



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/096,228	04/11/2016	AMANI SHAFEEK AWAAD	32693.67	7923
37833	7590	08/20/2020	EXAMINER	
Richard C. Litman Nath, Goldberg & Meyer 112 S. West Street Alexandria, VA 22314			HOFFMAN, SUSAN COE	
			ART UNIT	PAPER NUMBER
			1655	
			NOTIFICATION DATE	DELIVERY MODE
			08/20/2020	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

litman@4patent.com
mbashah@nathlaw.com
uspto_nva@nathlaw.com

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte AMANI SHAFEEK AWAAD, GHADA MOHAMED ZAIN,
REHAM M. EL-MELIGY, AMAL AHMED SAFHI,
VIDYA DEVENATHADESIKAN SESHADRI,
SHEKHAH SAUD ALMOQREN, and NOURAH AHMED AN QURAIN¹

Appeal 2020-000304
Application 15/096,228
Technology Center 1600

Before ERIC B. GRIMES, FRANCISCO C. PRATS, and LILAN REN,
Administrative Patent Judges.

GRIMES, *Administrative Patent Judge.*

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134(a) involving claims to a method of treating hypertension, which have been rejected as obvious. We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM.

¹ Appellant identifies the real party in interest as KING SAUD UNIVERSITY, RIYADH, SAUDI ARABIA. Appeal Br. 3. We use the word “Appellant” to refer to “applicant” as defined in 37 C.F.R. § 1.42(a).

STATEMENT OF THE CASE

The Specification states that “[c]hamomile (*Matricaria chamomilla* L.) is a medicinal plant species from the *Asteraceae* family often referred to as the ‘star among medicinal species.’” Spec. ¶ 18. “The present invention relates to the treatment of hypertension, and particularly to the treatment of hypertension using *Matricaria chamomilla* extracts.” *Id.* ¶ 1.

Claims 1 and 8–10 are on appeal. Claim 1, reproduced below, is illustrative:

1. A method of treating hypertension, comprising administering orally to a patient in need thereof a therapeutically effective amount of an extract of *Matricaria chamomilla* only, wherein the *Matricaria chamomilla* is from the Al-Alnofood desert region of Saudi Arabia, further wherein the therapeutically effective amount of the extract of *Matricaria chamomilla* is about 100 mg/kg to about 200 mg/kg.

The claims stand rejected as follows:

Claim 1 under 35 U.S.C. § 103 as obvious based on Yagi,² with evidence provided by USDA³ and ITIS⁴ (Ans. 3) and

Claims 1 and 8–10 under 35 U.S.C. § 103 as obvious based on Jamel⁵ and Yagi, with evidence provided by USDA and ITIS (Ans. 5).

² Yagi et al., US 2010/0240603 A1, published Sept. 23, 2010.

³ plants.usda.gov/core/profile?symbol=MARE6.

⁴ www.itis.gov/servlet/SingleRpt/SingleRpt?search_topic=TSN&search_value=780435#null.

⁵ Jamel et al., US 2010/0104674 A1, published April 29, 2010.

OPINION

Obviousness based on Yagi, USDA, and ITIS

Claim 1 stands rejected as obvious based on Yagi, which the Examiner cites as “teach[ing] a method of treating hypertension by administering an extract from *Matricaria recutita*.” Ans. 3. The Examiner cites USDA and ITIS as evidence that *M. recutita* is synonymous with *M. chamomilla*. *Id.* The Examiner also finds that Yagi teaches administration in dosages of 0.01 to 1000 mg/kg, preferably 0.1 to 100 mg/kg, which overlap with the range recited in claim 1. *Id.* at 4.

The Examiner acknowledges that Yagi “does not specifically teach that the chamomile plant is grown in the Al-Alnofood desert region of Saudi Arabia.” *Id.* However, the Examiner concludes that

utilizing a plant grown in a particular region is considered to be an obvious modification of the prior art. . . . Thus, the use of *M. recutita* (synonymous with *M. chamomilla*) from the Al-Alnofood desert region of Saudi Arabia is considered to be an obvious modification of what was known in the art.

