or a pharmaceutically acceptable salt thereof; wherein the compound of Formula I or the pharmaceutically acceptable salt thereof is dispersed in a solid matrix that comprises (a) at least one pharmaceutically acceptable water-soluble polymeric carrier and (b) at least one pharmaceutically acceptable surfactant,

wherein less than 5% of the compound or pharmaceutically acceptable salt thereof is in crystalline form, as observed by X-ray diffraction analysis,

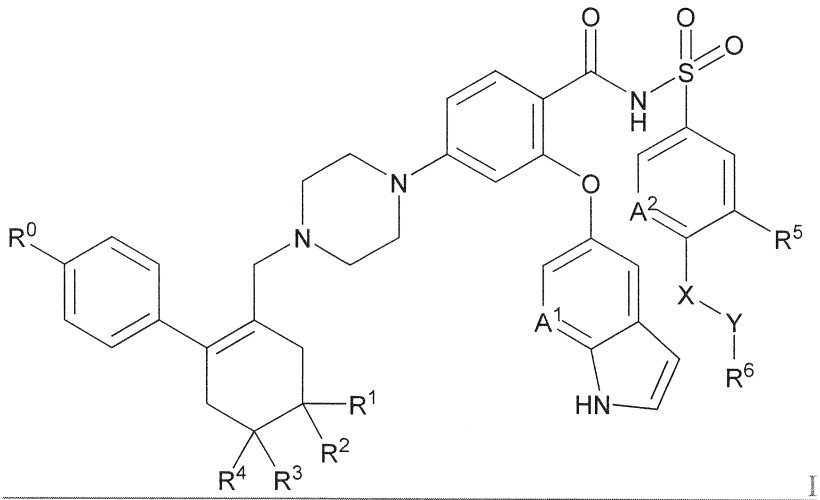
wherein the compound or pharmaceutically acceptable salt thereof is present in a parent-compound-equivalent amount of 5% to 40% by weight, the at least one pharmaceutically acceptable water-soluble polymeric carrier is present in an amount of 40% to 85% by weight, and the at least one pharmaceutically acceptable surfactant is present in an amount of 5% to 20% by weight,

wherein the at least one pharmaceutically acceptable water-soluble polymeric carrier is selected from the group consisting of N-vinyl lactams, cellulose esters, cellulose ethers, high molecular weight polyalkylene oxides, polyacrylates, polymethacrylates, polyacrylamides, vinyl acetate polymers, graft copolymers of polyethylene glycol, polyvinyl caprolactam and polyvinyl acetate, oligo- and polysaccharides and mixtures thereof, and

wherein the at least one pharmaceutically acceptable surfactant is selected from the group consisting of polyoxyethylene glycerides, fatty acid monoesters of sorbitan, polysorbates, α-tocopheryl polyethylene glycol succinate (TPGS) and mixtures thereof.

[0028b] In one aspect, there is provided a process for preparing a solid dispersion, comprising:

preparing a melt by subjecting to elevated temperature (i) an active pharmaceutical ingredient (API) that comprises a compound of Formula I



I

where:

R^0 is chloro;

R^1 and R^2 are H;

R^3 and R^4 are methyl;

A^1 is N and A^2 is CH;

R^5 is nitro;

X is –NH–;

Y is $-(CH_2)_n-$ where n is 1 ; and

R^6 is is selected from the group consisting of tetrahydropyranyl and 4-hydroxy-4-methylcyclohexyl;

or a pharmaceutically acceptable salt thereof, (ii) a pharmaceutically acceptable water-soluble polymeric carrier and (iii) a pharmaceutically acceptable surfactant to provide the melt, wherein the melt comprises an extrudable semi-solid or liquid mixture comprising the API, the pharmaceutically acceptable water-soluble polymeric carrier, and the pharmaceutically acceptable surfactant, and further wherein the elevated temperature is a temperature about a softening point of the pharmaceutically

acceptable water-soluble polymeric carrier;

(b) extruding the melt comprising the semi-solid or liquid mixture to thereby prepare an extrudate; and

(c) cooling the resulting extrudate to provide a solid matrix comprising the polymeric carrier and the surfactant and having the compound or salt thereof dispersed therein, wherein less 5% of the compound or pharmaceutically acceptable salt thereof is in crystalline form, as observed by X-ray diffraction analysis,

