No. 07-1662

UNITED STATES COURT OF APPEALS
FOR THE SEVENTH CIRCUIT

FEDERAL TRADE COMMISSION,
Plaintiff-Appellee,

v.

QT, INC., Q-RAY COMPANY, BIO-METAL, INC., and QUE TE PARK,
a.k.a. ANDREW Q. PARK,
Defendants-Appellants.

Appeal from the United States District Court for the
Northern District of Illinois, Magistrate Judge Morton Denlow
Case No. 03 C 3578

BRIEF AND REQUIRED SHORT APPENDIX OF DEFENDANTS-APPELLANTS

ORAL ARGUMENT REQUESTED

Helen E. Witt, P.C. (ARDC No. 6183630)
Anthony Casey (ARDC No. 6281142)
Wendy Netter Epstein (ARDC No. 6280712)
(Counsel of Record)

KIRKLAND & ELLIS LLP
200 East Randolph Drive
Chicago, Illinois 60601
Telephone: (312) 861-2000
Facsimile: (312) 861-2200

Attorneys for Defendants-Appellants
QT, INC., Q-RAY COMPANY, BIO-METAL, INC., and QUE TE PARK a.k.a. ANDREW Q. PARK

CIRCUIT RULE 26.1 CORPORATE DISCLOSURE STATEMENT

Appellate Court No: **07-1662**

Short Caption: **FTC v. QT Inc., et al.**

Pursuant to Circuit Rule 26.1, Defendants-Appellants, make the following disclosures:

(1) The full name of every party that the attorney represents in this case (if the party is a corporation, you must provide the corporate disclosure information required by Fed. R. App. P. 26.1 by completing No. 3):

QT, Inc.; Q-Ray Company; Bio-Metal, Inc.; Que Te Park, a.k.a. Andrew Q. Park.

(2) The names of all law firms whose partners or associates have appeared for the party in the case (including proceedings in the District Court or before an administrative agency or are expected to appear for the party in this Court).

Kirkland & Ellis LLP; Ungaretti & Harris LLP; Barnes & Thornburg; Venable LLP; Defrees & Fisk LLC.

(3) If the party or amicus is a corporation:

(i) Identify all of its parent companies, if any; and

None.

(ii) List any publicly held company that owns 10% or more of the party's or amicus' stock:

None.

_____ _____

Wendy Netter Epstein Date
Counsel for Defendants-Appellants

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JURISDICTIONAL STATEMENT

The District Court had subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1337(a) and 1345, and 15 U.S.C. §§ 45(a) and 53(b). The parties consented to a Magistrate Judge's jurisdiction pursuant to 28 U.S.C. § 636(c)(1) on July 21, 2003. (Docket #46)

This Court has jurisdiction pursuant to 28 U.S.C. § 1291. The District Court entered final judgment disposing of all claims on November 14, 2006. (Docket #211) Appellants filed a timely motion to alter or amend judgment pursuant to Fed. R. Civ. P. 52(b) on November 28, 2006. (Docket #218) The District Court denied Appellants' motion on January 22, 2007, except to amend a portion of the remedy. (Docket #245)

On February 23, 2007, all Appellants filed voluntary petitions for relief under Chapter 11 of the Bankruptcy Code in the United States Bankruptcy Court for the Northern District of Illinois. Appellants filed a timely notice of appeal on March 23, 2007. Fed. R. App. P. 4(a)(1)(B); 11 U.S.C. § 108(b)(2). (Docket #264)

STATEMENT OF ISSUES PRESENTED

1. Did the District Court err in holding, as a matter of law, that a product that is efficacious because of a placebo effect cannot be advertised as relieving pain?

2. Did the District Court err in holding that a claim that a product provides pain relief is not reasonably substantiated if the product has not been found effective in a randomized, double-blind, placebo-controlled study?

3. Did the District Court err in finding that six relevant studies, along with substantial anecdotal and observational evidence, did not provide QT with a reasonable basis for making its pain relief claims, where all studies were valid, scientific evidence that reached the same conclusion — that wearing the Q-Ray bracelet relieves pain?

4. Where the burden of proof was on the FTC, were the District Court's decisions to order a minimum disgorgement amount calculated based on the FTC's approximation of profits and to order that all purchasers who attempted to obtain a refund but were denied one as a result of the 10-day policy should be given a refund, clearly erroneous where neither decision was based on the weight of evidence?

5. Did the District Court err in ordering Que Te Park jointly and severally liable for consumer refunds and disgorgement of profits, where the District Court made no finding that Mr. Park knew that the infomercial statements were material misrepresentations, that he was recklessly indifferent to the truth of the representations, or that he was aware of a high probability of fraud, and where the weight of evidence was in fact to the contrary?

STATEMENT OF THE CASE

This is an appeal from the District Court's order following trial, finding that Defendants-Appellants had violated the Federal Trade Commission Act ("FTC Act") by marketing the Q-Ray bracelet in a way that was deceptive or misleading. The District Court granted the FTC permanent injunctive relief and found Defendants QT, Inc., Q-Ray Company, Bio-Metal, Inc. and Que Te Park jointly and severally liable, ordered them to disgorge their profits from the sale of the bracelet, and required them to provide full refunds to all persons who purchased a bracelet during the relevant period.

The District Court entered its final judgment on November 14, 2006. Defendants-Appellants moved for reconsideration on November 28, 2006. The District Court denied that motion on January 22, 2006, except that it lowered the minimum disgorgement amount for QT from $22 million to 15.9 million, and reduced Mr. Park's disgorgement liability to $8.6 million. Defendants-Appellants filed a timely notice of appeal on March 23, 2007.

STATEMENT OF FACTS

I. FACTUAL BACKGROUND

A. Mr. Park Discovers The Bio-Ray Bracelet In Spain.

Que Te Park (a.k.a. Andrew Park) ("Mr. Park"), was born and educated in Korea, where he earned a business degree from the University of Korea. (T.320)[1] He came to the United States in 1982. (T.321) Mr. Park attended classes at the Kellogg School of Management at Northwestern University, and in 1983, he founded QT, Inc. (T.321-322) The original business of QT, Inc. was to sell sunglasses on a wholesale basis. (T.322) Mr. Park also founded the Q-Ray Company, which sold photographic equipment. (T.322-323)

In 1994, Mr. Park came across the Bio-Ray bracelet while traveling in Barcelona. (T.353) He purchased two of the C-shaped bracelets, described by the manufacturer as "polarized" — one for himself and one for his wife, Jung Joo Park. (T.353-354, 360) Before wearing the bracelet, Mr. Park suffered from lower back pain. (T.353-354) He found that wearing the Bio-Ray bracelet completely alleviated that pain. (*Id.*) Additionally, Mrs. Park found that the bracelet relieved her migraine headaches. (*Id.*; R.11)[2]

Mr. Park is not a scientist, a medical doctor, nor a doctor of Oriental medicine, but having had personal results with the product, and as an entrepreneur, Mr. Park approached the Spanish manufacturer about his interest in the bracelets. (T.353-354, 590)

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[1] "(T.__)" refers to the transcript page of the trial before The Honorable Morton Denlow on June 6, 12-15, 19, and July 11, 2006. The transcripts can be found in Volumes 2-8 of the Record on Appeal.

[2] "(R.__)" refers to the page of the attached Required Short Appendix. Pages 1-136 refer specifically to the District Court's Memorandum Opinion and Order.

B. Scientific Studies All Say Bracelet Relieves Pain.

The Spanish manufacturer of the Bio-Ray bracelet provided Mr. Park with a study of the bracelet's efficacy for pain relief, referred to as the "Italian Study." (T.409) Mr. Park also obtained another scientific study, the "Korean Study," from a Bio-Ray distributor. (*Id*.) Both studies indicated that the bracelet was effective in relieving pain. (T.409-410) In addition, Mr. Park obtained the "Chinese Study" from a contact, as well as a letter from Dr. Masayuki Niwa summarizing Dr. Niwa's tests of the Bio-Ray bracelet's efficacy. (T.409-410)

The Q-Ray bracelet and Bio-Ray bracelet are identical products. (T.416-417) The only difference is the name under which the products are marketed. (*Id*.) Based on these four scientific studies, described more fully below, and his own personal experience, Mr. Park believed he had adequate evidence that the Q-Ray bracelet relieved pain. (T.409-410)

1. The Italian Study

The Italian Study was conducted in the early 1990s by Dr. Cesare Tossani at the Valdobbiadene Hospital, Department of General Medicine, in Italy. (A.22[3]; T.413-414) The purpose of the study was to compare the efficacy of the Bio-Ray bracelet, which at the time was termed a "new [] technique," against both a placebo and the transcutaneous electric nerve stimulation (or "TENS") therapy, a pain therapy already in use. (A.24)

The authors of the study described it as "[a] comparative double blind study, randomised and crossover, between BIORAY…and TENS."[4] (A.34) Ninety patients, 75 percent of whom

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[3] "(A.__)" refers to the page of the Joint Appendix submitted with this brief.

[4] A "double blind" study is one in which neither the patient nor the investigator knows whether the patient is receiving the treatment or a placebo. (*See* T.57-58) "Randomization is a statistical technique which provides each individual with the same probability of being either in the group receiving the experimental treatment or in the group receiving a placebo or sham treatment." (T.56-57) According to the FTC's expert, Dr. Hochberg, "the way a crossover study works is that the same (Continued…)

had tried other traditional pain relief therapies "to no avail," were put into three groups of thirty. Each group received one of the three therapies and then switched therapies in the following weeks. By the end of the study, all participants had received all three therapies. Data on the duration and level of patients' pain after receipt of each type of treatment was collected. (A.35, A.44) The data suggested that "the placebo in all groups…[was] the least effective means" and that there was an "important reduction in…pain symptomology [in those] treated with BIORAY…" (A.43)

Ultimately, the study found:

> After this trial we can, without doubt, maintain that BIORAY is valid as a therapeutic means on 2 levels in the treatment of pain of different origin.

