limitation of obtaining customer-specific information from a bank card. This additional element taken individually represents a conventional action of an ATM, as evidenced by the discussion of the prior art in the background specification. Further, the step is recited at a high level of generality such that it amounts to insignificant pre-solution activity, *e.g.*, a mere data gathering step necessary to use the abstract idea. The claim also recites the additional element of a processor comparing data. This processor is no more than a generic computer component, and the comparison performed by the processor does not represent any computer function beyond what processors typically perform. Taken individually therefore, the additional elements of claim 1 do not provide significantly more, *i.e.*, an inventive concept, to the claim.

Looking at the combination of elements in claim 1 also fails to show an inventive concept. Unlike the eligible claims in *Diehr* and *Bascom*, in which the elements limiting the exception were individually conventional but taken together provided an inventive concept because they improved a technical field, the claim here does not invoke any of the considerations that courts have identified as providing significantly more than an exception. The combination of elements is no more than the sum of their parts, and provides nothing more than mere automation of verification steps that were in years past performed mentally by tellers when engaging with a bank customer. Mere automation of an economic business practice does not provide significantly more (*i.e.*, provide an inventive concept). For these reasons, claim 1 is ineligible (*Step 2B: No*).

A rejection of claim 1 should identify the abstract idea by pointing to the language of the claim that describes fraud prevention by identity verification (*i.e.*, obtaining customer information, comparing the obtained customer information to customer information from a financial institution, and determining whether the transaction should proceed when a match from the comparison verifies the authenticity of the customer's identity) and explaining that fraud prevention by identity verification is similar to concepts that courts have previously found abstract. The rejection should identify the additional limitations regarding obtaining customer-specific information from a bank card and a processor that compares data, and explain why those limitations are conventional or are only generic computer components performing generic functions and are mere automation of economic business practices.

<u>Claim 2: Eligible</u>

The claim recites a method of conducting a secure automated teller transaction comprising a series of steps. Thus, the claim is directed to a process, which is a statutory category of invention (*Step 1: Yes*).

The claim is then analyzed to determine if the claim is directed to a judicial exception. Claim 2 recites steps of obtaining customer-specific information, comparing the obtained customer-specific information with customer information from the financial institution to authenticate the customer's identity, and determining whether the transaction should proceed when a match from the analysis verifies the authenticity of the customer's identity. Like the steps of obtaining and comparing customer information in claim 1, these steps in claim 2 describe a method of fraud prevention by identity verification before proceeding with a banking transaction, which as explained above is a fundamental business practice and is similar to ideas found abstract by the courts. Therefore, claim 2 is directed to an abstract idea (*Step 2A: Yes*).

Next, the claim as a whole is analyzed to determine whether any element, or combination of elements, is sufficient to ensure the claim amounts to significantly more than the abstract idea. In addition to

the steps that describe the abstract idea of preventing fraud through identity verification, the claim recites the additional limitations of obtaining customer-specific information from a bank card, a processor comparing data, generating a random code and transmitting it to the customer's mobile communication device, and the processor reading an image that was generated by the customer's mobile communication device in response to receipt of the random code, where the image includes encrypted code data. The encrypted code data from the image is then used by the processor to verify the customer's identity by decrypting the code data and analyzing the decrypted code data. Considered individually, the steps of obtaining information from a bank card and the comparing data do not provide significantly more for the same reasons as in claim 1. Similarly, the processor and the mobile communication device are recited at a high level of generality and perform programmed functions that represent conventional and generic operations for these devices, including reading data, generating random codes, and analyzing data.

