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20 **UNITED STATES DISTRICT COURT**
21 **SOUTHERN DISTRICT OF CALIFORNIA**

22 FEDERAL TRADE COMMISSION,

23 Plaintiff,

24 v.

25 ALFA SCIENTIFIC DESIGNS, INC.;
26 NAISHU WANG, M.D., Ph.D.; and
27 DAVID F. H. ZHOU, M.D., Ph.D.,

28 Defendants.

Case No. 00CV 0081 BTM (NLS)

**STIPULATED FINAL ORDER
FOR PERMANENT
INJUNCTION**

On January 13, 2000, plaintiff, the Federal Trade Commission ("FTC" or "Commission"),

1 filed a complaint for permanent injunction and other relief, pursuant to Section 13(b) of the
2 Federal Trade Commission Act ("FTC Act"), 15 U.S.C. § 53(b), against Alfa Scientific Designs,
3 Inc. The complaint was subsequently amended to name Naishu Wang, M.D., Ph.D., President of
4 Alfa Scientific Designs, Inc.; and David F. H. Zhou, M.D., Ph.D., an officer and director of Alfa
5 Scientific Designs, Inc., as defendants.
6

7 The Commission and defendants have stipulated to the entry of this Final Order for
8 Permanent Injunction ("Order") in settlement of the Commission's complaint against defendants.
9

10 The Court, being advised in the premises, finds as follows:

11 **FINDINGS**

12 1. In its complaint, the Commission alleged that defendants violated Sections 5(a)
13 and 12 of the FTC Act, 15 U.S.C. § § 45(a) and 52. The Commission sought permanent
14 injunctive relief for alleged deceptive acts or practices by defendants in connection with the
15 marketing and sale of tests that purportedly detected the human immunodeficiency virus in human
16 blood.
17

18 2. The Commission has the authority under Section 13(b) of the FTC Act, 15 U.S.C.
19 § 53(b), to seek the relief it has requested.
20

21 3. This Court has jurisdiction over the subject matter of this case, and jurisdiction
22 over defendants. Venue in the Southern District of California is proper, and the complaint states
23 a claim upon which relief can be granted against the defendants under Sections 5(a), 12, and 13(b)
24 of the FTC Act, 15 U.S.C. §§ 45(a), 52, and 53(b).
25

26 4. The activities of defendants as alleged in the Commission's complaint were or are
27

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1 successors or assigns;

2 2. Naishu Wang, M.D., Ph.D. (“Wang”), individually and in her capacity as
3 President of ASD;
4

5 3. David F. H. Zhou, M.D., Ph.D., (“Zhou”), individually and in his capacity
6 as a director or officer of ASD; and
7

8 4. Any combination of the foregoing.

9 B. “Participating associates” shall refer to defendants’ officers, agents, servants,
10 employees, and all those persons or entities in active concert or participation with
11 defendants who receive actual notice of this Order by personal service or
12 otherwise.
13

14 C. “Human immunodeficiency virus” (“HIV”) shall refer to all types or strains of the
15 virus that causes acquired immunodeficiency syndrome (“AIDS”), an infectious
16 disease characterized by immune system failure.
17

18 D. “HIV test” shall refer to any product that is advertised, marketed, promoted,
19 offered for sale, distributed or sold with express or implied representations that the
20 product will or may detect the presence of HIV in any human, including but not
21 limited to the “ASD HIV 1 / 2 Rapid Test” and any other substantially similar
22 product.
23

24 E. “Device” shall mean “device” as defined in Section 15(d) of the FTC Act, 15
25 U.S.C. § 55(d).
26

27 F. “Unapproved device” shall mean any device that is not approved by the U.S. Food
28

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1 and Drug Administration (“FDA”), pursuant to the Federal Food, Drug and
2 Cosmetic Act (“FD&C Act”) and Title 21 of the Code of Federal Regulations (“21
3 C.F.R.”), for sale, distribution, or delivery within the United States.
4

