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David Garrod (DG6759)

PUBLIC PATENT FOUNDATION, INC.

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New York, New York 10003

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UNITED STATE SOUTHERN DISTRI

Public Patent Foundation, Inc., a New York, not-for-profit corporation,

Plaintiff,

v.

Iovate Health Sciences Research Inc., a Canadian corporation, Iovate Health Sciences, Inc., a Canadian corporation, Iovate T & P, Inc., a Canadian corporation, Multi Formulations, Ltd., a Canadian corporation, and Iovate Health Sciences U.S.A. Inc., a Delaware corporation,

Defendants.

Civil Action No. CV

COMPLAINT FOR FALSE PATENT MARKING

(Jury Trial Demanded)

Nature of the Action

This is an action for false patent marking under Title 35, Section 292, of 1. the United States Code.

- 2. As set forth in detail below, defendants have violated 35 U.S.C. §292(a) by marking and/or advertising certain products with patent numbers of expired patents, and with patent numbers of patents that do not have a scope that even arguably covers the marked or advertised products, and/or with "patented" designations for non-patented aspects of their products.
- 3. Plaintiff seeks an award of monetary damages against defendants, one-half of which shall be paid to the United States pursuant to 35 U.S.C. §292(b).

Jurisdiction and Venue

- 4. This Court has subject matter jurisdiction over Plaintiff's present action for false patent marking pursuant to 28 U.S.C. §1338(a).
- 5. This Court has personal jurisdiction over the defendants pursuant to Rule 4(K)(1)(a) of the Federal Rules of Civil Procedure and §§ 301 and 302 of the New York Civil Practice Law and Rules because, upon information and belief, the defendants conduct substantial business in the State of New York.
- 6. Venue in this Judicial District is proper pursuant to 28 U.S.C. §§ 1391 and 1400 because a substantial part of the events giving rise to the claims asserted herein arise in this district and defendants, upon information and belief, are and at all times were doing business in this district.

The Parties

- 7. The Public Patent Foundation, Inc. ("PUBPAT") is a New York, not-for-profit corporation, with a principal place of business located at Benjamin N. Cardozo School of Law, 55 Fifth Avenue, New York, New York 10003.
- 8. PUBPAT represents the interests of otherwise unrepresented parties (e.g., consumers) against various misuses of patents and the patent system by commercial entities.
- 9. Upon information and belief, defendant Iovate Health Sciences Research Inc. is a corporation organized and existing under the laws of Canada, with offices located at 5100 Spectrum Way, Mississauga, Ontario L4W 5S2 Canada.
- 10. Upon information and belief, defendant Iovate Health Sciences, Inc. is a corporation organized and existing under the laws of Canada, and has a principal place of business at 5100 Spectrum Way, Mississauga, Ontario, L4W 5S2 Canada.
- 11. Upon information and belief, defendant Iovate T & P, Inc. is a corporation organized and existing under the laws of Canada, and has a principal place of business at 381 North Service Road West in Oakville, Ontario, L6M 0H4 Canada.
 - 12. Upon information and belief, defendant Multi Formulations, Ltd. is a

corporation organized and existing under the laws of Canada, and has a principal place of business at 381 North Service Road West in Oakville, Ontario, L6M 0H4 Canada.

- 13. Upon information and belief, defendant Iovate Health Sciences U.S.A. Inc. is a corporation formed under the laws of Delaware, and a subsidiary of Iovate Health Sciences Research Inc.
- 14. Upon information and belief, Iovate Health Sciences U.S.A. Inc. is authorized to do business in the State of New York, and maintains a facility at 25 Dewberry Lane, Cheektowaga, New York, 14227.
- 15. Defendants Iovate Health Sciences Research Inc., Iovate Health Sciences, Inc., Iovate T & P, Inc., Multi Formulations, Ltd., and/or Iovate Health Sciences U.S.A. Inc. (collectively, "IOVATE") distribute and/or sell Xenadrine® brand products to multiple retail stores in the Southern District of New York, including GNC (General Nutrition Centers, Inc.), Walgreens, Rite Aid Pharmacy, CVS Pharmacy, and many other retailers. (See http://www.xenadrine.com/retailers/retailers.shtml.)
- 16. Until shortly before May 1, 2009, IOVATE also distributed and/or sold Hydroxycut® brand products to multiple retail stores in the Southern District of New York, including GNC (General Nutrition Centers, Inc.), Walgreens, Rite Aid

Pharmacy, CVS Pharmacy, and many other retailers. Until shortly before May 1, 2009, such Hydroxycut® retailers were described at http://www.hydroxycut.com/fine_retailers.shtml.

