	ED STATES PATENT	and Trademark Office	UNITED STATES DEPAR United States Patent and Address: COMMISSIONER F P.O. Box 1450 Alexandria, Virginia 22: www.uspto.gov	FOR PATENTS	
APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
13/902,132	05/24/2013	Giorgio Calderari	23278.2.US.10	2532	
	7590 08/08/2013 RESPONDENCE		EXAM	EXAMINER	
ARNALL GOL	DEN GREGORY LLP		GEMBEH, SHIRLEY V		
171 17TH STRI SUITE 2100	EET NW		ART UNIT	PAPER NUMBER	
ATLANTA, GA	A 30363		1628		
			NOTIFICATION DATE	DELIVERY MODE	
			08/08/2013	ELECTRONIC	

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.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@agg.com

DOCKE.

Δ

Δ

R M

Dr. Reddy's Laboratories, Ltd., et al.
٧.
Helsinn Healthcare S.A. et al

The MAILING DATE of this communication appears Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS WHICHEVER IS LONGER, FROM THE MAILING DATE - Extensions of time may be available under the provisions of 37 CFR 1.136(a), after SIX (6) MONTHS from the maining date of this communication. - If NO period for reply is specified above, the maximum statutory period will apple - Faiture to reply within the set or extended period for reply will, by statute, cause Any reply received by the Office later than three months after the mailing date earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 24 May 22 A declaration(s)/affidavit(s) under 37 CFR 1.130(f) 2a) This action is FINAL. 2b) This act 3) An election was made by the applicant in response ; the restriction requirement and election hav A) Since this application is in condition for allowance or closed in accordance with the practice under Ex pare Disposition of Claims 5) Claim(s) 10-15 is/are pending in the application. 5a) Of the above claim(s) is/are withdrawn fr 6) Claim(s) 10-15 is/are rejected 8) Claim(s) 10-15 is/are rejected * If any claims have been determined <u>allowable</u> , you may be eligible participating intellectual property office for the corresponding applic http://www.uspto.gov/patents/init_events/pph/index.jsp or send an i Application Papers 10) The specification is objected to by the Examiner. 11) The drawing(s) filed onis/are: a) accepte Applicant may not request that any objection to the draw Replacement drawing sheet(s) including the correction is 2. Certified copies of the priority documents ha 3. Copies of the certified copies of the priority documents ha 3. Copies of the certified copies of the priority documents ha 3. Copies of the certified copies of the priority documents ha 3. Copies of the certified copies of the priority documents ha 3. Copi	ET TO EXPIRE <u>3</u> MONT F THIS COMMUNICAT and will expire SIX (6) MONTHS (he application to become ABANDO this communication, even if timely <u>13</u> . was/were filed on n is non-final. o a restriction requirement been incorporated into the cept for formal matters, te Quayle, 1935 C.D. 11 m consideration. tion requirement. to benefit from the Patent F ion. For more information, p	TH(S) OR THIRTY (30) DAYS, TON. be timely filed from the mailing date of this communication. ONED (35 U.S.C. § 133). (filed, may reduce any
Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS WHICHEVER IS LONGER, FROM THE MAILING DATE - Extensions of time may be available under the provisions of 37 CFR 1.136(a), after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apart to reply within the set or extended period for reply will, by statute, caus Any reply received by the Office later than three months after the mailing date earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on <u>24 May 27</u> A declaration(s)/affidavit(s) under 37 CFR 1.130(the 2a) This action is FINAL. 2a) This action is FINAL. 2b) This acti 3) An election was made by the applicant in response; the restriction requirement and election have; the restriction requirement and election have; the restriction requirement and election. 5) Claim(s) <u>10-15</u> is/are pending in the application. 5a) Of the above claim(s) is/are withdrawn fr 6) Claim(s) <u>10-15</u> is/are rejected. 8) 8) Claim(s) <u>10-15</u> is/are neglocted to. 9) 9) Claim(s) <u>10-15</u> is/are rejected. 8) 10 The above claim(s)	ET TO EXPIRE <u>3</u> MONT F THIS COMMUNICAT and will expire SIX (6) MONTHS (he application to become ABANDO this communication, even if timely <u>13</u> . was/were filed on n is non-final. o a restriction requirement been incorporated into the cept for formal matters, te Quayle, 1935 C.D. 11 m consideration. tion requirement. to benefit from the Patent F ion. For more information, p	TH(S) OR THIRTY (30) DAYS, TON. be timely filed from the mailing date of this communication. ONED (35 U.S.C. § 133). (filed, may reduce any
