US006503894B1

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

(10) **Patent No.: US 6,503,894 B1**
(45) **Date of Patent: Jan. 7, 2003**

(54) **PHARMACEUTICAL COMPOSITION AND METHOD FOR TREATING HYPOGONADISM**

(75) Inventors: **Robert E. Dudley**, Kenilworth, IL (US); **S. George Kottayil**, Long Grove, IL (US); **Olivier Palatchi**, L'Hay les Roses (FR)

(73) Assignees: **Unimed Pharmaceuticals, Inc.**, Marietta, GA (US); **Laboratories Besins Iscovesco**, Herndon, VA (US)

(*) 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.: **09/651,777**

(22) Filed: **Aug. 30, 2000**

(51) **Int. Cl.**[7] **A61K 31/56**
(52) **U.S. Cl.** **514/178**; 514/177
(58) **Field of Search** 514/178, 396, 514/406, 415, 177

(56) **References Cited**

U.S. PATENT DOCUMENTS

2,155,658	A	4/1939	Herrman et al.
3,068,188	A	12/1962	Beste et al.
3,218,283	A	11/1965	Miller
3,887,699	A	6/1975	Yolles
3,888,995	A	6/1975	Katz et al.
3,939,111	A	2/1976	Schollenberger et al.
4,009,254	A	2/1977	Renold
4,083,973	A	4/1978	Van der Vies
4,161,948	A	7/1979	Bichon
4,442,094	A	4/1984	Atkinson et al.
4,447,562	A	5/1984	Ivani
4,478,822	A	10/1984	Haslam et al.
4,496,556	A	1/1985	Orentreich
4,563,473	A	1/1986	Hofman et al.
4,631,188	A	12/1986	Stoy et al.
4,690,775	A	9/1987	Schott et al.
4,695,465	A	9/1987	Kigasawa et al.
4,704,282	A	11/1987	Campbell et al.
4,725,439	A	2/1988	Campbell et al.
4,745,160	A	5/1988	Churchill et al.
4,767,627	A	8/1988	Caldwell et al.
4,780,320	A	10/1988	Baker
4,788,062	A	11/1988	Gale et al.
4,863,970	A	9/1989	Patel et al.
4,920,203	A	4/1990	Tang et al.
4,946,870	A	8/1990	Partain, III et al.
4,981,696	A	1/1991	Loomis et al.
5,013,553	A	5/1991	Southard et al.
5,053,227	A	10/1991	Chiang et al.
5,059,603	A	10/1991	Rubin
5,071,657	A	12/1991	Oloff et al.
5,152,997	A	10/1992	Ebert et al.
5,231,087	A	7/1993	Thornfeldt
5,256,652	A	10/1993	El-Rashidy
5,324,521	A	6/1994	Gertner et al.
5,326,790	A	7/1994	Thornfeldt
5,332,577	A	7/1994	Gertner et al.
5,340,586	A	8/1994	Pike et al.
5,362,497	A	11/1994	Yamada et al.
5,413,794	A	5/1995	Suzuki et al.
5,446,070	A	8/1995	Mantelle
5,460,820	A	10/1995	Ebert et al.
5,610,150	A	3/1997	Labrie
5,629,021	A	5/1997	Wright
5,641,504	A	6/1997	Lee et al.
5,643,899	A	7/1997	Elias et al.

(List continued on next page.)

FOREIGN PATENT DOCUMENTS

DE	3238984		10/1982	
EP	0581587	A2	2/1994	
EP	0197753		10/1996	
EP	0804926		4/1997	
FR	2515041		4/1983	
FR	2518879		7/1983	
FR	2519252		7/1983	
FR	2705572		12/1994	
GB	2109231		6/1983	
WO	WO 93/25168	A1	12/1993	
WO	9408590		4/1994	
WO	9421230		9/1994	
WO	9421271		9/1994	
WO	WO-96/27372	A1 *	9/1996	..... A61K/31/21
WO	9636339		11/1996	
WO	9743989		11/1997	
WO	9808547		3/1998	
WO	9824451		6/1998	
WO	WO 98/34621	A1	8/1998	
WO	9837871		9/1998	
WO	WO-99/24041	A1 *	5/1999	..... A61K/31/56
WO	9932107		7/1999	
WO	WO 99/66870	A1	12/1999	
WO	0024362		5/2000	
WO	WO 00/66870	A2	8/2000	
WO	0076522		12/2000	
WO	WO 01/43775	A2	6/2001	

OTHER PUBLICATIONS

The trademark record for Androgel® Mar. 16, 1999.*
Manos, *FDA Approves Gel to Treat Low Testosterone Levels,* www.testocreme.com (Downloaded May 9, 2001).
Unimed Pharmaceuticals' Androgel Shows Solid Promise for Men, Fertility Industry News, www.INCIID.com (Aug. 19, 1998).
Lacayo, *Are You Man Enough?, Time Europe*, www.Time.com, vol. 155, No. 16 (Apr. 24, 2000).
MacroChem Accelerates Development of Top For Impotence, www.pslgroup.com (Apr. 10, 1997).
Kaufman, *Efficacy and Safety of a New, Topical Testosterone Gel (T–gel) For Male Hormonal Supplementation, International Journal of Impotence Research*, vol. 12, Supplement 3, p. S75 (B9) (Sep. 2000).

(List continued on next page.)

Primary Examiner—Russell Travers
Assistant Examiner—S. Jiang
(74) *Attorney, Agent, or Firm*—Mayer, Brown, Rowe & Maw; Joseph A. Mahoney; Thomas R. Stiebel

(57) **ABSTRACT**

A pharmaceutical composition useful for treating hypogonadism is disclosed. The composition comprises an androgenic or anabolic steroid, a C1–C4 alcohol, a penetration enhancer such as isopropyl myristate, and water. Also disclosed is a method for treating hypogonadism utilizing the composition.

42 Claims, 40 Drawing Sheets