



US00D962433S

(12) **United States Design Patent**
Smith et al.

(10) **Patent No.:** **US D962,433 S**
(45) **Date of Patent:** **** Aug. 30, 2022**

(54) **IMPLANT PLACEMENT GUIDE**

- (71) Applicant: **Intarcia Therapeutics, Inc.**, Boston, MA (US)
- (72) Inventors: **Jay S. Smith**, Wellesley Hills, MA (US); **Michael R. Cole**, Stratham, NH (US); **Amy K. Whitson**, Columbus, OH (US)
- (73) Assignee: **Intarcia Therapeutics, Inc.**, Boston, MA (US)
- (**) Term: **15 Years**
- (21) Appl. No.: **29/667,595**
- (22) Filed: **Oct. 23, 2018**

Related U.S. Application Data

- (62) Division of application No. 29/566,823, filed on Jun. 2, 2016, now Pat. No. Des. 840,030.
- (51) **LOC (13) Cl.** **24-02**
- (52) **U.S. Cl.**
USPC **D24/140**; D24/133
- (58) **Field of Classification Search**
USPC D24/133, 140, 141, 146, 147, 155, 169, D24/231
CPC A61B 17/3468; A61B 17/00491; A61B 17/32093; A61B 17/3211; A61B 17/3403; A61B 17/3494; A61M 5/427; A61M 19/00
See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

- 1,655,158 A 1/1928 Muir
- 2,110,208 A 3/1938 Eggert
- 2,168,437 A 8/1939 Buercklin
- 2,643,653 A 6/1953 Heidrich

(Continued)

FOREIGN PATENT DOCUMENTS

- DE 000000635692 A 9/1936
- EP 0079405 5/1983

(Continued)

OTHER PUBLICATIONS

International Search Report and Written Opinion for PCT Application No. PCT/US2016/035602 dated Nov. 29, 2016.

(Continued)

Primary Examiner — Keli L Hill

(74) *Attorney, Agent, or Firm* — Lathrop GPM LLP; Brian C. Trinque

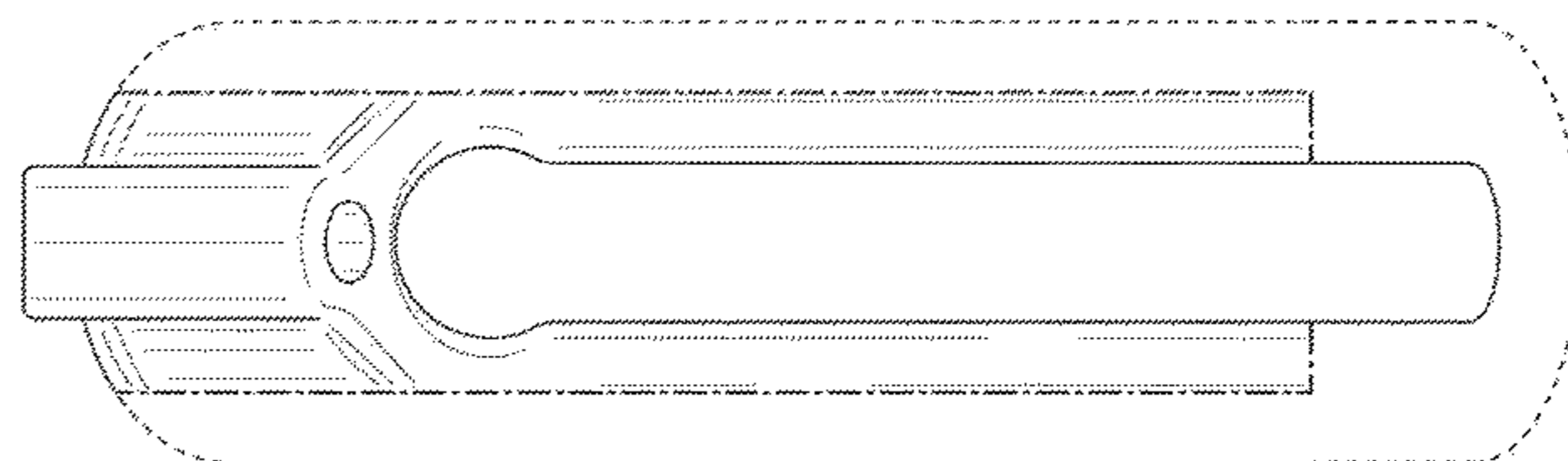
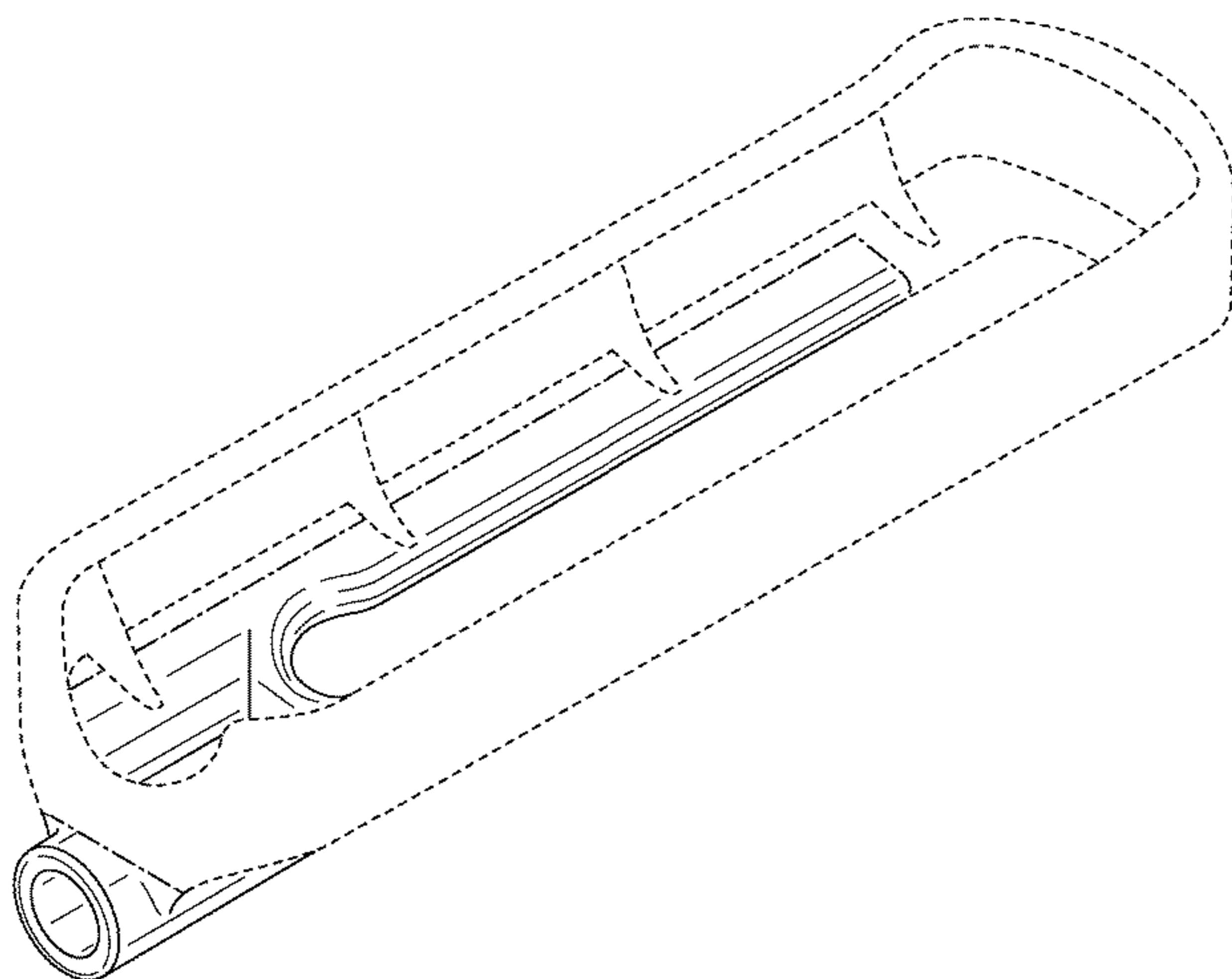
(57) **CLAIM**

The ornamental design for an implant placement guide, as shown and described.

DESCRIPTION

FIG. 1 is a perspective view of a design for an implant placement guide;
 FIG. 2 is a first side view of the design for the implant placement guide of FIG. 1;
 FIG. 3 is a second side view of the design for the implant placement guide of FIG. 1;
 FIG. 4 is a front view of the design for the implant placement guide of FIG. 1;
 FIG. 5 is a back view of the design for the implant placement guide of FIG. 1;
 FIG. 6 is a top view for the design for the implant placement guide of FIG. 1; and,
 FIG. 7 is a bottom view for the design of the implant placement guide of FIG. 1.
 The dot-dash broken lines immediately adjacent the shaded areas represent the bounds of the claimed design while all other broken lines are included for the purpose of illustrating portions of the implant placement guide; the broken lines form no part of the claimed design.

1 Claim, 7 Drawing Sheets



(56)

References Cited

U.S. PATENT DOCUMENTS

3,016,895 A	1/1962	Sein	4,865,845 A	9/1989	Eckenhoff et al.
3,025,991 A	3/1962	Gillon	4,871,094 A	10/1989	Gall et al.
3,122,162 A	2/1964	Sands	4,873,080 A	10/1989	Brickl et al.
3,523,906 A	8/1970	Vrancken et al.	4,874,388 A	10/1989	Wong et al.
3,538,916 A	11/1970	Groff et al.	4,876,781 A	10/1989	Balsells
3,620,216 A	11/1971	Szymanski	4,882,166 A	11/1989	Graham et al.
3,625,214 A	12/1971	Higuchi	4,885,166 A	12/1989	Meyer et al.
3,632,768 A	1/1972	Bergy et al.	4,886,668 A	12/1989	Haslam et al.
3,669,104 A	6/1972	Wyatt et al.	4,892,778 A	1/1990	Theeuwes et al.
3,691,090 A	9/1972	Kitajima et al.	4,893,795 A	1/1990	Balsells
3,732,865 A	5/1973	Higuchi et al.	4,897,471 A	1/1990	Stabinsky
3,737,337 A	6/1973	Schnoring et al.	4,907,788 A	3/1990	Balsells
3,766,915 A	10/1973	Rychlik	4,915,366 A	4/1990	Balsells
3,773,919 A	11/1973	Boswell et al.	4,915,949 A	4/1990	Wong et al.
3,797,492 A	3/1974	Place	4,915,954 A	4/1990	Ayer et al.
3,869,549 A	3/1975	Geller	4,917,887 A	4/1990	Hauptmann et al.
3,891,570 A	8/1975	Fukushima et al.	4,917,895 A	4/1990	Lee et al.
3,960,757 A	6/1976	Morishita et al.	4,923,805 A	5/1990	Reddy et al.
3,987,790 A	10/1976	Eckenhoff et al.	4,927,687 A	5/1990	Nuwayser
3,995,631 A	12/1976	Higuchi et al.	4,929,554 A	5/1990	Goeddel et al.
3,995,632 A	12/1976	Nakano et al.	4,931,285 A	6/1990	Edgren et al.
4,008,719 A	2/1977	Theeuwes et al.	4,934,666 A	6/1990	Balsells
4,034,756 A	7/1977	Higuchi et al.	4,940,465 A	7/1990	Theeuwes et al.
4,078,060 A	3/1978	Benson et al.	4,940,588 A	7/1990	Sparks et al.
4,105,030 A	8/1978	Kercso	4,952,402 A	8/1990	Sparks et al.
4,111,201 A	9/1978	Theeuwes	4,957,119 A	9/1990	de Nijs
4,111,202 A	9/1978	Theeuwes	4,961,253 A	10/1990	Balsells
4,111,203 A	9/1978	Theeuwes	4,964,204 A	10/1990	Balsells
4,203,439 A	5/1980	Theeuwes	4,969,884 A	11/1990	Yum
4,211,771 A	7/1980	Witkowski et al.	4,974,821 A	12/1990	Balsells
4,221,882 A	9/1980	Naito et al.	4,976,966 A	12/1990	Theeuwes et al.
4,223,674 A	9/1980	Fluent et al.	4,994,028 A	2/1991	Leonard et al.
4,243,030 A	1/1981	Lynch et al.	5,004,689 A	4/1991	Fiers et al.
4,305,927 A	12/1981	Theeuwes et al.	5,006,346 A	4/1991	Theeuwes et al.
4,310,516 A	1/1982	Chang et al.	5,019,382 A	5/1991	Cummins, Jr.
4,340,054 A	7/1982	Michaels	5,019,400 A	5/1991	Gombotz et al.
4,350,271 A	9/1982	Eckenhoff	5,023,088 A	6/1991	Wong et al.
4,373,527 A	2/1983	Fischell	5,024,842 A	6/1991	Edgren et al.
4,376,118 A	3/1983	Daher	5,030,216 A	7/1991	Theeuwes et al.
4,384,975 A	5/1983	Fong	5,034,229 A	7/1991	Magruder et al.
4,389,330 A	8/1983	Tice et al.	5,053,014 A	10/1991	Van Heugten
4,439,196 A	3/1984	Higuchi	5,057,318 A	10/1991	Magruder et al.
4,451,253 A	5/1984	Harman	5,059,423 A	10/1991	Magruder et al.
4,455,143 A	6/1984	Theeuwes et al.	5,066,436 A	11/1991	Komen et al.
4,455,145 A	6/1984	Theeuwes	5,071,642 A	12/1991	Lahr et al.
4,474,572 A	10/1984	McNaughton et al.	5,072,070 A	12/1991	Balsells
4,530,840 A	7/1985	Tice et al.	5,079,388 A	1/1992	Balsells
4,552,561 A	11/1985	Eckenhoff et al.	5,090,962 A	2/1992	Landry et al.
4,588,614 A	5/1986	Lauchenauer	5,091,188 A	2/1992	Haynes
4,594,108 A	6/1986	Greminger, Jr. et al.	5,108,078 A	4/1992	Balsells
4,597,753 A	7/1986	Turley	5,110,596 A	5/1992	Magruder et al.
4,609,374 A	9/1986	Ayer	5,112,614 A	5/1992	Magruder et al.
4,639,244 A	1/1987	Rizk et al.	5,113,938 A	5/1992	Clayton
4,655,462 A	4/1987	Balsells	5,117,066 A	5/1992	Balsells
4,673,405 A	6/1987	Guittard et al.	5,118,666 A	6/1992	Habener
4,675,184 A	6/1987	Hasegawa et al.	5,120,306 A	6/1992	Gosselin
4,695,623 A	9/1987	Stabinsky	5,120,712 A	6/1992	Habener
4,727,138 A	2/1988	Goeddel et al.	5,120,832 A	6/1992	Goeddel et al.
4,734,284 A	3/1988	Terada et al.	5,122,128 A	6/1992	Cardinal et al.
4,787,437 A	4/1988	Gutsell, Jr. et al.	5,122,377 A	6/1992	Miller
4,743,449 A	5/1988	Yoshida et al.	5,126,142 A	6/1992	Ayer et al.
4,753,651 A	6/1988	Eckenhoff	5,128,147 A	6/1992	Silvestri et al.
4,762,791 A	8/1988	Goeddel et al.	5,134,244 A	7/1992	Balsells
4,765,989 A	8/1988	Wong et al.	5,137,727 A	8/1992	Eckenhoff
4,783,337 A	11/1988	Wong et al.	5,147,295 A	9/1992	Stewart
4,818,517 A	4/1989	Kwee et al.	5,151,093 A	9/1992	Theeuwes et al.
4,820,267 A	4/1989	Harman	5,160,122 A	11/1992	Balsells
4,820,638 A	4/1989	Swetly et al.	5,160,743 A	11/1992	Edgren et al.
4,826,144 A	5/1989	Balsells	5,161,806 A	11/1992	Balsells
4,830,344 A	5/1989	Balsells	5,180,591 A	1/1993	Magruder et al.
4,834,708 A	5/1989	Pillari	5,190,765 A	3/1993	Jao et al.
4,845,196 A	7/1989	Cowling	5,192,273 A	3/1993	Bierman
4,847,079 A	7/1989	Kwan	5,203,849 A	4/1993	Balsells
4,851,228 A	7/1989	Zentner et al.	5,204,108 A	4/1993	Ilium
4,840,896 A	8/1989	Reddy et al.	5,207,752 A	5/1993	Sorensen et al.
			5,209,746 A	5/1993	Balaban et al.
			5,213,809 A	5/1993	Wright et al.
			5,213,810 A	5/1993	Steber
			5,219,572 A	6/1993	Sivaramakrishnan

