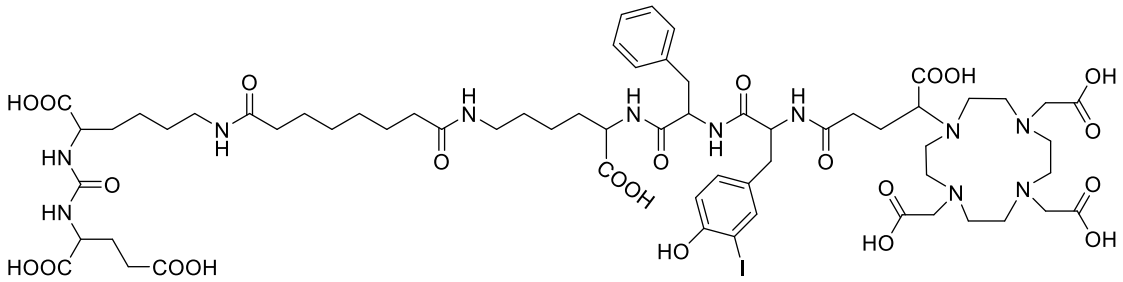
WHAT IS CLAIMED IS:

1. A pharmaceutical composition, comprising:

(a) an ^{225}Ac-radioconjugate or a pharmaceutically acceptable salt thereof,

wherein said ^{225}Ac-radioconjugate comprises ^{225}Ac chelated with a compound of Formula I, or a prodrug thereof:



(I),

wherein the ^{225}Ac-radioconjugate or the pharmaceutically acceptable salt thereof is present in the pharmaceutical composition at a concentration of 1 μg/mL to 100 μg/mL, or in an amount that provides a radioactivity concentration of 10 μCi/mL to 1000 μCi/mL of the pharmaceutical composition;

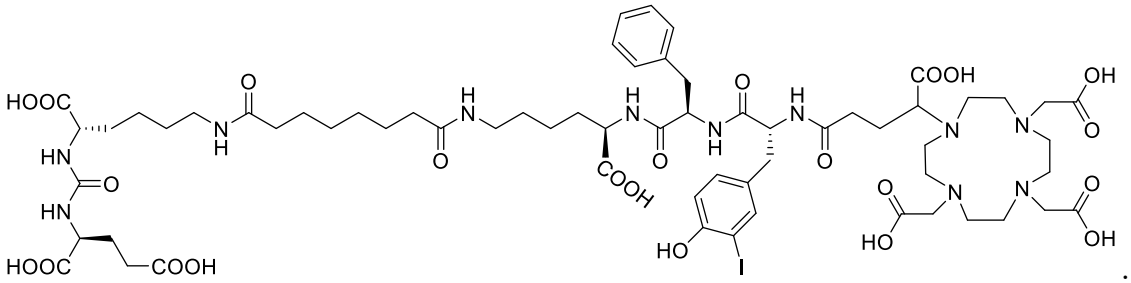
(b) sodium acetate, wherein the sodium acetate is present in the pharmaceutical composition at a concentration of 1 mg/mL to 400 mg/mL,

(c) sodium L-ascorbate, wherein the sodium L-ascorbate is present in the pharmaceutical composition at a concentration of 40 mg/mL to 150 mg/mL; and

(d) diethylenetriamine pentaacetate (DTPA), wherein the DTPA is present in the pharmaceutical composition at a concentration of 5 μg/mL to 60 μg/mL,

wherein the pharmaceutical composition is an aqueous formulation and is free of a gentisate compound.

2. The pharmaceutical composition of claim 1, wherein said ^{225}Ac-radioconjugate comprises ^{225}Ac chelated with the following structure:



3. The pharmaceutical composition of claim 1, wherein the ^{225}Ac-radioconjugate or the pharmaceutically acceptable salt thereof is present in the pharmaceutical composition at a concentration of 7 µg/mL to 9 µg/mL.

4. The pharmaceutical composition of claim 1, wherein the sodium acetate is present in the pharmaceutical composition at a concentration of 6 mg/mL to 10 mg/mL.

5. The pharmaceutical composition of claim 1, wherein the sodium L-ascorbate is present in the pharmaceutical composition at a concentration of about 50 mg/mL.

6. The pharmaceutical composition of claim 1, wherein the DTPA is present in the pharmaceutical composition at a concentration of about 50 µg/mL.