(A.44)

2. The Korean Study

The Korean Study was conducted in 1994 by the head of the Internal Medicine Department at Jeonjn Chinese Medical Hospital of Wonkwang University, Dr. Jo Young Shin. (A.120) Dr. Shin randomly selected and tested 50 patients. He asked all study participants to wear the bracelet for "6 weeks except sleeping hours." (A.118) Some participants wore the Bio-Ray Bracelet and others wore a placebo bracelet. (A.119)

Dr. Shin's report compares the efficacy of the active bracelet to the placebo by category of pain suffered. He found that 81.5% of headache sufferers who wore the Bio-Ray bracelet found pain relief as compared to only 26.3% of headache sufferers who wore the placebo. (*Id*.) He found similar results among the patients who suffered from isomatic and nerve pain. (*Id*.)

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patient or same participant really serves as his or her own control," because the same patient receives both active and placebo treatments, and the patient's responses to these treatments are compared. (T.78)

Dr. Shin reported that his study confirmed the product's effectiveness and approved it "for medical treatment." (A.117) The Mayo Clinic would later note that this study "reported benefit with use of the ionized bracelet for headache and for back, hip, leg, and hand pain over a 6-week period." (A.694)

3. The Chinese Study and Letter From Dr. Niwa

The Beijing Municipal Institute of Labor Protection in Beijing, China, designed a "clinical trial to test the function and efficiency of [the] bio-magnetic bracelet and [a] beetling accouterment [sic]" in May 1999. (A.112) It was a small study of 5 persons, three who wore the bracelet and two who wore the beetling device. (*Id*.) The study concluded that the three people who wore the bracelet had "obvious" improvements in their illnesses after wearing the bracelet, while those who wore the beetling accoutrement had no obvious change in their health conditions. (*Id*.)

Dr. Niwa reported similar results. He tested the Bio-Ray bracelet against other types of metal bracelets and found that only the Bio-Ray improved muscle flexibility in his patients. (A.121)

C. QT Markets Bracelet In The United States.

In 1996, QT began marketing the Spanish-manufactured Bio-Ray bracelet in the United States under the trade-name "Q-Ray." Because the term "polarized" (which was the term used by the Spanish manufacturer) was already trademarked by Polaroid, Mr. Park chose to call the Q-Ray bracelets "ionized," and trademarked that term. (DX-12; T.360) At first, QT sold the bracelets mostly on a wholesale basis. (T.327; R.11) Mr. Park and his employees also attended trade shows, where they passed out the bracelets and personally witnessed the pain relief effects on consumers. (T.441-442) Over time, QT received numerous customer letters stating the

customers' satisfaction with the bracelet's pain-relieving effects. (T.1016-1042; A.122-242; DX-17)

In August 2000, QT ran its first infomercial (referred to as the "Prime Time infomercial" in the District Court opinion) for direct to consumer sales of the Q-Ray bracelet. (A.738 ¶ 41; A.496; PX-47) At the time, Mr. Park had in his possession the Italian, Korean, and Chinese studies, as well as the letter from Dr. Niwa. (T.409) QT hired Prime Time Sports to produce this first infomercial, which ran from August 2000 through May 2001, and then in reedited form (the "Onyx infomercial") from June 2001 through October 2001. (A.738 ¶ 42) The infomercial consisted in large part of a series of testimonials, voluntarily given by consumers, most of which were given at a trade show where QT had distributed the bracelets. (PX-47) It is undisputed that the testimonials were real and unscripted. (A.739 ¶ 46; T.401) Many of the testimonialists described the pain-relief effects of the bracelet. (PX-47) Others discussed bracelet effects such as increasing energy, flexibility, and athletic performance. (PX-47)

The infomercial made no claim that the mechanism of efficacy was known or scientifically proven. (PX-47) The infomercial contains a testimonial from a single medical doctor (Dr. Jeremy Cole) who experienced relief from the Q-Ray bracelet and also "used it selectively on some patients." (*Id*. at 14) Dr. Cole did not state that his opinions were scientifically based; rather he reported on personal experience. (*Id*.)

Further infomercials were made in the same vein. The Onyx infomercial was a re-edited version of the Prime Time infomercial that added explicit disclaimers such as QT "makes no claim that there is a scientific consensus…" (PX-49) And while the Onyx infomercial states that the Q-Ray bracelet may work in a manner similar to acupuncture, it also explicitly conceded that "we cannot prove Q-Ray works scientifically…" (PX-49)

The third infomercial, the "Warren infomercial," ran from November 2001 through April 2002, and also contained real and unscripted testimonials relating to pain relief, increased energy, and better athletic performance. (A.738 ¶ 43; A.498; PX-51)

All three infomercials discussed that customers got pain relief from wearing the bracelet. Reflecting the studies Mr. Park had obtained, the Warren infomercial stated that the bracelet "has proven effective in various studies around the world." (PX-51) No claim was made that the method of action was proven or that there was a scientific consensus about the bracelets.

All three infomercials also stated that there was a 30-day money-back guarantee for the bracelets that allowed consumers to return them for a full refund if they were dissatisfied. (A.496-498; PX-47, 49, 51) The refund policy was different — 10 days — for Internet sales. (T.596) Consumers who requested refunds were in fact given their money back, although there were some administrative processing issues when sales of the bracelets quickly increased. (T.1085-1087) Those issues were ultimately resolved. (T.1085) In addition, some Internet purchasers complained about the 10-day policy. (PX-16, 17; A.545-553) This policy was changed so that all purchasers were entitled to a 30-day money back guarantee, but only prospectively. (T.1088)

D. Subsequent Relevant Studies.

Pain is very difficult to study because there is no objective way to test the level of pain a person is experiencing.[5] (T.138) In addition, it is difficult to design placebos when testing a bracelet, the mechanism of which is not completely understood (as opposed to a pill, for which a

[5] As a recent Newsweek article put it: "Doctors don't have any good way of measuring pain from one person to the next. The best they can do is ask patients to rate it for themselves on a scale of 1 to 10, with 10 being the greatest agony of their lives. This is absurdly imprecise." Mary Carmichael, *The Changing Science of Pain*, Newsweek, June 4, 2007, at 43.

sugar pill is easily substituted). (*See* T.1132 ("[Y]ou can't use the same approaches for CAM [complementary alternative medicine] as standard therapies because many of the therapies used in CAM are not pills."), 1148 ("[I]t's very challenging to do the proper study of acupuncture, sham acupuncture.")) Despite these limitations and challenges, a number of other studies were conducted after QT began to market the Q-Ray bracelet that provided further substantiation for its effectiveness.

1. Mayo Clinic Study[6]

In 1999, the Mayo Clinic expressed interest to QT in conducting a randomized, double-blind, placebo-controlled trial of the "Ionized" wrist bracelet. (T.568-569) QT agreed to have the Q-Ray bracelet studied, and in September 1999 signed a Clinical Research Agreement with the Mayo Clinic. (A.752 ¶ 208) QT, having confidence in its product, fully cooperated in the study. (T.568-569)

The study was performed at the Mayo Clinic in Jacksonville, Florida. (A.693) The study enrolled 305 pain-suffering participants who wore the ionized bracelet for four weeks and 305 participants who wore a placebo bracelet. (*Id*.) Participants rated a baseline intensity of pain and then did follow-up pain ratings after 1, 3, 7, 14, 21, and 28 days of wearing the bracelet. (*Id*.)

The study was published in the November 2002 Mayo Clinic Proceedings. It reported that 77.7% of those who wore the active bracelets experienced improvements in their total sum of pain scores after 28 days. (A.696) This meant that nearly 80% of patients wearing the Q-Ray bracelet reported significant improvement in the pain they felt in all body parts combined. (*Id*.)

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6 The District Court admitted the Mayo Clinic Study in evidence, not for the truth of the assertions therein, but for the limited purpose of establishing that Mr. Park had seen the study and for his actions relating to the study. (T.565-566)

Similarly, 77.4% of patients wearing the Q-Ray bracelet experienced a significant decrease in their "maximum pain score," which was the pain score at the most painful point on their body. (A.694, A.696) Mr. Park considered this a great result in terms of the efficacy of the bracelet — a result that was consistent with all other studies he had received. (T.617)

The Mayo study did not find a statistically significant difference in pain relief between those who wore the active bracelets and those who wore the placebos, suggesting that the pain relief was accomplished by virtue of the so-called "placebo effect."[7] (A.696) Methodological errors in the way the study was conducted may have dictated this result, however. For instance, the manager of the study admitted to problems with randomization of participants between the placebo and active groups. (T.177) There was also evidence that the study was underpowered, meaning that because of the relatively small number of participants, the number of drop-outs, and methods of statistical analysis, the study would have been unable to identify anything but a large statistical difference between active and placebo groups. (T.756-768)

Even if the placebo results were accurate, however, the study reported the benefit of promoting effective pain relief. It concludes that "[a]lthough the goal of our study was not to assess the effectiveness of placebos, our results supported the benefits of using placebos to treat pain." (A.696) And indeed, the lead investigator, in a presentation to his colleagues at a national convention, represented that the use of ionized bracelets for the treatment of muscle and joint pain is beneficial. (DX-43 at 63-64)

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[7] The "placebo effect" refers to the phenomenon of patients' conditions improving over the course of a clinical trial even though they receive the placebo and not the active treatment. (T.169)

2. Manginelli Study

In 2002, Dr. Michael Manginelli conducted a single-blind,[8] randomized, placebo-controlled trial through his medical practice in New Jersey. (A.2, A.4) He studied 46 patients who suffered from some degree of pain. (A.2) Dr. Manginelli gave the patients instructions on wearing the bracelet and had them fill out pain questionnaires at study day 3, and then weekly for weeks 1-4. His results indicated:

> The Q-Ray Ionized Bracelet ***relieved pain in 90% of patients compared to 13% for the placebo bracelet*** (P<0.001)…
>
> The Q-Ray Ionized Bracelet effectively relieved pain, increased strength, and improved flexibility.