Id.

We agree with the Examiner that the method of claim 1 would have been obvious based on Yagi, which discloses that “chamaemeloside contained in Roman chamomile or German chamomile . . . inhibited the expression of AP-1,” and “produce[d] remarkable effects on various diseases including inflammatory diseases.” Yagi ¶ 16. Yagi states that “the expression inhibitor . . . may contain, for example, purified chamaemeloside or the whole or a part of Roman chamomile or German chamomile plant body to contain chamaemeloside. An example in the former case is

chamaemeloside obtained by purification of an extract of Roman chamomile or German chamomile.” *Id.* ¶ 25.

Yagi discloses that its expression inhibitor can be “formed into, for example, tablets or capsules, the content can be, for example, 0.1 to 90 wt % per tablet or capsule.” *Id.* ¶ 29. Yagi states that the “dose of chamaemeloside is not limited but is preferably 0.01 to 1000 mg/kg and more preferably 0.1 to 100 mg/kg per day per adult.” *Id.* Yagi states that its “[p]harmaceuticals . . . [are] for prevention or treatment of diseases in which a nuclear transcription factor AP-1 is involved. . . . The aforementioned diseases include at least one disease selected from the group consisting of, for example, cancer, . . . hypertension, diabetes,” etc. *Id.* ¶ 39.

USDA states that the scientific name of German chamomile is *Matricaria recutita* L., and synonyms include “*Matricaria chamomilla* L. 1755 & 1763, non 1753” and “*Matricaria chamomilla* L. var. *coronata*.” USDA, first and third pages. Similarly, ITIS states that the common name of *Matricaria chamomilla* L. is German chamomile, and synonyms include *Matricaria recutita* L., “*Matricaria chamomilla* L. 1755 & 1763 non 1753,” and *Matricaria chamomilla* var. *coronata*. ITIS, first page (entries for “Synonym(s)” and “Species”).

Thus, Yagi suggests a method of treating hypertension using an extract of German chamomile, one synonym for which is *Matricaria chamomilla*, orally administered as a tablet or capsule, at a dosage of 0.01 to 1000 mg/kg.

Yagi does not specifically suggest obtaining the *Matricaria chamomilla* from the Al-Alnofood desert region of Saudi Arabia, and Appellant argues that

[t]he claimed species of chamomile is grown in the Al-Alnofood desert region of Saudi Arabia and possesses different chemical constituents and oil content. As is conventionally known by one of ordinary skill in the art, the different chemical constituents and oil content are due to the distinct ecological factors. It is known in the prior art that Chamomile contains flavonoids, volatile oils, terpenes, coumarins and tannins[]and that these constituent components are responsible for the lowering of the blood pressure. The link between the efficacy of the constituent components and the ecological factors of the growing region has been established by the prior art and deserve patentable consideration, rather than being dismissed.

Appeal Br. 9.

In support, Appellant cites Liu.⁶ *Id.* However, Liu is directed to a different plant (*Sinopodophyllum hexandrum*), grown in a different geographic region (China) and having a different pharmacological effect (anti-cancer). Appellant has pointed to no evidence showing that *Matricaria chamomilla* from the Al-Alnofood desert region of Saudi Arabia differs in any way from *Matricaria chamomilla* grown elsewhere; specifically, in a way that would affect its efficacy in treating hypertension.

