



US00D869311S

(12) **United States Design Patent** (10) **Patent No.:** **US D869,311 S**  
**Khattak et al.** (45) **Date of Patent:** **\*\* Dec. 10, 2019**

(54) **ANALYTE DETECTION SYSTEM**

- (71) Applicant: **Cue Health Inc.**, San Diego, CA (US)
- (72) Inventors: **Ayub Khattak**, San Diego, CA (US);  
**Clinton Sever**, San Diego, CA (US)
- (73) Assignee: **CUE HEALTH INC.**, San Diego, CA (US)
- (\*\*) Term: **15 Years**
- (21) Appl. No.: **29/647,395**
- (22) Filed: **May 11, 2018**

**Related U.S. Application Data**

- (62) Division of application No. 29/584,715, filed on Nov. 16, 2016, now Pat. No. Des. 820,130, which is a (Continued)
- (51) **LOC (12) Cl.** ..... **10-04**
- (52) **U.S. Cl.**  
USPC ..... **D10/81; D24/129**
- (58) **Field of Classification Search**  
USPC ..... **D10/81; D24/129**  
(Continued)

(56) **References Cited**

**U.S. PATENT DOCUMENTS**

- D115,326 S 6/1939 Chott
  - 3,915,806 A 10/1975 Horlach
- (Continued)

**FOREIGN PATENT DOCUMENTS**

- CA 159365 11/2015
  - CN 104232622 A 12/2014
- (Continued)

**OTHER PUBLICATIONS**

U.S. Appl. No. 14/479,158, filed Sep. 5, 2014, Khattak et al.  
(Continued)

*Primary Examiner* — Antoine Duval Davis  
(74) *Attorney, Agent, or Firm* — Foley & Lardner LLP;  
Marshall J. Brown; Antoinette F. Konski

(57) **CLAIM**

We claim the ornamental design for an analyte detection system, as shown and described.

**DESCRIPTION**

FIG. 1 is a top, front, and left side perspective view of an embodiment of a cartridge device and sample collection device for use with the reader device of the analyte detection system;

FIG. 2 is an exploded view thereof;

FIG. 3 is a left side view thereof;

FIG. 4 is a right side view thereof;

FIG. 5 is a top view thereof;

FIG. 6 is a bottom view thereof;

FIG. 7 is a front view thereof;

FIG. 8 is a rear view thereof;

FIG. 9 is a top, front, and left side perspective view of a second embodiment of a cartridge device and sample collection device for use with the reader device of the analyte detection system;

FIG. 10 is an exploded view thereof;

FIG. 11 is a left side view thereof;

FIG. 12 is a right side view thereof;

FIG. 13 is a top view thereof;

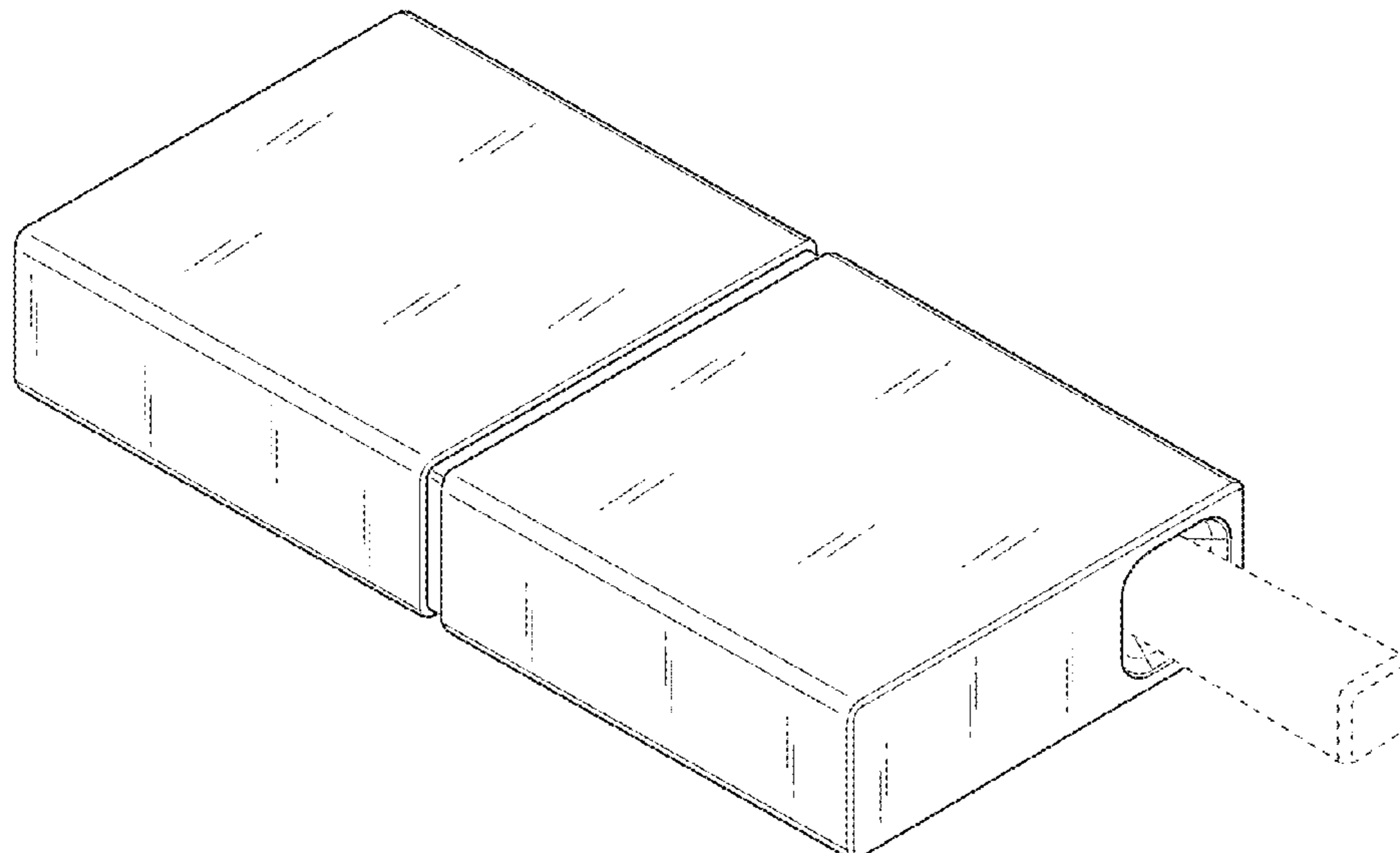
FIG. 14 is a bottom view thereof;

FIG. 15 is a front view thereof; and,

FIG. 16 is a rear view thereof.

The ornamental design which is claimed is shown in solid lines in the drawings. The broken lines formed by dashes show unclaimed subject matter and form no part of the claimed design.

**1 Claim, 10 Drawing Sheets**



**Related U.S. Application Data**

division of application No. 29/545,014, filed on Nov. 9, 2015, now Pat. No. Des. 774,407, which is a division of application No. 29/490,660, filed on May 12, 2014, now Pat. No. Des. 745,423.

(58) **Field of Classification Search**

CPC ..... G01N 35/08; G01N 33/542; G01N 21/64; G01N 33/48; G01N 1/00; G01N 21/00; G01N 33/543; G01N 35/085; G01N 35/1065; G01N 35/1067; G01N 2035/1069; G01N 35/1072; G01N 35/1074; G01N 2035/1076; G01N 35/1095; G01N 35/1097; G01N 2035/00306; G01N 2035/00326; B01L 3/00; C40B 30/04; C12M 1/34

See application file for complete search history.

8,361,808	B2	1/2013	Wang
D679,025	S	3/2013	Motadel et al.
8,435,738	B2	5/2013	Holmes
8,449,842	B2	5/2013	Knopp et al.
8,470,524	B2	6/2013	Gibbons et al.
8,475,739	B2	7/2013	Holmes et al.
8,528,777	B2	9/2013	Harder et al.
8,551,714	B2	10/2013	Jovanovich et al.
8,562,918	B2	10/2013	Jovanovich et al.
D698,036	S	1/2014	Dickinson
8,637,253	B2	1/2014	Piepenburg et al.
8,669,047	B2	3/2014	Holmes et al.
8,679,407	B2	3/2014	Holmes et al.
8,724,833	B1	5/2014	Shain et al.
8,735,104	B2	5/2014	Harder et al.
D707,847	S	6/2014	Motadel et al.
8,741,230	B2	6/2014	Holmes et al.
8,778,665	B2	7/2014	Gibbons et al.
8,802,445	B2	8/2014	Linder et al.
8,834,691	B2*	9/2014	Kondo ..... G01N 33/4875 204/403.01

(56)

