UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF VIRGINIA
Alexandria Division

BAYER CONSUMER CARE, AG., *a Swiss corporation; and* **BAYER HEALTHCARE LLC;** *a Delaware Limited Liability Company*, *Plaintiffs,* *– vs. –* **BELMORA, LLC**, *a Virginia Limited Liability Company*; **JAMIE BELCASTRO**, *an individual*; and **DOES 1-10**, *inclusive,* *Defendants.*	No. 1:14-cv-00847 (CMH)(JFA)
BELMORA, LLC, *a Virginia Limited Liability Company*, *Counterclaim plaintiff,* *– vs. –* **BAYER CONSUMER CARE, AG**, *a Delaware Limited Liability Company; and* **BAYER HEALTHCARE LLC**, *Counterclaim defendants.*	

BELMORA'S MEMORANDUM IN OPPOSITION
TO PLAINTIFFS' MOTION
TO DISMISS THE COUNTERCLAIMS

Defendants/Counterclaimants Belmora, LLC and Jamie Belcastro (collectively, "Belmora") submit this memorandum of law in opposition to the Motion to Dismiss the Counterclaims pursuant to Federal Rule of Civil Procedure 12(b)(6) filed on behalf of Plaintiffs/Counterclaim defendants Bayer Consumer Care, AG and Bayer Healthcare LLC (collectively, "Bayer"). Bayer's motion should be denied because it has misrepresented the allegations of the counterclaim and misstated the law applicable to the claims.

STATEMENT OF FACTS[1]

Ninety-five percent of the $425 billion U.S. pharmaceuticals market is controlled by only twenty companies, widely known as "Big Pharma." The remaining 3,000 U.S. pharmaceutical companies compete for a 5% share of the U.S. pharmaceutical market. Defendant Jamie Belcastro is a licensed pharmacist who has practiced pharmacy for over 25 years. During his career, Mr. Belcastro observed that persons for whom English is a second language are underserved by the U.S. pharmaceutical industry. 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.

Mr. Belcastro founded Belmora to serve U.S. residents for whom Spanish is the primary or secondary language, providing pharmaceutical products in ways that address cultural barriers to proper healthcare among Latinos. 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. 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. National retailers avoid

[1] The facts set out in this section are as alleged in the counterclaim.

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. Even achieving a breakthrough with a national chain is no guarantee of success, because major retailers will discontinue new brands if they are not hitting minimum sales expectations within six months. And 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.

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. Therefore, Belmora employed two well-established, legitimate and lawful strategies to bring its naproxen sodium product to market. 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. 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. The collective purchasing power of Latinos in the U.S. is enormous and growing.

Non-Supported Brands: 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. 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. 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.

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. 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. 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. Because such use is not "supported" by large marketing and sales expenses, non-supported brands offer lower cost products compared to "supported" brands of materially identical formulations.

Belmora's FLANAX Trademark: In early 2003, Belmora sought a brand name for its planned offering that was to be focused on the U.S. Hispanic marketing channel. An outside consultant recommended that Belmora employ the non-supported brand model and use the name FLANAX for its product. 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. (Bayer de México is a member of the Bayer family companies under the aegis of Bayer AG and not a party herein.) 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. 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.

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. Belmora's attorneys concluded, and advised Belmora, that use of the FLANAX name by Belmora would not be unlawful. 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. Indeed, Bayer has admitted in the course of these proceedings that it has no intention of ever using FLANAX in the U.S. Therefore, 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.

The PTO published Belmora's FLANAX trademark application for opposition on July 14, 2004. No person or entity opposed registration of Belmora's FLANAX trademark. On October 26, 2004, the PTO issued a Notice of Allowance to Belmora for its FLANAX trademark. Belmora filed a statement of use for its FLANAX trademark on December 23, 2004. On December 23, 2004, the PTO issued a Notice of Acceptance of Statement of Use in connection with Belmora's FLANAX trademark. 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"). 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. 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. 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. 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.

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

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 Bayer 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. 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: 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. 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). 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. Concomitantly, the managers of mercados and bodegas generally place fewer restrictions on merchandising and promotional activity than their mass-market counterparts. 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. For these reasons, the bilingual / Hispanic channel strategy originally contemplated by Mr. Belcastro constituted Belmora's best chance of success.

Belmora's Initial Marketing: 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. 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.

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. Notwithstanding Mr. Belcastro's diligence, passion and technical expertise, this door-to-door approach to selling Belmora products achieved only modest success. 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. 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 stable sales required constant effort by Mr. Belcastro.

The 2007 Survey, Brochure and Telemarketing: 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. 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. 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 budget.

Fernandez proposed, and Belmora agreed to, a three-phase marketing program designed to expand Belmora's base of distributors. 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. Fernandez designed and conducted a telephone survey consisting of sixteen (16) questions that it employed telemarketers to ask of five Belmora distributors. The Fernandez survey questions were not used to survey any consumers. While 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, none of the questions utilized by Fernandez suggested a connection between Bayer and Belmora.

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." 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.

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. 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. Despite the elaborate planning, what actually occurred was that the telemarketers found it almost impossible to get store owners to come to the phone. 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. Fewer than a half-dozen retailers requested and received free shipments of Flanax in response to the Fernandez campaign. None of them reordered.