5 G. “Competent and reliable scientific evidence” means tests, analyses, research,
6 studies, or other evidence based on the expertise of professionals in the relevant
7 area, that have been conducted and evaluated in an objective manner by persons
8 qualified to do so, using procedures generally accepted in the professions to yield
9 accurate and reliable results.
10

11 H. “Premarketing Approval” (“PMA”) means PMA pursuant to the FD&C Act and
12 21 C.F.R.
13

14 I. “Investigational Device Exemption” (“IDE”) means an IDE pursuant to the FD&C
15 Act and 21 C.F.R.
16

17 J. “Tier 1 Country” means Australia, Austria, Canada, Denmark, Finland, France,
18 Germany, Greece, Iceland, Ireland, Israel, Italy, Japan, Liechtenstein,
19 Luxembourg, Netherlands, New Zealand, Norway, South Africa, Spain, Sweden,
20 Switzerland, the United Kingdom, or any other country appearing in Section
21 802(b)(1)(A) of the FD&C Act, 21 U.S.C. § 382(b)(1)(A).
22

23 K. “Certificate of Exportability” means a certificate obtained from the FDA pursuant
24 to Section 801(e)(4) of the FD&C Act, 21 U.S.C. § 381(e)(4).
25

26 L. “Document(s)” or “record(s)” shall refer to

27 1. The original or a true copy of any written, typed, printed, electronically
28

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1 stored, transcribed, taped, recorded, filmed, punched, or graphic matter or
2 other data compilations of any kind, including, but not limited to, letters, e-
3 mail or other correspondence, messages, memoranda, interoffice
4 communications, notes, reports, summaries, manuals, magnetic tapes or
5 discs, tabulations, books, records, checks, invoices, workpapers, journals,
6 ledgers, statements, returns, reports, schedules, or files; and
7

8
9 2. Any information stored on any desktop personal computer (“PC”) and
10 workstations, laptops, notebooks, and other portable computers, whether
11 assigned to individuals or in pools of computers available for shared use;
12 and home computers used for work-related purposes; backup disks and
13 tapes, archive disks and tapes, and other forms of offline storage, whether
14 stored onsite with the computer used to generate them, stored offsite in
15 another company facility or stored offsite by a third-party, such as in a
16 disaster recovery center; and computers and related offline storage used by
17 defendants’ participating associates, which may include persons who are
18 not employees of the company or who do not work on company premises.
19
20

21 M. The terms “and” and “or” in this Order shall be construed conjunctively or
22 disjunctively as necessary, to make the applicable sentence or phrase inclusive
23 rather than exclusive.
24

25 N. The term “including” shall mean “without limitation.”

26 O. Any requirement that defendants “notify” or “provide” any information or material
27

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1 to the Commission, shall mean that defendants shall send the necessary information
2 or material via first-class mail, costs prepaid, to:

3 Associate Director for Advertising Practices
4 Federal Trade Commission
5 600 Pennsylvania Ave., N.W., Room S-4002
6 Washington, DC 20580
7 Attn: FTC v. Alfa Scientific Diagnostic Systems, Inc. et al.
8 Matter No. X000054

8 **II. BAN ON CERTAIN ACTIVITIES**

9 IT IS FURTHER STIPULATED AND ORDERED that defendants and their participating
10 associates, and each of them, are permanently enjoined from engaging, participating, or assisting
11 in any manner or capacity whatsoever, directly, or indirectly, in concert with others, or through
12 any business entity or other entity, in the advertising, marketing, promotion, offering for sale,
13 distribution, or sale of any unapproved HIV test; *provided, however*, that nothing in this Order
14 shall prohibit defendants, upon no less than three (3) business days notice to the Commission in
15 the form shown on Appendix A, from engaging in the:
16
17

18 A. advertising, marketing, promotion, offering for sale, distribution, or sale of any
19 unapproved HIV test within the United States pursuant to, and in conformity with:

- 20
21 1. an approved IDE, *and* for the sole purpose of conducting a clinical
22 investigation or research to determine the safety or effectiveness of the
23 unapproved HIV test; *or*
24 2. an approved PMA.
25
26
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1 B. advertising, marketing, promotion, offering for sale, distribution, or sale of any
2 unapproved HIV test to any country outside of the United States, provided that at
3 the time of such advertising, marketing, promotion, offering for sale, distribution,
4 or sale defendants act pursuant to, and in conformity with, all the relevant laws and
5 regulations of that country *and* pursuant to, and in conformity with,
6

7 1. an approved IDE for that country, *and* for the sole purpose of conducting a
8 clinical investigation or research to determine the safety or effectiveness of
9 the unapproved HIV test; *or*
10

11 2. an approved PMA for that unapproved HIV test; *or*

12 3. marketing authorization for the unapproved HIV test from a Tier One
13 Country, pursuant to the FD&C Act, *provided that*:
14

15 a. the country to which the defendants intend to export the
16 unapproved HIV test accepts the authorization of that Tier One
17 Country; *and*
18

19 b. defendants obtain a Certificate of Exportability for that country
20 from the FDA prior to the exportation of the unapproved HIV test
21 to that country.
22

23 Nothing in this Section shall be construed to override or invalidate any law or regulation
24 of the United States or its agencies, or any other jurisdiction.

25 **III. PROHIBITED BUSINESS ACTIVITIES**

26 IT IS FURTHER STIPULATED AND ORDERED that defendants and their participating
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1 associates, directly or indirectly, or acting through any corporation, entity or person under their
2 control, are permanently enjoined from:

- 3
- 4 A. Making, or assisting others in making, directly or by implication, any false or
5 misleading oral or written statement or representation in connection with the
6 advertising, marketing, promotion, offer for sale, distribution, or sale of any HIV
7 test or unapproved device, including misrepresenting, in any manner, directly or by
8 implication, the accuracy or efficacy of any HIV test or unapproved device;
9
- 10 B. Making, or assisting others in making, any representation, in any manner, directly
11 or by implication, regarding the accuracy or efficacy of any HIV test or
12 unapproved device, including any implied representation that such HIV test or
13 unapproved device is fit for its intended use, unless, at the time of making such
14 representation, defendants possess and rely upon competent and reliable scientific
15 evidence that substantiates the representation;
16
- 17 C. Misrepresenting, in any manner, directly or by implication, that the U.S. Food and
18 Drug Administration or any other local, state, regional, national or international
19 government or public health organization has reviewed, evaluated, is affiliated
20 with, or otherwise endorses or supports, any HIV test or unapproved device; and
21
- 22 D. Misrepresenting, in any manner, directly or by implication, any other fact material
23 to a customer's decision to purchase any HIV test or unapproved device.
24

25 **IV. NOTICE TO PAST PURCHASERS**

26 IT IS FURTHER STIPULATED AND ORDERED that, within ten (10) days of entry of
27

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1 this Order, defendants shall send by first class mail the notice set forth in Appendix B to this
2 Order to any person or entity who purchased any of defendants' HIV tests between February 1,
3 1998 to the date of entry of this Order. A list of all persons or entities that received such notice
4 shall be provided to the Commission sixty (60) days after the date of entry of this Order.
5

6 **V. PRESERVATION OF RECORDS**

7 IT IS FURTHER STIPULATED AND ORDERED that, for a period of five (5) years
8 from the date of entry of this Order, defendants and their participating associates, in connection
9 with defendant ASD and any business where (1) defendant Wang or defendant Zhou is the
10 majority owner or an officer or director of the business, or directly or indirectly manages or
11 controls the business and where (2) the business engages in the advertising, marketing, promotion,
12 offering for sale, distribution or sale of any HIV test or unapproved device, are permanently
13 enjoined from failing to create, or have such business create, and from failing to retain for a period
14 of five (5) years following the date of such creation, unless otherwise specified:
15
16