 WHICHEVER IS LONGER, FROM THE MAILING DATE Extensions of time may be available under the provisions of 37 CFR 1.136(a), after SX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will, agus Any reply received by the Office later than three months after the mailing date earned patent term adjustment. See 37 CFR 1.704(b). Status Responsive to communication(s) filed on <u>24 May 2</u> A declaration(s)/affidavit(s) under 37 CFR 1.130(fi 2a) This action is FINAL. 2b) This actii 3) An election was made by the applicant in response; the restriction requirement and election have 4) Since this application is in condition for allowance of closed in accordance with the practice under <i>Ex pa</i> Disposition of Claims 5) Claim(s) <u>10-15</u> is/are pending in the application. 5a) Of the above claim(s) is/are withdrawn free for the above claim(s) is/are withdrawn free for the above claim(s) is/are eligible participating intellectual property office for the corresponding applic http://www.uspto.gov/patents/init_events/pph/index.jsp or send an implication Papers Claim (s) 50 SU SU	DF THIS COMMUNICAT no event, however, may a reply b and will expire SIX (6) MONTHS i he application to become ABANDO this communication, even if timely <u>13</u> . was/were filed on n is non-final. o a restriction requirement been incorporated into the cept for formal matters, the Quayle, 1935 C.D. 11 m consideration. tion requirement. to benefit from the Patent F ion. For more information, p	 TON. be timely filed from the mailing date of this communication. ONED (35 U.S.C. § 133). (filed, may reduce any) — ent set forth during the interview on this action. prosecution as to the merits is , 453 O.G. 213. Prosecution Highway program at a please see <u>Sto.gov</u>. he Examiner.
 1) Responsive to communication(s) filed on <u>24 May 2</u> A declaration(s)/affidavit(s) under 37 CFR 1.130(f 2a) This action is FINAL. 2b) This actions and the problem of the application is in condition for allowance of closed in accordance with the practice under <i>Ex pa</i> Disposition of Claims 5) Claim(s) <u>10-15</u> is/are pending in the application. 5a) Of the above claim(s) is/are withdrawn fr 6) Claim(s) <u>10-15</u> is/are rejected. 8) Claim(s) <u>10-15</u> is/are rejected. 8) Claim(s) <u>10-15</u> is/are rejected. 8) Claim(s) is/are objected to. 9) Claim(s) are subject to restriction and/or elete the problem of the application is objected to. 9) Claim(s) are subject to restriction and/or elete the problem of the apple of the corresponding applic http://www.uspto.gov/patents/init_events/oph/index.jsp or send an in Application Papers 10) The specification is objected to by the Examiner. 11) The drawing(s) filed on is/are: a) accepte Applicant may not request that any objection to the draw Replacement drawing sheet(s) including the correction is Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign prior Certified copies: a) All b) Some * c) None of the: certified copies of the priority documents has 2 Certified copies of the priority documents has 3 Copies of the certified copies of the priority documents has 3	was/were filed on n is non-final. o a restriction requirement been incorporated into the cept for formal matters, te Quayle, 1935 C.D. 11 m consideration. tion requirement. to benefit from the Patent F tion. For more information, p	ent set forth during the interview on this action. prosecution as to the merits is , 453 O.G. 213. Prosecution Highway program at a please see <u>bto.gov</u> . he Examiner.
 A declaration(s)/affidavit(s) under 37 CFR 1.130(fill 2a) This action is FINAL. 2b) This action 3) An election was made by the applicant in response; the restriction requirement and election have 4) Since this application is in condition for allowance of closed in accordance with the practice under <i>Ex particle</i> 20 (and s) 10-15 is/are pending in the application. 5a) Of the above claim(s) is/are withdrawn for 6) Claim(s) is/are allowed. 7) Claim(s) 10-15 is/are rejected. 8) Claim(s) is/are objected to. 9) Claim(s) is/are objected to. 9) Claim(s) are subject to restriction and/or eleeter in a claim shave been determined allowable, you may be eligible participating intellectual property office for the corresponding applic http://www.uspto.gov/patents/init_events/pph/index.jsp or send an in Application Papers 10) The specification is objected to by the Examiner. 11) The drawing(s) filed on is/are: a) accepte Applicant may not request that any objection to the draw Replacement drawing sheet(s) including the correction is Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign prior Certified copies: a) All b) Some * c) None of the: certified copies of the priority documents have a copies of the copies of the priority documents have a copies of the copies of the priority documents have a copies of the copies of the priority documents have a copies of the copies of the priority documents have a copies of the copies of the priority documents have a copies of the copies of the priority documents have a copies of the copies of the priority documents have a copies of th	was/were filed on n is non-final. o a restriction requirement been incorporated into the cept for formal matters, te Quayle, 1935 C.D. 11 m consideration. tion requirement. to benefit from the Patent F tion. For more information, p	ent set forth during the interview on this action. prosecution as to the merits is , 453 O.G. 213. Prosecution Highway program at a please see <u>bto.gov</u> . he Examiner.