**References Cited**

U.S. PATENT DOCUMENTS

D249,062	S	8/1978	Crafoord et al.	D718,462	S	11/2014	Cook et al.
D298,166	S	10/1988	Chennault	8,883,518	B2	11/2014	Roy et al.
D302,585	S	8/1989	Elliott	D719,666	S	12/2014	Manian
D303,288	S	9/1989	Harboe et al.	8,945,880	B2	2/2015	Cloake et al.
D306,067	S	2/1990	Bogdanoff et al.	9,028,773	B2	5/2015	Ganesan
5,223,414	A	6/1993	Zarling et al.	9,034,168	B2	5/2015	Khattak et al.
5,273,881	A	12/1993	Sena et al.	9,052,275	B2	6/2015	Khattak et al.
D343,679	S	1/1994	Wong	9,086,417	B2	7/2015	Khattak et al.
5,455,166	A	10/1995	Walker	9,176,126	B2	11/2015	Holmes et al.
5,470,723	A	11/1995	Walker et al.	D745,185	S	12/2015	Kimura et al.
5,498,392	A	3/1996	Wilding et al.	D745,423	S	12/2015	Khattak et al.
D379,230	S	5/1997	Mark	9,207,244	B2	12/2015	Khattak et al.
5,708,247	A	1/1998	McAleer et al.	9,207,245	B2	12/2015	Khattak
5,714,320	A	2/1998	Kool	9,310,231	B2	4/2016	Bloss et al.
D402,753	S	12/1998	White	9,360,491	B2	6/2016	Sever et al.
5,935,804	A	8/1999	Laine et al.	9,435,793	B2	9/2016	Burd et al.
6,146,590	A	11/2000	Mazurek et al.	D774,407	S	12/2016	Khattak et al.
6,235,502	B1	5/2001	Weissman et al.	9,522,397	B2	12/2016	Khattak et al.
D458,456	S	6/2002	Dragan et al.	9,623,409	B2*	4/2017	Khattak ..... B01L 3/5027
6,410,278	B1	6/2002	Notomi et al.	9,636,676	B2	5/2017	Sever et al.
6,514,415	B2	2/2003	Hatch et al.	D789,815	S*	6/2017	Khattak ..... D10/81
6,523,560	B1	2/2003	Williams et al.	9,718,058	B2	8/2017	Khattak et al.
D472,975	S	4/2003	Iori et al.	9,724,691	B2	8/2017	Khattak et al.
6,686,195	B1	2/2004	Colin et al.	9,789,483	B2	10/2017	Khattak et al.
6,893,879	B2	5/2005	Petersen et al.	9,808,804	B2	11/2017	Khattak et al.
6,929,915	B2	8/2005	Benkovic et al.	9,962,703	B2	5/2018	Khattak et al.
D518,597	S	4/2006	Sommers	D820,130	S	6/2018	Khattak et al.
7,118,667	B2	10/2006	Lee	D821,602	S	6/2018	Sever et al.
7,195,036	B2	3/2007	Burns et al.	2002/0002326	A1	1/2002	Causey et al.
D542,931	S	5/2007	Pukall et al.	2002/0123048	A1	9/2002	Gau
7,282,328	B2	10/2007	Kong et al.	2002/0137234	A1	9/2002	Wohlstadter et al.
7,285,412	B2	10/2007	Casagrande et al.	2003/0019522	A1	1/2003	Parunak
7,291,497	B2	11/2007	Holmes et al.	2004/0082878	A1	4/2004	Baldwin et al.
7,399,590	B2	7/2008	Piepenburg et al.	2004/0173456	A1	9/2004	Boos et al.
7,432,106	B2	10/2008	Cox	2004/0189311	A1	9/2004	Glezer et al.
7,466,908	B1	12/2008	Lem et al.	2004/0214200	A1	10/2004	Brown et al.
7,478,792	B2	1/2009	Oh et al.	2004/0219732	A1	11/2004	Burns et al.
D591,864	S	5/2009	Schmidt	2005/0136529	A1	6/2005	Yang et al.
D600,578	S	9/2009	Tsuji	2005/0171528	A1	8/2005	Sartor et al.
7,635,594	B2	12/2009	Holmes et al.	2005/0178700	A1	8/2005	Tyvoll et al.
7,723,099	B2	5/2010	Miller et al.	2005/0200643	A1	9/2005	Falcon
7,888,125	B2	2/2011	Gibbons et al.	2006/0131994	A1	6/2006	D'Angelico et al.
7,981,696	B2	7/2011	Moreland et al.	2006/0160205	A1	7/2006	Blackburn et al.
8,007,999	B2	8/2011	Holmes et al.	2006/0207891	A1	9/2006	Althaus et al.
8,008,034	B2	8/2011	Gibbons et al.	2006/0243591	A1	11/2006	Plotkin et al.
8,012,744	B2	9/2011	Gibbons et al.	2007/0031283	A1	2/2007	Davis et al.
D646,189	S	10/2011	Dinter et al.	2007/0060815	A1	3/2007	Martin et al.
8,071,054	B2	12/2011	Oh et al.	2007/0154922	A1	7/2007	Collier et al.
8,071,308	B2	12/2011	Piepenburg et al.	2007/0184547	A1	8/2007	Handique et al.
8,101,402	B2	1/2012	Holmes	2007/0299364	A1	12/2007	Sangha
8,202,697	B2	6/2012	Holmes	2008/0124779	A1	5/2008	Oh et al.
8,216,832	B2	7/2012	Battrell et al.	2008/0160601	A1	7/2008	Handique
8,265,955	B2	9/2012	Michelson et al.	2008/0160622	A1	7/2008	Su et al.
8,283,155	B2	10/2012	Holmes et al.	2008/0160630	A1	7/2008	Liu et al.
				2008/0182301	A1	7/2008	Handique et al.
				2008/0275229	A1	11/2008	Lem et al.
				2008/0302193	A1	12/2008	Bommarito et al.
				2009/0061450	A1	3/2009	Hunter



(56)

## References Cited

## U.S. PATENT DOCUMENTS

2009/0130777 A1 5/2009 Arinaga et al.  
 2010/0236340 A1 9/2010 Lee et al.  
 2010/0274155 A1 10/2010 Battrell et al.  
 2010/0280146 A1 11/2010 Vanderlaan et al.  
 2010/0297708 A1 11/2010 Collier et al.  
 2010/0331652 A1 12/2010 Groll et al.  
 2011/0008813 A1 1/2011 Dilleen et al.  
 2011/0059468 A1 3/2011 Earhart et al.  
 2011/0129841 A1 6/2011 Heid et al.  
 2011/0165562 A1 7/2011 Pourahmadi et al.  
 2011/0171754 A1 7/2011 Redmond et al.  
 2011/0212440 A1 9/2011 Viovy et al.  
 2011/0233073 A1 9/2011 Laczka et al.  
 2011/0272294 A1 11/2011 Fujiwara  
 2012/0009588 A1 1/2012 Rajagopal et al.  
 2012/0014836 A1 1/2012 Dittmer  
 2012/0071342 A1 3/2012 Lochhead et al.  
 2012/0095316 A1 4/2012 Lewis et al.  
 2012/0164036 A1 6/2012 Stern et al.  
 2012/0180580 A1 7/2012 Immink et al.  
 2012/0190589 A1 7/2012 Anderson et al.  
 2012/0255860 A1 10/2012 Briman et al.  
 2012/0267258 A1 10/2012 Uraoka et al.  
 2012/0271127 A1 10/2012 Battrell et al.  
 2013/0011210 A1 1/2013 Toner et al.  
 2013/0029324 A1 1/2013 Rajagopal et al.  
 2013/0085680 A1 4/2013 Arlen et al.  
 2013/0137591 A1 5/2013 Clemens et al.  
 2013/0145591 A1 6/2013 Chen  
 2013/0244339 A1 9/2013 Ehrenkranz et al.  
 2013/0273528 A1 10/2013 Ehrenkranz  
 2013/0309778 A1 11/2013 Lowe et al.  
 2014/0027286 A1 1/2014 Ikegami et al.  
 2014/0030717 A1 1/2014 Zhong et al.  
 2014/0194305 A1 7/2014 Kayyem et al.  
 2014/0242622 A1 8/2014 Petrich et al.  
 2014/0335520 A1 11/2014 Jackson et al.  
 2014/0336083 A1 11/2014 Khattak et al.  
 2015/0129049 A1 5/2015 Khattak et al.  
 2015/0140556 A1 5/2015 Albert et al.  
 2016/0091518 A1 3/2016 Khattak et al.  
 2016/0279635 A1 9/2016 Sever et al.  
 2017/0043334 A1 2/2017 Khattak et al.  
 2017/0043335 A1 2/2017 Khattak et al.  
 2017/0043336 A1 2/2017 Khattak et al.  
 2017/0043342 A1 2/2017 Khattak et al.  
 2017/0045507 A1 2/2017 Khattak et al.  
 2017/0045508 A1 2/2017 Khattak et al.  
 2017/0080421 A1 3/2017 Khattak et al.  
 2017/0216842 A1 8/2017 Khattak et al.  
 2017/0241845 A1 8/2017 Hwang et al.  
 2017/0248622 A1 8/2017 Khattak et al.  
 2017/0266657 A1 9/2017 Khattak et al.  
 2018/0104682 A1 4/2018 Khattak et al.  
 2018/0147575 A1 5/2018 Khattak et al.

## FOREIGN PATENT DOCUMENTS

EP 1 183 102 B1 12/2003  
 EP 2 050 498 A1 4/2009  
 EP 2 179 294 A2 4/2010  
 GB 2 430 032 A 3/2007  
 JP 2007-505319 3/2007  
 JP 2009-531064 9/2009  
 JP 2009-226404 A 10/2009  
 JP 2011-013043 A 1/2011  
 JP 2012-504956 3/2012  
 JP 2012-127978 A 7/2012  
 JP 2012-173181 A 9/2012  
 JP 2012-521558 9/2012  
 JP 2012-528995 11/2012  
 WO WO-2005/026689 3/2005  
 WO WO-2006/121510 A1 11/2006  
 WO WO-2007/112114 A2 10/2007  
 WO WO-2009/018473 A1 2/2009

WO WO-2010/003212 A1 1/2010  
 WO WO-2010/036808 A1 4/2010  
 WO WO-2010/041231 4/2010  
 WO WO-2010/109392 A1 9/2010  
 WO WO-2010/140128 12/2010  
 WO WO-2012/025729 A1 3/2012  
 WO WO-2012/032294 A1 3/2012  
 WO WO-2012/147426 11/2012  
 WO WO-2012/170703 A1 12/2012  
 WO WO-2013/136115 A1 9/2013  
 WO WO-2013/144643 A2 10/2013  
 WO WO-2016/040642 A1 3/2016

