NOW & NEXT

Intellectual Property Alert

APRIL 3, 2023

# Patent Plantings: Understanding natural products claims

**By Nicole D. Kling, Ph.D. and David S. Resnick**

## We illustrate and analyze several successful approaches to obtaining IP protection for natural products.

### What's the Impact?

- Modified natural products may be sufficient to meet *Myriad*'s demands for patent eligibility, but conversely, may not meet criteria for "all-natural" labelling.
- Get creative—natural products can still be afforded patent protection in the US, but outside-the-box thinking is a must.
- Properly defining and identifying your product is key to obtaining significant IP protection.

Intellectual property rights for the "natural products" industries underwent a significant shift following the U.S. Supreme Court's 2013 *Myriad* decision. U.S. patent law had long been clear that ***merely*** isolating a thing from nature does not universally make the thing patent-eligible subject matter—it was necessary that the inventor cause some sort of change that made the invention "markedly different" from the naturally occurring counterpart, either structurally or functionally. See, e.g., the *Funk Bros. Seed Co.* (1948) and *Chakrabarty* (1980) decisions. But for several decades, the USPTO examined patent applications under the presumption that isolation

could, for certain biological materials, in fact provide the requisite marked difference. One of these materials was DNA, a gene. A gene isolated from its source chromosome was considered by the USPTO to be capable of satisfying the markedly different threshold and therefore eligible for a patent.

This presumption was challenged in *Myriad*, which involved claims to isolated breast cancer genes. The Court's decision reiterated that merely isolating something from nature was not sufficient to render that thing patent eligible subject matter, and at the same time created what can be confusing doctrine on what is or is not "isolated."

During *Myriad*'s oral arguments, the U.S. Solicitor General proposed to the Court that they use a "magic microscope" test to determine whether there was a structural marked difference when isolating DNA. The theory went: if one imagined using a "magic microscope" to view a natural source material, zooming and cropping the "image" at will, would enough zooming and cropping eventually produce an image of what is recited in the claim? If so, it is not markedly different from what occurred in nature and could not be patent eligible subject matter. If the "magic microscope" could not find something in nature that was identical to the claimed product, the product was a non-natural product and patent eligible subject matter.

This may have contributed to the outcome in *Myriad,* where it was found that small stretches of DNA were still patent ineligible natural products, even when isolated from the rest of the structure of a chromosome, so long as the contiguous DNA sequence recited in the claim was known to exist ***within*** the genome of the source organism. This further meant that the addition or absence of a chemical group on the end of a nucleotide molecule, the absence of chromosomal proteins, or the absence of a native promoter, would not change the Court's view of the DNA sequence as a patent ineligible natural product. Conversely, the deletion of even a short intron *within* the *DNA* sequence could move a claimed molecule into the realm of patent eligibility, as this spliced form would never be found in nature, no matter how much zooming and cropping a "magic microscope" did.

This is why early advice from many US legal practitioners often focused on how to change the biomolecule, or combine the biomolecule with a heterologous material and claim that changed or combined substance as a whole. But while such advice is often practical for applicants developing therapeutics or research tools, it fails to meet the needs of various economic sectors for whom an "all-natural" or "non-GMO" product is a critical part of their marketing and perhaps even their *raison d'etre*.

Given the US's unique stance on natural products IP, it is helpful to consider what different approaches have now proven to be successful in obtaining IP protection for natural products developers. The patents presented below illustrate some of the different ways that natural products can still be afforded patent protection in the US.

## Less is more strategy

*U.S. Patent 11,331,264*

- Titled: Fermented extract of aerial parts of bitter orange
- Inventors: Legangneux et al.
- Assignee: Chanel Parfums Beaute SAS (Neuilly sur Seine, France)
- Issued May 17, 2022
- Claim of interest:

> 1. An extract of aerial parts of *Citrus aurantium*, wherein said extract is in a form and effective amount suitable for cosmetic and/or dermatological use.

This claim was originally presented as:

> 1. An extract of aerial parts of *Citrus aurantium*, wherein said extract is a fermented extract.

No § 101 rejection was made against the original claim reciting "fermented." The rationale was not made of record, but it is plausible that fermentation was considered to effect enough structural changes to the extract to provide the requisite marked difference from aerial parts of *Citrus aurantium.* The amendment did not trigger a § 101 rejection.

***Lessons***

- **Don't miss the forest for the trees**. A marked difference can be rather expansive and simply stated. The balance against § 112 must be kept in mind, but this patent demonstrates that manufacturing processes that do something other than merely isolate or purify can be ample basis to overcome § 101.

