## REMARKS

Favorable reconsideration is respectfully solicited in view of the following remarks.

Initially, Applicant wishes to express its sincere thanks for the courtesy and cooperation provided to its undersigned representative by Examiner Thomas and Examiner Marschel during the personal interview held on March 13, 2008. The following is a summary of the items discussed during the interview.

Claim 19 has been amended as suggested by the Examiners to clarify that the claimed preparation has at least two components, the first component and the second component as described above.

Claims 39 and 40 have been amended consistent with the amendments to claim 19, to allow for rejoinder of these claims upon an allowance of claims 19-38.

New claims 41-63 have been added for additional patent protection. Claims 41-62 correspond to claims 19-40, respectively, except in reciting that the preparation "consists essentially of" the recited components. New claim 63 correponds to claim 19, except that the claim recites "consisting of" the recited components, together with optional components which are supported on page 12, lines 3-11 of the specification.

Turning to the Official Action, item 7 of the Official Action states that the Oath or Declaration is defective because it was not executed. An executed copy of the Declaration was filed on March 28, 2005. A check of the PTO image file history during the interview revealed that an executed copy of the Declaration has been received.

Accordingly, this defect is believed to be overcome.

Claims 19-24 and 31 are rejected under 35 U.S.C. 102 as anticipated by Gamache et al., WO 01/15677. This ground of rejection is respectfully traversed.

The subject matter of the present invention is directed to the specific combination of 2-amino-3-(4- bromobenzoyl)phenylacetic acid or a pharmacologically acceptable salt thereof or a hydrate thereof and an alkyl aryl polyether alcohol type polymer or a polyethylene glycol fatty acid ester.

On the other hand, Gamache et al. do not disclose this specific combination. Moreover the cited reference is directed to compositions comprising of 5-$HT_{1D}$ and/or $HT_{1B}$ agonists. The cited reference states that these agonists may be combined with an extensive list of other pharmaceutical agents, i.e. (1) anti-microbial agent, (2) anti-inflammatory agents or (3) anti-allergy agent (please see page 6, lines 1-3 of Gamache).

In addition, Gamache et al. only describes "bromfenac" as one of many examples of anti-inflammatory agents enumerated on page 12, lines 11-24. Gamache et al. does not concretely describe nor suggest the claimed preparation containing bromfenac.

Further, although tyloxapol (0.05% w/v) is added to an 1B/1D agonist (0.1-1.0% w/v) and moxifloxacin (0.3% w/v) in Example 4 (an Example of an otic/nasal suspension), there is no explanation about tyloxapol in the description of Gamache et al. or why it is included. Moreover in this Example, moxifloxacin is incorporated as a well-known antibacterial agent but is not an anti-inflammatory agent like bromfenac. Thus it is unclear from Gamache et al. why tyloxapol is added to the otic/nasal suspension containing 1B/1D agonist and moxifloxacin.

"Tyloxapol" described in Example 4 is just a single word description and does not give any clues and hints to the present invention. Therefore, the word "tyloxapol" described only in Example 4 does not destroy the novelty of the present invention.

Besides, Gamache et al. is silent about an alkyl aryl polyether alcohol type polymer or a polyethylene glycol fatty acid ester component according to the preparation of the present invention.

Thus, Gamache et al. neither describe or suggest the specific claimed preparation of the present invention.

As discussed during the interview, it is respectfully submitted that the disclosure of Gamache et al. does not constitute an "anticipation" of the claimed invention under 35 U.S.C. 102. It is not possible to envision the specific claimed combination from the great number of possible combinations suggested by the cited reference.

As stated by the Board of Appeals in a similar case many years ago,

"While the invention here claimed in its broader aspect is doubtless embraced within the

speculative teachings of the references, we doubt if references which are not directed to the same purpose and do not have the same inventive concept, can be fairly applied in rejecting claims such as those on appeal where anticipation can be found only by making one of a very great number of possible permutations which are covered by the reference disclosures. The likelihood of producing a composition such as here claimed from a disclosure such as shown by the Dykstra patent would be about the same as the likelihood of discovering the combination of a safe from a mere inspection of the dials thereof."

Ex parte Garvey, 41 USPQ 583 (POBA 1939). See also Ex parte Starr, 44 USPQ 545 (POBA 1938); and Application of Luvisi, 52 CCPA 1063 (CCPA 1963).

See also M.P.E.P. 2131.02, discussing In re Meyer, 202 USPQ 175 (CCPA 1979) ( A reference disclosing "alkaline chlorine or bromine solution" embraces a large number of species and cannot be said to anticipate claims to "alkali metal hypochlorite.").

For the foregoing reasons, it is respectfully submitted that the claimed invention is novel over Gamache et al.

Applicant gratefully acknowledges the Examiners' indication during the interview that this ground of rejection would be withdrawn.

Claim 19 is rejected under 35 U.S.C. 102 as anticipated by Dobrozsi, U.S. 6,319,513. This ground of rejection is respectfully traversed for the same reasons as stated above regarding the rejection over Gamache et al.