The 2007 Fernandez campaign was a dismal failure, resulting in exactly zero new customers for Belmora. The Fernandez campaign ended in 2007. There were no further mass mailings of the Fernandez brochure. 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: 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. 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. 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. This breakthrough vindicated Belmora's Hispanic channel marketing strategy.

Midway required Belmora spend at least $500,000 annually to advertise its products. 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. 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. Belmora now makes four different over-the-counter ("OTC") FLANAX products: a pain reliever tablet, a liniment, a liquid antacid, and a cough lozenge.

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

Belmora FLANAX pain reliever tablets are made by Amneal Pharmaceuticals, LLC, a

major U.S. contract drug manufacturer ("Amneal"). 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. 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. 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. 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. The Belmora logo also appears on all Belmora marketing communications, including its website, www.flanaxusa.com. 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.

Approximately 80% of Belmora's sales are now made through national retailers. 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. Belmora has never promoted, marketed or advertised its FLANAX-branded products in Mexico. Belmora has never utilized media or promotional platforms to advertise FLANAX-branded products that are directed to non-U.S. residents anywhere, including Mexico. 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. Belmora has never received, and is not aware of, a single bona fide report of confusion as to the origin of its Flanax products on the part of consumers, retailers, distributors or anyone else.

Bayer's Attacks on Competition for Aleve by Belmora: 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. 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"). 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 prevent 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.

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

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. 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. 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. Bayer admits in ¶ 29 of its Complaint to having knowledge of and acquiescing to such illegal in-store drug sales in its Complaint. Illegal Mexican Flanax is also readily available for online purchase in and shipment to the U.S. 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. 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. On information and belief, however, Bayer and Bayer de México, have actively promoted and encouraged such sales or have been willfully blind to them, from which they both benefit.

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. 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: 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. 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 FLANAX-branded product line. One example occurred when Belmora sought to purchase a pharmaceutical commodity, naproxen liquidgels, to fill substantial orders from national retail chains for FLANAX-branded naproxen liquidgel, a product that would compete directly with Bayer's Aleve liquidgels. Only one firm, Bionpharma, is approved by the FDA to produce and distribute naproxen liquidgels in the U.S. 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. Walmart, CVS, and Target also use the same repackager for its naproxen liquidgel products—*i.e.*, PL Developments. Bionpharma also supplies naproxen liquidgels to Bayer for its Aleve product.

PL Developments agreed to repackage naproxen liquidgels for Belmora for use in a Belmora FLANAX-branded naproxen product. 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. 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. As a result, Belmora is unable to obtain naproxen liquidgels from any U.S. supplier. 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.

ARGUMENT

A. MOTION TO DISMISS STANDARDS.

When ruling on a motion to dismiss pursuant to Fed. R. Civ. P. 12(b)(6), courts generally accept well-pled factual allegations as true and view them in the light most favorable to the non-moving party. *See generally, Bell Atlantic v. Twombly*, 550 U.S. 544 (2007). A pleading is sufficient if it contains "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). It is not necessary to plead all the facts that serve as a basis for the claim. *See Chao v. Rivendell Woods, Inc.*, 415 F.3d 342, 346-49 (4th Cir. 2005). A district court must ask "'not whether a plaintiff will ultimately prevail but whether the claimant is entitled to offer evidence to support the claims.'" *Twombly*, 550 U.S. at 563, n.8 (2007) *See Zaklit v. Global Linguist Solutions, LLC*, 2014 U.S. Dist. LEXIS 92623, at *41 (E.D. Va. 2014). Thus if a complaint alleges "each of the elements of a viable legal theory" – whether "directly or indirectly" – the claimant "should be given the opportunity to prove that claim." *Townsend v. Turcotte*, 2012 U.S. Dis. LEXIS 64666, at *5 (E.D. Va. May 8, 2012). The party challenging the sufficiency of the pleading bears the burden of showing that no claim has been presented.

Despite Bayer's claim to the contrary, "when a factual allegation is made on information and belief, a court applying *Iqbal* must still accept it as true for purposes of a motion to dismiss." *In re Lilley*, 2011 Bankr. LEXIS 1406 at *7 (Bankr. M.D.N.C. April 13, 2011). Bayer incorrectly cited *In re Lilley* for the exact opposite proposition. As the *Lilley* court explained, the Supreme Court "did not strike the phrase 'upon information and belief' from the lexicon when it made the pleading rules more demanding. Nothing in either *Twombly* or *Iqbal* suggests that pleading based upon 'information and belief' is necessarily deficient." *Id*. at *6-7. To the contrary: "Pleading on information and belief is a desirable and essential expedient when matters that are necessary to complete the statement of a claim are not within the knowledge of the

plaintiff . . . ." *Boykin v. KeyCorp*, 521 F.3d 202, 215 (2d Cir. 2008), (quoting 5 Charles Alan Wright & Arthur R. Miller, *Federal Practice and Procedure* § 1224 (3d ed. 2004)). *Accord, Mann Bracken, LLP v. Exec. Risk Indem., Inc.*, 2015 U.S. Dist. LEXIS 130867, at *21 (D. Md. Sep. 28, 2015) (pleading "upon information and belief" is appropriate "where a plaintiff does not have personal knowledge of the facts being asserted"). *Compare, Essex Ins. Co. v. Miles*, 2010 U.S. Dist. LEXIS 128888, at *6 (E.D. Pa. Dec. 3, 2010) (entire complaint, save one allegation, was pled "upon information and belief"; granting leave to re-plead).