## More is more strategy

*U.S. Patent 10,709,751*

- Titled: Chardonnay grape seed extract
- Inventors: Ianiro et al.
- Assignees: Shaklee Corporation (Pleasanton CA)
- Issued: July 14, 2020
- Claim of interest:

> 1. A composition comprising an effective amount of a water extract of Chardonnay grape seed and a pharmaceutically acceptable carrier, wherein the extract consists essentially of Fraction B or C which comprise by percentage dry weight:
>
> > Fraction B: 38-50% Polyphenols, 9-12% Fiber, 1-2% Protein, <1% Lipids, 25-30% Sugars; and

Fraction C: 45-55% Polyphenols, 26-30% Fiber, 2-3% Proteins, <1% Lipids, <1% Sugars;

wherein the extract is obtained by the steps of: (a) mixing washed grape seeds with heated water at a temperature below 100.degree. C.

Note that the "consists essentially" language is likely to exclude contents of the grapes other than the recited Fractions ***from the extract portion*** of the claim. This claim overcame § 101 rejections on the strength of arguments and evidence showing that "normal" grape seed extracts did not have the recited percentages of these components. Additionally, the Applicants argued that the relatively low lipid content (as compared to other known grape seed extracts) permits the claimed compositions to be formed into tablets, which is a unique property for grape seed extracts.

Returning to the "magic microscope" analogy—it is arguable that no amount of cropping and zooming with the microscope will produce a picture of the inside of a grape that has ***only*** the Fractions recited in this claim. Thus, this claim might be seen to relate not to mere purification, but the creation of a new composition via extraction.

***Lessons***

- **Claim more than your primary interest**. When a particularly useful compound is identified, the initial temptation is to claim that specific compound as an isolated molecule. But isolation of a specific molecule is not likely to be enough to confer patent eligibility. Unless your plans for the compound involve production of pure, reagent grade formulations, consider claiming a relevant extract, mixture, or solution comprising multiple compounds. The identity of the combination can be distinguished from a naturally occurring product, either in what is present, what is lacking, and/or the relative amounts.
- **Think creatively when identifying functional differences**. Include in your application at least one functional property that distinguishes your composition from the natural source material and/or related compositions. There is a temptation to focus on consumer-facing outcomes such as therapeutic efficacy, but as this patent illustrates, something as seemingly mundane as texture and its impact on manufacturing concerns can be sufficient to bolster patent eligibility. We do note that, particularly in the wake of the *Chromadex* decision discussed below, those properties should also be recited in at least a dependent claim.

## Recite your effects broadly

*U.S. Patent 10,688,158*

- Titled: Compositions comprising sulforaphane or a sulforaphane precursor and a milk thistle extract or powder
- Inventors: Cornblatt et al.
- Assignees: Nutramax Laboratories, Inc. (Edgewood, MD)

- Issued: June 23, 2020
- Claim of interest:

> 1. An orally administrable composition comprising a synergistic combination of a broccoli extract or powder and a milk thistle extract or powder.

Here, the Applicants relied on the strength of the synergistic effect on liver cell metabolism when one compound in the broccoli extract was combined with a second compound in the milk thistle extract. This was sufficient to demonstrate a "marked difference" from the single extracts. The Examiner maintained the § 101 rejection of this claim, arguing that:

> None of the claims require both sulforaphane and silibinin in combination in synergistically effective amounts. Merely claiming an extract of a botanical which is [a] known source of sulforaphane or silibinin does not require that the extract itself actually contain sulforaphane or silibinin as the extraction process may be one that does not extract said compounds.

This ground of rejection was overturned on appeal, with the BPAI finding that the "synergistic combination" language in view of a demonstration of synergism of at least some embodiments was sufficient to satisfy § 101. *Ex parte Cornblatt* Appeal 2019-005191 January 14, 2020. Addressing the Examiner's position that not all combinations might exhibit synergism, the BPAI held that such a concern was only proper as a § 112 written description rejection. The Examiner declined to raise such an objection and allowed the application.

***Lessons***

- **A functional "marked difference" sufficient to meet the requirements of § 101 can be recited broadly**. In some cases it may not be necessary to describe what the synergism provides, merely that the composition is in fact synergistic. Additionally, § 101 does not necessarily require recitation of the narrow structures of exemplary embodiments.

