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UNITED STATES DISTRICT COURT

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SOUTHERN DISTRICT OF OHIO

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DINO RIKOS, TRACEY BURNS, and
18 LEO JARZEMBROWSKI, On Behalf of
Themselves, All Others Similarly Situated
and the General Public,

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Plaintiffs,

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v.

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22 THE PROCTER & GAMBLE
COMPANY,

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Defendant.

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Case No.: 11-CV-00226-TSB

CLASS ACTION

SECOND AMENDED CLASS ACTION
COMPLAINT

Judge: Honorable Timothy S. Black
Courtroom: 815
Date Filed: September 21, 2010
Trial Date: TBD

DEMAND FOR JURY TRIAL

1 Plaintiffs Dino Rikos, Tracey Burns, and Leo Jarzembrowski (“plaintiffs”), by and
 2 through their attorneys, bring this action on behalf of themselves, all others similarly situated
 3 and the general public against defendant The Procter & Gamble Company (“Procter &
 4 Gamble”), and state:

5 NATURE OF THE ACTION

6 1. This is a consumer protection class action addressing the advertisements
 7 Procter & Gamble makes about its over-the-counter “digestive care” product called Align®.
 8 Through its advertising and labeling, Procter & Gamble claims that Align provides “digestive
 9 care” by helping to:

- 10 • **Build and maintain** a healthy digestive system
- 11 • **Restore** your natural digestive balance
- 12 • **Protect** against occasional digestive upsets

13 Procter & Gamble claims in its advertising, including the packaging for Align, that these
 14 health benefits result because “Only Align Contains Bifantis®, a Unique, Patented Probiotic,”
 15 that “**restore[s] your natural balance and bring peace to your digestive system.**” Procter &
 16 Gamble has no support for these claims, even though it states that it does, going so far as to
 17 claim it has clinical proof. Procter & Gamble’s representations are false, misleading and
 18 reasonably likely to deceive the public.

19 2. In March 2009, Procter & Gamble began nationally marketing Align.
 20 Prominently placed on its product packaging and in its other advertisements, Procter &
 21 Gamble stated and continues to state that Align contains the unique and patented probiotic
 22 bacteria “Bifantis®.” Procter & Gamble advertised and continues to advertise that “Align is
 23 different because only Align contains Bifantis, a patented probiotic strain,” that “brings peace
 24 to your digestive system” and provides a “restored natural balance to your digestive system.”
 25 For marketing its Align product, Procter & Gamble uses its trademarked phrase “GREAT
 26 DIGESTION THROUGH SCIENCE™.”

27 3. In truth, the ingredient matrix found in Align has never been substantiated,
 28 clinically or otherwise, and Procter & Gamble has no legitimate basis to make these claims. In

1 fact, the only purported clinical trial that Procter & Gamble discusses on its website concerns
2 the effects of Bifantis® in treating symptoms of inflammatory bowel disease (“IBS”), rather
3 than the general population, to whom the advertisements are targeted. Even then, the study
4 concludes that “[n]o statistically significant differences between [placebo and Bifantis] groups
5 were observed at any time-point” relating to daily IBS symptom assessments. Results from
6 this Procter & Gamble funded study are not published in a peer-reviewed scientific journal.

7 4. Procter & Gamble conveyed and continues to convey its deceptive claims about
8 Align through a variety of media, including the Internet, in-store sampling, point of sale
9 displays, and on the Align® probiotic supplement’s labels and labeling. These representations
10 appear prominently and conspicuously on every Align container.

11 5. Through this advertising, Procter & Gamble has conveyed one message: Align,
12 with its probiotic bacteria cultures, provides clinically proven digestive health benefits to the
13 general public. Attached as Exhibit 1 to the First Amended Complaint is a collection of some
14 of the advertisements and labeling containing the false and deceptive advertising claim. *See*
15 Docket Entry (“D.E”) No. 9-1.

16 6. Procter & Gamble’s advertising and marketing campaign is designed to cause
17 consumers to buy Align as a result of this deceptive message, and Procter & Gamble has
18 succeeded. Despite being nothing more than a sugared capsule filled with naturally occurring
19 bacteria, a 28-count package of Align retails for approximately \$30. According to Procter &
20 Gamble, even before its nationwide retail launch, Align was the No. 1 gastroenterologist-
21 recommended probiotic supplement.

22 7. Plaintiffs brings this action on behalf of themselves and other similarly situated
23 consumers in the United States to halt the dissemination of this false and misleading
24 advertising message, correct the false and misleading perception it has created in the minds of
25 consumers, and obtain redress for those who have purchased Align. Plaintiffs allege violations
26 of the California Consumers Legal Remedies Act, California’s Unfair Competition Law,
27 Florida’s Deceptive and Unfair Trade Practices Act, Florida’s Statutory False Advertising
28 prohibition, Illinois’ Consumer Fraud and Deceptive Business Practices Act, the New

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1 Hampshire Consumer Protection Act, North Carolina's Consumer Protection Act, and breach
2 of the express warranty created by its advertising, including its labeling.

3 **JURISDICTION AND VENUE**

4 8. This Court has original jurisdiction pursuant to 28 U.S.C. §1332(d)(2). The
5 matter in controversy, exclusive of interest and costs, exceeds the sum or value of \$5,000,000
6 and is a class action in which members of the Class of plaintiffs (defined below) are citizens of
7 states different from Procter & Gamble. Further, greater than two-thirds of the Class members
8 reside in states other than the state in which Procter & Gamble is a citizen.

9 9. By order dated April 13, 2011, the Southern District of California granted
10 Procter & Gamble's motion to transfer venue to this Court. Venue is proper in this Court
11 pursuant to 28 U.S.C. §1391 in that many of the acts and transactions giving rise to this action
12 occurred in this district and because defendant:

13 (a) is authorized to conduct business in this district and has intentionally
14 availed itself of the laws and markets within this district through the promotion, marketing,
15 distribution and sale of its products in this district;

16 (b) does substantial business in this district; and

17 (c) is subject to personal jurisdiction in this district.

18 **PARTIES**

19 10. Plaintiff Dino Rikos is a resident of the state of Illinois. During the Class
20 period, and in San Diego, California, and Naperville, Illinois, Plaintiff Rikos was exposed to
21 and saw Procter & Gamble's claims by reading the Align label, purchased Align at various
22 drug stores in San Diego, California, and Naperville, Illinois in reliance on these claims, and
23 suffered injury in fact and lost money as a result of the unfair competition described herein.
24 Plaintiff Rikos purchased Align at various times beginning in or about the second half of 2009,
25 and continued to purchase Align for close to, but less than one year.

26 11. Plaintiff Tracey Burns is a resident of the state of Florida. During the Class
27 period, and in Mooresville, North Carolina, and Orland, Florida, Plaintiff Burns was exposed
28 to and saw Procter & Gamble's claims by viewing the Align print and television

1 advertisements, and reading the Align label, purchased Align in Mooresville, North Carolina,
2 and Orland, Florida in reliance on these claims, and suffered injury in fact and lost money as a
3 result of the unfair competition described herein. In or about early April 2011, Plaintiff Burns
4 first purchased Align at the CVS on 274 North Main Street, Mooresville, NC 28155 and also
5 at the Wal-Mart on 169 Norman Station Blvd., Mooresville, NC 28117. Thereafter, and
6 beginning in or about May 2011, Plaintiff Burns purchased Align continuously through
7 approximately December 2011, primarily at the Publix Super Market on 2873 S. Orange Ave.,
8 Orlando, FL 32806-5403. Each time she purchased Align, Plaintiff Burns paid approximately
9 \$40 for the 42-count size of Align.