- 17. IOVATE promotes Xenadrine® brand products in the Southern District of New York through television and Internet advertising targeted at consumers in this Judicial District.
- 18. Until shortly before May 1, 2009, IOVATE also promoted Hydroxycut® brand products in the Southern District of New York through television and Internet advertising targeted at consumers in this Judicial District.

IOVATE's Hydroxycut® Weight Loss Products

- 19. Until shortly before May 1, 2009, IOVATE promoted Hydroxycut® as "America's #1 selling weight-loss supplement and is a brand name sold in over 70 countries around the world." Until shortly before May 1, 2009, this promotion was available at http://www.hydroxycut.com/products/hydroxycut/index.shtml.
- 20. Until shortly before May 1, 2009, IOVATE's advertising stated that Hydroxycut® can be used to: "[i]ncrease [e]nergy"; "[c]ontrol [a]ppetite"; and "[b]urn [c]alories"; and contains "[c]linically [p]roven [i]ngredients." Until shortly before May 1, 2009, this advertising was available at http://www.hydroxycut.com/

products/hydroxycut/index.shtml.

- 21. Until shortly before May 1, 2009, the same IOVATE advertising also described Hydroxycut® as "Protected by Multiple U.S. Patents #7,335,651, #6,814,986, #6,830,765, #6,875,891, #6,395,296, #6,160,172, #4,923,855, #4,954,492 and #5,194,615." (See id.)
- 22. Until shortly before May 1, 2009, packages of Hydroxycut[®] sold in retail stores (in this Judicial District and nationally) included substantially similar "patented" labeling that included, <u>inter alia</u>, the numbers of U.S. Patents 4,923,855 and 4,954,492.

The "Multiple" U.S. Patents that Allegedly "Protect" Hydroxycut®

- 24. The '986 patent contains a only one independent claim. This sole independent claim requires, inter alia, "a composition" that includes at least

- "EGCG" and "caffeine," where the relative concentration by mass of EGCG to caffeine in the composition is "between 2 and 10." (See id.)
- 25. To be "protected by" the '986 patent, a composition must, inter alia, contain between two and ten times as much EGCG as caffeine, with both substances measured by mass (weight).
- 26. Upon information and belief, until shortly before May 1, 2009, IOVATE marketed two formulations of Hydroxycut[®]: Hydroxagen Plus[®] and HydroxyTea[®]. (See Ex. A (showing Hydroxycut[®] product label).)
- 27. Upon information and belief, Hydroxagen Plus® contained no caffeine. (See Ex. A.)
- 28. Upon information and belief, HydroxyTea® contained both EGCG and caffeine. (See Ex. A.)
- 29. Upon information and belief, the concentration by mass of caffeine in HydroxyTea® was at least 200 mg / 473 mg = 42%. (See Ex. A.)
- 30. Upon information and belief, the concentration by mass of EGCG in HydroxyTea® was no greater than (473 mg 200 mg) / 473 mg = 58%. (See Ex. A.)
- 31. Upon information and belief, HydroxyTea® contained no more than 1.38 (i.e., 58% / 42%) times as much EGCG as caffeine.

- 32. Upon information and belief, no formulation of Hydroxycut® (i.e., neither Hydroxagen Plus® nor HydroxyTea®) was protected by the '986 patent.
- 33. U.S. Patent No. 6,830,765 ("the '765 patent"), entitled "Green tea extract for treating obesity," was issued by the PTO on December 14, 2004. (See http://patft.uspto.gov/netacgi/nph-Parser?Sect1=PTO1&Sect2=HITOFF&d=PALL
 &p=1&u=%2Fnetahtml%2FPTO2Fsrchnum.htm&r=1&f=G&l=50&s1=6,830,765.

