polytetrafluoroethylene membrane containing therein second inorganic particles having a second nominal particle size; and at least one impermeable layer, wherein at least one of said first polytetrafluoroethylene membrane, said second polytetrafluoroethylene membrane, said first inorganic particles, and said second inorganic particles has covalently bonded thereto an affinity ligand that reversibly binds to a targeted protein or antibody; wherein the at least one impermeable layer is stacked between the first and second polytetrafluoroethylene membrane.

[0003e] In another aspect, the present disclosure refers to a multi-well affinity chromatography device comprising: a plurality of wells; and a wound membrane assembly disposed within each of said wells, said wound membrane assembly comprising: a wound membrane assembly disposed within each of said wells, said wound membrane assembly comprising: at least one polytetrafluoroethylene membrane containing therein inorganic particles having at least one nominal particle size; and at least one impermeable layer, wherein at least one of said polytetrafluoroethylene membrane and said inorganic particles has covalently bonded thereto an affinity ligand that reversibly binds to a targeted protein or antibody, and wherein in cross-section, the wound membrane assembly comprises said polytetrafluoroethylene membrane in an alternating configuration with said impermeable layer.

[0003f] In another aspect, the present disclosure refers to a multi-well affinity chromatography device comprising: a plurality of wells; and a wound membrane assembly disposed within each of said wells, said wound membrane assembly comprising: a first polytetrafluoroethylene membrane containing therein first inorganic particles having a first nominal particle size; a second polytetrafluoroethylene membrane containing therein second inorganic particles having a second nominal particle size; and at least one impermeable layer, wherein at least one of said first polytetrafluoroethylene membrane, said second polytetrafluoroethylene membrane, said first inorganic particles, and said second inorganic particles has covalently bonded thereto an affinity ligand that reversibly binds to a targeted protein or antibody; wherein the at least one impermeable layer is stacked between the first and second polytetrafluoroethylene membrane.

[0003g] In ~~another aspect~~one example, the present disclosure refers to an affinity chromatography device comprising: a housing; an inlet to permit fluid flow into said housing; first and second flow distributors, said first flow distributor and said second flow distributor positioned at opposing ends of said housing; an outlet to permit fluid flow out of said housing, and a wound membrane assembly disposed within said housing, said wound membrane assembly comprising at least one polytetrafluoroethylene membrane containing therein inorganic particles having at

least one nominal particle size, wherein said inorganic particles have both epoxide and aldehyde functional groups attached thereto, and wherein at least one of said epoxide and aldehyde functional groups has bonded thereto an affinity ligand that reversibly binds to a targeted protein or antibody.

[0003h] In another ~~aspect~~example, the present disclosure refers to an affinity chromatography device comprising: a housing; an inlet to permit fluid flow into said housing; first and second flow distributors, said first flow distributor and said second flow distributor positioned at opposing ends of said housing; an outlet to permit fluid flow out of said housing, and a stacked membrane assembly disposed within said housing, said stacked membrane assembly comprising at least one polytetrafluoroethylene membrane containing therein inorganic particles having at least one nominal particle size; wherein said inorganic particles have both epoxide and aldehyde functional groups attached thereto, and wherein at least one of said epoxide and aldehyde said functional group has bonded thereto an affinity ligand that reversibly binds to a targeted protein or antibody.

[0004] One example relates to an affinity chromatography device that includes a housing, a first flow distributor and a second flow distributor positioned at opposing ends of the housing, an inlet to permit fluid flow into the housing, an outlet to permit fluid flow out of the housing, and a wound membrane assembly disposed within the housing. The wound membrane assembly includes (1) at least one polymer membrane containing therein inorganic particles having at least one nominal particle size and (2) at least one impermeable layer. The impermeable layer may include at least one thermoplastic polymer in a solid state. At least one polymer membrane and/or the inorganic particles has covalently bound thereto an affinity

WHAT IS CLAIMED IS:

1. An affinity chromatography device comprising:

a housing;

an inlet to permit fluid flow into said housing;

first and second flow distributors, said first flow distributor and said second flow distributor being positioned at opposing ends of said housing;

an outlet to permit fluid flow out of said housing, and

a wound membrane assembly disposed within said housing, said wound membrane assembly comprising:

at least one polytetrafluoroethylene membrane containing therein inorganic particles having at least one nominal particle size; and

at least one impermeable layer,

wherein at least one of said polytetrafluoroethylene membrane and said inorganic particles has covalently bonded thereto an affinity ligand that reversibly binds to a targeted protein or antibody, and

wherein in cross-section, the wound membrane assembly comprises said polytetrafluoroethylene membrane in an alternating configuration with said impermeable layer.

2. The affinity chromatography device of claim 1, wherein said at least one impermeable layer comprises at least one thermoplastic polymer membrane in a solid state.

3. The affinity chromatography device of claim 1, wherein said inorganic particles are selected from silica particles, zeolite particles, hydroxyapatite particles, metal oxide particles and combinations thereof.

4. The affinity chromatography device of claim 1, wherein said inorganic particles have a single nominal particle size.

5. The affinity chromatography device of claim 1, wherein said inorganic particles comprise a first nominal particle size and a second nominal particle size.

6. The affinity chromatography device of claim 1, wherein said polytetrafluoroethylene membrane comprises first inorganic particles having a first nominal particle size and second inorganic particles having a second nominal particle size.

7. The affinity chromatography device of claim 6, wherein said first and second inorganic particles are of the same particle type.

8. The affinity chromatography device of claim 6, wherein said first and second inorganic particles comprise different particle types.

9. The affinity chromatography device of claim 1, wherein said polytetrafluoroethylene membrane is an expanded polytetrafluoroethylene membrane.

10. The affinity chromatography device of claim 1, wherein said affinity ligand is selected from Protein A, Protein G, Protein L, human Fc receptor protein, antibodies, polysaccharides and combinations thereof.

11. The affinity chromatography device of claim 1, wherein said nominal particle size is selected from about 0.1 microns, about 0.5 microns, about 1 micron, about 5 microns, about 10 microns, about 15 microns, about 20 microns and about 25 microns.

12. The affinity chromatography device of claim 1, wherein in cross-section, the membrane assembly comprises said polytetrafluoroethylene membrane in an alternating configuration with said impermeable membrane.

13. The affinity chromatography device of claim 2, wherein said thermoplastic polymer is selected from polypropylene, polyethylene, fluorinated ethylene propylene and combinations thereof.

14. An affinity chromatography device comprising:
a housing;

an inlet to permit fluid flow into said housing;

first and second flow distributors, said first flow distributor and said second flow distributor positioned at opposing ends of said housing;

an outlet to permit fluid flow out of said housing, and

a wound membrane assembly disposed within said housing, said wound membrane assembly comprising:

a first polytetrafluoroethylene membrane containing therein first inorganic particles having a first nominal particle size;

a second polytetrafluoroethylene membrane containing therein second inorganic particles having a second nominal particle size; and

at least one impermeable layer,

wherein said at least one of said first polytetrafluoroethylene membrane, said second polytetrafluoroethylene membrane, said first inorganic particles, and said second inorganic particles has covalently bonded thereto an affinity ligand that reversibly binds to a targeted protein or antibody,

wherein the at least one impermeable layer is stacked between the first and second polytetrafluoroethylene membrane.

15. The affinity chromatography device of claim 14, wherein said at least one impermeable layer comprises at least one thermoplastic polymer membrane in a solid state.

16. The affinity chromatography device of claim 14, wherein said first and second inorganic particles are selected from silica particles, zeolite particles, hydroxyapatite particles, metal oxide particles and combinations thereof.

17. The affinity chromatography device of claim 14, wherein first and second inorganic particles have a single nominal particle size.

