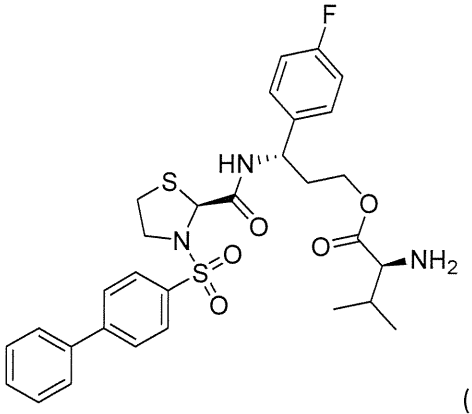
CLAIMS

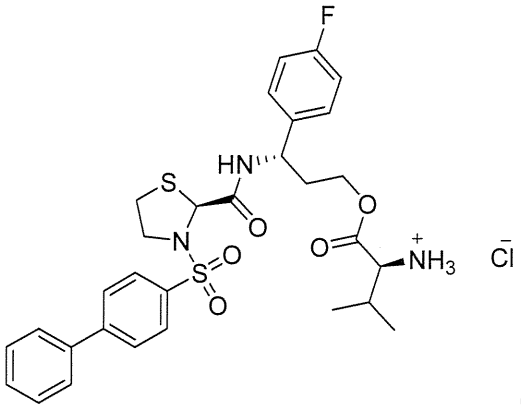
1. A compound represented by formula (**I**)



(**I**)

or a pharmaceutically acceptable salt thereof.

2. The compound of claim 1, wherein the compound is represented by formula (**III**)



(**III**).

3. The compound of claim 2, wherein the compound is in a crystalline state.

4. The compound of claim 3, wherein the compound exhibits characteristic X-ray powder diffraction peaks at about 7.0° 2θ, about 8.1° 2θ, about 10.0° 2θ, about 12.0° 2θ, about 13.1° 2θ, about 14.1° 2θ, about 16.4° 2θ, about 18.4° 2θ, about 20.1° 2θ, about 21.0° 2θ, about 23.5° 2θ, and about 29.5° 2θ.

5. The compound of claim 4, wherein the compound is characterized by an X-ray powder diffraction spectrum substantially as depicted in Figure 49.

6. The compound of claim 3, wherein the compound exhibits ^{1}H nuclear magnetic resonance (NMR) peaks centered at about 1.1 ppm, about 3.3 ppm, about 4.9 ppm, about 5.4 ppm, about 7.1 ppm, about 7.7 ppm, about 7.9 ppm, and about 8.0 ppm.

7. The compound of claim 6, wherein the compound is characterized by a ^{1}H NMR spectrum substantially as depicted in Figure 21.

8. The compound of claim 3, wherein the compound exhibits an endotherm at from about 145° C to about 147° C as measured by differential scanning calorimetry.

9. The compound of claim 8, wherein the compound is characterized by a differential scanning calorimetry curve substantially as depicted in Figure 20 or Figure 23.

10. The compound of claim 3, wherein the compound exhibits a weight loss of from about 0.2% to about 0.6% when heated from 25° C to 100° C as measured by thermogravimetric analysis.

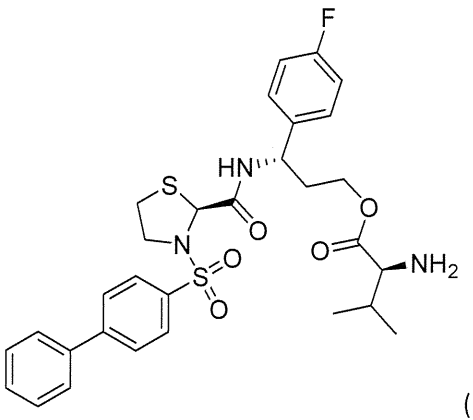
11. The compound of claim 10, wherein the compound exhibits a thermogravimetric analysis curve substantially as depicted in Figure 24.

