



US011116721B2

**(12) United States Patent**  
**Baker et al.****(10) Patent No.: US 11,116,721 B2**  
**(45) Date of Patent: Sep. 14, 2021****(54) PHARMACEUTICAL FORMULATIONS**  
**COMPRISING 4-[(1R)-2-[(6-{2-[(2,6-**  
**DICHLOROBENZYL)OXY]ETHOXY}**  
**HEXYL)AMINO]-1-HYDROXYETHYL]-2-**  
**(HYDROXYMETHYL) PHENOL****(75) Inventors: Darrell Baker, Middlesex (GB); Mark**  
**Bruce, Stevenage (GB); Marian**  
**Thomas, Ware (GB)****(73) Assignee: Glaxo Group Limited, Middlesex (GB)****(\*) Notice:** Subject to any disclaimer, the term of this  
patent is extended or adjusted under 35  
U.S.C. 154(b) by 0 days.**(21) Appl. No.: 13/148,982****(22) PCT Filed: Feb. 26, 2009****(86) PCT No.: PCT/EP2009/052306**

§ 371 (c)(1),

(2), (4) Date: **Aug. 11, 2011****(87) PCT Pub. No.: WO2010/097115**PCT Pub. Date: **Sep. 2, 2010****(65) Prior Publication Data**

US 2011/0319371 A1 Dec. 29, 2011

**(51) Int. Cl.****A61K 31/58** (2006.01)**A61K 31/138** (2006.01)**A61K 45/06** (2006.01)**A61K 9/00** (2006.01)**(52) U.S. Cl.**CPC ..... **A61K 9/0075** (2013.01); **A61K 31/138**  
(2013.01); **A61K 31/58** (2013.01); **A61K 45/06**  
(2013.01)**(58) Field of Classification Search**CPC .... **A61K 9/0075; A61K 31/138; A61K 31/58;**  
**A61K 45/06; A61K 2300/00**

See application file for complete search history.

**(56) References Cited**

## U.S. PATENT DOCUMENTS

4,778,054 A 10/1988 Newell et al.  
4,811,731 A 3/1989 Newell et al.  
4,832,880 A 5/1989 Staniforth  
4,994,276 A 2/1991 Baichwal et al.  
5,004,614 A 4/1991 Staniforth  
5,035,237 A 7/1991 Newell et al.  
5,135,757 A 8/1992 Baichwal et al.  
5,145,684 A 9/1992 Liversidge et al.  
5,376,386 A 12/1994 Ganderton et al.  
5,441,060 A 8/1995 Rose et al.  
5,478,578 A 12/1995 Arnold et al.  
5,503,662 A 4/1996 Berger  
5,506,203 A 4/1996 Backstrom et al.  
5,560,490 A 10/1996 Chawla  
5,590,645 A 1/1997 Davies et al.  
5,626,871 A 5/1997 Makino et al.  
5,642,728 A 7/1997 Anderson et al.  
5,663,198 A 9/1997 Reul et al.5,730,785 A 3/1998 Idol et al.  
5,746,937 A 5/1998 McKedy et al.  
5,829,434 A 11/1998 Ambrosio et al.  
5,860,419 A 1/1999 Davies et al.  
5,873,360 A 2/1999 Davies et al.  
5,972,388 A 10/1999 Sakon et al.  
6,032,666 A 3/2000 Davies et al.  
6,103,141 A 8/2000 Incorvia et al.  
6,119,853 A 9/2000 Garrill et al.  
6,132,394 A 10/2000 Lankinen  
6,153,224 A 11/2000 Staniforth  
6,153,322 A 11/2000 Lee et al.  
6,156,231 A 12/2000 McKedy  
6,179,118 B1 1/2001 Garrill et al.  
D440,874 S 4/2001 Shurtleff et al.  
6,221,338 B1 4/2001 Staniforth  
6,279,736 B1 8/2001 Hekal  
6,303,991 B1 10/2001 Harper, Jr. et al.  
6,315,112 B1 11/2001 Garrill et al.  
6,321,747 B1 11/2001 Dmitrovic et al.  
6,352,152 B1 3/2002 Anderson et al.  
6,378,519 B1 4/2002 Davies et al.  
6,378,579 B1 4/2002 Giltner  
6,390,291 B1 5/2002 Garrill et al.  
6,521,260 B1 2/2003 Staniforth  
6,533,321 B2 3/2003 Class et al.  
6,536,427 B2 3/2003 Davies et al.  
6,537,983 B1 3/2003 Biggadike et al.  
6,582,678 B2 6/2003 Staniforth  
6,679,374 B2 1/2004 Garrill et al.  
6,759,398 B2 7/2004 Biggadike  
6,792,945 B2 9/2004 Davies et al.  
6,878,698 B2 4/2005 Biggadike et al.  
7,011,818 B2 3/2006 Staniforth  
7,101,866 B2 9/2006 Biggadike et al.  
7,186,401 B2 3/2007 Keller et al.  
7,225,808 B2 6/2007 Davies et al.  
7,337,593 B2 3/2008 Blum et al.  
7,361,787 B2\* 4/2008 Box et al. .... 564/38  
7,389,775 B2 6/2008 Davies et al.  
7,439,393 B2\* 10/2008 Box et al. .... 564/38  
7,488,827 B2 2/2009 Laine et al.  
7,498,440 B2 3/2009 Laine et al.  
7,501,011 B2 3/2009 Powers et al.  
7,549,272 B2 6/2009 DeFedericis  
7,629,335 B2 12/2009 Biggadike et al.  
7,776,895 B2 8/2010 Box et al.  
(Continued)

## FOREIGN PATENT DOCUMENTS

CA 2347856 C 5/2000  
DE 10056855 A1 5/2002

(Continued)

## OTHER PUBLICATIONS

Westmeier et al., "Combination Particles Containing Salmeterol  
Xinafoate and Fluticasone Propionate: Formulation and Aerody-  
namic Assessment," Journal of Pharmaceutical Sciences, vol. 97,  
No. 6, Jun. 2008.\*

(Continued)

Primary Examiner — Kortney L. Klinkel

Assistant Examiner — William Y Lee

(74) Attorney, Agent, or Firm — James P. Riek

**(57) ABSTRACT**Novel pharmaceutical formulations of a beta-2 agonist for  
inhaled administration via the nose or mouth, and methods  
of using them are provided.**67 Claims, No Drawings**