18. The affinity chromatography device of claim 17, wherein said first and second inorganic particles are of the same particle type.

19. The affinity chromatography device of claim 17, wherein said first and second inorganic particles comprise different particle types.

20. The affinity chromatography device of claim 14, wherein first and second inorganic particles have different nominal particle sizes.

21. The affinity chromatography device of claim 20, wherein said first and second inorganic particles are of the same particle type.

22. The affinity chromatography device of claim 20, wherein said first and second inorganic particles comprise different particle types.

23. The affinity chromatography device of claim 14, wherein said first polytetrafluoroethylene membrane comprises first and second inorganic particles having different nominal particle sizes.

24. The affinity chromatography device of claim 14, wherein said second polytetrafluoroethylene membrane further comprises the first inorganic particles having the first nominal particle size.

25. The affinity chromatography device of claim 14, wherein said first polytetrafluoroethylene membrane further comprises third inorganic particles having a third nominal particle size, and

wherein said second polytetrafluoroethylene membrane further comprises fourth inorganic particles having a fourth nominal particle size.

26. The affinity chromatography device of claim 14, wherein said first and second polytetrafluoroethylene r membranes are an expanded polytetrafluoroethylene membrane.

27. The affinity chromatography device of claim 14, wherein said affinity ligand is selected from Protein A, Protein G, Protein L, human Fc receptor protein, antibodies, polysaccharides and combinations thereof.

28. The affinity chromatography device of claim 14, wherein said first nominal particle size and said second nominal particle size are selected from about 0.1

microns, about 0.5 microns, about 1 micron, about 5 microns, about 10 microns, about 15 microns, about 20 microns and about 25 microns.

29. A method for separating a target protein or antibody from an aqueous mixture comprising:

passing an aqueous mixture through a chromatography device comprising:

a housing;

first and second flow distributors, said first flow distributor and said second flow distributor being positioned at opposing ends of said housing; and

a wound membrane assembly disposed within said housing, said wound membrane assembly comprising:

at least one polytetrafluoroethylene membrane containing therein inorganic particles having at least one nominal particle size; and

at least one impermeable layer,

wherein said at least one of said polytetrafluoroethylene membrane and said inorganic particles has covalently bonded thereto an affinity ligand that reversibly binds to a targeted protein or antibody, and

wherein in cross-section, the wound membrane assembly comprises said polytetrafluoroethylene membrane in an alternating configuration with said impermeable layer.

30. The method of claim 29, wherein said at least one impermeable layer comprises at least one thermoplastic polymer membrane in a solid state.

31. A method for separating a target protein or antibody from an aqueous mixture comprising:

passing an aqueous mixture through a chromatography device comprising:

a housing;

first and second flow distributors, said first flow distributor and said second flow distributor being positioned at opposing ends of said housing; and

a wound membrane assembly disposed within said housing, wound membrane assembly comprising:

a first polytetrafluoroethylene membrane containing therein first inorganic particles having a first nominal particle size;

a second polytetrafluoroethylene membrane containing therein second inorganic particles having a second nominal particle size; and

at least one impermeable layer,

wherein at least one of said first polytetrafluoroethylene membrane, said second polytetrafluoroethylene membrane, said first inorganic particles, and said second inorganic particles has covalently bonded thereto an affinity ligand that reversibly binds to a targeted protein or antibody;

wherein the at least one impermeable layer is stacked between the first and second polytetrafluoroethylene membrane.

32. The method of claim 31, wherein said at least one impermeable layer comprises at least one thermoplastic polymer membrane in a solid state.

