

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

ASTRAZENECA AB, ASTRAZENECA LP,
AND ASTRAZENECA PHARMACEUTICALS
LP,

Plaintiffs,

v.

DR. REDDY'S LABORATORIES, INC.,

Defendant.

Case No.

JURY TRIAL DEMANDED

**COMPLAINT FOR TRADEMARK INFRINGEMENT,
COUNTERFEITING, FALSE DESIGNATION OF ORIGIN,
DILUTION, FALSE ADVERTISING, DECEPTIVE TRADE PRACTICES**

Plaintiffs AstraZeneca AB, AstraZeneca LP, and AstraZeneca Pharmaceuticals LP (collectively, "Plaintiffs" or "AZ") bring this action against Defendant Dr. Reddy's Laboratories, Inc. ("Defendant" or "DRL"). AZ alleges as follows, upon actual knowledge with respect to itself and its own acts, and upon information and belief as to all other matters:

NATURE OF THE ACTION

1. This is an action for trademark infringement and counterfeiting under 15 U.S.C. § 1114(1), trademark infringement and false designation of origin under 15 U.S.C. § 1125(a), trademark dilution under 15 U.S.C. § 1125(c), false advertising under 15 U.S.C. § 1125(a), unfair competition under the common law of Delaware, trademark dilution under Delaware Trademark Act, 6 Del. C. § 3313, *et seq.* deceptive trade practices under Delaware's Deceptive Trade Practices Act, 6 Del. C. § 2532, *et seq.*, and common-law trademark infringement and unfair competition.

2. For over two decades, AZ has offered relief to sufferers of severe heartburn and

other disorders caused by stomach acid reflux through its “Purple Pills” Prilosec® and Nexium®, known as “The Purple Pill®.” AZ’s Purple Pills have been famous for many years through extensive advertising both to doctors and patients, industry-leading commercial success, and extensive publicity, among other reasons. AZ brings this lawsuit to protect AZ’s rights in the face of generic drug manufacturer DRL’s introduction of a purple pill via its generic version of AZ’s Nexium® pharmaceutical, long after AZ’s trademarks became famous. If DRL is not enjoined from using the color purple, DRL’s purple generic pills are likely to cause confusion among consumers and others and are likely to dilute the distinctiveness of AZ’s federally registered purple color trademarks. DRL’s attempt to free-ride off the fame of AZ’s famous Purple Pills poses imminent irreparable harm to both AZ and the public if not enjoined.

THE PARTIES

3. Plaintiff AstraZeneca AB is a company operating and existing under the laws of Sweden, with its principal place of business at 5-151 85 Södertälje, Sweden.

4. Plaintiff AstraZeneca LP is a limited partnership organized and existing under the laws of Delaware with an address of 1800 Concord Park, Wilmington, DE 19803.

5. Plaintiff AstraZeneca Pharmaceuticals LP is a limited partnership organized and existing under the laws of Delaware with an address of 1800 Concord Park, Wilmington, DE 19803.

6. Defendant Dr. Reddy’s Laboratories, Inc. is a corporation organized and existing under the laws of the State of New Jersey, having a principal place of business at 107 College Road East, Princeton, NJ 08540.

JURISDICTION AND VENUE

7. This Court has jurisdiction over the subject matter of this action pursuant to

15 U.S.C. § 1121 and 28 U.S.C. §§ 1331, 1338(a) and (b). This Court has supplemental jurisdiction over Plaintiffs' state law claims pursuant to 28 U.S.C. § 1367 because those claims are so related to their federal claims that they form part of the same case or controversy and derive from a common nucleus of operative facts.

8. This Court has personal jurisdiction over Defendant and venue is proper in the District of Delaware pursuant to 28 U.S.C. § 1391(b) and (c). DRL transacts business in Delaware, including by offering and promoting the generic pharmaceuticals that violate AZ's trademarks in this District. Plaintiffs' claims arise in this District, where a substantial portion of the activity about which Plaintiffs' complain has taken place and where the effects of DRL's actions are felt.

FACTUAL ALLEGATIONS

AZ AND ITS PRILOSEC® AND NEXIUM® PRODUCTS

9. AZ is one of the world's leading pharmaceutical companies, with research and development facilities in the United States and other countries. AZ's North America headquarters are in Wilmington, Delaware, and it has more than 13,500 employees in North America.

10. In 1989, AZ introduced Prilosec® and with it, revolutionized the treatment of severe heartburn and other disorders caused by stomach acid reflux that have adverse impacts on the quality of life of tens of millions of Americans. Prilosec® was the first of a class of drugs known as "proton pump inhibitors," or "PPIs," that in effect turn off the mechanism in certain stomach cells that produce the acid we use in digestion. Prilosec® was the first prescription PPI. By late 1996, Prilosec® became the top-selling pharmaceutical in the U.S.

11. In 2001, AZ began selling Nexium®, a second-generation PPI the company's

scientists invented after years of research and whose improved properties provided relief to millions of patients who did not respond as well to treatment by Prilosec® or other companies' PPIs. Nexium® is an isomer of the Prilosec® molecule. Since its launch in 2001, Nexium® has generally been one of the top-ten-most prescribed drugs in the U.S. and one of the best-selling medicines of all time, benefiting millions of patients.

AZ'S USE OF THE COLOR PURPLE FOR PRILOSEC® AND NEXIUM®

12. Prior to launching Prilosec®, AZ selected the color purple for its Prilosec® capsules. The preference for purple was purely for branding purposes—purple contributes nothing to the safety or efficacy of AZ's products. Rather, purple is a completely arbitrary color that AZ intended from the outset to serve as a distinctive and unique brand for AZ's products. Since its launch in 1989 until present, AZ has sold purple Prilosec® capsules as shown below:¹



13. AZ later decided to also use the color purple for its Nexium® capsules and branding. Given the linkage between the Prilosec® and Nexium® compounds, AZ wanted to leverage the fame and goodwill of the purple branding of Prilosec® with its next generation Nexium® PPI products. AZ has continuously sold Nexium® from 2001 to present in purple-colored capsules with either two or three gold-colored bands displayed on the purple capsules as shown below:

¹ Once AZ introduced Nexium®, it changed the color of Prilosec® capsules for the 10 and 40 mg doses from solid purple to half purple and half peach. AZ, however, continued to sell prescription Prilosec® 20 mg doses in its original all-purple capsules and still sells them today.



To distinguish Nexium® from Prilosec® products, the Nexium® 20 mg and 40 mg capsules have two and three gold rings, respectively. AZ sells Nexium® only in prescription form.

14. In May 2014, Pfizer, under license from AZ, began sales of an over-the-counter (“OTC”) non-prescription 20 mg version of Nexium® under the name Nexium® 24HR. Pfizer paid AZ an up-front fee of \$250 million to gain access to exclusive global rights to sell OTC Nexium®, which includes a license to use AZ’s purple color mark and the word marks Nexium® and “The Purple Pill®.” Under the license, Pfizer also agreed to pay AZ milestone and royalty payments based on product launches and sales. Shown below are images of the OTC capsules.²



AZ’S SALES UNDER ITS PURPLE MARKS

15. As noted above, both Prilosec® and Nexium® are among the best-selling pharmaceuticals of all time. AZ sold more than 7.1 billion purple Prilosec® capsules in the U.S. between 1989 and 2014, and more than 15.5 billion purple Nexium® capsules in the U.S. between 2001 and 2014, for a total of more than 22.6 billion purple capsules. Those figures do not include the hundreds of millions of purple Nexium® pills that AZ provided to doctors as free samples for use with patients as detailed below. On an average annual basis since 2001, AZ has sold over \$3 billion of Prilosec® and Nexium® in purple capsules in the U.S. The vast majority of sales in the past ten years have been Nexium® products. On an average annual basis, more

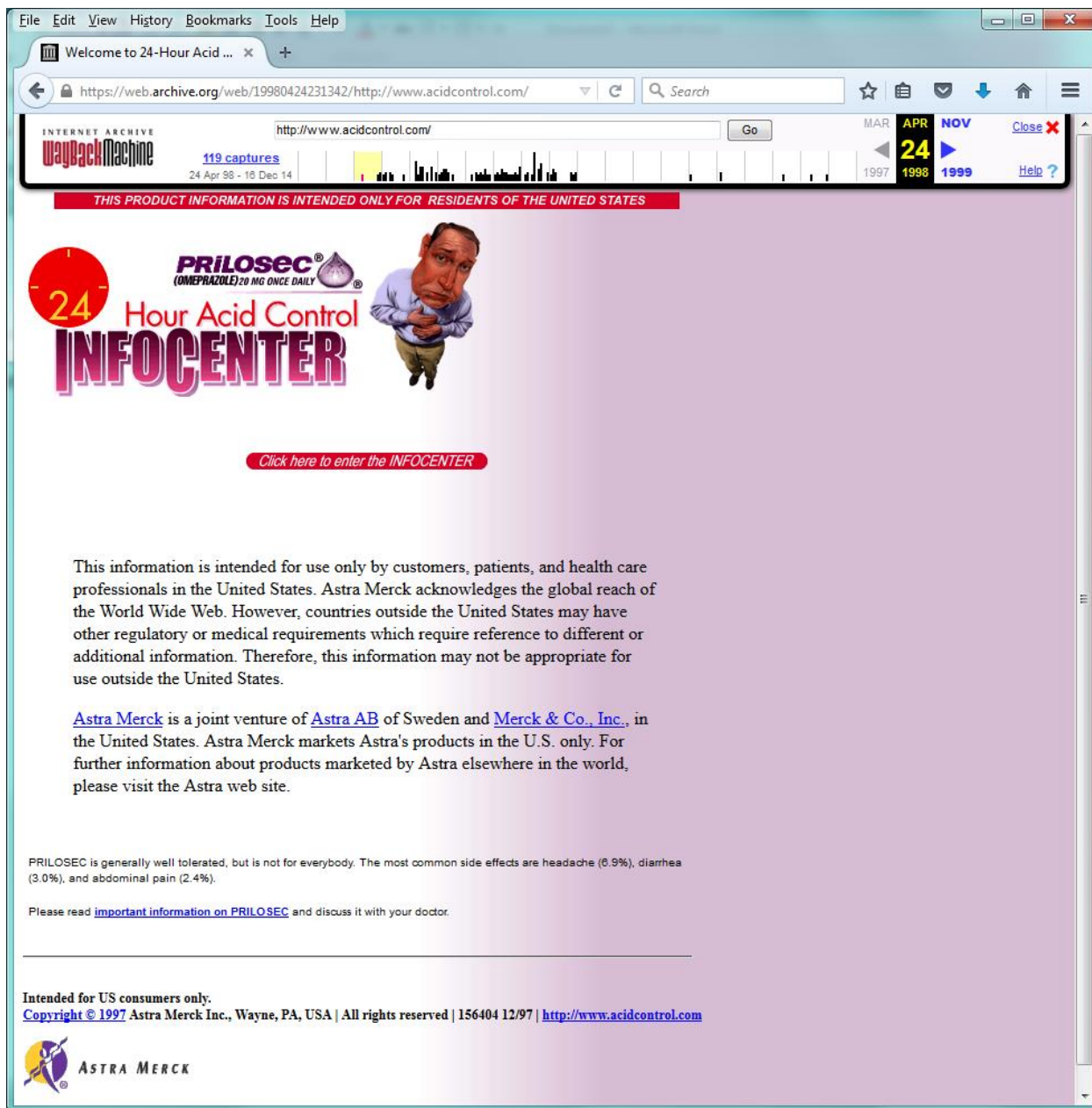
² The Nexium® 24HR capsules have a third gold ring around the middle of the capsule, which is a tamper resistant seal required by the FDA because this is an OTC product.

