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Table with columns: APPLICATION NO., FILING DATE, FIRST NAMED INVENTOR, ATTORNEY DOCKET NO., CONFIRMATION NO., EXAMINER, ART UNIT, PAPER NUMBER, MAIL DATE, DELIVERY MODE. Includes application details for Neil P. Desai and examiner TSAY, MARSHA M.

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.

This Office action is in response to Applicants' remarks received October 27, 2009.

Applicants' arguments filed have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous Office actions are hereby withdrawn.

Claim 1 is canceled. Claims 7-9, 14-23 are withdrawn. Claims 2-6, 10-13, 24-25 are currently under examination.

Priority: The request for priority to provisional application 60/432317, filed December 9, 2002, is acknowledged.

Objections and Rejections

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

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2-6, 10-13, 24-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Damascelli et al. (2001 Cancer 92(10): 2592-2602; previously cited) in view of Desai et al. (US 6537579; IDS 02.20.08) as evidenced by Ibrahim et al. (2000 Proc Am Soc Clin Oncol 19: abstract 609F). The Ibrahim et al. reference is cited as evidence to note that ABI-007 is cremophor-free.

Damascelli et al. disclose ABI-007, a paclitaxel-human albumin nanoparticle having a dimension of 150-200 nm (p. 2593 col. 2, Fig. 1). It is known that ABI-007 is cremophor-free

(evidenced by Ibrahim et al.). Damascelli et al. do not disclose a weight ratio of albumin to paclitaxel is about 1:1 to about 9:1.

Desai et al. disclose dosage forms of ABI-007 contain 30 mg, 100 mg, or 300 mg of paclitaxel in a vial (col. 14 lines 4-5). Desai et al. further disclose that unit vessels of ABI-007 may contain between 1 mg to 1000 mg of active drug (col. 15 lines 39-40).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the teachings of Damascelli et al. by determining the optimum weight ratio of albumin to paclitaxel, i.e. 9:1, as suggested by Desai et al. which will result in a composition that will deliver paclitaxel most effectively in an albumin delivery system (claims 2-6, 10-13, 25). The motivation to do so is given by Desai et al., which disclose a weight ratio of albumin to paclitaxel of 9:1. Since Desai et al. disclose ABI-007 can contain up to 1000 mg of active drug and further disclose that ABI-007 can contain 100 mg of paclitaxel, it would be reasonable for one of ordinary skill to note that a 1000 mg vial of ABI-007 would contain 100 mg paclitaxel and 900 mg albumin, i.e. a weight ratio of 9:1 of albumin to paclitaxel.

Regarding the ratio of 5:1 (albumin to paclitaxel) recited in claim 24, it should be noted that generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) ("The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum

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combination of percentages."); *In re Hoeschele*, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969) (Claimed elastomeric polyurethanes which fell within the broad scope of the references were held to be unpatentable thereover because, among other reasons, there was no evidence of the criticality of the claimed ranges of molecular weight or molar proportions.). For more recent cases applying this principle, see *Merck & Co. Inc. v. Biocraft Laboratories Inc.*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), *cert. denied*, 493 U.S. 975 (1989); *In re Kulling*, 897 F.2d 1147, 14 USPQ2d 1056 (Fed. Cir. 1990); and *In re Geisler*, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997). In this instance, since Desai et al. disclose the weight ratio of 9:1 (albumin to paclitaxel), it would be reasonable for one of ordinary skill to want to further determine which other weight ratios would optimize delivery of paclitaxel.

In view of Applicants' amendments and remarks, the Desai et al. reference has been added to the 103(a) rejection.

Therefore, the claims remain rejected under 103(a) for the reasons noted above.

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

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