Appellant’s argument that “chamomile . . . grown in the Al-Alnofood desert region of Saudi Arabia . . . possesses different chemical constituents and oil content,” Appeal Br. 9, is thus unsupported by evidence. “Attorneys’

⁶ Liu et al., “Influence of Ecological Factors on the Production of Active Substances in the Anti-Cancer Plant *Sinopodophyllum hexandrum* (Royle) T.S. Ying,” PLoS One 10(4):e0122981 (2015) (abstract only).

argument is no substitute for evidence.” *Johnston v. IVAC Corp.*, 885 F.2d 1574, 1581 (Fed. Cir. 1989). We are not persuaded by Appellant’s unsupported argument. We therefore affirm the rejection of claim 1 under 35 U.S.C. § 103 based on Yagi.

Obviousness based on Jamel, Yagi, USDA, and ITIS

Claims 1 and 8–10 stand rejected as obvious based on Jamel, Yagi, USDA, and ITIS. The Examiner finds that “Jamel teaches a method for treating hypertension by administering an essential oil extracted from *Matricaria recutita*,” which USDA and ITIS teach is synonymous with *Matricaria chamomilla*. Ans. 5. The Examiner finds that Jamel teaches oral administration, but does not teach the dosage recited in Appellant’s claims. *Id.* However, the Examiner finds that Yagi teaches a dosage of *M. recutita* extract of 0.01–1000 mg/kg, preferably 0.1–100 mg/kg. *Id.* The Examiner concludes that “[a]n artisan of ordinary skill would be motivated to utilize dosages within the ranges taught by Yagi in order to determine the optimal dosage of *M. recutita* to orally administer to a patient for the treatment of hypertension as suggested by the Jamel.” *Id.* at 5–6.

We agree with the Examiner that the method of claim 1 would have been obvious based on the cited references. Yagi, USDA, and ITIS are discussed above. Jamel discloses “a composition comprising the essential oil of *Chamomilla*, preferably the essential oil of *Matricaria recutita* L. (*Matricariae aetheroleum*) and/or of the essential oil of *Anthemis nobilis* L. (*Matricariae romanae aetheroleum*) for the treatment of hypertension.” Jamel ¶ 16. Jamel discloses oral administration. *Id.* ¶ 34.

Jamel states that “[t]he exact dosage and frequency of administration, depend on several factors.” *Id.* ¶ 35. However, Yagi teaches administering “chamaemeloside obtained by purification of an extract of Roman chamomile or German chamomile.” Yagi ¶ 25. Yagi teaches orally administered doses of 0.01–1000 mg/kg, preferably 0.1 –100 mg/kg, for treating hypertension, among other disorders. *Id.* ¶¶ 29, 39. Thus, it would have been obvious to use a dosage in the range suggested by Yagi in Jamel’s method of treating hypertension. As discussed above, USDA and ITIS both provide evidence that the *Matricaria recutita* discussed by Jamel is synonymous with the *Matricaria chamomilla* recited in Appellant’s claims.

Appellant again argues that “[t]he claimed species of chamomile is grown in the Al-Alnofood desert region of Saudi Arabia and possesses different chemical constituents and oil content” from chamomile grown elsewhere. Appeal Br. 11. However, as discussed above, Appellant’s evidence is related to a different plant, grown in a different region, and having a different pharmacological effect. The evidence of record does not show that *Matricaria chamomilla* grown in the Al-Alnofood desert region of Saudi Arabia differs in its composition or blood pressure-lowering effect from *Matricaria chamomilla* grown elsewhere. Appellant’s unsupported argument is therefore unpersuasive.

We affirm the rejection of claim 1 under 35 U.S.C. § 103 based on Jamel, Yagi, USDA, and ITIS. Claims 8–10 have not been argued separately and therefore fall with claim 1. 37 C.F.R. § 41.37(c)(1)(iv).

DECISION SUMMARY

In summary:

Claims Rejected	35 U.S.C. §	Reference(s)/Basis	Affirmed	Reversed
1	103	Yagi, USDA, ITIS	1	
1, 8–10	103	Jamel, Yagi, USDA, ITIS	1, 8–10	
Overall Outcome			1, 8–10	

TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a). *See* 37 C.F.R. § 1.136(a)(1)(iv).

AFFIRMED