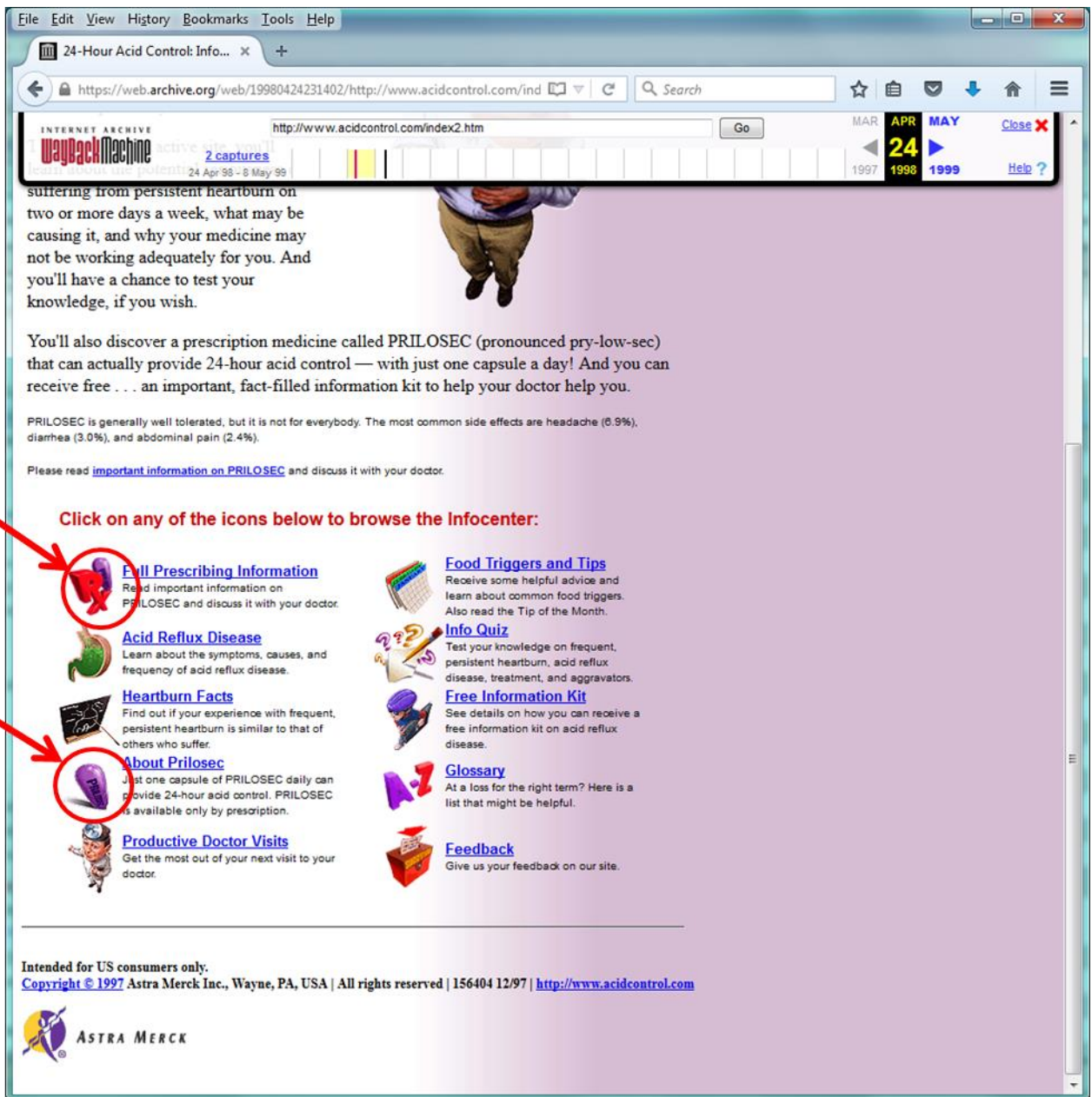
than 5 million Americans have benefitted from Nexium® between 2005 and 2014.

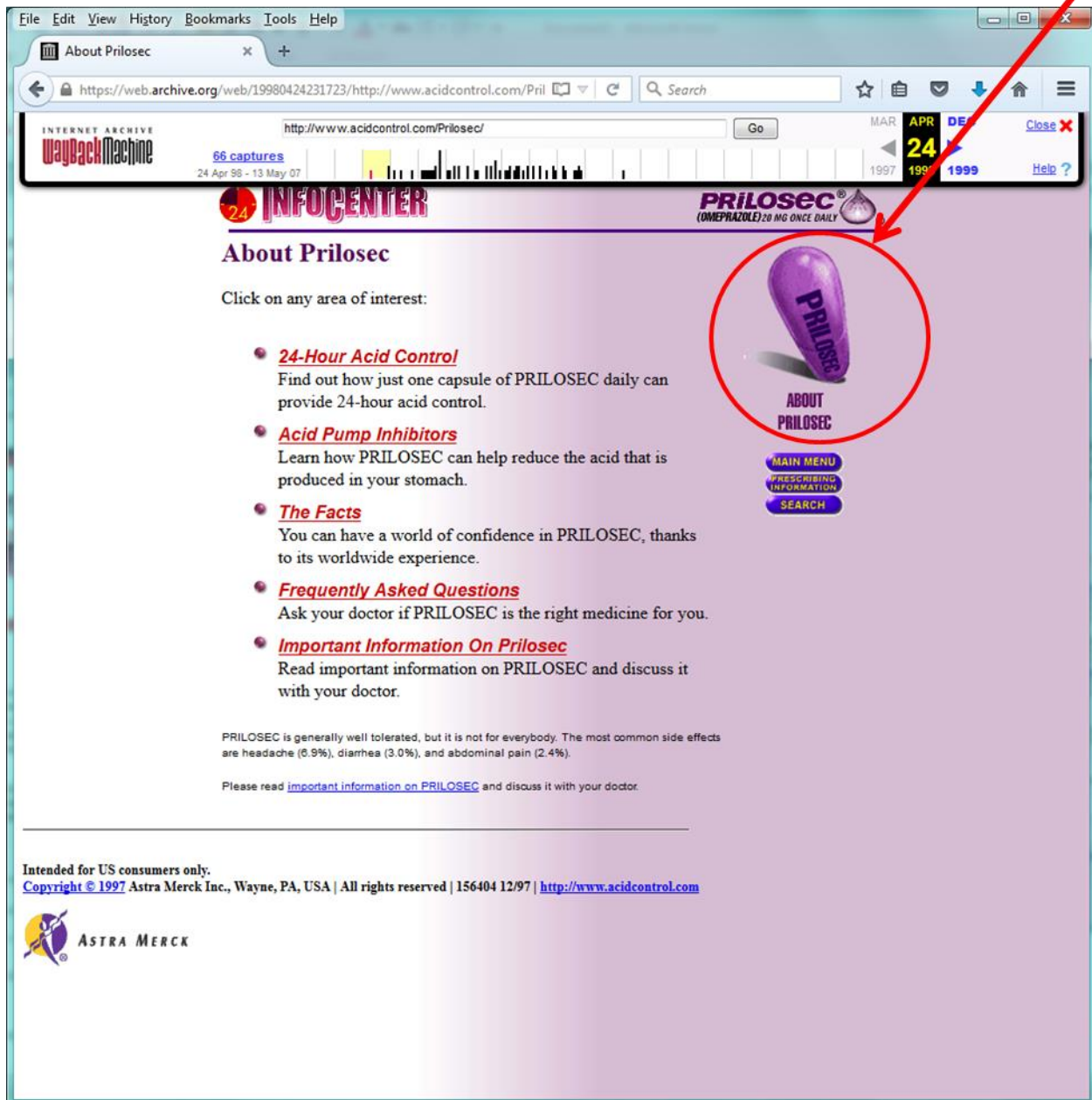
**AZ'S "PURPLE" WEBSITES
FOR PRILOSEC® AND NEXIUM®**

16. AZ registered the domain name ACIDCONTROL.COM in March 1997, and soon thereafter launched a website for its Prilosec® products. AZ's ACIDCONTROL.COM website as launched prominently used the color purple and displayed purple Prilosec® capsules, as shown below in the April 24, 1998 screen shots from Archive.org's records:³

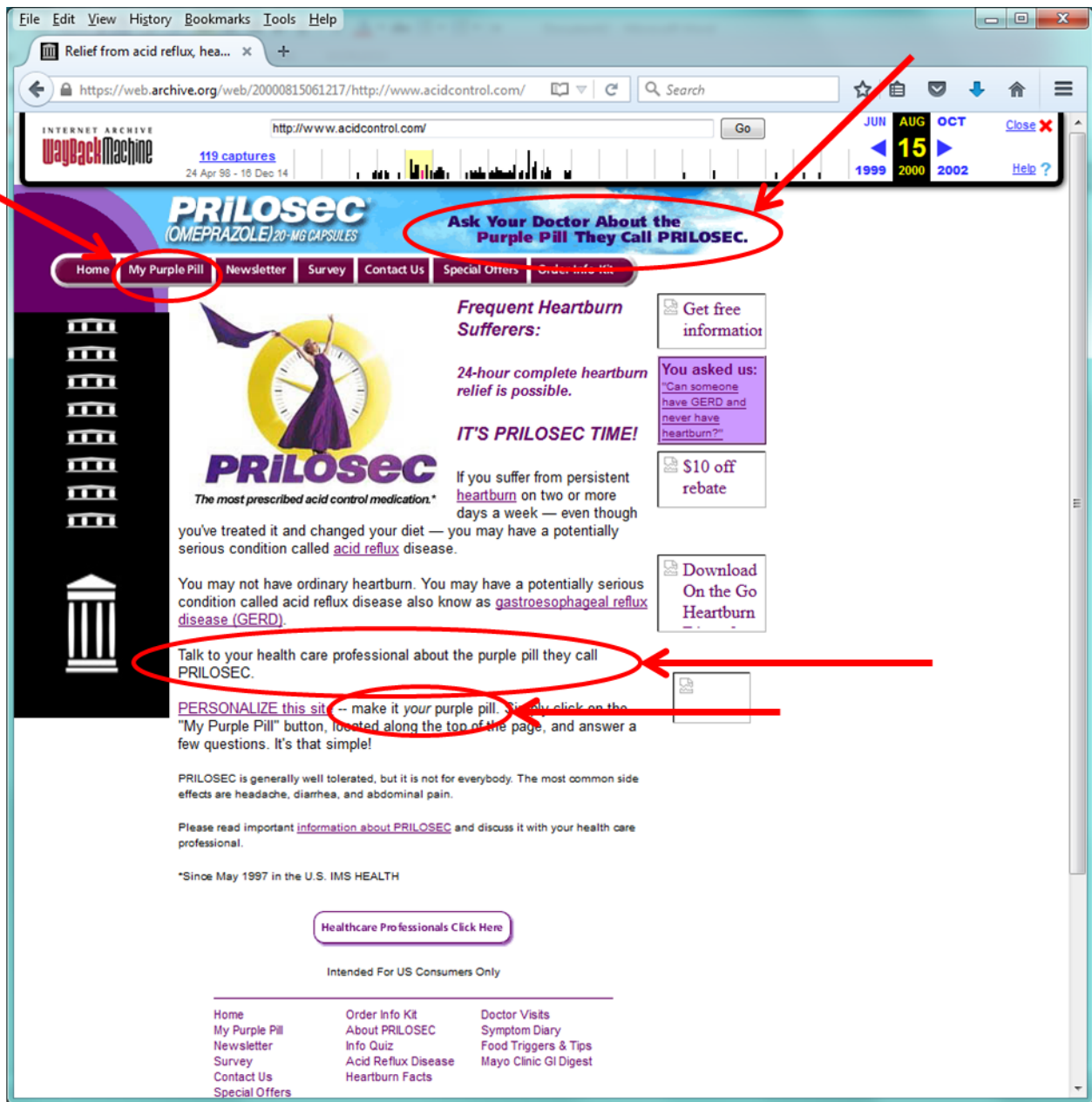
³ In the website screen shots displayed in Paragraphs 16-22 and 24 of this Complaint, for convenience to the reader AZ's counsel added the red arrows and circles to these screen shots to highlight the displays of various "purple" elements.





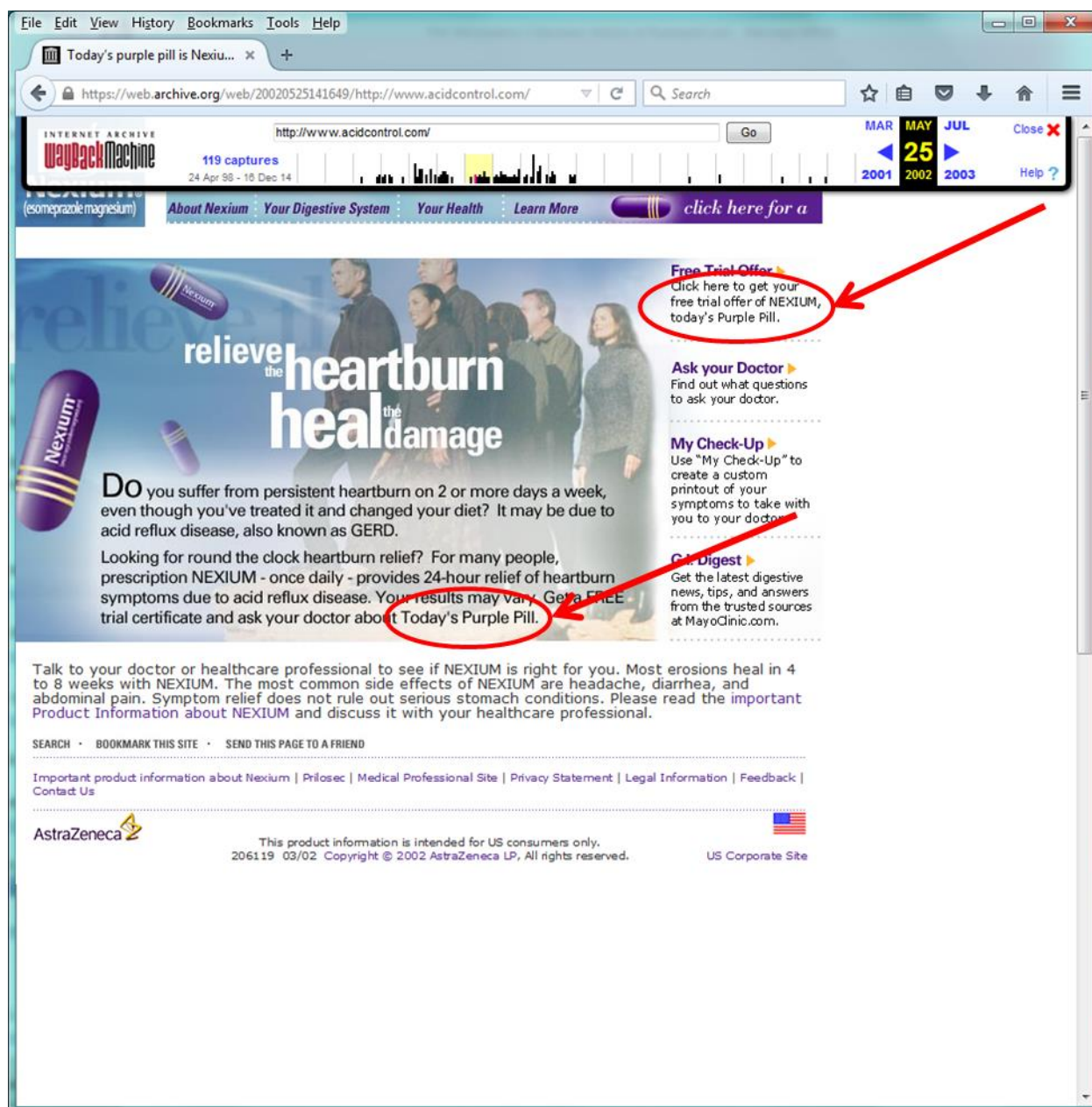


17. AZ continued to use its ACIDCONTROL.COM website in this way from 1998 to approximately late March 2001. In addition, in mid-2000, AZ updated its ACIDCONTROL.COM website to add the button “My Purple Pill,” the headline/tagline “Ask Your Doctor About the Purple Pill They Call Prilosec,” and the text “*your purple pill*,” as shown below in the August 15, 2000 screen shot from Archive.org’s records:

