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

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(54) **IMPLANT REMOVAL TOOL**

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USPC **D24/143**

(58) **Field of Classification Search**
USPC D24/143-144, 147, 133, 155; D8/57;
604/59-60, 73

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(56) **References Cited**

U.S. PATENT DOCUMENTS

1,655,158 A 1/1928 Muir
2,110,208 A 3/1938 Eggert

(Continued)

FOREIGN PATENT DOCUMENTS

DE 00000635692 A 9/1936
EP 0079405 5/1983

(Continued)

OTHER PUBLICATIONS

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).

(Continued)

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(57) **CLAIM**

The ornamental design for an implant removal tool, as shown and described.

DESCRIPTION

FIG. 1 is a perspective view of an embodiment of a design for an implant removal tool;

FIG. 2 is a front view of the design for the implant removal tool of FIG. 1;

FIG. 3 is a back view of the design for the implant removal tool of FIG. 1;

FIG. 4 is a first side view of the design for the implant removal tool of FIG. 1;

FIG. 5 is a second side view of the design for the implant removal tool of FIG. 1;

FIG. 6 is a top view for the design for the implant removal tool of FIG. 1;

FIG. 7 is a bottom view for the design of the implant removal tool of FIG. 1;

FIG. 8 is a perspective view of another embodiment of a design for an implant removal tool;

FIG. 9 is a front view of the design for the implant removal tool of FIG. 8;

FIG. 10 is a back view of the design for the implant removal tool of FIG. 8;

FIG. 11 is a first side view of the design for the implant removal tool of FIG. 8;

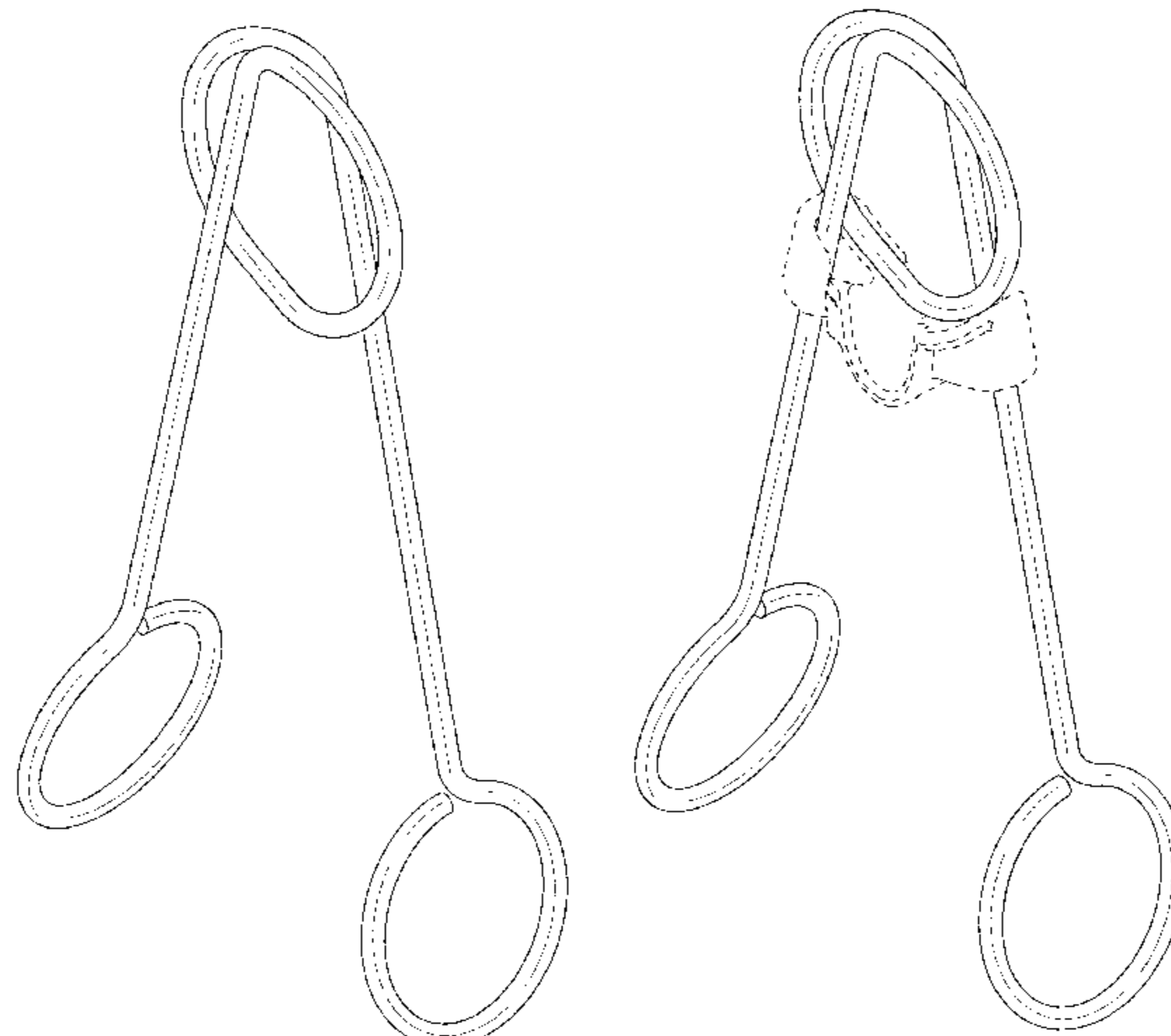
FIG. 12 is a second side view of the design for the implant removal tool of FIG. 8;

FIG. 13 is a top view for the design for the implant removal tool of FIG. 8; and,

FIG. 14 is a bottom view for the design of the implant removal tool of FIG. 8.

Any broken lines shown in the drawings form no part of the claimed design.

1 Claim, 14 Drawing Sheets



(58) **Field of Classification Search**
 CPC A61M 37/0069; A61B 17/3468; A61B
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 See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

2,168,437 A 8/1939 Buercklin
 2,531,724 A 11/1950 Cevasco
 2,643,653 A 6/1953 Heidrich
 D179,537 S 1/1957 Floyd et al.
 3,016,895 A 1/1962 Sein
 3,025,991 A 3/1962 Gillon
 3,122,162 A 2/1964 Sands
 3,463,157 A * 8/1969 Hunt A61D 1/00
 D24/143

 3,523,906 A 8/1970 Vrancken et al.
 3,538,916 A 11/1970 Groff
 3,620,216 A 11/1971 Szymanski
 3,625,214 A 12/1971 Higuchi
 3,632,768 A 1/1972 Bergy et al.
 3,669,104 A 6/1972 Wyatt
 3,691,090 A 9/1972 Kitajima et al.
 D226,915 S 5/1973 Huggins
 3,732,865 A 5/1973 Higuchi et al.
 3,737,337 A 6/1973 Sehnoring et al.
 3,766,915 A 10/1973 Rychlik
 3,773,919 A 11/1973 Boswell
 3,797,492 A 3/1974 Place
 3,869,549 A 3/1975 Geller
 3,891,570 A 6/1975 Fukushima et al.
 D236,035 S 7/1975 Ciencewicki
 3,960,757 A 6/1976 Morishita et al.
 3,987,790 A 10/1976 Eckenhoff et al.
 3,995,631 A 12/1976 Higuchi et al.
 3,995,632 A 12/1976 Nakano et al.
 4,008,719 A 2/1977 Theeuwes et al.
 4,034,756 A 7/1977 Higuchi et al.
 4,078,060 A 3/1978 Benson et al.
 4,105,030 A 8/1978 Kercso
 4,111,201 A 9/1978 Theeuwes
 4,111,202 A 9/1978 Theeuwes
 4,111,203 A 9/1978 Theeuwes
 4,203,439 A 5/1980 Theeuwes
 4,211,771 A 7/1980 Witkowski et al.
 4,221,862 A 9/1980 Naito et al.
 4,223,674 A 9/1980 Fluent et al.
 4,243,030 A 1/1981 Lynch et al.
 D258,837 S 4/1981 Spranger et al.
 D259,458 S 6/1981 Fuller et al.
 4,305,927 A 12/1981 Theeuwes et al.
 4,310,516 A 1/1982 Chang et al.
 4,340,054 A 7/1982 Michaels
 4,350,271 A 9/1982 Eckenhoff
 4,373,527 A 2/1983 Fischell
 4,376,118 A 3/1983 Daher et al.
 4,384,975 A 5/1983 Fong
 4,389,330 A 6/1983 Tice et al.
 4,439,196 A 3/1984 Higuchi
 4,444,498 A 4/1984 Heinemann
 4,451,253 A 5/1984 Harman
 4,455,143 A 6/1984 Theeuwes et al.
 4,455,145 A 6/1984 Theeuwes
 4,474,572 A 10/1984 McNaughton et al.
 4,530,840 A 7/1985 Tice et al.
 4,552,561 A 11/1985 Eckenhoff et al.
 4,588,614 A 5/1986 Lauchenauer
 4,594,108 A 6/1986 Greminger, Jr. et al.
 4,597,753 A 7/1986 Turley
 4,609,374 A 9/1986 Ayer
 4,639,244 A 1/1987 Rizk et al.
 4,655,462 A 4/1987 Balsells
 4,657,533 A * 4/1987 Oscarsson A61M 37/0069
 604/60

 4,673,405 A 6/1987 Guittard et al.
 4,675,184 A 6/1987 Hasegawa et al.

4,695,623 A 9/1987 Stabinsky
 4,727,138 A 2/1988 Goeddel et al.
 4,734,284 A 3/1988 Terada et al.
 4,737,437 A 4/1988 Gutsell, Jr. et al.
 4,743,449 A 5/1988 Yoshida et al.
 4,753,651 A 6/1988 Eckenhoff
 4,762,791 A 8/1988 Goeddel et al.
 4,765,989 A 8/1988 Wong et al.
 4,783,337 A 11/1988 Wong et al.
 4,818,517 A 4/1989 Kwee et al.
 4,820,267 A 4/1989 Harman
 4,820,638 A 4/1989 Swetly et al.
 4,826,144 A 5/1989 Balsells
 4,830,344 A 5/1989 Balsells
 4,834,708 A 5/1989 Pillari
 4,845,196 A 7/1989 Cowling
 4,847,079 A 7/1989 Kwan
 4,851,228 A 7/1989 Zentner et al.
 4,840,896 A 8/1989 Reddy
 4,865,845 A 9/1989 Eckenhoff et al.
 4,871,094 A 10/1989 Gall et al.
 4,873,080 A 10/1989 Brickl et al.
 4,874,388 A 10/1989 Wong et al.
 4,876,781 A 10/1989 Balsells
 4,882,166 A 11/1989 Graham et al.
 4,885,166 A 12/1989 Meyer et al.
 4,886,668 A 12/1989 Haslam et al.
 4,892,778 A 1/1990 Theeuwes et al.
 4,893,795 A 1/1990 Balsells
 4,897,471 A 1/1990 Stabinsky
 4,907,788 A 3/1990 Balsells
 4,915,366 A 4/1990 Balsells
 4,915,949 A 4/1990 Wong et al.
 4,915,954 A 4/1990 Ayer et al.
 4,917,887 A 4/1990 Hauptmann et al.
 4,917,895 A 4/1990 Lee et al.
 4,923,805 A 5/1990 Reddy et al.
 4,927,687 A 5/1990 Nuwayser
 4,929,554 A 5/1990 Goeddel et al.
 4,931,285 A 6/1990 Edgren et al.
 4,934,666 A 6/1990 Balsells
 4,940,465 A 7/1990 Theeuwes et al.
 4,940,588 A 7/1990 Sparks et al.
 4,952,402 A 8/1990 Sparks et al.
 4,957,119 A 9/1990 de Nijs
 4,961,253 A 10/1990 Balsells
 4,964,204 A 10/1990 Balsells
 4,969,884 A 11/1990 Yum
 4,974,821 A 12/1990 Balsells
 4,976,966 A 12/1990 Theeuwes et al.
 4,994,028 A 2/1991 Leonard et al.
 5,004,689 A 4/1991 Fiers et al.
 5,006,346 A 4/1991 Theeuwes et al.
 5,019,382 A 5/1991 Cummins, Jr.
 5,019,400 A 5/1991 Gombotz et al.
 5,023,088 A 6/1991 Wong et al.
 5,024,842 A 6/1991 Edgren et al.
 5,030,216 A 7/1991 Theeuwes et al.
 5,034,229 A 7/1991 Magruder et al.
 5,053,014 A 10/1991 Van Heugten
 5,056,718 A 10/1991 Wakefield
 5,057,318 A 10/1991 Magruder et al.
 5,059,423 A 10/1991 Magruder et al.
 5,066,436 A 11/1991 Komen et al.
 5,071,642 A 12/1991 Lahr et al.
 5,072,070 A 12/1991 Balsells
 5,079,388 A 1/1992 Balsells
 5,090,962 A 2/1992 Landry et al.
 5,091,188 A 2/1992 Haynes
 5,108,078 A 4/1992 Balsells
 5,110,596 A 5/1992 Magruder et al.
 5,112,614 A 5/1992 Magruder et al.
 5,113,938 A 5/1992 Clayton
 5,117,066 A 5/1992 Balsells
 D326,718 S 6/1992 Maxwell
 5,118,666 A 6/1992 Habener
 5,120,306 A 6/1992 Gosselin
 5,120,712 A 6/1992 Habener
 5,120,832 A 6/1992 Goeddel et al.

