

**UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF VIRGINIA
Alexandria Division**

<p>BAYER CONSUMER CARE, AG., a Delaware Limited Liability Company; and BAYER HEALTHCARE LLC, <i>Plaintiff,</i></p> <p style="text-align: center;">– vs. –</p> <p>BELMORA, LLC, a Virginia Limited Liability Company; JAMIE BELCASTRO, an individual; and DOES 1-10, inclusive, <i>Defendants.</i></p> <hr style="border-top: 1px dashed black;"/> <p>BELMORA, LLC, a Virginia Limited Liability Company, <i>Counterclaim plaintiff,</i></p> <p style="text-align: center;">– vs. –</p> <p>BAYER CONSUMER CARE, AG, a Delaware Limited Liability Company; and BAYER HEALTHCARE LLC, <i>Counterclaim defendants.</i></p>	<p>NO. 1:14-cv-00847 (CMH)(JFA)</p>
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**ANSWER AND
COUNTERCLAIMS**

Defendants Belmora, LLC (“Belmora”) and Jamie Belcastro, by their undersigned attorneys, by and for their answer to the Complaint by plaintiffs Bayer Consumer Care AG and Bayer Healthcare LLC, answer and say as follows:

THE PARTIES

1. Admitted.
2. Admitted.
3. Defendants deny knowledge and information sufficient to answer or deny this allegation of the Complaint.

4. Denied.
5. Denied.
6. Admitted.

JURISDICTION AND VENUE

7. Denied.
8. Denied.

FACTS

9. Defendants deny knowledge and information sufficient to answer or deny this allegation of the Complaint.

10. Defendants deny knowledge and information sufficient to answer or deny this allegation of the Complaint.

11. Defendants deny knowledge and information sufficient to answer or deny this allegation of the Complaint.

12. Defendants deny knowledge and information sufficient to answer or deny this allegation of the Complaint.

13. Defendants deny knowledge and information sufficient to answer or deny this allegation of the Complaint.

14. Denied.

15. Defendants deny knowledge and information sufficient to answer or deny this allegation of the Complaint.

16. Defendants deny knowledge and information sufficient to answer or deny this allegation of the Complaint.

17. Defendants deny knowledge and information sufficient to answer or deny this allegation of the Complaint.

18. Admitted.

19. Admitted.

20. Admitted.

21. Denied.

22. Defendants deny knowledge and information sufficient to answer or deny this allegation of the Complaint.

23. Admitted.

24. Admitted.

25. Admitted.

26. Admitted.

27. Admitted.

28. Denied, except admitted that Belmora's sales and marketing included such areas.

29. Admitted.

30. Denied.

31. Defendant refers the Court to Exhibit A to the Complaint for its full content, which speaks for itself.

32. Defendant refers the Court to Exhibit B to the Complaint for its full content, which speaks for itself.

33. Denied.

34. Denied.

35. Denied.

36. Denied.

37. Denied.

38. Denied.

39. Defendants deny knowledge and information sufficient to answer or deny this allegation of the Complaint.

40. Admitted that the petition made such a claim, the substance of which is denied.

41. Denied.

42. Admitted.

43. Admitted that the document referred to has been quoted accurately, but the characterization of the facts is denied.

44. Admitted that the document referred to has been quoted accurately, but the characterization of the facts is denied.

45. Admitted that the document referred to has been quoted accurately, but the characterization of the facts is denied.

46. Admitted that the document referred to has been quoted accurately, but the characterization of the facts is denied.

47. Admitted that the document referred to has been quoted accurately, but the characterization of the facts is denied.

48. Admitted that the document referred to has been quoted accurately, but the characterization of the facts is denied.

COUNT I

49. Defendants incorporate their responses to the respective allegations re-alleged herein.

50. Denied.

51. Denied.

52. Denied.

COUNT II

53. Defendants incorporate their responses to the respective allegations re-alleged herein.

54. Denied.

55. Denied.

56. Denied.

57. Denied.

58. Denied.

59. Denied.

COUNT III

60. Defendants incorporate their responses to the respective allegations re-alleged herein.

61. Denied.

62. Denied.

63. Denied.

64. Denied.

COUNT IV

65. Defendants incorporate their responses to the respective allegations re-alleged herein.

66. Denied.

67. Denied.

68. Denied.

69. Denied.

70. Denied.

COUNT V

71. Defendants incorporate their responses to the respective allegations re-alleged herein.

72. Denied.

73. Denied.

74. Denied.

75. Denied.

76. Denied.

AFFIRMATIVE DEFENSES

First Affirmative Defense

The Complaint should be dismissed under Fed. R. Civ. P. 12(b)(1) because the Court lacks subject matter jurisdiction over the claims set forth therein.

Second Affirmative Defense

The Complaint should be dismissed because plaintiffs lack standing to assert the claims set forth therein.

Third Affirmative Defense

The Complaint should be dismissed because the statute of limitations bars the claims set forth therein.

Fourth Affirmative Defense

The Complaint should be dismissed because the doctrine of laches bars the claims set forth therein.

Fifth Affirmative Defense

The Complaint should be dismissed because it fails to plead that plaintiffs have suffered a cognizable injury.

Sixth Affirmative Defense

The Complaint should be dismissed because of plaintiffs' unclean hands, as detailed in the Counterclaim herein.

Seventh Affirmative Defense

The Complaint should be dismissed because defendant Belmora's prior rights in the FLANAX trademark have priority over those asserted by plaintiffs.

Eighth Affirmative Defense

The Complaint should be dismissed because the doctrines of waiver, acquiescence and laches, as detailed in the Counterclaim herein.

Ninth Affirmative Defense

The Complaint should be dismissed because of plaintiffs' misuse of its purported trademark, or claims sounding in trademark or unfair competition, to effectuate unfair competition and as an anticompetitive practice, as detailed in the Counterclaim.

Tenth Affirmative Defense

The Complaint should be dismissed because the doctrine of *in pari delicto* bars the claims set forth therein, as detailed in the Counterclaim.

Eleventh Affirmative Defense

The allegations of the Complaint premised on Belmora's willfulness should be dismissed because Belmora acted reasonably in reliance on the advice of legal counsel with respect to existing law at the time of the conduct alleged.

