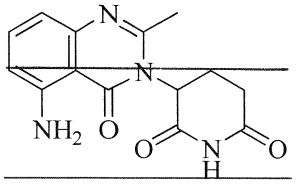
~~What is claimed is:~~

~~1. Use of a therapeutically effective amount of 3-(5-amino-2-methyl-4-oxo-4*H*-quinazolin-3-yl)-piperidine-2,6-dione, which has the following structure:~~



~~or an enantiomer or mixture of enantiomers thereof, or a pharmaceutically acceptable salt, solvate, hydrate, co-crystal, clathrate, or polymorph thereof in the manufacture of a medicament for treating or managing cancer.~~

~~2. The use of claim 1, wherein the cancer is advanced malignancy, amyloidosis, neuroblastoma, meningioma, hemangiopericytoma, multiple brain metastase, glioblastoma multiforms, glioblastoma, brain stem glioma, poor prognosis malignant brain tumor, malignant glioma, anaplastic astrocytoma, anaplastic oligodendroglioma, neuroendocrine tumor, rectal adenocarcinoma, Dukes C & D colorectal cancer, unresectable colorectal carcinoma, metastatic hepatocellular carcinoma, Kaposi's sarcoma, karotype acute myeloblastic leukemia, Hodgkin's lymphoma, non-Hodgkin's lymphoma, cutaneous T-Cell lymphoma, cutaneous B-Cell lymphoma, diffuse large B-Cell lymphoma, low grade follicular lymphoma, malignant melanoma, malignant mesothelioma, malignant pleural effusion mesothelioma syndrome, peritoneal carcinoma, papillary serous carcinoma, gynecologic sarcoma, soft tissue sarcoma, scleroderma, cutaneous vasculitis, Langerhans cell histiocytosis, leiomyosarcoma, fibrodysplasia ossificans progressive, hormone refractory prostate cancer, resected high-risk soft tissue sarcoma, unresectable hepatocellular carcinoma, Waldenstrom's macroglobulinemia, smoldering myeloma, indolent myeloma, fallopian tube cancer, androgen independent prostate cancer, androgen dependent stage IV non-metastatic prostate cancer, hormone-insensitive prostate cancer, chemotherapy-insensitive prostate cancer, papillary thyroid carcinoma, follicular thyroid carcinoma, medullary thyroid carcinoma, or leiomyoma.~~

~~3. The use of claim 1, wherein the cancer is a blood borne tumor.~~

~~4. The use of claim 1, wherein the cancer is myeloma or lymphoma.~~

~~5. The use of claim 1, wherein the cancer is a solid tumor.~~

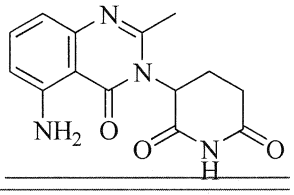
~~6. The use of claim 1, wherein the cancer is breast, colorectal, ovarian, prostate, pancreatic, or renal cancer.~~

~~7. The use of claim 1, wherein the cancer is hepatocellular carcinoma, prostate cancer, ovarian cancer, or glioblastoma.~~

~~8. The use of claim 1, wherein the cancer is non-Hodgkin's lymphoma.~~

~~9. The use of claim 8, wherein the non-Hodgkin's lymphoma is diffuse large B-cell lymphoma.~~What is claimed is:

1. ~~10. The use~~Use of ~~claim 9~~a therapeutically effective amount of 3-(5-amino-2-methyl-4-oxo-4*H*-quinazolin-3-yl)-piperidine-2,6-dione, which has the following structure:



or an enantiomer or mixture of enantiomers thereof, or a pharmaceutically acceptable salt, solvate, hydrate, co-crystal, clathrate, or polymorph thereof in the manufacture of a medicament for treating or managing non-Hodgkin's lymphoma, wherein the non-Hodgkin's lymphoma is ~~wherein~~ the diffuse large B-cell lymphoma ~~is~~ of ~~the~~an activated B-cell phenotype.

~~11.~~2. The use of claim ~~10~~1, wherein the diffuse large B-cell lymphoma is characterized by the expression of one or more biomarkers overexpressed in RIVA, U2932, TMD8 or OCI-Ly10 cell lines.

~~12.~~3. The use of ~~any of~~ claims 1 ~~to 11~~or 2, wherein the ~~cancer~~non-Hodgkin's lymphoma is relapsed or refractory.