2a) This action is FINAL. 2b)⊠ This action 3) An election was made by the applicant in response ; the restriction requirement and election have 4) Since this application is in condition for allowance of closed in accordance with the practice under <i>Ex participation</i> 5) Claim(s) <u>10-15</u> is/are pending in the application. 5a) Of the above claim(s) is/are withdrawn fr 6) Claim(s) <u>10-15</u> is/are rejected. 8) Claim(s) <u>10-15</u> is/are rejected. 9) Claim(s) <u>10-15</u> is/are rejected. 8) Claim(s) <u>10-15</u> is/are rejected. 9) Claim(s) <u>are subject to restriction and/or eleettion and/or eleettion and/or eleettion is objected to. 9) Claim(s) are subject to restriction and/or eleettion http://www.uspto.gov/patents/init_events/pph/index.jsp or send an interpet tip and interpet tip and is an accepted and interpet tip and accepted applicant may not request that any objection to the draw Replacement drawing sheet(s) including the correction is the applicant may not request that any objection to the draw Replacement drawing sheet(s) including the correction is an accepte applicant may not req</u>	n is non-final. o a restriction requiremend been incorporated into the cept for formal matters, <i>te Quayle</i> , 1935 C.D. 11 m consideration. tion requirement. to benefit from the Patent F ion. For more information, p	ent set forth during the interview on this action. prosecution as to the merits is , 453 O.G. 213. Prosecution Highway program at a please see <u>bto.gov</u> . he Examiner.
 3) An election was made by the applicant in response; the restriction requirement and election have a closed in accordance with the practice under <i>Ex pa</i> Disposition of Claims 5) Claim(s) <u>10-15</u> is/are pending in the application. 5a) Of the above claim(s) is/are withdrawn fr 6) Claim(s) <u>10-15</u> is/are allowed. 7) Claim(s) <u>10-15</u> is/are rejected. 8) Claim(s) <u>10-15</u> is/are objected to. 9) Claim(s) <u>10-15</u> is/are objected to. 9) Claim(s) <u>10-15</u> is/are subject to restriction and/or eleter is/are subject to restriction and/or eleter is/are subject to restriction and/or eleter is/are corresponding applicant is is a subject to be the corresponding applicant is and the corresponding applicant may not request that any objection to the draw Replacement drawing sheet(s) including the correction is Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign prior Certified copies: a) All b) Some * c) None of the: certified copies of the priority documents have a copies of the copies of the priority documents have a copies of the certified copies of the priority documents have a copies of the certified copies of the priority documents have a copies of the certified copies of the priority documents have a copies of the certified copies of the priority documents have a copies of the certified copies of the priority documents have a copies of the certified copies of the priority documents have a copies of the certified copies of the priority documents have a copies of the certified copies of the priority documents have a copies of the certified copies of the priority documents have a copies of the certified copies of the priority documents have a copies of the certified copies of the priority documents have a copies of the certified copies of the priority documents have a copies of the certified copies of the priority documents have a copies of the certified copies of the	o a restriction requiremend been incorporated into the cept for formal matters, <i>te Quayle</i> , 1935 C.D. 11 m consideration. ion requirement. to benefit from the Patent F ion. For more information, p	this action. prosecution as to the merits is , 453 O.G. 213. Prosecution Highway program at a please see <u>oto.gov</u> . he Examiner.
 ; the restriction requirement and election have a closed in accordance with the practice under <i>Ex pa</i> Disposition of Claims 5) Claim(s) <u>10-15</u> is/are pending in the application. 5a) Of the above claim(s) is/are withdrawn fr 6) Claim(s) <u>10-15</u> is/are rejected. 8) Claim(s) <u>10-15</u> is/are rejected. 8) Claim(s) <u>10-15</u> is/are rejected. 8) Claim(s) <u>10-15</u> is/are objected to. 9) Claim(s) <u>10-15</u> is/are subject to restriction and/or eleter is/are value been determined <u>allowable</u>, you may be eligible participating intellectual property office for the corresponding applic <u>http://www.uspto.gov/patents/init_events/pph/index.jsp</u> or send an i Application Papers 10) The specification is objected to by the Examiner. 11) The drawing(s) filed on is/are: a) accepte Applicant may not request that any objection to the draw Replacement drawing sheet(s) including the correction is Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign prior Certified copies: a) All b) Some * c) None of the: certified copies of the priority documents hat a. Copies of the certified copies of the priority documents hat a. 	been incorporated into the cept for formal matters, the <i>Quayle</i> , 1935 C.D. 11 m consideration.	this action. prosecution as to the merits is , 453 O.G. 213. Prosecution Highway program at a please see <u>oto.gov</u> . he Examiner.