(56)

References Cited

U.S. PATENT DOCUMENTS

5,122,128 A	6/1992	Cardinal et al.	5,456,679 A	10/1995	Balaban et al.
5,122,377 A	6/1992	Miller	5,458,888 A	10/1995	Chen
5,126,142 A	6/1992	Ayer et al.	5,464,929 A	11/1995	Bezwada et al.
5,126,147 A	6/1992	Silvestri et al.	5,472,708 A	12/1995	Chen
5,134,244 A	7/1992	Balsells	5,478,564 A	12/1995	Wantier et al.
5,137,727 A	8/1992	Eckenhoff	5,484,403 A	1/1996	Yoakum et al.
D329,278 S	9/1992	Gallup	5,486,365 A	1/1996	Takado et al.
5,147,295 A	9/1992	Stewart	5,498,255 A	3/1996	Wong et al.
5,151,093 A	9/1992	Theeuwes et al.	5,511,355 A	4/1996	Dingler
5,160,122 A	11/1992	Balsells	5,512,293 A	4/1996	Landrau et al.
5,160,743 A	11/1992	Edgren et al.	5,512,549 A	4/1996	Chen et al.
5,161,806 A	11/1992	Balsells	5,514,110 A	5/1996	Teh
5,180,591 A	1/1993	Margruder et al.	5,529,914 A	6/1996	Hubbell et al.
5,190,765 A	3/1993	Jao et al.	5,531,736 A	7/1996	Wong et al.
5,192,273 A	3/1993	Bierman	5,540,665 A	7/1996	Mercado et al.
5,203,849 A	4/1993	Balsells	5,540,912 A	7/1996	Roorda et al.
5,204,108 A	4/1993	Illum	5,541,172 A	7/1996	Labrie et al.
5,207,752 A	5/1993	Sorensen et al.	5,542,682 A	8/1996	Goldstein et al.
5,209,746 A	5/1993	Balaban et al.	5,543,156 A	8/1996	Roorda et al.
5,213,809 A	5/1993	Wright et al.	5,545,618 A	8/1996	Buckley et al.
5,213,810 A	5/1993	Steber	5,556,642 A	9/1996	Kobayashi et al.
5,219,572 A	6/1993	Sivaramakrishnan	5,557,318 A	9/1996	Gabriel
5,221,278 A	6/1993	Linkwitz et al.	5,558,637 A	9/1996	Allonen et al.
5,223,265 A	6/1993	Wong	5,569,289 A	10/1996	Yoon
5,225,205 A	7/1993	Orsolini	5,571,525 A	11/1996	Roorda et al.
5,231,176 A	7/1993	Goeddel et al.	5,574,008 A	11/1996	Johnson et al.
5,234,424 A	8/1993	Yum et al.	5,574,137 A	11/1996	Gray et al.
5,234,692 A	8/1993	Magruder et al.	5,580,578 A	12/1996	Oshlack et al.
5,234,693 A	8/1993	Magruder et al.	5,589,167 A	12/1996	Cleland et al.
5,234,695 A	8/1993	Hobbs et al.	5,595,751 A	1/1997	Bezwada
5,250,026 A	10/1993	Ehrlich et al.	5,595,759 A	1/1997	Wright et al.
5,252,338 A	10/1993	Jao et al.	5,597,579 A	1/1997	Bezwada et al.
5,260,069 A	11/1993	Chen	5,602,010 A	2/1997	Hauptmann et al.
D342,855 S	1/1994	Butler, II	5,605,688 A	2/1997	Himmeler et al.
5,278,151 A	1/1994	Korb et al.	5,607,687 A	3/1997	Bezwada et al.
5,279,544 A	1/1994	Gross et al.	5,609,885 A	3/1997	Rivera et al.
5,279,554 A	1/1994	Turley	5,613,954 A	3/1997	Nelson et al.
5,279,555 A	1/1994	Lifshey	5,614,221 A	3/1997	Fjellstrom
5,279,608 A	1/1994	Cherif Cheikh	5,614,492 A	3/1997	Habener
5,284,655 A	2/1994	Bogdansky et al.	5,618,552 A	4/1997	Bezwada et al.
5,288,501 A	2/1994	Nürnberg et al.	5,620,698 A	4/1997	Bezwada et al.
5,288,502 A	2/1994	Mcginity et al.	5,620,705 A	4/1997	Dong et al.
5,290,271 A	3/1994	Jernberg	5,630,796 A	5/1997	Bellhouse et al.
5,300,079 A	4/1994	Niezink et al.	5,633,011 A	5/1997	Dong et al.
5,300,302 A	4/1994	Tachon et al.	5,635,213 A	6/1997	Nystrom et al.
5,308,348 A	5/1994	Balaban et al.	5,639,477 A	6/1997	Maruyama et al.
5,312,335 A	5/1994	McKinnon et al.	5,639,640 A	6/1997	Reddy et al.
5,312,389 A	5/1994	Theeuwes et al.	5,645,850 A	7/1997	Bezwada et al.
5,312,390 A	5/1994	Wong	5,648,088 A	7/1997	Bezwada et al.
5,318,558 A	6/1994	Linkwitz et al.	5,650,173 A	7/1997	Ramstack et al.
5,318,780 A	6/1994	Viegas et al.	5,654,008 A	8/1997	Herbert et al.
5,320,616 A	6/1994	Magndu et al.	5,654,010 A	8/1997	Johnson et al.
5,324,280 A	6/1994	Wong et al.	5,656,297 A	8/1997	Bernstein et al.
5,336,057 A	8/1994	Fukuda et al.	5,656,299 A	8/1997	Kino et al.
5,336,505 A	8/1994	Ng et al.	5,658,593 A	8/1997	Orly et al.
5,348,544 A	9/1994	Sweeney et al.	5,660,847 A	8/1997	Magruder et al.
5,352,662 A	10/1994	Brooks et al.	5,660,858 A	8/1997	Parikh et al.
5,368,588 A	11/1994	Bettinger	5,660,861 A	8/1997	Jao et al.
5,368,863 A	11/1994	Eckenhoff et al.	5,667,808 A	9/1997	Johnson et al.
5,371,089 A	12/1994	Rattan	5,668,170 A	9/1997	Gyory
5,374,620 A	12/1994	Clark et al.	5,672,549 A	9/1997	Minami et al.
5,385,738 A	1/1995	Yamahira et al.	5,676,942 A	10/1997	Testa et al.
5,385,887 A	1/1995	Yim et al.	5,686,097 A	11/1997	Taskovich et al.
5,395,319 A	3/1995	Hirsch et al.	5,688,801 A	11/1997	Mesens et al.
5,407,609 A	4/1995	Tice et al.	5,690,925 A	11/1997	Gray et al.
D358,644 S	5/1995	Park	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.	5,697,113 A	12/1997	Shatz et al.
5,413,672 A	5/1995	Hirotsuji et al.	5,697,914 A	12/1997	Brimhall
5,424,286 A	6/1995	Eng	5,698,213 A	12/1997	Jamiolkowski et al.
5,428,024 A	6/1995	Chu et al.	5,700,486 A	12/1997	Canal et al.
5,429,602 A	7/1995	Hauser	5,700,583 A	12/1997	Jamiolkowski et al.
5,439,688 A	8/1995	Orsolini et al.	5,703,200 A	12/1997	Bezwada et al.
5,443,459 A	8/1995	Wong et al.	5,707,644 A	1/1998	Illum
5,445,829 A	8/1995	Paradissis et al.	5,711,967 A	1/1998	Juch
			5,713,847 A	2/1998	Howard, III et al.
			5,718,922 A	2/1998	Herrero-Vanrell
			5,725,497 A	3/1998	Woodruff et al.
			5,728,088 A	3/1998	Margruder et al.

(56)

References Cited

U.S. PATENT DOCUMENTS

5,728,396 A	3/1998	Peery et al.	D430,671 S	9/2000	Shute
5,733,572 A	3/1998	Unger et al.	6,113,938 A	9/2000	Chen et al.
5,736,159 A	4/1998	Chen et al.	6,113,947 A	9/2000	Cleland et al.
5,738,845 A	4/1998	Imakawa	6,120,787 A	9/2000	Gustafsson et al.
5,747,058 A	5/1998	Tipton et al.	6,124,261 A	9/2000	Stevenson et al.
5,756,450 A	5/1998	Hahn et al.	6,124,281 A	9/2000	Lewis et al.
5,767,251 A	6/1998	Reddy et al.	6,127,520 A	10/2000	Ueda et al.
5,770,231 A	6/1998	Mesens et al.	6,129,761 A	10/2000	Hubbell
5,782,396 A	7/1998	Mastri et al.	6,130,200 A	10/2000	Brodbeck et al.
5,792,477 A	8/1998	Rickey et al.	6,132,420 A	10/2000	Dionne et al.
5,795,591 A	8/1998	Lee et al.	6,133,249 A	10/2000	Hills
5,795,779 A	8/1998	McCormick et al.	6,133,429 A	10/2000	Davis et al.
5,807,876 A	9/1998	Armistead et al.	6,146,139 A	11/2000	Harrison, III
5,810,769 A	9/1998	Schlegel et al.	6,147,168 A	11/2000	Jamiolkowski et al.
5,814,323 A	9/1998	Lyle	6,156,331 A	12/2000	Peery et al.
D399,821 S	10/1998	Tyneski et al.	6,172,046 B1	1/2001	Albrecht
5,817,129 A	10/1998	Labrecque et al.	6,174,547 B1	1/2001	Dong et al.
5,827,297 A	10/1998	Boudjema	6,177,096 B1	1/2001	Zerbe et al.
5,830,501 A	11/1998	Dong et al.	6,183,461 B1	2/2001	Matsuura et al.
5,836,935 A	11/1998	Ashton et al.	6,187,095 B1	2/2001	Labrecque et al.
5,843,891 A	12/1998	Sherman	6,190,350 B1	2/2001	Davis et al.
5,844,017 A	12/1998	Jamiolkowski et al.	6,190,700 B1	2/2001	Okada et al.
5,851,451 A	12/1998	Takechi et al.	6,190,702 B1	2/2001	Takada et al.
5,858,746 A	1/1999	Hubbell et al.	6,191,102 B1	2/2001	DiMarchi et al.
5,859,150 A	1/1999	Jamiolkowski et al.	6,204,022 B1	3/2001	Johnson et al.
5,861,166 A	1/1999	Eckenhoff	6,217,893 B1	4/2001	Pellet et al.
5,871,770 A	2/1999	Margruder et al.	6,217,906 B1	4/2001	Gumucio et al.
5,871,778 A	2/1999	Kino et al.	6,217,908 B1	4/2001	Mathiowitz et al.
5,874,388 A	2/1999	Hsu	6,218,431 B1	4/2001	Schoen et al.
5,876,746 A	3/1999	Jona et al.	6,224,894 B1	5/2001	Jamiolkowski et al.
5,882,676 A	3/1999	Lee et al.	6,235,712 B1	5/2001	Stevenson et al.
D408,917 S	4/1999	Hacker	6,245,349 B1	6/2001	Yiv et al.
5,904,935 A	5/1999	Eckenhoff et al.	6,245,357 B1	6/2001	Edgren et al.
5,906,599 A	5/1999	Kaldany	6,248,112 B1	6/2001	Gambale et al.
5,906,816 A	5/1999	Soos et al.	6,251,435 B1	6/2001	Jamiolkowski et al.
5,906,830 A	5/1999	Farinas et al.	D445,975 S	7/2001	Stratford
5,908,621 A	6/1999	Glue et al.	6,258,377 B1	7/2001	New et al.
5,916,598 A	6/1999	Rickey et al.	6,261,584 B1	7/2001	Peery et al.
5,922,253 A	7/1999	Herbert et al.	6,268,343 B1	7/2001	Knudsen et al.
5,928,666 A	7/1999	Farinas et al.	6,270,700 B1	8/2001	Ignatious
5,932,547 A	8/1999	Stevenson et al.	6,270,787 B1	8/2001	Ayer
5,938,654 A	8/1999	Wong et al.	6,277,413 B1	8/2001	Sankaram
5,939,286 A	8/1999	Johnson et al.	6,283,949 B1	9/2001	Roorda
5,942,223 A	8/1999	Bazer et al.	6,284,264 B1	9/2001	Zerbe et al.
5,942,253 A	8/1999	Gombotz et al.	6,284,725 B1	9/2001	Coolidge et al.
5,945,126 A	8/1999	Thanoo et al.	6,284,727 B1	9/2001	Kim et al.
5,948,430 A	9/1999	Zerbe et al.	6,287,295 B1	9/2001	Chen et al.
5,951,521 A	9/1999	Mastrototaro et al.	6,329,336 B1	12/2001	Bridon et al.
5,958,909 A	9/1999	Habener	6,331,311 B1	12/2001	Brodbeck et al.
D415,073 S	10/1999	Meehan et al.	6,372,218 B1	4/2002	Cummins, Jr.
5,962,023 A	10/1999	Jamiolkowski et al.	6,372,256 B2	4/2002	Jamiolkowski et al.
5,965,168 A	10/1999	Mesens et al.	6,375,978 B1	4/2002	Kleiner 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
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	Woiszwillo 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.
6,023,802 A	2/2000	King	6,464,688 B1	10/2002	Harper et al.
6,029,361 A	2/2000	Newman	6,468,961 B1	10/2002	Brodbeck et al.
6,053,927 A	4/2000	Hamas	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.
			6,514,517 B2	2/2003	Jamilolkowski et al.
			6,524,305 B1	2/2003	Peterson et al.
			6,528,093 B1	3/2003	Kamei et al.
			6,528,486 B1	3/2003	Larsen et al.