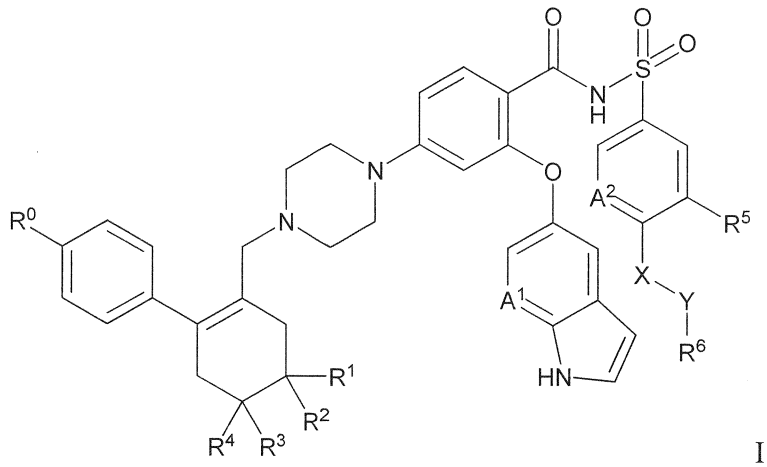
wherein the compound or pharmaceutically acceptable salt thereof is present in a parent-compound-equivalent amount of 5% to 40% by weight, the at least one pharmaceutically acceptable water-soluble polymeric carrier is present in an amount of 40% to 85% by weight, and the at least one pharmaceutically acceptable surfactant is present in an amount of 5% to 20% by weight,

wherein the at least one pharmaceutically acceptable polymeric carrier is selected from the group consisting of N-vinyl lactams, cellulose esters, cellulose ethers, high molecular weight polyalkylene oxides, polyacrylates, polymethacrylates, polyacrylamides, vinyl acetate polymers, graft copolymers of polyethylene glycol, polyvinyl caprolactam and polyvinyl acetate, oligo- and polysaccharides and mixtures thereof, and

wherein the at least one surfactant is selected from the group consisting of polyoxyethylene glycerides, fatty acid monoesters of sorbitan, polysorbates, α-tocopheryl polyethylene glycol succinate (TPGS) and mixtures thereof.

[0028cb] In one aspect, there is provided a process for preparing a solid dispersion, comprising:

(a) subjecting to elevated temperature (i) an active pharmaceutical ingredient (API) that comprises a compound of Formula I



I

where:

R^0 is chloro;

R^1 and R^2 are H;

R^3 and R^4 are methyl;

A^1 is N and A^2 is CH;

R^5 is nitro;

X is –NH–;

Y is $-(CH_2)_n-$ where n is 1 ; and

R^6 is is selected from the group consisting of tetrahydropyranyl and 4-hydroxy-4-methylcyclohexyl;

or a pharmaceutically acceptable salt thereof, (ii) a pharmaceutically acceptable water-soluble polymeric carrier and (iii) a pharmaceutically acceptable surfactant to provide an extrudable semi-solid mixture;

(b) extruding the semi-solid mixture; and

(c) cooling the resulting extrudate to provide a solid matrix comprising the polymeric carrier and the surfactant and having the compound or salt thereof dispersed therein, wherein less 5% of the compound or pharmaceutically acceptable salt thereof is in crystalline form, as observed by X-ray diffraction analysis,

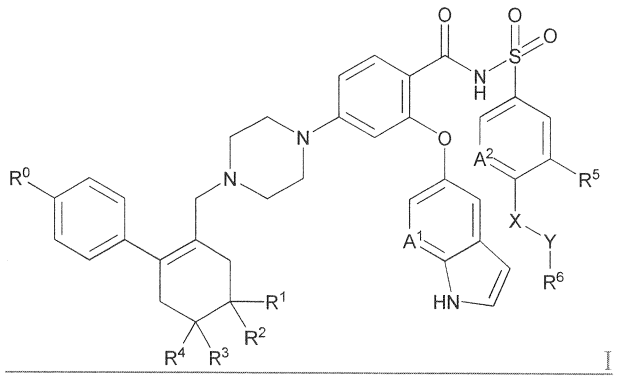
wherein the compound or pharmaceutically acceptable salt thereof is present in a parent-compound-equivalent amount of 5% to 40% by weight, the at least one pharmaceutically acceptable water-soluble polymeric carrier is present in an amount of 40% to 85% by weight, and the at least one pharmaceutically acceptable surfactant is present in an amount of 5% to 20% by weight,