However, the ***combination*** of the steps (*e.g.*, the ATM providing a random code, the mobile communication device's generation of the image having encrypted code data in response to the random code, the ATM's decryption and analysis of the code data, and the subsequent determination of whether the transaction should proceed based on the analysis of the code data) operates in a non-conventional and non-generic way to ensure that the customer's identity is verified in a secure manner that is more than the conventional verification process employed by an ATM alone. In combination, these steps do not represent merely gathering data for comparison or security purposes, but instead set up a sequence of events that address unique problems associated with bank cards and ATMs (*e.g.*, the use of stolen or "skimmed" bank cards and/or customer information to perform unauthorized transactions). Thus, like in *BASCOM*, the claimed combination of additional elements presents a specific, discrete implementation of the abstract idea. Further, the combination of obtaining information from the mobile communication device (instead of the ATM keypad) and using the image (instead of a PIN) to verify the customer's identity by matching identification information does not merely select information by content or source, in contrast to *Electric Power,* but instead describes a process that differs from the routine and conventional sequence of events normally conducted by ATM verification, such as entering a PIN, similar to the unconventional sequence of events in *DDR*. The additional elements in claim 2 thus represent significantly more (*i.e.,* provide an inventive concept) because they are a practical implementation of the abstract idea of fraud prevention that performs identity verification in a non-conventional and non-generic way, even though the steps use well-known components (a processor and mobile communication device). Claim 2 is eligible (*Step 2B: Yes*).

While an examiner would not be required to provide an explanation of eligibility, the record would be enhanced if clarifying remarks were provided to point to the reason for eligibility. In this instance, clarification could easily be made by simply pointing to the combination of elements used in the non-conventional implementation of identity verification in the method of fraud prevention.

<u>Claim 3: Eligible</u>

The claim recites a method of conducting a secure automated teller transaction comprising a series of steps. Thus, the claim is directed to a process, which is a statutory category of invention (*Step 1: Yes*).

The claim is then analyzed to determine if the claim is directed to a judicial exception. Claim 3 recites steps of obtaining customer-specific information, comparing the obtained customer-specific information with customer information from the financial institution to authenticate the customer's identity, and permitting the transaction to proceed when a match from the analysis verifies the authenticity of the customer's identity, and terminating the transaction when there is no match. Like the steps of obtaining and comparing customer information in claim 1, these steps in claim 3 describe

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a method of fraud prevention by identity verification before proceeding with a banking transaction, which as explained above is a fundamental business practice and is similar to ideas found abstract by the courts. Therefore, claim 3 is directed to an abstract idea (*Step 2A: Yes*).

Next, the claim as a whole is analyzed to determine whether any element, or combination of elements, is sufficient to ensure the claim amounts to significantly more than the abstract idea. In addition to the steps that describe the abstract idea of preventing fraud through identity verification, the claim recites the additional limitations of obtaining customer-specific information from a bank card, a processor comparing data, the ATM generating a random code and visibly displaying it on a customer interface, and the ATM obtaining a customer confirmation code that was generated by the customer's mobile communication device in response to the random code. The customer confirmation code is then used by the ATM to verify the customer's identity by analyzing the customer confirmation code with respect to the random code, and controlling the transaction by providing or preventing access to a keypad of the ATM based on the analysis of the code data. Considered individually, the ATM obtaining information from a bank card and the processor comparing data do not provide significantly more for the same reasons as in claim 1. Similarly, the ATM and the mobile communication device are recited at a high level of generality and perform programmed functions that represent conventional and generic operations for these devices, including reading data, generating random codes, and analyzing data.

However, the ***combination*** of the steps (*e.g.*, the ATM's provision of the random code, the mobile communication device's generation of the customer confirmation code in response to the random code, the ATM's analysis of the customer confirmation code, and the ATM's subsequent sending of a control signal to provide or prevent access to the keypad of the ATM and thus allow or prevent a transaction based on the analysis of the code data sets) operates in a non-conventional and non-generic way to ensure that the customer's identity is verified in a secure manner that is more than the conventional verification process employed by an ATM alone. In combination, these steps do not represent merely gathering data for comparison or security purposes, but instead set up a sequence of events that address unique problems associated with bank cards and ATMs (*e.g.*, the use of stolen or "skimmed" bank cards and/or customer information to perform unauthorized transactions). Thus, like in *BASCOM*, the claimed combination of additional elements presents a specific, discrete implementation of the abstract idea. Further, the combination of obtaining information from the mobile communication device (instead of the ATM keypad) and using the customer confirmation code (instead of a PIN) to verify the customer's identity does not merely select information by content or source, in contrast to *Electric Power,* but instead describes a process that differs from the routine and conventional sequence of events normally conducted by ATM verification, such as entering a PIN, similar to the unconventional sequence of events in *DDR*. The additional elements in claim 3 thus represent significantly more (*i.e.,* provide an inventive concept) because they are a practical implementation of the abstract idea of fraud prevention that performs identity verification in a non-conventional and non-generic way, even though the steps use a combination of well-known components (an ATM and mobile communication device). Claim 3 is eligible (*Step 2B: Yes*).

