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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/711,272	11/09/2000	Timothy Norris	62814-A/JPW/GJG	6700

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EXAMINER

MCKENZIE, THOMAS C

ART UNIT PAPER NUMBER

1624

9

DATE MAILED: 08/30/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/711,272

Applicant(s)

NORRIS ET AL.

Examiner

Thomas McKenzie Ph.D.

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 19 June 2002.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-7,14-32,50 and 52-72 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) 61 is/are allowed.
- 6) Claim(s) 1-7,14-32,50,52-60 and 62-68 is/are rejected.
- 7) Claim(s) 69-72 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s). _____
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) Notice of Informal Patent Application (PTO-152)

DETAILED ACTION

1. This action is in response to amendments filed on 6/19/02. Applicants have amended claims 5, 14, 23, and 50. Claims 55-72 are new. There are forty-eight claims pending and under consideration. Claims 1-4 are compound claims. Claims 5-7, 55-60, and 62 are composition claims. Claims 14-23, 50, and 63-72 are use claims. Claims 24-32, 52-54, and 61 are method of making claims. This is the second action on the merits. The application concerns a specific crystal form of N-(3-ethynylphenyl)-6,7-bis(2-methoxyethoxy)-4-quinazolinamine hydrochloride, which has Chemical Abstracts registry number 183319-69-9.

Response to Amendment

2. Applicants' addition of a carrier to composition claim 5 overcomes the indefiniteness rejection made in point #5. Applicants replaced "a hyperproliferative disorder" with "abnormal cell growth" in claim 14 and point the paragraph spanning pages 23 to 24 as indicating what they intend. Thus, the indefiniteness rejection made in point #6 is withdrawn.. Applicants point to the phase II studies in the passage spanning line 19, page 51 to line 35, page 52 as enabling their claims to treating specific cancers. This is persuasive, and the enablement rejection to claim 16 is withdrawn. Claim 50 is an independent claim, not limited to the polymorph of claim 1. In lines 9-10, column 14 of Schnur ('498) treatment of hepatic carcinoma with N-(3-ethynylphenyl)-6,7-bis(2-

Art Unit: 1624

methoxyethoxy)-4-quinazolinamine in taught. Prophylaxis is taught in lines 7 and 8, column 14. However, prophylaxis against basal cell carcinoma is nowhere taught in the reference. Thus, the anticipation rejection against claim 50 is withdrawn.

Information Disclosure Statement

3. The copy of PTO-1449 and the post card receipt supplied by Applicants is acknowledged. The Examiner cannot find any references in the file and a search has been started.

Claim Objections

4. Objection remains to claims 2-4 under 37 CFR 1.75 as being a substantial duplicate of claim 1. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). The four claims concern the B polymorph of N-(3-ethynylphenyl)-6,7-bis(2-methoxyethoxy)-4-quinazolinamine, monohydrochloride. There Applicants state that only two polymorphs are known, A and B. There are only two purity limitations in the four objected claims, “substantially homogeneous” in claim 1 and “substantially free of the A polymorph” in claim 3. A substance, which exhibits x-ray diffraction peaks, must be crystalline. The Examiner can see no difference in

these limitations. Thus, all four claims are to the same substance with the same purity limitation.

5. Objection remains to claims 6 and 7 under 37 CFR 1.75 as being a substantial duplicate of claim 5, for reasons cited previously.

6. Objection is made to claims 56 and 57 under 37 CFR 1.75 as being a substantial duplicate of claim 55, for reasons cited above.

7. Objection is made to claim 58 under 37 CFR 1.75 as being a substantial duplicate of claim 5. It is not logical that a composition intended for therapy, as is claim 5, would not contain a therapeutically effective amount of the compound of claim 1.

8. Objection is made to claim 62 under 37 CFR 1.75 as being a substantial duplicate of claim 5. Applicants have chosen a different and ultimately equivalent way of expressing the X-ray data. Both are compositions of the identical substance.

Applicants argue that claim 3 differs from claim 1 because “substantially homogeneous” is not necessarily “substantially free of the A polymorph”. This is not persuasive. Neither phrase is defined in the specification and any homogenous substance must be free of other substances. Applicants made no argument concerning the objection to claims 2, 4, and 6.

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