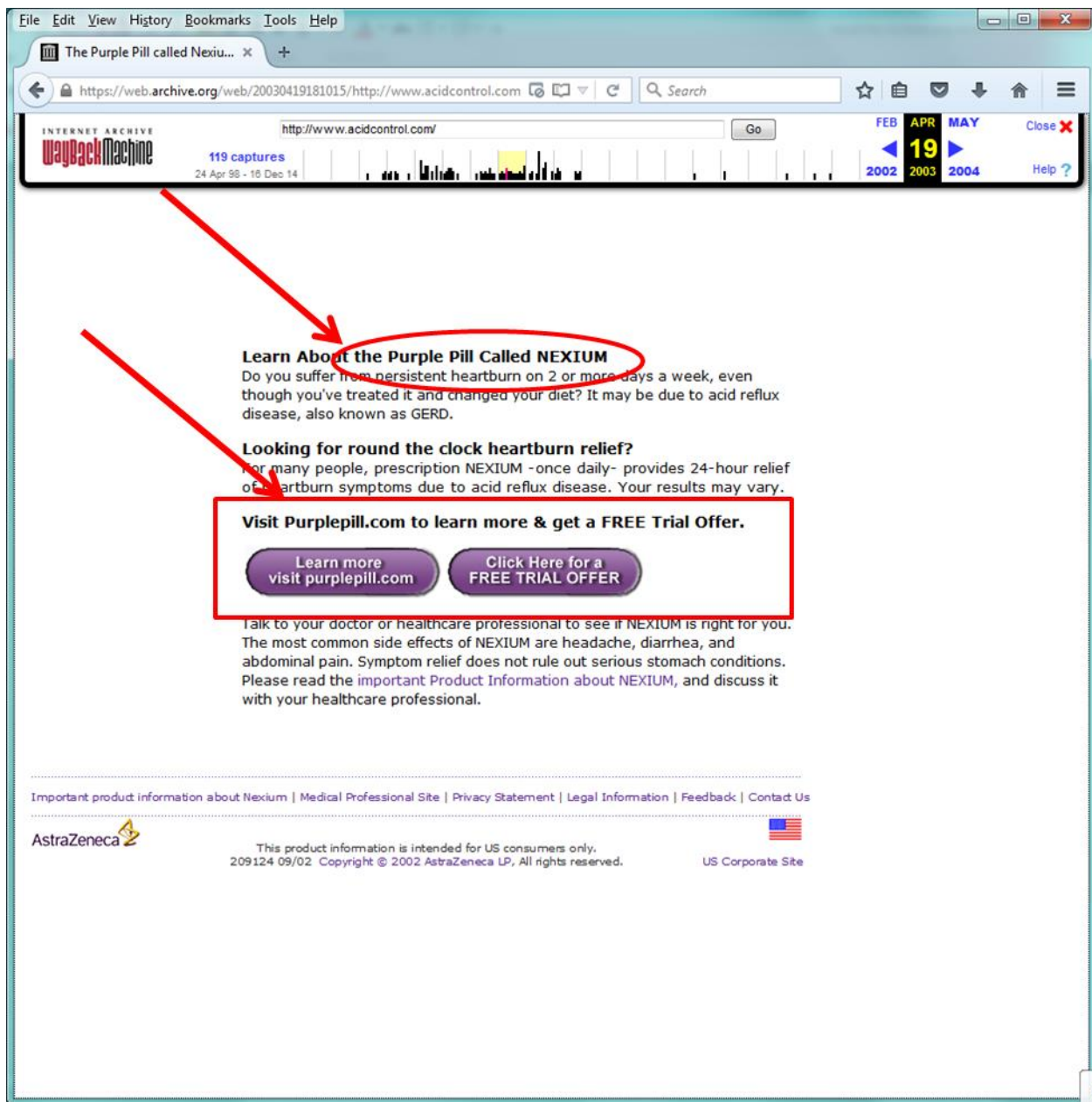


18. In late March 2001, AZ updated its ACIDCONTROL.COM website to announce its upcoming new website for AZ's Nexium® products, to provide a link to AZ's website PRILOSECONLINE.COM for its Prilosec® products, and to provide a link to a page of its ASTRAZENECA-US.COM website that provided information regarding its Nexium® products. In mid-2001, AZ updated its ACIDCONTROL.COM website to advertise its Nexium® products, including displaying purple Nexium® capsules and the wording "Today's Purple Pill" as shown

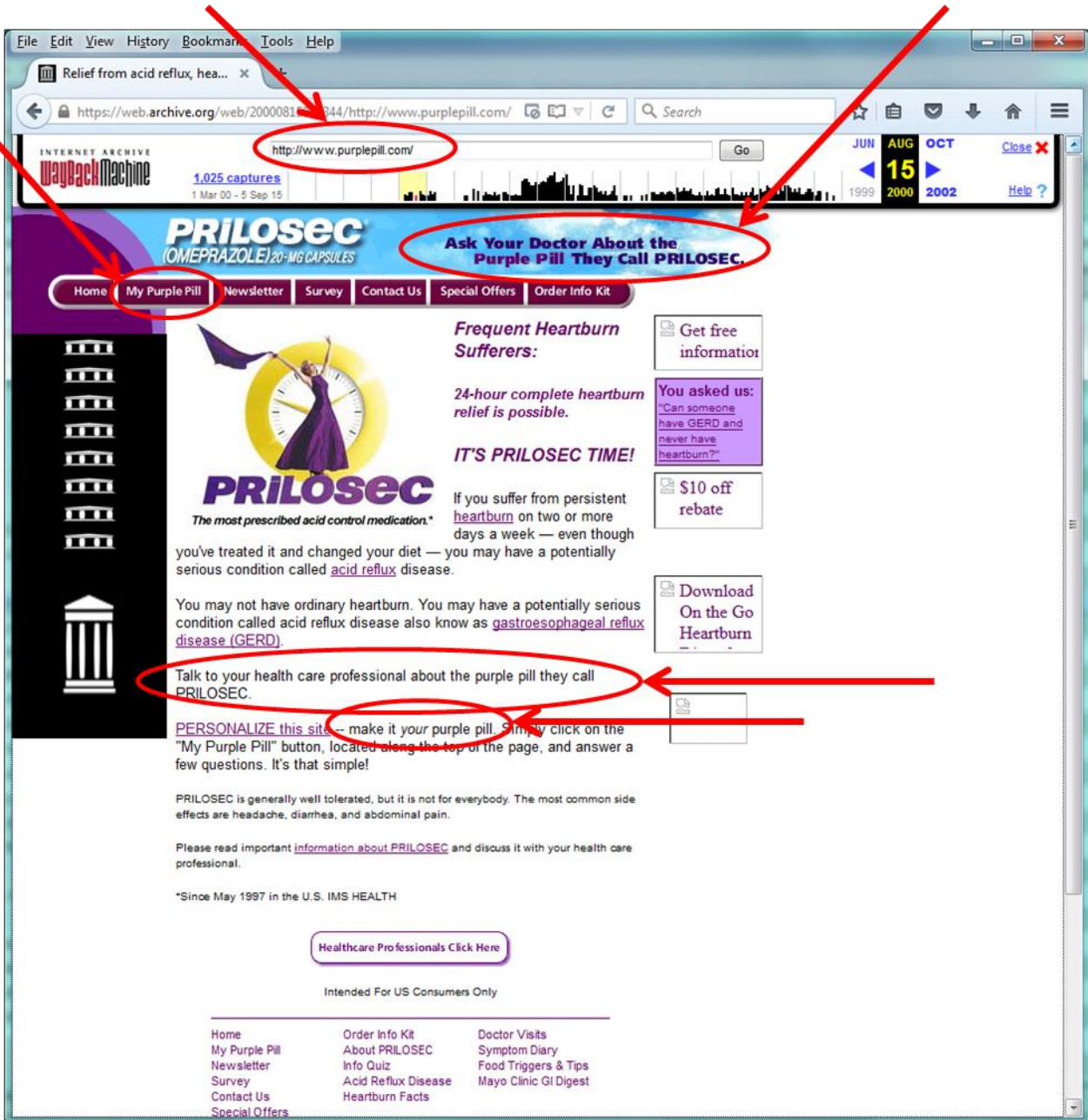
below in the May 25, 2002 screen shot from Archive.org's records:



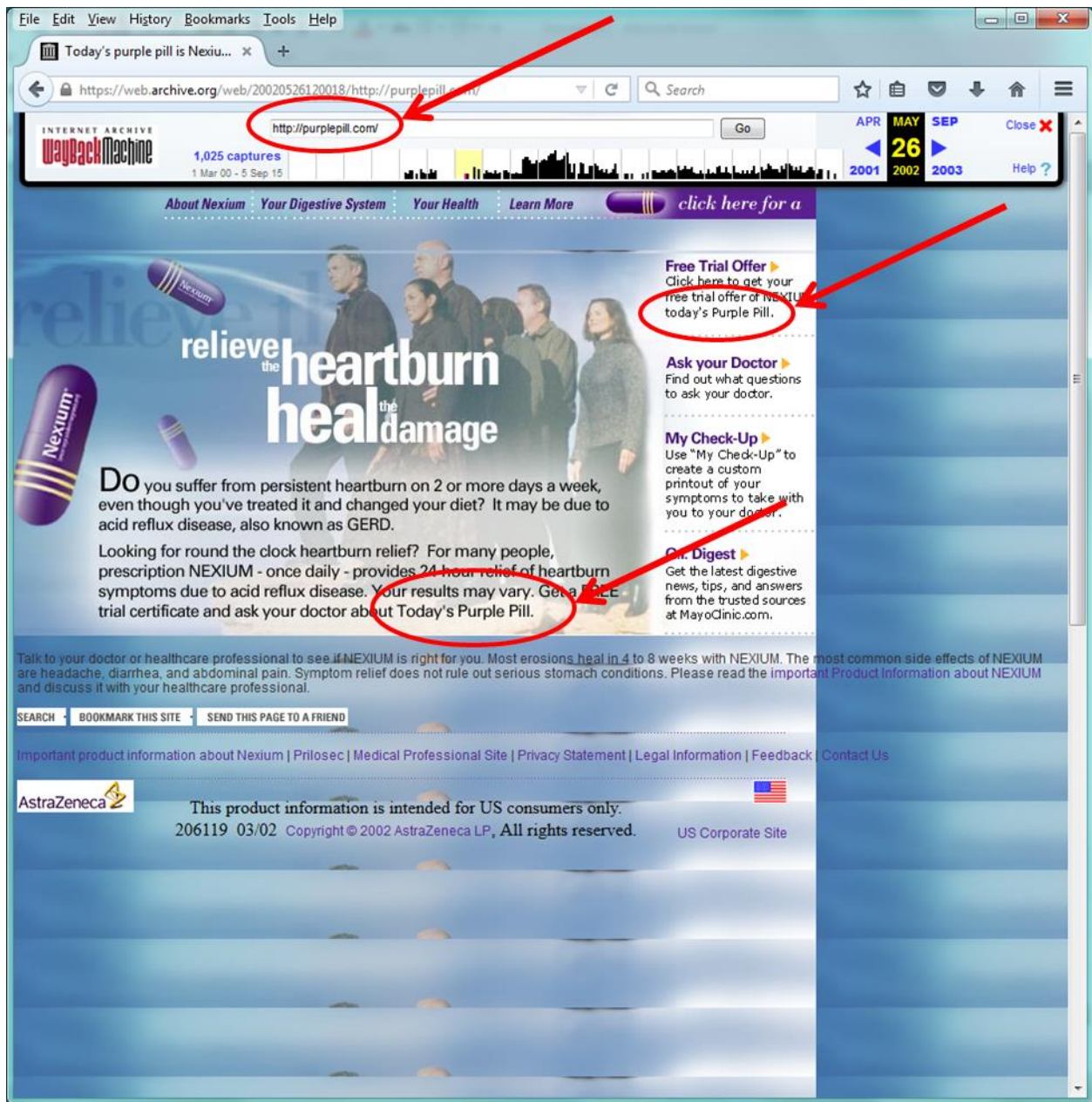
19. In early 2003, AZ updated its ACIDCONTROL.COM website to let users know that AZ was transitioning its Nexium® site to PURPLEPILL.COM. This transition page used the wording “The Purple Pill” and displayed purple capsule-shaped buttons to link visitors to the PURPLEPILL.COM website, as shown below in the April 19, 2003 screen shot from Archive.org's records:



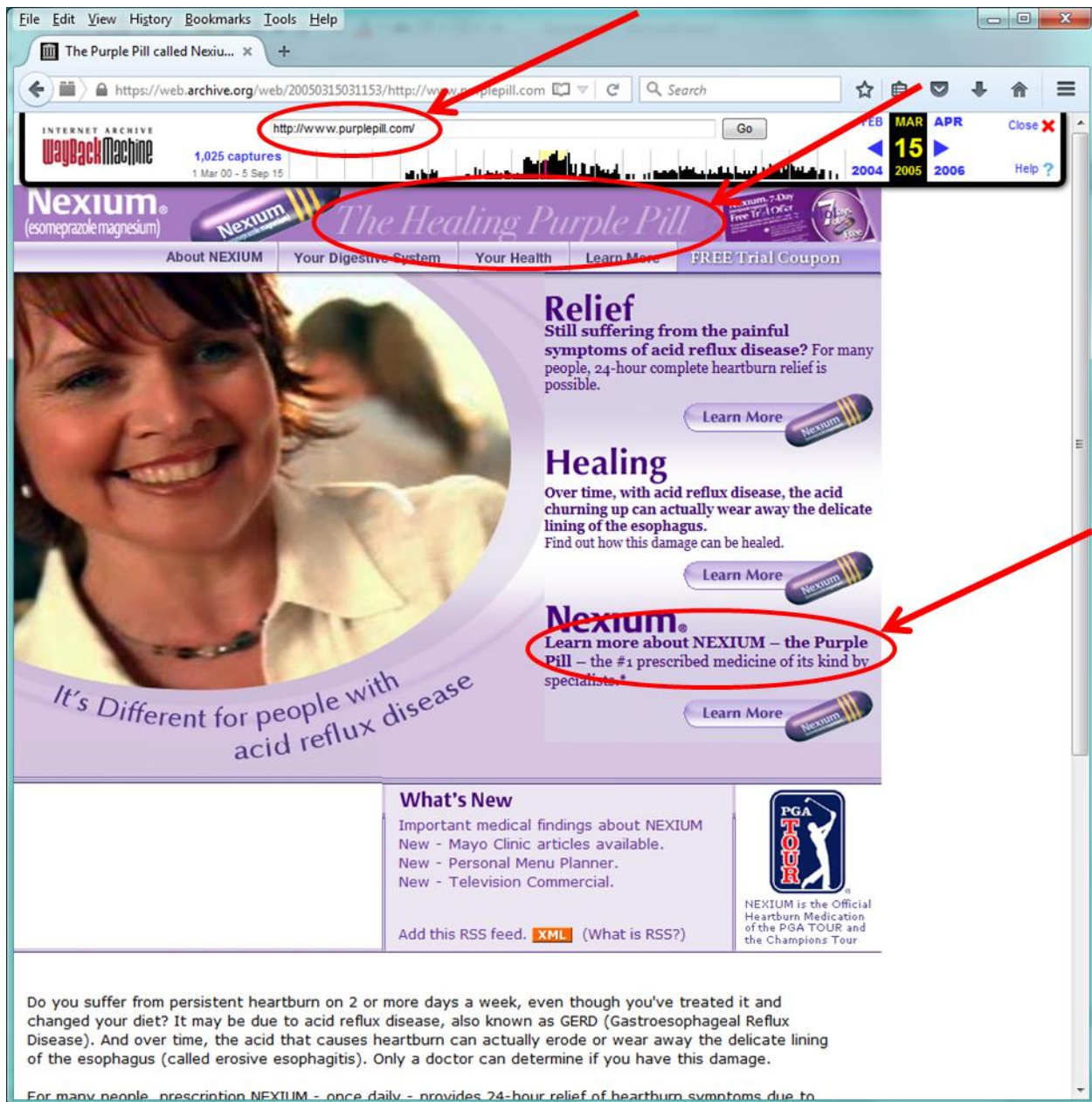
20. AZ registered the domain name PURPLEPILL.COM in October 1999, and soon thereafter began using it as its Prilosec® product website, as shown below in the August 15, 2000 screen shot from Archive.org’s records, which features the color purple, a “My Purple Pill” button, and the headline “Ask Your Doctor About the Purple Pill They Call Prilosec”:

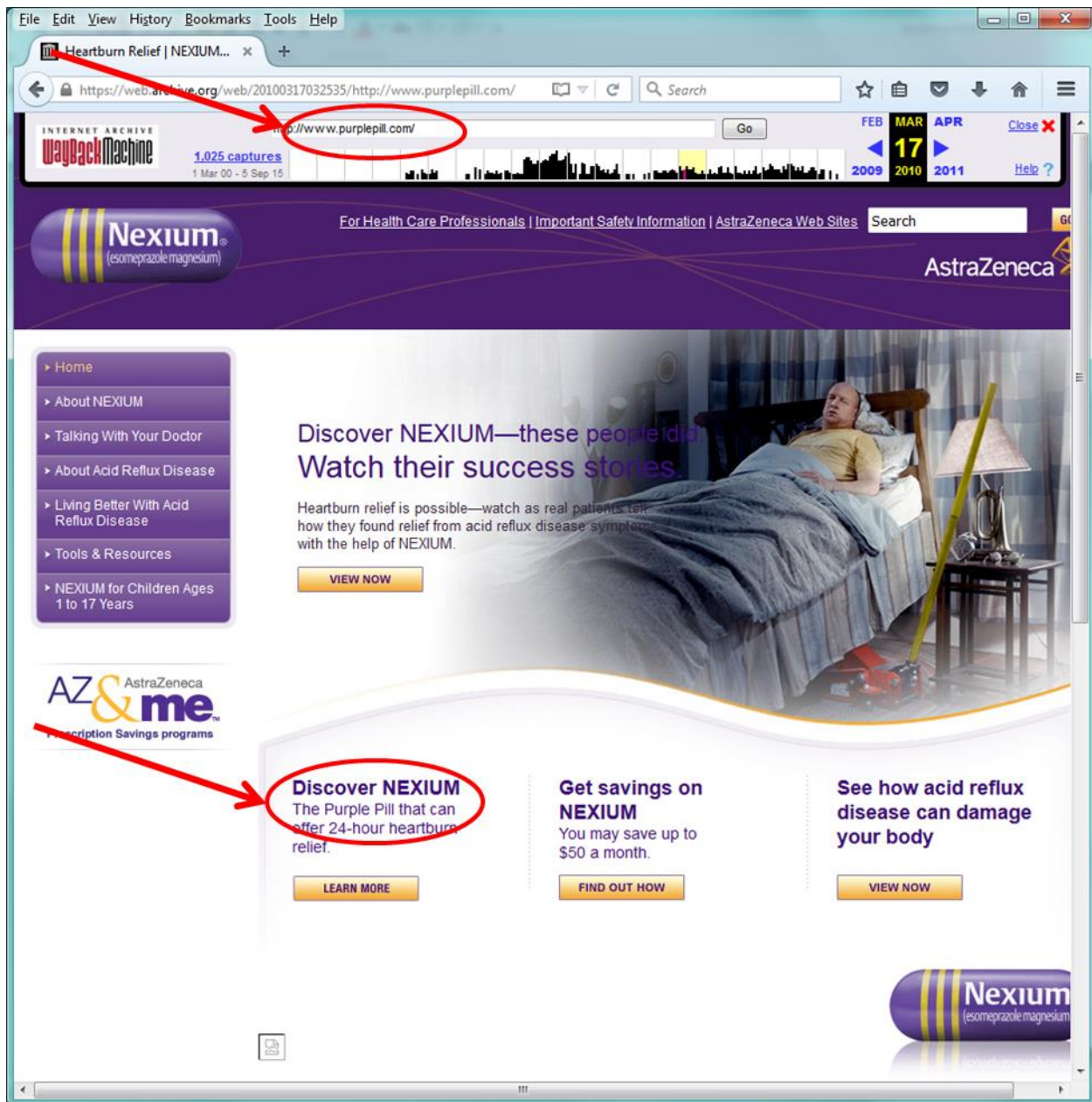


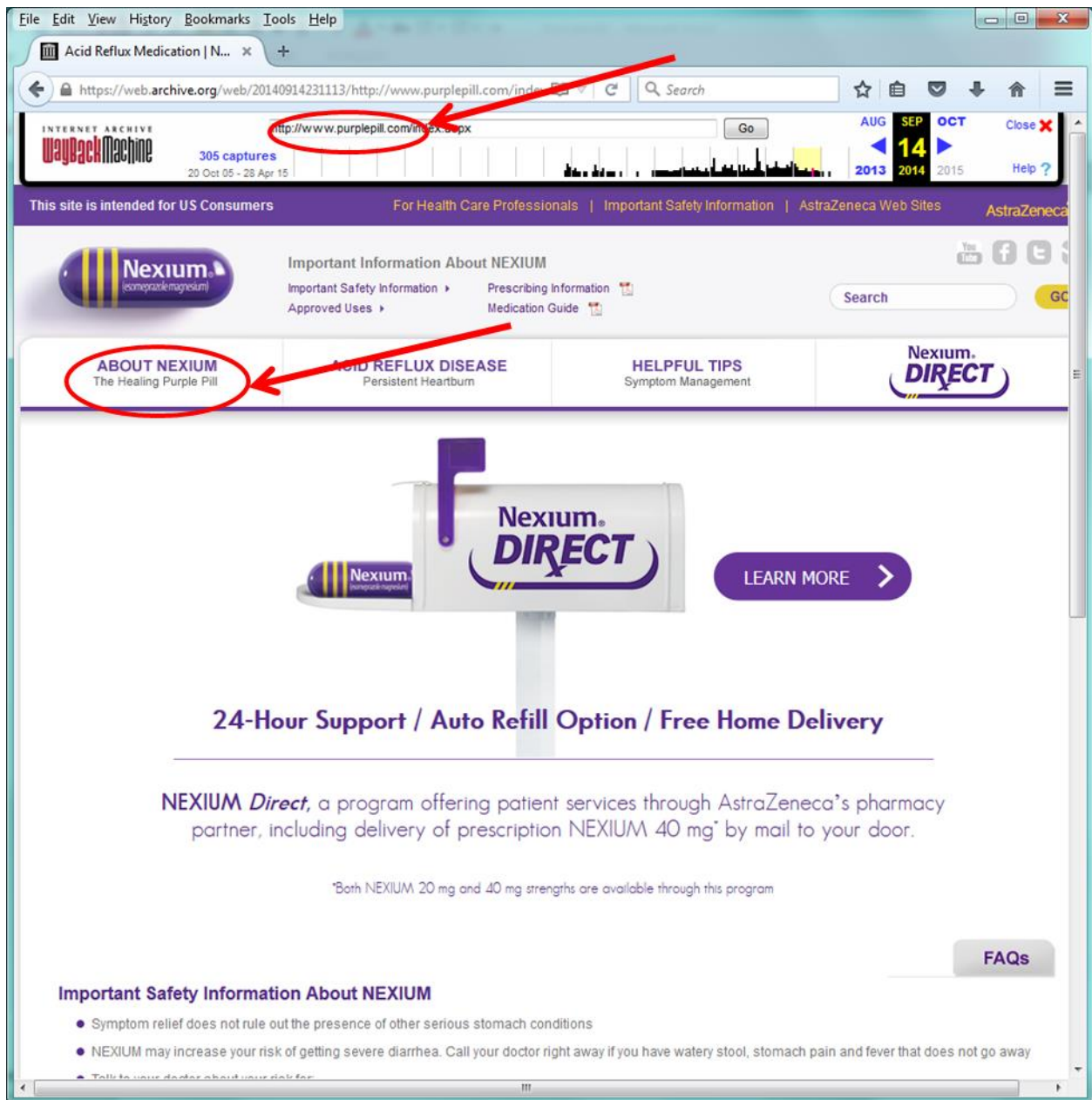
21. In 2002, AZ transitioned its PURPLEPILL.COM website from Prilosec® to Nexium®, as shown below in the May 26, 2002 screen shot from Archive.org's records, which displays purple Nexium® capsules and the wording "Today's Purple Pill":