 4) Since this application is in condition for allowance of closed in accordance with the practice under <i>Ex particle</i> accordance with the priority documents that any objection to the draw Replacement drawing sheet(s) including the correction is <i>Priority under 35 U.S.C. § 119</i> 12) Acknowledgment is made of a claim for foreign prior <i>Certified copies:</i> a) All b) Some * c) None of the: certified copies of the priority documents that a.g. Copies of the correction is of the priority documents that a.g. Copies of the certified copies of the priority documents that a.g. Copies of the certified copies of the priority documents that a.g. Copies of the certified copies of the priority documents that a.g. Copies of the certified copies of the priority documents that a.g. Copies of the certified copies of the priority documents that a.g. Copies of the certified copies of	cept for formal matters, te <i>Quayle</i> , 1935 C.D. 11 m consideration. tion requirement. to benefit from the Patent F ion. For more information, p	prosecution as to the merits is , 453 O.G. 213. Prosecution Highway program at a please see <u>oto.gov</u> . he Examiner.
closed in accordance with the practice under <i>Ex pa</i> Disposition of Claims 5) □ Claim(s) <u>10-15</u> is/are pending in the application. 5a) Of the above claim(s) is/are withdrawn fr 6) □ Claim(s) is/are allowed. 7) □ Claim(s) <u>10-15</u> is/are rejected. 8) □ Claim(s) is/are objected to. 9) □ Claim(s) are subject to restriction and/or elee r If any claims have been determined <u>allowable</u> , you may be eligible participating intellectual property office for the corresponding applic anttp://www.uspto.gov/patents/init_events/pph/index.jsp or send an it Application Papers 10) □ The specification is objected to by the Examiner. 11) □ The drawing(s) filed on is/are: a) □ accepte Applicant may not request that any objection to the draw Replacement drawing sheet(s) including the correction is Priority under 35 U.S.C. § 119 12) □ Acknowledgment is made of a claim for foreign prior Certified copies: a) □ All b) □ Some * c) □ None of the: 1. □ Certified copies of the priority documents hat 2. □ Certified copies of the priority documents hat 3. □ Copies of the certified copies of the priority documents hat	te Quayle, 1935 C.D. 11 m consideration. ion requirement. to benefit from the Patent F ion. For more information, p	, 453 O.G. 213. Prosecution Highway program at a please see <u>oto.gov</u> . he Examiner.
Disposition of Claims 5) ○ Claim(s) 10-15 is/are pending in the application. 5a) Of the above claim(s) is/are withdrawn fr 6) ○ Claim(s) is/are allowed. 7) ○ Claim(s) 10-15 is/are rejected. 8) ○ Claim(s) is/are objected to. 9) ○ Claim(s) is/are objected to. 9) ○ Claim(s) are subject to restriction and/or eleeter * If any claims have been determined allowable, you may be eligible participating intellectual property office for the corresponding applic http://www.uspto.gov/patents/init_events/pph/index.jsp 10) □ The specification is objected to by the Examiner. 11) □ The drawing(s) filed on is/are: a) □ accepte Applicant may not request that any objection to the draw Replacement drawing sheet(s) including the correction is Priority under 35 U.S.C. § 119 12) □ Acknowledgment is made of a claim for foreign prior Certified copies: a) □ All b) □ Some * c) □ None of the: 1.□ □ Certified copies of the priority documents hat 3.□ □ Copies of the certified copies of the priority documents hat	m consideration. tion requirement. to benefit from the Patent F ion. For more information, p	Prosecution Highway program at a please see <u>oto.gov</u> . he Examiner.
 5) ∑ Claim(s) <u>10-15</u> is/are pending in the application. 5a) Of the above claim(s) is/are withdrawn fr 6) ☐ Claim(s) is/are allowed. 7) ∑ Claim(s) <u>10-15</u> is/are rejected. 8) ☐ Claim(s) is/are objected to. 9) ☐ Claim(s) are subject to restriction and/or elected is and the second structure of the second structur	tion requirement. to benefit from the Patent F ion. For more information, p	please see <u>oto.gov</u> . he Examiner.
 5a) Of the above claim(s) is/are withdrawn fr 6) □ Claim(s) is/are allowed. 7) ⊠ Claim(s) <u>10-15</u> is/are rejected. 8) □ Claim(s) is/are objected to. 9) □ Claim(s) are subject to restriction and/or elected if any claims have been determined <u>allowable</u>, you may be eligible or the priority intellectual property office for the corresponding applic intellectual property office for the corresponding applic on the priority office for the corresponding applic on the priority under 35 U.S.C. § 119 12) □ Acknowledgment is made of a claim for foreign prior Certified copies: a) □ All b) □ Some * c) □ None of the: 1. □ Certified copies of the priority documents have a copies of the priority docum	tion requirement. to benefit from the Patent F ion. For more information, p	please see <u>oto.gov</u> . he Examiner.