~~13.~~4. The use of ~~any of~~ claims 1 ~~to 12~~or 2, wherein the ~~cancer~~non-Hodgkin's lymphoma is drug-resistant.

~~14. Use of a therapeutically effective amount of 3-(5-amino-2-methyl-4-oxo-4*H*-quinazolin-3-yl)-piperidine-2,6-dione or a pharmaceutically acceptable salt, solvate or hydrate thereof in the manufacture of a medicament for treating or managing non-Hodgkin's lymphoma, wherein the medicament is to be administered to a patient identified of having non-Hodgkin's lymphoma sensitive to treatment with 3-(5-amino-2-methyl-4-oxo-4*H*-quinazolin-3-yl)-piperidine-2,6-dione.~~

~~15. The use of claim 14, wherein the non-Hodgkin's lymphoma is diffuse large B-cell lymphoma.~~

~~16.~~5. ~~The use~~Use of ~~claim 14~~a therapeutically effective amount of 3-(5-amino-2-methyl-4-oxo-4*H*-quinazolin-3-yl)-piperidine-2,6-dione or a pharmaceutically acceptable salt, solvate or hydrate thereof in the manufacture of a medicament for treating or managing non-Hodgkin's lymphoma, wherein the non-Hodgkin's lymphoma is of ~~the~~an activated B-cell phenotype.

~~17. The use of claim 15, wherein the diffuse large B-cell lymphoma is of the activated B-cell phenotype.~~

~~18.~~6. The use of claim ~~17~~5, wherein the diffuse large B-cell lymphoma is characterized by the expression of one or more biomarkers overexpressed in RIVA, U2932, TMD8 or OCI-Ly10 cell lines.

~~19.~~7. The use of claim ~~14~~5, wherein the patient identified of having non-Hodgkin's lymphoma sensitive to treatment with 3-(5-amino-2-methyl-4-oxo-4*H*-quinazolin-3-yl)-piperidine-2,6-dione, or a salt, solvate or hydrate thereof, is identified by characterization of the non-Hodgkin's lymphoma phenotype of the patient as an activated B-cell subtype.

~~20. The use of claim 19, wherein the non-Hodgkin's lymphoma phenotype is characterized as an activated B-cell subtype of diffuse large B-cell lymphoma.~~

~~21. The use of claim 19, wherein the non-Hodgkin's lymphoma phenotype is characterized by the expression of one or more biomarkers overexpressed in RIVA, U2932, TMD8 or OCI-Ly10 cell lines.~~

~~22.~~8. The use of claim ~~14~~5, wherein the patient identified of having non-Hodgkin's lymphoma sensitive to treatment with 3-(5-amino-2-methyl-4-oxo-4*H*-quinazolin-3-yl)-piperidine-2,6-dione, or a salt, solvate or hydrate thereof, is identified by identification of a gene associated with the activated B-cell phenotype.

~~23.~~9. The use of claim ~~22~~8, wherein the gene associated with the activated B-cell phenotype is selected from the group consisting of IRF4/MUM1, FOXP1, SPIB, CARD11 and BLIMP/PDRM1.

~~24.~~10. The use of claim ~~14~~5, wherein the patient identified of having non-Hodgkin's lymphoma sensitive to treatment with 3-(5-amino-2-methyl-4-oxo-4*H*-quinazolin-3-yl)-

piperidine-2,6-dione, or a salt, solvate or hydrate thereof, is identified by measuring the level of NF-κB activity in a biological sample obtained from the patient.

~~25.~~11. The use of claim ~~24~~10, wherein the biological sample is a lymph node biopsy, a bone marrow biopsy, or a sample of peripheral blood tumor cells.

~~26.~~12. The use of claim ~~19~~11, wherein characterization of the non-Hodgkin's lymphoma phenotype of the patient as an activated B-cell subtype comprises measuring one or more of the following:

(i) overexpression of SPIB, a hematopoietic-specific Ets family transcription factor required for survival of activated B-cell subtype cells;

(ii) higher constitutive IRF4/MUM1 expression than GCB subtype cells;

(iii) higher constitutive FOXP1 expression up-regulated by trisomy 3;

(iv) higher constitutive Blimp1, *i.e.,* PRDM1, expression;

(v) higher constitutive CARD11 gene expression; and

(vi) an increased level of NF-κB activity relative to non-activated B-cell subtype DLBCL cells.