(56)

References Cited

U.S. PATENT DOCUMENTS

5,221,278 A	6/1993	Linkwitz et al.	5,571,525 A	11/1996	Roorda et al.
5,223,265 A	6/1993	Wong	5,574,008 A	11/1996	Johnson et al.
5,225,205 A	7/1993	Orsoini	5,574,137 A	11/1996	Gray et al.
5,231,176 A	7/1993	Goeddel et al.	5,580,578 A	12/1996	Oshlack et al.
5,234,424 A	8/1993	Yum et al.	5,589,167 A	12/1996	Cleland et al.
5,234,692 A	8/1993	Magruder et al.	5,595,751 A	1/1997	Bezwada
5,234,693 A	8/1993	Magruder et al.	5,595,759 A	1/1997	Wright et al.
5,234,695 A	8/1993	Hobbs et al.	5,597,579 A	1/1997	Bezwada et al.
5,250,026 A	10/1993	Ehrlich et al.	5,602,010 A	2/1997	Hauptmann et al.
5,252,338 A	10/1993	Jao et al.	5,605,688 A	2/1997	Himmeler et al.
5,260,069 A	11/1993	Chen	5,607,687 A	3/1997	Bezwada et al.
5,278,151 A	1/1994	Korb et al.	5,609,885 A	3/1997	Rivera et al.
5,279,544 A	1/1994	Gross et al.	5,613,954 A	3/1997	Nelson et al.
5,279,554 A	1/1994	Turley	5,614,221 A	3/1997	Fjellstrom
5,279,555 A	1/1994	Lifshey	5,614,492 A	3/1997	Habener
5,279,608 A	1/1994	Cherif Cheikh	5,618,552 A	4/1997	Bezwada et al.
5,284,655 A	2/1994	Bogdansky et al.	5,620,698 A	4/1997	Bezwada et al.
5,288,501 A	2/1994	Nürnberg et al.	5,620,705 A	4/1997	Dong et al.
5,288,502 A	2/1994	Mcginity et al.	5,630,796 A	5/1997	Bellhouse et al.
5,290,271 A	3/1994	Jemberg	5,633,011 A	5/1997	Dong et al.
5,300,079 A	4/1994	Niezink et al.	5,635,213 A	6/1997	Nystrom et al.
5,300,302 A	4/1994	Tachon et al.	5,639,477 A	6/1997	Maruyama et al.
5,308,348 A	5/1994	Balaban et al.	5,639,640 A	6/1997	Reddy et al.
5,312,335 A	5/1994	McKinnon et al.	5,645,850 A	7/1997	Bezwada et al.
5,312,389 A	5/1994	Theeuwes et al.	5,648,088 A	7/1997	Bezwada et al.
5,312,390 A	5/1994	Wong	5,650,173 A	7/1997	Ramstack et al.
5,318,558 A	6/1994	Linkwitz et al.	5,654,008 A	8/1997	Herbert et al.
5,318,780 A	6/1994	Viegas et al.	5,654,010 A	8/1997	Johnson et al.
5,320,616 A	6/1994	Magndu et al.	5,656,297 A	8/1997	Bernstein et al.
5,324,280 A	6/1994	Wong et al.	5,656,299 A	8/1997	Kino et al.
5,336,057 A	8/1994	Fukuda et al.	5,658,593 A	8/1997	Orly et al.
5,336,505 A	8/1994	Ng et al.	5,660,847 A	8/1997	Magruder et al.
5,348,544 A	9/1994	Sweeney et al.	5,660,858 A	8/1997	Parikh et al.
5,352,662 A	10/1994	Brooks et al.	5,660,861 A	8/1997	Jao et al.
5,368,588 A	11/1994	Bettinger	5,667,808 A	9/1997	Johnson et al.
5,368,863 A	11/1994	Eckenhoff et al.	5,668,170 A	9/1997	Gyory
5,371,089 A	12/1994	Rattan	5,672,549 A	9/1997	Minami et al.
5,374,620 A	12/1994	Clark et al.	5,676,942 A	10/1997	Testa et al.
5,385,738 A	1/1995	Yamahira et al.	5,686,097 A	11/1997	Taskovich et al.
5,385,887 A	1/1995	Yim et al.	5,688,801 A	11/1997	Mesens et al.
5,395,319 A	3/1995	Hirsch et al.	5,690,925 A	11/1997	Gray et al.
5,407,609 A	4/1995	Tice et al.	5,690,952 A	11/1997	Magruder et al.
5,411,951 A	5/1995	Mitchell	5,695,463 A	12/1997	Cherif-Cheikh
5,413,572 A	5/1995	Wong et al.	5,697,914 A	12/1997	Brimhall
5,413,672 A	5/1995	Hirotsuji et al.	5,698,213 A	12/1997	Jamiolkowski et al.
5,424,286 A	6/1995	Eng	5,700,486 A	12/1997	Canal et al.
5,428,024 A	6/1995	Chu et al.	5,700,583 A	12/1997	Jamiolkowski et al.
5,429,602 A	7/1995	Hauser	5,703,200 A	12/1997	Bezwada et al.
5,439,688 A	8/1995	Orsolini et al.	5,707,644 A	1/1998	Illum
5,443,459 A	8/1995	Wong et al.	5,711,967 A	1/1998	Juch
5,445,829 A	8/1995	Paradissis et al.	5,713,847 A	2/1998	Howard, III et al.
5,456,679 A	10/1995	Balaban et al.	5,718,922 A	2/1998	Herrero-Vanrell
5,458,888 A	10/1995	Chen	5,725,497 A	3/1998	Woodruff et al.
5,464,929 A	11/1995	Bezwada et al.	5,728,088 A	3/1998	Margruder et al.
5,472,708 A	12/1995	Chen	5,728,396 A	3/1998	Peery et al.
5,478,564 A	12/1995	Wantier et al.	5,733,572 A	3/1998	Unger et al.
5,484,403 A	1/1996	Yoakum et al.	5,736,159 A	4/1998	Chen et al.
5,486,365 A	1/1996	Takado et al.	5,738,845 A	4/1998	Imakawa
5,498,255 A	3/1996	Wong et al.	5,747,058 A	5/1998	Tipton et al.
5,511,355 A	4/1996	Dingier	5,756,450 A	5/1998	Lorenz et al.
5,512,293 A	4/1996	Landrau et al.	5,767,251 A	6/1998	Reddy et al.
5,512,549 A	4/1996	Chen et al.	5,770,231 A	6/1998	Mesens et al.
5,514,110 A	5/1996	Teh	5,782,396 A	7/1998	Mastri et al.
5,529,914 A	6/1996	Hubbell et al.	5,792,477 A	8/1998	Rickey et al.
5,531,736 A	7/1996	Wong et al.	5,795,591 A	8/1998	Lee et al.
5,540,665 A	7/1996	Mercado et al.	5,795,779 A	8/1998	McCormick et al.
5,540,912 A	7/1996	Roorda et al.	5,807,876 A	9/1998	Armistead et al.
5,541,172 A	7/1996	Labrie et al.	5,810,769 A	9/1998	Schlegel et al.
5,542,682 A	8/1996	Goldstein et al.	5,814,323 A	9/1998	Lyle
5,543,156 A	8/1996	Roorda et al.	5,817,129 A	10/1998	Labrecque et al.
5,545,618 A	8/1996	Buckley et al.	5,827,297 A	10/1998	Boudjema
5,556,642 A	9/1996	Kobayashi et al.	5,830,501 A	11/1998	Dong et al.
5,557,318 A	9/1996	Gabriel	5,836,935 A	11/1998	Ashton et al.
5,558,637 A	9/1996	Allonen et al.	5,843,891 A	12/1998	Sherman
5,569,289 A	10/1996	Yoon	5,844,017 A	12/1998	Jamiolkowski et al.
			5,851,451 A	12/1998	Takechi et al.
			5,858,746 A	1/1999	Hubbell et al.
			5,859,150 A	1/1999	Jamiolkowski et al.
			5,861,166 A	1/1999	Eckenhoff

(56)

References Cited

U.S. PATENT DOCUMENTS

5,871,770	A	2/1999	Margruder et al.	6,218,431	B1	4/2001	Schoen et al.
5,871,778	A	2/1999	Kino et al.	6,224,894	B1	5/2001	Jamiolkowski et al.
5,874,388	A	2/1999	Hsu	6,235,712	B1	5/2001	Stevenson et al.
5,876,746	A	3/1999	Jona et al.	6,245,349	B1	6/2001	Yiv et al.
5,882,676	A	3/1999	Lee et al.	6,245,357	B1	6/2001	Edgren et al.
5,904,935	A	5/1999	Eckenhoff et al.	6,248,112	B1	6/2001	Gambale et al.
5,906,599	A	5/1999	Kaldany	6,251,435	B1	6/2001	Jamiolkowski et al.
5,906,816	A	5/1999	Soos et al.	6,258,377	B1	7/2001	New et al.
5,906,830	A	5/1999	Farinas et al.	6,261,584	B1	7/2001	Peery et al.
5,908,621	A	6/1999	Glue et al.	6,268,343	B1	7/2001	Knudsen et al.
5,916,598	A	6/1999	Rickey et al.	6,270,700	B1	8/2001	Ignatious
5,922,253	A	7/1999	Herbert et al.	6,270,787	B1	8/2001	Ayer
5,928,666	A	7/1999	Farinas et al.	6,277,413	B1	8/2001	Sankaram
5,932,547	A	8/1999	Stevenson et al.	6,283,949	B1	9/2001	Roorda
5,938,654	A	8/1999	Wong et al.	6,284,264	B1	9/2001	Zerbe et al.
5,939,286	A	8/1999	Johnson et al.	6,284,727	B1	9/2001	Kim et al.
5,942,223	A	8/1999	Bazer et al.	6,287,295	B1	9/2001	Chen et al.
5,942,253	A	8/1999	Gombotz et al.	6,284,725	B1	12/2001	Coolidge et al.
5,945,126	A	8/1999	Thanoo et al.	6,329,336	B1	12/2001	Bridon et al.
5,948,430	A	9/1999	Zerbe et al.	6,331,311	B1	12/2001	Brodbeck et al.
5,951,521	A	9/1999	Mastrototaro et al.	6,372,218	B1	4/2002	Cummins
5,958,909	A	9/1999	Habener	6,372,256	B2	4/2002	Jamiolkowski et al.
5,962,023	A	10/1999	Jamiolkowski et al.	6,375,978	B1	4/2002	Kleiner et al.
5,965,168	A	10/1999	Mesens et al.	6,395,282	B1	5/2002	Kende et al.
5,972,370	A	10/1999	Eckenhoff et al.	6,395,292	B2	5/2002	Peery et al.
5,972,373	A	10/1999	Yajima et al.	6,402,716	B1	6/2002	Ryoo et al.
5,976,109	A	11/1999	Heruth	6,403,655	B1	6/2002	Bezwada et al.
5,980,945	A	11/1999	Ruiz	6,419,952	B2	7/2002	Wong et al.
5,981,719	A	11/1999	Woiszwilo et al.	6,428,517	B1	8/2002	Hochman et al.
5,984,890	A	11/1999	Gast et al.	6,433,144	B1	8/2002	Morris et al.
5,985,305	A	11/1999	Peery et al.	6,436,091	B1	8/2002	Harper et al.
5,989,463	A	11/1999	Tracy et al.	6,447,522	B2	9/2002	Gambale et al.
5,997,527	A	12/1999	Gumucio et al.	6,451,974	B1	9/2002	Hansen
5,997,902	A	12/1999	Maruyama et al.	6,458,385	B2	10/2002	Jamiolkowski et al.
6,007,805	A	12/1999	Foster et al.	6,458,387	B1	10/2002	Scott et al.
6,017,545	A	1/2000	Modi	6,458,924	B2	10/2002	Knudsen et al.
6,022,561	A	2/2000	Carlsson et al.	6,461,605	B1	10/2002	Cutler et al.
6,029,361	A	2/2000	Newman	6,464,688	B1	10/2002	Harper et al.
6,053,927	A	4/2000	Hamas	6,468,961	B1	10/2002	Brodbeck et al.
6,056,718	A	5/2000	Funderburk et al.	6,471,688	B1	10/2002	Harper et al.
6,060,450	A	5/2000	Soos et al.	6,472,512	B1	10/2002	LaFleur et al.
6,069,133	A	5/2000	Carlo et al.	6,478,768	B1	11/2002	Kneer
6,074,377	A	6/2000	Sanfilippo, II	6,485,706	B1	11/2002	McCoy et al.
6,074,660	A	6/2000	Jamiolkowski et al.	6,495,164	B1	12/2002	Ramstack et al.
6,074,673	A	6/2000	Guillen	6,506,724	B1	1/2003	Hiles et al.
6,100,346	A	8/2000	Jamiolkowski et al.	6,508,808	B1	1/2003	Carr et al.
6,110,503	A	8/2000	Rickey et al.	6,514,500	B1	2/2003	Bridon et al.
D430,671	S	9/2000	Shute	6,514,517	B2	2/2003	Jamiolkowski et al.
6,113,938	A	9/2000	Chen et al.	6,524,305	B1	2/2003	Peterson et al.
6,113,947	A	9/2000	Cleland et al.	6,528,093	B1	3/2003	Kamei et al.
6,120,787	A	9/2000	Gustafsson et al.	6,528,486	B1	3/2003	Larsen et al.
6,124,261	A	9/2000	Stevenson et al.	6,541,021	B1	4/2003	Johnson et al.
6,124,281	A	9/2000	Lewis et al.	6,544,239	B2	4/2003	Kinsey et al.
6,127,520	A	10/2000	Ueda et al.	6,544,252	B1	4/2003	Theeuwes et al.
6,129,761	A	10/2000	Hubbell	6,547,250	B1	4/2003	Noble
6,130,200	A	10/2000	Brodbeck et al.	6,551,613	B1	4/2003	Dong et al.
6,132,420	A	10/2000	Dionne et al.	6,569,420	B2	5/2003	Chen et al.
6,133,249	A	10/2000	Hills	6,572,890	B2	6/2003	Faour et al.
6,133,429	A	10/2000	Davis et al.	6,579,851	B2	6/2003	Goeke et al.
6,146,139	A	11/2000	Harrison, III	6,589,157	B2	7/2003	Fontayne et al.
6,147,168	A	11/2000	Jamiolkowski et al.	6,592,508	B1	7/2003	Ravins et al.
6,156,331	A	12/2000	Peery et al.	6,592,887	B2	7/2003	Zerbe et al.
6,172,046	B1	1/2001	Albrecht	6,593,295	B2	7/2003	Bridon et al.
6,174,547	B1	1/2001	Dong et al.	6,607,529	B1	8/2003	Jones et al.
6,177,096	B1	1/2001	Zerbe et al.	6,626,863	B1	9/2003	Berler
6,183,461	B1	2/2001	Matsuura et al.	6,635,268	B2	10/2003	Peery et al.
6,187,095	B1	2/2001	Labrecque et al.	6,645,192	B2	11/2003	Kenison et al.
6,190,350	B1	2/2001	Davis et al.	6,667,061	B2	12/2003	Ramstack et al.
6,190,700	B1	2/2001	Okada et al.	6,670,368	B1	12/2003	Breault et al.
6,190,702	B1	2/2001	Takada et al.	6,673,767	B1	1/2004	Brodbeck et al.
6,191,102	B1	2/2001	DiMarchi et al.	6,682,522	B2	1/2004	Carr et al.
6,204,022	B1	3/2001	Johnson et al.	6,703,225	B1	3/2004	Kojima et al.
6,217,893	B1	4/2001	Pellet et al.	6,703,359	B1	3/2004	Young et al.
6,217,906	B1	4/2001	Gumucio et al.	6,706,689	B2	3/2004	Coolidge et al.
6,217,908	B1	4/2001	Mathiowitz et al.	6,709,671	B2	3/2004	Zerbe et al.
				6,720,407	B1	4/2004	Hughes et al.
				6,730,328	B2	5/2004	Maskiwicz et al.
				6,767,887	B1	7/2004	Hoffmann et al.
				6,821,949	B2	11/2004	Bridon et al.

