

BLOOD HURST & O'REARDON, LLP

1 BLOOD HURST & O'REARDON, LLP  
TIMOTHY G. BLOOD (CA 149343)  
2 LESLIE E. HURST (CA 178432)  
THOMAS J. O'REARDON II (CA 247952)  
3 701 B Street, Suite 1700  
San Diego, CA 92101  
4 Tel: 619/338-1100  
619/338-1101 (fax)  
5 tblood@bholaw.com  
lhurst@bholaw.com  
6 toreardon@bholaw.com

7 Attorneys for Plaintiffs and the Class

8 [Additional counsel appear on signature page.]

9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28

**UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF OHIO**

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

Plaintiffs,

v.

THE PROCTER & GAMBLE  
COMPANY,

Defendant.

Case No.: 11-CV-00226-TSB

**CLASS ACTION**

**THIRD 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 Jarzembowski (“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 bring 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

BLOOD HURST & O'REARDON, LLP

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 Jarzembowski is a resident of the state of New Hampshire. During  
11 the Class period, and in New Hampshire, Plaintiff Jarzembowski was exposed to and saw  
12 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 Jarzembowski 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 Jarzembowski 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, scientists  
15 have yet to settle on a definition of probiotic. The World Health Organization's definition of  
16 probiotics is "Live microorganisms, which, when administered in adequate amounts, confer a  
17 health benefit on the host." The National Center for Complementary and Alternative Medicine  
18 ("NCCAM"), one of the centers that makes up the National Institutes of Health, adds that  
19 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 prove

1 harmful. The European Food Safety Authority (“EFSA”), established by the European Union  
 2 to promote food safety and evaluate food claims, reports that “The numbers/proportions of  
 3 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 that  
 would constitute a beneficial microbiota.

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

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

#### 21 PROCTER & GAMBLE’S CLAIMS ABOUT ALIGN

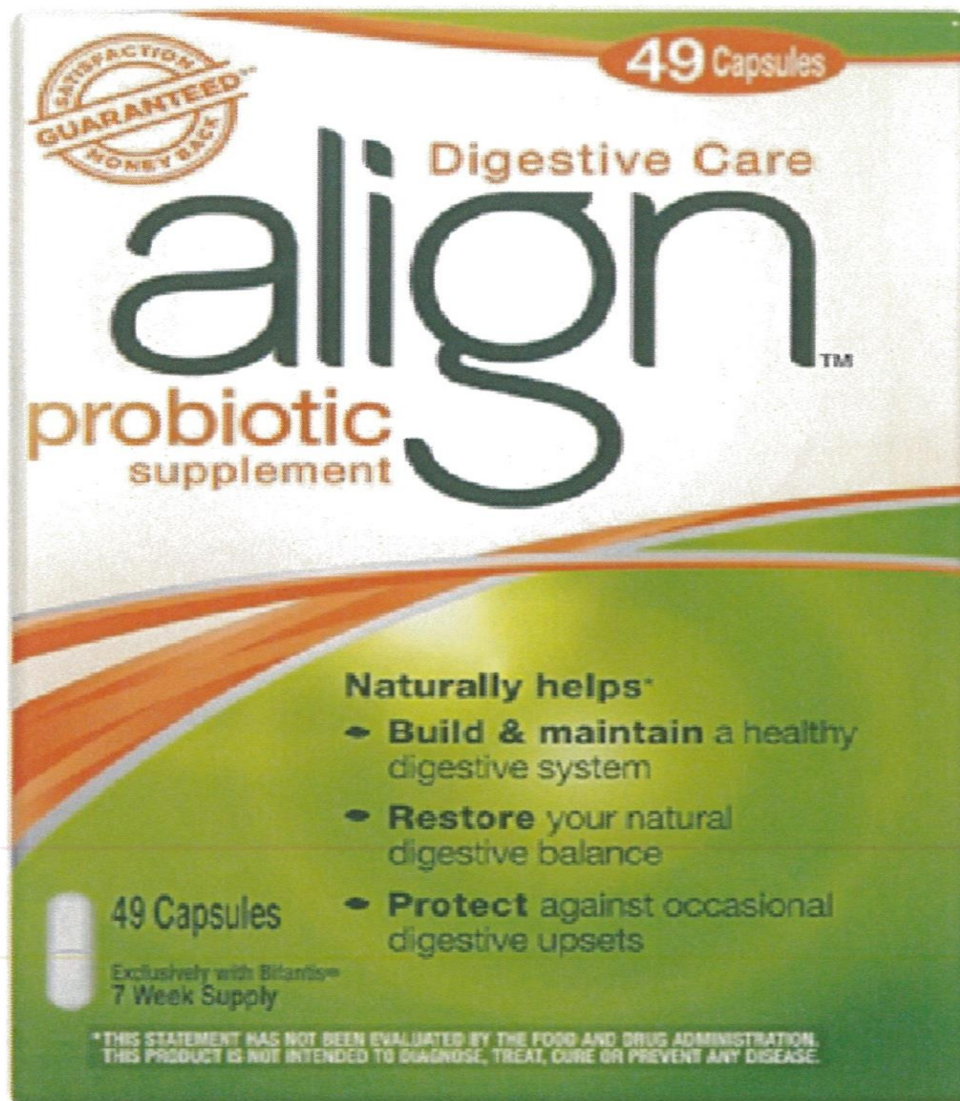
22 21. Procter & Gamble claims Align, “**Naturally helps: Build & maintain** a health  
 23 digestive system; **Restore** your natural digestive balance; [and] **Protect** against occasional  
 24 digestive upsets.” According to Procter & Gamble, “10 years of research went into the  
 25 formulation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

