Annex to the Defendant's Statement of Reasons

Additional claims and claim features are indicated in red text. Deleted granted claims are shown in ~~strikethrough~~. Moved claims and claim features are shown in green text.

Claim 1

A siliconized container means filled with a formulation which inhibits silicone induced aggregation of a polysaccharide-protein conjugate comprised in a siliconized container means, the formulation comprising

(i) a pH buffered saline solution, wherein the buffer has a pKa of about 3.5 to about 7.5,
(ii) an aluminum salt and
(iii) one or more polysaccharide-protein conjugates

wherein the polysaccharide-protein conjugate comprises one or more pneumococcal polysaccharides

and wherein the one or more pneumococcal polysaccharides are a *S. pneumoniae* serotype 4 polysaccharide, a *S. pneumoniae* serotype 6B polysaccharide, a *S. pneumoniae* serotype 9V polysaccharide, a *S. pneumoniae* serotype 14 polysaccharide, a *S. pneumoniae* serotype 18C polysaccharide, a *S. pneumoniae* serotype 19F polysaccharide, a *S. pneumoniae* serotype 23F polysaccharide, a *S. pneumoniae* serotype 1 polysaccharide, *a S. pneumoniae* serotype 3 polysaccharide, a *S. pneumoniae* serotype 5 polysaccharide, a *S. pneumoniae* serotype 6A polysaccharide, a *S. pneumoniae* serotype 7F polysaccharide and a *S. pneumoniae* serotype 19A polysaccharide.

Claim 2

The siliconized container means of claim 1, wherein the formulation further comprises a surfactant.

Claim 3

The siliconized container means of claim 2, wherein the surfactant is polysorbate 20 (Tween™20), polysorbate 40 (Tween™40), polysorbate 60 (Tween™60), polysorbate 65 (Tween™65), polysorbate 80 (Tween™80), polysorbate 85 (Tween™85), Triton™ N-101 or Triton™ X-100.

Claim 4

The siliconized container means of claim 1, wherein the formulation further comprises polysorbate 80 (Tween™80).

Claim 5

The siliconized container means of claim 4, wherein the final concentration of the polysorbate 80 in the formulation is at least 0.01% to 10% polysorbate 80 weight/volume of the formulation.

Claim 6

The siliconized container means of any one of claims 1 to 5, wherein the pH buffered saline solution in the formulation has a pH of 5.5 to 7.5.

Claim 7

The siliconized container means of any one of claims 1 to 6, wherein the buffer in the formulation is phosphate, succinate, histidine or citrate.

Claim 8

The siliconized container means of any one of claims 1 to 5, wherein the buffer is succinate at a final concentration of 1 mM to 10 mM and pH 5.8 to 6.0.

Claim 9

The siliconized container means of any one of claims 1 to 8, wherein the salt in the pH buffered saline solution comprises magnesium chloride, potassium chloride, sodium chloride or a combination thereof.

Claim 10

The siliconized container means of any one of claims 1 to 9, wherein the aluminum salt is aluminum hydroxide, aluminum phosphate or aluminum sulfate.

Claim 11

The siliconized container means of any one of claims 1 to 9, wherein the aluminum salt is aluminum phosphate.

~~Claim 10~~

~~The siliconized container means of any one of claims 1 to 9, wherein the one or more pneumococcal polysaccharides are a S. pneumoniae serotype 4 polysaccharide, a S. pneumoniae serotype 6B polysaccharide, a S. pneumoniae serotype 9V polysaccharide, a S. pneumoniae serotype 14 polysaccharide, a S. pneumoniae serotype 18C polysaccharide, a S. pneumoniae serotype 19F polysaccharide, a S. pneumoniae serotype 23F polysaccharide, a S. pneumoniae serotype 1 polysaccharide, a S. pneumoniae serotype 3 polysaccharide, a S. pneumoniae serotype 5 polysaccharide, a S. pneumoniae serotype 6A polysaccharide, a S. pneumoniae serotype 7F polysaccharide and a S. pneumoniae serotype 19A polysaccharide.~~

Claim 12

The siliconized container means of any one of claims 1 to 11, wherein the protein of the polysaccharide-protein conjugate formulation is selected from the group consisting of CRM197, a tetanus toxoid, a cholera toxoid, a pertussis toxoid, an E. coli heat labile toxoid (LT),a pneumolysin toxoid, pneumococcal surface protein A (PspA), pneumococcal adhesin protein A (PsaA), a C5a peptidase from Streptococcus, Haemophilus influenzae protein D, ovalbumin, keyhole limpet haemocyanin (KLH), bovine serum albumin (BSA) and purified protein derivative of tuberculin (PPD).

