

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Ashley, Robert	Examiner:	Susan Tran
Serial No.:	13/277,789	Group Art Unit:	1615
Confirmation No:	4179	Docket:	512-53 DIV/ CON II/RCE
Filed:	October 20, 2011	Dated:	February 22, 2013
For:	Methods of Treating Acne		

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Printed Name: Carla Bryan

Signature: /carla bryan/

**Response to November 19, 2012 Final Office Action
and Substance of February 7, 2013 Interview
in Reply to February 19, 2013 Interview Summary**

Sir:

In Reply to the November 19, 2012 Final Office Action and February 19, 2013
Interview Summary, applicant respectfully requests the instant Response be considered.
Accompanying this Response is a Request for Continued Examination, a 37 C.F.R. §1.132
Declaration by Dr. Vasant Manna, a Terminal Disclaimer in view of US 7,232,572, and an
Information Disclosure Statement.

Listing of the Claims begins on page 2 of this paper.

Remarks begin on page 5 of this paper.

Dr. Reddy's Laboratories, Ltd., et al. v. Galderma Laboratories, Inc. IPR2015-_____ Exhibit 1071

Listing of the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application.

Claims 1-20 (Cancelled).

21. (Previously Presented) A method for treating papules and pustules of rosacea in a human in need thereof, the method comprising
- administering orally to said human doxycycline, or a pharmaceutically acceptable salt thereof,
 - in an amount that
 - (i) is effective to treat the papules and pustules of rosacea;
 - (ii) is 10-80% of a 50 mg dose of doxycycline; and
 - (iii) results in no reduction of skin microflora during a six-month treatment, without administering a bisphosphonate compound.
22. (Previously Presented) The method according to Claim 21, wherein said doxycycline is doxycycline monohydrate.
23. (Previously Presented) The method according to Claim 22, wherein said doxycycline monohydrate is administered in an amount of 40 milligrams.
24. (Previously Presented) The method according to Claim 23, wherein said doxycycline monohydrate is administered by sustained release.
25. (Previously Presented) A method according to Claim 24, wherein said doxycycline monohydrate is administered once a day.
26. (Previously Presented) The method according to Claim 22, wherein said doxycycline monohydrate is administered in a dose of 20 mg twice a day.

27. (Previously Presented) The method according to Claim 21, wherein said doxycycline, or a pharmaceutically acceptable salt thereof, is administered in an amount which provides a serum concentration in the range of about 0.1 to about 0.8 µg/ml.

28. (Previously Presented) A method for treating papules and pustules of rosacea in a human in need thereof, the method comprising
administering orally to said human doxycycline, or a pharmaceutically acceptable salt thereof,
in an amount that
(i) is effective to treat the papules and pustules of rosacea;
(ii) is 40-80% of a 50 mg dose of doxycycline; and
(iii) results in no reduction of skin microflora during a six-month treatment, without administering a bisphosphonate compound.

29. (Previously Presented) The method according to Claim 28, wherein said doxycycline is doxycycline monohydrate.

30. (Previously Presented) The method according to Claim 29, wherein said doxycycline monohydrate is administered in an amount of 40 milligrams.

31. (Previously Presented) The method according to Claim 30, wherein said doxycycline monohydrate is administered by sustained release.

32. (Previously Presented) A method according to Claim 31, wherein said doxycycline monohydrate is administered once a day.

33. (Previously Presented) The method according to Claim 29, wherein said doxycycline monohydrate is administered in a dose of 20 mg twice a day.

34. (Previously Presented) The method according to Claim 28, wherein said doxycycline, or a pharmaceutically acceptable salt thereof, is administered in an amount which provides a serum concentration in the range of about 0.1 to about 0.8 µg/ml.

35. (Previously Presented) A method for treating papules and pustules of rosacea in a human in need thereof, the method comprising
administering orally to said human doxycycline, or a pharmaceutically acceptable salt thereof, in an amount of 40mg per day, wherein the amount results in no reduction of skin microflora during a six-month treatment, without administering a bisphosphonate compound.

36. (Previously Presented) The method according to Claim 35, wherein said doxycycline is doxycycline monohydrate.

37. (Previously Presented) The method according to Claim 36, wherein said doxycycline monohydrate is administered by sustained release.

38. (Previously Presented) A method according to Claim 37, wherein said doxycycline monohydrate is administered once a day.

39. (Previously Presented) The method according to Claim 36, wherein said doxycycline monohydrate is administered in a dose of 20 mg twice a day.