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

BLOOD HURST & O'REARDON, LLP

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:



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

24 **A few words on good bacteria**

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



BLOOD HURST & O'REARDON, LLP

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

3 **Why take Align®?**

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

8 **What are probiotics?**

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

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

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

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

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

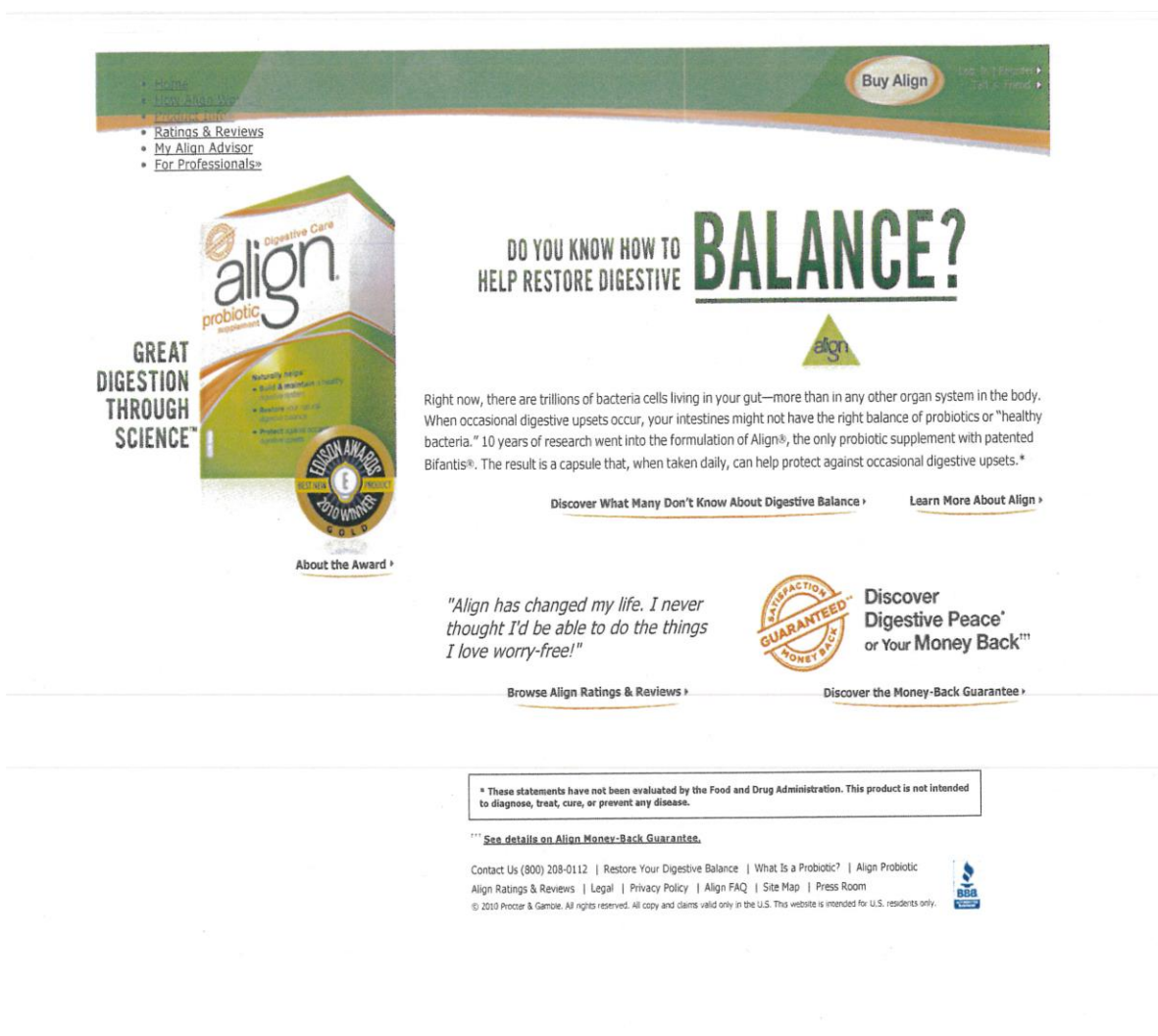
23  
24 ///

25  
26 ///

27  
28 ///

BLOOD HURST & O'REARDON, LLP

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28



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*  
16 *love 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  
28

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.<sup>1</sup>

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”).<sup>2</sup> 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 <sup>1</sup> R. Walker & M. Buckley, “Probiotic Microbes: The Scientific Basis,” at 19  
28 (colloquium convened before the American Society of Microbiology, Nov. 5-7, 2005).

<sup>2</sup> 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](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.<sup>3</sup>

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.<sup>4</sup> 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 <sup>3</sup> *Id.*

