Docket No.: PIR-88501
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
John C. Byrd, *et al.*

Application No.: 14/523,650 | Confirmation No.: 1095

Filed: October 24, 2014 | Art Unit: 1629

For: METHODS OF TREATING AND PREVENTING GRAFT VERSUS HOST DISEASE | Examiner: TRAN, My Chau T.

AMENDMENT AND RESPONSE TO FINAL OFFICE ACTION

Dear Sir:

In response to the pending Final Office Action, dated November 3, 2016, in connection with the above-referenced application, Applicant submits this Amendment and Response. Please amend the application as follows.

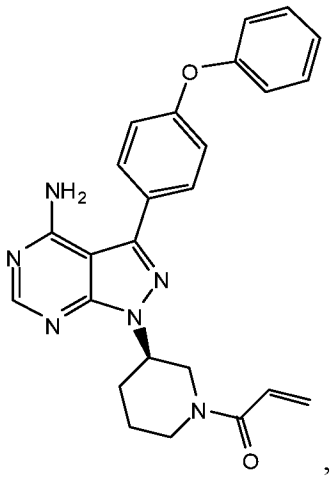
Amendments to the Claims begin on page 2.

Remarks begin on page 8.

IN THE CLAIMS:

1-20. (Canceled)

21. (Currently Amended) A method of treating chronic graft versus host disease (GVHD) comprising administering to a patient having chronic GVHD a therapeutically effective amount of a compound of the structure:



~~or a pharmaceutically acceptable salt thereof~~

thereby treating the chronic GVHD in the patient.

22. (Previously Presented) The method of claim 21, wherein the patient has classic chronic GVHD.

23. (Previously Presented) The method of claim 21, wherein the patient has overlap chronic GVHD.

24. (Previously Presented) The method of claim 21, wherein the patient has steroid-dependent/refractory chronic GVHD.

25. (Previously Presented) The method of claim 21, wherein the therapeutically effective amount of the compound is about 40 mg/day, about 140 mg/day, about 280 mg/day, about 420 mg/day, about 560 mg/day, or about 840 mg/day.

26. (New) The method of claim 21, wherein, following administration of the compound, the patient achieves partial response (PR), wherein the PR is an objective response in one involved organ in the patient with no evidence of progression elsewhere and no requirements for additional systemic therapy.

27. (New) The method of claim 21, wherein, following administration of the compound, the patient achieves complete response (CR), wherein the CR is a complete restoration of symptoms attributable to GVHD.

28. (New) The method of claim 21, wherein, following administration of the compound, the severity of the GVHD is reduced.

29. (New) The method of claim 21, wherein the patient has chronic lymphocytic leukemia (CLL).

30. (New) The method of claim 21, wherein the patient had a hematopoietic cell transplantation.

31. (New) The method of claim 21, wherein the chronic GVHD is sclerodermatous GVHD, steroid resistant GVHD, cyclosporin-resistant GVHD, refractory GVHD, oral GVHD, reticular oral GVHD, erosive GVHD, or ulcerative oral GVHD.

32. (New) The method of claim 21, wherein the chronic GVHD is sclerodermatous GVHD.

33. (New) The method of claim 21, wherein the chronic GVHD is steroid resistant GVHD.

34. (New) The method of claim 21, wherein the chronic GVHD is cyclosporin-resistant GVHD.

35. (New) The method of claim 21, wherein the chronic GVHD is refractory GVHD.

36. (New) The method of claim 21, wherein the chronic GVHD is oral GVHD.

37. (New) The method of claim 21, wherein the chronic GVHD is reticular oral GVHD.

38. (New) The method of claim 21, wherein the chronic GVHD is erosive GVHD.

39. (New) The method of claim 21, wherein the chronic GVHD is ulcerative oral GVHD.

40. (New) The method of claim 21, wherein about 420 mg/day of the compound is administered.

41. (New) The method of claim 21, wherein about 420 mg of the compound is administered once per day.

42. (New) The method of claim 21, wherein the compound is administered orally.

43. (New) The method of claim 21, wherein about 420 mg/day of the compound is administered orally.

44. (New) The method of claim 21, wherein about 420 mg of the compound is administered orally once per day.

45. (New) The method of claim 24, wherein about 420 mg/day of the compound is administered.

46. (New) The method of claim 24, wherein about 420 mg of the compound is administered once per day.

47. (New) The method of claim 24, wherein about 420 mg/day of the compound is administered orally.

48. (New) The method of claim 24, wherein about 420 mg of the compound is administered orally once per day.

49. (New) The method of claim 24, wherein, following administration of the compound, the patient achieves partial response (PR), wherein the PR is an objective response in one involved organ in the patient with no evidence of progression elsewhere and no requirements for additional systemic therapy.

50. (New) The method of claim 24, wherein, following administration of the compound, the patient achieves complete response (CR), wherein the CR is a complete restoration of symptoms attributable to GVHD.

51. (New) The method of claim 24, wherein, following administration of the compound, the severity of the GVHD is reduced.

52. (New) The method of claim 26, wherein about 420 mg/day of the compound is administered.

53. (New) The method of claim 26, wherein about 420 mg of the compound is administered once per day.

54. (New) The method of claim 26, wherein about 420 mg/day of the compound is administered orally.

55. (New) The method of claim 26, wherein about 420 mg of the compound is administered orally once per day.

56. (New) The method of claim 27, wherein about 420 mg/day of the compound is administered.

57. (New) The method of claim 27, wherein about 420 mg of the compound is administered once per day.

58. (New) The method of claim 27, wherein about 420 mg/day of the compound is administered orally.

59. (New) The method of claim 27, wherein about 420 mg of the compound is administered orally once per day.

60. (New) The method of claim 33, wherein about 420 mg/day of the compound is administered.

61. (New) The method of claim 33, wherein about 420 mg of the compound is administered once per day.

62. (New) The method of claim 33, wherein about 420 mg/day of the compound is administered orally.

63. (New) The method of claim 33, wherein about 420 mg of the compound is administered orally once per day.

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