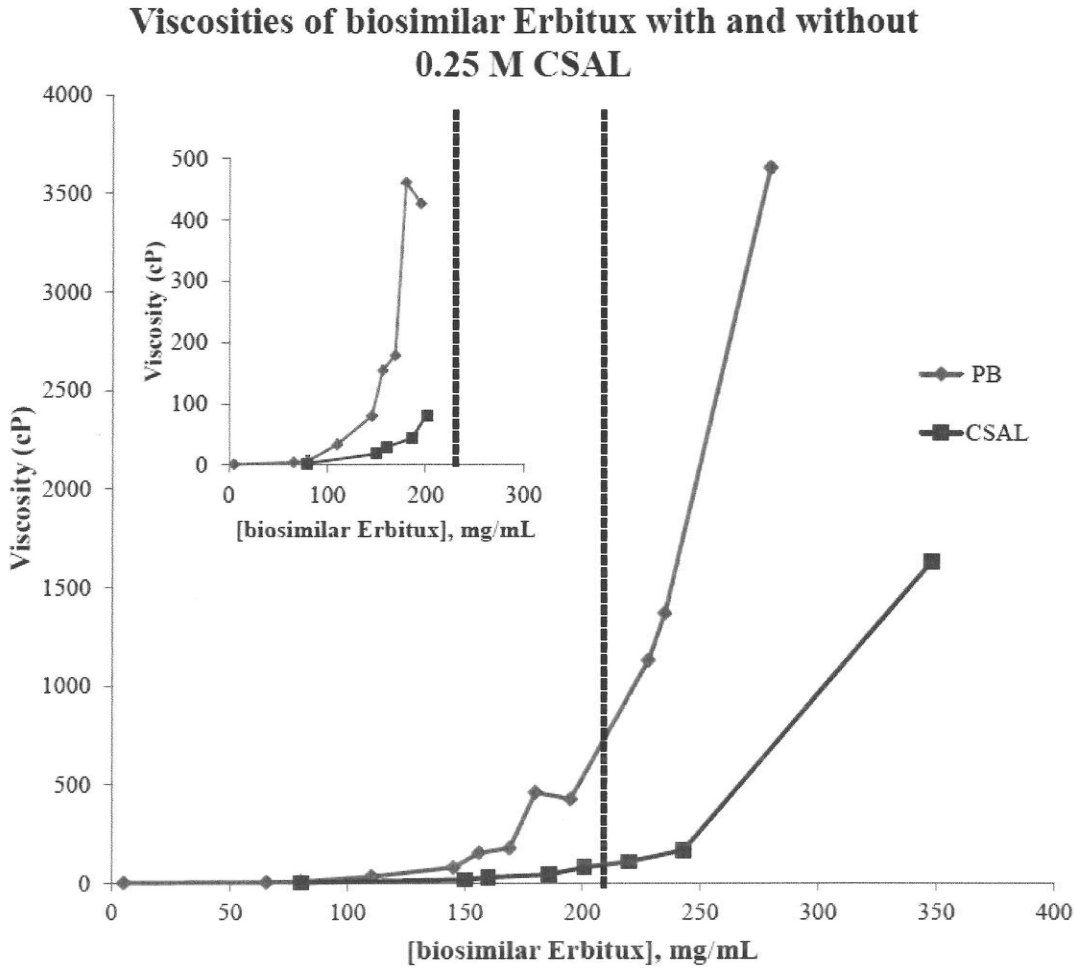
Viscosities of biosimilar Erbitux with and without 0.25 M CSAL
Viscosity (cP)
[biosimilar Erbitux], mg/mL
PB
CSAL
0
500
1000
1500
2000
2500
3000
3500
4000
0
50
100
150
200
250
300
350
400
Viscosity (cP)
[biosimilar Erbitux], mg/mL
0
100
200
300
400
500