## OTHER PUBLICATIONS

U.S. Appl. No. 15/664,904, filed Jul. 31, 2017, Khattak et al.  
 U.S. Appl. No. 15/785,394, filed Oct. 16, 2017, Khattak et al.  
 U.S. Appl. No. 15/945,646, filed Apr. 4, 2018, Khattak et al.  
 U.S. Appl. No. 29/584,030, filed Nov. 10, 2016, Khattak et al.  
 U.S. Appl. No. 29/584,715, filed Nov. 16, 2016, Khattak et al.  
 U.S. Appl. No. 29/591,165, filed Jan. 17, 2017, Khattak et al.  
 U.S. Appl. No. 29/648,269, filed May 18, 2018, Sever et al.  
 Boon, E.M. et al. (2003) "Reduction of Ferricyanide by Methylene Blue at a DNA-Modified Rotating-Disk Electrode," *Langmuir* 19(22):9255-9259.  
 Borjac-Natour, J.M. et al. (2004) "Divergence of the mRNA targets for the Ssb proteins of bacteriophages T4 and RB69," *Virol. J.* 1(4): 14 pages.  
 Brill, A.S. et al. (1967) "Reactions of Horseradish Peroxidase with Azide. Evidence for a Methionine Residue at the Active Site," *Biochemistry* 6(11):3528-3535.  
 Company Profile: Nemera (Injectables Offering), [www.ondrugdelivery.com](http://www.ondrugdelivery.com), Issue 71, Oct. 2016, pp. 32-35, retrieved from Internet <https://www.ondrugdelivery.com/publications/71/Nemera.pdf>.  
 Desplats, C. et al. (2002) "Snapshot of the Genome of the Pseudo-T-Even Bacteriophage RB49," *J. Bacteriol.* 184(10):2789-2804.  
 Dong, F. et al. (1996) "A coupled complex of T4 DNA replication helicase (gp41) and polymerase (pg43) can perform rapid and processive DNA strand-displacement synthesis," *Proc. Natl. Acad. Sci. USA* 93:14456-14461.  
 Frackman, S. et al. (1998) "Betaine and DMSA: Enhancing Agents for PCR," *Promega Notes* 65:27.  
 Fujisawa T AL. (1985) "Sequence of the T4 recombination gene, uvsX, and its comparison with that of recA gene of Escherichia coli," *Nucleic Acid Res.* 13(20):7473-7481.  
 Harada, K. et al. (1993) "In vitro selection of optimal DNA substrates for T4 RNA ligase," *Proc. Natl. Acad. Sci. USA* 90:1576-1579.  
 Jarvis, T.C. et al. (1990) "Macromolecular Crowding: Thermodynamic Consequences for Protein-Protein Interactions within the T4 DNA Replication Complex," *J. Biol. Chem.* 265(25):15160-15167.  
 Jarvis, T.C. et al. (1991) "Stimulation of the Processivity of the DNA Polymerase of Bacteriophage T4 by the Polymerase Accessory Proteins," *J. Biol. Chem.* 266(3):1830-1840.  
 Lavery, P.E. et al. (1992) "Enhancement of recA Protein-promoted DNA Strand Exchange Activity by Volume-occupying Agents," *J. Biol. Chem.* 267(13):9307-9314.  
 Ma, X. et al. (1988) "Role of oxygen during horseradish peroxidase turnover and inactivation," *Biochem Biophys Res Commun.* 157(1):160-165.  
 Morrical, S.W. et al. (1991) "Amplification of Snap-back DNA Synthesis Reactions by the uvsX Recombinase of Bacteriophage T4," *J. Biol. Chem.* 266(21):14031-14038.  
 Nemera Safe'n'Sound Product Leaflet, 2017, [http://www.nemera.net/wp-content/uploads/2017/11/Nemera-SAFENSOUND\\_ProductLeaflet\\_LD.pdf](http://www.nemera.net/wp-content/uploads/2017/11/Nemera-SAFENSOUND_ProductLeaflet_LD.pdf) (4 pages).  
 PCT International Preliminary Report on Patentability Chapter 1 for Application No. PCT/US2015/049439 dated Mar. 23, 2017. (10 pages).  
 PCT International Preliminary Report on Patentability Chapter I for Application No. PCT/US2016/042688 dated Jan. 23, 2018. (9 pages).



(56)

## References Cited

## OTHER PUBLICATIONS

- Reddy, M.K. et al. (1993) "Assembly of a functional replication complex without ATP hydrolysis: A direct interaction of bacteriophage T4 gp45 with T4 DNA polymerase," *Proc. Natl. Acad. Sci. USA* 90:3211-3215.
- Sun, S. et al. (2003) "Biochemical Characterization of Interactions between DNA Polymerase and Single-stranded DNA-binding Protein in Bacteriophage RB69," *J. Biol. Chem.* 278(6):3876-3881.
- Syrina Data Sheet, Bepak, Oct. 28, 2015, retrieved from Internet [http://www.bepak.com/wp-content/uploads/2015/10/U969\\_DATA-SHEET\\_Bepak\\_AW\\_TEMPLATE\\_SYRINA-ARTWORK1.pdf](http://www.bepak.com/wp-content/uploads/2015/10/U969_DATA-SHEET_Bepak_AW_TEMPLATE_SYRINA-ARTWORK1.pdf) (2 pages).
- U.S. Notice of Allowability for U.S. Appl. No. 29/584,030 dated May 18, 2018. (7 Pages).
- U.S. Office Action for U.S. Appl. No. 14/205,146 dated Jun. 23, 2017. (11 pages).
- U.S. Office Action for U.S. Appl. No. 15/172,077 dated Mar. 7, 2017. (4 pages).
- U.S. Office Action for U.S. Appl. No. 15/336,487 dated Jun. 6, 2017. (26 pages).
- U.S. Office Action for U.S. Appl. No. 15/336,502 dated Jul. 14, 2017. (11 pages).
- U.S. Office Action for U.S. Appl. No. 15/336,712 dated Jul. 12, 2017. (9 pages).
- U.S. Office Action for U.S. Appl. No. 15/336,712 dated Mar. 16, 2017. (25 pages).
- U.S. Office Action for U.S. Appl. No. 15/336,712 dated Sep. 20, 2017. (5 pages).
- U.S. Office Action for U.S. Appl. No. 15/336,715 dated Jun. 29, 2017. (3 pages).
- U.S. Office Action for U.S. Appl. No. 15/336,715 dated May 17, 2017. (17 pages).
- U.S. Office Action for U.S. Appl. No. 15/336,739 dated Jul. 21, 2017. (7 pages).
- U.S. Office Action for U.S. Appl. No. 15/336,739 dated Mar. 21, 2017. (18 pages).
- U.S. Office Action for U.S. Appl. No. 15/487,956 dated Mar. 14, 2018. (2 pages).
- U.S. Office Action for U.S. Appl. No. 15/487,956 dated Oct. 18, 2017. (6 pages).
- U.S. Office Action for U.S. Appl. No. 29/584,715 dated Feb. 20, 2018. (7 pages).
- Zhang, Z. et al. (1998) "Strand Exchange Protein 1 (Sep. 1) from *Saccharomyces cerevisiae* Does not Promote Branch Migration in Vitro," *J. Biol. Chem.* 273(9):4950-4956.
- Anderson, J.C. et al. (2008) "Thermally-Actuated Microfluidic Systems," *JALA* 13:65-72.
- Beyor, N. et al. (2008) "Immunomagnetic bead-based cell concentration microdevice for dilute pathogen detection," *Biomed Microdevices* 10:909-917.
- Cecchet, F. et al. (2006) "Redox Mediation at 11-Mercaptoundecanoic Acid Self-Assembled Monolayers on Gold," *J. Phys. Chem. B* 110:2241-2248.
- Chakrabarti, R. et al. (2001) "The enhancement of PCR amplification by low molecular weight amides," *Nucleic Acids Res.* 29(11):2377-2381.
- Chen, Z. et al. (2005) "Thermally-actuated, phase change flow control for microfluidic systems," *Lab Chip* 5:1277-1285.
- Cho, H. et al. (2007) "How the capillary burst microvalve works," *Journal of Colloid and Interface Science* 306:379-385.
- Clinical IVD Products: Liat™ Analyzer; IQuum, Inc.: <http://www.iquum.com/products/analyzer.shtml>. Last accessed May 5, 2014.
- Fan, R. et al. (2008) "Integrated barcode chips for rapid, multiplexed analysis of proteins in microliter quantities of blood," *Nature Biotechnology* 26(12):1373-1378.
- Ferguson, B.S. et al. (2009) "Integrated Microfluidic Electrochemical DNA Sensor," *Anal. Chem.* 81:6503-6508.
- Henares, T.G. et al. (2007) "Integration of Multianalyte Sensing Functions on a Capillary-Assembled Microchip: Simultaneous Determination of Ion Concentrations and Enzymatic Activities by a "Drop-and-Sip" Technique," *Anal. Chem.* 79:908-915.
- Jagannathan, H. et al. (2001) "Micro-Fluidic Channels with Integrated Ultrasonic Transducers," *IEEE Ultrasonics Symposium*:859-862.
- Kaigala, G.V. et al. (2008) "Electrically controlled microvalves to integrate microchip polymerase chain reaction and capillary electrophoresis," *Lab Chip* 8:1071-1078.
- Kim, D. et al. (2007) "A Bi-Polymer Micro One-Way Valve," *Sensors and Actuators A* 136:426-433.
- Kinoshita, T. et al. (2007) "Functionalization of Magnetic Gold/Iron-Oxide Composite Nanoparticles with Oligonucleotides and Magnetic Separation of Specific Target," *J. of Magnetism and Magnetic Materials* 311:255-258.
- Kwakye, S. et al. (2006) "Electrochemical Microfluidic Biosensor for Nucleic Acid Detection with Integrated Minipotentiostat," *Biosensors and Bioelectronics* 21: 2217-2223.
- Laschi, S. et al. (2010) "A New Gravity-Driven Microfluidic-Based Electrochemical Assay Coupled to Magnetic Beads for Nucleic Acid Detection," *Electrophoresis* 31: 3727-3736.
- Lawi, W. et al. (2009) "A Microfluidic Cartridge System for Multiplexed Clinical Analysis," *J. Assoc. Laboratory Automation* 14(6):407-412.
- Lee, C.S. et al. (2001) "Microelectromagnets for the Control of Magnetic Nanoparticles," *Applied Physics Letters* 79(20):3308-3310.
- Lillehoj, P.B. et al. (2010) "A Self-Pumping Lab-on-a-Chip for Rapid Detection of Botulinum Toxin," *Lab Chip* 10: 2265-2270.
- Liu, R.H. et al. (2004) "Self-Contained, Fully Integrated Biochip for Sample Preparation, Polymerase Chain Reaction Amplification, and DNA Microarray Detection," *Analytical Chemistry* 76(7):1824-1831.
- Liu, R.H. et al. (2004) "Single-use, Thermally Actuated Paraffin Valves for Microfluidic Applications," *Sensors and Actuators B* 98:328-336.
- Lomas, N. (2014) "Cue Is a Connected Lab-In-A-Box for On-Demand Health Testing At Home," *TechCrunch*.
- Marentis, T.C. et al. (2005) "Microfluidic Sonicator for Real-Time Disruption of Eukaryotic Cells and Bacterial Spores for DNA Analysis," *Ultrasound in Med. & Biol.* 31(9):1265-1277.
- Mrksich, M. et al. (1997) "Using Self-Assembled Monolayers that Present Oligo(ethylene glycol) Groups to Control the Interactions of Proteins with Surfaces," *American Chemical Society Symposium Series* 680:361-373.
- PCT International Preliminary Report on Patentability for Application No. PCT/US2014/023821 dated Sep. 24, 2015.
- PCT International Search Report and Written Opinion for Application No. PCT/US2018/015111 dated Apr. 13, 2018. (11 pages).
- PCT International Search Report and Written Opinion for Application No. PCT/US2016/042688 dated Jan. 10, 2017. (16 pages).
- PCT International Search Report and Written Opinion for Application No. PCT/US2015/049439 dated Dec. 7, 2015, (15 pages).
- PCT International Search Report and Written Opinion for Application No. PCT/US2014/023821 dated Jul. 7, 2014. (12 pages).
- Prindle, D. (2014) "Sick? Need more vitamin D? Testosterone? Lick a stick and Cue fills you in," [www.digitaltrends.com](http://www.digitaltrends.com).
- Rida, A. et al. (2004) "Manipulation of Self-Assembled Structures of Magnetic Beads for Microfluidic Mixing and Assaying," *Analytical Chemistry* 76(21):6239-6246.
- Roderee, K. et al. (2011) "DNA Hybridization Enhancement Using Piezoelectric Microagitation through a Liquid Coupling Medium," *Lab Chip*, doi:10.1039/C0LC00419G.
- Sharma, V. et al. (2007) "Surface Characterization of Plasma-Treated and PEG-Grafted PDMS for Micro Fluidic Applications," *Vacuum* 81:1094-1100.
- Shin, Y.S. et al. (2010) "Chemistries for Patterning Robust DNA MicroBarcodes Enable Multiplex Assays of Cytoplasm Proteins from Single Cancer Cells," *ChemPhysChem* 11:3063-3069.
- Simplexa™ Flu A/B & RSV Direct Kit; Focus Diagnostics, Inc.: <https://www.focusdx.com/product/MOL2650>. Last accessed May 5, 2014.