## Complex mixtures

### *U.S. Patent 10,683,241*

- Titled: Aqueous seaweed extract in the form of a solution concentrate
- Inventors: Arioli, et al.
- Assignees: Seasol International Party Ltd (Bayswater, Victoria AU)
- Issued: June 16, 2020
- Claim of interest:

> 1. An aqueous concentrate composition comprising:
>
> - (a) aqueous liquid seaweed extract formed by aqueous solvent extraction of seaweed and comprising dissolved solids extracted from the seaweed including soluble alginate, wherein the aqueous concentrate composition comprises 5% to 25% by weight soluble alginate based on the weight of the concentrate composition;

- (b) 0.1% to 5% calcium by weight based on the weight of the concentrate composition;
- (c) a calcium chelating agent selected from gluconodeltalactone and gluconic acid, or water soluble salt thereof, in the range of from 0.3% to 5% by weight based on the weight of the concentrate composition;
- (d) borate (as boron equivalent) in an amount in the range of from 0.02% to 5% by weight based on the weight of the concentrate composition; and
- (e) water in an amount of from 60% to 95% w/w of the concentrate composition, wherein the borate and calcium chelating agent inhibit formation of calcium alginate precipitate which would otherwise occur from the combination of calcium and the aqueous liquid seaweed extract.

This claim issued without any § 101 rejections and after protracted arguments regarding obviousness. When seeking a patent in a crowded prior art environment, an increased level of detail is often required. But given a careful eye to the ranges and aspects recited, this claim may not be as narrow as it would first appear.

***Lessons***

/ **Look to your end product for the sort of additional elements that will avoid a § 101 rejection**. § 101 rejections are avoided entirely by many Applicants by presenting claims which provide a significant level of additional elements and/or detail. While such limitations certainly have the potential to be narrowing, they are not ill-advised for all inventions, particularly when the details included are carefully selected to adequately distinguish from naturally occurring products while still encompassing likely work-arounds.

## Chromadex

Finally, we note that a recent February 2023 decision from the CAFC (*Chromadex, Inc. v. Elysium Health*) illustrated the need to carefully ensure that what is claimed is adequately distinguished from the natural counterpart, and any markedly different characteristics are ***claimed***. In question was a patent with the following independent claim:

/ A composition comprising
  - isolated nicotinamide riboside in combination with one or more of tryptophan, nicotinic acid, or nicotinamide, wherein said combination is in admixture with a carrier comprising a sugar, starch, cellulose, powdered tragacanth, malt, gelatin, talc, cocoa butter, suppository wax, oil, glycol, polyol, ester, agar, buffering agent, alginic acid, isotonic saline, Ringer's solution, ethyl alcohol, polyester, polycarbonate, or polyanhydride, wherein said composition is formulated for oral administration and increases NAD+ biosynthesis upon oral administration.

The patentee took the position that this described a man-made formulation. But the CAFC found that the natural counterpart—milk—a) also contains at least nicotinamide riboside, tryptophan, and lactose; b) also is formulated for oral administration; and c) also increases NAD+ biosynthesis. Therefore, ***the claim*** failed to recite a structural or functional markedly different characteristic. The patentee argued that their compositions provided more bioavailable nicotinamide riboside than milk. But the CAFC responded that this characteristic was not ***claimed*** and thus could not be relied upon to provide patent eligibility.

The CAFC's decision indicated that they likely would have found the claim to comply with § 101 if it had:

- either
  - recited a level of at least one component that was outside the range of what is naturally found in milk; or
  - recited a requirement that the composition did not comprise other elements of naturally occurring milk, such as casein or fatty acids; and
- recited the increased bioavailability of nicotinamide riboside.

## Conclusions:

Industries that rely on their products being what their customers would understand to be "natural" cannot obtain IP protection by the routes of chemical modification or recombinant biology, common in pharmaceutical inventions. While the US has generally foreclosed the option of simply claiming an isolated biomolecule which provides the desired effect, those in the relevant markets can still obtain valuable protection. The patents noted above show how this can be done in a granular fashion. More broadly, these patents illustrate that success can be found by avoiding a narrow focus on a single chemical compound. It is important to:

- find the right scope in defining the invention, so that what is claimed cannot be "found" in nature in the unique way that the US courts look at the molecular world; and
- identify and claim at least one "marked difference" between what is claimed and the biological source material.

As the examples above show, critical and creative thinking about these points can provide significant IP protection.

For more information on the content of this alert, please contact your Nixon Peabody attorney or:

**Nicole D. Kling, Ph.D.**
617.345.1013
nkling@nixonpeabody.com

**David S. Resnick**
617.345.6057
dresnick@nixonpeabody.com