B. BELMORA'S SHERMAN ACT COUNTERCLAIM IS PLED ADEQUATELY.

"Section 2 of the Sherman Act condemns 'every person who shall monopolize, or attempt to monopolize'" and Section 4 of the Clayton Act, 15 U.S.C. § 15, authorizes private causes of action under Section 2 of the Sherman Act. *Christianson v. Colt Indus. Operating Corp.*, 486 U.S. 800, 810 (1988). A monopolization claim under Section 2 consists of two elements: "(1) the possession of monopoly power in the relevant market and (2) the willful acquisition or maintenance of that power as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident." *United States v. Grinnell Corp.*, 384 U.S. 563, 570-571 (1966). Belmora has alleged facts supporting both these elements here.

Nevertheless, Bayer seeks dismissal of Belmora's Section 2 claim (the Sixth Counterclaim), asserting that Belmora fails adequately to allege a relevant market or exclusionary conduct by Bayer having anticompetitive effects. Bayer's argument, however, misconstrues the law and inexplicably disregards allegations that, in the context of the allegations as a whole and under the appropriate legal standard, do state a Section 2 claim.

C. BELMORA ADEQUATELY PLEADS THE EXISTENCE OF THE BRANDED, NON-PRESCRIPTION NAPROXEN SODIUM MARKET.

As the Fourth Circuit noted in *E. I. du Pont de Nemours & Co. v. Kolon Indus.*, 637 F.3d

435, 443 (4th Cir. 2011) ("*Kolon*"), "dismissal of an antitrust claim for failure to adequately plead the relevant market can be problematic." It is not sufficient for a movant to argue, as Bayer essentially does, that the market definition alleged in a complaint does not sound convincing. In the words of now-Justice Sotomayor quoted in *Kolon* – along with a raft of other supporting cases – "Because market definition is a deeply fact-intensive inquiry, courts hesitate to grant motions to dismiss for failure to plead a relevant product market." *Id.* citing *Todd v. Exxon Corp*., 275 F.3d 191, 199 (2d Cir. 2001). For this reason, there is no requirement that facts making out a relevant market be pled with specificity. *Id*. "[S]ince the validity of the 'relevant market' is typically a factual element rather than a legal element, alleged markets may survive scrutiny under Rule 12(b)(6) subject to factual testing by summary judgment or trial." *Newcal Indus. v. Ikon Office Solution*, 513 F.3d 1038, 1045 (9th Cir. 2008) (citations omitted).

For purposes of antitrust law, a market is defined by two components: the relevant ***product*** market and the relevant ***geographic*** market.[2] *See Kolon*, 637 F.3d at 441. Defining a relevant product market involves the fact-intensive process of establishing "the reasonable interchangeability of use or the cross-elasticity of demand between the product itself and substitutes for it." *Brown Shoe Co. v. United States*, 370 U.S. 294, 325 (1962). Put differently, cross-elasticity of demand is "the extent to which customers will change their consumption of one product in response to a price change in another." *Eastman Kodak Co. v. Image Tech. Servs., Inc*., 504 U.S. 451, 469 (1992). Additionally, even within a relatively broad market, "well-defined submarkets may exist which, in themselves, constitute product markets for antitrust purposes . . ." *Brown Shoe, id*. A product market or cognizable sub-market may be in

[2] Bayer does not challenge the adequacy of the counterclaim's pleading of the relevant geographical market, so that factor need not be addressed here. The counterclaim does allege the United States as a whole as the relevant geographical market at issue. (*See* Counterclaim, ¶¶ 122-123, 136.)

some instances as narrow as a single brand of a category of products. *See*, *Eastman Kodak Co.*, 504 U.S. at 481-482 ("one brand of a product can constitute a separate market"; complaint alleged monopoly in market for parts and service for Kodak equipment).

Defining a submarket is a highly fact-dependent matter, ultimately requiring proof of non-exclusive "practical indicia as industry or public recognition of the submarket as a separate economic entity, the product's peculiar characteristics and uses, unique production facilities, distinct customers, distinct prices, sensitivity to price changes, and specialized vendors." *Id*. Thus, once a market is defined plausibly and with sufficient detail to put an antitrust defendant on notice, "proper market definition can be determined only after a factual inquiry into the commercial realities faced by consumers." *Queen City Pizza v. Domino's Pizza*, 124 F.3d 430, 436 (3d Cir. 1997). In recognition of the fact sensitivity of such an exercise, antitrust plaintiffs are not tasked it meeting a heightened pleading as to allegations of interchangeability or cross-elasticity of demand. Rather, at the pleading stage, "it is sufficient that plaintiff has alleged specific facts that support a narrow product market in a way that is plausible and bears a rational relation to the methodology courts prescribe to define a market for antitrust purposes." *Foam Supplies, Inc. v. Dow Chem. Co.*, 2006 U.S. Dist. LEXIS 53497, at *12 (E.D. Mo. Aug. 2, 2006) (quoting *Todd, supra*, 275 F.3d at 203).