(56)

References Cited

U.S. PATENT DOCUMENTS

D472,896 S	4/2003	Peiker	7,205,409 B2	4/2007	Pei et al.
6,541,021 B1	4/2003	Johnson et al.	7,207,982 B2	4/2007	Dionne et al.
6,544,239 B2	4/2003	Kinsey et al.	7,214,206 B2	5/2007	Rue et al.
6,544,252 B1	4/2003	Theeuwes et al.	7,241,457 B2	7/2007	Chen et al.
6,547,250 B1	4/2003	Noble	7,258,869 B1	8/2007	Berry et al.
6,551,613 B1	4/2003	Dong et al.	D555,589 S	11/2007	Hussaini et al.
6,569,420 B2	5/2003	Chen et al.	7,297,761 B2	11/2007	Beeley et al.
6,572,890 B2	6/2003	Faour et al.	7,316,680 B2	1/2008	Gilbert
6,579,851 B2	6/2003	Goeke et al.	7,393,827 B2	7/2008	Nadler
6,589,157 B2	7/2003	Fontayne et al.	7,407,499 B2	8/2008	Trautman
6,592,508 B1	7/2003	Ravins et al.	7,442,682 B2	10/2008	Kitaura et al.
6,592,887 B2	7/2003	Zerbe et al.	7,456,254 B2	11/2008	Wright et al.
6,593,295 B2	7/2003	Bridon et al.	7,459,432 B2	12/2008	Cowley et al.
6,607,529 B1	8/2003	Jones et al.	7,521,423 B2	4/2009	Young et al.
6,626,863 B1	9/2003	Berler	7,563,871 B2	7/2009	Wright et al.
6,635,268 B2	10/2003	Peery et al.	7,589,169 B2	9/2009	Bolotin
6,645,192 B2	11/2003	Kenison	7,604,647 B2	10/2009	Chen
6,667,061 B2	12/2003	Ramstack et al.	7,612,176 B2	11/2009	Wright et al.
6,670,368 B1	12/2003	Breault et al.	7,632,256 B2	12/2009	Mosler et al.
6,673,767 B1	1/2004	Brodbeck et al.	7,635,463 B2	12/2009	Bolotin et al.
6,682,522 B2	1/2004	Carr et al.	D608,447 S	1/2010	Meyer et al.
6,703,225 B1	3/2004	Kojima et al.	7,655,254 B2	2/2010	Dennis et al.
6,703,359 B1	3/2004	Young et al.	7,655,257 B2	2/2010	Peery et al.
6,706,689 B2	3/2004	Coolidge et al.	7,666,835 B2	2/2010	Bloom et al.
6,709,671 B2	3/2004	Zerbe et al.	7,682,356 B2	3/2010	Alessi et al.
6,720,407 B1	4/2004	Hughes et al.	7,727,519 B2	6/2010	Moran
6,730,328 B2	5/2004	Maskiwicz et al.	7,731,947 B2	6/2010	Eliasz et al.
6,752,753 B1	6/2004	Hoskins et al.	7,736,665 B2	6/2010	Patel et al.
D492,995 S *	7/2004	Rue D24/133	7,741,269 B2	6/2010	Young et al.
6,767,887 B1	7/2004	Hoffmann et al.	7,766,924 B1	8/2010	Bombard et al.
6,821,949 B2	11/2004	Bridon et al.	7,790,140 B2	9/2010	Bolotin
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	Weyer 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	4/2011	Young et al.
6,875,748 B2	4/2005	Manthorpe et al.	D638,478 S	5/2011	Block
6,887,470 B1	5/2005	Bridon et al.	7,959,938 B2	6/2011	Rohloff et al.
6,887,849 B2	5/2005	Bridon et al.	7,964,183 B2	6/2011	Eliasz et al.
6,899,887 B2	5/2005	Ayer	8,039,432 B2	10/2011	Bridon et al.
6,899,898 B2	5/2005	Albayrak	8,048,438 B2	11/2011	Berry et al.
6,902,744 B1	6/2005	Kolterman et al.	8,052,996 B2	11/2011	Lautenbach et al.
6,903,186 B1	6/2005	Dong	8,058,233 B2	11/2011	Cowley et al.
6,913,767 B1	7/2005	Cleland et al.	8,101,576 B2	1/2012	Bloom
6,923,800 B2	8/2005	Chen et al.	8,114,430 B2	2/2012	Rohloff et al.
6,924,264 B1	8/2005	Prickett et al.	8,114,437 B2	2/2012	Rohloff et al.
6,939,556 B2	9/2005	Lautenbach	8,158,150 B2	4/2012	Lautenbach et al.
6,956,026 B2	10/2005	Beeley et al.	8,173,150 B2	5/2012	Berry et al.
6,960,192 B1	11/2005	Flaherty et al.	8,190,702 B1	5/2012	Sakata et al.
6,969,702 B2	11/2005	Bertilsson et al.	8,202,836 B2	6/2012	Moore et al.
6,976,981 B2	12/2005	Ayer	8,206,745 B2	6/2012	Rohloff et al.
6,989,366 B2	1/2006	Beeley et al.	8,211,467 B2	7/2012	Rohloff et al.
6,992,065 B2	1/2006	Okumu	8,217,001 B2	7/2012	Cowley et al.
6,997,922 B2	2/2006	Theeuwes et al.	8,231,859 B2	7/2012	Bolotin et al.
7,008,439 B1	3/2006	Janzen et al.	8,251,946 B2	8/2012	Bardy
7,014,636 B2	3/2006	Gilbert	8,257,682 B2	9/2012	Bolotin et al.
7,022,674 B2	4/2006	DeFelippis et al.	8,257,691 B2	9/2012	Eliasz et al.
7,041,646 B2	5/2006	Pan et al.	8,262,667 B1	9/2012	Silver et al.
7,074,423 B2	7/2006	Fereira et al.	8,263,545 B2	9/2012	Levy et al.
7,084,243 B2	8/2006	Glaesner et al.	8,263,736 B2	9/2012	Berry
7,101,567 B1	9/2006	Sano et al.	8,268,341 B2	9/2012	Berry et al.
7,101,843 B2	9/2006	Glaesner et al.	8,273,365 B2	9/2012	Lautenbach et al.
7,112,335 B2	9/2006	Lautenbach	8,273,713 B2	9/2012	Pittner et al.
7,115,569 B2	10/2006	Beeley et al.	D669,589 S	10/2012	Delaey
7,138,375 B2	11/2006	Beeley et al.	8,277,776 B2	10/2012	Bolotin et al.
7,138,486 B2	11/2006	Habener et al.	8,278,267 B2	10/2012	Weyer et al.
7,141,547 B2	11/2006	Rosen et al.	8,288,338 B2	10/2012	Young et al.
7,144,863 B2	12/2006	DeFelippis et al.	8,298,561 B2	10/2012	Alessi et al.
7,153,825 B2	12/2006	Young et al.	8,299,025 B2	10/2012	Alessi et al.
7,157,555 B1	1/2007	Beeley et al.	8,343,140 B2	1/2013	Alessi et al.
7,163,688 B2	1/2007	Peery et al.	8,367,095 B2	2/2013	Lautenbach et al.
7,163,697 B2	1/2007	Hanes et al.	8,372,424 B2	2/2013	Berry et al.
7,199,217 B2	4/2007	DiMarchi et al.	D678,889 S	3/2013	Chiu
			8,398,967 B2	3/2013	Eliasz et al.
			8,440,226 B2	5/2013	Rohloff et al.
			8,454,552 B2	6/2013	Bardy
			8,460,694 B2	6/2013	Rohloff et al.

(56)

References Cited

U.S. PATENT DOCUMENTS

8,470,353	B2	6/2013	Lautenbach et al.	2003/0215515	A1	11/2003	Truong-Le et al.
8,722,037	B2	5/2014	Veenstra et al.	2003/0220617	A1	11/2003	Dickerson
8,747,412	B2	6/2014	Bae et al.	2003/0233101	A1	12/2003	Lubbock et al.
8,801,700	B2	8/2014	Alessi et al.	2004/0001689	A1	1/2004	Goldsmith et al.
8,815,802	B2	8/2014	Kalthoff et al.	2004/0001889	A1	1/2004	Chen et al.
8,858,621	B2	10/2014	Oba et al.	2004/0002442	A1	1/2004	Pan et al.
8,865,202	B2	10/2014	Zerbe et al.	2004/0022859	A1	2/2004	Chen et al.
8,888,745	B2	11/2014	Van Der Graaf et al.	2004/0024068	A1	2/2004	Levy et al.
8,926,595	B2	1/2015	Alessi et al.	2004/0024069	A1	2/2004	Chen et al.
8,940,316	B2	1/2015	Alessi et al.	2004/0029784	A1	2/2004	Hathaway
8,992,961	B2	3/2015	Berry et al.	2004/0039376	A1	2/2004	Peery et al.
8,992,962	B2	3/2015	Lautenbach et al.	2004/0047888	A1	3/2004	Kenison et al.
9,044,209	B2	6/2015	Dayton et al.	2004/0097906	A1	5/2004	Fereira et al.
9,078,900	B2	7/2015	Kuzma et al.	2004/0101557	A1	5/2004	Gibson et al.
9,095,553	B2	8/2015	Rohloff et al.	2004/0102762	A1	5/2004	Gilbert
9,241,722	B2	1/2016	Yu	2004/0115236	A1	6/2004	Chan et al.
D750,764	S	3/2016	DeSocio	2004/0142867	A1	7/2004	Oi et al.
9,332,995	B2	5/2016	Russo	2004/0142902	A1	7/2004	Struijker-Boudier
9,526,763	B2	12/2016	Rohloff et al.	2004/0151753	A1	8/2004	Chen et al.
9,539,200	B2	1/2017	Lautenbach	2004/0157951	A1	8/2004	Wolf
9,572,889	B2	2/2017	Alessi et al.	2004/0198654	A1	10/2004	Glaesner et al.
D789,539	S	6/2017	Kleiner et al.	2004/0199140	A1	10/2004	Rue et al.
D789,540	S	6/2017	Gyorgy	2004/0209801	A1	10/2004	Brand et al.
9,682,127	B2	6/2017	Alessi et al.	2004/0215133	A1	10/2004	Weber et al.
RE46,577	E	10/2017	Collins et al.	2004/0224903	A1	11/2004	Berry et al.
9,889,085	B1	2/2018	Alessi et al.	2004/0225113	A1	11/2004	LaFleur et al.
2001/0012511	A1	8/2001	Bezwada et al.	2004/0243106	A1	12/2004	Ayer
2001/0021377	A1	9/2001	Jamiolkowski et al.	2004/0265273	A1	12/2004	Li et al.
2001/0021822	A1	9/2001	Ayer	2004/0266683	A1	12/2004	Hathaway et al.
2001/0022974	A1	9/2001	Ayer	2004/0266692	A1	12/2004	Young et al.
2001/0026793	A1	10/2001	Jamiolkowski et al.	2005/0004557	A1	1/2005	Russell
2001/0027311	A1	10/2001	Chen et al.	2005/0008661	A1	1/2005	Fereira et al.
2001/0031940	A1	10/2001	Loos	2005/0009742	A1	1/2005	Bertilsson et al.
2001/0031790	A1	11/2001	Beisswenger	2005/0010196	A1	1/2005	Fereira et al.
2001/0036472	A1	11/2001	Wong et al.	2005/0010942	A1	1/2005	Kim et al.
2001/0040326	A1	11/2001	Balczun	2005/0070883	A1	3/2005	Brown et al.
2002/0001631	A1	1/2002	Okumu	2005/0070927	A1	3/2005	Feinberg
2002/0004481	A1	1/2002	Cleland et al.	2005/0079200	A1	4/2005	Rathenow et al.
2002/0012818	A1	1/2002	Ruppi et al.	2005/0079202	A1	4/2005	Chen et al.
2002/0034532	A1	3/2002	Brodbeck et al.	2005/0095284	A1	5/2005	Trautman
2002/0037309	A1	3/2002	Jaworowicz et al.	2005/0101943	A1	5/2005	Ayer et al.
2002/0048600	A1	4/2002	Bhatt et al.	2005/0106214	A1	5/2005	Chen
2002/0077599	A1	6/2002	Wojcik	2005/0112188	A1	5/2005	Eliaz et al.
2002/0098180	A1	7/2002	Lei	2005/0118206	A1	6/2005	Luk et al.
2002/0136848	A1	9/2002	Yoshii et al.	2005/0118221	A1	6/2005	Blakely et al.
2002/0137666	A1	9/2002	Beeley et al.	2005/0131386	A1	6/2005	Freeman et al.
2002/0141985	A1	10/2002	Pittner et al.	2005/0131389	A1	6/2005	Peterson et al.
2002/0197185	A1	12/2002	Jamiolkowski et al.	2005/0143749	A1	6/2005	Zalenski et al.
2002/0197235	A1	12/2002	Moran	2005/0175701	A1	8/2005	Pan et al.
2003/0007992	A1	1/2003	Gibson et al.	2005/0201980	A1	9/2005	Moran
2003/0032947	A1	2/2003	Harper et al.	2005/0215475	A1	9/2005	Ong et al.
2003/0040699	A1	2/2003	Talling et al.	2005/0216087	A1	9/2005	Zucherman et al.
2003/0044467	A1	3/2003	Brodbeck et al.	2005/0266087	A1	12/2005	Junnarkar et al.
2003/0045454	A1	3/2003	Okumu et al.	2005/0271702	A1	12/2005	Wright et al.
2003/0059376	A1	3/2003	Libbey et al.	2005/0276856	A1	12/2005	Fereira et al.
2003/0059471	A1	3/2003	Compton et al.	2005/0281879	A1	12/2005	Chen et al.
2003/0060425	A1	3/2003	Ahlem et al.	2006/0013879	A9	1/2006	Brodbeck et al.
2003/0078616	A1	4/2003	Fey 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	5/2003	Jolly 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	Laridon 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	Hagemeyer	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.
				2006/0251618	A1	11/2006	Dennis et al.
				2006/0263433	A1	11/2006	Ayer et al.
				2006/0264890	A1	11/2006	Moberg et al.
				2006/0280795	A1	12/2006	Penhasi et al.