FIG. 1

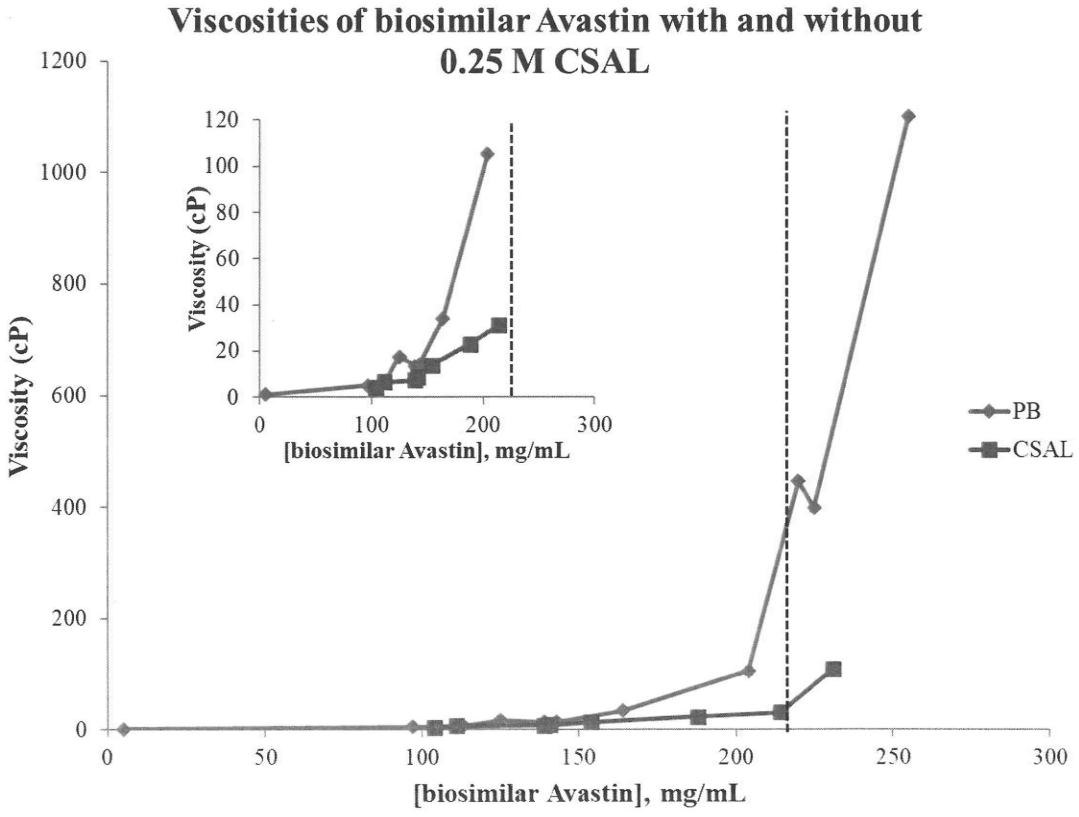
Viscosities of biosimilar Avastin with and without 0.25 M CSAL
Viscosity (cP)
[biosimilar Avastin], mg/mL
PB
CSAL
0
200
400
600
800
1000
1200
0
50
100
150
200
250
300
Viscosity (cP)
[biosimilar Avastin], mg/mL
0
20
40
60
80
100
120

