IN THE UNITED STATE FOR THE SOUTHERN D	
FEDERAL TRADE COMMISSION and	DOC#:
Plaintiffs,	ATE FILED: 2
v.	) Civil Action No. 7:15-cv-09304-VB
TOMMIE COPPER, INC., et al.,	)
Defendants.	)

# STIPULATED FINAL JUDGMENT AND ORDER FOR PERMANENT INJUNCTION AND OTHER EQUITABLE RELIEF

Plaintiff, the Federal Trade Commission ("Commission" or "FTC"), filed its Complaint for Permanent Injunction and Other Equitable Relief in this matter, pursuant to Section 13(b) of the Federal Trade Commission Act ("FTC Act"), 15 U.S.C. § 53(b). The Commission and Defendants Tommie Copper, Inc., and Thomas Kallish stipulate to the entry of this Stipulated Final Judgment and Order for Permanent Injunction and Other Equitable Relief ("Order") to resolve all matters in dispute in this action between them.

# THEREFORE, IT IS ORDERED as follows:

#### FINDINGS

- 1. This Court has jurisdiction over this matter.
- 2. The Complaint charges that Defendants participated in deceptive acts or practices and false advertisements in violation of Sections 5 and 12 of the FTC Act, 15 U.S.C. §§ 45(a) and 52, in connection with the labeling, advertising, marketing, distribution, and sale of Tommie Copper Garments.

(AW)

- 3. Defendants neither admit nor deny any of the allegations in the Complaint, except as specifically stated in this Order. Only for purposes of this action, Defendants admit the facts necessary to establish jurisdiction.
- 4. Defendants waive any claim that they may have under the Equal Access to Justice Act, 28 U.S.C. § 2412, concerning the prosecution of this action through the date of this Order, and agree to bear their own costs and attorney fees.
- 5. Defendants waive all rights to appeal or otherwise challenge or contest the validity of this Order. This action and the relief awarded herein are in addition to, and not in lieu of, other remedies as may be provided by law.

#### **DEFINITIONS**

For the purpose of this Order:

- 1. "Advertising" and "promotion" mean any written or verbal statement, illustration, or depiction designed to effect a sale or create interest in the purchasing of products or services, whether it appears in a brochure, newspaper, magazine, pamphlet, leaflet, circular, mailer, book insert, free standing insert, letter, catalogue, poster, chart, billboard, public transit card, point of purchase display, packaging, package insert, label, film, slide, radio, television or cable television, audio program transmitted over a telephone system, program-length commercial ("infomercial"), the Internet, email, press release, video news release, or in any other medium.
  - "Commerce" means as defined in Section 4 of the FTC Act, 15 U.S.C. § 44.
- "Corporate Defendant" means Tommie Copper, Inc. and its successors and assigns.
- 4. "Covered Health Product" means any Covered Product, or any food, drug, or cosmetic, as defined in 15 U.S.C. § 55(b), (c), and (e), respectively.

- 5. "Covered Product" means any device or garment.
- 6. "Defendants" means the Individual Defendant and the Corporate Defendant.
- 7. "Device" means as defined in Section 15 of the FTC Act, 15 U.S.C. § 55(d).
- 8. "Endorsement" means as defined in 16 C.F.R. § 255.0(b).
- 9. "Essentially Equivalent Product" means any product that contains the identical ingredients, except for inactive ingredients (e.g., binders, colors, fillers, excipients), in the same form and dosage, and with the same route of administration (e.g., orally, sublingually); provided that it may contain additional ingredients if reliable scientific evidence generally accepted by experts in the field demonstrates that the amount and combination of additional ingredients is unlikely to impede or inhibit the effectiveness of the ingredients in the Essentially Equivalent Product.
  - 10. "Garment" means an article of clothing.
  - 11. "Individual Defendant" means Thomas Kallish.
- 12. "Person" means a natural person, an organization, or other legal entity, including a corporation, partnership, sole proprietorship, limited liability company, association, cooperative, or any other group or combination acting as an entity.
- 13. "Reliably Reported," for a human clinical test or study ("test"), means a report of the test has been published in a peer-reviewed journal, and such published report provides sufficient information about the test for experts in the relevant field to assess the reliability of the results.
  - 14. The term "including" in this Order means "including without limitation."
- 15. The terms "and" and "or" in this Order shall be construed conjunctively or disjunctively as necessary, to make the applicable phrase or sentence inclusive rather than

exclusive.