12. A pharmaceutical composition comprising the compound of claim 1 or 2 and one or more excipients.

13. The pharmaceutical composition of claim 1, wherein the compound is formulated for oral administration to a human patient.

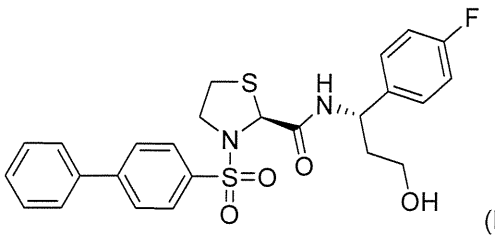
14. The pharmaceutical composition of claim 13, wherein the compound is formulated as a tablet, capsule, gel cap, powder, liquid solution, or liquid suspension.

15. A method of synthesizing a compound represented by formula (**I**),



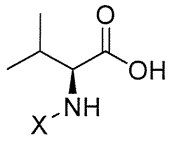
(**I**)

or a pharmaceutically acceptable salt thereof, the method comprising reacting a precursor represented by formula (**IV**)



(**IV**)

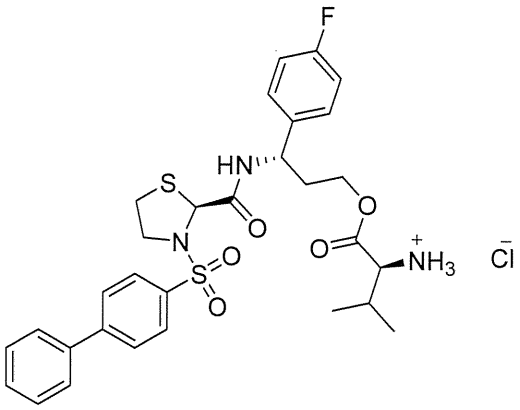
with a precursor represented by formula (**V**)



(**V**)

to form an amino ester, wherein X is a protecting group, and wherein the method further comprises reacting the amino ester with a reagent capable of deprotecting the amino ester.

16. The method of claim 15, wherein the compound is represented by formula (**III**)

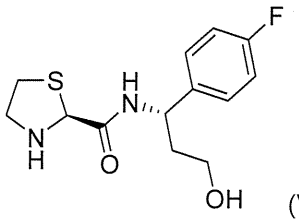


(**III**).

17. The method of claim 15, wherein the protecting group is *tert*-butoxycarbonyl and wherein the reagent is methanesulfonic acid.

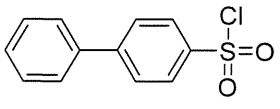
18. The method of claim 15, the method comprising reacting the precursor represented by formula (**IV**) with the precursor represented by formula (**V**), 1-ethyl-3-(3-dimethylaminopropyl)carbodiimide, 1-hydroxybenzotriazole, and *N*,*N*-dimethylaminopyridine.

19. The method of claim 15, the method comprising synthesizing the precursor represented by formula (**IV**) by reacting a precursor represented by formula (**VI**)



(**VI**)

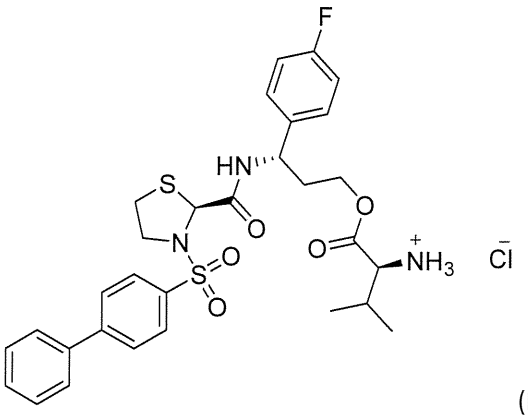
with a precursor represented by formula (**VII**).