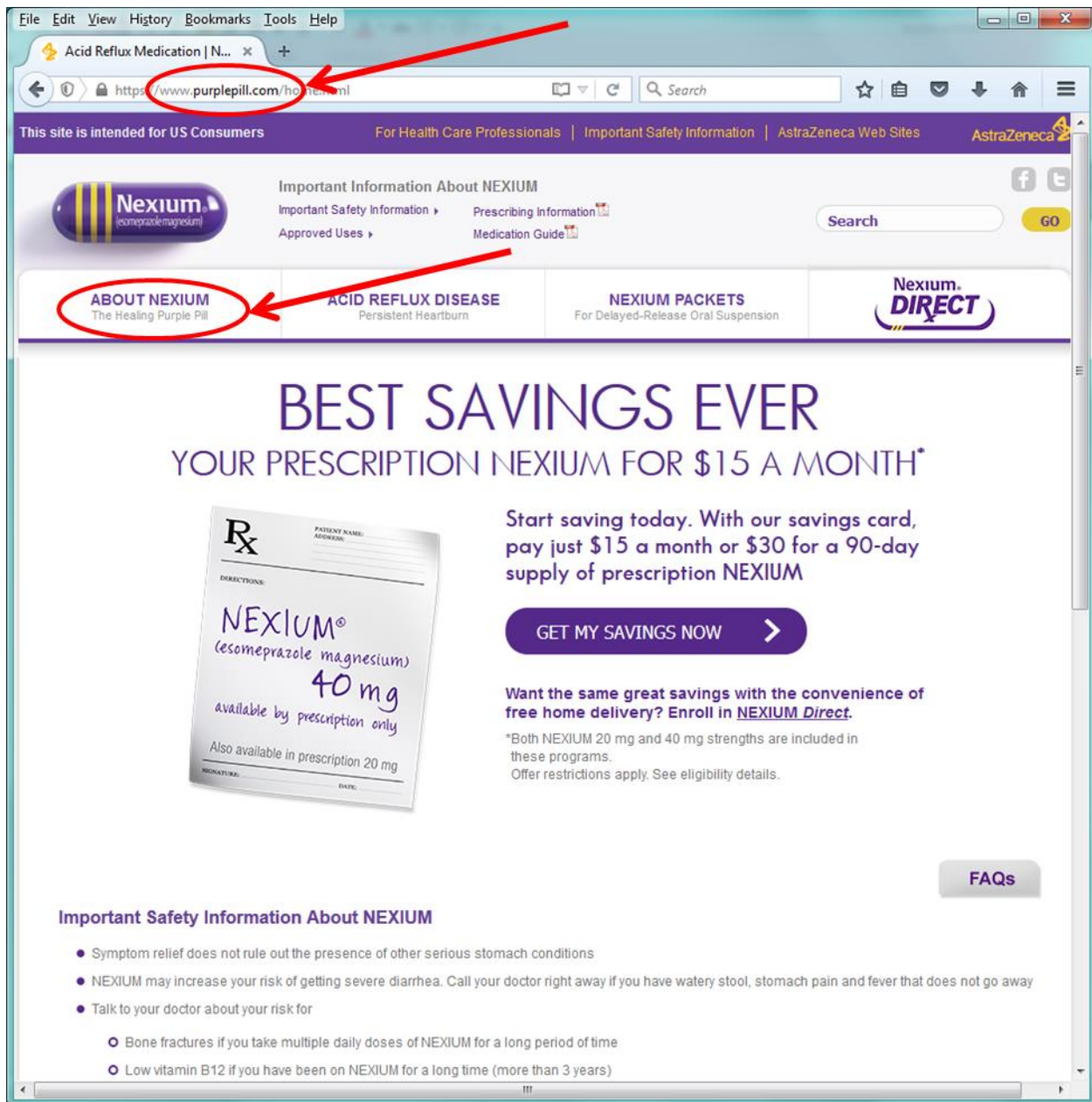


22. AZ has used its PURPLEPILL.COM domain name and associated website for its Nexium® products from 2002 to the present, as shown in the representative screen shots below from Archive.org’s records from 2005, 2010, and 2014 and a screen shot from October 2015, all of which prominently display the color purple, the wording “the Purple Pill” and/or “The Healing Purple Pill,” and purple Nexium® capsules:

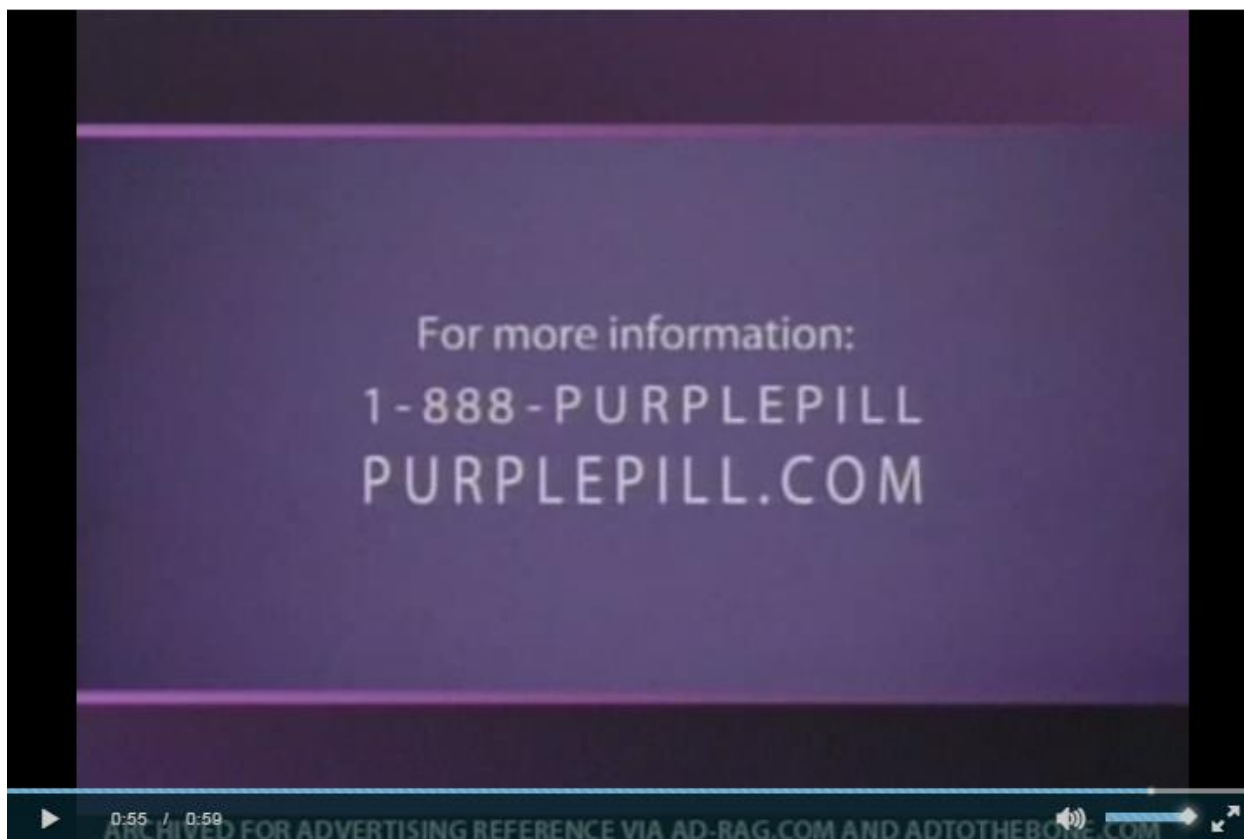




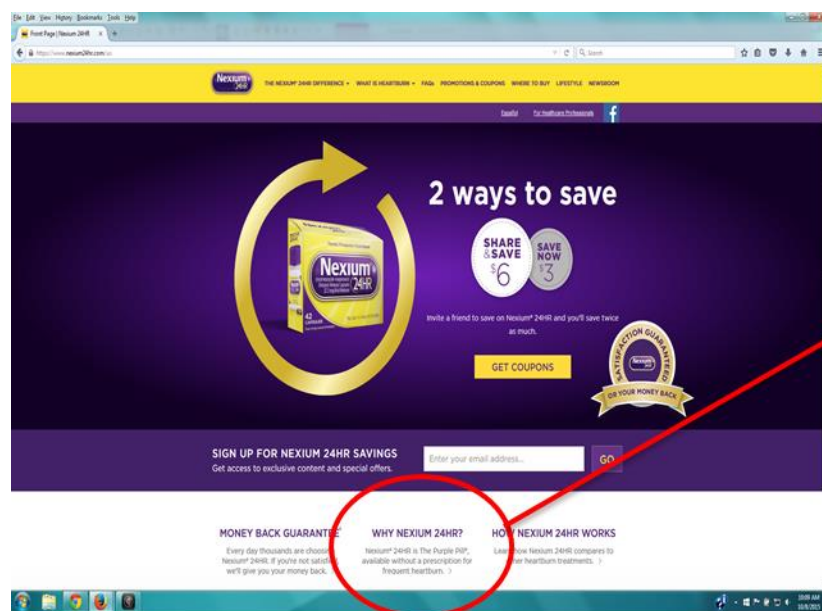




23. The PURPLEPILL.COM has been visited by tens of millions of people over the years, including more than 5 million in 2004 alone and nearly 20 million between 2009 and 2014. Much of AZ's advertising has invited the public to visit the www.purplepill.com website, including the TV commercial screenshot shown below.



24. Pfizer promotes the licensed Nexium® 24HR product on its website www.nexium24HR.com/us, a predominantly purple website prominently displaying purple Nexium® capsules and the phrase “The Purple Pill®,” shown below.



WHY NEXIUM 24HR?

Nexium® 24HR is The Purple Pill®, available without a prescription for frequent heartburn. >

**AZ'S "PURPLE" AND
"THE PURPLE PILL®" ADVERTISING AND PROMOTION**

25. To reinforce the brand significance of the color purple, in addition to its "purple" websites, AZ's advertising and promotional efforts from as early as 2000 to present have consistently focused on educating the public to associate the color purple as applied to capsules for treatment of gastrointestinal ("GI") diseases and the phrase "The Purple Pill®" (collectively, the "Purple Marks") with its PPI products, first with Prilosec® and then Nexium®. The express purpose of this "look for" advertising was to establish the purple color and the phrase "The Purple Pill®" as symbols of origin and quality of GI drugs that emanate only from AZ, i.e., as brands of AZ. AZ has devoted significant resources over the years to advertise and promote its Prilosec® and then Nexium® purple pills using this "look for" purple advertising.

26. AZ's advertising in visual media since 2000 has consistently emphasized the color purple and the "look for" purple theme, including for example depicting floating purple drug capsules, persons wearing purple-colored clothes, and purple backgrounds and borders. Also, AZ's advertising text has used various "purple" phrases in addition to "The Purple Pill®," including "Visit us at purplepill.com," "Purple. It's Not Just Another Pretty Color," "Ask your doctor about the purple pill," and "Talk to your doctor about the purple pill they call Prilosec®." With the 2001 introduction of Nexium®, AZ also used the phrases "Do you know there's a new purple pill," "Today's Purple Pill," "The New Purple Pill," and "The Healing Purple Pill." The initial TV ads started with "I am every man and every woman who ever suffered from frequent, persistent heartburn." It went on to describe the problem in more detail and then said, "But today there's a purple pill called Nexium. It's from the makers of Prilosec." After discussing the effect and side effects of Nexium® the ad ended with the line "Relive the heartburn, heal the damage. It's possible with today's purple pill called Nexium." Below is a small sample of AZ's TV

commercials, print advertising, and consumer communications (or excerpts from them) between 1999-2012 showing AZ's emphasis of both the color purple and its Purple Marks.



27. AZ has, since as early as 2000, advertised “The Purple Pill®” in the ways

described above in many consumer publications that are widely distributed to the general U.S. public, including *Bon Appetit*, *Family Circle*, *Fortune*, *Good Housekeeping*, *Ladies Home Journal*, *Life*, *National Geographic*, *Newsweek*, *People*, *Readers Digest*, *Sports Illustrated*, *US News & World Report*, *Wall Street Journal*, *Weight Watchers' Magazine*, and in the *Washington Post* and other U.S. city newspapers. These publications have reached tens of millions of people each year over the years. Below are examples of such print advertisements.

2001

Today's purple pill is **NEXIUM**.
From the makers of Prilosec.

Follow the heartburn. Meet the damage.

For many, it's possible with NEXIUM. It's a powerful prescription medicine that works fast to relieve heartburn and prevent it from coming back. NEXIUM also helps protect the lining of the stomach and esophagus from the damage caused by stomach acid. NEXIUM is a powerful medicine that works fast to relieve heartburn and prevent it from coming back. NEXIUM also helps protect the lining of the stomach and esophagus from the damage caused by stomach acid.

FREE Trial Offer
1-888-PURPLEPILL

Nexium.
(esomeprazole)

2008

A LITTLE PURPLE FOR THE RED, WHITE AND BLUE.

THE MAJORITY OF PEOPLE WITH PRESCRIPTION COVERAGE IN THE UNITED STATES CAN GET THE PURPLE PILL™ FOR LESS THAN \$30 A MONTH*

If you suffer from constant heartburn, it's time that a week, NEXIUM is a powerful prescription medicine that works fast to relieve heartburn and prevent it from coming back. NEXIUM also helps protect the lining of the stomach and esophagus from the damage caused by stomach acid. NEXIUM is a powerful medicine that works fast to relieve heartburn and prevent it from coming back. NEXIUM also helps protect the lining of the stomach and esophagus from the damage caused by stomach acid.

For information about NEXIUM, the Healthy Purple Pill, visit www.purplepill.com or call 1-888-PURPLEPILL. Prescription coverage and cost offer is your responsibility. NEXIUM may be able to help.

Nexium.
(esomeprazole)

2012

Save **BIG** on The Purple Pill.

Pay as little as \$18.*

On each of your next 12 prescriptions.