FIG. 2

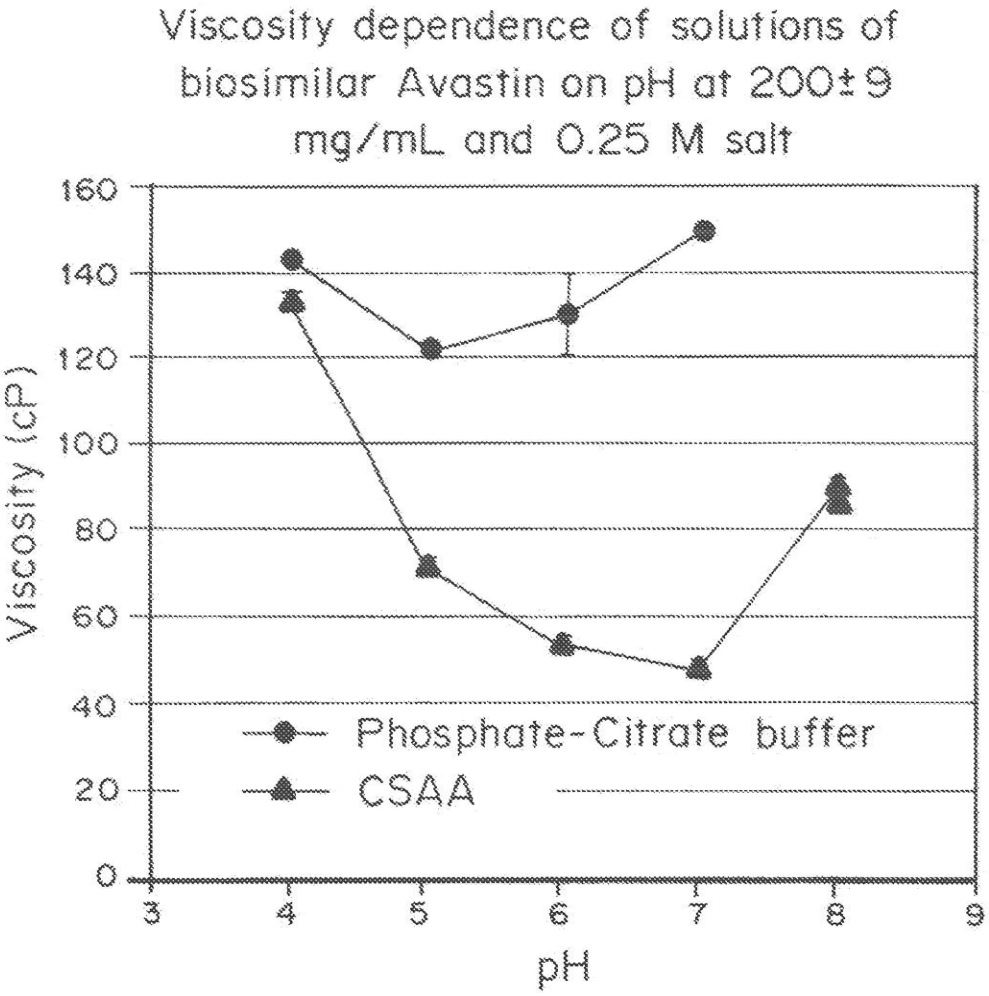
Viscosity dependence of solutions of biosimilar Avastin on pH at 200±9 mg/mL and 0.25 M salt
Viscosity (cP)
160
140
120
100
80
60
40
20
0
3
4
5
6
7
8
9
pH
Phosphate-Citrate buffer
CSAA

FIG. 3

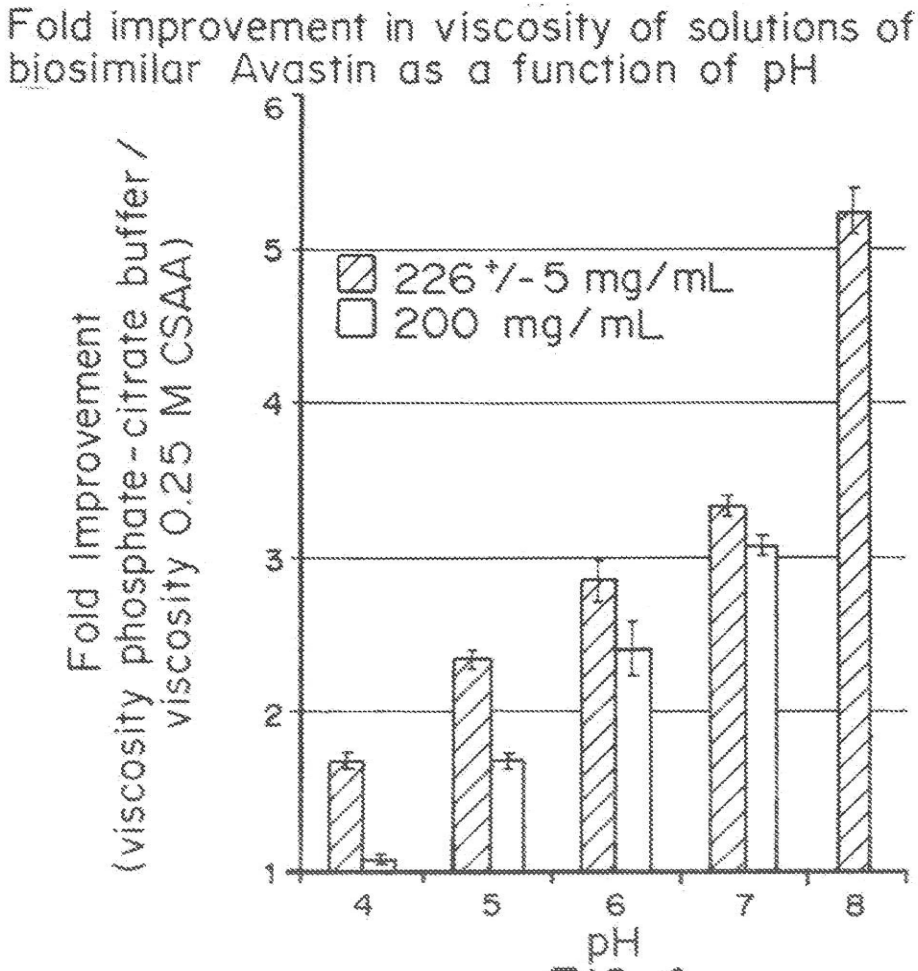
Fold improvement in viscosity of solutions of biosimilar Avastin as a function of pH
Fold Improvement (viscosity phosphate-citrate buffer / viscosity 0.25 M CSAA)
226 +/- 5 mg/mL
200 mg/mL
1
2
3
4
5
6
4
5
6
7
8
pH

