What Is Claimed Is:

1. Pirfenidone for use in treating a patient in need of pirfenidone therapy, characterized in that the treating comprises (a) avoiding, contraindicating, discontinuing or using with caution concomitant use or co-administration of a cytochrome P450 1A2 (CYP1A2) inhibitor that is a moderate to strong inhibitor of both (i) cytochrome P450 1A2 (CYP1A2) and (ii) another CYP enzyme selected from the group consisting of CYP3A4, CYP2C9, CYP2C19, CYP2B6 and/or CYP2D6, or (b) using with caution pirfenidone in patients receiving a strong inhibitor of CYP1A2, or (c) using with caution a strong CYP1A2 inhibitor in patients receiving pirfenidone.

2. Use of pirfenidone in preparation of a medicament for treating a patient in need of pirfenidone therapy, characterized in that the treating comprises (a) avoiding, contraindicating, discontinuing or using with caution concomitant use or co-administration of a cytochrome P450 1A2 (CYP1A2) inhibitor that is a moderate to strong inhibitor of both (i) cytochrome P450 1A2 (CYP1A2) and (ii) another CYP enzyme selected from the group consisting of CYP3A4, CYP2C9, CYP2C19, CYP2B6 and/or CYP2D6, or (b) using with caution pirfenidone in patients receiving a strong inhibitor of CYP1A2, or (c) using with caution a strong CYP1A2 inhibitor in patients receiving pirfenidone.

3. A method of administering pirfenidone therapy to a patient in need thereof, comprising administering an effective amount of pirfenidone, and (a) avoiding, contraindicating, discontinuing or using with caution a cytochrome P450 1A2 (CYP1A2) inhibitor that is a moderate to strong inhibitor of both (i) cytochrome P450 1A2 (CYP1A2) and (ii) another CYP enzyme selected from the group consisting of CYP3A4, CYP2C9, CYP2C19, CYP2B6 and/or CYP2D6, or (b) using with caution pirfenidone in patients receiving a strong inhibitor of CYP1A2, or (c) using with caution a strong CYP1A2 inhibitor in patients receiving pirfenidone.

4. The pirfenidone, use or method of any of claims 1-3 wherein the CYP1A2 inhibitor is a moderate to strong inhibitor of CYP1A2 and another CYP enzyme selected from the group consisting of CYP2C9, CYP2C19 and/or CYP2D6.

5. The pirfenidone, use or method of any of claims 1-3 wherein the CYP1A2 inhibitor is a strong CYP1A2 inhibitor.

6 The pirfenidone, use or method of any of claims 1-4 wherein the CYP1A2 inhibitor is discontinued prior to starting pirfenidone therapy to avoid an adverse drug interaction with pirfenidone, or to avoid a reduced clearance of pirfenidone.

7. The pirfenidone of any one of claims 1-6 wherein the CYP1A2 inhibitor is discontinued within 1 month prior to starting pirfenidone therapy.

8. The pirfenidone of any one of claims 1-7 wherein the CYP1A2 inhibitor is discontinued within 2 weeks prior to starting pirfenidone therapy.

9. The pirfenidone, use or method of any of claims 1-4 wherein the CYP1A2 inhibitor is avoided during pirfenidone therapy.

10. The pirfenidone, use or method of any of claims 1-9 wherein the patient is in need of therapy with a CYP1A2 inhibitor.