(56)

**References Cited**

## OTHER PUBLICATIONS

Taylor, M.T. et al. (2001) "Lysing Bacterial Spores by Sonication through a Flexible Interface in a Microfluidic System," *Analytical Chemistry* 73(3):492-496.

The FilmArray System; Biofire Diagnostics, Inc.: <http://filmarray.com/the-panels/>. Last accessed May 5, 2014.

US Office Action for U.S. Appl. No. 14/205,146 dated Sep. 26, 2014. (6 pages).

US Office Action for U.S. Appl. No. 14/205,146 dated Apr. 3, 2015. (13 pages).

US Office Action for U.S. Appl. No. 14/205,146 dated Oct. 22, 2015. (13 pages).

US Office Action for U.S. Appl. No. 14/205,146 dated Apr. 6, 2016. (9 pages).

US Office Action for U.S. Appl. No. 14/205,146 dated Dec. 21, 2016. (13 pages).

US Office Action for U.S. Appl. No. 14/479,149 dated Jan. 13, 2015. (21 pages).

U.S. Office Action for U.S. Appl. No. 14/479,149 dated Mar. 6, 2015. (14 pages).

U.S. Office Action for U.S. Appl. No. 14/543,842 dated Feb. 12, 2015. (14 pages).

U.S. Office Action for U.S. Appl. No. 14/543,842 dated Apr. 24, 2015. (10 pages).

U.S. Office Action for U.S. Appl. No. 14/599,365 dated May 1, 2015. (13 pages).

U.S. Office Action for U.S. Appl. No. 14/599,369 dated May 7, 2015. (6 pages).

U.S. Office Action for U.S. Appl. No. 14/599,369 dated Aug. 18, 2015. (15 pages).

U.S. Office Action for U.S. Appl. No. 14/599,369 dated Jan. 4, 2016. (8 pages).

U.S. Office Action for U.S. Appl. No. 14/599,369 dated Apr. 22, 2016. (9 pages).

U.S. Office Action for U.S. Appl. No. 14/599,369 dated May 11, 2016. (4 pages).

U.S. Office Action for U.S. Appl. No. 14/599,372 dated Mar. 27, 2015 (15 pages).

U.S. Office Action for U.S. Appl. No. 14/599,372 dated Sep. 14, 2015. (17 pages).

U.S. Office Action for U.S. Appl. No. 14/599,375 dated Jun. 19, 2015. (20 pages).

U.S. Office Action for U.S. Appl. No. 14/599,375 dated Aug. 26, 2015. (13 pages).

U.S. Office Action for U.S. Appl. No. 14/954,817 dated Feb. 2, 2016. (21 pages).

U.S. Office Action for U.S. Appl. No. 14/954,817 dated May 23, 2016. (15 pages).

U.S. Office Action for U.S. Appl. No. 14/954,817 dated Sep. 19, 2016. (8 pages).

U.S. Office Action for U.S. Appl. No. 14/954,817 dated Nov. 3, 2016. (9 pages).

U.S. Office Action for U.S. Appl. No. 15/172,077 dated Feb. 10, 2017. (19 pages).

U.S. Office Action for U.S. Appl. No. 15/336,487 dated Jan. 30, 2017. (27 pages).

U.S. Office Action for U.S. Appl. No. 15/336,502 dated Jan. 27, 2017. (31 pages).

U.S. Office Action for U.S. Appl. No. 15/336,502 dated Feb. 21, 2018. (14 pages).

U.S. Office Action for U.S. Appl. No. 15/336,715 dated Feb. 9, 2017. (8 pages).

U.S. Office Action for U.S. Appl. No. 15/336,735 dated Jan. 5, 2017. (10 pages).

U.S. Office Action for U.S. Appl. No. 15/336,735 dated Feb. 13, 2017. (5 pages).

U.S. Office Action for U.S. Appl. No. 15/336,739 dated Feb. 26, 2018. (8 pages).

U.S. Office Action for U.S. Appl. No. 15/487,956 dated Jan. 31, 2018. (8 pages).

U.S. Office Action for U.S. Appl. No. 15/785,394 dated Apr. 13, 2018. (6 pages).

U.S. Office Action for Design U.S. Appl. No. 29/490,660 dated Jun. 25, 2014. (6 pages).

U.S. Restriction Requirement for Design U.S. Appl. No. 29/490,660 dated Jun. 2, 2015. (8 pages).

U.S. Notice of Allowance for Design U.S. Appl. No. 29/490,660 dated Aug. 20, 2015. (9 pages).

U.S. Restriction Requirement for Design U.S. Appl. No. 29/545,014 dated May 10, 2016. (15 pages).

U.S. Notice of Allowance for Design U.S. Appl. No. 29/545,014 dated Sep. 2, 2016. (10 pages).

U.S. Office Action for U.S. Appl. No. 29/574,538 dated Feb. 17, 2017. (8 pages).

U.S. Office Action for U.S. Appl. No. 29/584,030 dated Nov. 29, 2017. (8 pages).

U.S. Office Action for U.S. Appl. No. 29/584,030 dated Feb. 22, 2018. (6 pages).

U.S. Office Action for U.S. Appl. No. 29/591,165 dated Nov. 29, 2017. (18 pages).

U.S. Notice of Allowance for U.S. Appl. No. 29/591,165 dated Apr. 11, 2018. (9 pages).

Wang, J. (2002) "Portable Electrochemical Systems," *Trends in Analytical Chemistry* 21(4):226-232.

Wang, J. et al. (2005) "Self-Actuated, Thermo-Responsive Hydrogel Valves for Lab on a Chip," *Biomedical Microdevices* 7(4):313-322.

Wang, J. et al. (2010) "A Self-Powered, One-Step Chip for Rapid, Quantitative and Multiplexed Detection of Proteins from Pinpricks of Whole Blood," *Lab Chip* 10:3157-3162.

Wu, C. et al. (2011) "Ultrasonication on a Microfluidic Chip to Lyse Single and Multiple Pseudo-Nitzschia for Marine Biotxin Analysis," *Biotechnology Journal* 6:150-155.

Xpert® Flu; Cepheid: <http://www.cepheid.com/us/cepheid-solutions/clinical-ivd-tests/critical-infectious-diseases/xpert-flu>. Last accessed May 5, 2014.

Yoshioka, K. et al. (2010) "Suppression of Non-specific Adsorption Using Densified Tri(ethylene glycol) Alkanethiols: Monolayer Characteristics Evaluated by Electrochemical Measurements," *Analytical Sciences* 26:33-37.

Ziegler, J. et al. (2008) "High-Performance Immunoassays Based on Through-Stencil Patterned Antibodies and Capillary Systems," *Analytical Chemistry* 80(5):1763-1769.

U.S. Notice of Allowability for U.S. Appl. No. 29/591,165 dated May 21, 2018. (4 pages).

U.S. Office Action for U.S. Appl. No. 15/945,646 dated Jul. 3, 2018. (23 pages).

