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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte ANNE MUELLER, ELIZABETH STUART, and BARRIE TAN¹

Appeal 2015-006306
Application 11/411,079
Technology Center 1600

Before DEMETRA J. MILLS, ERIC B. GRIMES, and RYAN H. FLAX,
Administrative Patent Judges.

FLAX, *Administrative Patent Judge.*

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134(a) involving claims directed to a method of treating chlamydia infection. Claims 1, 2, 4, 5, 7–9, 13, 14, 16, 17, 20, and 22–25 are on appeal as rejected under 35 U.S.C. § 103(a). We have jurisdiction under 35 U.S.C. § 6(b).

We affirm.

¹ We understand the Real Party in Interest to be American River Nutrition, Inc. App. Br. 3.

STATEMENT OF THE CASE

The Specification indicates “[t]he invention [relates to] the use of Vitamin E to inhibit and disrupt the developmental cell cycle and infection of *Chlamydia*, and its use to alleviate the effects of *Chlamydia*-related diseases.” Spec.² 3 (last paragraph).

The appealed claims can be found in the Claims Appendix of the Appeal Brief. Claims 1 and 22, the independent claims, are representative and read as follows:

1. A method of treatment for a *Chlamydia* infection, comprising administering daily for at least 3 days a pharmaceutically effective amount of a tocotrienol to a mammal in need of treatment;

wherein the amount of the tocotrienol is a dose between 10 mg and 1000 mg per day, and

wherein the tocotrienol treats the *Chlamydia* bacterium.

22. A method of treatment for a *Chlamydia* infection, comprising administering daily for at least one month a pharmaceutically effective amount of a combination of a tocotrienol and an agent that restricts cholesterol to a mammal in need of treatment for a *Chlamydia* bacterium.

App. Br. 28 and 29 (Claims App’x).

² Substitute Specification filed Oct. 12, 2010.

The following rejections are on appeal:

Claims 1, 2, 4, 7–9, 13, 14, 16, 17, 20, 24 and 25 stand rejected under 35 U.S.C. § 103(a) over Dementyeva,³ Dzhumigo,⁴ and Schaffer.⁵ Final Action 9–10.

Claims 1, 2, 4, 7–9, 13, 14, 16, 17, 20 and 25 stand rejected under 35 U.S.C. § 103(a) over Kalayoglu,⁶ Stephens,⁷ and Schaffer. Final Action 15.

Claim 5 stands rejected under 35 U.S.C. § 103(a) over Kalayoglu, Stephens, Schaffer, and Shiizu.⁸ Final Action 21.

Claims 22 and 23 stand rejected under 35 U.S.C. § 103(a) over Kalayoglu, Stephens, Schaffer, and Yamaguchi.⁹ Final Action 21.

³ Russian Patent Application Pub. No. RU 1731226 A1 (published July 5, 1992) (English version of record) (hereinafter “Dementyeva”).

⁴ Russian Patent Application Pub. No. RU 2057544 C1 (published Oct. 4, 1996) (English version of record) (hereinafter “Dzhumigo”).

⁵ Sebastian Schaffer et al., *Tocotrienols: Constitutional Effects in Aging and Disease*, 135 J. NUTRITION 151–54 (2004) (hereinafter “Schaffer”).

⁶ Murat V. Kalayoglu et al., *Cellular Oxidation of Low-Density Lipoprotein by Chlamydia pneumoniae*, 180 J. INFECTIOUS DISEASES 780–90 (1999) (hereinafter “Kalayoglu”).

⁷ L.C. Stephens et al., *Improved Recovery of Vitamin E-treated Lambs that have been Experimentally Infected with Intratracheal Chlamydia*, 135 BRIT. VET. J. 291–93 (1979) (hereinafter “Stephens”).

⁸ Japanese Patent Application Pub. No. JP 10-087480 A (published 1998) (machine-translated English version of record) (hereinafter “Shiizu”).

⁹ Tetsuya Yamaguchi, *Some Antihyperlipidemic Drugs Might have an Additional Effectiveness on Prevention of Atherosclerosis by Controlling Chlamydomphila Pneumoniae Infection*, Abstract Am. Soc. For Microbiology (Nov. 2, 2004) (hereinafter “Yamaguchi”).