11. The pirfenidone, use or method of any of claims 1-5 wherein the CYP1A2 inhibitor is used with caution.

12. The pirfenidone of any one of claims 1-11 wherein the patient has idiopathic pulmonary fibrosis (IPF).

13. The pirfenidone of any of claims 1-11 wherein the patient suffers from a disease selected from idiopathic pulmonary fibrosis, pulmonary fibrosis, , idiopathic interstitial pneumonia, autoimmune lung diseases, benign prostate hypertrophy, coronary or myocardial infarction, atrial fibrillation, cerebral infarction, myocardiac fibrosis, musculoskeletal fibrosis, post-surgical adhesions, liver cirrhosis, renal fibrotic disease, fibrotic vascular disease, scleroderma, Hermansky-Pudlak syndrome, neurofibromatosis, Alzheimer's disease, diabetic retinopathy, or skin lesions, lymph node fibrosis associated with HIV, chronic obstructive pulmonary disease (COPD), inflammatory pulmonary fibrosis, rheumatoid arthritis; rheumatoid spondylitis; osteoarthritis; gout, other arthritic conditions; sepsis; septic shock; endotoxic shock; gram-negative sepsis; toxic shock syndrome; myofacial pain syndrome (MPS); Shigellosis; asthma; adult respiratory distress syndrome; inflammatory bowel disease; Crohn's disease; psoriasis; eczema; ulcerative colitis; glomerular nephritis; scleroderma; chronic thyroiditis; Grave's disease; Ormond's disease; autoimmune gastritis; myasthenia gravis; autoimmune hemolytic anemia; autoimmune neutropenia; thrombocytopenia; pancreatic fibrosis; chronic active hepatitis including hepatic fibrosis; acute or chronic renal disease; renal fibrosis; diabetic nephropathy; irritable bowel syndrome; pyresis; restenosis; cerebral malaria; stroke or ischemic injury; neural trauma; Alzheimer's disease; Huntington's disease; Parkinson's disease; acute or chronic pain; allergies, including allergic rhinitis or allergic conjunctivitis; cardiac hypertrophy, chronic heart failure; acute coronary syndrome; cachexia; malaria; leprosy; leishmaniasis; Lyme disease; Reiter's syndrome; acute synoviitis; muscle degeneration, bursitis; tendonitis;

tenosynoviitis; herniated, ruptured, or prolapsed intervertebral disk syndrome; osteopetrosis; thrombosis; silicosis; pulmonary sarcosis; bone resorption diseases, such as osteoporosis or multiple myeloma-related bone disorders; cancer, including but not limited to metastatic breast carcinoma, colorectal carcinoma, malignant melanoma, gastric cancer, or non-small cell lung cancer; graft-versus-host reaction; or auto-immune diseases, such as multiple sclerosis, lupus or fibromyalgia; AIDS or other viral diseases such as Herpes Zoster, Herpes Simplex I or II, influenza virus, Severe Acute Respiratory Syndrome (SARS) or cytomegalovirus; or diabetes mellitus, proliferative disorders (including both benign or malignant hyperplasias), acute myelogenous leukemia, chronic myelogenous leukemia, Kaposi's sarcoma, metastatic melanoma, multiple myeloma, breast cancer, including metastatic breast carcinoma; colorectal. carcinoma; malignant melanoma; gastric cancer; non-small cell lung cancer (NSCLC); bone metastases; pain disorders including neuromuscular pain, headache, cancer pain, dental pain, or arthritis pain; angiogenic disorders including solid tumor angiogenesis, ocular neovascularization, or infantile hemangioma; conditions associated with the cyclooxygenase or lipoxygenase signaling pathways, including conditions associated with prostaglandin endoperoxide synthase-2 (including edema, fever, analgesia, or pain); organ hypoxia; thrombin-induced platelet aggregation; or protozoal diseases.

14. The pirfenidone of any one of claims 1 through 13 wherein the pirfenidone is administered at a total daily dosage of at least 1800 mg.

15. The pirfenidone of any one of claims 1 through 13 wherein the pirfenidone is administered at a total daily dosage of about 2400 mg or 2403 mg.

16. The pirfenidone of any one of claims 1 through 13 wherein 800 or 801 mg of pirfenidone is administered to the patient three times per day, with food.

17. The pirfenidone of any one of claims 1 through 16 wherein the CYP1A2 inhibitor is fluvoxamine.

18. The pirfenidone of any one of claims 1 through 17 wherein the CYP1A2 inhibitor is ciprofloxacin, amiodarone or propafenone.

19. The pirfenidone of any one of claims 1 through 16 wherein the CYP1A2 inhibitor is grapefruit juice.

20. A package or kit comprising (a) pirfenidone, optionally in a container, and (b) a package insert, package label, instructions or other labeling comprising avoiding or discontinuing or contraindicating concomitant use of or co-administration of or using with caution (1) a strong inhibitor of CYP1A2, or (2) a moderate to strong inhibitor of both (i)

CYP1A2 and (ii) another CYP enzyme selected from the group consisting of CYP3A4, CYP2C9, CYP2C19, CYP2B6 and/or CYP2D6, optionally according to any of the embodiments of claims 1-19.