33. A multi-well affinity chromatography device comprising:

a plurality of wells; and

a wound membrane assembly disposed within each of said wells, said wound membrane assembly comprising:

a wound membrane assembly disposed within each of said wells, said wound membrane assembly comprising:

at least one polytetrafluoroethylene membrane containing therein inorganic particles having at least one nominal particle size; and

at least one impermeable layer,

wherein at least one of said polytetrafluoroethylene membrane and said inorganic particles has covalently bonded thereto an affinity ligand that reversibly binds to a targeted protein or antibody, and

wherein in cross-section, the wound membrane assembly comprises said polytetrafluoroethylene membrane in an alternating configuration with said impermeable layer.

34. The multi-well affinity chromatography device of claim 33, wherein said at least one impermeable layer comprises at least one thermoplastic polymer membrane in a solid state.

35. A multi-well affinity chromatography device comprising:

a plurality of wells; and

a wound membrane assembly disposed within each of said wells, said wound membrane assembly comprising:

a first polytetrafluoroethylene membrane containing therein first inorganic particles having a first nominal particle size;

a second polytetrafluoroethylene membrane containing therein second inorganic particles having a second nominal particle size; and

at least one impermeable layer,

wherein at least one of said first polytetrafluoroethylene membrane, said second polytetrafluoroethylene membrane, said first inorganic particles, and said second inorganic particles has covalently bonded thereto an affinity ligand that reversibly binds to a targeted protein or antibody;

wherein the at least one impermeable layer is stacked between the first and second polytetrafluoroethylene membrane.

36. The multi-well affinity chromatography device of claim 35, wherein said at least one impermeable layer comprises at least one thermoplastic polymer membrane in a solid state.

~~37. An affinity chromatography device comprising:~~

~~a housing;~~

~~an inlet to permit fluid flow into said housing;~~

~~first and second flow distributors, said first flow distributor and said second flow distributor positioned at opposing ends of said housing;~~

~~an outlet to permit fluid flow out of said housing, and~~

~~a wound membrane assembly disposed within said housing, said wound membrane assembly comprising at least one polytetrafluoroethylene membrane containing therein inorganic particles having at least one nominal particle size,~~

~~wherein said inorganic particles have both epoxide and aldehyde functional groups attached thereto, and~~

~~wherein at least one of said epoxide and aldehyde functional groups has bonded thereto an affinity ligand that reversibly binds to a targeted protein or antibody.~~

38. The affinity chromatography device of claim 37, wherein the wound membrane assembly further comprises at least one impermeable layer, and wherein in cross-section, the wound membrane assembly comprises said polytetrafluoroethylene membrane in an alternating configuration with said impermeable layer.

39. The affinity chromatography device of claim 37, wherein said at least one impermeable layer comprises at least one thermoplastic polymer membrane in a solid state.

40. An affinity chromatography device comprising:

a housing;

an inlet to permit fluid flow into said housing;

first and second flow distributors, said first flow distributor and said second flow distributor positioned at opposing ends of said housing;

an outlet to permit fluid flow out of said housing, and

a stacked membrane assembly disposed within said housing, said stacked membrane assembly comprising at least one polytetrafluoroethylene membrane containing therein inorganic particles having at least one nominal particle size;

wherein said inorganic particles have both epoxide and aldehyde functional groups attached thereto, and

wherein at least one of said epoxide and aldehyde said functional group has bonded thereto an affinity ligand that reversibly binds to a targeted protein or antibody.

41. The affinity chromatography device of any one of claims 1-28 or 37-40 or the multi-well affinity chromatography device of any one of claims 33-36, wherein when the affinity ligands comprise Fc binding proteins, the affinity chromatography device is configured to provide a dynamic binding capacity of at least 30 mg/ml at 10% breakthrough at a residence time of 20 seconds or less.

42. The affinity chromatography device of any one of claims 1-28 or 37-40 or the multi-well affinity chromatography device of any one of claims 33-36, wherein when the affinity ligands comprise at least one of antibodies, non-Fc binding proteins, or

~~polysaccharides, the device is configured to provide a dynamic binding capacity of at least 0.7 μmol/ml, at 10% breakthrough, and at a residence time of 20 seconds or less.~~