(56)

References Cited

U.S. PATENT DOCUMENTS

2006/0293232 A1 12/2006 Levy et al.
 2007/0027105 A1 2/2007 Junnarkar et al.
 2007/0141102 A1 6/2007 De Graaff et al.
 2007/0149011 A1 6/2007 Kent et al.
 2007/0166352 A1 7/2007 Wright et al.
 2007/0248572 A1 10/2007 Moran et al.
 2007/0281024 A1 12/2007 Lautenbach et al.
 2008/0020016 A1 1/2008 Li et al.
 2008/0038316 A1 2/2008 Wong et al.
 2008/0064636 A1 3/2008 Bloom et al.
 2008/0065090 A1 3/2008 Scribner et al.
 2008/0091176 A1 4/2008 Alessi
 2008/0110515 A1 5/2008 Angelosanto et al.
 2008/0112994 A1 5/2008 Junnarkar et al.
 2008/0200383 A1 8/2008 Jennings et al.
 2008/0207512 A1 8/2008 Roth et al.
 2008/0208194 A1 8/2008 Bickenbach
 2008/0226625 A1 9/2008 Berry
 2008/0226689 A1 9/2008 Betty et al.
 2008/0260838 A1 10/2008 Hokenson et al.
 2008/0260840 A1 10/2008 Alessi et al.
 2008/0269725 A1 10/2008 Deem et al.
 2008/0312157 A1 12/2008 Levy et al.
 2009/0012463 A1 1/2009 Beelen et al.
 2009/0022727 A1 1/2009 Houston et al.
 2009/0036364 A1 2/2009 Levy et al.
 2009/0042781 A1 2/2009 Petersen et al.
 2009/0074734 A1 3/2009 Rottiers
 2009/0087408 A1 4/2009 Berry et al.
 2009/0156474 A1 6/2009 Roth et al.
 2009/0163447 A1 6/2009 Maggio
 2009/0186817 A1 7/2009 Ghosh et al.
 2009/0202481 A1 8/2009 Li et al.
 2009/0202608 A1 8/2009 Alessi 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.
 2009/0234392 A1 9/2009 Dziejcz
 2009/0247463 A1 10/2009 Wright et al.
 2009/0254143 A1 10/2009 Tweden et al.
 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
 2010/0331878 A1* 12/2010 Kleinwachter A61B 17/3468
 606/205
 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.
 2012/0208755 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.
 2015/0001118 A1 1/2015 Selepack et al.
 2015/0057227 A1 2/2015 Leung
 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.
 2016/0158577 A1* 6/2016 Escarguel A61M 37/0069
 600/1
 2016/0354115 A1 12/2016 Smith et al.
 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
 2017/0273706 A1 9/2017 Mirza et al.
 2017/0319470 A1 11/2017 Eliaz et al.
 2017/0319662 A1 11/2017 Berry et al.
 2017/0348392 A1 12/2017 Rohloff
 2017/0368145 A1 12/2017 Alessi et al.
 2018/0009871 A1 1/2018 Blackwell et al.
 2018/0185451 A1 7/2018 Young et al.
 2018/0368875 A1* 12/2018 Castillo A61B 17/3468

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
 GB 2501400 A 10/2013
 JP H02124814 A 5/1990
 JP H07196479 A 8/1995
 JP 09-509346 A 9/1997
 JP 1997/509346 9/1997
 JP 9241153 9/1997
 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 WO1989003678 A1 5/1989

(56)

References Cited

FOREIGN PATENT DOCUMENTS			WO	WO		
WO	WO1990013285	A1	11/1990	WO	WO 00/045790	8/2000
WO	WO1990013361	A1	11/1990	WO	WO 00/054745	9/2000
WO	WO1990013780	A1	11/1990	WO	WO2000059476	A1 10/2000
WO	WO 91/07160		5/1991	WO	WO 00/066138	11/2000
WO	WO1992019241	A1	11/1992	WO	WO 00/067728	11/2000
WO	WO 93/06819		4/1993	WO	WO2000066087	A2 11/2000
WO	WO 93/06821		4/1993	WO	WO2001019345	A1 3/2001
WO	WO 93/008832		5/1993	WO	WO 01/28631	A1 4/2001
WO	WO 93/09763		5/1993	WO	WO2001028525	A2 4/2001
WO	WO 93/23083		11/1993	WO	WO 01/043528	6/2001
WO	WO 94/09743		5/1994	WO	WO 01/051041	7/2001
WO	WO1994010982	A1	5/1994	WO	WO 01/68168	A1 9/2001
WO	WO 94/21262		9/1994	WO	WO 01/78683	10/2001
WO	WO 95/01167		1/1995	WO	WO 02/028366	4/2002
WO	WO 95/09006		4/1995	WO	WO 02/036072	5/2002
WO	WO 95/09007		4/1995	WO	WO 02/043800	6/2002
WO	WO1995013799	A1	5/1995	WO	WO 02/045752	6/2002
WO	WO 95/34285		12/1995	WO	WO 02/47716	6/2002
WO	WO 96/001134		1/1996	WO	WO 02/067895	9/2002
WO	WO 96/003116		2/1996	WO	WO 02/069983	9/2002
WO	WO1996036317	A1	11/1996	WO	02083216	A1 10/2002
WO	WO 96/39142		12/1996	WO	WO 02/76344	10/2002
WO	WO 96/40049		12/1996	WO	WO 02/085428	10/2002
WO	WO 96/40139		12/1996	WO	WO 03/000230	1/2003
WO	WO 96/40355		12/1996	WO	WO 03/007981	1/2003
WO	WO1996040049	A1	12/1996	WO	WO 03/011892	2/2003
WO	WO 97/15289		5/1997	WO	WO 03/024357	3/2003
WO	WO 97/15296		5/1997	WO	WO 03/024503	3/2003
WO	WO 97/28181		8/1997	WO	WO2003020245	A1 3/2003
WO	WO1997031943	A1	9/1997	WO	WO 03/030923	4/2003
WO	WO1997044039	A1	11/1997	WO	WO 03/041684	5/2003
WO	WO 97/46204		12/1997	WO	WO 03/041757	5/2003
WO	WO 97/47339		12/1997	WO	WO 03/053400	7/2003
WO	WO 98/00152		1/1998	WO	WO2003066585	A2 8/2003
WO	WO 98/00157		1/1998	WO	WO 03/072113	9/2003
WO	WO 98/00158		1/1998	WO	WO 03/072133	9/2003
WO	WO 98/02169		1/1998	WO	WO 04/002565	1/2004
WO	WO1997041837	A3	2/1998	WO	WO 2004/026106	A2 4/2004
WO	WO1998007412	A1	2/1998	WO	WO2004034975	A2 4/2004
WO	9813092	A1	4/1998	WO	WO2004035754	A2 4/2004
WO	WO 98/13092	A1	4/1998	WO	WO2004035762	A2 4/2004
WO	WO 98/16250		4/1998	WO	WO2004036186	A2 4/2004
WO	WO 98/17315		4/1998	WO	WO 04/052336	6/2004
WO	WO 1998/13091		4/1998	WO	WO 04/056338	7/2004
WO	WO 98/20930		5/1998	WO	WO 04/089335	10/2004
WO	WO 98/27960		7/1998	WO	WO 2004/089458	A1 10/2004
WO	WO 98/027962		7/1998	WO	WO2004103342	A2 12/2004
WO	WO 98/27963		7/1998	WO	WO 05/048930	6/2005
WO	WO 98/030231		7/1998	WO	WO 05/048952	6/2005
WO	WO 98/32463		7/1998	WO	WO 05/102293	11/2005
WO	WO1998030231	A1	7/1998	WO	WO2005102293	A1 11/2005
WO	WO 98/42317		10/1998	WO	WO2005110425	11/2005
WO	WO 98/47487		10/1998	WO	WO 06/017772	2/2006
WO	WO 98/51282		11/1998	WO	WO 06/023526	3/2006
WO	WO 98/58698	A1	12/1998	WO	WO 2006/077242	A1 7/2006
WO	WO 99/03453		1/1999	WO	WO 2006/077250	A1 7/2006
WO	WO 99/04767		2/1999	WO	WO 06/081279	8/2006
WO	WO 99/004768		2/1999	WO	WO 06/083761	8/2006
WO	WO1999012549	A2	3/1999	WO	WO 06/084139	8/2006
WO	WO 99/16419		4/1999	WO	WO 06/086727	8/2006
WO	WO 99/025728		5/1999	WO	WO 06/101815	9/2006
WO	WO 99/29306		6/1999	WO	WO 06/111169	10/2006
WO	WO 99/033446		7/1999	WO	WO2006/131730	12/2006
WO	WO 99/33449		7/1999	WO	WO 07/024700	3/2007
WO	WO 99/39700		8/1999	WO	WO 07/056681	5/2007
WO	WO 99/040788		8/1999	WO	WO 07/075534	7/2007
WO	WO 99/04659		9/1999	WO	WO 07/084460	7/2007
WO	WO 99/062501		12/1999	WO	WO 2007/082889	A1 7/2007
WO	WO 99/064061		12/1999	WO	WO 07/133778	11/2007
WO	WO 00/013663		3/2000	WO	WO 07/140416	12/2007
WO	WO 00/029206		5/2000	WO	WO 08/021133	2/2008
WO	WO 00/038652		7/2000	WO	WO2008041245	A2 4/2008
WO	WO 00/039280		7/2000	WO	WO 08/061355	5/2008
WO	WO 00/040273		7/2000	WO	WO2008/086086	A2 7/2008
WO	WO 00/041548		7/2000	WO	WO 08/133908	11/2008
				WO	WO 08/134425	11/2008
				WO	WO 09/109927	9/2009
				WO	WO2009143265	A2 11/2009
				WO	WO2009143285	A2 11/2009

(56)

References Cited

FOREIGN PATENT DOCUMENTS

WO	WO 2010/045169	A1	4/2010
WO	2011011697	A1	1/2011
WO	WO 2013/004983	A1	1/2013
WO	2013160347	A1	10/2013
WO	WO 2013/184235	A1	12/2013

OTHER PUBLICATIONS

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.