Except where otherwise indicated, we adopt the Examiner's findings of fact, reasoning on scope and content of the prior art, and conclusions set out in the Final Action and Answer. The findings of fact set forth below are provided only to highlight certain evidence of record.

FINDINGS OF FACT

FF1. Dementyeva is directed to a “method of treating Chlamydia infection in premature newborns” with reiferon (an interferon) administered for 5 days, and a 30% oil solution of vitamin E administered “internally” at a dose of 50 mg/kg body mass (in milk) twice daily. Dementyeva 1 (title), 2 (5th paragraph); *see also* Final Action 10–15 (discussing Dementyeva). An exemplary patient weight was disclosed to be 2,700 g (2.7 kg), therefore, the dose of vitamin E administered twice daily was 135 mg (50 mg/kg x 2.7 kg = 135 mg). Dementyeva 2 (6th paragraph); *see also* Final Action 10–15 (discussing Dementyeva).

FF2. Dementyeva disclosed, “[t]he use of reiferon in combination with vitamins C and E made it possible to shorten the intensity and duration of antibacterial treatment.” Dementyeva 5 (1st partial paragraph); *see also* Final Action 10–15 (discussing Dementyeva).

FF3. Dzhumigo disclosed a chlamydia treatment, known “to treat viral infections, consisting of interferon, which is administered rectally in the form of an aqueous solution, and vitamins E and C, which are administered i.m. in the form of a solution in parallel with the interferon.” Dzhumigo 2 (1st and 2nd paragraphs); *see also* Final Action 10–15 (discussing Dzhumigo).

FF4. Dzhumigo disclosed:

The administration, in parallel with the interferon, of vitamin E and C substances that possess antioxidant properties helps to prevent a significant disruption of lipid metabolism owing to intensification of peroxidation of lipids, normalizes the function of the interferon system, and ultimately results in an intensive reduction in the amount of infection pathogen.

Dzhumigo 2 (2nd paragraph); *see also* Final Action 10–15 (discussing Dzhumigo).

FF5. Dzhumigo disclosed:

The essence of the invention is that the preparation for the treatment of viral, chlamydial, and bacterial infections, including gene-engineered interferon, in accordance with the invention also contains alpha-tocopherol acetate in the following ratio of components: interferon 500000 IU, alpha-tocopherol acetate 0.01-0.2 g.

Alpha-tocopherol acetate is a synthetic preparation of vitamin E and is produced in the form of an oil-based solution.

Dzhumigo 3 (last full and partial paragraphs); *see also* Final Action 10–15 (discussing Dzhumigo).

FF6. Dzhumigo disclosed:

The creation of a single medicinal form containing interferon and alpha-tocopherol acetate considerably simplifies the treatment process and, at the same time, assures preservation of that same antiviral activity that is observed with separate administration of individual preparations of interferon and antioxidant by different methods.

Dzhumigo 4 (3rd full paragraph); *see also* Final Action 10–15 (discussing Dzhumigo).

FF7. Dzhumigo disclosed, “[i]n addition, it has been found that inclusion of alpha-tocopherol acetate in the preparation, which has

anti-oxidant properties, prevents destruction of the molecular structure of the interferon.” Dzhumigo 4 (last paragraph); *see also* Final Action 10–15 (discussing Dzhumigo).

FF8. Schaffer disclosed, “[t]ocotrienols, a class of vitamin E analogs, modulate several mechanisms associated with the aging process and aging-related diseases. Most studies compare the activities of tocotrienols with those of tocopherols (‘classical vitamin E’).” Schaffer 151 (Abstract); *see also* Final Action 11–12 (discussing Schaffer).

FF9. Schaffer disclosed, “the absorption mechanisms are essentially the same for all vitamin E analogs,” and “[t]ocotrienols possess excellent antioxidant activity in vitro and have been suggested to suppress ROS [reactive oxygen species] production more efficiently than tocopherols. In addition, tocotrienols show promising antioxidant activities in various in vitro and in vivo models.” Schaffer 151 (Abstract); *see also* Final Action 11–12 (discussing Schaffer).

FF10. Kalayoglu disclosed “*Chlamydia pneumoniae* has been associated with atherosclerosis by an array of epidemiologic and clinical studies” (Kalayoglu 780) and “*C. pneumoniae* induces cellular oxidation of LDL” (*id.* at 782), which “suggest[s] a pathogenic mechanism for *C. pneumoniae* in atherosclerosis” (*id.* at 783), and “the antioxidant vitamin E (α -tocopherol) inhibited *C. pneumoniae*-induced monocyte oxidation of LDL” (*id.*). *See also* Final Action 15–17 (discussing Kalayoglu).