\* cited by examiner

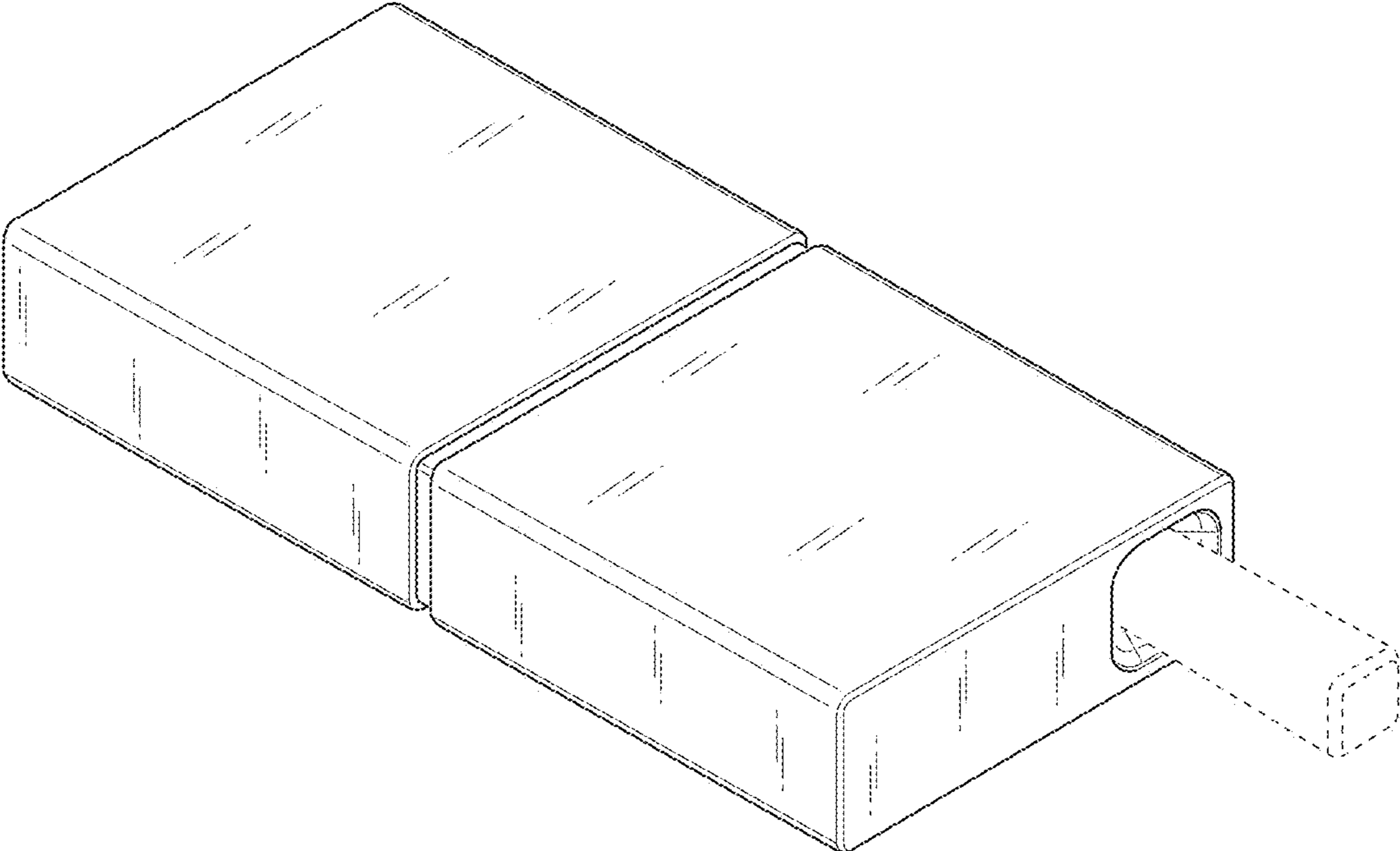
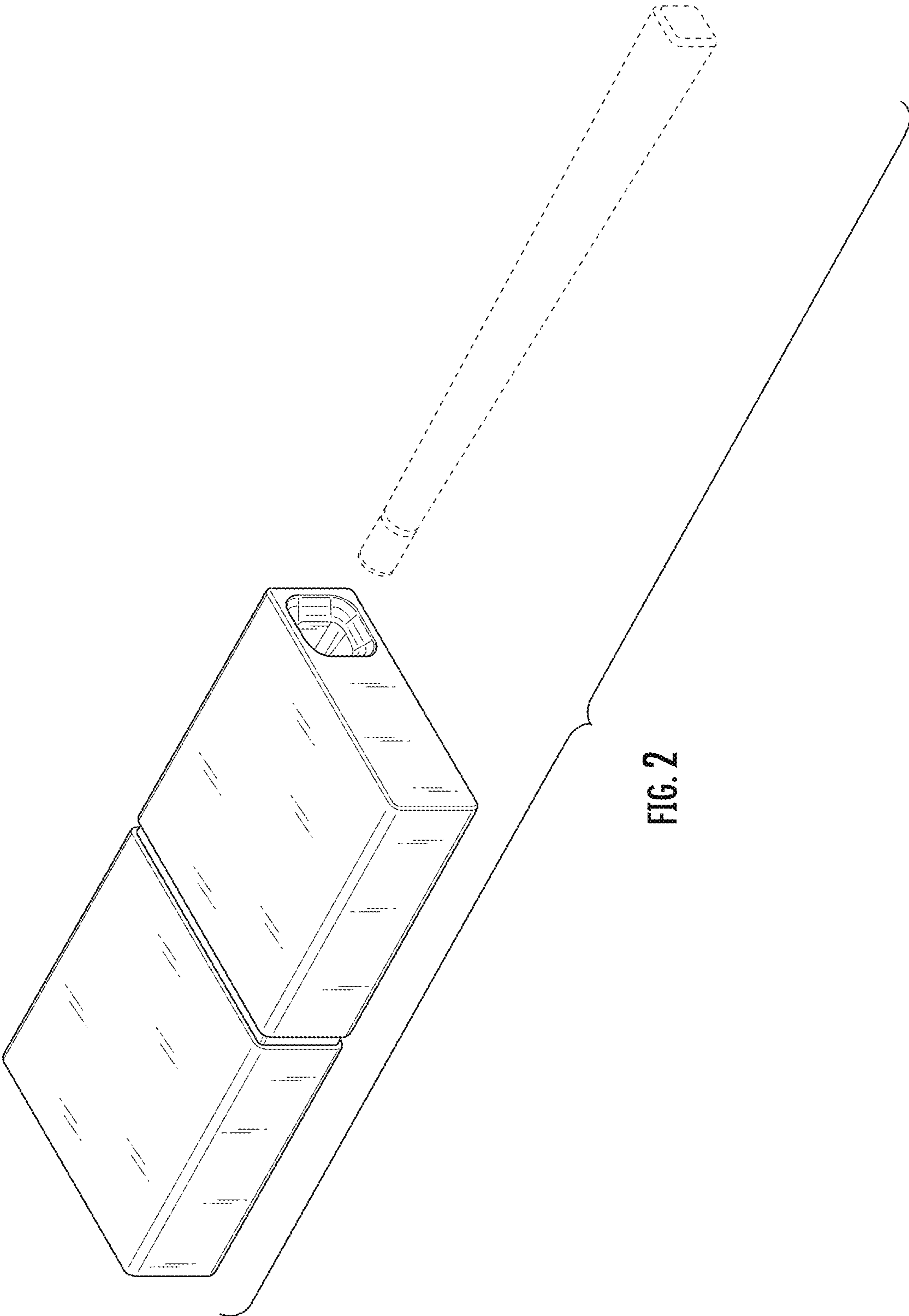