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.

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

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).

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).

Thomassin, 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).

Bray, "Gut Signals and Energy Balance: Ghrelin, Peptide YY, Leptin, and Amylin," (Dec. 19, 2007) (slides and transcript for presentation at Medscape CME).

"Implantable infusion pumps: technology poised for takeoff," *BBI Newsletter* 17(12):209-211 (Dec. 1994).

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 ω 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-Gamma," *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).

(56)

References Cited

OTHER PUBLICATIONS

- 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).
- Boué 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 anathermal solvents: fluid phase coexistence," *J. Chem. Physics* 104(20):8082-8095 (1996).
- CAS Number: 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).
- 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 p 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 ribarivin plus interferon α ," *Lancet* 356(9223):41 (Jul. 2000).
- 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).
- 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 beta-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).

(56)

References Cited

OTHER PUBLICATIONS

- 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/a1.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).
- 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 β -1b therapy in patients with MS," *Neurology* 54(1):193-199 (Jan. 2000).
- 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 preproglucagon 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 preproglucagon 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 α -2b alone or in combination with ribavirin as initial treatment for chronic hepatitis C," *N. Engl. J. Med.* 339(21):1485-1492 (Nov. 1998).
- 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 α -interferon and response to therapy in chronic hepatitis C virus infection," *Liver* 13(3):146-150 (Jun. 1993).

(56)

References Cited

OTHER PUBLICATIONS

- 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- α -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 III*, 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(Supp. 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 α 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 α 2b plus ribavirin for 48 weeks or for 24 weeks versus interferon α 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).
- 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," *J. Biol. Chem.* 267(8):5017-5020 (Mar. 1992).
- Shiffman 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., "Peginterferon- α -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):1640-1645 (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).

(56)

References Cited

OTHER PUBLICATIONS

- 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).
- 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 (*Macaca mulatta*)," *Diabetes*, 48(5):1026-1034 (1999).
- Younossi et al., "The role of amantadine, rimantadine, ursodeoxycholic acid, and NSAIDs, alone or in combination with α 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 α 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).
- 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, v. 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.
- Adolf, "Human interferon omega-a review," *Mult. Sclr.* 1:S44-47 (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).
- 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 (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).

(56)

References Cited

OTHER PUBLICATIONS

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 (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.

Georgios, et al., "Pharmacokinetics and Tolerability of Exenatide Delivered by 7-Day Continuous Subcutaneous Infusion in Healthy Volunteers", *Advances in Therapy, Health Communications, Metuchen, NJ, US*, vol. 32, No. 7, Jul. 10, 2015, pp. 650-661.

Yu et al., "Glucagon-like peptide 1 based therapy for type 2 diabetes", *World Journal of Pediatrics* vol. 4, No. 1, Feb. 1, 2008, pp. 8-13.

Taylor et al., "Day-long subcutaneous infusion of exenatide lowers glycemia in patients with type 2 diabetes", *Horm Metab Res* 37: 627-632 (2005).

Gao et al., "Target-Mediated Pharmacokinetic and Pharmacodynamic Model of Exendin-4 in Rats, Monkeys, And Humans," *Drug Metabolism and Disposition*, vol. 40, No. 5, pp. 990-997 (2012).

Franchetti et al., "Furanfuran and Thiophenfuran: Two Novel Tiazofuran Analogues, Synthesis, Structure, Antitumor Activity, and Interactions with Inosine Monophosphate Dehydrogenase," *J. Medicinal Chem.* 38(19):3829-3837 (1995).

Fujii et al., "Effect of phosphatidylethanolamine 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 Ryoho, "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).

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 ©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.

Henry et al. (2014) "Continuous subcutaneous delivery of exenatide via ITCA 650 leads to sustained glycemic control and weight loss for 48 weeks in metformin-treated subjects with type 2 diabetes," *Journal of Diabetes and Its Complications*, 28:393-398.

Schepis et al. (2001) "Which patients with cirrhosis should undergo endoscopic screening for esophageal varices detection," *Hepatology*, 33(2):333-338.