40. (Previously Presented) The method according to Claim 35, wherein said doxycycline, or a pharmaceutically acceptable salt thereof, is administered in an amount which provides a serum concentration in the range of about 0.1 to about 0.8 µg/ml.

REMARKS

Claims 1-20 were previously cancelled. Claims 21-40 were previously added. Thus, Claims 21-40 are pending.

Substance of Interview

Applicant wishes to thank Examiner Susan Tran and Supervisory Patent Examiner Robert Wax for taking the time to discuss the instant application and for their courtesy during a personal interview with Ms. Cécile Cousin, Dr. Vasant Manna, Dr. Irving N. Feit and the undersigned on February 7, 2013. Dr. Manna stated to the examiners that he is a Medical Doctor with expertise in dermatology.

The Claimed Invention

During the interview applicant's representatives explained that the claimed invention is a method for treating papules and pustules of rosacea by oral administration of doxycycline (or a salt thereof). Papules and pustules occur on skin in facial rosacea. The doxycycline dose is expressed differently in each independent claim, i.e., 10-80% of a 50 mg, 40-80% of a 50 mg dose, and a 40 mg. The claims recite that all these doses result in no reduction of skin microflora during a six-month treatment. Applicant's representative emphasized that the treatment of papules and pustules of rosacea with such a dose was major development in the treatment of this condition, and was unknown in the prior art.

Obviousness Rejections under 35 U.S.C. §103(a) in View of Perricone and Pflugfelder

In the Final Office Action, the examiner maintained the obviousness rejections, under 35 U.S.C. §103(a), of Claims 21, 23, 25-28, 30, 32-35 and 38-40 over US 6,365,623 (hereinafter "*Perricone*") in view of US 6,455,583 (hereinafter "*Pflugfelder*"); of Claims 24, 25, 31, 32, 37 and 38 over *Perricone* in view of *Pflugfelder* and US 5,300,304; and of Claims

22, 29 and 36 over *Perricone* in view of *Pflugfelder* and US Patent Application Publication No. 2002/0165220.

During the interview, the undersigned reviewed the teachings of the cited references, as follows.

Perricone teaches that lipoic acid can be topically applied to the faces of persons with acne. In some embodiments, “lipoic acid may also be used in combination with... antibiotics such as tetracycline, clindamycin and erythromycin” to treat papules and pustules of acne (col. 8, lines 24-30). The undersigned pointed to col. 8, lines 27-32, of *Perricone* where the following is stated: “Lipoic acid may be added to an antibiotic preparation, or applied before, during, or after antibiotic treatment.”

During the interview, Dr. Manna stated that at a certain threshold dose, tetracycline exhibits antibiotic properties in humans. Depending on various factors, including the severity of an ailment, a physician may prescribe tetracycline at a dose that is well above the antibiotic threshold dose, at a minimum antibiotic dose, or at a dose somewhere in between such doses. As the dosage is increased, adverse effects increase. Nonetheless, above the threshold dose, treatment with tetracycline will be an antibiotic treatment.

Dr. Manna noted that *Perricone* groups tetracycline together with clindamycin and erythromycin; and clindamycin and erythromycin do not have anti-inflammatory properties. The property that these three compounds have in common is that they are all antibiotic. Thus, it is apparent that such antibiotic property is what *Perricone* teaches is required for his treatment. Dr. Manna concluded that a skilled artisan would believe that *Perricone* teaches that an antibiotic dose is necessary for his method.

It is true, as the examiner pointed out, that *Perricone* mentions the potential adverse effects of the use of antibiotic compounds (i.e., tetracycline, clindamycin and erythromycin) and states that it may be advantageous to minimize antibiotic doses. However, *Perricone* does not state that a sub-antibiotic dose is effective in treating acne. The method of *Perricone* requires an antibiotic dose. A minimum antibiotic dose is still an antibiotic dose.

Pflugfelder teaches treating the ocular disorder of meibomian gland disease (MGD) with sub-antimicrobial doses of tetracycline compounds.

During the interview, Dr. Manna noted that MGD and rosacea are distinct diseases. Meibomian gland disease is an ocular disease. The papules and pustules of rosacea appear on the skin.

No Reason to Combine the References

During the interview, the undersigned stated that there is no basis to combine the cited references for at least two reasons.

First, there would have been no reasonable expectation of success in achieving the presently claimed invention by the combination of the teachings of the cited prior art references.