FIG. 1



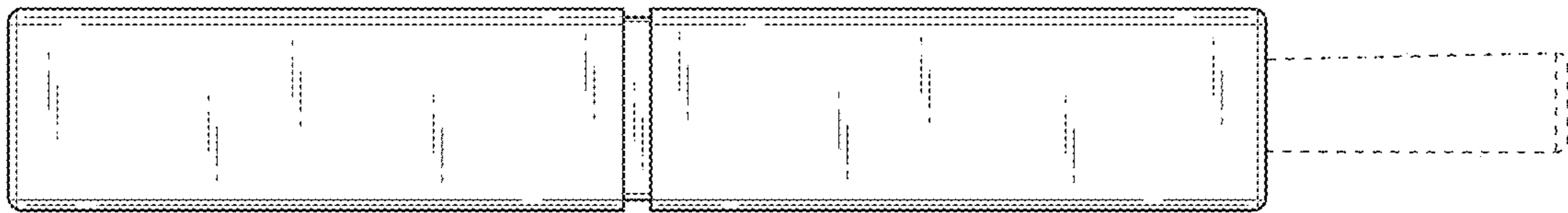


FIG. 3

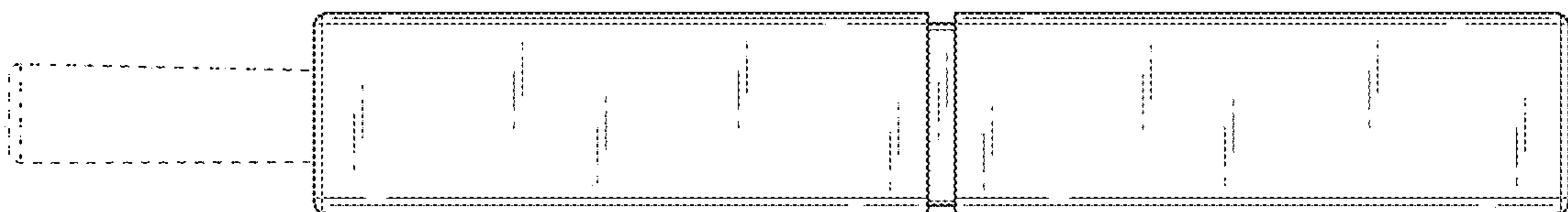


FIG. 4



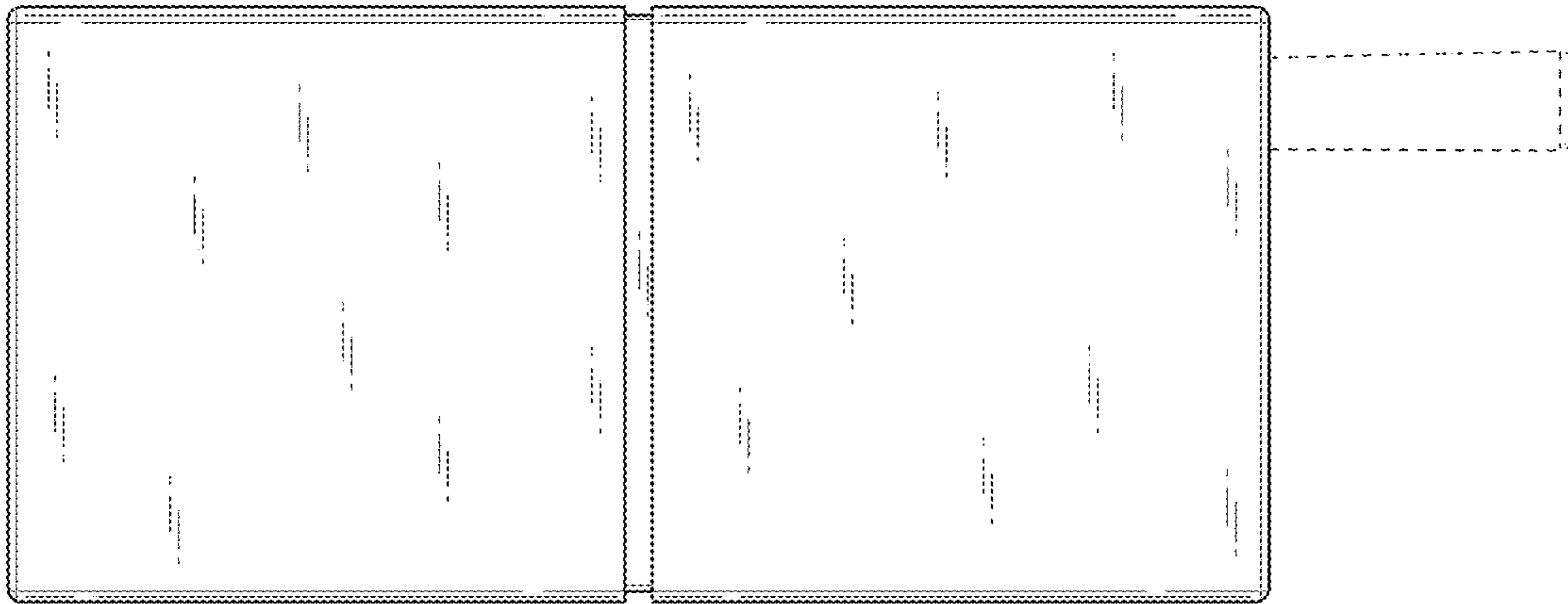


FIG. 5

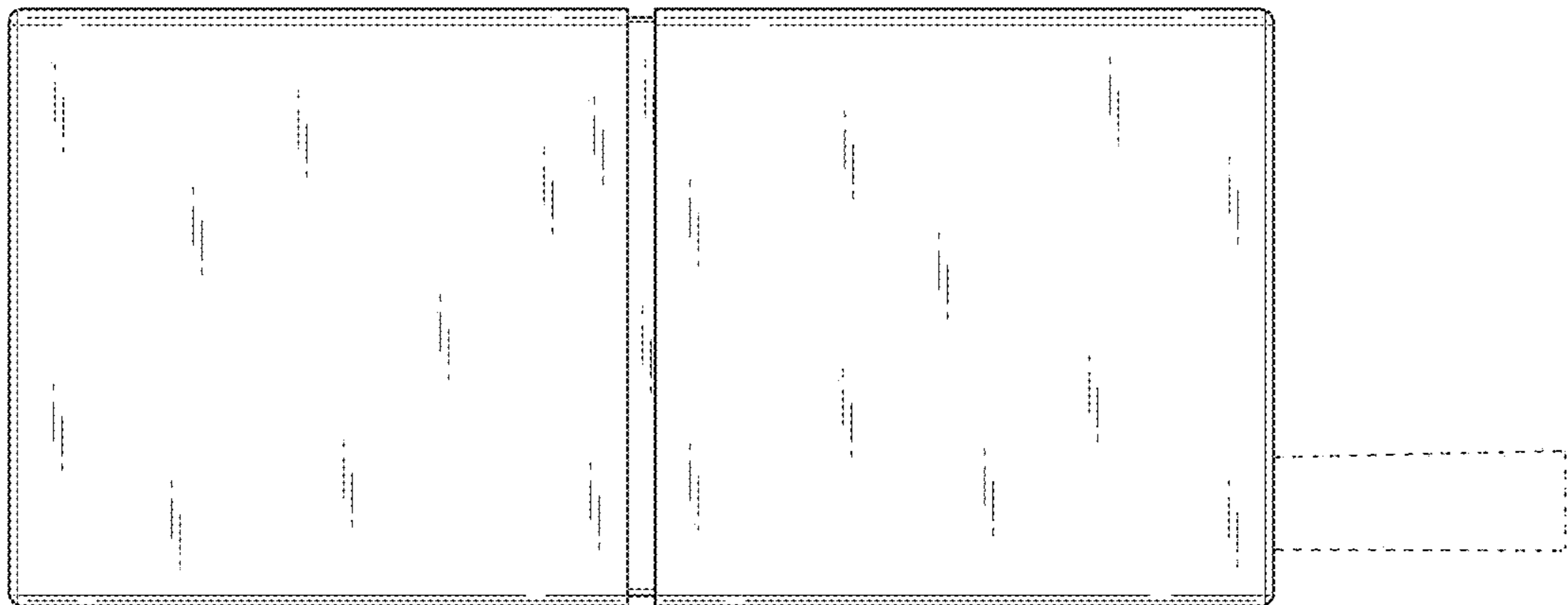


FIG. 6

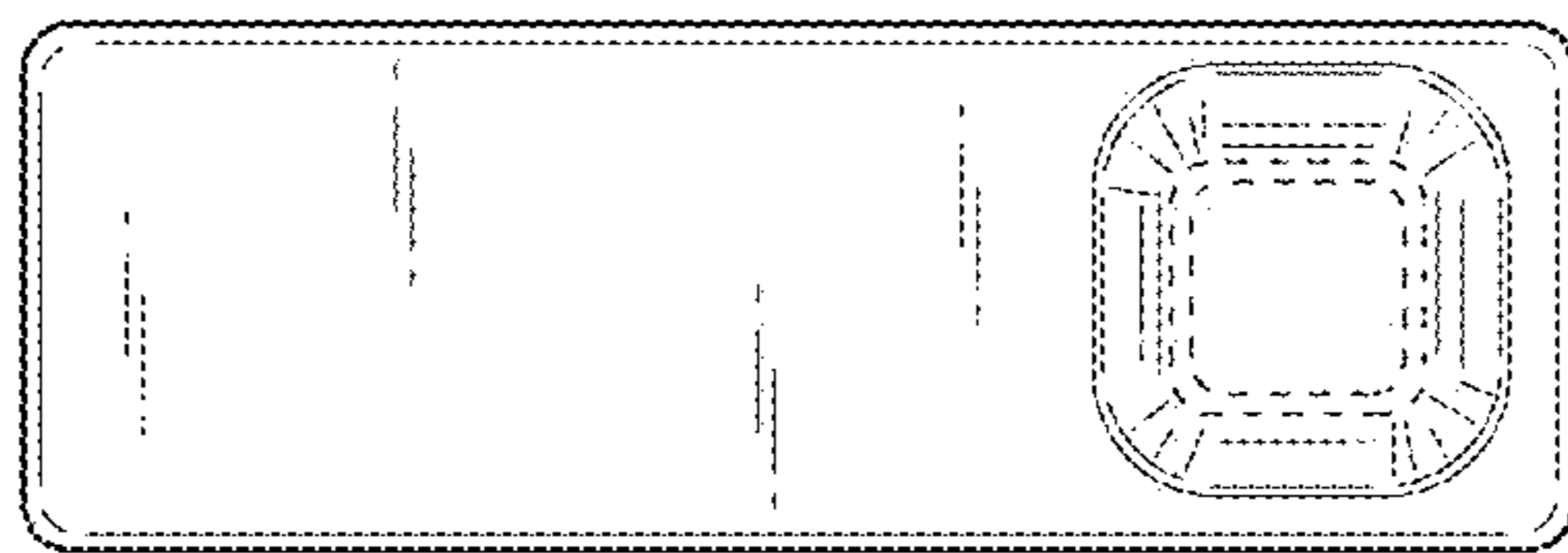