~~27. The use of any one of claims 1-26, wherein the compound is 3-(5-amino-2-methyl-4-oxo-4*H*-quinazolin-3-yl)-piperidine-2,6-dione hydrochloride, or a salt, solvate or hydrate thereof.~~

~~28.~~13. The use of any one of claims 1-~~27~~12, wherein the medicament further comprises administration of a therapeutically effective amount of one or more additional active agents.

~~29.~~14. The use of claim ~~28~~13, wherein the additional active agent is selected from the group consisting of an alkylating agent, an adenosine analog, a glucocorticoid, a kinase inhibitor, a SYK inhibitor, a PDE3 inhibitor, a PDE7 inhibitor, doxorubicin, chlorambucil, vincristine, bendamustine, forskolin and rituximab.

~~30.~~15. The use of claim ~~29~~14, wherein the additional active agent is rituximab.

~~31.~~16. The use of any one of claims 1-~~30~~15, wherein 3-(5-amino-2-methyl-4-oxo-4*H*-quinazolin-3-yl)-piperidine-2,6-dione, or a pharmaceutically acceptable salt, solvate or hydrate thereof is to be administered in an amount of from about 0.5 to about 50 mg per day.

~~32.~~17. The use of claim ~~31~~16, wherein the compound is to be administered in an amount of about 0.5 to about 5 mg per day.

~~33.~~18. The use of claim ~~31~~17, wherein the compound is to be administered in an amount of about 0.5, 1, 2, 4, 5, 10, 15, 20, 25 or 50 mg per day.

~~34.~~19. The use of claim ~~31~~17, wherein the compound is to be administered orally.

~~35.~~20. The use of claim ~~31~~17, wherein the compound is to be administered in a capsule or tablet.

~~36.~~21. The use of claim ~~35~~20, wherein the compound is to be administered in 10 mg or 25 mg of a capsule.

~~37. The use of any one of claims 1-3621, wherein the diffuse large B-cell lymphoma is relapsed, refractory or resistant to conventional therapy.~~

~~38.~~22. The use of any one of claims 1-~~37~~21, wherein the compound is to be administered for 21 days followed by seven days rest in a 28 day cycle.

~~39. An *in vitro* method for predicting tumor response to treatment in a non-Hodgkin's lymphoma patient, comprising:~~

~~(i) measuring the level of NF-κB activity in a biological sample obtained from the patient; and~~

~~(ii) comparing the level of NF-κB activity in the biological sample to that of a biological sample of a non-activated B-cell lymphoma subtype;~~

~~wherein an increased level of NF-κB activity relative to non-activated B-cell subtype lymphoma cells indicates a likelihood of an effective patient tumor response to 3-(5-amino-2-methyl-4-oxo-4*H*-quinazolin-3-yl)-piperidine-2,6-dione treatment.~~

40. An *in vitro* method of monitoring tumor response to treatment in a non-Hodgkin's lymphoma patient, comprising:

(i) measuring the level of NF-κB activity in a first biological sample obtained from the patient;

(ii) measuring the level of NF-κB activity in a second biological sample obtained from the patient after said patient had been adminstered a therapeutically effective amount of 3-(5-amino-2-methyl-4-oxo-4*H*-quinazolin-3-yl)-piperidine-2,6-dione, or a salt, solvate or hydrate thereof; and

(iii) comparing the level of NF-κB activity in the first biological sample to that in the second biological sample;

wherein a decreased level of NF-κB activity in the second biological sample relative to the first biological sample indicates a likelihood of an effective patient tumor response.

41. An *in vitro* method for monitoring patient compliance with a drug treatment protocol in a non-Hodgkin's lymphoma patient, comprising:

(i) measuring the level of NF-κB activity in a biological sample obtained from the patient; and

(ii) comparing the level of NF-κB activity in the biological sample to a control untreated sample;

wherein a decreased level of NF-κB activity in the biological sample relative to the control indicates patient compliance with the drug treatment protocol.

42. The method of any one of claims 39-41, wherein the non-Hodgkin's lymphoma is diffuse large B-cell lymphoma.

43. The method of any one of claims 39-42, wherein the level of NF-κB activity is measured by an enzyme-linked immunosorbent assay.

