SEÑORA DIRECTORA
DIRECCIÓN DE NUEVAS CREACIONES
SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO

EXPEDIENTE No. : NC2017/0004974
ASUNTO : SOLICITUD DE PATENTE DE INVENCIÓN TITULADA "**EXTRACTOS DE CANNABIS Y MÉTODOS DE PREPARACIÓN**".
SOLICITANTE : UNITED CANNABIS CORP.

Yo, **FERNANDO TRIANA SOTO**, ciudadano colombiano, mayor de edad, abogado en ejercicio y debidamente identificado como aparece al pie de mi firma, en mi calidad de apoderado de la sociedad **UNITED CANNABIS CORP.** existente y organizada de acuerdo con las leyes de los Estados Unidos de América, con domicilio en Denver, Colorado, Estados Unidos de América, de acuerdo con el oficio No. 2114 expedido por ésa entidad, me permito presentar respuesta al referido oficio, de acuerdo con las siguientes consideraciones:

1. DE LA SOLICITUD DE PATENTE

1.1. En relación a las reivindicaciones, el señor examinador expresa que la reivindicación 20 no es clara, ya que hace referencia a Neobee 895, que es una marca registrada y por tanto no definen al producto porque su composición puede cambiar con el paso del tiempo aunque conserve el mismo nombre y sugiere aclarar cuáles son las características del producto en cuestión.

Además advierte que las reivindicaciones 20 y 21 no son claras, ya que en el paso c) se refiere a de -28,889º (-20º) sin indicar las unidades. Por otra parte, indica que la temperatura es 75°F cuando en la descripción aparece -75°F, que son -59.4°C (Ej. 3). Además, en el paso e) y la reiv. 21 indica que 284°F son 29.536°C, cuando en realidad son 140°C.

Agrega que, la reivindicación 21 no es clara, ya que el término *"alrededor"* no permite limitar el alcance de la invención y se sugiere definir la característica en un rango o valor específico.

Al respecto, es necesario señalar que no obstante a no estar de acuerdo con la objeción de claridad que el oficio hace sobre la reivindicación 20, únicamente con el propósito de acelerar el trámite, la reivindicación 20 se modifica para recitar "(b) extraer los cannabinoides del material vegetal para producir un primer extracto, en donde la extracción comprende una extracción con un triglicérido de cadena media que comprende una combinación de uno o más ácidos grasos de C-6; C-8; C-10 y C-12".

De acuerdo con lo anterior, la reivindicación 20 en su versión enmendada, no enseña ni sugiere la marca comercial Neobee 895, por lo que solicitamos reconsiderar y el retirar la observación sobre la reivindicación 20.

1.2. En respuesta, presentamos un nuevo pliego reivindicatorio que ha sido modificado en las reivindicaciones 1, 17, 18, 20 y 21 y el sustento para las reivindicaciones enmendadas 1, 17 y 18 se puede encontrar en los párrafos [0062] - [0063] de la especificación presentada. El soporte para la reivindicación 20 modificada se puede

encontrar en el párrafo [0030], [0034], [0056] - [0057], [0063], [0076] y [00108]. Adicionalmente, se enmendaron las temperaturas que se describen en las reivindicaciones 20 y 21. La reivindicación 21 enmendada elimina la palabra *"alrededor"*, por lo que dicha objeción también es superada.

1.3. En relación a la descripción, el señor examinador indica que no es divulgada la invención de manera suficientemente completa para que la persona normalmente versada en la materia técnica correspondiente pueda ejecutarla o reproducirla, porque no se especifican las condiciones de la extracción cuando se hace con hidrocarburos o extracción supercrítica de CO2, siendo estas condiciones críticas para establecer el tipo de compuestos extraídos del material vegetal y su proporción.

Al respecto, el solicitante respetuosamente señala que no está de acuerdo. A pesar de no compartir las afirmaciones descritos en el Oficio, y únicamente para acelerar el proceso, la reivindicación 20 se ha modificado.

1.4. De esta forma, la reivindicación 20 enmendada no recita la extracción por hidrocarburos o CO_2 supercrítico. Por lo tanto, el solicitante sostiene respetuosamente que la memoria descriptiva describe de manera suficiente y completa la invención de la reivindicación 20 y las reivindicaciones 21-29, que dependen adecuadamente de la misma. Se solicita, respetuosamente, la reconsideración y el retiro de la objeción.

2. NO ES UNA INVENCIÓN

2.1. El señor examinador, procede también a definir que la solicitud no es una invención dado que el objeto de las reivindicaciones 1 a 19 no es patentable, pues se refiere a formulaciones donde el 95% o más del total de cannabinoides en la formulación es ácido tetrahidrocanabinoico o tetrahidrocanabinol o canabidiol y hace a la formulación indistinguible de los compuestos puros. Adicionalmente, caracterizar la formulación porque es líquida no permite distinguirla de los compuestos puros, indicando que se deben incluir en la composición los componentes y sus proporciones que hacen que esta sea líquida. Las reivindicaciones dependientes que se refieren a que la composición comprende "menos de…" o "no más de…" un porcentaje de otro componente, no subsana el problema, ya que el porcentaje podría ser cero y se estaría reclamando el compuesto puro.

2.2. En ese sentido, el solicitante respetuosamente no está de acuerdo. Como primera medida, las reivindicaciones 37 y 38 se cancelaron previamente sin perjuicio o renuncia de responsabilidad, por lo que se inició el rechazo con respecto a estas reivindicaciones. Con respecto a la respuesta previa del solicitante, en el oficio se declara que "dentro del rango de concentración reclamado, que es mayor al 95%, cabe la sustancia pura que sería una resina como indica el solicitante y no es posible que la sustancia pura cambie su estado físico a líquido". El solicitante respetuosamente expresa que la Oficina interpreta erróneamente la reivindicación 1.

La reivindicación 1 recita una formulación líquida de cannabinoides "en la que el 95% o más del total de cannabinoides en la formulación" se selecciona del grupo de cannabinoides y combinaciones de cannabinoides citados en la reivindicación.

2.3. Por lo tanto, los principales cannabinoides enumerados por (a) - (k) de la nueva reivindicación 1 enmendada no son el 95% o más de la formulación, sino más bien "el 95% o más del total de cannabinoides en la formulación " (reivindicación 1, énfasis agregado). El beneficio de esta característica de la invención es que diferentes cannabinoides pueden administrarse por separado a un sujeto como parte de un régimen terapéutico. Por ejemplo, se pueden administrar diferentes formulaciones de cannabinoides durante el día y la hora de acostarse (consulte la descripción párrafo [0084] y los ejemplos 7-9). Por lo tanto, la sustancia pura no tiene que cambiar su estado físico, como afirma el Oficio, para que la formulación sea un líquido. Además, se afirma en el oficio, "ya que {la solicitud} al referirse a formulaciones donde el 95% o más del total de cannabinoides en la formulación es ácido tetrahidrocanabinoico, tetrahidrocanabinol o canabidiol, hace a la formulación indistinguible de los compuestos puros". Sin aceptar las afirmaciones del Oficio y únicamente para acelerar el proceso, la reivindicación 1 se modifica aquí para recitar una formulación líquida de cannabinoides "en la que la formulación líquida de cannabinoides comprende un vehículo, diluyente o excipiente farmacéuticamente aceptable".

2.4. El solicitante sostiene respetuosamente que la formulación de la reivindicación 1, y las reivindicaciones 2 a 19, que dependen adecuadamente de ellos, se distinguen de los compuestos puros por el "portador, diluyente o excipiente farmacéuticamente aceptable" mencionado en la reivindicación 1 enmendada. Esta característica distintiva de las formulaciones de cannabinoides reivindicadas es relevante para la naturaleza de la invención como sustancia farmacológica botánica. Por ejemplo, las composiciones farmacéuticas reivindicadas que comprenden un vehículo, diluyente o excipiente farmacéuticamente aceptable pueden formularse para administración oral, sublingual o tópica. De hecho, la especificación establece que "la elección de diluyentes, vehículos o excipientes dependerá de la forma de dosificación deseada, que a su vez puede depender de la vía de administración prevista para el paciente" (Párrafo [0062]). Por lo tanto, la formulación de la reivindicación 1 y de las reivindicaciones 2 a 19, que dependen adecuadamente de la misma, puede distinguirse de los compuestos puros.

2.5. Por último, el solicitante desea llamar la atención de la Oficina de Patentes de Colombia sobre una orden reciente del Tribunal de Distrito de los Estados Unidos para el Distrito de Colorado, que analiza reivindicaciones independientes similares en los procedimientos de litigio de la patente estadounidense No. 9,730,911. La patente de EE. UU. Nº 9.730.911, que es una contraparte de la presente solicitud.

Al igual que el Artículo 15, Literal b) de la Decisión 486 de la Comunidad Andina, el Tribunal Supremo de los Estados Unidos ha encontrado que "las leyes de la naturaleza, los fenómenos naturales y las ideas abstractas no son patentables" (Alice Corp. Pty. V. CLS Bank Int'l , 573 US, 134 S. Ct. 2347, 2354, 110 USPQ2d 1976, 1980 (2014), p. 5, se adjunta copia de cortesía adjunta).

Con respecto a las reivindicaciones bajo análisis en la patente 9,730,911, el Tribunal de Distrito de Colorado, al negar la moción del Demandado, sostiene que "las reivindicaciones no son declaraciones de 'la obra de la naturaleza', 'Funk Brothers, 333 US a 131', sino {United Cannabis Corp} propio {trabajo}, ' *Chakrabarty* , 447

US a 310 ”(United Cannabis Corp. v. Pure Hemp Collective, Orden del 17 de abril de 2019, pág. 13, copia de cortesía que se incluye a continuación).

2.6. Por todo lo anterior, el solicitante sostiene que las reivindicaciones 1-19 están dirigidas a materia patentable, y el rechazo en virtud del literal b) Artículo 15 de la Decisión 486 ha sido superado. Respetuosamente, solicitamos reconsiderar y el retirar el rechazo sobre este argumento en la presente solicitud.

3. RESPECTO AL ESTADO DE LA TÉCNICA

3.1. El señor examinador, procede a determinar el examen del estado de la técnica con base en el documento D1: US8846409. En ese sentido procede a establecer una tabla de comparación y concluye que la presente no comprende altura inventiva frente a D1 así:

Ítem	Documento	Reivindicaciones afectadas	Requisito que afecta
D1	US8846409	20 a 29	Nivel inventivo

3.2. Por su parte, el documento D1 divulga métodos para preparar un extracto de cannabis que incluye descarboxilar, extraer los canabinoides y retirar el material ceroso (Col. 17).

3.3. En el oficio No. 2114 es considerado D1 como el documento de la técnica anterior más cercana, que describe dos pasos de "tratamiento con solventes" cuando se purifican los cannabinoides (ver D1, columna 7, líneas 44-46). D1 describe los disolventes preferidos de D1 como "alcoholes, particularmente alcoholes C1-C5, siendo particularmente preferido el metanol, y también alcanos de cadena ramificada o lineal C5-C12, lo más preferiblemente pentano" (D1, columna 8, líneas 1-4). Como se muestra en las hojas de datos de seguridad del material adjunto, tanto el metanol como el pentano, los disolventes preferidos de D1, son riesgos para la salud. Por ejemplo, la Ficha de Datos de seguridad (o MSDS por su sigla en inglés) para el metanol dice "¡Peligro! ¡Veneno!”. Por otro lado, la MSDS para pentano indica que el pentano tiene “toxicidad específica de órganos diana después de una exposición única”. Una persona versada en la técnica, proveyendo un extracto de cannabis preparado utilizando los métodos de D1, el cual podría razonablemente contener trazas de disolventes peligrosos utilizados en el proceso de extracción como el metanol o el pentano, probablemente no considerarán el extracto adecuado para la administración a sujetos humanos.

3.4. En contraste, la reivindicación 20 enmendada, de la cual dependen adecuadamente todas las demás reivindicaciones sujetas al rechazo, recita los pasos de:

a. Proporcionar material vegetal de cannabis fresco o vivo;
b. extraer los cannabinoides desde el material de plantas para producir un primer extracto, en donde la extracción comprende una extracción con un triglicérido de cadena media que comprende una combinación de uno o más ácidos grasos de C-6; C-8; C-10 y C-12 ; c. congelar el extracto de la etapa (b) para producir un extracto almacenado, en donde la preparación congelada comprende agregar etanol frío al primer extracto o almacenar el primer extracto a una temperatura de -20º a -75º F durante 48 horas para producir un precipitado ceroso;

d. purgar el extracto congelado de la etapa (c) al vacío para producir un extracto de cannabis; y
e. calentar el extracto de la etapa (d) a 284 ° F durante 45-74 minutos, seguido de calentamiento a 29 3 ° F durante al menos 55-90 minutos "(énfasis agregado).

Como se indica en la especificación, el triglicérido de cadena media (MCT) con el que se extraen los cannabinoides es "adecuado para el consumo humano" (Párrafo [0063]). Por lo tanto, a diferencia de los métodos de D1, los métodos de la reivindicación 20 comprenden la extracción de cannabinoides directamente en un disolvente que es adecuado para el consumo humano y, por lo tanto, es seguro para el consumo humano.

3.5. Los métodos de la reivindicación 20 y las reivindicaciones 21-29 que dependen adecuadamente de los mismos, por lo tanto producen extractos de cannabis con una seguridad e idoneidad inesperadas y superiores para el consumo humano sobre los extractos de cannabis producidos por los métodos de D1. D1 no enseña ni sugiere los métodos y solventes de las reivindicaciones actuales 20-29. Una persona versada en el arte, considerando los métodos de D1 y el conocimiento de la técnica en la presentación, no hubiera podido modificar las enseñanzas de D1 para llegar a la invención de las reivindicaciones 20-29. Por lo tanto, las reivindicaciones 20-29 son inventivas sobre D1. La reconsideración y el retiro del rechazo son respetuosamente solicitados.

