WHAT IS CLAIMED IS:

1. A pharmaceutical composition comprising, as an active ingredient, plant cells expressing a high mannose recombinant protein and a pharmaceutically acceptable carrier.

2. A pharmaceutical composition comprising, as an active ingredient, plant cells expressing a recombinant lysosomal enzyme and a pharmaceutically acceptable carrier.

3. The pharmaceutical composition of claim 1 or 2, wherein said plant cells comprise whole plant cells.

4. The pharmaceutical composition of claim 1 or 2, said high mannose recombinant protein or recombinant lysosomal enzyme is attached at an N-terminus thereof to an endoplasmic reticulum signal peptide.

5. The pharmaceutical composition of claim 1 or 4, wherein said high mannose recombinant protein or recombinant lysosomal enzyme is attached to an endoplasmic reticulum retention signal.

6. The pharmaceutical composition of claim 1 or 4, wherein said recombinant lysosomal enzyme is attached to a vacuolar targeting signal.

7. The pharmaceutical composition of claim 6, wherein said vacuolar targeting signal is as set forth in SEQ ID NO: 2.

8. The pharmaceutical composition of claim 1, wherein said high mannose recombinant protein is selected from the group consisting of α-L-iduronidase, acid sphingomyelinase, hexosaminidase, α-N-acetylgalactosaminidise, acid lipase, α-galactosidase, iduronate sulfatase, α-mannosidase and sialidase.

9. The pharmaceutical composition of claim 1, wherein said high mannose recombinant protein is a lysosomal protein.

10. The pharmaceutical composition of claim 1 being lyophilized.

11. The pharmaceutical composition of any of claims 1-10, formulated for oral administration.

12. The pharmaceutical composition of claim 1, wherein said high mannose recombinant protein is a human alpha galactosidase.

13. Use of the pharmaceutical composition of claim 12 for the manufacture of a medicament for treating Fabry disease.

14. The pharmaceutical composition of claim 1, wherein said high mannose recombinant protein is a human iduronate sulfatase.

15. Use of the pharmaceutical composition of claim 14 for the manufacture of a medicament for treating Hunters disease.

16. A recombinant protein comprising an iduronate-2-sulfatase attached to a plant endoplasmic reticulum (ER) signal peptide at an N-terminus thereof.

17. The recombinant protein of claim 16 having a high mannose glycosylation.

18. The recombinant protein of claim 16 or 17, comprising at least one fucose having an alpha (1-3) glycosidic bond and at least one xylose.

19. The recombinant protein of claim 16 being biologically active.

20. The recombinant protein of claim 16 further comprising an ER retention signal.

21. The recombinant protein of claim 20, wherein said ER retention signal is attached at a C terminus thereof.

22. The recombinant protein of claim 16, further comprising a vacuolar targeting signal.

23. The recombinant protein of claim 22, wherein said vacuolar targeting signal is attached at a C terminus thereof.

24. The recombinant protein of claim 23, wherein said vacuolar targeting signal is as set forth in SEQ ID NO: 2.

25. The recombinant protein of claim 16 being isolated.

26. A pharmaceutical composition comprising, as an active ingredient, the recombinant protein of any one of claims 16 to 25 and a pharmaceutically acceptable carrier.

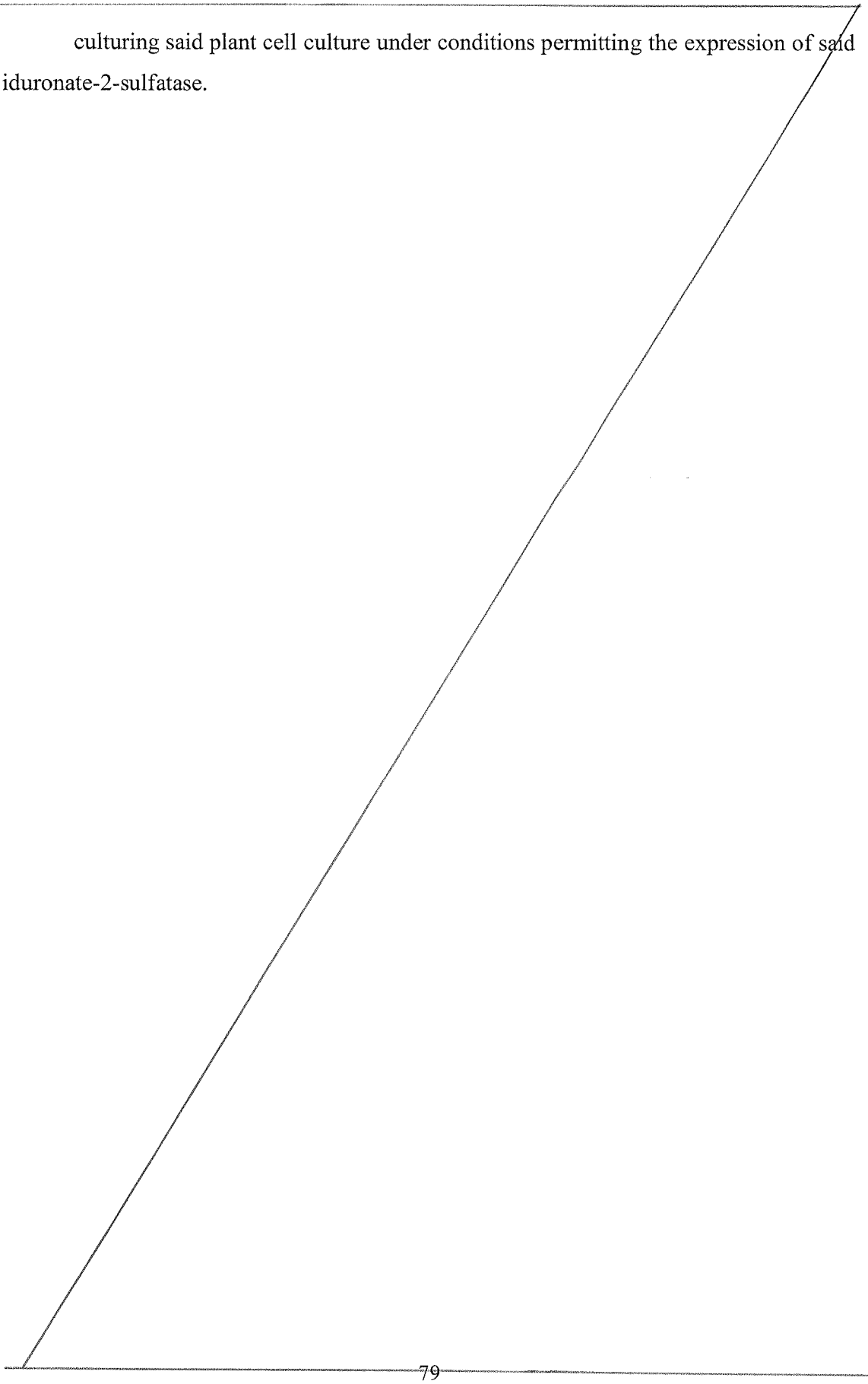
27. Use of the recombinant protein of any one of claims 16 to 25 for the manufacture of a medicament for the treatment of Hunter's syndrome.

