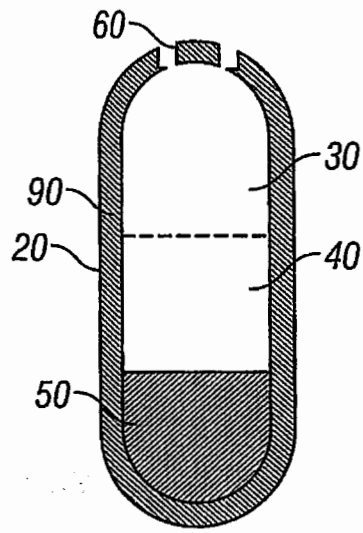

60
30
90
20
40
50

FIG. 1

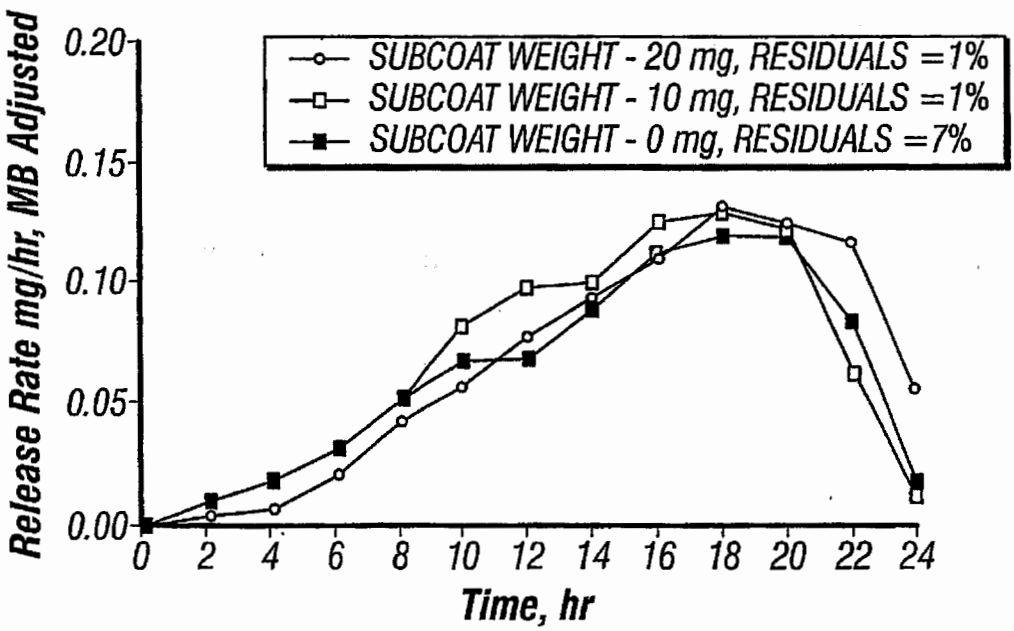

SUBCOAT WEIGHT - 20 mg, RESIDUALS =1%
SUBCOAT WEIGHT - 10 mg, RESIDUALS =1%
SUBCOAT WEIGHT - 0 mg, RESIDUALS =7%
Release Rate mg/hr, MB Adjusted
0.20
0.15
0.10
0.05
0.00
0 2 4 6 8 10 12 14 16 18 20 22 24
Time, hr