Moreover, submarkets are, by definition, not defined solely by cross-elasticity of demand. Thus "the boundaries of such a submarket may be determined by examining such practical indicia as industry or public recognition of the submarket as a separate economic entity, the product's peculiar characteristics and uses, unique production facilities, distinct customers, distinct prices, sensitivity to price changes, and specialized vendors." *Brown Shoe*, 370 U.S. at 325. A market may be pled adequately regardless of whether the specific terminology of

interchangeability or cross-elasticity is used. *Kolon*, 637 F.3d at 441 (facts alleging market for "para-aramid fibers" were sufficiently pled even though detailed recitations of interchangeability or cross-elasticity factors were not cited); *United States v. Dean Foods Co.*, 2010 U.S. Dist. LEXIS 34137, at *5 (E.D. Wis. April 7, 2010) (claimant need not "include magic words in order to survive a motion to dismiss" on grounds of market definition at the pleading stage).

Under these standards, Belmora's Sherman Act counterclaim adequately sets out the existence of a relevant product market or submarket by describing the market for branded non-prescription naproxen drugs. The counterclaim's allegations concerning Belmora's efforts to identify an appropriate brand name for its new over-the-counter naproxen sodium product – including its efforts to establish the availability of FLANAX as a trademark in the U.S. – describe a business strategy premised on the fact that brand name over-the-counter pharmaceutical products directly compete with each other within their own markets or sub-markets. Belmora's decision to choose a "non-supported brand" (*i.e.*, a brand that "Big Pharma … has abandoned or is otherwise not utilizing in the U.S. market") was, pursuant to an established, widespread and legitimate business strategy, expected to equip Belmora with a brand name suitable for competing with "'supported' brands of materially identical formulations." (Counterclaim, ¶¶ 34-40).

Belmora's monopolization counterclaim also alleges, *inter alia*, that "brand name recognition is critical when dealing with drugs because consumers are wary of products they have never heard" and "'first-mover' or brand loyalty advantage" is a "particularly acute" barrier to entry in the pharmaceutical industry "because the quality of a substitute generic product is generally unknown and requires one to experience it" (Counterclaim, ¶¶ 192, 194) (emphasis added). As one of the world's great pharmaceutical brand owners and marketers of branded

consumer merchandise, it is hard to imagine Bayer contesting these allegations; but even if it were to do so, the dispute would be over proof, not pleading. Other allegations supporting Belmora's description of relevant market include the allegations that only one manufacturer in the U.S. of naproxen sodium liquidgels is approved by the United States Food and Drug Administration as well as the detailed description of the barriers to entry in the pharmaceutical industry which result in the scramble for brand acquisition, maintenance and development. (Counterclaim, ¶¶ 152, 189-191, 193, 201).

Whether, and to what extent, branded non-prescription naproxen sodium products and generic non-prescription naproxen products may be substitutes are factual questions. And, again, the existence of a market can be affected not only by similarity of function or formulation but also whether or not the relevant industry and its customers recognize the distinct categories of merchandise claimed to be substitutes, the existence of pricing differences between the categories and whether competitors employ different marketing techniques – all fact questions. *See*, *Greyhound Comput. Corp. v. Int'l Bus. Machs. Corp*., 559 F.2d 488, 493 (9th Cir. 1977). In short, factors other than cross-elasticity can describe a market "taking into consideration the economic and commercial realities of a particular industry." *Sterling Merch., Inc. v. Nestle, S.A.*, 724 F. Supp. 2d 245, 257 (D.P.R. 2010). And Belmora's counterclaim then sets forth the kind of "practical indicia" including "industry or public recognition of the submarket as a separate economic entity" set out in *Brown Shoe* and its progeny. Belmora's facts, taken as a whole, amount to a claim that generic or store-brand (i.e., private label) non-prescription naproxen products are not readily interchangeable with branded non-prescription naproxen sodium products such as Belmora's Flanax and Bayer's Aleve.

The two cases upon which Bayer relies as a basis for asserting that, as a matter of law,

branded non-prescription naproxen cannot constitute a cognizable antitrust market are completely inapposite. *Virginia Vermiculite, Ltd. v. W.R. Grace & Co – Conn.*, 108 F. Supp. 2d 549 (W.D. Va. 2000) was decided on summary judgment, not on a Rule 12(b)(6) motion to dismiss, and its holding was premised on extensive findings of fact bearing on the proposed product market at issue – a factual record developed through exactly the type of discovery Bayer seeks to prematurely foreclose. It was only after that discovery was taken – and defense experts conducted their own cross-elasticity analysis – that the court found the alleged submarket wanting. *Id*. at 549 ("*in the face of evidence* that different grades of vermiculite are used interchangeably . . . it is the plaintiffs' burden to conduct some rudimentary analysis of the products' functional interchangeability, and of competition and cross-elasticity between grades") (emphasis added). There is no such evidence here, nor any such analysis by Bayer.