* cited by examiner

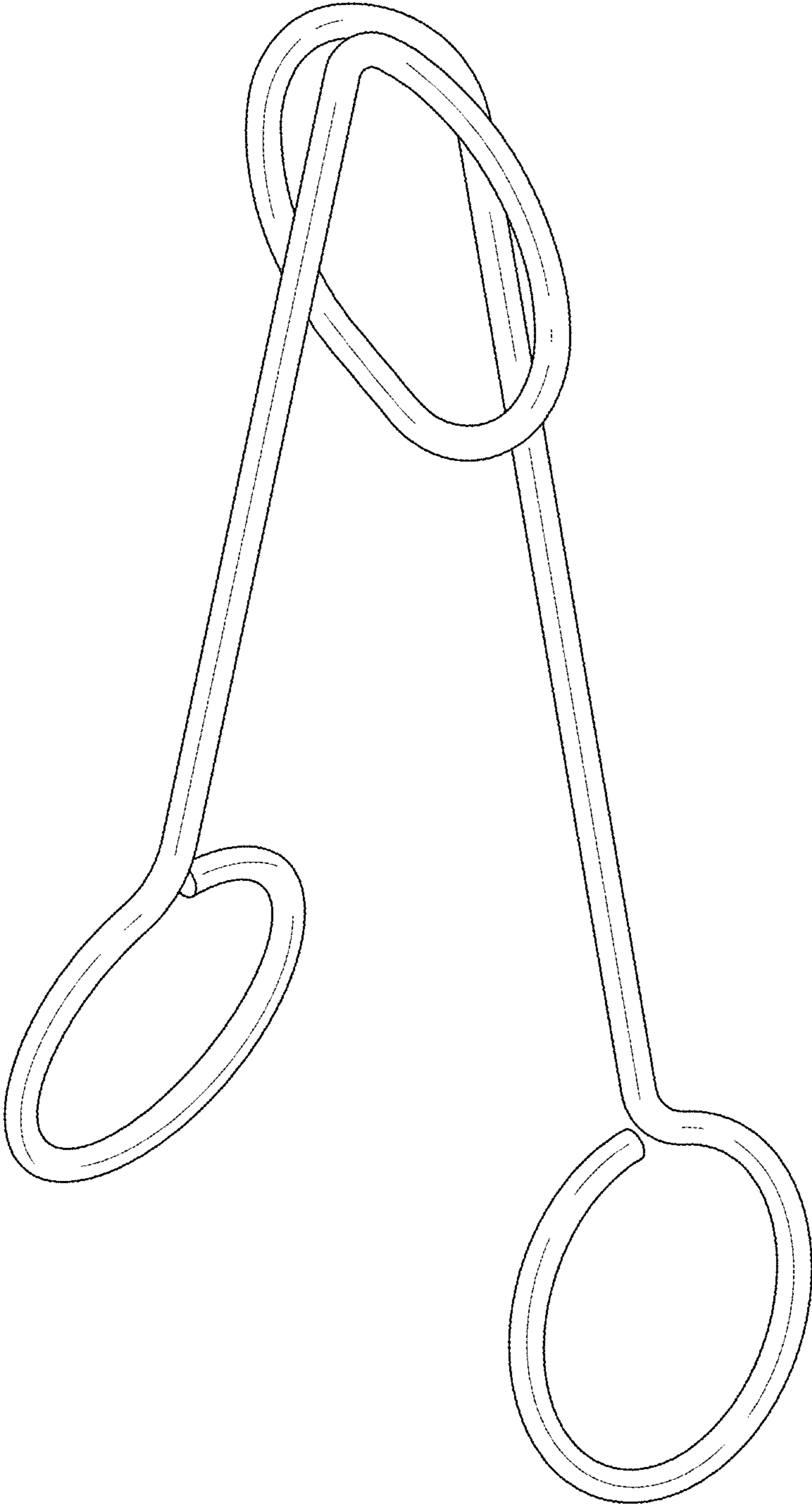


FIG. 1

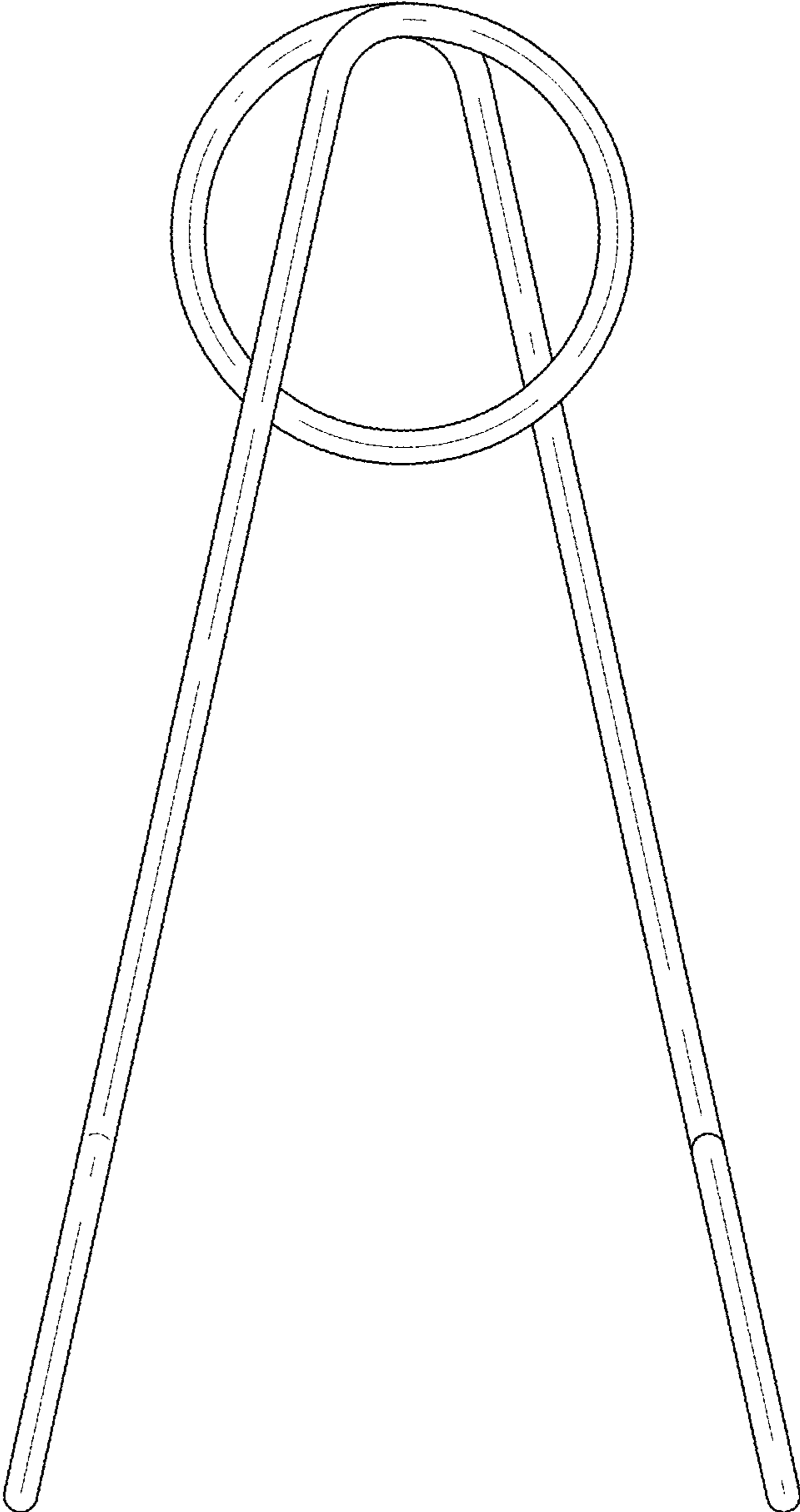


FIG. 2

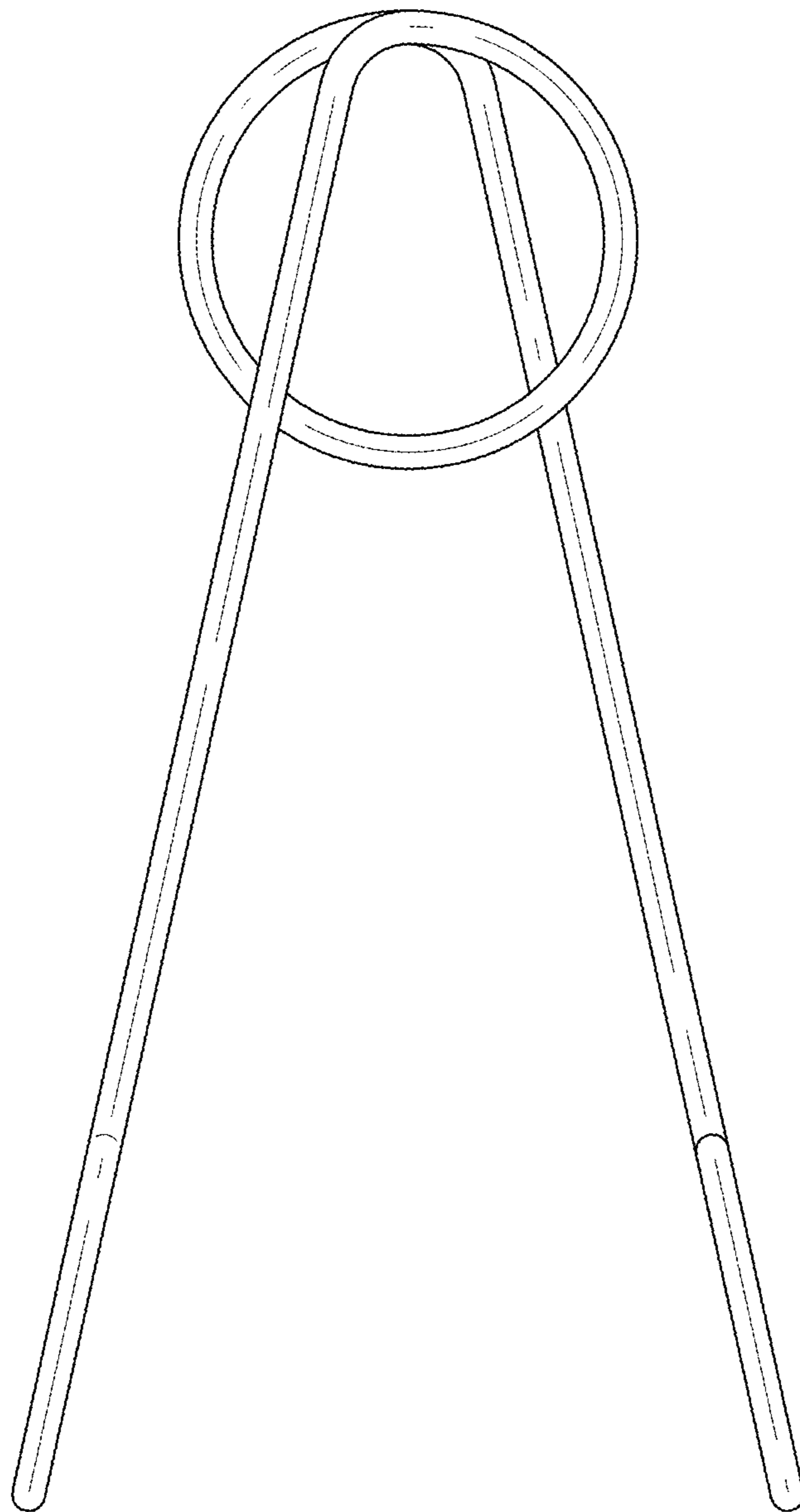


FIG. 3

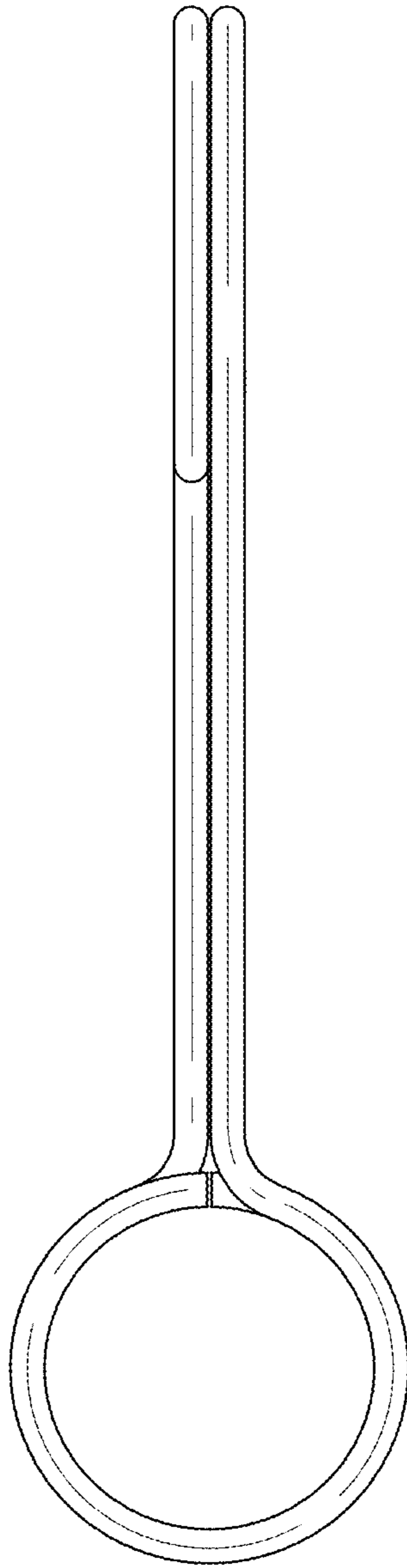


FIG. 4