28 <sup>4</sup> 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.” The  
8 second study (O’Mahony, McCarthy, et al. 2005) also fails to provide substantiation for the  
9 claims. Like the first purported clinical data publication, the second study analyzed persons  
10 with IBS, not the population to which Procter & Gamble markets Align. Moreover, the study  
11 arm receiving the Align bacteria did not experience any improvement in all bowel movement  
12 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.

27  
28





BLOOD HURST & O'REARDON, LLP

- 1 (c) whether Procter & Gamble's alleged conduct violates public policy;
- 2 (d) whether the alleged conduct constitutes violations of the laws asserted
- 3 herein;
- 4 (e) whether Procter & Gamble engaged in false or misleading advertising;
- 5 (f) whether plaintiffs and Class members have sustained monetary loss and
- 6 the proper measure of that loss;
- 7 (g) whether plaintiffs and Class members are entitled to restitution; and
- 8 (h) whether plaintiffs and Class members are entitled to an award of
- 9 punitive damages.

10 48. **Typicality.** Plaintiffs' claims are typical of the claims of the members of the

11 Class in that plaintiffs assert the same claims.

12 49. **Adequacy of Representation.** Plaintiffs will fairly and adequately protect the

13 interests of the members of the Class. Plaintiffs have retained counsel highly experienced in

14 complex consumer class action litigation, and plaintiffs intend to prosecute this action

15 vigorously. Plaintiffs have no adverse or antagonistic interests to those of the Class.