28. An isolated nucleic acid sequence encoding the recombinant protein of claim 16.

29. A method of producing the recombinant protein of claim 16 comprising:

preparing a culture of plant cells expressing the human iduronate-2-sulfatase of claim 16; and

culturing said plant cell culture under conditions permitting the expression of said iduronate-2-sulfatase.



WHAT IS CLAIMED IS:

1. Use of lyophilized plant cells expressing a recombinant lysosomal enzyme for the manufacture of a medicament for treatment of a lysosomal storage disease in a subject.

2. A pharmaceutical composition comprising, as an active ingredient, plant cells expressing a recombinant lysosomal enzyme and a pharmaceutically acceptable carrier.

3. The use or pharmaceutical composition of claim 1 or 2, wherein said plant cells comprise whole plant cells.

4. The use or pharmaceutical composition of any one of claims 1-3, wherein said recombinant lysosomal enzyme is attached at an N-terminus thereof to an endoplasmic reticulum signal peptide.

5. The use or pharmaceutical composition of any one of claims 1-4, wherein said recombinant lysosomal enzyme is attached to an endoplasmic reticulum retention signal.

6. The use or pharmaceutical composition of any one of claims 1-5, wherein said recombinant lysosomal enzyme is attached to a vacuolar targeting signal.

7. The use or pharmaceutical composition of claim 4, wherein said vacuolar targeting signal is as set forth in SEQ ID NO: 2.

8. The use or pharmaceutical composition of any one of claims 1-7, wherein said recombinant lysosomal enzyme is selected from the group consisting of human α-L-iduronidase, acid sphingomyelinase, hexosaminidase, α-N-acetylgalactosaminidise, acid lipase, α-galactosidase, iduronate sulfatase, α-mannosidase, glucocerebrosidase and sialidase.

9. The pharmaceutical composition of any one of claims 2-8 wherein said plant cells are lyophilized plant cells.

10. The use or pharmaceutical composition of any one of claims 1-9, wherein said plant cells are formulated for oral administration.

11. The use or pharmaceutical composition of any one of claims 1-10, wherein said plant cells are carrot cells.

12. The use or pharmaceutical composition of claim 11, wherein said carrot cells are carrot cells from suspension culture.

13. The use or pharmaceutical composition of any one of claims 1-12, wherein said recombinant lysosomal enzyme is a human alpha galactosidase.

14. The use of claim 13 wherein said recombinant lysosomal enzyme is a human alpha galactosidase and said lysosomal storage disease is Fabry disease.

15. The use or pharmaceutical composition of any one of claims 1-12, wherein said recombinant lysosomal enzyme is a human iduronate sulfatase.

16. The use of claim 15, wherein said recombinant lysosomal enzyme is a human iduronate sulfatase and said lysosomal storage disease is Hunters disease.

17. The use or pharmaceutical composition of any one of claims 1-12, wherein said recombinant lysosomal enzyme is a human glucocerebrosidase.

18. The use or pharmaceutical composition of claim 17, wherein said human glucocerebrosidase protein comprises a human glucocerebrosidase protein linked at its C terminus to a vacuolar targeting signal peptide.

19. The use or pharmaceutical composition of claim 18, wherein said vacuolar targeting signal peptide as set forth in SEQ ID NO: 2

20. The use or pharmaceutical composition of claim 18, wherein said human glucocerebrosidase comprises the amino acid sequence as set forth in SEQ ID NO: 8 linked at its C terminus to the vacuolar targeting signal peptide as set forth in SEQ ID NO: 2.

21. The use or pharmaceutical composition of claim 17 or 18, wherein said human glucocerebrosidase protein is linked at its N-terminal to an endoplasmic reticulum signal peptide.

22. The use or pharmaceutical composition of claim 21, wherein said endoplasmic reticulum signal peptide is as set forth in SEQ ID NO: 1.

23. The use or pharmaceutical composition of claim 17, wherein said human glucocerebrosidase protein comprises the amino acid sequence as set forth in SEQ ID NO: 14.

24. The use of any one of claims 17-23, wherein said recombinant lysosomal enzyme is human glucocerebrosidase and said lysosomal storage disease is Gaucher's disease.