(*Id*. (emphasis added))

3. Trapp Pain Study

Also in 2002, Deann Trapp, a faculty member at Clarke College in Iowa, conducted a study entitled "An Investigation to Determine the Effectiveness of Q-Ray Ionized Bracelets as Pain Reducers." The District Court referred to this as the "Second Trapp Study." She enrolled 45 volunteers, all of whom were experiencing pain in at least one body part. (A.91) She administered a baseline pain scale to each participant and after giving participants a bracelet (some received Q-Ray bracelets and others received placebo bracelets), asked participants to fill out pain surveys after 5 minutes, 1 hour, 24 hours, and then every day for 5 days. (A.93-94) After performing a statistical analysis, she reported the following results:

> The participants wearing the Q-Ray Ionized Bracelets experienced a significant decrease in self-reported pain after one hour of application of the Q-Ray Ionized Bracelet (p=.000). The pain stayed significantly lower than the self-reported

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[8] A "single-blind" study is one in which the investigator, but not the patient, knows whether the patient has received the treatment under study or a placebo. (T.486)

> baseline pain throughout the course of the research protocol… The participants wearing the placebo bracelets did not have a patterned response to pain… The pain fluctuated inconsistently throughout the study.

(A.95-96)

E. QT Continues To Sell Bracelets And Have High Rates Of Repeat Business.

QT continued to get very positive feedback on the efficacy of the Q-Ray bracelet following the infomercials. Mr. Park estimated at time of trial that approximately 55 percent of current bracelet purchasers were repeat customers. (T.605) Thousands of warranty cards voluntarily sent in by customers also contained positive feedback about the pain-relieving effects.[9] (T.1005-1016; DX-16)

With this positive feedback and studies indicating the pain relief benefits of the bracelet, QT continued to run infomercials. From May 2002 through June 2003, it ran the infomercial attached to Plaintiff's complaint ("the Complaint Infomercial"). (A.738-739 ¶ 44) That infomercial stated prominently on the very first screen that the Q-Ray bracelet:

> is not intended to diagnose, treat, cure or prevent any disease. Q-Ray makes no claim that there is a scientific consensus regarding this product or that the endorsers results are typical. The statements in this program have not been evaluated by the FDA.

(A.447) On multiple occasions throughout, the infomercial reminded viewers that "Q-Ray makes no claim that there is a scientific consensus regarding this product" and "Individual Results May Vary." (*Id*.)

In addition, the infomercial, which, like the others, contained real, unscripted testimonials, emphasized that the bracelet is a "non-medical device," and that the mechanism of

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[9] Some of the warranty cards provided that customers who submitted testimonials for QT's use would be entitled to a discount off a future Q-Ray bracelet purchase. (DX-16; T.1080-1081) This offer would only have been of interest to anyone genuinely happy with the bracelet and therefore likely to purchase another.

efficacy is not necessarily clear. (A.455, A.466, *e.g.* "All I know is it helps. I don't really care the mechanics of it or the science of it. I just know that it's helped me a great deal;" "How does it work? If you're asking me to tell you scientifically how it works, I have no idea. All I can tell you is that when I put it on, I feel better.")

II. PROCEDURAL HISTORY

The FTC filed its complaint against QT, Inc., Q-Ray Company, Bio-Metal, Inc., Que Te Park, and Jung Joo Park pursuant to Section 13(b) of the FTC Act. (Docket #1) The FTC did not first bring an administrative action.

The FTC alleged that the defendants violated § 5(a) and § 12(a) of the Act by making false or unsubstantiated claims that (a) the Q-Ray bracelet provides "immediate significant or complete relief from various types of pain" (count I); (b) tests prove that the Q-Ray bracelet relieves pain (count II); and (c) the 30-day money-back guarantee allowed customers to receive a full refund if they returned the bracelet within 30 days (count III).

A. Trial

The District Court, Magistrate Judge Morton Denlow, conducted a seven-day bench trial. The FTC presented only a single expert who discussed the level of substantiation QT should have been required to have for its claims — Dr. Hochberg.[10] (T.20) The FTC did not offer any expert testimony or any evidence at all of consumer surveys to establish consumers expectations regarding the advertisements, and in fact, did not elicit any consumer testimony at all. Likewise,

[10] The FTC called one other expert — Dr. John Wikswo, Jr., an expert in biological physics, biomedical engineering, and electromagnetism. (T.269; R.9) He testified that the postulated ionization mechanism was not possible because the bracelets could not maintain a charge for any meaningful period of time. However, he also testified that he did not conduct any tests on the Q-Ray bracelets, and he agreed "that if a postulated mechanism for how a product might work is disproven, that doesn't mean the product itself doesn't work." (T.301) He did not give any opinions on the efficacy of the bracelet.

the FTC did not call a damages expert. The only testimony about damages was elicited from Mr. Park using a demonstrative exhibit never received into evidence. (T.363-364)

Defendants called several expert witnesses. Most notably, Dr. Feldstein testified about the requisite substantiation and Dr. Olshansky testified at length about the placebo effect, its benefits, and why the Mayo study should be considered adequate substantiation of efficacy.

1. Dr. Hochberg (FTC Expert)

Dr. Marc Hochberg testified as the FTC's expert in rheumatic diseases, clinical testing related to the prevention and treatment of rheumatic diseases, and pain due to rheumatic disease. (A.756-757 ¶ 259; R.8) On the issue of the level of substantiation required to support the claim that the QT bracelet provides pain relief, Dr. Hochberg testified that a "randomized double-blind placebo- or sham-controlled trial" is required. (T.54) Dr. Hochberg was the only witness to testify in support of this "gold standard."

While postulating this high standard for the QT bracelet, however, Dr. Hochberg at the same time testified that he himself concluded that acupuncture reduced pain by relying on two pilot studies, ***neither of which was a randomized, double-blind, placebo-controlled trial***. (T.164-165) Specifically, in 1997, Dr. Hochberg co-authored a paper that concluded that acupuncture reduced people's perception of pain and that doctors should therefore prescribe acupuncture for pain reduction. (T.164) He came to that conclusion based on one pilot study that tested twelve people and a second involving sixty-eight people. (T.164) Further, he came to that conclusion despite recognizing methodological limitations in the studies. (T.165) For instance, even though the studies did not have a control group, he testified that "[a] study without a control group can be a good study." (T.165) And he agreed that a study without a control group can answer questions about whether an intervention appears to work:

Q. And in the first pilot study you did on acupuncture on 12 people, there was no control group, correct?

A. That's correct.

Q. Based on that study, you concluded that acupuncture appeared to work, correct?

A. In those — yes.

Q. You agree with me that generally a study that is not randomized may be a good study?

A. It certainly may be.

Q. You agree with me that generally a study without a placebo may be a good study?

A. Certainly.

Q. You agree with me generally that a single-blinded study may be a good study?

A. It might be.

(T.165-166 (emphasis added))[11]

In general, even in the absence of a randomized double-blind placebo-controlled trial that "proves" efficacy, Dr. Hochberg testified that he would prescribe a pain intervention if it appeared to be safe. (T.150-151) For instance, he advises his patients to try dietary supplements for three months despite the lack of gold standard evidence of their efficacy because the supplements are safe. (*Id*.) This is the advice he has suggested that his colleagues give to their patients, as well. (T.151) In fact, Dr. Hochberg agreed that generally "in the absence of trial data when there is no harm associated with intervention and there appears to be a benefit, one could make a recommendation to use that intervention based on weaker evidence." (T. 156)

[11] Dr. Hochberg also testified: "Q. You would agree with me that a good observational study may provide better evidence of efficacy than a poor quality randomized study? A. Correct." (T.163-164)

Dr. Hochberg also wrote an editorial in February 2006 on a study of Glucosamine Chondroitin ("GC"), which concluded that although clinical data suggests that GC is no more effective that a placebo, physicians should recommend GC as a treatment for patients because it is safe. (T.143-150; A.243-245)

Dr. Hochberg acknowledged certain difficulties in studying pain relief. For instance, he agreed that pain is wholly subjective. (T.138) He agreed that if people who wear the Q-Ray bracelet say the bracelet helps reduce their perceptions of pain, there is no way to dispute it. (T.139) In other words, only the person experiencing the pain can actually experience it. There is no way to test that pain experience. (T.138)

Lastly, Dr. Hochberg agreed that it is not necessary to know the mechanism by which a treatment works to conclude that it does indeed work. (T.136) He also conceded that despite any methodological limitations in the studies QT offered as substantiation, at least three of them "showed a consistent outcome in a within-group analysis of pain improvement." (T.161) Aside from surgery, Dr. Hochberg was not aware of ***any*** interventions in the field of rheumatology that eliminate pain in 80 percent of the patients other than the Q-Ray bracelet. (T.131-132)

2. Dr. Feldstein (Defendants' Expert)

Dr. Michael Feldstein testified as Defendants' expert in statistics, biostatistics, and the conduct of clinical trials. (T.673-679; R.9) Although he agrees that "double-blind, placebo-controlled, and randomized" studies represent "the epitome or the gold standard of what we do in our business," (T.688) he reviewed the studies QT relied upon to substantiate its pain relief claims (T.681-683), and in his expert opinion, despite some limitations in the studies, he believes the Italian, Chinese, and Korean studies "demonstrate scientific evidence of efficacy." (T.685-686)

Further, after reviewing the full protocol,[12] Dr. Feldstein testified to certain study limitations in the Mayo Clinic study that may account for the lack of a statistical difference in the pain relief effect of the active versus placebo bracelets. (*See, e.g.*, T.770-771)

