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(73) Proprietor Coherus Biosciences, Inc., 201 Redwood Shores Parkway Suite 200, Redwood City, CA 94065, USA

(72) Inventor MANNING, Mark, 4630 Sorrel Lane, Johnstown, CO 80534, USA
PAYNE, Robert W., 221 Cleopatra Street, Fort Collins, CO 80525, USA

(54) Title **STABLE AQUEOUS FORMULATIONS OF ADALIMUMAB**

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Enclosed is a translation of the patent claims in Norwegian. Please note that as per the Norwegian Patents Acts, section 66i the patent will receive protection in Norway only as far as there is agreement between the translation and the language of the application/patent granted at the EPO. In matters concerning the validity of the patent, language of the application/patent granted at the EPO will be used as the basis for the decision. The patent documents published by the EPO are available through Espacenet (<http://worldwide.espacenet.com>) or via the search engine on our website here: <https://search.patentstyret.no/>

Patentkrav

1. Vandig farmasøytisk sammensetning som består av:

- (A)
- 5 (i) 50 mg/ml adalimumab,
(ii) 10 mM histidinbuffer,
(iii) 120 mM glysin,
(iv) 120 mM arginin, og
(v) 0,1 vekt-% polysorbat 80;
- 10 (B)
- (i) 50 mg/ml adalimumab,
(ii) 10 mM histidinbuffer,
(iii) 120 mM glysin,
(iv) 120 mM arginin, og
15 (v) 0,05 vekt-% polysorbat 80;
- (C)
- (i) 50 mg/ml adalimumab,
(ii) 10 mM histidinbuffer,
(iii) 120 mM glysin,
20 (iv) 120 mM arginin, og
(v) 0,01 vekt-% polysorbat 80;
- (D)
- (i) 50 mg/ml adalimumab,
(ii) 10 mM histidinbuffer,
25 (iii) 120 mM glysin,
(iv) 120 mM arginin, og
(v) 0,05 vekt-% polysorbat 20;
- (E)
- (i) 50 mg/ml adalimumab,
30 (ii) 10 mM histidinbuffer,
(iii) 120 mM glysin,
(iv) 120 mM arginin, og
(v) 0,1 vekt-% Pluronic F-68;
- (F)
- 35 (i) 50 mg/ml adalimumab,
(ii) 20 mM histidinbuffer,
(iii) 150 mM glysin,
(iv) 100 mM arginin, og

- (v) 0,01 vekt-% polysorbat 80; eller
 - (G)
 - (i) 50 mg/ml adalimumab,
 - (ii) 20 mM histidinbuffer,
 - 5 (iii) 120 mM glysin,
 - (iv) 120 mM arginin, og
 - (v) 0,01 vekt-% polysorbat 20;
- hvor i hver av (A)-(G) har en pH på 5,2.
- 10 **2.** Sammensetning for anvendelse i en fremgangsmåte for å behandle en inflammatorisk tilstand hos et individ, hvor i fremgangsmåten omfatter administrering av en terapeutisk effektiv mengde av den farmasøytiske sammensetningen ifølge krav 1.