While an examiner would not be required to provide an explanation of eligibility, the record would be enhanced if clarifying remarks were provided to point to the reason for eligibility. In this instance, clarification could easily be made by simply pointing to the combination of elements used in the non-conventional implementation of identity verification in the method of fraud prevention.

36. Tracking Inventory

The following fact pattern and claims are hypothetical. Assume that the claims are presented in a recently filed application that is under examination and thus each claim is given its broadest reasonable interpretation in view of the specification as it would be understood by one of ordinary skill in the art. In this example, the terms in the claim are given their plain meaning in the art because no special definitions have been set forth in the specification. An abbreviated version of the hypothetical specification is provided below. Claim 1 is ineligible, because it is directed to an abstract idea and does not recite additional elements that amount to significantly more. Claims 2 and 3 are directed to the same abstract idea, but are eligible because they recite specific limitations other than what would be well-understood, routine, conventional activities in the field, which amount to significantly more (i.e., provide an inventive concept).

Background

Inventory management is a commercial practice involving the acquisition and monitoring of stocked goods to maintain stock levels in a business. Particularly when goods are stored in large warehouses, managing inventory requires monitoring what goods are currently in stock and where those goods are located in the warehouse in order to fulfill orders in an efficient manner. Some prior methods of tracking inventory required items of inventory to have an attached tracking device such as a RFID or GPS transmitter, but these methods were cumbersome to implement since each item needed a transmitter to be affixed and detached as the item entered and exited the warehouse. In addition, these methods could not accurately track an item if the transmitter was obscured, improperly affixed, or detached from the item. Other prior methods used imaging technology to acquire and process images to track the items of inventory, but these methods did not have much success because they used the view of a single camera to track an object and attempted to identify items solely based upon character data (such as identification codes or product names) printed on the item. Due to using the view of a single camera to track an object, it was difficult to determine an object's physical three-dimensional (3-D) location. Therefore, these methods required items that were moved to be reimaged or otherwise tracked through manual scanning or logging. Mistakes in data entry or failure to scan a moved item resulted in lost or misplaced items. Accordingly, previous attempts to implement image recognition to track items of inventory have not achieved a high rate of accuracy.

Applicant has invented a system for tracking the presence and location of items of inventory in a warehouse using an integrated camera system with computer vision technology that overcomes many of the problems in the existing technologies typically used in the industry. Applicant's system overcomes the issues relating to accurately identifying items and tracking missing items by using a high resolution video camera array with overlapping views in combination with a recognition model that uses not only the character data of the item but also contour information (*i.e.* shape) from the collected images and predictive location data. By using a combination of character and contour recognition, applicant's system greatly reduces the possibility of item misidentification and significantly improves accuracy of inventory over prior techniques that used only character information. Because the cameras in the array have overlapping views, objects can be tracked across multiple cameras and the 3-D location of the objects can be automatically reconstructed. Applicant's improvement to computer vision technology to manage inventory within existing warehouse operations thus results in more accurate inventory tracking while eliminating the need for procedures such as scanning and logging items.

In practice, the invention uses high resolution video cameras positioned to have overlapping fields of view in pre-determined locations throughout the inventory storage space. Such cameras enable the system to automatically track an item across the entire storage space and estimate its physical location. An inventory recognition model is also stored in the memory and comprises a mathematical

representation of each item of inventory handled by the particular warehouse. This model may be a Gaussian mixture model, neural network, Bayes classifier or other known pattern classifier. The model is developed using a supervised training algorithm using numerous images of each item at multiple distances and positions with respect to the camera. During training, characteristics of each item are extracted from the images including character information such as the item's name and identification code and contour information such as the shape of the item and/or the shape of the packaging for the item. The recognition model may be updated as needed when items are added or discontinued.