3. Dr. Olshansky (Defendants' Expert)

Dr. Brian Olshansky testified as an expert in the fields of electrophysiology, complementary and alternative medicine, and the placebo effect. (T.1104-1105, 1110-1111; R.9-10) He confirmed that, contrary to the view in the late 1980s, scientists and doctors no longer believe that a placebo is "inherently worthless." (T.1111-1113) To the contrary, current research shows that even interventions that work solely by the placebo effect can create chemical reactions in the brain that result in a release of endorphins. Essentially, there may be an actual physical, or chemical mechanism by which the placebo effect results in pain relief. (T.1120-1121) Dr. Oshansky testified that placebos may have substantial — even life-saving — benefits for patients. (T.1113) Further, he has often recommended interventions to his patients which he knew were safe, but for which there was no conclusive trial data. (*See* T.1117-1119)

B. District Court Opinion

The court held that the FTC was required to prove that Defendants "lacked a ***reasonable basis***" for asserting that their claim was true, but went on to find that only a "a well-conducted, placebo-controlled, randomized, double-blind study, the ***gold standard***," can be adequate substantiation of a pain-relief claim. (R.100, 108 (emphasis added)) Relying on the Ninth Circuit's decision in *FTC v. Pantron I Corp.*, 33 F.3d 1088 (9th Cir. 1994), concerning a hair regrowth product, the court determined as a matter of law that the Mayo Clinic study, which

[12] Dr. Hochberg's entire review of the Mayo Study was based on his read of the 5-page conclusory report. He did not review any of the underlying data. (T.172)

found 80% efficacy, was irrelevant because a "placebo effect possesses no substantiation value." (R.108-109) It further found that none of Defendants' other studies met the requisite "gold standard" for substantiation. (R.108-110)

The court made these findings without testimony from any expert in consumer psychology or consumer behavior or the assistance of a consumer market survey. (R.104) It held that because the QT infomercials represented to consumers that the Q-Ray bracelet provides immediate pain relief and because such a claim is a "medical, health-related claim," a heightened level of substantiation was required. (R.105-106) The court did not consider the scientific consensus that the bracelets actually provide pain relief in a staggeringly high percentage of users or that the bracelet is a completely safe treatment. The standard the court required to substantiate advertising claims was higher than the standard the FTC's medical expert requires before prescribing treatments for his patients. (T.150-151)

SUMMARY OF ARGUMENT

Before ever advertising the pain-relief effects of the Q-Ray bracelet, QT had in its possession several relevant scientific studies, each of which documented that wearers of the Q-Ray bracelet experienced pain relief. Yet, the District Court held that QT and Mr. Park violated the FTC Act's requirement that advertisements not be materially misleading because none of these studies was a randomized, double-blind, placebo-controlled study. In holding Defendants to this "gold standard," the District Court erred in several respects.

First, the District Court incorrectly held as a matter of law that a placebo effect cannot substantiate a claim of pain relief. This holding is contrary to the purpose of the FTC Act, which is to protect consumer expectations. An advertiser that represents a product as an effective pain relief product when 80 percent of people who use the product experience pain relief cannot be

held to have misled consumers. Nor was the District Court correct to hold that the placebo effect is "worthless" where all of the evidence presented at trial was to the contrary.

Second, the District Court erred in finding as a fact that only a randomized, double-blind, placebo-controlled study can substantiate claims of pain relief. The District Court is the first court ever to have made such a finding, and did so ignoring consumer expectations and evidence specific to this case that dictates a more flexible standard of substantiation.

These two errors led to the District Court's decision that QT did not have adequate substantiation. A review of the substantiating evidence QT presented at trial — six studies, as well as various observational and anecdotal evidence — requires reversal of that decision.

Third, the court's findings with respect to QT's profits (on which its damages calculation was based) and refund policies find no support in the factual record of the case and should be reversed.

Fourth, the court failed to apply the correct legal standard to the question of whether Mr. Park should be held individually liable. Had the court properly conducted the analysis of whether Mr. Park had or should have had knowledge or awareness of any misrepresentations, it necessarily would have found Mr. Park not individually liable.

STANDARD OF REVIEW

Review of the District Court's holding that a claim of pain relief is not substantiated by the placebo effect as a matter of law is *de novo*. *See Murdock & Sons Constr., Inc. v. Goheen Gen. Constr., Inc.*, 461 F.3d 837, 840 (7th Cir. 2006) (conclusions of law reviewed de novo); *FTC v. Verity Int'l, Ltd.*, 443 F.3d 48, 63 (2d Cir. 2006) (same). The court's findings that only a randomized, double-blinded, placebo-controlled study can provide adequate substantiation for a pain relief claim and that defendants did not have adequate substantiation for their claims are

reviewed for clear error. *See Murdock*, 461 F.3d at 840 (findings of fact reviewed for clear error); *Verity Int'l*, 443 F.3d at 63 (same).

This Court reviews a district court's decision to award equitable relief for abuse of discretion, *FTC v. Febre*, 128 F.3d 530, 534 (7th Cir. 1997), and a district court's calculation of damages for clear error. *Lapinee Trade, Inc. v. Boon Rawd Brewery Co.*, 91 F.3d 909, 911 (7th Cir. 1996). A district court abuses its discretion when "the record contains no evidence upon which the court could have rationally based its decision" or "the decision is based on clearly erroneous factual findings." *Gile v. United Airlines, Inc.*, 95 F.3d 492, 495 (7th Cir. 1996).

Finally, this Court reviews the District Court's failure to apply the correct legal standard in determining Mr. Park's individual liability *de novo*. *See Baptist v. City of Kankakee*, 481 F.3d 485, 490 (7th Cir. 2007).

ARGUMENT

I. THE DISTRICT COURT'S CONCLUSION THAT DEFENDANTS VIOLATED THE FTC ACT SHOULD BE REVERSED.

Section 12 of the FTC Act, by its very terms, protects consumers from the dissemination of "false advertisement." 15 U.S.C. § 52(b). The FTC has interpreted this section to require "that advertisers and ad agencies have a reasonable basis for advertising claims before they are disseminated." FTC Policy Statement Regarding Advertising Substantiation at 2 (attached as appendix to *In re Thompson Med. Co.*, 104 F.T.C. 648 (1984)) ("FTC Policy Statement") A "false advertisement" is one "which is misleading in a material respect." FTC Act § 15(a)(1), 15 U.S.C. § 15(a)(1). The FTC may prove that an advertisement is misleading either by proving (1) that the advertisement is false, or (2) that the advertiser lacked a "reasonable basis" for making the representation. *See In re Thompson Med. Co.*, 104 F.T.C. at 818-19. Absent an express or implied reference to a specific level of support, the level of substantiation that provides an

advertiser with a "reasonable basis" for its claims is assumed to be the level of substantiation a consumer reasonably expects based on the claims being made. FTC Policy Statement at 3-4. At all times, the definition of "false advertisement" must be considered in light of the overriding purpose of the FTC Act: "to protect the consumer from being misled by governing the conditions under which goods and services are advertised and sold to individual purchasers." *Nat'l Petroleum Refiners Ass'n v. FTC*, 482 F.2d 672, 685 (D.C. Cir. 1973), *cert. denied*, 415 U.S. 951 (1974).

The District Court made two significant errors — one of law and one of fact flowing from that error of law — in holding QT and Mr. Park liable. First, adopting the reasoning of the Ninth Circuit in *FTC v. Pantron I Corp.*, 33 F.3d 1088 (9th Cir. 1994), it held that when a product's effectiveness results from a placebo effect, any advertising of effectiveness is without reasonable basis as a matter of law, because "[e]vidence of a placebo effect does not constitute 'competent and reliable scientific evidence' and it possesses no substantiation value." (R.114) The court concluded that "[a]n advertiser cannot sell a product based solely on the placebo effect by misleading its customers and making them believe a worthless product actually works." (R.113-114) But, the notion that that an advertiser "mislead[s]" consumers when it represents a product as an effective pain reliever when 80 percent of people who use it experience pain relief defies common sense and frustrates the very consumer expectations the FTC Act is designed to protect. Furthermore, the court's factual determination that products that are efficacious based on the placebo effect are "worthless" is contrary to the consensus of evidence presented at trial, including the testimony of the FTC's own expert.

Second, the District Court concluded that for a "medical, health-related claim," an advertiser only has a reasonable basis when it possesses "'competent and reliable scientific

evidence' to substantiate the claim." (R.106, citing *Sterling Drug, Inc. v. FTC*, 741 F.2d 1146, 1156-57 (9th Cir. 1984).) It then erroneously equated "competent and reliable scientific evidence" for what it termed defendants' "strong, medical claim" with "a gold-standard study," defined as "a well-conducted, placebo-controlled, randomized, double-blind study." (R.108) Setting the reasonable substantiation bar this high was contrary to the weight of the evidence.

Each of these errors compels reversal.

A. The District Court's Conclusion That A Placebo Effect Cannot Substantiate A Claim Of Plain Relief As A Matter Of Law Should Be Rejected.

1. The District Court's Holding Frustrates Consumer Expectations.

The court's holding that claims of product efficacy cannot be substantiated if the product works because of the placebo effect finds no support in the FTC Act. That statute "is concerned not with how [products] work, but with how [they] are sold." *Sears, Roebuck and Co. v. FTC*, 676 F.2d 385, 392 (9th Cir. 1982). Thus, the FTC Act itself does not impose any requirement that advertisers prove a product's mechanism of efficacy; rather, the FTC must look to "what level of substantiation *consumers* expect to support a particular product claim." FTC Policy Statement at 4 (emphasis added). "Extrinsic evidence, such as expert testimony or consumer surveys, is useful to determine what level of substantiation consumers expect." *Id*.

Here, the FTC presented no expert testimony or consumer surveys to establish what level of substantiation consumers reasonably expect when an advertiser claims that a product provides pain relief. Instead, it presented only evidence of what would be required by "qualified experts in the field of pain due to rheumatic disease to support a claim that a product relieves or treats musculo-skeletal pain." (R.106) The purported "gold standard," however, is not even a requirement in the expert's own practice. *See supra* pages 14-16.

