What is claimed is:

1. Use of pirfenidone in the manufacture of a medicament for treating a patient ~~who would benefit from pirfenidone administration, optionally a patient with idiopathic pulmonary fibrosis (IPF)~~suffering from fibrosis, said patient having exhibited a Grade 2 abnormality in one or both of alanine transaminase (ALT) and aspartate transaminase (AST) that is greater than 2.5-times and less than or equal to 5-times the upper limit of normal, after pirfenidone administration, wherein (a) said patient is to be administered pirfenidone at doses of at least 1600 mg/day.

~~2. Pirfenidone for use in treating a patient who would benefit from pirfenidone administration, optionally a patient with idiopathic pulmonary fibrosis (IPF), said patient having exhibited a Grade 2 abnormality in one or both of alanine transaminase (ALT) and aspartate transaminase (AST) pirfenidone administration, wherein (a) said patient is to be administered pirfendione at doses of at least 1600 mg/day.~~

2. The use according to claim 1, wherein (a) said patient is administered pirfenidone at doses of 2200 to 2600 mg/day.

3. The use ~~or pirfenidone~~ according to claim 1~~ or claim 2~~, wherein (a) said patient is to be administered pirfenidone at doses of 2400 mg/day or 2403 mg/day.

4. The use according to claim 1~~, or claim 2~~ wherein, prior to step (a), said patient is to be administered pirfenidone at doses lower than 2400 mg/day for a time period.

5. The use ~~or pirfenidone~~ according to claim 1~~ or claim 2~~, wherein, prior to step (a), said patient is to be administered pirfenidone at doses lower than 1600 mg/day for a time period.

~~6. The use or pirfenidone according to any of claims 1-5, wherein, prior to step (a), about 800 mg/day or 801 mg/day pirfenidone is to be administered to said patient for a period of time, optionally about one week, or until the biomarkers of liver function are within normal limits.~~

~~7. The use or pirfenidone according to any of claims 1-6, wherein, prior to step (a), about 600-1000 mg/day is to be administered to said patient for a period of time, optionally about one week, or until the biomarkers of liver function are within normal limits.~~

~~8. The use or pirfenidone according to any of claims 1-7 wherein, prior to step (a), about 800 mg/day or 801 mg/day pirfenidone is to be administered to said patient for a period of time, optionally about one week, or until the biomarkers of liver function are within normal limits, and then about 1600 mg/day or 1602 mg/day pirfenidone is to be administered to said patient for a period of time, optionally about one week, or until the biomarkers of liver function are within normal limits.~~

~~9~~6. The use ~~or pirfenidone~~ according to any of claims 1-~~8~~5, wherein, prior to step (a), administration of pirfenidone is discontinued for a time period~~, optionally about one week, or~~ until the biomarkers of liver function are within normal limits, and then ~~about~~ 800 mg/day or 801 mg/day pirfenidone is administered for a time period~~, optionally about one week or~~ until the biomarkers of liver function are within normal limits, and then ~~about~~ 1600 mg/day or 1602 mg/day pirfenidone is administered for a time period~~, optionally about one week or~~ until the biomarkers of liver function are within normal limits.

~~10~~7. The use ~~or pirfenidone~~ according to any of claims 1-~~9~~ 6 wherein, prior to step (a), pirfenidone is to be discontinued for a period of time~~, optionally about one week, or~~ until the biomarkers of liver function are within normal limits.

~~11~~8. The use ~~or pirfenidone~~ according to any of claims 1-~~10~~7, wherein the pirfenidone is to be administered three times per day with food.

~~12. The use or pirfenidone according to any of claims 1-11 further comprising the step of measuring one or more biomarkers of liver function.~~

~~13~~9. The use ~~or pirfenidone~~ according to any of claims 1-~~12~~8, wherein the patient ~~who would benefit from pirfenidone administration~~suffering from fibrosis suffers from a condition selected from the group consisting of 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, skin lesions~~hepatic fibrosis, pancreatic fibrosis, renal fibrosis, and lymph node fibrosis associated with HIV.

~~14. The use or pirfenidone according to any of claims 1-12, wherein the patient who would benefit from pirfenidone administration suffers from a condition selected from the group consisting of chronic obstructive pulmonary disease (COPD), inflammatory pulmonary fibrosis (IPF), rheumatoid arthritis, rheumatoid spondylitis, osteoarthritis, gout, 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, acute and chronic renal disease, renal fibrosis, irritable bowel syndrome, pyresis, restenosis, cerebral malaria, stroke and ischemic injury, neural trauma, Huntington's disease, Parkinson's disease, acute and chronic pain, allergies, 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, cancer, graft-versus-host reaction; and auto-immune diseases, AIDS, Herpes Zoster, Herpes Simplex I or II, influenza virus, Severe Acute Respiratory Syndrome (SARS), cytomegalovirus, and diabetes mellitus.~~

~~15. The use or pirfenidone according to any of claims 1-12, wherein the patient who would benefit from pirfenidone administration suffers from a fibrosis condition.~~

~~16~~10. The use ~~or pirfenidone~~ according to any of claims 1-~~12 or 15~~8, wherein the patient ~~who would benefit from pirfenidone administration~~suffering from fibrosis suffers from idiopathic pulmonary fibrosis.

~~17. The use or pirfenidone according to any preceding claim, wherein the patient has exhibited an abnormal level of alanine transaminase and/or aspartate transaminase, after pirfenidone administration, and wherein the abnormal level is greater than 2.5 times and less than or equal to 5 times the upper limit of normal.~~