FIG. 2

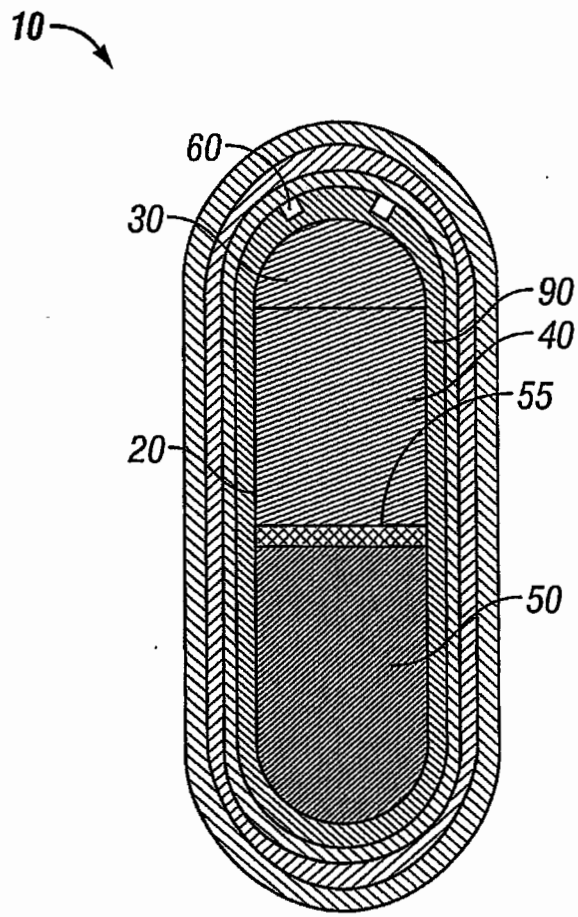

10
60
30
90
40
55
20
50

FIG. 3

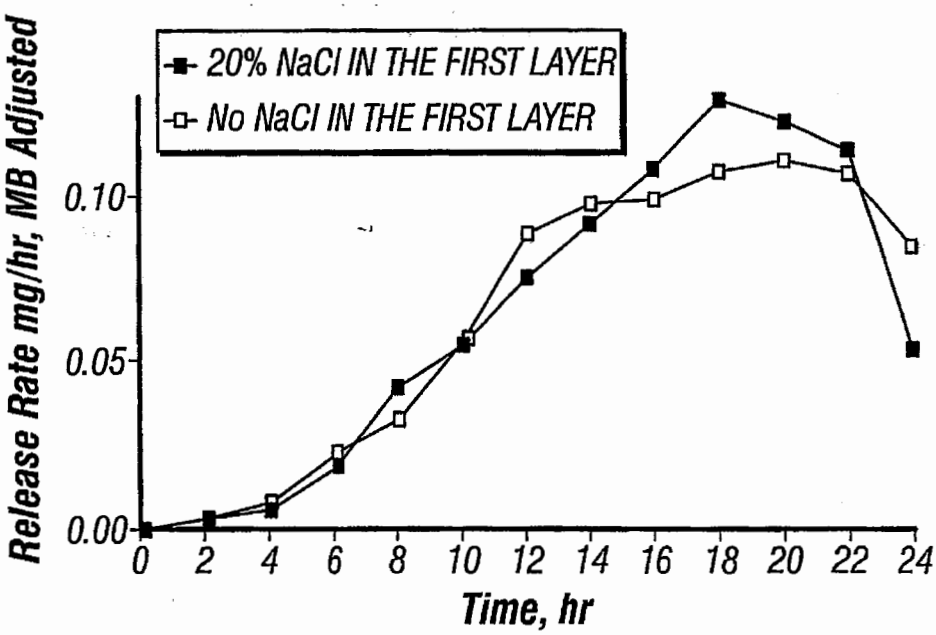

20% NaCl IN THE FIRST LAYER
No NaCl IN THE FIRST LAYER
Release Rate mg/hr, MB Adjusted
0.00
0.05
0.10
0 2 4 6 8 10 12 14 16 18 20 22 24
Time, hr