During operation, the video cameras capture an image sequence (*e.g.*, multiple images from one or more of the cameras) comprising overlapping images of an item, which is stored in the memory in an inventory record. The system then uses a programmed computer to extract characteristics of an item including character and contour information from the high resolution images in the image sequence using a combination of existing text and edge detection algorithms. The programmed computer uses the characteristics to form feature vectors, and then classify the item by processing the feature vectors with the inventory recognition model to determine the most likely item in the image. A positive recognition result indicates the presence of the item in the warehouse. After an item is recognized, it is tracked in real-time throughout the warehouse using a tracking algorithm that takes advantage of the overlapping camera views to confirm the location of the item (thus improving retrieval time and accuracy). Specifically, the item is tracked in the image sequence of one camera using a known method, such as Kalman filtering, and once that item enters the field of vision of a second camera, its position in the first camera's view is used to quickly locate the item in the second camera's view. The item can then be tracked similarly in the image sequence of the second and subsequent cameras. The computer then reconstructs the 3-D coordinates of the item based upon the item's location in multiple overlapping images and prior knowledge of the location and field of view of the camera(s) that are tracking the item. Finally, the computer updates the item's inventory record with the 3-D location information.

In this hypothetical scenario, computer vision technology has not been used in the manner disclosed by this inventor prior to the filing of the application.

<u>Claims</u>

1. A system for managing an inventory record comprising a memory and processor configured to perform the steps of:

   (a) creating an inventory record for an item of inventory comprising acquired images of the item;

   (b) adding classification data relating to the acquired images to the inventory record;

   (c) adding location data relating to each acquired image to the inventory record; and

   (d) updating the inventory record with a physical location of each item of inventory in the warehouse to thereby manage the items of inventory.

2. A system for managing an inventory record by tracking the location of items of inventory in a warehouse:

   a high-resolution video camera array, each video camera positioned at pre-determined locations with overlapping views, for acquiring at least one high-resolution image sequence of each item of inventory;

a memory and processor configured to perform the steps of:

(a) creating an inventory record for an item of inventory comprising the acquired image sequence of the item from the video camera array;

(b) adding classification data relating to the acquired image sequence to the inventory record;

(c) adding location data relating to each acquired image to the inventory record, the location data providing a position of the item of inventory in the image sequence;

(d) reconstructing the 3-D coordinates of an item of inventory using the location data from multiple overlapping images and prior knowledge of the location and field of view of the camera(s); and

(e) automatically updating the inventory record with the 3-D coordinates of each item of inventory in the warehouse to thereby manage the items of inventory.

3. A system for managing inventory by tracking the location of items of inventory in a warehouse using image recognition, comprising:

a high-resolution video camera array for acquiring at least one high resolution image sequence of each item;

a memory for storing the acquired image sequences, classification and location data relating to the acquired image sequences, and a recognition model representing contour information and character information of each item; and

a processor that is configured to manage inventory by performing, for each item, the steps of:

(a) creating an inventory record for the item comprising the acquired image sequence(s) of the item;

(b) extracting characteristics from the acquired image sequence(s) of an item to form feature vectors, the characteristics comprising contour information and character information that is stored in the inventory record as classification data relating to the acquired image sequence(s);

(c) recognizing and tracking the position of item in the image sequence as classification and location data by processing the feature vectors using the stored recognition model and adding the classification and location data to the inventory record;

(d) determining a physical location of the item in the warehouse using the location data relating to the item in the image sequence(s); and

(e) automatically updating the inventory record with the physical location of the item.

<u>Analysis</u>

<u>Claim 1: Ineligible</u>

The claim recites a system for managing an inventory record comprising a memory and a processor configured to perform a series of steps. The claimed system is a device or set of devices, which is a machine and thus a statutory category of invention (*Step 1: Yes*).