- 17 A. All documents evidencing or referring to the accuracy or efficacy of any HIV test
18 or unapproved device advertised, marketed, promoted, offered for sale, distributed
19 or sold by defendants, including, but not limited to, all tests, reports, studies,
20 demonstrations, or other evidence that confirm, contradict, qualify, or call into
21 question the accuracy or efficacy of such HIV test or unapproved device;
22
23 B. All documents referring or relating to the advertisement, marketing, promotion,
24 offering for sale, distribution or sale of any unapproved HIV test by defendants,
25 including, but not limited to any PMA, IDE, Certificate of Exportability, or
26
27
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1 marketing authorization.

2 C. Books, records and accounts that, in reasonable detail, accurately and fairly reflect
3 the cost of HIV tests or other unapproved devices and revenues generated;
4

5 D. Records accurately reflecting: the name, address, and telephone number of each
6 person employed by defendants, including as an independent contractor, who is
7 engaged in the advertising, marketing, promotion, offer for sale, distribution, or
8 sale of any HIV test or unapproved device; that person's job title or position; the
9 date upon which the person commenced work; and the date and reason for the
10 person's termination, if applicable;
11

12 E. Records containing the names, addresses, telephone numbers, dollar amounts paid,
13 quantity of items or services purchased, and description of items or services
14 purchased, for all purchasers to whom defendants has sold, invoiced or shipped
15 any HIV test or unapproved device;
16

17 F. Records that reflect, for every customer complaint or refund request relating to
18 any HIV test or unapproved device, whether received directly or indirectly or
19 through any third party: (1) the customer's name, address, telephone number and
20 the dollar amount paid by the customer; (2) the written complaint or refund
21 request, if any, and the date of the complaint or refund request; (3) the basis of the
22 complaint, including the name of any defendant or participating associate
23 complained against, and the nature and result of any investigation conducted
24 concerning any complaint; (4) each response and the date of the response; (5) any
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1 final resolution and the date of the resolution; and (6) in the event of a denial of a
2 refund request, the reason for the denial; and

- 3
4 G. Copies of all advertisements, promotional materials, sales scripts, training
5 materials, or other marketing materials utilized relating to any HIV test or
6 unapproved device.

7 **VI. MONITORING**

8
9 IT IS FURTHER STIPULATED AND ORDERED, in order to monitor compliance with
10 this Order, that:

- 11 A. Within five (5) days of the entry of this Order, defendants Wang and Zhou shall
12 each notify the Commission of (1) her or his residence address and mailing
13 address; (2) her or his telephone number(s); (3) the name, address and telephone
14 number of her or his employers; (4) the full names of her or his employer's
15 principals; (5) if applicable, the names of her or his supervisors; and (6) a
16 description of her or his employer's activities, and defendant's duties and
17 responsibilities; and
18 responsibilities;

- 19
20 B. For a period of five (5) years from the date of entry of this Order, defendants
21 Wang and Zhou shall each notify the Commission within ten (10) business days of
22 any changes in her or his residence or mailing addresses, or employment involving
23 the advertising, marketing, promotion, offer for sale, distribution, or sale of any
24 HIV test or unapproved device. Notice of changes in employment shall include:
25 (1) the new employer's name, address and telephone number; (2) the full names of
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1 the employer's principals; (3) if applicable, the names of defendant's supervisor(s),
2 and (4) a description of the employer's activities, and defendant's duties and
3 responsibilities;
4

5 C. For a period of five (5) years from the date of entry of this Order, defendants shall
6 deliver the notice set forth in Appendix C to this Order to all current and future
7 principals, officers, directors, and managers, and to all current and future
8 employees, agents, and customers involved in the advertising, marketing,
9 promotion, offering for sale, distribution or sale of any HIV test or unapproved
10 device. Defendants shall deliver the notice set forth in Appendix C to this Order to
11 current personnel within ten (10) days after the date of service of this Order, and
12 to future personnel within ten (10) days after the person assumes such position or
13 responsibilities;
14