(**VII**)

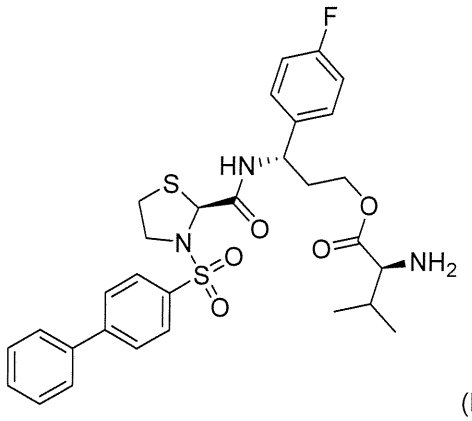
20. The method of claim 19, the method comprising reacting the precursor represented by formula (**VI**) with the precursor represented by formula (**VII**), diisopropylethylamine, and *N*,*N*-dimethylaminopyridine.

21. A method of making a compound represented by formula (**III**) in a crystalline state,



(**III**)

the method comprising mixing a compound represented by formula (**I**)



(I)

with aqueous hydrochloric acid.

22. The method of claim 20, the method comprising:

a) dissolving the compound represented by formula (**I**) in ethanol;

b) mixing the aqueous hydrochloric acid with ethanol and ethyl acetate;

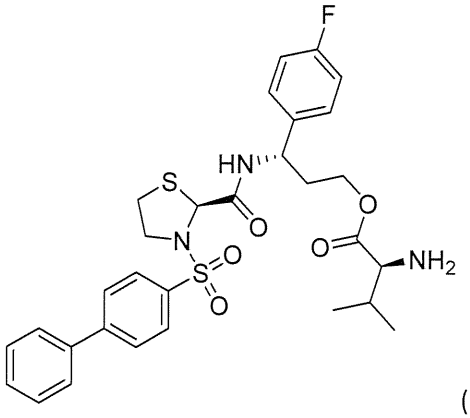
c) adding the compound represented by formula (**I**) to the aqueous hydrochloric acid over a period of from about 20 to about 30 minutes to form a mixture and maintaining the temperature of the mixture at from about 15° C to about 25° C during the adding;

d) reducing the temperature of the mixture to about 5° C following the adding; and

e) stirring the mixture for from about 50 to about 70 minutes at from about 0° C to about 5° C following the reducing.

23. The method of claim 22, wherein the compound represented by formula (**I**) and the aqueous hydrochloric acid are mixed in equimolar amounts.

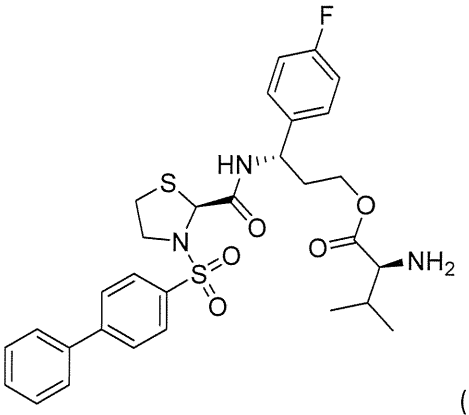
24. A compound represented by formula (**I**),



(I)

or a pharmaceutically acceptable salt thereof, for use in treating or preventing preterm labor in a human patient.

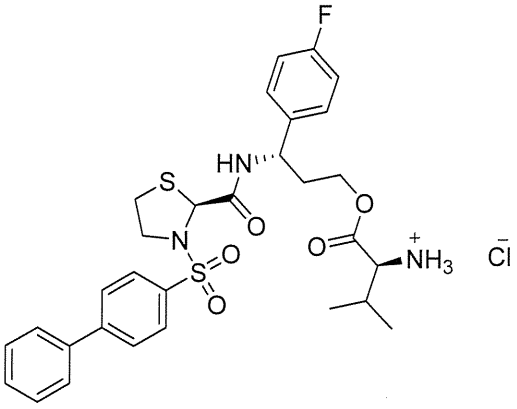
25. A compound represented by formula (**I**),



(**I**)

or a pharmaceutically acceptable salt thereof, for use in preventing labor prior to cesarean delivery in a human patient.

26. The compound of claim 24 or 25, wherein the compound is represented by formula (**III**)



(**III**).

