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, or 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 CYP2C9, CYP2C19, and/or CYP2D6, or (b) ~~using with caution pirfenidone in patients receiving a strong inhibitor of CYP1A2, or (c)~~ avoiding, contraindicating, or discontinuing ~~or using with caution~~ a strong CYP1A2 inhibitor in patients 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 patients receiving pirfenidone~~ wherein the patient is in need of the CYP1A2 inhibitor.

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, or 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 CYP2C9, CYP2C19, and/or CYP2D6, or (b) ~~using with caution pirfenidone in patients receiving a strong inhibitor of CYP1A2, or (c)~~ avoiding, contraindicating, or discontinuing ~~or using with caution~~ a strong CYP1A2 inhibitor in patients 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 patients receiving pirfenidone~~ wherein the patient is in need of the CYP1A2 inhibitor.

3. The pirfenidone or use of claim 1 or claim 2 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.

4. The pirfenidone or use of claim 1 or claim 2 wherein the CYP1A2 inhibitor is a strong CYP1A2 inhibitor.

5. The pirfenidone or use 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.

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

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

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

~~9. The pirfenidone or use of any of claims 1-8 wherein the patient is in need of therapy with a CYP1A2 inhibitor.~~

~~10~~9. The pirfenidone or use of any of claims ~~1-4~~1-8 wherein the ~~CYP1A2 inhibitor is used with caution~~patient is suffering from a fibrotic condition.

~~11~~10. The pirfenidone or use of any one of claims ~~1-10~~1-9 wherein the patient has idiopathic pulmonary fibrosis (IPF).

~~12~~11. The pirfenidone or use of any of claims ~~1-10~~1-9 wherein the patient suffers from a disease selected from the group consisting of 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,~~ 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; chronic thyroiditis; Grave's disease; Ormond's disease; autoimmune gastritis; myasthenia gravis; autoimmune hemolytic anemia; autoimmune neutropenia; thromboeytopenia;~~ pancreatic fibrosis, ~~;~~ ~~chronic active hepatitis including~~ hepatic fibrosis, ~~;~~ ~~acute or chronic renal disease;~~ and renal fibrosis ~~; diabetic nephropathy; irritable bowel syndrome; pyresis; restenosis; cerebral malaria; stroke or ischemic injury; neural trauma; 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; cancer, including but not limited to metastatic breast carcinoma, colorectal carcinoma, 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, colorectal carcinoma; 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~~.

~~13~~12. The pirfenidone or use of any one of claims ~~1-12~~1-11 wherein the pirfenidone is administered at a total daily dosage of at least 1800 mg.

~~14~~13. The pirfenidone or use of any one of claims ~~1-12~~1-11 wherein the pirfenidone is administered at a total daily dosage of 2400 mg or 2403 mg.

~~15~~14. The pirfenidone or use of any one of claims ~~1-12~~1-11 wherein 800 or 801 mg of pirfenidone is administered to the patient three times per day, with food.

~~16~~15. The pirfenidone or use of any one of claims ~~1-15~~1-14 wherein the CYP1A2 inhibitor is fluvoxamine.

~~17. The pirfenidone or use of any one of claims 1 through 16 wherein the CYP1A2 inhibitor is ciprofloxacin, amiodarone or propafenone.~~

~~18~~16. The pirfenidone or use of any one of claims ~~1-15~~1-14 wherein the CYP1A2 inhibitor is enoxacin.

17. The pirfenidone or use of claim 2 wherein the CYP1A2 inhibitor is amiodarone.

18. The pirfenidone or use of claim 2 wherein the CYP1A2 inbibitor is propafenone.

19. 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, CYP2C9, CYP2C19, and/or CYP2D6, or (3) a CYP1A2 inhibitor selected from the group consisting of fluvoxamine~~,~~ and enoxacin~~, ciprofloxacin, amiodarone and propafenone~~ in patients receiving pirfenidone, optionally according to any of the embodiments of claims 1-18.