 PN.&OS=PN/6,830,765&RS=PN/6,830,765.)
- 34. The '765 patent contains thee independent claims, numbers 1, 5 and 9. (See id.)
- 35. Each of the '765 patent's independent claims requires, <u>inter alia</u>, "an extract" that includes at least "EGCG" and "caffeine," where the relative concentration by mass of EGCG to caffeine in the composition is "between 2 and 10." (See id.)
- 36. To be "protected by" the '765 patent, an extract must, <u>inter alia</u>, contain between two and ten times as much EGCG as caffeine, with both substances measured by mass (weight).
- 37. Upon information and belief, no formulation of Hydroxycut® (i.e., neither Hydroxagen Plus® nor HydroxyTea®) was protected by the '765 patent.
 - 38. U.S. Patent No. 4,923,855 ("the '855 patent"), entitled "Synthetic GTF

chromium material and process therefor," was issued by the PTO on May 8, 1990, and expired on May 8, 2007. (See http://patft.uspto.gov/netacgi/nph-Parser?
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- 39. Because the '855 patent is expired, it cannot "protect" anything.
- 40. Since at least May 9, 2007, Hydroxycut® was not "protected by" the '855 patent.
- 41. U.S. Patent No. 4,954,492 ("the '492 patent"), entitled "Synthetic GTF chromium material for decreasing blood lipid levels and process therefor," was issued by the PTO on September 4, 1990, and expired on September 4, 2007. (See http://patft.uspto.gov/netacgi/nph-Parser?Sect1=PTO1&Sect2=HITOFF&d=PALL &p=1&u=%2Fnetahtml%2FPTO2Fsrchnum.htm&r=1&f=G&l=50&s1=4,954,492.

 PN.&OS=PN/4,954,492&RS=PN/4,954,492.)
 - 42. Because the '492 patent is expired, it cannot "protect" anything.
- 43. Since at least September 5, 2007, Hydroxycut® was not "protected by" the '492 patent.

The Hydroxycut® Television Commercials

- 44. Until shortly before May 1, 2009, IOVATE promoted Hydroxycut® through a series of nationally run television commercials, including commercials targeted at consumers in the Southern District of New York.
- 45. One IOVATE television commercial featured "Charlene from California," "Dr. Jon Marshall, Resident Physician," "Eric from New Jersey" and "Stephanie from Wisconsin." (See http://www.youtube.com/watch? v=cc1PKXU78pc&feature=PlayList&p=0E733EBFF092F8D5&index=0&playnex t=1.)
- 46. A second IOVATE television commercial featured "Gillian from Illinois," "Dr. Jon Marshall, Resident Physician" and "Katherine from Texas." (See <a href="http://www.youtube.com/watch?v=ciJXKqR12OI&feature=PlayList&p="http://www.youtube.com/watch?v=ciJXKqR12OI&feature=PlayList&p="0E733EBFF092F8D5&index=1.")
- 47. A third IOVATE television commercial featured "Gillian from Illinois," "Dr. Jon Marshall, D.O." and "Charlene from California." (See http://www.youtube.com/watch?v=B8BeGgT1v5M&feature=related.)
- 48. All three of these television commercials included a clip of "Dr. Jon Marshall" displaying what appears to be a United States patent and referring to "the *patented* primary ingredients in Hydroxycut."

IOVATE's Acquisition and Subsequent Sale/Promotion of Xenadrine®

- 49. On or about April 15, 2008, IOVATE acquired "the Xenadrine family of brand names." (See http://www.ironmagazine.com/blog/2008/iovate-group-of-companies-acquires-xenedrine-cytodyne-and-related-brand-names/.)
- According to IOVATE's Internet advertising, "Clinical Strength 50. Xenadrine® RFA-1[™] isn't like regular diet pills. Right from your very first dose, this revolutionary formula works together with your body's metabolism and is so powerful you'll actually feel its potent energizing effects every time you use it! With its cutting-edge weight-loss driver and patented triple-action technology, Clinical Strength Xenadrine RFA-1 is designed to help you burn more calories, metabolism supercharge fat burning!" (See ignite your and http://www.xenadrine.com/product_info/product_info.shtml (emphasis in original).)
- 51. Also, according to IOVATE's Internet advertising, Xenadrine RFA-1 is "Protected by US Patents # 6,277,396, # 7,335,651, # 6,814,986, # 6,830,765, # 6,875,891, # 6,395,296, # 6,160,172, # 4,954,492 and # 5,194,615." (See http://www.xenadrine.com/.)