15
16 D. Within thirty (30) days after entry of this Order, defendants shall send by first class
17 mail a notice, in the form shown on Appendix C, to each of their distributors
18 involved in the advertising, marketing, promotion, offering for sale, distribution or
19 sale of any HIV test or unapproved device with whom defendants have done
20 business since February 1, 1998. Defendants shall require each distributor to
21 execute and return the original of the letter as a condition of remaining or once
22 again becoming a distributor for defendants.
23

24
25 E. Sixty days (60) days after the date of entry of this Order, defendants shall provide
26 a written report to the Commission, signed under penalty of perjury, detailing their
27

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1 past and present efforts to comply with this Order;

2 F. For a period of five (5) years from the date of entry of this Order, defendants shall
3 notify the Commission of any proposed change in the structure of defendant ASD,
4 such as dissolution, assignment, sale, merger, creation or dissolution of
5 subsidiaries, proposed filing of a bankruptcy petition, or change in the business or
6 corporate name or address, or any other change that may affect compliance
7 obligations arising out of this Order, thirty (30) days prior to the effective date of
8 any proposed change; *provided, however,* that, with respect to any proposed
9 change in ASD about which defendants learn less than thirty (30) days prior to the
10 date such action is to take place, defendants shall notify the Commission as soon as
11 is practicable after learning of such proposed change;
12

13 G. For a period of five (5) years from the date of entry of this Order, defendants shall
14 notify the Commission, in writing, of any complaint or refund request defendants
15 receive, whether received directly or indirectly or through any third party, related
16 to the efficacy or accuracy of any HIV test or unapproved device advertised,
17 marketed, promoted, offered for sale, distributed or sold by defendants or their
18 participating associates, directly or indirectly, or acting through any corporation,
19 entity or person under their control. Such notification shall be made, in writing, to
20 the Commission within three (3) business days of receipt by defendants and shall
21 include, but is not limited to, the following:
22

23 1. a true and exact copy of the written complaint or refund request, including
24
25
26
27

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1 any documents accompanying the written complaint or refund request; if
2 the complaint or refund request is made orally, such oral request shall be
3 fully memorialized in writing by defendants and provided to the
4 Commission;

- 5
- 6 2. the name, address, telephone number, and e-mail address of the person or
7 entity making the complaint or refund request received by defendants;
- 8
- 9 3. the basis of the complaint or refund request, including the name of any
10 defendant or participating associate complained against, the lot number of
11 the HIV test or unapproved device complained against, and the nature and
12 result of any investigation conducted concerning any complaint;
- 13
- 14 4. each response and the date of the response; and
- 15 5. in the event of a denial of a refund request, the reason for the denial.

16 If defendants are unable, despite good faith efforts, to provide the Commission
17 with any of the information enumerated in Section VI(F)(1-5) within three (3)
18 business days of receipt by defendants of any such complaint or refund request,
19 defendants shall provide the Commission, in writing, with the reason(s) for their
20 inability to provide the Commission with such information. Defendants shall
21 provide the Commission with any supplemental materials within two (2) business
22 days after receipt.

- 23
- 24
- 25 I. For a period of five (5) years from the date of entry of this Order, defendants shall
26 permit representatives of the Commission, within forty-eight (48) hours of receipt
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1 of written notice from the Commission:

- 2
- 3 1. access during normal business hours to any office, or facility storing any
- 4 HIV test or unapproved device advertised, marketed, promoted, offered
- 5 for sale, distributed or sold by defendants or their participating associates,
- 6 directly or indirectly, or acting through any corporation, entity or person
- 7 under their control, to inspect and randomly select for testing by an expert
- 8 designated by the Commission at least ten (10) HIV tests or unapproved
- 9 devices from each lot number then present at such office or facility;
- 10
- 11 2. access during normal business hours to any office, or facility storing
- 12 documents, of any business owned by defendants or of which any
- 13 defendant is a principal, director, officer, partner, or other controlling
- 14 party, to inspect and copy all documents belonging to such business or
- 15 defendants relating to the advertising, marketing, promotion, offer for sale,
- 16 distribution, or sale of any HIV test or unapproved device; and shall permit
- 17 Commission representatives to remove documents relating to the
- 18 advertising, marketing, promotion, offer for sale, distribution, or sale of
- 19 any HIV test or unapproved device for a period not to exceed five (5)
- 20 business days so that the documents may be inspected, inventoried, and
- 21 copied;
- 22
- 23 3. refrain from interfering with any duly authorized representatives of the
- 24 Commission reasonably interviewing defendants' employers, employees
- 25
- 26
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1 (whether designated as employees, consultants, independent contractors or
2 otherwise), or agents, about any matter relating to the advertising,
3 marketing, promotion, offer for sale, distribution, or sale of any HIV test or
4 unapproved device; *provided however* that nothing in this subsection shall
5 limit defendants, or defendants' employers, employees, or agents from
6 having present, consulting with, and following the advice of legal counsel;
7 and
8

9
10 4. upon reasonable written request by any duly authorized representative of
11 the Commission, submit written reports (under oath, if requested), and
12 produce documents, on five (5) days notice, relating to the advertising,
13 marketing, promotion, offer for sale, distribution, or sale of any HIV test or
14 unapproved device;
15

16 J. The Commission is authorized to monitor the compliance of defendants with this
17 Order by all lawful means, including but not limited to the following means:
18

- 19 1. The Commission is authorized, without further leave of court, to obtain
20 discovery from any person in the manner provided by Chapter V of the
21 Federal Rules of Civil Procedure, Fed. R. Civ. P. 26-37, including the use
22 of compulsory process pursuant to Fed. R. Civ. P. 45, for the purpose of
23 monitoring and investigating the compliance of defendants with this Order;
24
25 2. The Commission is authorized to use representatives posing as customers
26 and suppliers to defendants, to the employees of defendants, or to any
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1 other entity managed or controlled in whole or in part by defendants,
2 without the necessity of identification or prior notice; and

3
4 3. Nothing in this Order shall limit the Commission's lawful use of
5 compulsory process, pursuant to Sections 9 and 20 of the FTC Act, 15
6 U.S.C. §§49, 57b-1, to investigate whether defendants have violated any
7 provision of this Order or Sections 5 or 12 of the FTC Act, 15 U.S.C.
8 §§45, 52.
9

10 **VII. COOPERATION WITH THE COMMISSION**

11 IT IS FURTHER STIPULATED AND ORDERED that defendants shall, in connection
12 with this action or any subsequent Commission investigations related to or associated with the
13 transactions or the occurrences that are the subject of the Commission's complaint, cooperate in
14 good faith with the Commission and appear at such places and times as the Commission shall
15 reasonably request, after written notice to defendants or their counsel of record, for interviews,
16 conferences, pretrial discovery, review of documents, and for such other matters as may be
17 reasonably requested by the Commission; *provided, however*, defendants shall not be deemed to
18 have waived any rights or defenses they may have under law governing discovery or admissibility
19 of evidence in any action brought against defendants. If requested in writing by the Commission,
20 defendants shall appear and provide truthful testimony in any trial, deposition, or other proceeding
21 related to or associated with the transactions or the occurrences that are the subject of the
22 Complaint, without the service of a subpoena.
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24
25

26 **VIII. ACKNOWLEDGMENT OF RECEIPT OF ORDER**

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1 IT IS FURTHER STIPULATED AND ORDERED that, within five (5) business days
2 after receipt by defendants of this Order as entered by the Court, defendant Wang, individually
3 and on behalf of defendant ASD, and defendant Zhou, shall each execute and submit to the
4 Commission a truthful sworn statement, in the form shown on Appendix D, that shall
5 acknowledge receipt of this Order.
6