#### **ORDER**

I.

# PROHIBITED REPRESENTATIONS: CLAIMS REGARDING COPPER, CHRONIC OR SEVERE PAIN, DISEASES, DRUGS, AND SURGERY

IT IS ORDERED that Defendants, Defendants' officers, agents, employees, and attorneys, and all other persons in active concert or participation with any of them, who receive actual notice of this Order, whether acting directly or indirectly, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any Covered Product are hereby permanently restrained and enjoined from making, or assisting others in making, expressly or by implication, including through the use of a product or program name, endorsement, depiction, or illustration, any representation that:

- A. The copper in any Covered Product provides a pain relief benefit to consumers;
- B. Any Covered Product treats or relieves chronic or severe pain, or pain or inflammation caused by diseases including multiple sclerosis, arthritis, and fibromyalgia; or
- C. Any Covered Product provides pain relief comparable or superior to drugs or surgery,

unless the representation is non-misleading and, at the time of making such representation,

Defendants possess and rely upon competent and reliable scientific evidence to substantiate that
the representation is true. For purposes of this Section, competent and reliable scientific
evidence shall consist of human clinical testing of the Covered Product that is sufficient in
quality and quantity, based on standards generally accepted by relevant medical experts, when
considered in light of the entire body of relevant and reliable scientific evidence, to substantiate

that the representation is true. Such testing shall: (1) be randomized, double-blind, and placebo-controlled; and (2) be conducted by researchers qualified by training and experience to conduct such testing. In addition, all underlying or supporting data and documents generally accepted by relevant medical experts as relevant to an assessment of such testing as described in the Section entitled Preservation of Records Relating to Competent and Reliable Human Clinical Tests or Studies must be available for inspection and production to the Commission.

II.

#### PROHIBITED REPRESENTATIONS: OTHER HEALTH-RELATED CLAIMS

IT IS FURTHER ORDERED that Defendants, Defendants' officers, agents, employees, and attorneys, and all other persons in active concert or participation with any of them, who receive actual notice of this Order, whether acting directly or indirectly, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any Covered Health Product, are permanently restrained and enjoined from making, or assisting others in making, directly or by implication, including through the use of a product or program name, endorsement, depiction, or illustration, any representation, other than representations covered under Section I of this Order, about the health benefits or health efficacy of any Covered Health Product, unless the representation is non-misleading, and, at the time of making such representation, Defendants possess and rely upon competent and reliable scientific evidence that is sufficient in quality and quantity based on standards generally accepted in the relevant scientific fields, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that the representation is true.

For purposes of this Section, competent and reliable scientific evidence means tests, analyses, research, or studies (1) that have been conducted and evaluated in an objective manner

by qualified persons; (2) that are generally accepted in the profession to yield accurate and reliable results; and (3) as to which, when they are human clinical tests or studies, shall consist of human clinical testing on the Covered Health Product (or, where such product is a food or drug, on the Covered Health Product or an Essentially Equivalent Product), that is sufficient in quality and quantity, that conforms to acceptable designs and protocols, and whose results, when considered in light of the entire body of relevant and reliable scientific evidence, is sufficient to substantiate that the representation is true; and further, that with respect to such clinical testing, all underlying or supporting data and documents generally accepted by experts in the field as relevant to an assessment of such testing as set forth in the Section entitled Preservation of Records Relating to Competent and Reliable Human Clinical Tests or Studies are available for inspection and production to the Commission. Defendants shall have the burden of proving that a product satisfies the definition of an Essentially Equivalent Product.

## III.

# FDA-APPROVED CLAIMS

**IT IS FURTHER ORDERED** that nothing in this Order shall prohibit Defendants from:

- A. Making any representation for any drug that is permitted in labeling for such drug under any tentative or final monograph promulgated by the Food and Drug Administration, or under any new drug application approved by the Food and Drug Administration; and
- B. Making any representation for any product that is specifically permitted in labeling for such product by regulations promulgated by the Food and Drug Administration pursuant to the Nutrition Labeling and Education Act of 1990 or permitted under Sections 303-304 of the Food and Drug Administration Modernization Act of 1997.