27. The compound of claim 26, wherein the compound is in a crystalline state.

28. The compound of claim 27, wherein the compound exhibits characteristic X-ray powder diffraction peaks at about 7.0° 2θ, about 8.1° 2θ, about 10.0° 2θ, about 12.0° 2θ, about 13.1° 2θ, about 14.1° 2θ, about 16.4° 2θ, about 18.4° 2θ, about 20.1° 2θ, about 21.0° 2θ, about 23.5° 2θ, and about 29.5° 2θ.

29. The compound of claim 28, wherein the compound is characterized by an X-ray powder diffraction spectrum substantially as depicted in Figure 49.

30. The compound of claim 27, wherein the compound exhibits ^{1}H nuclear magnetic resonance (NMR) peaks centered at about 1.1 ppm, about 3.3 ppm, about 4.9 ppm, about 5.4 ppm, about 7.1 ppm, about 7.7 ppm, about 7.9 ppm, and about 8.0 ppm.

31. The compound of claim 30, wherein the compound is characterized by a ^{1}H NMR spectrum substantially as depicted in Figure 21.

32. The compound of claim 27, wherein the compound exhibits an endotherm at from about 145° C to about 147° C as measured by differential scanning calorimetry.

33. The compound of claim 32, wherein the compound is characterized by a differential scanning calorimetry curve substantially as depicted in Figure 20 or Figure 23.

34. The compound of claim 27, wherein the compound exhibits a weight loss of from about 0.2% to about 0.6% when heated from 25° C to 100° C as measured by thermogravimetric analysis.

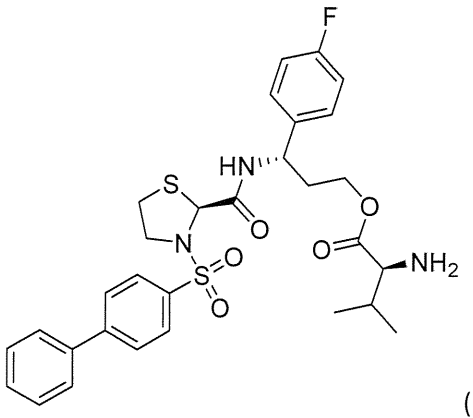
35. The compound of claim 34, wherein the compound exhibits a thermogravimetric analysis curve substantially as depicted in Figure 24.

36. The compound of claim 24 or 25, wherein the patient is characterized by a gestational age of from about 24 weeks to about 34 weeks.

37. The compound of claim 24 or 25, wherein the patient exhibits a reduction in the amplitude of uterine contractions following administration of the compound to the patient.

38. The compound of claim 24 or 25, wherein the compound is formulated for oral administration to the patient.

39. A kit comprising a compound represented by formula (I),

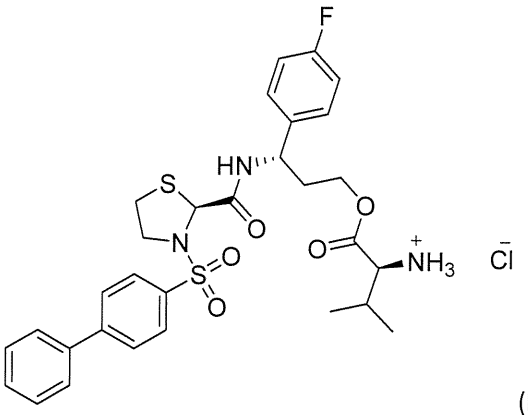


(I)

or a pharmaceutically acceptable salt thereof, and a package insert, wherein the package insert instructs

a user of the kit to administer the compound to a human patient experiencing or at risk of undergoing preterm labor.

40. The kit of claim 39, wherein the compound is represented by formula (**III**)



(**III**).

41. The kit of claim 39 or 40, wherein the patient is characterized by a gestational age of from about 24 weeks to about 34 weeks.

42. The kit of claim 39 or 40, wherein the package insert instructs a user of the kit to orally administer the compound or pharmaceutical composition to the patient.