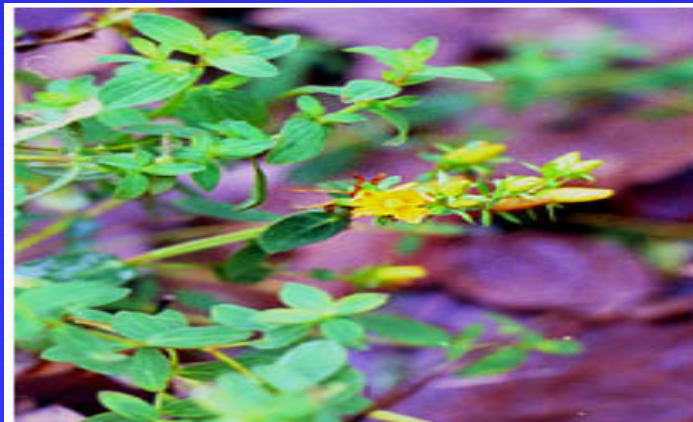


Defensive Protection of Traditional Knowledge At the United States Patent and Trademark Office



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Topics

- Background
- Searching for Prior Art
- Legal Standards and Common Rejections
- Examples of Common Art Situations

Background - United States

Native Americans
passed along
medicinal knowledge
of indigenous
plants to the early
American settlers



Background - USPTO

Policy Interest: Granting valid patents

- Predictable legal rights
- Defensive protection for TK-holders

Background - USPTO

Challenges in search (Turmeric,
Basmati)

- Accessibility
- Foreign languages

Challenges in examination

Background - USPTO

USPTO Response

- Increased access to commercial and public tools for searching TK
- Development of Intranet and Internet site for TK-related search tools
- Creation of TK Working Group
- Increased Examiner training
- TKDL Access Agreement signed with CSIR

Background - TKDL

- TKDL Access Agreement - Nov. 2009
- USPTO STIC search experts visit CSIR for TKDL training - Nov. 2010
- USPTO working on TKDL manual for USPTO examiners
- Plans for follow-up training
- Examiners now required to consult TKDL when searching TK-related inventions

Herbal Medicines in U.S. Patents

424/725-779:

- Plant material or plant extract of undetermined constitution as an active ingredient (e.g., herbal remedy, herbal extract, powder, oil, etc.)

514/783:

- Plant extract or plant material of undetermined constitution as a nonactive ingredient

Examiner NPL search resources

Traditional Knowledge and Medicine

website:

- Dictionaries
- Handbooks
- Formularies
- Journals
- Historical and Classical works

Alternative search terms

- **Arbre aux quarante ecus (forty coin tree)**
- **eun-haeng (fossil tree)**
- **ginan**
- **icho**
- **ityo**
- **kew tree**
- **maidenhair tree**
- **pei-wen**
- ***Pterophyllus salisburyensis* Nelson**
- ***Salisburia adiantifolia* Smith**
- ***Salisburia macrophylla* C. Koch**
- **temple balm**
- **tempeltrae**
- **yin guo**
- **yinhsing**
- **olium ginkgo**
- ***Ginkgo folium* ... gin-nan**
- **ginkgoblatter**
- **ginkgo balm**
- ***Ginkgo biloba***



Examples of frequently used NPL databases

- Agricola-agriculture, animal science
- Biosis-biological and biomedical sciences
- CAPlus/CASearch-chemistry, life sciences
- Embase-clinical medicine, drugs
- Medline-clinical medicine, life sciences, biology

Legal Standards and Common Rejections of Traditional Knowledge-Related Applications

- 35 U.S.C. § 101: Product of Nature rejection
- 35 U.S.C. § 102: Anticipation rejection
- 35 U.S.C. § 103: Obviousness rejection
- 35 U.S.C. § 112, 1st paragraph: Enablement reject
- 35 U.S.C. § 112, 2nd paragraph: Indefinite reject

*Products of Nature are not
Patentable under
35 U.S.C. § 101*

“A composition comprising phytochemical X.”
reads on the plant itself



Anticipation under 35 U.S.C. § 102

Webster's dictionary defines 'extract' as follows:

1 a : to draw forth (as by research) <*extract* data> **b** : to pull or take out forcibly <*extracted* a wisdom tooth> **c** : to obtain by much effort from someone unwilling <*extracted* a confession> **2** : to withdraw (as a juice or fraction) by physical or chemical process; *also* : to treat with a solvent so as to remove a soluble substance **3** : to separate (a metal) from an ore **4** : to determine (a mathematical root) by calculation **5** : to select (excerpts) and copy out or cite.

