UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

WALGREEN COMPANY et al., Plaintiffs, v. ASTRAZENECA PHARMACEUTICALS L.P. et al., Defendants.	)	Civil Action No. 06-2084 (RWR)
RITE AID CORPORATION et al., Plaintiffs, v. ASTRAZENECA PHARMACEUTICALS L.P. et al., Defendants.	)	Civil Action No. 06-2089 (RWR)
MEIJER, INC. et al., Plaintiffs, v. ASTRAZENECA PHARMACEUTICALS L.P. et al., Defendants.	)	Civil Action No. 06-2155 (RWR)

LOUISIANA WHOLESALE DRUG CO., INC. et al.,	)	
Plaintiffs,	)	
v.	)	**Civil Action No. 06-2157 (RWR)**
ASTRAZENECA PHARMACEUTICALS LP et al.,	)	
Defendants.	)	
BURLINGTON DRUG COMPANY, INC. et al.,	)	
Plaintiffs,	)	
v.	)	**Civil Action No. 07-0041 (RWR)**
ASTRAZENECA PHARMACEUTICALS LP et al.,	)	
Defendants.	)	

MEMORANDUM OPINION

Plaintiffs in the five above-captioned cases filed substantively identical complaints,[1] alleging that defendants

[1] The plaintiffs in each case are as follows: Walgreen Co., Eckerd Corp., Maxi Drug, Inc., The Kroger Co., New Albertson's, Inc., Safeway, Inc., Hy-Vee, Inc. and American Sales Company, Inc. in Civil Action No. 06-2084; Rite Aid Corp. and Rite Aid Headquarters Corp. in Civil Action No. 06-2089; Meijer, Inc. and Meijer Distribution, Inc. in Civil Action No. 06-2155; Louisiana Wholesale Drug Co., Inc. in Civil Action No. 06-2157; and Burlington Drug Company, Inc., Dik Drug Company, and King Drug Company of Florence, Inc. in Civil Action No. 07-41. The latter three actions were filed on behalf of a proposed class consisting of all persons and entities in the United States who

AstraZeneca Pharmceuticals L.P., AstraZeneca L.P., Zeneca, Inc., and Zeneca Holdings, Inc. (collectively, "AstraZeneca") have violated Section 2 of the Sherman Act, 15 U.S.C. § 2, which prohibits actual or attempted market monopolization. Plaintiffs allege that AstraZeneca deliberately switched the market from its prescription heartburn drug Prilosec, just as Prilosec's patent was about to expire, to both its newly FDA-approved equivalent Nexium, which had a patent that would not expire for several years, and to its newly FDA-approved over-the-counter ("OTC") Prilosec. AztraZeneca, arguing that its conduct was procompetitive rather than anticompetitive, filed motions to dismiss the complaints under Federal Rule of Civil Procedure 12(b)(6) for failure to state a claim upon which relief may be granted. Because plaintiffs have not alleged facts sufficient to support a reasonable inference that AstraZeneca's decision to market and aggressively promote Nexium was exclusionary conduct prohibited by Section 2 of the Sherman Act, the motions to dismiss will be granted and the complaints will be dismissed. Because these cases do not survive the motions to dismiss, all other pending motions will be denied as moot.

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purchased omeprazole and/or any of its enantiomers directly from any of the defendants after December 18, 2002. Because the complaints are otherwise virtually identical, all references to a complaint will be made to the complaint in the first-filed case.

FACTUAL BACKGROUND

Prilosec is a brand-name prescription drug used to treat heartburn and related conditions.[2] (Walgreen Co. et al. v. AstraZeneca Pharms. et al., Civil Action No. 06-2084, First Am. Compl. ("FAC") ¶ 42.) Prilosec contains the drug substance omeprazole, composed of equal parts of two mirror-image molecular structures, (S)-omeprazole and (R)-omeprazole, which are transformed into an active drug in the parietal cells of the stomach of a person who ingests the substance. (Id. ¶¶ 53-54.) AstraZeneca obtained a patent for Prilosec in 1981, and began marketing 20 mg Prilosec capsules in September 1989 after obtaining approval from the Food and Drug Administration ("FDA").[3] By 1999, prescription Prilosec was producing $4 billion in revenue to AstraZeneca. The Prilosec patent expired in October 2001, and a company not involved in this case first marketed a generic equivalent of Prilosec in December 2002. AstraZeneca still manufactures and markets its prescription Prilosec capsules. In June 2003, the FDA approved an OTC version of prescription Prilosec, and granted AstraZeneca exclusivity in

[2] These conditions are also known as erosive esophogitis and symptomatic gastroesophageal reflux disease.