FIG. 4

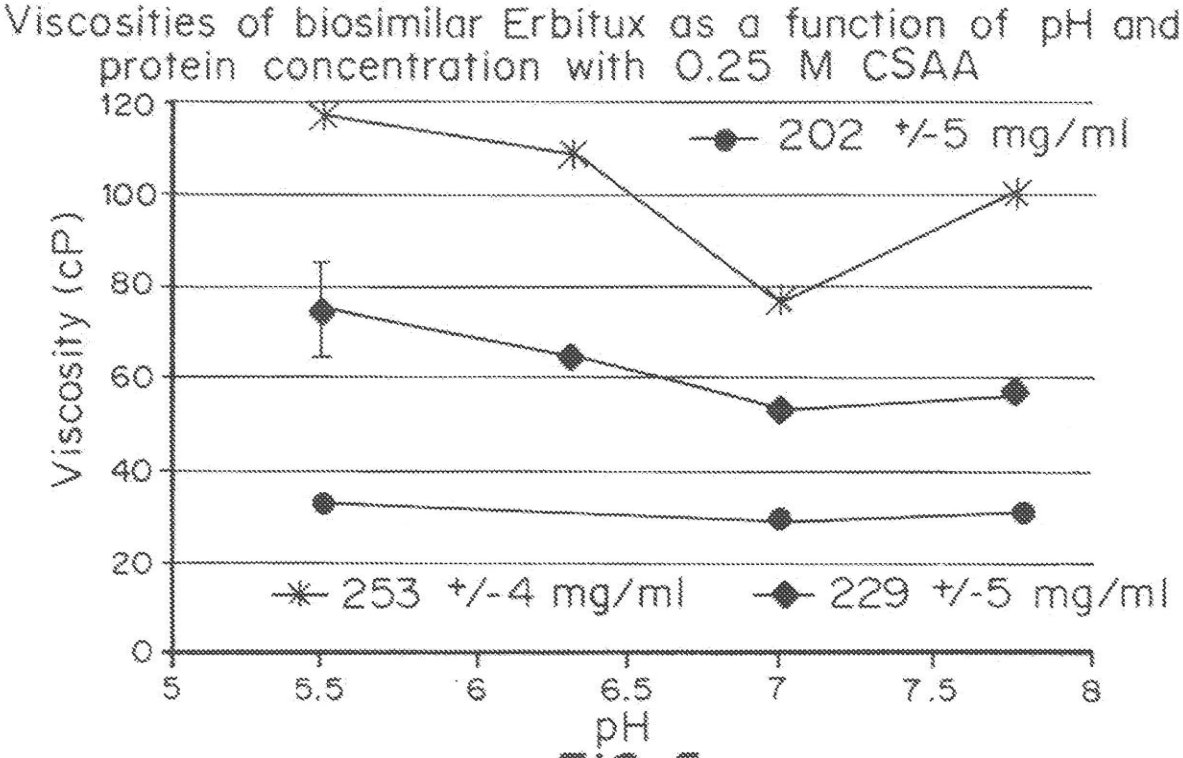
Viscosities of biosimilar Erbitux as a function of pH and protein concentration with 0.25 M CSAA
Viscosity (cP)
120
100
80
60
40
20
0
202 +/-5 mg/ml
253 +/-4 mg/ml
229 +/-5 mg/ml
5
5.5
6
6.5
7
7.5
8
pH