Twelfth Affirmative Defense

The allegations of the Complaint premised on California law should be dismissed because pursuant to the Lanham Act, California law does not apply to this dispute.

Thirteenth Affirmative Defense

The Complaint should be dismissed because Bayer would be unjustly enriched if permitted to recover against Belmora on the claims set forth in the Complaint, as detailed in the Counterclaim.

Fourteenth Affirmative Defense

The Complaint should be dismissed because the claims therein are barred, in whole or in part, by the doctrine of equitable estoppel, as detailed in the Counterclaim.

Fifteenth Affirmative Defense

The Complaint should be dismissed because any recovery based on the claims therein is barred, in whole or in part, by Bayer's failure to mitigate its alleged damages.

WHEREFORE, defendants Belmora, LLC and Jamie Belcastro demand judgment:

- a. dismissing the Complaint in its entirety; and
- b. awarding defendants' costs and disbursements of this action, attorneys' fees, and such other relief as provided by law and the Federal Rules of Civil Procedure and which the Court deems just.

COUNTERCLAIM

For its counterclaims against counterclaim defendants Bayer Consumer Care AG and Bayer Healthcare LLC, counterclaim plaintiff Belmora, LLC, alleges as follows:

PARTIES

1. Counterclaim plaintiff Belmora, LLC is a limited liability company organized and existing under the laws of the State of Virginia, having an office and place of business at 2231 Crystal Drive, Arlington, Virginia.

2. Counterclaim defendant Bayer Healthcare LLC is a limited liability company organized and existing under the laws of State of Delaware, having an office and place of business at 100 Bayer Boulevard, Whippany, New Jersey.

3. Counterclaim defendant Bayer Consumer Care AG is a corporation organized and existing under the laws of Switzerland, having an office and place of business at Peter Merian-Str. 84, Basel, Switzerland.

4. Bayer Healthcare LLC and Bayer Healthcare Consumer Care AG are jointly referred to herein as “Bayer” or “counterclaim defendants.”

JURISDICTION

5. This court has jurisdiction over this action under 15 U.S.C. § 1121 and § 1125 and 28 U.S.C. §§ 1331, 1337 and 1338 because it involves claims arising under the Lanham Act and the Sherman Act and 28 U.S.C. § 1332(a)(1), as the parties are of diverse citizenship and the controversy exceeds \$75,000, exclusive of interest and costs.

6. The court has supplemental jurisdiction over counterclaim plaintiff’s state law claims under 28 U.S.C. § 1367.

FACTS

The Belmora Story

7. Ninety-five percent of the \$425 billion U.S. pharmaceuticals market is controlled by only twenty companies, widely known as “Big Pharma.”

8. The remaining 3,000 U.S. pharmaceutical companies compete for a 5% share of the U.S. pharmaceutical market.

9. Jamie Belcastro is a licensed pharmacist who has practiced pharmacy for over 25 years.

10. During his pharmacy career, Mr. Belcastro observed that persons for whom English is a second language are underserved by the U.S. pharmaceutical industry.

11. Mr. Belcastro also observed that many of these Americans are Hispanics, are unfamiliar with the basic categories and types of over-the-counter (“OTC”) pharmaceutical products in the United States, and that many are more comfortable when medications are described or promoted in their native language.

12. Perceiving this gap as an opportunity to provide pharmaceutical care to Americans with less education and acculturation than the majority population and to build a business around OTC pharmaceutical products that speak that community’s language, Mr. Belcastro founded Belmora to serve U.S. residents for whom Spanish is the primary or secondary language.

13. Recent research continues to support Mr. Belcastro’s observations concerning the opportunity for providing pharmaceutical products in ways that address cultural barriers to proper healthcare among Latinos.

14. For example, the findings of a Pew Hispanic Center study reported in a 2013 *Atlantic* magazine article regarding education, country of birth, and health insurance coverage suggests widespread Latino uneasiness with the American style of healthcare.

15. The *Atlantic* article also reported that 45% of Latinos rely on home remedies rather than purchase expensive pharmaceuticals and that 72% of Hispanics never use prescription drugs, often preferring natural medicine for a wide range of health elements. According to the author, a major deficiency in the offering of healthcare to Latinos in America is a lack of emotional connection or *confianza* (trust) between patients and providers of healthcare solutions.

16. Similarly, a 2013 article on Univision's English-language website observes, "The Hispanic multigenerational family structure means multiple family members are influencers, often chiming in with their opinions about health; and fatalism may lead Hispanics to want to leave things in 'God's hands.' Marketers can counter fatalism with education and step-by-step instruction."

17. Consistent with these observations, Belmora promotes its products in the U.S. Latino community in a number of ways designed to suggest to them a line of healthcare products that is created with them and their sensibilities in mind.

18. To do this, Belmora developed packaging and labels with directions and drug facts in both Spanish and English.

19. Belmora's Flanax also features medical pictographs inserted into the product packaging to provide users with better understanding of the product's usage.

20. Belmora also deploys Spanish-language television commercials that depict a Latino consumer afflicted by an ailment and proposing a Belmora product as a solution;

maintains a bilingual website that provides health information about common ailments and, when applicable, recommending Belmora drugs to treat them; and offers bilingual assistance via a toll-free telephone number.

Belmora's Humble Origins

21. Notwithstanding Belmora's innovative business strategy, the quality of its products and the technical expertise of its founder, like all small businesses seeking to break into mature industries the fledgling Belmora faced significant challenges.

22. Chief among Belmora's obstacles to initial success was the uphill battle faced by any unknown manufacturer of convincing national retail chains to carry its products.

23. The top two drugstore companies in the United States are Walgreens, which includes the Rite Aid retail pharmacy chain, and CVS, which together account for more than 75% of the US pharmacy market share by store count.

24. Even before CVS's 2015 acquisition of over 1,600 pharmacies located in Target stores, CVS and Walgreens together controlled between 50 and 75 percent of the drugstore market in each of the country's 14 largest metro-areas, home to more than 100 million Americans. Walgreens' 8,200 U.S. store locations together with CVS's 7,800 also held at least 50% of the market share in 70 of the top 100 metro-areas in the country.