7. The pharmaceutical composition of claim 1, wherein the composition has a pH of between 3 and 9.

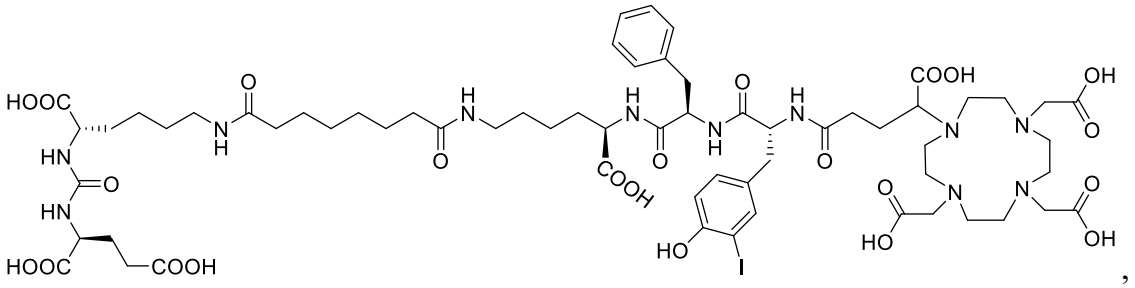
8. The pharmaceutical composition of claim 1, wherein the composition further comprises ethanol, wherein the ethanol is present in the pharmaceutical composition at a concentration of less than 40 mg/mL or 40 mg/mL to 100 mg/mL.

9. The pharmaceutical composition of claim 1, wherein the composition is free of ethanol.

10. The pharmaceutical composition of claim 1, comprising:

(a) ^{225}Ac-radioconjugate or a pharmaceutically acceptable salt thereof,

wherein said ^{225}Ac-radioconjugate comprises ^{225}Ac chelated with the following structure:



,

wherein the ^{225}Ac-radioconjugate or the pharmaceutically acceptable salt thereof is present in the pharmaceutical composition at a concentration of 7-9 µg/mL;

(b) sodium acetate present in the pharmaceutical composition at a concentration of 7-8 mg/mL,

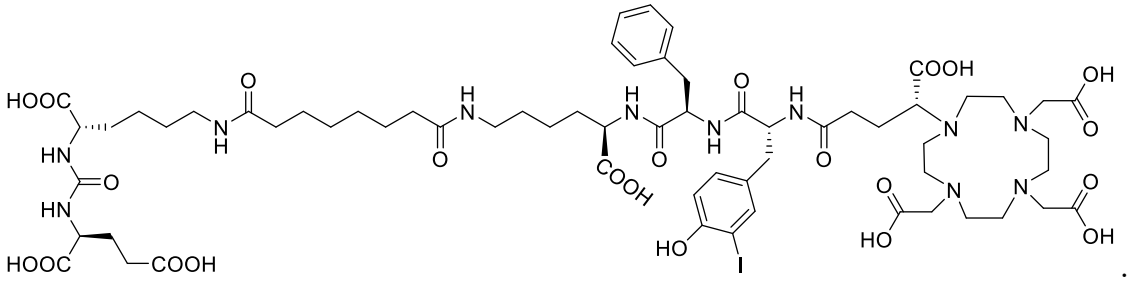
(c) sodium L-ascorbate present in the pharmaceutical composition at a concentration of 51-54 mg/mL; and

(d) diethylenetriamine pentaacetate (DTPA), wherein the DTPA is diethylenetriaminepentaacetic acid pentasodium salt, present in the pharmaceutical composition at a concentration of 51-54 µg/mL.

11. The pharmaceutical composition of claim 1, wherein the pharmaceutical composition retains at least 95% of said ^{225}Ac-radioconjugate or the pharmaceutically acceptable salt thereof after 72 hours at 2 ºC to 25 ºC as determined by radio thin-layer chromatography (radio-TLC).

12. The pharmaceutical composition of claim 11, wherein the pharmaceutical composition retains at least 95% of said ^{225}Ac-radioconjugate or the pharmaceutically acceptable salt thereof after 7-10 days at 2 ºC to 25 ºC as determined by radio-TLC.

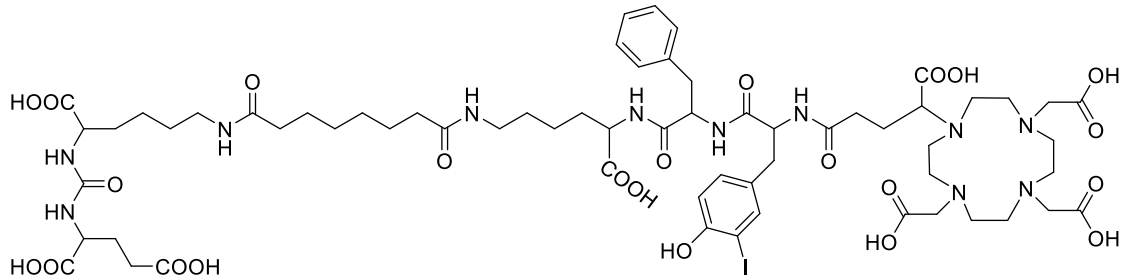
13. The pharmaceutical composition of claim 1, wherein said ^{225}Ac-radioconjugate comprises ^{225}Ac chelated with the following structure:



14. A pharmaceutical composition, consisting essentially of:

(a) an ^{225}Ac-radioconjugate or a pharmaceutically acceptable salt thereof,

wherein said ^{225}Ac-radioconjugate comprises ^{225}Ac chelated with a compound of Formula I, or a prodrug thereof:



(I),

wherein the ^{225}Ac-radioconjugate or the pharmaceutically acceptable salt thereof is present in the pharmaceutical composition at a concentration of 1 μg/mL to 100 μg/mL, or in an amount that provides a radioactivity concentration of 10 μCi/mL to 1000 μCi/mL of the pharmaceutical composition;

(b) sodium acetate, wherein the sodium acetate is present in the pharmaceutical composition at a concentration of 1 mg/mL to 400 mg/mL,

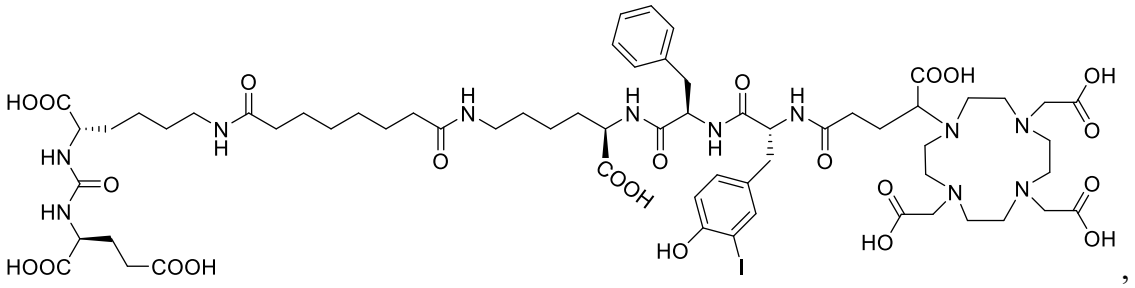
(c) sodium L-ascorbate, wherein the sodium L-ascorbate is present in the pharmaceutical composition at a concentration of 40 mg/mL to 150 mg/mL; and

(d) diethylenetriamine pentaacetate (DTPA), wherein the DTPA is present in the pharmaceutical composition at a concentration of 5 μg/mL to 60 μg/mL,

wherein the pharmaceutical composition is an aqueous formulation and is free of a gentisate compound.

15. The pharmaceutical composition of claim 14, wherein:

(a) said ^{225}Ac-radioconjugate comprises ^{225}Ac chelated with the following structure:



,

wherein the ^{225}Ac-radioconjugate or the pharmaceutically acceptable salt thereof is present in the pharmaceutical composition at a concentration of 7-9 µg/mL;

(b) said sodium acetate is present in the pharmaceutical composition at a concentration of 7-8 mg/mL,

(c) said sodium L-ascorbate is present in the pharmaceutical composition at a concentration of 51-54 mg/mL; and

(d) said DTPA is diethylenetriaminepentaacetic acid pentasodium salt, present in the pharmaceutical composition at a concentration of 51-54 µg/mL.

16. The pharmaceutical composition of claim 1 or 14 for use in treating a patient having cancer expressing Prostate Specific Membrane Antigen (PSMA).

17. The pharmaceutical composition for use of claim 16, wherein the PSMA expressing cancer is selected from the group consisting of prostate cancer, breast cancer, colorectal cancer, renal cell cancer, bladder cancer, testicular cancer, neuroendocrine cancer, and brain tumor.

18. A method for preparing an ^{225}Ac-PSMA I&T composition, comprising:

(a) radiolabeling PSMA I&T with ^{225}Ac in a reaction buffer solution in the absence of a gentisate compound, wherein the reaction buffer solution comprises sodium acetate and sodium L-ascorbate;

(b) heating the mixture from step (a) for a pre-determined time to form a radiolabeled product; and

(c) mixing the radiolabeled product with a formulation buffer solution to form an ^{225}Ac-PSMA I&T composition, wherein the formulation buffer solution comprises sodium L-ascorbate and diethylenetriaminepentaacetic acid pentasodium salt.