The claim is then analyzed to determine if the claim is directed to a judicial exception. The claim recites a system that performs the steps of (a)-(c) storing acquired images and related classification

and location data, and (d) updating the inventory record with the physical location of each item of inventory in the warehouse. That is, the claim describes the steps of managing inventory by creating an inventory record for each item of inventory comprising images of the item, adding classification data relating to the images to the inventory record, adding location data for each image to the inventory record, and updating the inventory record with the physical location of each item of inventory in the warehouse. The data collection, recognition, and storage concept described in the claim is similar to the data collection and management concepts that were held to be abstract ideas in *Content Extraction, TLI Communications*, and *Electric Power Group.* Although the claim enumerates the type of information (*i.e.*, the images, classification data, and location data) that is acquired, stored and analyzed, the Federal Circuit has explained in *Electric Power Group* and *Digitech* that the mere selection and manipulation of particular information by itself does not make an abstract concept any less abstract. Further, the claim is not made any less abstract by the invocation of a programmed computer. Unlike *Enfish*, where the claims were focused on a specific improvement in ***how*** the computer functioned, the claim here merely uses the computer as a tool to perform the abstract concepts. Therefore, based on the similarity of the concept described in this claim to abstract ideas identified by the courts, claim 1 is directed to an abstract idea (*Step 2A: Yes*).

Next, the claim as a whole is analyzed to determine whether any element, or combination of elements, is sufficient to ensure the claim amounts to significantly more than the abstract idea. The claim recites the additional limitations of a memory and processor to perform the steps of inventory tracking. A memory for storing data and a processor for processing data are well-understood, routine, conventional computer components, which in this claim are recited at a high level of generality and perform generic computer functions (*e.g.*, storing and processing information). Generic computer components performing generic computer functions, alone, do not amount to significantly more than the abstract idea.

Viewing the limitations in combination also fails to amount to significantly more than the abstract idea. The claimed invention seeks to record, process, and archive digital images simply, fast, and in such a way that the information may be easily tracked, but these functions reflect ordinary usage typically performed by a generic computer, as would be recognized by those of ordinary skill in the field of data processing. For example, as noted in *TLI Communications*, using a computer to attach classification data, such as dates and times, to images for purposes of storing those images in an organized manner does not add significantly more to a judicial exception. The recitation of conventional processing technology performing well-understood, routine, conventional functions such as recognizing and storing data from specific data fields does not reflect an "inventive concept." Thus, whether viewed individually or in combination, the additional limitations do not amount to a claim as a whole that is significantly more than the abstract idea (*Step 2B: No*). The claim is not patent eligible.

A rejection of claim 1 should identify the abstract idea by pointing to the language of the claim that describes inventory management and explaining that inventory management is similar to concepts that courts have previously found abstract. The rejection should identify the additional limitations regarding the memory and processor and explain why those limitations comprise only a generic computer performing well-understood, routine, conventional generic functions in the particular technological environment of image processing, for the reasons noted above.

<u>Claim 2: Eligible</u>

The claim recites a system comprising a video camera array, a memory and a processor. The system is a device or set of devices and therefore is a machine, which is a statutory category of invention (*Step 1: Yes*).

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The claim is then analyzed to determine if the claim is directed to a judicial exception. Like claim 1, claim 2 recites a system that performs the steps of (a)-(c) acquiring and storing images and related data about items of inventory, and (e) updating the inventory record with the physical location of each item of inventory in the warehouse. Claim 2 thus describes using data collection and management techniques to practice the concept of inventory management, which as explained above is an abstract idea. Therefore, the claim is directed to an abstract idea (*Step 2A: Yes*).

Next, the claim as a whole is analyzed to determine whether any element, or combination of elements, is sufficient to ensure the claim amounts to significantly more than the abstract idea. The claim recites the additional limitations of a high-resolution video camera array at predetermined positions with overlapping views, memory and processor to (d) reconstruct the 3-D coordinates of the item of inventory from multiple overlapping images obtained from the camera array and prior knowledge of the location and field of view of the camera(s). Individually, the memory and processor limitations do not amount to significantly more for the reasons discussed above for claim 1. For example, they are still well-understood, routine, conventional devices that are used in this invention for their conventional functions of processing and storing information. Similarly, high-resolution video cameras are widely used and, in this invention, perform their typical function of acquiring image sequences.