FIG. 7

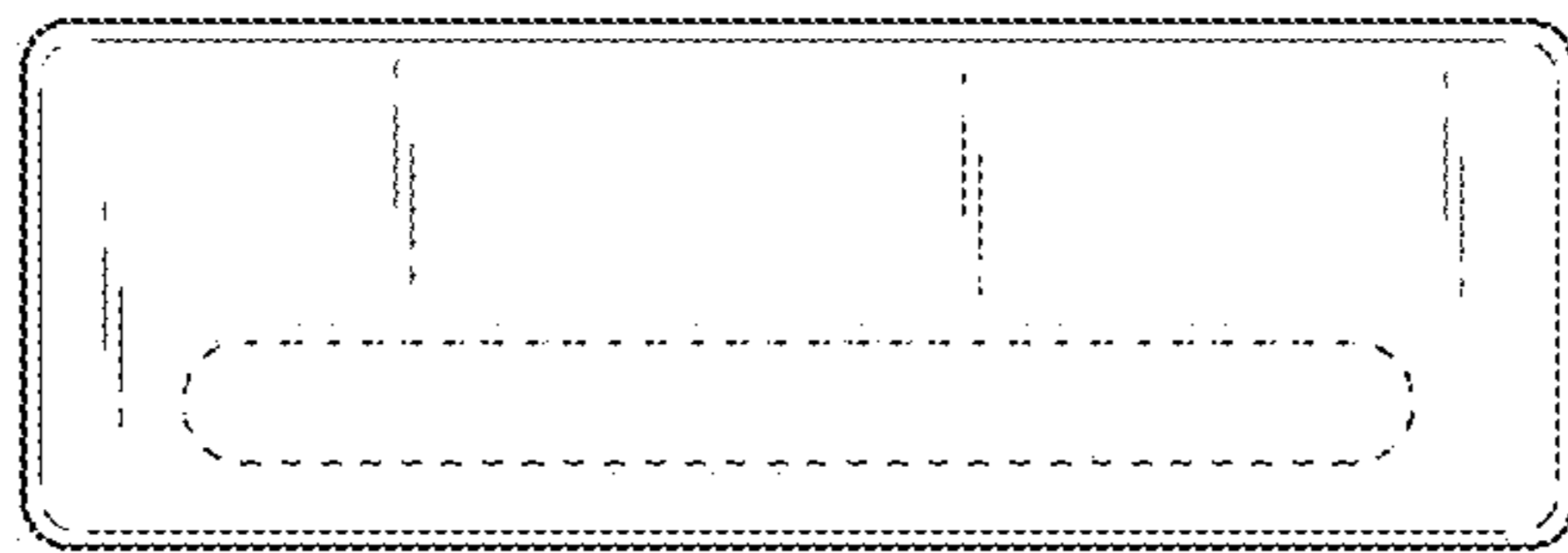


FIG. 8



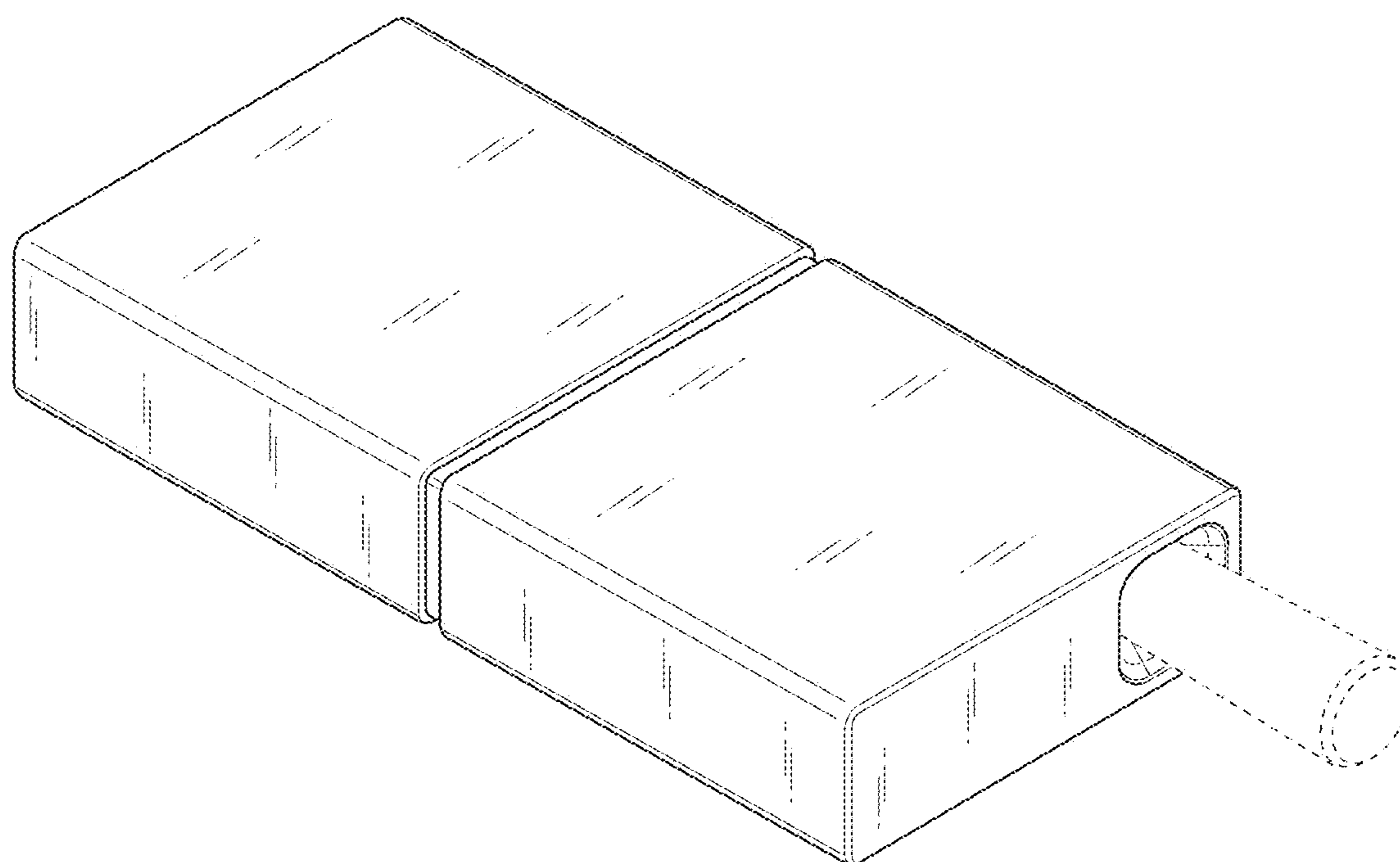


FIG. 9

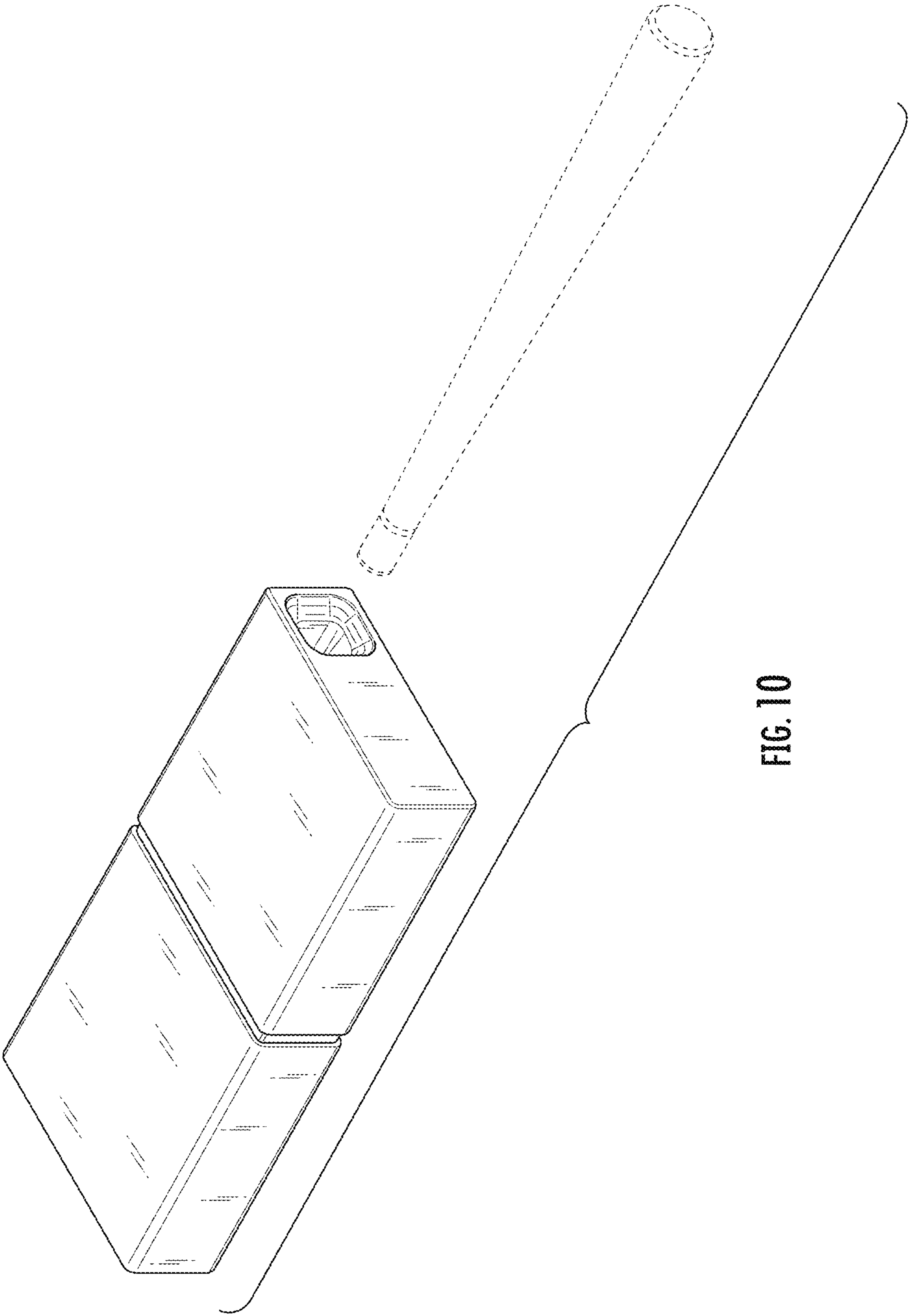


FIG. 10



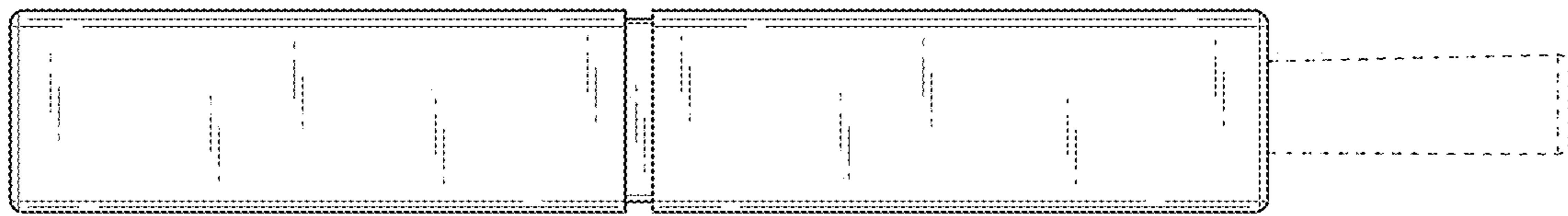


FIG. 11