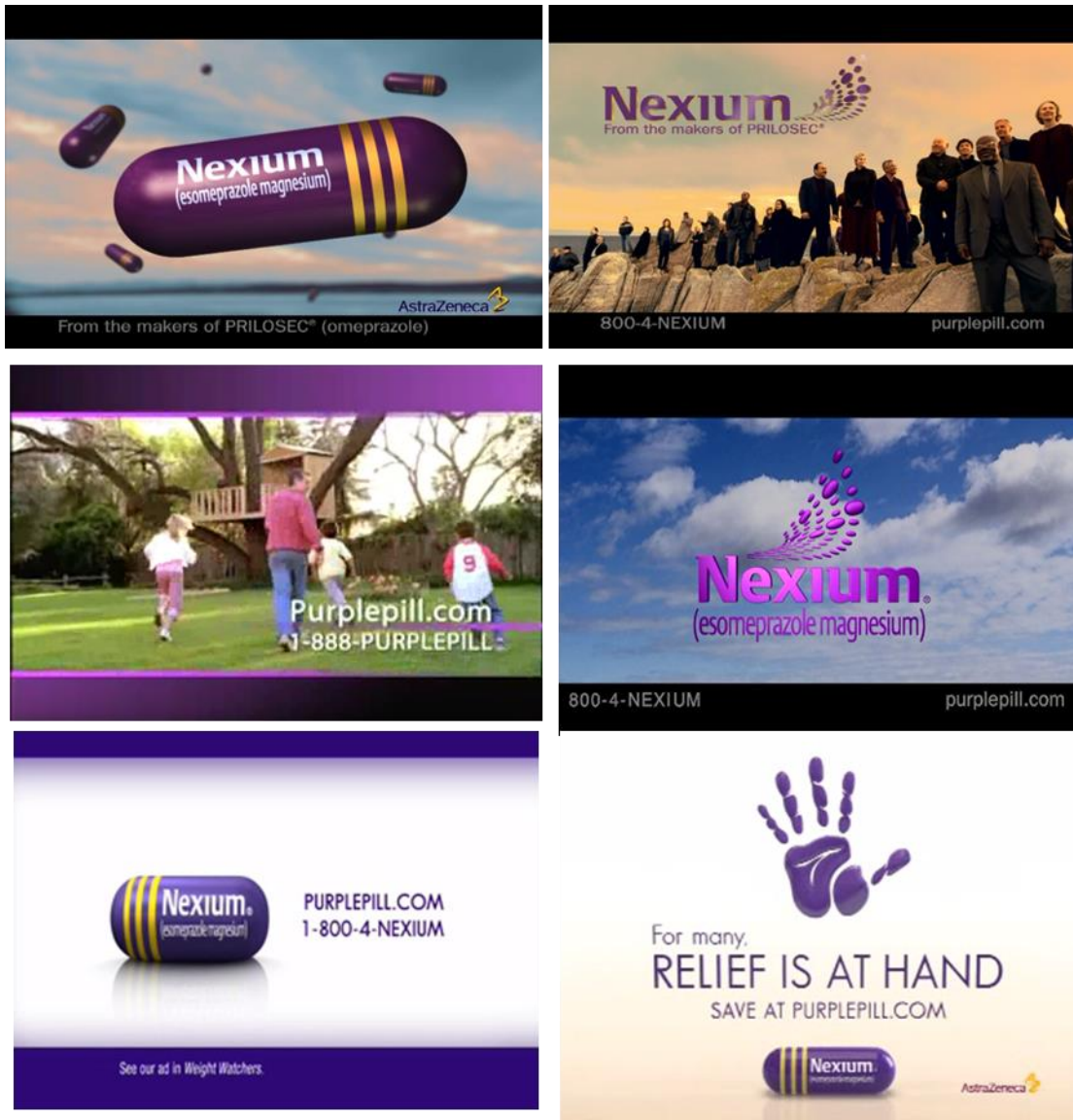
Nexium.
(esomeprazole)

2015

Rx
Nexium.
(esomeprazole)

DON'T FORGET.
FOR YOUR PATIENTS WHO PREFER PURPLE...

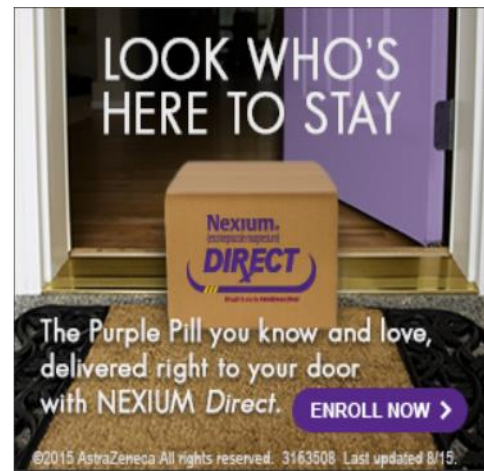
28. AZ has also extensively advertised “The Purple Pill®” on network and cable television, and on radio, also reaching tens of millions of people each year over the years. TV advertisements for Prilosec® and then Nexium® products, including “Purple Pill”-themed advertisements, aired during many high-profile TV programs such as the Olympics and the Golden Globe Awards. Representative screen shots from six of AZ’s TV ads are shown below. These “Purple Pill” themed advertisements also contain audio references to “The Purple Pill®” in the text and the voiceover of the advertisements, including: “Today there’s a Purple Pill called Nexium, from the makers of Prilosec,” “Your Doctor knows about the Purple Pill called Nexium,” and “It’s possible with the Purple Pill called Nexium.”



29. Other brand-building activities for “The Purple Pill®” have consistently included for many years direct mail to the public and to doctors, newsletters, distribution of product samples, charts and cards to doctors, and advertising in medical publications.

30. AZ has for many years placed ads on different online sites, including numerous popular and highly trafficked websites. These include the websites for Google, Yahoo, WebMD, Weight Watchers, Scripps, iVillage, Fox News, NBC, AOL, Facebook, and Woman’s Day. AZ’s online advertising is and has been exposed to many millions of people. Below are representative

examples of online ads placed by AZ, all of which prominently feature the color purple and the wording “The Purple Pill,” “Your Purple Pill,” “Start Seeing Purple,” and/or “purplepill.com.”



31. Like its other advertising and promotional activities discussed above, AZ's Nexium® Facebook page, located at <https://www.facebook.com/NEXIUM/timeline>, also promotes AZ's purple pills and the color purple using “look for” purple advertising. Shown below are representative images from the Nexium Facebook page.



32. AZ has also carried out advertising campaigns, built around the “Purple Pill” theme in high-traffic public places such as New York's Port Authority Bus Terminal, Philadelphia's 30th Street Railroad Station and San Francisco's Embarcadero BART Station. Examples are shown below.



World Trade Center, New York



30th Street Station, Philadelphia

33. AZ's purple branding has also included the use of "purple" vanity phone numbers such as 1-888-PURPLEPILL, which AZ has featured in TV and print ads, such as the ones shown in Paragraphs 23, 26, 28, and 30 above.

34. The FDA recognized the trademark significance of AZ's color purple as early as 2001 as part of an advertising review. In considering whether a television ad for Prilosec® (that did not mention Prilosec® by name) should be considered a "product-specific advertisement," the FDA's Division of Drug Marketing, Advertising and Communications ruled in 2001 that the

ad in question was a product-specific advertisement because it discussed acid-reflux disease in conjunction with “the purple pill,” and AZ’s Prilosec® “is the only purple pill that treats heartburn due to acid-reflux disease.”

35. Pfizer, through its license from AZ, promotes “The Purple Pill®” and AZ’s Purple Marks through its Nexium® 24HR product packaging and in-store displays. Shown below are representative examples of Nexium® 24HR product packaging and displays prominently displaying the color purple and the Nexium® mark displayed in a purple capsule-shaped background, and in some case also “The Purple Pill®”.



36. AZ has devoted significant resources to marketing, advertising and promotional activities for its Prilosec® and Nexium®” products since 1995, the vast majority of which have prominently featured AZ’s purple capsules, “The Purple Pill®” and other “Purple Pill” phrases, and purple backgrounds, purple text and/or other purple design elements as shown above. On an average annual basis since 1995, AZ has spent over \$250 million building its purple brand.

**BUILDING PURPLE BRAND AWARENESS THROUGH NATIONWIDE
DISTRIBUTION OF FREE NEXIUM® SAMPLES**

37. AZ has also built its purple brand, and benefitted the public, since the launch of Nexium® in 2001 to the present through nationwide distribution of free samples to doctors. These samples are given by doctors to patients at no cost to patients. At considerable cost to itself, AZ has provided to doctors more than 500 million Nexium® pills as free samples. Over the years AZ has typically distributed its Nexium® pills as free samples in a bottle containing five pills. Below is an image of the current bottle used for Nexium® free samples, which bottle prominently features the color purple. AZ has used this bottle for the past 4-5 years and bottles used in prior years were similar to this bottle.



THE MEDIA AND THE PUBLIC HAVE LONG ASSOCIATED THE COLOR PURPLE WITH AZ AND ITS PRILOSEC® AND NEXIUM® PRODUCTS

38. There have been countless independent, unsolicited references in U.S. print and online media to AZ's Prilosec® and Nexium® drugs. In many of these references, news reporters or persons quoted by them have associated AZ's products with the color purple and/or with the words "Purple Pill." These include the following representative examples:

"And then there is Prilosec. 'It's really an incredible medication,' [Dr.] Walker said. 'People call it the little purple miracle pill'." [*Syracuse Herald-Journal*, February 23, 1996]

"People come in and they want 'the little purple pill.' Many doctors relent, rather than risk losing the patient to a rival, says Peter Penna, head of Pharmacy services for Cigna Healthcare." [*Forbes*, April 5, 1999]

"Perhaps only Welch's, the Minnesota Vikings and Oprah Winfrey are as closely linked to the color purple as Prilosec." [*Advertising Age*: June 26, 2000]

"AstraZeneca will continue pushing purple in its bid for green. The drug marketer is expected to shift its marketing theme for prescription heartburn pill Prilosec, which revolves around the color purple, to its successor drug Nexium. Prilosec has been a blockbuster, in part because of consumer campaigns pegging it as 'the purple pill'. Purple-themed promotions have been splashed on prime-time TV, the web site *purplepill.com*, even the floorboards in New York's Port Authority Bus Terminal." [*Advertising Age*, October 30, 2000] (emphasis added)

"The heartburn and ulcer drug Prilosec - widely known as 'the purple pill' - will lose its patent protection in October." [*The Dallas Morning News*, March 11, 2001]

"A little purple pill is the world's biggest selling prescription drug, generating \$6.3 billion a year in sales." [*Associated Press*, May 5, 2001]

"There's the world's best-selling drug, Prilosec, promoted as the 'purple pill' in advertising. Even if patients cannot remember the ulcer treatment's proper name, they can request Prilosec by its color and alliterative nickname." [*Boston Globe*, May 20, 2001]

"Prilosec is one of the most recognizable drugs, thanks to a distinctive purple color and hundreds of millions of dollars spent on consumer ads -- some telling people to 'ask your doctor about Prilosec, the purple pill.'" [*Wall Street Journal*, 2002]

“Purple reign: Nexium’s launch strategy is based on the successful branding of Prilosec, which became the bestselling drug in the world.” [*Med Ad News*, March 1, 2002]

“This is the story of a pill. The pill was colored purple so consumers would remember it as the purple pill. The purple pill hit the market in 1989 to treat a humble condition, heartburn the purple pill became a financial star. In 1995, drugmaker AstraZeneca sold more than \$1 billion of the purple pill in the US. In 1997, sales crossed the \$2 billion mark. At the height of its popularity, in the year 2000, sales of the purple pill exceeded \$4 billion. Prilosec was the most popular pill in the U.S. and in the world.” [*NPR: All Things Considered*, April 18, 2002]

“Prilosec is one of the most recognizable drugs, thanks to a distinctive purple color and hundreds of millions of dollars spent on consumer ads- some telling people to ‘ask your doctor about Prilosec, the purple pill’.” [*The Wall Street Journal*, June 6, 2002]

“Purple Prodigy” (used as a shorthand for AZ’s Prilosec® product) [*The Wall Street Journal*, June 21, 2002]

“FDA seeks input on OTC Prilosec Regulators want an advisory panel’s opinion on proper uses for an over-the-counter form of AstraZeneca’s blockbuster heartburn drug. They are mulling whether to OK the famous ‘purple pill’ for nonprescription sales.” [*Investor’s Business Daily*, June 21, 2002]

“The Costly Case of the Purple Pill” -- AstraZeneca has been able to keep the purple profits flowing when they later found themselves sitting on a doctor’s padded exam table, they didn’t even have to recall the drug’s name. All they had to remember was its color even critics of the purple juggernaut got around to saying: “It’s a very good drug.”” [*The Boston Globe Magazine*, November 17, 2002]

“In 1977, the Tagamet revolution began. Whereas the common antacids like Maalox and Tums neutralized acid, prescription Tagamet blocked it. It made a huge difference. Still, there was a group of people who needed something more powerful than Tagamet and its successors, included in a class of drugs that came to be known as H2 blockers. In 1989, that power came in spades and in the unforgettable shade of purple. . . . Here’s the thing: Unlike many hyped drugs, Prilosec is a wonder drug that actually deserves its title. In dozens of interviews for this article, even critics of the purple juggernaut got around to saying: “It’s a very good drug.” But that doesn’t mean a slew of people couldn’t do fine on something much cheaper.” [*Boston Globe*, November 19, 2002]

“AstraZeneca’s relentless promotion of its heartburn medication over the years helped make Prilosec the world’s best-selling purple pill, generating \$4.6 billion sales in 2002.” [*Smart Money*, June 2003]

“As executive vice president in charge of Prilosec, Nexium and Entocort, she developed the famous ‘purple pill strategy’ which helped make Prilosec the top-selling drug in history, and turned Nexium into its \$3 billion successor.” [*PR Newswire US*, December 3, 2004]

“With the approval in hand, AstraZeneca set in motion one of most expensive marketing campaigns ever with the goal of getting doctors and patients to switch from Prilosec to the almost identical Nexium. The company immediately quadrupled its sales force assigned to those products and according to Medical Marketing & Media, an advertising trade publication, spent \$16 million in one month alone. The blitz worked. At this point, who hasn't heard of the "little purple pill"?” [*NBC News*, August 14, 2007, http://www.nbcnews.com/id/20249591/ns/health-second_opinion/t/costly-side-effects-nexiums-ad-blitz/]