16 50. **Superiority.** A class action is superior to all other available means for the fair

17 and efficient adjudication of this controversy. The damages or other financial detriment

18 suffered by individual Class members is relatively small compared to the burden and expense

19 that would be entailed by individual litigation of their claims against the defendant. It would

20 thus be virtually impossible for the Class, on an individual basis, to obtain effective redress for

21 the wrongs done to them.

22 51. Unless stated otherwise, the claims asserted herein are applicable to all persons

23 who purchased Align.

24 52. Plaintiffs seek equitable relief on behalf of the entire Class, on grounds

25 generally applicable to the entire Class, to defendant to provide full restitution to plaintiffs and

26 Class members.

27 53. Unless a class is certified, defendant will retain monies received as a result of

28 its conduct that were taken from plaintiffs and proposed Class members.

COUNT I

**For Violations of the Consumers Legal Remedies Act – Civil Code §1750, et seq.**

54. Plaintiffs reallege and incorporate by reference the allegations contained in the paragraphs above as if fully set forth herein.

55. This cause of action is brought pursuant to the Consumers Legal Remedies Act, Civil Code §1750, et seq. (the “Act”). Plaintiffs are consumers as defined by Civil Code §1761(d). Align is a good within the meaning of the Act.

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

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

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

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

59. Pursuant to §1782 of the Act, by letter dated September 21, 2010, Plaintiffs notified Procter & Gamble in writing by certified mail of the particular violations of §1770 of the Act and demanded that Procter & Gamble rectify the problems associated with the actions detailed above and give notice to all affected consumers of its intent to so act. On September 27, 2010, Procter & Gamble signed the certified mail receipt acknowledging receipt of the

BLOOD HURST & O’REARDON, LLP

BLOOD HURST & O'REARDON, LLP

1 letter. A true and correct copy of this letter is attached as Exhibit 2 to the First Amended  
2 Complaint. *See* D.E. No. 9-2.

3 60. Procter & Gamble has failed to rectify or agree to rectify the problems  
4 associated with the actions detailed above or give notice to all affected consumers within 30  
5 days of the date of written notice pursuant to §1782 of the Act. Therefore, Plaintiffs further  
6 seek claims for actual, punitive and statutory damages, as appropriate.

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

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

13 **COUNT II**

14 **For Violations of California Business & Professions Code §17200, et seq.**

15 63. Plaintiffs repeat and reallege the allegations contained in the paragraphs above,  
16 as if fully set forth herein.

17 64. Business & Professions Code §17200 prohibits any “unlawful, unfair or  
18 fraudulent business act or practice and unfair, deceptive, untrue or misleading advertising.”  
19 For the reasons discussed above, Procter & Gamble has violated each of these provisions of  
20 Business & Professions Code §17200.

21 65. Procter & Gamble has violated §17200’s prohibition against engaging in  
22 unlawful acts and practices by, *inter alia*, making the representations and omissions of  
23 material facts, as set forth more fully herein, and violating Civil Code §§1572, 1573, 1709,  
24 1710, 1711, 1770, Business & Professions Code §17200, *et seq.*, Health & Safety Code  
25 §110765, 21 U.S.C. §321, 21 U.S.C. §343, by misbranding food, in violation of federal law,  
26 and by violating the common law.

27  
28

BLOOD HURST & O'REARDON, LLP

1           66. Plaintiffs and the Class reserve the right to allege other violations of law which  
2 constitute other unlawful business acts or practices. Such conduct is ongoing and continues to  
3 this date.

4           67. Procter & Gamble’s acts, omissions, misrepresentations, practices and non-  
5 disclosures as alleged herein also constitute “unfair” business acts and practices within the  
6 meaning of Business & Professions Code §17200, *et seq.* in that its conduct is substantially  
7 injurious to consumers, offends public policy, and is immoral, unethical, oppressive, and  
8 unscrupulous as the gravity of the conduct outweighs any alleged benefits attributable to such  
9 conduct.

