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(54) **USE OF EQUOL FOR TREATING ANDROGEN MEDIATED DISEASES**

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(58) **Field of Classification Search**

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See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

4,390,559	A	6/1983	Zilliken
4,814,346	A	3/1989	Albert et al.
5,141,746	A	8/1992	Fleury et al.
RE34,457	E	11/1993	Okamoto et al.
5,352,384	A	10/1994	Shen
5,424,331	A	6/1995	Shlyankevich
5,468,501	A	11/1995	Kydonieus et al.
5,498,631	A	3/1996	Gorbach et al.
5,523,087	A	6/1996	Shlyankevich
5,613,958	A	3/1997	Kochinke et al.
5,693,018	A	12/1997	Kriesel et al.
5,726,034	A	3/1998	Bryan et al.
5,733,926	A	3/1998	Gorbach
5,804,234	A	9/1998	Suh et al.
5,830,887	A	11/1998	Kelly
5,848,991	A	12/1998	Gross et al.
5,849,798	A	12/1998	Charpentier et al.
5,855,892	A	1/1999	Potter et al.
5,942,539	A	8/1999	Hughes, Jr. et al.
5,952,374	A	9/1999	Clarkson et al.
5,958,946	A	9/1999	Styczynski et al.
5,990,291	A	11/1999	Waggle et al.
6,004,558	A	12/1999	Thurn et al.
6,020,471	A	2/2000	Johns et al.
6,054,636	A	4/2000	Fader
6,060,070	A	5/2000	Gorbach
6,083,526	A	7/2000	Gorbach
6,146,668	A	11/2000	Kelly et al.
6,159,959	A	12/2000	Miller
6,194,450	B1	2/2001	Charpentier et al.
6,242,594	B1	6/2001	Kelly

(Continued)

FOREIGN PATENT DOCUMENTS

AU	20006896 A4	5/2000
CA	2389560	11/2002

(Continued)

OTHER PUBLICATIONS

Aldercreutz, H., et al., "Urinary Excretion of Lignans and Isoflavonoid Phytoestrogens in Japanese Men and Women Consuming a Traditional Japanese Diet," *Am. J. Clin. Nutr.*, 54:1093-1100 (1991).

(Continued)

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(57) **ABSTRACT**

Equol (7-hydroxy-3(4'hydroxyphenyl)-chroman), the major metabolite of the phytoestrogen daidzein, specifically binds and blocks the hormonal action of 5α-dihydrotestosterone (DHT) in vitro and in vivo. Equol can bind circulating free DHT and sequester it from the androgen receptor, thus altering growth and physiological hormone responses that are regulated by androgens. These data suggest a novel model to explain equol's biological properties. The significance of equol's ability to specifically bind and sequester DHT from the androgen receptor have important ramifications in health and disease and may indicate a broad and important usage for equol in the treatment and prevention of androgen-mediated pathologies. Thus, equol can specifically bind DHT and prevent DHT's biological actions in physiological and pathophysiological processes.

5 Claims, 61 Drawing Sheets