FIG. 4

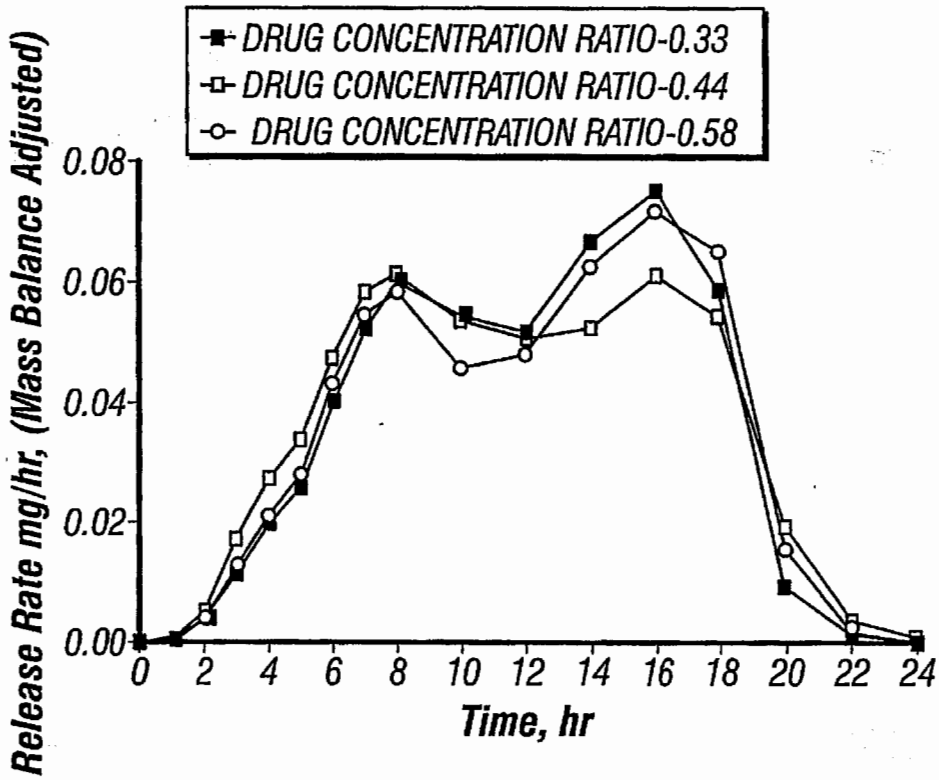

DRUG CONCENTRATION RATIO-0.33
DRUG CONCENTRATION RATIO-0.44
DRUG CONCENTRATION RATIO-0.58
Release Rate mg/hr, (Mass Balance Adjusted)
0.08
0.06
0.04
0.02
0.00
0
2
4
6
8
10
12
14
16
18
20
22
24
Time, hr