10          68. As stated in this Complaint, Plaintiffs allege violations of consumer protection,  
11 unfair competition and truth in advertising laws in California and other states resulting in harm  
12 to consumers. Plaintiffs assert violations of the public policy of engaging in false and  
13 misleading advertising, unfair competition and deceptive conduct towards consumers. This  
14 conduct constitutes violations of the unfair prong of Business & Professions Code §17200, *et*  
15 *seq.*

16          69. There were reasonably available alternatives to further Procter & Gamble’s  
17 legitimate business interests, other than the conduct described herein.

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

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

23          72. Procter & Gamble’s conduct caused and continues to cause substantial injury to  
24 Plaintiffs and the other Class members. Plaintiffs have suffered injury in fact and have lost  
25 money as a result of Procter & Gamble’s unfair conduct.

26          73. Procter & Gamble has thus engaged in unlawful, unfair and fraudulent business  
27 acts and practices and false advertising, entitling Plaintiffs to judgment and equitable relief  
28 against Procter & Gamble, as set forth in the Prayer for Relief.

BLOOD HURST & O'REARDON, LLP

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28

74. Additionally, pursuant to Business & Professions Code §17203, Plaintiffs and the Class are entitled to restitution.

**COUNT III**

**For Violations of the Florida Deceptive and Unfair Trade Practices Act  
Florida Statute §501.201, et seq.**

75. Plaintiffs repeat and reallege the allegations contained in the paragraphs above, as if fully set forth herein.

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

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

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

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

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

BLOOD HURST & O'REARDON, LLP

1 81. Plaintiffs and the Class have been aggrieved by Procter & Gamble’s unfair and  
2 deceptive practices and acts of false advertising in that they paid for Align.

3 82. The harm suffered by Plaintiffs and the Class were directly and proximately  
4 caused by the deceptive, misleading and unfair practices of Procter & Gamble, as more fully  
5 described herein.

6 83. Pursuant to Fla. Stat. §501.211(1), Plaintiffs and the Class seek an order for  
7 restitution, disgorgement, and damages.

8 84. Additionally, pursuant to Fla. Stat. §§501.211(2) and 501.2105, Plaintiffs and  
9 the Class make claims for damages, attorneys’ fees and costs.

10 **COUNT IV**

11 **For Violations of Florida Statutory False Advertising,**  
12 **Florida Statute §§817.06 and 817.40-817.47**

13 85. Plaintiffs repeat and reallege the allegations contained in the paragraphs above,  
14 as if fully set forth herein.

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

18 It shall be unlawful for any person to make or disseminate or cause to be made  
19 or disseminated before the general public of the state, or any portion thereof,  
20 any misleading advertisement. Such making or dissemination of misleading  
21 advertising shall constitute and is hereby declared to be fraudulent and  
unlawful, designed and intended for obtaining money or property under false  
pretenses.

22 87. As fully explained herein, Procter & Gamble has made, disseminated or caused  
23 to be made or disseminated advertising which is false and misleading. Such false and  
24 misleading advertising has been made to Plaintiffs and Class members. Procter & Gamble’s  
25 misrepresentations and omissions were designed with the intent that Plaintiffs and Class  
26 members rely on the same and purchase Align as a result of the false and deceptive  
27 advertisements.  
28

BLOOD HURST & O'REARDON, LLP

1 88. Plaintiffs and the Class have been aggrieved by Procter & Gamble’s misleading  
2 advertising in that they paid for Align.

3 89. Plaintiffs and the Class make claims for restitution, disgorgement, damages,  
4 attorneys’ fees and costs.

5 **COUNT V**

6 **For Violations of Illinois’ Consumer Fraud and Deceptive Business Practices Act,**  
7 **815 ILCS 505/1, et seq.**

8 90. Plaintiffs reallege and incorporate by reference the allegations contained in the  
9 paragraphs above as if fully set forth herein.

10 91. Plaintiffs and Class members are consumers within the meaning of the Illinois  
11 Consumer Fraud and Deceptive Business Practices Act (the “Illinois Consumer Fraud Act”).