19. The method of claim 18, wherein the gentisate compound is gentisic acid.

20. The method of claim 18, wherein the pre-determined time is less than 25 minutes.

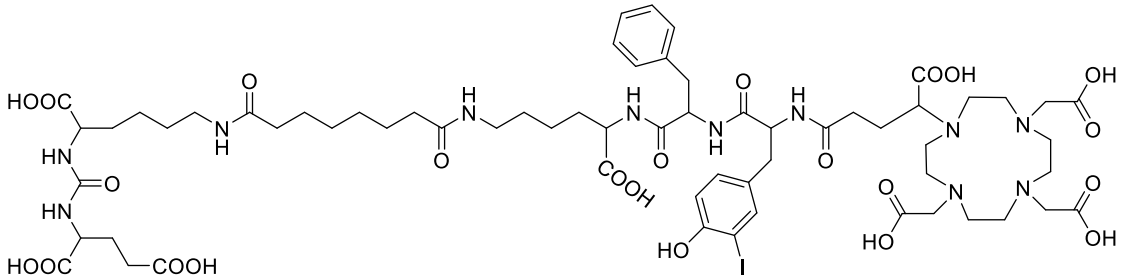
21. The method of claim 18, wherein said ^{225}Ac is reconstituted in an HCl solution having a concentration of less than 0.05 M.

22. The method of claim 18, wherein the ^{225}Ac-PSMA I&T composition is free of a gentisate compound and retains intact at least 99% of ^{225}Ac-PSMA I&T for 7 days or longer at 2 ^{o}C to 8 ^{o}C as determined by radio-TLC.

23. A pharmaceutical composition, comprising:

(b) an ^{225}Ac-radioconjugate or a pharmaceutically acceptable salt thereof,

wherein said ^{225}Ac-radioconjugate comprises ^{225}Ac chelated with a compound of Formula I, or a prodrug thereof:



(I),

wherein the ^{225}Ac-radioconjugate or the pharmaceutically acceptable salt thereof is present in the pharmaceutical composition at a concentration of 1 µg/mL to 100 µg/mL, or in an amount that provides a radioactivity concentration of 10 µCi/mL to 1000 µCi/mL of the pharmaceutical composition;

(b) sodium acetate, wherein the sodium acetate is present in the pharmaceutical composition at a concentration of 1 mg/mL to 400 mg/mL,

(c) sodium L-ascorbate, wherein the sodium L-ascorbate is present in the pharmaceutical composition at a concentration of 40 mg/mL to 150 mg/mL; and

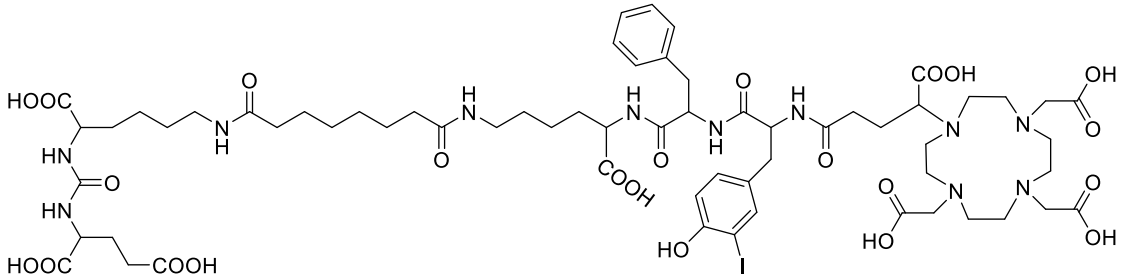
(d) diethylenetriamine pentaacetate (DTPA), wherein the DTPA is present in the pharmaceutical composition at a concentration of 5 µg/mL to 60 µg/mL,

wherein the pharmaceutical composition is an aqueous formulation and is substantially free of a gentisate compound.

24. A pharmaceutical composition, consisting essentially of:

(b) an ^{225}Ac-radioconjugate or a pharmaceutically acceptable salt thereof,

wherein said ^{225}Ac-radioconjugate comprises ^{225}Ac chelated with a compound of Formula I, or a prodrug thereof:



(I),

wherein the ^{225}Ac-radioconjugate or the pharmaceutically acceptable salt thereof is present in the pharmaceutical composition at a concentration of 1 µg/mL to 100 µg/mL, or in an amount that provides a radioactivity concentration of 10 µCi/mL to 1000 µCi/mL of the pharmaceutical composition;

(b) sodium acetate, wherein the sodium acetate is present in the pharmaceutical composition at a concentration of 1 mg/mL to 400 mg/mL,

(c) sodium L-ascorbate, wherein the sodium L-ascorbate is present in the pharmaceutical composition at a concentration of 40 mg/mL to 150 mg/mL; and

(d) diethylenetriamine pentaacetate (DTPA), wherein the DTPA is present in the pharmaceutical composition at a concentration of 5 µg/mL to 60 µg/mL,

wherein the pharmaceutical composition is an aqueous formulation and is substantially free of a gentisate compound.

25. The method of claim 18, wherein the ^{225}Ac-PSMA I&T composition is substantially free of a gentisate compound and retains intact at least 99% of ^{225}Ac-PSMA I&T for 7 days or longer at 2 ºC to 8 ºC as determined by radio-TLC.