FIG. 5

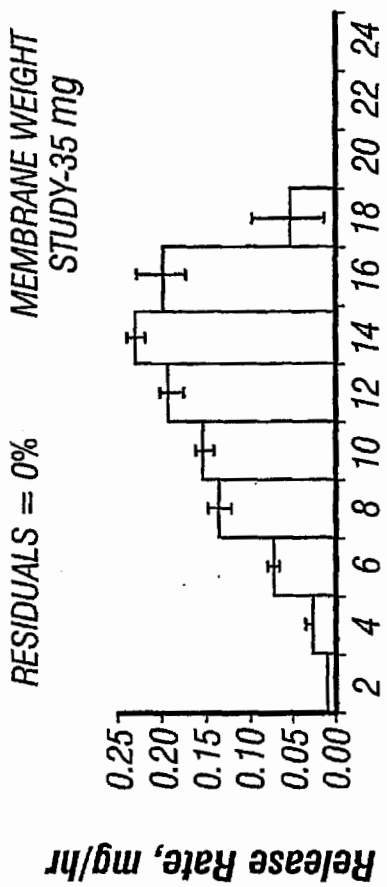



FIG. 6B

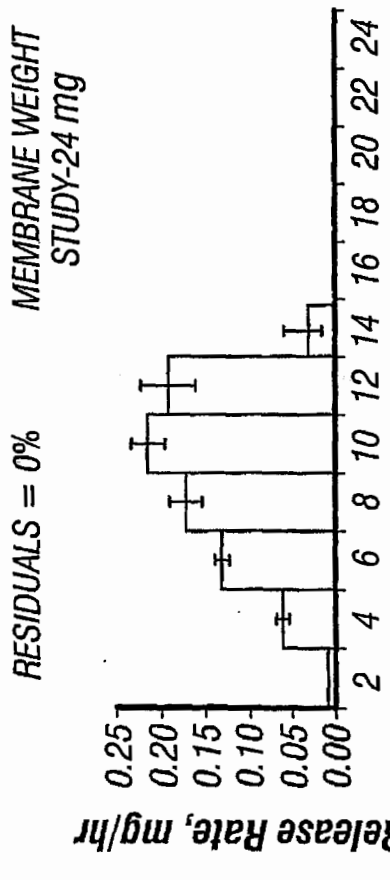



FIG. 6A

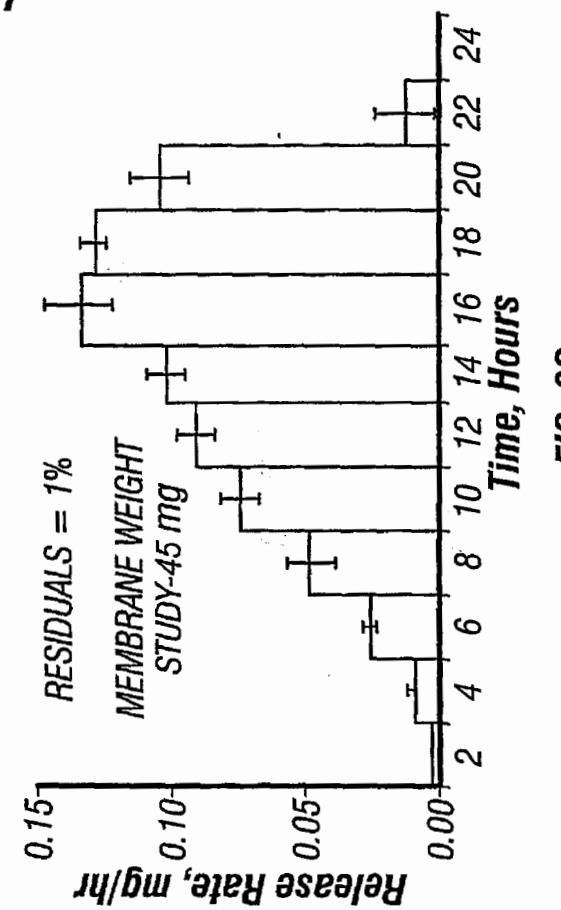



FIG. 6C

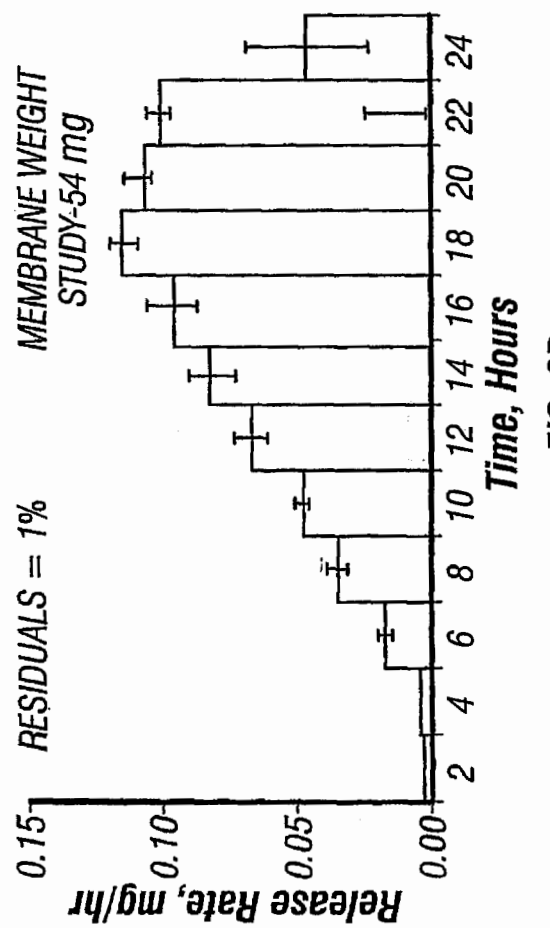



FIG. 6D