The U.S. Patents that Allegedly "Protect" Xenadrine RFA-1

- 52. To be "protected by" the '986 patent, a composition must, inter alia, contain between two and ten times as much EGCG as caffeine, with both substances measured by mass (weight).
- 53. Upon information and belief, Xenadrine RFA-1 contains both EGCG and caffeine. (See Ex. B (showing Xenadrine product formulation information).)
- 54. Upon information and belief, the concentration by mass of caffeine in Xenadrine RFA-1 is 200 mg / 462 mg = 43%. (See Ex. B.)
- 55. Upon information and belief, the concentration by mass of EGCG in Xenadrine RFA-1 is no greater than (462 mg 200 mg) / 462 mg = 57%. (See Ex. B.)
- 56. Upon information and belief, Xenadrine RFA-1 contains no more than 1.33 (i.e., 57% / 43%) times as much EGCG as caffeine.
- 57. Upon information and belief, Xenadrine RFA-1 is not protected by the '986 patent.
- 58. To be "protected by" the '765 patent, an extract must, <u>inter alia</u>, contain between two and ten times as much EGCG as caffeine, with both substances measured by mass (weight).
 - 59. Upon information and belief, Xenadrine RFA-1 is not protected by the

'765 patent.

- 60. U.S. Patent No. 6,395,296 ("the '296 patent"), entitled "Soluble double metal salt of group IA and IIA of hydroxycitric acid, process of preparing the same and its use in beverages and other food products without effecting their flavor and properties," was issued by the PTO on May 28, 2002. (See http://patft.uspto.gov/netacgi/nph-Parser?Sect1=PTO1&Sect2=HITOFF&d=PALL-bell-web-1&u=%2Fnetahtml%2FPTO2Fsrchnum.htm&r=1&f=G&l=50&s1=6,395,296.
 PN.&OS=PN/6,395,296&RS=PN/6,395,296.)
 - 61. All claims of the '296 patent claim a "food product." (See id.)
- 62. Xenadrine RFA-1 is not a "food product." (See Ex. B.) Therefore, Xenadrine RFA-1 is not "protected by" the '296 patent.
 - 63. The '492 patent expired on September 4, 2007.
 - 64. Because the '492 patent is expired, it cannot "protect" anything.
 - 65. Xenadrine RFA-1 is not "protected by" the '492 patent.

The Xenadrine® Television Commercials

66. IOVATE promotes Xenadrine® through a series of nationally run television commercials, including commercials targeted at consumers in the Southern District of New York.

- 67. One IOVATE television commercial features administrative assistant Stacey Beier discussing her allegedly Xenadrine-induced weight loss, and contains a voice-over track that states "... the *patented triple action technology* burns calories, increases metabolism and burns fat." (See http://www.xenadrine.com/commercial/commercial.shtml.)
- 68. A second IOVATE television commercial features medical assistant Cari Kalama discussing her allegedly Xenadrine-induced weight loss, and contains the same voice-over track stating "... the *patented triple action technology* burns calories, increases metabolism and burns fat." (See http://www.xenadrine.com/commercial/commercial.shtml.)
- 69. A third IOVATE television commercial features 911 dispatcher Veronica Makowski discussing her allegedly Xenadrine-induced weight loss, and again contains the same voice-over track stating "... the patented triple action technology burns calories, increases metabolism and burns fat." (See http://www.xenadrine.com/commercial/commercial.shtml.)
- 70. In addition to running each of the above-identified Xenadrine® commercials on television stations within this District and nationally, IOVATE also transmits each of these commercials over the Internet to customers in this District and nationally through its Web site www.xenadrine.com, using the URL

http://toolbar.netcraft.com/site_report?url=http://www.xenadrine.com (showing that IOVATE owns/controls the www.xenadrine.com Web site).)

