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(73)	Proprietor	AM-Pharma B.V., Stadsplateau 6, 3521 AZ Utrecht, Nederland
(72)	Inventor	Jonk, Luigi Johannes Cornelius, Van Lynden van Sandenburglaan 2, 3571 BC Utrecht, Nederland Connor, Stephen Edward, 12a Springfield Road, Cambridge, CB4 1AD, Storbritannia van den Berg, Erik Jan, c/o Rumpsterweg 6, 3981 AK Bunnik, Nederland van Elsas, Andrea, Ruusbroecgaarde 139, 5343 JL Oss, Nederland Shukla, Abhinav Alok, 102 Rexmore Court, Morrisville, NC 27560, USA Horne, Heather Bethea, 6012 Chatford Drive, Raleigh, NC 27612, USA Cook, Susan, c/o Rumpsterweg 6, 3981 AK Bunnik, Nederland Kelly, Timothy Martin, 709 Glen Eden Dr, Raleigh, NC 27612, USA Dowling, Victoria Anne, 3301 Arapahoe AveUnit 427, Boulder, CO 80303, USA Ramaroson, Mialy Fanjamalala, 102 McIntire Lane, Cary, NC 27513, USA
(74)	Agent or Attorney	BRYN AARFLOT AS, Stortingsgata 8, 0161 OSLO, Norge

(54) Title **DOWNSTREAM PROCESSING OF AN ALKALINE PHOSPHATASE**

(56) References
Cited: WO-A1-2009/106368
WO-A1-2008/094037
WO-A2-2012/169892

EP-A1- 0 791 658 , WO-A2-2008/133511, US-A1- 2002 055 098

SHUKLA ABHINAV A ET AL: "Host cell protein clearance during protein A chromatography: development of an improved column wash step", BIOTECHNOLOGY PROGRESS,, vol. 24, no. 5, 1 September 2008 (2008-09-01), pages 1115-1121, XP002562071, ISSN: 1520-6033, DOI: 10.1002/BTPR.50 [retrieved on 2008-10-14]

LINDNER N M ET AL: "Design and applications of biomimetic anthraquinone dyes", JOURNAL OF CHROMATOGRAPHY, ELSEVIER SCIENCE PUBLISHERS B.V, NL, vol. 473, 1 January 1989 (1989-01-01), pages 227-240, XP026484601, ISSN: 0021-9673, DOI: 10.1016/S0021-9673(00)91304-9 [retrieved on 1989-01-01]

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Patentkrav

1. Fremgangsmåte for å fremstille en fysisk stabil sammensetning omfattende en isolert alkalisk fosfatase (AP), hvor fremgangsmåten er omfattende
 - 5 - oppløsningen eller fortynningen av en AP i en buffer, resulterer i en sammensetning som har en pH på mellom 6,5 og 7,5 og er omfattende
 - mellom 200 - 300 mM sorbitol, og
 - mellom 5 - 40 mM histidin og/eller mellom 10 - 40 mM citrat.
- 10 2. Fremgangsmåte ifølge krav 1, hvori sammensetningen omfatter mindre enn 100 ppm vertscelleprotein (HCP).
3. Fremgangsmåte ifølge krav 1 eller 2, hvori den alkaliske fosfatasen er et protein som har minst 95 % sekvensidentitet, mer foretrukket som har minst 98 % sekvensidentitet, mer
 - 15 foretrukket som har minst 99 % sekvensidentitet, mest foretrukket som har minst 100 % sekvensidentitet med aminosyresekvensen ifølge SEQ ID NO: 1.
4. Fremgangsmåte ifølge et hvilket som helst av kravene 1 - 3, hvori HCP-en er et katepsinlignende protein og/eller hvori den rekombinante alkaliske fosfatasen oppnås fra et
 - 20 cellebasert ekspresjonssystem, fortrinnsvis omfattende en pattedyrvertscelle, mer foretrukket en ovarievertscelle fra kinesisk hamster (CHO).
5. Fremgangsmåte ifølge et hvilket som helst krav 1 - 4, hvori sammensetningen omfatter mer enn 0,1 mM magnesium.
- 25 6. Fremgangsmåte ifølge et hvilket som helst krav 1 - 5, hvori sammensetningen omfatter mer enn 10 μ M sink.