CLAIMS

~~1. A method of treating or preventing sepsis or multiple sclerosis in a subject, the method comprising administering a therapeutically effective amount of any one or more of:~~

~~i) a soluble CD52 glycoprotein,~~

~~ii) a fusion protein comprising soluble CD52 glycoprotein as a first protein, and a second protein;~~

~~iii) a polynucleotide encoding the peptide portion of soluble CD52 glycoprotein of part i) or the fusion protein of part ii);~~

~~iv) a vector comprising the polynucleotide of part iii);~~

~~v) an isolated cell comprising the polynucleotide of part iii) or the vector of part iv);~~

~~vi) an isolated $CD52^{hi}$ cell capable of producing soluble CD52 glycoprotein;~~

~~vii) an isolated cell population comprising a plurality of $CD52^{hi}$ cells capable of producing soluble CD52 glycoprotein;~~

~~viii) cell culture medium, or a fraction thereof comprising soluble CD52 glycoprotein, isolated from a cell culture comprising the cell of part vi) or the cell population of part vii);~~

~~ix) an agent capable of increasing the level of expression of soluble CD52 glycoprotein by a cell; and~~

~~x) a pharmaceutical composition comprising any one or more of i) to ix) and a pharmaceutically acceptable carrier,~~

~~to the subject.~~

~~21~~. Any one or more of:

i) a soluble CD52 glycoprotein,

ii) a fusion protein comprising soluble CD52 glycoprotein as a first protein, and a second protein;

iii) a polynucleotide encoding the peptide portion of soluble CD52 glycoprotein of part i) or the fusion protein of part ii);

iv) a vector comprising the polynucleotide of part iii);

v) an isolated cell comprising the polynucleotide of part iii) or the vector of part iv);

vi) an isolated $CD52^{hi}$ cell capable of producing soluble CD52 glycoprotein;

vii) an isolated cell population comprising a plurality of $CD52^{hi}$ cells capable of producing soluble CD52 glycoprotein;

viii) cell culture medium, or a fraction thereof comprising soluble CD52 glycoprotein, isolated from a cell culture comprising the cell of part vi) or the cell population of part vii);

ix) an agent capable of increasing the level of expression of soluble CD52 glycoprotein by a cell; and

x) a pharmaceutical composition comprising any one or more of i) to ix) and a pharmaceutically acceptable carrier,

for use in treating or preventing sepsis or multiple sclerosis.

~~32~~. The use of any one or more of:

i) a soluble CD52 glycoprotein,

ii) a fusion protein comprising soluble CD52 glycoprotein as a first protein, and a second protein;

iii) a polynucleotide encoding the peptide portion of soluble CD52 glycoprotein of part i) or the fusion protein of part ii);

iv) a vector comprising the polynucleotide of part iii);

v) an isolated cell comprising the polynucleotide of part iii) or the vector of part iv);

vi) an isolated $CD52^{hi}$ cell capable of producing soluble CD52 glycoprotein;

vii) an isolated cell population comprising a plurality of $CD52^{hi}$ cells capable of producing soluble CD52 glycoprotein;

viii) cell culture medium, or a fraction thereof comprising soluble CD52 glycoprotein, isolated from a cell culture comprising the cell of part vi) or the cell population of part vii);

ix) an agent capable of increasing the level of expression of soluble CD52 glycoprotein by a cell; and

x) a pharmaceutical composition comprising any one or more of i) to ix) and a pharmaceutically acceptable carrier,

in the manufacture of a medicament for the treatment or prevention of sepsis or multiple sclerosis.

~~43~~. The ~~method of claim 1, the~~ soluble CD52 glycoprotein, fusion protein, polynucleotide, vector, cell, $CD52^{hi}$ cell, cell population, cell culture medium, agent or pharmaceutical composition of claim ~~21~~, or the use of claim ~~32~~, wherein the soluble CD52 glycoprotein comprises an amino acid sequence at least 60% identical to the amino acid sequence of any one or more of GQNDTSQTSSPS (SEQ ID NO: 3), SQNATSQSSPS (SEQ ID NO: 4), GQATTAASGTNKNSTSTKKTPLKS (SEQ ID

NO: 5), GQNSTAVTTPANKAATTAAATTKAAATTATKTTTAVRKTPGKPPKA (SEQ ID NO: 6) or GNSTTPRMTTKKVKSATPA (SEQ ID NO:7) and a carbohydrate.