[3] AstraZeneca was not the sole manufacturer in the market for prescription treatment of heartburn and related conditions, however. Prevacid, Protonix, and Aciphex are prescription treatments manufactured by others for the same medical conditions. (See Mot. to Dismiss at 12.)

that market through June 2006 after Astrazeneca conducted and submitted safety studies to the FDA.

AstraZeneca also owns the patent for, manufactures, and markets the brand-name prescription drug Nexium. Nexium contains the drug substance esomeprazole, or (S)-omeprazole. (Id. ¶ 53.) The FDA approved Nexium for sale in February 2001, just eight months before the Prilosec patent expired. The Nexium patent does not expire until 2014, and Nexium is not subject to generic substitutions before that time. Upon the introduction of Nexium, AstraZeneca very aggressively promoted and "detailed"[4] Nexium to doctors, and at the same time ceased promoting and detailing Prilosec.

Based on sales data, plaintiffs calculate that in 2002 -- the year after Nexium hit the market -- Nexium siphoned off one-third of the prescriptions that would have been written for Prilosec if Nexium had not been an alternative. (See id. ¶¶ 63, 65.) Plaintiffs also project that if Nexium had not gone to market, the manufacturers of generic substitutes to prescription Prilosec would have far more than their current 30% of the market, and consumers would have collectively saved $11.5 billion by the end of the year 2006. (Id. ¶ 68.)

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[4] "Detailing" in the retail pharmaceutical business refers to the practice of sending company representatives to doctors' offices to distribute samples and promotional materials and information.

The gravamen of plaintiffs' complaint is that AstraZeneca "switch[ed] the market from Prilosec, which now has generic competition, to a virtually identical drug, Nexium, which does not [have generic competition.]" (Id. ¶ 1.) Asserting that there is almost no difference between Nexium and Prilosec, and that there is no pharmacodynamic reason why a dose of (S)-omeprazole, i.e., Nexium, would interact with the stomach's parietal cells any differently than would an equal dose of omeprazole, i.e., Prilosec (id. ¶ 54), plaintiffs contend that this switching is exclusionary and violates § 2 of the Sherman Act. They also allege that to effectuate this market switch, AstraZeneca used distortion and misdirection in marketing, promoting and detailing Nexium. (See id. ¶¶ 69, 90-95, 116, 122.) In addition, plaintiffs contend that AstraZeneca engaged in prohibited exclusionary conduct when it introduced OTC Prilosec and obtained a grant of exclusivity for three years from the FDA. (See id. ¶¶ 96-103.)

DISCUSSION

Federal Rule of Civil Procedure 12(b)(6) authorizes dismissal of a complaint for failure to state a claim upon which relief can be granted. See Fed. R. Civ. P. 12(b)(6). A court considering a Rule 12(b)(6) motion to dismiss assumes all factual allegations to be true, even if they are doubtful. Bell Atl. Corp. v. Twombly, 127 S. Ct. 1955, 1965 (2007); Kowal v. MCI

Communc'ns Corp., 16 F.3d 1271, 1276 (D.C. Cir. 1994) (noting that a court must construe the complaint "liberally in the plaintiffs' favor" and "grant plaintiffs the benefit of all inferences that can be derived from the facts alleged"). A court need not, however, "accept inferences drawn by plaintiffs if such inferences are unsupported by the facts set out in the complaint. Nor must [a] court accept legal conclusions cast in the form of factual allegations." Kowal, 16 F.3d at 1276. "While a complaint attacked by a Rule 12(b)(6) motion to dismiss does not need detailed factual allegations, . . . a plaintiff's obligation to provide the grounds of his entitle[ment] to relief requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do . . . ." Twombly, 127 S. Ct. at 1964-65 (internal citations and quotations omitted) (alteration in original).

The antitrust laws were enacted to protect competition, not competitors. Brown Shoe Co. v. United States, 370 U.S. 294, 320 (1962). As a threshold matter, then, to obtain antitrust relief an antitrust plaintiff must prove an "antitrust injury, which is to say injury of the type the antitrust laws were intended to prevent and that flows from that which makes defendants' acts unlawful." Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc., 429 U.S. 477, 489 (1977). Antitrust plaintiffs do not suffer antitrust injury merely because they are in a worse position than they

would have been in had the challenged conduct not occurred. Id. at 486-87. "The antitrust injury requirement ensures that a plaintiff can recover only if the loss stems from a competition-*reducing* aspect or effect of the defendant's behavior." Atl. Richfield Co. v. USA Petroleum Co., 495 U.S. 328, 344 (1990) (emphasis in the original). "Thus, antitrust injuries include only those injuries that result from interference with the freedom to compete." Johnson v. Univ. Health Servs., Inc., 161 F.3d 1334, 1338 (11th Cir. 1998).