10 12. Plaintiff Leo Jarzembrowski is a resident of the state of New Hampshire.
11 During the Class period, and in New Hampshire, Plaintiff Jarzembrowski was exposed to and
12 saw Procter & Gamble's claims by reading the Align label, purchased Align at Walgreens in
13 Milford, NH, Rite-Aid in Milford, NH and/or CVS on Route 101-A in Merrimack, NH, in
14 reliance on these claims, and suffered injury in fact and lost money as a result of the unfair
15 competition described herein. Plaintiff Jarzembrowski purchased Align at various times
16 beginning in or about January or February 2011, and continued to purchase Align until
17 approximately late summer 2011. Plaintiff Jarzembrowski paid approximately \$30 for 30-day
18 supplies of Align.

19 13. Defendant Procter & Gamble is a global company headquartered in Cincinnati,
20 Ohio with operations in approximately 80 countries. Procter & Gamble is the self-described
21 largest consumer packaged goods company in the world. Procter & Gamble designs,
22 manufactures, markets and sells beauty and grooming, health and well-being, and household
23 care products, including Align. In 2009, Procter & Gamble spent \$7.5 billion on advertising,
24 and had sales exceeding \$76.7 billion.

25 **FACTUAL ALLEGATIONS**

26 14. In March 2009, on the heels of very successful marketing launches of
27 "functional," "probiotic" products by food industry giants, and following two years of a
28 scripted marketing plan selling Align exclusively through its website, a toll-free number, and

1 doctors specializing in stomach ailments, Procter & Gamble announced the U.S. retail launch
2 of Align. According to Align's brand manager at Procter & Gamble, "People take vitamins on
3 a regular basis to help keep their bodies in shape. This dietary supplement can help your body,
4 just like a vitamin." The brand manager also stated, "[w]e know consumers with episodic
5 digestive problems are looking for real solutions, and Align is a clinically proven option....
6 Because Align is grounded in real science and meets a real consumer health need, we expect it
7 to become a cornerstone brand in our personal health care portfolio."

8 15. Since the launch, Procter & Gamble has consistently conveyed the message to
9 consumers throughout the United States that Align, with its unique, patented probiotic bacteria
10 Bifantis®, provides probiotic protection and builds and maintains a healthy digestive system.
11 According to Procter & Gamble, the benefits of Align are backed by clinical proof supporting
12 the "patented probiotic strain exclusively found in Align." These claims are not substantiated
13 and are factually baseless.

14 16. The use of bacteria for probiotic use is in its scientific infancy. In fact,
15 scientists have yet to settle on a definition of probiotic. The World Health Organization's
16 definition of probiotics is "Live microorganisms, which, when administered in adequate
17 amounts, confer a health benefit on the host." The National Center for Complementary and
18 Alternative Medicine ("NCCAM"), one of the centers that makes up the National Institutes of
19 Health, adds that probiotics have an ultimate goal of prevention and treatment of disease.

20 17. On its packaging and labeling, Procter & Gamble defines probiotics: "**What**
21 **are probiotics?** Simply put, probiotics are good bacteria essential for many vital body
22 functions, including healthy digestion." On its website, Procter & Gamble provides a
23 substantially similar definition of probiotics: "What Is a Probiotic? Simply put, probiotics are
24 good bacteria that confer a health benefit and are essential for many vital body functions,
25 including healthy digestion."

26 18. Scientists have not yet mapped the tens of thousands of bacteria strains in the
27 human body's intestinal flora, and do not know whether increasing one type of bacteria
28 provides health benefits. It is also not known whether increasing one type of bacteria can

1 prove harmful. The European Food Safety Authority (“EFSA”), established by the European
2 Union to promote food safety and evaluate food claims, reports that “The numbers/proportions
3 of bacterial groups that would constitute a ‘balanced/healthy’ intestinal flora have not been
4 established. Increasing the number of any groups of bacteria is not in itself considered as
5 beneficial.” EFSA states that:

6 The gastrointestinal tract is populated with a large number of microorganisms
7 and it normally acts as an effective barrier against generalized systemic
8 infections. It is not possible to provide the exact number of bacterial groups
9 that would constitute a beneficial microbiota.

10 19. There is almost no scientific support for the notion that healthy people, such as
11 those targeted by Procter & Gamble, benefit from bacterial supplements, such as the bacteria at
12 issue. If probiotic bacteria do have any health benefits, they must survive the digestive tract in
13 sufficient quantities to achieve the possible benefit. However, there is no consensus on the
14 quantities of probiotics people might need to ingest, or for how long, in order to achieve a
15 probiotic effect, if probiotics have any such effect in healthy people.

16 20. Using the term as a marketing tool, and without regard to whether it actually
17 delivers any probiotic benefits, Procter & Gamble calls its product “Align® probiotic
18 supplement.” In fact, Procter & Gamble has no legitimate basis to claim that the bacteria with
19 which it laces Align has any beneficial effects when people consume it, that it helps or
20 replaces bacteria naturally found in the human body, that it reduces the growth of “harmful”
21 bacteria, promotes healthy digestion or restores the digestive system.

