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| 3M INNOVATIVE PROPERTIES COMPANY |             |                      | MAEWALL, SNIGDHA    |                  |
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***Notice of Pre-AIA or AIA Status***

The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

**Detailed Action**

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. Patentability shall not be negated by the manner in which the invention was made.

**Claims 1 and 20-23 are rejected under 35 U.S.C. 103 as being unpatentable over Wlaschin et al (USP 8,460,689).**

Wlaschin discloses an oral moisturizing composition that also decolonized mammalian oral tissue (e.g., composition that contacted oral tissue), see title and [abstract]. Wlaschin, teaches that a significant segment of the population suffers from xerostomia (dry mouth) and as such, it is extremely important that oral treatment regiments address both the reduction of microorganisms (plaque removal and reduction of opportunistic organisms in the oral cavity), and xerostomia, see [col 1, lines 22-23] and [col 1, lines 60-63]. Wlaschin discloses that the composition comprises edible vegetable oils in an amount of at least 30 %, see [col 12, lines 14-15] and [col 33, lines 9-13]; significant amounts of water (e.g., at least 20 wt. %; e.g., 87.8 % water disclosed in the example formulations of Table 3), [col 32, lines 1-2]; nonionic surfactants, generally, [col 29, line 63] (0.1 to 10 wt. % disclosed at [col 28, lines 30-38]); 1.6 % xanthan gum (e.g.,

polymeric viscosity modifier) as disclosed in Table 3, Example Formulation # 1]. The composition was formulated as an oil-in-water emulsion with a pH of 3-8 see [col 8, lines 5-7], and [col 11, lines 16-26]. Additionally, Wlaschin generally discloses use of excipients [col 33, line 48]. Wlaschin teaches use of thickeners, humectants and excipients in column 19, lines 52-59. Claim 1 recites 5-70 % plant based oil; 35-95 % aqueous phase; 0.1-7.5 % surfactant; 0.05-3 % viscosity modifier; pH of 4.5-9.5. Wlaschin disclosed edible vegetable oils in an amount of at least 30 %; significant amounts of water (e.g., at least 20 wt. %; e.g., 87.8 % water disclosed in the example formulations of Table 3); nonionic surfactants, generally, (0.1 to 10 wt. % disclosed at [col 28, lines 30-38]); 1.6 % xanthan gum (e.g., polymeric viscosity modifier) [Table 3, Example Formulation # 1]; pH of 3-8. In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art", a prima facie case of obviousness exists. MPEP 2144.05 A. Wlaschin discloses use of fumed silica, see [col 31, line 56]. Wlaschin discloses use of oils, including olive, cottonseed, peanut, corn, sesame, safflower, soybean oils, and the like, see [col 32, lines 54-57] natural. Further, at Table 2, Wlaschin discloses coconut oil as a comparative example of an ingredient found in commercially available oral moisturizers. Wlaschin discloses sweeteners, see [col 17, line 3]. Wlaschin discloses use of aloe vera, see [Table 1]. Wlaschin disclosed enhancer components, including sugar, at not greater than 20 % [col 25, line 38 to col 26, line, 3]. Wlaschin does not disclose a quaternary antimicrobial compound as a required ingredient. Wlaschin discloses a viscosity of at least 10,000 or in excess of 50,000 cps, see [col 11, lines 41-49]. Wlaschin discloses a physically stable compositions at 25 ° C, see [col 17, lines 23-27]. Wlaschin taught excipients at increasing amounts (e.g., Wlaschin disclosed excipients at 0.5-2 % at Tables 12-16). Since the art

teaches treating xerostomia, it would implicitly increase lubriciousness in an oral tissue. Since the art teaches pH of 3-8. In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art", a prima facie case of obviousness exists. MPEP 2144.05 A. Thus, it would have been obvious to one of ordinary skill to have formulated an oral composition for treating xerostomia comprising plant based oils, aqueous phase, surfactant and viscosity modifier with a pH of 3-8 which overlaps with the claimed range of 4.5 to 9.5 and thus creates case of obviousness and combining prior art elements according to their known function would have provided predictable results of oral composition for treating xerostomia, see MPEP 2143 part (I)(A).

**Claim 22 is rejected under 35 U.S.C. 103 as being unpatentable over Wlaschin et al (USP 8,460,689), in view of Hunter et al (USP 6,159,459).**

Wlaschin generally discloses [col 33, line 49] lubricants.

Wlaschin does not specifically disclose that the composition increased lubricity or lubriciousness, as recited in claim 22.

Hunter discloses [abstract] an oral lubricant (beta-glucan polymer) having particular usefulness for alleviating the symptoms of xerostomia. As per Hunter [col 1, lines 16-22], xerostomia, in which the salivary glands do not produce sufficient quantities of saliva, causes discomfort which can in some cases be quite severe. Without saliva, the mouth burns and the throat and tongue can undergo radical changes. Teeth can decay rapidly and the tongue can become smooth, cracked and vulnerable to infection. As such, [col 2, lines 13-23], it is most desirable to have an oral lubricating composition for human use, to relieve the discomforts and inconveniences incurred by xerostomia and dryness of the mouth. Hunter's composition [col 2, lines 13-23 and at lines 31-37] had



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