Bayer's second case, *Therapearl, LLC v. Rapid Aid Ltd.*, Civ. No. CCB-13-2792, 2014 U.S. Dist. LEXIS 135851 (D. Md. Sept. 25, 2014), also fails to support Bayer's argument. Unlike Belmora's brand-based market definition, the definition in *Therapearl* was simply incoherent.[3] While alleging that it simultaneously supplied essentially identical Therapearl-branded and store-brand hot/cold therapy packs for sale at the very same retailer, the plaintiff in *Therapearl* failed to allege facts demonstrating that there was no reasonable interchangeability between the two products. The court also held that Therapearl failed to allege facts supporting the unsuitability of other possible products as substitutes for its packs. *Id*.

In contrast, Belmora has alleged facts describing the nature of the pharmaceutical industry, including, among other things, the relative inelasticity of consumer demand among drugs and drug brands, as exemplified by consumer "war[iness] of products they have never

[3] In light of the facts and holding of the court in *Therapearl*, the portions of that case quoted by Bayer in its Motion (*see* Moving Brief at 16) are in any event *dicta*.

heard" and "'first-mover' or brand loyalty advantage" (Counterclaim, ¶¶ 192, 194). Under the rules of *Brown Shoe*, courts do not hesitate to find allegations such as those in the counterclaim here sufficient to state a plausible market or submarket. For example, a market defined as "premium, natural, and organic supermarkets" was also found to be a cognizable antitrust product market, notwithstanding that some consumers could shop at "less expensive" conventional supermarkets in *FTC v. Whole Foods Market*, 548 F.3d 1028, 1037-1039 (D.C. Cir. 2008). *See also, Greyhound, supra*; *E. Dental Corp. v. Isaac Masel Co.*, 502 F. Supp. 1354, 1361 (E.D. Pa. 1980) (differences in marketing power and methods resulted in industry perception of distinct submarkets for otherwise substitutable products).

In light of these factual allegations, Bayer's assertion that Belmora's Counterclaim "fails to allege facts plausibly showing that branded [non-prescription] naproxen is a separate market from private-label naproxen" is merely a "plausibility" opinion by Bayer, and a rather self-serving one. Even less compelling is Bayer's conclusory factual assertion that "[a]nyone who has walked the aisles of their local pharmacy knows that consumers have a large array of alternatives to choose from when seeking pain relief" (Motion at pp. 15-16). If such "anyone knows" arguments were accepted by the courts in this context, no antitrust plaintiff could plead a market or submarket. Nor would there be any reason for discovery to ascertain the extent of interchangeability. Yet the Supreme Court has made it clear that product market definition is a factual issue for development during discovery. *Eastman Kodak Co.*, 504 U.S. at 453.[4]

The cases cited by Bayer on this point of the pleading standards for defining relevant product markets are, again, inapposite. Thus in *Purple Heart Services Foundation v. Others*

[4] Moreover, courts routinely permit the amendment of pleadings where a market definition is found insufficient. *See, e.g., Coolmath.com*, 2015 U.S. Dist. LEXIS 181845, *4; *Purple Heart Services Foundation*, 2012 U.S. Dist. LEXIS 182513, *17.

First, Inc., No. GLR-12-1483, 2012 U.S. Dist. LEXIS 182513 (D. Md. Dec. 28, 2012), the court found that the product market definition failed under the well-established rule that "a trademark does not define its own relevant product market." Id. at *12. Belmora's claim, however, describes the relevant product market as branded naproxen sodium, not a single brand of it. Likewise, in *Coolmath.com, LLC v. Coolmathgames.com*, No. 1:14-cv-1185, 2015 U.S. Dist. LEXIS 181845 (E.D. Va. Apr. 10, 2015), the antitrust counterclaim's simply alleged a product market consisting of "online math games"; there is no indication of any factual detail comparable to Belmora's. The *Coolmath.com* antitrust counterclaimant also failed to identify a geographic market, whereas Bayer has conceded the geographic market issue in this case.[5]

D. BELMORA ALLEGES EXCLUSIONARY CONDUCT WITH ANTICOMPETITIVE EFFECTS.

A Section 2 claim also requires allegation of facts showing that "the use of monopoly power 'to foreclose competition, to gain a competitive advantage, or to destroy a competitor.'" *Eastman Kodak Co., supra*, 504 U.S. at 482-483 (quoting *United States v. Griffith*, 334 U.S. 100, 107 (1948)). "[A] plaintiff must show that the defendant's conduct was 'exclusionary,' 'anticompetitive,' or 'predatory'. . . . " *Cloverleaf Enters. v. Md. Thoroughbred Horsemen's Ass'n*, 730 F. Supp. 2d 451, 465 (D. Md. 2010) (citing *Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*, 472 U.S. 585, 602 (1985)). At the pleadings stage, then, an antitrust claim must allege "an adverse effect on competition market-wide." *Todd*, 275 F.3d at 213 (citation omitted).