22 PROCTER & GAMBLE’S CLAIMS ABOUT ALIGN

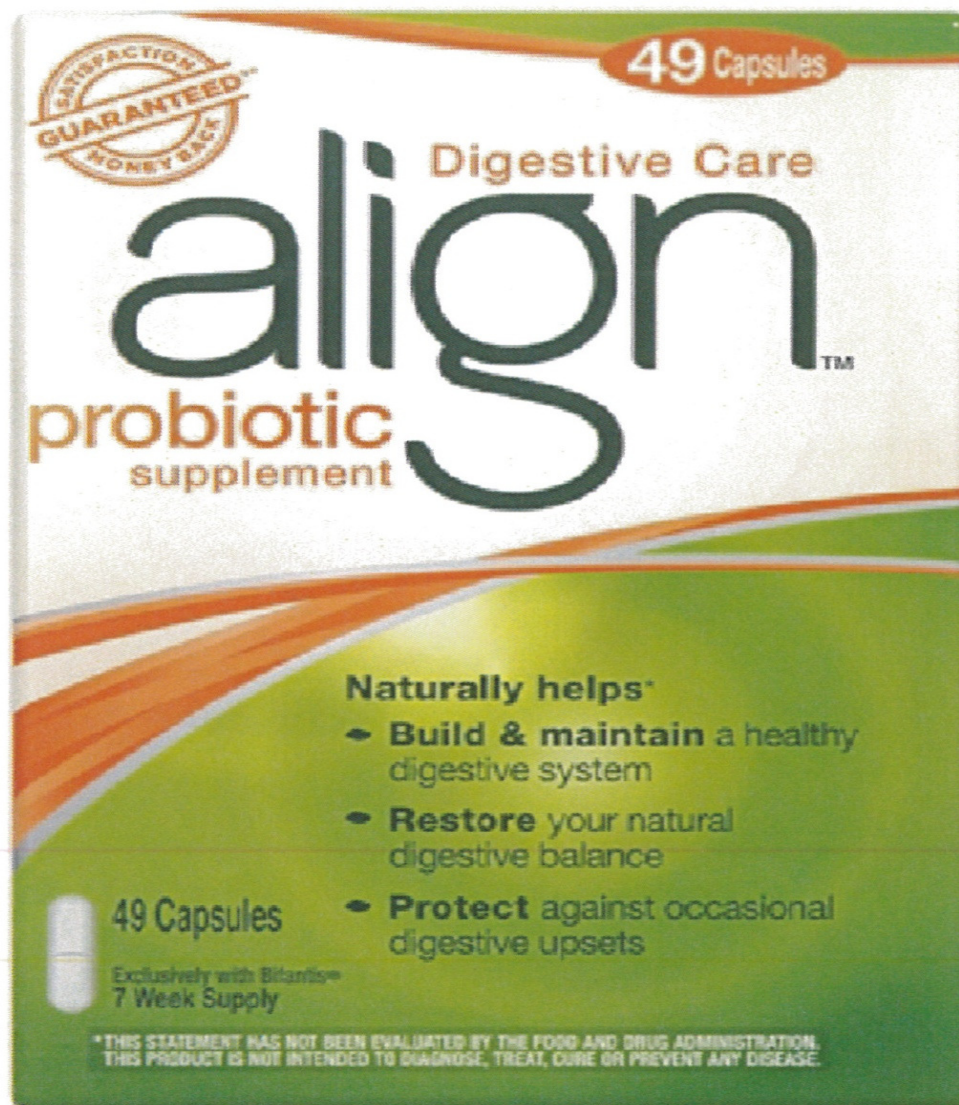
23 21. Procter & Gamble claims Align, “**Naturally helps: Build & maintain** a health
24 digestive system; **Restore** your natural digestive balance; [and] **Protect** against occasional
25 digestive upsets.” According to Procter & Gamble, “10 years of research went into the
26 formulation of Align®, the only probiotic supplement with patented Bifantis®.”

27 22. Despite inadequate testing, Procter & Gamble states that Align is beneficial for
28 healthy and unhealthy people alike; Align is “for people with healthy digestive function who

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1 are looking for help with occasional digestive upsets or who are interesting in promoting their
2 digestive health.”

3 23. Align is described in a medical manner as coming in a “capsule” form. The
4 label on each package of Align substantially appears as follows:



24. On every Align label, Procter & Gamble also prominently claims:

25 **A few words on good bacteria**

26 Your body needs beneficial bacteria for a number of things, including healthy
27 digestion. But they’re fragile. Common issues, such as diet, antibiotic use, changes in
28 routine, travel and stress can disrupt your natural balance of good bacteria. Bifantis®,

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1 only found in Align®, is a probiotic that naturally replenishes your digestive system
2 with healthy bacteria.

3 **Why take Align®?**

4 With just one capsule a day each day, Align helps to build and maintain your digestive
5 health with active probiotic bacteria that support your body's own natural defenses,
6 providing ongoing protection against occasional digestive upsets.

7 **What are probiotics?**

8 Simply put, probiotics are good bacteria essential for many vital body functions,
9 including health digestion.

10 **What makes Align Digestive Care special?**

11 Align contains the patented, pure-strain probiotic bacteria Bifantis® (*Bifidobacterium*
12 *infantis* 35624), which helps naturally balance your digestive system. Bifantis was
13 developed by Gastroenterologists and, when taken daily, will help your body build and
14 maintain a healthy digestive system.

15 Procter & Gamble did not and does not have substantiation for these statements, which are
16 false and misleading and reasonably likely to deceive the average consumer.

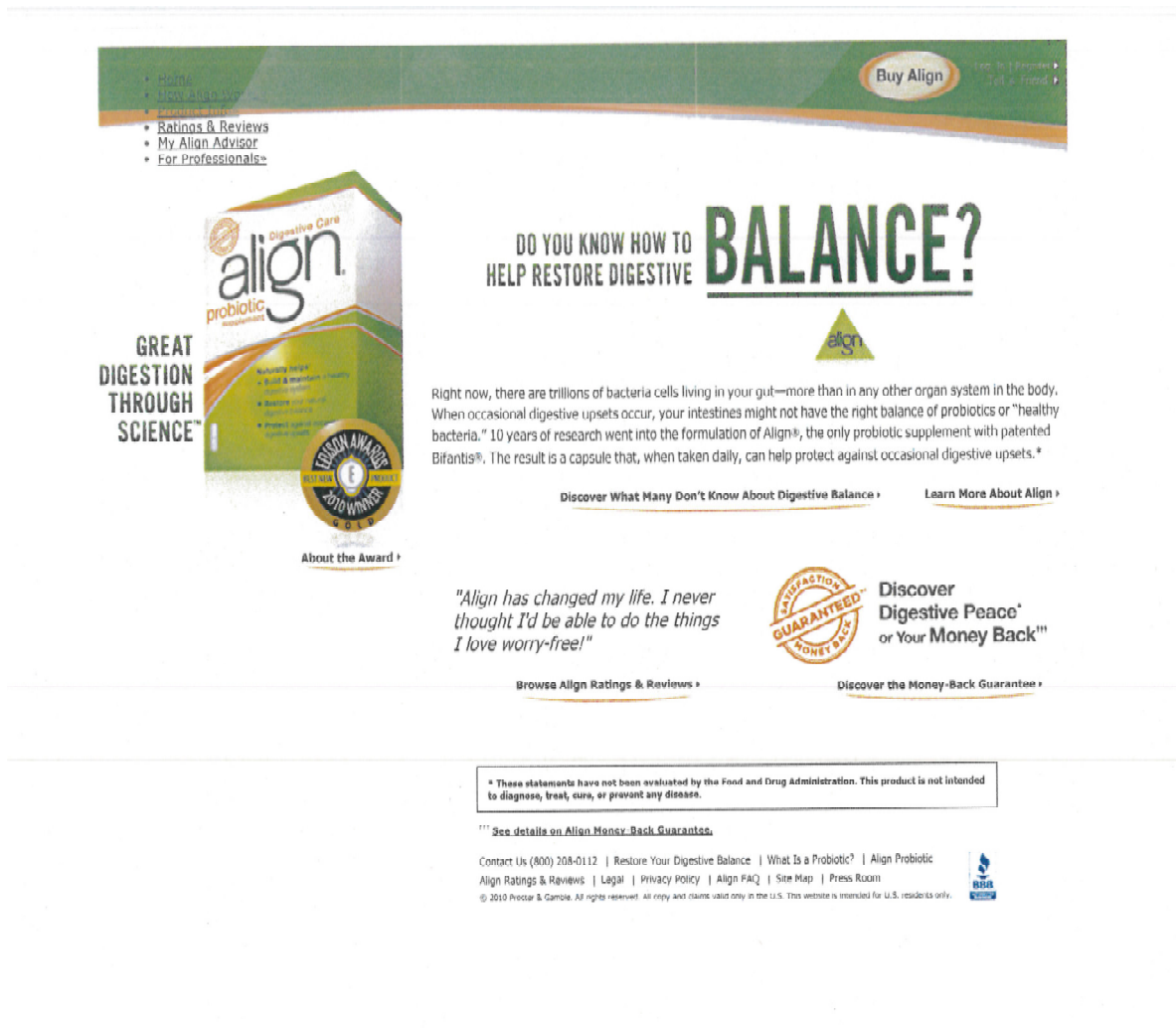
17 25. Procter & Gamble deceptively describes Align and Bifantis® on its
18 www.aligngi.com and www.bifantis.com websites. These websites are available to the general
19 public and Procter & Gamble's advertisements in other media promote these websites.
20 Without sufficient testing or substantiation, Procter & Gamble makes the following similar
21 claims on its websites:

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26. On the Align packaging and websites, Procter & Gamble claims that the bacteria culture in Align was developed by doctors and is supported by clinical proof. The Align advertising statements – conspicuously stated on the product label and websites – include:

- Bifantis was developed by Gastroenterologists and, when taken daily, will help your body build and maintain a healthy digestive system.
- **Proof:** Bifantis has been the subject of several clinical studies and has been featured in peer-reviewed journals. Please see Bifantis.com for full details.
- Recommended by Gastroenterologists
- **GREAT DIGESTION THROUGH SCIENCE™**

1 27. In addition to making untested and unsubstantiated claims, Procter & Gamble's
2 advertising claims that Align has a "Money-Back Guarantee," is likely to deceitfully induce a
3 placebo effect on consumers, irrespective of any actual probiotic effect.

4 28. On Align packaging, reprinted below, Procter & Gamble states
5 "SATISFACTION – **GUARANTEED** – MONEY BACK."

6 29. On the Align website, Procter & Gamble also promotes the limited "money-
7 back guarantee":

- 8 • **Find Digestive Peace ...**
9 **or Your Money Back.**

- 10 • **Peace of Mind at Checkout**

11 We proudly stand behind the performance of Align® and believe that our
12 patented supplement can help you with your occasional digestive upsets.

13 30. The front page of the Align website also contains purported testimonials from
14 consumers regarding the benefits of Align:

- 15 • *"Align has changed my life. I never thought I'd be able to do the things I love*
16 *worry-free!"*

17 The Align website has a page entitled "Align Rating & Reviews" where Procter & Gamble
18 states that "Others have experienced an occasional digestive imbalance and have found Align
19 to be an effective solution." The Align ratings and testimonials reinforce the deceptive
20 advertising, misrepresenting Align's ability to combat and ward off digestive system
21 deficiencies. These statements are not adequately supported by the scientific evidence or
22 otherwise substantiated.

23 **SUBSTANTIATION FOR THE CLAIMS DOES NOT EXIST**

24 31. According to a June 2006 report on probiotics published by the American
25 Academy of Microbiology "there is no conclusive evidence that altering the microbiota of a
26 healthy human adult is beneficial." The report, entitled "Probiotic Microbes: The Scientific
27 Basis," was prepared by the American Academy of Microbiology, a leadership group of the
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1 American Society of Microbiology, which is the leading professional association of
2 microbiologists.

3 32. Procter & Gamble deceptively conveys the marketing message that Align has
4 been clinically tested and proven. For example, the product labeling states “Clinically proven
5 to naturally defend against 5 signs of digestive imbalance.” And on its website, Procter &
6 Gamble provides purported scientific information and data, including “clinical publications,”
7 regarding Bifantis®.

8 33. There are no proper clinical studies that provide substantiation, clinical or
9 otherwise, for Align’s digestive health claims.

10 34. There is widespread consensus within the legitimate scientific community
11 concerning the proper research and testing that must be conducted to substantiate a claim made
12 for a given effect ascribed to a probiotic bacteria. As the American Society for Microbiology
13 concluded in a symposium focusing on purported probiotic bacteria used in food:

14 There is a pronounced need for large, carefully designed (randomized, placebo
15 controlled) clinical trials of probiotics that undertake broad sampling of host
16 microbiota, have clear end points, and have well informed participants who
17 consent to treatment. Investigations like these are needed to overcome the
18 placebo effect [of probiotic treatments] and other barriers to the thorough
19 investigation of probiotic products.¹

20 35. A properly conducted clinical or scientific trial – *e.g.*, one capable of providing
21 substantiation for Procter & Gamble’s claims – is the well-designed, randomized controlled
22 trial (“RCT”).² In RCTs, human study subjects similar to each other are randomly assigned to
23 receive either the test substance or a placebo. Double-blind RCTs, where neither the patient
24 nor the administering researcher knows which intervention is placebo, is preferred and
25 considered more accurate than a single-blind RCT. Procter & Gamble has not so much as
26 attempted to undertake such a process for Align.

27 ¹ R. Walker & M. Buckley, “Probiotic Microbes: The Scientific Basis,” at 19 (colloquium
28 convened before the American Society of Microbiology, Nov. 5-7, 2005).

² M. Araya, *et al.*, “Guidelines for the Evaluation of Probiotics in Food” (Food and
Agriculture Organization of the United Nations and World Health Organization, Report of
a Joint Working Group, April 30 and May 1, 2002), http://www.who.int/foodsafety/fs_management/en/probiotic_guidelines.pdf (last visited March 29, 2012).

1 36. According to a leading group of international scientists and researchers, there
2 should be a proven correlation in human trials when claiming probiotic health benefits in food
3 products:

4 The principle outcome of efficacy studies on probiotics should be proven
5 benefits in human trials, such as statistically and biologically significant
6 improvement in condition, symptoms, signs, well-being or quality of life;
7 reduced risk of disease or longer time to next occurrence; or faster recovery
8 from illness. Each should have a proven correlation with the probiotic tested.³

9 37. On its bifantis.com website, Procter & Gamble identifies clinical publications
10 which purportedly substantiate the advertising claims for Align. As explained below, a review
11 of the studies identified by Procter & Gamble demonstrates the falsity of its claims.

12 38. On its website, Procter & Gamble cites to an unpublished purported “clinical
13 trial” involving *B. infantis*, which it funded.⁴ The cited trial involved persons with IBS
14 symptoms, not the general health population to whom Procter & Gamble markets Align.
15 Moreover, the Procter & Gamble trial concluded that the group receiving *B. infantis* did **not**
16 report greater relief in IBS symptoms. That is, the Procter & Gamble trial concluded that “[n]o
17 statistically significant differences between [the control group and *B. infantis* group] were
18 observed at any time-point” relating to daily IBS symptom assessments. Regarding “[w]eekly
19 IBS symptom assessments” the Procter & Gamble trial concluded that “[n]o statistically
20 significant differences were observed between groups during any week except for one
21 parameter at Week 3.” And regarding “[m]icrobiology measures,” the Procter & Gamble trial
22 concluded that “[o]nly 1 measure was statistically different in *B. infantis*-IBS subjects at Week
23 4, Week 8, or Follow-up.”