Reason suggests that consumers expect a product advertised as effective for pain relief to be *more effective than no product at all*. That is, if using the product relieves pain better than not using it, then the product is, in any ordinary-consumer sense of the word, effective. Moreover, a consumer would not reasonably conclude that the product does not live up to its advertiser's claims of pain relief merely because a better pain reliever exists. If that were the case, then no claim of efficacy could escape liability under the FTC Act unless the subject product was proven to be the best available. Thus, under the FTC Act's consumer-oriented provisions, an advertiser is not required, based solely on claims of efficacy, to have proof that its product is more effective than a placebo.

That this is a correct understanding of what reasonable consumers expect from claims of efficacy is borne out by the evidence introduced at trial. While the FTC presented no evidence on the issue, QT presented uncontradicted testimony to the effect that approximately 55 percent of later-year purchasers of the Q-Ray bracelet were repeat customers. (T.605) In addition, QT introduced warranty cards sent in by thousands of grateful Q-Ray wearers. (DX-16) None of these satisfied customers needed to know whether the Q-Ray bracelet worked only because of a placebo effect or was more effective than a placebo before concluding that it lived up to QT's advertising claims. They simply knew that the bracelet relieved their pain, as claimed. The District Court's rejection of this evidence as irrelevant and unsubstantiating under its erroneous legal conclusion should be reversed.

Finally, although the court found that QT "conveyed the claim that the Q-Ray bracelet provides immediate, significant, or complete pain relief from various types of pain" (R.105), nowhere did the court find that QT made any representation about how the Q-Ray bracelet

works.[13] Neither did the FTC's complaint allege that QT had made any such representation. Accordingly, the District Court's ruling that consumers care about whether a product works by means of some mechanism other than the placebo effect was not based on a finding that QT made unsubstantiated claims about a different mechanism of action.

2. The District Court's Ruling Ignored Uncontradicted Trial Evidence.

The District Court's conclusion that a product that works by way of the placebo effect is "worthless" is not only wrong from the point of view of a consumer (the only point of view that matters under the FTC Act), it is also bad science. The FTC's own expert acknowledged as much. Dr. Hochberg authored an editorial in the New England Journal of Medicine on the dietary supplement Glucosamine Chondroitin. (T.143-151; A.243-245) In that editorial, he opined that, notwithstanding clinical studies showing that Glucosamine Chondroitin was no more effective in treating knee pain than a placebo, doctors should nonetheless continue to prescribe it to patients for whom it does relieve pain. (*Id*.) Similarly, as discussed above, Dr. Hochberg concluded that acupuncture "appeared to work" as a pain reliever, despite the absence of "gold standard" evidence that acupuncture is any more effective than a placebo. (T.165 (acknowledging that no control group was used in the relevant acupuncture studies)) In both of these situations, the FTC's expert concluded that a therapy that may well work only because of a placebo effect is a valuable medical tool that benefits patients. Yet the District Court's holding

[13] In fact, the District Court appears to have recognized that QT made no claims regarding the mechanism of the Q-Ray bracelet. At closing argument, the court queried: "I think the infomercial says they don't really know how it works, doesn't it? Doesn't the infomercial say, we don't really know — we're not claiming we know exactly, we're doing a little chi action here. But they're not representing the mechanism of action, are they?" (T.1267)

would make it fraudulent to advertise this benefit. Such a result should not be the law in this Circuit.

Defendants' witness, Dr. Olshansky, an expert in the fields of complementary alternative medicine and the placebo effect — and the only expert in those fields presented at trial — made the point even more forcefully. When asked, "[T]oday, does the scientific community believe that a placebo is inherently worthless?," he responded: "No, the placebo is not inherently worthless, not only to me, but to the scientific community." (T.1111)

3. *Pantron* Was Wrongly Decided And Should Not Be Followed.

The District Court's ruling that the placebo effect cannot substantiate claims of pain relief is unsupported in the statute or the evidence in this case, and is inconsistent with mainstream clinical practice. As the District Court's brief discussion of this issue makes clear, the primary basis for its ruling was the Ninth Circuit's decision in the *Pantron* case. (R.111-114) For reasons similar to those discussed above, *Pantron*, which involved a hair-growth tonic, not a pain relief treatment, is a fatally flawed opinion, and should be rejected by this Court.

The Ninth Circuit in *Pantron* completely ignored the consumer-protective aim of the FTC Act, and its consequent consumer-oriented approach to false advertising. The court's reasoning demonstrates that its definitions of "truth" and "falsity" were driven by an anti-placebo bias that is not consistent with the statute it was interpreting. For example, the court ridiculed the notion that an efficacy representation for sugar pills could ever be "true" even if the sugar pills actually relieved pain "for some people some of the time[.]" *Pantron*, 33 F.3d at 1099. It then leapt to the conclusion of law that there could be no set of facts (or more accurately, no set of studies or data no matter how supportive of efficacy) that could make a sugar pill efficacy claim "true" if the efficacy was based on a placebo effect even if the product "does work to some extent." Further, the Ninth Circuit went on to declare that whether an advertisement is true in "ordinary

parlance" is irrelevant under the FTC Act. *Id*. at 1099-1100. As it is the ordinary parlance of consumers that dictates what claims are made and how they are reasonably understood in advertising, this aspect of the Ninth Circuit's ruling is inexplicable. *See, e.g., Kraft, Inc, v. FTC*, 970 F.2d 311, 314 (7th Cir. 1992) ("[A]n advertisement is deceptive under the Act if it is likely to mislead *consumers, acting reasonably under the circumstances*, in a material respect." (emphasis added)); *Nat'l Bakers Servs., Inc. v. FTC*, 329 F.2d 365, 367 (7th Cir. 1964) ("The important criterion in determining the meaning of an advertisement is the net impression that it is likely to make on *the general populace*." (emphasis added)).

The District Court's opinion in this case highlights the absurdity of the *Pantron* reasoning. The court said: "when a product's efficacy is based solely on the placebo effect, the advertiser must misrepresent the effectiveness of the product. The customer must be duped." (R.113) Again, QT made *no representation* that its product did not work by way of the placebo effect. This ruling, therefore, effectively declares that customers are "duped" by statements that are "true" in "ordinary parlance."

The crux of *Pantron*'s holding is its conclusion that advertising claims are necessarily misleading if they are in some measure self-fulfilling. 33 F.3d at 1100; *see also U.S. v. An Article . . . Acu-Dot . . . ,* 483 F. Supp. 1311, 1315 (N.D. Ohio 1980). The District Court adopts this error in pointing out that the Q-Ray bracelet would have been less effective as a pain reliever had it not been marketed as one. (*See* R.113) But this observation is beside the point, because a self-fulfilling advertisement can be just as true as any other. The statute's sole concern is *whether* an advertiser's claims are fulfilled (substantiated), not *how*. A claim that substantiates itself is no less truthful than claims substantiated otherwise, and consumers are not improperly misled by such claims. This is most certainly true in the context of pain relief, where (unlike hair

growth) subjective self-perception is all that matters. If an advertiser has a reasonable basis to claim that a product will reduce pain, it is no more "misleading" to advertise that claim than it is unethical for a doctor to prescribe Glucosamine Chondroitin.

Of course, the essential error in the *Pantron* court's ruling was its assumption that a placebo is "inherently worthless." 33 F.3d at 1090 n.1. For the reasons addressed above, this contention is wrong from the point of view of a consumer and clinical science, especially when considered in the context of the medical profession's evolving understanding of the value of the placebo effect. According to Dr. Olshansky, scientific consensus that the placebo effect has significant clinical value has been growing "since the mid 1990s." (T.1114) The *Pantron* opinion, issued more than a decade ago, cannot reflect the current scientific understanding. *Acu-Dot*, the 1980 Ohio District Court case relied upon in *Pantron*, *see Pantron*, 33 F.3d at 1100 (quoting *Acu-Dot*, 483 F. Supp. at 1315), is likewise out of step with current clinical thinking.

Finally, the *Pantron* ruling is vastly overbroad. The Ninth Circuit ruled that the placebo effect cannot substantiate claims of efficacy, *as a matter of law*, in any context. Determining the level of substantiation required under the FTC Act, however, is necessarily an intensely factual inquiry. *See* FTC Policy Statement at 3-4. Regardless of whether the *Pantron* court's conclusion was correct under the facts of that case, it was inappropriate for the court to rule that the placebo effect cannot constitute adequate substantiation of efficacy claims under *any* circumstances.

Indeed, the factual distinctions between the *Pantron* hair growth claims and the pain relief claims here are of precisely the type that one would expect to be significant to the substantiation inquiry. For instance, in *Pantron*, the FDA had issued a regulation determining that all labeling claims for external hair loss products were "false, misleading, or unsupported by

scientific data." 33 F.3d at 1092 (quoting 21 C.F.R. § 310.527(a)). To the contrary, contemporary medical consensus is that the placebo effect is an especially powerful tool for the treatment of pain (and is not necessarily applicable to other physical ailments).[14] This evolving science should be reflected in the law as well. *See* Anup Malani, Regulation with Placebo Effects at 42-43 (2007) (unpublished manuscript), *available online at*: http://works.bepress.com/anup_malani/1/ (arguing that *Pantron* should be overruled because its ban on advertising based on placebo effects "bars the promotion of — or at least artificially raises the price of — an otherwise valuable product." "[S]urely it is wrong-headed to forego valuable placebo effects simply because they are not an 'inherent' in a given product.").

B. The District Court Erred In Finding That Only A "Gold Standard" Study Could Provide Reasonable Substantiation For QT's Claims.

The District Court was the first court ever to find that a company possessing numerous supporting studies, all supporting the same conclusion, cannot advertise that the product relieves pain because the company did not have a randomized, double-blinded, placebo-controlled study proving pain relief. (R.108-110) This Court should reject this remarkably high standard. The District Court's requirement that only a "gold standard" study can be sufficient substantiation is (a) unsupported by the case law, (b) contrary to the purpose of the FTC Act, and (c) unsupported by the factual record.