FF11. Kalayoglu also disclosed, “[a]therosclerosis and chlamydial diseases are both chronic inflammatory conditions that may result from a variety of risk factors.” Kalayoglu 787.

FF12. Stephens disclosed, “[i]n chlamydia-inoculated lambs, those supplemented with vitamin E had less extensive pneumonia, greater post-infection feed consumption and significantly ($P < 0.05$) heavier weight gains than non-supplemented lambs. Chlamydia were isolated from lungs of 40% of non-supplemented lambs but were not isolated from lungs of supplemented lambs.” Stephens 291 (Summary); *see also* Final Action 17–18 (discussing Stephens).

FF13. Stephens disclosed administering to two groups of ten chlamydia-infected lambs 13.6 kg/group/day (i.e., 1.36 kg/lamb/day) alfalfa pellets containing 300 i.u./kg of vitamin E (dl- α -tocopheryl acetate) for 15 days. Stephens 291; *see also* Final Action 17–18 (discussing Stephens).

FF14. Shiizu disclosed administering geranyl geraniol as an anti-arteriosclerosis (i.e., atherosclerosis) treatment and manufacturing the pharmaceutical preparation of geranyl geraniol with an antioxidant and other components. Shiizu claim 1, ¶ 15; *see also* Final Action 21–22 (discussing Shiizu).

FF15. Yamaguchi disclosed “some antihyperlipidemic drugs inhibit growth of *Chlamydophila pneumoniae* (*C. pneumoniae*),” and such “drugs pose clinical effectiveness for prevention of atherosclerosis by inhibiting *C. pneumoniae* infections as well as

reducing levels of serum lipids,” e.g., cholesterol. Yamaguchi; *see also* Final Action 23 (discussing Yamaguchi).

DISCUSSION

Rejection of claims 1, 2, 4, 7–9, 13, 14, 16, 17, 20, 24 and 25 under 35 U.S.C. § 103(a) over Dementyeva, Dzhumigo, and Schaffer.

The Examiner has established a prima facie case that claim 1 would have been obvious over the cited combination of prior art (*see* FF1–FF9, *supra*) and Appellants have not presented persuasive evidence or argument that the Examiner is incorrect. We address Appellants’ arguments below.

Appellants argue that the cited art does not disclose each element of claim 1 because, in view of the art, the skilled artisan would not understand to use vitamin E (tocopherol) as the sole agent to treat chlamydia; Appellants’ argument is that the art discloses vitamin E as only part of a combination of components, used as a preservative for the active. App. Br. 8–12. Appellants also argue that one would not substitute tocotrienol for tocopherol because it is only disclosed in the cited prior art as a preservative and because only the α -tocopherol form of vitamin E, and not the recited tocotrienol form, was recognized by the NIH to meet human requirements. App. Br. 11. Relating to this argument, Appellants also contend Schaffer is not directed to using tocotrienol/tocopherol for infection treatment and, so, does not remedy the deficiencies otherwise identified in Dementyeva and Dzhumigo. *Id.* at 12. Appellants also argue that the Examiner improperly based the rejection on hindsight reasoning. App. Br. 12, *et seq.* Appellants also argue that it was improper for the Examiner to base any part of the

rejection on the principle of inherency because the rejection falls under 35 U.S.C. § 103, rather than § 102. These arguments are not persuasive.

The broadest reasonable interpretation of claim 1 does not restrict the claimed chlamydia treatment to only tocotrienol. The claim uses the transition term “comprising” to define the method steps of the invention. The transitional term “comprising” does not exclude additional, unrecited steps. *See, e.g., Invitrogen Corp. v. Biocrest Manufacturing, L.P.*, 327 F.3d 1364, 1368 (Fed. Cir. 2003) (“The transition ‘comprising’ in a method claim indicates that the claim is open-ended and allows for additional steps.”). Further, the phrase of claim 1 reciting, “wherein the tocotrienol treats the *Chlamydia* bacterium,” identifies the intended result of the claimed method. A “whereby [or wherein] clause in a method claim is not given weight when it simply expresses the intended result of a process step positively recited.” *Hoffer v. Microsoft Corp.*, 405 F.3d 1326, 1329 (Fed. Cir. 2005) (quoting *Minton v. Nat’l Assn. of Securities Dealers, Inc.*, 336 F.3d 1373, 1381 (Fed. Cir. 2003)). Therefore, claim 1 does not require that chlamydia be treated solely by tocotrienol and Appellants’ arguments relying on this premise are not persuasive.