Dr. Manna elaborated. *Perricone* teaches treating a different ailment than *Pflugfelder* (i.e., acne vis-à-vis MGD). *Perricone* teaches treating a different organ of the body than *Pflugfelder* (i.e., skin vis-à-vis the eye). *Perricone* teaches a different treatment modality than *Pflugfelder* (i.e., antibiotic vis-à-vis sub-antibiotic). Thus, although a skilled artisan may have believed that a sub-antibiotic dose of tetracycline may lead to fewer side effects, the skilled artisan would have had no reason to believe that such sub-antibiotic dose would be effective in the method of *Perricone*.

That is, success in treating an eye disease with a sub-antibiotic treatment is not relevant to treating a skin disease with an antibiotic treatment. Medical science is much too unpredictable to make such a connection. Thus, a skilled artisan would not combine the teachings of the references.

Second, the undersigned pointed to the M.P.E.P. § 2143.01 VI, which is entitled, “The Proposed Modification Cannot Change the Principle of Operation of a Reference.” That is, it is not proper to combine two references if the secondary reference would change the principle of operation of the primary reference. In the instant case, *Perricone* teaches antibiotic treatment; whereas, *Pflugfelder* teaches a mode other than antibiotic treatment by prescribing a sub-antimicrobial dose. Therefore, the two treatment modalities are based on different principles of operation. Thus, it is not proper to combine the teachings of the two references.

In summary, it would not have been proper to combine a reference directed to treating acne with an antibiotic dose of tetracycline with a reference directed to treating an ocular disorder with a sub-antibiotic dose. Accordingly, withdrawal of the obviousness rejection was, and is, respectfully requested.

Examiner’s Response during the Interview

The examiners graciously listened to the applicants’ representatives. SPE Wax then asked Examiner Tran if she still had any issues that she wanted addressed. Examiner Tran requested that a Terminal Disclaimer be filed in view of US 7,232,572, and stated that she had three concerns. She suggested that such concerns may best be addressed in a 37 C.F.R. § 1.132 Declaration.

First, Examiner Tran requested a further description of MGD. The examiner suggested that an expert address that MGD is simply an ocular disorder thereby clearly distinguishing it from a skin condition.

Second, the examiner requested an explanation of the phrase “meibomian gland disease associated with rosacea” at col. 4, lines 18-25, of *Pflugfelder*.

Third, Examiner Tran suggested that an expert address whether a skilled artisan reading *Perricone* would understand that the *Perricone* treatment requires an antibiotic amount of tetracycline.

Applicant's Reply to the Examiner's Specific Concerns

As suggested by the examiner, accompanying this Response is a Terminal Disclaimer in view of US 7,232,572.

As suggested by the examiner, accompanying this Response is a 1.132 Declaration by Dr. Vasant Manna. Dr. Manna is a Senior Medical Advisor / Project Leader at Galderma R&D Inc., the assignee of the instant application. In his declaration, Dr. Manna reiterates and embellishes the statements he made during the personal interview.

1. MGD is an ocular disorder that is clearly distinguished from a skin condition

To address the examiner's first concern, in paragraphs 3-7 of his declaration, Dr. Manna establishes that MGD is a disease which is exclusive to the eye. In particular, Dr. Manna states that, “Meibomian glands are anatomically and functionally organs of the eye.” And Dr. Manna describes MGD as involving “dysfunction of the meibomian gland” which “can lead to inflammation of the meibomian glands (meibomianitis) and excess oil in the tear film.” Dr. Manna also describes other symptoms of MGD, all of which are “unique to the eye.”

The disclosure in *Pflugfelder* concurs with Dr. Manna's statements. In particular, at col. 1, lines 8-10 and 19-23, *Pflugfelder* describes MGD as a “tear film and ocular surface

disorder." Symptoms include "blurred or filmy vision, burning or foreign body sensations in the eye, photophobia, and pain." In addition, patients' "meibomian glands can atrophy."

Pflugfelder describes the treatment of a patient having MGD as follows:

According to the subject invention, treatment of a patient having MGD includes reducing or reversing irritation symptoms, delayed tear clearance, recurrent corneal epithelial erosion or aqueous tear deficiency. (Col. 3, lines 39-42.)

All of these manifestations of MGD described by *Pflugfelder* relate to the eye. Thus, as Dr. Manna states, "Since MGD is an ailment that solely affects the eye, a skilled artisan would understand *Pflugfelder* as disclosing the use of tetracyclines to treat the eye." (Paragraph 8 of the declaration.)