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[14] *See, e.g.*, A.696 ("[O]ur results supported the benefits of using placebos to treat pain."); T.1111-17 (detailing the progression of medical consensus on placebos). *See also* Asbjorn Brobjartsson & Peter C. Gotzsche, *Is The Placebo Powerless? An Analysis of Clinical Trials Comparing Placebo with No Treatment*, 344 New Eng. J. Med. 1594 (2001) (seminal study cited in A.693-697 finding a statistically-significant placebo effect for pain relief). Even the Food and Drug Administration, which condemned all external hair growth formulas, recognizes "The Healing Power of Placebos." *See* http://www.fda.gov/fdac/features/2000/100_heal.html (last visited 6/6/2007).

1. The Requirement That All "Heath-Related" Claims Have "Gold Standard" Substantiation Does Not Find Support In The Case Law.

None of the cases cited by the District Court supports its conclusion that all health-related advertising requires gold-standard substantiation. (*Cf.* R.106-108) *Sterling Drug, Inc. v. FTC*, 741 F.2d 1146, 1156-57 (9th Cir. 1984), states that the FTC may require claims of "therapeutic performance" to be supported with "competent and reliable scientific evidence." *Id*. at 1156. As the District Court recognized, *Sterling Drug* left open the issue of "what amounts to 'competent and reliable scientific evidence.'" (R.106) In fact, in a passage not acknowledged by the District Court, the *Sterling Drug* court noted that the FTC has "acknowledged that the requirement of competent and reliable scientific evidence was intended to be flexible. The Commission refused to equate the requirement with the well-controlled clinical tests standard, stating instead it would determine the standard on a case-by-case basis." 741 F.2d at 1156.

FTC v. Sabal, 32 F. Supp. 2d 1004, 1007 (N.D. Ill. 1998), says nothing about the appropriate standard of substantiation because that issue was not before the court. The advertiser in *Sabal* did not contest that gold standard clinical testing was required in that case. *Id*. at 1007-08. Nor does *FTC v. SlimAmerica, Inc.*, 77 F. Supp. 2d 1263, 1274 (S.D. Fla. 1999), provide support. That case turned on express representations made by the advertiser that it had "credible clinical studies" that "scientifically validated" its claims. The Florida court appropriately focused on what evidence consumers would expect in light of those express representations and required the heightened standard. *Id*.; *see also FTC v. California Pacific Research, Inc.*, No. CV-N-88-602BRT, 1991 WL 208470, at *4 (D. Nev. Aug. 27, 1991) (same).

QT, on the other hand, made no such representation and stated in its infomercial that it "makes no claim that there is a scientific consensus…" and "cannot prove Q-Ray works scientifically…" (PX-49; *see also* A.443-495) While the District Court concluded that

Defendants' infomercials "imply efficacy proved by scientific principles" (R.41-42), it cites only portions of the infomercials that suggest a relationship between the mechanism of the bracelets and certain eastern medicine therapies in support of this conclusion. In fact, the manifest weight of the evidence is that defendants did not make any claim that they had clinical, let alone gold standard studies supporting the bracelets' efficacy.[15]

2. The District Court Did Not Consider The Level Of Substantiation the FTC Act Contemplates, Nor The Evidence In This Case That Dictates A More Flexible Standard Of Substantiation.

The District Court's conclusion that only a "***gold standard***" study can be sufficient substantiation is not what the FTC Act contemplates, nor is it what the evidence in this case dictates.

As a threshold matter, the District Court's analysis improperly collapses the falsity and reasonable basis tests into one. *See, e.g., FTC v. Enforma,* 362 F.3d 1204, 1217 n.14 (9th Cir. 2004) (explaining that FTC requirement to produce gold standard test to prove falsity does not mean gold standard testing required for an advertiser to reasonably substantiate its claims). By requiring a gold standard study, the District Court incorrectly requires QT to prove that its claims are true, and by the highest standard imposed by the scientific community, instead of reasonably substantiated. The District Court therefore improperly shifts the burden of proof from the FTC, where it is placed by statute, to advertisers. *Porter & Dietsch, Inc. v. FTC,* 605 F.2d 294, 306 (7th Cir. 1979) (burden of proof must remain entirely on the Commission). This cannot be the

[15] The District Court pointed to a single line, delivered by an announcer in a single infomercial, that "Q-Ray has proven effective in various studies around the world." (R.41) This line in the Warren infomercial is not tantamount to a claim of scientific validity. (PX-51) This statement referred to the various confirmatory studies QT had in its possession at the time it was made and conveys no claim about the specific methodology of those studies. Without some evidence that consumers would have necessarily concluded that the "various studies" were of the type the District Court subsequently found were required, its conclusion that the representation was misleading is clearly erroneous.

requirement that Congress had in mind, lest there be a massive barrier to entry for any small business or entrepreneur wanting to advertise a new, safe product that actually works. The District Court's finding that ***all*** health-related claims require such gold-standard testing could result in a significant stifling of innovation that is completely at odds with the consumer-friendly goals of the FTC Act.

Additionally, the court's analysis does not take into account consumer expectations and consumer's interests in light of the actual claims QT made. The court concluded that a heightened level of substantiation was *per se* required because QT made a claim that "tests prove" the efficacy of the bracelet. (R.116) But an advertiser need have only the level of substantiation *a consumer* would expect based on the actual claims. The FTC's policy statement takes the position that when an advertiser makes an express substantiation claim "(e.g., 'tests prove', 'doctors recommend', and 'studies show'), the Commission expects the firm to have at least ***the advertised level of substantiation***." FTC Policy Statement at 3 (emphasis added). Accordingly, if an advertiser conveys that clinical testing has proven the efficacy of a product, the advertiser is required to have gold standard clinical testing. But QT did not make such claims. Indeed, it explicitly conceded that "Q-Ray makes no claim that there is a scientific consensus regarding this product" and "we cannot prove Q-Ray works scientifically," (A.443-495; PX-49).

None of the record evidence the District Court relies on is to the contrary. For instance, the District Court finds that the infomercials "convey the message that the Q-Ray bracelet is analogous to acupuncture and other eastern medicine theories as proof that it is a scientifically proven remedy." (R.41) While the infomercials do state that the bracelet's potential mechanism is "often related" to acupuncture, analogizing the bracelets to forms of Eastern medicine does not

convey that clinical tests have proven their efficacy. Rather, it suggests to consumers that the Q-Ray bracelet is, like acupuncture and tai chi, a treatment that lies outside the medical mainstream.

The District Court also makes much of a segment in the Complaint infomercial with Dr. James Christiansen. (*See* R.37-39) Dr. Christiansen performs a test of the Q-Ray bracelet using an "infrared imager" to measure the body temperature of a patient. The result of the test is a decrease in the patient's blood flow, which Dr. Christiansen explains is typically associated with inflammation and pain, after five minutes of wearing the Q-Ray bracelet. The District Court ruled that "[t]he totality of the discussion [with Dr. Christiansen] creates the net impression that tests prove the Q-Ray bracelet relieves pain." (R.39) But this too is an unreasonable interpretation. In fact, the segment indicates not that "tests prove," but only that ***one particular experiment is consistent*** with the assertion that the Q-Ray bracelet relieves pain.

Nor is the testimonial from a single medical doctor (Dr. Jeremy Cole) who experienced relief from the Q-Ray bracelet and also "used it selectively on some patients," tantamount to a claim that gold standard testing proves the bracelet's efficacy. (*See* R.39-41)

While the Court cited the FTC's policy statement enumerating factors to consider in determining what constitutes a "reasonable basis" for a claim, it largely failed to consider them. (R.101-102) The FTC's policy statement is not binding, but provides a guideline for the sort of factual questions the court should take into consideration. *See, e.g., Kraft,* 970 F.2d 311 (extensively citing the policy statement). The FTC's policy statement suggests that a court consider: "[1] the type of claim, [2] the product, [3] the consequences of a false claim, [4] the benefits of a truthful claim, [5] the cost of developing substantiation for the claim, and [6] the amount of substantiation experts in the field believe is reasonable." FTC Policy Statement at 3-

4. Applying these factors to the evidence before the court, it is apparent that the court abused its discretion by requiring gold standard testing.

First, the claims at issue are claims of pain relief. Such claims, as the FTC's primary expert acknowledged, can in fact be, and commonly are, substantiated by studies that do not meet the gold standard. Dr. Hochberg testified that studies lacking a control group, a placebo, or double-blinding, can be good studies. (T.165-166) Indeed, as discussed above, Dr. Hochberg was comfortable concluding from a non-placebo-controlled study that acupuncture is an effective pain reliever.

Second, the product at issue is a pain relief device with a largely unknown mechanism of action. Designing a placebo for such a device is a logical impossibility. A placebo is by definition "inert," but where a device's mechanism of action is unknown, one could never be absolutely certain that the placebo is inactive. (T.58)

Third, the consequences of a false claim in this case would be limited. The FTC has never suggested that the Q-Ray bracelet adversely affects consumers' health. Accordingly, were QT's pain-relief claims not ultimately provable, though reasonably based, the only harm to consumers would be economic.[16] That harm would be further limited by the fact that a significant fraction of the sale price for the higher-end bracelets is attributable to their aesthetic value. (*See* T.1047-1048)

Fourth, the benefits of an accurate claim are high. It is uncontested that pain is exceedingly difficult to treat. The FTC's expert conceded that for arthritis pain, as an example,

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[16] Although a violation of the FTC Act may involve purely economic harm, the fact that a product threatens no physical harm to consumers is relevant in determining the appropriate level of substantiation for efficacy claims. *See In re Thompson Med. Co.*, 104 FTC 648, 824-25 (1984).

other than surgery, there is no known treatment that relieves pain in 80 percent of patients. (T.131-132) Studies relied upon by QT relate that many study participants who found relief by wearing the Q-Ray bracelet were previously unable to alleviate their pain despite having tried traditional pain-relief methods. (*See* A.44)

Fifth, the cost of developing the kind of substantiation required by the District Court (a "gold standard" study) is high. (T.807)

Sixth, and finally, the expert testimony does not support imposition of a gold standard testing requirement for pain relief claims. Dr. Hochberg's testimony on this point was self-contradictory. Although he initially suggested that gold standard testing was absolutely essential to substantiate claims of pain relief (*see* T.54), he nevertheless acknowledged that "a study without a control group can be a good study," that "a study that is not randomized may be a good study," that "a study without a placebo may be a good study," and that "a single-blinded study may be a good study." (T.165-166) Indeed, as noted at various points above, Dr. Hochberg himself accepted the results of less-than-gold standard studies in concluding that acupuncture and Glucosamine Chondroitin should be used to treat pain. (T.165; T.143-151; A.243-245) Dr. Feldstein, for his part, acknowledged that gold standard clinical testing is the best scientific evidence available (T.688), but denied that scientific experts would necessarily require such evidence to substantiate claims of pain relief. (*Cf.* T.869-870 (Feldstein testimony that even the FDA "doesn't always require that kind of study"))

In short, the factual inquiry the District Court did not conduct suggests that the substantiation required for QT's claims of pain relief is much more flexible than the strict gold standard the court imposed.