3.6. En consecuencia, a la luz de todo lo anterior, me permito solicitar a ese Despacho, que la invención citada en la referencia sea concedida bajo el tenor de las reivindicaciones que se presentan como adjunto a ésta respuesta. Sin embargo, incluso si el examinador lo considera insuficiente en conjunto con las nuevas reivindicaciones o el razonamiento que aquí se presenta, la solicitante ruega respetuosamente que se le ofrezca una nueva oportunidad, a través un nuevo Oficio para expresarse sobre cualquier tema en controversia.

4. ANEXOS

4.1. Un nuevo capítulo reivindicatorio.

4.2. Copia de *Alice Corp. Pty. V. CLS Bank Int'l , 573 US, 134 S. Ct. 2347, 2354, 110 USPQ2d 1976, 1980 (2014), p. 5.*

4.3. Copia de *United Cannabis Corp. v. Pure Hemp Collective, Orden del 17 de abril de 2019, pág. 13.*

4.4. Ficha de Datos de Seguridad (MSDS) Metanol y Pentano.

5. NOTIFICACIONES

Para efectos de notificaciones que por disposición debe hacer su Despacho, informo que mi representada y el suscrito recibiremos notificaciones en la Secretaría de su Despacho o en mis oficinas de abogado situadas en la Calle 93B No. 12-48, Piso 4, de la ciudad de Bogotá.

Del Señor Director,

FERNANDO TRIANA SOTO
C.C. 79.154.036 de Bogotá
T.P.A. 45.265 del C. S. de la J.

6252861092155/Mgr
Colo 7804 0301 76755

REIVINDICACIONES

1. Una formulación líquida de canabinoides, en donde la formulación líquida de canabinoides se selecciona del grupo que consiste en:
   a. Una formulación donde el 95% o más del total de canabinoides en la formulación es ácido tetrahidrocanabinoico (THCa);
   b. Una formulación donde el 95% o más del total de canabinoides en la formulación es tetrahidrocanabinol (THC);
   c. Una formulación donde el 95% o más del total de canabinoides en la formulación es canabidiol (CBD);
   d. Una formulación donde el 95% o más del total de canabinoides en la formulación es THCa y ácido canabidiólico (CBDa);
   e. Una formulación donde el 95% o más del total de canabinoides en la formulación es THC y CBD;
   f. Una formulación donde el 95% o más del total de canabinoides en la formulación es CBD, canabinol (CBN) y THC.
   g. Una formulación en la que al menos el 95% del total de cannabinoides en la formulación es cannabidiol (CBDa);
   h. Una formulación en la que al menos el 95% del total de cannabinoides en la formulación es cannabicromeno (CBC);
   i. Una formulación en la que al menos el 95% del total de cannabinoides en la formulación es ácido cannabicroménico (CBCa);
   j. Una formulación que comprende al menos un 95% de tetrahidrocannabinol (THC) como el único cannabinoide en la formulación; y
   k. Una formulación en donde al menos el 95% del total de cannabinoides en la formulación es tetrahidrocannabinol (THC) de cannabis indica o cannabis ruderalis; y

   en donde la formulación líquida de cannabinoides comprende un vehículo, diluyente o excipiente farmacéuticamente aceptable.

2. La formulación de canabinoides de la reivindicación 1, donde la formulación comprende además uno o más terpenos o flavonoides.
3. La formulación de canabinoides de la reivindicación 2, donde la formulación de canabinoides comprende no más del 4% de terpenos.
4. La formulación de canabinoides de la reivindicación 1, donde el 95% o más del total de canabinoides de la formulación es CBD y la formulación comprende menos de 1% de THC.
5. La formulación de canabinoides de la reivindicación 1, donde el 95% o más del total de canabinoides de la formulación son CBD, CBN y THC, y la formulación comprende menos del 9% de THC.
6. La formulación de canabinoides de la reivindicación 1, donde el 95% o más de los canabinoides de la formulación es THCa, y la formulación comprende no más de 4% en terpenos.
7. La formulación de canabinoides de la reivindicación 1, donde el 95% o más de los canabinoides de la formulación es THC, y la formulación comprende no más de 4% en terpenos.
8. La formulación de canabinoides de las reivindicaciones 6 ó 7, donde el terpeno comprende mirceno, cariofileno y limoneno.

9. La formulación de canabinoides de la reivindicación 1, donde el 95% o más de los canabinoides de la formulación es CBD, y la formulación comprende no más de 4% en terpenos.
10. La formulación de canabinoides de las reivindicación 9, donde el terpeno comprende mirceno, cariofileno y limoneno.
11. La formulación de canabinoides de la reivindicación 1, donde el 95% o más de los canabinoides de la formulación son THCa y CBDa, y la formulación comprende no más de 4% en terpenos.
12. La formulación de canabinoides de la reivindicación 1, donde el 95% o más de los canabinoides de la formulación son THC y CBD, y la formulación comprende no más de 4% en terpenos.
13. La formulación de canabinoides de las reivindicaciones 11 ó 12, donde el terpeno comprende limoneno, pineno y cariofileno.
14. La formulación de canabinoides de las reivindicaciones 11 ó 12, donde el terpeno comprende mirceno, limoneno, pineno y cariofileno.
15. La formulación de canabinoides de la reivindicación 1, donde el 95% o más de los canabinoides de la formulación son CBD, CBN y THC, y la formulación comprende no más de 4% en terpenos.
16. La formulación de canabinoides de las reivindicación 15, donde el terpeno comprende mirceno, pineno y cariofileno.
17. La formulación de canabinoides según cualquiera de las reivindicaciones precedentes, donde el portador, diluyente o excipiente farmacéuticamente aceptable comprende un triglicérido de cadena mediana.
18. La formulación de canabinoides de las reivindicación 17, en la que el triglicérido de cadena media comprende una combinación de uno o más de C-6; C-8; Ácidos grasos C-10 y C-12.
19. La formulación de canabinoides según cualquiera de las reivindicaciones precedentes, donde el pH de la formulación de canabinoides es de 8,0 o más.
20. Un método para preparar un extracto de cannabis, donde el método comprende:
    a. Proveer material de plantas de cannabis vivas o frescas;
    b. Extraer los canabinoides desde el material de plantas para producir un primer extracto, en donde la extracción comprende una extracción con un triglicérido de cadena media que comprende una combinación de uno o más de C-6; C-8; Ácidos grasos C-10 y C-12;
    c. congelar el extracto del paso (b) para producir un extracto almacenado, en donde la preparación congelada comprende agregar etanol frío al primer extracto o almacenar el primer extracto a una temperatura de -6,64°C (-20ºF) a -59,4°C (-75ºF) durante 48 horas para producir un precipitado ceroso;
    d. Purgar el extracto congelado del paso (c) al vacio para producir un extracto de cannabis; y,
    e. calentar el extracto de la etapa (d) a 140ºC (284 °F) durante 45-74 minutos, seguido de calentamiento a 145 ºC (293 °F) durante al menos 55-90 minutos.
21. El método de la reivindicación 20, el que además comprende descarboxilar los fitocanabinoides antes del paso (b), y donde la descarboxilación comprende calentar las plantas secas a una temperatura de alrededor de

105ºC (221°F) durante 15 minutos o más, seguido por calentamiento a alrededor de 140ºC (284 °F) durante 45 minutos o más.

22. El método de la reivindicación 20, donde el material de plantas consiste en flores o flores y hojas.
23. El método de la reivindicación 20, en donde el material de plantas de cannabis se congela a una temperatura entre -23,333ºC (-10°F) a -45,556ºC (-50°F), por 36 horas o más antes de ser extraídas.
24. El método de la reivindicación 20, el material de plantas de cannabis ha sido propagado desde una semilla única o un tejido cultivado con razones específicas de canabinoides.
25. El método de la reivindicación 20, el que además comprende filtrar el extracto congelado a través de carbón activado.
26. El método de la reivindicación 20, donde el material de planta de cannabis se deriva de una cepa que tiene un mínimo de 15% de THC y un mínimo de 1% de CBD.
27. El método de la reivindicación 20, donde el material de planta de cannabis se deriva de las cepas Sour Tsunami x Catatonic Sour Tsunami x Sour Tsunami, Sour Tsunami, Harlequin, R4 o ACDC.
28. El método de la reivindicación 20, donde el material de planta de cannabis se deriva de las cepas CBD1, Sour Pineapple, CBD Diesel, Harlequin, ACDC o R4.
29. El método de la reivindicación 21, donde el material de planta de cannabis se deriva de las cepas Sour Tsunami x Catatonic, Sour Tsunami x Sour Tsunami, Sour Tsunami, Harlequin, R4, Swiss Gold, ACDC, CBD1, Sour Pineapple o CBD Diesel.

Syllabus

NOTE: Where it is feasible, a syllabus (headnote) will be released, as is being done in connection with this case, at the time the opinion is issued. The syllabus constitutes no part of the opinion of the Court but has been prepared by the Reporter of Decisions for the convenience of the reader. See *United States* v. *Detroit Timber & Lumber Co.,* 200 U. S. 321, 337.

SUPREME COURT OF THE UNITED STATES

Syllabus

ALICE CORPORATION PTY. LTD. *v.* CLS BANK INTERNATIONAL ET AL.

CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

No. 13–298. Argued March 31, 2014—Decided June 19, 2014

Petitioner Alice Corporation is the assignee of several patents that disclose a scheme for mitigating "settlement risk," *i.e.,* the risk that only one party to an agreed-upon financial exchange will satisfy its obligation. In particular, the patent claims are designed to facilitate the exchange of financial obligations between two parties by using a computer system as a third-party intermediary. The patents in suit claim (1) a method for exchanging financial obligations, (2) a computer system configured to carry out the method for exchanging obligations, and (3) a computer-readable medium containing program code for performing the method of exchanging obligations.

Respondents (together, CLS Bank), who operate a global network that facilitates currency transactions, filed suit against petitioner, arguing that the patent claims at issue are invalid, unenforceable, or not infringed. Petitioner counterclaimed, alleging infringement. After *Bilski* v. *Kappos*, 561 U. S. 593, was decided, the District Court held that all of the claims were ineligible for patent protection under 35 U. S. C. §101 because they are directed to an abstract idea. The en banc Federal Circuit affirmed.

Held: Because the claims are drawn to a patent-ineligible abstract idea, they are not patent eligible under §101. Pp. 5–17.

(a) The Court has long held that §101, which defines the subject matter eligible for patent protection, contains an implicit exception for '"[l]aws of nature, natural phenomena, and abstract ideas.'" *Association for Molecular Pathology* v. *Myriad Genetics, Inc.*, 569 U. S. ___, ___. In applying the §101 exception, this Court must distinguish patents that claim the "'buildin[g] block[s]'" of human ingenuity, which are ineligible for patent protection, from those that integrate

the building blocks into something more, see *Mayo Collaborative Services* v. *Prometheus Laboratories, Inc.*, 566 U. S. ___, ___, thereby "transform[ing]" them into a patent-eligible invention, *id.,* at ___. Pp. 5–6.

(b) Using this framework, the Court must first determine whether the claims at issue are directed to a patent-ineligible concept. 566 U. S., at ___. If so, the Court then asks whether the claim's elements, considered both individually and "as an ordered combination," "transform the nature of the claim" into a patent-eligible application. *Id.,* at ___. Pp. 7–17.

(1) The claims at issue are directed to a patent-ineligible concept: the abstract idea of intermediated settlement. Under "the longstanding rule that '[a]n idea of itself is not patentable,' " *Gottschalk* v. *Benson*, 409 U. S. 63, 67, this Court has found ineligible patent claims involving an algorithm for converting binary-coded decimal numerals into pure binary form, *id.,* at 71–72; a mathematical formula for computing "alarm limits" in a catalytic conversion process, *Parker* v. *Flook*, 437 U. S. 584, 594–595; and, most recently, a method for hedging against the financial risk of price fluctuations, *Bilski*, 561 U. S, at 599. It follows from these cases, and *Bilski* in particular, that the claims at issue are directed to an abstract idea. On their face, they are drawn to the concept of intermediated settlement, *i.e.,* the use of a third party to mitigate settlement risk. Like the risk hedging in *Bilski*, the concept of intermediated settlement is " 'a fundamental economic practice long prevalent in our system of commerce,' " *ibid.*, and the use of a third-party intermediary (or "clearing house") is a building block of the modern economy. Thus, intermediated settlement, like hedging, is an "abstract idea" beyond §101's scope. Pp. 7–10.

(2) Turning to the second step of *Mayo*'s framework: The method claims, which merely require generic computer implementation, fail to transform that abstract idea into a patent-eligible invention. Pp. 10–16.

(i) "Simply appending conventional steps, specified at a high level of generality," to a method already "well known in the art" is not "*enough*" to supply the " 'inventive concept' " needed to make this transformation. *Mayo, supra,* at ___, ___. The introduction of a computer into the claims does not alter the analysis. Neither stating an abstract idea "while adding the words 'apply it,' " *Mayo*, *supra,* at ___, nor limiting the use of an abstract idea " 'to a particular technological environment,' " *Bilski*, *supra,* at 610–611, is enough for patent eligibility. Stating an abstract idea while adding the words "apply it with a computer" simply combines those two steps, with the same deficient result. Wholly generic computer implementation is not generally the

Syllabus

sort of "additional featur[e]" that provides any "practical assurance that the process is more than a drafting effort designed to monopolize the [abstract idea] itself." *Mayo*, *supra,* at ___. Pp. 11–14.