FIG. 5

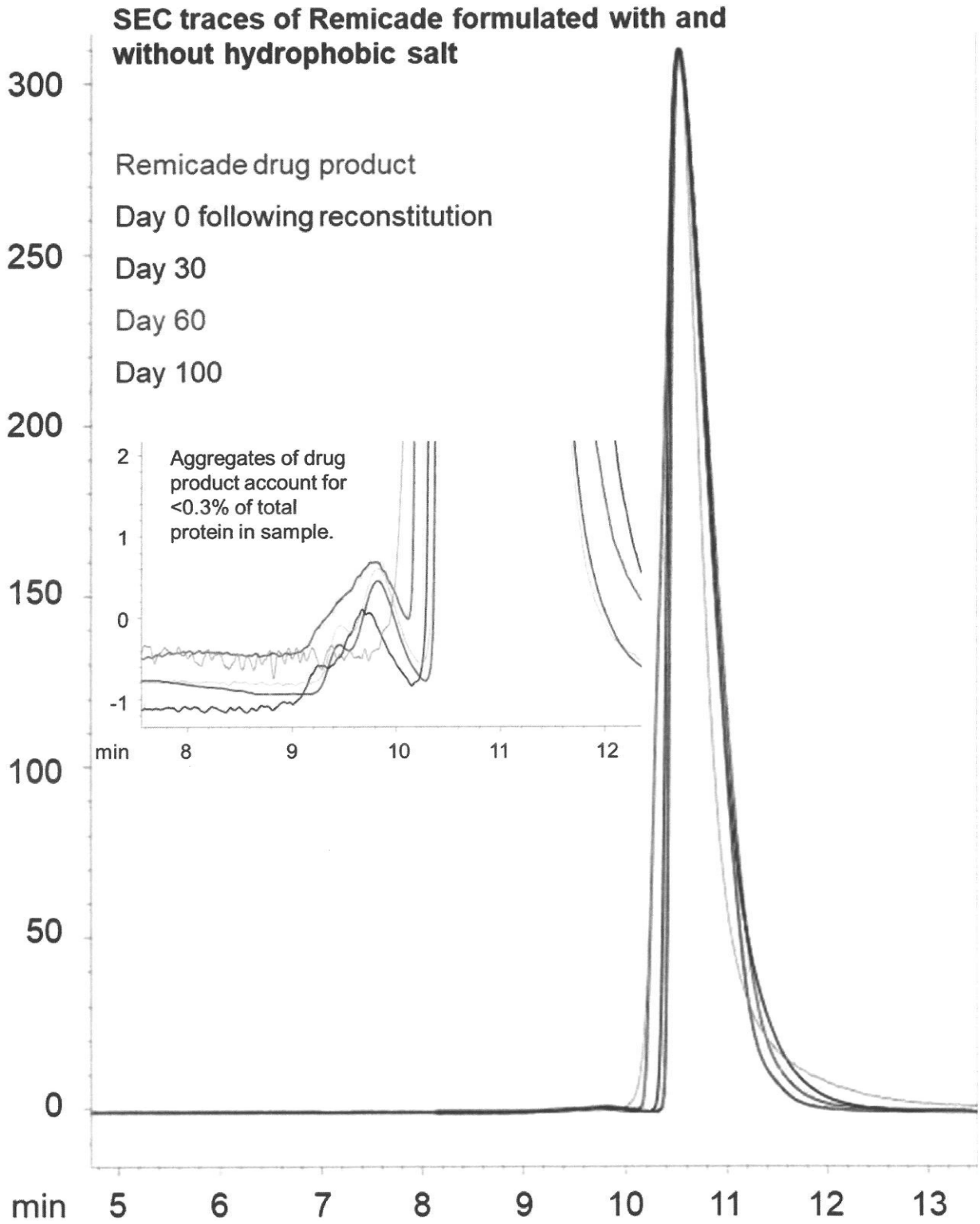
SEC traces of Remicade formulated with and without hydrophobic salt
Remicade drug product
Day 0 following reconstitution
Day 30
Day 60
Day 100
Aggregates of drug product account for <0.3% of total protein in sample.
300
250
200
150
100
50
0
min 5 6 7 8 9 10 11 12 13
2
1
0
-1
min 8 9 10 11 12