Plant Extracts are Ubiquitous

- An extract of *Coffea arabica*: Coffee
- An extract of *Camillia sinensis*: Tea
- An extract of broccoli: Soup
- An extract of orange: Orange juice

Obviousness under 35 U.S.C. § 103

As set forth in *In re Kerkhoven*, 626 F.2d 846, 850, 205 U.S.P.Q. 1069 (CCPA 1980), “It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition which is to be used for the very same purpose...the idea of combining them flows logically from their having been individually taught in the prior art”

An Enabling Disclosure

Under 35 U.S.C. § 112, 1st paragraph, the application is required to sufficiently describe how to make and use the claimed extract or herbal medicine

- **The plant name/names**
- **The part/parts of the plant used**
- **The type/types of solvent used**
- **Extraction temperature and pH**
- **Material used fresh or dried and/or chopped or powdered**
- **Separation/fractionation/recovery/isolation steps**

The particular part of the plant from which the extract is obtained is often essential

- Roots/rhizome/bulb: asparagus, beet, garlic, ginseng, *Narcissus*, *Polygonatum*
- Leaves: aloe, *Barosma*, *Betula*, *Camellia*, *Cassia*, *Ginkgo*, *Prunus laurocerasus*
- Bark: Canella, poplar, *Prunus serotina*, *Quercus robur*
- Flower: *Artemisia*, *Arum*, *Prunus spinosa*
- Fruit: *Barberry*, *Vaccinium*, *Sorbus*, *Pyrus*, *Rhamnus*

Clarity of Claims

If the identity of the plant named in the claims is unclear, then a rejection of the claims under 35 USC 112, 2nd paragraph is warranted

Example 1

Claim 1. A composition for treating diabetes comprising tryptophan, proline, niacin, methionine and palmitic acid

Smith et al. teach that *Brassica chinensis* (Chinese mustard) has been evaluated for its phytochemical constituents and it has found that this plant contains all of these ingredients, but it fails to teach that this plant can be used to treat diabetes

Example 1 analysis

1. Smith et al teaches that all claimed ingredients are present in *B. chinensis*
2. The use of “comprising” in the claim allows for the composition to further contain anything else
3. The intended use of “for treating diabetes” does not materially change the composition and therefore does not hold any patentable weight
4. All claim limitations are met, the claim is anticipated by Smith et al

Example 2

Claim 1. A method for treating inflammation comprising administering to a mammal an effective amount of quercetin

Jones et al. teach a method for treating inflammation comprising orally administering rutin. Rutin is taught by the reference as quercetin-3-O glycoside

Smith teaches that quercetin-3-O glycoside is degraded in the stomach to quercetin

Example 2 analysis

1. The Jones et al method for treating inflammation results in the administration of quercetin because the degradation of quercetin-3-O glycoside in the stomach inherently results in the administration of quercetin when rutin (quercetin-3-O glycoside) is orally consumed
2. Therefore the claim is anticipated by Jones et al (as evidenced by Smith)

Example 3

Claim 1. A pharmaceutical composition for facilitating weight loss comprising L-carnitine, green tea extract, witch hazel extract, and capsaicin.

Smith teaches L-carnitine and green tea extract are beneficial for use in foods for weight loss.

Jones et al teach an anti-obesity agent comprising freeze-dried capsaicin.

Henry et al teach that witch hazel extract can act as an appetite suppressant.

Example 3 analysis

1. It would have been obvious to combine the ingredients since they are known for the same purpose.
2. It is arguable whether anti-obesity/weight-loss is the same purpose as appetite suppression so an alternative approach may be better: that it would have been obvious to combine the anti-obesity and weight-loss ingredients together because they are known for the same purpose, and it would have been further obvious to add witch hazel extract to the resulting composition because (additional art) teaches that appetite suppressants are advantageously added to weight-loss formulas.

Example 4

Claim 1. A composition for treating insomnia comprising chamomile, lavender, St. John's wort, and 1-5% by weight catnip.

Jones et al. teach that chamomile, lavender, St. John's wort and catnip have all been used in separate compositions as the active ingredients for treating insomnia. This reference also teaches that although small amounts of catnip are effective for treatment of insomnia, consumption of too much catnip actually increases insomnia.

Example 4 analysis

1. It would have been obvious to combine the claimed ingredients since they are known for the same purpose.
2. Although Jones et al do not specifically teach that 1-5% catnip should be used, it does teach that the amount of catnip is a result-effective variable, i.e. a variable which achieves a recognized result. One of ordinary skill in the art would have been motivated to use routine experimentation to optimize the catnip concentration, arriving at the effective range of 1-5% catnip, especially because using too high concentration of catnip is taught in the art as reducing the effectiveness of the composition for the stated purpose of insomnia treatment.

Conclusion

1. TK poses unique challenges for the search and examination process
2. USPTO Examiners undergo training for search and examination of TK-related inventions
3. USPTO Examiners are required to use the TKDL for searching TK-related inventions
4. Examiners work hard to find and apply relevant art by interpreting the claims as broadly as is reasonable and searching using the alternative names for the particular plants
5. Examination of TK-related inventions is subject to the same legal standards as other technologies