12 92. The Illinois Consumer Fraud Act prohibits:  
13 Unfair methods of competition and unfair or deceptive acts or practices,  
14 including but not limited to the use or employment of any deception, fraud  
15 pretense, false promise, misrepresentation or the concealment, suppression or  
16 omission of any material fact, with the intent that others rely upon the  
17 concealment, suppression or omission of such material fact, or the use or  
18 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.

19 815 ILCS 505/2.

20 93. As a result of the deceptive and misleading promises and affirmations of fact  
21 made by Procter & Gamble on the Align labels and throughout the Align marketing campaign,  
22 as described above, Procter & Gamble has deceived Plaintiffs and Class members.

23 94. Procter & Gamble intentionally engaged in these unfair and deceptive acts and  
24 made false or misleading representations, intending that Plaintiffs and Class members rely on  
25 the deception.

26 95. Procter & Gamble’s deceptive conduct occurred in the course of engaging in  
27 trade or commerce.  
28

BLOOD HURST & O'REARDON, LLP

1 96. Plaintiffs and the Class have purchased Align and suffered actual damages,  
2 proximately caused by Procter & Gamble’s unfair and deceptive acts and practices.

3 97. Additionally, Plaintiffs and the Class make claims for damages, attorneys’ fees  
4 and costs.

5 **COUNT VI**

6 **For Violations of the New Hampshire Consumer Protection Act,**  
7 **N.H.R.S.A. 358-A, et seq.**

8 98. Plaintiffs reallege and incorporate by reference the allegations contained in the  
9 paragraphs above as if fully set forth herein.

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

13 100. Procter & Gamble is a “person” under the Act. Procter & Gamble’s marketing  
14 and selling of Align is “trade” and “commerce” within the meaning of the Act.

15 101. Procter & Gamble’s unfair or deceptive acts or practices as described herein  
16 violate the Act. Procter & Gamble violated §358-A:2 of the Act in the conduct of trade or  
17 commerce with Plaintiffs and the Class through, among other things:

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

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

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

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

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

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



BLOOD HURST & O'REARDON, LLP

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

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

6 104. Procter & Gamble's unfair and/or deceptive acts or practices as described  
7 herein caused and continue to cause substantial injury to Plaintiffs and the other Class  
8 members. Plaintiffs and the other Class members have suffered injury in fact and have lost  
9 money as a result of Procter & Gamble's unfair and/or deceptive conduct.

10 105. Thus, pursuant to N.H.S.R.A. 358-A:10 and 358-A:10-a, Plaintiffs and the  
11 other Class members are entitled to damages and equitable relief and an order requiring  
12 Procter & Gamble to engage in a corrective advertising campaign.

13 106. As provided by N.H.R.S.A. 358-A:10-a, Plaintiffs may bring this class action  
14 under N.H.R.S.A. 358-A:10 because Procter & Gamble has continuously engaged in  
15 uniformly unfair and/or deceptive acts or practices throughout the relevant period, which have  
16 caused similar injury to the other Class members.

17 107. Moreover, because Procter & Gamble's unfair and/or deceptive conduct was  
18 willful or knowing, Plaintiffs and the other Class members are entitled to treble damages.  
19 Plaintiffs are also entitled to recover costs and reasonable fees.

20 **COUNT VII**

21 **For Violations of North Carolina's Consumer Protection Statute,**  
22 **N.C. Gen. Stat. §75-1.1, et seq.**

23 108. Plaintiffs reallege and incorporate by reference the allegations contained in the  
24 paragraphs above as if fully set forth herein.

25 109. This cause of action is brought pursuant to North Carolina's consumer  
26 protection statute, N.C. Gen. Stat. §75-1.1, et seq. (the "North Carolina Act").

27 110. Plaintiffs are persons within the meaning of the North Carolina Act.  
28



BLOOD HURST & O'REARDON, LLP

1 is part of a standardized contract between Plaintiffs and the members of the Class on the one  
2 hand, and Procter & Gamble on the other.

3 120. All conditions precedent to Procter & Gamble's liability under this contract has  
4 been performed by Plaintiffs and the Class.