~~Claim 12~~

~~The siliconized container means of any one of claims 1 to 9, wherein the polysaccharide-protein conjugate formulation is a 7-valent pneumococcal conjugate (7vPnC) formulation comprising a S. pneumoniae serotype 4 polysaccharide conjugated to a CRM197~~

~~polypeptide, a S. pneumoniae serotype 6B polysaccharide conjugated to a CRM197 polypeptide, a S. pneumoniae serotype 9V polysaccharide conjugated to a CRM197 polypeptide, a S. pneumoniae serotype 14 polysaccharide conjugated to a CRM197 polypeptide, a S. pneumoniae serotype 18C polysaccharide conjugated to a CRM197 polypeptide, a S. pneumoniae serotype 19F polysaccharide conjugated to a CRM197 polypeptide and a S. pneumoniae serotype 23F polysaccharide conjugated to a CRM197 polypeptide.~~

Claim 13

The siliconized container means of any one of claims 1 to 11, wherein the polysaccharide-protein conjugate formulation is a 13-valent pneumococcal conjugate (13vPnC) formulation comprising a *S. pneumoniae* serotype 4 polysaccharide conjugated to a CRM197 polypeptide, a *S. pneumoniae* serotype 6B polysaccharide conjugated to a CRM197 polypeptide, a *S. pneumoniae* serotype 9V polysaccharide conjugated to a CRM197 polypeptide, a *S. pneumoniae* serotype 14 polysaccharide conjugated to a CRM197 polypeptide, a *S. pneumoniae* serotype 18C polysaccharide conjugated to a CRM197 polypeptide, a *S. pneumoniae* serotype 19F polysaccharide conjugated to a CRM197 polypeptide, a *S. pneumoniae* serotype 23F polysaccharide conjugated to a CRM197 polypeptide, a *S. pneumoniae* serotype 1 polysaccharide conjugated to a CRM197 polypeptide, a *S. pneumoniae* serotype 3 polysaccharide conjugated to a CRM197 polypeptide, a *S. pneumoniae* serotype 5 polysaccharide conjugated to a CRM197 polypeptide, a *S. pneumoniae* serotype 6A polysaccharide conjugated to a CRM197 polypeptide, a *S. pneumoniae* serotype 7F polysaccharide conjugated to a CRM197 polypeptide and a *S. pneumoniae* serotype 19A polysaccharide conjugated to a CRM197 polypeptide.

Claim 14

The siliconized container means of any one of claims 1 to 13 wherein said container is a syringe.

Claim 15

The siliconized container means of claim 14 wherein said container is a glass syringe.

Claim 16

Use of a formulation to inhibit silicone induced aggregation of a polysaccharide-protein conjugate comprised in a siliconized container means, the formulation comprising

(i) a pH buffered saline solution, wherein the buffer has a pKa of about 3.5 to about 7.5,
(ii) an aluminum salt, and
(iii) one or more polysaccharide-protein conjugates

wherein the polysaccharide-protein conjugate comprises one or more pneumococcal polysaccharides

wherein the one or more pneumococcal polysaccharides are a *S. pneumoniae* serotype 4 polysaccharide, a *S. pneumoniae* serotype 6B polysaccharide, a *S. pneumoniae* serotype 9V polysaccharide, a *S. pneumoniae* serotype 14 polysaccharide, a *S. pneumoniae* serotype 18C polysaccharide, a *S. pneumoniae* serotype 19F polysaccharide, a *S. pneumoniae* serotype 23F polysaccharide, a *S. pneumoniae* serotype 1 polysaccharide, a *S. pneumoniae* serotype 3 polysaccharide, a *S. pneumoniae* serotype 5 polysaccharide, a *S. pneumoniae*

serotype 6A polysaccharide, a *S. pneumoniae* serotype 7F polysaccharide and a *S. pneumoniae* serotype 19A polysaccharide.

Claim 17

The use of claim 16, wherein the formulation further comprises a surfactant.

Claim 18

The use of claim 17, wherein the surfactant is polysorbate 20 (Tween™20), polysorbate 40 (Tween™40), polysorbate 60 (Tween™60), polysorbate 65 (Tween™65), polysorbate 80 (Tween™80), polysorbate 85 (Tween™85), Triton™ N-101 or Triton™ X-100.

Claim 19

The use of claim 16, wherein the formulation further comprises polysorbate 80 (Tween™80).

Claim 20

The use of any one of claims 16 to 19, wherein the protein of the polysaccharide-protein conjugate is CRM_{197}.