Dobrozsi discloses compositions comprising colloidal particles selected from the group consisting of silica, titanium dioxide, clay, and mixtures thereof. To the colloidal particle compositions may be added a great number of additional ingredients such as (1) analgesics, (2) decongestants, (3) expectorants, (4) antitussives, (5) antihistamines, (6) broncholilator, (7) topical anesthetics, (8) sensory agents, (9) oral care agents, (10) miscellaneous respiratory agents, (11) gastrointestinal agents, and mixtures thereof (please see column 2, lines 33-45 of Dobrozsi).

Dobrozsi describes on column 9, line 66 - column 10, line 11 that "[t]he analgesics useful for this invention include any narcotic and non-narcotic analgesics, such as --- bromfenac, ---". That is, Dobrozsi only describes "bromfenac" as one of so many examples of agents enumerated.

Further, Dobrozsi does not describe nor suggest an alkyl aryl polyether alcohol type polymer or a polyethylene glycol fatty acid ester component according to the preparation of the

present invention.

Besides, Dobrozsi neither describes nor suggests the specific combination of 2-amino-3-(4- bromobenzoyl)phenylacetic acid or a pharmacologically acceptable salt thereof or a hydrate thereof and an alkyl aryl polyether alcohol type polymer or a polyethylene glycol fatty acid ester of the claimed invention.

Although tyloxapol is added to oxymethazoline hydrochloride in the preparation of mucoretentive intrasal spray decongestant (Example 10) on column 23, line 46 in Dobrozsi, no explanation about tyloxapol is given.

Besides, oxymethazoline hydrochloride is a well known adrenergic, and is not an anti-inflammatory agent like bromfenac.

For the same reasons as the 102 rejection over Gamache et al., it is respectfully submitted that the present invention is novel over Dobrozsi.

Applicant gratefully acknowledges the Examiners' indication during the interview that this ground of rejection would be withdrawn.

Claims 19-38 are further rejected under 35 U.S.C. 102(e) as being anticipated by Sawa, U.S. 2007/0082857. This ground of rejection is respectfully traversed.

The cited reference is a published U.S. patent application of a U.S. national stage application based upon PCT/JP04/16849 filed November 12, 2004. International Application No. PCT/JP2004/016849 was published in Japanese language under Publication No. WO2005/046700. Please see Appendix A. Accordingly, the published patent application has no 102(e) date, nor does the published international application WO2005/046700 have a 102(e) date. Please see Appendix B, which is a copy of Example 5 of the Examination Guidelines for 35 U.S.C. 102(e) published by the USPTO.

Accordingly, the earliest effective date of the cited reference as a prior art reference is its publication date of April 12, 2007. Moreover, the earliest effective date of the published international application WO2005/046700 is its publication date of May 26, 2005.

In conclusion, the cited reference is not available as prior art against the present invention, and this ground of rejection should be withdrawn.

Applicant gratefully acknowledges the Examiners' indication during the interview that this ground of rejection would be withdrawn.

Claims 19-29, 31-34 and 36-38 are rejected under 35 U.S.C. 103 as being unpatentable over Gamache et al. and ISTA Pharmaceuticals or Nolan et al. (abstract). This ground of rejection is respectfully traversed.

The essential features of the preparation of the present invention cannot be derived from the combination of Gamache et al. and ISTA Pharmaceuticals or Nolan (abstract).

Gamache et al. is discussed above. This reference does not suggest the claimed invention. Gamache et al. is directed to 5-HT agonist compositions with a great number of other possible ingredients. The reference does not suggest the claimed aqueous liquid preparation comprises at least the following two components according to claims 19-38, the first component comprising 2-amino-3-(4- bromobenzoyl)phenylacetic acid or a pharmacologically acceptable salt thereof or a hydrate thereof, and the second component comprising an alkyl aryl polyether alcohol type polymer or a polyethylene glycol fatty acid ester.

Regarding claims 41-60, the claim recites the transitional phrase "consisting essentially of" means that the claim is limited to the specified ingredients and those that do not materially affect the basic and novel characteristics of the claimed invention. See M.P.E.P. 2111.03.

It is respectfully submitted that the principal 5-HT agonist of the Gamache composition would affect the basic novel properties of the claimed preparation.

The Examiners indicated during the interview that this amendment would be helpful to overcome this ground of rejection.

The cited ISTA publication was discussed during the interview. Although the cited reference has a publication date of May 25, 2004 after the effective U.S. filing date of the instant application, the reference is cited for its statement that "ISTA acquired U.S. marketing rights for Xibrom in May 2002 under a license from Senju." Thus the rejection is based upon the position that the claimed invention was known by others in the U.S. prior to the effective filing date of the instant application in the U.S. of January 16, 2004. And since the knowledgeable person(s) of ISTA is not an inventor of the invention, the reference is available as a reference under 35 U.S.C.

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