(ii) Here, the representative method claim does no more than simply instruct the practitioner to implement the abstract idea of intermediated settlement on a generic computer. Taking the claim elements separately, the function performed by the computer at each step—creating and maintaining "shadow" accounts, obtaining data, adjusting account balances, and issuing automated instructions—is "[p]urely 'conventional. ' " *Mayo*, 566 U. S., at ___. Considered "as an ordered combination," these computer components "ad[d] nothing . . . that is not already present when the steps are considered separately." *Id.,* at ___. Viewed as a whole, these method claims simply recite the concept of intermediated settlement as performed by a generic computer. They do not, for example, purport to improve the functioning of the computer itself or effect an improvement in any other technology or technical field. An instruction to apply the abstract idea of intermediated settlement using some unspecified, generic computer is not "*enough*" to transform the abstract idea into a patent-eligible invention. *Id.,* at ___. Pp. 14–16.

(3) Because petitioner's system and media claims add nothing of substance to the underlying abstract idea, they too are patent ineligible under §101. Petitioner conceded below that its media claims rise or fall with its method claims. And the system claims are no different in substance from the method claims. The method claims recite the abstract idea implemented on a generic computer; the system claims recite a handful of generic computer components configured to implement the same idea. This Court has long "warn[ed] . . . against" interpreting §101 "in ways that make patent eligibility 'depend simply on the draftsman's art.' " *Mayo*, *supra,* at ___. Holding that the system claims are patent eligible would have exactly that result. Pp. 16–17.

717 F. 3d 1269, affirmed.

THOMAS, J., delivered the opinion for a unanimous Court. SOTOMAYOR, J., filed a concurring opinion, in which GINSBURG and BREYER, JJ., joined.

SUPREME COURT OF THE UNITED STATES

No. 13–298

ALICE CORPORATION PTY. LTD, PETITIONER *v.* CLS BANK INTERNATIONAL ET AL.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

[June 19, 2014]

JUSTICE THOMAS delivered the opinion of the Court.

The patents at issue in this case disclose a computer-implemented scheme for mitigating "settlement risk" (*i.e.,* the risk that only one party to a financial transaction will pay what it owes) by using a third-party intermediary. The question presented is whether these claims are patent eligible under 35 U. S. C. §101, or are instead drawn to a patent-ineligible abstract idea. We hold that the claims at issue are drawn to the abstract idea of intermediated settlement, and that merely requiring generic computer implementation fails to transform that abstract idea into a patent-eligible invention. We therefore affirm the judgment of the United States Court of Appeals for the Federal Circuit.

I

A

Petitioner Alice Corporation is the assignee of several patents that disclose schemes to manage certain forms of financial risk.[1] According to the specification largely

[1]The patents at issue are United States Patent Nos. 5,970,479 (the

shared by the patents, the invention "enabl[es] the management of risk relating to specified, yet unknown, future events." App. 248. The specification further explains that the "invention relates to methods and apparatus, including electrical computers and data processing systems applied to financial matters and risk management." *Id.,* at 243.

The claims at issue relate to a computerized scheme for mitigating "settlement risk"—*i.e.,* the risk that only one party to an agreed-upon financial exchange will satisfy its obligation. In particular, the claims are designed to facilitate the exchange of financial obligations between two parties by using a computer system as a third-party intermediary. *Id.*, at 383–384.[2] The intermediary creates "shadow" credit and debit records (*i.e.,* account ledgers)

'479 patent), 6,912,510, 7,149,720, and 7,725,375.

[2]The parties agree that claim 33 of the '479 patent is representative of the method claims. Claim 33 recites:

"A method of exchanging obligations as between parties, each party holding a credit record and a debit record with an exchange institution, the credit records and debit records for exchange of predetermined obligations, the method comprising the steps of:

"(a) creating a shadow credit record and a shadow debit record for each stakeholder party to be held independently by a supervisory institution from the exchange institutions;

"(b) obtaining from each exchange institution a start-of-day balance for each shadow credit record and shadow debit record;

"(c) for every transaction resulting in an exchange obligation, the supervisory institution adjusting each respective party's shadow credit record or shadow debit record, allowing only these transactions that do not result in the value of the shadow debit record being less than the value of the shadow credit record at any time, each said adjustment taking place in chronological order, and

"(d) at the end-of-day, the supervisory institution instructing on[e] of the exchange institutions to exchange credits or debits to the credit record and debit record of the respective parties in accordance with the adjustments of the said permitted transactions, the credits and debits being irrevocable, time invariant obligations placed on the exchange institutions." App. 383–384.

that mirror the balances in the parties' real-world accounts at "exchange institutions" (*e.g.,* banks). The intermediary updates the shadow records in real time as transactions are entered, allowing "only those transactions for which the parties' updated shadow records indicate sufficient resources to satisfy their mutual obligations." 717 F. 3d 1269, 1285 (CA Fed. 2013) (Lourie, J., concurring). At the end of the day, the intermediary instructs the relevant financial institutions to carry out the "permitted" transactions in accordance with the updated shadow records, *ibid.*, thus mitigating the risk that only one party will perform the agreed-upon exchange.

In sum, the patents in suit claim (1) the foregoing method for exchanging obligations (the method claims), (2) a computer system configured to carry out the method for exchanging obligations (the system claims), and (3) a computer-readable medium containing program code for performing the method of exchanging obligations (the media claims). All of the claims are implemented using a computer; the system and media claims expressly recite a computer, and the parties have stipulated that the method claims require a computer as well.

B

Respondents CLS Bank International and CLS Services Ltd. (together, CLS Bank) operate a global network that facilitates currency transactions. In 2007, CLS Bank filed suit against petitioner, seeking a declaratory judgment that the claims at issue are invalid, unenforceable, or not infringed. Petitioner counterclaimed, alleging infringement. Following this Court's decision in *Bilski* v. *Kappos*, 561 U. S. 593 (2010), the parties filed cross-motions for summary judgment on whether the asserted claims are eligible for patent protection under 35 U. S. C. §101. The District Court held that all of the claims are patent ineligible because they are directed to the abstract idea of

"employing a neutral intermediary to facilitate simultaneous exchange of obligations in order to minimize risk." 768 F. Supp. 2d 221, 252 (DC 2011).

A divided panel of the United States Court of Appeals for the Federal Circuit reversed, holding that it was not "manifestly evident" that petitioner's claims are directed to an abstract idea. 685 F. 3d 1341, 1352, 1356 (2012). The Federal Circuit granted rehearing en banc, vacated the panel opinion, and affirmed the judgment of the District Court in a one-paragraph *per curiam* opinion. 717 F. 3d, at 1273. Seven of the ten participating judges agreed that petitioner's method and media claims are patent ineligible. See *id.,* at 1274 (Lourie, J., concurring); *id.,* at 1312–1313 (Rader, C. J., concurring in part and dissenting in part). With respect to petitioner's system claims, the en banc Federal Circuit affirmed the District Court's judgment by an equally divided vote. *Id.,* at 1273.

Writing for a five-member plurality, Judge Lourie concluded that all of the claims at issue are patent ineligible. In the plurality's view, under this Court's decision in *Mayo Collaborative Services* v. *Prometheus Laboratories, Inc.*, 566 U. S. ___ (2012), a court must first "identif[y] the abstract idea represented in the claim," and then determine "whether the balance of the claim adds 'significantly more.'" 717 F. 3d, at 1286. The plurality concluded that petitioner's claims "draw on the abstract idea of reducing settlement risk by effecting trades through a third-party intermediary," and that the use of a computer to maintain, adjust, and reconcile shadow accounts added nothing of substance to that abstract idea. *Ibid.*

Chief Judge Rader concurred in part and dissented in part. In a part of the opinion joined only by Judge Moore, Chief Judge Rader agreed with the plurality that petitioner's method and media claims are drawn to an abstract idea. *Id.,* at 1312–1313. In a part of the opinion joined by Judges Linn, Moore, and O'Malley, Chief Judge Rader

would have held that the system claims are patent eligible because they involve computer "hardware" that is "specifically programmed to solve a complex problem." *Id.,* at 1307. Judge Moore wrote a separate opinion dissenting in part, arguing that the system claims are patent eligible. *Id.,* at 1313–1314. Judge Newman filed an opinion concurring in part and dissenting in part, arguing that all of petitioner's claims are patent eligible. *Id.,* at 1327. Judges Linn and O'Malley filed a separate dissenting opinion reaching that same conclusion. *Ibid.*

We granted certiorari, 571 U. S. ___ (2013), and now affirm.

II

Section 101 of the Patent Act defines the subject matter eligible for patent protection. It provides:

> "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title." 35 U. S. C. §101.

"We have long held that this provision contains an important implicit exception: Laws of nature, natural phenomena, and abstract ideas are not patentable." *Association for Molecular Pathology* v. *Myriad Genetics, Inc.*, 569 U. S. ___, ___ (2013) (slip op., at 11) (internal quotation marks and brackets omitted). We have interpreted §101 and its predecessors in light of this exception for more than 150 years. *Bilski*, *supra,* at 601–602; see also *O'Reilly* v. *Morse*, 15 How. 62, 112–120 (1854); *Le Roy* v. *Tatham*, 14 How. 156, 174–175 (1853).

We have described the concern that drives this exclusionary principle as one of pre-emption. See, *e.g., Bilski*, *supra,* at 611–612 (upholding the patent "would pre-empt use of this approach in all fields, and would effectively

grant a monopoly over an abstract idea"). Laws of nature, natural phenomena, and abstract ideas are "'"the basic tools of scientific and technological work."'" *Myriad*, *supra,* at ___ (slip op., at 11). "[M]onopolization of those tools through the grant of a patent might tend to impede innovation more than it would tend to promote it," thereby thwarting the primary object of the patent laws. *Mayo*, *supra*, at ___ (slip op., at 2); see U. S. Const., Art. I, §8, cl. 8 (Congress "shall have Power . . . To promote the Progress of Science and useful Arts"). We have "repeatedly emphasized this . . . concern that patent law not inhibit further discovery by improperly tying up the future use of" these building blocks of human ingenuity. *Mayo*, *supra,* at ___ (slip op., at 16) (citing *Morse, supra*, at 113).

At the same time, we tread carefully in construing this exclusionary principle lest it swallow all of patent law. *Mayo*, 566 U. S., at ___ (slip op., at 2). At some level, "all inventions . . . embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas." *Id.,* at ___ (slip op., at 2). Thus, an invention is not rendered ineligible for patent simply because it involves an abstract concept. See *Diamond* v. *Diehr*, 450 U. S. 175, 187 (1981). "[A]pplication[s]" of such concepts "'to a new and useful end,'" we have said, remain eligible for patent protection. *Gottschalk* v. *Benson*, 409 U. S. 63, 67 (1972).

Accordingly, in applying the §101 exception, we must distinguish between patents that claim the "'buildin[g] block[s]'" of human ingenuity and those that integrate the building blocks into something more, *Mayo*, 566 U. S., at ___ (slip op., at 20), thereby "transform[ing]" them into a patent-eligible invention, *id.,* at ___ (slip op., at 3). The former "would risk disproportionately tying up the use of the underlying" ideas, *id.,* at ___ (slip op., at 4), and are therefore ineligible for patent protection. The latter pose no comparable risk of pre-emption, and therefore remain eligible for the monopoly granted under our patent laws.

III

In *Mayo Collaborative Services* v. *Prometheus Laboratories, Inc.*, 566 U. S. ___ (2012), we set forth a framework for distinguishing patents that claim laws of nature, natural phenomena, and abstract ideas from those that claim patent-eligible applications of those concepts. First, we determine whether the claims at issue are directed to one of those patent-ineligible concepts. *Id.,* at ___ (slip op., at 8). If so, we then ask, "[w]hat else is there in the claims before us?" *Id.,* at ___ (slip op., at 9). To answer that question, we consider the elements of each claim both individually and "as an ordered combination" to determine whether the additional elements "transform the nature of the claim" into a patent-eligible application. *Id.,* at ___ (slip op., at 10, 9). We have described step two of this analysis as a search for an "'inventive concept'"—*i.e.,* an element or combination of elements that is "sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the [ineligible concept] itself." *Id.,* at ___ (slip op., at 3).[3]

A

We must first determine whether the claims at issue are directed to a patent-ineligible concept. We conclude that they are: These claims are drawn to the abstract idea of intermediated settlement.

The "abstract ideas" category embodies "the longstanding rule that '[a]n idea of itself is not patentable.'" *Benson*, *supra,* at 67 (quoting *Rubber-Tip Pencil Co.* v. *Howard*, 20 Wall. 498, 507 (1874)); see also *Le Roy*, *supra*, at

---

[3] Because the approach we made explicit in *Mayo* considers all claim elements, both individually and in combination, it is consistent with the general rule that patent claims "must be considered as a whole." *Diamond* v. *Diehr*, 450 U. S. 175, 188 (1981); see *Parker* v. *Flook*, 437 U. S. 584, 594 (1978) ("Our approach . . . is . . . not at all inconsistent with the view that a patent claim must be considered as a whole").

175 ("A principle, in the abstract, is a fundamental truth; an original cause; a motive; these cannot be patented, as no one can claim in either of them an exclusive right"). In *Benson*, for example, this Court rejected as ineligible patent claims involving an algorithm for converting binary-coded decimal numerals into pure binary form, holding that the claimed patent was "in practical effect . . . a patent on the algorithm itself." 409 U. S., at 71–72. And in *Parker* v. *Flook*, 437 U. S. 584, 594–595 (1978), we held that a mathematical formula for computing "alarm limits" in a catalytic conversion process was also a patent-ineligible abstract idea.