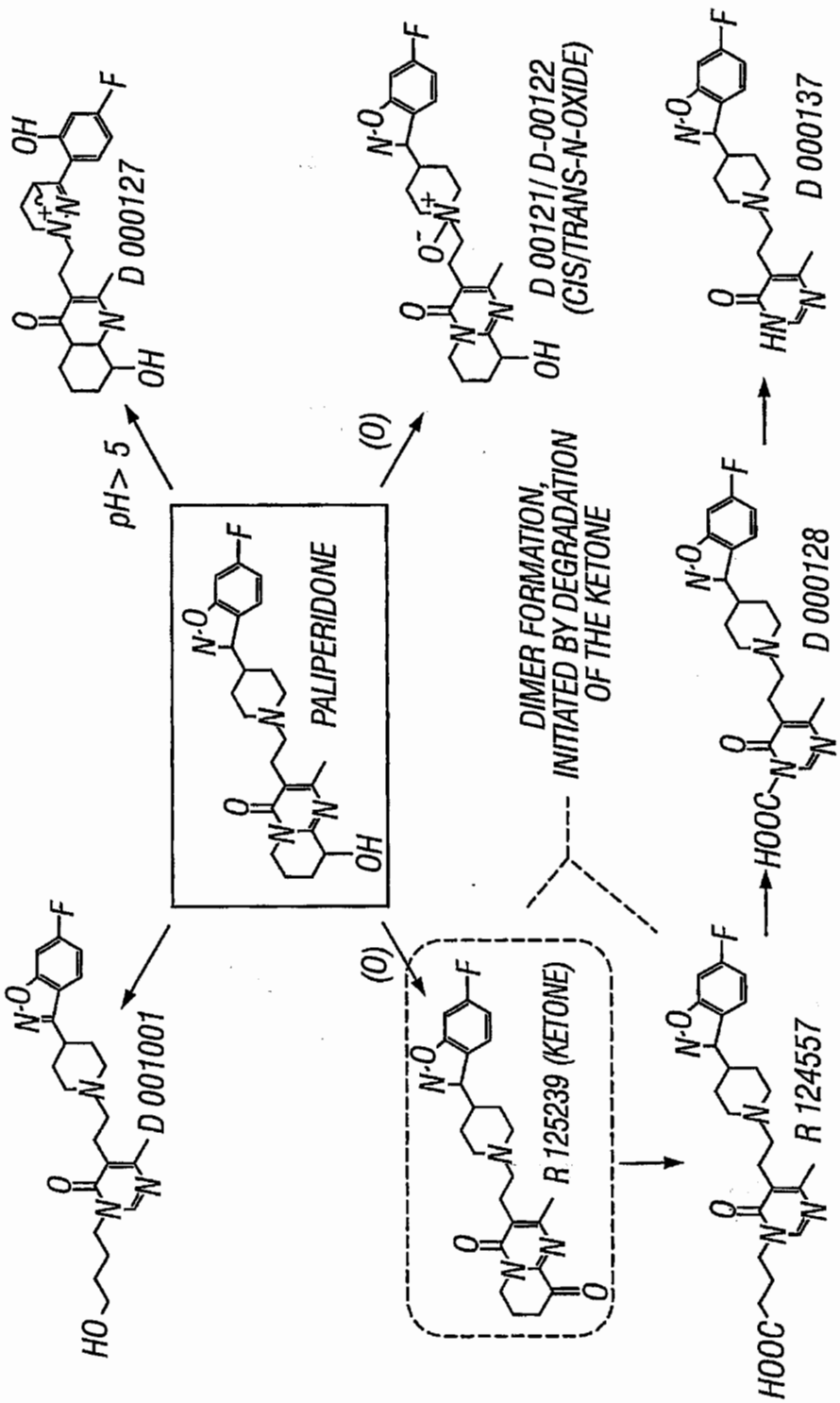

PALIPERIDONE
pH> 5
D 000127
(O)
D 00121/ D-00122
(CIS/TRANS-N-OXIDE)
D 000137
DIMER FORMATION,
INITIATED BY DEGRADATION
OF THE KETONE
D 001001
(O)
R 125239 (KETONE)
D 000128
R 124557