# IV.

# PRESERVATION OF RECORDS RELATING TO COMPETENT AND RELIABLE HUMAN CLINICAL TESTS OR STUDIES

IT IS FURTHER ORDERED that, with regard to any human clinical test or study

("test") upon which Defendants rely to substantiate any claim covered by this Order, Defendants shall secure and preserve all underlying or supporting data and documents generally accepted by experts in the field as relevant to an assessment of the test, including, but not necessarily limited to:

- A. All protocols and protocol amendments, reports, articles, write-ups, or other accounts of the results of the test, and drafts of such documents reviewed by the test sponsor or any other person not employed by the research entity;
- B. All documents referring or relating to recruitment; randomization; instructions, including oral instructions, to participants; and participant compliance;
- C. Documents sufficient to identify all test participants, including any participants who did not complete the test, and all communications with any participants relating to the test; all raw data collected from participants enrolled in the test, including any participants who did not complete the test; source documents for such data; any data dictionaries; and any case report forms;
- D. All documents referring or relating to any statistical analysis of any test data, including, but not limited to, any pretest analysis, intent-to-treat analysis, or between-group analysis performed on any test data; and
- E. All documents referring or relating to the sponsorship of the test, including all communications and contracts, between any sponsor and the test's researchers.

*Provided, however*, the preceding preservation requirement shall not apply to a Reliably

Reported test, unless the test was conducted, controlled, or sponsored, in whole or in part by: (1) any Defendant; (2) any Defendant's officers, agents, representatives, or employees; (3) any other person or entity in active concert or participation with any Defendant; (4) any person or entity affiliated with or acting on behalf of any Defendant; (5) any supplier of any ingredient contained in the product at issue to any of the foregoing or to the product's manufacturer; or (6) the supplier or manufacturer of such product.

For any test conducted, controlled, or sponsored, in whole or in part, by Defendants,

Defendants must establish and maintain reasonable procedures to protect the confidentiality,
security, and integrity of any personal information collected from or about participants. These
procedures shall be documented in writing and shall contain administrative, technical, and
physical safeguards appropriate to Defendants' size and complexity, the nature and scope of
Defendants' activities, and the sensitivity of the personal information collected from or about the
participants.

V.

#### MONETARY JUDGMENT AND CONSUMER REDRESS

## IT IS FURTHER ORDERED that:

- A. Judgment in the amount of eighty-six million, eight hundred fifteen thousand, seven hundred seventy-eight dollars (\$86,815,778.00) is entered in favor of the Commission against Defendants, jointly and severally, as equitable monetary relief.
- B. Defendants are ordered to pay to the Commission one million, three hundred fifty thousand dollars (\$1,350,000.00), which, as Defendants stipulate, their undersigned counsel holds in escrow for no purpose other than payment to the Commission. Such payment must be made within 7 days of entry of this Order by electronic fund transfer in accordance with

instructions previously provided by a representative of the Commission. Upon such payment, the remainder of the judgment is suspended, subject to the Subsections below.

- C. The Commission's agreement to the suspension of part of the judgment is expressly premised upon the truthfulness, accuracy, and completeness of Defendants' sworn financial statements and related documents (collectively, "financial representations") submitted to the Commission, namely:
- the Financial Statement of Individual Defendant Thomas Kallish signed and sworn by Thomas Kallish on June 22, 2015, including the attachments;
- the Financial Statement of Corporate Defendant Tommie Copper, Inc. signed and sworn by Sol Jacobs, Chief Executive Officer, on June 23, 2015, including the attachments; and
- 3. the additional documentation submitted by electronic mail from Defendants' counsel Steven Steinborn, Veronica Colas, and/or Corey Roush to Commission counsel Carolyn Hann and Tawana Davis, dated July 17, 2015; July 21, 2015; July 23, 2015; September 8, 2015; September 11, 2015; September 17, 2015; September 24, 2015; and September 25, 2015; including all attachments thereto.
- D. The suspension of the judgment will be lifted as to any Defendant if, upon motion by the Commission the Court finds that Defendant failed to disclose any material asset, materially misstated the value of any asset, or made any other material misstatement or omission in the financial representations identified above.
- E. If the suspension of the judgment is lifted, the judgment becomes immediately due as to that Defendant in the amount specified in Subsection A. above which the parties stipulate only for purposes of this Section represents the consumer injury alleged in the

Complaint, less any payment previously made pursuant to this Section, plus interest computed from the date of entry of this Order.