We most recently addressed the category of abstract ideas in *Bilski* v. *Kappos*, 561 U. S. 593 (2010). The claims at issue in *Bilski* described a method for hedging against the financial risk of price fluctuations. Claim 1 recited a series of steps for hedging risk, including: (1) initiating a series of financial transactions between providers and consumers of a commodity; (2) identifying market participants that have a counterrisk for the same commodity; and (3) initiating a series of transactions between those market participants and the commodity provider to balance the risk position of the first series of consumer transactions. *Id.,* at 599. Claim 4 "pu[t] the concept articulated in claim 1 into a simple mathematical formula." *Ibid.* The remaining claims were drawn to examples of hedging in commodities and energy markets.

"[A]ll members of the Court agree[d]" that the patent at issue in *Bilski* claimed an "abstract idea." *Id.,* at 609; see also *id.,* at 619 (Stevens, J., concurring in judgment). Specifically, the claims described "the basic concept of hedging, or protecting against risk." *Id.,* at 611. The Court explained that "'[h]edging is a fundamental economic practice long prevalent in our system of commerce and taught in any introductory finance class.'" *Ibid.* "The concept of hedging" as recited by the claims in suit was

therefore a patent-ineligible "abstract idea, just like the algorithms at issue in *Benson* and *Flook*." *Ibid.*

It follows from our prior cases, and *Bilski* in particular, that the claims at issue here are directed to an abstract idea. Petitioner's claims involve a method of exchanging financial obligations between two parties using a third-party intermediary to mitigate settlement risk. The intermediary creates and updates "shadow" records to reflect the value of each party's actual accounts held at "exchange institutions," thereby permitting only those transactions for which the parties have sufficient resources. At the end of each day, the intermediary issues irrevocable instructions to the exchange institutions to carry out the permitted transactions.

On their face, the claims before us are drawn to the concept of intermediated settlement, *i.e.,* the use of a third party to mitigate settlement risk. Like the risk hedging in *Bilski*, the concept of intermediated settlement is "'a fundamental economic practice long prevalent in our system of commerce.'" *Ibid.*; see, *e.g.,* Emery, Speculation on the Stock and Produce Exchanges of the United States, in 7 Studies in History, Economics and Public Law 283, 346–356 (1896) (discussing the use of a "clearing-house" as an intermediary to reduce settlement risk). The use of a third-party intermediary (or "clearing house") is also a building block of the modern economy. See, *e.g.*, Yadav, The Problematic Case of Clearinghouses in Complex Markets, 101 Geo. L. J. 387, 406–412 (2013); J. Hull, Risk Management and Financial Institutions 103–104 (3d ed. 2012). Thus, intermediated settlement, like hedging, is an "abstract idea" beyond the scope of §101.

Petitioner acknowledges that its claims describe intermediated settlement, see Brief for Petitioner 4, but rejects the conclusion that its claims recite an "abstract idea." Drawing on the presence of mathematical formulas in some of our abstract-ideas precedents, petitioner contends

that the abstract-ideas category is confined to "preexisting, fundamental truth[s]" that "'exis[t] in principle apart from any human action.'" *Id.,* at 23, 26 (quoting *Mayo*, 566 U. S., at ___ (slip op., at 8)).

Bilski belies petitioner's assertion. The concept of risk hedging we identified as an abstract idea in that case cannot be described as a "preexisting, fundamental truth." The patent in *Bilski* simply involved a "series of steps instructing how to hedge risk." 561 U. S., at 599. Although hedging is a longstanding commercial practice, *id.,* at 599, it is a method of organizing human activity, not a "truth" about the natural world "'that has always existed,'" Brief for Petitioner 22 (quoting *Flook*, *supra,* at 593, n. 15). One of the claims in *Bilski* reduced hedging to a mathematical formula, but the Court did not assign any special significance to that fact, much less the sort of talismanic significance petitioner claims. Instead, the Court grounded its conclusion that all of the claims at issue were abstract ideas in the understanding that risk hedging was a "'fundamental economic practice.'" 561 U. S., at 611.

In any event, we need not labor to delimit the precise contours of the "abstract ideas" category in this case. It is enough to recognize that there is no meaningful distinction between the concept of risk hedging in *Bilski* and the concept of intermediated settlement at issue here. Both are squarely within the realm of "abstract ideas" as we have used that term.

B

Because the claims at issue are directed to the abstract idea of intermediated settlement, we turn to the second step in *Mayo*'s framework. We conclude that the method claims, which merely require generic computer implementation, fail to transform that abstract idea into a patent-eligible invention.

1

At *Mayo* step two, we must examine the elements of the claim to determine whether it contains an "'inventive concept'" sufficient to "transform" the claimed abstract idea into a patent-eligible application. 566 U. S., at ___, ___ (slip op., at 3, 11). A claim that recites an abstract idea must include "additional features" to ensure "that the [claim] is more than a drafting effort designed to monopolize the [abstract idea]." *Id.,* at ___ (slip op., at 8–9). *Mayo* made clear that transformation into a patent-eligible application requires "more than simply stat[ing] the [abstract idea] while adding the words 'apply it.'" *Id.*, at ___ (slip op., at 3).

Mayo itself is instructive. The patents at issue in *Mayo* claimed a method for measuring metabolites in the bloodstream in order to calibrate the appropriate dosage of thiopurine drugs in the treatment of autoimmune diseases. *Id.,* at ___ (slip op., at 4–6). The respondent in that case contended that the claimed method was a patent-eligible application of natural laws that describe the relationship between the concentration of certain metabolites and the likelihood that the drug dosage will be harmful or ineffective. But methods for determining metabolite levels were already "well known in the art," and the process at issue amounted to "nothing significantly more than an instruction to doctors to apply the applicable laws when treating their patients." *Id.,* at ___ (slip op., at 10). "Simply appending conventional steps, specified at a high level of generality," was not "*enough*" to supply an "'inventive concept.'" *Id.,* at ___, ___, ___ (slip op., at 14, 8, 3).

The introduction of a computer into the claims does not alter the analysis at *Mayo* step two. In *Benson*, for example, we considered a patent that claimed an algorithm implemented on "a general-purpose digital computer." 409 U. S., at 64. Because the algorithm was an abstract idea, see *supra,* at 8, the claim had to supply a "'new and use-

ful'" application of the idea in order to be patent eligible. 409 U. S., at 67. But the computer implementation did not supply the necessary inventive concept; the process could be "carried out in existing computers long in use." *Ibid.* We accordingly "held that simply implementing a mathematical principle on a physical machine, namely a computer, [i]s not a patentable application of that principle." *Mayo*, *supra*, at ___ (slip op., at 16) (citing *Benson*, *supra,* at 64).

Flook is to the same effect. There, we examined a computerized method for using a mathematical formula to adjust alarm limits for certain operating conditions (*e.g.,* temperature and pressure) that could signal inefficiency or danger in a catalytic conversion process. 437 U. S., at 585–586. Once again, the formula itself was an abstract idea, see *supra,* at 8, and the computer implementation was purely conventional. 437 U. S., at 594 (noting that the "use of computers for 'automatic monitoring-alarming'" was "well known"). In holding that the process was patent ineligible, we rejected the argument that "implement[ing] a principle in some specific fashion" will "automatically fal[l] within the patentable subject matter of §101." *Id.,* at 593. Thus, "*Flook* stands for the proposition that the prohibition against patenting abstract ideas cannot be circumvented by attempting to limit the use of [the idea] to a particular technological environment." *Bilski*, 561 U. S., at 610–611 (internal quotation marks omitted).

In *Diehr*, 450 U. S. 175, by contrast, we held that a computer-implemented process for curing rubber was patent eligible, but not because it involved a computer. The claim employed a "well-known" mathematical equation, but it used that equation in a process designed to solve a technological problem in "conventional industry practice." *Id.,* at 177, 178. The invention in *Diehr* used a "thermocouple" to record constant temperature measure-

ments inside the rubber mold—something "the industry ha[d] not been able to obtain." *Id.,* at 178, and n. 3. The temperature measurements were then fed into a computer, which repeatedly recalculated the remaining cure time by using the mathematical equation. *Id.,* at 178–179. These additional steps, we recently explained, "transformed the process into an inventive application of the formula." *Mayo*, *supra*, at ___ (slip op., at 12). In other words, the claims in *Diehr* were patent eligible because they improved an existing technological process, not because they were implemented on a computer.

These cases demonstrate that the mere recitation of a generic computer cannot transform a patent-ineligible abstract idea into a patent-eligible invention. Stating an abstract idea "while adding the words 'apply it'" is not enough for patent eligibility. *Mayo*, *supra,* at ___ (slip op., at 3). Nor is limiting the use of an abstract idea "'to a particular technological environment.'" *Bilski*, *supra,* at 610–611. Stating an abstract idea while adding the words "apply it with a computer" simply combines those two steps, with the same deficient result. Thus, if a patent's recitation of a computer amounts to a mere instruction to "implemen[t]" an abstract idea "on . . . a computer," *Mayo*, *supra,* at ___ (slip op., at 16), that addition cannot impart patent eligibility. This conclusion accords with the preemption concern that undergirds our §101 jurisprudence. Given the ubiquity of computers, see 717 F. 3d, at 1286 (Lourie, J., concurring), wholly generic computer implementation is not generally the sort of "additional featur[e]" that provides any "practical assurance that the process is more than a drafting effort designed to monopolize the [abstract idea] itself." *Mayo*, 566 U. S., at ___ (slip op., at 8–9).

The fact that a computer "necessarily exist[s] in the physical, rather than purely conceptual, realm," Brief for Petitioner 39, is beside the point. There is no dispute that

a computer is a tangible system (in §101 terms, a "machine"), or that many computer-implemented claims are formally addressed to patent-eligible subject matter. But if that were the end of the §101 inquiry, an applicant could claim any principle of the physical or social sciences by reciting a computer system configured to implement the relevant concept. Such a result would make the determination of patent eligibility "depend simply on the draftsman's art," *Flook*, *supra,* at 593, thereby eviscerating the rule that "'[l]aws of nature, natural phenomena, and abstract ideas are not patentable,'" *Myriad*, 569 U. S., at ___ (slip op., at 11).

2

The representative method claim in this case recites the following steps: (1) "creating" shadow records for each counterparty to a transaction; (2) "obtaining" start-of-day balances based on the parties' real-world accounts at exchange institutions; (3) "adjusting" the shadow records as transactions are entered, allowing only those transactions for which the parties have sufficient resources; and (4) issuing irrevocable end-of-day instructions to the exchange institutions to carry out the permitted transactions. See n. 2, *supra*. Petitioner principally contends that the claims are patent eligible because these steps "require a substantial and meaningful role for the computer." Brief for Petitioner 48. As stipulated, the claimed method requires the use of a computer to create electronic records, track multiple transactions, and issue simultaneous instructions; in other words, "[t]he computer is itself the intermediary." *Ibid.* (emphasis deleted).

In light of the foregoing, see *supra,* at 11–14, the relevant question is whether the claims here do more than simply instruct the practitioner to implement the abstract idea of intermediated settlement on a generic computer. They do not.

Taking the claim elements separately, the function performed by the computer at each step of the process is "[p]urely conventional." *Mayo*, *supra,* at ___ (slip op., at 10) (internal quotation marks omitted). Using a computer to create and maintain "shadow" accounts amounts to electronic recordkeeping—one of the most basic functions of a computer. See, *e.g., Benson*, 409 U. S., at 65 (noting that a computer "operates . . . upon both new and previously stored data"). The same is true with respect to the use of a computer to obtain data, adjust account balances, and issue automated instructions; all of these computer functions are "well-understood, routine, conventional activit[ies]" previously known to the industry. *Mayo*, 566 U. S., at ___ (slip op., at 4). In short, each step does no more than require a generic computer to perform generic computer functions.

Considered "as an ordered combination," the computer components of petitioner's method "ad[d] nothing . . . that is not already present when the steps are considered separately." *Id.,* at ___ (slip op., at 10). Viewed as a whole, petitioner's method claims simply recite the concept of intermediated settlement as performed by a generic computer. See 717 F. 3d, at 1286 (Lourie, J., concurring) (noting that the representative method claim "lacks *any* express language to define the computer's participation"). The method claims do not, for example, purport to improve the functioning of the computer itself. See *ibid.* ("There is no specific or limiting recitation of . . . improved computer technology . . ."); Brief for United States as *Amicus Curiae* 28–30. Nor do they effect an improvement in any other technology or technical field. See, *e.g.*, *Diehr*, 450 U. S., at 177–178. Instead, the claims at issue amount to "nothing significantly more" than an instruction to apply the abstract idea of intermediated settlement using some unspecified, generic computer. *Mayo,* 566 U. S., at ___ (slip op., at 10). Under our precedents, that is not "*enough*" to

transform an abstract idea into a patent-eligible invention. *Id.,* at ___ (slip op., at 8).