25. National retailers avoid products they perceive as niche brands and small suppliers for various reasons, including the economics of stocking products with low initial sales volume and the lack of major advertising and promotional support for sales of such products.

26. Even achieving a breakthrough with a national chain is no guarantee of success, because major retailers will discontinue new brands if they are not performing

up to their minimum sales expectations within six months. For this reason, even if a product is accepted for placement at any retailer, the onus is on the manufacturer to create demand and drive consumption at retail by whatever lawful and ethical means available, or it will fail.

27. Like many startups, Belmora lacked the capital to fund the kind or volume of advertising necessary to develop and sustain the level of sales necessary to introduce a product via the dominant major-chain channel.

28. Therefore, Belmora employed two well-established, legitimate and lawful strategies to bring its naproxen sodium product to market.

29. The first strategy was an initial focus on a niche market, similar to the manner in which the founder of “5 Hour Energy” drinks initially focused on marketing energy drinks to college students.

30. Mr. Belcastro had already concluded that the Latino market presented a unique opportunity for Belmora’s initial product offerings, and thus constituted an appropriate initial niche target market.

31. Numbering more than 48 million persons, U.S. Latinos comprise the largest and most rapidly growing minority or ethnic group in the U.S. There are large concentrations of Latinos in New York, Chicago, Denver, Miami and Boston as well as in border areas such as Texas, Arizona and Southern California.

32. There is also considerable cultural diversity among Latinos, as significant numbers of them hail not only from Mexico and Latin America but also Cuba and the Caribbean nations, Europe and South America.

33. The collective purchasing power of Latinos in the U.S. is enormous and growing.

Non-Supported Brands

34. Belmora complemented its focus on the U.S. Latino market by utilizing a second strategy, called the “non-supported brands business model,” which has been successfully employed by pharmaceutical startups and outsiders for decades.

35. The non-supported brands business model is used by small pharmaceutical manufacturers to establish a presence, generate revenue and open up distribution relationships in the pharmaceutical market.

36. Under the non-supported brands model, smaller U.S. companies analyze and monitor the U.S. pharmaceuticals market to identify brand name pharmaceutical products that offer a degree of consumer, prescriber or retail recognition but which Big Pharma, for its own reasons, has abandoned or is otherwise not utilizing in the U.S. market.

37. The term “non-supported” refers to the fact that the brand is not “supported,” as Big Pharma brands typically are, by armies of pharmaceutical sales representatives descending on doctors and hospitals who offer extravagant “incentives” to prescribers to keep their products “in mind” and spend tens of millions of dollars per year on television and other major-media advertising.

38. After identifying good candidates among abandoned brands, small pharmaceutical companies obtain or develop formulations that are comparable or identical them, secure trademark rights to them and, upon receiving Food and Drug Administration (“FDA”) approval, bring these products to market as niche offerings. .

39. The non-supported brand strategy enables smaller manufacturers to lawfully reintroduce into the market a product that is no longer being used by a Big Pharma and making it available to a niche category of U.S. consumers.

40. Because such use is not “supported” by large marketing and sales expenses, non-supported brands benefit consumers due to their lower cost compared to “supported” brands of materially identical formulations.

41. One firm, King Pharmaceuticals, succeeded in building its annual sales to over \$1 billion by identifying unsupported prescription brands and putting them back on the U.S. market and was eventually acquired by Big Pharma company Pfizer.

42. Pfizer’s willingness to acquire King Pharmaceuticals at a premium supports the validity, legitimacy and legality of the non-supported brands business model.

Belmora’s FLANAX Trademark

43. In early 2003, Belmora sought a brand name for its planned offering that was to be focused on the U.S. Hispanic marketing channel.

44. An outside consultant recommended that Belmora employ the non-supported brand model and use the name FLANAX for its product.

45. The FLANAX name was identified to Belmora as being utilized abroad, but not in the U.S., for a naproxen analgesic product sold by Bayer de México.

46. Bayer de México is a member of the Bayer family companies under the aegis of Bayer AG and not a party herein.

47. Mexican Flanax is not approved for sale in the United States and, in its present formulation, cannot be, because it contains a higher dosage of naproxen than that approved for OTC use by the FDA.

48. At the same time, Bayer's U.S. naproxen sodium offering, Aleve, is by far the dominant branded product in the naproxen / naproxen sodium category in the U.S.

49. Prior to settling on the FLANAX name for its product, Belmora consulted with an attorney experienced in intellectual property matters to ascertain whether there were any legal obstacles to using the name.

50. Belmora's attorneys concluded, and advised Belmora, that use of the FLANAX name by Belmora would not be unlawful.

51. Moreover, because Bayer's Aleve monopolized the U.S. market for branded naproxen sodium and its Mexican Flanax formulation could not be sold in the U.S., the likelihood of Bayer ever using the Flanax name for a product in the U.S. is very remote.

52. Indeed, Bayer has admitted in the course of these proceedings that it has no intention of ever using FLANAX in the U.S.

53. Belmora's attorneys applied to the U.S. Patent and Trademark Office ("PTO") to register, on an intent-to-use basis, the FLANAX trademark for its naproxen sodium analgesic on October 6, 2003.

54. The PTO published Belmora's FLANAX trademark application for opposition on July 14, 2004.

55. No person or entity opposed registration of Belmora's FLANAX trademark.

56. On October 26, 2004, the PTO issued a Notice of Allowance to Belmora for its FLANAX trademark.

57. Belmora filed a statement of use for its FLANAX trademark on December 23, 2004.

58. On December 23, 2004, the PTO issued a Notice of Acceptance of Statement of Use in connection with Belmora's FLANAX trademark.

59. On February 1, 2005, the PTO placed Belmora's FLANAX trademark for orally ingestible tablets of naproxen sodium for use as an analgesic on the Principal Register in International Class 5, assigning to it Registration Number 2,924,440 (the "Belmora FLANAX Registration").

60. On November 9, 2010, Belmora's attorneys filed a Declaration of Use and/or Excusable Nonuse of Mark in Commerce under Section 8 for the Belmora FLANAX Registration with the PTO.