wherein the at least one pharmaceutically acceptable polymeric carrier is selected from the group consisting of N-vinyl lactams, cellulose esters, cellulose ethers, high molecular weight polyalkylene oxides, polyacrylates, polymethacrylates, polyacrylamides, vinyl acetate polymers, graft copolymers of polyethylene glycol, polyvinyl caprolactam and polyvinyl acetate, oligo- and polysaccharides and mixtures thereof, and

wherein the at least one surfactant is selected from the group consisting of polyoxyethylene glycerides, fatty acid monoesters of sorbitan, polysorbates, α-tocopheryl polyethylene glycol succinate (TPGS) and mixtures thereof.

[0028d] In one aspect, there is provided a process for preparing a solid dispersion, comprising:

(a) preparing a melt by subjecting to elevated temperature (i) an active pharmaceutical ingredient (API) that comprises a compound of Formula I



I

where:

R^0 is chloro;

R^1 and R^2 are H;

R^3 and R^4 are methyl;

A^1 is N and A^2 is CH;

R^5 is nitro;

X is –NH–;

Y is $-(CH_2)_n-$ where n is 1; and

R^6 is is selected from the group consisting of tetrahydropyranyl and 4-hydroxy-4-methylcyclohexyl;

or a pharmaceutically acceptable salt thereof, (ii) a pharmaceutically acceptable water-soluble polymeric carrier and (iii) a pharmaceutically acceptable surfactant to provide the melt, wherein the melt comprises an extrudable semi-solid or liquid mixture comprising the API, the pharmaceutically acceptable water-soluble polymeric carrier, and the pharmaceutically acceptable surfactant, and further wherein the elevated temperature is a temperature above a softening point of the pharmaceutically acceptable water-soluble polymeric carrier;

(b) extruding and calendering the melt comprising the semi-solid or liquid mixture to thereby prepare an extrudate; and

(c) cooling the resulting extrudate to provide a solid matrix comprising the polymeric

carrier and the surfactant and having the compound or salt thereof dispersed therein, wherein less 5% of the compound or pharmaceutically acceptable salt thereof is in crystalline form, as observed by X-ray diffraction analysis,

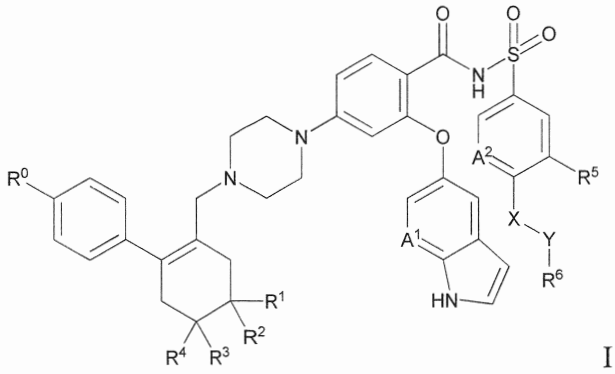
wherein the compound or pharmaceutically acceptable salt thereof is present in a parent-compound-equivalent amount of 5% to 40% by weight, the at least one pharmaceutically acceptable water-soluble polymeric carrier is present in an amount of 40% to 85% by weight, and the at least one pharmaceutically acceptable surfactant is present in an amount of 5% to 20% by weight,

wherein the at least one pharmaceutically acceptable polymeric carrier is selected from the group consisting of N-vinyl lactams, cellulose esters, cellulose ethers, high molecular weight polyalkylene oxides, polyacrylates, polymethacrylates, polyacrylamides, vinyl acetate polymers, graft copolymers of polyethylene glycol, polyvinyl caprolactam and polyvinyl acetate, oligo- and polysaccharides and mixtures thereof, and

wherein the at least one surfactant is selected from the group consisting of polyoxyethylene glycerides, fatty acid monoesters of sorbitan, polysorbates, α-tocopheryl polyethylene glycol succinate (TPGS) and mixtures thereof.