C

Petitioner's claims to a computer system and a computer-readable medium fail for substantially the same reasons. Petitioner conceded below that its media claims rise or fall with its method claims. En Banc Response Brief for Defendant-Appellant in No. 11–1301 (CA Fed.) p. 50, n. 3. As to its system claims, petitioner emphasizes that those claims recite "specific hardware" configured to perform "specific computerized functions." Brief for Petitioner 53. But what petitioner characterizes as specific hardware—a "data processing system" with a "communications controller" and "data storage unit," for example, see App. 954, 958, 1257—is purely functional and generic. Nearly every computer will include a "communications controller" and "data storage unit" capable of performing the basic calculation, storage, and transmission functions required by the method claims. See 717 F. 3d, at 1290 (Lourie, J., concurring). As a result, none of the hardware recited by the system claims "offers a meaningful limitation beyond generally linking 'the use of the [method] to a particular technological environment,' that is, implementation via computers." *Id.,* at 1291 (quoting *Bilski*, 561 U. S., at 610–611).

Put another way, the system claims are no different from the method claims in substance. The method claims recite the abstract idea implemented on a generic computer; the system claims recite a handful of generic computer components configured to implement the same idea. This Court has long "warn[ed] . . . against" interpreting §101 "in ways that make patent eligibility 'depend simply on the draftsman's art.'" *Mayo*, *supra,* at ___ (slip op., at 3) (quoting *Flook*, 437 U. S., at 593); see *id.*, at 590 *(*"The concept of patentable subject matter under §101 is not

'like a nose of wax which may be turned and twisted in any direction . . .'"). Holding that the system claims are patent eligible would have exactly that result.

Because petitioner's system and media claims add nothing of substance to the underlying abstract idea, we hold that they too are patent ineligible under §101.

* * *

For the foregoing reasons, the judgment of the Court of Appeals for the Federal Circuit is affirmed.

It is so ordered.

SUPREME COURT OF THE UNITED STATES

No. 13–298

ALICE CORPORATION PTY. LTD, PETITIONER *v.* CLS BANK INTERNATIONAL ET AL.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

[June 19, 2014]

JUSTICE SOTOMAYOR, with whom JUSTICE GINSBURG and JUSTICE BREYER join, concurring.

I adhere to the view that any "claim that merely describes a method of doing business does not qualify as a 'process' under §101." *Bilski* v. *Kappos*, 561 U. S. 593, 614 (2010) (Stevens, J., concurring in judgment); see also *In re Bilski*, 545 F. 3d 943, 972 (CA Fed. 2008) (Dyk, J., concurring) ("There is no suggestion in any of th[e] early [English] consideration of process patents that processes for organizing human activity were or ever had been patentable"). As in *Bilski*, however, I further believe that the method claims at issue are drawn to an abstract idea. Cf. 561 U. S., at 619 (opinion of Stevens, J.). I therefore join the opinion of the Court.

Methanol MSDS

Effective Date: January 04, 2013
24 Hour Emergency Contact:
ChemTel: (800)255-3924
www.pioneerforensics.com

1. PRODUCT AND COMPANY IDENTIFICATION

Product:	**Methanol**
Product Number(s):	PF032, PF033, PF034
CAS#:	67-56-1
Synonyms:	Wood alcohol, Carbinol
Manufacturer:	Pioneer Forensics, LLC 804 E. Eisenhauer Blvd. Loveland, CO 80537 Ph: (970) 292-8487
Emergency Number:	(800) 255-3924 (CHEM-TEL)
Customer Service:	(970) 292-8487

2. HAZARDS IDENTIFICATION

Emergency Overview: DANGER! POISON! FLAMMABLE LIQUID AND VAPOR. MAY BE FATAL OR CAUSE BLINDNESS IF SWALLOWED. CANNOT BE MADE NONPOISONOUS. HARMFUL IF INHALED OR ABSORBED THROUGH SKIN. CAUSES IRRITATION TO SKIN, EYES, AND RESPIRATORY TRACT. HIGH VAPOR CONCENTRATIONS MAY CAUSE DROWSINESS. MAY CAUSE HARM TO THE UNBORN CHILD. PROLONGED EXPOSURE MAY CAUSE CHRONIC EFFECTS.

Safety Ratings:	Health: 3, Severe	Reactivity: 1, Slight
	Flammability: 3, Severe	Contact: 3, Severe

OSHA Regulatory Status: This product is considered a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

Potential Acute Health Effects:

Routes of Exposure: Inhalation, ingestion, skin contact, eye contact

Inhalation: May cause irritation of respiratory tract. Toxic effects exerted upon nervous system, particularly the optic nerve. Once absorbed into the body, it is very slowly eliminated. Symptoms of overexposure may include headache, drowsiness, nausea, vomiting, blurred vision, blindness, coma and death. A person may get better but then worse again up to 30 hours later.

Ingestion: Poison - may be fatal if swallowed. Even small amounts (30-250 ml methanol) may be fatal. Symptoms are stomach ache, nausea, vomiting, dullness, visual disorder and blindness.

Skin Contact: Causes irritation. Prolonged or repeated contact with skin may cause redness, itching, irritation and eczema/chapping. Skin absorption can occur, symptoms may parallel ingestion exposure.

Eye Contact: Causes irritation.

Target Organs: Skin, central nervous system, liver, reproductive system, eyes

Chronic Health Effects: In serious cases absorption of methanol in the body may lead to damage to the eyesight. May cause adverse reproductive effects - such as birth defects, miscarriages, or infertility based on animal data. May cause central nervous system disorder (e.g., narcosis involving a loss of coordination, weakness, fatigue, mental confusion and blurred vision) and/or damage. Frequent or prolonged contact may defat and dry the skin, leading to discomfort and dermatitis.

Potential Environmental Effects: The product components are not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

3. COMPOSITION AND INFORMATION ON INGREDIENTS

Components	CAS#	Chemical Formula	Formula Weight	Hazardous	% by Weight
Methanol	67-56-1	CH_4O	32.04	Yes	>99.85

4. FIRST AID MEASURES

First Aid Procedures:

Inhalation: Remove to fresh air. If breathing is difficult, administer oxygen. If the victim is not breathing, provide artificial respiration. Get medical attention.

Ingestion: Do not induce vomiting unless directed to do so by medical personnel. If vomiting occurs, keep head low so that vomit does not enter lungs. Never give anything by mouth to an unconscious person. GET MEDICAL ATTENTION IMMEDIATELY.

Skin Contact: Wash affected area with plenty of water for at least 15 minutes. Remove contaminated clothing and shoes. Wash clothing before reuse. Get medical attention if symptoms occur.

Eye Contact: Check for and remove contact lenses. Immediately flush eyes with gentle but large stream of water for at least 15 minutes, lifting lower and upper eyelids occasionally. Get medical attention.

General Advice: In the case of accident or if you feel unwell, seek medical advice immediately (show the label where possible). Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. Show this safety data sheet to the doctor in attendance.

Notes to Physician: Treat symptomatically. Symptoms may be delayed.

5. FIRE FIGHTING MEASURES

NFPA Ratings: Health: 2 Flammability: 3 Reactivity: 0

Flammable Properties:	HIGHLY FLAMMABLE! Vapors may cause a flash fire or ignite explosively. Vapors may travel considerable distance to a source of ignition and flash back. Heat may cause sealed containers to explode.
Flash Point:	12° C (53.6° F)
Auto-ignition Temp:	464° C (867° F)
Flammable Limits in Air (% by volume):	Lower Explosion Limit: 6% Upper Explosion Limit 36.5%
Suitable Extinguishing Media:	Water spray, dry powder, alcohol resistant foam, carbon dioxide
Unsuitable Extinguishing Media:	Do not use a solid (straight) water stream as it may scatter and spread fire.
Hazardous Combustion Products:	Carbon monoxide, carbon dioxide
Specific Hazards:	Can be ignited easily by heat, sparks, or flame and burns vigorously. Material may burn with an invisible flame. Sealed containers may explode when heated or involved in fire. Material is sensitive to static discharge. Vapor from the solvent may accumulate in container headspace resulting in flammability hazard.
Special Protective Equipment For Firefighters:	As in any fire, wear MSHA/NIOSH approved (or equivalent) self-contained positive pressure or pressure-demand breathing apparatus and full protective gear.
Specific Methods:	Use water spray to cool unopened containers. Move containers from fire area if you can do so without risk. Some of these materials, if spilled, may evaporate leaving a flammable residue. In the event of fire and/or explosion do not breathe fumes.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions:	Ventilate area of leak or spill. Isolate hazard area and keep unnecessary and unprotected personnel away from the area of the leak or spill. Keep upwind. Keep out of low areas. Wear appropriate personal protective equipment as specified in the Exposure Control and Personal Protection Section 8. Avoid contact with eyes, skin, and clothing. Pay attention to flashback. Take precautionary measures against static discharges.
Environmental Precautions:	Prevent further leakage or spillage if safe to do so. Do not contaminate water. Avoid discharge into drains, water courses or onto the ground. In case of large spill, dike if needed.
Methods for Containment:	Eliminate all sources of ignition. Stop the flow of material, if this is without risk. Prevent entry into waterways, sewer, basements or confined areas. Dike the spilled material, where this is possible. In case of large spill, water spray or vapor suppressing foam may be used to reduce vapors, but may not prevent ignition in closed spaces.
Methods for Cleaning Up:	Use spark-proof tools and explosion-proof equipment. All equipment used when handling the product must be grounded. Absorb spill with an inert material (e.g. vermiculite, dry sand, earth, cloth, fleece), and place in a suitable container for reclamation or disposal. Do not use combustible materials, such as sawdust. Clean contaminated surface thoroughly. Never return spills in original containers for re-use. Clean up in accordance with all applicable regulations.

7. HANDLING AND STORAGE

Handling: Do not handle or open near flame, sources of heat, or sources of ignition. Wear personal protective equipment (see section 8). Use only in well-ventilated areas. Provide sufficient air exchange and/or exhaust in work rooms. Avoid contact with skin, eyes and clothing. Do not breathe vapors or spray mist. Do not ingest. When using, do not smoke. To avoid ignition of vapors by static electricity discharge, all metal parts of the equipment must be grounded. Keep away from incompatible materials. Handle in accordance with good industrial hygiene and safety practice. Wash thoroughly after handling. Containers of this material may be hazardous when empty since they retain product residues (vapors, liquids). Observe all warnings and precautions listed for the product

Storage: Store in a cool, dry, ventilated area. Store in a segregated and approved area away from flame, sources of ignition, heat, and incompatible materials. Store in original container. Keep containers tightly closed and upright. Keep away from food, drink and animal feedingstuffs. Keep out of the reach of children. Ground container and transfer equipment to eliminate static electric sparks. Comply with all national, state, and local codes pertaining to the storage, handling, dispensing, and disposal of flammable liquids.

8. EXPOSURE CONTROL AND PERSONAL PROTECTION

Exposure Limits:

ACGIH:	TWA:	200 ppm
	STEL:	250 ppm
	BEL:	15 mg/L
OSHA:	PEL:	200 ppm
		260 mg/m^3

Engineering Controls: Ensure adequate ventilation. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level. Explosion proof exhaust ventilation should be used.

Personal Protective Equipment:

Eye/Face Protection: Wear goggles or safety glasses with side shields and a face shield.

Skin Protection: Wear appropriate chemical resistant clothing (with long sleeves) and appropriate chemical resistant gloves.

Respiratory Protection: Use a positive-pressure air-supplied respirator if there is any potential for an uncontrolled release, exposure levels are not known, or any other circumstances where air-purifying respirators may not provide adequate protection.

General Hygiene Considerations: Avoid contact with skin, eyes and clothing. When using, do not eat, drink or smoke. Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants. Provide eyewash station and safety shower.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State: Liquid
Appearance: Transparent
Color: Colorless
Odor: Alcoholic, pungent, characteristic
Molecular Formula: CH_4O

Molecular Weight:	32.04
pH:	No information found
Specific Gravity:	0.79
Freezing/Melting Point:	-97.8 °C (-144 °F)
Boiling Point:	64.7 °C (149 °F)
Flash Point:	12 °C (53.6 °F)
Auto Ignition Temperature:	464 °C (867 °F)
Flammable Limits in Air (% by Volume):	
Upper:	36.5%
Lower:	6%
Solubility:	Miscible with water
Vapor Pressure:	16.9 kPa at 25 °C
Vapor Density:	1.1
Percent Volatile:	100%
Odor threshold (ppm):	100
Evaporation Rate:	5.9 BuAc
Partition Coefficient (n-octanol/water):	-0.77

10. STABILITY AND REACTIVITY

Stability: Stable under normal conditions.

Conditions to Avoid: Heat, flames, sparks, ignition sources, incompatibles.

Incompatible Materials: Oxidizing agents, metals, acids, alkali metals

Hazardous Decomposition Products: Carbon dioxide, carbon monoxide, irritants, toxic gas, formaldehyde

Possibility of Hazardous Reactions: Can react vigorously, violently or explosively with the incompatible materials listed above.

Hazardous Polymerization: Will not occur.

11. TOXICOLOGICAL INFORMATION

Toxicological Data:

Oral Rat LD50:	5628 mg/kg
Inhalation Rat LC50:	87.5 mg/L 6 H
Dermal Rabbit LD50:	15800 mg/kg

Acute Effects: May be fatal or cause blindness if swallowed. Cannot be made nonpoisonous. Harmful if inhaled or absorbed through skin.

Local Effects: Causes eye irritation. Prolonged or repeated skin contact may cause drying, cracking, or irritation. High vapor concentrations may cause drowsiness and irritation of the eyes or respiratory tract.

Sensitization: Not a skin sensitizer.

Chronic Effects: May cause central nervous system effects. In serious cases methanol absorption into the body may lead to damage to eyesight. Prolonged or repeated skin contact may cause dermatitis and defatting, dryness, and cracking of the skin.

Carcinogenic Effects: This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.

Skin Corrosion/Irritation: Irritation, defatting, drying, and cracking of skin.

Epidemiology: No epidemiological data is available for this product.