II. THE DISTRICT COURT'S CONCLUSION THAT QT DID NOT HAVE ADEQUATE SUBSTANTIATION RESULTED FROM APPLICATION OF ITS ERRONEOUS STANDARD AND SHOULD BE REVERSED.

The District Court acknowledged that while the Defendants bear the initial burden of establishing what substantiation they relied on for their claim, "[t]he FTC has the burden of proving that Defendants' purported substantiation is inadequate." (R.105) QT met its initial burden by proffering multiple consistent studies showing that wearing the Q-Ray bracelet relieves pain. (A.1-54, A.86-121) As a result, the burden of proving that the substantiation was inadequate shifted to the FTC, which did not prove that the substantiation was not reasonable except by resort to the gold standard requirement. Nor did the Mayo Clinic study, which was not published until November 2002, refute QT's evidence of efficacy.[17] The District Court's decision that QT did not have adequate substantiation for its claims flowed from the incorrect legal standard the District Court applied and various erroneous factual conclusions.

First, applying its erroneous conclusion of law, the District Court completely discounted all studies in which a possible placebo effect could not be ruled out. *See supra* § I(A). Had the District Court correctly determined that a study showing pain relief in 80% of the study population provides reasonable substantiation for a claim regardless of the mechanism of efficacy, the Mayo Clinic Study would have provided adequate substantiation for Defendants' pain relief claims. (A.693-697)

[17] As noted above, *supra* page 10, the Mayo Study was flawed in several respects. These criticisms do not automatically invalidate the Mayo Study, but they certainly mean it was not a gold standard study sufficient to refute the totality of QT's other evidence.

Second, the District Court's conclusion determined that only a gold standard study could substantiate Defendants' pain relief claims was also incorrect, *see supra* § I(B), and should not have been a basis for finding QT's six scientific studies to be inadequate substantiation.

Third, the District Court committed clear error in determining that QT's studies did not satisfy even a "copper" standard. (R.114) The evidence clearly showed that the studies were valid, scientific evidence that reasonably demonstrated that wearing the Q-Ray bracelets relieved pain. (T.161 (Hochberg concession that studies showed a "consistent outcome in a within-group analysis of pain improvement"); T.685-686 (Feldstein testimony that studies "demonstrate scientific evidence of efficacy"))

The Korean Study, which was provided to QT before it ever ran an infomercial, was a randomized, placebo-controlled study conducted at a medical hospital. (A.117-120) The court found the study to be insufficient substantiation because (a) QT received only the final report and not the underlying data, statistical analysis, or description of procedures; (b) the study used the Bio-Ray bracelet and not the Q-Ray bracelet; and (c) the study does not claim to be double-blinded. (R.44-45, 68)

The fact that QT did not receive the underlying data is particularly irrelevant given that the FTC's own expert, Dr. Hochberg, testified that the Mayo Clinic study was a "gold standard" study without reviewing any of the underlying data. (T.172) If Dr. Hochberg, a Professor of Medicine, Epidemiology & Preventive Medicine, and the Head of the Division of Rheumatology & Clinical Immunology at the University of Maryland School of Medicine (A.755 ¶ 254; PX-293), can reach that conclusion without reviewing the underlying data, Mr. Park, a non-scientist (T.409-410), should certainly have been entitled to rely on the study summary. Nor is it availing that the study tested the Bio-Ray bracelet and not the Q-Ray

bracelet. The evidence is undisputed that the bracelets are, identical, but for name. (T.416-417) The reality is that while the court's criticisms may support a conclusion that the Korean Study is not gold, they do not support the conclusion that it is not reasonable scientific evidence of efficacy.

The same holds true for the other studies as well. The Manginelli study was a single-blind, randomized, placebo-controlled outpatient trial. (A.1-21) The court criticizes it on the basis that QT did not receive the underlying data, it was only single-blinded, it lacked specificity, was labeled "draft," and Mr. Park knew Dr. Manginelli personally. (R.51) None of these criticisms leads to a reasonable conclusion that the study is not worthy of any weight. (T.165-166)

The Italian study was a "comparative double blind study, randomised and crossover, between BIORAY…and TENS." (A.22-54) Again, the District Court maintained erroneously that there was significance to the fact that the Bio-Ray bracelet was used in the study, despite evidence that the Bio-Ray and Q-Ray bracelets are identical in all but name. (R.45, 64-66) The District Court also faulted the study write-up for not adequately describing the population being studied, the placebo itself, or the pain measurements taken and for not being properly blinded. (R.65-66) None of these criticisms merit wholly discounting the study.

The Trapp pain study was placebo-controlled. (A.86-108) The District Court faulted the study for the patient population being too small, although with 45 participants, the study population was four times larger than the population of a study Dr. Hochberg relied upon to determine that acupuncture provided pain relief. (T.164) The District Court also found the study inadequate because it was single-blinded and did not contain enough information in the write-up. (R.64)

The totality of the District Court's criticisms of all these studies does not reasonably lead to the conclusion that they should be rejected as reasonable basis for QT's advertising claims, especially when considered together. Nor do the criticisms even call into question the overall conclusion that wearing the bracelet relieves pain in a large percentage of people who try it. In sum, these studies provide a wealth reasonable substantiation for the conclusion that the bracelets relieve pain.[18]

Finally, adding to the study evidence was QT's anecdotal and observational evidence, which the District Court erred by discounting entirely. (R.60, 66) The FTC did not dispute that the infomercial testimonials were all true, that Mr. Park spoke to many thousands of satisfied customers, (T.328), that 55% of later year customers were repeat customers (T.605), or that QT received thousands of warranty cards and letters espousing the pain-relief benefits of the bracelet. (T.1005-1016; A.122-242; DX-16, 17) Dr. Hochberg agreed that observational evidence may provide evidence of efficacy. (T.163-164) The District Court clearly erred in holding that all of this evidence did not amount to adequate substantiation.

III. THE DISTRICT COURT'S FINDINGS WITH RESPECT TO QT'S PROFITS AND REFUND POLICIES WERE CLEARLY ERRONEOUS.

The District Court ordered QT to disgorge "profits made during the period of the four infomercials plus interest." (R.133) Specifically, the court ruled that the FTC's approximation of the relevant profits at $22 million was reasonable, and based its disgorgement award on that figure. (*See id*; R.176) The court also ruled that QT's advertised refund policies were false because of a shorter internet-purchase policy, and ordered a refund to all purchasers who were

[18] The Chinese Study (A.109-116) and Dr. Niwa letter (A.121), although small studies, were at the very least in agreement with the other studies and useful as additional evidence of efficacy.

denied one as a result of the 10-day policy. (R.79-88, 117-121) Each of these rulings was clearly erroneous.

In awarding monetary relief under the FTC Act, a District Court must engage in a burden-shifting analysis. *FTC v. Febre*, 128 F.3d 530, 535 (7th Cir. 1997). First, the FTC must show that its calculation of damages represents a reasonable approximation. *Id.* Only then does the burden shift to the defendant to show that the calculation is inaccurate. *Id.* For a District Court to accept the FTC's damages calculation as reasonable, and thus proceed beyond the first step, that calculation must be "properly supported in the record." *Id.* at 536.

In this case the FTC presented ***no evidence whatsoever*** to support its damages calculation. Although the parties stipulated to various ***sales*** figures, defendants did not stipulate to any ***profit*** numbers. (*See* A.764-765 ¶¶ 377-383) Nor did the FTC present any additional evidence on the subject of QT's profits. Nevertheless, the District Court initially accepted the FTC's $22 million profit figure as reasonable based on an exhibit, PX-70, that was never entered into evidence. (*See* R.90) Upon QT's motion for reconsideration, the court acknowledged this error, but maintained that the $22 million figure was adequately supported by the trial testimony of Que Te Park relating to that exhibit:

> Q. Why don't we go to an exhibit. It would be Plaintiff's Exhibit 70. Plaintiff's Exhibit 70 is a profit and loss statement that QT, Inc., has provided the Federal Trade Commission, and I…would like to blow up the column on the year 2002…
>
> ***
>
> Q. [F]or 2002, the net income to the company was approximately $9 million…Can you see that?
>
> A. Yeah. I can see that, yes.
>
> Q. Okay. And for 2003 going across, the net income was about $12 million; is that correct?

A. Yes, I can see that.

Q. And then the net income for the years 1996 though September of '03 is about $22 million; is that correct?

A. Yes, I can see that.

(T.363-364; R.174) The District Court concluded that by this testimony Mr. Park had confirmed the $9 million, $12 million, and $22 million numbers as accurate. (*See id*. at R.176) That conclusion is clearly erroneous. The FTC asked Mr. Park in the very first question only whether he "could see" the numbers displayed in the exhibit for 2002. Mr. Park's consistent answer to this and subsequent questions, "[y]es, I can see that," was evidence of nothing more than his observation of PX-70. Mr. Park was not asked to verify the accuracy of the stated numbers, and did not adopt the numbers as his own. The document was never authenticated and absolutely no other foundation was laid for the figures. It was therefore clear error for the District Court to rely on these numbers to find that "[t]he FTC's approximation, while far from ideal, was reasonable." (*See* R.176) Because the $22 million had no factual support in the record, it was an unreasonable approximation of QT's profit, and the FTC did not meet its initial burden. The District Court abused its discretion in calculating a minimum disgorgement based on that amount, and the disgorgement order should be vacated.