[0028ee] In one aspect, there is provided a process for preparing a solid dispersion, comprising:

(a) subjecting to elevated temperature (i) an active pharmaceutical ingredient (API) that comprises a compound of Formula I



I

where:

R^0 is chloro;

R^1 and R^2 are H;

R^3 and R^4 are methyl;

A^1 is N and A^2 is CH;

R^5 is nitro;

X is –NH–;

Y is $–(CH_2)_n–$ where n is 1; and

R^6 is is selected from the group consisting of tetrahydropyranyl and 4-hydroxy-4-methylcyclohexyl;

or a pharmaceutically acceptable salt thereof, (ii) a pharmaceutically acceptable water-soluble polymeric carrier and (iii) a pharmaceutically acceptable surfactant to provide an extrudable semi-solid mixture;

(b) extruding and calendering the semi-solid mixture; and

(c) cooling the resulting extrudate to provide a solid matrix comprising the polymeric carrier and the surfactant and having the compound or salt thereof dispersed

therein, wherein less 5% of the compound or pharmaceutically acceptable salt thereof is in crystalline form, as observed by X-ray diffraction analysis,

wherein the compound or pharmaceutically acceptable salt thereof is present in a parent-compound-equivalent amount of 5% to 40% by weight, the at least one pharmaceutically acceptable water-soluble polymeric carrier is present in an amount of 40% to 85% by weight, and the at least one pharmaceutically acceptable surfactant is present in an amount of 5% to 20% by weight,

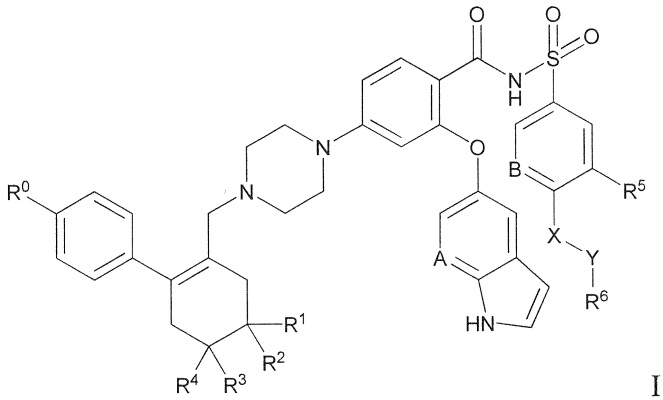
wherein the at least one pharmaceutically acceptable polymeric carrier is selected from the group consisting of N-vinyl lactams, cellulose esters, cellulose ethers, high molecular weight polyalkylene oxides, polyacrylates, polymethacrylates, polyacrylamides, vinyl acetate polymers, graft copolymers of polyethylene glycol, polyvinyl caprolactam and polyvinyl acetate, oligo- and polysaccharides and mixtures thereof, and

wherein the at least one surfactant is selected from the group consisting of polyoxyethylene glycerides, fatty acid monoesters of sorbitan, polysorbates, α-tocopheryl polyethylene glycol succinate (TPGS) and mixtures thereof.

[0028fd] In one aspect, there is provided an orally deliverable pharmaceutical dosage form comprising the solid dispersion as disclosed herein.

[0028ge] In one aspect, there is provided the use of the solid dispersion as disclosed herein in the manufacture of a medicament for treating a neoplastic, immune or autoimmune disease, said use comprising orally administering to a subject having the disease a therapeutically effective amount of the medicament.

[0029] There is now provided a solid dispersion comprising, in essentially non-crystalline, for example amorphous, form, a compound of Formula I:



I

where:

R^0 is halo;

R^1 and R^2 are H or are independently methyl or methoxy;

R^3 and R^4 are independently methyl or methoxy if R^1 and R^2 are H, or are H if R^1 and R^2 are independently methyl or methoxy;

A and B are each independently CH or N;

R^5 is C_{1-4} alkyl or haloalkyl, C_{1-4} alkylsulfonyl or haloalkylsulfonyl, halo, nitro or cyano;

X is –O– or –NH–;