(56)

References Cited

U.S. PATENT DOCUMENTS

6,833,256 B1	12/2004	Pontzer et al.	7,825,091 B2	11/2010	Bloom et al.
6,835,194 B2	12/2004	Johnson et al.	7,829,109 B2	11/2010	Chen et al.
6,840,931 B2	1/2005	Peterson et al.	7,833,543 B2	11/2010	Gibson et al.
6,849,708 B1	2/2005	Habener	7,879,028 B2	2/2011	Alessi et al.
6,849,714 B1	2/2005	Bridon et al.	7,879,794 B2	4/2011	Berry et al.
6,858,576 B1	2/2005	Young et al.	7,919,109 B2	4/2011	Berry et al.
6,872,700 B1	3/2005	Young et al.	7,928,065 B2	6/2011	Rohloff et al.
6,875,748 B2	4/2005	Manthorpe et al.	7,964,183 B2	6/2011	Eliasz et al.
6,887,470 B1	5/2005	Bridon et al.	8,039,432 B2	10/2011	Bridon et al.
6,887,849 B2	5/2005	Bridon et al.	7,959,938 B2	11/2011	Lautenbach et al.
6,899,887 B2	5/2005	Ayer	8,048,438 B2	11/2011	Berry et al.
6,899,898 B2	5/2005	Albayrak	8,052,996 B2	11/2011	Lautenbach et al.
6,902,744 B1	6/2005	Kolterman et al.	8,058,233 B2	11/2011	Cowley et al.
6,903,186 B1	6/2005	Dong	8,101,576 B2	1/2012	Bloom
6,913,767 B1	7/2005	Cleland et al.	8,114,430 B2	2/2012	Rohloff et al.
6,923,800 B2	8/2005	Chen et al.	8,114,437 B2	2/2012	Rohloff et al.
6,924,264 B1	8/2005	Prickett et al.	8,158,150 B2	4/2012	Lautenbach et al.
6,939,556 B2	9/2005	Lautenbach	8,173,150 B2	5/2012	Berry et al.
6,956,026 B2	10/2005	Beeley et al.	8,202,836 B2	6/2012	Moore et al.
6,960,192 B1	11/2005	Flaherty et al.	8,206,745 B2	6/2012	Rohloff et al.
6,969,702 B2	11/2005	Bertilsson et al.	8,211,467 B2	7/2012	Rohloff et al.
6,976,981 B2	12/2005	Ayer	8,217,001 B2	7/2012	Cowley et al.
6,989,366 B2	1/2006	Beeley et al.	8,231,859 B2	7/2012	Bolotin et al.
6,992,065 B2	1/2006	Okumu	8,251,946 B2	8/2012	Bardy
6,997,922 B2	2/2006	Theeuwes et al.	8,257,682 B2	9/2012	Bolotin et al.
7,008,439 B1	3/2006	Janzen et al.	8,257,691 B2	9/2012	Eliasz et al.
7,014,636 B2	3/2006	Gilbert	8,262,667 B1	9/2012	Silver et al.
7,022,674 B2	4/2006	DeFelippis et al.	8,263,545 B2	9/2012	Bloom
7,041,646 B2	5/2006	Pan et al.	8,263,736 B2	9/2012	Berry
7,074,423 B2	7/2006	Fereira et al.	8,268,341 B2	9/2012	Berry
7,084,243 B2	8/2006	Glaesner et al.	8,273,365 B2	9/2012	Lautenbach et al.
7,101,567 B1	9/2006	Sano et al.	8,273,713 B2	9/2012	Pittner et al.
7,101,843 B2	9/2006	Glaesner et al.	8,277,776 B2	10/2012	Bolotin et al.
7,112,335 B2	9/2006	Lautenbach	8,278,267 B2	10/2012	Weyer et al.
7,115,569 B2	10/2006	Beeley et al.	8,288,338 B2	10/2012	Alessi et al.
7,138,375 B2	11/2006	Beeley et al.	8,298,561 B2	10/2012	Alessi et al.
7,138,486 B2	11/2006	Habener et al.	8,299,025 B2	10/2012	Alessi et al.
7,141,547 B2	11/2006	Rosen et al.	8,343,140 B2	1/2013	Alessi et al.
7,144,863 B2	12/2006	DeFelippis et al.	8,367,095 B2	2/2013	Lautenbach et al.
7,153,825 B2	12/2006	Young et al.	8,372,424 B2	2/2013	Berry et al.
7,157,555 B1	1/2007	Beeley et al.	8,398,967 B2	3/2013	Eliasz et al.
7,163,688 B2	1/2007	Peery et al.	8,440,226 B2	5/2013	Rohloff et al.
7,163,697 B2	1/2007	Hanes et al.	8,454,552 B2	6/2013	Bardy
7,199,217 B2	4/2007	DiMarchi et al.	8,460,694 B2	6/2013	Rohloff et al.
7,205,409 B2	4/2007	Pei et al.	8,470,353 B2	6/2013	Lautenbach et al.
7,207,982 B2	4/2007	Dionne et al.	8,722,037 B2	5/2014	Veenstra et al.
7,214,206 B2	5/2007	Rue et al.	8,747,412 B2	6/2014	Bae et al.
7,241,457 B2	7/2007	Chen et al.	8,801,700 B2	8/2014	Alessi et al.
7,258,869 B1	8/2007	Berry et al.	8,815,802 B2	8/2014	Kalthoft et al.
7,297,761 B2	11/2007	Beeley et al.	8,865,202 B2	10/2014	Zerbe et al.
7,316,680 B2	1/2008	Gilbert	8,888,745 B2	11/2014	Van Der Graaf et al.
D565,179 S *	3/2008	Kubo A61B 17/3468 D24/155	8,926,595 B2	1/2015	Alessi et al.
7,393,827 B2	7/2008	Nadler	8,940,316 B2	1/2015	Alessi et al.
7,407,499 B2	8/2008	Trautman	8,992,961 B2	3/2015	Berry et al.
7,442,682 B2	10/2008	Kitaura et al.	8,992,962 B2	3/2015	Lautenbach et al.
7,456,254 B2	11/2008	Wright et al.	9,044,209 B2	6/2015	Dayton et al.
7,459,432 B2	12/2008	Cowley et al.	9,078,900 B2	7/2015	Kuzma et al.
7,521,423 B2	4/2009	Young et al.	9,095,553 B2	8/2015	Rohloff et al.
7,563,871 B2	7/2009	Wright et al.	9,526,763 B2	12/2016	Rohloff et al.
7,589,169 B2	9/2009	Bolotin	9,539,200 B2	1/2017	Lautenbach
7,604,647 B2	10/2009	Chen	9,572,889 B2	2/2017	Alessi et al.
7,612,176 B2	11/2009	Wright et al.	D789,539 S *	6/2017	Kleiner D24/155
7,632,256 B2	12/2009	Mosier et al.	9,682,127 B2	6/2017	Alessi et al.
7,635,463 B2	12/2009	Bolotin et al.	9,889,085 B1	2/2018	Alessi et al.
7,655,254 B2	2/2010	Dennis et al.	D816,843 S *	5/2018	Lewis D24/155
7,655,257 B2	2/2010	Peery et al.	D835,783 S *	12/2018	Smith D24/140
7,666,835 B2	2/2010	Bloom et al.	D840,030 S *	2/2019	Smith D24/140
7,682,356 B2	3/2010	Alessi et al.	2001/0012511 A1	8/2001	Bezwada et al.
7,727,519 B2	6/2010	Moran	2001/0021377 A1	9/2001	Jamiolkowski et al.
7,731,947 B2	6/2010	Eliasz et al.	2001/0021822 A1	9/2001	Ayer
7,736,665 B2	6/2010	Patel et al.	2001/0022974 A1	9/2001	Ayer
7,741,269 B2	6/2010	Young et al.	2001/0026793 A1	10/2001	Jamiolkowski et al.
7,766,924 B1	8/2010	Bombard et al.	2001/0027311 A1	10/2001	Chen et al.
7,790,140 B2	9/2010	Bolotin	2001/0031940 A1	10/2001	Loos
			2001/0031790 A1	11/2001	Beisswenger
			2001/0036472 A1	11/2001	Wong et al.
			2001/0040326 A1	11/2001	Balczun
			2002/0001631 A1	1/2002	Okumu
			2002/0004481 A1	1/2002	Cleland et al.

(56)

References Cited

U.S. PATENT DOCUMENTS

2002/0012818	A1	1/2002	Ruppi et al.	2005/0095284	A1	5/2005	Trautman
2002/0034532	A1	3/2002	Brodbeck et al.	2005/0101943	A1	5/2005	Ayer et al.
2002/0037309	A1	3/2002	Jaworowicz et al.	2005/0106214	A1	5/2005	Chen
2002/0048600	A1	4/2002	Bhatt et al.	2005/0112188	A1	5/2005	Eliasz et al.
2002/0077599	A1	6/2002	Wojcik	2005/0118206	A1	6/2005	Luk et al.
2002/0098180	A1	7/2002	Lei	2005/0118221	A1	6/2005	Blakely et al.
2002/0136848	A1	9/2002	Yoshii et al.	2005/0131386	A1	6/2005	Freeman et al.
2002/0137666	A1	9/2002	Beeley et al.	2005/0131389	A1	6/2005	Peterson et al.
2002/0141985	A1	10/2002	Pittner et al.	2005/0143749	A1	6/2005	Zalenski et al.
2002/0197185	A1	12/2002	Jamiolkowski et al.	2005/0175701	A1	8/2005	Pan et al.
2002/0197235	A1	12/2002	Moran	2005/0201980	A1	9/2005	Moran
2003/0007992	A1	1/2003	Gibson et al.	2005/0215475	A1	9/2005	Ong et al.
2003/0032947	A1	2/2003	Harper et al.	2005/0216087	A1	9/2005	Zucherman et al.
2003/0040699	A1	2/2003	Talling et al.	2005/0266087	A1	12/2005	Junnarkar et al.
2003/0044467	A1	3/2003	Brodbeck et al.	2005/0271702	A1	12/2005	Wright et al.
2003/0045454	A1	3/2003	Okumu et al.	2005/0276856	A1	12/2005	Ferreira et al.
2003/0059376	A1	3/2003	Libbey et al.	2005/0281879	A1	12/2005	Chen et al.
2003/0059471	A1	3/2003	Compton et al.	2006/0013879	A9	1/2006	Brodbeck et al.
2003/0060425	A1	3/2003	Ahlem et al.	2006/0014678	A1	1/2006	Cowley et al.
2003/0078618	A1	4/2003	Fey et al.	2006/0030526	A1	2/2006	Liu et al.
2003/0097121	A1	6/2003	Babcock et al.	2006/0069029	A1	3/2006	Kolterman et al.
2003/0104063	A1	6/2003	Babcock et al.	2006/0073182	A1	4/2006	Wong et al.
2003/0108608	A1	6/2003	Berry et al.	2006/0084604	A1	4/2006	Kitaura et al.
2003/0108609	A1	6/2003	Berry et al.	2006/0084922	A1	4/2006	Botha
2003/0113380	A1	6/2003	Ramstack et al.	2006/0094652	A1	5/2006	Levy et al.
2003/0114837	A1	6/2003	Peterson et al.	2006/0094693	A1	5/2006	Aziz et al.
2003/0118660	A1	6/2003	Rickey et al.	2006/0106399	A1	5/2006	Taras et al.
2003/0135153	A1	7/2003	Hagemeier	2006/0141040	A1	6/2006	Chen et al.
2003/0138403	A1	7/2003	Drustrup	2006/0142234	A1	6/2006	Chen et al.
2003/0138491	A1	7/2003	Tracy et al.	2006/0160736	A1	7/2006	Nadler
2003/0157178	A1	8/2003	Chen et al.	2006/0178304	A1	8/2006	Juul-Mortensen et al.
2003/0170289	A1	9/2003	Chen et al.	2006/0193918	A1	8/2006	Rohloff et al.
2003/0180364	A1	9/2003	Chen et al.	2006/0216242	A1	9/2006	Rohloff et al.
2003/0186858	A1	10/2003	Arentsen	2006/0224145	A1	10/2006	Gills
2003/0191099	A1	10/2003	Bohlmann et al.	2006/0233841	A1	10/2006	Brodbeck et al.
2003/0211974	A1	11/2003	Brodbeck et al.	2006/0246138	A1	11/2006	Rohloff et al.
2003/0215515	A1	11/2003	Truong-Le et al.	2006/0251618	A1	11/2006	Dennis et al.
2003/0220617	A1	11/2003	Dickerson	2006/0263433	A1	11/2006	Ayer et al.
2003/0233101	A1	12/2003	Lubock et al.	2006/0264890	A1	11/2006	Moberg et al.
2004/0001689	A1	1/2004	Goldsmith et al.	2006/0280795	A1	12/2006	Penhasi et al.
2004/0001889	A1	1/2004	Chen et al.	2006/0293232	A1	12/2006	Levy et al.
2004/0002442	A1	1/2004	Pan et al.	2007/0027105	A1	2/2007	Junnarkar et al.
2004/0022859	A1	2/2004	Chen et al.	2007/0141102	A1	6/2007	De Graaff et al.
2004/0024068	A1	2/2004	Chen et al.	2007/0149011	A1	6/2007	Kent et al.
2004/0024069	A1	2/2004	Chen et al.	2007/0166352	A1	7/2007	Wright et al.
2004/0029784	A1	2/2004	Hathaway	2007/0207958	A1	9/2007	Bridon et al.
2004/0039376	A1	2/2004	Peery et al.	2007/0248572	A1	10/2007	Moran et al.
2004/0047888	A1	3/2004	Kenison et al.	2007/0281024	A1	12/2007	Lautenbach et al.
2004/0097906	A1	5/2004	Ferreira et al.	2008/0020016	A1	1/2008	Li et al.
2004/0101557	A1	5/2004	Gibson et al.	2008/0038316	A1	2/2008	Wong et al.
2004/0102762	A1	5/2004	Gilbert	2008/0064636	A1	3/2008	Bloom et al.
2004/0115236	A1	6/2004	Chan et al.	2008/0065090	A1	3/2008	Scribner et al.
2004/0142867	A1	7/2004	Oi et al.	2008/0091176	A1	4/2008	Alessi et al.
2004/0142902	A1	7/2004	Struijker-Boudier	2008/0110515	A1	5/2008	Angelosanto et al.
2004/0151753	A1	8/2004	Chen et al.	2008/0112994	A1	5/2008	Junnarkar et al.
2004/0157951	A1	8/2004	Wolf	2008/0200383	A1	8/2008	Jennings et al.
2004/0198654	A1	10/2004	Glaesner et al.	2008/0207512	A1	8/2008	Roth et al.
2004/0199140	A1	10/2004	Rue et al.	2008/0226625	A1	9/2008	Berry et al.
2004/0209801	A1	10/2004	Brand et al.	2008/0226689	A1	9/2008	Berry et al.
2004/0215133	A1	10/2004	Weber et al.	2008/0260838	A1	10/2008	Hokenson et al.
2004/0224903	A1	11/2004	Berry et al.	2008/0260840	A1	10/2008	Alessi et al.
2004/0225113	A1	11/2004	LaFleur et al.	2008/0269725	A1	10/2008	Deem et al.
2004/0243106	A1	12/2004	Ayer	2008/0312157	A1	12/2008	Levy et al.
2004/0265273	A1	12/2004	Li et al.	2009/0012463	A1	1/2009	Beelen et al.
2004/0266683	A1	12/2004	Hathaway et al.	2009/0022727	A1	1/2009	Houston et al.
2004/0266692	A1	12/2004	Young et al.	2009/0036364	A1	2/2009	Levy et al.
2005/0004557	A1	1/2005	Russell	2009/0042781	A1	2/2009	Petersen et al.
2005/0008661	A1	1/2005	Ferreira et al.	2009/0074734	A1	3/2009	Rottiers
2005/0009742	A1	1/2005	Bertilsson et al.	2009/0087408	A1	4/2009	Berry et al.
2005/0010196	A1	1/2005	Ferreira et al.	2009/0156474	A1	6/2009	Roth et al.
2005/0070883	A1	3/2005	Brown et al.	2009/0163447	A1	6/2009	Maggio
2005/0070927	A1	3/2005	Feinberg	2009/0186817	A1	7/2009	Ghosh et al.
2005/0079200	A1	4/2005	Rathenow et al.	2009/0202481	A1	8/2009	Li et al.
2005/0079202	A1	4/2005	Chen et al.	2009/0202608	A1	8/2009	Alessi et al.
2005/0010942	A1	5/2005	Eliasz et al.	2009/0209460	A1	8/2009	Young et al.
				2009/0210019	A1	8/2009	Kim et al.
				2009/0215694	A1	8/2009	Kolterman et al.
				2009/0247463	A1	10/2009	Wright et al.
				2009/0254143	A1	10/2009	Tweden et al.