Further, even if there were support in the record for the amount of QT, Inc.'s *total profits* during the relevant period, the FTC still did not meet its burden of proving the amount of QT's *ill-gotten gains* from the allegedly deceptive advertising. That is, the equitable relief of disgorgement is remedial, intended not to be punitive, and is ordered only to "prevent[] the defendant from being unjustly enriched by his fraud." *Febre*, 128 F.3d at 537 (citing *Randall v. Loftsgaarden*, 478 U.S. 647, 671-72 (1986)). The FTC made no attempt to establish what portion of QT's total profits were attributable to the alleged fraud. Although the District Court

reduced the $22 million disgorgement figure to account for wholesale sales (which undisputedly did not result from any false advertising), the court still erred in failing to put the FTC to its burden to reasonably establish what amount of QT's total sales were attributable to the alleged fraud and not to businesses irrelevant to the FTC Act claims.

Similarly, the record contains no evidence to suggest that QT's refund policy constituted false advertising. The District Court cited QT's different return policies for different methods of purchase (i.e., by telephone or by Internet) and thereby determined that some customers were adversely affected by the different return periods. But there is no evidence that any claim in QT's advertising was false or that customers were not aware of the different return periods. The District Court relied upon a few affidavits and e-mails to conclude that customers were confused by QT's return policies. (*See* R.83 (citing PX-16, 17; A.545-553)) In fact, however, most of these communications were from potential customers who had questions about the differing policies. (*See* A.545-553) In other words, they at least recognized that the policies did differ.

The testimony of QT's Executive Vice President, Charles Park, explaining that in 2003, QT made "prospective" improvements to the refund policy to make it 30 days for all methods of purchase is not to the contrary. (T.1088) This testimony does not support the conclusion that any infomercial purchasers did not receive refunds if they requested them within 30 days or that any Internet purchasers were misled into thinking they had 30 rather than 10 days to request a refund. In sum, all infomercial purchasers received the benefit of the 30 day refund policy. (T.1087) The court's decision that the refund policy was deceptive is not based in any record evidence and is clearly erroneous.

IV. THE DISTRICT COURT APPLIED THE WRONG LEGAL STANDARD IN FINDING MR. PARK INDIVIDUALLY LIABLE AND IN ORDERING MONETARY RESTITUTION.

The District Court found Mr. Park "individually liable for the violations" and entered

judgment against him "jointly and severally" with the corporate defendants. (R.129, 135) For an individual to be held liable under the FTC Act, the FTC must prove that the individual "had actual knowledge of material misrepresentations, [was] reckless[ly] indifferen[t] to the truth or falsity of a misrepresentation, or [had] an awareness of a high probability of fraud along with an intentional avoidance of the truth." *FTC v. Amy Travel Serv., Inc.*, 875 F.2d 564, 574 (7th Cir. 1989) (internal citation and quotation omitted); R.129. Here, the District Court found Mr. Park liable based solely on the fact that he had authority to control the corporate defendants' allegedly deceptive acts and participated directly in them. (R.129) The District Court did not find that Mr. Park knew that the infomercial statements were material misrepresentations, that he was recklessly indifferent to the truth of the representations, or that he was aware of a high probability of fraud. *Id.*; *FTC v. Garvey*, 383 F.3d 891, 900 (9th Cir. 2004). This was an error of law.

Amy Travel is not to the contrary. (*Cf.* R.129) There, this Court rejected the argument that the FTC was required to prove subjective intent to defraud, but explicitly held that "[t]he FTC is required to establish the defendants had or should have had knowledge or awareness of the misrepresentations." 875 F.2d at 574. The *Amy Travel* defendants wrote the deceptive scripts at issue in that case, were "undoubtedly aware of the avalanche of consumer complaints," and further, the court specifically found that the defendants' attempts to clear up problems (of which they were accordingly aware) were "grossly inadequate." *Id.* at 575. Essentially, the court found that the individual defendants in that case were liable even under the standard that they had or should have had knowledge of the misrepresentations. *Id.*

The District Court in this case, however, made no such finding, nor could it have. The evidence showed that while Mr. Park knew what statements were being made in the infomercials

and approved the scripts, he thought the infomercial statements were ***true***. (T.409-410) This belief was not based on intentional ignorance, but rather on scientific studies, which the FTC's own expert agreed were relevant to the question of whether the Q-Ray bracelets relieved pain. (A.1-54, A.86-121; T.161) Mr. Park is neither a scientist nor an expert in statistics. (T.409-410) He had access to several studies that, despite certain imperfections he could not be expected to recognize, presented a consensus that the bracelets relieved pain. He had personally worn the bracelet and experienced pain relief, as had his wife. (T.353-354; R.11) He also had had upwards of 8,100 conversations with users who told him that the bracelet relieved their pain. (T.328) Given these facts, Mr. Park should not have been held liable.

At the very least, the District Court erred in holding Mr. Park liable for individual, monetary restitution. *See Porter & Dietsch*, 605 F.2d at 309 (extent of party's culpability should affect nature of relief granted). Contrasted with injunctive relief, several courts have held that the FTC is required to meet a higher burden to establish that restitution from an individual defendant is appropriate. *See, e.g.*, *Garvey*, 383 F.3d at 900 "to hold an individual liable for restitution, the FTC must also show that the individual had actual knowledge of the material misrepresentations, was recklessly indifferent to the truth or falsity of a misrepresentation, or had an awareness of a high probability of fraud along with an intentional avoidance of the truth." *Cf. Amy Travel Serv., Inc.*, 875 F.2d at 574 (rejecting distinction between restitution and injunctive relief, but requiring proof of knowledge for both equitable awards). *See also FTC v. Kitco of Nevada, Inc.*, 612 F. Supp. 1282, 1292 (D. Minn. 1985) (to obtain monetary equivalent of rescission, FTC must prove defendant had knowledge that corporation or its agents "engaged in dishonest or fraudulent conduct").

Mr. Park is similar to the defendant in *Garvey*. Steve Garvey was a celebrity spokesperson for the Enforma weight loss system. He personally lost weight using the system, as did his wife. *Garvey*, 383 F.3d at 894. In addition, he read booklets from Enforma that seemed to substantiate the claims, he spoke to several individuals who had experienced positive results, and he learned of a relevant study. *Id*. The *Garvey* court found that based on this record, the defendant did not have knowledge of material misrepresentations. *Id*. at 896.

Just like *Garvey*, it was reasonable for Mr. Park to believe the representations the infomercials made about pain relief given his personal experience, his wife's experience, the customer feedback he personally received, and the studies that all found the bracelets relieved pain. In fact, Mr. Park had far more evidence of efficacy allowing him to believe the truth of the pain relief claims than Mr. Garvey did in that case.

CONCLUSION

For all of the foregoing reasons, Defendants-Appellants respectfully request that the judgment of the District Court be reversed and judgment be entered in favor of Defendants-Appellants.

Dated: June 14, 2007

Respectfully submitted,

Helen E. Witt, P.C. (ARDC No. 6183630)
Anthony Casey (ARDC No. 6281142)
Wendy Netter Epstein (ARDC No. 6280712)
(Counsel of Record)

KIRKLAND & ELLIS LLP
200 East Randolph Drive
Chicago, Illinois 60601
(312) 861-2000 (telephone)
(312) 861-2200 (facsimile)

Attorneys for Defendants-Appellants QT, Inc., Q-Ray Company, Bio-Metal, Inc., and Que Te Park, a.k.a. Andrew Q. Park

CERTIFICATE OF COMPLIANCE

The undersigned counsel certifies that this brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) because this brief contains 13,481 words. Counsel further certifies that this brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type-style requirements of Fed. R. App. P. 32(a)(6) because this brief has been prepared in a proportionally spaced typeface using Microsoft Word in Times New Roman type style and 12 point type in the body of the brief and 11 point type in the footnotes.

_____ _____

Wendy Netter Epstein Date
Counsel for Defendants-Appellants

CIRCUIT RULE 30(d) STATEMENT

Pursuant to Circuit Rule 30(d), I hereby certify that all material required by Circuit Rule 30(a) and (b) are included in the attached Required Short Appendix.

_____ _____

Wendy Netter Epstein
Counsel for Defendants-Appellants

Date

CIRCUIT RULE 31(e) CERTIFICATION

Pursuant to Circuit Rule 31(e), the undersigned counsel certifies that a digital version of this brief has been filed with the Court on CD-Rom, that the digital version is in a PDF format and was generated by printing to a PDF from the original word processing file, and that the CD-Rom containing the digital version is virus-free. Counsel further certifies that the documents contained in the Rule 30, Required Short Appendix, are also available on the CD-Rom, but in non-searchable PDF format.

_____ _____

Wendy Netter Epstein Date
Counsel for Defendants-Appellants

CERTIFICATE OF SERVICE

I, Wendy Netter Epstein, certify that on June 14, 2007, I caused 15 copies of the attached BRIEF AND REQUIRED SHORT APPENDIX OF DEFENDANTS-APPELLANTS, and a digital version of the brief in PDF format, to be filed with the Clerk of the Court for the United States Court of Appeals for the Seventh Circuit via hand delivery. I further certify that I caused two copies of the BRIEF AND REQUIRED SHORT APPENDIX OF DEFENDANTS-APPELLANTS, and a digital version of the brief in PDF format to be delivered by overnight Federal Express:

John F. Daly
Imad D. Abyad
Federal Trade Commission
600 Pennsylvania Ave., N.W.
Washington, D.C. 20580

_____

Wendy Netter Epstein

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