 6) ☐ Claim(s) is/are allowed. 7) ⊠ Claim(s) <u>10-15</u> is/are rejected. 8) ☐ Claim(s) is/are objected to. 9) ☐ Claim(s) are subject to restriction and/or elected to reactive to restrict and/or elected to restrict and/or elected to restrict and/or elected to restrict and to responding application application property office for the corresponding applicant application is objected to by the Examiner. 10) ☐ The specification is objected to by the Examiner. 11) ☐ The drawing(s) filed on is/are: a) ☐ accepte Applicant may not request that any objection to the draw Replacement drawing sheet(s) including the correction is Priority under 35 U.S.C. § 119 12) ☐ Acknowledgment is made of a claim for foreign prior Certified copies: a) ☐ All b) ☐ Some * c) ☐ None of the: 1. ☐ Certified copies of the priority documents has 3. ☐ Copies of the certified copies of the priority documents has 	tion requirement. to benefit from the Patent F ion. For more information, p	please see <u>oto.gov</u> . he Examiner.
 7) ☐ Claim(s) <u>10-15</u> is/are rejected. 8) ☐ Claim(s) is/are objected to. 9) ☐ Claim(s) are subject to restriction and/or elected to reactive to restrict and a set of a number of the set of the corresponding application application papers 10) ☐ The specification is objected to by the Examiner. 11) ☐ The drawing(s) filed on is/are: a) ☐ accepte Applicant may not request that any objection to the draw Replacement drawing sheet(s) including the correction is Priority under 35 U.S.C. § 119 12) ☐ Acknowledgment is made of a claim for foreign prior Certified copies: a) ☐ All b) ☐ Some * c) ☐ None of the: 1. ☐ Certified copies of the priority documents hat a. ☐ Copies of the certified copies of the priority documents hat a. ☐ Copies of the certified copies of the priority documents hat a. ☐ Copies of the certified copies of the priority documents hat a. ☐ Copies of the certified copies of the priority documents hat a. ☐ Copies of the certified copies of the priority documents hat a. ☐ Copies of the certified copies of the priority documents hat a. ☐ Copies of the certified copies of the priority documents hat a. ☐ Copies of the certified copies of the priority documents hat a. ☐ Copies of the certified copies of the priority documents hat a. ☐ Copies of the certified copies of the priority documents hat a. ☐ Copies of the certified copies of the priority documents hat a. ☐ Copies of the certified copies of the priority documents hat a. ☐ Copies of the certified copies of the priority documents hat a. ☐ Copies of the certified copies of the priority documents hat a. ☐ Copies of the certified copies of the priority documents hat a. ☐ Copies of the certified copies of the priority documents hat a. ☐ Copies of the certified copies of the priority documents hat a. ☐ Copies of the certified copies of the priority documents hat a. ☐ Copies of the certified copies of the certified copies of the priority documents ha	o benefit from the Patent F ion. For more information, p	please see <u>oto.gov</u> . he Examiner.
 8) Claim(s) is/are objected to. 9) Claim(s) are subject to restriction and/or elements of any claims have been determined allowable, you may be eligible or the property office for the corresponding application property office for the corresponding application to the corresponding application property office for the corresponding application to the corresponding application property office for the corresponding application property office for the corresponding application property office for the corresponding application to the specification is objected to by the Examiner. 10) The specification is objected to by the Examiner. 11) The drawing(s) filed on is/are: a) accepte Applicant may not request that any objection to the draw Replacement drawing sheet(s) including the correction is Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign prior Certified copies: a) All b) Some * c) None of the: 1. Certified copies of the priority documents has a. Copies of the priority documents has a. Copies of the certified copies of the priority documents has a. Copies of the certified copies of the priority documents has a. 	o benefit from the Patent F ion. For more information, p	please see <u>oto.gov</u> . he Examiner.