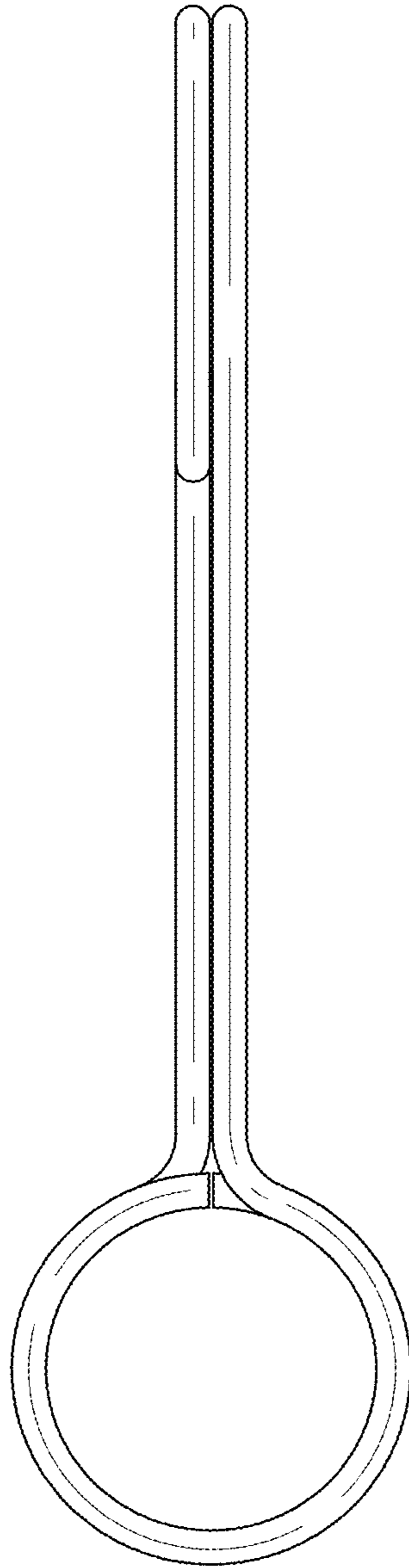


FIG. 5

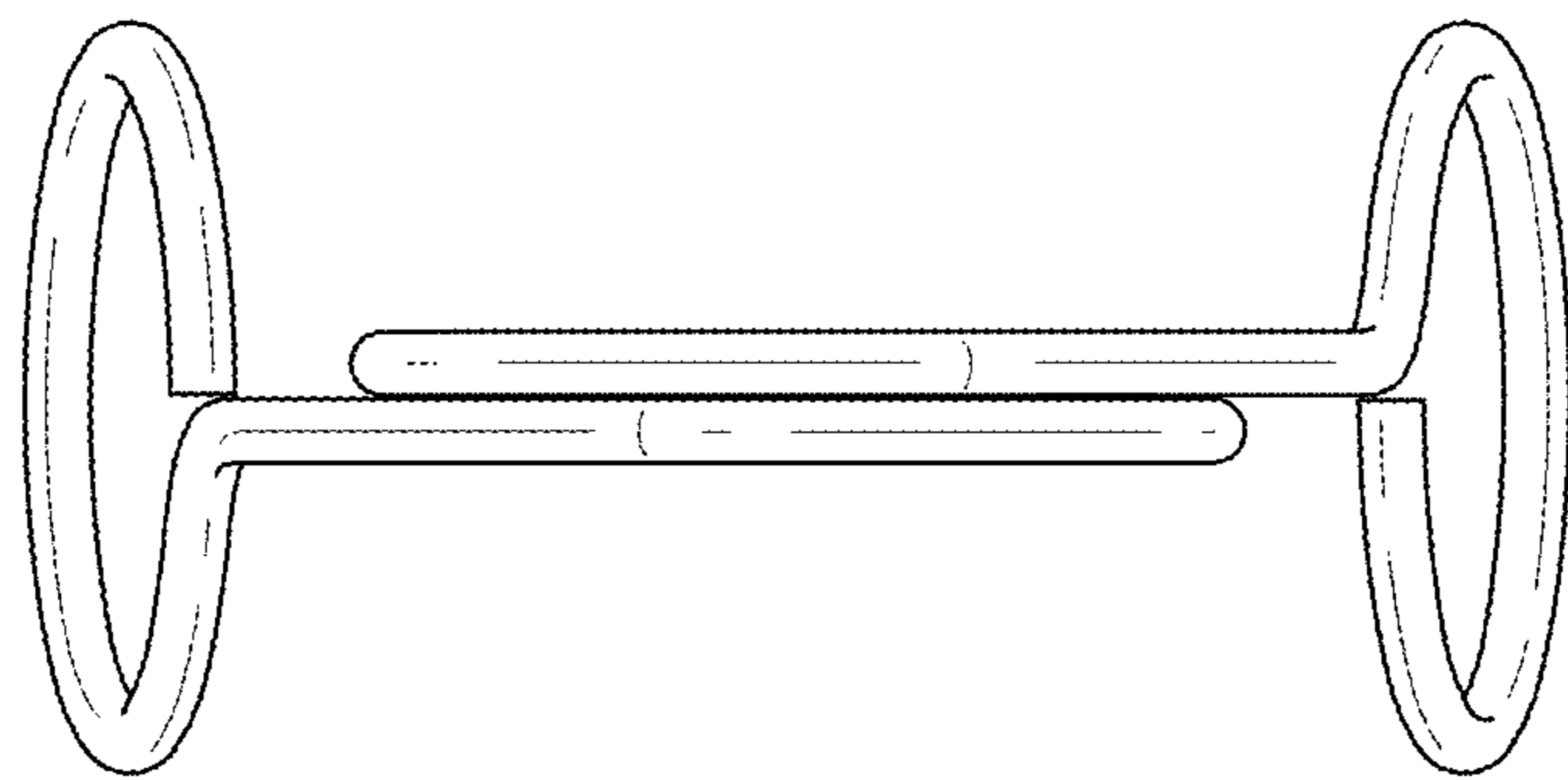


FIG. 6

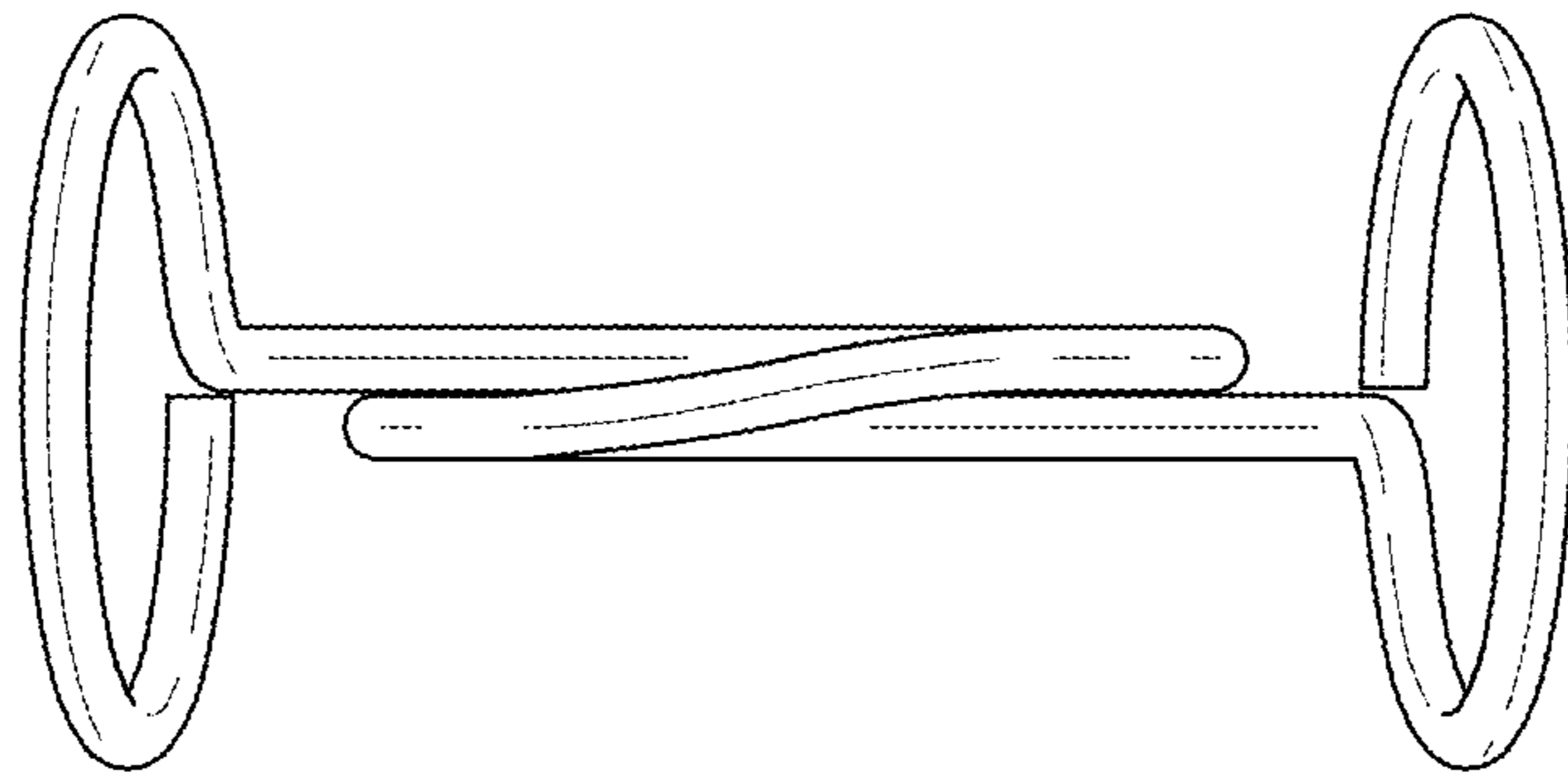


FIG. 7

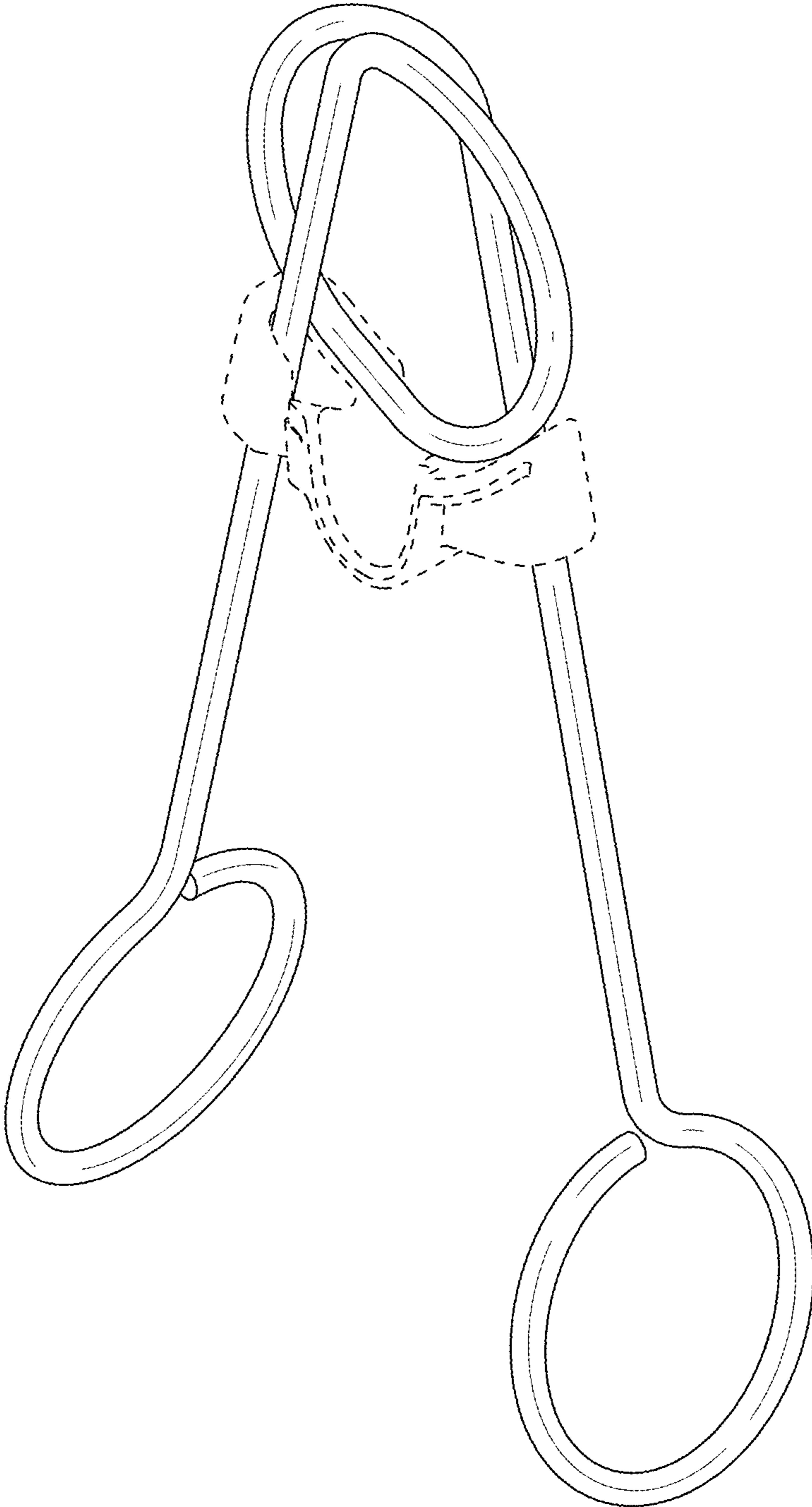


FIG. 8

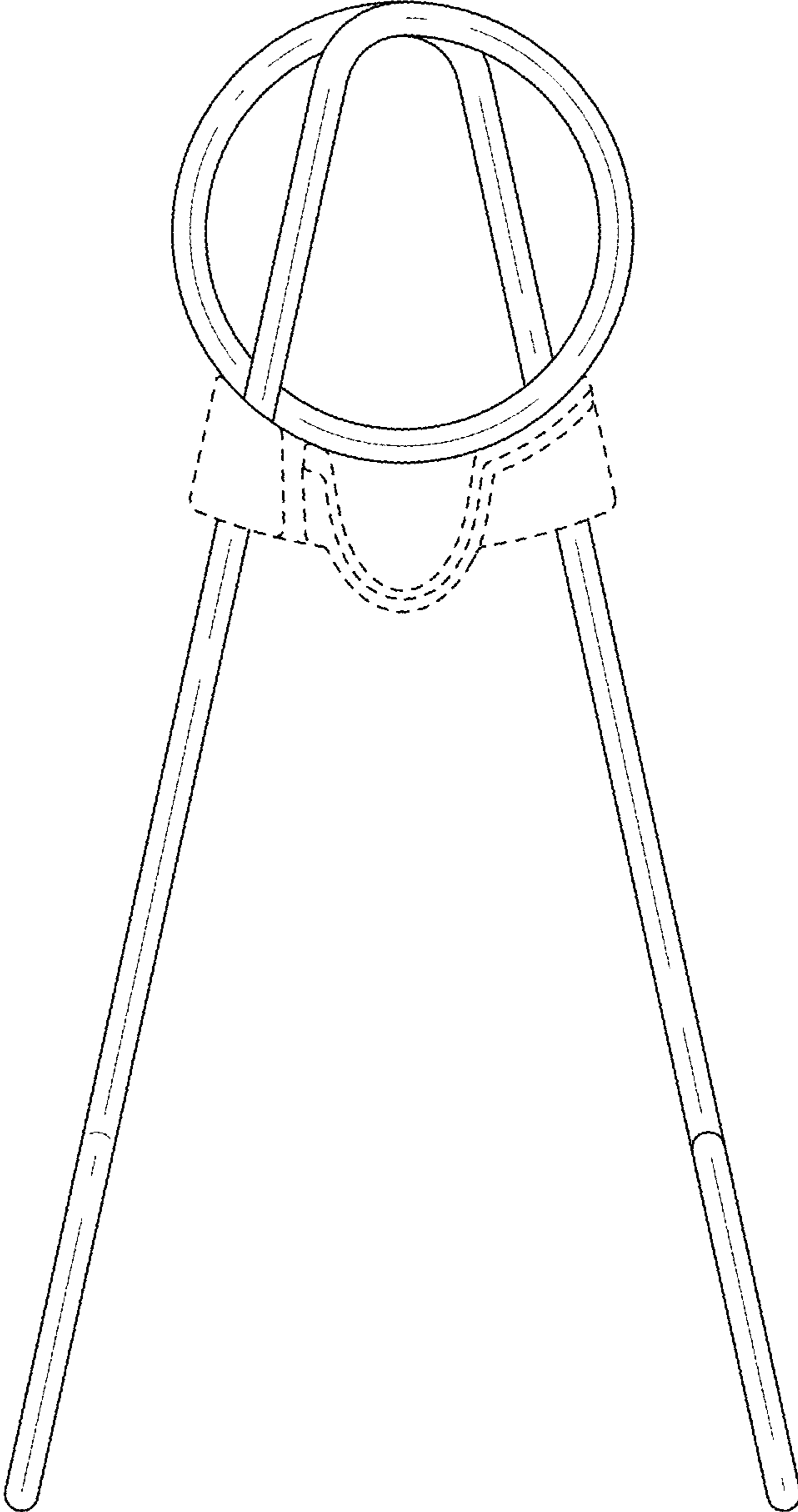


FIG. 9