Mutagenicity: No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.

Neurological Effects: High vapor/aerosol concentrations (attainable only at elevated temperatures) may cause central nervous system effects such as dizziness, drowsiness or headaches. May cause central and or peripheral nervous system damage.

Reproductive Effects: May cause adverse reproductive effects. Suspected of damaging fertility.

Teratogenic Effects: May cause birth defects (teratogenic effects) based on animal test data.

Target Organs and Symptoms: Skin, central nervous system, nervous system, liver, kidneys, eyes, optic nerve. Irritation, drowsiness, dizziness, blindness, cough, shortness of breath, unconsciousness.

12. ECOLOGICAL INFORMATION

Ecotoxicological Data:

EC50 Water flea (Daphnia magna):	> 10000 mg/L 48 H
LC50 Fathead minnow (Pimephales promelas):	> 100 mg/L 96 H

Ecotoxicity: This product is not expected to be harmful to aquatic organisms.

Environmental Effects: This product is not expected to be harmful to the environment.

Persistence and Degradability: Expected to be readily biodegradable.

Partition Coefficient (n-octanol/water): -0.77

13. DISPOSAL INFORMATION

Disposal Instructions: All wastes must be handled in accordance with local, state and federal regulations.

Contaminated Packaging: Since emptied containers retain product residue, follow label warnings even after container is emptied. Residual vapors may explode on ignition; do not cut, drill, grind, or weld on or near this container. Offer rinsed packaging material to local recycling facilities.

Waste Codes: U154 (US RCRA Hazardous Waste U List)

14. TRANSPORT INFORMATION

DOT:

UN Number: UN1230

Proper Shipping Name: Methanol

Hazard Class: 3

Packaging Group: II

ERG Number: 131

15. REGULATORY INFORMATION

U.S. Federal Regulations:

OSHA: This product is considered a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

TSCA Inventory: Methanol

U.S. EPCRA (SARA Title III):

Sections 311/312:

Hazard Categories	List (Yes/No)
Section 311 – Hazardous Chemical	Yes
Immediate Hazard	Yes
Delayed Hazard	Yes
Fire Hazard	Yes
Pressure Hazard	No
Reactivity Hazard	No

Section 313: Toxic Chemical or Category: Methanol

De Minimis Concentration: 1.0%

CERCLA: Methanol: 5000 lbs

International Inventories:

Country(s) or Region	Inventory Name	On Inventory (Yes/No)*
Australia	Australian Inventory of Chemical Substances (AICS)	Yes
Canada	Domestic Substances List (DSL)	Yes
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	Yes
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	Yes
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	Yes
Korea	Existing Chemicals List (ECL)	Yes
New Zealand	New Zealand Inventory	Yes
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	Yes

*A "Yes" indicates that the listed component(s) of this product comply with the inventory requirements administered by the governing country(s)

16. OTHER INFORMATION

Product Use: Laboratory and/or field reagent

Disclaimer: Pioneer Forensics LLC provides the information in this Material Safety Data Sheet in the belief that it is reliable but assumes no responsibility for its completeness or accuracy. The physical properties reported in this MSDS are obtained from the literature and do not

constitute product specifications. Pioneer Forensics LLC makes and gives no representations or warranties with respect to the information contained herein or the product to which it refers, whether express, implied, or statutory, including without limitation, warranties of accuracy, completeness, merchantability, non-infringement, performance, safety, suitability, stability, and fitness for a particular purpose. No warranty against infringement of any patent, copyright or trademark is made or implied. This MSDS is intended only as a guide to the appropriate handling of the material by a properly trained person. It shall be the user's responsibility to develop proper methods of handling and personal protection based on the actual conditions of use. Accordingly, Pioneer Forensics LLC assumes no liability whatsoever for the use of or reliance upon this information including results obtained, incidental or consequential damages, or lost profits.

Issue Date: 01/04/2013

Reason for Revision: Not applicable

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO
Judge William J. Martínez

Civil Action No. 18-cv-1922-WJM-NYW

UNITED CANNABIS CORPORATION, a Colorado Corporation,

Plaintiffs,

v.

PURE HEMP COLLECTIVE INC., a Colorado Corporation,

Defendant.

ORDER DENYING DEFENDANT'S EARLY MOTION FOR PARTIAL SUMMARY JUDGMENT

United Cannabis Corporation (which refers to itself as "UCANN") sues Pure Hemp Collective Inc. ("Pure Hemp") for infringement of UCANN's patent, U.S. Patent No. 9,730,911 ("911 Patent"), which issued on August 15, 2017. Currently before the Court is Pure Hemp's Early Motion for Partial Summary Judgment. (ECF No. 32.) Pure Hemp argues that all of the patent claims asserted against it are invalid, and therefore requests a ruling to that effect, "which will substantially reduce the number of issues before the Court in this case." (*Id*. at 1.) Indeed it would—because it would end the case. For the reasons explained below, however, the Court finds that Pure Hemp is not entitled to summary judgment on this record.

I. LEGAL STANDARD

Summary judgment is warranted under Federal Rule of Civil Procedure 56 "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a); *see also Anderson v.*

Liberty Lobby, Inc., 477 U.S. 242, 248–50 (1986). A fact is "material" if, under the relevant substantive law, it is essential to proper disposition of the claim. *Wright v. Abbott Labs., Inc.*, 259 F.3d 1226, 1231–32 (10th Cir. 2001). An issue is "genuine" if the evidence is such that it might lead a reasonable trier of fact to return a verdict for the nonmoving party. *Allen v. Muskogee*, 119 F.3d 837, 839 (10th Cir. 1997).

In analyzing a motion for summary judgment, a court must view the evidence and all reasonable inferences therefrom in the light most favorable to the nonmoving party. *Adler v. Wal-Mart Stores, Inc.*, 144 F.3d 664, 670 (10th Cir. 1998) (citing *Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986)). In addition, the Court must resolve factual ambiguities against the moving party, thus favoring the right to a trial. *See Houston v. Nat'l Gen. Ins. Co.*, 817 F.2d 83, 85 (10th Cir. 1987).

II. BACKGROUND

Per the undersigned's Revised Practice Standards, the parties submitted statements of material fact and responses and replies thereto. (*See* ECF No. 32 at 1–3; ECF No. 36 at 6–10; ECF No. 38 at 3–4.) However, the Court finds that the 911 Patent itself is the only evidence relevant to the challenges Pure Hemp raises in its current motion.

The 911 Patent addresses itself to the field of cannabinoids—various chemicals derived from the *cannabis sativa* plant—for human consumption. The patent says that

> [t]here presently exists the need to provide more effective and safer *cannabis* extracts for various medical uses, extraction methods that provide unique active compounds that are useful to treat pain and various medical conditions. Additionally, presently known extraction procedures do not provide the desired active ingredient(s) for the particular medical purpose. The present invention overcomes these limitations and provides other related advantages.

911 Patent at 1:32–39. To this end, the "Summary of the Invention" portion of the specification announces that the invention covers four areas:

1. "an extract comprising a mixture of at least 95% total cannabinoids, and at least one terpene/flavonoid," *id*. at 1:43–45;[1]
2. "[specific] formulations containing the extracts according to the invention," *id*. at 1:63–64;
3. "a method for preparing cannabis juice," *id*. at 3:4–5; and
4. "a method of relieving symptoms associated with" various medical conditions, *id*. at 3:15–19.

However, it appears the Patent was substantially narrowed during its prosecution without a corresponding update in the specification, because the Patent ultimately claims only the first two types of inventions. *See* Claims 1–36.

As to those claims, every independent claim describes "[a] liquid cannabinoid formulation, wherein at least 95% of the total cannabinoids is" a specified cannabinoid or combination of them. *See* Claims 1, 5, 10, 16, 20, 25. The dependent claims mostly add requirements for terpenes and/or flavonoids. *See* Claims 2–4, 6–9, 11–15, 17–19, 21–24, 27–30. Claim 33 addresses itself to any of the independent claims and adds that the required liquid is "formulated for oral, sublingual, buccal, or topical administration."

[1] The Patent describes terpenes as "organic hydrocarbons that are the building blocks of cannabinoids," which supposedly "act synergistically with the cannabinoids to provide a therapeutic effect." *Id*. at 6:11–17. The Patent does not distinguish terpenes from flavonoids. Merriam-Webster Online defines "flavonoid" as "any of a large group of typically biologically active water-soluble plant compounds (such as the anthocyanins and flavones) that include pigments ranging in color from yellow to red to blue and occur especially in fruits, vegetables, and herbs (such as grapes, citrus fruits, peppers, and dill)." *See* https://www.merriam-webster.com/dictionary/flavonoid (last accessed Apr. 15, 2019).

III. ANALYSIS

Through infringement contentions, Pure Hemp learned that UCANN accuses Pure Hemp of infringing Claims 10, 12, 14, 20–22, 25, 27, 28, 31, and 33 of the 911 Patent. (ECF No. 32 at 1.) Pure Hemp attacks all these claims under one theory of invalidity, and then alternatively attacks Claim 31 alone under a separate theory of invalidity. The Court will first address the argument against all of the asserted claims, and then address the separate argument against Claim 31.

A. All Asserted Claims

1. The "*Alice*" Patentability Test

Pure Hemp's motion raises a "patentability" challenge to the asserted claims of the 911 Patent, *i.e.*, whether those claims are directed at something the Patent Act deems patent-protectable. See 35 U.S.C. §§ 1 *et seq*. The following principles are therefore relevant.

The Patent Act provides that "[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title." 35 U.S.C. § 101. The Supreme Court has "long held," however, "that this [broadly worded] provision contains an important implicit exception: Laws of nature, natural phenomena, and abstract ideas are not patentable." *Alice Corp. Pty. v. CLS Bank Int'l*, 573 U.S. 208, 216 (2014) (internal quotation marks omitted).

"[D]istinguishing patents that claim laws of nature, natural phenomena, and abstract ideas from those that claim patent-eligible applications of those concepts" first requires a court to "determine whether the claims at issue are directed to one of those patent-ineligible concepts." *Id*. at 217. If the answer is no, the inquiry ends; but if the

answer is yes, a court must then determine whether the claims in question nonetheless offer "an inventive concept—*i.e.*, an element or combination of elements that is sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the ineligible concept itself." *Id*. at 217–18 (internal quotation marks omitted; alterations incorporated). This second inquiry requires the court to "consider the elements of each claim both individually and as an ordered combination to determine whether the additional elements transform the nature of the claim into a patent-eligible application." *Id*. at 217 (internal quotation marks omitted).

The foregoing two-part inquiry is often known as the "*Alice* test." A court may apply the *Alice* test at an early stage in the case. *See, e.g.*, *Cleveland Clinic Found. v. True Health Diagnostics LLC*, 859 F.3d 1352, 1360 (Fed. Cir. 2017), *cert. denied*, 138 S. Ct. 2621 (2018); *Genetic Techs. Ltd. v. Merial LLC*, 818 F.3d 1369, 1373–74 (Fed. Cir. 2016), *cert. denied*, 137 S. Ct. 242 (2016). But the second inquiry, in particular, sometimes requires the court to consider whether claim limitations are "well-understood, routine and conventional to a skilled artisan in the relevant field." *Berkheimer v. HP Inc.*, 881 F.3d 1360, 1368 (Fed. Cir. 2018). If so, the court is faced with a fact question. *Id*. If it is a genuine dispute of material fact, resolution at the pleading phase is not appropriate. *See, e.g.*, *Aatrix Software, Inc. v. Green Shades Software, Inc.*, 882 F.3d 1121, 1129 (Fed. Cir. 2018); *Berkheimer*, 881 F.3d at 1370. The Court presumes the same is true where a defendant moves for early summary judgment (as here), but the motion does not dispel a genuine dispute of material fact.

2. Potentially Relevant Precedent

The Court begins by summarizing certain Supreme Court and Federal Circuit decisions in which those courts have examined questions of patentability in roughly

similar contexts.

In *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127 (1948), the inventor discovered, contrary to agriculture industry assumptions, that certain forms of nitrogen-fixing bacteria could mix with each other without inhibiting their nitrogen-fixing capacity. *Id*. at 129–30. This was useful because it allowed farmers to "inoculate" various types of seeds (*i.e.*, prepare them for more effective growth) with a single bacterial mixture, rather than buying a seed-specific unmixed culture designed for each type of seed. *Id*. at 130.

The Supreme Court held the new mixture unpatentable:

> [P]atents cannot issue for the discovery of the phenomena of nature. The qualities of these bacteria, like the heat of the sun, electricity, or the qualities of metals, are part of the storehouse of knowledge of all men. . . .
>
> 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.

Id. at 130–31 (citation omitted).

Decades later, in *Diamond v. Chakrabarty*, 447 U.S. 303 (1980) ("*Chakrabarty*"), the inventor was studying bacteria that break down hydrocarbons (useful for cleaning up oil spills) and faced a problem somewhat resembling that addressed in *Funk Brothers*—namely, that mixtures of different strains of bacteria, "each [strain] capable of degrading one component of the oil complex," were less effective by virtue of being mixed. *Id*. at 305 n.2. The inventor in *Chakrabarty*, however, did not solve the problem by finding a way to create an effective mixture of naturally occurring bacteria. Rather, he genetically engineered a single bacterium capable of doing the hydrocarbon-degrading work of four naturally occurring strains. *Id*. at 305 & n.1.