Section 2 of the Sherman Act makes it a felony to "monopolize or attempt to monopolize . . . any part of the trade or commerce among the several States . . . ." 15 U.S.C. § 2. "The offense of monopolization has 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. Microsoft Corp., 253 F.3d 34, 50 (D.C. Cir. 2002) (quoting United States v. Grinell Corp., 384 U.S. 563, 570-71 (1966)). The undesirable "willful acquisition or maintenance" conduct that § 2 prohibits is often referred to as "exclusionary." See Philip R. Areeda & Herbert Hovenkamp, 3 Antitrust Law § 650a(1) at 67 (rev. ed. 1996) ("Areeda & Hovenkamp"). Exclusionary conduct is "that which prevents actual or potential rivals from competing or

impairs their opportunities to do so effectively." Id. § 651b at 76. The term encompasses "at most behavior that not only (1) tends to impair the opportunities of rivals, but also (2) either does not further competition on the merits or does so in an unnecessarily restrictive way." Id. § 651b at 77. "Whether any particular act of a monopolist is exclusionary, rather than merely a form of vigorous competition, can be difficult to discern: the means of illicit exclusion, like the means of legitimate competition, are myriad. The challenge for an antitrust court lies in stating a general rule for distinguishing between exclusionary acts, which reduce social welfare, and competitive acts, which increase it." Microsoft, 253 F.3d at 58. Here, then, the issue to be determined is whether plaintiffs' assertions that AstraZeneca engaged in exclusionary conduct are supported by factual allegations -- which must be taken as true for the purposes of this motion -- that yield a reasonable inference that AstraZeneca's conduct was of the type that is prohibited by § 2 as exclusionary, or whether plaintiffs' assertions of exclusionary conduct amount to no more than "labels and conclusions, and a formulaic recitation" of this essential element of a Section 2 Sherman Act claim. Twombly, 127 S. Ct. at 1965.

Plaintiffs allege that AstraZeneca engaged in exclusionary conduct "by introducing Nexium, a drug virtually identical to and

no more effective than Prilosec" (FAC ¶¶ 116, 122), and "switching the market from Prilosec, which now has generic competition, to a virtually identical drug, Nexium, which does not [have generic competition.]" (Id. ¶ 1.) To make their case, plaintiffs contend that AstraZeneca's conduct is analogous to conduct held unlawful in Microsoft, 253 F.3d 34, and in Abbott Labs. v. Teva Pharms. USA, Inc., 432 F. Supp. 2d 408 (D. Del. 2006). The analogy, however, fails on the facts. In Microsoft, the firm violated antitrust laws when it tied a specific internet browser to a specific operating system on which it had a monopoly, and by so doing effectively eliminated the customers' choice of internet browsers.[5] Microsoft, 253 F.3d at 64-65. In Teva, the complaint alleged that Teva was a monopolizer that sought to defeat competition from generic substitutes and deliberately limit rather than expand consumers' choices when it successively introduced new patented drugs by merely changing the formulation of the drug -- once from capsule form to tablet form and then again to a second tablet form -- and then stopped manufacturing the prior formulations, and repurchased all existing prior formulations. Teva, 432 F. Supp. 2d at 415, 422.

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[5] Tying, which is not alleged against AstraZeneca in this case, is classic exclusionary conduct. See Philip R. Areeda & Herbert Hovenkamp, 3A Antitrust Law § 776c at 242-53 (2d ed. 2002) ("Areeda & Hovenkamp 2d ed.") (discussing the tying presented in the Microsoft case); see id. generally, Ch. 7D-4 at 228-67; (discussing various issues involved in vertical integration).

The elimination of choice was a critical factor in the court's decision to deny Teva's motion to dismiss the complaint. Id. at 422 ("But here . . . consumers were not presented with a choice between . . . formulations. Instead, Defendants allegedly prevented such a choice by removing the old formulations from the market while introducing new formulations."). Thus, in both Microsoft and Teva, the defendants' offending conduct had to do with eliminating choices available to the consumer. Yet, here, there is no allegation that AstraZeneca eliminated any consumer choices. Rather, AstraZeneca added choices. It introduced a new drug to compete with already-established drugs -- both its own and others' -- and with the generic substitutes for at least one of the established drugs.

Plaintiffs argue that because Nexium is protected by a patent and not superior to Prilosec, AstraZeneca's conduct is exclusionary. Plaintiffs are not able to show that enjoying the benefits of patent protection is exclusionary conduct under § 2. "[A] patent is presumptively not a monopoly . . . [and] is no different than any other property right . . . [such as] ownership of an airplane or pipeline [that] excludes others from using them. . . . Further, the Patent Act creates a federal right to exclude others from practicing the patent . . . . As a result, antitrust must tread lightly." Areeda & Hovenkamp, § 704a at 151. See also id. § 706d at 164-66 (advising that § 2

antitrust remedies should not be applied to monopolists who introduce new products under patents or, presumably, other official grants of exclusivity).