“The development of Nexium, the famous "purple pill," is one of my favorite stories.” [*Huffington Post*, August 15, 2007, http://www.huffingtonpost.com/dr-harry-lodge/walmart-the-four-dollar-p_b_60610.html]

“Last year U.S. consumers and their insurance companies spent an astonishing \$4.8 billion on Nexium, one of several prescription proton-pump inhibitors (PPIs) to treat heartburn and acid reflux. It’s no wonder the “purple pill” was the second-highest-selling branded drug in 2008, behind Lipitor.” [*Consumer Reports*, October 29, 2009, <http://www.consumerreports.org/cro/news/2009/10/overprescribed-and-overpriced-just-say-no-to-nexium/index.htm>]

“Now Nexium is up to bat. AstraZeneca's famous "purple pill" for acid reflux lost patent protection in May, and India's Ranbaxy Laboratories has acquired FDA approval for a generic.” [*The Motley Fool*, June 19, 2014, <http://www.fool.com/investing/general/2014/06/19/is-astrazenecas-dividend-in-danger.aspx>]

39. Numerous consumers have likewise associated the color purple with AZ’s Nexium® product as shown by the following representative comments as posted by consumers on AZ’s Nexium® Facebook page during 2014-2015:

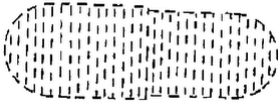
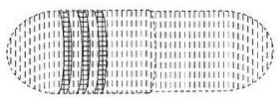
- I love that purple pill
- I've benn taking Nexium for over 15 years , nothing else works. I have tried all other over the counter and perscription drugs. Thank god for the "purple pill".
- I don't go anywhere without my little purple pill
- I take 2 a day and have for years it's the only thing that I can take to help. I have tried to take over the counter but none ever help just made things a

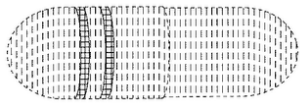
lot worse ! I love the Nexium and can't do without it ! By the way I could go for that purple phone too !! Thanks for my life savor for my stomach.

- We are now 85 yrs and feeling great thanks to that neat littl purple pill.
- Tried lots of stuff, only thing that works for me is the purple pill!
- My doctor and surgery and this purple pill saved my life.
- I'm back on regular nexium the purple pill
- I am proud of the red, white and blue totally.....but I like the purple because it helps my tummy
- The purple pill...Nexium... Helps if you need it!
- Couldn't live without the purple.
- I am so grateful for the purple pill it is the only one that helps my acid reflux.

AZ'S FEDERAL TRADEMARK REGISTRATIONS FOR ITS "PURPLE" TRADEMARKS

40. AZ owns the following federal trademark registrations for the Purple Marks on the Principal Register: (1) the single color "purple" applied to a capsule, (2) the single color purple applied to a capsule with three gold rings, (3) the single color purple applied to a capsule with two gold rings, and (4) the word mark THE PURPLE PILL, all for the treatment of GI diseases:

Mark (Description Of Mark)	Reg. No/ Reg. Date	Goods
 The mark consists of the color purple as applied to the goods or to containers therefor.	2806099 1/20/04	Pharmaceutical preparations and substances for the treatment of gastrointestinal diseases
 The mark consists of the colors purple and gold as applied to the surface of a pharmaceutical capsule. The capsule is	2980749 8/2/05	Pharmaceutical preparations and substances for the treatment of gastrointestinal diseases

Mark (Description Of Mark)	Reg. No/ Reg. Date	Goods
purple with three side-by-side gold rings that encircle the top of the capsule.		
 <p>The colors purple and gold as applied to the surface of a pharmaceutical capsule. The capsule is purple with two side-by-side gold rings that encircle the top of the capsule.</p>	3062072 2/28/06	Pharmaceutical preparations and substances for the treatment of gastrointestinal diseases
THE PURPLE PILL	3188285 12/19/06	Pharmaceutical preparations for the treatment of gastrointestinal diseases

True and accurate copies of the Certificates of Registration are attached as Exhibit 1. The United States Patent and Trademark Office registered each of the above marks finding that each had acquired distinctiveness (also known as secondary meaning) based on evidence submitted by AZ in 2002 and 2004 regarding its length of use, volume of sales, advertising expenditures, and “look for” purple advertising, among other evidence. Since these trademark registrations issued, AZ has sold tens of billions of dollars of Nexium® purple pills and spent billions of dollars advertising and promoting Nexium® purple pills featuring AZ’s “look for” purple advertising.

41. AZ is not aware of any third-party trademark registrations covering the mark purple applied to capsules or pills for the treatment of GI diseases. Moreover, AZ is not aware of any third parties that have promoted the color purple as a trademark for any pharmaceutical preparations for the treatment of GI diseases.

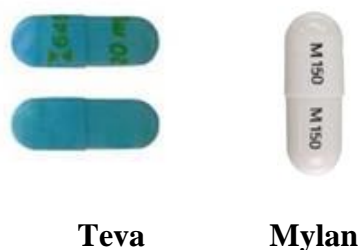
42. The federal trademark registrations listed above are prima facie evidence of AZ’s ownership and the validity of the AZ’s Purple Marks. Registration Nos. 2806099, 2980749, and 3062072 are incontestable and constitute conclusive evidence of AstraZeneca’s ownership and the validity of the purple capsule registrations.

43. AZ has for many years identified its trademarks on Nexium® packaging,

advertising, and promotional materials, among other things. For example, for many years AZ has stated on such materials that “the color purple as applied to the capsule is a registered trademark” of AZ.

THE INTRODUCTION OF GENERIC VERSIONS OF NEXIUM® IN 2014 AND 2015

44. Several companies have recently entered the market with generic prescription versions of the Nexium® esomeprazole magnesium compound. The first two companies permitted by the FDA to sell generic versions of Nexium®—Teva and Mylan—use blue and white capsules for their respective generics as shown below:

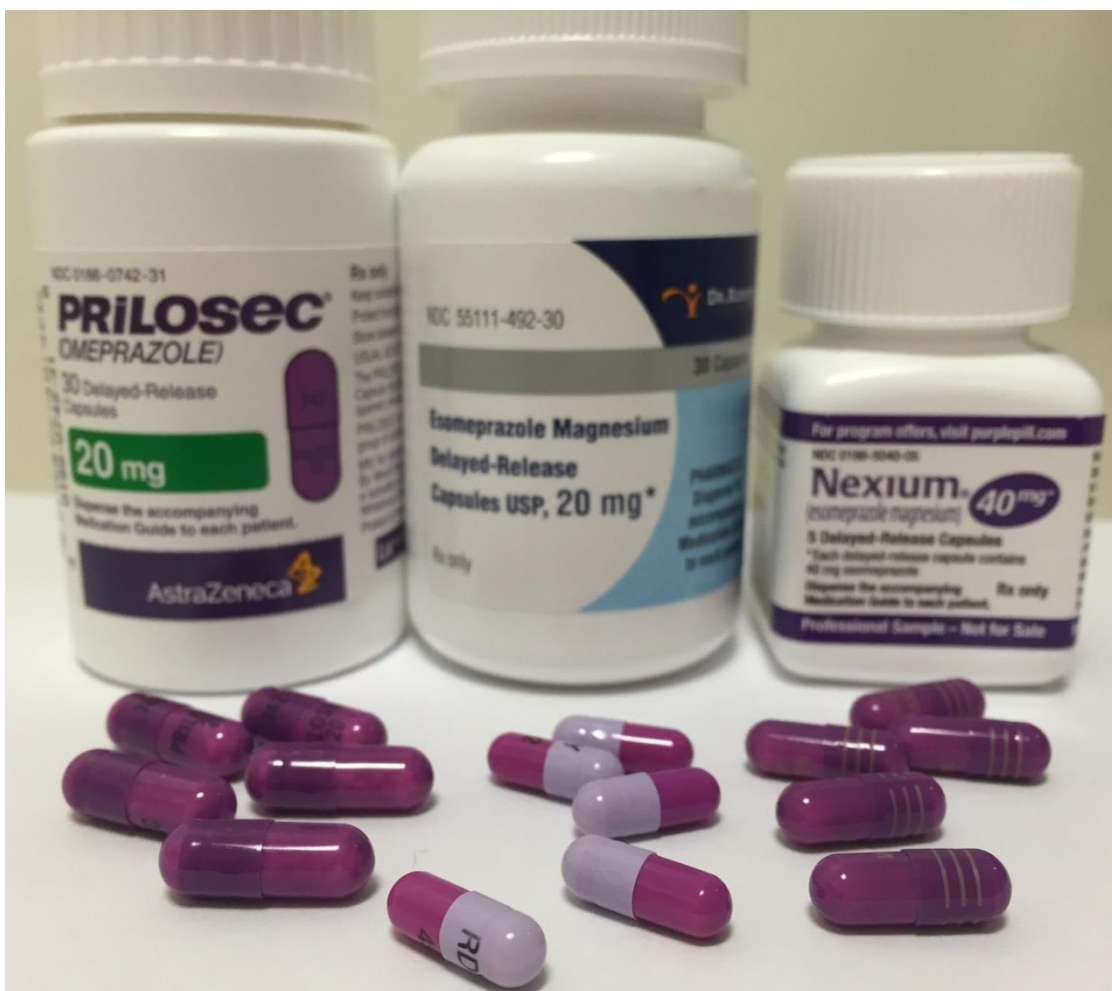


45. FDA regulations do not require generic versions of brand-name drugs to be identical to the brand. Rather, under FDA regulations, the generics need only be “bioequivalent,” meaning that the same active ingredient is released into the bloodstream within parameters deemed therapeutically equivalent, but not necessarily identical to, the brand. Other differences can also exist, including for example, non-active ingredients, manufacturing conditions and quality control and assurance. This is why generic drugs are described as “substitutable for” the brand, not “identical to” the brand.

46. Camber Pharmaceuticals, Inc. (“Camber”), one of the next two generic companies approved by the FDA to enter the market, used purple for its generic esomeprazole magnesium capsules. AZ filed a civil action on October 13, 2015 in this Court against Camber and moved

for a temporary restraining order to restrain Camber from selling, distributing, and producing its purple generic esomeprazole magnesium capsules, among other activities. (Case No. 15-927-SLR.) This Court orally granted AZ's Motion for Temporary Restraining Order against Camber on October 16, 2015, which was confirmed in a written Order on October 19, 2015.

47. Defendant DRL, the other in the second wave of generic companies entering the market, uses purple capsules for its prescription generic esomeprazole magnesium. As shown below, DRL's capsule is all purple, with half of the capsule virtually identical in color to the color used by AZ for 20 years and the other half a lighter shade of purple. DRL's esomeprazole magnesium capsules bear the letters RDY and the numeral 492. AZ only very recently learned of DRL's use of a purple pill for its generic and AZ first saw DRL's physical product on October 13, 2015, when AZ received product samples in Delaware.



AZ's PRILOSEC®

DRL

AZ'S NEXIUM®

48. DRL had previously come out with generic prescription versions of the Prilosec® omeprazole compound, but DRL did not use an all-purple pill as it is now doing with its generic versions of the Nexium® esomeprazole magnesium compound. Rather, DRL chose capsules for its omeprazole product that are half gray or yellow and half a shade of purple not used by AZ and not virtually identical to the purple used by AZ as is the case with DRL's esomeprazole magnesium product.

49. AZ is generally familiar with the distribution and sales of DRL's products and the products of other generics manufacturers. Like AZ's Nexium® prescription capsules, DRL's prescription purple capsules are or will be sold to wholesalers, government agencies, retailers,

and others, as well as to consumers via prescription through national, regional, and local drug stores and pharmacies, among other channels. Because DRL's products are a generic substitute for Nexium®-branded esomeprazole magnesium for the treatment of the same GI diseases, the potential customer base for the products is the same.

50. AZ's Nexium® products have faced competition from other branded PPIs over the years, including a number of popular pharmaceuticals that have achieved annual sales of tens or hundreds of millions or even a billion plus dollars. These PPIs have included including Aciphex (yellow tablets), Dexilant (blue and blue/gray capsules), Prevacid (pink/maroon and pink/green capsules), and Zegerid (white and white/blue capsules), none of which sold their products in purple capsules or pills.

HARM TO AZ AND THE PUBLIC

51. Defendant's unauthorized use and promotion of generic esomeprazole magnesium capsules bearing AZ's trademarked purple color is likely to cause confusion, mistake, and deception as to the source or origin of the generic medication, and is likely to falsely suggest a sponsorship, connection, affiliation, license, or association of Defendant and its purple pill with AZ and AZ's Prilosec® and Nexium® products.

52. Defendant's activities, if not enjoined, will irreparably harm the general public, which has an interest in being free from confusion, mistake, and deception.

53. Defendant's activities, if not enjoined, will irreparably harm AZ and its Purple Marks.

54. Defendant's actions described above are likely to dilute and, if not enjoined, are likely to continue to dilute the distinctiveness and value of and tarnish AZ's famous Purple Marks.

55. Defendant's false and/or misleading statements, individually and collectively, are material and irreparably injure the public and AZ by deceiving consumers into mistakenly believing that Defendant's generic esomeprazole magnesium has qualities and characteristics that it does not, including without limitation, that those pills are identical to and offered by, authorized, sponsored, connected with, licensed by, affiliated, or associated with AZ.