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1 **IX. RETENTION OF JURISDICTION**

2 IT IS FURTHER STIPULATED AND ORDERED that this Court shall retain jurisdiction
3 of this matter for purposes of construction, modification and enforcement of this Order.
4

5 SO STIPULATED:

6
7 _____
8 DARREN A. BOWIE
9 KAREN JAGIELSKI
10 Federal Trade Commission
11 600 Pennsylvania Ave., N.W., Room S-4002
12 Washington, DC 20580
13 (202) 326-2018, -2509 (voice)
14 (202) 326-3259 (facsimile)

15 GREGORY A. VEGA
16 United States Attorney
17 D. MICHAEL WALTZ
18 Assistant United States Attorney
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20 Federal Office Building
21 880 Front Street
22 Room 6293
23 San Diego, CA 92101-8893
24 (619) 557-7184 (voice)
25 (619) 557-5004 (facsimile)
26 Attorneys for Plaintiff
27 FEDERAL TRADE COMMISSION

NAISHU WANG, M.D, Ph.D.
Individually and on behalf of
Alfa Scientific Designs, Inc.

DAVID F. H. ZHOU, M.D., Ph.D.
Individually and as an officer and director
of Alfa Scientific Designs, Inc.

HAROLD C. POPE
MICHAEL J. BLAKE
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633 West Fifth Street, Suite 3500
Los Angeles, CA 90071-2007
(213) 229-0990 (voice)
(213) 229-0992 (facsimile)

Attorneys for Defendants
ALFA SCIENTIFIC DESIGNS, INC.,
NAISHU WANT, M.D., Ph.D. and
DAVID ZHOU, M.D., Ph.D.

22 IT IS SO ORDERED, this _____ day of _____, 2000.

24 _____
25 THE HONORABLE BARRY TED MOSCOWITZ
26 UNITED STATES DISTRICT COURT

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1 **APPENDIX A**

2
3 [To Be Printed on Defendant's Letterhead]

4 TO: Federal Trade Commission

5 FROM: [NAME OF DEFENDANT]

6 [DATE]:

7 RE: Matter No. X000054

8
9
10 Pursuant to Section II of the Stipulated Final Order, this notice serves to inform you that
11 *[name of defendant]* intends to *[advertise, market, promote, offer for sale, distribute, or sell]* an
12 unapproved HIV test to *[name, address, telephone number and e-mail address of person or*
13 *organization, if applicable]*.

14 Enclosed please find the following supporting documents (check all that apply):

- 15 _____ copy of PMA
16 _____ copy of IDE
17 _____ copy of Certificate of Exportability
18 _____ copy of Tier One Country marketing authorization.
19

20
21 Sincerely,

22
23 *[Name of Sender]*
24
25
26
27

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1 **APPENDIX B**

2
3 [To Be Printed on Defendant's Letterhead]

4 [NAME AND ADDRESS OF RECIPIENT]

5 [DATE]

6
7 Dear [RECIPIENT'S NAME]:

8 The United States Federal Trade Commission (FTC) alleged that some of the HIV rapid
9 tests distributed by Alfa Scientific Designs, Inc. ("ASD") gave a negative result when tested on a
10 patient under clinical care known to be HIV positive.

11 ASD has signed a settlement agreement with the Federal Trade Commission which was
12 entered by the United States District Court of the Southern District of California [*date of entry of*
13 *the Stipulated Final Order*]. This agreement is for settlement purposes only and does not
14 constitute an admission by ASD of any wrongdoing.