2. A clarification of the phrase "meibomian gland disease associated with rosacea" in *Pflugfelder*

The examiner mentioned during the interview that *Pflugfelder* uses the phrase "meibomian gland disease associated with rosacea." See col. 4, lines 17-21, of *Pflugfelder*. The examiner asked for a clarification of this phrase.

There is no discussion in *Pflugfelder* of the nature of the alleged association between MGD and rosacea. *Pflugfelder* does however mention that sometimes these two disorders may appear together. As stated by Dr. Manna, it is true that "Patients sometimes present with both symptoms of rosacea and symptoms of MGD." However, despite appearing together, Dr. Manna clearly states that "MGD is a condition which is distinct from rosacea." (Paragraph 9 of the declaration.)

Moreover, the alleged “association” between MGD and rosacea does not suggest a treatment for rosacea. That is, simply because two ailments present together does not mean that they are related in an etiological manner, or that they respond to the same treatment. For example, MGD may appear with (i.e., be “associated with”) many different ailments, such as, for example, a headache. However, treatment of MGD would not suggest treatment of the headache.

Furthermore, the rosacea with which *Pflugfelder* reports MGD is somehow associated is **ocular** rosacea (i.e., not skin rosacea). In particular, whenever *Pflugfelder* mentions rosacea, the focus is exclusively on meibomian glands which, as Dr. Manna states, are “anatomically and functionally organs of the eye.” (Paragraph 4 of the declaration.)

Specifically, the phrase “MGD associated with rosacea” is found three times in *Pflugfelder*. The first occurrence of the phrase is found in the paragraph bridging columns 3 and 4. There, it is stated that the activity of gelatinase B “... is markedly increased in the tear fluid of patients with meibomian gland disease associated with rosacea,” and that the “... activity of gelatinase B appears to be inversely correlated with tear clearance.” Dr. Manna states that from this description of tear composition and clearance, a skilled artisan would understand that MGD is associated with **ocular** rosacea. (Paragraph 10 of the declaration.)

In the next paragraph, *Pflugfelder* states *explicitly* that the rosacea contemplated is **ocular** rosacea. See column 4, lines 5-10, especially line 9, where *Pflugfelder* refers to certain factors “that have been found to be strongly correlated with the development of **ocular** rosacea in our studies.” (Emphasis added.).

At col. 4, lines 17-21, *Pflugfelder* discloses treating MGD “associated with rosacea” by topical administration of a tetracycline analogue in an ointment or in solution (e.g., “eye drops”). Referring to such description, Dr. Manna states that “a skilled artisan would recognize a topical treatment of the eye as being for ocular symptoms.” (Paragraph 11 of the declaration.)

That the phrase “meibomian gland disease associated with rosacea” refers to **ocular** rosacea is confirmed by the third appearance of the phrase in example 5 at col. 8, line 55 *et seq.* of *Pflugfelder*. Example 5 discloses the treatment of eleven patients with MGD “associated with rosacea.” The treatment included “... topical administration to the ocular surface or the eyelids” of oxytetracycline. See col. 8, line 64. Table 2 at the top of col. 9 summarizes the results of the experiment in example 5 of *Pflugfelder*. The title of table 2 is “Patients with **Ocular** Rosacea Treated with Oxytetracycline Ointment 1.” (Emphasis added.)

Referring to such description, Dr. Manna states that: “A skilled artisan would understand that treatment of MGD by topical administration ‘to the ocular surface or the eyelids’ means treating the eye.” (Paragraph 12 of the declaration.)

Dr. Manna concludes: “A skilled artisan would clearly understand, therefore, that the rosacea with which *Pflugfelder* reports MGD is *somehow associated* is **ocular** rosacea.” (Paragraph 13 of the declaration. Emphasis added.)

The unexplained association between MGD and ocular rosacea reported in *Pflugfelder* is, therefore, not relevant to treating the papules and pustules of facial rosacea. There is no disclosure or suggestion in *Pflugfelder* of treating any condition or symptom outside of the eye. There is no disclosure of treating any skin condition in *Pflugfelder*, let alone treating the papules and pustules of facial rosacea.

3. A skilled artisan would understand that *Perricone* requires an antibiotic amount of tetracycline

To address the examiner's third concern, Dr. Manna establishes that a skilled artisan reading *Perricone* would understand that the *Perricone* treatment requires an antibiotic amount of tetracycline. ..." (Paragraphs 15-20 of the Manna Declaration.)

As a first reason, Dr. Manna points to col. 8, lines 27-32, of *Perricone*. There it is stated that lipoic acid is added to "an antibiotic preparation, or applied before, during, or after antibiotic treatment..." (Paragraph 16 of the declaration.)