61. On December 15, 2010, the PTO issued a Notice of Acceptance stating that the declaration filed by Belmora in connection the Belmora FLANAX Registration met the requirements of Section 8 of the Trademark Act, 15 U.S.C. §1058, that the declaration was accepted and that the registration remained in force.

62. On January 26, 2015, Belmora filed a Combined Declaration of Use and/or Excusable Nonuse/Application for Renewal of Registration of a Mark under Sections 8 & 9 for the Belmora FLANAX Registration.

63. On February 7, 2015, the PTO issued a Notice of Acceptance and Renewal Sections pursuant to Sections 8 and 9 for the Belmora FLANAX Registration.

64. While Bayer and its predecessors in interest took no action in the PTO to prevent Belmora's registration for FLANAX from being allowed, on February 27, 2004 HLR Consumer Health, Inc., a unit of Big Pharma company Hoffman LaRoche and a predecessor in interest of Bayer with respect to its Flanax claims ("HLR"), filed its own

intent-to-use application for FLANAX with the PTO for analgesic preparations (the “HLR Application”).

65. The PTO issued an Office Action on May 16, 2005 informing HLR that its registration was refused under Section 2(d) of the Lanham Act because the applicant’s mark, when used in connection with the identified goods, is likely to be confused with the Belmora FLANAX Registration.

66. The Office Action stated, “Although the examining attorney has refused registration, the applicant may respond to the refusal to register by submitting evidence and arguments in support of registration.”

67. HLR did not respond and on December 16, 2005 the HLR Application was deemed abandoned by the PTO.

68. Because of the advice Belmora received from its attorneys; because Bayer and its predecessors in interest did not oppose the registration of the Belmora FLANAX Registration during the opposition period; because they took no action affirmatively to prevent Belmora from use of the FLANAX mark; and given the abandonment of the HLR Application, Belmora inferred that Bayer had concluded that it had no legal basis to stop Belmora from using the FLANAX mark in the U.S.

69. Belmora’s inference regarding the acquiescence by Bayer and its predecessors in interest to Belmora’s use of the FLANAX mark for over ten years was reasonable.

70. In reliance on the reasonable inference from Bayer’s inaction concerning Belmora’s use and registration of the FLANAX trademark, Belmora continued to use the

FLANAX mark, promote and invest in its FLANAX brand, and to expand Belmora's line of FLANAX-branded analgesics at considerable expense.

Belmora's Marketing to the Hispanic Retail Channel

71. The U.S. Hispanic independent retail channel is recognized as the most dynamic area of growth in U.S. retail consumables and in the Hispanic independent channel, because the surging U.S. Latino population has fueled demand for stores that cater specifically to the Hispanic shopper.

72. Latino-owned retailers, and others located in Latino trade areas that focus on the Hispanic market, are commonly referred to as *mercados* (markets) and *bodegas* (convenience stores).

73. Independent Hispanic retailers typically employ a more loosely structured and open design concept than the dense aisle format of traditional supermarkets. They typically feature a relaxed, informal shopping environment that in contrast to the "corporate," regimented and standardized atmosphere of national chains that focus on the majority "Anglo" market.

74. Concomitantly, the managers of *mercados* and *bodegas* generally place fewer restrictions on merchandising and promotional activity than their mass-market counterparts.

75. Like the small convenience stores that served as the launching pad for the introduction of "5 Hour Energy" drink, the independence of *mercados* and *bodegas* also gives manufacturers, resellers and store managers flexibility to devise, test and benefit from innovative, culturally relevant marketing initiatives not available in major national chains.

76. For these reasons, the bilingual / Hispanic channel strategy originally contemplated by Mr. Belcastro constituted Belmora's best chance of success.

Belmora's Initial Marketing

77. During the first few years of Belmora's business, from 2003 through 2006, Mr. Belcastro personally undertook the marketing of Belmora's products without any outside assistance.

78. These efforts consisted of advertising a toll free number in the U.S. Hispanic Yellow Page Directories that directed consumers to call a toll free number to receive information about pain management. Callers encountered an interactive voice response message that supplied general advice concerning symptoms and causes of back pain, muscle pain, headaches, and menstrual cramps and suggested Belmora Flanax as a potential treatment.

79. Mr. Belcastro, trained as a pharmacist and not a marketing or sales professional, would nonetheless research retail prospects and "cold call" individual "mom and pop" stores, ask for the owner or manager and offer to demonstrate the potential success of Belmora's offerings by providing a free initial order.

80. Notwithstanding Mr. Belcastro's diligence, passion and technical expertise, this door-to-door approach to selling Belmora products achieved only modest success.

81. Mr. Belcastro then shifted his sales efforts to wholesalers and distributors which supply multiple retailers. While this too was a difficult and time-consuming process, Mr. Belcastro succeeded in establishing relationships with about two dozen independent distributors throughout the country.

82. Even among this group, only some were willing to commit to and invest in the potential success of the Belmora line. Others would abandon Belmora after a few disappointing orders. Merely keeping Belmora afloat and establishing a stable level of sales required a constant effort by Mr. Belcastro.

The 2007 Survey, Brochure and Telemarketing

83. The development and maturation of Belmora's early marketing approach was uneven and evolutionary, consisting of numerous disparate initiatives, a number of which were abandoned because of poor results.

84. One such failed initiative was a brief campaign developed and coordinated by a single outside advertising agency, K. Fernandez & Associates of San Antonio, Texas ("Fernandez"), which began and ended in 2007.

85. Belmora chose Fernandez because it had demonstrated experience in marketing consumer packaged goods to Latino store owners or stores in Latino trade areas and offered its services at a price level appropriate for Belmora's modest budget.

86. Fernandez proposed, and Belmora agreed to, a three-phase marketing program designed to expand Belmora's base of distributors.

87. The Fernandez program was to survey current distributors to better understand present buying behavior; create a marketing brochure for mailing to store owners in under-served Latino neighborhoods not serviced by any Belmora distributor; and to follow up these mailings with a telemarketing program aimed at key brochure recipients.

88. Fernandez designed and conducted a telephone survey consisting of sixteen (16) questions that it employed telemarketers to ask of five Belmora distributors.

89. The Fernandez survey questions were not used to survey any consumers.

90. Several of the responses summarized by Fernandez reflected what appeared to be responses by distributors to the effect that Bayer's Flanax product is "popular" and "well known" in Mexico.