5 121. Procter & Gamble breached the terms of this contract, including the express  
6 warranties, with Plaintiffs and the Class by not providing the Align product which could  
7 provide the benefits described above.

8 122. As a result of Procter & Gamble's breach of its contract, Plaintiffs and the Class  
9 have been damaged in the amount of the purchase price of the Align they purchased.

10 **PRAYER FOR RELIEF**

11 Wherefore, plaintiffs pray for a judgment:

- 12 A. Certifying the Class as requested herein;
- 13 B. Awarding Plaintiffs and the proposed Class members damages;
- 14 C. Awarding restitution and disgorgement of Procter & Gamble's revenues to  
15 Plaintiffs and the proposed Class members;
- 16 D. Awarding attorneys' fees and costs; and
- 17 E. Providing such further relief as may be just and proper.

18 **JURY DEMAND**

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

20 Respectfully submitted,

21 Dated: September 29, 2017

BLOOD HURST & O'REARDON, LLP  
TIMOTHY G. BLOOD (CA 149343)  
LESLIE E. HURST (CA 178432)  
THOMAS J. O'REARDON II (CA 247952)

24 By: s/Timothy G. Blood  
TIMOTHY G. BLOOD

25 701 B Street, Suite 1700  
26 San Diego, CA 92101  
27 Tel: 619/338-1100  
619/338-1101 (fax)  
28 tblood@bholaw.com  
lhurst@bholaw.com

BLOOD HURST & O'REARDON, LLP

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28

toreardon@bholaw.com  
*Attorneys for Plaintiffs and the Class*

FUTSCHER LAW PLLC  
DAVID A. FUTSCHER  
913 N. Oak Drive  
Villa Hills, KY 41017  
Tel: 859/912-2394  
david@futscherlaw.com

NICHOLAS & TOMASEVIC, LLP  
CRAIG M. NICHOLAS (178444)  
ALEX M. TOMASEVIC (245598)  
225 Broadway, 19th Floor  
San Diego, CA 92101  
Tel: 619/325-0492  
619/325-0496 (fax)  
cnicholas@nicholaslaw.org  
atomasevic@nicholaslaw.org

MORGAN & MORGAN, P.A.  
RACHEL L. SOFFIN  
One Tampa City Center  
201 N. Franklin St., 7th Floor  
Tampa, FL 33602  
Tel: 813/223-5505  
813/223-5402 (fax)  
rsoffin@forthepeople.com

O'BRIEN LAW FIRM, PC  
EDWARD K. O'BRIEN  
One Sundial Avenue, 5th Floor  
Manchester, NH 03103  
Tel: 603/668-0600  
603/672-3815 (fax)  
eobrien@ekoblaw.com

SAMUEL ISSACHAROFF  
40 Washington Square South  
New York, NY 10012  
Tel: 212/998-6580  
sil3@nyu.edu

BONNETT, FAIRBOURN, FRIEDMAN  
& BALINT, P.C.  
ANDREW S. FRIEDMAN  
ELAINE A. RYAN  
PATRICIA N. SYVERSON (203111)  
2325 E. Camelback Road, Suite 300  
Phoenix, AZ 85016  
Tel: 602/274-1100  
602/798-5860 (fax)  
afriedman@bffb.com  
eryan@bffb.com  
psyverson@bffb.com

*Additional Attorneys for Plaintiffs*

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28

**CERTIFICATE OF SERVICE**

I hereby certify that on September 29, 2017, 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, and I hereby certify that I have mailed the foregoing document or paper via the United States Postal Service to the non-CM/ECF participants indicated 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 September 29, 2017.

*s/ Timothy G. Blood*  
TIMOTHY G. BLOOD

BLOOD HURST & O'REARDON, LLP  
701 B Street, Suite 1700  
San Diego, CA 92101  
Tel: 619/338-1100  
619/338-1101 (fax)  
tblood@bholaw.com

BLOOD HURST & O'REARDON, LLP