As a second reason, Dr. Manna states that *Perricone* groups tetracycline together with two other compounds (i.e., clindamycin and erythromycin) which do not have anti-inflammatory properties. "The property that these three compounds have in common is that they are all antibiotic. Thus, it is apparent that such antibiotic property is what *Perricone* teaches is required for his treatment." (Paragraph 17 of the declaration.)

As a third reason, Dr. Manna states that at the time *Perricone* was filed, as well as at the priority date of the instant application, "acne was thought to be caused by bacteria, *P. acnes*. Thus, a skilled artisan would have understood from *Perricone* that an antibiotic preparation was required for the treatment of acne." (Paragraph 18 of the declaration.)

Applicant believes that the examiner's concerns have been addressed. If the examiner has any further questions or concerns, it is requested that the examiner contact applicant's undersigned representative at the telephone number provided below.

Applicant: Robert A. Ashley
Serial No.: 13/277,789
Filed: October 20, 2011
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For all the reasons given above, this application is now believed to be in condition for allowance. Notice to that effect at the examiner's earliest convenience is respectfully requested.

Respectfully submitted,

/susan a. sipos/
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/277,789	10/20/2011	Robert A. Ashley	512-53 DIV/CON II	4179
23869	7590	02/19/2013		
Hoffmann & Baron LLP 6900 Jericho Turnpike Syosset, NY 11791			EXAMINER TRAN, SUSAN T	
			ART UNIT 1615	PAPER NUMBER
			MAIL DATE 02/19/2013	DELIVERY MODE PAPER

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.

<i>Applicant-Initiated Interview Summary</i>	Application No.	Applicant(s)	
	13/277,789	ASHLEY, ROBERT A.	
	Examiner	Art Unit	
	SUSAN TRAN	1615	

All participants (applicant, applicant's representative, PTO personnel):

(1) SUSAN TRAN/ ROBERT WAX. (3) CECILE COUSIN.

(2) IRVING N. FEIT/SUSAN SIPOS. (4) VASANT K. MANNA.

Date of Interview: 07 February 2013.

Type: ☐ Telephonic ☐ Video Conference
☒ Personal [copy given to: ☐ applicant ☐ applicant's representative]

Exhibit shown or demonstration conducted: ☐ Yes ☐ No.
If Yes, brief description: _____.

Issues Discussed ☐101 ☐112 ☐102 ☒103 ☐Others
(For each of the checked box(es) above, please describe below the issue and detailed description of the discussion)

Claim(s) discussed: _____.

Identification of prior art discussed: US 7,232,572, Pflugfelder et al. and Perricone.

Substance of Interview
(For each issue discussed, provide a detailed description and indicate if agreement was reached. Some topics may include: identification or clarification of a reference or a portion thereof, claim interpretation, proposed amendments, arguments of any applied references etc...)

Applicants' attorneys pointed out that there is no motivation to combine Pflugfelder with Perricone because Pflugfelder is directed to a method for treating meibomian gland. Applicants pointed out that treating meibomian gland disease and rosacea are not related. It was suggested that Applicants in a reply in writing, further point out the distinction between the claimed invention and what is taught on column 4, lines 18-25 of Pflugfelder. Applicants will respond in writing along with a terminal disclaimer to US 7,232,572.

Applicant recordation instructions: The formal written reply to the last Office action must include the substance of the interview. (See MPEP section 713.04). If a reply to the last Office action has already been filed, applicant is given a non-extendable period of the longer of one month or thirty days from this interview date, or the mailing date of this interview summary form, whichever is later, to file a statement of the substance of the interview

Examiner recordation instructions: Examiners must summarize the substance of any interview of record. A complete and proper recordation of the substance of an interview should include the items listed in MPEP 713.04 for complete and proper recordation including the identification of the general thrust of each argument or issue discussed, a general indication of any other pertinent matters discussed regarding patentability and the general results or outcome of the interview, to include an indication as to whether or not agreement was reached on the issues raised.

☐ Attachment

/S. TRAN/ Primary Examiner, Art Unit 1615	
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Summary of Record of Interview Requirements

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record

A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews

Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.

All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:

- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:

- 1) A brief description of the nature of any exhibit shown or any demonstration conducted,
- 2) an identification of the claims discussed,
- 3) an identification of the specific prior art discussed,
- 4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
- 5) a brief identification of the general thrust of the principal arguments presented to the examiner,
(The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
- 6) a general indication of any other pertinent matters discussed, and
- 7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.