The Patent and Trademark Office granted a patent on the method of genetically engineering the new bacterium and on a method for distributing it on oil spills, but refused a patent on the new bacterium itself. *Id*. at 305–06. The Supreme Court reversed this refusal: "[In] contrast [to *Funk Brothers*], the [inventor] has produced a new bacterium with markedly different characteristics from any found in nature and one having the potential for significant utility. His discovery is not nature's handiwork, but his own; accordingly it is patentable subject matter under § 101." *Id*. at 310.

More than twenty years later, the Supreme Court returned to this topic in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 566 U.S. 66 (2012). There, the inventors had discovered that concentrations of a certain metabolite in the bloodstream within a certain measurable range correlated with an effective dosage of a thiopurine (used for treating autoimmune diseases), whereas metabolite concentrations below that range correlated with ineffectiveness and concentrations above that range correlated with potentially dangerous side effects. *Id*. at 73–74. The resulting patents

essentially instructed doctors to measure the metabolite in the patient's bloodstream and then consider adjusting the patient's thiopurine dosage if the metabolites were above or below the specified range. *Id*. at 74–75.

The Supreme Court held that the claimed invention was unpatentable: "[The] patents set forth laws of nature—namely, relationships between concentrations of certain metabolites in the blood and the likelihood that a dosage of a thiopurine drug will prove ineffective or cause harm." *Id*. at 77. And the fact that the patents also included steps such as administering the drug and measuring metabolites was not enough to save them because those additional steps "consist[ed] of well-understood, routine, conventional activity already engaged in by the scientific community; and those steps, when viewed as a whole, add nothing significant beyond the sum of their parts taken separately." *Id*. at 79–80. This two-part inquiry—whether the patent claim addresses a law of nature, and if so, whether additional steps in the claim add anything significant—is what the Supreme Court systematized two years later into what is now the "*Alice* test." *See Alice*, 573 U.S. at 217 ("In *Mayo* . . . we set forth [the relevant] framework . . . ."); *cf*. *Aatrix Software, Inc. v. Green Shades Software, Inc.*, 882 F.3d 1121, 1126 (Fed. Cir. 2018) (referring to the *Alice* test as the "*Alice*/*Mayo* analysis").

One of the earlier Federal Circuit decisions to apply the *Alice* test, as recently formulated, was *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371 (Fed. Cir. 2015). In that dispute, the inventors

> discovered cell-free fetal DNA ("cffDNA") in maternal plasma and serum, the portion of maternal blood samples that other researchers had previously discarded as medical waste. cffDNA is non-cellular fetal DNA that circulates freely in the blood stream of a pregnant woman. Applying a combination of known laboratory techniques to their discovery, [the

> inventors] implemented a method for detecting the small fraction of paternally inherited cffDNA in maternal plasma or serum to determine fetal characteristics, such as gender. The invention . . . created an alternative for prenatal diagnosis of fetal DNA that avoids the risks of widely-used techniques that took samples from the fetus or placenta.

Id. at 1373.

At step one of the *Alice* analysis, the Federal Circuit found that "the claims are directed to matter that is naturally occurring," *i.e.*, cffDNA. *Id*. at 1376. At step two of the *Alice* analysis, the Federal Circuit found that the claimed procedures and techniques for isolating and amplifying paternally inherited cffDNA "were well-understood, conventional and routine" at the time the inventors made their discovery, and so "the method of detecting paternally inherited cffDNA is not new and useful." *Id*. at 1377. Consequently, the invention was "not directed to patent eligible subject matter and [was], therefore, invalid." *Id*. at 1378.[2]

* * *

As the foregoing summary of case law suggests, the proper application of the Supreme Court's *Alice* standard is an evolving and sometimes hazy area of law. Deciding whether a patent claim is "directed to" a law of nature is not as straightforward as the Supreme Court makes it sound in *Alice* itself. Moreover, the Federal Circuit itself has remarked on the difficulty, at times, of distinguishing the first *Alice* inquiry from the second, *see, e.g.*, *Elec. Power Grp., LLC v. Alstom S.A.*, 830 F.3d 1350, 1353 (Fed. Cir.

[2] Through notices of supplemental authority (ECF Nos. 39, 47, 48), the parties have directed the Court's attention to the United States Patent and Trademark Office 2019 Revised Patent Subject Matter Eligibility Guidance, 84 Fed. Reg. 50 (Jan. 7, 2019); *Natural Alternatives, Inc. v. Creative Compounds, LLC*, 918 F.3d 1338 (Fed. Cir. 2019); and *Cleveland Clinic Foundation v. True Health Diagnostics LLC*, ___ F. App'x ___, 2019 WL 1452697 (Fed. Cir. Apr. 1, 2019). The Court finds that none of these authorities inform the Court's analysis here.

2016); or distinguishing the two *Alice* inquiries (comprising a patentability analysis rooted in 35 U.S.C. § 101) from other common inquiries such as anticipation and obviousness (which are rooted in 35 U.S.C. §§ 102–03), *see, e.g.*, *Rapid Litig. Mgmt. Ltd. v. CellzDirect, Inc.*, 827 F.3d 1042, 1052 & n.2 (Fed. Cir. 2016).

3. Application

Despite the potential ambiguities, the Court is convinced under the current state of the case law that the challenged claims of the 911 Patent are not directed at unpatentable subject matter.

a. *Preliminary Observations*

At the outset, the Court notes that every claim in the 911 Patent describes a liquid formulation with partly specified ingredients, but no claim in the 911 Patent states a *purpose* or *use* for any of these formulations. Pure Hemp does not challenge it on these grounds, however, and the patent's specification makes that purpose clear in any event. Taken as a whole, the obvious thrust of the patent is a supposedly new means by which humans can consume cannabinoids so that those cannabinoids can produce the pharmacological effects they are known to have, thus (hopefully) treating or ameliorating various diseases and symptoms. *See* 911 Patent at 1:32–39, 3:16–4:3, 10:5–24, 10:59–11:20, 14:4–18:17. The Court thus keeps this purpose in mind as it evaluates Pure Hemp's *Alice* challenge.

Before proceeding further, however, it is helpful to understand that the 911 Patent does ***not*** claim any of the following:

- a process for extracting cannabinoids from cannabis plants—"[a]ny suitable method for extraction known in the art may be used," *id*. at 9:29;
- a process for making the "*liquid* cannabinoid formulation" required by

every independent claim, *see* Claims 1, 5, 10, 20, 25 (emphasis added)—apparently any liquification method will do;

- a requirement with respect to the inactive ingredients within the formulation—"any convenient pharmaceutically acceptable carriers, diluents or excipients" are appropriate, *id*. at 7:51–53;
- a ratio between the cannabinoid portion of the liquid formulation and the inactive ingredients;
- a process for ensuring that the "at least 95%" threshold has been met—"methods of calculating cannabinoid content (as %) are well known in the art," *id*. at 7:7–8; or
- a method for using any claimed formulation to treat any particular disease, condition, or symptom.

It is further helpful to understand that, apart from the *claims*, the *specification* does ***not*** assert either that:

- a threshold of "at least 95%" for various cannabinoids, or combinations of them, has any clinical significance—the provenance of that percentage is unexplained; or
- any claimed combination of cannabinoids making up the "at least 95% of the total cannabinoids" in a liquid formulation is more effective than any other combination in treating a particular disease or symptom.

The Court now turns to the patentability dispute as presented by the parties.

b. Alice*, Step One*

Every disputed independent claim is a "liquid cannabinoid formulation, wherein at

least 95% of the total cannabinoids" is some combination of one or more specified cannabinoids. *See* Claims 10, 20, 25. Most disputed dependent claims add either (1) a requirement of "at least one terpene/flavonoid" as an additional ingredient, *see* Claims 12, 14, 21, 27; or (2) a directive that "the formulation comprises no more than 4% terpene," *see* Claims 22, 28. The only other relevant disputed dependent claim, for present purposes, is Claim 33, which narrows the formulation in Claims 10, 20, and 25 (among others) to one "formulated for oral, sublingual, buccal, or topical administration." Accordingly, the question at step one of the *Alice* analysis "whether [these claims] are directed to one of [the] patent-ineligible concepts," that is, "laws of nature, natural phenomena, and abstract ideas." 573 U.S. at 217.

Pure Hemp argues that these claims are "directed to" the unpatentable natural phenomenon of the specified chemical compounds (cannabinoids, terpenes, and flavonoids), as if UCANN is trying to secure a monopoly on use of these compounds. (ECF No. 32 at 5–12.) UCANN counters that "the claims are not directed to laws of nature or natural phenomena because they claim human-modified liquid formulations that require converting solid cannabinoids into a different state with markedly different physiological characteristics." (ECF No. 36 at 12.) UCANN's counterargument contains two components: (1) the liquid formulation itself, which is supposedly novel; and (2) the alleged "markedly different physiological characteristics" of the liquid (which the Court takes to mean physiological *effects*—a liquid does not have a physiology).

The Court need not and does not address the second of UCANN's arguments because the Court is persuaded by the first. Pure Hemp has failed to establish beyond genuine dispute that a liquefied version of cannabinoids and related chemicals at the

concentrations specified in the 911 Patent is anything like a natural phenomenon. It may be true, as Pure Hemp insists, that cannabinoids in nature can take the form of a resin; that a resin can be highly viscous; that a highly viscous substance may at times be considered a liquid; and therefore it is logically possible that cannabinoids in nature might appear in a form that could, in some sense, be deemed a "liquid." (ECF No. 38 at 6–7.) Even accepting as much, the 911 Patent specifies threshold concentrations of cannabinoids and related chemicals. Pure Hemp nowhere claims that these precise concentrations, or anything close to them, occur in liquid form in nature. Accordingly, UCANN's claims are not restatements of "the handiwork of nature," *Funk Brothers*, 333 U.S. at 131, "but [UCANN's] own [handiwork]," *Chakrabarty*, 447 U.S. at 310.

To be clear, the Court sees reason to question whether the 911 Patent claims anything novel, useful, or nonobvious. (*See* Part III.A.3.a, above.) But, as far as the *Alice* inquiry goes, the 911 Patent is not "directed to" an unpatentable law of nature, a natural phenomenon, or an abstract idea. It is instead "directed to" a non-naturally occurring delivery method of naturally occurring chemicals in (as far as the record reveals) non-naturally occurring proportions and concentrations.

Because the 911 Patent does not fail at step one of the *Alice* inquiry, the Court need not address step two.

B. Claim 31

Pure Hemp brings a separate argument against Claim 31. That Claim reads as follows: "The [liquid cannabinoid] formulation of any one of the [preceding] claims, wherein the formulation is infused in a medium chain triglyceride (MCT)."[3] This sort of

[3] Claim 31 originally said "proceeding" where the Court has inserted "preceding." The Patent Act requires that "a claim in dependent form shall contain a reference to a claim

claim is known in the Patent Act as a "multiple dependent claim." 35 U.S.C. § 112(e). "A multiple dependent claim shall not serve as a basis for any other multiple dependent claim." *Id*. Pure Hemp notes that two "preceding claims" are themselves multiple dependent claims, namely, Claim 9, which depends on either of Claims 1 or 5; and Claim 24, which depends on either of Claims 16 or 20. (ECF No. 32 at 15.) Pure Hemp therefore argues that Claim 31 must be held invalid as a multiple dependent claim connected to a multiple dependent claim. (*Id*.)

The Patent Act states that "[a] patentee . . . may . . . make disclaimer of any complete claim . . . . Such disclaimer shall be in writing, and recorded in the Patent and Trademark Office; and it shall thereafter be considered as part of the original patent . . . ." 35 U.S.C. § 253(a). In response to Pure Hemp's argument, UCANN invoked this procedure to disclaim Claims 9 and 24. (ECF No. 36-13.) "A statutory disclaimer under 35 U.S.C. § 253 has the effect of canceling the claims from the patent and the patent is viewed as though the disclaimed claims had never existed in the patent." *Guinn v. Kopf*, 96 F.3d 1419, 1422 (Fed. Cir. 1996). One would expect that this would end the argument as to Claim 31.

Pure Hemp's reply brief, however, insists that the Court can still declare Claim 31 invalid as a multiple dependent claim that relies on multiple dependent claims, even though those underlying multiple dependent claims are now deemed nonexistent. (ECF No. 38 at 11–12.) Pure Hemp relies on *Rembrandt Wireless Technologies, LP v.*

---

previously set forth and then specify a further limitation of the subject matter claimed." 35 U.S.C. § 112(d) (emphasis added). Obviously, referring to "proceeding claims" fails this requirement, and Pure Hemp requested summary judgment of invalidity on this basis, among others. (ECF No. 32 at 12–15.) UCANN has since obtained a certificate of correction from the U.S. Patent & Trademark Office ("PTO"), stating that "proceeding" should read "preceding." (ECF No. 52-2.) Accordingly, the § 112(d) invalidity argument is moot.

Samsung Electronics Co., 853 F.3d 1370 (Fed. Cir. 2017). In *Rembrandt*, the plaintiff accused the defendant of infringing two claims of its patent, which the Court will call "Claim A" and "Claim B," to avoid confusion with any claim at issue between UCANN and Pure Hemp. As it turned out, one of the plaintiff's licensees had been selling products incorporating Claim B without marking those products as patent-protected. *Id*. at 1382. This potentially entitled the defendant to a limitation on damages, because the Patent Act states that "[i]n the event of failure so to mark, no damages shall be recovered by the patentee in any action for infringement, except on proof that the infringer was notified of the infringement and continued to infringe thereafter, in which event damages may be recovered only for infringement occurring after such notice." 35 U.S.C. § 287(a).