~~54~~. The ~~method of claim 1 or claim 4, the~~ soluble CD52 glycoprotein, fusion protein, polynucleotide, vector, cell, $CD52^{hi}$ cell, cell population, cell culture medium, agent or pharmaceutical composition of claim ~~2~~ 1 or claim 43, or the use of claim ~~3~~ 2 or claim 43, wherein the glycoprotein comprises an amino acid sequence which is at least 65%, at least 70%, at least 75%, at least 80%, at least 85%, at least 90%, at least 95% identical, or is 100% identical, to any one or more of the amino acid sequences identified in SEQ ID NOs: 3, 4, 5, 6 or 7.

~~65~~. The ~~method of any one of claims 1 and 4-5, the~~ soluble CD52 glycoprotein, fusion protein, polynucleotide, vector, cell, $CD52^{hi}$ cell, cell population, cell culture medium, agent or pharmaceutical composition of any one of claims ~~2~~ 1 and 43-~~54~~, or the use of any one of claims ~~32~~-~~54~~, wherein any one or more of the soluble CD52 glycoprotein, fusion protein, polynucleotide, vector, cell, $CD52^{hi}$ cell, cell population, cell culture medium, agent and pharmaceutical composition is present in an amount sufficient to suppress sepsis and/or multiple sclerosis or to reduce or eliminate at least one symptom thereof.

~~76~~. The ~~method of any one of claims 1 and 4-6, the~~ soluble CD52 glycoprotein, fusion protein, polynucleotide, vector, cell, $CD52^{hi}$ cell, cell population, cell culture medium, agent or pharmaceutical composition of any one of claims ~~2~~ 1 and 43-~~65~~, or the use of any one of claims ~~32~~-~~65~~, wherein the carbohydrate portion of soluble CD52 glycoprotein is linked to one or more asparagine, serine, threonine, tyrosine, hydroxylysine, hydroxyproline, phosphoserine or tryptophan residues if present in the amino acid sequence.

~~87~~. The ~~method of any one of claims 1 and 4-7, the~~ soluble CD52 glycoprotein, fusion protein, polynucleotide, vector, cell, $CD52^{hi}$ cell, cell population, cell culture medium, agent or pharmaceutical composition of any one of claims ~~2~~ 1 and 43-~~76~~, or the use of any one of claims ~~32~~-~~76~~, wherein the carbohydrate portion of soluble CD52 glycoprotein is linked to the asparagine (N) residue in SEQ ID NO: 3.

~~98~~. The ~~method of any one of claims 1 and 4-8, the~~ soluble CD52 glycoprotein, fusion protein, polynucleotide, vector, cell, $CD52^{hi}$ cell, cell population, cell culture

medium, agent or pharmaceutical composition of any one of claims ~~2~~ 1 and ~~43~~ 87, or the use of any one of claims ~~32~~ 87, wherein the carbohydrate portion of soluble CD52 glycoprotein is any carbohydrate known to be attached to the extracellular portion of soluble CD52 glycoprotein in a host cell, such as a host lymphocyte or a host genital tract cell.

~~109~~. The ~~method of any one of claims 1 and 4-9, the~~ soluble CD52 glycoprotein, fusion protein, polynucleotide, vector, cell, $CD52^{hi}$ cell, cell population, cell culture medium, agent or pharmaceutical composition of any one of claims ~~2~~ 1 and ~~43~~ 98, or the use of any one of claims ~~32~~ 98, wherein the carbohydrate portion of soluble CD52 glycoprotein comprises one or more bi-, tri- or tetra-antennary sugars, which may be terminally sialylated.