91. None of the questions utilized by Fernandez suggested a connection between Bayer and Belmora.

92. The next step in the Fernandez plan was the creation and targeted distribution of a marketing brochure that was mailed to several thousand retailers, which contained a passage, written by the Fernandez agency, that read, "For generations, Flanax has been a brand that Latinos have turned to for various common ailments. Now you too can profit from this highly recognized top-selling brand among Latinos. Flanax is now made in the U.S. and continues to show record sales growth everywhere it is sold. Flanax acts as a powerful attraction for Latinos by providing them with products they know, trust and prefer."

93. The verbiage quoted above was approved by Mr. Belcastro, who understood it as literally accurate and assumed that the retailers to whom it was addressed would be aware, given their professional familiarity with consumer goods, that the manufacturer of U.S. Flanax, Belmora, was not the same as Bayer, the manufacturer of Mexican Flanax.

94. After the Fernandez brochure was mailed, Belmora engaged independent telemarketing contractors to follow up with the retailers who received the mailing utilizing a prepared script.

95. The script required marketers to identify themselves as representatives of Belmora by stating, "I'm with Belmora LLC, we're the direct producers of Flanax in the U.S." and proceeding from that point in a vein similar to that set out in the brochure.

96. Despite the elaborate planning, what actually occurred was that the telemarketers found it almost impossible to get store owners to come to the phone.

97. Moreover, when owners or managers would speak to the telemarketers, they refused to discuss new products over phone, were unfamiliar with product and not interested in learning about it, had no room on their shelves for new items, or some combination of these.

98. Fewer than a half dozen retailers requested and received free shipments of Flanax in response to the Fernandez campaign. None of them reordered.

99. The 2007 Fernandez campaign was a dismal failure, resulting in exactly zero new customers for Belmora.

100. The Fernandez campaign ended in 2007.

101. There were no further mass mailings of the Fernandez brochure.

102. After the failed Fernandez campaign in 2007, Belmora never again conducted any marketing effort that employed a marketing narrative suggesting a connection to Flanax from another country.

Belmora's Breakthrough and Post-2007 Marketing

103. Despite the failure of the Fernandez campaign, the small retail inroads Belmora had achieved through Mr. Belcastro's diligence and the quality, pricing, bilingual labeling, medical pictographs on the product package, and effectiveness of Flanax began a trickle of interest by national retailers beginning in 2006.

104. Because of this interest, in 2008 Belmora was offered the opportunity to shift all its distribution to the Midway Importing, Inc., the leading Hispanic health and

beauty care distributor in the United States (“Midway”). Midway offered established sales relationships with most of the leading national chains.

105. As a result of Midway’s efforts, CVS and Walgreens, which had not been targeted by or, on information and belief, aware of the 2007 Fernandez campaign, started to carry Belmora products.

106. This breakthrough vindicated Belmora’s Hispanic channel marketing strategy.

107. Midway required Belmora spend at least \$500,000 annually to advertise its products.

108. Therefore, in 2009 Belmora produced and ran a television commercial on Univision’s U.S. cable network in major metropolitan markets in California, Texas, Illinois, Arizona and Colorado, among other states.

109. Belmora’s distribution relationship with Midway, and the modest but, for Belmora, significant investment by Belmora in national advertising, resulted in substantial growth for Belmora’s business.

110. Belmora now makes four (4) different OTC FLANAX products: a pain reliever tablet, a liniment, liquid antacid, and cough lozenges.

111. In order for any drug product to be lawfully sold in the U.S., it must comply with regulations promulgated by the U.S. Food and Drug Administration (FDA).

112. Belmora’s pain reliever tablets contain a dosage of 220 mg of naproxen sodium, which is the maximum dosage allowed by the FDA to be sold without a prescription.

113. The FDA also specifies the format of information that appears on the outside packaging of pharmaceutical products. Words must be in bold type of a size that is equal to or larger than a prescribed minimum size of type. The product container must include the name of the manufacturer, packer or distributor. Also, a drug or drug product is misbranded (and therefore unlawful) if the label does not bear conspicuously the name and place of business of the manufacturer, packer, or distributor.

114. No U.S. manufacturer can produce a drug without FDA approval of a New Drug Application (NDA) or an Abbreviated New Drug Application (ANDA).

115. Belmora FLANAX pain reliever tablets are made by Amneal Pharmaceuticals, LLC, a major U.S. contract drug manufacturer (“Amneal”).

116. Amneal’s license to produce Belmora’s pain reliever tablets is ANDA 079096 “for naproxen sodium tablets USP, 220 mg.” A template of the packaging and labeling disclosures for Belmora’s Flanax pain reliever tablets is maintained by Amneal with the FDA, as required by law.

117. The packages and labels of all of Belmora’s FLANAX products have always identified their source as “Belmora LLC,” in full compliance with applicable FDA regulations.

118. Moreover, since 2008, the packaging and labels of Belmora’s FLANAX pain reliever tablets and all other FLANAX products include not only the government-mandated source identifications described above, but also feature Belmora’s logo on the front panel of the package.

119. Belmora’s logo consists of a bright yellow sunburst with the large-type words “Belmora LLC” in white letters with a dark border immediately below it.

120. The Belmora logo also appears on all Belmora marketing communications, including its website, www.flanaxusa.com.

121. Belmora uses a yellow logo because of its prominence and the great extent to which it captures the attention of a human viewer, all for the purpose of clearly identifying Belmora as the source of Flanax products in the U.S.

122. Approximately 80% of Belmora's sales are now made through national retailers such as Wal-Mart, Safeway, Kroger, Target, Walgreen's, CVS, Rite Aid and K-Mart.

123. Since 2009, Belmora's marketing focus has not been limited to or focused on any geographic or demographic segment. Belmora's success depends on it being marketed to the broadest possible range of consumers, most of whom are not Latino; available in all types and sizes of retail outlets, most of whose customers are not Latino; and in locations throughout the U.S., including areas where Latinos are not prevalent.

124. Belmora has never promoted, marketed or advertised its FLANAX-branded products in Mexico.

125. Belmora has never utilized media or promotional platforms to advertise FLANAX-branded products that are directed to non-U.S. residents anywhere, including Mexico.