(56)

References Cited

U.S. PATENT DOCUMENTS

2009/0286723 A1 11/2009 Levy et al.
 2009/0312246 A1 12/2009 Baron et al.
 2010/0092566 A1 4/2010 Alessi et al.
 2010/0094252 A1 4/2010 Wengreen et al.
 2010/0105627 A1 4/2010 Salama et al.
 2010/0144621 A1 6/2010 Kim et al.
 2010/0185184 A1 7/2010 Alessi et al.
 2010/0297209 A1 11/2010 Rohloff et al.
 2010/0298807 A1 11/2010 Jansen et al.
 2010/0298840 A1 11/2010 Schwartz
 2010/0331868 A1 12/2010 Bardy
 2011/0076317 A1 3/2011 Alessi et al.
 2011/0091527 A1 4/2011 Moonen et al.
 2011/0104111 A1 5/2011 Rohloff et al.
 2011/0152181 A1 6/2011 Alsina-Fernandez et al.
 2011/0152182 A1 6/2011 Alsina-Fernandez et al.
 2011/0160708 A1 6/2011 Berry et al.
 2011/0166554 A1 7/2011 Alessi et al.
 2011/0264077 A1 10/2011 Rohloff et al.
 2011/0306549 A1 12/2011 Tatarkiewicz et al.
 2012/0178687 A1 7/2012 Alessi et al.
 2012/0208755 A1 8/2012 Leung
 2012/0303045 A1 11/2012 Cooper et al.
 2013/0030417 A1 1/2013 Alessi
 2013/0034210 A1 2/2013 Rohloff et al.
 2013/0052237 A1 2/2013 Eliaz et al.
 2013/0296661 A1 11/2013 Bornzin et al.
 2013/0324977 A1 12/2013 Vanderpool
 2014/0058409 A1 2/2014 Bratlie
 2014/0058425 A1 2/2014 Porat
 2014/0121741 A1 5/2014 Bennett et al.
 2014/0163057 A1 6/2014 Patel et al.
 2014/0236162 A1 8/2014 Barongan
 2014/0257272 A1 9/2014 Clark, III et al.
 2014/0324067 A1 10/2014 Emken et al.
 2014/0378900 A1 12/2014 Alessi et al.
 2015/0111818 A1 1/2015 Alessi et al.
 2015/0057227 A1 2/2015 Leung
 2015/0001118 A1 4/2015 Alessi et al.
 2015/0133791 A1 5/2015 Sato et al.
 2015/0231062 A1 8/2015 Lautenbach et al.
 2015/0231256 A1 8/2015 Berry et al.
 2015/0297509 A1 10/2015 Schwarz
 2015/0359553 A1 12/2015 Harnisch
 2016/0022582 A1 1/2016 Alessi et al.
 2016/0030337 A1 2/2016 Kuzma et al.
 2016/0354115 A1* 12/2016 Smith A61B 17/3468
 2016/0354305 A1 12/2016 Alessi et al.
 2017/0056476 A1 3/2017 Rohloff et al.
 2017/0079906 A1 3/2017 Alessi et al.
 2017/0119854 A1 5/2017 Alessi et al.
 2017/0119855 A1 5/2017 Berry et al.
 2017/0181964 A1 6/2017 Lautenbach et al.
 2017/0252409 A1 9/2017 Leung
 2017/0319470 A1 11/2017 Eliaz et al.
 2017/0319662 A1 11/2017 Berry et al.
 2017/0348392 A1 12/2017 Rohloff et al.
 2017/0368145 A1 12/2017 Alessi et al.
 2018/0009871 A1 1/2018 Blackwell et al.

FOREIGN PATENT DOCUMENTS

EP 0254394 1/1988
 EP 0295411 12/1988
 EP 0304107 A1 2/1989
 EP 0368339 5/1990
 EP 0373867 6/1990
 EP 0431942 6/1991
 EP 0486959 A1 5/1992
 EP 0497575 A1 8/1992
 EP 0521586 A1 1/1993
 EP 0596161 A1 5/1994
 EP 0379147 9/1994
 EP 0627231 12/1994
 EP 0631794 A1 1/1995

EP 0729747 5/1997
 EP 0771817 5/1997
 EP 0596161 B1 2/1998
 EP 0841359 5/1998
 EP 0767689 6/1999
 EP 1046399 10/2000
 EP 1084703 3/2001
 EP 1300129 A2 4/2003
 EP 1300173 A2 4/2003
 EP 1300129 A3 5/2003
 EP 1323450 A1 7/2003
 EP 1600187 1/2009
 EP 2133073 A1 12/2009
 EP 2020990 9/2010
 FR 640907 7/1928
 FR 2616665 A2 12/1988
 GB 1049104 11/1966
 GB 1518683 7/1978
 GB 2138298 B 11/1986
 GB 2501400 10/2013
 JP H02124814 A 5/1990
 JP H07196479 A 8/1995
 JP 1997/509346 9/1997
 JP 9241153 9/1997
 JP 11-100353 4/1999
 JP 2006/213727 A 8/2006
 NL 8901004 A 11/1990
 NL 9000948 A 11/1990
 NL 9100160 8/1992
 NL 9100160 A 8/1992
 NZ 592113 8/2012
 TW 200634060 10/2006
 WO WO-1989/003678 A1 5/1989
 WO WO-1990/013285 A1 11/1990
 WO WO-1990/013361 A1 11/1990
 WO WO-1990/013780 A1 11/1990
 WO WO 91/07160 5/1991
 WO WO-1992/019241 A1 11/1992
 WO WO 93/06819 4/1993
 WO WO 93/06821 4/1993
 WO WO 93/008832 5/1993
 WO WO 93/09763 5/1993
 WO WO 93/23083 11/1993
 WO WO 94/09743 5/1994
 WO WO-1994/010982 A1 5/1994
 WO WO 94/21262 9/1994
 WO WO 95/01167 1/1995
 WO WO 95/09006 4/1995
 WO WO 95/09007 4/1995
 WO WO-1995/013799 A1 5/1995
 WO WO 95/34285 12/1995
 WO WO 96/001134 1/1996
 WO WO 96/003116 2/1996
 WO WO-1996/036317 A1 11/1996
 WO WO 96/39142 12/1996
 WO WO 96/40049 12/1996
 WO WO 96/40139 12/1996
 WO WO 96/40355 12/1996
 WO WO-1996/040049 A1 12/1996
 WO WO 97/15289 5/1997
 WO WO 97/15296 5/1997
 WO WO 97/28181 8/1997
 WO WO-1997/031943 A1 9/1997
 WO WO-1997/044039 A1 11/1997
 WO WO 97/46204 12/1997
 WO WO 97/47339 12/1997
 WO WO 98/00152 1/1998
 WO WO 98/00157 1/1998
 WO WO 98/00158 1/1998
 WO WO 98/02169 1/1998
 WO WO-1997/041837 A3 2/1998
 WO WO-1998/007412 A1 2/1998
 WO WO 98/13092 A1 4/1998
 WO WO 98/16250 4/1998
 WO WO 98/17315 4/1998
 WO WO 98/13091 4/1998
 WO WO 98/20930 5/1998
 WO WO 98/27960 7/1998
 WO WO 98/027962 7/1998

(56)

References Cited

FOREIGN PATENT DOCUMENTS

WO WO 98/27963 7/1998
 WO WO 98/030231 7/1998
 WO WO 98/32463 7/1998
 WO WO-1998/030231 A1 7/1998
 WO WO 98/42317 10/1998
 WO WO 98/47487 10/1998
 WO WO 98/51282 11/1998
 WO WO 98/58698 A1 12/1998
 WO WO 99/03453 1/1999
 WO WO 99/04767 2/1999
 WO WO 99/004768 2/1999
 WO WO-1999/012549 A2 3/1999
 WO WO 99/16419 4/1999
 WO WO 99/025728 5/1999
 WO WO 99/29306 6/1999
 WO WO 99/033446 7/1999
 WO WO 99/33449 7/1999
 WO WO 99/39700 8/1999
 WO WO 99/040788 8/1999
 WO WO 99/044659 9/1999
 WO WO 99/062501 12/1999
 WO WO 99/064061 12/1999
 WO WO 00/013663 3/2000
 WO WO 00/029206 5/2000
 WO WO 00/038652 7/2000
 WO WO 00/039280 7/2000
 WO WO 00/040273 7/2000
 WO WO 00/041548 7/2000
 WO WO 00/045790 8/2000
 WO WO 00/054745 9/2000
 WO WO-2000/059476 A1 10/2000
 WO WO 00/066138 11/2000
 WO WO 00/067728 11/2000
 WO WO-2000/066087 A2 11/2000
 WO WO-2001/019345 A1 3/2001
 WO WO 01/28631 A1 4/2001
 WO WO-2001/028525 A2 4/2001
 WO WO 01/043528 6/2001
 WO WO 01/051041 7/2001
 WO WO 01/68168 A1 9/2001
 WO WO 01/78683 10/2001
 WO WO 02/028366 4/2002
 WO WO 02/036072 5/2002
 WO WO 02/043800 6/2002
 WO WO 02/045752 6/2002
 WO WO 02/47716 6/2002
 WO WO 02/067895 9/2002
 WO WO 02/069983 9/2002
 WO WO 02/76344 10/2002
 WO WO 02/085428 10/2002
 WO WO 03/000230 1/2003
 WO WO 03/007981 1/2003
 WO WO 03/011892 2/2003
 WO WO 03/024357 3/2003
 WO WO 03/024503 3/2003
 WO WO-2003/020245 A1 3/2003
 WO WO 03/030923 4/2003
 WO WO 03/041684 5/2003
 WO WO 03/041757 5/2003
 WO WO 03/053400 7/2003
 WO WO-2003/066585 A2 8/2003
 WO WO 03/072113 9/2003
 WO WO 03/072133 9/2003
 WO WO 04/002565 1/2004
 WO WO 2004/026106 A2 4/2004
 WO WO-2004/034975 A2 4/2004
 WO WO-2004/035754 A2 4/2004
 WO WO-2004/035762 A2 4/2004
 WO WO-2004/036186 A2 4/2004
 WO WO 04/046338 6/2004
 WO WO 04/052336 6/2004
 WO WO 04/056338 7/2004
 WO WO 04/089335 10/2004
 WO WO 2004/089458 A1 10/2004
 WO WO-2004/103342 A2 12/2004

WO WO 05/048930 6/2005
 WO WO 05/048952 6/2005
 WO WO 05/102293 11/2005
 WO WO-2005/102293 A1 11/2005
 WO WO-2005/110425 11/2005
 WO WO 06/017772 2/2006
 WO WO 06/023526 3/2006
 WO WO 2006/077242 A1 7/2006
 WO WO 2006/077250 A1 7/2006
 WO WO 06/081279 8/2006
 WO WO 06/083761 8/2006
 WO WO 06/084139 8/2006
 WO WO 06/086727 8/2006
 WO WO 06/101815 9/2006
 WO WO 06/111169 10/2006
 WO WO-2006/131730 12/2006
 WO WO 07/024700 3/2007
 WO WO 07/056681 5/2007
 WO WO 07/075534 7/2007
 WO WO 07/084460 7/2007
 WO WO 2007/082889 A1 7/2007
 WO WO 07/133778 11/2007
 WO WO 07/140416 12/2007
 WO WO 08/021133 2/2008
 WO WO-2008/041245 A2 4/2008
 WO WO 08/061355 5/2008
 WO WO-2008/086086 A2 7/2008
 WO WO 08/133908 11/2008
 WO WO 08/134425 11/2008
 WO WO 09/109927 9/2009
 WO WO-2009/143285 A2 11/2009
 WO WO 2010/045169 A1 4/2010
 WO WO 2013/004983 A1 1/2013
 WO WO 2013/184235 A1 12/2013

OTHER PUBLICATIONS

Croxatto. "Clinical profile of Implanon: a single-rod etonogestrel contraceptive implant." *Eur J Contracept Reprod Health Care*. Sep. 2000; 5 Suppl 2:21-8.

Implanon Prescribing Information. Manufactured for Merck Sharp & Dohme Corp. Copyright © 2006, 2009, 2012 Merck Sharp & Dohme B.V., a subsidiary of Merck & Co., Inc. Revised Mar. 2016.

Nexplanon Prescribing Information. Manufactured for Merck Sharp & Dohme Corp. Copyright © 2011 Merck Sharp & Dohme B.V., a subsidiary of Merck & Co., Inc. Revised Mar. 2016.

Probuphine Prescribing Information. Distributed by Braeburn Pharmaceuticals, Inc. Revised May 2016.

Glumetza Brochure 2009, 13 Pages.

EROWID, "Introduction to the Federal Controlled Substance Analog Act" 2001, 4 pages.

Li et al. "Glucagon-Like Peptide-I Receptor Agonists Versus Insulin Glargine for Type 2 Diabetes Mellitus: A Systematic Review and Meta-Analysis of Randomized Controlled Trials" in *Current Therapeutic Research*, vol. 71, No. 4, Aug. 2010.

Palmeri et al., "5-Fluorouracil and recombinant α -interferon-2a in the treatment of advanced colorectal carcinoma: a dose optimization study," *J. Chemotherapy* 2(5):327-330 (Oct. 1990).

Akers, et al., "Formulation Design and Development of Parenteral Suspensions," *Journal of Parenteral Science & Technology*, 41(3): 88-96 (1987).

Alonso, et al., "Determinants of Release Rate of Tetanus Vaccine from Polyester Microspheres," *Pharmaceutical Research*, 10(7):945-953 (1993).

Beck, et al., "Poly(dl-lactide-co-glycolide)/norethisterone microcapsules: An injectable biodegradable contraceptive," *Biology of Reproduction*, 28(1): 186-195 (1983).

Bodmeier and McGinity, "Solvent selection in the preparation of poly(dl-lactide) microspheres prepared by the solvent evaporation method," *International Journal of Pharmaceutics*, 43(1-2): 179-186 (Apr. 1988).

Cha and Pitt, "A one-week subdermal delivery system for l-methadone based on biodegradable microcapsules," *Journal of Controlled Release*, 7: 69-78 (1988).