24 39. On its website, Procter & Gamble cites to two “*Bifidobacterium infantis* 35624
25 Clinical Data Publications.” Neither study provides proof, clinical or otherwise, for the Align
26 claims. The first study (Whorwell, Altringer et al. 2006), looked at women who were primary

27 ³ *Id.*

28 ⁴ A double-blind, randomized, placebo-controlled study of the effects of Bifantis (*Bifidobacterium infantis* 35624) on fecal microflora and gastrointestinal symptoms in adults with irritable bowel syndrome. P&G Study 2005054. Summary available at <http://www.bifantis.com/probiotic-scientific-data.php#additional> (last visited August 25, 2010).

1 care IBS patients – not the audience to whom Procter & Gamble markets Align – and tested
2 endpoints that are irrelevant for purposes of providing substantiation for Procter & Gamble’s
3 advertising claims. Notwithstanding, the study tested *Bifidobacterium infantis* 35624 at
4 amounts (referred to as “colony-forming units” or “CFUs”) different than what is present in
5 Align® probiotic supplement. The study authors expressly emphasized the variability of
6 results depending on the amount of CFUs: “The lack of benefits observed with the other
7 dosage levels of the probiotic highlight the need for clinical data in the final dosage form.”
8 The second study (O’Mahony, McCarthy, *et al.* 2005) also fails to provide substantiation for
9 the claims. Like the first purported clinical data publication, the second study analyzed
10 persons with IBS, not the population to which Procter & Gamble markets Align. Moreover,
11 the study arm receiving the Align bacteria did not experience any improvement in all bowel
12 movement markers.

13 40. Procter & Gamble’s website also identifies “preclinical data publications” and
14 “review articles” as purported substantiation for the marketing claim made on Align’s
15 packaging and labeling. None provide substantiation for the marketing claim:

- 16 • Debonnet, Garrett, *et al.* 2008: Analyzed potential antidepressant properties of
17 *B. infantis* in rats, and concluded that the “preliminary” findings indicate there
18 is “encouraging evidence” that the probiotic “may possess antidepressant
19 properties.”
- 20 • O’Mahony, Scully, *et al.* 2008: Analyzed cellular interactions in mice infused
21 with *B. infantis* and infected with salmonella.
- 22 • O’Hara, O’Regan, *et al.* 2006: Non-clinical analysis of intestinal cells incubated
23 with *B. infantis*.
- 24 • Sheil, MacSharry, *et al.* 2006: The effects of *B. infantis* consumption on colitis
25 in mice prior to onset of chronic inflammation.
- 26 • O’Mahony, O’Callaghan, *et al.* 2005: In vivo lymph node cell reaction of
27 humans with inflammatory bowel disease undergoing colectomy or small bowel
28 resection to *B. infantis*.

- 1 • Gilman, Cashman 2006: The effect of *B. infantis* on calcium uptake in human
2 intestinal-like cells in culture. Cells exposed to *B. infantis* did not experience
3 calcium uptake.
- 4 • McCarthy, O'Mahony, *et al.* 2003: Analyzed *B. infantis*' ability to attenuate
5 colitis in mice.
- 6 • MacConaill, Butler, *et al.* 2003: Analyzed the molecular biology of the *B.*
7 *infantis* strain.
- 8 • Brenner, Moeller, *et al.* 2009: Review article concerning randomized controlled
9 trials involving probiotics in the treatment of IBS.
- 10 • Brenner, Chey, 2009: Review article concerning *B. infantis*' reported effects on
11 IBS symptoms.
- 12 • Parkes, Brostoff, *et al.* 2008: Review article exploring the role of the gut
13 microbiota in IBS.
- 14 • O'Sullivan, O'Halloran *et al.* 2005: Generalized review article concerning
15 probiotics, acknowledging that "[k]nowledge of the normal [gut] flora is still
16 relatively meager" and "controlled clinical trials are necessary to validate the
17 benefit of probiotics."
- 18 • Dunne, Murphy, *et al.* 1999: Review article concerning the strategy adopted for
19 selection of potentially effective probiotics.

20 41. The studies cited by Procter & Gamble do not constitute clinical substantiation
21 for Align's marketing claims because, *inter alia*, the studies, preclinical or otherwise, involve
22 human and animal disease states, test irrelevant endpoints, and do not analyze *B. infantis* in the
23 quantity and medium delivered in Align.

24 42. Despite inadequate and inapposite testing, Procter & Gamble continues to
25 unequivocally claim that with its proprietary bacterial strain, Align provides digestive system
26 benefits to all persons.

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1 43. Although it is just a tiny, sugared “capsule” of natural bacteria, Align retails for
2 approximately \$30 for a 28-count package.⁵

3 CLASS ACTION ALLEGATIONS

4 44. Plaintiffs bring this lawsuit on behalf of themselves and the proposed Class
5 members under Rule 23(b)(2) and (3) of the Federal Rules of Civil Procedure. The proposed
6 Classes (collectively referred to as the “Class”) consists of:

7 **The California Class:** All persons who purchased Align® in California until
8 the date notice is disseminated.

9 **The Florida Class:** All persons who purchased Align® in Florida until the date
10 notice is disseminated.

11 **The Illinois Class:** All persons who purchased Align® in Illinois until the date
12 notice is disseminated.

13 **The New Hampshire Class:** All persons who purchased Align® in New
14 Hampshire until the date notice is disseminated.

15 **The North Carolina Class:** All persons who purchased Align® in North
16 Carolina until the date notice is disseminated.

17 45. Excluded from the Class are the defendant, its officers, directors and
18 employees, and those who purchased Align® for the purpose of resale.

19 46. *Numerosity.* The members of the Class are so numerous that their individual
20 joinder is impracticable. Plaintiffs are informed and believe, and on that basis allege, that the
21 proposed Class contains many thousands of members. The precise number of Class members
22 is unknown to plaintiffs.

23 47. *Existence and Predominance of Common Questions of Law and Fact.*
24 Common questions of law and fact exist as to all members of the Class and predominate over
25

26 ⁵ See, e.g., <http://www.cvs.com> (\$29.99 for 28-count Align probiotic supplement) (last
27 visited Aug. 30, 2010); <http://www.walmart.com> (\$29.44 for 28-count Align probiotic
28 supplement (last visited Aug. 30, 2010); <http://www.walgreens.com> (\$29.99 for 28-count
Align probiotic supplement (last visited Aug. 30, 2010); <http://www.target.com> (\$29.49 for
28-count Align probiotic supplement (last visited Aug. 30, 2010).

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1 any questions affecting only individual Class members. These common legal and factual
2 questions include, but are not limited to, the following:

3 (a) whether Procter & Gamble had adequate substantiation for its claims
4 prior to making them;

5 (b) whether the claims discussed above are true, or are misleading, or
6 reasonably likely to deceive;

7 (c) whether Procter & Gamble's alleged conduct violates public policy;

8 (d) whether the alleged conduct constitutes violations of the laws asserted
9 herein;

10 (e) whether Procter & Gamble engaged in false or misleading advertising;

11 (f) whether plaintiffs and Class members have sustained monetary loss and
12 the proper measure of that loss;

13 (g) whether plaintiffs and Class members are entitled to restitution; and

14 (h) whether plaintiffs and Class members are entitled to an award of
15 punitive damages.

