US008044017B2

(12) **United States Patent**
Emery et al.

(10) **Patent No.: US 8,044,017 B2**
(45) **Date of Patent: Oct. 25, 2011**

(54) **PROTEIN PURIFICATION**

(75) Inventors: **Jefferson C. Emery**, San Mateo, CA (US); **Paul J. McDonald**, San Francisco, CA (US); **Rhona O'Leary**, San Francisco, CA (US)

(73) Assignee: **Genentech, Inc.**, South San Francisco, CA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 930 days.

(21) Appl. No.: **10/659,825**

(22) Filed: **Sep. 10, 2003**

(65) **Prior Publication Data**

US 2004/0082047 A1 Apr. 29, 2004

Related U.S. Application Data

(60) Provisional application No. 60/410,334, filed on Sep. 11, 2002.

(51) **Int. Cl.**

A61K 38/00	(2006.01)
A61K 51/00	(2006.01)
A61K 9/14	(2006.01)
A23J 1/00	(2006.01)
C07K 1/00	(2006.01)
C07K 14/00	(2006.01)
C07K 16/00	(2006.01)
C07K 17/00	(2006.01)

(52) **U.S. Cl.** **514/1.1**; 530/300; 530/416; 424/1.69; 424/483

(58) **Field of Classification Search** ..... None
See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

5,571,720	A *	11/1996	Grandics et al.	435/286.1
5,677,171	A	10/1997	Hudziak et al.	
6,339,142	B1	1/2002	Basey et al.	530/387.3
6,417,355	B1	7/2002	Chapman et al.	540/466
6,433,144	B1	8/2002	Morris et al.	530/351
2001/0034053	A1 *	10/2001	Winge	435/212

FOREIGN PATENT DOCUMENTS

WO	WO 98/30694	7/1998
WO	WO 99/57134	* 11/1999
WO	WO9957134	* 11/1999
WO	WO 00/02921	1/2000
WO	WO0002921	* 1/2000
WO	WO 00/55184	9/2000

OTHER PUBLICATIONS

Carter et al., "Humanization of an Anti-P185HER2 Antibody for Human Cancer Therapy" Proceedings of the National Academy of Sciences of USA, National Academy of Science, Washington, DC, US., 89(10):4285-4289 (1992), XP000275844, ISSN: 0027-8424.

Harris et al., "Identification of Multiple Sources of Charge Heterogeneity in a Recombinant Antibody" Journal of Chromatography B: Biomedical Sciences & Applications, Elsevier, Amsterdam, NL, 752(2):233-245 (2001), XP004317158, ISSN: 1570-0232.

Fukuoka, et al., "Studies of quality control of ^{99m}Tc-labelled macroaggregated Albumin—part 1. Aggregation of non-mercaptalbumin and its conformation", Nucl. Med. Biol., vol. 20, No. 5, pp. 643-648, (1993).

Kawaguchi, et al., "Rapid analysis of serum lactate dehydrogenase isoenzymes by high-performance ion-exchange chromotography", Journal of Chromatography, 378:456-461, (1986).

* cited by examiner

Primary Examiner — Maury Audet
(74) *Attorney, Agent, or Firm* — Arnold & Porter LLP; Diane Marschang; Ginger R. Dreger

(57) **ABSTRACT**

A method for purifying a polypeptide by ion exchange chromatography is described in which a gradient wash is used to resolve a polypeptide of interest from one or more contaminants.

25 Claims, 4 Drawing Sheets