Plaintiffs have also not identified any antitrust law that requires a product new on the market -- with or without a patent -- to be superior to existing products. Antitrust law holds, and has long held, to the contrary. Courts and juries are not tasked with determining which product among several is superior. Those determinations are left to the marketplace. New products are not capable of affecting competitors' market share unless consumers prefer the new product, regardless of whether that product is superior, equivalent, or inferior to existing products. "[N]o one can determine with any reasonable assurance whether one product is 'superior' to another. Preference is a matter of individual taste. The only question that can be answered is whether there is sufficient demand for a particular product to make its production worthwhile, and the response, so long as the free choice of consumers is preserved, can only be inferred from the reaction of the market." Berkey Photo, Inc. v. Eastern Kodak Co., 603 F.2d 263, 287 (2d Cir. 1979). "If a monopolist's products gain acceptance in the market, therefore, it is of no importance that a judge or jury may later regard them as inferior, so long as that success was not based on any form of coercion." Id. See also Areeda & Hovenkamp 2d ed., § 776b2

at 236 (discussing the basic analytical points the court made in Berkey Photo); id. § 781e at 271 ("We therefore conclude that all product innovation should be lawful in the absence of bundling . . . ."). Here, plaintiffs have alleged no coercion, bundling, or elimination of consumer choice.

Plaintiffs also complain that when AstraZeneca transferred its considerable sales efforts from Nexium to Prilosec, it used distortion in its efforts to persuade doctors and other medical professionals that Nexium offered advantages to Prilosec and in its advertising directed to lay persons. Plaintiffs have not identified any antitrust law that prohibits market switching through sales persuasion short of false representations or fraud,[6] or any court that has identified such conduct as exclusionary for purposes of § 2 of the Sherman Act. The law allows AstraZeneca "to bathe [its] cause in the best light possible. Advertising that emphasizes a producer's strengths and minimizes its weaknesses does not, at least unless it amounts to deception, constitute anticompetitive conduct violative of § 2." Berkey Photo, 603 F.2d at 287-88 (footnotes omitted). Furthermore, before a court allows "misrepresentation to buyers to be the basis of a competitor's treble damage action under § 2," it should "at least require the plaintiff to overcome a

[6] Plaintiffs allege that the sales persuasion directed to medical professionals and lay persons was distorted in multiple respects. They have not, however, asserted a claim for fraud.

presumption that the effect on competition of such a practice was de minimis." Id. at 288 n.41. Areeda and Hovenkamp posit that the de minimis presumption should be overcome only where the plaintiff can show "cumulative proof that the representations were clearly false, clearly material, clearly likely to induce reasonable reliance, made to buyers without knowledge of the subject matter, continued for prolonged periods, and not readily susceptible of neutralization or other offset by rivals." Areeda & Hovenkamp 2d ed., § 782b at 274. Plaintiffs cannot hope to make such a showing because Nexium sales necessarily depended on prescriptions written by medical professionals, that is, persons knowledgeable of the subject matter. In short, plaintiffs have not alleged facts that support an inference that AstraZeneca's conduct in switching the market from Prilosec to Nexium is anticompetitive for the purposes of § 2, rather than procompetitive albeit to the disadvantage of plaintiffs.

Indeed, plaintiffs here have not identified an antitrust injury that they have suffered. They complain that AstraZeneca's conduct cost them sales of their generic substitutes. The fact that a new product siphoned off some of the sales from the old product and, in turn, depressed sales of the generic substitutes for the old product, does not create an antitrust cause of action. Simply stated, plaintiffs have not alleged facts showing that AstraZeneca "interfere[d] with the[ir] freedom to compete."

Johnson, 161 F.3d at 1338. Plaintiffs are as free to compete with Prilosec as they would have been had Nexium never been introduced. Prilosec remains available as a consumer choice either by prescription or over-the-counter. The complaint reflects little reason for plaintiffs' circumscribed ability to realize sales other than AstraZeneca introducing a new competitive product and successfully competing in marketing the new product. This is not an antitrust injury.

CONCLUSION

Plaintiffs have not pled facts that support a reasonable inference that they have been damaged by an antitrust injury, or that AstraZeneca engaged in exclusionary conduct prohibited by § 2 of the Sherman Act. Without such facts, plaintiffs' allegations of antitrust injury and exclusionary conduct constitute no "more than labels and conclusions, and a formulaic recitation of the elements of a cause of action." Twombly, 127 S. Ct. at 1965. Accordingly, AstraZeneca's motion to dismiss will be granted for plaintiffs' failure to state a claim upon which relief may be granted.

An appropriate order accompanies this memorandum opinion.

SIGNED this 25th day of February, 2008.

/s/
RICHARD W. ROBERTS
United States District Judge