126. From 2003 to the present, Belmora has sold a million or so of units of FLANAX-branded products in an estimated 10,000 retail locations.

127. Belmora has never received, and is not aware of, a single *bona fide* report of confusion as to the origin of its Flanax naproxen sodium analgesic products on the part of consumers, retailers, distributors or anyone else.

Bayer's Attacks on Competition for Aleve by Belmora

128. As Belmora's sales have grown, Bayer has had to contemplate the possibility that the lucrative monopoly position of Aleve as the only branded naproxen sodium product could be threatened.

129. In June of 2007, Bayer filed an *ex parte* cancellation proceeding in the PTO seeking to cancel the Belmora FLANAX Registration (the "Bayer Cancellation Action").

130. Recognizing, however, that it never used, claimed to use or even successfully asserted its own right to use the FLANAX mark in the U.S., Bayer made no attempt to seek injunctive relief preventing Belmora from utilizing the mark until the filing of its Complaint in this action in 2014, or more than ten years after Belmora filed to register the FLANAX mark and built up the Flanax line of products at considerable expense.

131. In the course of the Bayer Cancellation Action, Bayer's outside computer forensics consultant was granted access to 43,980 business records comprising more than 95,000 separate pages or images stored on Belmora's computer.

132. In addition, Disc Graphics, a printing company that produces Belmora's product packaging and labels, separately produced to Bayer 4,624 files comprising 21,638 pages relating to its FLANAX work since 2004.

133. Other third parties, Belmora's suppliers and distributors, also produced thousands of documents and were deposed by Bayer.

134. All told, Bayer inspected over 50,000 files and 120,000 document pages relating to Belmora's sales and marketing of FLANAX products back to the inception of its business in 2003.

135. Despite this extensive disclosure, Bayer did not produce any evidence of actual confusion as between Belmora's Flanax and Bayer's Mexican product over the course of Belmora's use of the FLANAX mark.

136. Bayer, however, continued prosecuting this action in order to eliminate Belmora's Flanax as a lower-cost alternative to Aleve, which has virtually no other U.S. competition as a branded naproxen sodium analgesic.

137. Bayer has also acted to eliminate or restrain competition between Belmora's FDA-approved Flanax and black-market Mexican Flanax sold unlawfully in the United States.

138. According to the label on the package of Bayer's naproxen sodium Flanax pain reliever, the dosage is 275 mg. That strength cannot lawfully be distributed or sold OTC in the U.S.

139. Illegal Mexican Flanax is readily available for purchase by U.S. consumers in brick-and-mortar retail locations in areas with high or predominant Latino populations.

140. Bayer admits in ¶ 29 of its Complaint to having knowledge of and acquiescing to such illegal in-store drug sales.

141. Illegal Mexican Flanax is also readily available for online purchase in and shipment to the U.S.

142. Such online offers to sell illegal Mexican Flanax in the U.S. include sales by Mexico-based online pharmacies that are licensed and regulated by the Mexican government.

143. Because of the prominence, resources and institutional influence of Bayer's Mexican affiliate, Bayer de México, it would have little difficulty preventing such illegal sales and shipments to the U.S.

144. On information and belief, Bayer and Bayer de México, have actively promoted and encouraged such sales or have been willfully blind to them.

145. Counterclaim defendants benefit economically from the illegal sale of Mexican Flanax in the U.S.

146. Bayer has also attempted to undermine Belmora's ability to conduct its lawful business by using its enormous economic and market power to dissuade pharmaceutical manufacturers and suppliers and, on information and belief, others not to do business with Belmora.

147. Bayer's ability to benefit economically from illegal U.S. sales of Mexican drugs and from its Aleve monopoly would be greatly enhanced if it were permitted to strip Belmora of its statutory and common law rights to sell its lawful, FDA-approved product with the trademark protected by the Belmora FLANAX Registration and which Belmora has used in interstate commerce since 2003.

Restraints on Belmora's Ability to Compete

148. Belmora's ability to compete on a level playing field for a place in the branded naproxen / naproxen sodium market has been stymied unfairly and unlawfully.

149. On information and belief, Bayer has, directly or indirectly, restrained and interfered with Belmora's relationship with suppliers of inputs necessary for it to expand and service its lawful FLANAX-branded product line.

150. One example of such restraint occurred when Belmora sought to purchase a pharmaceutical commodity, naproxen liquidgels, to fill substantial orders from national retail chains for FLANAX-branded naproxen liquidgels.

151. Such a product offering from Belmora would compete directly with Bayer's Aleve liquidgels.

152. Only one firm, Bionpharma, is approved by the FDA to produce and distribute naproxen liquidgels in the U.S.

153. Bionpharma supplies bulk naproxen liquidgels to private manufacturers of store-brand naproxen national chain stores such as Walmart to be repackaged as store-brand naproxen sodium products.

154. Walmart, CVS, and Target also use the same repackager for its naproxen liquidgel products, PL Developments, located in Westbury, New York.

155. Bionpharma also supplies naproxen liquidgels to Bayer for its Aleve product.

156. PL Developments agreed to repackage naproxen liquidgels for Belmora for use in a Belmora FLANAX-branded naproxen product.

157. When, in turn, PL Developments attempted to place an order for naproxen Liquidgels with its sole authorized U.S. supplier, Bionpharma, Bionpharma inquired as to the identity of PL Developments' new client.

158. When, in response, PL Developments advised Bionpharma that the customer was Belmora and that the product was Flanax, Bionpharma refused to supply bulk naproxen liquidgels to PL Developments.

159. As a result, Belmora is unable to obtain naproxen liquidgels from any U.S. supplier.

160. Belmora is aware of no person or firm that has either the market power with respect to naproxen liquidgels or the incentive and animus to target Belmora by causing a manufacturer to refuse to provide such products besides Bayer.

CLAIMS FOR RELIEF

FIRST COUNTERCLAIM

Lanham Act – Registered Trademark Infringement

161. Belmora incorporates the foregoing allegations herein as if set forth in full.

162. The Belmora FLANAX Registration is incontestable pursuant to §§ 15 and 33(b) of the Lanham Act, 15 U.S.C. §§ 1065 and 115(b).