(56)

References Cited

OTHER PUBLICATIONS

- Cha and Pitt, "The acceleration of degradation-controlled drug delivery from polyester microspheres," *Journal of Controlled Release*, 8: 259-265 (1989).
- Cohen, et al., "Controlled delivery systems for proteins based on poly(lactic/glycolic acid) microspheres," *Pharmaceutical Research*, 8(6): 713-720 (1991).
- Conti, et al., "Use of polylactic acid for the preparation of microparticulate drug delivery systems," *Journal of Microencapsulation*, 9(2): 153-166 (1992).
- Hodgman, et al., Eds., *Handbook of Chemistry and Physics*, 35th Edition, 1024-1025 (1953).
- Jalil and Nixon, "Biodegradable poly(lactic acid) and poly(lactide-co-glycolide) microcapsules: Problems associated with preparative techniques and release properties," *Journal of Microencapsulation*, 7(3): 297-325 (Jul.-Sep. 1990).
- Lee and Timasheff, "The stabilization of proteins by sucrose," *J. Biological Chem.*, 256(14): 7193-7201 (Jul. 1981).
- Li, et al., "Prediction of solvent removal profile and effect on properties for peptide-loaded PLGA microspheres prepared by solvent extraction/evaporation method," *Journal of Controlled Release*, 37:199-214 (1995).
- Maa and Hsu, "Liquid-liquid emulsification by static mixers for use in microencapsulation," *Journal of Microencapsulation*, 13(4): 419-433 (Jul.-Aug. 1996).
- Maulding, et al., "Biodegradable microcapsules: Acceleration of polymeric excipient hydrolytic rate by incorporation of a basic medicament," *Journal of Controlled Release*, 3: 103-117 (1986).
- Mehta, et al., "Peptide containing microspheres from low molecular weight and hydrophilic poly(D,L-lactide-co-glycolide)," *Journal of Controlled Release*, 41: 249-257 (1996).
- Sah, et al., "A novel method of preparing PLGA microcapsules utilizing methylethyl ketone," *Pharmaceutical Research*, 13(3): 360-367 (1996).
- Sato, et al., "Porous biodegradable microspheres for controlled drug delivery. I. Assessment of processing conditions and solvent removal techniques," *Pharmaceutical Research*, 5(1): 21-30 (1988).
- Szayna, et al., "Exendin-4 decelerates food intake, weight gain, and fat deposition in Zucker rats," *Endocrinology*, 141(6): 1936-1941 (2000).
- Thomasin, et al., "A contribution to overcoming the problem of residual solvents in biodegradable microspheres prepared by coacervation," *Eur. J. Pharm. Biopharm.*, 42(1): 16-24 (1996).
- Van Santbrink and Fauser, "Urinary follicle-stimulating hormone for normogonadotropic colomiphene-resistant anovulatory infertility: Prospective, randomized comparison between low dose step-up and step-down dose regimens," *J. Clin. Endocrin. Metab.*, 82(11): 3597-3602 (1997).
- Tracy et al., "Factors affecting the degradation rate of poly(lactide-co-glycolide) microspheres in vivo and in vitro," *Biomaterials*, 20(11): 1057-1062(1999).
- Ertl et al., "Poly (DL-lactide-co-glycolide) microspheres as carriers for peptide vaccines," *Vaccine* 14(9):879-885.(1996).
- Thompson et al., "Biodegradable microspheres as a delivery system for rismorelin porcine, a porcine-growth-hormone-releasing hormone," *Journal of Controlled Release* 43(1):9-22 (1997).
- Adolf, "Human interferon omega-a review," *Mult. Scrl. ES44-47* (1995).
- Costantino et al., "Protein Spray Freeze Drying. 2. Effect of Formulation Variables on particle Size and Stability," *J. Pharm. Sci.* 91:388-395 (2002).
- Henry et al., "Comparing ITCA 650, continuous subcutaneous delivery of exenatide via DUROS® device, vs. twice daily exenatide injections in metformin-treated type 2 diabetes," oral presentation at the 46th Annual Meeting of the European Association for the Study of Diabetes in Stockholm, Sweden, 21 pages (Sep. 20-24, 2010).
- Huggins et al., "Synergistic antiviral effects of ribavirin and the C-nucleoside analogs tiazofurin and selenazofurin against togaviruses, bunyaviruses, and arenaviruses," *Antimicrobial Agents & Chemotherapy*, 26(4):476-480 (1984).
- Ishiwata et al., "Clinical effects of the recombinant feline interferon-omega on experimental parvovirus infection in beagle dogs," *J. Vet. Med. Sci.* 60(8):911-917 (1998).
- Johnson et al., "How interferons fight disease," *Sci. Am.* 270(5):68-75 (May 1994).
- Lublin et al., "Defining the clinical course of multiple sclerosis: results of an international survey," *Neurology*. 46:907-911 (1996).
- Madsbad, "Exenatide and liraglutide: different approaches to develop GLP-1 receptor agonists (incretin mimetics)—preclinical and clinical results," *Best Practice & Research Clinical Endocrinology & Metabolism* 23:463-77 (2009).
- Nielsen, "Incretin mimetics and DPP-IV inhibitors for the treatment of type 2 diabetes," *Drug Discovery Today* 10(10):703-710 (May 15, 2005).
- Palmeri et al., "5-Fluorouracil and recombinant α -interferon-2a in the treatment of advanced colorectal carcinoma: a dose optimization study," *J. Chemotherapy* 2(5):327-330 (Oct. 1990).
- Patti et al., "Natural interferon-b treatment of relapsing-remitting and secondary progressive multiple sclerosis patients: two-year study," *Acta. Neurol. Scand.* 100:283-289 (1999).
- Paty et al., "Interferon beta-1 b is effective in relapsing-remitting multiple sclerosis," *Neurology* 43:662-667 (1993).
- PCT International Search Report for PCT/US2009/000916, 4 pages (dated Aug. 12, 2009).
- "Intarcia Therapeutics Announces Final Results from a Phase 2 Study of Injectable Omega Interferon plus Ribavirin for the Treatment of Hepatitis C Genotype-1," NLV Partners Press Coverage Portfolio News (Apr. 12, 2007) (Press Release).
- Quianzon et al., "Lixisenatide-Once-daily Glucagon-like Peptide-1 Diabetes," *US Endocrinology* 7(2): 104-109 (2011).
- Ratner et al., "Dose-dependent effects of the one-daily GLP-1 receptor agonist lixisenatide in patients with Type 2 diabetes inadequately controlled with metformin: a randomized, double-blind, placebo-controlled trial," *Diabetic Medicine* 27(9): 1024-1032 (Sep. 2010).
- Roberts et al., "The Evolution of the Type I Interferons 1," *J. Interferon Cytokine Res.* 18(10):805-816(Oct. 1998).
- Rohloff et al., "DUROS Technology Delivers Peptides and Proteins at Consistent Rate Continuously for 3 to 12 Months," *J. Diabetes Sci. & Tech.*, 2(3):461-467 (May 1, 2008).
- "Sequence Listings for International Patent Application Publication No. W02009109927, Wipo Patentscope", http://patentscope.wipo.int/search/docservicepdf_pct/id00000008776887, 1 page (last visited Nov. 14, 2012).
- Shire et al., "Challenges in the Development of High Protein Concentration Formulations," *J. Pharm. Sci.* 93:1390-1402 (2004).
- Smith, "Peripheral Neuro-hormones as a Strategy to Treat Obesity," oral presentation at the 2007 Cardiometabolic Health Congress in Boston, MA, pp. 1-35 (Sep. 26-29, 2007).
- Written Opinion for International Patent Application No. PCT/US2009/005629 (corresponding to U.S. Appl. No. 12/587,946), 5 pages (dated Apr. 15, 2011).
- Zhang et al., "Efficacy observations of different dosages of interferon to treat 150 Hepatitis B carriers," *Current Physician* 2(12):45-46 (1997).
- Pratley et al., "Targeting Incretins in Type 2 Diabetes: Role of GLP-1 Receptor Agonists and DPP-4 Inhibitors," *Rev. Diabet. Stud.*, 5(2):73-94 (2008).
- Gonzalez, et al., "Hemoglobin Alc: A Reliable and Accurate Test for Diabetes Care? A Prospective Study in Mexico," *Salud Publica Mex* 55:462-468 (2013).
- Ahn et al., "A New Approach to Search for the Bioactive Confirmation of Glucagon: Positional Cyclization Scanning" *Journal of Medicinal Chemistry*, vol. 44, No. 19, (2001): 3109-3116.
- "Abstracts 2007," *Diabetologia Clinical & Experimental Diabetes & Metabolism*, Springer, Berlin, Germany, vol. 50 S243 (Aug. 21, 2007) (paragraph [0586]) (XP002538652).
- Jetschmann et al., "Open-label rising-dose study of omega interferon in IFN-naïve patients with chronic hepatitis C," *Gastroenterology* 122:A278-A347 (Apr. 1, 2002) (Abstract M1454).
- Bray, "Gut Signals and Energy Balance: Ghrelin, Peptide YY, Leptin, and Amylin," (Dec. 19, 2007) (slides and transcript for presentation at Medscape CME).

(56)

References Cited

OTHER PUBLICATIONS

- "Implantable infusion pumps: technology poised for takeoff," BBI Newsletter 17(12):209-211 (Dec. 1994).
- "Search Report and Written Opinion" dated Dec. 19, 2008 for PCT/US2008/005235, filed Apr. 22, 2008.
- Adamson et al., "Phase I trial and pharmacokinetic study of all-trans-retinoic acid administered on an intermittent schedule in combination with interferon-alpha2a in pediatric patients with refractory cancer," *J. Clin. Oncol.* 15(11):3330-3337 (Nov. 1997).
- Adolf et al., "Monoclonal antibodies and enzyme immunoassays specific for human interferon (IFN) ω 1. evidence that IFN- ω 1 is a component of human leukocyte IFN," *Virology* 175(2):410-471 (Apr. 1990).
- Adolf et al., "Antigenic structure of human interferon ω 1 (Interferon α 11 1): comparison with other human interferons," *J. Gen. Virol.* 68(6): 1669-1676 (Jun. 1987).
- Adolf et al., "Purification and characterization of natural human interferon ω 1," *J. Bio. Chem.* 265(16):9290-9295 (Jun. 1990).
- Adolf et al., "Human interferon ω 1. isolation of the gene, expression in Chinese hamster ovary cells and characterization of the recombinant protein," *Biochim. Biophys. Acta* 108(9): 167-174 (Jun. 1991).
- ANDRX Pharmaceuticals, LLC, ANDA for Concerta® Extended-Release Tablets, 6 pages (correspondence dated Sep. 6, 2005).
- ASTM International, Annual Book of ASTM Standards, 8.02:208-211, 584-587 (1984).
- Ansel et al., "Dosage Form Design: Pharmaceutical and Formulation Considerations," *Pharmaceutical Dosage Forms and Drug Delivery Systems*, Ch. 3 at 87-92 (7th ed. Lippincott Williams & Wilkins 1999).
- Ansel et al., "Modified-Release Dosage Forms and Drug Delivery Systems," *Pharmaceutical Dosage Forms and Drug Delivery Systems*, Ch. 8 at 229-243 (7th ed. Lippincott Williams & Wilkins 1999).
- Aulitzky, "Successful Treatment of Metastatic Renal Cell Carcinoma With a Biologically Active Dose of Recombinant Interferon-Gama," *Journal of Clinical Oncology* 7(12):1875-1884 (1989).
- Hauck, "Engineer's Guide to Plastics," *Materials Engineering* 5(72):38-45 (Jul. 17, 1972).
- Bailon et al., "Rational Design of a Potent, Long-lasting Form of Interferon: A 40 kDa Branched Polyethylene Glycol-conjugated Interferon Alpha-2a for the Treatment of Hepatitis C," *Bioconjugate Chemistry* 12(2):195-202 (2001).
- Bakan et al., "Physicochemical Characterization of a Synthetic Lipid Emulsion for Hepatocyte-Selective Delivery of Lipophilic Compounds: Application to Polyiodinated triglycerides as Contrast Agents for Computed Tomography," *J. Pharm. Sci.*, 85(9):908-914 (1996).
- Bakhtiar et al., "Taking Delivery," *Soap Perfumery & Cosmetics* 76(3):59-65 (2003) (liposomes in cosmetic delivery systems).
- Balkwill, F., "Interferons," *Lancet* 1(8646): 1060-1063 (May 1989).
- Bauer et al., "Non-aqueous emulsions as vehicles for capsule fillings," *Drug Dev. & Industrial Pharmacy* 10(5):699-712 (1984).
- Bekkering et al., "Estimation of early hepatitis C viral clearance in patients receiving daily interferon and ribavirin therapy using a mathematical model," *Hepatology* 33(2):419-423 (Feb. 2001).
- Bell et al., "Hamster preproglucagon contains the sequence of glucagon and two related peptides," *Nature* 302:716-718 (1983).
- Bell et al., "Impact of moisture on thermally induced denaturation and decomposition of lyophilized bovine somatotropin," *Drug Delivery Research & Dev. Biopolymers*, (35):201-209 (1995).
- Bertoncello et al., "Haematopoietic radioprotection by Cremophor EL: a polyethoxylated castor oil," *Int. J. Radiat. Biol.* 67(1):57-64 (1995).
- Bohlinder et al., "Use and characteristics of a novel lipid particle-forming matrix as a drug-carrier system," *Euro. J. Pharm. Sci.* 2(4):271-279 (1994).
- Bolinger et al., "Recombinant interferon γ for treatment of chronic granulomatous disease and other disorders," *Clin. Pharm.* 11(10):834-850 (Oct. 1992).
- Bonkovsky et al., "Outcomes research in chronic viral hepatitis C: effects of interferon therapy," *Can. J. Gastroenterol.* 14(Supp. B):21B-29B (Jul.-Aug. 2000).
- Borden et al., "Second-generation interferons for cancer: clinical targets," *Semin. Cancer Biol.* 10(2): 125-144 (Apr. 2000).
- Boue et al., "Antiviral and antiluteolytic activity of recombinant bovine IFN- ω 1 obtained from *Pichia pastoris*," *J. Interferon & Cytokine Res.* 20:677-683 (2000).
- Buckwold et al. "Antiviral activity of CHO-SS cell-derived human omega interferon and other human interferons against HCV RNA replicons and related viruses," *Antiviral Res.* 73(2): 118-25 (Feb. 2007) (Epub Sep. 11, 2006).
- Cantor, "Theory of lipid monolayers comprised of mixtures of flexible and stiff amphiphiles in anthermal solvents: fluid phase coexistence," *J. Chem. Physics* 104(20):8082-8095 (1996). CAS No. 56-81-5 (Nov. 16, 1984).
- Chang et al., "Biodegradable polyester implants and suspension injection for sustained release of a cognitive enhancer," *Pharm. Tech.* 20(1):80-84 (1996).
- Chapman et al., "Physical Studies of Phospholipids. VI. Thermotropic and Lyotropic Mesomorphism of Some 1,2-Diacylphosphatidylcholines (lecithins)," *Chem. & Physics of Lipids* 1(5):445-475 (1967).
- Chaumeil, "Micronization: a method of improving the bioavailability of poorly soluble drugs," *Methods & Findings in Experimental & Clinical Pharmacology* 20(3):211-215 (1998).
- Clark et al., "The diabetic Zucker fatty rat," *Proc. Soc. Exp. Biol.* 173(1):68-75 (1983).
- Condino-Neto, "Interferon- γ improves splicing efficiency of CYBB gene transcripts in an interferon responsive variant of chronic granulomatous disease due to a splice site consensus region mutation," *Blood* 95(11):3548-3554 (Jun. 2000).
- Darney, "Subdermal progestin implant contraception," *Current Opinion in Obstetrics & Gynecology* 3:470-476 (1991).
- Das et al., "Reviewing Antisense Oligonucleotide Therapy: Part 2, Delivery Issues," *BioPharm*, 2(11):44-51 (1999).
- Dash et al., "Therapeutic applications of implantable drug delivery systems," *Journal of Pharmacological and Toxicological Methods*, 40(1): 1-12 (1998).
- Davis et al., "Durability of viral response to interferon alone or in combination with oral ribavirin in patients with chronic hepatitis C," *Prog. Abstr. 50th Annu. Mtg. Postgrad. Courses Am. Assn. Study Liver Dis.*, Dallas, TX (Nov. 5-9, 1999)(Abstract 570).
- Deacon et al., "GLP-1-(9-36) amide reduces blood glucose in anesthetized pigs by a mechanism that does not involve insulin secretion," *Am. J. Physiol. Endocrinol. Metab.*, 282:E873-E879 (2002).
- Desai et al., "Protein structure in the lyophilized state: a hydrogen isotope exchange/NMR study with bovine pancreatic trypsin inhibitor," *J. Am. Chem. Soc.* 116(21):9420-9422 (1994).
- Di Marco et al., "Combined treatment of relapse of chronic hepatitis C with high-dose α -2B interferon plus ribavirin for 6 or 12 months," *Prog. Abstr. 50th Annu. Mtg. Postgrad. Courses Am. Assn. Study Liver Dis.*, Dallas, TX (Nov. 5-9, 1999)(Abstract 569).
- Dorr et al., "Phase I-II trial of interferon-alpha 2b by continuous subcutaneous infusion over 28 days," *J. Interferon Res.* 8:717-725 (1988).
- Uhlig et al., "The electro-osmotic actuation of implantable insulin micropumps," *J. Biomed. Materials Res.* 17:931-943 (1983).
- Efendic et al., "Overview of incretin hormones," *Horm. Metab. Res.*, 36(11-12):742-746 (2004).
- Eissele et al., "Rat gastric somatostatin and gastrin release: interactions of exendin-4 and truncated glucagon-like peptide-1 (GLP-1) amide," *Life Sci.*, 55(8):629-634 (1994).
- Elias et al., "Infusional Interleukin-2 and 5-fluorouracil with subcutaneous interferon- α for the treatment of patients with advanced renal cell carcinoma: a southwest oncology group Phase II study," *Cancer* 89(3):597-603 (Aug. 2000).
- Eng et al., "Isolation and characterization of exendin-4, an exendin-3 analogue, from *Heloderma suspectum* venom. Further evidence for an exendin receptor on dispersed acini from guinea pig pancreas," *J. Biol. Chem.*, 267(11):7402-7405 (1992).