16 48. **Typicality.** Plaintiffs' claims are typical of the claims of the members of the
17 Class in that plaintiffs assert the same claims.

18 49. **Adequacy of Representation.** Plaintiffs will fairly and adequately protect the
19 interests of the members of the Class. Plaintiffs have retained counsel highly experienced in
20 complex consumer class action litigation, and plaintiffs intend to prosecute this action
21 vigorously. Plaintiffs have no adverse or antagonistic interests to those of the Class.

22 50. **Superiority.** A class action is superior to all other available means for the fair
23 and efficient adjudication of this controversy. The damages or other financial detriment
24 suffered by individual Class members is relatively small compared to the burden and expense
25 that would be entailed by individual litigation of their claims against the defendant. It would
26 thus be virtually impossible for the Class, on an individual basis, to obtain effective redress for
27 the wrongs done to them.
28

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1 51. Unless stated otherwise, the claims asserted herein are applicable to all persons
2 who purchased Align.

3 52. Plaintiffs seek equitable relief on behalf of the entire Class, on grounds
4 generally applicable to the entire Class, to defendant to provide full restitution to plaintiffs and
5 Class members.

6 53. Unless a class is certified, defendant will retain monies received as a result of
7 its conduct that were taken from plaintiffs and proposed Class members.

8 **COUNT I**

9 **For Violations of the Consumers Legal Remedies Act – Civil**
10 **Code §1750 et seq. On Behalf of Plaintiff Rikos and the**
11 **California Class**

12 54. Plaintiff Rikos realleges and incorporates by reference the allegations contained
13 in the paragraphs above as if fully set forth herein.

14 55. This cause of action is brought pursuant to the Consumers Legal Remedies Act,
15 Civil Code §1750, *et seq.* (the “Act”). Plaintiff Rikos is a consumer as defined by Civil Code
16 §1761(d). Align is a good within the meaning of the Act.

17 56. Procter & Gamble violated and continues to violate the Act by engaging in the
18 following practices proscribed by §1770(a) of the Act in transactions with Plaintiff Rikos and
19 the California Class which were intended to result in, and did result in, the sale of the Align®:

- 20 (a) Representing that [Align has] . . . characteristics, . . . uses [or]
21 benefits . . . which [it does] not have
- 22 (b) Representing that [Align is] of a particular standard, quality or
23 grade . . . if [it is] of another.
- 24 (c) Advertising goods . . . with intent not to sell them as advertised.
- 25 (d) Representing that [Align has] been supplied in accordance with a
26 previous representation when it has not.

27 57. Procter & Gamble violated the Act by making the representations described
28 above when it knew, or should have known, that the representations were unsubstantiated,
false and misleading.

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1 58. Pursuant to §1782(d) of the Act, Plaintiff Rikos and the California Class seek a
2 Court order enjoining the above-described wrongful acts and practices of Procter & Gamble
3 and for restitution and disgorgement.

4 59. Pursuant to §1782 of the Act, by letter dated September 21, 2010, Plaintiff
5 Rikos notified Procter & Gamble in writing by certified mail of the particular violations of
6 §1770 of the Act and demanded that Procter & Gamble rectify the problems associated with
7 the actions detailed above and give notice to all affected consumers of its intent to so act. On
8 September 27, 2010, Procter & Gamble signed the certified mail receipt acknowledging receipt
9 of the letter. A true and correct copy of this letter is attached as Exhibit 2 to the First
10 Amended Complaint. *See* D.E. No. 9-2.

11 60. Procter & Gamble has failed to rectify or agree to rectify the problems
12 associated with the actions detailed above or give notice to all affected consumers within 30
13 days of the date of written notice pursuant to §1782 of the Act. Therefore, Plaintiff Rikos
14 further seeks claims for actual, punitive and statutory damages, as appropriate.

15 61. Procter & Gamble’s conduct is malicious, fraudulent and wanton, and provides
16 misleading information that can lead to the delayed treatment of serious and life-threatening
17 illness and diseases.

18 62. Pursuant to §1780(d) of the Act, attached as Exhibit 3 to the First Amended
19 Complaint is the affidavit showing that this action was commenced in the proper forum. *See*
20 D.E. No. 9-3.

21 **COUNT II**

22 **Violations of California Business & Professions Code Section**
23 **17200, et seq., On Behalf of Plaintiff Rikos, and the**
24 **California Class**

25 63. Plaintiff Rikos repeats and realleges the allegations contained in the paragraphs
26 above, as if fully set forth herein.

27 64. Business & Professions Code §17200 prohibits any “unlawful, unfair or
28 fraudulent business act or practice and unfair, deceptive, untrue or misleading advertising.”

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1 For the reasons discussed above, Procter & Gamble has violated each of these provisions of
2 Business & Professions Code §17200.

3 65. Procter & Gamble has violated §17200's prohibition against engaging in
4 unlawful acts and practices by, *inter alia*, making the representations and omissions of
5 material facts, as set forth more fully herein, and violating Civil Code §§1572, 1573, 1709,
6 1710, 1711, 1770, Business & Professions Code §17200 *et seq.*, Health & Safety Code
7 §110765, 21 U.S.C. §321, 21 U.S.C. §343, by misbranding food, in violation of federal law,
8 and by violating the common law.

9 66. Plaintiff Rikos and the California Class reserve the right to allege other
10 violations of law which constitute other unlawful business acts or practices. Such conduct is
11 ongoing and continues to this date.

12 67. Procter & Gamble's acts, omissions, misrepresentations, practices and non-
13 disclosures as alleged herein also constitute "unfair" business acts and practices within the
14 meaning of Business & Professions Code §17200, *et seq.* in that its conduct is substantially
15 injurious to consumers, offends public policy, and is immoral, unethical, oppressive, and
16 unscrupulous as the gravity of the conduct outweighs any alleged benefits attributable to such
17 conduct.

18 68. As stated in this Complaint, Plaintiff Rikos alleges violations of consumer
19 protection, unfair competition and truth in advertising laws in California and other states
20 resulting in harm to consumers. Plaintiff Rikos asserts violations of the public policy of
21 engaging in false and misleading advertising, unfair competition and deceptive conduct
22 towards consumers. This conduct constitutes violations of the unfair prong of Business &
23 Professions Code §17200, *et seq.*

24 69. There were reasonably available alternatives to further Procter & Gamble's
25 legitimate business interests, other than the conduct described herein.

26 70. Procter & Gamble's claims, nondisclosures and misleading statements, as more
27 fully set forth above, were also false, misleading and/or likely to deceive the consuming
28 public within the meaning of Business & Professions Code §17200.

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1 71. Procter & Gamble’s advertising, including its labeling, as described herein, also
2 constitutes unfair, deceptive, untrue and misleading advertising.

3 72. Procter & Gamble’s conduct caused and continues to cause substantial injury to
4 Plaintiff Rikos and the other California Class members. Plaintiff Rikos has suffered injury in
5 fact and has lost money as a result of Procter & Gamble’s unfair conduct.