IOVATE as a Patent Plaintiff in New York

- 71. Since April 2007, IOVATE has commenced at least eight suits for patent infringement in the New York federal courts.
- 72. As part of commencing these lawsuits for patent infringement, IOVATE necessarily performed the pre-filing investigations required by Fed. R. Civ. P. 11, including determining that a reasonable basis existed to bring an infringement claim on each asserted patent.
- 73. "Determining infringement, [for Rule 11 purposes], requires that the patent claims be interpreted." S. Bravo Systems, Inc. v. Containment Technologies Corp., 96 F.3d 1372, 1375 (Fed. Cir. 1996).
- 74. IOVATE has asserted a claim for infringement of the '765 patent in at least four separate cases brought since April 2007.
- 75. IOVATE has asserted a claim for infringement of the '986 patent in at least four separate cases brought since April 2007.
 - 76. As a result of the numerous Rule 11 investigations that necessarily

preceded IOVATE's patent infringement filings, IOVATE became, and remains, well-aware of the limited scope of the '765 and '986 patents. Specifically, IOVATE appreciates that both of these patents require, at a minimum, that the "patented" product contain between two and ten times as much EGCG as caffeine, with both substances measured by mass (weight).

The May 1, 2009 Recall of IOVATE's Hydorxycut® Products

- 77. On May 1, 2009, the U.S. Food and Drug Administration ("FDA") issued an advisory entitled "FDA Warns Consumers to Stop Using Hydroxycut Products: Dietary Supplements Linked to One Death; Pose Risk of Liver Injury."

 (See http://www.fda.gov/bbs/topics/NEWS/2009/NEW02006.html.)
- 78. The May 1 FDA advisory states that: "The FDA has received 23 reports of serious health problems ranging from jaundice and elevated liver enzymes, an indicator of potential liver injury, to liver damage requiring liver transplant. One death due to liver failure has been reported to the FDA. Other health problems reported include seizures; cardiovascular disorders; and rhabdomyolysis, a type of muscle damage that can lead to other serious health problems such as kidney failure. ... The agency has not yet determined which ingredients, dosages, or other health-related factors may be associated with risks

related to these Hydroxycut products. The products contain a variety of ingredients and herbal extracts." (See id.)

IOVATE's Deliberate and Repeated Violations of 35 U.S.C. §292(a)

- 79. IOVATE employs an in-house patent attorney (Gavin T. Bogle) who, because of his training and expertise in patent law, would know, or should have known, that IOVATE's misuse of the terms "patent," "patented" and the like violates 35 U.S.C. §292(a). (See https://oedci.uspto.gov/OEDCI/details.do? regisNum=56724.)
- 80. Moreover, IOVATE is well-aware of legal restrictions on its advertising. For example, until shortly before May 1, 2009, IOVATE included the following disclaimer on its Web site: "These statements have not been evaluated by the FDA. These products (sic) is not intended to diagnose, treat, cure or prevent any disease." (See http://www.hydroxycut.com/, as of April 2009.)
- 81. Upon information and belief, IOVATE used the language "Protected by Multiple U.S. Patents #7,335,651, #6,814,986, #6,830,765, #6,875,891, #6,395,296, #6,160,172, #4,923,855, #4,954,492 and #5,194,615" in its advertising for the purpose of deceiving the public into believing that Hydroxycut®, or something in Hydroxycut®, is protected by each of the listed

patents.

- 82. Upon information and belief, IOVATE knew, or reasonably should have known, that the statement "Protected by Multiple U.S. Patents # 7,335,651, # 6,814,986, # 6,830,765, # 6,875,891, # 6,395,296, # 6,160,172, # 4,923,855, # 4,954,492 and # 5,194,615" is false. At a minimum, IOVATE had no reasonable basis to believe that the statement is true.
- 83. Moreover, since long before May 1, 2009, IOVATE was well-aware that the FDA questioned at least the safety of its Hydroxycut® products. By intentionally and falsely overstating the number of "patents" that covered its Hydroxycut® products, IOVATE intended to mislead consumers into confusing patent protection for FDA approval or endorsement, thus diluting the effect of its "have not been evaluated by the FDA" disclaimer and instead misleading consumers into believing that the federal government had, in fact, endorsed the safety and efficacy of Hydroxycut® products.
- 84. Each time IOVATE transmitted web content that included false patent information concerning Hydroxycut (e.g., "Protected by Multiple U.S. Patents # 7,335,651, # 6,814,986, # 6,830,765, # 6,875,891, # 6,395,296, # 6,160,172, # 4,923,855, # 4,954,492 and # 5,194,615" or the like) to a Web browser located in the United States, IOVATE committed an "offense," as defined in 35 U.S.C.