163. Belmora has used its FLANAX mark in interstate commerce since 2003.

164. Belmora's FLANAX mark has been in continuous use in U.S. commerce since its adoption and first use by Belmora in 2003.

165. Belmora has made substantial investments in advertising and promoting its FLANAX-branded analgesic products.

166. By virtue of Belmora's longstanding use, promotion and sale of its FLANAX-branded analgesic products, its FLANAX trademark is associated in the mind of U.S. consumers and the trade exclusively with Belmora so as to constitute secondary meaning.

167. The foregoing acts of counterclaim defendants, including but not limited to their use of the FLANAX mark in the U.S. in connection with the sale, promotion or distribution of identical or closely-related goods, are likely to cause confusion, reverse confusion, mistake or deception.

168. By such conduct, counterclaim defendants have damaged Belmora's trademark goodwill, diverted sales from plaintiff and wrongfully created the impression that Belmora is an infringer or is engaged in unfair competition despite the fact that it is the owner of an incontestable trademark registration for FLANAX.

169. The aforesaid acts constitute infringement of Belmora's registered FLANAX trademark per the valid, subsisting and incontestable Bayer FLANAX Registration.

170. Counterclaim defendants have also, on information and belief, knowingly or with willful blindness induced one or more persons to infringe Belmora's registered FLANAX trademark or supplied products, distribution resources, financing, marketing or other business or logistical support to one or more persons whom they know or have reason to know are engaging in trademark infringement.

171. For the foregoing reasons, counterclaim defendants are contributorily liable for such registered trademark infringement.

SECOND COUNTERCLAIM
Common Law Trademark Infringement

172. Belmora incorporates the foregoing allegations herein as if set forth in full.

173. The aforesaid acts of counterclaim defendants constitute infringement of the Belmora's common law rights in its U.S. FLANAX trademark.

174. Counterclaim defendants have also, on information and belief, knowingly or with willful blindness induced one or more persons to infringe Belmora's common law FLANAX trademark or supplied products, distribution resources, financing, marketing or other business or logistical support to one or more persons whom they know or have reason to know are engaging in trademark infringement.

175. For the foregoing reasons, counterclaim defendants are contributorily liable for such infringement.

THIRD COUNTERCLAIM
Lanham Act – Unfair Competition
and False Designation of Origin

176. Belmora incorporates the foregoing allegations herein as if set forth in full.

177. The aforesaid acts of counterclaim defendants constitute the use of false designations of origin, false descriptions, and false representations in violation of 15 U.S.C. § 1125(a) and common law.

178. Counterclaim defendants have also, on information and belief, knowingly or with willful blindness induced one or more persons to engage in the use of false designations of origin, false descriptions, and false representations or supplied products, distribution resources, financing, marketing or other business or logistical support to one or more persons whom they know or have reason to know is engaging in such unfair competition and false designation of origin.

179. For the foregoing reasons, counterclaim defendants are contributorily liable for such unfair competition and false designation of origin.

FOURTH COUNTERCLAIM
Tariff Act – Importation of Unauthorized Goods

180. Belmora incorporates the foregoing allegations herein as if set forth in full.

181. The aforesaid acts of counterclaim defendants constitute importation of unauthorized good in a violation of § 526 of the Tariff Act of 1930, as amended (19 U.S.C. § 1526).

182. Counterclaim defendants have also, on information and belief, knowingly or with willful blindness induced one or more persons to engage in importation of

unauthorized goods or supplied products, distribution resources, financing, marketing or other business or logistical support to one or more persons whom they know or have reason to know are doing so.

183. For the foregoing reasons, counterclaim defendants are contributorily liable for such unlawful importation.

FIFTH COUNTERCLAIM
Lanham Act – Importation of Infringing Goods

184. Belmora incorporates the foregoing allegations herein as if set forth in full.

185. The aforesaid acts of counterclaim defendants constitute importation and sale of unauthorized goods is in violation of 15 U.S.C. § 1124.

186. Counterclaim defendants have also, on information and belief, knowingly or with willful blindness induced one or more persons to engage in the unlawful importation and sale of unauthorized goods or supplied products, distribution resources, financing, marketing or other business or logistical support to one or more persons whom they know or have reason to know is doing so.

187. For the foregoing reasons, counterclaim defendants are contributorily liable for such unlawful importation.

SIXTH COUNTERCLAIM
Sherman Act, Section 2 – Monopoly

188. Belmora incorporates the foregoing allegations herein as if set forth in full.

189. As set forth above, the barriers to entry into any category in the pharmaceutical market are high. Economics and business textbooks routinely cite the pharmaceutical sector as examples when describing barriers to entry.

190. While most countries have some barriers to legal drug sector entry due to the research and manufacturing startup costs, FDA and other health care regulations make the U.S. a special case.

191. Economies of scale play an important role in industries where producers manufacture large quantities of small products, such as with pharmaceuticals. New companies face significant barriers to competition when they attempt to offer the same drug as a larger, established drug firm because the larger firm already has a large established infrastructure and distribution network and has achieved better marginal economies.

192. While the natural road to competition in the drug sector is through product differentiation and marketing, in which Belmora has engaged diligently, brand name recognition is critical when dealing with drugs because consumers are wary of products they have never heard.

193. The pharmaceutical industry also faces normal manufacturing barriers including high startup costs, time to build and maintain functioning capital equipment, and uncertain legal liabilities.

194. Another barrier to entry that is particularly acute in the pharmaceutical industry is a “first-mover” or brand loyalty advantage. A drug innovator can usually acquire and maintain a first-mover advantage because the quality of a substitute generic product is generally unknown and requires one to experience it.

195. Branded OTC pharmaceutical products are a legally and economically cognizable submarket separate and distinct, though related to, generic pharmaceuticals having comparable formulations and properties.

196. Naproxen / naproxen sodium products constitute a sub-market of the market for OTC analgesics.

197. Aleve was the first entrant in the naproxen sodium submarket to build a substantial brand in the U.S.

198. Aleve's brand is the dominant brand in that submarket and has all the advantages associated with being the first-mover.