Y is $–(CH_2)_n–$ where n is 0, 1, 2 or 3; and

R^6 is an unsubstituted or substituted 3- to 7-membered carbocyclic or heterocyclic ring as defined herein, or is NR^7R^8;

wherein, if R^6 is NR^7R^8, R^7 and R^8 are each independently H or $R^9–(CH_2)_m–$ groups, no more than one of R^7 and R^8 being H, where each R^9 is independently a 3- to 7-membered carbocyclic or heterocyclic ring, optionally substituted with no more than two Z^1 groups as defined below, and each m is independently 0 or 1; and

wherein, if R^6 is a substituted carbocyclic or heterocyclic ring, substituents thereon are no more than two Z^1 groups and/or no more than one Z^2 group, Z^1 groups

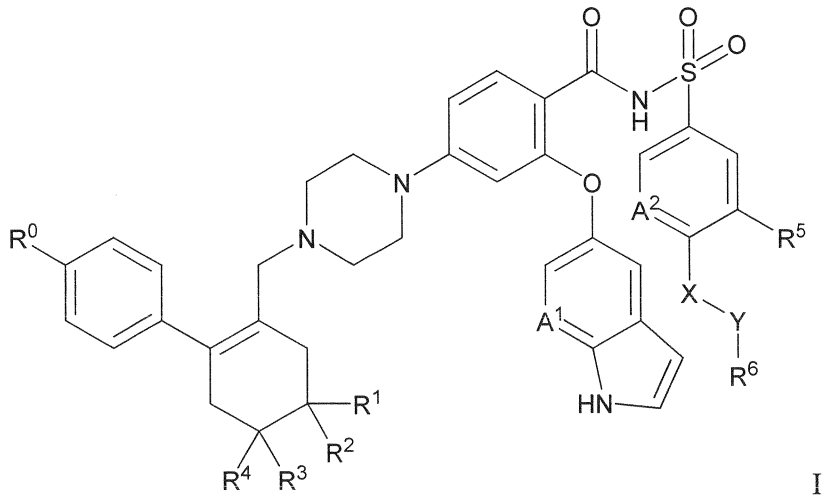
14. The solid dispersion of Claim 13, wherein the at least one surfactant is a polysorbate.

15. The solid dispersion of Claim 14, further comprising at least one glidant.

16. The solid dispersion of Claim 15, wherein the at least one glidant comprises colloidal silicon dioxide.

17. A process for preparing a solid dispersion, comprising:

(a) preparing a melt by subjecting to elevated temperature (i) an active pharmaceutical ingredient (API) that comprises a compound of Formula I



I

where:

R^0 is chloro;

R^1 and R^2 are H;

R^3 and R^4 are methyl;

A^1 is N and A^2 is CH;

R^5 is nitro;

X is –NH–;

Y is $-(CH_2)_n-$ where n is 1 ; and

R^6 is is selected from the group consisting of tetrahydropyranyl and 4-hydroxy-4-methylcyclohexyl;

or a pharmaceutically acceptable salt thereof, (ii) a pharmaceutically acceptable water-soluble polymeric carrier and (iii) a pharmaceutically acceptable surfactant to provide the melt, wherein the melt comprises an extrudable semi-solid or liquid mixture comprising the API, the pharmaceutically acceptable water-soluble polymeric carrier, and the pharmaceutically acceptable surfactant, and further wherein the elevated temperature is a temperature about a softening point of the pharmaceutically acceptable water-soluble polymeric carrier;

(b) extruding the melt comprising the semi-solid or liquid mixture to thereby prepare an extrudate; and

(c) cooling the resulting extrudate to provide a solid matrix comprising the polymeric carrier and the surfactant and having the compound or salt thereof dispersed therein, wherein less 5% of the compound or pharmaceutically acceptable salt thereof is in crystalline form, as observed by X-ray diffraction analysis,

wherein the compound or pharmaceutically acceptable salt thereof is present in a parent-compound-equivalent amount of 5% to 40% by weight, the at least one pharmaceutically acceptable water-soluble polymeric carrier is present in an amount of 40% to 85% by weight, and the at least one pharmaceutically acceptable surfactant is present in an amount of 5% to 20% by weight,

wherein the at least one pharmaceutically acceptable polymeric carrier is selected from the group consisting of N-vinyl lactams, cellulose esters, cellulose ethers, high molecular weight polyalkylene oxides, polyacrylates, polymethacrylates, polyacrylamides, vinyl acetate polymers, graft copolymers of polyethylene glycol, polyvinyl caprolactam and polyvinyl acetate, oligo- and polysaccharides and mixtures thereof, and

wherein the at least one surfactant is selected from the group consisting of polyoxyethylene glycerides, fatty acid monoesters of sorbitan, polysorbates, α-tocopheryl polyethylene glycol succinate (TPGS) and mixtures thereof.