Furthermore, the cited Dementyeva and Dzhumigo references each disclose a chlamydia treatment including administering to a mammal in need of such treatment a dose of vitamin E (as an antioxidant), within the claimed range. *See, e.g.,* FF1, FF5. While these references utilize the α -tocopherol acetate version of vitamin E for this purpose, Schaffer explains that tocopherol and tocotrienol are related compounds within the greater class of vitamin E analogs and that they are absorbed similarly by the body, but that

tocotrienols are potentially better antioxidants. FF8, FF9. Whether or not, as Appellants contend, the NIH favors tocopherol for human use, Shaffer teaches that the two variants of vitamin E are substitutable alternatives, and claim 1 is directed to treating a mammal, not only humans. Therefore, the Examiner has established that the recited tocotrienol is a suitable alternative for tocopherol, and would be obvious to substitute therefor in compositions where its antioxidant properties are desirable, such as in the compositions of Dementyeva and Dzhumigo for treating chlamydia.

“The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.” *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 416 (2007). “[W]hen the question is whether a patent claiming the combination of elements of prior art is obvious,” the answer depends on “whether the improvement is more than the predictable use of prior art elements according to their established functions.” *Id.* at 417. “[T]he analysis need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ.” *Id.* at 418. Moreover, it is obvious to those skilled in the art to substitute one known equivalent for another. *See In re Omeprazole Patent Litigation*, 483 F.3d 1364, 1374 (Fed. Cir. 2007) (“no . . . error . . . to substitute one [alkaline reactive compound] for another.”).

“Any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning, but so long as it takes into account only knowledge which was within the level of ordinary skill at the

time the claimed invention was made and does not include knowledge gleaned only from applicant's disclosure, such a reconstruction is proper." *In re McLaughlin*, 443 F.2d 1392, 1395 (CCPA 1971). The Examiner's determinations are based on the express disclosures of the cited prior art. We find no improper use of hindsight in the appealed rejection.

Finally, the Examiner made no error in identifying the inherent properties of prior art chlamydia-treating compositions, which included vitamin E. "The discovery of a new property or use of a previously known composition, even when that property and use are unobvious from the prior art, cannot impart patentability to the known composition." *Tyco Healthcare Group LP v. Mutual Pharma Co., Inc.*, 642 F.3d 1370 (Fed. Cir. 2011) (finding the claims obvious and quoting *In re Spada*, 911 F.2d 705, 708 (Fed. Cir. 1990)). The prior art chlamydia-treating-compositions and their properties cannot be separated and it was expressly recognized within the references themselves that vitamin E contributed to treating chlamydia. *See* FF2, FF4, FF6, FF7.

For the reasons above, we find Appellants' arguments unpersuasive and affirm the Examiner's obviousness rejection over Dementyeva, Dzhumigo, and Shaffer.

Rejection of claims 1, 2, 4, 7–9, 13, 14, 16, 17, 20 and 25 under 35 U.S.C. § 103(a) over Kalayoglu, Stephens, and Schaffer.

The Examiner has established a prima facie case that claim 1 would have been obvious over the cited combination of prior art (*see* FF8, FF9, FF12, FF13 *supra*) and Appellants have not presented persuasive evidence

or argument that the Examiner is incorrect. We address Appellants' arguments below.

Appellants argue Kalayoglu discloses treating a symptom of chlamydia (cellular oxidation of LDL and atherosclerosis) using α -tocopherol, but not treating chlamydia itself with the compound (or tocotrienol) and, so, does not disclose each feature of claim 1. App. Br. 19–20. Appellants also argue Stephens did not disclose treating (sheep infected with) chlamydia using vitamin E because the reference did not disclose a significant difference in results when treating with and without the compound. *Id.* at 20–21. Finally, Appellants present the same arguments regarding Shaffer as set forth above for the preceding rejection. These arguments are not persuasive.