[5] Bayer also misleadingly cites the cases in its footnote 3 for the proposition that some courts "have rejected attempts to limit the relevant market to a single drug." In fact, in *Am. Sales Co. v. Astrazeneca AB*, 10 Civ. 6062 (PKC), 2011 U.S. Dist. LEXIS 41182, *10 (S.D.N.Y. Apr. 14, 2011), no such rule was stated. Rather, the complaint "failed to allege any product characteristics or evidence of consumer buying patterns that limit Prilosec OTC's interchangeability of use or the cross-elasticity of demand." And *Mylan Pharms. Inc. v. Warner Chilcott Pub. Ltd. Co.*, 838 F.3d 421 (3d Cir. 2016) was decided not on a motion to dismiss but on summary judgment and, again, made extensive reference to evidence going to the question of whether the different products were or were not interchangeable. The court did not resolve the question by positing an imaginary stroll through the aisle at the local pharmacy.

Belmora has adequately pleaded an adverse effect on competition. Specifically, the Counterclaim alleges, *inter alia*, that:

- Non-supported brands generally "benefit consumers due to their lower cost compared to 'supported' brands" like Bayer's Aleve (Counterclaim, ¶ 40);
- Bayer is in "the lucrative monopoly position of [having] Aleve as the only branded naproxen sodium product" but that position could be threatened by the growth of competing non-supported branded products like Belmora's Flanax (Counterclaim, ¶ 128);
- Bayer's Aleve product "has virtually no other U.S. competition as a branded naproxen sodium analgesic" and "Belmora's Flanax [is] a lower-cost alternative" (Counterclaim, ¶ 136); \
- Belmora's attempt to obtain naproxen liquidgels from the sole FDA-approved U.S. manufacturer in order to be able to sell Flanax-branded liquidgels which "would compete directly with Bayer's Aleve liquidgels" in the branded non-prescription naproxen sodium market (Counterclaim, ¶¶ 150-152);
- Bayer, due to its market power in the branded non-prescription naproxen sodium market and status as by far the largest purchaser of naproxen liquidgels, pressured Bionpharma, the U.S. manufacturer of naproxen liquidgels, to refuse to sell liquidgels to Belmora, thereby cutting off Belmora's access to the key input for that product and excluding Belmora from competing in the branded naproxen sodium market (Counterclaim, ¶¶ 158-160, 200-202, 207-211); and
- Bayer has permitted, benefited from and even premised its own claim against Belmora on the illegal sale of its Mexican Flanax (Counterclaim, ¶¶ 139-145).

These allegations readily establish a plausible pleading basis for Belmora to prove, with the benefit of discovery, that Bayer acted in an exclusionary (and, indeed, illegal) manner to harm the competitive pharmaceutical landscape with respect to the branded non-prescription naproxen sodium market by excluding lower-priced branded alternatives. Courts do not require more than the obvious implications of anticompetitive conduct to be set out at the pleading stage. Thus, for example, in *Cloverleaf Enters.* the court found that the plaintiff, a "standardbred" horse racetrack that also provided off-track betting on simulcasts of races from other tracks (particularly from higher-end thoroughbred tracks), sufficiently pleaded anticompetitive effects by alleging that the defendants "encouraged myriad out-of-state tracks and horsemen's groups to cease sending

simulcast signals to [the plaintiff's track]" before a particularly remunerative race (the Kentucky Derby). "The alleged purposeful exclusion of [plaintiff's track] from gaining access to Defendants'' and out-of-state racetracks' simulcasts constitutes the type of circumstances that can give rise to antitrust liability." 730 F. Supp. 2d at 465. The parallel in *Cloverleaf Enters.* to the behavior of Bayer in excluding Belmora from access to naproxen liquidgels – a key input needed to compete in the branded naproxen sodium market – is striking, and compels the same result here. *See also, Advanced Health-Care Servs. V. Radford Community Hospital*, 910 F.2d 139, 148-149 (4th Cir 1990) (allegations of purposeful exclusion of plaintiff medical equipment supplier from access to area hospitals due to exclusive dealing arrangements with competing supplier adequately pleaded exclusionary conduct).

Bayer cites *Mountain State Mech. Insulation Inc. v Bell Constructors, LLC*, 2012 U.S. Dist. LEXIS 101399 (N.D. W. Va. July 23, 2012), a case in which there was no allegation that defendants had a significant role in the market nor of an impact on competition due to their conduct. Here, in contrast, Belmora has detailed the impact of Bayer's exclusionary conduct – including higher prices, fewer branded non-prescription naproxen product choices, lack of access to key supplies and reduced choice in poor neighborhoods. None of the other cases primarily relied upon by Bayer is factually or legally relevant in light of the various anticompetitive effects alleged in the Counterclaim.[6] *Masco Contr. Servs. East, Inc. v. Beals*, 279 F. Supp. 2d 699 (E.D. Va. 2003) (allegations of harm only to the plaintiff, not to competition as a whole); *America Online, Inc. v. GreatDeals.Net*, 49 F. Supp. 2d 851 (E.D. Va., 1999) (allegation that defendant

[6] Bayer's argument that its filing of suit is protected from antitrust scrutiny under the *Noerr-Pennington* doctrine also misses the forest for the trees because Belmora claim is based on exclusionary acts unrelated to the filing of suit. It is an entirely appropriate, however, to include the fact of this litigation in a narrative describing Bayer's conduct as well as the competitive environment. Indeed, ignoring the role of the lawsuit in a description of Bayer's efforts to retain its monopoly would be preposterous.