56. By copying AZ's purple color trademarks, in addition to creating a likelihood of confusion as to source, sponsorship, or affiliation with AZ, DRL creates the false impression that its generic esomeprazole magnesium capsules are either identical to Nexium® or are an "authorized generic," i.e., a generic drug made or put-out by the brand name company, which in this case would be AZ.

57. Defendant's false and/or misleading statements, individually and collectively, have caused, and if not enjoined, will continue to cause actual and irreparable harm to AZ and the public.

58. Defendant's unauthorized use and promotion of the Purple Marks, if not enjoined, will continue to cause actual and irreparable harm to AZ and the public.

59. Defendant knew or should have known that its activities described above were infringing and dilutive, and that its advertising was false and/or misleading, and thus Defendant acted knowingly, willfully, in reckless regard of the truth, and in bad faith.

FIRST CLAIM FOR RELIEF
Trademark Counterfeiting Under
Section 32(1) of the Lanham Act, 15 U.S.C. § 1114(1)

60. AZ repeats and realleges each and every allegation set forth above.

61. Without AZ's consent, Defendant used and continues to use in commerce reproductions, substantially indistinguishable variations, counterfeits, copies, and colorable

imitations of AZ's registered purple color marks set forth in Paragraph 41 above in connection with the offering, distribution, and/or advertising of goods and services, which is likely to cause confusion, or to cause mistake, or to deceive, in violation of Section 32(1) of the Lanham Act, 15 U.S.C. § 1114(1). Defendant's activities described above have at all times been willful and/or knowing.

62. As a direct and proximate result of actions of Defendant described above, AZ has been damaged and will continue to be damaged.

SECOND CLAIM FOR RELIEF
Trademark Infringement Under
Section 32(1) of the Lanham Act, 15 U.S.C. § 1114(1)

63. AZ repeats and realleges each and every allegation set forth above.

64. Without AZ's consent, Defendant used and continues to use in commerce reproductions, copies, and colorable imitations of AZ's registered purple color marks set forth in Paragraph 40 above in connection with the offering, distribution, and/or advertising of goods and services, which is likely to cause confusion, or to cause mistake, or to deceive, in violation of Section 32(1) of the Lanham Act, 15 U.S.C. § 1114(1).

65. Defendant's activities described above have at all times been willful and/or knowing.

66. As a direct and proximate result of actions of Defendant described above, AZ has been damaged and will continue to be damaged.

THIRD CLAIM FOR RELIEF
Trademark Infringement, False Designation
of Origin, Passing Off, and Unfair Competition
Under Section 43(a)(1)(A) of the Lanham Act, 15 U.S.C. § 1125(a)(1)(A)

67. AZ repeats and realleges each and every allegation set forth above.

68. Defendant's actions, as described above, including without limitation the use and promotion of the purple generic esomeprazole magnesium capsule are likely to cause confusion, or to cause mistake, or to deceive as to the origin, sponsorship, or approval of Defendant, its products, and/or its commercial activities by or with AZ, and thus constitute trademark infringement, false designation of origin, passing off, and unfair competition in violation of Section 43(a)(1)(A) of the Lanham Act, 15 U.S.C. § 1125(a)(1)(A).

69. Defendant's activities described above have at all times been willful and/or knowing.

70. As a direct and proximate result of actions of Defendant described above, AZ has been damaged and will continue to be damaged.

FOURTH CLAIM FOR RELIEF
False Advertising in Violation of Federal Law
Under Section 43(a)(1)(B) of the Lanham Act, 15 U.S.C. § 1125(a)(1)(B)

71. AZ repeats and realleges each and every allegation set forth above.

72. Defendant's actions, as described above, constitute false and misleading descriptions and misrepresentations of fact in commerce which, in commercial advertising and promotion, misrepresent the nature, characteristics, and qualities of Defendant's products and/or AZ's products in violation of Section 43(a)(1)(B) of the Lanham Act, 15 U.S.C. § 1125(a)(1)(B).

73. Defendant's activities described above have at all times been willful and/or knowing.

74. As a direct and proximate result of actions of Defendant described above, AZ has

been damaged and will continue to be damaged.

FIFTH CLAIM FOR RELIEF
Trademark Dilution Under Section
43(c) of the Lanham Act, 15 U.S.C. § 1125(c)

75. AZ repeats and realleges each and every allegation set forth above.

76. AZ's Purple Marks are famous, as that term is used in 15 U.S.C. § 1125(c), and were famous before Defendant first used or promoted its purple generic esomeprazole magnesium capsule, based on, among other things, federal registration of AZ's Purple Marks, the substantial commercial success under those marks, and the extensive nationwide use, advertising, promotion, publicity, and recognition of those marks.

77. Defendant's actions, as described above, are likely to dilute the distinctive quality of and tarnish AZ's famous Purple Marks in violation of Section 43(c) of the Lanham Act, 15 U.S.C. §1125(c), as amended by the Trademark Dilution Revision Act of 2006.

78. Defendant's activities described above have at all times been willful and/or knowing.

79. As a direct and proximate result of actions of Defendant described above, AZ has been damaged and will continue to be damaged.

SIXTH CLAIM FOR RELIEF
Trademark Dilution Under 6 Del. C. § 3313

80. AZ repeats and realleges each and every allegation set forth above.

81. AZ's Purple Marks are famous in Delaware, and were famous before Defendant first used or promoted its purple generic esomeprazole magnesium capsule, based on, among other things, the federal registration of AZ's Purple Marks, the substantial commercial success under those marks, the extensive nationwide use, advertising, promotion, publicity, and

recognition of those marks.

82. Defendant's actions, as described above, are likely to dilute the distinctive quality of and tarnish AZ's famous Purple Marks in violation of 6 Del. C. § 3301, *et seq.* (the "Delaware Trademark Act").

83. The above-described acts of Defendant constitute trademark dilution in violation of the Delaware Trademark Act, specifically § 3313 of the Delaware Trademark Act.

84. Defendant's activities described above have at all times been willful and/or knowing.

85. As a direct and proximate result of actions of Defendant described above, AZ has been damaged and will continue to be damaged.

SEVENTH CLAIM FOR RELIEF
Unfair Competition Under 6 Del. C. § 2532

86. AZ repeats and realleges each and every allegation set forth above.

87. As described above, Defendant has infringed AZ's Purple Marks in violation of AZ's proprietary rights, and has engaged in unfair, deceptive, untrue, and/or misleading advertising. Such acts constitute unfair trade practices, false advertising, and unfair competition under the Delaware Deceptive Trade Practices Act, 6 Del. C. § 2531, *et seq.*, specifically 6 Del. C. § 2532.

88. As a direct and proximate result of actions of Defendant described above, AZ has been damaged and will continue to be damaged.

EIGHTH CLAIM FOR RELIEF
Common Law Trademark Infringement, Unfair Competition, Misappropriation

89. AZ repeats and realleges each and every allegation set forth above.

90. Defendant has infringed AZ's Purple Marks in violation of AZ's proprietary rights

and has engaged in false and misleading advertising. Such acts constitute unfair trade practices and unfair competition under the common law.

91. Defendant's activities described above have at all times been willful and/or knowing.

92. As a direct and proximate result of actions of Defendant described above, AZ has been damaged and will continue to be damaged.

JURY DEMAND

Pursuant to Fed. R. Civ. P. 38, AZ respectfully demands a trial by jury on all issues properly triable by a jury in this action.

PRAYER FOR RELIEF

WHEREFORE, AZ prays that this Court enter judgment in its favor on each and every claim for relief set forth above and award it relief including, but not limited to, the following:

A. A temporary restraining order and preliminary and permanent injunctions enjoining DRL and its employees, agents, partners, officers, directors, owners, shareholders, principals, parents, subsidiaries, related companies, affiliates, distributors, wholesalers, repackagers, retailers, and all persons in active concert or participation with any of them:

1. From using in any manner the Purple Marks, and any marks, names, trade dress, and designs that are confusingly similar to or likely to dilute or tarnish any such marks, including without limitation, on Defendant's genericesomeprazole magnesium capsules and any associated packaging, displays, and advertising and promotional materials in any media or format;

2. From using in any manner any other mark or colored capsule which so resembles the Purple Marks as to be likely to cause confusion, deception, or mistake on or in connection with the manufacture, distribution, promotion, offer for sale, and sale of any product not emanating from AZ or not authorized by AZ to be sold in connection with the Purple Marks;
3. From passing off, inducing, or enabling others to sell or pass off any product as and for products produced by AZ, which are not in fact AZ's products, or not produced under the control and supervision of AZ and/or approved by AZ for advertising and sale under AZ's Purple Marks;
4. From committing any acts calculated to cause consumers to believe that Defendant's products are sold under the control or supervision of AZ, or that they are sponsored or approved by, connected with, guaranteed by, or produced under the control and supervision of AZ;
5. From further diluting and infringing AZ's Purple Marks and damaging AZ's reputation and its goodwill in the Purple Marks;
6. From otherwise competing unfairly with AZ in any manner;
7. From shipping, delivering, transferring, or otherwise disposing of, in any manner, products or inventory which bear AZ's Purple Marks or any mark confusingly similar thereto or that is likely to dilute the distinctiveness of the Purple Marks;
and
8. From assisting, aiding, or abetting any other person or business entity in engaging in or performing any of the activities referred to in subparagraph A. 1-7 above;

B. An Order directing Defendant to withdraw and retract from the marketplace in the United States all products, product packaging and displays, product inserts and instructions, data sheets, advertisements, commercials, and other materials in connection with pharmaceutical preparations and substances for the treatment of gastrointestinal diseases, regardless of where those materials are situated in the distribution chain (including, without limitation, affiliates, related companies, wholesalers, repackagers, distributors, sales agents, and retailers), that consist of, bear, or display AZ's Purple Marks, and/or any marks, names, trade dress, and designs that are confusingly similar to or likely to dilute or tarnish the Purple Marks (including, without limitation, Defendant's purple capsules that are generic versions of AZ's Nexium® products and associated packaging, displays, advertising, and promotional materials);

C. An Order directing Defendant to destroy all products and materials that consist of, bear, or display AZ's purple color marks on capsules for pharmaceutical preparations and substances for the treatment of gastrointestinal diseases or any other unauthorized uses of the Purple Marks, or any marks, names, trade dress, and designs that are confusingly similar to or likely to dilute or tarnish such marks, in accordance with 15 U.S.C. § 1118 and other applicable laws;

D. An Order directing Defendant to withdraw, retract, and/or destroy as applicable all advertisements, commercials, and other materials containing: (1) any of the false or misleading statements complained of herein; and (2) any false, misleading, or deceptive statements regarding a purple generic esomeprazole magnesium, AZ, AZ's products, or AZ's business activities or Defendant, Defendant's products, or Defendant's business activities;

E. An Order directing Defendant to file with this Court and serve on AZ's attorneys, thirty (30) days after the date of entry of any injunction, a report in writing and under oath setting forth in detail the manner and form in which it has complied with the injunction;

F. An Order requiring Defendant to pay statutory damages in accordance with 15 U.S.C. § 1117(c) of up to \$2,000,000 per mark per type of product or service sold, offered for sale, or distributed by Defendant deemed to be counterfeits of AZ's Purple Marks;

G. An Order requiring Defendant to account for and to pay any and all profits arising from the foregoing acts of infringement, dilution, false designation of origin, false advertising, unfair competition, and an increasing of such profits for payment to AZ in accordance with 15 U.S.C. § 1117, and other applicable statutes and laws;

H. An Order requiring Defendant to pay AZ the cost for corrective advertising and/or to engage in corrective advertising in a manner directed by the Court;

I. An Order requiring Defendant to pay compensatory damages in an amount as yet undetermined caused by the foregoing acts of infringement, dilution, false designation of origin, unfair competition, and trebling such compensatory damages for payment to AZ in accordance with 15 U.S.C. § 1117, and other applicable statutes and laws;

J. An Order requiring Defendant to pay AZ's costs and attorney's fees in this action pursuant to 15 U.S.C. § 1117, and other applicable statutes and laws;

K. An Order requiring Defendant to pay AZ punitive damages in an amount as yet undetermined caused by the foregoing acts of Defendant pursuant to Delaware Trademark Act, 6 Del C. § 3314;

L. An Order requiring Defendant to pay AZ punitive damages in an amount as yet undetermined caused by the foregoing acts of Defendant pursuant to Delaware Deceptive Trade Practices Act, 6 Del C. § 2533;

M. Restitutionary relief against Defendant and in favor of AZ, including disgorgement of wrongfully obtained profits and any other appropriate relief;

N. An Order requiring Defendant to pay the costs of suit and reasonable attorneys' fees to the extent not specified above; and

O. Other relief as the Court may deem appropriate, including without limitation all remedies provided for in 6 Del C. §§ 2501, 3301, et seq., and under any other applicable laws.

Dated: October 28, 2015

MCCARTER & ENGLISH, LLP

/s/ Daniel M. Silver

Michael P. Kelly (#2295)

Daniel M. Silver (#4758)

Benjamin A. Smyth (#5528)

Renaissance Centre

405 N. King Street, 8th Floor

Wilmington, Delaware 19801

(302) 984-6300

mkelly@mccarter.com

dsilver@mccarter.com

bsmyth@mccarter.com

David M. Kelly (Of Counsel)

Robert D. Litowitz (Of Counsel)

Jane W. Wise (Of Counsel)

KELLY IP, L.L.P.

1919 M Street, NW, Suite 610

Washington, D.C. 20036

Telephone: (202) 808-3570

Attorneys for Plaintiffs