The Board can rely on fewer than all references in affirming an obviousness rejection. MPEP § 1207.3.II (citing *In re Kronig*, 539 F.2d 1300, 1303 (CCPA 1976) (reliance upon fewer references in affirming obviousness rejection does not constitute new ground of rejection)). In affirming the Examiner's rejection we do not rely on Kalayoglu (*see* FF11) because claim 1 would have been obvious over Stephens and Schaffer. *See* FF12, FF13.

Stephens teaches that treatment with vitamin E allows mammals to recover from chlamydia infection and disclosed that such treatment reduced the bacteria in the lungs of treated subjects. FF12, FF13. Combining this with Schaffer's teaching that the two forms of vitamin E (tocotrienols and tocopherols) are interchangeable alternatives and that tocotrienols are likely

more effective antioxidants (providing motivation for such a substitution) renders the subject matter of claim 1 obvious.

For the reasons above, we find Appellants' arguments unpersuasive and affirm the Examiner's obviousness rejection over Stephens and Shaffer, with or without Kalayoglu.

Rejection of claim 5 under 35 U.S.C. § 103(a) over Kalayoglu, Stephens, Schaffer, and Shiizu.

The Examiner has established a prima facie case that claim 1 would have been obvious over the cited combination of prior art (*see* FF10, FF11, FF14 *supra*) and Appellants have not presented persuasive evidence or argument that the Examiner is incorrect. We address Appellants' arguments below.

Appellants argue, “[w]hether geranyl geraniol does or does not have an effect on atherosclerosis is unimportant as it concerns the present claims. Geranyl geraniol may have many effects against various ‘things’, which also are unimportant concerning a claim to a treatment of ‘wherein the tocotrienol treats the *Chlamydia* bacterium.’” App. Br. 25. This argument is not persuasive.

Kalayoglu disclosed that there is an association between chlamydia infection and atherosclerosis. FF10. Therefore, it would be reasonable to combine treatments for chlamydia, which may result in atherosclerosis, and treatments for atherosclerosis. Further, Shiizu provides motivation to combine the use geranyl geraniol as an anti-arteriosclerosis (i.e., atherosclerosis) treatment, which is manufactured with an antioxidant, with

treatments for chlamydia relying on the antioxidant effects of vitamin E. *See* FF14.

For the reasons above, we find Appellants' arguments unpersuasive and affirm the Examiner's obviousness rejection over Kalayoglu, Stephens Shaffer, and Shiizu.

Rejection of claims 22 and 23 under 35 U.S.C. § 103(a) over Kalayoglu, Stephens, Schaffer, and Yamaguchi.

The Examiner has established a *prima facie* case that claim 22 would have been obvious over the cited combination of prior art (*see* FF15, *supra*) and Appellants have not presented persuasive evidence or argument that the Examiner is incorrect. We address Appellants' arguments below.

Appellants argue, generally, that Yamaguchi fails to cure the deficiencies of other the references and that it does not disclose the claim limitations. App. Br. 26. These arguments are not persuasive.

Yamaguchi discloses several anti-lipid (cholesterol-controlling) drugs that also inhibit chlamydia. *See* FF15. "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. . . . [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850 (CCPA 1980). Here, it would be obvious to combine the chlamydia-inhibiting, antihyperlipidemic drugs of Yamaguchi with the chlamydia-infection treatment of Stephens.

For the reasons above, we find Appellants' arguments unpersuasive and affirm the Examiner's obviousness rejection over Kalayoglu, Stephens, Shaffer, and Yamaguchi.

SUMMARY

The rejection of claims 1, 2, 4, 7–9, 13, 14, 16, 17, 20, 24 and 25 under 35 U.S.C. § 103(a) over Dementyeva, Dzhumigo, and Schaffer is affirmed.

The rejection of claims 1, 2, 4, 7–9, 13, 14, 16, 17, 20 and 25 under 35 U.S.C. § 103(a) over Kalayoglu, Stephens, and Schaffer is affirmed.

The rejection of claim 5 under 35 U.S.C. § 103(a) over Kalayoglu, Stephens, Schaffer, and Shiizu is affirmed.

The rejection of claims 22 and 23 under 35 U.S.C. § 103(a) over Kalayoglu, Stephens, Schaffer, and Yamaguchi is affirmed.

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).

AFFIRMED