44. An *in vitro* method for predicting tumor response to treatment in a non-Hodgkin's lymphoma patient, comprising:

(i) purifying protein or RNA from a sample obtained from the patient; and

(ii) identifying increased expression of a gene associated with the activated B-cell phenotype of non-Hodgkin's lymphoma relative to control non-activated B-cell phenotype of non-Hodgkin's lymphoma;

wherein increased expression of a gene associated with the activated B-cell phenotype of non-Hodgkin's lymphoma indicates a likelihood of an effective patient tumor response to 3-(5-amino-2-methyl-4-oxo-4*H*-quinazolin-3-yl)-piperidine-2,6-dione treatment.

45. The method of claim 44, wherein the biological sample is tumor tissue.

46. The method of claim 44, wherein increased expression is an increase of about 1.5X, 2.0X, 3X, 5X, or more.

47. The method of any one of claims 39-44, wherein the gene associated with the activated B-cell phenotype is selected from the group consisting of IRF4/MUM1, FOXP1, SPIB, CARD11 and BLIMP/PDRM1.

48. The method of any one of claims 39-44, wherein identifying the expression of a gene associated with the activated B-cell phenotype of non-Hodgkin's lymphoma is performed by quantitative real-time PCR.

49. A kit for predicting tumor response to treatment with 3-(5-amino-2-methyl-4-oxo-4*H*-quinazolin-3-yl)-piperidine-2,6-dione, or a salt, solvate or hydrate thereof, in a non-Hodgkin's lymphoma patient, comprising:

(i) a solid support; and

(ii) a means for detecting the expression of a biomarker of an activated B-cell phenotype of non-Hodgkin's lymphoma in a biological sample.

50. The kit of claim 49, wherein the biomarker is NF-κB.

51. The kit of claim 49, wherein the biomarker is a gene associated with the activated B-cell phenotype and is selected from the group consisting of IRF4/MUM1, FOXP1, SPIB, CARD11 and BLIMP/PDRM1.

52. An *in vitro* method of selecting a group of cancer patients based on the level of CRBN expression, or the levels of DDB1, DDB2, IRF4 or NFκB expression within the cancer, for the purposes of predicting clinical response, monitoring clinical response, or monitoring patient compliance to dosing by 3-(5-amino-2-methyl-4-oxo-4*H*-quinazolin-3-

yl)-piperidine-2,6-dione, a stereoisomer thereof, or a pharmaceutically acceptable salt, solvate, hydrate, co-crystal, clathrate, or polymorph thereof, wherein the cancer patients are selected from multiple myeloma, non-Hodgkin's lymphoma, diffuse large B-cell lymphoma, melanoma and solid tumor patients.

53. The method of claim 52, wherein the cancer patients are multiple myeloma patients.

54. The method of claim 52, wherein the cancer patients are non-Hodgkin's lymphoma patients.

55. The method of claim 52, wherein the method of selecting a group of cancer patients is based on the level of DDB1 expression within the cancer.

56. The method of claim 52, wherein the method of selecting a group of cancer patients is based on the level of DDB2 expression within the cancer.

57. The method of claim 52, wherein the method of selecting a group of cancer patients is based on the level of IRF4 expression within the cancer.

58. The method of claim 52, wherein the method of selecting a group of cancer patients is based on the level of NFκB expression within the cancer.

59. An *in vitro* method of selecting a group of cancer patients responsive to treatment with 3-(5-amino-2-methyl-4-oxo-4*H*-quinazolin-3-yl)-piperidine-2,6-dione, a stereoisomer thereof, or a pharmaceutically acceptable salt, solvate, hydrate, co-crystal, clathrate, or polymorph thereof; based on the level of CRBN expression, or the levels of DDB1, DDB2, IRF4 or NFκB expression within the patient's T cells, B cells, or plasma cells, for the purposes of predicting clinical response, monitoring clinical response, or monitoring patient compliance to dosing by 3-(5-amino-2-methyl-4-oxo-4*H*-quinazolin-3-yl)-piperidine-2,6-dione, a stereoisomer thereof, or a pharmaceutically acceptable salt, solvate, hydrate, co-crystal, clathrate, or polymorph thereof.

~~60. The method of claim 59, wherin the cancer patients are selected from multiple myeloma, non-Hodgkin's lymphoma, diffuse large B-cell lymphoma, melanoma and solid tumor patients.~~