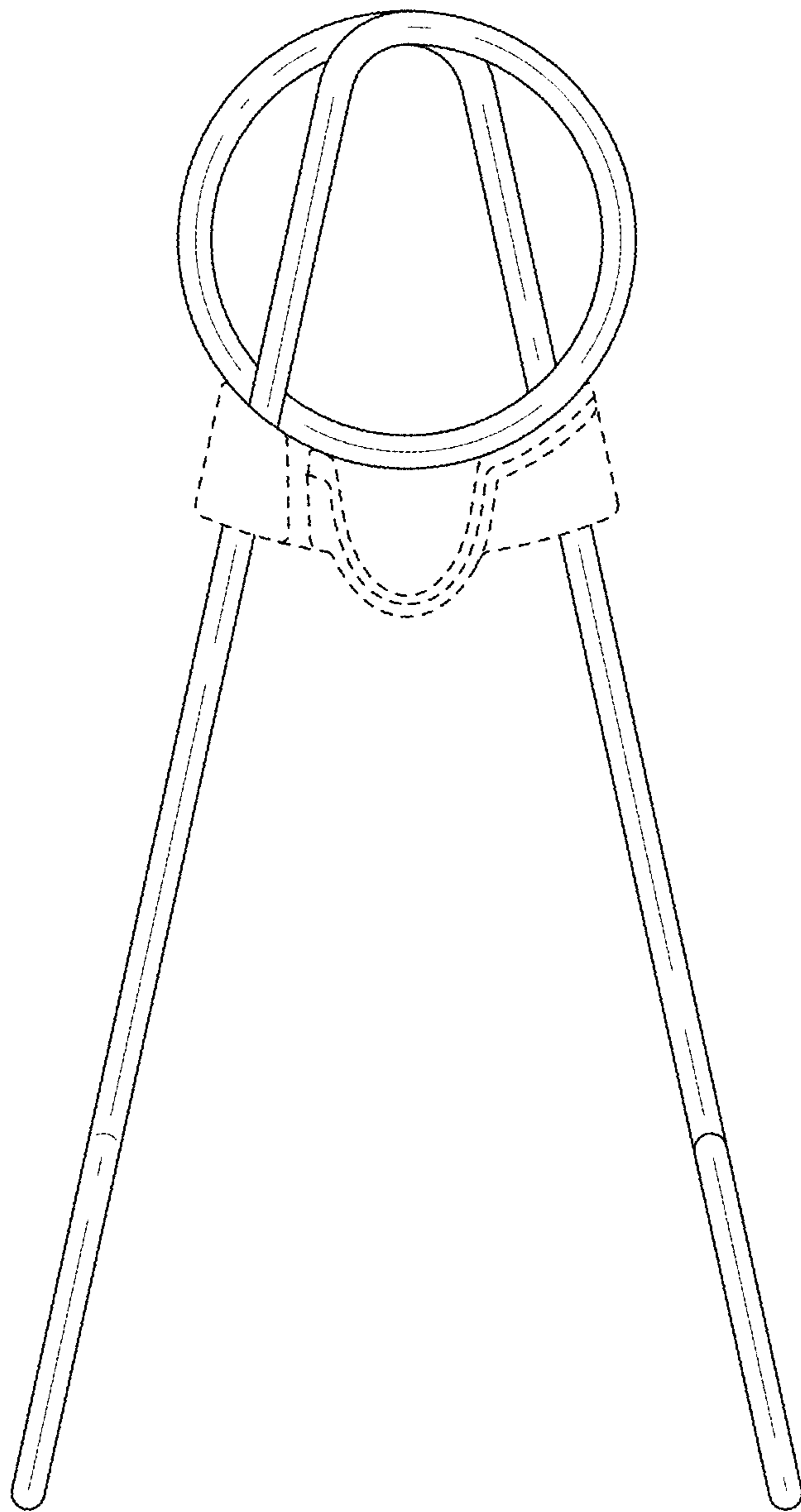


FIG. 10

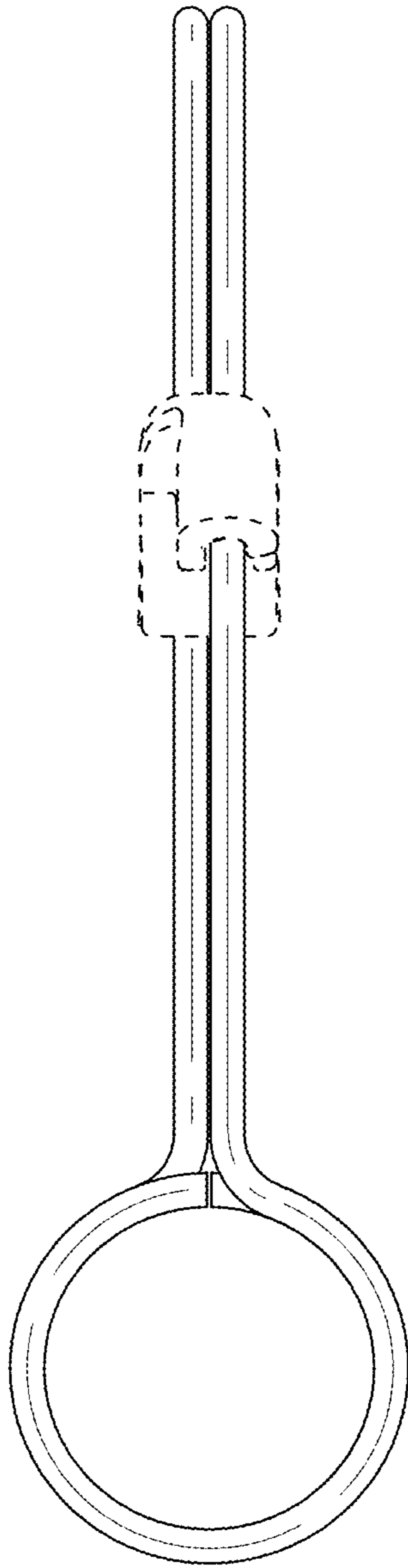


FIG. 11

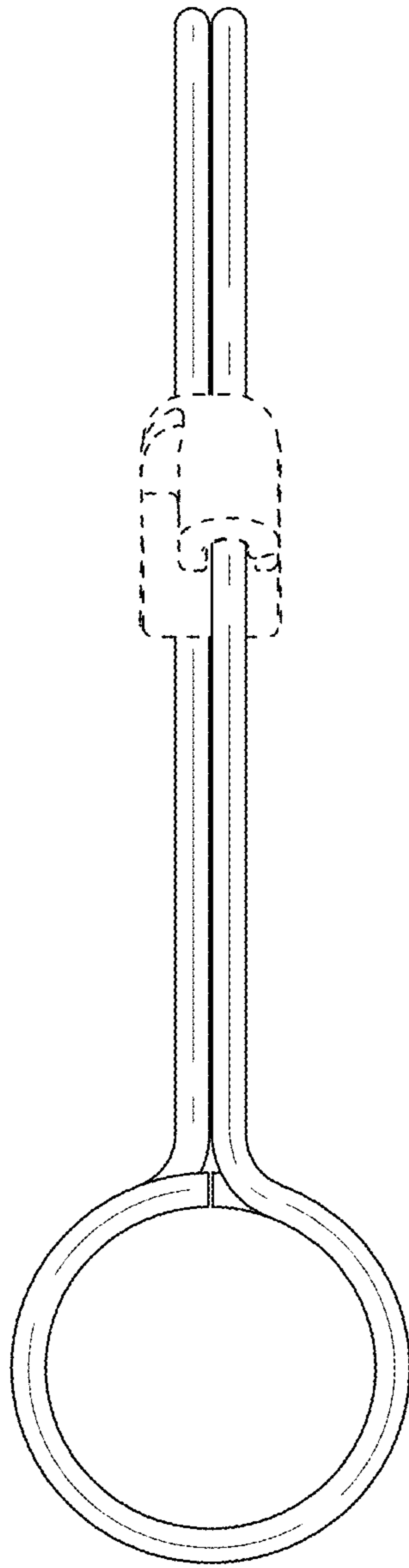


FIG. 12

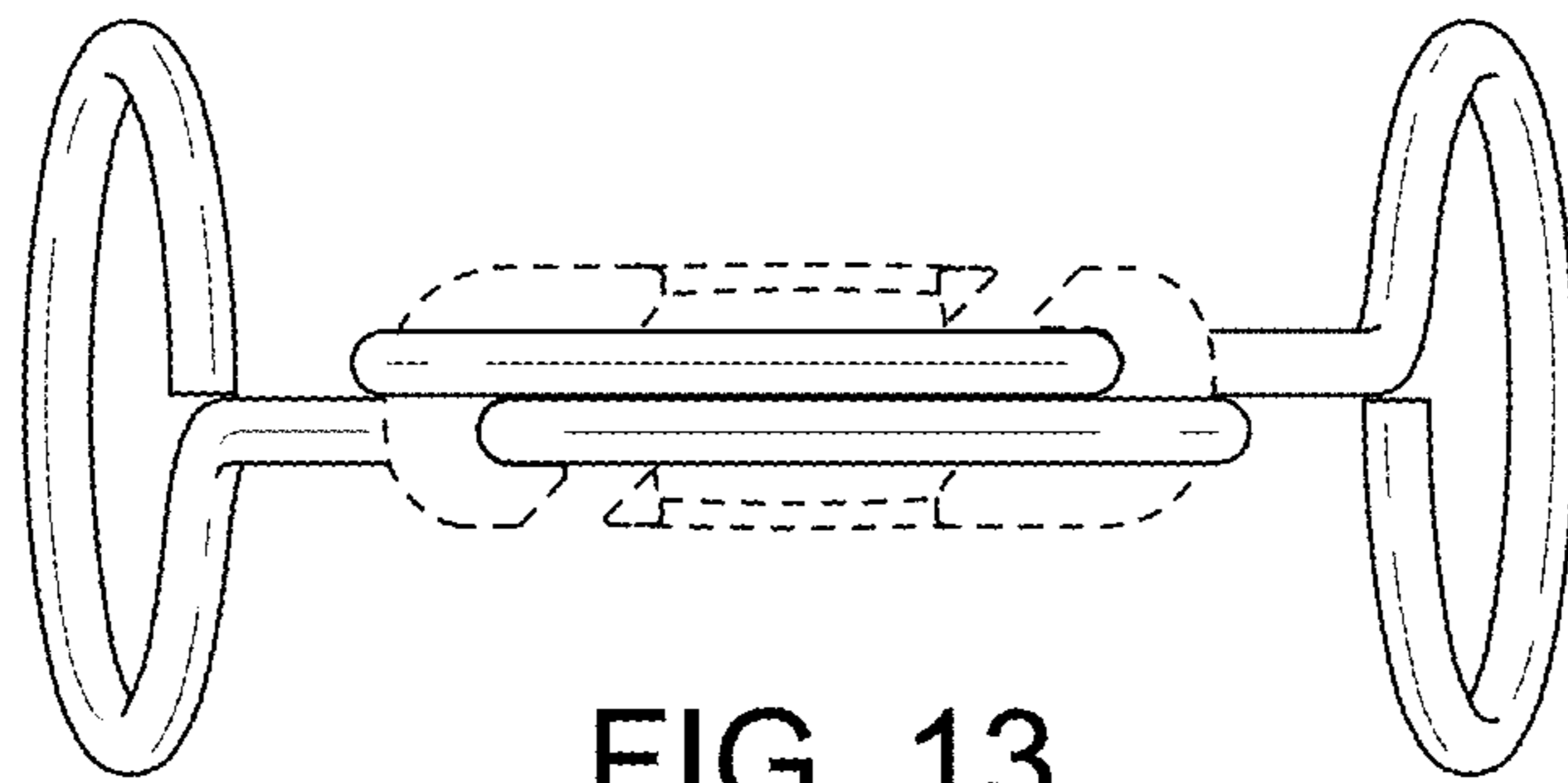


FIG. 13

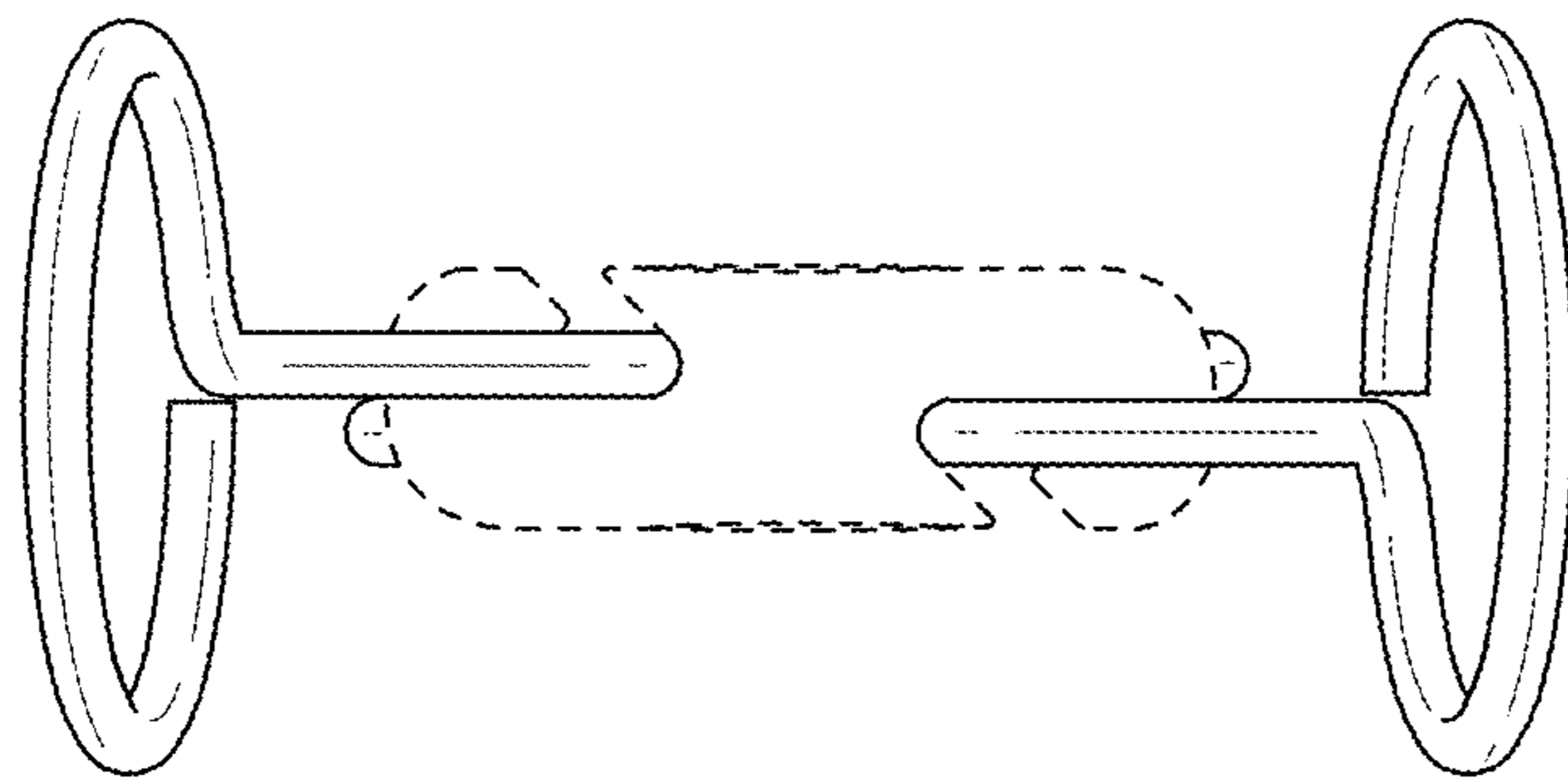


FIG. 14