15
16 Sincerely,

17 Naishu Wang, M.D., Ph.D., President
18 Alfa Scientific Designs, Inc.
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1 **APPENDIX C**

2 [To Be Printed on Defendant’s Letterhead]

3 [NAME AND ADDRESS OF DISTRIBUTOR]

4 [DATE]

5 Dear [DISTRIBUTOR]:

6
7 [Name of Defendant] has settled a civil dispute with the United States Federal Trade
8 Commission (“FTC”) involving advertising claims for HIV rapid tests. The FTC alleged that
9 some of the HIV rapid tests distributed by Alfa Scientific Designs, Inc. (“ASD”) gave a negative
10 result when tested on a patient under clinical care known to be HIV positive. We do not admit
11 that the FTC’s allegations are true, but as part of the settlement, we have agreed to make sure
12 that all of our distributors follow the guidelines set forth in the settlement agreement which was
13 entered by the United States District Court for the Souther District of California on [date].

14 In accordance with the settlement, we have agreed to make no claims about the accuracy
15 of efficacy of any HIV test or device not approved by the United States Food and Drug
16 Administration (“Products”) unless those claims are supported by scientific evidence. We
17 therefore require that our distributors:

- 18 • **NOT** use, rely on or distribute any advertising or promotional materials for our
19 Products unless those materials have been reviewed and approved by ASD; and
- 20 • **NOT** use any advertising or promotional materials containing unsubstantiated
21 claims and **NOT** to make unsubstantiated oral representations for any of our
22 Products.

23 We also ask that you notify any of your retail or wholesale customers **NOT** to make any
24 unsubstantiated claims for our Products and expect that you will monitor their compliance with
25 this requirement. In the event that you fail to comply with our requirements, then we will stop
26 doing business with you.

27 These conditions are material parts of the agreement under which we will supply our
28 Products to you. Please sign, date, and return this letter to [defendant] at the above address
acknowledging your agreement to the terms set forth herein.

00CV 0081 BTM (NLS)

1 Thank you very much for your assistance,

2
3
4 [Defendant's signature]

5
6 **ACKNOWLEDGMENT AND AGREEMENT**

7 The undersigned acknowledges receipt of this letter and hereby agrees to its terms and
8 conditions.

9
10 _____
Date

10 _____
Signature

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28 00CV 0081 BTM (NLS)

1 **APPENDIX D**

2 **UNITED STATES DISTRICT COURT**
3 **SOUTHERN DISTRICT OF CALIFORNIA**

4
5 FEDERAL TRADE COMMISSION,

6 Plaintiff,

7
8 v.

Case No. 00CV 0081 BTM (NLS)

9
10 ALFA SCIENTIFIC DESIGNS, INC., et al.,

AFFIDAVIT OF [DEFENDANT]

11 Defendants.

12 _____
13
14 [Name of Defendant] being duly sworn, hereby states and affirms as follows:

15 1. My name is *[name of defendant]*. I am a defendant in the above-captioned civil
16 action. I am a citizen of the United States and am over the age of eighteen. I have personal
17 knowledge of the facts set forth in this Affidavit, and if called as a witness, I could and would
18 competently testify as to the matter stated herein.
19

20 2. My current business address is _____. My current
21 business telephone number is _____. My current residential address is
22 _____.
23 My current residential telephone number is _____.

24 3. On [date], I received, individually [and for defendant Wang “and on behalf of Alfa
25 Scientific Designs, Inc.”], a copy of the Stipulated Final Order for Permanent Injunction, which
26 was signed by the Honorable [name of Judge] and entered by the Court on [date of entry of
27

28 00CV 0081 BTM (NLS)

1 Order]. A true and correct copy of the Order that I received is appended to this Affidavit.

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I declare under penalty of perjury under the laws of the United States that the foregoing is true and correct. Executed on [date], at [city and state].

[Name of Defendant]

BEFORE ME this day personally appeared [name of defendant], who being first duly sworn, deposes and says that he has read and understands the foregoing statement and that he has executed the same for the purposes contained therein.

SUBSCRIBED AND SWORN to before me this ____ day of _____, 2000, by [name of defendant]. He is personally known to me or has presented (state identification) _____ as identification.

PRINT NAME

NOTARY PUBLIC,
STATE OF _____

Commission Number
My Commission Expires: _____

Affix Seal