 9) ☐ Claim(s) are subject to restriction and/or elegent of any claims have been determined <u>allowable</u>, you may be eligible or participating intellectual property office for the corresponding applicant the priority <u>accepted</u> of the specification is objected to by the Examiner. 10) ☐ The specification is objected to by the Examiner. 11) ☐ The drawing(s) filed on is/are: a) ☐ accepted Applicant may not request that any objection to the draw Replacement drawing sheet(s) including the correction is correction is accepted. Priority under 35 U.S.C. § 119 12) ☐ Acknowledgment is made of a claim for foreign prior Certified copies: a) ☐ All b) ☐ Some * c) ☐ None of the: 1. ☐ Certified copies of the priority documents has a. ☐ Copies of the priority documents has a. ☐ Copies of the certified copies of the priority documents has a. ☐ Copies of the certified copies of the priority documents has a. ☐ Copies of the certified copies of the priority documents has a. ☐ Copies of the certified copies of the priority documents has a. ☐ Copies of the certified copies of the priority documents has a. ☐ Copies of the certified copies of the priority documents has a. ☐ Copies of the certified copies of the priority documents has a. ☐ Copies of the certified copies of the priority documents has a. ☐ Copies of the certified copies of the priority documents has a. ☐ Copies of the certified copies of the priority documents has a. ☐ Copies of the certified copies of the priority documents has a. ☐ Copies of the certified copies of the priority documents has a. ☐ Copies of the certified copies of the priority documents has a. ☐ Copies of the certified copies of the priority documents has a. ☐ Copies of the certified copies of the priority documents has a. ☐ Copies of the certified copies of the priority documents has a. ☐ Copies of the certified copies of the priority documents has a. ☐ Copies of the certified copies of the certified copies of the certif	o benefit from the Patent F ion. For more information, p	please see <u>oto.gov</u> . he Examiner.
If any claims have been determined <u>allowable</u> , you may be eligible participating intellectual property office for the corresponding application ttp://www.uspto.gov/patents/init_events/pph/index.jsp or send an in Application Papers 10) The specification is objected to by the Examiner. 11) The drawing(s) filed on is/are: a) accepte Applicant may not request that any objection to the draw Replacement drawing sheet(s) including the correction is Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign prior Certified copies: a) All b) Some * c) None of the: 1. Certified copies of the priority documents has 3. Copies of the certified copies of the priority documents has	o benefit from the Patent F ion. For more information, p	please see <u>oto.gov</u> . he Examiner.
 barticipating intellectual property office for the corresponding applic http://www.uspto.gov/patents/init_events/pph/index.jsp or send an in a send to be the specification is objected to by the Examiner. 10) The specification is objected to by the Examiner. 11) The drawing(s) filed on is/are: a) accepte Applicant may not request that any objection to the draw Replacement drawing sheet(s) including the correction is Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign prior Certified copies: a) All b) Some * c) None of the: Certified copies of the priority documents has a. Copies of the certified copies of the priority documents has a. Copies of the certified copies of the priority documents has a. 	ion. For more information, p	please see <u>oto.gov</u> . he Examiner.
http://www.uspto.gov/patents/init_events/pph/index.jsp or send an it Application Papers 10) The specification is objected to by the Examiner. 11) The drawing(s) filed on is/are: a) accepte Applicant may not request that any objection to the draw Replacement drawing sheet(s) including the correction is Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign prior Certified copies: a) All b) Some * c) None of the: 1. Certified copies of the priority documents has 3. Copies of the certified copies of the priority documents has	- NAVI - CARAMANANAN NYA MANINA ANA	<u>bto.gov</u> . he Examiner.
Application Papers 10) The specification is objected to by the Examiner. 11) The drawing(s) filed on is/are: a) accepte Applicant may not request that any objection to the draw Replacement drawing sheet(s) including the correction is Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign prior Certified copies: a) All b) Some * c) None of the: 1. Certified copies of the priority documents has 2. Certified copies of the priority documents has	uiry to PPHfeedback@usp	he Examiner.
 10) The specification is objected to by the Examiner. 11) The drawing(s) filed on is/are: a) accepte Applicant may not request that any objection to the draw Replacement drawing sheet(s) including the correction is Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign prio Certified copies: a) All b) Some * c) None of the: Certified copies of the priority documents has a. Copies of the certified copies of the priority documents has a. 		