§292(a).

- 85. Upon information and belief, IOVATE uses the language "Protected by US Patents # 6,277,396, # 7,335,651, # 6,814,986, # 6,830,765, # 6,875,891, # 6,395,296, # 6,160,172, # 4,954,492 and # 5,194,615" in its advertising for the purpose of deceiving the public into believing that Zenadrine®, or something in Zenadrine®, is protected by each of the listed patents.
- 86. Upon information and belief, IOVATE knows, or reasonably should know, that the statement "Protected by US Patents # 6,277,396, # 7,335,651, # 6,814,986, # 6,830,765, # 6,875,891, # 6,395,296, # 6,160,172, # 4,954,492 and # 5,194,615" is false. At a minimum, IOVATE has no reasonable basis to believe that the statement is true.
- 87. Each time IOVATE transmits web content that includes false patent information concerning Zenadrine (e.g., "Protected by US Patents # 6,277,396, # 7,335,651, # 6,814,986, # 6,830,765, # 6,875,891, # 6,395,296, # 6,160,172, # 4,954,492 and # 5,194,615" or the like) to a Web browser located in the United States, IOVATE commits an "offense," as defined in 35 U.S.C. §292(a).
- 88. Upon information and belief, IOVATE's statement(s) concerning Xenadrine's "patented triple action technology" are false because there exists no unexpired U.S. patent covering such "triple action technology [that] burns calories,

increases metabolism and burns fat."

- 89. Upon information and belief, IOVATE includes statements concerning Xenadrine's "patented triple action technology" for the purpose of deceiving the public into believing that such "triple action technology" is "patented," when in fact it isn't.
- 90. Upon information and belief, IOVATE knows, or reasonably should know, that Xenadrine's "triple action technology" is not "patented." At a minimum, IOVATE has no reasonable basis to believe that such statement is true.
- 91. Each time IOVATE runs, or causes to be run, a television advertisement that targets viewers located in the United States and makes reference to Xenadrine's "patented triple action technology," IOVATE commits an "offense," as defined in 35 U.S.C. §292(a).
- 92. Each time IOVATE creates, or causes to be created, an Internet transmission that contains written and/or audio/visual content referring to "patented triple action technology" to consumers in this District or nationally, it commits an "offense," as defined in 35 U.S.C. §292(a).
- 93. Upon information and belief, IOVATE listed and/or lists patent numbers on its product packages for the purpose of deceiving the public into believing that the product embodied or contained therein is protected by the listed

patents.

- 94. Upon information and belief, IOVATE knew, knows, or reasonably should know, that at least some of the patent numbers it listed/lists (e.g., the expired patents) on its packages do not cover anything embodied or contained in the marked packages. At a minimum, IOVATE had/has no reasonable basis to believe that each patent it listed/lists on its product packages actually covers anything embodied or contained in the packages.
- 95. Each time IOVATE made/makes, has made, used/uses, offered/offers to sell, or sold/sells within the United States, or imported/imports into the United States, a package containing false patent information (e.g., a package that lists expired or inapplicable patents), IOVATE committed/commits an "offense," as defined in 35 U.S.C. §292(a).

PRAYER FOR RELIEF

WHEREFORE, plaintiff PUBPAT respectfully requests that this Court:

- (1) Find that IOVATE's Internet advertising, television advertising, and product labeling violates 35 U.S.C. §292(a);
- (2) Determine an appropriate "fine," not more than \$500 per offense, but sufficient to appropriately penalize IOVATE's violations of §292(a), and to deter

IOVATE and others similarly situated from violating §292(a) in the future;

- Direct that half of the fine be paid to the United States government; (3) and,
 - Direct that the other half of the fine be paid to PUBPAT. (4)

Request for Jury Trial

Pursuant to Fed. R. Civ. P. 38(b)(1), PUBPAT hereby demands a jury 96. trial on all issues so triable.

Respectfully submitted,

PUBLIC PATENT FOUNDATION, INC.

By:

Dated: New York, New York

May 6, 2009

Daniel Ravicher, Esq. (DR1498) David Garrod, Ph.D., Esq. (DG6759) PUBLIC PATENT FOUNDATION, INC.

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