REMARKS

Favorable reconsideration is respectfully requested in view of the foregoing amendments and following remarks.

Applicants express their sincere appreciation to the Examiner for her courtesy and helpful assistance provided to the Applicants' undersigned representative and representative Dr. Toan Vo during the telephone interview held on September 18, 2013.

The foregoing amendments are presented according to the discussion with the Examiner, and for the reasons discussed during the interview, are believed to overcome all grounds of rejection.

I. INFORMALITIES

In item 5 and 7 of the Office Action summary page, it is respectfully requested that the pending claims be corrected to claims 19-48.

In item 12 of the Office Action summary page, it is respectfully requested that the claim of foreign priority be acknowledged, and receipt of the certified copy of the priority document be acknowledged, which copy is present in the Image File Wrapper.

II. SUPPORT FOR AMENDED CLAIMS

Claims 19, 27 and 32 are amended to specify that "the first component is the sole pharmaceutical active ingredient contained in the preparation;". This amendment is supported by page 7 (lines 14-17) and page 13 (lines 11-13) of the specification, which teaches that the claimed preparation may be prepared with 2-amino-3-(4-bromobenzoyl)phenylacetic acid or a pharmacologically acceptable salt thereof or a hydrate thereof (hereinafter "bromfenac"), and with "other same or different kind of active ingredients" so long as the purpose of the present invention is achieved. Thus, a preparation containing bromfenac as the sole active ingredient is clearly taught by the specification.

The amendment is further supported by the Examples of the specification which teach compositions having bromfenac as the sole pharmaceutical active ingredient contained in the preparation. The first specific composition taught in the specification is found in Experimental Example 1 (pages 14-15). The sole pharmaceutical active ingredient contained in the preparation is Sodium 2-amino-3-(4-bromobenzoyl)phenylacetate, i.e. bromfenac.

The second specific composition taught in the specification is found in Experimental Example 2 (pages 16-18). The sole pharmaceutical active ingredient contained in the preparation is Sodium 2-amino-3-(4-bromobenzoyl)phenylacetate, i.e. bromfenac.

The third specific composition taught in the specification is found in Example 1 (page 21). The sole pharmaceutical active ingredient contained in the preparation is Sodium 2-amino-3-(4-bromobenzoyl)phenylacetate 3/2 hydrate, i.e. bromfenac.

The fourth specific composition taught in the specification is found in Example 2 (page 22). The sole pharmaceutical active ingredient contained in the preparation is Sodium 2-amino-3-(4-bromobenzoyl)phenylacetate 3/2 hydrate, i.e. bromfenac.

The fifth and final specific composition taught in the specification is found in Example 3 (page 23). The sole pharmaceutical active ingredient contained in the preparation is Sodium 2-amino-3-(4-bromobenzoyl)phenylacetate 3/2 hydrate, i.e. bromfenac.

In summary, a preparation containing bromfenac as the sole active ingredient is clearly taught by the specification. Thus, the amendment to claims 19, 27 and 32 is clearly supported by the specification.

A minor error has been corrected in claim 25 which is evident from claim 31.

Claims 44-48 are amended to specify the preservative efficacy standard of EP-criteria B of the European Pharmacopoeia, which is explicitly supported on page 20, last line, to page 21 of the specification. Thus, the claims are amended to recite "as follows:

viable cell counts of bacteria (*S. aureus, P.aeruginosa*) 24 hours and 7 days after inoculation decrease to not more than 1/10 and not more than 1/1000, respectively, and thereafter, the cell count levels off or decreases; and

viable cell count of fungi (*C. albicans, A. niger*) 14 days after inoculation decreases to not more than 1/10, and thereafter, the cell count keeps the same level as that of 14 days after inoculation".

III. REJECTION OF CLAIMS 44-48 UNDER 35 U.S.C. 112

Claims 44-48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for the recitation of the standard of EP-criteria B of the European Pharmacopoeia.

This ground of rejection is deemed to be overcome by the foregoing amendments.

IV. REJECTION OF CLAIMS 19, 21-24, 26, 28-30, 32, 34-36, 38, 40-42 and 44-48 UNDER 35 U.S.C. § 103(a) BASED UPON GAMACHE

A. Claims 19, 21-24, 32, 34-36, 38, 40-42, 44 and 46-48

Claims 19, 27 and 32 now recite that the preparation comprises the first component, 2-amino-3-(4-bromobenzoyl)phenylacetic acid or a pharmacologically acceptable salt thereof or a hydrate thereof (i.e. "bromfenac"), as the sole pharmaceutical active ingredient contained in the preparation.

Gamache does not teach or suggest any preparation comprising bromfenac as the sole pharmaceutical active ingredient.

Gamache teaches only compositions that must contain 5-HT1D and/or 5-HT1B receptor agonists. Gamache's compositions may contain additional pharmaceutical active ingredients. Gamache does not teach or suggest any composition comprising bromfenac as the sole pharmaceutical active ingredient.

Thus, Gamache does not teach or suggest claims 19, 27 or 32 as amended. Accordingly, Gamache fails to teach or suggest claims 21-24, 34-36, 38, 40-42, 44 and 46-48 which are dependent upon claims 19 and 32.

Consequently, Gamache does not render these claims obvious.

