Section 75

Application to amend the specification of a patent

Application for Amendment of Specification now open to Opposition

Section 75 before the Court

If you intend to oppose the amendments filed under Section 75 before the court, you must **within 14 days** from the appearance of this advertisement, file and serve on all parties and the comptroller a notice opposing the application. This must include the grounds relied on.

Section:	75
Patent Number:	EP2944306
Patent Court Action Number: 2024-	HP-2024-000015, HP-2024-000035, HP- 000035
Title of patent:	VEGF ANTAGONIST FORMULATIONS SUITABLE FOR INTRAVITREAL ADMINISTRATION
International classification:	A61K
Name of proprietor:	Regeneron Pharmaceuticals, Inc.
Proprietor's address for service: One Southampton Row London WC1B 5HA	Carpmaels & Ransford LLP

These amendments may be viewed on our website and have been offered on an unconditional and conditional basis.

Conditional amendments to EP(UK) 2 944 306:

1. A pre-filled syringe comprising an ophthalmic formulation of a vascular endothelial growth factor (VEGF) antagonist, comprising:

(a) 1-100 mg/ml of the VEGF antagonist comprising <u>being</u> a VEGFspecific fusion protein, <u>wherein the VEGF-specific fusion protein comprises</u> <u>amino acids 27-457 of SEQ ID NO: 4 and is glycosylated at Asn residues 62,</u> <u>94, 149, 222 and 308</u>;

(b) 0.01-5% of one or more organic co-solvent(s) which is one or more of polysorbate, polyethylene glycol (PEG), and propylene glycol;

(c)30-150 mM of a tonicity agent selected from sodium chloride and potassium chloride;

(d)5-40 mM of sodium phosphate buffer; and

(e)1.0-7.5% of a stabilizing agent selected from the group consisting of sucrose, sorbitol, glycerol, trehalose, and mannitol;

having a pH of 5.8-7.0, wherein the formulation is suitable for intravitreal administration,

wherein the liquid stable ophthalmic formulation comprises 40 mg/ml of the VEGF-specific fusion protein, 10 mM sodium phosphate, 40 mM NaCl, 0.03% polysorbate, and 5% sucrose, pH 6.2-6.3.

- 2. The pre-filled syringe according to claim 1, wherein the VEGF specific fusion protein comprises a receptor component comprising an immunoglobulin like (lg) domain 2 of a first VEGF receptor and Ig domain 3 of a second VEGF receptor, and a multimerizing component.
- 3. The pre-filled syringe according to claim 2, wherein the first VEGF receptor is Fltl and the second VEGF receptor is Flkl or Flt4.
- 4. The pre-filled syringe according to any one of claims 1-3, wherein the VEGF specific fusion protein comprises amino acids 27-457 of SEQ ID No:4, and is glycosylated at Asn residues 62, 94, 149, 222 and 308.
- 5. The pre-filled syringe according to any one of claims 1-4, wherein the liquid stable ophthalmic formulation comprises 40 mg/mL of the VEGF specific fusion protein, 10 mM sodium phosphate, 40 mM NaCl, 0.03% polysorbate 20, and 5% sucrose, pH 6.2-6.3.