FIG. 6

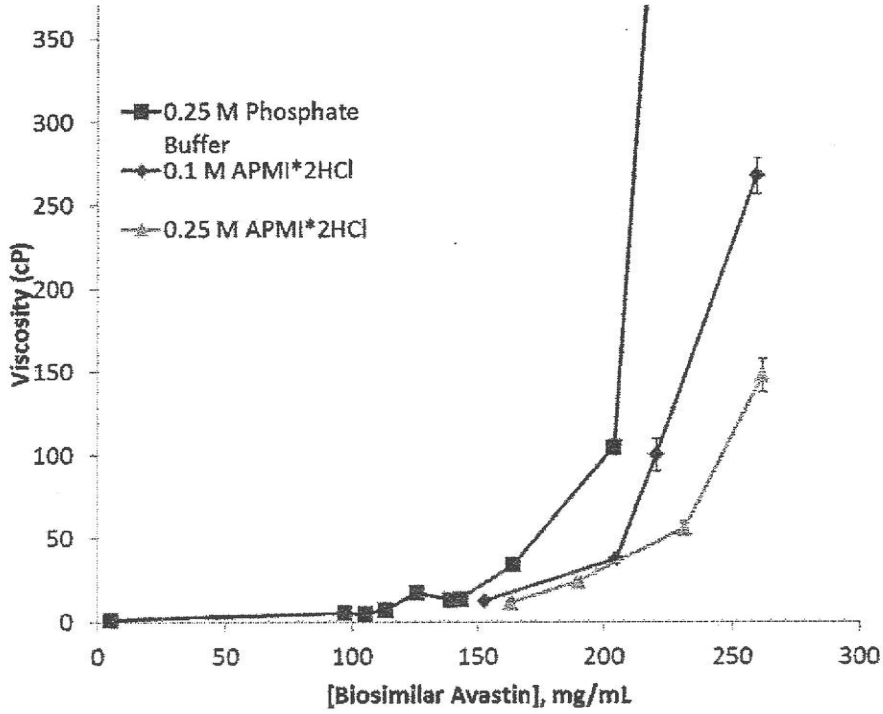
350
300
250
200
150
100
50
0
Viscosity (cP)
0.25 M Phosphate Buffer
0.1 M APMI*2HCl
0.25 M APMI*2HCl
0
50
100
150
200
250
300
[Biosimilar Avastin], mg/mL

FIG. 7

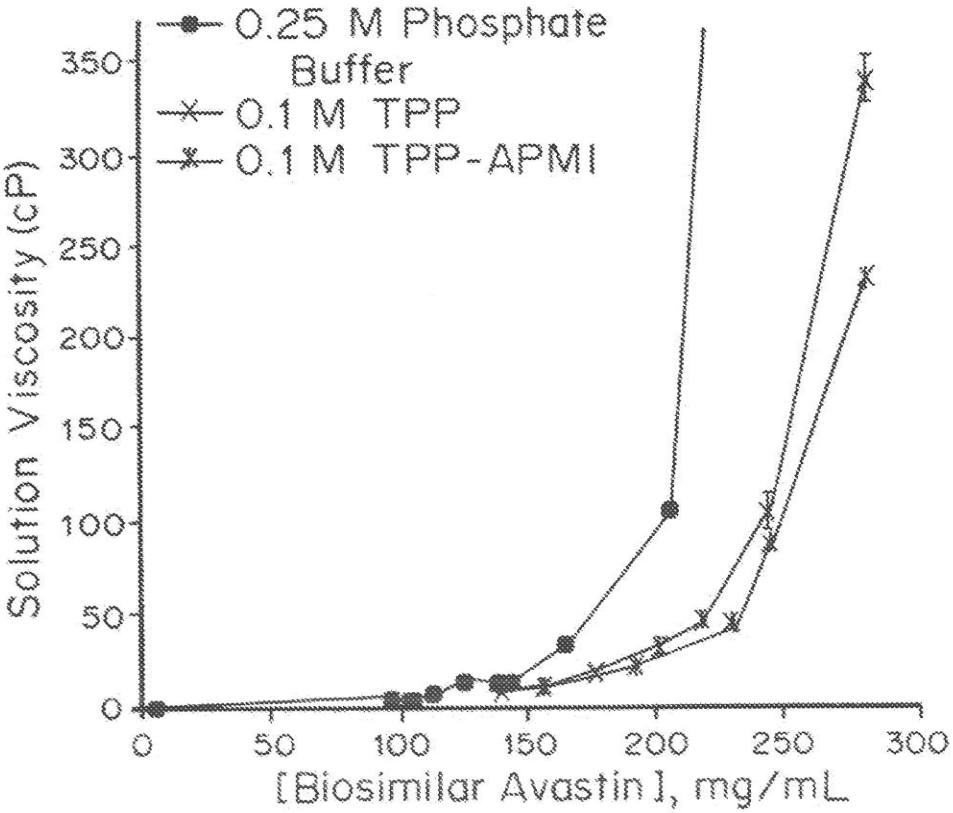
0.25 M Phosphate Buffer
0.1 M TPP
0.1 M TPP-APMI
Solution Viscosity (cP)
0
50
100
150
200
250
300
350
0
50
100
150
200
250
300
[Biosimilar Avastin], mg/mL