charged advertisers fees for access to its subscribers, without more, did not allege anticompetitive conduct). Bayer also asserts that "Belmora offers no rational explanation" for why Bayer excluded Belmora but not major retailers from access to naproxen liquidgels (Moving Brief at 8). This statement ignores the facts alleging the relevant market or submarket as **branded** non-prescription naproxen sodium, not naproxen drugs sold as generic or store brand products. It is therefore quite rational for Bayer not to exclude retailers like Walmart *et al.* from access to naproxen liquidgels, and actually supports the inference that it is **branded** competition that Bayer seeks to exclude in order to retain its monopoly.[7]

E. BELMORA HAS ADEQUATELY STATED A CLAIM UNDER §526 OF THE TARIFF ACT.

Bayer's arguments for dismissal of Belmora's Tariff Act claim fail for a few reasons. First, Bayer argues that Belmora fails to plead that Bayer participated in or assisted anyone in importing Mexican Flanax into the U.S. (Moving Brief at 13). But, in fact, Belmora specifically alleges such illegal, "gray market" sales: "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"; "Bayer admits in ¶ 29 of its Complaint to having knowledge of and acquiescing to such illegal in-store drug sales";[8] and "[i]llegal Mexican Flanax is also readily available for online purchase" in and shipment to the U.S. (Counterclaim, ¶¶139-141). Belmora also alleges, on information and belief, that "Bayer and Bayer de México, have actively promoted and encouraged such sales or have been willfully blind to them." (Id., ¶¶144). Finally, Belmora alleges (Counterclaim ¶182) that

[7] Bayer also misleadingly suggests that Belmora alleged that retailers selling generic or store brand naproxen, "due to their size, pose a greater challenge to Bayer than Belmora (Bayer Motion, at p. 18), but the Counterclaim makes no such assertion.

[8] Paragraph 29 of Bayer's Complaint reads, "Belmora's FLANAX medicine has appeared on the shelves on the same store as ***gray market packages of Bayer's FLANAX medicine*** in Orange County, California, and possibly elsewhere" (emphasis added).

> 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.

These allegations are made against the background of Bayer's own Complaint, which acknowledges that Bayer Healthcare LLC and Bayer Healthcare Consumer Care AG "are both part of the Bayer family of companies, under the aegis of Bayer AG." (Complaint, ¶ 3). Further, Bayer admits that Bayer Consumer Care's Flanax (its Mexican brand of naproxen sodium) and Bayer Healthcare's Aleve (its US brand of naproxen sodium) "are marketed with a coordinated marketing strategy, and the same person within the Bayer family of companies is responsible for the marketing and sale of both medicines" (Complaint, ¶17). And they are premised on the Fourth Circuit's holding that "we are not concluding that BCC has any specific trademark rights to the FLANAX mark in the United States. Belmora owns that mark." *Belmora Ltd. Liab. Co. v. Bayer Consumer Care AG*, 819 F.3d 697, 713 (4th Cir. 2016).

Bayer's position is based upon the false notion that Belmora is required to plead specifically that Bayer itself brought the offending goods into the United States. In fact, the Courts have imposed liability upon persons other than those who actually transport the offending merchandise. *Philip Morris USA, Inc. v. Lee*, 547 F. Supp. 2d 667 (W.D. Tex. 2008) (defendant orchestrated importation of merchandise but did not ship merchandise directly); *Disenos Artisticos E Industriales, S.A. v. Work,* 676 F. Supp. 1254 (E.D.N.Y. 1987) (citing 19 U.S.C. § 1526(c) and rejecting the argument that liability is limited to the actual importer, but extends to a distributor as among "any person **dealing** in such merchandise"). Moreover, Belmora's claim under the Tariff Act may succeed on the basis of the vicarious liability, which may be imposed upon a finding "that the defendant and the infringer have an apparent or actual partnership, have

authority to bind one another in transactions with third parties or exercise joint ownership or control over the infringing product." *Rosetta Stone Ltd. v. Google, Inc.*, 676 F.3d 144, 165 (4th Cir. 2012). Section 526(b) of the Act "subjects the dealer to the same liability for damages and profits as for wrongful use of a trademark." *Olympus Corp. v. United States*, 792 F.2d 315, 317 (2d Cir. 1986). Belmora is entitled to ascertain whether one of the parties to this litigation is amenable to vicarious liability arising from the acts of an as-yet non-party affiliate.

Here, Belmora admittedly did not, and cannot, detail in its Counterclaim the precise conduct of Bayer that contributed to the importation of their "Mexican Flanax." Belmora has not yet taken discovery on this claim. But it is not Belmora's task to plead evidence or all the facts that serve as a basis for its claims. *See, Chao v. Rivendell Woods, Inc.*, 415 F.3d 342, 346-49 (4th Cir. 2005). The allegations of the counterclaim are more than sufficient to give Bayer fair notice of what Belmora's claim is and the grounds upon which it rests. *See Swierkiewicz v. Sorema N.A.*, 534 U.S. 506, 512 (2002). These allegations are not only entitled to a presumption of truth on a motion under 12(b)(6), but they are particularly plausible given Bayer's own allegations in the Complaint concerning the close relationship among the Bayer entities and their coordinated naproxen marketing efforts in the U.S.

