

Handout for Life Sciences Example Workshop

This workshop training will demonstrate the application of several key aspects of the Interim Eligibility Guidance including how the broadest reasonable interpretation affects the eligibility analysis, how to identify judicial exceptions in Step 2A, how to evaluate additional elements in Step 2B, particularly in combination, and how to write a rejection that satisfies your burden to make a *prima facie* case of ineligibility.

This workshop training will step through the analysis of several claims taken from the [Life Sciences Examples](#) issued in May 2016, using the generic and Nature-Based Products Subject Matter Eligibility Worksheets. The examples should be analyzed under the 2014 Interim Guidance on Patent Subject Matter Eligibility (IEG). As the examples are intended to be illustrative only, they should be interpreted based on the fact patterns set forth in the workshop materials. Other fact patterns may have different eligibility outcomes. For purposes of this workshop, other patentability requirements under §§ 102, 103, 112 and 101 (utility, inventorship, double patenting) and non-statutory double patenting need not be addressed.

29. Diagnosing and Treating Julitis

This hypothetical example illustrates the eligibility analysis of diagnostic and treatment claims directed to a hypothetical disease. The claims in this example should be analyzed using the generic Subject Matter Eligibility Worksheet. The graphic on page 2 of the [July 2015 Update: Interim Eligibility Guidance Quick Reference Sheet](#) and the [case law chart](#) available on the website may also be used as a guide for identifying abstract ideas.

Background

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

Applicant has discovered that the presence of a protein known as “JUL-1” in a person’s body is indicative that the person has julitis. All julitis patients have JUL-1 in their plasma, skin, hair and nails, but this protein is not found in persons who do not have julitis (*e.g.*, patients with rosacea). Applicant discloses detecting JUL-1 by routine and conventional methods such as (i) physical biopsies of skin, hair or nails, or (ii) immunoassays in which a sample from a patient (*e.g.*, a plasma or skin sample) is contacted with an antibody to the protein being detected, and then binding between the antibody and the protein is detected using a laboratory technique such as fluoroscopy. In particular, applicant discloses detecting JUL-1 using anti-JUL-1 antibodies that may be naturally occurring (*e.g.*, a human anti-JUL-1 antibody isolated from a patient known to have julitis), or non-naturally occurring (*e.g.*, a porcine anti-JUL-1 antibody created by injecting pigs with JUL-1, or a specific monoclonal antibody named “mAb-D33” that was created by applicant). Prior to applicant’s invention, and at the time the application was filed, the use of porcine antibodies in veterinary therapeutics was known to most scientists in the field, but these antibodies were not routinely or conventionally used to detect human proteins such as JUL-1.

Prior to applicant’s invention, and at the time the application was filed, julitis was conventionally treated with anti-tumor necrosis factor (TNF) antibodies, but for unknown reasons, some patients do not respond well to this conventional treatment. Because rosacea treatments (*e.g.*, antibiotics) are not effective against julitis, julitis patients who were misdiagnosed as having rosacea also did not respond well to the treatments they were given. Some anti-TNF antibodies are naturally occurring in

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patients with other autoimmune diseases such as lupus. Applicant has successfully treated juitis patients (even those who are non-responsive to anti-TNF antibodies) with topical vitamin D. Prior to applicant's invention, and at the time the application was filed, vitamin D was commonly used as an oral supplement to maintain bone health (*e.g.*, in fortified dairy products), but doctors were not commonly or routinely administering topical vitamin D to patients with juitis or other diseases.

Claims

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

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

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

30. Dietary Sweeteners

This example illustrates the eligibility analysis of claims reciting hypothetical nature-based products including mixtures. The claims in this example should be analyzed using the Nature-Based Products Subject Matter Eligibility Worksheet. The graphic on page 2 of the [July 2015 Update: Interim Eligibility Guidance Quick Reference Sheet](#) and the [case law chart](#) available on the website may also be used as a guide for identifying abstract ideas.

Background

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

- A dietary sweetener comprising texiol mixed with other components such as water to form a heterogeneous or homogenous mixture, *e.g.*, a solution or suspension. Applicant discloses

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that trained sensory panels reviewed formulations having varying concentrations of texiol in water, and found that the sensory perceptions of texiol's sweetness and bitter aftertaste both increased with concentration, *e.g.*, higher concentrations of texiol were perceived as having stronger sweet and bitter tastes. Based on the panel's review, and from a consumer's perspective, applicant discloses a preferred dietary sweetener comprising 1-5% texiol and at least 90% water. This preferred sweetener retains the naturally occurring texiol's sweetness and bitter aftertaste.

