IN THE HIGH COURT OF JUSTICE **Claim No. HP-2018-000024**

BUSINESS AND PROPERTY COURT OF

ENGLAND AND WALES

INTELLECTUAL PROPERTY LIST

PATENTS COURT

BETWEEN:

(1) SAMSUNG BIOEPIS UK LIMITED **Claimants**

(2) BIOGEN IDEC LIMITED

-and-

FRESENIUS KABI DEUTSCHLAND GMBH **Defendant**

ANNEX B TO THE

STATEMENT OF GROUNDS FOR

AMENDMENT OF EP (UK) 3 148 510

Claims

1. An aqueous pharmaceutical composition comprising:
(a) adalimumab;
(b) histidine buffering agent (or histidine buffer system);
(c) sugar stabiliser is selected from the group including trehalose, sucrose, sorbitol, maltose, lactose, xylitol, arabitol, erythritol, lactitol, maltitol, inositol; and
(d) 0.05 mg/mL to 2 mg/mL Polysorbate 20;
wherein the composition:
• has a pH between 5.0 and 6.7;
• is either free of amino acids other than histidine or comprises one or more amino acids other than histidine in a (collective) concentration of at most 0.1 mM; and
• is either free of phosphate buffering agents or comprises a phosphate buffer system in a concentration of at most 0.1 mM.

2. The aqueous pharmaceutical composition as claimed in any preceding claim, wherein the composition has a pH between 6.3 and 6.5.

3. The aqueous pharmaceutical composition as claimed in any preceding claim, wherein the composition comprises adalimumab at a concentration of about 50 mg/mL.

4. The aqueous pharmaceutical composition as claimed in any preceding claim, wherein the composition comprises the histidine buffering agent (or histidine buffer system) at a concentration of 2 to 50 mM.

5. The aqueous pharmaceutical composition as claimed in any preceding claim, wherein the composition comprises the sugar stabiliser at a concentration of 100-210 mM.

6. The aqueous pharmaceutical composition as claimed in any preceding claim, wherein the composition comprises the surfactant at a concentration of 0.05 to 1.5 mg/mL.

7. The aqueous pharmaceutical composition as claimed in any preceding claim, wherein the composition comprises the surfactant at a concentration of 0.9 to 1.5 mg/mL.

8. The aqueous pharmaceutical composition as claimed in any preceding claim, wherein the sugar stabiliser is a sugar alcohol selected from the group consisting of sorbitol, xylitol, arabitol, erythritol, lactitol, maltitol, and inositol.

9. The aqueous pharmaceutical composition as claimed in any preceding claim, wherein the sugar stabiliser is sorbitol.

10. The aqueous pharmaceutical composition as claimed in any preceding claim, wherein the composition further comprises a citrate buffer.

11. The aqueous pharmaceutical composition as claimed in any preceding claim, wherein if the composition comprises sodium chloride as an optional tonicifier, the sodium chloride is present at a concentration between 25 and 100 mM.

12. The aqueous pharmaceutical composition as claimed in any preceding claim, wherein the composition comprises:
(a) 45 mg/mL to 55 mg/mL adalimumab;
(b) 2 to 50 mM histidine buffering agent (or histidine buffer system);
(c) 50-300 mM sorbitol; and
(d) 0.05 mg/mL to 2 mg/mL Polysorbate 20;
wherein the composition:
• is either free of amino acids other than histidine or comprises one or more amino acids other than histidine in a (collective) concentration of at most 0.1 mM; and
• is either free of phosphate buffering agents or comprises a phosphate buffer system in a concentration of at most 0.1 mM.

13. The aqueous pharmaceutical composition as claimed in any preceding claim, wherein the composition comprises:
(a) 45 mg/mL to 55 mg/mL adalimumab;
(b) 2 to 50 mM histidine buffering agent (or histidine buffer system);
(c) 50-300 mM sorbitol; and
(d) 0.9 mg/mL to 1.5 mg/mL Polysorbate 20;
wherein the composition:
• has a pH between 5.0 and 6.7;
• is free of amino acids other than histidine; and
• is free of phosphate buffering agents.

14. A drug delivery device comprising an aqueous pharmaceutical composition as claimed in any preceding claim.

15. An aqueous pharmaceutical composition as claimed in any of claims 1 to 13 for use in the treatment of rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, Crohn's disease, ulcerative colitis, moderate to severe chronic psoriasis and/or juvenile idiopathic arthritis.