What Is Claimed Is:

1. Use of pirfenidone in the manufacture of a medicament for treating a patient in need of pirfenidone therapy, characterized in that the treating comprises (a) avoiding, contraindicating or discontinuing concomitant use or co-administration of a cytochrome P450 1A2 (CYP1A2) inhibitor that is a moderate to strong inhibitor of both (i) cytochrome P450 1A2 (CYP1A2) and (ii) another CYP enzyme selected from the group consisting of CYP2C9, CYP2C19, CYP2D6 and/or CYP2E1 in a patient receiving pirfenidone, or (b) using with caution pirfenidone in a patient receiving a strong inhibitor of CYP1A2, or (c) avoiding, contraindicating, discontinuing or using with caution a strong CYP1A2 inhibitor in a patient receiving pirfenidone, or (d) avoiding, contraindicating, discontinuing or using with caution a CYP1A2 inhibitor selected from the group consisting of fluvoxamine, enoxacin, ciprofloxacin, amiodarone and propafenone in a patient receiving pirfenidone, or (e) reducing the dose of pirfenidone in patients receiving a strong inhibitor of CYP1A2.

2. The use of claim 1 wherein the CYP1A2 inhibitor is a moderate to strong inhibitor of CYP1A2 and another CYP enzyme selected from the group consisting of CYP2C9, CYP2C19, CYP2D6 and/or CYP2E1.

3. The use of claim 1 wherein the CYP1A2 inhibitor is a strong CYP1A2 inhibitor.

4. The use of any of claims 1-3 wherein the CYP1A2 inhibitor is discontinued prior to starting pirfenidone therapy to avoid an adverse drug interaction with pirfenidone, or to avoid a reduced clearance of pirfenidone.

5. The use of any one of claims 1-4 wherein the CYP1A2 inhibitor is discontinued within 1 month prior to starting pirfenidone therapy.

6. The use of any one of claims 1-5 wherein the CYP1A2 inhibitor is discontinued within 2 weeks prior to starting pirfenidone therapy.

7. The use of any of claims 1-3 wherein the CYP1A2 inhibitor is avoided during pirfenidone therapy.

8. The use of any of claims 1-7 wherein the patient is in need of therapy with a CYP1A2 inhibitor.

9. The use of any of claims 1-3 or 8 wherein the CYP1A2 inhibitor is used with caution.

10. The use of any one of claims 1-9 wherein the pirfenidone is administered at a total daily dosage of about 1800 mg.

11. The use of any one of claims 1-9 wherein the pirfenidone is administered at a total daily dosage of about 2400 mg or 2403 mg.

12. The use of any one of claims 1-9 wherein the CYP1A2 inhibitor is fluvoxamine.

13. The use of any one of claims 1-9 wherein the CYP1A2 inhibitor is enoxacin.

14. The use of any one of claims 1-9 wherein the CYP1A2 inhibitor is ciprofloxacin, amiodarone or propafenone.

15. The use of claim 1(e) wherein the dose of pirfenidone is reduced in a patient receiving a strong inhibitor of CYP1A2.

16. The use of claim 1(e) characterized in that the dose of pirfenidone is reduced to a total daily dose of 801 mg/day in the patient receiving a strong inhibitor of CYP1A2.

17. The use of any one of claims 15-16 wherein the strong inhibitor of CYP1A2 is fluvoxamine.

18. The use of any one of claims 15-16 wherein the strong inhibitor of CYP1A2 is enoxacin.

19. The use of any one of claims 1-18 wherein the patient has idiopathic pulmonary fibrosis (IPF).

20. The use of any of claims 1-18 wherein the patient suffers from a disease selected from idiopathic pulmonary fibrosis, pulmonary fibrosis, idiopathic interstitial pneumonia, autoimmune lung diseases, benign prostate hypertrophy, coronary or