However, the memory and processor in combination with a high-resolution video camera array with predetermined overlapping views that reconstructs the 3-D coordinates of the item of inventory using overlapping images of the item and prior knowledge of the location and field of view of the camera(s) provides significantly more than the abstract idea of using data collection techniques to manage inventory. As explained in the specification, at the time of this invention, using a high-resolution video camera array with overlapping views to track items of inventory was not well-understood, routine, conventional activity to those in the field of inventory control. In fact, the use of this camera array provides the ability to track objects throughout the entire storage space rather than simply the view of a single camera and determine their 3-D location without any of the manual steps that were required of previous methods. That is, the video camera array with reconstruction software provides the technological solution to the technological problem of automatically tracking objects and determining their physical position using a computer vision system. Like in *DDR*, the claimed solution here is necessarily rooted in computer technology to address a problem specifically arising in the realm of computer vision systems. The claimed limitations are not simply an attempt to generally link the abstract idea to the technological environment of computer vision systems. Rather, these are meaningful limitations that confine the claim to a particular useful application. Accordingly, when viewed as a combination, the additional elements thus yield a claim as a whole that amounts to significantly more than the abstract idea of inventory management (*Step 2B: Yes*). The claim is patent eligible.

If the examiner believes the record would benefit from clarification, remarks could be added to the Office action or reasons for allowance indicating that the claim recites the abstract idea of inventory management. Nevertheless, the claim is eligible because analyzing the claim elements in combination demonstrates the claim is a technology-based solution to address a problem arising in the realm of computer vision systems and is not simply limiting the abstract idea to a particular technological environment.

<u>Claim 3: Eligible</u>

The claim recites a system comprising one or more video cameras, memory and a processor. The system is a device or set of devices and therefore is a machine, which is a statutory category of invention (*Step 1: Yes*).

The claim is then analyzed to determine if the claim is directed to a judicial exception. Like claim 1, claim 3 recites a system that performs the steps of (a) & (c) storing acquired images and related classification and location data, and (e) updating the inventory record with the physical location of each item of inventory in the warehouse. Claim 3 thus describes using data collection and management techniques to practice the concept of inventory management, which as explained above is an abstract idea. Therefore, the claim is directed to an abstract idea (*Step 2A: Yes*).

Next, the claim as a whole is analyzed to determine whether any element, or combination of elements, is sufficient to ensure the claim amounts to significantly more than the abstract idea. The claim recites the additional limitations of a high-resolution video camera array for acquiring high resolution image sequences of items of inventory, a memory to store the acquired images, related data, and the recognition model, and a processor to perform step (b)'s extracting characteristics from the acquired images, step (c)'s recognizing and tracking the position of the item using the recognition model and step (d)'s determining a physical location of the item using the position of the item in the images. Individually, the camera array, memory and processor limitations do not amount to significantly more for the reasons discussed above for claims 1 and 2. For example, these components are used in this invention for their well-understood, routine, conventional functions of acquiring, processing and storing information.

In combination, however, the limitations do amount to significantly more than the abstract idea of inventory management. As explained in the specification, the combination of the camera array's acquisition of high resolution image sequences, and the processor's performance of step (b)'s extracting contour and character information from the images to create feature vectors, step (c)'s recognizing and tracking items of inventory using the feature vectors and a recognition model, and step (d)'s determining the physical location of the recognized items using the position of the item in the image sequence(s) is not well-understood, routine, conventional activity in this field. This combination of limitations provides a hardware and software solution that improves upon previous inventory management techniques by avoiding the cumbersome use of RFID and GPS transmitters and the inaccuracy issues that plagued previous computer vision solutions. This combination of features provide meaningful limitations to the practical application of inventory tracking with computer vision, by improving the system's ability to identify and track objects across multiple cameras in a three-dimensional space. These limitations do not simply limit the abstract idea to the technological environment of image processing, but are instead meaningful limitations that integrate the abstract idea into a particular application that uses character and contour information from high resolution images to recognize items of inventory. When viewed as a combination, the additional elements thus yield a claim as a whole that amounts to significantly more than the abstract idea of inventory management (*Step 2B: Yes*). The claim is patent eligible.

If the examiner believes the record would benefit from clarification, remarks could be added to the Office action or reasons for allowance indicating that the claim recites the abstract idea of inventory management. Nevertheless, the claim is eligible because analyzing the claim elements in combination demonstrates the claim is a particular application rather than well-understood, routine, conventional activity or simply limiting the abstract idea to a particular technological environment.