~~1110~~. The ~~method of any one of claims 1 and 4-10, the~~ fusion protein, polynucleotide, vector, cell, $CD52^{hi}$ cell, cell population, cell culture medium, agent or pharmaceutical composition of any one of claims ~~2~~ 1 and ~~43~~ 109, or the use of any one of claims ~~32~~ 109, wherein the fusion protein comprises a second protein which comprises an antibody fragment.

~~1211~~. The ~~method of claim 11, the~~ fusion protein, polynucleotide, vector, cell, $CD52^{hi}$ cell, cell population, cell culture medium, agent or pharmaceutical composition of claim ~~11~~ 10, or the use of claim ~~11~~ 10, wherein the antibody fragment is an Fc.

~~1312~~. The ~~method of any one of any one of claims 1 and 4-12, or the~~ soluble CD52 glycoprotein, fusion protein, cell culture medium, agent or pharmaceutical composition of any one of claims ~~2~~ 1 and ~~43~~ ~~12~~11, wherein the soluble CD52 glycoprotein, fusion protein, cell culture medium, agent or composition is administered at a mucosal or transdermal site.

~~1413~~. The use of any one of claims ~~3-12~~2-11, wherein the medicament is formulated for administration at a mucosal or transdermal site.

~~1514~~. A method of diagnosing a subject's susceptibility to developing sepsis or multiple sclerosis, the method comprising:

detecting the level of soluble CD52 glycoprotein in a sample taken from the subject; and

comparing the level of soluble CD52 glycoprotein detected in the sample taken from the subject with a reference level determined from one or more healthy subjects,
wherein a lower level of soluble CD52 glycoprotein detected in the sample taken from the subject compared to the reference level indicates that the subject has an increased susceptibility to developing sepsis or multiple sclerosis.

~~16~~15. A method of diagnosing a subject's susceptibility to developing sepsis or multiple sclerosis, the method comprising:

detecting the frequency of $CD52^{hi}$ cells in a sample taken from a subject; and

comparing the frequency of $CD52^{hi}$ cells detected in the sample taken from the subject with a reference level determined from one or more healthy subjects,
wherein a lower frequency of $CD52^{hi}$ cells detected in the sample taken from the subject compared to the reference level indicates that the subject has an increased susceptibility to developing sepsis or multiple sclerosis.

~~17~~16. A method of diagnosing a subject's susceptibility to developing sepsis or multiple sclerosis, the method comprising:

detecting the activity of $CD52^{hi}$ cells in a sample taken from a subject; and

comparing the activity of $CD52^{hi}$ cells detected in the sample taken from the subject with a reference level determined from one or more healthy subjects,
wherein a reduced activity of $CD52^{hi}$ cells detected in the sample taken from the subject compared to the reference level indicates that the subject has an increased susceptibility to developing sepsis or multiple sclerosis.

~~18~~17. The method of claim ~~16~~15, wherein the frequency of $CD52^{hi}$ cells is detected by detecting the level of membrane bound CD52 in the sample, by detecting the level of expression of CD52 protein in the sample, and/or by detecting the level of expression of CD52 mRNA in the sample.

~~19~~18. The method of any one of claims ~~15-18~~14-17, wherein the sample is taken from a subject to which an antigen has been administered.

~~20~~19. The method of any one of claims ~~15-19~~14-18, wherein the sample is taken from a local disease site in the subject.

~~21~~20. A method of identifying a potential therapeutic agent for the treatment or prevention of sepsis or multiple sclerosis, the method comprising contacting a test agent with a $CD52^{hi}$ cell or $CD52^{hi}$ cell population, and detecting any one or more of the level of soluble CD52 glycoprotein produced by the cell or cell population, the frequency of $CD52^{hi}$ cells and/or the activity of $CD52^{hi}$ cells, and identifying the test agent as a potential therapeutic agent for the treatment or prevention of sepsis or multiple sclerosis, if the level of soluble CD52 glycoprotein, the frequency of $CD52^{hi}$ cells and/or the activity of $CD52^{hi}$ cells is increased after contact with the test agent.