myocardial infarction, atrial fibrillation, cerebral infarction, myocardiac fibrosis, musculoskeletal fibrosis, post-surgical adhesions, liver cirrhosis, renal fibrotic disease, fibrotic vascular disease, scleroderma, Hermansky-Pudlak syndrome, neurofibromatosis, Alzheimer's disease, diabetic retinopathy, or skin lesions, lymph node fibrosis associated with HIV, chronic obstructive pulmonary disease (COPD), inflammatory pulmonary fibrosis, rheumatoid arthritis; rheumatoid spondylitis; osteoarthritis; gout, other arthritic conditions; sepsis; septic shock; endotoxic shock; gram-negative sepsis; toxic shock syndrome; myofacial pain syndrome (MPS); Shigellosis; asthma; adult respiratory distress syndrome; inflammatory bowel disease; Crohn's disease; psoriasis; eczema; ulcerative colitis; glomerular nephritis; scleroderma; chronic thyroiditis; Grave's disease; Ormond's disease; autoimmune gastritis; myasthenia gravis; autoimmune hemolytic anemia; autoimmune neutropenia; thrombocytopenia; pancreatic fibrosis; chronic active hepatitis including hepatic fibrosis; acute or chronic renal disease; renal fibrosis; diabetic nephropathy; irritable bowel syndrome; pyresis; restenosis; cerebral malaria; stroke or ischemic injury; neural trauma; Alzheimer's disease; Huntington's disease; Parkinson's disease; acute or chronic pain; allergies, including allergic rhinitis or allergic conjunctivitis; cardiac hypertrophy, chronic heart failure; acute coronary syndrome; cachexia; malaria; leprosy; leishmaniasis; Lyme disease; Reiter's syndrome; acute synoviitis; muscle degeneration, bursitis; tendonitis; tenosynoviitis; herniated, ruptured, or prolapsed intervertebral disk syndrome; osteopetrosis; thrombosis; silicosis; pulmonary sarcosis; bone resorption diseases, such as osteoporosis or multiple myeloma-related bone disorders; cancer, including but not limited to metastatic breast carcinoma, colorectal carcinoma, malignant melanoma, gastric cancer, or non-small cell lung cancer; graft-versus-host reaction; or auto-immune diseases, such as multiple sclerosis, lupus or fibromyalgia; AIDS or other viral diseases such as Herpes Zoster, Herpes Simplex I or II, influenza virus, Severe Acute Respiratory Syndrome (SARS) or cytomegalovirus; or diabetes mellitus, proliferative disorders (including both benign or malignant hyperplasias), acute myelogenous leukemia, chronic myelogenous leukemia, Kaposi's sarcoma, metastatic melanoma, multiple myeloma, breast cancer, including metastatic breast carcinoma; colorectal. carcinoma; malignant melanoma; gastric cancer; non-small cell lung cancer

(NSCLC); bone metastases; pain disorders including neuromuscular pain, headache, cancer pain, dental pain, or arthritis pain; angiogenic disorders including solid tumor angiogenesis, ocular neovascularization, or infantile hemangioma; conditions associated with the cyclooxygenase or lipoxygenase signaling pathways, including conditions associated with prostaglandin endoperoxide synthase-2 (including edema, fever, analgesia, or pain); organ hypoxia; thrombin-induced platelet aggregation; or protozoal diseases.

21. The use of any one of claims 1-18 wherein the patient is in need of an anti-fibrotic agent.

22. The use of any one of claims 1-18 wherein the patient has pulmonary fibrosis, myocardiac fibrosis, musculoskeletal fibrosis, pancreatic fibrosis, hepatic fibrosis, renal fibrosis, fibrotic vascular disease or scleroderma.

23. The use of any one of claims 1-22 wherein pirfenidone is administered to the patient three times per day, with food.

24. A package or kit for use in treating a patient in need of pirfenidone therapy, comprising (a) pirfenidone, optionally in a container, and (b) a package insert, package label, instructions or other labeling comprising avoiding or discontinuing or contraindicating concomitant use of or co-administration of or using with caution (1) a strong inhibitor of CYP1A2, or (2) a moderate to strong inhibitor of both (i) CYP1A2 and (ii) another CYP enzyme selected from the group consisting of CYP2C9, CYP2C19, CYP2D6, and/or CYP2E1, or (3) a CYP1A2 inhibitor selected from the group consisting of fluvoxamine, enoxacin, ciprofloxacin, amiodarone and propafenone in patients receiving pirfenidone.