 11) The drawing(s) filed on is/are: a) accepte Applicant may not request that any objection to the draw Replacement drawing sheet(s) including the correction is Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priot Certified copies: a) All b) Some * c) None of the: Certified copies of the priority documents has a. Copies of the certified copies of the priority documents has a. Copies of the certified copies of the priority documents has a. 		
Applicant may not request that any objection to the draw Replacement drawing sheet(s) including the correction is Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign prio Certified copies: a) All b) Some * c) None of the: 1. Certified copies of the priority documents has 2. Certified copies of the priority documents has 3. Copies of the certified copies of the priority documents has		
Replacement drawing sheet(s) including the correction is Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign prior Certified copies: a) All b) Some * c) None of the: 1. Certified copies of the priority documents have a set of the prior set of the priority documents have a set of	or b) objected to by th	See 37 CFR 1.85(a).
Priority under 35 U.S.C. § 119 12) ☐ Acknowledgment is made of a claim for foreign prior Certified copies: a) ☐ All b) ☐ Some * c) ☐ None of the: 1. ☐ Certified copies of the priority documents had 2. ☐ Certified copies of the priority documents had 3. ☐ Copies of the certified copies of the priority documents had	g(s) be held in abeyance.	
 12) Acknowledgment is made of a claim for foreign prior Certified copies: a) All b) Some * c) None of the: Certified copies of the priority documents have a copies of the priority documents have a copies of the priority documents have a copies of the certified copies of the priority documents have a copies of the certified copies of the priority documents have a copies of the certified copies of the priority documents have a copies of the certified copies of the priority documents have a copies of the certified copies of the priority documents have a copies of the certified copies of the priority documents have a copies of the certified copies of the priority documents have a copies of the certified copies of the priority documents have a copies of the certified copies of the priority documents have a copies of the certified copies of the priority documents have a copies of the certified copies of the priority documents have a copies of the certified copies of the priority documents have a copies of the certified copies of the priority documents have a copies of the certified copies of the priority documents have a copies of the certified copies of the priority documents have a copies of the certified copies of the priority documents have a copies of the certified copies of the certif	equired if the drawing(s) is	s objected to. See 37 CFR 1.121(d).
 12) Acknowledgment is made of a claim for foreign prior Certified copies: a) All b) Some * c) None of the: Certified copies of the priority documents have a copies of the priority documents have a copies of the priority documents have a copies of the certified copies of the priority documents have a copies of the certified copies of the priority documents have a copies of the certified copies of the priority documents have a copies of the certified copies of the priority documents have a copies of the certified copies of the priority documents have a copies of the certified copies of the priority documents have a copies of the certified copies of the priority documents have a copies of the certified copies of the priority documents have a copies of the certified copies of the priority documents have a copies of the certified copies of the priority documents have a copies of the certified copies of the priority documents have a copies of the certified copies of the priority documents have a copies of the certified copies of the priority documents have a copies of the certified copies of the priority documents have a copies of the certified copies of the priority documents have a copies of the certified copies of the priority documents have a copies of the certified copies of the certif		
Certified copies: a) All b) Some * c) None of the: 1. Certified copies of the priority documents had 2. Certified copies of the priority documents had 3. Copies of the certified copies of the priority documents had	ty under 35 U.S.C. § 119	9(a)-(d) or (f).
 a) All b) Some * c) None of the: 1. Certified copies of the priority documents has 2. Certified copies of the priority documents has 3. Copies of the certified copies of the priority of	aw Ab	ಮ ನಂದು ಪ್ರೇ ಪ್ರೇ ಪ್ರೇ ಪ್ರೇ
2. Certified copies of the priority documents has3. Copies of the certified copies of the priority		
3. Copies of the certified copies of the priority	e been received.	
		ication No
application from the International Bureau (PC	FRule 17.2(a)).	
* See the attached detailed Office action for a list of the	ertified copies not received.	l
Attachment(s)		
1) X Notice of References Cited (PTO-892)		nary (PTO-413)
2) X Information Disclosure Statement(s) (PTO/SB/08)	3) 🔲 Interview Summ	17.12