(56)

References Cited

OTHER PUBLICATIONS

- Eng et al., "Purification and structure of exendin-3, a new pancreatic secretagogue isolated from *Heloderma horridum* venom," *J. Biol. Chem.*, 265(33):20259-20262 (1990).
- Eppstein et al., "Biological activity of liposome-encapsulated murine interferon γ is mediated by a cell membrane receptor," *PNAS USA* 82:3688-3692 (1985).
- Eros et al., "Multiple phase emulsions as controlled drug delivery therapeutic systems," *Proc.-Conf. Colloid Chem.* 193-196 (1993).
- Fang et al., "The impact of baseline liver histology on virologic response to interferon α -2b \pm ρ ribavirin therapy in patients with chronic hepatitis C," *Prog. Abstr. 50th Annu. Mtg. Postgrad. Courses Am. Assn. Study Liver Dis., Dallas, TX (Nov. 5-9, 1999)*(Abstract 572).
- Felker et al., "The Rate of Transfer of Unesterified Cholesterol from Rat Erythrocytes to Emulsions Modeling Nascent Triglyceride-Rich Lipoproteins and Chylomicrons Depends on the Degree of Fluidity of the Surface," *J. Nutritional Biochem.* 4(1):630-634 (1993).
- Ferenci et al., "Combination of interferon (IFN) induction therapy and ribavirin in chronic hepatitis C," *Prog. Abstr. Dig. Dis. Week 2000, San Diego, CA (May 21-24, 2000)* (Abstract 977).
- Fontaine et al., "Recovery from chronic hepatitis C in long-term responders to ribavirin plus interferon α ," *Lancet* 356(9223):41 (Jul. 2000).
- Franchetti et al., "Furanfuran and Thiophenfurin: Two Novel Tiazofurin Analogues. Synthesis, Structure, Antitumor Activity, and Interactions with Inosine Monophosphate Dehydrogenase," *J. Medicinal Chem.* 38(19):3829-3837 (1995).
- Fujii et al., "Effect of phosphatidylcholine on Skin Permeation of Indomethacin from gel prepared with Liquid Paraffin and Hydrogenated Phospholipid," *Int'l J. Pharmaceutics* 222(1):57-64 (2001).
- Fujii et al., "Enhancement of skin permeation of miconazole by phospholipid and dodecyl 2-(N, N-dimethylamino) propionate (DDAIP)," *Int'l J. Pharmaceutics* 234(1-2): 121-128 (2002).
- Luft et al., "Electro-osmotic valve for the controlled administration of drugs," *Med. & Biological Engineering & Computing* 45-50 (Jan. 1978) (non-English with English abstract).
- Gan To Kagaku Ry Oho, "Phase II study of recombinant leukocyte A interferon (Ro22-8181) in malignant brain tumors," *Cancer & Chemotherapy* 12(4):913-920 (Apr. 1985) (non-English with English abstract).
- Gappa et al., "Juvenile laryngeal papillomatosis—a case report," *Pneumologie* 45(11):936-938 (Nov. 1991) (XP009079028) (non-English with English abstract).
- Gause et al., "Phase I study of subcutaneously administered interleukin-2 in combination with interferon alfa-2a in patients with advanced cancer," *J. Clin. Oncol.* 14(8):2234-2241 (Aug. 1996).
- Ghiglione et al., "How glucagon-like is glucagon-like peptide-1?" *Diabetologia* 27:599-600 (1984).
- Glue et al., "A dose-ranging study of Peg-intron and ribavirin in chronic hepatitis C—safety, efficacy, and virological rationale," *Prog. Abstr. 50th Annu. Mtg. Postgrad. Courses Am. Assn. Study Liver Dis., Dallas, TX(Nov. 5-9, 1999)*(Abstract 571).
- Goke et al., "Exendin-4 is a high potency agonist and truncated exendin-(9-39)-amide an antagonist at the glucagon-like peptide 1-(7-36)-amide receptor of insulin-secreting β cells," *J. Biol. Chem.*, 268(26): 19650-19655 (1993).
- Gonzales et al., "Randomized controlled trial including an initial 4-week 'induction' period during one year of high-dose interferon α -2B treatment for chronic hepatitis C," *Prog. Abstr. Dig. Dis. Week 2000, San Diego, CA (May 21-24, 2000)* (Abstract 975).
- Gosland et al., "A phase I trial of 5-day continuous infusion cisplatin and interferon alpha," *Cancer Chemother. Pharmacol.* 37(1-2):39-46 (1995).
- Grant et al., "Combination therapy with interferon- α plus N-acetyl cysteine for chronic hepatitis C: a placebo controlled double-blind multicentre study," *J. Med. Virol.* 61(4):439-442 (Aug. 2000).
- Gutniak et al., "Antidiabetogenic effect of glucagon-like peptide-1 (7-36)amide in normal subjects and patients with diabetes mellitus," *N. Engl. J. Med.*, 326(20): 1316-1322 (1992).
- Hageman, "The Role of Moisture in Protein Stability," *Drug Dev. & Ind. Pharm.* 14(14):2047-2070(1988).
- Heathcote et al., "Peginterferon alfa-2a in Patients With Chronic Hepatitis C and Cirrhosis," *New England J. Med.* 343(23): 1673-1680 (2000).
- Heim et al., "Intracellular signaling and antiviral effects of interferons," *Dig. Liver Dis.* 32(3):257-263 (Apr. 2000).
- Heinrich et al., "Pre-proglucagon messenger ribonucleic acid: nucleotide and encoded amino acid sequences of the rat pancreatic complementary deoxyribonucleic acid," *Endocrinol.*, 115:2176-2181 (1984).
- Hellstrand et al., "Histamine and cytokine therapy," *Acta Oncol.* 37(4):347-353 (1998).
- Hellstrand et al., "Histamine and the response to IFN- α in chronic hepatitis C," *Interferon Cytokine Res.* 18(1):21-22 (Jan. 1998).
- Hellstrand et al., "Histamine in immunotherapy of advanced melanoma: a pilot study," *Cancer Immunol Immunother.* 39(6):416-419 (Dec. 1994).
- Hisatomi et al., "Toxicity of polyoxyethylene hydrogenated castor oil 60 (HCO-60) in experimental animals," *J. Toxicol. Sci.*, 18(3): 1-9 (1993).
- Hodoshima et al., "Lipid nanoparticles for delivering antitumor drugs," *International Journal of Pharmaceutics*, 146(1): 81-92 (1997).
- Hoffmann-La Roche Inc., Pegasys® (peginterferon alfa-2a), 15 pages (2002).
- Horton et al., "Antitumor effects of interferon-omega: in vivo therapy of human tumor xenografts in nude mice" *Cancer Res* 59(16):4064-4068 (Aug. 1999).
- Hubel et al., "A phase I/II study of idarubicin, dexamethasone and interferon-alpha (1-Dexa) in patients with relapsed or refractory multiple myeloma" *Leukemia* 11 Suppl 5:S47-S51 (Dec. 1997).
- Iacobelli et al., "A phase I study of recombinant interferon-alpha administered as a seven-day continuous venous infusion at circadian-rhythm modulated rate in patients with cancer," *Am. J. Clin. Oncol.* 18(1):27-31 (1995).
- IFNB Multiple Sclerosis Study Group, "Interferon β -1b is effective in relapsing-remitting multiple sclerosis," *Neurology* 43(4):655-667 (Apr. 1993).
- Intermune® Inc., Infergen® (Interferon alfacon-1), 5 pages (2002).
- "Introduction to Antibodies", <http://www.chemicon.com/resource/ANT101/al.asp>, 8 pages (retrieved May 2, 2007).
- Isaacs et al., "Virus interference. I. The interferon," *Pro. R. Soc. Lond. B. Biol. Sci.* 147:258-267(1957).
- Jain et al., "Controlled delivery of drugs from a novel injectable in situ formed biodegradable PLGA microsphere system," *J. Microencapsulation* 17(3):343-362 (2000).
- Jordan et al., "Guidelines for Antiemetic Treatment of Chemotherapy-Induced Nausea and Vomiting: Past, Present and Future Recommendations," *The Oncologist* 12(9): 1143-1150(2007).
- Kabalnov et al., "Macroemulsion type and stability of alkane-water-phospholipid systems," *Abstracts of Papers, Part 1, 210th ACS National Meeting, 0-8412-3222-9, American Chemical Society, Chicago, IL (Aug. 20-24, 1995)* (Abstract only).
- Kabalnov et al., "Phospholipids as Emulsion Stabilizers.2. Phase Behavior Versus Emulsion Stability," *Journal of Colloid and Interface Science* 184(1):227-235 (1996).
- Khalili et al., "Interferon and ribavirin versus interferon and amantadine in interferon nonresponders with chronic hepatitis C," *Am. J. Gastroenterol.* 95(5): 1284-1289 (May 2000).
- Kildsig et al., "Theoretical Justification of Reciprocal Rate Plots in Studies of Water Vapor Transmission through Films," *J. Pharma. Sci.* 29(11): 1634-01637 (Nov. 17, 1970).
- Kirkwood et al., "Interferon alfa-2b adjuvant therapy of high-risk resected cutaneous melanoma: The Eastern Cooperative Oncology Group Trial EST 1684," *J. Clin. Oncol.* 14(1):7-17 (1996).
- Kita et al., "Characterization of a polyethylene glycol conjugate of recombinant human interferon- γ ," *Drug Des. Deliv.* 6(3): 157-0167 (Sep. 1990).
- Knepp et al., "Identification of antioxidants for prevention of peroxide-mediated oxidation of recombinant human ciliary neurotrophic factor and recombinant human nerve growth factor," *J. Pharm. Sci. Tech.* 50(3): 163-171 (1996).

(56)

References Cited

OTHER PUBLICATIONS

- Knepp et al., "Stability of nonaqueous suspension formulations of plasma derived factor IX and recombinant human alpha interferon at elevated temperatures," *Pharma. Res.* 15(7): 1090-1095 (1998).
- Knobler et al., "Systemic α -interferon therapy of multiple sclerosis," *Neurology* 34(10): 1273-1279 (Oct. 1984).
- Kovacevic et al., "Treatment of chronic viral hepatitis B in secondary membranoproliferative glomerulonephritis using recombinant α -2 interferon," *Maksic Dj Vojnosanit. Pregl.* 57(2):235-240 (Mar.-Apr. 2000) (non-English with English abstract).
- Kracke et al., "Mx proteins in blood leukocytes for monitoring interferon P-1b therapy in patients with MS," *Neurology* 54(1): 193-199 (Jan. 2000).
- Kronenberger et al., "Influence of interferon-a on CD82-expression in HCV-positive patients," *Prog. Abstr. Dig. Dis. Week 2000, San Diego, CA (May 21-24, 2000) (Abstract 976)*.
- Krown et al., "Interferons and interferon inducers in cancer treatment," *Semin. Oncol.* 13(2):207-217(1986).
- Kubes et al., "Cross-species antiviral and antiproliferative activity of human interferon- ω ," *J. Interferon Res.* 14:57-59 (1994).
- Kunzi et al., "Role of interferon-stimulated gene ISG-15 in the interferon- ω -mediated inhibition of human immunodeficiency virus replication," *J. Interferon Cytokine Res.* 16(11):919-927(Nov. 1996).
- Larsson, "Stability of emulsions formed by polar lipids," *Progress in the Chemistry of Fats and Other Lipids* 16:163-0169 (1978).
- Lee et al., "Dynamics of hepatitis C virus quasispecies turnover during interferon-A treatment," *Prog. Abstr. Dig. Dis. Week 2000, San Diego, CA (May 21-24, 2000) (Abstract 974)*.
- Lee, "Therapy of hepatitis C: interferon alfa-2A trials," *Hepatology* 26: 89S-95S (Sep. 1997) (XP000981288).
- Lopez et al., "Mammalian pancreatic proglucagon contains three glucagon-related peptides," *Proc. Natl. Acad. Sci. USA*, 80(18):5485-5489 (1983).
- Lukaszewski et al., "Pegylated α interferon is an effective treatment for virulent Venezuelan equine encephalitis virus and has profound effects on host immune response to infection," *J. Virol.* 74(11):5006-5015 (Jun. 2000).
- Lund et al., "Pancreatic proglucagon cDNA contains two glucagon-related coding sequences arranged in tandem," *Proc. Natl. Acad. Sci. USA*, 79(2):345-349 (1982).
- Lundberg, "A submicron lipid emulsion coated with amphipathic polyethylene glycol for parenteral administration of paclitaxel (Taxol)," *J. Pharm. & Pharmacol.* 49(1): 16-21 (1997).
- Magnuson et al. "Enhanced recovery of a secreted mammalian protein from suspension culture of genetically modified tobacco cells," *Protein Expression & Purification* 7:220-228 (1996).
- Malley et al., "Chronic Toxicity And Oncogenicity Of N-Methylpyrrolidone (Nmp) In Rats And Mice By Dietary Administration," *Drug Chem Toxicol.* 24(4):315-38 (Nov. 2001).
- Manning et al., "Stability of protein pharmaceuticals," *Pharm. Res.* 6(11): 903-918 (1989).
- Marincola et al., "Combination therapy with interferon alfa-2a and interleukin-2 for the treatment of metastatic cancer," *J. Clinical Oncol.* 13(5): 1110-1122 (1995) (XP009078965).
- Massey, "Interaction of vitamin E with saturated phospholipid bilayers," *Biochem. & Biophys. Res. Comms.* 106(3):842-847 (1982).
- McHutchison et al., "Interferon a-2b alone or in combination with ribavirin as initial treatment for chronic hepatitis C," *N. Engl. J. Med.* 339(21): 1485-1492 (Nov. 1998).
- McHutchison et al., "Open-label phase IB study of hepatitis C viral dynamics with omega interferon treatment," *Hepatology* 34(4):A333 (Oct. 1, 2001) (XP004716177) (Abstract Only).
- Meier et al., "The glucagon-like peptide-1 metabolite GLP-1-(9-36) amide reduces postprandial glycemia independently of gastric emptying and insulin secretion in humans," *Am. J. Physiol. Endocrinol. Metab.*, 290(6):E1118-E1123 (2006).
- Merad et al., "Generation of monocyte-derived dendritic cells from patients with renal cell cancer: modulation of their functional properties after therapy with biological response modifiers (IFN- α plus IL-2 and IL-12)," *J. Immunother.* 23(3):369-378 (May-Jun. 2000).
- Milella et al., "Neutralizing antibodies to recombinant a-interferon and response to therapy in chronic hepatitis C infection," *Liver* 13(3): 146-150 (Jun. 1993).
- Mohler, "Primer on electrodeposited coatings," *Materials Engineering* 5:38-45 (1972).
- Mojsov, "Structural requirements for biological activity of glucagon-like peptide-I," *Int. J. Peptide Protein Research*, 40:333-343 (1992).
- Morgan, "Structure and Moisture Permeability of Film-Forming Polymers," *Ind. Eng. Chem.* 45(10):2296-2306 (1953).
- Motzer et al., "Phase I trial of 40-kd branched pegylated interferon alfa-2a for patients with advanced renal cell carcinoma," *J. Clinical Oncol.* 19(5): 1312-1319 (2001).
- Nauck et al., "Normalization of fasting glycaemia by intravenous GLP-1 ([7-36 amide] or [7-37]) in type 2 diabetic patients," *Diabet. Med.*, 15(11):937-945(1998).
- Neumann et al., "Hepatitis C Viral Dynamics In Vivo and the Antiviral Efficacy of Interferon-alpha Therapy," *Science* 282:103-107 (Dec. 1998).
- Nieforth et al., "Use of an indirect pharmacodynamic stimulation model of MX protein induction to compare in vivo activity of interferon-a-2a and a polyethylene glycol-modified derivative in healthy subjects," *Clin. Pharmacol. Ther.* 59(6):636-646 (Jun. 1996).
- Norden et al., "Physicochemical characterization of a drug-containing phospholipid-stabilized o/w emulsion for intravenous administration," *Eur. J. Pharm. Sci.* 13(4):393-401 (2001).
- Olaso et al., "Early prediction of lack of response to treatment with interferon and interferon plus ribavirin using biochemical and virological criteria in patients with chronic hepatitis C," *Esp. Quimioter.* 12(3):220-228 (Sep. 1999) (non-English with English abstract).
- Ortiz et al., "A differential scanning calorimetry study of the interaction of α -tocopherol with mixtures of phospholipids," *Biochim et Biophys Acta* 898(2):214-222 (1987).
- Panitch, "Interferons in multiple sclerosis," *Drugs* 44(6):946-962 (Dec. 1992).
- Patzelt et al., "Identification and processing of proglucagon in pancreatic islets," *Nature*, 282:260-266 (1979).
- Peterson et al., "Zucker Diabetic Fatty Rat as a Model for Non-insulin-dependent Diabetes Mellitus," *ILAR Journal*, 32(3): 16-19 (1990).
- Peterson et al., "Neuropathic complications in the Zucker diabetic fatty rat (ZDF/Drt-fa)," *Frontiers in diabetes research. Lessons from Animal Diabetes* 111, Shafir, E. (ed.), pp. 456-458, Smith-Gordon, London (1990).
- Pimstone et al., "High dose (780 MIU/52 weeks) interferon monotherapy is highly effective treatment for hepatitis C," *Prog. Abstr. Dig. Dis. Week 2000, San Diego, CA (May 21-24-2000) (Abstract 973)*.
- Plauth et al., "Open-label phase II study of omega interferon in previously untreated HCV infected patients," *Hepatology* 34(4):A331 (Oct. 1, 2001) (XP004716169) (Abstract Only).
- Plauth et al., "Open-label study of omega interferon in previously untreated HCV-infected patients," *J. Hepatology* 36(Suppl. 1):125 (Apr. 2002) (XP002511882) (Abstract Only).
- Pohl et al., "Molecular cloning of the helodermin and exendin-4 cDNAs in the lizard. Relationship to vasoactive intestinal polypeptide/pituitary adenylate cyclase activating polypeptide and glucagon-like peptide 1 and evidence against the existence of mammalian homologues," *J. Biol. Chem.*, 273(16):9778-9784 (1998).
- Poynard et al., "Is an 'a la carte' combined interferon a 2b plus ribavirin possible for the first line treatment in patients with chronic hepatitis C," *Hepatology* 31(1):211-218 (Jan. 2000).
- Poynard et al., "Randomized trial of interferon a 2b plus ribavirin for 48 weeks or for 24 weeks versus interferon a 2b plus placebo for 48 weeks for the treatment of chronic infection with hepatitis C virus," *Lancet* 352(9138): 1426-1432 (Oct. 1998).
- "Intarcia Presents Positive ITCA 650 Phase 2 Study Results for Type 2 Diabetes at EASD," *Intarcia Therapeutics, Inc.* (Sep. 22, 2010) (Press Release).
- Quesada et al., "Interferons in Hematological Malignancies", eds. Baron et al., U. Tex. 487-495 (1987).