- A dietary sweetener comprising texiol mixed with water and Compound N (a natural flavor excreted from mushrooms and having a mild umami taste). Applicant discloses that when combined with texiol in particular amounts, Compound N neutralizes the bitter aftertaste of texiol. Applicant discloses that this neutralization does not involve a chemical reaction. The same sensory panel tasted mixtures having various concentrations of Compound N and texiol, and found that a formulation comprising 1-5% texiol, 1-2% Compound N, and the balance water produced the most palatable results for a dietary sweetener with no bitter aftertaste. When Compound N is added in the specified amount, the changed taste perception occurs whether or not the texiol is fully dissolved, *e.g.*, even when large crystals of texiol are used.
- A dietary sweetener solid gel formulation comprising 5% texiol mixed with water and/or fruit juice and sufficient pectin to provide a solid gel. The Texas mint plant does not contain pectin in nature. Solid gel formulations are useful commercial sweeteners because their solid, jelly-like consistency makes them spreadable onto other foods, such as bread, cake layers, or pastry dough. Solid gels can also be formed into candies such as jellybeans. Applicant discloses that the same sensory panel tasted the gel formulation and found that it had improved organoleptic properties (*e.g.*, a more pleasant mouthfeel) and a solid but easily-spreadable consistency as compared to naturally occurring texiol (either in the sap or crystallized).
- A dietary sweetener comprising texiol in granular form for use by consumers. Naturally occurring texiol forms irregular crystals that aggregate into large chunks of varying size and shape. Due to this variation, sweeteners formed from these irregular crystals do not have consistent and commercially acceptable dissolution rates. For example, a consumer attempting to sweeten iced tea with irregular texiol crystals will typically experience a need to add more than the expected amount of texiol in order to obtain the desired level of sweetness, because the larger particles of texiol dissolve more slowly (if at all) than the smaller particles even with vigorous stirring. The presence of these undissolved crystals may also cause an undesirable gritty mouth feel as the sweetened tea is consumed. To solve the problem of inconsistent and slow dissolution rates, applicant has produced granulated texiol formulations having even and regular particle size distributions, *e.g.*, by grinding or milling coarse texiol crystals into an even and regular powder, or by crystallizing texiol in a controlled manner that forms regularly sized and shaped crystals. Granular texiol having a particle size of X10 of 80 microns and X90 of 300 microns is preferred, because this particle size distribution results in a greatly increased (and consistent) dissolution rate in water-based liquids as compared to naturally occurring texiol crystals. The terms "X10" and "X90" refer to the median diameter of the particles, as measured on a volume basis by a laser diffraction particle sizing system. For "X10", 10 percent of the particles have a diameter smaller than the specified size, and 90 percent of the particles have a larger diameter, and for "X90", 90 percent of the particles have a diameter smaller than the specified size, and 10 percent of the particles have a larger diameter.
- A dietary sweetener comprising texiol in a controlled release formulation. Applicant discloses that the same sensory panel, upon tasting naturally occurring texiol, reported perceiving an

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immediate burst of sweetness that rapidly dissipated. Applicant discloses formulations that achieve controlled release (*e.g.*, release of specific amounts of texiol from the formulation at specific time intervals, or over a prolonged period of time) by mixing the texiol with other substances such as polymers and/or changing the form of the texiol so that a controlled perception of sweetness is achieved. For example, in one such formulation, texiol particles are encapsulated in a polymer-emulsifier mixture that delays release of the texiol as compared to unencapsulated (*e.g.*, naturally occurring) texiol particles. These controlled release formulations prolong enjoyment of a texiol-sweetened product such as chewing gum, by altering the time over which texiol's sweetness is perceived.

Claims

2. A dietary sweetener comprising:
1-5 percent texiol; and
at least 90 percent water.
3. A dietary sweetener comprising:
1-5 percent texiol;
at least 90 percent water; and
1-2 percent Compound N.
6. A dietary sweetener comprising texiol in a controlled release formulation.