

**REMARKS**

Claims 24 and 25 were pending. All pending claims were rejected in the Non-Final Rejection. In view of the foregoing amendments and arguments that follow, Applicants respectfully request withdrawal of all rejections upon reconsideration.

Applicants acknowledge with appreciation the Office's withdrawal of the objections to claim 24 under 35 U.S.C. 112, second paragraph, as being indefinite.

**Rejection Under 35 U.S.C. § 112, First Paragraph**

Claim 24 was amended with the RCE filing and was again rejected as allegedly being indefinite. The Office alleges that the specification is enabling for a humanized antibody comprising a heavy chain variable domain and a light chain variable domain, with all 6 CDRs, and does not provide enablement for a humanized antibody heavy chain variable domain alone. The Office is clearly disregarding the fact that the CDR-grafted chains can be combined with other chains, as disclosed in the specification, including chimeric and mouse chains. Thus, it is not necessary for the claims to recite both chains. Applicants traverse this rejection but have amended claim 24 to recite a humanized antibody comprising a heavy chain variable domain.

Applicants respectfully submit that this rejection has been overcome.

**Rejection Under 35 U.S.C. 102(e)**

Claims 24 and 25 were rejected under 35 U.S.C. 102(e) as allegedly being anticipated by Queen, et al US Patent 5,585,089 the "'089 patent". Claim 25 has been cancelled. Applicants traverse this rejection as it applies to claim 24.

With all due respect, the Office has apparently misread the claims. Initially, the office states that the claims recite that the framework region comprises a **non-human** amino acid

substitution at a residue selected from 23, 24, 49, 71, 73, and 78, and combinations thereof. The Office then asserts that the “‘089 patent” teaches an antibody comprising a humanized heavy chain variable domain comprising human residues at positions except the CDRs, and the following framework positions—27, 93, 95, 98, 107-109, 11, 30, 67, 48, and 68. The Office concludes, thus, that all the remaining framework positions are the human antibody allegedly taught in the “‘089 patent”. The Office then states that, since the claims recite substitution to **human** residues in the heavy chain in residues 23, 24, 49, 71, 73, and 78, and the “‘089 patent” teaches human residues in all of those positions, the claim limitations are met. As the Office previously acknowledged, however, these residues are **non-human** residues in claim 24. The “‘089 patent”, thus, does not anticipate the Applicants invention.

Applicants respectfully request that this rejection be withdrawn.

**DOCKET NO.: CARP0001-112**  
**APPLICATION SERIAL NO. 11/284,261**

**PATENT**

**CONCLUSION**

Applicants respectfully submit that claim 24 is allowable and early allowance of the same. If a telephonic conversation with Applicants' attorney would help expedite the prosecution of the above-identified application, the Examiner is urged to call the undersigned at 215-665-5593.

Respectfully submitted,

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Date: September 9, 2009

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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

<p>(51) International Patent Classification <sup>5</sup> : C12P 21/08, C12N 15/13 A61K 39/395, C07K 15/06 C12N 5/10, 15/62</p>	<p><b>A1</b></p>	<p>(11) International Publication Number: <b>WO 91/09967</b>  (43) International Publication Date: 11 July 1991 (11.07.91)</p>
<p>(21) International Application Number: PCT/GB90/02017 (22) International Filing Date: 21 December 1990 (21.12.90) (30) Priority data: 8928874.0 21 December 1989 (21.12.89) GB (71) Applicant (for all designated States except US): CELLTECH LIMITED [GB/GB]; 216 Bath Road, Slough, Berkshire SL1 4EN (GB). (72) Inventors; and (75) Inventors/Applicants (for US only): ADAIR, John, Robert [GB/GB]; 23 George Road, Stokenchurch, High Wycombe, Buckinghamshire HP14 3RN (GB). ATHWAL, Diljeet, Singh [GB/GB]; Flat 35, Knollys House, Tavistock Square, London WC1 (GB). EMTAGE, John, Spencer [GB/GB]; 49 Temple Mill Island, Temple, Marlow, Buckinghamshire SL7 1SQ (GB).</p>	<p>(74) Agent: MERCER, Christopher, Paul; Carpmaels &amp; Ransford, 43 Bloomsbury Square, London WC1A 2RA (GB).  (81) Designated States: AT, AT (European patent), AU, BB, BE (European patent), BF (OAPI patent), BG, BJ (OAPI patent), BR, CF (OAPI patent), CG (OAPI patent), CH, CH (European patent), CM (OAPI patent), DE, DE (European patent), DK, FI, FR (European patent), GA (OAPI patent), GB, GB (European patent), GR, HU, IT (European patent), JP, KP, KR, LK, LU, LU (European patent), MC, MG, ML (OAPI patent), MR (OAPI patent), MW, NL, NL (European patent), NO, RO, SD, SE, SE (European patent), SN (OAPI patent), SU, TD (OAPI patent), TG (OAPI patent), US.  <b>Published</b> <i>With international search report.</i> <i>Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i> <i>With a request for rectification under Rule 91.1(f).</i></p>	
<p>(54) Title: HUMANISED ANTIBODIES</p>		
<p>(57) Abstract</p> <p>CDR-grafted antibody heavy and light chains comprise acceptor framework and donor antigen binding regions, the heavy chains comprising donor residues at at least one of positions (6, 23) and/or (24, 48) and/or (49, 71) and/or (73, 75) and/or (76) and/or (78) and (88) and/or (91). The CDR-grafted light chains comprise donor residues at at least one of positions (1) and/or (3) and (46) and/or (47) or at at least one of positions (46, 48, 58) and (71). The CDR-grafted antibodies are preferably humanised antibodies, having non human, e.g. rodent, donor and human acceptor frameworks, and may be used for <i>in vivo</i> therapy and diagnosis. A generally applicable protocol is disclosed for obtaining CDR-grafted antibodies.</p>		

Carter Exhibit 2005

Carter v. Adair

Interference No. 105 744

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