(56)

References Cited

OTHER PUBLICATIONS

- Quintanar-Guerrero et al., "Applications of the ion-pair concept to hydrophilic substances with special emphasis on peptides," *Pharm. Res.* 14(2): 119-127 (1997).
- Rajkumar et al., "Phase I evaluation of radiation combined with recombinant interferon alpha-2a and BCNU for patients with high-grade glioma," *Int'l J. Radiat. Oncol. Biol. Phys.* 40(2):297-302 (Jan. 15, 1998).
- Roche Pharmaceuticals, Roferon®-A (Interferon alfa-2a, recombinant), 22 pages (2003).
- Roff et al., "Handbook of Common Polymers", Cleveland Rubber Co. 72 pages (1971).
- Rogers et al., "Permeability Valves," *Ind. & Eng. Chem.* 49(11): 1933-1936 (Nov. 17, 1957).
- Roman et al., "Cholestasis in the rat by means of intravenous administration of cyclosporine vehicle, Cremophor EL," *Transplantation* 48(4):554-558 (1989).
- Roth et al., "High Dose Etrretinate and Interferon-alpha—A Phase I Study in Squamous Cell Carcinomas and Transitional Cell Carcinomas," *Acta Oncol.* 38(5):613-617 (1999).
- Roth et al., "Combination therapy with amylin and peptide YY[3-36] in obese rodents: anorexigenic synergy and weight loss additivity," *Endocrinol.* 148(12):6054-61 (Dec. 2007).
- Schepp et al., "Exendin-4 and exendin-(9-39)NH₂: agonist and antagonist, respectively, at the rat parietal cell receptor for glucagon-like peptide-1-(7-36)NH₂," *Eur. J. Pharmacol.*, 269(2):183-191 (1994).
- Schering Corp., Intron® A for Injection, 6 pages (2001).
- Schering Corp., PEG-Intron™ (Peginterferon alfa-2b) Powder for Injection, 29 pages (2003).
- Schmalhub et al., "Modification of drug penetration into human skin using microemulsions," *J. Controlled Release* 46(3):279-285 (1997).
- Sen et al., "The interferon system: a bird's eye view of its biochemistry," *I. Biol. Chem.* 267(8):5017-5020 (Mar. 1992).
- Shtffiman et al., "A decline in HCV-RNA level during interferon or interferon/ribavirin therapy in patients with virologic nonresponse is associated with an improvement in hepatic histology," *Prog. Abstr. 50th Annu. Mtg. Postgrad. Courses Am. Assn. Study Liver Dis.*, Dallas, TX (Nov. 5-9, 1999) (Abstract 567).
- Shima et al., "Serum total bile acid level as a sensitive indicator of hepatic histological improvement in chronic hepatitis C patients responding to interferon treatment," *J. Gastroenterol. Hepatol.* 15(3):294-299 (Mar. 2000).
- Shiratori et al., "Histologic improvement of fibrosis in patients with hepatitis C who have sustained response to interferon therapy," *Ann. Int. Med.* 132(7):517-524 (Apr. 2000).
- Simon et al., "A longitudinal study of T1 hypointense lesions in relapsing MS: MSCRG trial of interferon β_{1a}," *Neurology* 55(2): 185-192 (Jul. 2000).
- Sparks et al., "Lipoprotein alterations in 10- and 20-week-old Zucker diabetic fatty rats: hyperinsulinemic versus insulinopenic hyperglycemia," *Metabolism*, 47(11): 1315-1324 (1998).
- Sulkowski et al., "Pegylated Interferon Alfa-2A (Pegasys™) and Ribavirin Combination Therapy for Chronic Hepatitis C: A Phase II Open-Label Study," *Gastroenterology* 118(4, Supp. 2)(2000)(Abstract 236).
- Sulkowski et al., "Peginterferon-a-2a (40kD) and ribavirin in patients with chronic hepatitis C: a phase II open label study," *Biodrugs* 16(2): 105-109 (2002).
- Talpaz et al., "Phase I study of polyethylene glycol formulation of interferon alpha-2B (Schering 54031) in Philadelphia chromosome-positive chronic myelogenous leukemia," *Blood* 98(6):1708-1713 (2001).
- Talsania et al., "Peripheral exendin-4 and peptide YY(3-36) synergistically reduce food intake through different mechanisms in mice," *Endocrinology* 146(9):3748-56 (Sep. 2005).
- Tanaka et al., "Effect of interferon therapy on the incidence of hepatocellular carcinoma and mortality of patients with chronic hepatitis C: a retrospective cohort study of 738 patients," *Int. J. Cancer* 87(5):741-749 (Sep. 2000).
- Tong et al., "Prediction of response during interferon α 2b therapy in chronic hepatitis C patients using viral and biochemical characteristics: a comparison," *Hepatology* 26(6): 1640-01645 (Dec. 1997).
- Touza Rey et al., "The clinical response to interferon-γ in a patient with chronic granulomatous disease and brain abscesses due to *Aspergillus fumigatus*," *Ann. Med. Int.* 17(2):86-87 (Feb. 2000).
- Trudeau et al., "A phase I study of recombinant human interferon alpha-2b combined with 5-fluorouracil and cisplatin in patients with advanced cancer," *Cancer Chemother. Pharmacol.* 35(6):496-500 (1995).
- Tseng et al., "Glucose-dependent insulinotropic peptide: structure of the precursor and tissue-specific expression in rat," *PNAS USA*, 90(5): 1992-1996 (1993).
- Tsung et al., "Preparation and Stabilization of Heparin/Gelatin Complex Coacervate Microcapsules," *J. Pharm. Sci.* 86(5):603-7 (May 1997).
- Unniappan et al., "Effects of dipeptidyl peptidase IV on the satiety actions of peptide YY," *Diabetologia; Clinical and Experimental Diabetes and Metabolism* 49(8): 1915-1923 (Jun. 27, 2006).
- Vokes et al., "A phase I trial of concomitant chemoradiotherapy with cisplatin dose intensification and granulocyte-colony stimulating factor support for advanced malignancies of the chest," *Cancer Chemother. Pharmacol.* 35(4):304-312 (1995).
- Vrabec, "Tympanic membrane perforations in the diabetic rat: a model of impaired wound healing," *Otolaryngol. Head Neck Surg.*, 118(3 Pt. 1):304-308 (1998).
- Wang et al., "Preferential interaction of α-tocopherol with phosphatidylcholines in mixed aqueous dispersions of phosphatidylcholine and phosphatidylethanolamine," *Eur. J. Biochem.* 267(21):6362-6368 (2000).
- Wang et al., "Ripple phases induced by α-tocopherol in saturated diacylphosphatidylcholines," *Archives of Biochem. & Biophys.* 377(2):304-314 (2000).
- Wang et al., "The distribution of α-tocopherol in mixed aqueous dispersions of phosphatidylcholine and phosphatidylethanolamine," *Biochimica et Biophysica Acta-Biomembranes* 1509(1-2):361-372 (2000).
- Wang et al., "Parenteral formulations of proteins and peptides: stability and stabilizers," *J. Parenter. Sci. Technol.* 42(2S):S4-S26 (1988).
- Weinstock-Guttman et al., "What is new in the treatment of multiple sclerosis?" *Drugs* 59(3):401-410 (Mar. 2000).
- Weissmann et al., "The interferon genes," *Prog. Nucleic Acid Res. Mol. Biol.* 33:251-300 (1986).
- Wright et al., "Preliminary experience with α-2b-interferon therapy of viral hepatitis in liver allograft recipients," *Transplantation* 53(1): 121-123 (Jan. 1992).
- Young et al., "Glucose-lowering and insulin-sensitizing actions of exendin-4: studies in obese diabetic (ob/ob, db/db) mice, diabetic fatty Zucker rats, and diabetic rhesus monkeys (*Macacamulatta*)," *Diabetes*, 48(5): 1026-1034 (1999).
- Younossi et al., "The role of amantadine, rimantadine, ursodeoxycholic acid, and NSAIDs, alone or in combination with a interferons, in the treatment of chronic hepatitis C," *Semin. Liver Dis.* 19(Supp. 1):95-102 (1999).
- Yu et al., "Preparation, characterization, and in vivo evaluation of an oil suspension of a bovine growth hormone releasing factor analog," *J. Pharm. Sci.* 85(4):396-401 (1996).
- Zeidner et al., "Treatment of FeLV-induced immunodeficiency syndrome (feLV-FAIDS) with controlled release capsular implantation of 2',3'-dideoxycytidine," *Antivir. Res.* 11(3): 147-0160 (Apr. 1989).
- Zein, "Interferons in the management of viral hepatitis," *Cytokines Cell Mol. Ther.* 4(4)229-241 (Dec. 1998).
- Zeuzem et al., "Peginterferon Alfa-2a in Patients with Chronic Hepatitis C," *New Engl. J. Med.* 343(23): 1666-1672 (2000).
- Zeuzem et al., "Hepatitis C virus dynamics in vivo: effect of ribavirin and interferon a on viral turnover," *Hepatology* 28(1)245-252 (Jul. 1998).
- Zhang et al., "Report on Large Dosage Interferon to Treat 30 Cases of Viral Encephalitis," *J. Clinical Pediatrics* 14(2):83-84 (1996).

(56)

References Cited

OTHER PUBLICATIONS

Zhang et al., "A new strategy for enhancing the stability of lyophilized protein: the effect of the reconstitution medium on keratinocyte growth factor," *Pharm. Res.* 12(10): 1447-1452 (1995).

Zheng et al. "Therapeutic Effect of Interferon Varied Dose in Treating Virus Encephalitis," *Beijing Med. J.* 13(2):80-81 (1998).

Ziesche et al., "A preliminary study of long-term treatment with interferon γ -1b and low-dose prednisolone in patients with idiopathic pulmonary fibrosis," *New Engl. J. Med.* 341(17): 1264-1269 (Oct. 1999).

Sanofi-Aventis U.S. LLC, Prescribing Information for ADLYXIN® (Lixisenatide) Injection, for Subcutaneous Use, rev. Jul. 2016, 31 pages.

Amylin Pharmaceuticals, Inc., Prescribing Information for BYETTA® (Exenatide) Injection, rev. Oct. 2009, 34 pages.

Astrazeneca Pharmaceuticals LP, Prescribing Information for BYDUREON® (Exenatide Extended-Release for Injectable Suspension), rev. Mar. 2015, 60 pages.

Novo Nordisk A/S, Prescribing Information for Victoza® (Liraglutide [rDNA Origin] Injection), Solution for Subcutaneous Use, vol. 1, Jan. 2010, 23 pages.

Glaxosmithkline LLC, Prescribing Information for TANZEUM® (Albiglutide) for Injection, for Subcutaneous Use, rev. Jun. 2014, 55 pages.

Eli Lilly & Company, Prescribing Information for TRULICITY® (Dulaglutide) Injection, for Subcutaneous Use, rev. Mar. 2015, 19 pages.