6 73. Procter & Gamble has thus engaged in unlawful, unfair and fraudulent business
7 acts and practices and false advertising, entitling Plaintiff Rikos to judgment and equitable
8 relief against Procter & Gamble, as set forth in the Prayer for Relief.

9 74. Additionally, pursuant to Business & Professions Code §17203, Plaintiff
10 Rikos and the California Class are entitled to restitution.

11 **COUNT III**

12 **Violations of the Florida Deceptive and Unfair Trade**
13 **Practices Act, Florida Statute §501.201 et seq., on Behalf of**
14 **Plaintiff Burns and the Florida Class**

15 75. Plaintiff Burns repeats and realleges the allegations contained in the paragraphs
16 above, as if fully set forth herein.

17 76. This cause of action is brought pursuant to the Florida Deceptive and Unfair
18 Trade Practices Act, Fla. Stat. §501.201 et seq. (“FDUTPA”). The stated purpose of the
19 FDUTPA is to “protect the consuming public . . . from those who engage in unfair methods of
20 competition, or unconscionable, deceptive, or unfair acts or practices in the conduct of any
21 trade or commerce.” Fla. Stat. §501.202(2).

22 77. Plaintiff Burns and Florida Class members are consumers as defined by Fla.
23 Stat. §501.203. Align is a good within the meaning of the FDUTPA. Procter & Gamble is
24 engaged in trade or commerce within the meaning of the FDUTPA.

25 78. Florida Statute §501.204(1) declares unlawful “[u]nfair methods of
26 competition, unconscionable acts or practices, and unfair or deceptive acts or practices in the
27 conduct of any trade or commerce.” The FDUTPA also prohibits false and misleading
28 advertising.

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1 79. Florida Statute §501.204(2) states that “due consideration and great weight
2 shall be given to the interpretations of the Federal Trade Commission and the federal courts
3 relating to [section] 5(a)(1) of the Federal Trade Commission Act.” Procter & Gamble’s
4 unfair and deceptive practices are likely to mislead – and have misled – the consumer acting
5 reasonably in the circumstances, and violate Fla. Stat. §500.04 and 21 U.S.C. §343.

6 80. Procter & Gamble has violated the FDUTPA by engaging in the unfair and
7 deceptive practices as described herein which offend public policies and are immoral,
8 unethical, unscrupulous and substantially injurious to consumers.

9 81. Plaintiff Burns and the Florida Class have been aggrieved by Procter &
10 Gamble’s unfair and deceptive practices and acts of false advertising in that they paid for
11 Align.

12 82. The harm suffered by Plaintiff Burns and the Florida Class were directly and
13 proximately caused by the deceptive, misleading and unfair practices of Procter & Gamble, as
14 more fully described herein.

15 83. Pursuant to Fla. Stat. §501.211(1), Plaintiff Burns and the Florida Class seek an
16 order for restitution, disgorgement, and damages.

17 84. Additionally, pursuant to Fla. Stat. §§501.211(2) and 501.2105, Plaintiff Burns
18 and the Florida Class make claims for damages, attorneys’ fees and costs.

19 **COUNT IV**

20 **For Violations of Florida Statutory False Advertising,**
21 **Florida Statute §§817.06 and 817.40-817.47, on Behalf of**
22 **Plaintiff Burns and the Florida Class**

23 85. Plaintiff Burns repeats and realleges the allegations contained in the paragraphs
24 above, as if fully set forth herein.

25 86. This cause of action is brought pursuant to Florida’s Statutory False
26 Advertising prohibition, Fla. Stat. §§817.06, 817.40 – 817.47. Fla Stat. §817.41(1), provides,
27 in relevant part, that:

28 It shall be unlawful for any person to make or disseminate or cause to be made
or disseminated before the general public of the state, or any portion thereof,
any misleading advertisement. Such making or dissemination of misleading
advertising shall constitute and is hereby declared to be fraudulent and

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1 unlawful, designed and intended for obtaining money or property under false
2 pretenses.

3 87. As fully explained herein, Procter & Gamble has made, disseminated or caused
4 to be made or disseminated advertising which is false and misleading. Such false and
5 misleading advertising has been made to Plaintiff Burns and Florida Class members. Procter
6 & Gamble's misrepresentations and omissions were designed with the intent that Plaintiff
7 Burns and Florida Class members rely on the same and purchase Align as a result of the false
8 and deceptive advertisements.

9 88. Plaintiff Burns and the Florida Class have been aggrieved by Procter &
10 Gamble's misleading advertising in that they paid for Align.

11 89. Plaintiff Burns and the Florida Class make claims for restitution, disgorgement,
12 damages, attorneys' fees and costs.

13 **COUNT V**

14 **For Violations of Illinois' Consumer Fraud and Deceptive**
15 **Business Practices Act, 815 ILCS 505/1 et seq., on Behalf of**
16 **Plaintiff Rikos and the Illinois Class**

17 90. Plaintiff Rikos realleges and incorporates by reference the allegations contained
18 in the paragraphs above as if fully set forth herein.

19 91. Plaintiff Rikos and Illinois Class members are consumers within the meaning of
20 the Illinois Consumer Fraud and Deceptive Business Practices Act (the "Illinois Consumer
21 Fraud Act").

22 92. The Illinois Consumer Fraud Act prohibits:
23 Unfair methods of competition and unfair or deceptive acts or practices,
24 including but not limited to the use or employment of any deception, fraud
25 pretense, false promise, misrepresentation or the concealment, suppression or
26 omission of any material fact, with the intent that others rely upon the
27 concealment, suppression or omission of such material fact, or the use or
28 employment of any practice described in Section 2 of the "Uniform Deceptive
Trade Practices Act," approved August 5, 1965, in the conduct of any trade or
commerce are hereby declared unlawful whether any person has in fact been
misled, deceived or damaged thereby.

815 ILCS 505/2.

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1 93. As a result of the deceptive and misleading promises and affirmations of fact
2 made by Procter & Gamble on the Align labels and throughout the Align marketing campaign,
3 as described above, Procter & Gamble has deceived Plaintiff Rikos and Illinois Class
4 members.

5 94. Procter & Gamble intentionally engaged in these unfair and deceptive acts and
6 made false or misleading representations, intending that Plaintiff Rikos and Illinois Class
7 members rely on the deception.

8 95. Procter & Gamble's deceptive conduct occurred in the course of engaging in
9 trade or commerce.

10 96. Plaintiff Rikos and the Illinois Class have purchased Align and suffered actual
11 damages, proximately caused by Procter & Gamble's unfair and deceptive acts and practices.

12 97. Additionally, Plaintiff Rikos and the Illinois Class make claims for damages,
13 attorneys' fees and costs.

14 **COUNT VI**

15 **For Violations of the New Hampshire Consumer Protection**
16 **Act, N.H.R.S.A. 358-A et seq., on Behalf of Plaintiff**
17 **Jarzembrowski and the New Hampshire Class**

18 98. Plaintiff Jarzembrowski realleges and incorporates by reference the allegations
19 contained in the paragraphs above as if fully set forth herein.