#### VI.

# ADDITIONAL MONETARY PROVISIONS

#### IT IS FURTHER ORDERED that:

- A. Defendants relinquish dominion and all legal and equitable right, title, and interest in all assets transferred pursuant to this Order and may not seek the return of any assets.
- B. The facts alleged in the Complaint will be taken as true, without further proof, in any subsequent civil litigation by or on behalf of the Commission, including in a proceeding to enforce its rights to any payment or monetary judgment pursuant to this Order, such as a nondischargeability complaint in any bankruptcy case.
- C. The facts alleged in the Complaint establish all elements necessary to sustain an action by the Commission pursuant to Section 523(a)(2)(A) of the Bankruptcy Code, 11 U.S.C. § 523(a)(2)(A), and this Order will have collateral estoppel effect for such purposes.
- D. Defendants acknowledge that their Taxpayer Identification Numbers (Social Security Numbers or Employer Identification Numbers), which Defendants must submit to the Commission, may be used for collecting and reporting on any delinquent amount arising out of this Order, in accordance with 31 U.S.C. § 7701.
- E. All money paid to the Commission pursuant to this Order may be deposited into a fund administered by the Commission or its designee to be used for equitable relief, including consumer redress and any attendant expenses for the administration of any redress fund. If a representative of the Commission decides that direct redress to consumers is wholly or partially impracticable or money remains after redress is completed, the Commission may apply any

remaining money for such other equitable relief (including consumer information remedies) as it determines to be reasonably related to Defendants' practices alleged in the Complaint. Any money not used for such equitable relief is to be deposited to the U.S. Treasury as disgorgement. Defendants have no right to challenge any actions the Commission or its representatives may take pursuant to this Subsection.

#### VII.

#### **CUSTOMER INFORMATION**

IT IS FURTHER ORDERED that Defendants, Defendants' officers, agents, employees, and attorneys, and all other persons in active concert or participation with any of them, who receive actual notice of this Order, are permanently restrained and enjoined from directly or indirectly failing to provide sufficient customer information to enable the Commission to efficiently administer consumer redress. Defendants represent that they have provided this redress information to the Commission. If a representative of the Commission requests in writing any information related to redress, Defendants must provide it, in the form prescribed by the Commission, within 14 days.

#### VIII.

#### ORDER ACKNOWLEDGMENTS

IT IS FURTHER ORDERED that Defendants obtain acknowledgments of receipt of this Order:

A. Each Defendant, within seven days of entry of this Order, must submit to the Commission an acknowledgment of receipt of this Order sworn under penalty of perjury.

- B. For ten years after entry of this Order, the Individual Defendant for any business that such Defendant, individually or collectively with the Corporate Defendant, is the majority owner or controls directly or indirectly, and the Corporate Defendant must deliver a copy of this Order to: (1) all principals, officers, directors, and LLC managers and members; (2) all employees, agents, and representatives who participate in conduct related to the subject matter of the Order; and (3) any business entity resulting from any change in structure as set forth in the Section titled Compliance Reporting. Delivery must occur within seven days of entry of this Order for current personnel. For all others, delivery must occur before they assume their responsibilities.
- C. From each individual or entity to which a Defendant delivered a copy of this Order, that Defendant must obtain, within 30 days, a signed and dated acknowledgment of receipt of this Order.

#### IX.

# **COMPLIANCE REPORTING**

IT IS FURTHER ORDERED that Defendants make timely submissions to the Commission:

- A. One year after entry of this Order, each Defendant must submit a compliance report, sworn under penalty of perjury.
- 1. Each Defendant must: (a) identify the primary physical, postal, and email address and telephone number, as designated points of contact, which representatives of the Commission may use to communicate with Defendant; (b) identify all of that Defendant's businesses by all of their names, telephone numbers, and physical, postal, email, and Internet addresses; (c) describe the activities of each business, including the products and services

offered, the means of advertising, marketing, and sales, and the involvement, if any, of the other Defendant (which the Individual Defendant must describe if he knows or should know due to his own involvement); (d) describe in detail whether and how that Defendant is in compliance with each Section of this Order; and (e) provide a copy of each Order Acknowledgment obtained pursuant to this Order, unless previously submitted to the Commission;