* cited by examiner

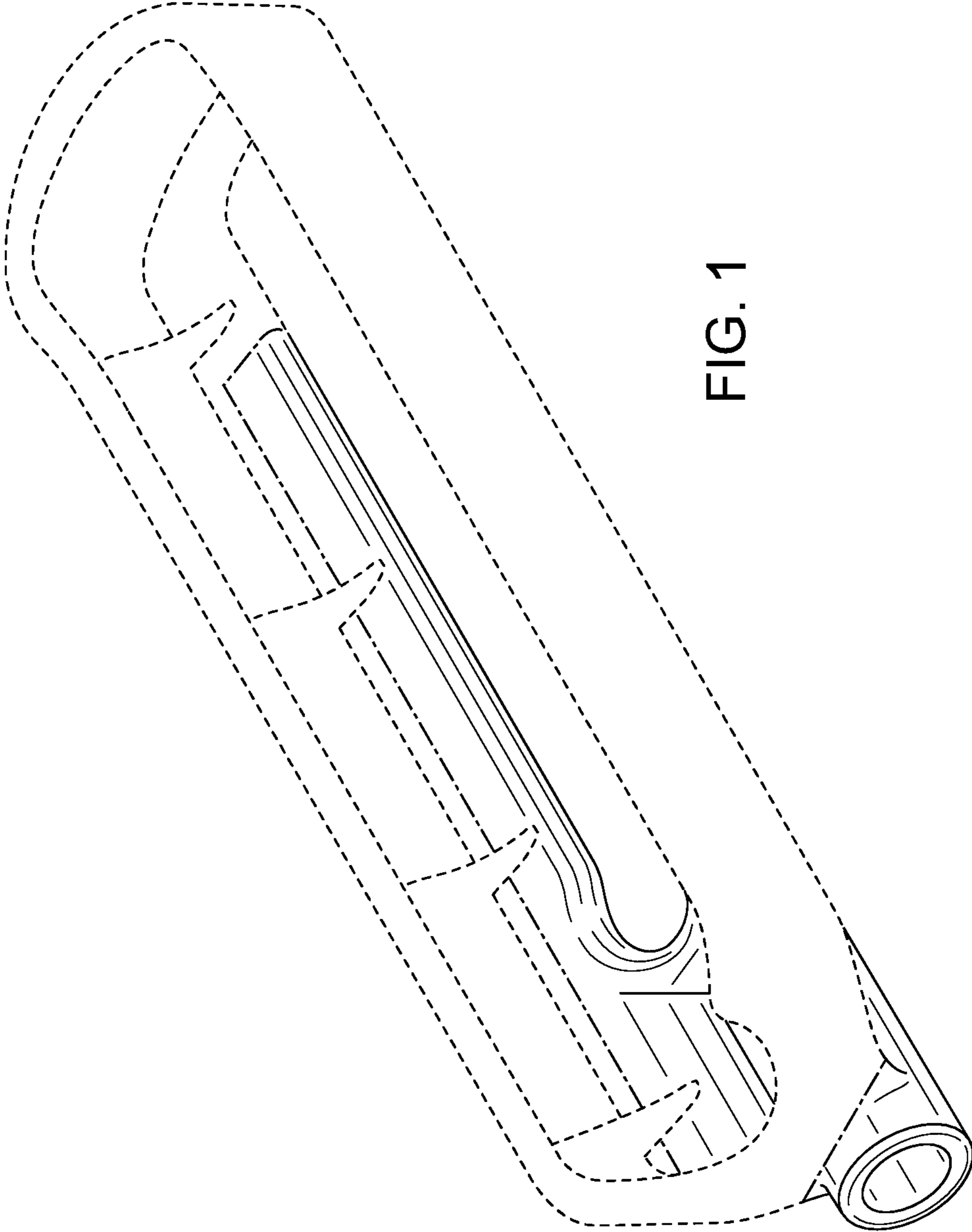


FIG. 1

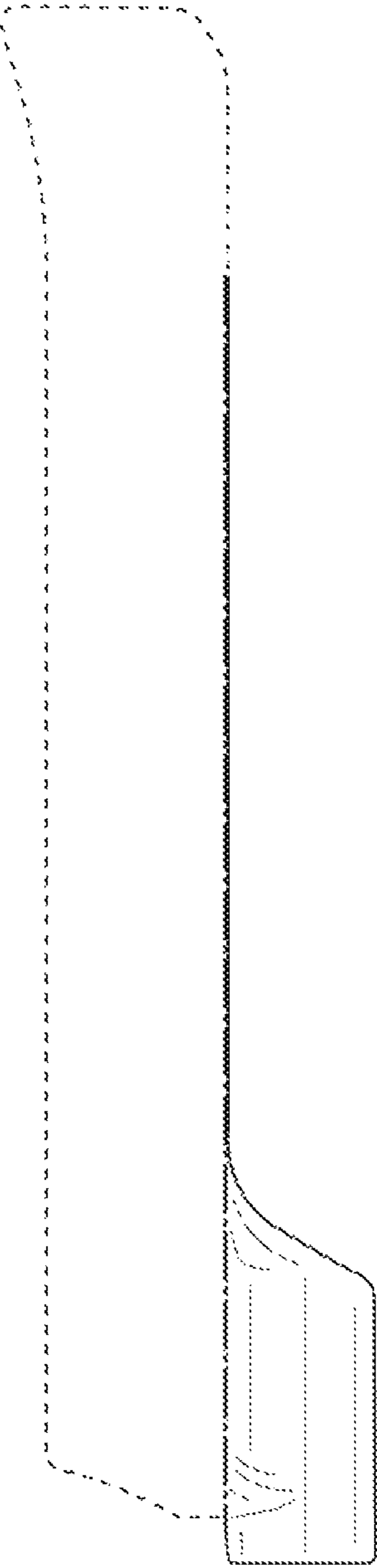


FIG. 2

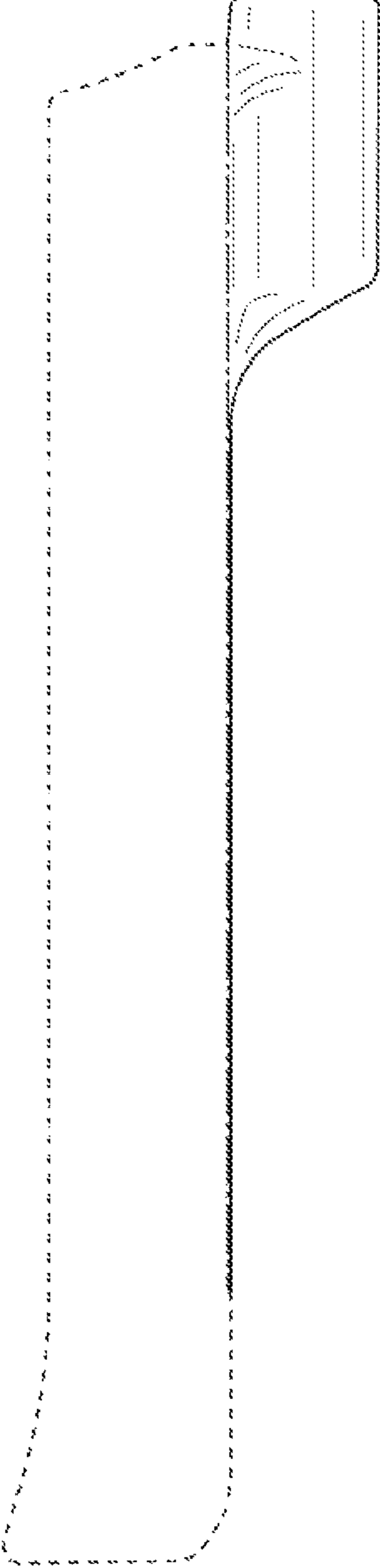


FIG. 3

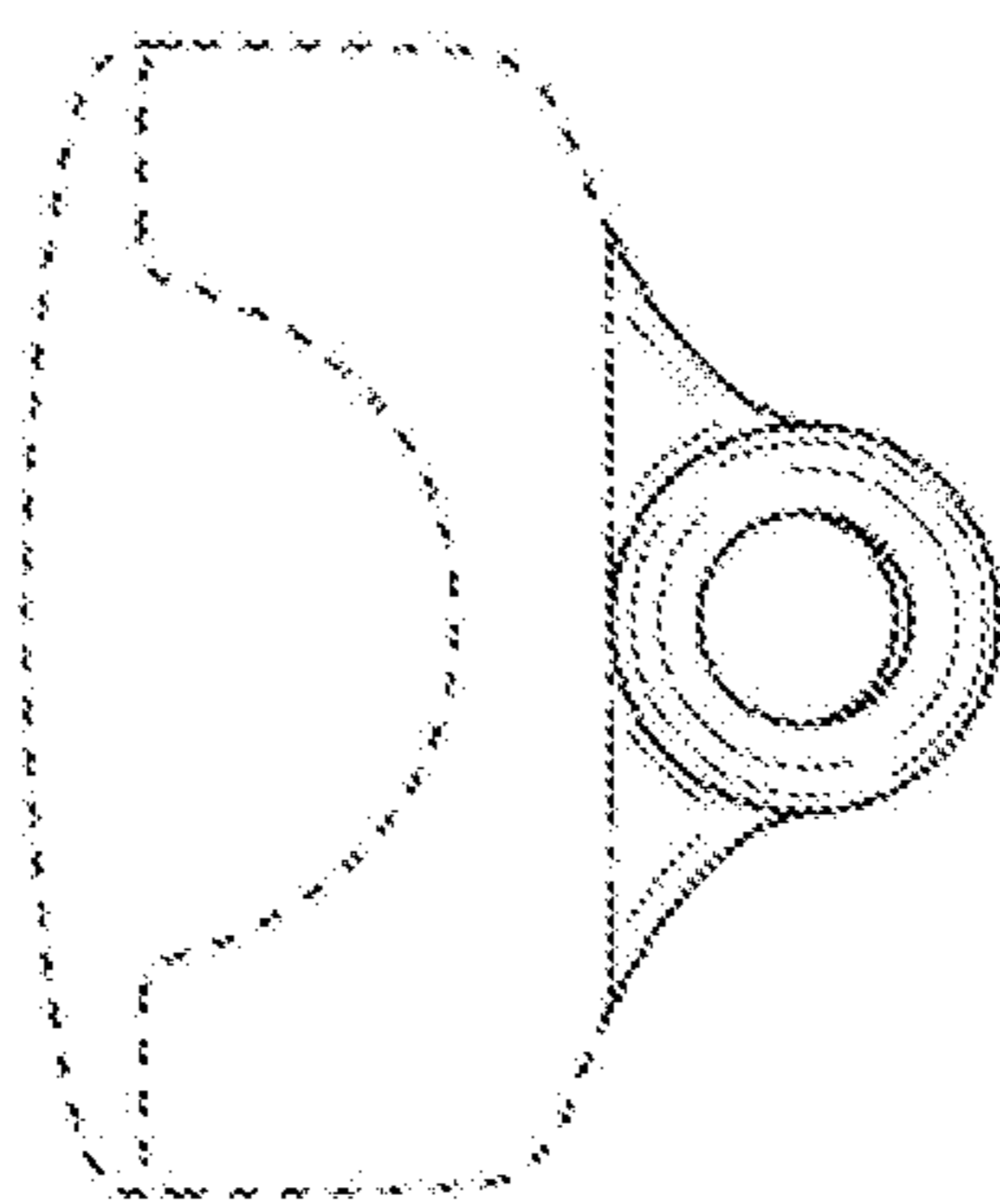


FIG. 4

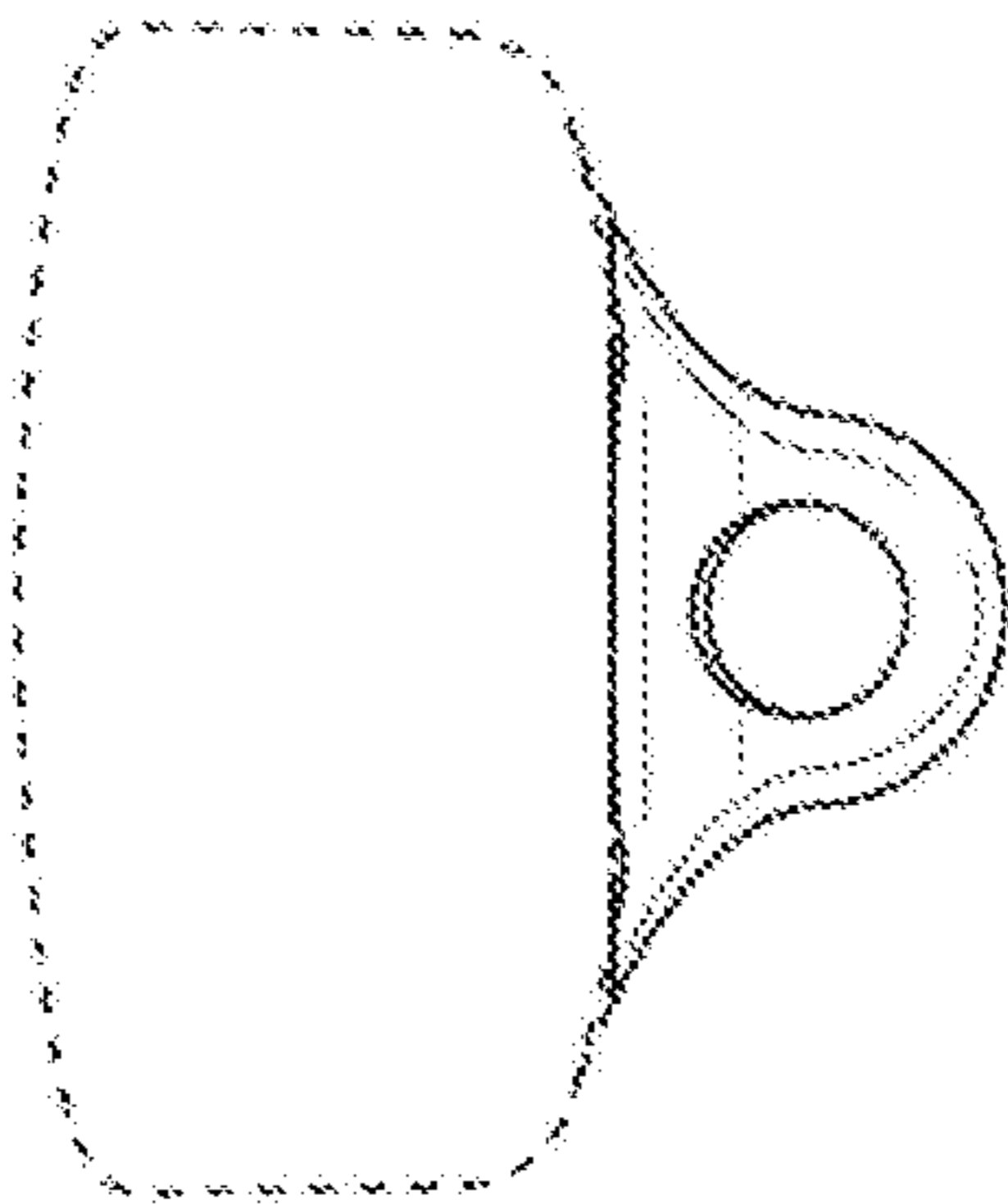


FIG. 5

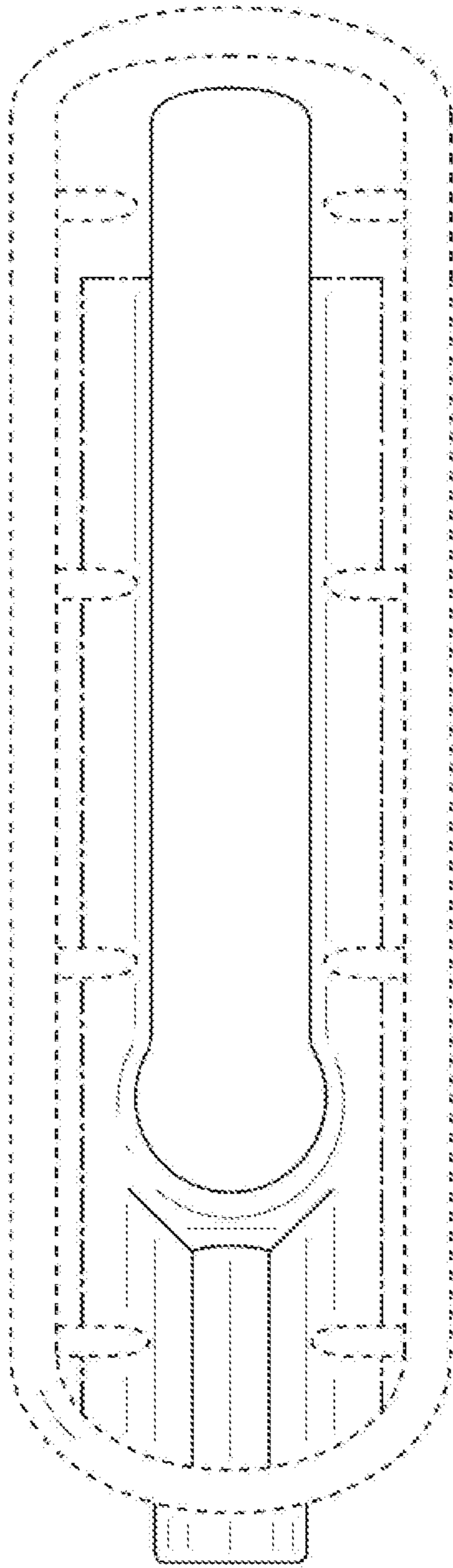


FIG. 6

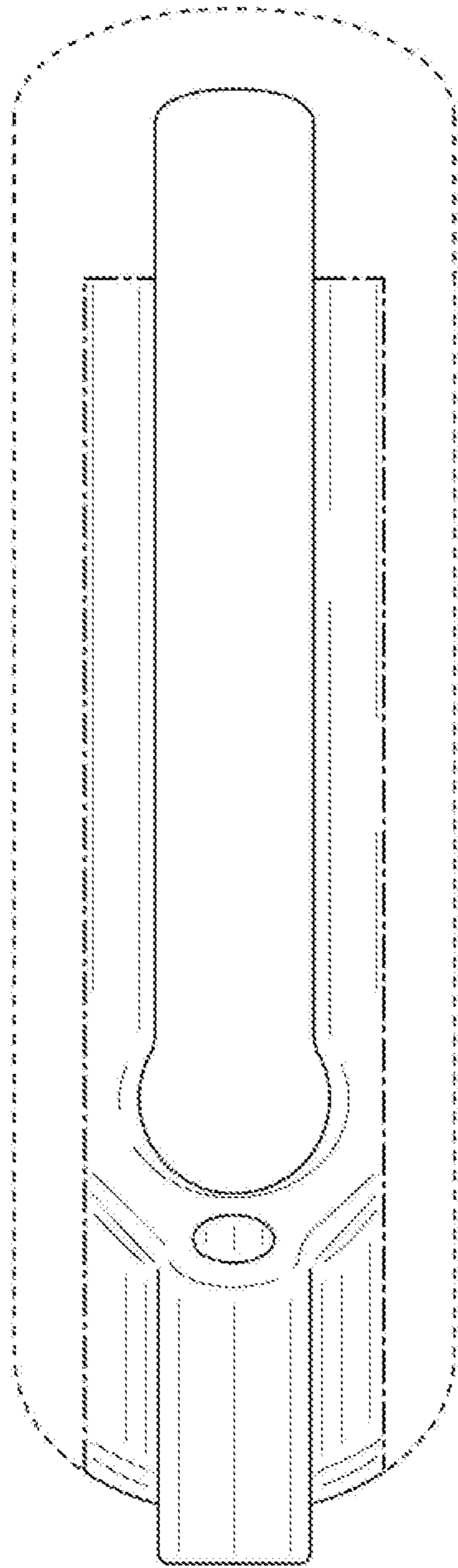


FIG. 7