18. The process of Claim 17, wherein the API, polymeric carrier and surfactant are mixed together before said subjecting to elevated temperature.

19. The process of Claim 17, wherein the API, polymeric carrier and surfactant are mixed together while subjecting to elevated temperature.

20. The process of Claim 17, wherein said elevated temperature is about 70°C to about 250°C.

21. The process of Claim 17, wherein said elevated temperature is about 90°C to about 160°C.

22. The process of Claim 17, further comprising calendering the extrudate before or while cooling.

23. The process of Claim 17, wherein API is 4-(4-{[2-(4-chlorophenyl)-4,4-dimethylcyclohex-1-en-1-yl]methyl}piperazin-1-yl)-N-({3-nitro-4-[(tetrahydro-2H-pyran-4-ylmethyl)amino]phenyl}sulfonyl)-2-(1H-pyrrolo[2,3-b]pyridin-5-yloxy)benzamide or a pharmaceutically acceptable salt thereof.

24. The process of Claim 17, wherein the API is 4-(4-{[2-(4-chlorophenyl)-4,4-dimethylcyclohex-1-en-1-yl]methyl}piperazin-1-yl)-N-[(4-{[(trans-4-hydroxy-4-methylcyclohexyl)methyl]amino}-3-nitrophenyl)sulfonyl]-2-(1H-pyrrolo[2,3-b]pyridin-5-yloxy)benzamide.

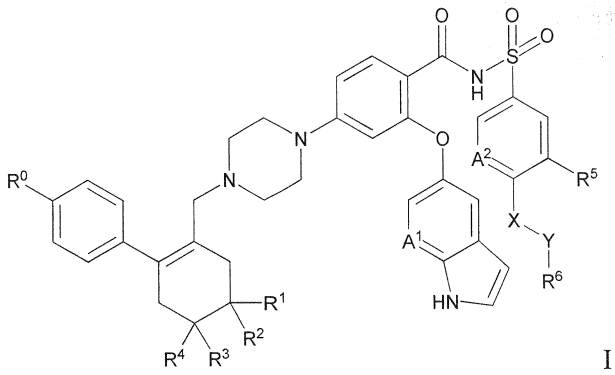
25. The process of Claim 17, wherein the API is 4-(4-{[2-(4-chlorophenyl)-4,4-dimethylcyclohex-1-en-1-yl]methyl}piperazin-1-yl)-N-[(4-{[(cis-4-hydroxy-4-methylcyclohexyl)methyl]amino}-3-nitrophenyl)sulfonyl]-2-(1H-pyrrolo[2,3-b]pyridin-5-yloxy)benzamide.

26. The process of claim 23, wherein the polymeric carrier is a copovidone.

27. The process of Claim 26, wherein the surfactant is a polysorbate.

28. A process for preparing a solid dispersion, comprising:

(a) preparing a melt by subjecting to elevated temperature (i) an active pharmaceutical ingredient (API) that comprises a compound of Formula I



I

where:

R^0 is chloro;

R^1 and R^2 are H;

R^3 and R^4 are methyl;

A^1 is N and A^2 is CH;

R^5 is nitro;

X is –NH–;

Y is $–(CH_2)_n–$ where n is 1; and

R^6 is is selected from the group consisting of tetrahydropyranyl and 4-hydroxy-4-methylcyclohexyl;

or a pharmaceutically acceptable salt thereof, (ii) a pharmaceutically acceptable water-soluble polymeric carrier and (iii) a pharmaceutically acceptable surfactant to provide the melt, wherein the melt comprises an extrudable semi-solid or liquid mixture comprising the API, the pharmaceutically acceptable water-soluble polymeric carrier, and the pharmaceutically acceptable surfactant, and further wherein the elevated temperature is a temperature above a softening point of the pharmaceutically acceptable water-soluble polymeric carrier;

(b) extruding and calendering the melt comprising the semi-solid or liquid mixture to thereby prepare an extrudate; and

(c) cooling the resulting extrudate to provide a solid matrix comprising the polymeric carrier and the surfactant and having the compound or salt thereof dispersed therein, wherein less