- 2. Additionally, the Individual Defendant must: (a) identify all telephone numbers and all physical, postal, email and Internet addresses, including all residences; (b) identify all business activities, including any business for which such Defendant performs services whether as an employee or otherwise and any entity in which such Defendant has any ownership interest; and (c) describe in detail such Defendant's involvement in each such business, including title, role, responsibilities, participation, authority, control, and any ownership.
- B. For 20 years after entry of this Order, each Defendant must submit a compliance notice, sworn under penalty of perjury, within 14 days of any change in the following:
- 1. Each Defendant must report any change in: (a) any designated point of contact; or (b) the structure of the Corporate Defendant or any entity that Defendant has any ownership interest in or controls directly or indirectly that may affect compliance obligations arising under this Order, including: the creation, merger, sale, or dissolution of the entity or any subsidiary, parent, or affiliate that engages in any acts or practices subject to this Order.
- 2. Additionally, the Individual Defendant must report any change in: (a) name, including aliases or fictitious name, or residence address; or (b) title or role in any business activity, including any business for which such Defendant performs services, whether as an employee or otherwise, and any entity in which such Defendant has any ownership interest,

and identify the name, physical address, and any Internet address of the business or entity.

- C. Each Defendant must submit to the Commission notice of the filing of any bankruptcy petition, insolvency proceeding, or any similar proceeding by or against such Defendant within 14 days of its filing.
- D. Any submission to the Commission required by this Order to be sworn under penalty of perjury must be true and accurate and comply with 28 U.S.C. § 1746, such as by concluding: "I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on: \_\_\_\_\_" and supplying the date, signatory's full name, title (if applicable), and signature.
- E. Unless otherwise directed by a Commission representative in writing, all submissions to the Commission pursuant to this Order must be emailed to <u>DEbrief@ftc.gov</u> or sent by overnight courier (not the U.S. Postal Service) to: Associate Director for Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, D.C. 20580. The subject line must begin: *FTC v. Tommie Copper, Inc., et al.*, (S.D.N.Y).

## X.

#### RECORD KEEPING PROVISIONS

IT IS FURTHER ORDERED that Defendants must create certain records for 20 years after entry of the Order, and retain each such record for five years. Specifically, the Corporate Defendant and the Individual Defendant for any business that the Individual Defendant, individually or collectively with the Corporate Defendant, is a majority owner or controls directly or indirectly, must create and retain the following records:

- A. Accounting records showing the revenues from all products or services sold, all
   costs incurred in generating those revenues, and the resulting net profit or loss;
- B. Personnel records showing, for each person providing services, whether as an employee or otherwise, that person's: name, addresses, telephone numbers; job title or position; dates of service; and, if applicable, the reason for termination;
- Complaints and refund requests, whether received directly or indirectly, such as through a third party, and any response;
- D. All records necessary to demonstrate full compliance with each provision of this
   Order, including all submissions to the Commission; and
- E. A copy of each unique advertisement or other marketing material disseminated since the date of entry of this Order.

#### XI.

#### COMPLIANCE MONITORING

IT IS FURTHER ORDERED that, for the purpose of monitoring Defendants' compliance with this Order:

- A. Within 14 days of receipt of a written request from a representative of the Commission, each Defendant must: submit additional compliance reports or other requested information, which must be sworn under penalty of perjury; appear for depositions; and produce documents, for inspection and copying. The Commission also is authorized to obtain discovery, without further leave of court, using any of the procedures prescribed by Federal Rules of Civil Procedure 29, 30 (including telephonic depositions), 31, 33, 34, 36, 45, and 69.
- B. For matters concerning this Order, the Commission is authorized to communicate through counsel of record or other counsel designated by a Defendant or, if Defendant is



unrepresented by counsel with regard to this Order, directly with that Defendant. Defendants must permit representatives of the Commission to interview any employee or other person affiliated with any Defendant who has agreed to such an interview. The person interviewed may have counsel present.

C. The Commission may use all other lawful means, including posing, through its representatives, as consumers, suppliers, or other individuals or entities, to Defendants or any individual or entity affiliated with Defendants, without the necessity of identification or prior notice. Nothing in this Order limits the Commission's lawful use of compulsory process, pursuant to Sections 9 and 20 of the FTC Act, 15 U.S.C. §§ 49, 57b-1.

# XII.

#### RETENTION OF JURISDICTION

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

SO ORDERED:

DATED

UNITED STATES DISTRICT JUDGE



#### SO STIPULATED AND AGREED:

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TAWANA E. DAVIS

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FOMMIE COPPER, INC.

Ву.

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TOMMIE COPPER, INC.

THOMAS KALLISH, individually

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