Application/Control Number: 13/902,132 Art Unit: 1628

DETAILED ACTION

Status of Claims

Claims 10-15 are pending and are under examination in this office action.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 5/24/13 is

acknowledged and has been reviewed.

Claim Rejections - 35 USC § 112

The following is a quotation of 35 U.S.C. 112(b): (b) CONCLUSION.—The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.

The following is a quotation of 35 U.S.C. 112 (pre-AIA), second paragraph: The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10-15 are rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA),

second paragraph, as being indefinite for failing to particularly point out and distinctly

claim the subject matter which the inventor or a joint inventor, or for pre-AIA the

applicant regards as the invention.

DOCKE

RM

Regarding claim 10, the word "means" is preceded by the word(s) "making" in an

attempt to use a "means" clause to recite a claim element as a means for performing a

specified function. However, since no function is specified by the word(s) preceding

"means," it is impossible to determine the equivalents of the element, as required by

Application/Control Number: 13/902,132 Art Unit: 1628

35 U.S.C. 112(f) or 35 U.S.C. 112 (pre-AIA), sixth paragraph. See *Ex parte Klumb*, 159 USPQ 694 (Bd. App. 1967).

The term "making" has no functional meaning, therefore it is confusing what Applicant is refereeing to.

However to accelerate prosecution Examiner has interpreted the claim as a formulation comprising palonosetron.

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

In the event the determination of the status of the application as subject to AIA 35 U.S.C. 102 and 103 (or as subject to pre-AIA 35 U.S.C. 102 and 103) is incorrect, any correction of the statutory basis for the rejection will not be considered a new ground of rejection if the prior art relied upon, and the rationale supporting the rejection, would be the same under either status

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

DOCKF

Claims 10-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Baroni et al. (WO 2004/073714).

Application/Control Number: 13/902,132 Art Unit: 1628

Baroni et al. teach a Palonosetron has surprisingly been found to exhibit an efficacy plateau as a single dose (see pg 8, lines 20+) and can be in a concentration of 0.25 mg (see pgs 11, lines 14-16 and 13, lines 20-25) for the treatment of emesis induced by chemotherapy (see pg 13, lines 18-20, as required by instant claims10-11) in a single intravenous unit (see pg 13, lines 3-5).

With regards to the limitations means for making said formulation stable for 24 months or 18 months, Baroni teaches their formulation prepared as shown in Example 3, Table 8, therefore it is expected that the aqueous formulation of palonosetron will be stable for 24 or 18 months. Additionally Baroni teaches that their formulation is stable for extended times ranging from 1 yr, 18 months , 6 months (see pg 18, lines 21-24, as required by instant claim 10)

Therefore Baroni anticipates instant claims 10-11.

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 of this title, 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. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103 are summarized as follows:

DOCKF

1. Determining the scope and contents of the prior art.

DOCKET A L A R M



Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.