Bayer also argues that the counterclaim does not explicitly plead that Belmora has filed a copy of its FLANAX registration certificate with the U.S. Customs Service, which it says is an essential element of Belmora's Tariff Act counterclaim (Moving Brief at 12). Neither of the cases Bayer cites in support of dismissal on this ground, however, actually dismissed such a claim under Rule 12(b)(6). The case of *Shaw v. Rolex Watch U.S.A., Inc.*, 776 F. Supp. 128, 129 (S.D.N.Y. 1991), involved no consideration of the issue at all. Nor does Bayer provide authority to the effect that, even if the failure to file is properly before the court at the pleading stage, such

an omission would not be cured by the filing of an amended complaint. See *Belton v. United States*, Civil Action No. 3:15-1456-MBS, 2015 U.S. Dist. LEXIS 150116, at *6 (D.S.C. Nov. 3, 2015) (reversing dismissal where amended complaint cured jurisdictional defect).

F. BELMORA HAS ADEQUATELY STATED CLAIMS FOR TRADEMARK INFRINGEMENT, UNFAIR COMPETITION, AND FALSE DESIGNATION OF ORIGIN.

Bayer begins its argument regarding the supposed deficiencies of Belmora's trademark and related unfair competition claims by again serially misstating and mischaracterizing the allegations of the counterclaim. As set out in the previous section addressing Belmora's claims under the Tariff Act, the counterclaim explicitly and clearly alleges Bayer's benefit and involvement, directly or otherwise, in the unauthorized and unlawful U.S. sale of Mexican Flanax – *i.e*., merchandise bearing the FLANAX trademark in the U.S. It also refers to Bayer's acknowledgment of the fact that such illegal – not grey market, but black market – pharmaceuticals are offered for sale in the U.S., and that Bayer is very much at peace with this fact – which is not surprising, for such sales axiomatically result in revenue to Bayer Consumer Care AG, the Bayer "mother ship" in Switzerland. Indeed, Bayer is so at home with the smuggling and sale of its illegal Mexican Flanax in the U.S. that it alleged, in Paragraph 29 of its Complaint, that it was harmed by alleged confusion in the U.S. between its black-market goods and the legal merchandise sold by Belmora under its registered U.S. FLANAX trademark.

Bayer nonetheless attempts to build a judicial estoppel argument around the fact that in 2011 Belmora stated, in the TTAB, that "the mere presence of Mexican Flanax in the United States does not permit the inference that Bayer imported it" (Moving Brief at 13.) But Belmora is not asserting an "inference" in the counterclaim. It is not relying on an inference. It is not justifying allegations concerning its own conduct based on an inference. Rather, Belmora is – on bona fide information and belief, as discussed above – making a factual ***allegation***. If this

allegation is proved true, it will become an adjudicated fact. If the allegation, alternatively, is not proved true, perhaps there will be an occasion to test the applicability of Belmora's 2011 statement. Even if this motion were that occasion, however, judicial estoppel would not apply here anyway. First, "The doctrine of judicial estoppel prevents a party from asserting a claim in a legal proceeding that is inconsistent with a claim taken by that party in a previous proceeding." *New Hampshire v. Maine*, 532 U.S. 742, 749 (2001) (quoting 18 C. Wright, A. Miller, & E. Cooper, Federal Practice and Procedure § 4477, p. 782 (1981)). Whatever "position" Belmora took in the TTAB about inferences that may or may not be appropriate, it did not "assert a claim" on the topic. Moreover, "although the party against whom estoppel is being invoked need not have prevailed on the ultimate merits of its case, it must have convinced the judicial or quasi-judicial body to adopt its position." *Scott v. Land Span Motor, Inc.*, 781 F. Supp. 1115, 1120 (D.S.C. 1991). "Judicial integrity is compromised if the court's determination was based on that party's prior position and whose basis is now on a position wholly in contradiction." *In re Cohn-Phillips*, 193 B.R. 757, 764 (Bankr. E.D. Va. 1996). Bayer has not shown that here.

Similarly, Bayer's suggestion that it is entitled do dismissal because it can come up with a "more plausible" story explaining why Mexican Flanax is sold illegally in the United States than the allegations of the counterclaim is unworthy of consideration. A district court has no occasion, on a motion under Rule 12(b)(6), to "under[take] to determine whether a lawful alternative explanation appear[s] more likely" than allegations which themselves meet the standard of *Iqbal*. *Houck v. Substitute Tr. Servs.*, 791 F.3d 473, 484 (4th Cir. 2015). "To survive a motion to dismiss, a plaintiff need not demonstrate that her right to relief is probable or that alternative explanations are less likely . . . The district court's inquiry into whether an alternative explanation was more probable undermined the well-established plausibility standard." *Id*.

CONCLUSION

For the foregoing reasons, Belmora prays that the Court deny plaintiffs' the Motion to Dismiss the Counterclaims or, in the alternative, grant leave to Belmora to file an amended counterclaim.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on June 30, 2017, the foregoing was filed and served electronically by the Court's CM/ECF system upon all registered users in this case:

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