199. Bayer's Aleve accounts for at least two-thirds of sales of branded naproxen sodium in the U.S.

200. Bayer also controls, or has exercised control over a key input in the manufacture of naproxen sodium, specifically the production and distribution of naproxen sodium liquidgels in the U.S.

201. Currently one firm, Bionpharma, is approved to produce and distribute naproxen liquidgels in the U.S.

202. Bionpharma supplies naproxen liquidgels to Bayer for its Aleve product.

203. Bionpharma also supplies naproxen liquidgels to private manufacturers of store-brand naproxen national chain stores such as Walmart for use in their store brand naproxen sodium products.

204. Walmart, CVS, and Target also use the same repackager for its naproxen liquidgel products, PL Developments, located in Westbury, New York.

205. PL Developments purchases bulk naproxen liquidgels from Bionpharma for repackaging into bottles and cartons for the store brands under their store brand identity.

206. PL Developments agreed to repackage naproxen liquidgels for Belmora for use in a Belmora FLANAX-branded naproxen product.

207. When, in turn, PL Developments attempted to place an order for naproxen Liquidgels with its sole authorized U.S. supplier, Bionpharma, Bionpharma inquired as to the identity of PL Developments' new client.

208. When, in response, PL Developments advised Bionpharma that the customer was Belmora and that the product was Flanax, Bionpharma refused to supply bulk naproxen liquidgels to PL Developments.

209. As a result, Belmora is unable to obtain naproxen liquidgels from any U.S. supplier.

210. By virtue of its market power in the submarket for branded naproxen sodium, Bayer can raise its prices and take actions to exclude competitors from the submarket.

211. On information and belief, the refusal by Bionpharma to sell naproxen liquidgels to Belmora for use in a FLANAX-branded product was the result of pressure placed on Bionpharma by Bayer, by far its largest customer for such products.

212. Bayer has monopolized, intends to monopolize and has taken action, alone and in concert with others, for purposes of monopolizing and maintaining its monopoly in the branded naproxen / naproxen sodium submarket in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2.

213. Bayer's actions include the above-alleged actions and, without limitation, Bayer's filing of this action in 2014 after more than a decade of acquiescence to Belmora's use and registration of the FLANAX mark.

214. If, alternatively, Bayer does not currently have monopoly control of the branded naproxen / naproxen sodium submarket, there is a dangerous probability that, if not enjoined, Bayer will succeed in obtaining such a monopoly.

215. As a result of Bayer's maintenance of or attempt to obtain monopoly control of the branded naproxen / naproxen sodium submarket, Belmora has suffered and will continue to suffer substantial competitive injury and economic harm.

SEVENTH COUNTERCLAIM
Tortious Interference with Contract /
Prospective Economic Advantage

216. Belmora incorporates the foregoing allegations herein as if set forth in full.

217. But for the interference, on information and belief, by Bayer with Belmora's attempt to obtain naproxen liquidgels to fulfill a substantial retail order for a FLANAX-branded naproxen liquidgel product, Belmora would have been able to fulfill that order utilizing the preferred, and only domestic, source of naproxen sodium liquidgels.

218. The retail orders for FLANAX-branded naproxen liquidgel that Belmora had to cancel as a result of Bayer's interference constituted an executory contract or, alternatively, an objectively ascertainable business expectancy of economic benefit.

219. As a result of Bayer's intentional misconduct, Belmora is unable to fill two substantial retail orders for FLANAX-branded naproxen sodium liquidgels and has been wrongfully and unlawfully deprived of the benefit of likely future orders as well as of the commercial advantage, in the form of orders from other retailers, that would likely have flowed from the fulfillment of these initial orders.

220. Counterclaim defendant Bayer's acts as alleged herein have caused and will cause substantial and irreparable injury to Belmora and, unless enjoined, such injury will continue and worsen.

221. Belmora has no adequate remedy at law.

WHEREFORE, counterclaim plaintiff Belmora, LLC prays for an order of the Court:

- A. Entering judgment in its favor and against counterclaim defendants Bayer Consumer Care AG and Bayer Healthcare LLC on Belmora's counterclaims;
and
- B. Granting a preliminary and permanent injunction restraining counterclaim defendants and all individuals acting in concert or participation with them from:
 - 1. utilizing the word "FLANAX" in any fashion in connection with the marketing, promotion, sale or offering of analgesic products in the U.S.; or
 - 2. importing, or acting in concert with persons importing, any such products into the U.S.; or
 - 3. taking any action that could have the effect of restraining any supplier, manufacturer or other third party from dealing with Belmora in any manner whatsoever;
 - 4. otherwise infringing Belmora's trademark rights;
 - 5. otherwise competing unfairly or interfering with contracts or business expectancies of Belmora;

6. otherwise engaging in business practices by which they maintain or are likely to obtain a monopoly in the submarket for naproxen / naproxen sodium analgesics;
- C. Directing counterclaim defendants to use their best efforts to recall from all third parties any and all marketing, advertising and promotional material used in connection with any unauthorized product bearing the word “FLANAX”;
- D. Directing counterclaim defendants to file with the Court and serve on counsel for Belmora, within thirty days of the entry of any injunction issued by the Court in this action, a sworn statement as provided in 15 U.S.C. §1116 setting forth in detail the manner and form in which the counterclaim defendants have complied with the injunction;
- E. Directing counterclaim defendants to account to Belmora for any and all profits derived by them from the sale of goods in the U.S. utilizing Belmora’s FLANAX trademark;
- F. Awarding Belmora a money judgment against defendant for Belmora’s damages and counterclaim defendants’ profits;
- G. Awarding Belmora punitive damages on account of counterclaim-defendants’ willful or willfully blind conduct;
- H. Awarding Belmora actual, statutory and treble damages under the Sherman Act;
- I. Awarding Belmora its reasonable attorneys’ fees, costs and disbursements incurred herein in view of counterclaim defendants’ intentional and willful infringement and restraint of trade; and

J. Awarding Belmora such other and further relief as the Court may deem just and proper.

Dated: May 15, 2017

Respectfully submitted,

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on May 15, 2017, I electronically filed the foregoing document with the Clerk of the Court using CM/ECF. I also certify that the foregoing document is being served this day on all counsel of record via transmission of Notice of Electronic Filing Generated by CM/ECF.

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