FIG. 7

| | | ACCELERATED STABILITY CONDITIONS | |
|---|---|---|---|
| NON-SUBCOATED SYSTEM | STABILITY TIME POINT | 40°C/75%RH | 50°C/75%RH |
| | T= 0 | 0.66 | 0.66 |
| | 2 WEEKS | 0.82 | 0.92 |
| | 1 MONTH | 0.83 | 1.19 |
| | 2 MONTHS | 1.12 | 1.65 |
| | 3 MONTHS | 1.02 | 2.07 |
| | 4 MONTHS | 1.10 | |
| | | | |
| SUBCOATED SYSTEM | T=0 | 0.68 | 0.68 |
| | 2 WEEKS | 0.77 | 0.79 |
| | 1 MONTH | 0.76 | 0.98 |
| | 2 MONTHS | 0.96 | 1.50 |
| | 3 MONTHS | 0.88 | 1.54 |
| | 4 MONTHS | 0.96 | |

FIG. 8

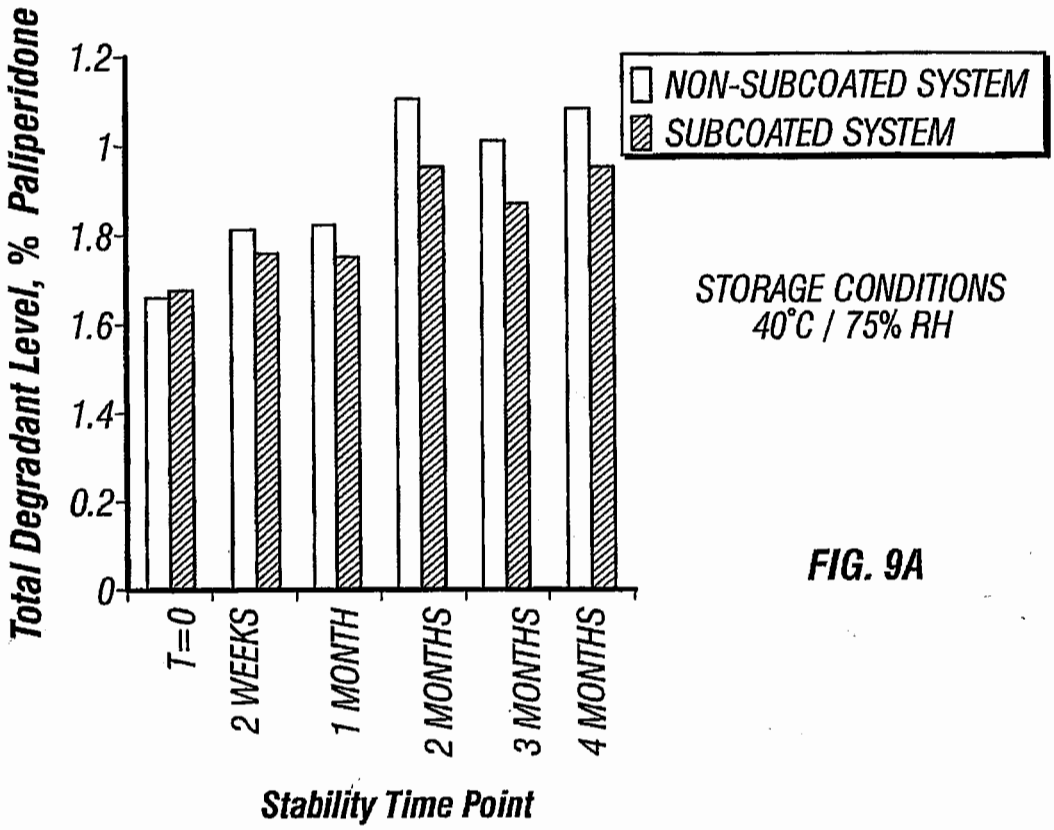

Total Degradant Level, % Paliperidone
1.2
1
1.8
1.6
1.4
0.2
0
T=0
2 WEEKS
1 MONTH
2 MONTHS
3 MONTHS
4 MONTHS
Stability Time Point
NON-SUBCOATED SYSTEM
SUBCOATED SYSTEM
STORAGE CONDITIONS
40°C / 75% RH

FIG. 9A

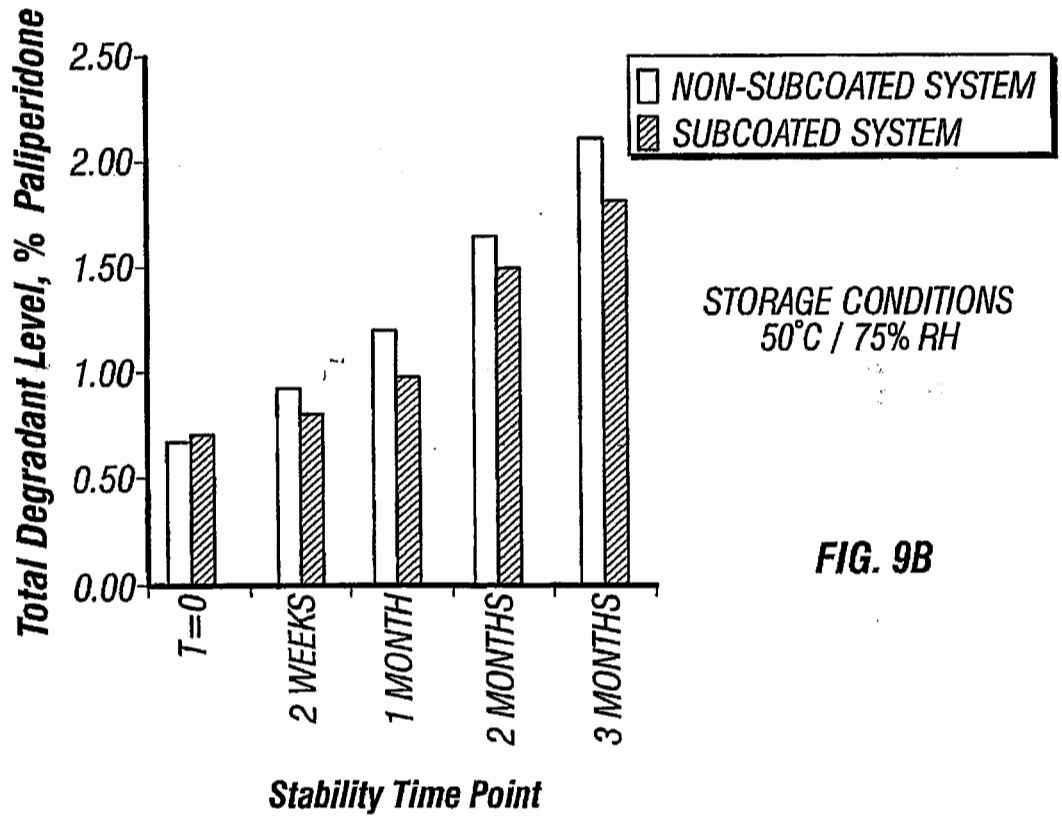

Total Degradant Level, % Paliperidone
2.50
2.00
1.50
1.00
0.50
0.00
T=0
2 WEEKS
1 MONTH
2 MONTHS
3 MONTHS
Stability Time Point
NON-SUBCOATED SYSTEM
SUBCOATED SYSTEM
STORAGE CONDITIONS
50°C / 75% RH

FIG. 9B