B. Claims 26, 28-30 and 45

Claim 26 recites that "said stable liquid preparation is formulated for ophthalmic administration; and wherein the stable aqueous liquid preparation is characterized in that greater than about 90% of the original amount of the first component remains in the preparation after storage at about 60 °C for 4 weeks."

Gamache does not teach or suggest any preparation comprising bromfenac and tyloxapol, wherein greater than 90% of the original amount of bromfenac remains after storage at 60 °C for 4 weeks.

Gamache disclosed generally that anti-inflammatory drugs, such as bromfenac or others, may be used in a composition including any surfactants "known to those skilled in the art," including polysorbate 80. However, Gamache did not recognize the problem that bromfenac degrades rapidly in the presence of polysorbate 80, a surfactant "known to those skilled in the

art" (according to Gamache), as Applicant demonstrated in the grandparent application Serial No. 10/525,006.

Applicant recognized this problem and surprisingly found that the degradation of bromfenac could be avoided by specifically including tyloxapol in the preparation.

Thus, the preparation of claim 26, and its dependent claims, are not obvious from Gamache.

V. REJECTION OF CLAIMS 20, 27, 33, and 39 UNDER 35 U.S.C. § 103(a) OVER GAMACHE IN VIEW OF DESAI

Claim 20 is dependent upon independent claim 19. As pointed out above, claim 19 is nonobvious over Gamache because Gamache does not teach or suggest any composition wherein bromefenac is the sole pharmaceutical active ingredient. Therefore, adding Desai to show the use of benzalkonium chloride still does not overcome the deficiency of Gamache. Therefore, claim 20 is nonobvious over Gamache in view of Desai.

Claim 27 is amended to recite that bromfenac is the sole pharmaceutical active ingredient in the preparation. As pointed out above, claim 27 is nonobvious over Gamache because Gamache does not teach or suggest any composition wherein bromefenac is the sole pharmaceutical active ingredient. Therefore, adding Desai to show the use of benzalkonium chloride still does not overcome the deficiency of Gamache. Therefore, claim 27 is nonobvious over Gamache in view of Desai.

Claims 33 and 39 are dependent upon independent claim 32. As pointed out above, claim 32 is nonobvious over Gamache because Gamache does not teach or suggest any composition wherein bromfenac is the sole pharmaceutical active ingredient. Therefore, adding Desai to show the use of benzalkonium chloride still does not overcome the deficiency of Gamache. Moreover, all Desai's experiments include mannitol, which is excluded from the compositions of present claims 33 and 39. Therefore, the combination of Gamache and Desai does not teach or suggest any composition wherein bromfenac is the sole pharmaceutical active ingredient and wherein mannitol is excluded. Consequently, claims 33 and 39 are nonobvious over Gamache in view of Desai.

VI. REJECTION OF CLAIMS 25, 31, 37 AND 43 UNDER 35 U.S.C. § 103(a) OVER GAMACHE IN VIEW OF OGAWA AND DE BRUIJU

Claim 25 is dependent upon independent claim 19. As pointed out above, claim 19 is nonobvious over Gamache because Gamache does not teach or suggest any composition wherein bromefenac is the sole pharmaceutical active ingredient. Therefore, adding Ogawa and De Bruiju to show the use of sodium tetraborate, sodium sulfite, polyvinylpyrrolidone and boric acid does not overcome the deficiency of Gamache. Therefore, claim 25 is nonobvious over Gamache in view of Ogawa and De Bruiju.

Claim 31 is dependent upon independent claim 26. As pointed out above, claim 26 is nonobvious over Gamache because Gamache does not teach or suggest any preparation comprising bromfenac and tyloxapol, wherein greater than 90% of the original amount of bromfenac remains after storage at 60 °C for 4 weeks. Therefore, adding Ogawa and De Bruiju to show the use of sodium tetraborate, sodium sulfite, polyvinylpyrrolidone and boric acid does not overcome the deficiency of Gamache. Therefore, claim 31 is nonobvious over Gamache in view of Ogawa and De Bruiju.

Claim 37 is dependent upon independent claim 32. As pointed out above, claim 32 is nonobvious over Gamache because Gamache does not teach or suggest any composition wherein bromefenac is the sole pharmaceutical active ingredient. Therefore, adding Ogawa and De Bruiju to show the use of sodium tetraborate, sodium sulfite, polyvinylpyrrolidone and boric acid does not overcome the deficiency of Gamache. Therefore, claim 37 is nonobvious over Gamache in view of Ogawa and De Bruiju.

Claim 43 is dependent upon independent claim 32. As pointed out above, claim 32 is nonobvious over Gamache because Gamache does not teach or suggest any composition wherein bromefenac is the sole pharmaceutical active ingredient. Therefore, adding Ogawa and De Bruiju to show the use of sodium tetraborate, sodium sulfite, polyvinylpyrrolidone and boric acid does not overcome the deficiency of Gamache. Therefore, claim 43 is nonobvious over Gamache in view of Ogawa and De Bruiju.

VII. DOUBLE PATENTING REJECTIONS

All claims are rejected on the ground of nonstatutory double patenting as being unpatentable over claims of U.S. Patent No. 7,829,544, U.S. Patent No. 8,129,431, U.S. Serial No. 11/755,662 and U.S. Serial No. 13/353,653.

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