The defendant asserted that it had no notice of the plaintiff's patent until the lawsuit itself, and apparently the plaintiff did not contest this assertion. *Rembrandt*, 853 F.3d at 1382. Accordingly, the defendant moved to limit the plaintiff's damages. *Id*. Eight days later, the plaintiff disclaimed Claim B, electing to proceed only under Claim A. *Id*. The district court accepted this maneuver and allowed the plaintiff to seek damages further back in time than the failure-to-mark limitation would allow. *Id*. at 1382–83. The Federal Circuit reversed: "while we have held that a disclaimer relinquishes the rights of the patent owner, we have never held that the patent owner's disclaimer relinquishes the rights of the public." *Id*. at 1383–84. Nonetheless, due to proceedings in the district court that interrupted briefing on the matter, the Federal Circuit remanded to the district court to decide whether a failure to mark limits damages under *any* claim of the patent—such that damages under Claim A should not have been

awarded before the date the plaintiff filed a lawsuit—or whether a failure to mark only limits damages flowing from the claim embodied by the unmarked product. *Id*. at 1384–85.

Pure Hemp argues that "[s]imilar public notice concerns undergird the [multiple dependent] requirements of [35 U.S.C. § 112(e)]." (ECF No. 38 at 11.) Pure Hemp contends that there must be "clear public notice" of invalidity. (*Id*. at 12.) This is circular. Claim 31 is *not* invalid anymore, at least not on account of the multiple dependency problem that existed before UCANN's disclaimer.

Even if Claim 31 were invalid, however, a ruling from this Court would not serve as clear public notice of that. The PTO would not reissue the 911 Patent with Claim 31 crossed out, for example. Those using databases like Westlaw and LexisNexis would see a red flag or stop sign icons, but that is hardly *public* notice.

In short, there is neither a good reason nor a statutory basis to declare Claim 31 invalid, even though it *previously* depended on multiple dependent claims. The Court therefore rejects this argument.

IV. CONCLUSION

For the reasons set forth above, Pure Hemp's Early Motion for Partial Summary Judgment (ECF No. 32) is DENIED.

Dated this 17th day of April, 2019.

BY THE COURT:

William J. Martínez
United States District Judge

Pentane

SECTION 1 : Identification of the substance/mixture and of the supplier

Product name : **Pentane**

Manufacturer/Supplier Trade name:

Manufacturer/Supplier Article number: **S25457**

Recommended uses of the product and uses restrictions on use:

Manufacturer Details:

AquaPhoenix Scientific
9 Barnhart Drive, Hanover, PA 17331

Supplier Details:

Fisher Science Education
15 Jet View Drive, Rochester, NY 14624

Emergency telephone number:

Fisher Science Education Emergency Telephone No.: 800-535-5053

SECTION 2 : Hazards identification

Classification of the substance or mixture:

Flammable
Flammable liquids, category 2

Health hazard
Aspiration hazard, category 1

Irritant
Specific target organ toxicity following single exposure, category 3

Environmentally Damaging
Chronic hazards to the aquatic environment, category 2

Flam. Liq. 2
Asp. Tox. 1
STOT SE3
Aquatic Chronic 2

Signal word :Danger

Hazard statements:
Highly flammable liquid and vapour
May be fatal if swallowed and enters airways
May cause drowsiness or dizziness
Toxic to aquatic life with long lasting effects

Precautionary statements:
If medical advice is needed, have product container or label at hand
Keep out of reach of children

Read label before use
Keep away from heat/sparks/open flames/hot surfaces. No smoking
Keep container tightly closed
Ground/bond container and receiving equipment
Use explosion-proof electrical/ventilating/light/equipment
Use only non-sparking tools
Take precautionary measures against static discharge
Wear protective gloves/protective clothing/eye protection/face protection
Avoid release to the environment
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do. Continue rinsing
In case of fire: Use ... for extinction
IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing
Collect spillage
Store in a well ventilated place. Keep cool
Store locked up
Dispose of contents and container to an approved waste disposal plant

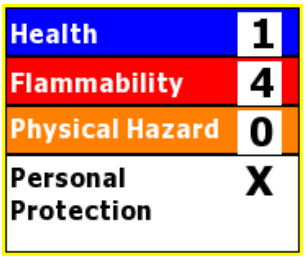
Other Non-GHS Classification:

WHMIS

B2

NFPA/HMIS

NFPA SCALE (0-4)



HMIS RATINGS (0-4)

SECTION 3 : Composition/information on ingredients

Ingredients:		
CAS 109-66-0	n-Pentane	100 %
		Percentages are by weight

SECTION 4 : First aid measures

Description of first aid measures

After inhalation: Loosen clothing as necessary and position individual in a comfortable position.Move exposed to fresh air. Give artificial respiration if necessary. If breathing is difficult give oxygen.Get medical assistance if

cough or other symptoms appear.

After skin contact: Rinse/flush exposed skin gently using soap and water for 15-20 minutes.Seek medical advice if discomfort or irritation persists.

After eye contact: Protect unexposed eye.Rinse/flush exposed eye(s) gently using water for 15-20 minutes.Remove contact lens(es) if able to do so during rinsing.Seek medical attention if irritation persists or if concerned.

After swallowing: Rinse mouth thoroughly. Do not induce vomiting. Seek medical attention if irritation, discomfort, or vomiting persists.Never give anything by mouth to an unconscious person.

Most important symptoms and effects, both acute and delayed:

Irritation.Headache.Nausea.Shortness of breath.;

Indication of any immediate medical attention and special treatment needed:

If seeking medical attention provide SDS document to physician. Physician should treat symptomatically.

SECTION 5 : Firefighting measures

Extinguishing media

Suitable extinguishing agents: Use water, dry chemical, chemical foam, carbon dioxide, or alcohol-resistant foam.

For safety reasons unsuitable extinguishing agents:

Special hazards arising from the substance or mixture:

Carbon oxides.Thermal decomposition can lead to release of irritating gases and vapors.

Advice for firefighters:

Protective equipment: Use NIOSH-approved respiratory protection/breathing apparatus.

Additional information (precautions): Avoid inhaling gases, fumes, dust, mist, vapor, and aerosols. Avoid contact with skin, eyes, and clothing.

SECTION 6 : Accidental release measures

Personal precautions, protective equipment and emergency procedures:

Ensure adequate ventilation.Ensure that air-handling systems are operational.

Environmental precautions:

Should not be released into environment.Prevent from reaching drains, sewer, or waterway.

Methods and material for containment and cleaning up:

Always obey local regulations.If necessary use trained response staff or contractor. Evacuate personnel to safe areas. Keep in suitable closed containers for disposal.

Reference to other sections:

SECTION 7 : Handling and storage

Precautions for safe handling:

Avoid contact with skin, eyes, and clothing.Do not eat, drink, smoke, or use personal products when handling chemical substances.

Conditions for safe storage, including any incompatibilities:

Store in a cool location. Keep away from food and beverages.Protect from freezing and physical damage.Provide ventilation for containers. Keep container tightly sealed.Store away from incompatible materials.

SECTION 8 : Exposure controls/personal protection



Control Parameters: 109-66-0, Pentane, NIOSH TWA 350 mg/m3
109-66-0, Pentane, ACGIH TLV TWA 600 ppm
109-66-0, Pentane, OHSA PEL TWA 1000 ppm

Appropriate Engineering controls: Emergency eye wash fountains and safety showers should be available in the immediate vicinity of use or handling. Provide exhaust ventilation or other engineering controls to keep the airborne concentrations of vapor and mists below the applicable workplace exposure limits (Occupational Exposure Limits-OELs) indicated above.

Respiratory protection: Where risk assessment shows air-purifying respirators are appropriate use a full-face particle respirator type N100 (US) or type P3 (EN 143) respirator cartridges as a backup to engineering controls.When necessary use NIOSH approved breathing equipment.

Protection of skin: Select glove material impermeable and resistant to the substance.Select glove material based on rates of diffusion and degradation. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices.Use proper glove removal technique without touching outer surface. Avoid skin contact with used gloves.Wear protective clothing.

Eye protection: Wear equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).Safety glasses or goggles are appropriate eye protection.

General hygienic measures: Perform routine housekeeping. Wash hands before breaks and at the end of work. Avoid contact with skin, eyes, and clothing.Before wearing wash contaminated clothing.

SECTION 9 : Physical and chemical properties

Appearance (physical state,color):	Clear, colorless liquid.	**Explosion limit lower**: **Explosion limit upper**:	Not Determined Not Determined
Odor:	Gasoline-like odor	**Vapor pressure**:	573 mbar @ 20°C
Odor threshold:	Not Determined	**Vapor density**:	2.5 (Air = 1)
pH-value:	Not Determined	**Relative density**:	0.626
Melting/Freezing point:	- 130 ° C / - 202°F	**Solubilities**:	Material is slightly water soluble.
Boiling point/Boiling range:	36 ° C / 96.8°F	**Partition coefficient (n-octanol/water)**:	Not Determined
Flash point (closed cup):	- 49°C / - 56.2°F	**Auto/Self-ignition temperature**:	Not Determined
Evaporation rate:	28.6	**Decomposition temperature**:	Not Determined

Pentane

Flammability (solid,gaseous):	Very flammable	**Viscosity**:	a. Kinematic:Not Determined b. Dynamic: Not Determined
Density: Not Determined			

SECTION 10 : Stability and reactivity

Reactivity: Nonreactive under normal conditions.
Chemical stability: Stable under normal conditions.
Possible hazardous reactions: None under normal processing.
Conditions to avoid: Incompatible materials.Ignition sources, excess heat.
Incompatible materials: Strong oxidizing agents.
Hazardous decomposition products: Oxides of carbon.

SECTION 11 : Toxicological information

Acute Toxicity:		
Oral:	5,000 mg/kg	LD50 mouse
Inhalation:	4 h - 364,000 mg/m3	LC50 rat
Dermal:	3,000 mg/kg	LD50 rabbit
Chronic Toxicity: No additional information.		
Corrosion Irritation: No additional information.		
Sensitization:		No additional information.
Single Target Organ (STOT):		No additional information.
Numerical Measures:		No additional information.
Carcinogenicity:		No additional information.
Mutagenicity:		No additional information.
Reproductive Toxicity:		No additional information.

SECTION 12 : Ecological information

Ecotoxicity

EC50 - Daphnia magna (Water flea): 9.74 mg/l - 48 h

Persistence and degradability:
Bioaccumulative potential:
Mobility in soil:
Other adverse effects:

SECTION 13 : Disposal considerations

Waste disposal recommendations:

Contact a licensed professional waste disposal service to dispose of this material.Dispose of empty containers as unused product.It is the responsibility of the waste generator to properly characterize all waste materials according to applicable regulatory entities (US 40CFR262.11). Chemical waste generators must determine

whether a discarded chemical is classified as a hazardous waste. Chemical waste generators must also consult local, regional, and national hazardous waste regulations. Ensure complete and accurate classification.

SECTION 14 : Transport information

UN-Number

1465

UN proper shipping name

Pentanes

Transport hazard class(es)

Class:
3 Flammable liquids

Packing group:II
Environmental hazard:
Transport in bulk:
Special precautions for user:

SECTION 15 : Regulatory information

United States (USA)

SARA Section 311/312 (Specific toxic chemical listings):

Chronic, Fire

SARA Section 313 (Specific toxic chemical listings):

None of the ingredients is listed

RCRA (hazardous waste code):

None of the ingredients is listed

TSCA (Toxic Substances Control Act):

All ingredients are listed.

CERCLA (Comprehensive Environmental Response, Compensation, and Liability Act):

None of the ingredients is listed

Proposition 65 (California):

Chemicals known to cause cancer:

None of the ingredients is listed

Chemicals known to cause reproductive toxicity for females:

None of the ingredients is listed

Chemicals known to cause reproductive toxicity for males:

None of the ingredients is listed

Chemicals known to cause developmental toxicity:

None of the ingredients is listed

Canada

Canadian Domestic Substances List (DSL):

All ingredients are listed.

Canadian NPRI Ingredient Disclosure list (limit 0.1%):

None of the ingredients is listed

Canadian NPRI Ingredient Disclosure list (limit 1%):

None of the ingredients is listed

SECTION 16 : Other information

This product has been classified in accordance with hazard criteria of the Controlled Products Regulations and the SDS contains all the information required by the Controlled Products Regulations.Note:. The responsibility to provide a safe workplace remains with the user.The user should consider the health hazards and safety information contained herein as a guide and should take those precautions required in an individual operation to instruct employees and develop work practice procedures for a safe work environment.The information contained herein is, to the best of our knowledge and belief, accurate.However, since the conditions of handling and use are beyond our control, we make no guarantee of results, and assume no liability for damages incurred by the use of this material.It is the responsibility of the user to comply with all applicable laws and regulations applicable to this material.

GHS Full Text Phrases:

Abbreviations and acronyms:
IMDG: International Maritime Code for Dangerous Goods
PNEC: Predicted No-Effect Concentration (REACH)
CFR: Code of Federal Regulations (USA)
SARA: Superfund Amendments and Reauthorization Act (USA)
RCRA: Resource Conservation and Recovery Act (USA)
TSCA: Toxic Substances Control Act (USA)
NPRI: National Pollutant Release Inventory (Canada)
DOT: US Department of Transportation
IATA: International Air Transport Association
GHS: Globally Harmonized System of Classification and Labelling of Chemicals
ACGIH: American Conference of Governmental Industrial Hygienists
CAS: Chemical Abstracts Service (division of the American Chemical Society)
NFPA: National Fire Protection Association (USA)
HMIS: Hazardous Materials Identification System (USA)
WHMIS: Workplace Hazardous Materials Information System (Canada)
DNEL: Derived No-Effect Level (REACH)

Effective date : 02.10.2015
Last updated : 03.19.2015