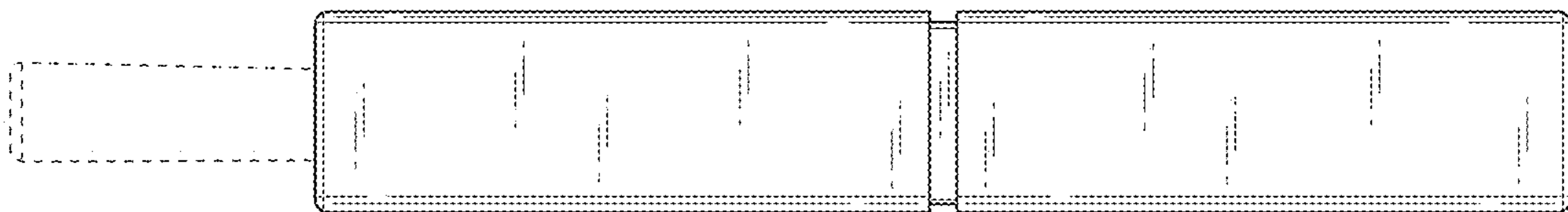


FIG. 12

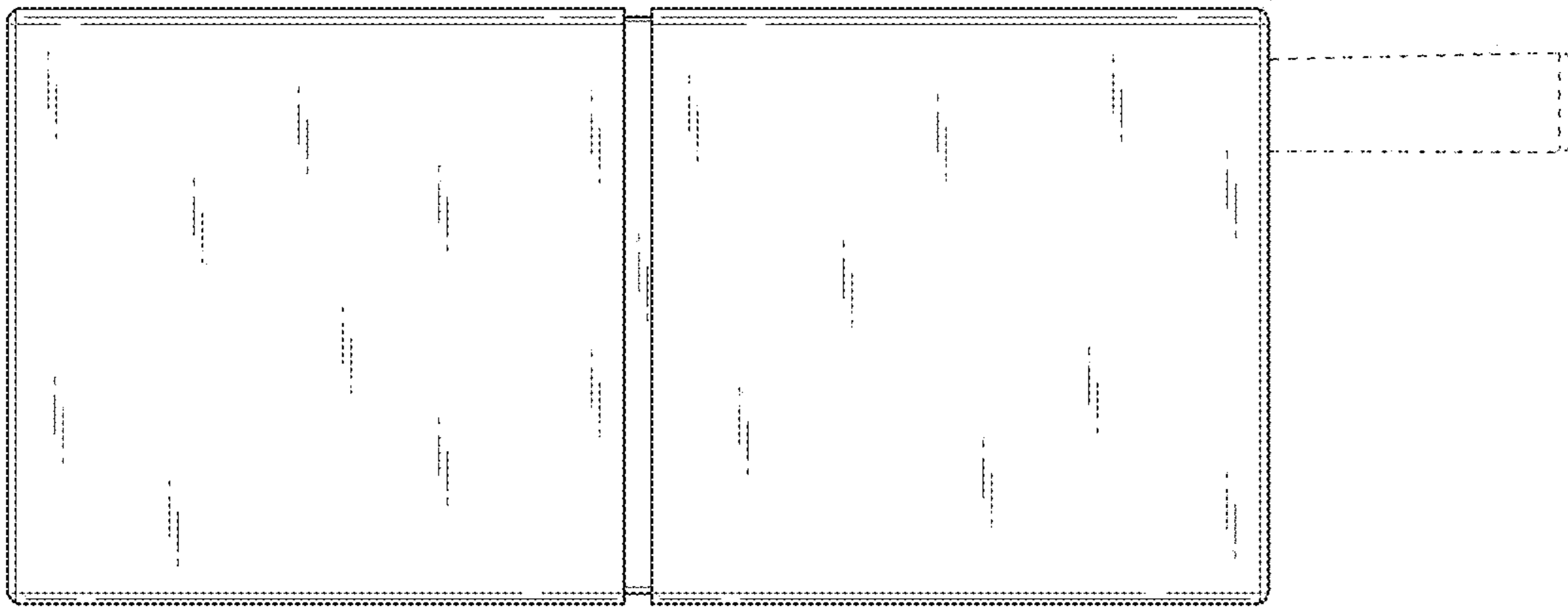


FIG. 13

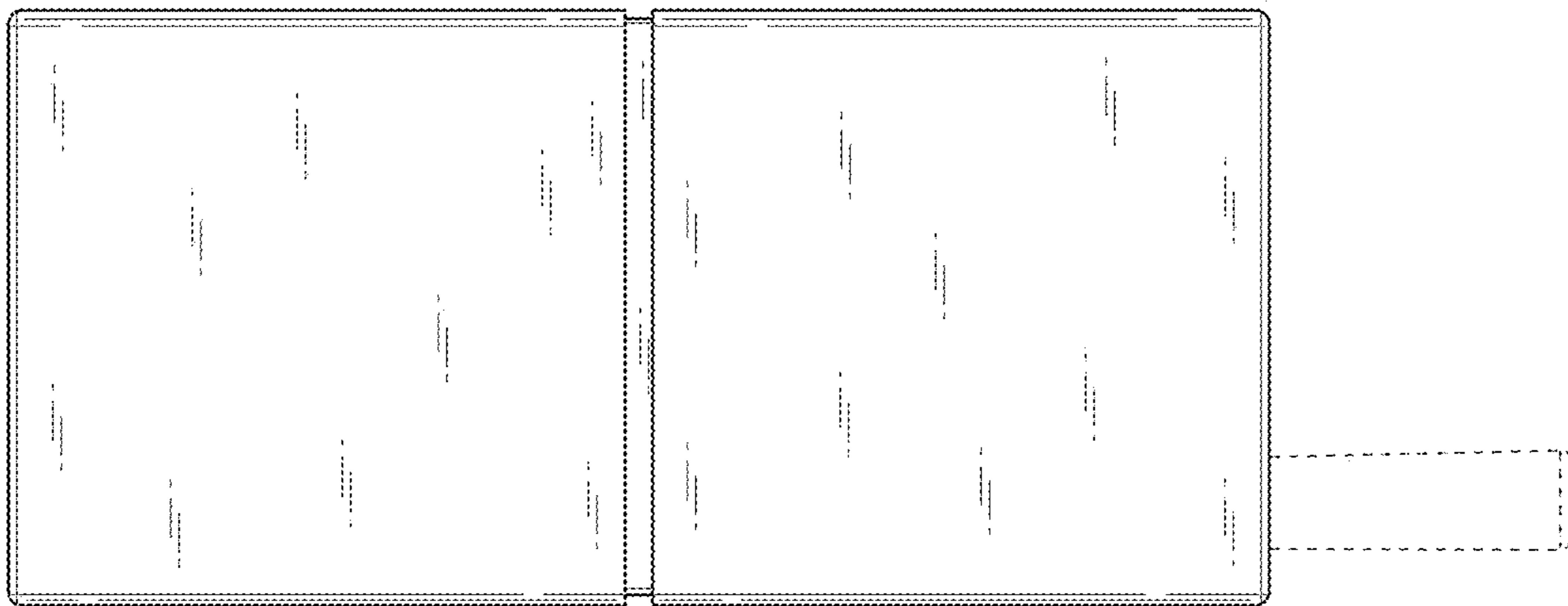


FIG. 14



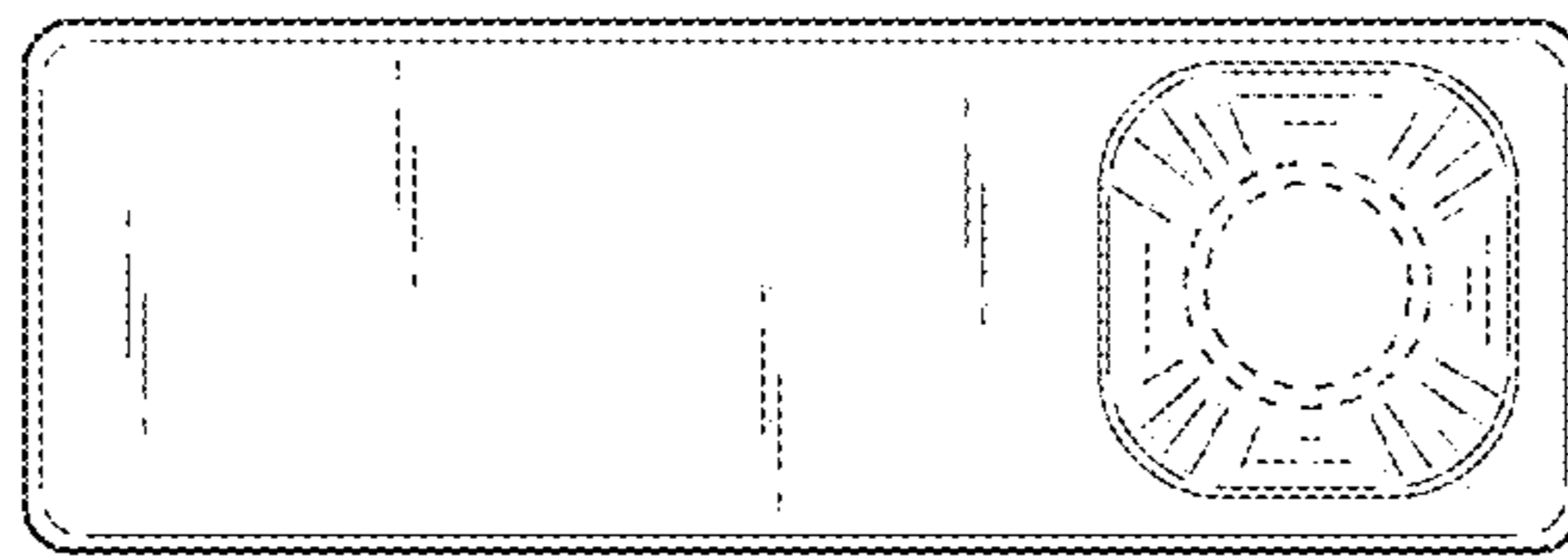


FIG. 15

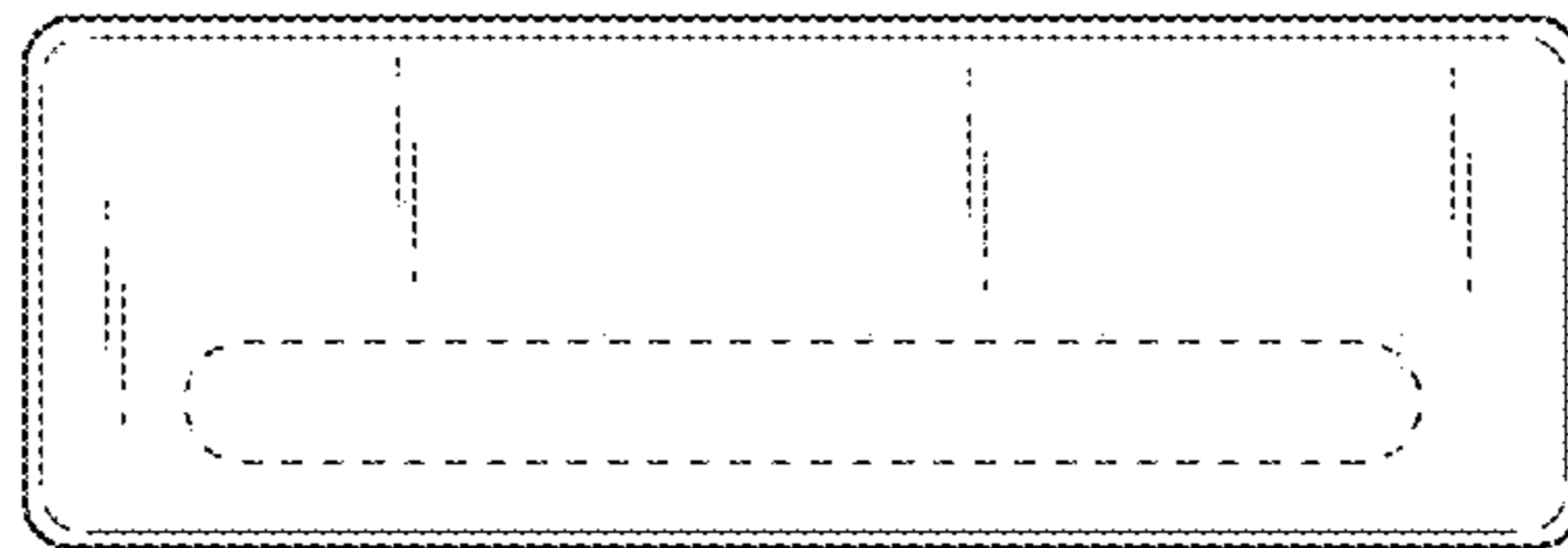


FIG. 16