20 99. The New Hampshire Consumer Protection Act (the "Act") makes it unlawful
21 for "any person to use any unfair method of competition or any unfair or deceptive act or
22 practice in the conduct of any trade or commerce." N.H.R.S.A. 358-A:2.

23 100. Procter & Gamble is a "person" under the Act. Procter & Gamble's marketing
24 and selling of Align is "trade" and "commerce" within the meaning of the Act.

25 101. Procter & Gamble's unfair or deceptive acts or practices as described herein
26 violate the Act. Procter & Gamble violated §358-A:2 of the Act in the conduct of trade or
27 commerce with Plaintiff Jarzembrowski and the New Hampshire Class through, among other
28 things:

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1 V. Representing that [Align] has sponsorship, approval,
2 characteristics, ingredients, uses, benefits, or quantities that [it
3 does] not have...

4 VII. Representing that [Align is] of a particular standard, quality or
5 grade . . . if [it is] of another.

6 IX. Advertising goods . . . with intent not to sell them as advertised.

7 102. Furthermore, N.H.R.S.A. 638:6, entitled "Deceptive Business Practices,"
8 declares a person guilty of a class B misdemeanor if, in the course of business, he:

9 (d) Sells, offers or exposes for sale adulterated or mislabeled
10 commodities...; or

11 (e) Makes a false or misleading statement in any advertising
12 addressed to the public...for the purpose of promoting the
13 purchase or sale of property or services.

14 Procter & Gamble's violations of N.H.R.S.A. 638:6 constitute independent violations of the
15 Act.

16 103. Procter & Gamble violated the Act by representing through its advertisements
17 Align as described above when it knew, or should have known, that the representations and
18 advertisements were unfair and/or deceptive.

19 104. Procter & Gamble's unfair and/or deceptive acts or practices as described
20 herein caused and continue to cause substantial injury to Plaintiff Jarzembrowski and the other
21 New Hampshire Class members. Plaintiff Jarzembrowski and the other New Hampshire Class
22 members have suffered injury in fact and has lost money as a result of Procter & Gamble's
23 unfair and/or deceptive conduct.

24 105. Thus, pursuant to N.H.S.R.A. 358-A:10 and 358-A:10-a, Plaintiff
25 Jarzembrowski and the other New Hampshire Class members are entitled to damages and
26 equitable relief and an order requiring Procter & Gamble to engage in a corrective advertising
27 campaign.

28 106. As provided by N.H.R.S.A. 358-A:10-a, Plaintiff Jarzembrowski may bring this
class action under N.H.R.S.A. 358-A:10 because Procter & Gamble has continuously engaged

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1 in uniformly unfair and/or deceptive acts or practices throughout the relevant period, which
2 have caused similar injury to the other New Hampshire Class members.

3 107. Moreover, because Procter & Gamble’s unfair and/or deceptive conduct was
4 willful or knowing, Plaintiff Jarzembrowski and the other New Hampshire Class members are
5 entitled to treble damages. Plaintiff Jarzembrowski is also entitled to recover costs and
6 reasonable fees.

7 **COUNT VII**

8 **For Violations of North Carolina’s Consumer Protection**
9 **Statute, N.C. Gen. Stat. § 75-1.1 et seq., on Behalf of Plaintiff**
10 **Burns and the North Carolina Class**

11 108. Plaintiff Burns realleges and incorporates by reference the allegations contained
12 in the paragraphs above as if fully set forth herein.

13 109. This cause of action is brought pursuant to North Carolina’s consumer
14 protection statute, N.C. Gen. Stat. § 75-1.1 *et seq.* (the “North Carolina Act”).

15 110. Plaintiff Burns is a person within the meaning of the North Carolina Act.

16 111. The North Carolina Act, § 75-1.1, declares that “unfair methods of competition
17 in or affecting commerce, and unfair or deceptive acts or practices in or affecting commerce,
18 are declared unlawful.” Procter & Gamble’s marketing, advertising, and sale of Align is
19 “commerce” as defined by the North Carolina Act.

20 112. Procter & Gamble violated the North Carolina Act by representing through
21 their advertisements of Align when such representations and advertisements were
22 unsubstantiated, false, and misleading.

23 113. Procter & Gamble’s conduct, including misrepresenting the efficacy of Align in
24 the course of commerce, inflicted real injury and damage upon Plaintiff Burns and the North
25 Carolina Class.

26 114. Thus, as a result of Procter & Gamble’s unlawful conduct, Plaintiff Burns and
27 the North Carolina Class are entitled to judgment, full restitution and damages, including
28 treble damages. N.C. Gen. Stat. § 75-16 (“if damages are assessed in such case judgment shall

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1 be rendered in favor the plaintiff and against the defendant for treble the amount fixed by the
2 verdict”).

3 115. Plaintiff Burns and North Carolina Class members also seek costs, including
4 attorneys’ fees and expenses.

5 116. Procter & Gamble has willfully engaged in the unfair and deceptive acts and
6 practices that constitute violations of the North Carolina Act.

7 117. Procter & Gamble knew or should have known that its unfair and deceptive acts
8 and practices were frivolous and malicious.

9 **COUNT VIII**

10 **Breach of Express Warranty**
11 **On Behalf of Plaintiff Rikos and the California Class**

12 118. Plaintiff Rikos realleges and incorporate by reference the allegations contained
13 in the paragraphs above as if fully set forth herein.

14 119. Plaintiff Rikos, and each member of the California Class, formed a contract
15 with defendant at the time Plaintiff Rikos and the other members of the California Class
16 purchased Align. The terms of that contract include the promises and affirmations of fact
17 made by Procter & Gamble on its Align product labels and through other marketing
18 campaigns, as described above. This advertising, including labeling, constitutes express
19 warranties, became part of the basis of the bargain, and is part of a standardized contract
20 between Plaintiff Rikos and the members of the California Class on the one hand, and Procter
21 & Gamble on the other.

22 120. All conditions precedent to Procter & Gamble’s liability under this contract has
23 been performed by Plaintiff Rikos and the California Class.

24 121. Procter & Gamble breached the terms of this contract, including the express
25 warranties, with Plaintiff Rikos and the California Class by not providing the Align product
26 which could provide the benefits described above.

27
28

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1 122. As a result of Procter & Gamble's breach of its contract, Plaintiff Rikos and the
2 California Class have been damaged in the amount of the purchase price of the Align they
3 purchased.

4 **PRAYER FOR RELIEF**

5 Wherefore, plaintiffs pray for a judgment:

- 6 A. Certifying the Class as requested herein;
- 7 B. Awarding plaintiffs and the proposed Class members damages;
- 8 C. Awarding restitution and disgorgement of Procter & Gamble's revenues to
9 plaintiffs and the proposed Class members;
- 10 D. Awarding attorneys' fees and costs; and
- 11 E. Providing such further relief as may be just and proper.

12 **JURY DEMAND**

13 Plaintiffs demand a trial by jury on all issues so triable.

14
15 Dated: August 17, 2012

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RON PARRY

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CERTIFICATE OF SERVICE

I hereby certify that on August 17, 2012, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the e-mail addresses denoted on the Electronic Mail Notice List.

I certify under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on August 17, 2012.

By: s/David A. Futscher
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