FIG. 8

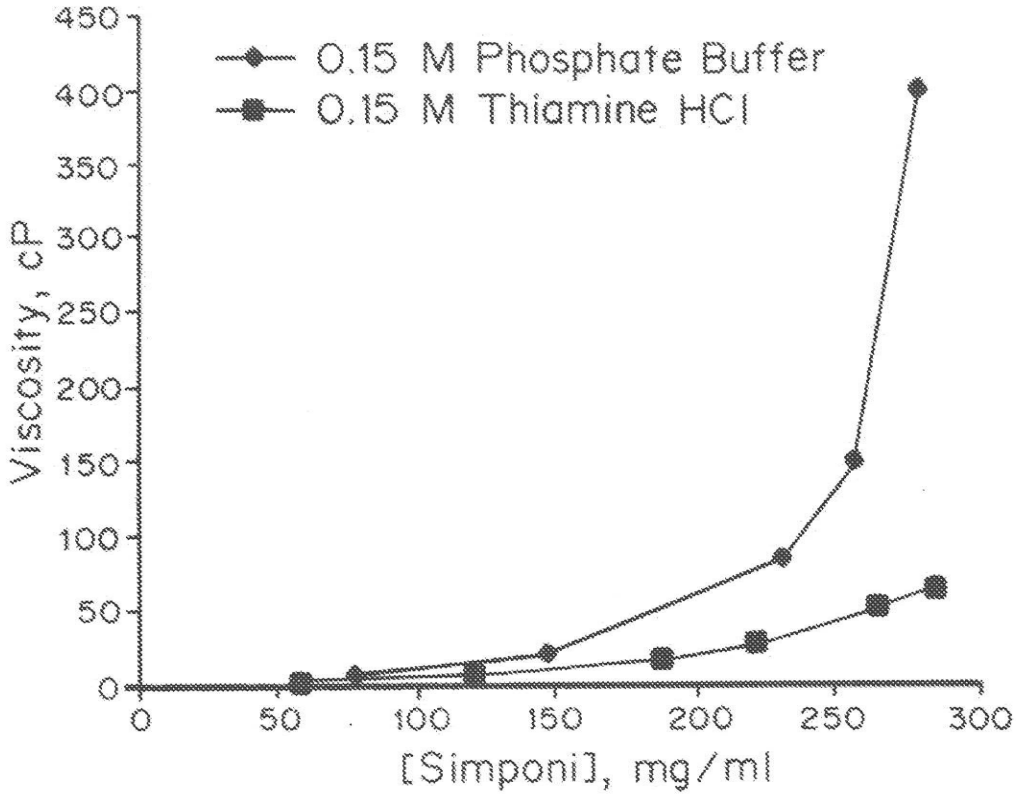
0.15 M Phosphate Buffer
0.15 M Thiamine HCl
Viscosity, cP
0
50
100
150
200
250
300
350
400
450
0
50
100
150
200
250
300
[Simponi], mg/ml

FIG. 9